From:	Nath, Avindra (NIH/NINDS) [E] [/O=EXCHANGELABS/OU (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B81CA051950		
Sent:	5/23/2021 7:00:38 PM	70-10-3007-0377-07	j
To:	b6		
Subject:	Re: Possible COVID vaccine patient with	b6	
You could o Avi	contact <b>b6</b> in Dept of Neurology at	b6	
From:	b6		
Date: Sund	day, May 23, 2021 at 2:49 PM		
To: Nath,	Avindra (NIH/NINDS) [E] b6	]	
Subject: R	e: Possible COVID vaccine patient with	b6	
Is there sor	meone studying types of patients like me who may wa	nt to know about	this case?
On Sun, Ma	ay 23, 2021, 12:48 PM <b>b6</b>	wrote:	
Thank you	ı.		
On Sun, N	ay 23, 2021, 12:45 PM Nath, Avindra (NIH/NINDS) [E]	b6	wrote:
Avi			
From:	<b>b6</b>		
Date: Su	ınday, May 23, 2021 at 2:40 PM		
To: Nath	n, Avindra (NIH/NINDS) [E] <b>b6</b> Re: Possible COVID vaccine patient with		
Subject:	Re: Possible COVID vaccine patient with	b6	
l suppose	e my question is, does this type of patient presentation	n mean anything t	o you as far as diagnosis initially? Was
this react	tion seen in others? Does this sound like <b>b6</b>	My reaction	to the vaccine itself <b>b6</b>
	ere someone else I should be contacting related to the		
	_but doesn't seem to care about correlation of my vac ng a different type of <u>b6</u> doctor?	cine reaction and	to be honest, has blown it off. Should
200			
On Sun, I	May 23, 2021, 12:32 PM Nath, Avindra (NIH/NINDS) [E	]b6	wrote:
Dear[	b6		
	hear of your illness. If the symptoms are vaccine relations about the possibility of treating with <b>b6</b>	ted then it may we	e worth discussing with your
Best wis	shes.		

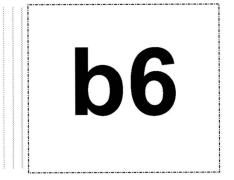
Avi
Avindra Nath MD
Chief, Section of Infections of the Nervous System
Clinical Director,
National Institute of Neurological Disorders and Stroke
National Institutes of Health, Bethesda, MD
b6 (Office)
b6
From: b6   Date: Sunday, May 23, 2021 at 1:55 PM
To: Nath, Avindra (NIH/NINDS) [E] b6
Subject: Possible COVID vaccine patient with b6
Dear Dr. Avindra Nath,
My name is b6 I am a b6 I apologize for the lengthy email but I
think it is important I reach you about this situation and explain in as much detail as I can. I am reaching out because I
both had a very serious COVID-19 Moderna vaccine reaction b6 and am having some very unexplained sequela from that now. I did file a report with the vaccine reaction registry as well and am currently pending a
response. I am not sure if you are the correct person to contact but I am really suffering and need to be pointed in
the direction of the right treatments.
I received my first Moderna vaccine in my left upper arm
that first vaccine was a little more serious of a localized response than the ordinary but nothing systemic. I had pain in that arm for three days that required b6 and it was painful to even lift the arm up
over my head. The arm felt weak and excessively sore beyond what my colleagues, patients, friends, and family
described.
After my second Moderna dose I became very sick. I received the vaccine at around 1 pm. My arm within
hours felt similar to what I described above. I started to feel mildly systemically unwell about 10 pm before bed with chills, headache, generalized aches, and fatigue. I went to bed and was able to sleep. I awoke suddenly at around 7
am with very serious symptoms. I was not completely paralyzed but all of my limbs had severe deficits in fine and
gross motor. The symptoms were more severe on the left side of my body than the right but there was only a small

variation. I was unable to dress myself or feed myself. I was not able to stand or walk. When I would try to bend my legs, you would typically fire a quad muscle, but it was as if the quad muscle was already firing so I couldn't use it to use my leg. My arms were so weak I couldn't lift them. I had a lot of systemic pain that was as deep as my bones and I had a lot of neck pain and occipital headaches. It felt as if my spine was being pulled to the left toward the vaccine site in the lower C-spine and upper T-spine.

The above symptoms lasted for about 36 hours. I then began to be able to move a little more, but my limbs were very heavy, and I lacked full gross motor control. I was able to stand but walking was one step at a time slowly and I needed to hold on to something for support. On day 3 my husband was having to put a sandwich in my hand and then fold my fingers around it so I could put it in my mouth myself for example. I started to return to more gross motor control on day 4 but started with some very serious nausea, vomiting, headaches, and tinnitus. Throughout all of this I was able to keep very hydrated but found it difficult to urinate as I had to strain harder than usual to initiate the stream of urine. My urine was yellow throughout those first 4 days. On day 5 to day 6 I believe I had a moderate form of rhabdomyolysis. My urine was very dark brown with sediment and almost smelled metallic. I had a metallic taste in my mouth for about a week.

I know this s	ounds like a po	or decision but I was not seen	in a hospital during all of th	is as I am not someone
who goes to the ER and		b6	I enjoy my privacy and	d did not want to
present as a patient	to my local hos	oital. I felt comfortable	<b>b6</b> that if I was	drinking fluids, able to
		on, to manage myself at hom	e. In hindsight I regret this r	now, as I have done
,		dition and realize how serious		
		o return to work on day 11.	, ,	
-				
From	b6	I had three episo	odes of what felt like shingle	es without a rash to the
left side of my neck.	It started with	pain in my scalp on the left sid	le and left ear. My ear was v	ery hot and throbbing.
The skin down the le	ft side of my ne	ck was hypersensitive and pa	inful even to light touch. I to	ook <b>b6</b>
		is made a difference and it su		
times.				
It wasn't unt	ill b6	that I started developing	some very serious left trape	zius pain that radiates
	L	some numbness intermittentl	1.5	
		me way with self-massage on		
b6		luate the left arm and view th	-	
		b6		10 L
h6		They treated the trapezius pa	ain with <b>b6</b>	It was a strange
outcome, but after	b6	the pain in my trapezoid trar	·	
symptoms happened	l hefore	i che pani il il y chapezona chan	b6	l court in a change in
Tymptoms nappened				
		h6		
L				j
		b6		
		<b>L</b> C	Ĩ	
		nn		
		N	!	
	b6	; I expressed t	hat I just feel that somethin	g else is going on with
my nerves. It just fee	els as if my nerv	es are all irritated without a si	1.2	
had a hard time expl			b6	Some days the
<b>b6</b> will be very pair		days <b>b6</b> on the left of n	ny neck is unbearable. There	

very limited activity level to explain these changing levels of left side		noted as well, when b6 ight I went home and had
almost continuous strangling traveling paresthesia in the entire lef	'	_
radiating into the left side of my face and scalp. It was a very seriou	Maria de la compansión de	b6
b6	L	i
	as hyperactivated by this	stillidation. Haces of
these strange paresthesia continued to some extent for 2-3 days.		
Last week things herema were Landed up in the FD for	h.C	ibaaaysa I bad
Last week things became worse. I ended up in the ER for		because I had
sudden complete loss of sensation in my left arm that lasted a few		
sneezed a few times and my upper lip, left side of the tip of my nos	20	
if given local anesthetic by the dentist. This happened 3 times with		
fearful. It seemed as if increased pressure from crying or sneezing		
point that day the trigeminal symptoms almost seemed bilateral ac	cross the entire maxillary	V2 distribution but
b6		
Currently I remain with severe left cervical and thoracic spi	ne nerve pain, left arm g	eneralized tingling and
numbness, intermittent hypersensitivity in the skin of my left trice	os region, pain in my left	subclavicular region, left
anterior neck pain, and paresthesia to the left side of my face. I am	not quite sure if saying	that the vaccine caused
the physical spine pathology is possible but I believe that the inflan	.6 1 (2)	
mechanical problem and exacerbated the condition and has cause		
The charmon progress and charge sales and containing that has cause.	anny om om on on one	
As far as my overall health, I am a very active, healthy,	b6	I have a history of <b>b6</b>
nn		
<u> </u>		
I originally felt very strange telling providers, "I think the va	accine did this to me. I be	lieve the vaccine hurt my
spine". It seemed unreal that this was all correlated. As I recently b		-
I started doing some research online. I stumbled upon some cases	• •	• •
	b6	3e myends m 43 covid
infected patients in 3 post vaccinated patients.	50	المسامة بالمغايات
<u> </u>		l absolutely do not
want my rare and isolated reaction to affect vaccine distribution, a		
do need to report what happened in the attempt to get the proper	treatment for my long to	erm symptoms.
If someone can please reach out to me to provide some insight and	I follow up to my case, I	would very much
appreciate this.		
Thank you,		
and an interest		
h6		
<b>b6</b>		



From: Sent:	b6  10/12/2021 3:56:51 PM  Gavin, Angelique (NIH/NINDS) [C] [/o=Eychange labs/ou=Eychange Administrative Group
To:	davin, Angenque (Min) Minos [e] [/o-Exchange Easts / ou-Exchange Administrative Group
Subject:	(FYDIBOHF23SPDLT)/cn=Recipients/cn=6e97392e947e4f7ebb17eeb8ac87c5d5 b6 RE: Female suffering from Johnsons and johnsons vaccine severe reactions
Appreciate th	nat Angelique
Sent from Ya	ahoo Mail on Android
On Tue, Oc	t 12, 2021 at 5:56 PM, Gavin, Angelique (NIH/NINDS) [C]  b6 wrote:
	for your quick reply. We will place you on the wait list and will contact you when the study and active. All my best to you.
Sincerely,	
Angelique	
Angelique G	Gavin, MS (Contractor)
NIH/NINDS	Clinical Operations Manager
Contractor P	referred Solutions Group
National Inst	citutes of Health
10 Center Dr	rive
Building 10,	Room 3B19, MSC 1251
Bethesda, M	D 20814-9692
<b>b6</b>	(office)
DO	(cell)
(301) 480-53	68 (efax)
b	6
https://clinica	altrials.gov - study number 000089-N

From: b6
Sent: Tuesday, October 12, 2021 11:53 AM  To: Gavin, Angelique (NIH/NINDS) [C] b6
Subject: RE: Female suffering from Johnsons and johnsons vaccine severe reactions
Yes, I am interested
My name is <b>b6</b> and my phone number is <b>b6</b>
Sent from Yahoo Mail on Android
On Tue, Oct 12, 2021 at 5:43 PM, Gavin, Angelique (NIH/NINDS) [C]
b6 wrote:
Dear b6
Thank you for your interest in our research. I received your information from Dr. Avindra Nath. We are currently
developing an online survey system to collect stories about people's complications after receiving COVID vaccines. At this time, if you are willing, we can take your name and contact information. We will reach back out to you when the
survey system is completed to see if you are willing to volunteer in our on-line study.
Thank you,
Angelique
Angelique Gavin, MS (Contractor)
NIH/NINDS Clinical Operations Manager
Contractor Preferred Solutions Group
National Institutes of Health
10 Center Drive
Building 10, Room 3B19, MSC 1251

Bethesda, MD 20814-9692
b6 (office)
(cell)
(301) 480-5368 (efax)
<b>b6</b>
https://clinicaltrials.gov - study number 000089-N
From: Nath, Avindra (NIH/NINDS) [E] b6  Sent: Monday, October 11, 2021 1:10 AM  To: b6 NINDSPostCovid19 < nindspostcovid19@ninds.nih.gov>
To: b6 NINDSPostCovid19 < nindspostcovid19@ninds.nih.gov > Subject: Re: Female suffering from Johnsons and johnsons vaccine severe reactions
Dear <b>b6</b> Sorry to hear of your illness. Currently, we are trying to gather information on the side effects of the vaccines. I have copied our research team, who can guide you on how to provide us the information. Your help would be vital in this
Thanks
Avi
Avindra Nath MD
Chief, Section of Infections of the Nervous System
Clinical Director,
National Institute of Neurological Disorders and Stroke
National institutes of fleatiff, betriesua, MD
National Institutes of Health, Bethesda, MD
b6

From: b6	
Date: Sunday, October 10, 2021 at 10:54 PM	
To: Nath, Avindra (NIH/NINDS) [E] b6	
Subject: Female suffering from Johnsons and johnsons vaccine severe reactions	
•	
Hello	
This is <b>b6</b> a <b>b6</b> who suffered since <b>b6</b> from fatigue, chest pain, abd	ominal pain, bruises
and numbness in legs and arms. I need help please if you can and I am in <b>b6</b>	
Thank you,	
<i>γ</i>	
b6	
<u>Sent from Yahoo Mail on Android</u>	

From:	Gavin, Angelique (NIH/NINDS) [C] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6E97392E947E4F7EBB17EEB8AC87C5D5 <b>b6</b>
Sent:	4/27/2021 1:43:14 PM
То:	b6
Subject:	RE: NIH studies and VAERS
Thank you	I look forward to speaking with you then.
Angelique	
	Gavin, MS (Contractor)
	Clinical Operations Manager
	Preferred Solutions Group
	stitutes of Health
10 Center I	
_	, Room 3B19, MSC 1251
Bethesda,	MD 20814-9692
b6	(office)
L	(cell)
(301) 480-	b6
https://clir	icaltrials.gov - study number 000089
nttps.//ciii	ilicalitrais.gov - study frumber 000009
-	
From:	b6
l	
Sent: Ivion	day, April 26, 2021 6:46 PM
	day, April 26, 2021 6:46 PM Angelique (NIH/NINDS) [C]: <b>b6</b>
To: Gavin,	Angelique (NIH/NINDS) [C] b6
To: Gavin,	
To: Gavin, Subject: Re	Angelique (NIH/NINDS) [C] <b>b6</b> e: NIH studies and VAERS
To: Gavin, Subject: Re	Angelique (NIH/NINDS) [C] b6
To: Gavin, Subject: Re	Angelique (NIH/NINDS) [C] <b>b6</b> e: NIH studies and VAERS
<b>To:</b> Gavin, <b>Subject:</b> Re	Angelique (NIH/NINDS) [C] <b>b6</b> e: NIH studies and VAERS
<b>To:</b> Gavin, <b>Subject:</b> Re	Angelique (NIH/NINDS) [C] b6  NIH studies and VAERS  I be great. Thank you!
To: Gavin, Subject: Re That would	Angelique (NIH/NINDS) [C] b6  NIH studies and VAERS  I be great. Thank you!
To: Gavin, Subject: Re That would On	Angelique (NIH/NINDS) [C] b6  E: NIH studies and VAERS  I be great. Thank you!  Apr 26, 2021, at 6:39 PM, Gavin, Angelique (NIH/NINDS) [C] b6 wrote:
To: Gavin, Subject: Re That would On Th	Angelique (NIH/NINDS) [C] b6  E: NIH studies and VAERS  I be great. Thank you!  Apr 26, 2021, at 6:39 PM, Gavin, Angelique (NIH/NINDS) [C] b6 wrote:  ank you b6 for getting back to me! Would Friday, May 7 at noon EST work for you?
To: Gavin, Subject: Re That would On The	Angelique (NIH/NINDS) [C] b6 e: NIH studies and VAERS  I be great. Thank you!  Apr 26, 2021, at 6:39 PM, Gavin, Angelique (NIH/NINDS) [C] b6 wrote:  ank you b6 for getting back to me! Would Friday, May 7 at noon EST work for you?  gelique
To: Gavin, Subject: Re That would On The An NIII Co	Angelique (NIH/NINDS) [C] b6  E: NIH studies and VAERS  I be great. Thank you!  Apr 26, 2021, at 6:39 PM, Gavin, Angelique (NIH/NINDS) [C] b6 wrote:  ank you b6 for getting back to me! Would Friday, May 7 at noon EST work for you?  gelique  gelique  Gavin, MS (Contractor)  H/NINDS Clinical Operations Manager intractor Preferred Solutions Group
To: Gavin, Subject: Re That would On Th An An NII Co Na	Angelique (NIH/NINDS) [C] b6  E: NIH studies and VAERS  I be great. Thank you!  Apr 26, 2021, at 6:39 PM, Gavin, Angelique (NIH/NINDS) [C] b6 wrote:  ank you b6 for getting back to me! Would Friday, May 7 at noon EST work for you?  gelique  gelique  gelique Gavin, MS (Contractor)  H/NINDS Clinical Operations Manager  intractor Preferred Solutions Group  tional Institutes of Health
To: Gavin, Subject: Re That would On The An NII Co Na 10	Angelique (NIH/NINDS) [C] b6  E: NIH studies and VAERS  I be great. Thank you!  Apr 26, 2021, at 6:39 PM, Gavin, Angelique (NIH/NINDS) [C] b6 wrote:  ank you b6 for getting back to me! Would Friday, May 7 at noon EST work for you?  gelique  gelique  gelique  Gavin, MS (Contractor)  H/NINDS Clinical Operations Manager  intractor Preferred Solutions Group  tional Institutes of Health  Center Drive
To: Gavin, Subject: Re That would On The An NII Co Na 10 Bu	Angelique (NIH/NINDS) [C] b6  b6: NIH studies and VAERS  I be great. Thank you!  Apr 26, 2021, at 6:39 PM, Gavin, Angelique (NIH/NINDS) [C] b6 wrote:  ank you b6 for getting back to me! Would Friday, May 7 at noon EST work for you?  gelique  gelique  Gavin, MS (Contractor)  H/NINDS Clinical Operations Manager  intractor Preferred Solutions Group  tional Institutes of Health  Center Drive  ilding 10, Room 3B19, MSC 1251
To: Gavin, Subject: Re That would On The An NII Co Na 10 Bu	Angelique (NIH/NINDS) [C] b6  be: NIH studies and VAERS  Apr 26, 2021, at 6:39 PM, Gavin, Angelique (NIH/NINDS) [C] b6 wrote:  ank you b6 for getting back to me! Would Friday, May 7 at noon EST work for you?  gelique  gelique  Gavin, MS (Contractor)  H/NINDS Clinical Operations Manager  intractor Preferred Solutions Group  tional Institutes of Health  Center Drive  ilding 10, Room 3B19, MSC 1251  thesda, MD 20814-9692
To: Gavin, Subject: Re That would On The An NII Co Na 10 Bu	Angelique (NIH/NINDS) [C] b6  b6: NIH studies and VAERS  I be great. Thank you!  Apr 26, 2021, at 6:39 PM, Gavin, Angelique (NIH/NINDS) [C] b6 wrote:  ank you b6 for getting back to me! Would Friday, May 7 at noon EST work for you?  gelique  gelique Gavin, MS (Contractor)  H/NINDS Clinical Operations Manager intractor Preferred Solutions Group  tional Institutes of Health  Center Drive  ilding 10, Room 3B19, MSC 1251  thesda, MD 20814-9692  (office)
To: Gavin, Subject: Re That would On The An NII Co Na 10 Bu Be	Angelique (NIH/NINDS) [C] b6  E: NIH studies and VAERS  I be great. Thank you!  Apr 26, 2021, at 6:39 PM, Gavin, Angelique (NIH/NINDS) [C] b6 wrote:  ank you b6 for getting back to me! Would Friday, May 7 at noon EST work for you?  gelique  gelique  gelique Gavin, MS (Contractor)  H/NINDS Clinical Operations Manager  ntractor Preferred Solutions Group  tional Institutes of Health  Center Drive  ilding 10, Room 3B19, MSC 1251  thesda, MD 20814-9692  b6 (office)  (cell)
To: Gavin, Subject: Re That would On The An NII Co Na 10 Bu Be	Angelique (NIH/NINDS) [C] b6  b6: NIH studies and VAERS  I be great. Thank you!  Apr 26, 2021, at 6:39 PM, Gavin, Angelique (NIH/NINDS) [C] b6 wrote:  ank you b6 for getting back to me! Would Friday, May 7 at noon EST work for you?  gelique  gelique Gavin, MS (Contractor)  H/NINDS Clinical Operations Manager intractor Preferred Solutions Group  tional Institutes of Health  Center Drive  ilding 10, Room 3B19, MSC 1251  thesda, MD 20814-9692  (office)

**Contractor Preferred Solutions Group** 

Building 10, Room 3B19, MSC 1251

National Institutes of Health

10 Center Drive

REL0000229858

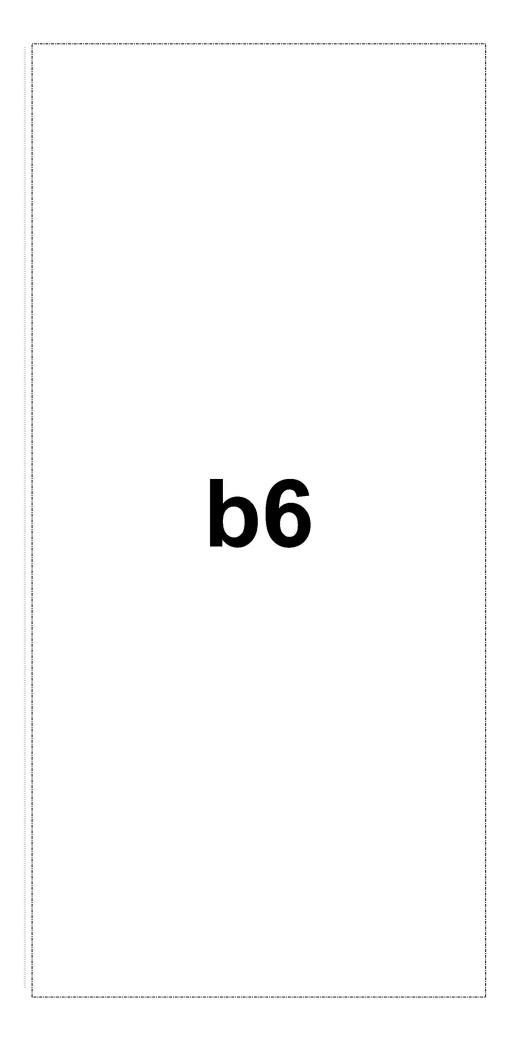
Bethesda, MD 20814-9692
b6 (office)
(cell)
(301) 480-5368 (efax)
b6
https://clinicaltrials.gov - study number 000089
-
From: b6
Sent: Sunday, April 25, 2021 11:35 AM  To: Gavin, Angelique (NIH/NINDS) [C] b6
Subject: Fwd: NIH studies and VAERS
Good morning,
My name is b6 Gayle McCrossin indicated that you may have a study where my case would be an interest. Please don't hesitate to contact me.
Would be all interest. Thease don't hesitate to contact me.
Thank you!
<b>b6</b>
Forwarded message From: <b>b6</b>
Date: Sun, Apr 25, 2021 at 11:33 AM
Subject: Re: NIH studies and VAERS  To: McCrossin, Gayle (NIH/CC/RMD) [E] <b>b6</b>
Hi Gayle,

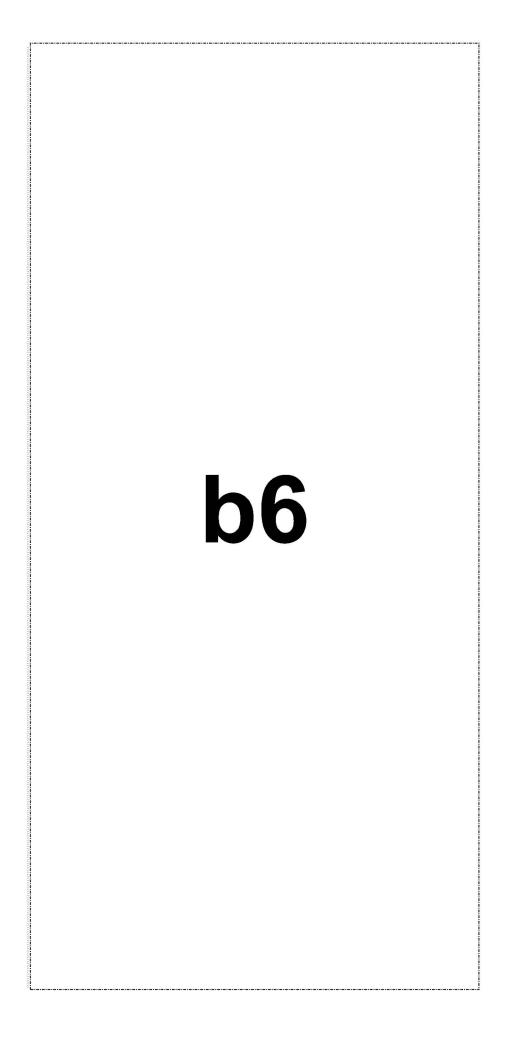
Thank you so much for the information!! I really appreciate it. I'll follow up with the contact you provided.
Best of luck on the study!
Thank you again.
On Fri, Apr 23, 2021 at 8:22 AM McCrossin, Gayle (NIH/CC/RMD) [E] b6 wrote:
Good morning b6
I hope your morning is off to a good start! I just want to thank you again for your interest and willingness to be part of our study. We are all happy that our prospects start to feel better after their vaccine. Your feeling better was definitely hard fought! A link to the vaccine study can be found here:
https://www.clinicaltrials.gov/ct2/show/NCT04761822?cond=covid+19+vaccine+reaction&cntry=US&state=US%3AMD&draw=2&rank=1
However, it appears through a brief review they are only looking for people who have not received a vaccine yet, and at a 90 minute reaction window following vaccine. It may be worthwhile to peruse the site and see if you can find a different study.
I forgot to ask you if you reported the adverse event after your vaccine. I would definitely contact VAERS with your experience. The link is to the information sheet regarding reporting adverse events:
https://www.fda.gov/media/83546/download
Lastly, Angelique is the contact for Dr. Bryan Smith's post covid study, I do not know the particulars, but she would be interested in speaking with you. They may want subjects closer to their initial acute Covid stage. Thankfully you are beyond that!
Angelique Gavin, MS (Contractor)
NIH/NINDS Clinical Operations Manager
Contractor Preferred Solutions Group

National Institutes of Health
10 Center Drive
Building 10, Room 3B19, MSC 1251
Bethesda, MD 20814-9692
h6 (office)
b6 (office) (cell)
(301) 480-5368 (efax)
<b>b6</b>
https://clinicaltrials.gov - study number 000089
Thank you so very much b6 Wishing you the very best!!
Gayle
Gayle McCrossin, MSN, FNP-BC, CNRN
NIH Clinical Center Department of Rehabilitation Medicine
Applied Physiology and Exercise Science Lab
Building 10 CRC, 1-1469
Bethesda, MD 20892-1604
Office Phone: <b>b6</b>
Cell: b6
Fax: 301.480.5086
<image001.png></image001.png>

From:	Gavin, Angelique (NIH/NINDS) [C] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6E97392E947E4F7EBB17EEB8AC87C5D5 b6
Sent:	10/28/2021 1:35:46 PM
To:	DE Madana Advara Rostina
Subject:	RE: Moderna Adverse Reaction
Thank you	b6
Angelique	
NIH/NINDS CI Contractor Pri National Instit 10 Center Driv Building 10, R Bethesda, ME 6 (301) 480-536	oom 3B19, MSC 1251 20814-9692 (office) (cell) (8 (efax)
_	
To: Gavin, And Subject: Re: N	b6 y, October 28, 2021 12:06 AM gelique (NIH/NINDS) [C] b6 doderna Adverse Reaction e great. Here's my information.
b	6
On Mon, Oct	25, 2021 at 8:24 AM Gavin, Angelique (NIH/NINDS) [C] <b>b6</b> wrote:
stories abou name and co	for your interest in our research. We are currently developing an online survey system to collect people's complications after receiving COVID vaccines. At this time, if you are willing, we can take your intact information. We will reach back out to you when the survey system is completed to see if you are unteer in our on-line study.
Sincerely,	
Angelique	
Angelique G	Pavin, MS (Contractor)

NIH/NINDS Clinical Operations Manager
Contractor Preferred Solutions Group
National Institutes of Health
10 Center Drive
<u>Building 10</u> , Room 3B19, MSC 1251
Bethesda, MD 20814-9692
b6 (cell)
(301) 480-5368 (efax)
b6
https://clinicaltrials.gov - study number 000089-N
-
From: b6  Sent: Friday, October 22, 2021 6:51 PM  To: Gavin, Angelique (NIH/NINDS) [C] b6  Subject: Moderna Adverse Reaction
Hello Dr. Gavin,
I heard you might be looking for candidates for a study soon. I'd really love to be apart of it. I got Moderna on b6 and an immediate reaction then 11 days later ended up in ER. My VAERS has been updated to serious and permanent disability. I still have on going neurological and cardiac issues.
Thank you for your time, b6





From: b6  Sent: 10/19/2022 5:02:25 AM  To: Gavin, Angelique (NIH/NINDS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6e97392e947e4f7ebb17eeb8ac87c5d5 b6  Subject: [EXTERNAL] Re: NIH Vaccine Study  Attachments: b6  Hi! Yes; I went on vacation and this got lost in the shuffle. Sorry. Answers are in bold.				
• What is your full name? <b>b6</b>				
• What is your preferred phone number? <b>b6</b>				
• How old are you? <b>b6</b>				
• Are you fluent in speaking, reading and writing English? Yes /No				
5. Do you live in the United States? Yes/No a. If yes, please provide the city, state and zip code where you live.  b6				
• Are you an NIH employee, contractor, trainee or otherwise affiliated with the NIH? Yes/No	0			
	7. Have you had a COVID-19 infection? <b>b6</b> a. If yes, how many COVID-19 infections have you had? <b>b6</b>			
b6				
b. What is the date of your first COVID-19 infection? b6				
b. What is the date of your first COVID-19 infection?  b6  c. Are you having persistent side effects after your first COVID-19 infection?  d. Do you have test results confirming your COVID 19 infection?  e. If you responded yes, please provide a copy of your COVID 19 test results with your emainersponse  b6  For tests performed at a laboratory or by a medical provider, results need to include your name, date of test result, type of test, and result of test. If you do not have a copy of your test result, please let us know and we can assist you in obtaining your records from your medical lab or provider.  For tests performed using a home testing kit, a photograph of the results with time and date are required.	il			
c. Are you having persistent side effects after your first COVID-19 infection? b6 d. Do you have test results confirming your COVID 19 infection? b6 e. If you responded yes, please provide a copy of your COVID 19 test results with your emairesponse b6 For tests performed at a laboratory or by a medical provider, results need to include your name, date of test result, type of test, and result of test. If you do not have a copy of your test result, please let us know and we can assist you in obtaining your records from your medical lab or provider. For tests performed using a home testing kit, a photograph of the results with time and				
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b6 left lymph node swollen, "pins and needles" from left shoulder to left ring and pinky finger	r,
muscle aches. Coincidentally had annual OB/GYN exam that day and described symptoms; she	
recommended b6	
b6 left arm paresthesia continued. Regular PCP was not available, so visited other healthcare	
provider, who prescribed b6 for arm pain. Afterwards, chills, bo	ody
aches, fatigue, faster heart rate, random muscle twitches spread from left arm to rest of body,	
neurological "pinpricks" or "zaps" throughout body. This would get worse; see Continuation Page.	
b6 paresthesia and fasciculations throughout body (but mostly left arm and leg), rapid heart	
rate, muscle and body aches, and fatigue continued. Fever, night sweats; did not take temperature. Felt	t
shaky in the morning. Stiffness on left side of body upon waking; did not sleep on left side.	
b6 sudden shooting pain in back of left thigh to the point of limping. Telehealth and urgent ca	re
advised going to ER if medication did not improve symptoms b6 Although the	
shooting pain faded to a dull ache, went to emergency room as instructed. In hospital, left leg tested negative for b6 Advised follow-up appointment	
negative for b6 Advised follow-up appointment	nt
with PCP.	
b6 Described symptoms at follow-up appointment. Left leg felt better, but other symptoms	
continued. Blood work taken. Upon results, advised to b6	
b6 Woke up in pain. For past few days, had new symptoms of stiff, sore arms in mornings, her	art
palpitations especially when trying to sleep, chest pain, shortness of breath, and occasionally a sore	
stomach in mornings (may have been due muscle spasms at night). Neuropathy and fasciculations	
continuing. Inability to walk in mornings. Limbs feel heavy and hard to move for several hours. Possib	le
b6 but was not tested for it.	
b6 Follow-up blood work. Also, menstrual period unusually late.	
b6 Follow-up appointment and more blood work. Some symptoms improving after deciding to	0
go on anti-inflammatory diet. Still taking b6 Leg pain gone,	
muscle twitches still exist, peripheral neuropathy primarily in right fingers, foot, and left thigh.	
Cramping in left arm. Right arm numbness persists. Left hand feels cool to the touch but not in pain.	
Fewer muscle twitches, but intermittently persist in right lower rib cage. b6	7
b6	-i
b6 More severe symptoms mostly resolved, but left eye often twitches and left arm does not fee	ه ا
normal.	<b>C1</b>
b6 Still getting random occasional muscle twitches; they persist to this day, especially after	
eating inflammatory foods. Left arm still weaker than right.	
cating inflammatory loods. Left af in still weaker than right.	
Started having cold-like symptoms.	
Cold-like symptoms.  Cold-like symptoms continued off and on. Additionally, new tingling down to ring and pinl	1,,,
fingers of left arm, as they did after the vaccine. Due to this, took a COVID-19 test, b6	K y
	!
During quarantine, besides a cough, mild cold-like symptoms, and temporary loss of smell, had a	
(fortunately milder) replay of vaccine side effects, with paresthesia in left arm down to the same fingers	
left leg feeling weak, more muscle fasciculations, fever, and tachycardia, but for a much shorter duration of the state of	
It was as if my immune system attacked the spike protein, but also the same nerves as before, suggesting	ıg
a new autoimmune reaction from the vaccine.	
	·i
For me personally, the side effects from the vaccine were multitudes worse than b6	
L.C	İ
b6	
b6 But my vaccine	
	2

	e content is safe.	nless you recognize the
	b6	
wrote: <mail attachme<="" td=""><td>nt.png&gt; e (NIH/NINDS) [C]  b6  has sent you an early your identity at the link below to access the encrypted email.</td><td></td></mail>	nt.png> e (NIH/NINDS) [C]  b6  has sent you an early your identity at the link below to access the encrypted email.	

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From: Sent: To: Subject:	Gavin, Angelique (NIH/NINDS) [C] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6E97392E947E4F7EBB17EEB8AC87C5D5 b6  10/19/2022 12:27:57 PM  b6  RE: [EXTERNAL] Re: NIH Vaccine Study			
Thank you <b>b</b> great day!	6 for your response! We will review and get back to you soon with the next steps in the process. Have a			
Angelique				
NIH/NINDS Cli Contractor Pro National Instit 10 Center Driv Building 10, R Bethesda, MD <b>b6</b> (301) 480-536	oom 3B19, MSC 1251 20814-9692 (office) (cell) 8 (efax)			
From:	b6			
Sent: Wednes To: Gavin, Ang Subject: [EXTE	day, October 19, 2022 1:02 AM gelique (NIH/NINDS) [C] b6 ERNAL] Re: NIH Vaccine Study t on vacation and this got lost in the shuffle. Sorry. Answers are in bold.			
• What is you	r full name? <b>b6</b>			
• What is you	r preferred phone number? <b>b6</b>			
• How old are	you? b6			
• Are you flue	nt in speaking, reading and writing English? <b>Yes</b> /No			
•	re in the United States? <b>Yes</b> /No se provide the city, state and zip code where you live. <b>b6</b>			
• Are you an I	NIH employee, contractor, trainee or otherwise affiliated with the NIH? Yes/ <b>No</b>			
a. If yes, how	ad a COVID-19 infection? b6 many COVID-19 infections have you had? b6 date of your first COVID-19 infection? b6			

b6			
c. Are you having persistent side effects after your first COVID-19 infection? b6			
d. Do you have test results confirming your COVID 19 infection? b6			
e. If you responded yes, please provide a copy of your COVID 19 test results with your email			
response. <b>b6</b>			
For tests performed at a laboratory or by a medical provider, results need to include			
your name, date of test result, type of test, and result of test. If you do not have a copy			
of your test result, please let us know and we can assist you in obtaining your records			
from your medical lab or provider.			
For tests performed using a home testing kit, a photograph of the results with time and			
date are required.			
8. Have you received a COVID-19 vaccine? <b>Yes</b> No			
a. If you responded yes, please provide a copy of your COVID 19 vaccination card with your			
email response. Attached.			
b. If yes, do you have persistent side effects after receiving a COVID-19 vaccination?			
Yes No			
Since the survey also asked for a short summary, here is the timeline of symptoms from my VAERS report compiled			
from CDC V-Safe check-ins, medical records, and personal notes.			
b6 stiff left elbow; was more mild by b6 check-in on CDC's V-Safe.			
ierc lymph node swonen, pins and needles monter shoulder to left ring and pinky miger, muscle			
aches. Coincidentally had annual OB/GYN exam that day and described symptoms; she recommended b6			
b6 left arm paresthesia continued. Regular PCP was not available, so visited other healthcare provider, who			
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Started having cold-like symptoms.  Cold-like symptoms continued off and on. Additionally, new tingling down to ring and pinky fingers of left arm, as they did after the vaccine. Due to this, took a COVID-19 test, b6 During quarantine, besides a cough, mild cold-like symptoms, and temporary loss of smell, had a (fortunately milder) replay of vaccine side effects, with paresthesia in left arm down to the same fingers, left leg feeling weak, more muscle fasciculations, fever, and tachycardia, but for a much shorter duration. It was as if my immune system attacked the spike protein, but also the same nerves as before, suggesting a new autoimmune reaction from the vaccine.			
		·	
For me personally, the side effects from the vacc	b6	b6	
b6 But my vaccine reaction in nobody cared, and/or were reluctant to address	b6 was the worst experience of the possibility that something was wr	-	
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	6		
On Sep 24, 2022, at 2:42 PM, Gavin, Ange	elique (NIH/NINDS) [C] <b>b6</b>	wrote:	

<iviali attachment.png=""></iviali>		
Gavin, Angelique (NIH/NINDS) [C]	b6	has sent you an encrypted email. Please
verify your identity at the link below to	access the encr	ypted email.
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Sent:	(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6E97392E947E4F7EBB17EEB8AC87C5D5 <b>b6</b> 10/2/2022 1:02:18 PM
To:	b6
Subject:	RE: [EXTERNAL] Re: NIH Vaccine Study
Hi <b>b6</b> Yes	, please add your responses to the questions below.
Thank you, Angelique	
NIH/NINDS CI Contractor Pr National Insti 10 Center Dri Building 10, R Bethesda, ME <b>b6</b> (301) 480-536	oom 3B19, MSC 1251 0 20814-9692 (office) (cell) 68 (efax)
To: Gavin, An	b6 October 2, 2022 12:06 AM gelique (NIH/NINDS) [C] b6 ERNAL] Re: NIH Vaccine Study
Hi,	
Do I respond	to the questions here or is there a form within that link that I'm missing?
On Se	p 24, 2022, at 2:42 PM, Gavin, Angelique (NIH/NINDS) [C] <b>b6</b> wrote:
<mai< td=""><td>I Attachment.png&gt;</td></mai<>	I Attachment.png>
(	Bavin, Angelique (NIH/NINDS) [C] <b>b6</b> has sent you an encrypted email.  Please verify your identity at the link below to access the encrypted email.
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From:	Gavin, Angelique (NIH/NINDS) [C] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6E97392E947E4F7EBB17EEB8AC87C5D5 <b>b6</b> 10/18/2022 5:03:15 PM
Sent: To:	10/16/2022 5.05.15 PW
Subject:	RE: [EXTERNAL] Re: NIH Vaccine Study
	ope all is well! I am following up with you as I have not received your responses to the questions I had let me know if you remain interested in participating. I am looking forward to your reply.
Sincerely, Angelique	
NIH/NINDS C	lawin, MS (Contractor)  linical Operations Manager  referred Solutions Group
	itutes of Health
1000	Room 3B19, MSC 1251 D 20814-9692
b6	(office) (cell)
(301) 480-536 b	
-	attrials.gov - study flumber 000085-iv
From:	<b>b6</b> , October 2, 2022 12:06 AM
To: Gavin, An	rgelique (NIH/NINDS) [C] b6 ERNAL] Re: NIH Vaccine Study
Hi,	
Do I respond	to the questions here or is there a form within that link that I'm missing?
On Se	ep 24, 2022, at 2:42 PM, Gavin, Angelique (NIH/NINDS) [C] b6 wrote:
<ma< td=""><td>il Attachment.png&gt;</td></ma<>	il Attachment.png>
(	Gavin, Angelique (NIH/NINDS) [C] <b>b6</b> has sent you an encrypted email.  Please verify your identity at the link below to access the encrypted email.
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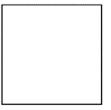
From:	, , ,	,	ELABS/OU=EXCHANGE ADMINISTRATIVE GROUP 92E947E4F7EBB17EEB8AC87C5D5 <b>b6</b>	
Sent:	10/19/2022 1:49:11		92E94/E4F/EBB1/EEB6AC6/C3D3  <b>D6</b>	
To:	b6			
Subject:	RE: [EXTERNAL] Re:	 NIH Vaccine Study		
Subject.	NE. [EXTERNAL] Ne.	Will vaccine Study		
Thank you	<b>b6</b> for your kind of	fer! We are close to our n	nax for recruitment but could possibly use a few more in case	
some are n	ot eligible. Please ha	ve your friends contact us	at our email address of <u>nindspostcovid19@ninds.nih.gov</u> if	
they are int	terested. Much appre	ciated!		
Sincerely,				
Angelique				
	Gavin, MS (Contra			
	Clinical Operations N			
	Preferred Solutions G	roup		
	stitutes of Health			
10 Center D				
	, Room 3B19, MSC 12	51		
Bethesda, N	MD 20814-9692			
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From{		06		
	nesday, October 19, 2			
To: Gavin, A	Angelique (NIH/NINDS	6) [C] <b>b6</b>		
Subject: Re	: [EXTERNAL] Re: NIH	Vaccine Study		
You're weld	come! If you need mo	re people with vaccine inju	uries for the study, I know a few more. One is <b>b6</b>	
	b6	and another is	b6	
<b>b6</b> And	ther is	b6	ь6 I can also ask around in online support groups. There's a	
few thousa				
	0.40.0000 .000	AAA G : A !: /AIII	1/NIN(DC) [C]	
On	Oct 19, 2022, at 8:28	AIVI, Gavin, Angelique (Nif	H/NINDS) [C] <b>b6</b> wrote:	
Tha	ank you be lifer you	r responsel. We will review	v and get back to you soon with the next steps in the	
	ocess. Have a great da		valid get back to you soon with the next steps in the	
Ang	gelique			
An	gelique Gavin, MS (	Contractor)		
	I/NINDS Clinical Oper	\ <del>-</del>		
Cor	Contractor Preferred Solutions Group			
Nat	National Institutes of Health			

10 Center Drive
Building 10, Room 3B19, MSC 1251
Bethesda, MD 20814-9692
LC (office)
DO (cell)
(301) 480-5368 (efax)
b6
https://clinicaltrials.gov - study number 000089-N
The political distriction of the state of th
From: b6 Sent: Wednesday, October 19, 2022 1:02 AM To: Gavin, Angelique (NIH/NINDS) [C] b6
Sent: Wednesday, October 19, 2022 1:02 AM
To: Gavin, Angelique (NIH/NINDS) [C] b6
Subject: [EXTERNAL] Re: NIH Vaccine Study
Hi! Yes; I went on vacation and this got lost in the shuffle. Sorry. Answers are in <b>bold.</b>
• What is your full name? b6
That is your rain named.
• What is your preferred phone number? b6
What is your preferred priorie number :
• How old are you? <b>b6</b>
How old are you! Do :
A
<ul> <li>Are you fluent in speaking, reading and writing English? Yes /No</li> </ul>
5. Do you live in the United States? <b>Yes/</b> No
a. If yes, please provide the city, state and zip code where you live. <b>b6</b>
<ul> <li>Are you an NIH employee, contractor, trainee or otherwise affiliated with the NIH? Yes/No</li> </ul>
7. Have you had a COVID-19 infection? b6
a. If yes, how many COVID-19 infections have you had? b6
b. What is the date of your first COVID-19 infection? b6
b6
c. Are you having persistent side effects after your first COVID-19 infection? b6
d. Do you have test results confirming your COVID 19 infection? b6
e. If you responded yes, please provide a copy of your COVID 19 test results with your email
response. b6
For tests performed at a laboratory or by a medical provider, results need to include
your name, date of test result, type of test, and result of test. If you do not have a copy
of your test result, please let us know and we can assist you in obtaining your records
from your medical lab or provider.
For tests performed using a home testing kit, a photograph of the results with time and
date are required.
8. Have you received a COVID-19 vaccine? <b>Yes</b> No
a. If you responded yes, please provide a copy of your COVID 19 vaccination card with your
email response. Attached.

Since the survey also asked for a short summary, here is the timeline of symptoms from my VAERS report compiled from CDC V-Safe check-ins, medical records, and personal notes.

,	
b6	stiff left elbow; was more mild by b6 check-in on CDC's V-Safe.
	left lymph node swollen, "pins and needles" from left shoulder to left ring and pinky
recommend	le aches. Coincidentally had annual OB/GYN exam that day and described symptoms; she
	left arm paresthesia continued. Regular PCP was not available, so visited other
	provider, who prescribed b6 for arm pain. Afterwards,
	aches, fatigue, faster heart rate, random muscle twitches spread from left arm to rest of
E 15	logical "pinpricks" or "zaps" throughout body. This would get worse; see Continuation
Page.	rogical pripriets of Lups throughout body. This would get worse, see continuation
b6	paresthesia and fasciculations throughout body (but mostly left arm and leg), rapid hear
rate, muscle	and body aches, and fatigue continued. Fever, night sweats; did not take temperature.
1000	the morning. Stiffness on left side of body upon waking; did not sleep on left side.
	sudden shooting pain in back of left thigh to the point of limping. Telehealth and urgent
care advised	going to ER if medication did not improve symptoms b6 Although
the shooting	pain faded to a dull ache, went to emergency room as instructed. In hospital, left leg
tested	b6 Advised follow-up
appointmen	
b6	Described symptoms at follow-up appointment. Left leg felt better, but other symptoms
continued. E	Blood work taken b6
b6	
L	Woke up in pain. For past few days, had new symptoms of stiff, sore arms in mornings,
(5)	ations especially when trying to sleep, chest pain, shortness of breath, and occasionally a
	h in mornings (may have been due muscle spasms at night). Neuropathy and
hours. Possi	ns continuing. Inability to walk in mornings. Limbs feel heavy and hard to move for several ble b6 , but was not tested for it.
	Follow-up blood work. Also, menstrual period unusually late.
<b>b6</b>	Follow-up appointment and more blood work. Some symptoms improving after deciding
to go on ant	i-inflammatory diet. Still taking b6 Leg pain gone,
	ches still exist, peripheral neuropathy primarily in right fingers, foot, and left thigh.
	left arm. Right arm numbness persists. Left hand feels cool to the touch but not in pain.
	le twitches, but intermittently persist in right lower rib cage. b6
	b6
b6	More severe symptoms mostly resolved, but left eye often twitches and left arm does
not feel nor	mal.
b6	Still getting random occasional muscle twitches; they persist to this day, especially after
eating inflan	nmatory foods. Left arm still weaker than right.
,	
b6	Started having cold-like symptoms.
i	Cold-like symptoms continued off and on. Additionally, new tingling down to ring and
	s of left arm, as they did after the vaccine. Due to this, took a COVID-19 test, b6
r	ring quarantine, besides a cough, mild cold-like symptoms, and temporary loss of smell,
	nately milder) replay of vaccine side effects, with paresthesia in left arm down to the
	s, left leg feeling weak, more muscle fasciculations, fever, and tachycardia, but for a much ation. It was as if my immune system attacked the spike protein, but also the same nerves
	liggesting a new autoimmune reaction from the vaccine.
us vervie, st	ASSESSING A NEW AUTOMINIONE FEACTION HOME THE VACCINE.

	s from the vaccine were multitudes worse	than b6
	<b>b6</b>	
ny vaccine reaction in b6 ared, and/or were reluctant to a	was the worst experience of my life, ddress the possibility that something was v	But and it seemed like nobody wrong.
AUTION: This email originated from o	outside of the organization. Do not click links or nt the content is safe.	open attachments unless you
	<b>b6</b>	



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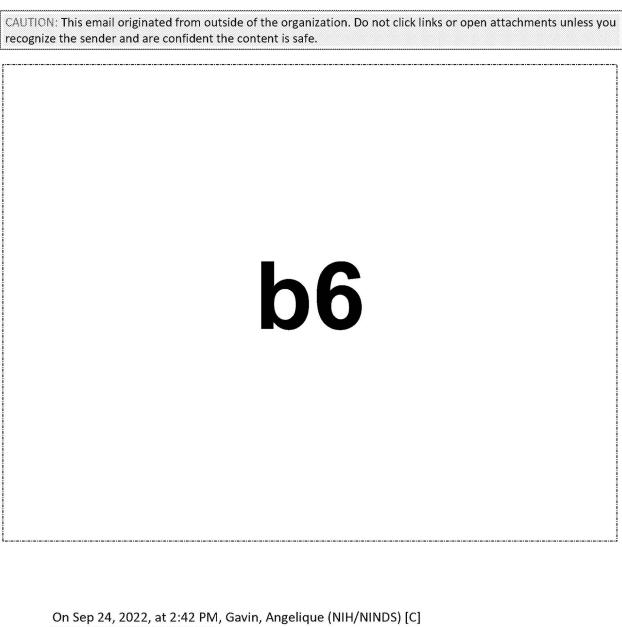
<message\_v4.rpmsg>

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From:	Gavin, Angelique (NIH/NINDS) [C] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP
	(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6E97392E947E4F7EBB17EEB8AC87C5D5 <b>b6</b>
Sent:	10/20/2022 4:59:07 PM
То:	b6
Subject:	RE: [EXTERNAL] Re: NIH Vaccine Study
Thank yo	u 🕲
Angeliqu	ue Gavin, MS (Contractor)
	OS Clinical Operations Manager
	or Preferred Solutions Group
	Institutes of Health
10 Cente	10, Room 3B19, MSC 1251
	a, MD 20814-9692
	(office)
be	(cell)
(301) 480	0-5368 (efax)
[ 	b6
https://c	linicaltrials.gov - study number 000089-N
-	
From:	b6
Sent: Thu	ursday, October 20, 2022 12:48 PM
	n, Angelique (NIH/NINDS) [C] <b>b6</b>
Subject:	Re: [EXTERNAL] Re: NIH Vaccine Study
If I can fii	nd it! I'll look tonight.
C	On Oct 20, 2022, at 12:39 PM, Gavin, Angelique (NIH/NINDS) [C] <b>b6</b> wrote:
Т	hanks again b6 Can you send us a pic of the back of your vaccine card as well?
A	Angelique
(	Ingelique Gavin, MS (Contractor)
	NIH/NINDS Clinical Operations Manager
(	Contractor Preferred Solutions Group
	National Institutes of Health
	.0 Center Drive
	Building 10, Room 3B19, MSC 1251
E F	Sethesda, MD 20814-9692
	b6 (office) (cell)
l 1	301) 480-5368 (efax)
1	b6
ر ۲	nttps://clinicaltrials.gov - study number 000089-N

From:	b6
Sent: Wednesda	y, October 19, 2022 1:02 AM
To: Gavin, Angel	ique (NIH/NINDS) [C] <b>b6</b>
Subject: [EXTERI	NAL] Re: NIH Vaccine Study
Hil Vas. Lwant a	was the and this get lost in the shortfle Course Anguerous and in hald
HI! Yes; I went o	n vacation and this got lost in the shuffle. Sorry. Answers are in <b>bold.</b>
• What is your fo	ull name? b6
<ul> <li>What is your p</li> </ul>	referred phone number? b6
a Havy ald avayy	
<ul> <li>How old are yo</li> </ul>	)u ( <u>b6</u> )
Are you fluent	in speaking, reading and writing English? Yes /No
,	
5. Do you live i	in the United States? <b>Yes</b> /No
a. If yes, please p	provide the city, state and zip code where you live. <b>b6</b>
<ul> <li>Are you an NII-</li> </ul>	Hemployee, contractor, trainee or otherwise affiliated with the NIH? Yes/ <b>No</b>
7	- COVID 10 infantion 3
7. Have you nad	a COVID-19 infection? b6 any COVID-19 infections have you had? b6
a. If yes, now ma	any COVID-19 Infections have you had?
L	ate of your first COVID-19 infection? b6
b. what is the da	
L	b6
	g persistent side effects after your first COVID-19 infection? b6
	test results confirming your COVID 19 infection? b6
	ded yes, please provide a copy of your COVID 19 test results with your email
response b	
	ned at a laboratory or by a medical provider, results need to include
	of test result, type of test, and result of test. If you do not have a copy
•	ılt, please let us know and we can assist you in obtaining your records
•	cal lab or provider.
	ned using a home testing kit, a photograph of the results with time and
date are require	d.
8 Have you rece	eived a COVID-19 vaccine? <b>Yes</b> No
	ded yes, please provide a copy of your COVID 19 vaccination card with your
email response.	
	have persistent side effects after receiving a COVID-19 vaccination?
Yes No	have persistent side effects after receiving a COVID-15 vaccination:
163 110	
Since the survey	also asked for a short summary, here is the timeline of symptoms from my VAERS
	I from CDC V-Safe check-ins, medical records, and personal notes.
- when a sample upon	
he stif	ff left elbow; was more mild by b6 check-in on CDC's V-Safe.
lef	t lymph node swollen, "pins and needles" from left shoulder to left ring and pinky
finger, muscle a	ches. Coincidentally had annual OB/GYN exam that day and described symptoms; she
recommended	b6

palthrare n	•		lar PCP was not avail		
•	rovider, who prescr	\	b6	for arm pain. A	
100 T	ATA 1000		m muscle twitches s	2.6	
	logical "pinpricks" o	r "zaps" througho	ut body. This would g	get worse; see Conti	nuation
age.	Ingresthesis and for	aia. Jatia na thua	haut hadu (but mad	lulaft avec and lact	vanid baavt
			hout body (but most		
	-	-	d. Fever, night swear	•	
-	_		body upon waking; d		
			high to the point of I		
			rove symptoms		Although
ested	pain raueu to a uui	b6	nergency room as ins	Advised follo	
ppointmen	t with DCD	D0		Advised iolio	w-up
b6		ns at follow-up an	pointment. Left leg f	alt hatter but other	cumntome
	lood work taken.	is at ionow-up ap	b6	en better, but other	Symptoms
b6	Woke up in pain. F	or past few days. h	nad new symptoms o	f stiff, sore arms in n	nornings.
eart palpita			chest pain, shortnes		10 mm
	5 151	15 ( <del>5</del> )	iscle spasms at night		.o.oay a
			ings. Limbs feel heav	S (5)	for several
ours. Possil			ut was not tested for	E2	
	_		al period unusually l		
b6	i	30	ood work. Some sym		er deciding
go on ant	i-inflammatory diet.		b6		ain gone,
_	•	- L	primarily in right fing		-
			s. Left hand feels coo		-
			in right lower rib cag		<u>-</u>
	b6	The state of the s			
L C	More severe sympt	toms mostly resolv	ed, but left eye ofte	n twitches and left a	rm does
b6					
	•				
ot feel norr	nal.	n occasional muscl	e twitches; they pers	list to this day, espec	cially after
ot feel norr b6	nal.			sist to this day, espec	cially after
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On Sep 24, 2022, at 2:42 F	PM, Gavin, Angeliq	ue (NIH/NINDS	5) [C]
b6	wrote:		
<mail attachment.png=""></mail>			
Gavin, Angelique (NIH/NII	NDS) [C]	b6	has sent you an encrypted
email. Please verify your i	dentity at the link l	below to acces	s the encrypted email.
There is a second of the secon			
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500000000000000000000000000000000000000							
Erom	he						
From: Sent:							
To:							
Subject:							
Good morni	ng!						
classify any	my symptoms persist, but for today (I qualify my answer because things seem to change on a whim) I would not as severe. I am able to live my life, albeit with some weakness that remains on the left side. Brain fog seems ut not back to 100%.						
Internal vibr Neuropathy	rations last for seconds and seem to mostly occur in my legs.						
Random ner	ve pain (warmth, sharp pain, crawling sensation) left arm, left leg, and right thigh.  mbness from bicep to fingertips is constant						
Left hand tro	emor occurs sporadically but seems mostly resolved (for the last three days). When I wake up in the morning the ere but mostly dissipates once I am fully awake.						
Left leg wea	kness (I feel unstable at times) continues and numbness from mid thigh to foot.						
	otom is muscle twitching in my left leg lower quad ching in both calves, but intensity has reduced						
	from back of skull to forehead (above eyes)						
Facial parae bottom lip in	quick Sharp searing pain in my head mostly on my left side above my ear region and occasionally on the right side. sthesia continues 24/7. My lips burn 24/7 and I have developed nerve pain and intense itching right under my a place where I used to get cold sores all the time. The skin peels like a sunburn. There are times I feel like						
	pped my face - nerve pain?  ning has greatly reduced as has the hot nerve pain that was occurring under my eyes.						
My vision st	ill gets blurry, but I have dry eyes and that could be the culprit						
The pain in	my upper right back (from spine to scapula) is nearly resolved and a non-issue at this point.						
The internal	purning in my inner ear, but this has reduced as well to occur every few days quaking has reduced and has not returned for about 3 days. This internal feeling is akin to anxiety remely constipated						
I have fleeting of high bloo	ng moments of dizziness and I am going to have my blood pressure checked. I know some people have complained d pressure,						
Stress, of co	urse, makes everything worse						
	concern is the one no one can answer at this point: Will I develop an autoimmune disease, ALS, Parkinson's, or ars down the road because of this vaccine reaction?						
Farinaz, I ap	preciate you and your efforts to dig for answers,						
b6							
C							
On	Apr 11, 2021, at 2:49 PM, Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b>						

wrote:

Hi b6 How are your symptoms?are they still severe?				
Farinaz				
From: b6  Sent: Sunday, April 11, 2021 5:47:32 PM  To: Safavi, Farinaz (NIH/NINDS) [E] b6  Subject: Re: Neurological reaction to vaccine.				
Hello, Dr. Safavi! Somehow I overlooked your email dated April 3 and found it while looking back through my emails today for something completely unrelated to my health. I am so glad I found it!  I have an appointment with my neurologist b6 I have emailed Amanda all the signed ROIs for every				
physician I have seen since receiving my vaccination b6  Because every test I have had to date b6 is there a necessity for b6				
I am always open to a televisit with you (I am sorry I missed the opportunity you mentioned in your email). I am also willing to fly to NIH if there is great benefit to be obtained. I am hoping that with the ROI you would be able to converse with my neurologist,  b6				
Thank you for what you are accomplishing - this is no small feat!				
<b>b6</b>				
On Apr 3, 2021, at 1:48 PM, Safavi, Farinaz (NIH/NINDS) [E]    b6				
Regarding the blood sample, can you please contact Amanda and send us medical release form and schedule the consent then we can send you a kit to collect blood sample?				
Thank you very much Farinaz PS;I might be able to talk to you through televisit this week let me know does Tuesday work for you?				
Farinaz				
From: b6  Sent: Tuesday, March 30, 2021 4:44:03 PM  To: Safavi, Farinaz (NIH/NINDS) [E] b6  Subject: Re: Neurological reaction to vaccine				

Thank you for following up with me. Since we last spoke on our Telehealth meeting my symptoms are the following: Increased numbness - left arm and left hand from bicep to fingertips 24/7. Right index finger is numb (hot) and other right hand fingers are slightly numb. Nerves firing in both calves 24/7 Neuropathy in both feet 24/7 with fluctuating intensity Global scalp pressure and tingling from base of neck to forehead with fluctuating intensity Nerves fire hot on left side of scalp behind left ear. Intermittent hot or painful nerves (stabbing pain) in my head or near temple. Intermittent buzzing (I don't know how else to describe this feeling) in limbs or in my feet that lasts seconds and then goes away. Brain fog - I forget how to spell common words; I get confused at times or am unable to focus my attention, which is a problem as a Bilateral facial paraesthesia with hot nerves firing under right eye, on the corner of left eye. Numb lips 24/7 with nerves firing around my mouth. Occasionally. My smile is normal. Recently, I have been concerned by a slight hand tremor that has developed in my left arm and hand. I have days where I have an internal quaking that is through my entire body. The other night I woke up out of a sound sleep to a feeling that I was sinking into myself (I don't know how to explain it) and then my entire leg jumped. And then that feeling again and my left arm jumped. My first thought was "am I going to have convulsions?" My hand jumped, my foot twitched - all involuntarily. I got up and moved around before going back to bed. This has not reoccurred, but now **b6** Nerves fire all over my body like little pin pricks (sometimes feels like itching). I had something similar many years ago during a stressful time, but it resolved. My energy level is normal. I have noticed that I have several "good days" in succession and then a string of 3-5 days where I am weak, the internal quaking is nearly intolerable and the tremor in left arm and hand is increased. I had my b6 I am sending medical releases to Amanda so you can gain access to THANK YOU for your effort and energy! I appreciate you. **b6** P.S. Is there blood work you would want from me?

Hello Dr. Safavi,

REL0000230321

On Mar	26, 2021, at 6:47 AM, Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b> wrote:
and get (	<b>b6</b> is well.I am writing to follow up with you about your symptoms update how you are doing. It me know
Division	Safavi MD, PhD of Neuroimmunology and Neurovirology NIH, Bethesda, MD
To: Safav	b6 nday, March 14, 2021 4:04 AM vi, Farinaz (NIH/NINDS) [E] Re: Neurological reaction to vaccine.
	am attaching a file with a summary letter of my journey since he Moderna vaccine on b6 Additionally, I have included b6
	b6
L	<b>b6</b> I look forward to ou
	on Monday at 11:00AM ET. ou so much!
b6	
·	On Mar 10, 2021, at 4:44 PM, Safavi, Farinaz
(	On Mar 10, 2021, at 4:44 PM, Safavi, Farinaz NIH/NINDS) [E] <b>b6</b> wrote:
l i r V	Dear b6 am really sorry to hear about your illness. b6 s correct.We started an effort at NIH to look into neurological complications of the covid vaccine. We can schedule a televisit in a mutual convenient time and discuss your symptoms.
7	n a meanwhile,you can send me a summary of your disease and work up you already had since vaccination.
a	have an available spot in my schedule on Friday at 1pm ET and Monday at 11am ET. Please let me know the tine works for you.

Best Regards, Farinaz
Farinaz
<a81a3af1ff0b4a2d87b1a640fd6a1814.png></a81a3af1ff0b4a2d87b1a640fd6a1814.png>
From: b6
Sent: Wednesday, March 10, 2021 1:07:30 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
b6
Subject: Neurological reaction to vaccine.
Hello!
b6 told me you graciously offered a
consultation related to neurological symptoms post-
vaccine to the others in our "group". I had 1st dose of
Moderna on <b>b6</b> and presented at the Emergency
Room with stroke-like symptoms on <b>b6</b>
I now experience bilateral facial paraesthesia,
Left leg/ arm numbness and weakness. Neuropathy in
hands, feet. Scalp pressure. Brain fog.
I would love to connect with you as b6 said you
were incredibly helpful to a situation that no one else
seems to acknowledge.
Thank you,
L.C
nn

Sent from my iPhone

From: Sent: To: Subject:	b6 3/11/2021 1:46:08 AM Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 b6 Re: Neurological reaction to vaccine.
I will ta	you so much, Farinaz! ake your available spot on Monday at 11:00AM ET. I will send you my medical information by this morning so you may have time to review. I look forward to meeting you.
Sent fro	om my iPhone
	On Mar 10, 2021, at 4:44 PM, Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b> wrote:
	Dear b6 I am really sorry to hear about your illness b6 is correct. We started an effort at NIH to look into neurological complications of the covid vaccine.  we can schedule a televisit in a mutual convenient time and discuss your symptoms.
	In a meanwhile, you can send me a summary of your disease and work up you already had since vaccination.
	I have an available spot in my schedule on Friday at 1pm ET and Monday at 11am ET. Please let me know the tine works for you.
	Best Regards, Farinaz
	Farinaz
i	From: b6  Sent: Wednesday, March 10, 2021 1:07:30 PM  To: Safavi, Farinaz (NIH/NINDS) [E] b6  Subject: Neurological reaction to vaccine.  Hello!  b6 told me you graciously offered a consultation related to neurological symptoms post-vaccine to the others in our "group". I had 1st dose of Moderna on b6 and presented at the Emergency Room with stroke-like symptoms on b6  I now experience bilateral facial paraesthesia,  Left leg/ arm numbness and weakness. Neuropathy in hands, feet. Scalp pressure. Brain fog.  I would love to connect with you as b6 said you were incredibly helpful to a situation that no one else seems to acknowledge.  Thank you,
	<b>b6</b>

REL0000230346

Sent from my iPhone

From: Sent: To: Subject:	b6 3/16/2021 10:25:47 PM Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 b6 Re: Kit
I will, than	nks. I hope you are right that I will continue to improve.
Sent from	my iPhone
	Mar 16, 2021, at 3:00 PM, Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b> ote:
	ease keep me in loop how your symptoms ho in a couple of weeks. rinaz
	nt from my T-Mobile 4G LTE Device et <u>Outlook for Android</u>
Sei To Sui	b6 nt: Tuesday, March 16, 2021 2:47:29 PM : Safavi, Farinaz (NIH/NINDS) [E] b6 bject: Re: Kit anks Farinaz. I continue with milder symptoms for the past week or two. This remains at a
	ble level with occasional flare ups. I hope it will continue to improve.
Se	nt from my iPhone
	On Mar 16, 2021, at 11:40 AM, Safavi, Farinaz (NIH/NINDS) [E]  b6 wrote:
	Thank you for sending the paper.  I agree that molecular mimicry is a well known mechanisms for potential autoimmune response post infection and vaccination but those immune responses are usually delayed type immune response requiring weeks to develop.  Following speaking with several people with post vaccine reactions similar to your condition, I think the type of immune response we see here is not delayed type immune reaction since it happens acutely and very close to inoculation time. Unfortunately, we still at the beginning of this road to know and understand more about COVID itself and new mRNA vaccine.  Hope all is better with your symptoms.  Best  Farinaz

Farinaz Safavi MD, PhD

Division of Neuroimmunology and Neurovirology NINDS, NIH, Bethesda, MD

From: b6 Sent: Tuesday, March 16, 2021 1:39 PM To: Safavi, Farinaz (NIH/NINDS) [E] Subject: Re: Kit
Thanks Farinaz. Have you seen this?
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7833091/
Sent from my iPhone
On Mar 16, 2021, at 9:30 AM, Safavi, Farinaz (NIH/NINDS) [E]  b6 wrote:  Hi b6 Amanda sent you a kit for blood.Just to let you know. Farinaz  Farinaz Safavi MD, PhD Division of Neuroimmunology and Neurovirology
NINDS, NIH, Bethesda, MD
From: b6  Sent: Wednesday, March 10, 2021 9:58:39 PM  To: Safavi, Farinaz (NIH/NINDS) [E] b6  Cc: Wiebold, Amanda (NIH/NINDS) [E] b6  Subject: Re: b6
That will be fine. I will await the instructions from Amanda for the blood sample.
Sent from my iPhone
On Mar 10, 2021, at 4:52 PM, Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:
We can meet on Friday 2pm ET. if it works for you I will send you the link.

Regarding Blood samples I leave to Amanda answer your questions. Best Farinaz Sent: Wednesday, March 10, 2021 7:44:51 PM To: Safavi, Farinaz (NIH/NINDS) [E] Cc: Wiebold, Amanda (NIH/NINDS) [E] Subject: Re: Friday would be fine. What time? Please send me the blood instructions and kit and I will send you a sample. Redtop serum separator? Spun or not spun down? Also, the radiologist said you could open the program using my user name and password **b6** Thanks for everything. b6 Sent from my iPhone On Mar 10, 2021, at 4:38 PM, Safavi, Farinaz (NIH/NINDS) [E] wrote: b6 Thank you very much for the information.I cc Amanda in the email since I am not sure we can access your personal account to get b6 I am so glad to hear your symptoms has been improving. It would be great if we can collect some blood. Can you get blood draw and send us some serum? We also may be able to

> It wod be great we do another short follow up televist in next afew days in a mutual convenient time.

> send you a kit for blood deaw. I leave it to Amanda for further advice.

Friday afternoon works for me.Please let me know and I will send you the link.

Best Regards

Fa		

From: b6
b6
Sent: Wednesday, March 10, 2021
4:44:39 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
b6
Subject: b6
Hi Farinaz,
You may be able to access <b>b6</b>
,
<b>b6</b> through this site.
My user name is
b6
Password is <b>b6</b>
Let me know if it works. If not, I signed
a release of records for <b>b6</b>
It is in my electronic chart with you.
Thanks so much,
<b>b6</b>

PS my symptoms are starting to be less severe. I hope it is a trend. If you want a blood sample, let me know. Sent from my iPhone

From:	<b>b</b> 6				
Sent: To:	6/28/2021 7:47:35 PM Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group				
Carleta ada	(FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 b6				
Subject:         Re: Update           Attachments:         1213B1F4B7F0494E98CED431FDABEA1B.png; F519BD1908004E6580CE44136DC207F4.png;					
	D898F569B48A4F49A0764AE3A7E95B0A.png				
Hello,					
That sounds Thank you!	like a plan! I finished b6 I will fill those out and get them back to you.				
On Mon, Jur	a 28, 2021, 3:00 PM Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b> wrote:				
Hi b6					
I discussed	your case in our meeting and I would like to bring you back 3 months after b6  b6				
	ease fill out attached file and send it back to me. It would be great if you can approximately score from the time you saw us at NIH and one scoring for today.				
Thank you!					
Farinaz Saf	avi MD, PhD				
Division of	Neuroimmunology and Neurovirology				
NINDS, NI	H, Bethesda, MD				
	b6 lesday, June 23, 2021 7:27 AM Farinaz (NIH/NINDS) [E] e: Update				

Good morning,

Ok! I was just curious. I'm doing pretty good, my extremities feel weak and fatigue easily right now, especially my arms and that has been constant for about the last 2-3 weeks. I have bouts of facial tingling and derealization, but it is much less. A follow up sounds good.
Thank you,
b6
On Wed, Jun 23, 2021, 7:21 AM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:
<b>b6</b>
as a follow up in some weeks.
How are you doing?
Farinaz
From: b6 Sent: Wednesday, June 23, 2021 7:14:32 AM To: Safavi, Farinaz (NIH/NINDS) [E] b6 Subject: Re: Update
Hello!  I did have a question too, as to the b6 do we think they need to be rechecked? Or is there something we can do to b6  Thank you,
b6
On Wed, Jun 16, 2021, 1:15 AM Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b> wrote:
Hi,
Thanks for the update.This is a good news that severity of your symptoms has subsided. b6 will let you know when I have update.

arinaz		
From:  b6  ent: Tuesday, June 15, 2021 6:45:56 PM  co: Safavi, Farinaz (NIH/NINDS) [E]  b6  ubject: Re: Update		
Hello,  have had a good stretch of days, the only symptoms that have been comi	ng and going a	are my arms fe
weak, the derealization comes and goes and my eyes are still very sensitive there, but definitely feel it is less frequent.  b6	e to light, also	
'hank you,	!	
·-		
<b>b6</b>		
<b>b6</b> On Mon, Jun 14, 2021, 2:39 AM Safavi, Farinaz (NIH/NINDS) [E]	b6	wrote:
	b6	wrote:
On Mon, Jun 14, 2021, 2:39 AM Safavi, Farinaz (NIH/NINDS) [E]	b6	wrote:
On Mon, Jun 14, 2021, 2:39 AM Safavi, Farinaz (NIH/NINDS) [E]	b6	wrote:
On Mon, Jun 14, 2021, 2:39 AM Safavi, Farinaz (NIH/NINDS) [E]  Hi  How are you doing?please update me with your symptoms.	b6	wrote:
On Mon, Jun 14, 2021, 2:39 AM Safavi, Farinaz (NIH/NINDS) [E]  Hi b6  How are you doing?please update me with your symptoms.  Thanks	b6	wrote:
On Mon, Jun 14, 2021, 2:39 AM Safavi, Farinaz (NIH/NINDS) [E]  Hi b6  How are you doing?please update me with your symptoms.  Thanks	b6	wrote:
On Mon, Jun 14, 2021, 2:39 AM Safavi, Farinaz (NIH/NINDS) [E]  Hi b6  How are you doing?please update me with your symptoms.  Thanks  Farinaz  From: b6	b6	wrote:
On Mon, Jun 14, 2021, 2:39 AM Safavi, Farinaz (NIH/NINDS) [E]  Hi b6  How are you doing?please update me with your symptoms.  Thanks  Farinaz	b6	wrote:

I just wanted to check in, I'm feeling like		
week the burning in my temples and across but my eyes and vision are still off some, es	<u> </u>	
b6	<u></u>	ngs at this point. Also,
did you have a chance to look at the bloodw wondering your thoughts.		just
Thank you!		
b6		







- transference of the	i LC				
From:	2/14/2021 7:50:40 AM				
Sent: Fo:	3/14/2021 7:59:49 AM Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group				
0.	(FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 <b>b6</b>				
ubject:	Re: Neurological reaction to vaccine.				
ttachments:	b6				
n (1474)					
	attaching a file with a summary letter of my journey since getting the Moderna vaccine on				
<b>b6</b> Ad	ditionally, I have included documents of all the blood work and b6				
	b6				
	I look forward to our meeting on Monday at 11:00AM ET.				
hank you s	o much!				
b6					
On N	Mar 10, 2021, at 4:44 PM, Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b>				
wrote	· · · · · · · · · · · · · · · · · · ·				
***************************************					
Dear	b6				
	really sorry to hear about your illness. b6 is correct.We started an effort at NIH to look				
	neurological complications of the covid vaccine.				
	an schedule a televisit in a mutual convenient time and discuss your symptoms.				
****	an concede a toleviole in a materi convenient and and alleged year cymptome.				
In a i	meanwhile,you can send me a summary of your disease and work up you already had				
	e vaccination.				
	e an available spot in my schedule on Friday at 1pm ET and Monday at 11am ET.				
Pleas	se let me know the tine works for you.				
	Regards,				
Farin	ıaz				
T!					
Farin					
From	: b6				
	Wednesday, March 10, 2021 1:07:30 PM				
	afavi, Farinaz (NIH/NINDS) [E] <b>b6</b>				
	ect: Neurological reaction to vaccine.				
Subje	:ct. Neurological reaction to vaccine.				
Hello	.1				
	b6 told me you graciously offered a consultation related to neurological symptoms post-				
Vacci	ne to the others in our "group". I had 1st dose of Moderna on <b>b6</b> and presented at the				
	ergency Room with stroke-like symptoms on b6				
	nergency Room with stroke-like symptoms on:				
	leg/ arm numbness and weakness. Neuropathy in hands, feet. Scalp pressure. Brain fog.				
	ald love to connect with you as Danice said you were incredibly helpful to a situation that no one else				
	s to acknowledge.				
	k you,				
111011					
	<b>b6</b>				

Sent from my iPhone























From: Sent: To: Subject:	Safavi, Farinaz (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=94807CE146E045D4B61655DA26A0C246 b6 5/25/2021 3:26:22 PM b6 RE: Update
Hi <b>b6</b> Thank you fo	r the update. <b>b6</b>
I am still hopi	ing your symptoms gradually improve. Please update me intermittently and I will discuss your case as well.
I will be out o Best	of office for next 2 weeks with limited access to email.
	i MD, PhD euroimmunology and Neurovirology Bethesda, MD
	b6 y, May 25, 2021 7:33 AM rinaz (NIH/NINDS) [E] ate
in my temple	to check in, I'm feeling like b6 helping in some ways, but not in others. Last week the burning s and across my face came back for about 3 days, but that went away, but my eyes and vision are still off
	ally in lower light. I did take b6 trying things at this point. Also, did you have a chance to look at the bloodwork, b6
	ist wondering your thoughts.

From:	Safavi, Farinaz (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=94807CE146E045D4B61655DA26A0C246 <b>b6</b>			
Sent:	3/11/2021 1:06:58 PM			
To:	b6			
CC:	Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group			
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540 b6			
Subject:	Re: <b>b6</b>			
Dear	b6			
Based or the relea medical provider	our policies at NIH,we can not have access to your personal chart.Regarding b6 you already signed se form and we will get b6 but we have not received signed record release form enabling our team to ask your medical record directly from your health care			
A A	ate if you sign the release form(which is different from b6 release form) and send it to us. o not have access to the form Amanda can send you again.			
I certainl	y need infornation from your visits at the onset of your symptoms.			
Please le Best Reg	t me know if you have any questions. ards,			
Farinaz				
r	b6			
From:				
Sent: We	dnesday, March 10, 2021 <u>9:58:39 PM</u>			
To: Safav	i, Farinaz (NIH/NINDS) [E] b6			
Cc: Wiebo	old, Amanda (NIH/NINDS) [E] <b>b6</b>			
Subject: I	Re: <b>b6</b>			
	<u></u>			
That will	be fine. I will await the instructions from Amanda for the blood sample.			
Sent from	m my iPhone			
	On Mar 10, 2021, at 4:52 PM, Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b> Vrote:			
We can meet on Friday 2pm ET. if it works for you I will send you the link. Regarding Blood samples I leave to Amanda answer your questions. Best Farinaz				
	rom: b6			
	ent: Wednesday, March 10, 2021 7:44:51 PM			
To: Safavi, Farinaz (NIH/NINDS) [E] b6				
C	c: Wiebold, Amanda (NIH/NINDS) [E] b6			
S	ubject: Re: b6			

Friday would be fine. What time? Please send me the blood instructions and kit and I will send you a sample. Redtop serum separator? Spun or not spun down? Also, the radiologist said you could open the program using my user name and password
<b>b6</b>
Thanks for everything.
Sent from my iPhone
On Mar 10, 2021, at 4:38 PM, Safavi, Farinaz (NIH/NINDS) [E]  b6 wrote:
Hi b6  Thank you very much for the information. I cc Amanda in the email since I am not sure we can access your personal account to get b6
I am so glad to hear your symptoms has been improving. It would be great if we can collect some blood. Can you get blood draw and send us some serum? We also may be able to send you a kit for blood deaw. I leave it to Amanda for further advice.
It wod be great we do another short follow up televist in next afew days in a mutual convenient time.
Friday afternoon works for me.Please let me know and I will send you the link.
Best Regards
Farinaz
From: b6  Sent: Wednesday, March 10, 2021 4:44:39 PM  To: Safavi, Farinaz (NIH/NINDS) [E] b6  Subject: Ambra   Home
Hi Farinaz, You may be able to access b6 through this site.  My user name b6 Password is b6 Let me know if it works. If not, I signed a release of records for b6 It is in my electronic chart with you. Thanks so much,
PS my symptoms are starting to be less severe. I hope it is a trend. If you want a blood sample, let me know. Sent from my iPhone

REL0000230754

From: Sent: To: Subject:	Safavi, Farinaz (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=94807CE146E045D4B61655DA26A0C246 b6 3/9/2021 11:11:34 PM b6 RE: medical record link			
Farinaz Saf Division of	works. you the link shortly favi MD, PhD i Neuroimmunology and Neurovirology H, Bethesda, MD			
To: Safavi, Subject: Re	b6 day, March 9, 2021 6:10 PM Farinaz (NIH/NINDS) [E] e: medical record link you do Thursday at 2:00?			
	my iPhone  n Mar 9, 2021, at 12:13 PM, Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b> wrote:			
	day is a very busy for me. Thursday afternoon between 1:30pm to 3pm works for me.Let me know if it orks and I will send you the link.			
Div	rinaz Safavi MD, PhD vision of Neuroimmunology and Neurovirology NDS, NIH, Bethesda, MD			
Se To Su	om: b6 nt: Tuesday, March 9, 2021 10:30 AM : Safavi, Farinaz (NIH/NINDS) [E] bject: Re: medical record link			
	. Safavi, ould you be available to speak Thursday or Friday at your convenience?			

Thank you.		
b6		
On Sat, Mar 6, 2021 at 6:34 PM Safavi, Farinaz (NIH/NINDS) [E]	b6	wrote:
Dear <u>b6</u> Thank you for an update. Of course,I would be happy you like to set up a short e-meeting to talk?  Best	≀ to answer y	our questions.Do
Farinaz		
<8BF0608204FA48AF83BCAC93A4D36994.png> From: b6 Sent: Saturday, March 6, 2021 6:25:39 PM To: Safavi, Farinaz (NIH/NINDS) [E] b6 Subject: Re: medical record link		
Dr. Safavi, Thank you for speaking with me on Wednesday and discu covid vaccine. I did receive an email from Amanda reques I have some questions about the clinical study that I woul to contact me and I hope you have a nice weekend. Thank you.  b6	ting my medic	al record and consent.
On Thu, Mar 4, 2021 at 6:20 PM Safavi, Farinaz (NIH/NINE wrote:  Dear b6 I spoke with the team and we would like to bring you to Amanda(our research nurse) already sent you the link for process. Please let me know if you have any questions.  Best Regards	NIH for furth	

Farinaz

Thanks Farinaz Safavi	uroimmunology and Neurovirology
To: Safavi, Far	p6 , March 22, 2021 4:20 PM rinaz (NIH/NINDS) [E] nedical record link
	me that she received my imaging and health record today and that she sent them to you. know if you got them.
On Sun, Mar 2	21, 2021 at 9:23 PM Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b> wrote:
Thanks <b>b</b>	<b>6</b>
	ady requested your records.If you can bring the imaging that would be great.If not I still prefer to see you he imaging whenever its available.
No worries!	
See you on T	uesday
Farinaz	
Farinaz Safav	
	euroimmunology and Neurovirology
NINDS, NIH,	Bethesda, MD

Sent: Sunday, March 21, 2021 9:21 PM  To: Safavi, Farinaz (NIH/NINDS) [E]  Subject: Re: medical record link
Hi,
I sent Amanda my medical release paperwork last week. So she should have submitted that already. I can try to go to the hospital and get the imaging; however, I cannot guarantee that this can be done on such short notice. If I cannot get the imaging by tomorrow, should be postpone my appointment on Tuesday until you receive them or I am able to get my imaging?
b6
Sent from my iPhone
On Mar 21, 2021, at 9:07 PM, Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b> wrote:
Hi b6
Hope all is well.
I would like to ask if you can please bring imagings CD with you for your appointment on Tuesday.We also have not received any of your medical recotds yet (I was told it takes 10-14 days) and it may be helpful if you can bring the reports with you.
Thank you
Farinaz
From: b6 Sent: Tuesday, March 9, 2021, 6:10 PM
To: Safavi, Farinaz (NIH/NINDS) [E]

Subject: Re: medical record link

Great. Can you do Thursday at 2:00?
Thank you
b6
Sent from my iPhone
On Mar 9, 2021, at 12:13 PM, Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b> wrote:
Hi b6
Friday is a very busy for me. Thursday afternoon between 1:30pm to 3pm works for me.Let me know if it works and I will send you the link.
Best
Farinaz Safavi MD, PhD
Division of Neuroimmunology and Neurovirology
NINDS, NIH, Bethesda, MD
From: b6 Sent: Tuesday, March 9, 2021 10:30 AM To: Safavi, Farinaz (NIH/NINDS) [E] Subject: Re: medical record link
Dr. Safavi,

Would you be available to speak Thursday or Friday at your convenience?

REL0000230797

b6	
	r 6, 2021 at 6:34 PM Safavi, Farinaz (NIH/NINDS) [E]  b6 wrote:
	Dear <b>b6</b>
	Thank you for an update. Of course,I would be happy to answer your questions.Do you like to set up a short e-meeting to talk?
	Best
	Farinaz
	<8BF0608204FA48AF83BCAC93A4D36994.png>
	From: b6 Sent: Saturday, March 6, 2021 6:25:39 PM To: Safavi, Farinaz (NIH/NINDS) [E] b6 Subject: Re: medical record link
	Dr. Safavi,
	Thank you for speaking with me on Wednesday and discussing my reaction to the second covid vaccine. I did receive an email from Amanda requesting my medical record and consent. I have some questions about the clinical study that I would like to discuss with you. Feel free to contact me and I hope you have a nice weekend.
	Thank you.
	b6
	On Thu, Mar 4, 2021 at 6:20 PM Safavi, Farinaz (NIH/NINDS) [E]  b6 wrote:
	Dear <b>b6</b>
	I spoke with the team and we would like to bring you to NIH for further evaluations. I believe Amanda(our research nurse) already sent you the link for consent and starting the process. Please let me know if you have any questions.

Best Regards

Farinaz

From:	Safavi, Farinaz (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=94807CE146E045D4B61655		
Sent:	6/26/2021 6:07:08 PM	DAZOAUCZ40	<u>9</u> j
To:	b6		
Subject:	Re: Update		
Hi b6 Your b6 please let m Farinaz Farinaz	result return yesterday and <b>b6</b> ne know if you have any question.		
	<b>b6</b> esday, June 23, 2021 7:27:13 AM arinaz (NIH/NINDS) [E] <b>b6</b> Update		
my arms and	ust curious. I'm doing pretty good, my extremities feel weak d that has been constant for about the last 2-3 weeks. I have n, but it is much less. A follow up sounds good.		
On Wed, Ju	un 23, 2021, 7:21 AM Safavi, Farinaz (NIH/NINDS) [E]	b6	wrote:
D6	b6 sinc	e I think we shou	ld see you as a follow
up in some		o i timik wo onod	na soo you ao a ronow
How are yo			
Farinaz			
	b6 nesday, June 23, 2021 7:14:32 AM Farinaz (NIH/NINDS) [E] b6 : Update		
Hello! I did have a can do to Thank you,		be rechecked? Oi	is there something we
On Wed, Ju	un 16, 2021, 1:15 AM Safavi, Farinaz (NIH/NINDS) [E]	b6	wrote:
2	or the update.This is a good news that severity of your symp	toms has subside	ed. <b>b6</b>
b6	l will let you know when I have update.		
Thanks			

From: b6
<b>Sent:</b> Tuesday, June 15, 2021 6:45:56 PM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Re: Update
Hello,
I have had a good stretch of days, the only symptoms that have been coming and going are my arms feel
weak, the derealization comes and goes and my eyes are still very sensitive to light, also the POTS is still
there, but definitely feel it is less frequent. <b>b6</b>
b6
Thank you,
<b>b6</b>
On Mon, Jun 14, 2021, 2:39 AM Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b> wrote:
On Mon, Jun 14, 2021, 2:39 AM Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b> wrote:
How are you doing?please update me with your symptoms.
Thanks
Farinaz
From: b6
Sent: Tuesday, May 25, 2021 4:02:44 PM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Update
Subject. Opulate
Good morning!
I just wanted to check in, I'm feeling like b6 helping in some ways, but not in others. Last week
the burning in my temples and across my face came back for about 3 days, but that went away, but my eyes
and vision are still off some, especially in lower light. I did take <b>b6</b>
b6 I'm just trying things at this point. Also, did you have a chance to
look at the bloodwork, <b>b6</b> just wondering your thoughts.
Thank you!
b6
- Landan and the state of the s

Farinaz

From:	Safavi, Farinaz (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHAN		
Sent:	(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=94807CE146E045D4B6 6/28/2021 7:00:08 PM	1655DA26A0C24	b
To:	b6		
Subject:	RE: Update		
Attachments:	WHO scale post-COVID.docx		
Hi b6			
I discussed yo	our case in our meeting and I would like to bring you back 3 r	months after[	b6
L	b6		
	se fill out attached file and send it back to me. It would be gr	eat if you can a	pproximately score those items
Thank you!	e you saw us at NIH and one scoring for today.		
mank you:			
Farinaz Safav	vi MD, PhD		
Division of Ne	euroimmunology and Neurovirology		
NINDS, NIH, E	Bethesda, MD		
From:	b6		
	esday, June 23, 2021 7:27 AM		
	arinaz (NIH/NINDS) [E]		
Subject: Re: U			
Good mornin			
	t curious. I'm doing pretty good, my extremities feel weak an		
	been constant for about the last 2-3 weeks. I have bouts of f	acial tingling ar	nd derealization, but it is much
Thank you,	up sounds good.		
b6			
i			
On Wed, Jun	23, 2021, 7:21 AM Safavi, Farinaz (NIH/NINDS) [E]	b6	wrote:
b6			
	b6	since I think	we should see you as a
	in some weeks.		
How are	you doing?		
Farinaz			
		***************************************	
From:	b6		
	dnesday, June 23, 2021 7:14:32 AM		
To: Safavi, Farinaz (NIH/NINDS) [E] < <u>farinaz.safavi@nih.gov</u> > Subject: Re: Update			
Subject: K	ne. Opuale		
Hello!			
	a question too, as to the <b>b6</b> do we think they need to	be rechecked	? Or is there something we can
do to	b6	······································	
h			

Thank you,  b6	
On Wed, Jun 16, 2021, 1:15 AM Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b> wrote:	
Hi, Thanks for the update.This is a good news that severity of your symptoms has subsided.  b6 I will let you know when I have update. Thanks	<b>b</b> 6
Farinaz	
From: b6	
<b>Sent:</b> Tuesday, June 15, 2021 6:45:56 PM	
To: Safavi, Farinaz (NIH/NINDS) [E] b6	
Subject: Re: Update	
Hello,	
I have had a good stretch of days, the only symptoms that have been coming and going are my a	rms feel weak
the derealization comes and goes and my eyes are still very sensitive to light, also the POTS is still	•
definitely feel it is less frequent. <b>b6</b>	circi e, but
b6	
Thank you,	
b6	
On Mon, Jun 14, 2021, 2:39 AM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:  Hi b6 How are you doing?please update me with your symptoms. Thanks	
Farinaz	
From: b6	
<b>Sent:</b> Tuesday, May 25, 2021 4:02:44 PM	
To: Safavi, Farinaz (NIH/NINDS) [E] b6	
Subject: Update	
Good morning!	
I just wanted to check in, I'm feeling like <u>b6</u> helping in some ways, but not in othe	rs. Last week
the burning in my temples and across my face came back for about 3 days, but that went away	,, but my eyes
and vision are still off some, especially in lower light. I did take b6	
b6 I'm just trying things at this point. Also, did you have a c	hance to look at
the bloodwork, b6 just wondering your thoughts.	
Thank you!	
b6	

Date				
Over the past 7 days, how much difficulty have you had with the following:				
Standing for long periods such as 30 minutes?				
Taking care of your household responsibilities?				
Learning a new task, e.g. learning how to get to a new place?				
Joining in community activities (e.g. festivities, religious, other)?				
Being emotionally affected by your health problems?				
Concentrating on doing something for ten minutes?			 	
Walking a long distance such as a kilometre (or equivalent)?			 	
Washing your whole body?				
Getting dressed?				
Dealing with people you do not know?				
Maintaining a friendship?				
Your day-to-day work/school?				
Total Score				

- Score:
  0 No Difficulty
  1 Mild Difficulty
  2 Moderate Difficulty
  3 Severe Difficulty
  4 Extreme Difficulty or Cannot do

From: Sent: To: CC: Subject:	Safavi, Farinaz (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=94807CE146E045D4B61655DA26A0C246
Hi b6	b6
I am really so millions of pe patients with I do not have	ults takes months and we suggest to all of our patients to get care from community physicians.  rry about what happened to you but I also would like to mention that the vaccine has been administered to ople with very good safety profile. Development of rare side effects may happen in a very small group of any medication or vaccination which depends on many factors.  any knowledge, experience and understanding about role of those diets and complements you mentioned any medication needs to be taken by clinical indication.
Sent: Saturda To: <u>Safavi, Fa</u> Cc: <u>Nahar, Ky</u>	b6 y, February 19, 2022 10:48 AM rinaz (NIH/NINDS) [E] mani (NIH/NINDS) [C] EXTERNAL] Re: Follow-up Visit Week 3/28/22
	email originated from outside of the organization. Do not click links or open attachments unless you recognize the confident the content is safe.
Hi Dr. Safavi,	
	etter from the beginning of this week. However, I still get quite tired by midday and typically nap, which is n my sick normal. I am also still getting headaches, especially if I exert myself. Is it normal to still be  b6
	elaborating on the tests. Are you planning on b6 b6
cause? I am a important life devastating the	here absolutely anything else I can be doing to treat this? Do you have any speculation at all about the root t such a loss on how a healthy b6 can become so disabled after the vaccine. I need to make many edecisions and cannot because I do not know how much longer I will be sick for. This is the most ning to have ever happened to me and has ruined my life. I have not had a good day since I got this vaccine. think the research will come back? I am extremely desperate. It is very hard to watch mandates and mask

requirements be lifted because I am now <b>b6</b> and I got this vaccine in part to help prote	ect others. I will
do anything to get my life back. I am already eating an autoimmune and antihistamine diet, taking and various supplements. Please let me know.	b6
Thank you,  b6	
On Sat, Feb 19, 2022 at 8:47 AM Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b> wrote:	
Hi b6	
How are you feeling?	
<b>b6</b>	
Please let me know if you have further question	
Farinaz Safavi MD, PhD	
Division of Neuroimmunology and Neurovirology	
NINDS, NIH, Bethesda, MD	
From: Nahar, Kymani (NIH/NINDS) [C] Sent: Friday, February 18, 2022 1:10 PM To: Safavi, Farinaz (NIH/NINDS) [E] Subject: Fwd: [EXTERNAL] Re: Follow-up Visit Week 3/28/22	
Please contact <b>b6</b> See email below. Thanks	
Sent from my IPhone	
Kymani A. Nahar	
Patient Care Coordinator III	
Clinical Monitoring Research Program	
Frederick National Laboratory	

Leidos Biomedical Research, Inc.
Support to: National Institutes of Neurological Disorders and Stroke (NINDS)
9000 Rockville Pike, Bethesda
NIH/ Building 10, Room 7C103
Bethesda, Maryland 20892
Office: b6
Mobile: b6
Fax: 301.402.1007
b6
Notice: This email and any attachments to it are intended only for the identified recipient. It may contain proprietary or otherwise legally protected information for Leidos Biomedical Research, Inc. Any unauthorized use or disclosure of this communication is strictly prohibited. If you have received this communication in error, please notify the sender and delete or otherwise destroy the e-mail and all attachments immediately.
Begin forwarded message:
From: b6  Date: February 18, 2022 at 11:59:13 EST  To: "Nahar, Kymani (NIH/NINDS) [C]" b6  Subject: Re: [EXTERNAL] Re: Follow-up Visit Week 3/28/22
CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.
Yes, could you ask <b>b6</b>
b6 Thanks so much.
On Fri, Feb 18, 2022 at 11:28 AM Nahar, Kymani (NIH/NINDS) [C] <b>b6</b> wrote:
That should be ok, I'll check and get back to you. Elaborate as far as how long? If it's a clinical question about labs or testing it'd be best to ask Dr. Safavi! Thanks

Kymani N. Howard (C)
Patient Care Coordinator III
Clinical Monitoring Research Program Directorate (CMRPD)
Frederick National Laboratory for Cancer Research
Leidos Biomedical Research, Inc.
Support to: National Institutes of Neurological Disorders and Stroke (NINDS)
9000 Rockville Pike
NIH, Building 10, Room 7C103
Bethesda, Maryland 20892
Office: b6
Mobile: b6
Fax: 301.402.1137
b6
From: b6
Date: Friday, February 18, 2022 at 11:09 AM  To: Kymani Howard b6
Subject: [EXTERNAL] Re: Follow-up Visit Week 3/28/22
CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless
you recognize the sender and are confident the content is safe.
you recognize the sender and are confident the content is safe.

Thank you,
b6
On Fri, Feb 18, 2022 at 8:29 AM Nahar, Kymani (NIH/NINDS) [C] <b>b6</b> wrote:
Good Morning <b>b6</b>
I hope you've been well! Dr. Safavi would like to bring you back to the NIH for a visit the week on 3/28 for b6 Do you think you'd be available during that time? Thanks so much!
Best,
Kymani N. Howard (C)
Patient Care Coordinator III
Clinical Monitoring Research Program Directorate (CMRPD)
Frederick National Laboratory for Cancer Research
Leidos Biomedical Research, Inc.
Support to: National Institutes of Neurological Disorders and Stroke (NINDS)
9000 Rockville Pike
NIH, Building 10, Room 7C103
Bethesda, Maryland 20892
Office: b6
Mobile: b6
Fax: 301.402.1137
<b>b6</b>

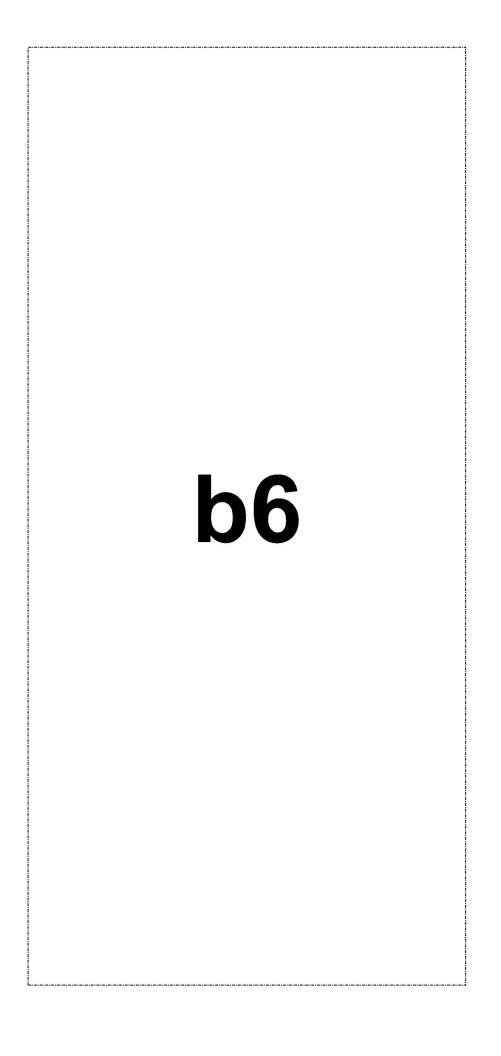
From: Sent: To: Subject:	b6   4/15/2021 12:33:55 PM   Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6   b6   Safavi, Farinaz (NIH/NINDS)   [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246   b6   Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540   b6   Re: COVID-19 Vaccine and   b6   b6   COVID-19 Vaccine and   b6   COVID-19 Vaccine and   covid and covid
Dr Nath Thank you f b6	for all of your help and advice. I am sure he would consent if it only means giving permission to
Get Outlook	for iOS
Sent: Wedner To: (NIH/NINDS) Subject: Re: F Yes, we would study for that long a waiting	Avindra (NIH/NINDS) [E] b6 sday, April 14, 2021 9:29:53 PM b6 Safavi, Farinaz (NIH/NINDS) [E] b6 Wiebold, Amanda [E] b6 wd: COVID-19 Vaccine and b6 d be interested in b6 We would need to consent him and enroll him to our research purpose. Yes, b6 is an excellent rehab center, however, early rehab is important and am not sure how g list they have. Since these places require prolonged treatment, it is often best to get the rehab closest to end there is not much of a difference between most institutions.
From:	b6 }
	esday, April 14, 2021 at 1:56 PM
<del></del>	indra (NIH/NINDS) [E] b6 Safavi, Farinaz (NIH/NINDS) [E]
<u> </u>	
Subject: Re:	Fwd: COVID-19 Vaccine and b6
Dear Dr Nat	h.
	or speaking with <b>b6</b> yesterday. My understanding is that they will be
Ī	b6 you agreed with b6 and you recommended b6 Is
that correct	? In regards to next steps after completion of the <b>b6</b> they plan to move him to rehab. In
your experie	ence, is there a difference in potential outcome based on location and expertise of the rehab
facility? I he	ard that <b>b6</b> is premier for this type of rehabilitation.
l appreciate <b>b6</b>	all of your help and insights.
	Avindra (NIH/NINDS) [E] <u>b6</u> y, April 12, 2021 2:49 PM
To:	b6 Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Re: F	wd: COVID-19 Vaccine and b6

Thanks. Would it also be possible for <u>b6</u> to provide that information directly to <u>b6</u> Also please share my contact information with <u>b6</u> so that he is not surprised when we contact him.  Avi
From: b6
Date: Monday, April 12, 2021 at 3:43 PM  To: Nath, Avindra (NIH/NINDS) [E] b6 Safavi, Farinaz (NIH/NINDS) [E]
Subject: Fw: Fwd: COVID-19 Vaccine and b6
Dear Drs. Nath and Safavi,
b6 has provided the permission (email below) to contact his neurologist at b6
Thank you for all of your help!
Best regards,  b6
Lancas and the second s
From: b6 Sont Manday April 12, 2021 2,27 DM
Sent: Monday, April 12, 2021 2:37 PM  To: b6  Subject: Re: Fwd: COVID-19 Vaccine and b6
b6 give permission to b6 to provide and share any medical information pertaining to myself with Dr. Nath. signed b6 Original Message From b6 To: b6 Sent: Mon, 12 Apr 2021 13:57:26 -0400 (EDT) Subject: Fwd: COVID-19 Vaccine and b6
Get Outlook for
iOS   b6
<b>b6</b>
From: Nath, Avindra (NIH/NINDS) [E]
Subject: Re: COVID-19 Vaccine and b6
Dear <b>b6</b>
Terribly sorry to hear of b6 illness. With b6 permission, we would be interested in talking to the

working with me and interested in these issues.
Avi
Avindra Nath MD
Chief, Section of Infections of the Nervous System
Clinical Director,
National Institute of Neurological Disorders and Stroke
National Institutes of Health, Bethesda, MD
LG (Office)
DO (cell)
b6
From: b6
Date: Monday, April 12, 2021 at 1:45 PM To: Nath, Avindra (NIH/NINDS) [E]
Cc: b6
Subject: COVID-19 Vaccine and b6
Dear Dr. Nath,
Appreciating your interest and expertise in regards to CNS Adverse events and the COVID-19 vaccines, I am writing in
regards to b6 In short, he is b6 male who was otherwise healthy. He received his 2nd dose of the Moderna vaccine on b6 On b6 he developed low back pain and numbness in his legs. On
b6 he presented to the Emergency Department of b6 due to inability to walk, pain and
numbness in his lower extremities. b6 Yesterday he had b6 b6 Today he was told his diagnosis is b6
b6 He remains hospitalized with bilateral foot drop, inability to walk and inability to urinate. Since this is a very
rare adverse event, I thought it best to reach out to you or others at NIH to determine if there are further tests or
treatments that are appropriate. Any help or referrals would be greatly appreciated.
Thank you for your help.
h6

neurologists taking care of him to see if there is anything we can do to help. I have copied Dr. Safavi who is a neurologist

F	ļ	
From: Sent:	9/2/2021 7:47:54 PM	
To:	Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative	Group
10;	(FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246	
	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group	i Natii, Aviildia (Niii/NiiNDS)
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6	h6
Subject:	RE: WHO scale 2	1 06
Attachments	Cov-Sars-2 Vaccine Persistent Neuro Symptoms Survey 9-1.pdf; WHO scale	h6
retucinita.	tov sais 2 vaccine i elsistem reard symptoms saivey s 1.pai, vviio scale	
Working Atta	chments	
WHO scale		
Symptoms Su	ırvey	
Sent from Ma	ail for Windows	
From:	b6	
Sent: Sunday	, August 22, 2021 10:15 PM	
To: Safavi, Fa	rinaz (NIH/NINDS) [E]	
Subject: Re: \	WHO scale 2	
	b6	My brain
vibration sen	sations got really bad and I got suuuuper depressed and ended up full on	sobbing every day until I stopped.
lol.	b6 Felt much better after I stopped.	
I went down	nilll the week of july 20th. I remember things just going downhill from the	re.
	o go downhill after my call with you both, My husband looked at me last v	
bedridden ag	ain, worse than when I went to the NIH) and told me to	b6
	b6	It definitely made
enough of a c	lifference to where I am out of bed again.	······································
My new favo	rite thing is this <b>b6</b> looks like the last couple weeks	things leveled off



20	

Farinaz

On Aug 20, 2021, at 7:37 AM, Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:
Hi b6 Thank you for updating me about your symptoms. Hopefully you can b6 B I also would like to ask you is it possible you send me a couple of pieces of information about your
disease course <b>b6</b>
Thank you
Farinaz
From: b6  Sent: Wednesday, August 18, 2021 11:31 AM  To: Safavi, Farinaz (NIH/NINDS) [E]  Subject: Re: WHO scale 2
Thank you Dr Safavi.
You are SO smart. :) I got way way sicker after meeting with you both my husband recommended I b6
b6
Have left several messages with my new neurologist about b6 have yet to hear back.
<b>b6</b>
On Aug 18, 2021, at 9:19 AM, Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b> wrote:
Thank you very much for updated scale. I think I missed answering your email regarding
<b>b6</b>
Please let me know if you have any questions or concerns.  Best

Farinaz Safavi MD, PhD Division of Neuroimmunology and Neurovirology NINDS, NIH, Bethesda, MD

	/
From:	b6
	L

Sent: Saturday, August 14, 2021 12:24 PM

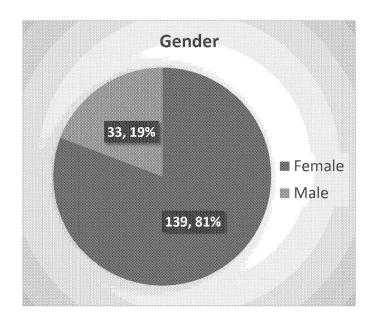
To: Safavi, Farinaz (NIH/NINDS) [E]

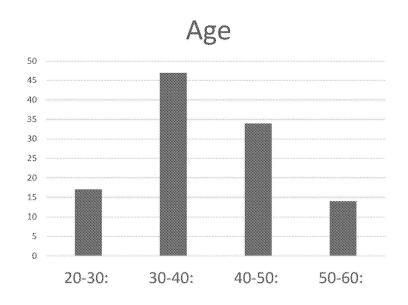
Subject: WHO scale 2

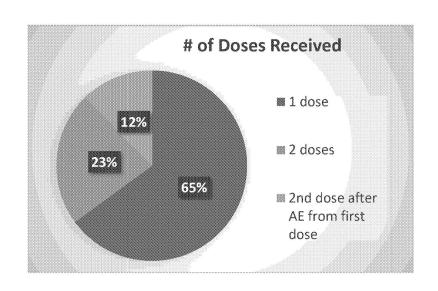
Updates to my scores

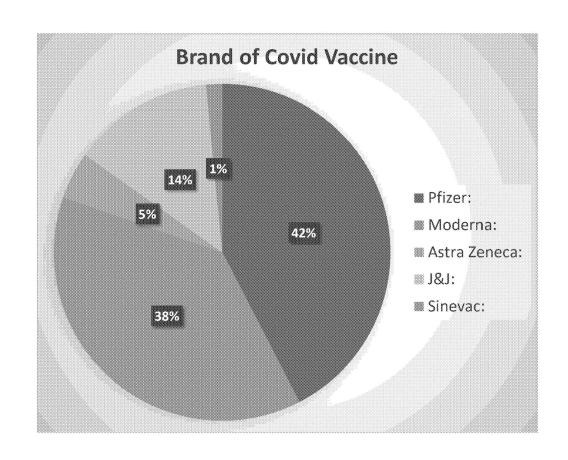
# Covid Vaccine Persistent Symptoms Survey

Survey Gathered from 382 patients suffering persistent neurological symptoms after receiving the Sars-Cov2 Vaccine in the United States - 8/31/21









# Medical History

# Have you ever had a positive Covid infection?

No: 85%

Yes: 4%

Don't know: 11%

## PRE-EXISTING HEALTH CONDITION:

NO: 71%

Yes: 29%

Prior to Covid vaccination, have you ever reacted to any previous vaccine you had received?

NO: 94%

YES: 6%

Are you the only one in your family to have a persistent adverse reaction to the vaccine?

**Yes:** 142 **No:** 13

Have you had EBV in the past:

**Yes:** 30 **No:** 24

**High Cholesterol pre vax:** 

No: 101 Yes: 23

Do you have any known mutations to the mthfr gene?

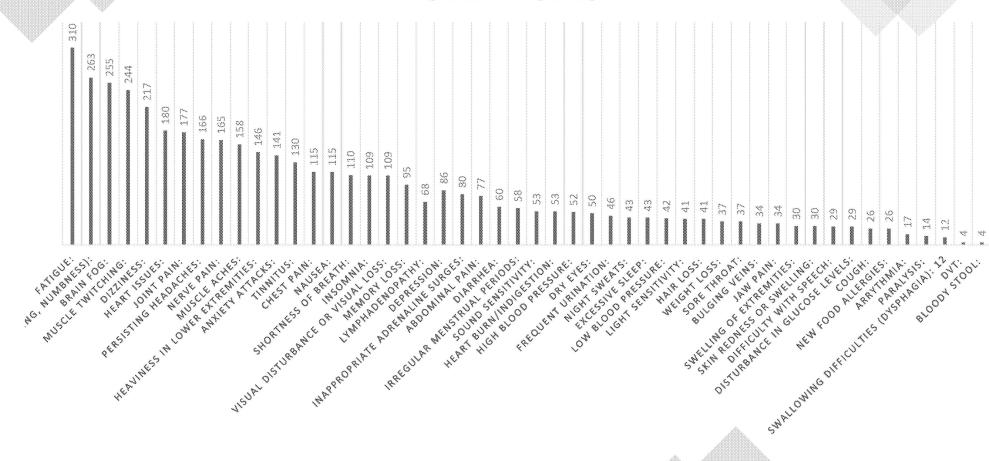
Never been tested: 93

**Yes:** 19 **No:** 13

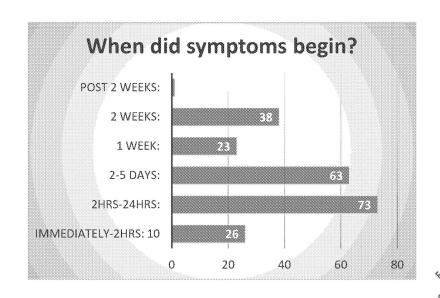
# TOP REPORTED SYMPTOMS

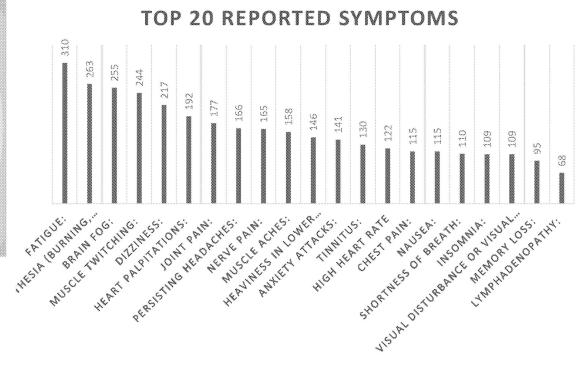
Constitutional		HEENT		Gastrointestinal		Allergy/Immunology	
Fatigue:	310	Tinnitus:	130	Nausea:	115	Lymphadenopathy:	68
Exercise Intolerance:	178	Visual disturbance / loss:	109	Diarrhea:	60	New Food Allergies:	26
Insomnia:	109	Sound Sensitivity:	53	Abdominal Pain:	77		
Chills:	60	Dry eyes:	50	Dysphagia:	12	Musculoskeletal	
Night Sweats:	43	Light Sensitivity:	41	Heart Burn/Indigestion:	53	Muscle Twitching:	224
Excessive Sleep:	43	Sore Throat:	37	Bloody Stool:	4	Joint Pain:	177
Weight Loss:	37	Jaw Pain:	34			Muscle Aches:	158
				Genitourinary/ Reproduct	ive	Heaviness in Lower Extremities:	146
Neurologic		Respiratory:		Frequent Urination:	46	Muscle Atrophy:	68
Paresthesia (burning, tingling):	263	Shortness of Breath:	110	Irregular Menstrual Periods:	58	Swelling in Extremities:	30
Brain Fog:	255	Cough:	26				
Dizziness:	217			Endocrinologic		Dermatologic	
Persisting Headaches:	166	Cardiovascular:		Heat Intolerance:	97	Skin Redness or Swelling:	30
Nerve Pain:	165	Palpitations:	180	Adrenaline Surges:	80		
Memory Loss:	95	Tachycardia:	119	Increased Thirst:	64	Psychiatric	
Difficulty with Speech:	29	Chest Pain:	115	Hair Loss:	41	Depression:	86
Paralysis:	14	High Blood Pressure:	52	Disturbance in glucose levels:	29	Anxiety Attacks:	141
		Low Blood Pressure:	42				
		Arrythmia:	17			Hematologic	
						DVT:	4
						Bulging Veins:	34

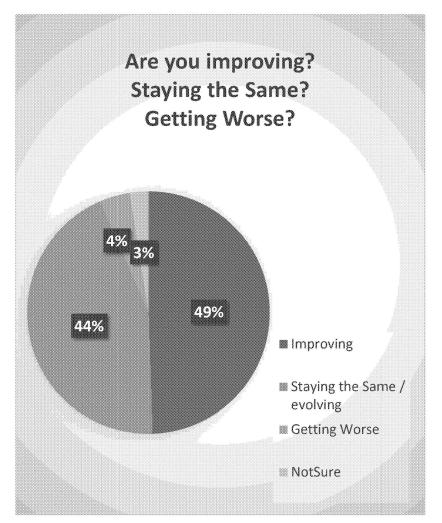
## **SYMPTOMS**



## SYMPTOMS TIMELINE AND OVERVIEW







## **HELPING WITH SYMPTOMS:**

## **CAUSES SYMPTOMS TO WORSEN:**

Time	110	Lack of Sleep	93
Rest	80	Stress:	92
Supplements	59	Overdoing:	67
Gentle Exercise	36	Heat:	55
Anti-inflammatory Diet	28	Menstrual Cycle:	36
Positive Outlook	25	Sunlight:	23
Antihistamines	28	Humidity:	19
Meditation, vague nerve		Heavy Endurance Training:	19
exercise	6	Unhealthy food:	13
Acupuncture	4	Dairy:	12
Distraction	12	Walking:	11
Fasting	11	Gluten	10
Ivermectin	7	Too much screen time:	10
Steroids	10	Those with Neuropathy	
Red Light therapy	2	warm water:	9
Miraviroc	2	Those with Neuropathy	
Gabapentin	8	cold water:	4
Antidepressants fluvox /		Caffeine:	9
doxepin	4	Greasy foods:	3
IVIG	3		

Date	
Over the past 7 days, how much difficulty have you had with the following:	
Standing for long periods such as 30 minutes?	
Taking care of your household re- sponsibilities?	
Learning a new task, e.g. learning how to get to a new place?	b6
Joining in community activities (e.g. festivities, religious, other)?	DO
Being emotionally affected by your health problems?	
Concentrating on doing something for ten minutes?	
Walking a long distance such as a kilometre (or equivalent)?	
Washing your whole body?	
Getting dressed?	
Dealing with people you do not know?	
Maintaining a friendship?	
Your day-to-day work/school?	
Total Score	

## Score:

- 0 No Difficulty
  1 Mild Difficulty
  2 Moderate Difficulty
  3 Severe Difficulty
  4 Extreme Difficulty or Cannot do

Timeline Notes:

From:	b6						
Sent:	4/11/2021 3:26:41 PM						
To:	4/11/2021 3:26:41 PM Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group						
10.	(FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 <b>b6</b>						
Subject:	Re: Negative reaction to Moderna Vaccine b6						
	<u></u> j						
3nm would	be perfect.						
Thanks so	*						
Thanks so i	inden:::						
b6							
	<u></u>						
Sent from \	Yahoo Mail for iPhone						
On Sunday,	, April 11, 2021, 8:22 AM, Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b> wrote:						
Doe	es Monday 2 or 3 pm work for you?						
Fari	inaz						
***************************************							
Fro							
Sen	nt: Saturday, April 10, 2021 8:54:24 PM Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b>						
To:	Safavi, Farinaz (NIH/NINDS) [E1] <b>b6</b>						
	oject: Re: Negative reaction to Moderna Vaccine <b>b6</b>						
Sur	goes to regative reaction to modeline vaccine						
Ole	no mahlam						
	no problem.						
Is th	here another time next week that you are available?						
	b6						
Sen	t from Yahoo Mail for iPhone						
On	Saturday, April 10, 2021, 7:37 PM, Safavi, Farinaz (NIH/NINDS) [E] b6						
Wro							
37.20							
	Actually we need ro have a dedicated 1hour tele-health visit.We can reschedule						
	if you can not make this time.						
	ii you can not make this time.						
	Farinaz						
	railiaz						
	From: b6						
	From: b6						
	From: b6  Sent: Saturday, April 10, 2021 7:35:27 PM  To: Safavi, Farinaz (NIH/NINDS) [E] b6  Subject: Re: Negative reaction to Moderna Vaccine b6						
	To: Safavi, Farinaz (NIH/NINDS) [E] b6						
	Subject: Re: Negative reaction to Moderna Vaccine <b>b6</b>						
	Ok great						
	Ok great.						
	I can't thank you enough for taking the time to meet with me.						
	I'm not sure how much time you have alloted.						

I have	e a <b>b6</b> So I'll just go there and chat w	with
	hile I am in the car.	
Have a	a nice weekend	
[	b6	
I	·	
Sent fi	From Yahoo Mail for iPhone	
On Sat	turday, April 10, 2021, 5:14 PM, Safavi, Farinaz (NIH/NINDS) [E]  b6 wrote:	
	Yes 4/12 at 11am ET.I will send you microsoft team link shortly	
	Farinaz	
	From: b6	
	Sent: Saturday, April 10, 2021 5:04:11 PM  To: Safavi, Farinaz (NIH/NINDS) [E] b6	
	To: Safavi, Farinaz (NIH/NINDS) [E] b6 Subject: Re: Negative reaction to Moderna Vaccine b6	
	b6	الـــــ
	Hi,	
	Yes I can meet monday at 11am. You are referring to	
	Monday 4/12 right?	
	Looking forward to meeting with you virtually!!!	
	<b>b6</b>	
	On Saturday, April 10, 2021, 04:38:47 PM EDT, Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b> wrote:	
	Hi <b>b6</b>	
	We can we meet next Monday at 11am?	
	Farinaz	
	From: Safavi, Farinaz (NIH/NINDS) [E] b6	5000000X
	Sent: Saturday, April 3, 2021 4.40.00 PM	
	To: b6 Subject: Re: Negative reaction to Moderna Vaccine b6	]
	Hi b6	
	Thank you for the information. We are in the process some	or
	improvement in our workforce this week. I will get back to you lat to arrange a televisit.	ег
	Thank you for your patience.	

Farinaz

From: b6
Sent: Friday, April 2, 2021 8:55:25 PM  To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Re: Negative reaction to Moderna Vaccine b6
I live in <b>b6</b>
<b>b6</b>
Thanks so much for getting back to me
<b>b6</b>
Sent from Yahoo Mail for iPhone
On Friday, April 2, 2021, 8:29 PM, Safavi, Farinaz (NIH/NINDS [E] <b>b6</b> wrote:
Hi b6
I am sorry to hear about your illness.
Can you provide me with bellow information?
where do you live? Have you had Hx of COVID infection by any
chance?
Thank you
Farinaz
From: b6
<b>Sent:</b> Wednesday, March 31, 2021 6:32:37 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
b6   Wiebold, Amanda (NIH/NINDS) [E]b6
Subject: Negative reaction to Moderna Vaccine -  b6
Good evening Dr. Safavi & Amanda,
I am reaching out in hopes of connecting with you regarding a negative reaction i am having following 1 injection of Moderna vaccine. I found your information on the CO-19 VASE Family FB group i recently joined.
My story:
I had the moderna vaccine on <b>b6</b> left arm.

Within 5 minutes i was experiencing a tingling feeling in my throat. It only lasted about 5 minutes and subsided. b6 they asked me to stay 30 minutes. I waited the time and didn't feel anything bad, so i continued home. That evening i started to feel muscle aches, nausea and back pain. I could not sleep that night, started having rapid heart rate and shortness of breath b<sub>6</sub> The increased heart rate b6 continued all day along with the other symptoms mentioned. In the evening i went to my bedroom upstairs and attempted to change the sheets. I had an episode of loosing vision (all white) and fainting loosing consciousness. When i woke up i was on the floor of my bedroom not knowing how i got there and having a really hard time catching my breath. I called my PCP office and they advised an ER visit, so i went. At the ER, they! These same increased heart rate, shortness of breath, tingling sensations all over body, intense back pain continued for several more days. I developed a rash all over my face and neck, severe tinnitus and felt the tingling in my throat again. Concerned about anaphylaxis, my doctor sent me back to ER for evaluation. ER doctor b6 b6 b6 lmade me super jittery but provided no symptom relief. Dizziness, fatigue, muscle aches, tingling pain in legs continue along with tingling in my tongue which makes me very uncomfortable.

At this point i am looking for some help in diagnosing what is actually going on as my

providers have not been able to figure this out. Are you doing any virtual visits? I am currently in b6 am interested in joining any research study you may be working on.

Thank you for listening and i look forward to connecting with you,

From:	b6
Sent: To:	4/12/2021 7:51:40 PM Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6 b6 Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 b6
CC:	Des Fords COVID 10 Version and 10 Ve
Subject:	Re: Fwd: COVID-19 Vaccine and <b>b6</b>
Flag:	Flag for follow up
Yes, I will ha	ve <b>b6</b> do that. Thank you again!
b6	
	Avindra (NIH/NINDS) [E] b6 b6 April 13, 2021 2:40 PM
To:	y, April 12, 2021 2:49 PM <b>b6</b> Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b>
L	wd: COVID-19 Vaccine and b6
	ld it also be possible for <b>b6</b> to provide that information directly to <b>b6</b> Also please share formation with <b>b6</b> so that he is not surprised when we contact him.
From:	b6
Date: Mond	ay, April 12, 2021 at 3:43 PM
To: Nath, Av	rindra (NIH/NINDS) [E] <b>b6</b> Safavi, Farinaz (NIH/NINDS) [E]
k	p6
Subject: Fw:	Fwd: COVID-19 Vaccine and <b>b6</b>
D D N -	alound Cafari
	hth and Safavi,
b6	has provided the permission (email below) to contact his neurologist at <b>b6 b6</b>
Thank you fo	or all of your help!
Best regards	
b6	
Erom.	b6
Sent: Monday	y, April 12, 2021 2:37 PM
To:	b6
·	wd: COVID-19 Vaccine and b6
l b6	give permission to <b>b6</b> to provide and share any medical information pertaining
l	h Dr. Nath. signed b6 Original Message
From:	b6
То:	b6
	2 Apr 2021 13:57:26 -0400 (EDT)
Subject: Fwd:	COVID-19 Vaccine and b6

Get Outlook for b6
<b>b6</b>
From: Nath, Avindra (NIH/NINDS) [E] b6  Sent: Monday, April 12, 2021 12:55:26 PM  To: b6  Cc: b6  Safavi, Farinaz (NIH/NINDS) [E]  Subject: Re: COVID-19 Vaccine and myelitis
Dear b6
Terribly sorry to hear of b6 illness. With b6 permission, we would be interested in talking to the neurologists taking care of him to see if there is anything we can do to help. I have copied Dr. Safavi who is a neurologist working with me and interested in these issues.
Avi
Avindra Nath MD
Chief, Section of Infections of the Nervous System
Clinical Director,
National Institute of Neurological Disorders and Stroke
National Institutes of Health, Bethesda, MD
b6 (Office) (cell)

From: b6
Date: Monday, April 12, 2021 at 1:45 PM

To: Nath, Avindra (NIH/NINDS) [E]

Cc:	D6		_j	
Subject: COVII	0-19 Vaccine and bo	6	-	
	<u> </u>			
Dear Dr. Nath,				
Appreciating y	our interest and expert	tise in regards to CNS Advers	se events and the CO	VID-19 vaccines, I am writing in
		a <b>b6</b> male who was othe		
				and numbness in his legs. On
b6	he presented to the	Emergency Department of	b6	due to inability to walk, pain and
numbness in h	is lower extremities.	b6	Yesterday he had	b6 
	b6	Today he was tol	d his diagnosis is	b6
				ity to urinate. Since this is a very
rare adverse e	vent, I thought it best t	o reach out to you or others	at NIH to determine	e if there are further tests or
treatments tha	at are appropriate. Any	help or referrals would be g	reatly appreciated.	
Thank you for	your help.			
k				
	<b>16</b>			
N				

From: **b6**Sent: 8/14/2021 4:24:43 PM

To: Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246

Subject: WHO scale 2
Attachments: WHO scale 2.docx

Updates to my scores

Date	
Over the past 7 days, how much difficulty have you had with the following:	b6
Standing for long periods such as 30 minutes?	
Taking care of your household responsibilities?	
Learning a new task, e.g. learning how to get to a new place?	
Joining in community activities (e.g. festivities, religious, other)?	
Being emotionally affected by your health prob- lems?	
Concentrating on doing something for ten minutes?	
Walking a long distance such as a kilometre (or equivalent)?	
Washing your whole body?	

Getting dressed?  Dealing with people you do not know?  Maintaining a friendship?  Your day-to-day work/school?	<b>b6</b>
Total Score	

- Score:
  0 No Difficulty
  1 Mild Difficulty
  2 Moderate Difficulty
  3 Severe Difficulty
  4 Extreme Difficulty or Cannot do

From:	b6		
rrom: Sent:	6/28/2021 2:26:17 AM		
Го:		] [/o=ExchangeLabs/ou=Exchange Admi	nistrative Group
		pients/cn=94807ce146e045d4b61655da	
	b6		<u> </u>
CC:	ij		
iubject:	Re: [External] Re: Fwd: COVID-	-Hello all,19 Vaccine and <b>b6</b>	
J;			
Hi,	anting last work		
was on v	acation last week.		
	<b>36</b>		
	70		
1			
	<b>b6</b>		
	j		
f vou nee	d more info please let me kn	ow!	
,	,		
Thanks			
b6			
	i		
rom: Safa	vi, Farinaz (NIH/NINDS) [E]	b6	
ent: Thurs	day, June 24, 2021 8:58:25 AM		
o:			
c:	b6		
	: [External] Re: Fwd: COVID-He	!	
,	· [External] Not / that ob / ib / ie	<u></u>	
li all,			
lone all ic	well.We are planning to	b6	and I really appreciate if you can
rovide us	tala i	h6	land i really appreciate if you call
hank you	with <sub>i</sub>	~~~	
nank you			
avin C - C	oui MD DbD		
	avi MD, PhD	See Largery	
	Neuroimmunology and Neurov	rrology	
	, Bethesda, MD		
	<b>b6</b>		

To: Safavi, Farinaz (NIH/NINDS) [E]; b6
Cc: b6
Subject: RE: [External] Re: Fwd: COVID-19 Vaccine and b6
Name and a second secon
OK. I checked and we still had <b>b6</b>
I put in the order for it to be shipped.
I will check back tomorrow to make sure it has been taken care of.
I will check back tomorrow to make sure it has been taken care of.
<u>b6</u>
From: Safavi, Farinaz (NIH/NINDS) [E] b6
<b>Sent:</b> Friday, May 14, 2021 10:15 PM
To: b6
b6
Сс: b6
Subject: Re: [External] Re: Fwd: COVID-19 Vaccine and <b>b6</b>
The alternation is the second
Thank you b6
There is the address.
Here is the address:
9000 Rockville Pike
Building 10 Room 7C120
Bethesda MD 20892
Attention Dr. Avi Nath
Best to ship on dry ice. You can use our Fed Ex number: b6
<b>b6</b>
b6
Please let me know If you need further information.
Please let me know If you need further information.
Please let me know If you need further information. Thank you
Please let me know If you need further information. Thank you
Please let me know If you need further information. Thank you Farinaz  From: b6
Please let me know If you need further information. Thank you Farinaz  From: b6 Sent: Friday, May 14, 2021 4:21:30 PM
Please let me know If you need further information. Thank you Farinaz  From: b6 Sent: Friday, May 14, 2021 4:21:30 PM
Please let me know If you need further information. Thank you Farinaz  From: b6 Sent: Friday, May 14, 2021 4:21:30 PM
Please let me know If you need further information. Thank you Farinaz  From: b6 Sent: Friday, May 14, 2021 4:21:30 PM To: b6 Safavi, Farinaz (NIH/NINDS) [E] b6 Cc: b6
Please let me know If you need further information. Thank you Farinaz  From: b6 Sent: Friday, May 14, 2021 4:21:30 PM To: b6 Safavi, Farinaz (NIH/NINDS) [E] b6 Cc: b6
Please let me know If you need further information. Thank you Farinaz  From: b6 Sent: Friday, May 14, 2021 4:21:30 PM To: b6 Cc: b6 Subject: RE: [External] Re: Fwd: COVID-19 Vaccine and b6
Please let me know If you need further information. Thank you Farinaz  From: b6 Sent: Friday, May 14, 2021 4:21:30 PM To: b6 Safavi, Farinaz (NIH/NINDS) [E] b6 Cc: b6
Please let me know If you need further information. Thank you Farinaz  From: b6 Sent: Friday, May 14, 2021 4:21:30 PM To: b6 Cc: b6 Subject: RE: [External] Re: Fwd: COVID-19 Vaccine and b6  OK let me check on b6
Please let me know If you need further information. Thank you Farinaz  From: b6 Sent: Friday, May 14, 2021 4:21:30 PM To: b6 Safavi, Farinaz (NIH/NINDS) [E] b6 Cc: b6 Subject: RE: [External] Re: Fwd: COVID-19 Vaccine and b6  OK let me check on b6 A couple of things.
Please let me know If you need further information. Thank you Farinaz  From: b6 Sent: Friday, May 14, 2021 4:21:30 PM To: b6 Safavi, Farinaz (NIH/NINDS) [E] b6 Cc: b6 Subject: RE: [External] Re: Fwd: COVID-19 Vaccine and b6  OK let me check on b6  A couple of things.  1. Where does it need to be shipped?
Please let me know If you need further information.  Thank you Farinaz  From:
Please let me know If you need further information. Thank you Farinaz  From: b6 Sent: Friday, May 14, 2021 4:21:30 PM To: b6 Safavi, Farinaz (NIH/NINDS) [E] b6 Cc: b6 Subject: RE: [External] Re: Fwd: COVID-19 Vaccine and b6  OK let me check on b6  A couple of things.  1. Where does it need to be shipped?
Please let me know If you need further information.  Thank you Farinaz  From:
Please let me know If you need further information.  Thank you Farinaz  From:
Please let me know If you need further information. Thank you Farinaz  From:
Please let me know If you need further information. Thank you Farinaz  From:
Please let me know If you need further information. Thank you Farinaz  From: b6 Sent: Friday, May 14, 2021 4:21:30 PM To: b6 Safavi, Farinaz (NIH/NINDS) [E] b6 Cc: b6 Subject: RE: [External] Re: Fwd: COVID-19 Vaccine and b6  OK let me check on b6  A couple of things.  1. Where does it need to be shipped? 2. How does it need to be shipped? 3. How much b6 do you need?  b6  From: b6
Please let me know If you need further information. Thank you Farinaz  From:

Cc: b6	
ubject: Re: [External] Re: Fwd: COVID-19 Vaccine and b6	
Dear Farinaz,	
We will need to follow up with <b>b6</b> and <b>b6</b> hospital. I will write to them today.	
b6	
rom: Safavi, Farinaz (NIH/NINDS) [E] b6	A00000
r <b>om:</b> Safavi, Farinaz (NIH/NINDS) [E][ <b>b6</b> E <b>ent:</b> Thursday, May 13, 2021 8:26 AM	
o: Nath, Avindra (NIH/NINDS) [E] b6	1
c: b6	j
i i	
ubject: Re: [External] Re: Fwd: COVID-19 Vaccine and b6	
Door! h6	
Dear b6	
would like to follow up regarding <u>b6</u> yet. Really appreciate if you kindly update us.	
Thank you	
Hallk you	
Farinaz	
dillaz	
rom: b6	environe:
ent: Tuesday, April 13, 2021 7:53:04 AM	
o: Nath, Avindra (NIH/NINDS) [E] b6 Cc: b6 Safavi, Farinaz (NIH/NINDS) [E] b6	
b6	
Li de la companya de	
ubject: Re: [External] Re: Fwd: COVID-19 Vaccine and 66	
low about 2pm EST?	
Do you want me to call your office number?	
lappy to Zoom as well, but I have no idea how to set that up.	
%	
hanks!	
b6	
ent from my iPhone	
ent from my iPhone	
ent from my iPhone On Apr 12, 2021, at 10:14 PM, Nath, Avindra (NIH/NINDS) [E] b6 wrote:	
On Apr 12, 2021, at 10:14 PM, Nath, Avindra (NIH/NINDS) [E] <b>b6</b> wrote:	
On Apr 12, 2021, at 10:14 PM, Nath, Avindra (NIH/NINDS) [E] b6 wrote:  Thanks for your quick reply. How about between 1-3 pm EST (Tuesday)?	
On Apr 12, 2021, at 10:14 PM, Nath, Avindra (NIH/NINDS) [E] <b>b6</b> wrote:	
On Apr 12, 2021, at 10:14 PM, Nath, Avindra (NIH/NINDS) [E] b6 wrote:  Thanks for your quick reply. How about between 1-3 pm EST (Tuesday)?	
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On Apr 12, 2021, at 10:14 PM, Nath, Avindra (NIH/NINDS) [E] b6 wrote:  Thanks for your quick reply. How about between 1-3 pm EST (Tuesday)?  Avi  From: b6  Date: Monday, April 12, 2021 at 8:08 PM	
On Apr 12, 2021, at 10:14 PM, Nath, Avindra (NIH/NINDS) [E] b6 wrote:  Thanks for your quick reply. How about between 1-3 pm EST (Tuesday)?  Avi  From: b6  Date: Monday, April 12, 2021 at 8:08 PM  To: Nath, Avindra (NIH/NINDS) [E] b6	
On Apr 12, 2021, at 10:14 PM, Nath, Avindra (NIH/NINDS) [E] b6 wrote:  Thanks for your quick reply. How about between 1-3 pm EST (Tuesday)?  Avi  From: b6  Date: Monday, April 12, 2021 at 8:08 PM  To: Nath, Avindra (NIH/NINDS) [E] b6  Cc: b6 Safavi, Farinaz (NIH/NINDS) [E]	
On Apr 12, 2021, at 10:14 PM, Nath, Avindra (NIH/NINDS) [E] b6 wrote:  Thanks for your quick reply. How about between 1-3 pm EST (Tuesday)?  Avi  From: b6  Date: Monday, April 12, 2021 at 8:08 PM  To: Nath, Avindra (NIH/NINDS) [E] b6	

Just let me know when is a good time.  66	
nave our neuroimmunologists see him today and they ordered b6	
ks! <b>b6</b>	
from my iPhone	
On Apr 12, 2021, at 6:43 PM, Nath, Avindra (NIH/NINDS) [E] <b>b6</b> wrote:	
Dear b6 Please see correspondence below. I was wondering if we might be able to talk to you to see if we can be of any help and if b6 might qualify for our research protocol. Thanking you. Avi Avindra Nath MD Chief, Section of Infections of the Nervous System Clinical Director, National Institute of Neurological Disorders and Stroke National Institutes of Health, Bethesda, MD  b6 (Office) (cell) b6	5
From: b6  Date: Monday, April 12, 2021 at 3:43 PM	voccor
To: Nath, Avindra (NIH/NINDS) [E] b6 Safavi, Farinaz	
(NIH/NINDS) [E] <b>b6</b>	
Subject: Fw: Fwd: COVID-19 Vaccine and b6	
Dear Drs. Nath and Safavi,	
<b>b6</b> has provided the permission (email below) to contact his neurologis	st
announnument.	
<b>b6</b>	
Thank you for all of your help!	
Best regards,	
b6	
From: b6	
Sent: Monday, April 12, 2021 2:37 PM	

To: b6
Subject: Re: Fwd: COVID-19 Vaccine and b6
b6 give permission to b6 to provide and share any medical information pertaining to myself with Dr. Nath. signed b6
Original Message
From: b6
To: <b>b6</b>
Sent: Mon, 12 Apr 2021 13:57:26 -0400 (EDT)
Subject: Fwd: COVID-19 Vaccine and <b>b6</b>
Get Outlook for
iOS b6
h.C
DO
b6
From: Nath, Avindra (NIH/NINDS) [E] <b>b6</b>
Sent: Monday, April 12, 2021 12:55:26 PM
To: <b>b6</b>
Cc: b6 Safavi, Farinaz
(NIH/NINDS) [E] b6
Subject: Re: COVID-19 Vaccine and <b>b6</b>
Dear b6
Lancation and the state of the
Terribly sorry to hear of <b>b6</b> illness. With <b>b6</b> permission, we
would be interested in talking to the neurologists taking care of him to see if there is
anything we can do to help. I have copied Dr. Safavi who is a neurologist working with me and interested in these issues.
The and interested in these issues.
Avi
Avindra Nath MD
Chief, Section of Infections of the Nervous System
Clinical Divertor
Clinical Director,
National Institute of Neurological Disorders and Stroke
National Institutes of Health, Bethesda, MD
(Office)
b6 (Office)
(cell)

From: <b>b6</b>
Date: Monday, April 12, 2021 at 1:45 PM
To: Nath, Avindra (NIH/NINDS) [E]
Cc: b6
Cc: b6 Subject: COVID-19 Vaccine and b6
Dear Dr. Nath,
Appreciating your interest and expertise in regards to CNS Adverse events and the
COVID-19 vaccines, I am writing in regards to <b>b6</b> In short, he is a <b>b6</b> male
who was otherwise healthy. He received his 2nd dose of the Moderna vaccine on
b6Onb6he developed low back pain and numbness in hislegs. Onb6he presented to the Emergency Department ofb6
hospital due to inability to walk, pain and numbness in his lower extremities. <b>b6</b>
b6 Yesterday he had b6
b6 Today he was told his diagnosis is b6
b6 Today he was told his diagnosis is b6 b6 He remains hospitalized with bilateral foot drop, inability
b6   Today he was told his diagnosis is b6   He remains hospitalized with bilateral foot drop, inability to walk and inability to urinate. Since this is a very rare adverse event, I thought it best
b6 Today he was told his diagnosis is b6 b6 He remains hospitalized with bilateral foot drop, inability to walk and inability to urinate. Since this is a very rare adverse event, I thought it best to reach out to you or others at NIH to determine if there are further tests or
b6   Today he was told his diagnosis is b6   He remains hospitalized with bilateral foot drop, inability to walk and inability to urinate. Since this is a very rare adverse event, I thought it best
b6 Today he was told his diagnosis is b6 b6 He remains hospitalized with bilateral foot drop, inability to walk and inability to urinate. Since this is a very rare adverse event, I thought it best to reach out to you or others at NIH to determine if there are further tests or

**b6** 

**b6** 

**b6** 

From:	b6
Sent:	4/19/2021 4:56:51 PM
То:	Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540 <b>b6</b>
CC:	b6
Subject:	Re: COVID-19 Vaccine and b6
Attachments:	HPSCAN_20210419165201945_2021-04-19_165251652.pdf
Amanda	he assessment of decreases to the methods as FAV # feather he assisted as 1 All of his treatment
has been at	he executed document. I do not have a FAX # for the hospital or <b>b6</b> All of his treatment
b6	j
L!	
	ld, Amanda (NIH/NINDS) [E] b6
To:	April 16, 2021 4:18 PM
Cc:	b6
Subject: COV	ID-19 Vaccine and b6
b6	
	with Dr. Nath and Dr. Safavi at the National Institutes of Health in Bethesda Maryland. I
understand	<b>b6</b> is interested in participating in our research study. I will help get him enrolled.
Attached yo	u will find two forms.
Δ release of	medical records. This form gives us permission to request and review medical records. Please
have <b>b</b> (	
L	tissue collection please write "NA" in that section. Please fill out one form for each facility.
The protoco	l consent form. Please only review this form at this time and write down any questions you
150000000000000000000000000000000000000	ot sign until we talk on the phone. After you have reviewed the consent form we will schedule a
	by phone. We will go over the consent form together and then you can sign it and send it back to
	e email or fax.
If you need t	to send any medical records to us directly you can attach them to this secure email. If you
	ave any imaging scans you can upload them directly to our radiology department using this link:
	.cc.nih.gov/dcri/imaginglibrary.html
51	
Please let me	e know if you have any questions.
Thank you,	
Amanda W	Viebold, BSN, RN, CNRN
Research Nur	•
	ection of Infections of the Nervous System
10 Center Driv	ve, Building 10/Room 7C107/MSC 1430

Bethesda, Maryland 20892

Office: b6
Cell: b6
Fax: 301-408-5594
Email: b6
From: Nath, Avindra (NIH/NINDS) [E] b6
Sent: Wednesday, April 14, 2021 10:30 PM
To: b6 Safavi, Farinaz (NIH/NINDS) [E] b6 Wiebold, Amanda
(NIH/NINDS) [E] b6
Subject: Re: Fwd: COVID-19 Vaccine and b6
Ver we would be interested in her would need to concert him and appell him to our receases
Yes, we would be interested in the world need to consent him and enroll him to our research
study for that purpose. Yes, <b>b6</b> is an excellent rehab center, however, early rehab is important and am not sure how
long a waiting list they have. Since these places require prolonged treatment, it is often best to get the rehab closest to
home. In the end there is not much of a difference between most institutions.
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F
From: b6
Date: Wednesday, April 14, 2021 at 1:56 PM
To: Nath, Avindra (NIH/NINDS) [E] 66 Safavi, Farinaz (NIH/NINDS) [E]
b6
Subject: Re: Fwd: COVID-19 Vaccine and b6
Danis Dis North
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b6 you agreed with b6 and you recommended b6 Is that correct? In regards to next steps after b6 they plan to move him to rehab. In
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your experience, is there a difference in potential outcome based on location and expertise of the rehab
facility? I heard that b6 is premier for this type of rehabilitation.
I appreciate all of your help and insights.
b6
<u></u>
From: Nath, Avindra (NIH/NINDS) [E] b6
Sent: Monday, April 12, 2021 2:49 PM
To: b6 Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Re: Fwd: COVID-19 Vaccine and b6
t- t
Thanks. Would it also be possible for b6 to provide that information directly to b6 Also please share
my contact information with <b>b6</b> so that he is not surprised when we contact him.
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Date: Monday, April 12, 2021 at 3:43 PM
To: Nath, Avindra (NIH/NINDS) [E] b6 Safavi, Farinaz (NIH/NINDS) [E]
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Subject: Fw: Fwd: COVID-19 Vaccine and b6
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b6
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To: b6
Sent: Mon, 12 Apr 2021 13:57:26 -0400 (EDT)
Subject: Fwd: COVID-19 Vaccine and <b>b6</b>
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iOS <b>b6</b>
<b>b6</b>
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From: Noth Avindra (NIIII/NINDS) [E]
From: Nath, Avindra (NIH/NINDS) [E] <b>b6</b> Sent: Monday, April 12, 2021 12:55:26 PM
To: <b>b6</b>
Cc: b6 Safavi, Farinaz (NIH/NINDS) [E]
b6
Subject: Re: COVID-19 Vaccine and <b>b6</b>
Subject. Net covid is vaccine and bo
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A College Mark AAD
Avindra Nath MD
Chief, Section of Infections of the Nervous System
enter, because of the cutoffs of the ructivous system

Clinical Director,

National Institute of Neurological Disorders and Stroke

National Institutes of Health, Bethesda, MD

h6	(Office)
DO	(cell)
b(	6

From: <b>b6</b>		
Date: Monday, April 12, 2021 at 1:45 PM		
To: Nath, Avindra (NIH/NINDS) [E]	b6	
Cc: <b>b6</b>		
Subject: COVID-19 Vaccine and <b>b6</b>		
Dear Dr. Nath,		

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Thank you for your help.



#### REQUEST FOR MEDICAL INFORMATION FROM SOURCE OUTSIDE THE NATIONAL INSTITUTES OF HEALTH INSTRUCTIONS: Complete this form in its entirety and forward directly to the requesting facility. CC PATIENT IDENTIFICATION b6 **b6** (Patient Number) (Patient Name) (Date of Birth) SOURCE OF INFORMATION REQUESTED b6 (Name of Health Care Organization or Physician) (Phone Number) (Fax Number) b6 (City) (Street Address) (State) (Zip Code) **INFORMATION REQUESTED** The purpose or need for disclosure: Review of clinical care and consideration for research study NIH Requestor/Point of Contact: Amanda Wiebold Identify the specific items and related dates pertaining to the information to be released. Medical Reports: Laboratory results, clinic notes, and brain MRI or head CT reports from National Institutes of Health Clinical Center Send to: OR National Institute of Neurological Disorders and Stroke Fax to: (301) 480-5594 Building 10, Room 7C103 Attn: Amanda Wiebold or 10 CENTER DRIVE MSC 1430 BETHESDA, MD 20892-1430 Dr. Bryan Smith ATTENTION: Amanda Wiebold/ Dr. Bryan Smith MRI scans on CD from b6 2 date(s) Send to: National Institutes of Health Clinical Center National Institute of Neurological Disorders and Stroke Building 10, Room 7C103 10 CENTER DRIVE MSC 1430 BETHESDA, MD 20892-1430 ATTENTION: Amanda Wiebold/ Dr. Bryan Smith b6 3. Tissue/Pathology Slides from date(s). National Institutes of Health Clinical Center Send to: Laboratory of Pathology Building 10, Room 2B50 10 CENTER DRIVE MSC 1500 BETHESDA, MD 20892-1500 **AUTHORIZATION** I hereby authorize the release of the above-requested medical information. b<sub>6</sub> b6 (Sig (Printed Name of Patient) (Date Signed) b6 (Street Address) (City) (State) (Zip Code)

Patient Identification Request for Medical Information From Source Outside The
National Institutes of Health

NIH-1208 (8-17) P.A. 09-25-0099

From: Sent:	<b>b6</b> 4/27/2021 10:30:46 PM
To: CC:	Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540 b6
Subject:	RE: COVID-19 Vaccine and b6
From: Wiebol To: Sent: Tue, 2	nda. nal Message ld, Amanda (NIH/NINDS) [E] <u>b6</u> 27 Apr 2021 18:24:56 -0400 (EDT) : COVID-19 Vaccine and <u>b6</u>
Great. So I Then you can	I will send a kit and instructions out to you on May 12th. You should receive it May 13th. In have your blood drawn sometime in the last two weeks of May.
Let me know	if you have any questions.
Thanks, Amanda	
To: Wiebold,	b6       ay, April 27, 2021 6:18 PM         ay, Amanda (NIH/NINDS) [E]
	b6
Get Outlook	for iOS <https: aka.ms="" ooukef=""></https:>
From: Wiebol Sent: Tuesda To:	ld, Amanda (NIH/NINDS) [E]   <b>b6</b> ay, April 27, 2021 5:16:45 PM b6
	b6: COVID-19 Vaccine and b6
	looks perfect. Thank you.
What was the b6 doesn't	e date ofb6 We need to wait 4-6 weeks to collect blood sob6 t affect our testing.
Thanks,	
Amanda	
From: Sent: Tuesda To: Wiebold,	b6 ay, April 27, 2021 6:12 PM , Amanda (NIH/NINDS) [E] b6
Subject: Re:	b6 : COVID-19 Vaccine and i b6
Amanda	
b6	asked that I scan and forward the attached consent form.
b6	
From: Wiebol Sent: Friday To:	ld, Amanda (NIH/NINDS) [E]

Cc: b6
Subject: RE: COVID-19 Vaccine and <b>b6</b>
Hello. Would you be available Tuesday, April 27, 2021, at 1:00 PM EST (12:00 Noon CST)?
Thanks, Amanda
Original Message From: b6
Sent: Thursday, April 22, 2021 3:19 PM
To: Wiebold, Amanda (NIH/NINDS) [E]   b6
Subject: RE: COVID-19 Vaccine and b6
Dear Amanda, thank you for your interest in my medical condition. Except for Monday Apr. 26 10am-1pm    b6   I will be available at anytime for a phone conversation with you. My phone number is   b6     b6   Thanks again.   b6     Original Message
From: Wiebold, Amanda (NIH/NINDS) [E]   b6
Sent: Thu, 22 Apr 2021 10:07:02 -0400 (EDT) Subject: RE: COVID-19 Vaccine and b6
b6
I wanted to let you know that I requested records and imaging on Monday. Would it be possible to schedule a telephone call to review the consent? If you give me a few times that work for you next week I can probably make one of the work!
Thanks, Amanda
From: Wiebold, Amanda (NIH/NINDS) [E] Sent: Monday, April 19, 2021 1:03 PM To:
Thank you. I will track down a fax number.
Thanks, Amanda
From: b6
ь6
Sent: Monday, April 19, 2021 12:57 PM To: Wiebold, Amanda (NIH/NINDS) [E]
b6   b6
CC:
Subject: Re: COVID-19 Vaccine and <b>b6</b>
Amanda Please find the executed document. I do not have a FAX # for the hospital or b6 All of his treatment has been at b6 b6
From: Wiebold, Amanda (NIH/NINDS) [E]
b6
Sent: Friday, April 16, 2021 4:18 PM To:   b6
CC: 56 1
b6
Subject: COVID-19 Vaccine and b6

Hello. I work with Dr. Nath and Dr. Safavi at the National Institutes of Health in Bethesda Maryland. I understand <b>b6</b> is interested in participating in our research study. I will help get him enrolled.
Attached you will find two forms.
A release of medical records. This form gives us permission to request and review medical records. Please have be a fill out the sections highlighted in yellow and return to me by secure email or fax. If he has not had any tissue collection please write "NA" in that section. Please fill out one form for each facility.
The protocol consent form. Please only review this form at this time and write down any questions you have. Do not sign until we talk on the phone. After you have reviewed the consent form we will schedule a time to talk by phone. We will go over the consent form together and then you can sign it and send it back to me by secure email or fax.
If you need to send any medical records to us directly you can attach them to this secure email. If you personally have any imaging scans you can upload them directly to our radiology department using this link:
<b>b6</b>
Please let me know if you have any questions.
Thank you,
Amanda Wiebold, BSN, RN, CNRN
Research Nurse Specialist
NIH/NINDS/Section of Infections of the Nervous System
10 Center Drive, Building 10/Room 7C107/MSC 1430
Bethesda, Maryland 20892
Office: b6
Cell: <b>b6</b>
Fax: 301-408-5594
Email: <b>b6</b>
<u>                                     </u>
From: Nath, Avindra (NIH/NINDS) [E]
<b>b6</b> Sent: Wednesday, April 14, 2021 10:30 PM

,To: b6	L.C	
[ Farinaz (NIH/NINDS) [E]	D6	Safavi,
b6 Wiebold, Amanda (NIH/	NTNDS) [F]	
	b6	
L Subject: Re: Fwd: COVID-19 Vaccine a	and <b>b6</b>	
Yes, we would be interested in our research study for that purpose important and am not sure how long a treatment, it is often best to get t difference between most institutions	the renab closest to home. In	ld need to consent him and enroll him to ab center, however, early rehab is e these places require prolonged the end there is not much of a
Avi		
From: b6		
Date: Wednesday, April 14, 2021 at 1	1:56 PM	
To: Nath, Avindra (NIH/NINDS) [E]		
b6 Safavi, Farinaz (NIH/NINDS)	[E]	
b6		
Subject: Re: Fwd: COVID-19 Vaccine a	and   b6	
Dear Dr Nath,		
Thank you for speaking with b6 you that correct? In regards to next st rehab. In your experience, is there the rehab facility? I heard that rehabilitation.	b6 yesterday. u agreed with b6 teps after b6 a difference in potential out	My understanding is that they will be and you recommended b6 Is they plan to move him to they based on location and expertise of is premier for this type of
I appreciate all of your help and ir	nsights.	
b6		
From: Nath, Avindra (NIH/NINDS) [E]	b6	
b6 : Sent: Monday, April 12, 2021 2:49 PM	л	
To: Fitzsimmons. Bill	b6	1
   Farinaz (NIH/NINDS) [E]		Safavi,
	<b>b6</b>	
Subject: Re: Fwd: COVID-19 Vaccine a	and <b>b6</b>	
Thanks. Would it also be possible for Also please share my contact informa	or b6 to provide that ation with b6 so that h	t information directly to <b>b6</b> e is not surprised when we contact him.
Avi		
	<b>56</b>	
Date: Monday, April 12, 2021 at 3:43 To: Nath, Avindra (NIH/NINDS) [E]	3 PM	
	b6	
b6   Safavi, Farinaz (NIH/NINDS)	<sub>LEJ</sub>	
	50	

Subject: Fw: Fwd: COVID-19 Vaccine and myelitis Dear Drs. Nath and Safavi, b6 has provided the permission (email below) to contact his neurologist at Thank you for all of your help! Best regards, b6 Subject: Re: Fwd: COVID-19 Vaccine and to provide and share any medical information give permission to pertaining to myself with Dr. Nath. signed -- Original Message -----Sent: Mon, 12 Apr 2021 13:57:26 -0400 (EDT) Subject: Fwd: COVID-19 Vaccine and **b6** Get Outlook for ios From: Nath, Avindra (NIH/NINDS) [E] b6 **b6** |Safavi, Farinaz (NIH/NINDS) [E] b6

b6
Subject: Re: COVID-19 Vaccine and b6
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Avi
Avindra Nath MD
Chief, Section of Infections of the Nervous System
Clinical Director,
National Institute of Neurological Disorders and Stroke
National Institutes of Health, Bethesda, MD
b6 (Office)
(cell)
From: 1 b6 5
Date: Monday, April 12, 2021 at 1:45 PM
To: Nath, Avindra (NIH/NINDS) [E]  66
CC:
<b>b6</b>
Subject: COVID-19 Vaccine and <b>b6</b>
Dear Dr. Nath,
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Thank you for your help.
<b>b6</b>

From: Sent: To: CC: Subject: Attachments:	Wiebold, Amanda (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROU (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4491EE2AE9804610899C741100150540 b6 4/16/2021 9:18:38 PM b6 COVID-19 Vaccine and b6 NIH-1208 Authorization for the Release of Medical Information modified.pdf; 15-N-0125.2.Samp Consent.pdf	
b6		
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personally ha	to send any medical records to us directly you can attach them to this secure ema ave any imaging scans you can upload them directly to our radiology department c.cc.nih.gov/dcri/imaginglibrary.html	•
Please let me	e know if you have any questions.	
Thank you,		
Research Nurs NIH/NINDS/Se 10 Center Driv Bethesda, Mar	section of Infections of the Nervous System ve, Building 10/Room 7C107/MSC 1430 ryland 20892 b6	
	Avindra (NIH/NINDS) [E] <b>b6</b>	
,	sday, April 14, 2021 10:30 PM	Violental A
To: (NIH/NINDS) [ Subject: Re: Fr		Viebold, Amanda

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Subject: Re: COVID-19 Vaccine and b6
Dear <b>b6</b>
Terribly sorry to hear of b6 illness. With b6 permission, we would be interested in talking to the neurologists taking care of him to see if there is anything we can do to help. I have copied Dr. Safavi who is a neurologist working with me and interested in these issues.
Avi
Avindra Nath MD
Chief, Section of Infections of the Nervous System
Clinical Director,
National Institute of Neurological Disorders and Stroke
National Institutes of Health, Bethesda, MD
h6 (Office)
DO <sub>(cell)</sub>
b6

From: b6
Date: Monday, April 12, 2021 at 1:45 PM
To: Nath, Avindra (NIH/NINDS) [E]
Cc: <b>b6</b>
Subject: COVID-19 Vaccine and <b>b6</b>
Dear Dr. Nath,
Appreciating your interest and expertise in regards to CNS Adverse events and the COVID-19 vaccines, I am writing in
regards to <b>b6</b> In short, he is a <b>b6</b> male who was otherwise healthy. He received his 2nd dose of the
Moderna vaccine on <b>b6</b> On <b>b6</b> he developed low back pain and numbness in his legs. On
b6 he presented to the Emergency Department of b6 due to inability to walk, pain and
numbness in his lower extremities. b6 Yesterday he had b6 b6 Today he was told his diagnosis is b6
<b>b6</b> Today he was told his diagnosis is <b>b6</b>
b6 He remains hospitalized with bilateral foot drop, inability to walk and inability to urinate. Since this is a very
rare adverse event, I thought it best to reach out to you or others at NIH to determine if there are further tests or
treatments that are appropriate. Any help or referrals would be greatly appreciated.
Thank you for your help.
b6

# REQUEST FOR MEDICAL INFORMATION FROM SOURCE OUTSIDE THE NATIONAL INSTITUTES OF HEALTH

INSTRUCTIONS: Complete this form in its entirety and forward directly to the requesting facility.  CC PATIENT IDENTIFICATION							
(Pat	ient Name)		(Patier	nt Number)	(Date of Birth)		
sol	JRCE OF INF	FORMATION REQUESTED					
(Nai	ne of Health	Care Organization or Physician)		(Phone Number)	(Fax Number)		
(Str	eet Address)		(City)	(State)	(Zip Code)		
NF	ORMATION I	REQUESTED					
The	purpose or n	eed for disclosure: Review of clinical care a	nd consideration for re	search study			
NIH	Requestor/P	oint of Contact: <u>Amanda Wiebold</u>	b6				
	are or						
iden 1.	Medical Re	fic items and related dates pertaining to the	information to be relea	ised.			
1.		results, clinic notes, and brain MRI or head	CT reports from	date(s).			
					*		
	Send to:	National Institutes of Health Clinical Cen National Institute of Neurological Disorde		OR			
		Building 10, Room 7C103		Fax to: (301) 480-5594			
		10 CENTER DRIVE MSC 1430 BETHESDA, MD 20892-1430		Attn: Amanda Wiebold or			
		ATTENTION: Amanda Wiebold/ Dr. Brya	an Smith	Dr. Bryan Smith			
2.	MRI scans	MRI scans on CD from date(s).					
	Send to:	National Institutes of Health Clinical Cen National Institute of Neurological Disorde Building 10, Room 7C103 10 CENTER DRIVE MSC 1430 BETHESDA, MD 20892-1430 ATTENTION: Amanda Wiebold/ Dr. Brya	ers and Stroke				
3.	Tissue/Pathology Slides fromdate(s).						
	Send to:	National Institutes of Health Clinical Cer Laboratory of Pathology Building 10, Room 2B50 10 CENTER DRIVE MSC 1500 BETHE: MD 20892-1500					
AU1	HORIZATIO	N					
l he	reby authoriz	e the release of the above-requested medic	al information.				
(Sig	nature of Pat	ient/Legal Guardian)	(Printe	d Name of Patient)	(Date Signed)		
(Str	eet Address)		(City)	(State)	(Zip Code)		
Pa	tient Identi	fication	Reques	st for Medical Information From S	ource Outside The		
			Nationa NIH-12	al Institutes of Health 08 (8-17) -25-0099			

PRINCIPAL INVESTIGATOR: Avindra Nath, MD

STUDY TITLE: Natural History Study of Inflammatory and Infectious Diseases of the

**Nervous System** 

STUDY SITE: NIH Clinical Center

Cohort: Biological Samples Only Consent

Consent Version: 03/17/2020

# WHO DO YOU CONTACT ABOUT THIS STUDY?

Principal Investigator: Avindra Nath, MD,
Study Coordinator: Amanda Wiebold, RN,

This consent form describes a research study and is designed to help you decide if you would like to be a part of the research study.

You are being asked to take part in a research study at the National Institutes of Health (NIH). Members of the study team will talk with you about the information described in this document. Some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). Take the time needed to ask any questions and discuss this study with NIH staff, and with your family, friends, and personal health care providers. Taking part in research at the NIH is your choice.

If the individual being enrolled is a minor then the term "you" refers to "you and/or your child" throughout the remainder of this document.

If the individual being asked to participate in this research study is not able to give consent to be in this study, you are being asked to give permission for this person as their decision-maker. The term "you" refers to you as the decision-maker and/or the individual being asked to participate in this research, throughout the remainder of this document.

#### IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

You may choose not to take part in this study for any reason. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. In either case, you will not lose any benefits to which you are otherwise entitled. However, to be seen at the NIH, you must be taking part in a study or are being considered for a study. If you do choose to leave the study, please inform your study team to ensure a safe withdrawal from the research.

#### WHY IS THIS STUDY BEING DONE?

The purpose of this study is to learn more about how inflammation and infections hurt the brain and nervous system so we can develop better tests and treatments for them.

# PATIENT IDENTIFICATION

Consent to Participate in a Clinical Research Study

NIH-2977 (4-17)

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#### BACKGROUND

Inflammation is the way your body reacts to infection or injury. Signs of inflammation can include swelling, pain, redness or heat. Infections and/or inflammation in the brain can cause major health problems. Brain infections can be hard to find sometimes because we do not always have good tests for them. Sometimes inflammation in the brain can happen and doctors do not know what caused it. We would like to learn more about how diseases work and affect the brain, so we can figure out better ways to test for them and treat them. We hope that with better and earlier testing and treatment, we can help people avoid serious health problems and death.

This consent form describes the participation of those who are sending biological samples (such as blood or spinal fluid) collected during care procedures to NIH for analysis.

#### STUDY POPULATION

Up to 1000 people will take part in this study.

•

#### PROCEDURES/STUDY OVERVIEW

Your own clinician outside of NIH will collect blood, tissue, and/or other samples from you, such as cerebrospinal fluid (CSF) as part of the care for your condition. These samples will be sent to the NIH. We may ask you to send us additional blood, urine, and/or saliva for research. We will analyze your samples using research tests to try to give you and your own clinicians more information about your illness. Your samples may be processed in new ways that cannot currently be done by your own clinicians.

# **Induced Pluripotent Stem Cells (iPS)**

We may use your skin or blood cells to create adult stem cells, also called iPS (induced pluripotent stem) cells. Stem cells can be turned into different cell types. Studying different cell types from the iPS cells may help us better understand the conditions we are studying. The iPS cells will not be used for cloning. iPS cells cannot currently be used to grow artificial organs or organisms, but this may change in the future.

#### **Genetic Testing**

Your blood may be used for genetic research purposes. The genetic material, DNA, will be taken from the sample. Different types of genetic testing may be done, depending on your condition:

- 1. It may be analyzed to identify the genes that might be causing your condition. This will help us understand how changes in the genes may cause symptoms. Genetic testing can be helpful in establishing a diagnosis. It may eventually lead to improved treatment or prevention.
- 2. To try to identify genetic changes that may be associated with your condition we may sequence the part of the DNA that provides instructions for making proteins, called the "exome." The exome makes up about 1% of your DNA.

# PATIENT IDENTIFICATION

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3. We may analyze the DNA and do "whole genome" sequencing. Whole genome sequencing provides information on most of your DNA. Sequencing takes months to complete. It may take even longer for us to analyze the results of the sequencing and to understand which genes might be involved in your condition.

After the genetic sequencing and analysis are complete, you may meet again with the study team and the genetic counselor to discuss the results. Results about known or likely disease-causing gene variations will be given to you as part of genetic counseling.

The genetic testing for this study will not detect all gene changes that are associated with known diseases. However, we will tell you if we find gene changes in your DNA that are known to have major and direct medical significance and are associated with illnesses or conditions that could benefit from early treatment. We call these "reportable gene changes." We suggest you share this information with your own doctors and that you have a clinical laboratory confirm the "reportable gene change" before you take any action on this information.

We will find individual DNA variations in everyone. We will not inform you of all gene variations, as not all of them have health implications. For example, we will not tell you about gene changes that only predispose to a particular disease--like a gene change that influences the risk for heart disease, but where the development of heart disease depends on other factors (such as diet and smoking). We will also not tell you if you are a carrier of a recessive mutation, which means that you have one copy of a recessive mutation and one copy of the normal gene, if being a carrier causes no known health problems for you.

The results from this research study will be preliminary. Further research may be necessary before they are fully understood. We do not plan to provide you with research results. However, if we obtain information that may be important for your health, we will share it with you. By participating in this study, you do not waive any rights that you may have regarding access to and

# disclosure of your records. Banking and Sharing

Your blood, saliva, urine, tissue sample, spinal fluid or blood cells samples and MRI and other clinical data will be stored securely on the NIH campus. Your data and samples may be sent to a repository for storage and may be released for research purposes. Your name and identifying information will not be on the samples and data. A code will be assigned. The key to the code will

be kept at NIH in a separate, secure area.

If you withdraw from this research study before it is complete, you may ask that your remaining samples be destroyed. Results obtained before you withdraw will be kept. Your privacy will be protected as much as possible.

Your blood, saliva, urine, tissue sample, spinal fluid or blood cells samples and MRI and other clinical data may be used for other research projects, including those not related to your current condition. If you do not want your samples and data used for other projects, you should not participate in this study.

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# RISKS, INCONVENIENCES AND DISCOMFORTS

There are minimal risks to you from sharing your samples collected by your outside clinician with us.

# **Genetic Testing**

Genetic testing can provide information about how illness is passed on within a family. This knowledge may affect your emotional wellbeing. You might feel differently about your life if you learned that you or your children were at increased risk of a disease, especially if there were no treatment. Your children, brothers or sisters may find out that they are at risk for health problems because of your genetic information. This might affect your relationships. Other family members may also be affected by uncovering risks they did not want to know about. This information can cause stress, anxiety, or depression.

Some genetic testing shows if people are directly related. Some genetic tests can show that people were adopted or that their biological parent is someone other than their legal parent. If these facts were not known previously, they could be troubling. Genetic counseling is available at NIH to help you understand the implications of your genetic testing.

Because of the emotional risk, some people do not want to know the results of genetic testing. It is our policy to not disclose the results of research genetic testing unless it may have direct medical implications for you or your family.

Results of the research genetic testing in this study are often difficult to interpret because the testing is being done for research purposes only and the laboratories are not clinically certified.

You may be referred to a CLIA certified laboratory, possibly outside of NIH, for additional testing or confirmation of the research results. NIH will not cover the cost of the additional testing. You or your insurer will be responsible for the cost.

The results from this research study will be preliminary. Further research may be necessary before they are fully understood. We do not plan to provide you with research results. However, if we obtain information that may be important for your health, we will share it with you. By participating in this study, you do not waive any rights that you may have regarding access to and disclosure of your records.

Your genetic information will be kept confidential to the extent possible. The results of your genetic testing will be kept in a locked and secured manner at the NIH.

# **Banking and Sharing**

We will remove any information that could identify you from data and samples that are sent to repositories or shared. Data and samples will be sent with a code. This linking code will be kept at NIH. However, there is a very small chance that the data or samples could be identified as yours.

Research using data or samples from this study may lead to new tests, drugs, or devices with commercial value. You will not receive any payment for any product developed from research using your data or samples.

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#### ANTICIPATED BENEFITS

There are no expected direct benefits for you in this study. This study will likely increase our general knowledge of how infections and immune conditions affect the brain and will probably help us to diagnose brain infections and immune disorders earlier and manage patients better. The study results may help to develop new treatments in the future.

#### RIGHT OF WITHDRAWAL AND CONDITIONS FOR EARLY WITHDRAWAL

You may withdraw from the study at any time and for any reason without loss of benefits or privileges to which you are otherwise entitled. If you withdraw from this research project before it is complete, any remaining samples you have contributed will be discarded. Results obtained before you withdraw will be kept and your privacy will be protected.

#### CONFLICT OF INTEREST

The National Institutes of Health reviews NIH staff researchers at least yearly for conflicts of interest. The following link contains details on this process <a href="http://ethics.od.nih.gov/forms/Protocol-Review-Guide.pdf">http://ethics.od.nih.gov/forms/Protocol-Review-Guide.pdf</a>. You may ask your research team for additional information or a copy of the Protocol Review Guide.

#### RESULTS FROM THIS STUDY

We will share the results of the tests performed in this study with you. With your written permission, we will discuss and/or send test results and a letter to your doctors.

# ALTERNATIVES TO PARTICIPATION

This study does not provide treatment and you do not have to stop any treatment in order to participate. You may choose not to participate in this study, but to receive diagnostic and treatment care from your own physicians. The alternative is not to participate.

# COMPENSATION, REIMBURSEMENT, AND PAYMENT

# Will you receive compensation for participation in the study?

Some NIH Clinical Center studies offer compensation for participation in research. The amount of compensation, if any, is guided by NIH policies and guidelines.

You will not receive compensation for participation in this study.

# Will you receive reimbursement or direct payment by NIH as part of your participation?

Some NIH Clinical Center studies offer reimbursement or payment for travel, lodging or meals while participating in the research. The amount, if any, is guided by NIH policies and guidelines.

This study does not offer reimbursement for, or payment of, travel, lodging or meals.

# Will taking part in this research study cost you anything?

NIH does not bill health insurance companies or participants for any research or related clinical care that you receive at the NIH Clinical Center.

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#### CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

# Will your medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The NIH and other government agencies, like the Food and Drug Administration (FDA), which are involved in keeping research safe for people.
- National Institutes of Health Intramural Institutional Review Board

When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

If we share your specimens or data with other researchers, in most circumstances we will remove your identifiers before sharing your specimens or data. You should be aware that there is a slight possibility that someone could figure out the information is about you.

Further, the information collected for this study is protected by NIH under a Certificate of Confidentiality and the Privacy Act.

# **Certificate of Confidentiality**

To help us protect your privacy, the NIH Intramural Program has received a Certificate of Confidentiality (Certificate). With this certificate, researchers may not release or use data or information about you except in certain circumstances.

NIH researchers must not share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if requested by a court.

The Certificate does not protect your information when it:

- 1. is disclosed to people connected with the research, for example, information may be used for auditing or program evaluation internally by the NIH; or
- 2. is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA);
- 3. is for other research;
- 4. is disclosed with your consent.

The Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing below you consent to those

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disclosures. Other permissions for release may be made by signing NIH forms, such as the Notice and Acknowledgement of Information Practices consent.

# **Privacy Act**

The Federal Privacy Act generally protects the confidentiality of your NIH medical records we collect under the authority of the Public Health Service Act. In some cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act allows release of information from your medical record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to those engaged by the agency for research purposes, to certain federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to tumor registries, for quality assessment and medical audits, or when the NIH is involved in a lawsuit. However, NIH will only release information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act.

# POLICY REGARDING RESEARCH-RELATED INJURIES

The NIH Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH, the NIH Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

# PROBLEMS OR QUESTIONS

If you have any problems or que	estions about this st	tudy, or about your	rights as a research
participant, or about any research-	elated injury, contac	ct the Principal Inves	stigator Avindra Nath,
MD, b6	You may	also call the NIH C	Clinical Center Patient
Representative at 301-496-2626, of	r the NIH Office of	f IRB Operations at	301-402-3713, if you
have a research-related complaint of	or concern.		

# CONSENT DOCUMENT

Please keep a copy of this document in case you want to read it again.

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Adult Research Participant: I to discuss it and to ask question			have been given the opportur		
Signature of Research Participa	nt	Print Name of Research Par	ticipant Date		
Legally Authorized Represent about this study and have been a to make research decisions on be consent to this study. As applicationable to consent who agrees to	given the oppo chalf of the adu ble, the inform	ortunity to discuss it and to ask quality participant unable to consent nation in the above consent was	uestions. I am legally authori and have the authority to prov		
Signature of LAR		Print Name of LAR	Date		
Parent/Guardian of a Minor I the opportunity to discuss it and	•				
Signature of Parent/Guardian		Print Name of Parent/Guard	lian Date		
Signature of Parent/Guardian (a.	s applicable)	Print Name of Parent/Guard	lian Date		
<b>Assent:</b> (Use this section only when this process is approved by an IRB for older minors. Do not use if an II requires a separate assent form for this population.)					
I have had this study explained to me in a way that I understand, I have been given the opportunity to discuit, and I have had the chance to ask questions. I agree to take part in this study.					
Assent of Minor: (as applicable)					
Signature of Minor		Print Name of Minor	Date		
Investigator:					
Signature of Investigator Witness to the oral short-form short-consent process and this Etranslation.					
FIENT IDENTIFICATION	NIH-2977 (4 File in Secti	on 4: Protocol Consent (2) e: 3/17/2020 IRB	earch Study  NUMBER: 15N0125 APPROVAL DATE: 04/09/2020		

MEDICAL RECORD	CONSENT TO	PARTICIPATE IN AN NIH CL	LINICAL RESEARCH STUDY
XX7°			
Witness:			
Circotus of Witness		Driet Name of Witness	
Signature of Witness*		Print Name of Witness	Date
*NIH ADMINISTRATIVE INTERPRETER:	SECTION TO	BE COMPLETED REGAR	DING THE USE OF AN
INTERIKETER.			
		eaks English and the participant's	
also serve as the witness.	a consent and ser	ved as a witness. The investigat	or obtaining consent may not
An interpreter, or other in	dividual, who spe	eaks English and the participant's	preferred language facilitated

the administration of informed consent but did not serve as a witness. The name or ID code of the person

PATIENT IDENTIFICATION

providing interpretive support is:

Consent to Participate in a Clinical Research Study

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From: Sent: To: CC: Subject:	b6  4/23/2021 2:45:51 PM Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540 b6  RE: COVID-19 Vaccine and b6
Origin From: Wiebol To:   Cc:   Sent: Fri, 2	, I will be available Apr. 27 at 1:00 pm EST. thank you b6    hal Message   d, Amanda (NIH/NINDS) [E]   b6   b6   23 Apr 2021 09:19:50 -0400 (EDT)   COVID-19 Vaccine and b6
Hello. Woul	ld you be available Tuesday, April 27, 2021, at 1:00 PM EST <b>b6</b> ?
Thanks, Amanda	
Origina From: [ Sent: Thurso To: Wiebold, Cc: [	al Message  b6 day, April 22, 2021 3:19 PM , Amanda (NIH/NINDS) [E] b6 b6 COVID-19 Vaccine and b6
b6 I b6 Th Origin From: Wiebol To: Sent: Thu, 2	thank you for your interest in my medical condition. Except for Monday Apr. 26 10am-1pm will be available at anytime for a phone conversation with you. My phone number is b6 hanks again b6 hal Message  Id. Amanda (NIH/NINDS) [E] b6 hal b6  22 Apr 2021 10:07:02 -0400 (EDT)  12 COVID-19 Vaccine and b6
b6	
schedule a t	let you know that I requested records and imaging on Monday. Would it be possible to telephone call to review the consent? If you give me a few times that work for you next week oly make one of the work!
Thanks, Amanda	
Sent: Monday	ld, Amanda (NIH/NINDS) [E] y, April 19, 2021 1:03 PM
Thank you.	I will track down a fax number.
Thanks, Amanda	
To: Wiebold, Cc:	b6 y, April 19, 2021 12:57 PM , Amanda (NIH/NINDS) [E] <b>b6</b> : COVID-19 Vaccine and <b>b6</b>
Amanda Please find treatment ha	the executed document. I do not have a FAX # for the hospital or <b>b6</b> All of his as been at <b>b6</b>
From: Wiebol	ld, Amanda (NIH/NINDS) [E] <b>b6</b>
	y, April 16, 2021 4:18 PM b6 b6
Subject: COV	/ID-19 Vaccine and b6 ]

<b>b6</b>
Hello. I work with Dr. Nath and Dr. Safavi at the National Institutes of Health in Bethesda Maryland. I understand b6 is interested in participating in our research study. I will help get him enrolled.
Attached you will find two forms.
A release of medical records. This form gives us permission to request and review medical records. Please have b6   fill out the sections highlighted in yellow and return to me by secure email or fax. If he has not had any tissue collection please write "NA" in that section. Please fill out one form for each facility.
The protocol consent form. Please only review this form at this time and write down any questions you have. Do not sign until we talk on the phone. After you have reviewed the consent form we will schedule a time to talk by phone. We will go over the consent form together and then you can sign it and send it back to me by secure email or fax.
If you need to send any medical records to us directly you can attach them to this secure email. If you personally have any imaging scans you can upload them directly to our radiology department using this link:
<b>b6</b>
Please let me know if you have any questions.
Thank you,
Amanda Wiebold, BSN, RN, CNRN
Research Nurse Specialist
NIH/NINDS/Section of Infections of the Nervous System
10 Center Drive, Building 10/Room 7C107/MSC 1430
Bethesda, Maryland 20892
Office: b6
Cell: <b>b6</b>
Fax: 301-408-5594
Email: b6
From: Nath, Avindra (NIH/NINDS) [E]   b6 Sent: Wednesday, April 14, 2021 10:30 PM To:   Safavi, Farinaz (NIH/NINDS) [E]
b6   Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Fwd: COVID-19 Vaccine and b6

Yes, we would be interested in b6 We would need to consent him and enroll him to our research study for that purpose. Yes, b6 is an excellent rehab center, however, early rehab is important and am not sure how long a waiting list they have. Since these places require prolonged treatment, it is often best to get the rehab closest to home. In the end there is not much of a difference between most institutions.
Avi
From:
Dear Dr Nath,
Thank you for speaking with b6 yesterday. My understanding is that they will be b6 you agreed with b6 and you recommended b6 Is that correct? In regards to next steps after b6 they plan to move him to rehab. In your experience, is there a difference in potential outcome based on location and expertise of the rehab facility? I heard that b6 is premier for this type of rehabilitation.
I appreciate all of your help and insights.
b6
From: Nath, Avindra (NIH/NINDS) [E]
Subject: Re: Fwd: COVID-19 Vaccine and b6
Thanks. Would it also be possible for <u>b6</u> to provide that information directly to <u>b6</u> Also please share my contact information with <u>b6</u> so that he is not surprised when we contact him.
Avi
From:
Dear Drs. Nath and Safavi,
My brother has provided the permission (email below) to contact his neurologist at b6
<b>b6</b>
Thank you for all of your help!
Best regards,

From: b6  Sent: Monday, April 12, 2021 2:37 PM  To: b6  Subject: Re: Fwd: COVID-19 Vaccine and b6
I b6 give permission to b6 to provide and share any medical information pertaining to myself with Dr. Nath. signed b6 Original Message From: b6 To: b6 Sent: Mon, 12 Apr 2021 13:57:26 -0400 (EDT) Subject: Fwd: COVID-19 Vaccine and b6
Get_Outlook for iOS
<b>b6</b>
From: Nath, Avindra (NIH/NINDS) [E]
To: b6
b6 Subject: Re: COVID-19 Vaccine and b6 Subject: Re: COVID-19 Vaccine and b6
Dear b6
Terribly sorry to hear of b6 illness. With b6 permission, we would be interested in talking to the neurologists taking care of him to see if there is anything we can do to help. I have copied Dr. Safavi who is a neurologist working with me and interested in these issues.
Avi
Avindra Nath MD
Chief, Section of Infections of the Nervous System  Clinical Director,
National Institute of Neurological Disorders and Stroke
National Institutes of Health, Bethesda, MD
(Office)
<b>b6</b> (cell)
b6
From: [
To: Nath, Avindra (NIH/NINDS) [E]   b6
Subject: COVID-19 Vaccine and b6
Dear Dr. Nath,

REL0000231118

Appreciating your interest and expertise i writing in regards to b6 In shor his 2nd dose of the Moderna vaccine on and numbness in his legs. On b6 hospital due to inability to walk, pain an	t, he is a   b6   male who was otherwise   b6   On   b6   he de	healthy. He received veloped low back pain
b6 Yesterday he had	b6	
Today he was told his diagnosis is	b6	He remains
hospitalized with bilateral foot drop, in rare adverse event, I thought it best to r further tests or treatments that are appro	ability to walk and inability to urinate each out to you or others at NIH to dete	rmine if there are
<b>b6</b>		

From: Sent: To:	b6 4/27/2021 10:11:55 PM Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
10.	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540 b6
Subject: Attachments:	Re: COVID-19 Vaccine and b6 informed consent b6
Amanda	
b6	asked that I scan and forward the attached consent form.
b6	
	d, Amanda (NIH/NINDS) [E] <b>b6</b> April 23, 2021 8:19 AM <b>b6</b>
Cc: Subject: RE: C	OVID-19 Vaccine and b6
Hello. Would	l you be available Tuesday, April 27, 2021, at 1:00 PM EST (12:00 Noon CST)?
Thanks, Amanda	
To: Wiebold,	Message  b6  y, April 22, 2021 3:19 PM  Amanda (NIH/NINDS) [E] b6  b6  COVID-19 Vaccine and b6
will be availa again	thank you for your interest in my medical condition. Except for Monday Apr. 26 10am-1pm b6 I ble at anytime for a phone conversation with you. My phone number is b6 Thanks b6
Original	Message ld, Amanda (NIH/NINDS) [E] b6
To:	b6
	Apr 2021 10:07:02 -0400 (EDT) COVID-19 Vaccine and <b>b6</b>
b6	
	t you know that I requested records and imaging on Monday. Would it be possible to schedule a telephone the consent? If you give me a few times that work for you next week I can probably make one of the work!
Thanks, Amanda	
Sent: Monday To:	d, Amanda (NIH/NINDS) [E]  7, April 19, 2021 1:03 PM  66  COVID-19 Vaccine and 66
Thank you. I	will track down a fax number.

REL0000231119

Thanks, Amanda
From: b6  Sent: Monday, April 19, 2021 12:57 PM  To: Wiebold, Amanda (NIH/NINDS) [E] b6  Cc: Subject: Re: COVID-19 Vaccine and b6
Amanda Please find the executed document. I do not have a FAX # for the hospital or b6 All of his treatment has been at b6
From: Wiebold, Amanda (NIH/NINDS) [E]   <b>b6</b> Sent: Friday, April 16, 2021 4:18 PM  To:   b6
b6
Hello. I work with Dr. Nath and Dr. Safavi at the National Institutes of Health in Bethesda Maryland. I understand b6 is interested in participating in our research study. I will help get him enrolled.
Attached you will find two forms.
A release of medical records. This form gives us permission to request and review medical records. Please have b6 fill out the sections highlighted in yellow and return to me by secure email or fax. If he has not had any tissue collection please write "NA" in that section. Please fill out one form for each facility.
The protocol consent form. Please only review this form at this time and write down any questions you have. Do not sign until we talk on the phone. After you have reviewed the consent form we will schedule a time to talk by phone. We will go over the consent form together and then you can sign it and send it back to me by secure email or fax.
If you need to send any medical records to us directly you can attach them to this secure email. If you personally have any imaging scans you can upload them directly to our radiology department using this link:
<b>b6</b>

b6	 	 	
DU		 	

Please let me know if you have any questions.
Thank you,
Amanda Wiebold, BSN, RN, CNRN
Research Nurse Specialist
NIH/NINDS/Section of Infections of the Nervous System
10 Center Drive, Building 10/Room 7C107/MSC 1430
Bethesda, Maryland 20892
Office: b6
Cell: b6
Fax: 301-408-5594
Email: b6
From: Nath, Avindra (NIH/NINDS) [E] b6
Sent: Wednesday, April 14, 2021 10:30 PM  To: Safavi, Farinaz (NIH/NINDS) [E]
b6 Wiebold, Amanda (NIH/NINDS) [E]
Subject: Re: Fwd: COVID-19 Vaccine and <b>b6</b>
Yes, we would be interested in b6 We would need to consent him and enroll him to our research study for that purpose. Yes, b6 is an excellent rehab center, however, early rehab is important and am not sure how long a waiting list they have. Since these places require prolonged treatment, it is often best to get the rehab closest to home. If the end there is not much of a difference between most institutions.  Avi
From:  Date: Wednesday, April 14, 2021 at 1:56 PM  To: Nath, Avindra (NIH/NINDS) [E]  b6  Safavi, Farinaz

(NIH/NINDS) [E] b6 Subject: Re: Fwd: COVID-19 Vaccine and b6
Dear Dr Nath,
Thank you for speaking with b6 you agreed with b6 and you recommended b6 Is that correct? In regards to next steps after b6 they plan to move him to rehab. In your experience, is there a difference in potential outcome based on location and expertise of the rehab facility? I heard that b6 is premier for this type of rehabilitation.  I appreciate all of your help and insights.
From: Nath, Avindra (NIH/NINDS) [E] b6  Sent: Monday, April 12, 2021 2:49 PM  To: b6  Subject: Re: Fwd: COVID-19 Vaccine and b6  Thanks. Would it also be possible for b6 to provide that information directly to b6  Also please share my contact information with b6 so that he is not surprised when we contact him.
Avi
From: b6  Date: Monday, April 12, 2021 at 3:43 PM  To: Nath, Avindra (NIH/NINDS) [E] b6  Safavi, Farinaz (NIH/NINDS) [E] b6  Subject: Fw: Fwd: COVID-19 Vaccine and b6
Dear Drs. Nath and Safavi,
has provided the permission (email below) to contact his neurologist b6  66  66  66  66  66  66  66  66  66

Thank you for all of your help!
Best regards,
From: b6
Sent: Monday, April 12, 2021 2:37 PM To: <b>b6</b>
Subject: Re: Fwd: COVID-19 Vaccine and b6
I b6 give permission to b6 to provide and share any medical information pertaining to myself with Dr. Nath. signed b6 Original Message From: b6
From: b6 To: b6
Sent: Mon, 12 Apr 2021 13:57:26 -0400 (EDT)
Subject: Fwd: COVID-19 Vaccine and <b>b6</b>
Get Outlook for iOS b6
h6
NU
From: Nath, Avindra (NIH/NINDS) [E] <b>b6</b>
Sent: Monday, April 12, 2021 12:55:26 PM
Sent: Monday, April 12, 2021 12:55:26 PM  To: Cc:  b6
Sent: Monday, April 12, 2021 12:55:26 PM  To: Cc: b6  Safavi, Farinaz (NIH/NINDS) [E]
Sent: Monday, April 12, 2021 12:55:26 PM  To: Cc:  b6
Sent: Monday, April 12, 2021 12:55:26 PM  To: Cc: b6  Safavi, Farinaz (NIH/NINDS) [E]
Sent: Monday, April 12, 2021 12:55:26 PM  To:
Sent: Monday, April 12, 2021 12:55:26 PM  To:

REL0000231119

Chief, Section of Infections of the Nervous System
Clinical Director,
National Institute of Neurological Disorders and Stroke
National Institutes of Health, Bethesda, MD
b6 (Office) (cell)
b6
From: b6  Date: Monday, April 12, 2021 at 1:45 PM  To: Nath, Avindra (NIH/NINDS) [E] b6  Co: b6
Cc: b6  b6  Subject: COVID-19 Vaccine and b6
Dear Dr. Nath,
Appreciating your interest and expertise in regards to CNS Adverse events and the COVID-19 vaccines, I am writing in regards to b6 In short, he is a b6 male who was otherwise healthy. He received his 2nd dose of the Moderna vaccine on b6 On b6 he developed low back pain and numbness in his legs. On b6 he presented to the Emergency Department of b6 hospital due to inability to walk, pain and numbness in his lower extremities. b6 Yesterday he had b6 b6 He remains hospitalized with bilateral foot drop, inability to walk and inability to urinate. Since this is a very rare adverse event, I thought it best to reach out to you or others at NIH to determine if there are further tests or treatments that are appropriate. Any help or referrals would be greatly appreciated.
Thank you for your help.
b6

Avindra Nath MD

PRINCIPAL INVESTIGATOR: Avindra Nath, MD

STUDY TITLE: Natural History Study of Inflammatory and Infectious Diseases of the

**Nervous System** 

STUDY SITE: NIH Clinical Center

Cohort: Biological Samples Only Consent

Consent Version: 03/17/2020

# WHO DO YOU CONTACT ABOUT THIS STUDY?

Principal Investigator: Avindra Nath, MD,

Study Coordinator: Amanda Wiebold, RN,

b6

This consent form describes a research study and is designed to help you decide if you would like to be a part of the research study.

You are being asked to take part in a research study at the National Institutes of Health (NIH). Members of the study team will talk with you about the information described in this document. Some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). Take the time needed to ask any questions and discuss this study with NIH staff, and with your family, friends, and personal health care providers. Taking part in research at the NIH is your choice.

If the individual being enrolled is a minor then the term "you" refers to "you and/or your child" throughout the remainder of this document.

If the individual being asked to participate in this research study is not able to give consent to be in this study, you are being asked to give permission for this person as their decision-maker. The term "you" refers to you as the decision-maker and/or the individual being asked to participate in this research, throughout the remainder of this document.

## IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

You may choose not to take part in this study for any reason. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. In either case, you will not lose any benefits to which you are otherwise entitled. However, to be seen at the NIH, you must be taking part in a study or are being considered for a study. If you do choose to leave the study, please inform your study team to ensure a safe withdrawal from the research.

# WHY IS THIS STUDY BEING DONE?

The purpose of this study is to learn more about how inflammation and infections hurt the brain and nervous system so we can develop better tests and treatments for them.

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#### BACKGROUND

Inflammation is the way your body reacts to infection or injury. Signs of inflammation can include swelling, pain, redness or heat. Infections and/or inflammation in the brain can cause major health problems. Brain infections can be hard to find sometimes because we do not always have good tests for them. Sometimes inflammation in the brain can happen and doctors do not know what caused it. We would like to learn more about how diseases work and affect the brain, so we can figure out better ways to test for them and treat them. We hope that with better and earlier testing and treatment, we can help people avoid serious health problems and death.

This consent form describes the participation of those who are sending biological samples (such as blood or spinal fluid) collected during care procedures to NIH for analysis.

# STUDY POPULATION

Up to 1000 people will take part in this study.

### PROCEDURES/STUDY OVERVIEW

Your own clinician outside of NIH will collect blood, tissue, and/or other samples from you, such as cerebrospinal fluid (CSF) as part of the care for your condition. These samples will be sent to the NIH. We may ask you to send us additional blood, urine, and/or saliva for research. We will analyze your samples using research tests to try to give you and your own clinicians more information about your illness. Your samples may be processed in new ways that cannot currently be done by your own clinicians.

# Induced Pluripotent Stem Cells (iPS)

We may use your skin or blood cells to create adult stem cells, also called iPS (induced pluripotent stem) cells. Stem cells can be turned into different cell types. Studying different cell types from the iPS cells may help us better understand the conditions we are studying. The iPS cells will not be used for cloning. iPS cells cannot currently be used to grow artificial organs or organisms, but this may change in the future.

## **Genetic Testing**

Your blood may be used for genetic research purposes. The genetic material, DNA, will be taken from the sample. Different types of genetic testing may be done, depending on your condition:

- 1. It may be analyzed to identify the genes that might be causing your condition. This will help us understand how changes in the genes may cause symptoms. Genetic testing can be helpful in establishing a diagnosis. It may eventually lead to improved treatment or prevention.
- 2. To try to identify genetic changes that may be associated with your condition we may sequence the part of the DNA that provides instructions for making proteins, called the "exome." The exome makes up about 1% of your DNA.

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3. We may analyze the DNA and do "whole genome" sequencing. Whole genome sequencing provides information on most of your DNA. Sequencing takes months to complete. It may take even longer for us to analyze the results of the sequencing and to understand which genes might be involved in your condition.

After the genetic sequencing and analysis are complete, you may meet again with the study team and the genetic counselor to discuss the results. Results about known or likely disease-causing gene variations will be given to you as part of genetic counseling.

The genetic testing for this study will not detect all gene changes that are associated with known diseases. However, we will tell you if we find gene changes in your DNA that are known to have major and direct medical significance and are associated with illnesses or conditions that could benefit from early treatment. We call these "reportable gene changes." We suggest you share this information with your own doctors and that you have a clinical laboratory confirm the "reportable gene change" before you take any action on this information.

We will find individual DNA variations in everyone. We will not inform you of all gene variations, as not all of them have health implications. For example, we will not tell you about gene changes that only predispose to a particular disease—like a gene change that influences the risk for heart disease, but where the development of heart disease depends on other factors (such as diet and smoking). We will also not tell you if you are a carrier of a recessive mutation, which means that you have one copy of a recessive mutation and one copy of the normal gene, if being a carrier causes no known health problems for you.

The results from this research study will be preliminary. Further research may be necessary before they are fully understood. We do not plan to provide you with research results. However, if we obtain information that may be important for your health, we will share it with you. By participating in this study, you do not waive any rights that you may have regarding access to and disclosure of your records.

# Banking and Sharing

Your blood, saliva, urine, tissue sample, spinal fluid or blood cells samples and MRI and other clinical data will be stored securely on the NIH campus. Your data and samples may be sent to a repository for storage and may be released for research purposes. Your name and identifying information will not be on the samples and data. A code will be assigned. The key to the code will

be kept at NIH in a separate, secure area.

If you withdraw from this research study before it is complete, you may ask that your remaining samples be destroyed. Results obtained before you withdraw will be kept. Your privacy will be protected as much as possible.

Your blood, saliva, urine, tissue sample, spinal fluid or blood cells samples and MRI and other clinical data may be used for other research projects, including those not related to your current condition. If you do not want your samples and data used for other projects, you should not participate in this study.

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## RISKS, INCONVENIENCES AND DISCOMFORTS

There are minimal risks to you from sharing your samples collected by your outside clinician with us.

# **Genetic Testing**

Genetic testing can provide information about how illness is passed on within a family. This knowledge may affect your emotional wellbeing. You might feel differently about your life if you learned that you or your children were at increased risk of a disease, especially if there were no treatment. Your children, brothers or sisters may find out that they are at risk for health problems because of your genetic information. This might affect your relationships. Other family members may also be affected by uncovering risks they did not want to know about. This information can cause stress, anxiety, or depression.

Some genetic testing shows if people are directly related. Some genetic tests can show that people were adopted or that their biological parent is someone other than their legal parent. If these facts were not known previously, they could be troubling. Genetic counseling is available at NIH to help you understand the implications of your genetic testing.

Because of the emotional risk, some people do not want to know the results of genetic testing. It is our policy to not disclose the results of research genetic testing unless it may have direct medical implications for you or your family.

Results of the research genetic testing in this study are often difficult to interpret because the testing is being done for research purposes only and the laboratories are not clinically certified.

You may be referred to a CLIA certified laboratory, possibly outside of NIH, for additional testing or confirmation of the research results. NIH will not cover the cost of the additional testing. You or your insurer will be responsible for the cost.

The results from this research study will be preliminary. Further research may be necessary before they are fully understood. We do not plan to provide you with research results. However, if we obtain information that may be important for your health, we will share it with you. By participating in this study, you do not waive any rights that you may have regarding access to and disclosure of your records.

Your genetic information will be kept confidential to the extent possible. The results of your genetic testing will be kept in a locked and secured manner at the NIH.

# **Banking and Sharing**

We will remove any information that could identify you from data and samples that are sent to repositories or shared. Data and samples will be sent with a code. This linking code will be kept at NIH. However, there is a very small chance that the data or samples could be identified as yours.

Research using data or samples from this study may lead to new tests, drugs, or devices with commercial value. You will not receive any payment for any product developed from research using your data or samples.

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# ANTICIPATED BENEFITS

There are no expected direct benefits for you in this study. This study will likely increase our general knowledge of how infections and immune conditions affect the brain and will probably help us to diagnose brain infections and immune disorders earlier and manage patients better. The study results may help to develop new treatments in the future.

# RIGHT OF WITHDRAWAL AND CONDITIONS FOR EARLY WITHDRAWAL

You may withdraw from the study at any time and for any reason without loss of benefits or privileges to which you are otherwise entitled. If you withdraw from this research project before it is complete, any remaining samples you have contributed will be discarded. Results obtained before you withdraw will be kept and your privacy will be protected.

# CONFLICT OF INTEREST

The National Institutes of Health reviews NIH staff researchers at least yearly for conflicts of interest. The following link contains details on this process <a href="http://ethics.od.nih.gov/forms/Protocol-Review-Guide.pdf">http://ethics.od.nih.gov/forms/Protocol-Review-Guide.pdf</a>. You may ask your research team for additional information or a copy of the Protocol Review Guide.

# RESULTS FROM THIS STUDY

We will share the results of the tests performed in this study with you. With your written permission, we will discuss and/or send test results and a letter to your doctors.

## ALTERNATIVES TO PARTICIPATION

This study does not provide treatment and you do not have to stop any treatment in order to participate. You may choose not to participate in this study, but to receive diagnostic and treatment care from your own physicians. The alternative is not to participate.

# COMPENSATION, REIMBURSEMENT, AND PAYMENT

# Will you receive compensation for participation in the study?

Some NIH Clinical Center studies offer compensation for participation in research. The amount of compensation, if any, is guided by NIH policies and guidelines.

You will not receive compensation for participation in this study.

# Will you receive reimbursement or direct payment by NIH as part of your participation?

Some NIH Clinical Center studies offer reimbursement or payment for travel, lodging or meals while participating in the research. The amount, if any, is guided by NIH policies and guidelines.

This study does not offer reimbursement for, or payment of, travel, lodging or meals.

# Will taking part in this research study cost you anything?

NIH does not bill health insurance companies or participants for any research or related clinical care that you receive at the NIH Clinical Center.

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## CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

## Will your medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The NIH and other government agencies, like the Food and Drug Administration (FDA), which are involved in keeping research safe for people.
- National Institutes of Health Intramural Institutional Review Board

When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

If we share your specimens or data with other researchers, in most circumstances we will remove your identifiers before sharing your specimens or data. You should be aware that there is a slight possibility that someone could figure out the information is about you.

Further, the information collected for this study is protected by NIH under a Certificate of Confidentiality and the Privacy Act.

# Certificate of Confidentiality

To help us protect your privacy, the NIH Intramural Program has received a Certificate of Confidentiality (Certificate). With this certificate, researchers may not release or use data or information about you except in certain circumstances.

NIH researchers must not share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if requested by a court.

The Certificate does not protect your information when it:

- 1. is disclosed to people connected with the research, for example, information may be used for auditing or program evaluation internally by the NIH; or
- 2. is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA);
- 3. is for other research;
- 4. is disclosed with your consent.

The Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing below you consent to those

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disclosures. Other permissions for release may be made by signing NIH forms, such as the Notice and Acknowledgement of Information Practices consent.

## Privacy Act

The Federal Privacy Act generally protects the confidentiality of your NIH medical records we collect under the authority of the Public Health Service Act. In some cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act allows release of information from your medical record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to those engaged by the agency for research purposes, to certain federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to tumor registries, for quality assessment and medical audits, or when the NIH is involved in a lawsuit. However, NIH will only release information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act.

## POLICY REGARDING RESEARCH-RELATED INJURIES

The NIH Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH, the NIH Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

## PROBLEMS OR QUESTIONS

If you ha	ive any problems	or questions	about this	study, c	or about	your rights	as a r	research
participar	nt, or about any res	search-related	injury, con	tact the P	rincipal I	nvestigator	Avind	ra Nath,
MD,	b6		You ma	y also ca	all the NI	H Clinical	Center	Patient
Represen	tative at 301-496-	2626, or the N	VIH Office	of IRB (	Operation	s at 301-40	2-3713	, if you
have a re	search-related com	plaint or conc	ern.					

## CONSENT DOCUMENT

Please keep a copy of this document in case you want to read it again.

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IRB NUMBER: L5N0125 IRB APPROVAL DATE: 04/09/2020

**Adult Research Participant:** I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to participate in this study. **b6 b6 b6** Print Name of Research Participant Date Legally Authorized Representative (LAR) for an Adult Unable to Consent: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I am legally authorized th make research decisions on behalf of the adult participant unable to consent and have the authority to provide donsent to this study. As applicable, the information in the above consent was described to the adult participant unable to consent who agrees to participate in the study. Print Name of LAR Signature of LAR Date Parent/Guardian of a Minor Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I give permission for my child to take part in this study. Signature of Parent/Guardian Print Name of Parent/Guardian Date Signature of Parent/Guardian (as applicable) Print Name of Parent/Guardian Date Assent: (Use this section only when this process is approved by an IRB for older minors. Do not use if an IRB requires a separate assent form for this population.) I have had this study explained to me in a way that I understand, I have been given the opportunity to discuss , and I have had the chance to ask questions. I agree to take part in this study. Assent of Minor: (as applicable) Print Name of Minor Signature of Minor Date Investigator: Signature of Investigator Print Name of Investigator Date Vitness to the oral short-form consent process only: This section is only required if you are doing the oral hort-consent process and this English consent form has been approved by the IRB for use as the basis of ranslation. PATIENT IDENTIFICATION Consent to Participate in a Clinical Research Study NIH-2977 (4-17) File in Section 4: Protocol Consent (2) Version Date: 3/17/2020 IRB NUMBER: 15N0125 Page 8 of 9

IRB APPROVAL DATE: 04/09/2020

MEDICAL RECORD	CONSENT T	TO PARTICIPATE IN	NICAL RESE	AL RESEARCH STUD		
tness:						
<b>b6</b>		k	06	, ,	<b>b6</b>	
DO		Print Name of W	1	<b>NO</b>		
		_1				

# \*NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER:

An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent <u>and served as a witness</u>. The investigator obtaining consent may not also serve as the witness.

	An interpreter, or other individual, who speaks English and the participant's preferred language facilitated
t	he administration of informed consent but did not serve as a witness. The name or ID code of the person
	roviding interpretive support is:

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IRB NUMBER: 15N0125

IRB APPROVAL DATE: 04/09/2020

From:	Wiebold, Amanda (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP
_	(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4491EE2AE9804610899C741100150540 b6
Sent:	4/29/2021 2:18:11 PM
То:	<b>b6</b>
CC:	
Subject:	RE: COVID-19 Vaccine and b6
Attachments:	b6
Thank you, AmandaOrigina From: Sent: Tuesday To: Wiebold, Cc: Subject: RE:	l Message  b6  y, April 27, 2021 6:32 PM  Amanda (NIH/NINDS) [E]   b6  b6  COVID-19 Vaccine and b6
Origina From: Wiebola To: Sent: Tue, 22	. Will do Amanda. al Message d, Amanda (NIH/NINDS) [E]   b6
Great. So I Then you can	will send a kit and instructions out to you on May 12th. You should receive it May 13th. have your blood drawn sometime in the last two weeks of May.
Let me know	if you have any questions.
Thanks, Amanda	
To: Wiebold,	b6       y, April 27, 2021 6:18 PM       Amanda (NIH/NINDS) [E] b6       COVID-19 Vaccine and b6
	b6
From: Wiebold Sent: Tuesday To:	for iOS <https: aka.ms="" o0ukef=""> d, Amanda (NIH/NINDS) [E]   b6 y, April 27, 2021 5:16:45 PM</https:>
Got it. It	looks perfect. Thank you.
What was the ыб doesn't	date of b6 We need to wait 4-6 weeks to collect blood so that b6 affect our testing.
Thanks,	
Amanda	
From:	b6
Sent: Tuesday To: Wiebold,	y, April 27, 2021 6:12 PM Amanda (NIH/NINDS) [E]   <b>b6</b>
	COVID-19 Vaccine and b6

Amanda
<b>b6</b> asked that I scan and forward the attached consent form.
b6
From: Wiebold, Amanda (NIH/NINDS) [E] b6
Sent: Friday, April 23, 2021 8:19 AM To:
Cc: Subject: RE: COVID-19 Vaccine and b6
<u> </u>
Hello. Would you be available Tuesday, April 27, 2021, at 1:00 PM EST (12:00 Noon CST)?
Thanks,
Amanda
Original Message From:   b6
Sent: Thursday, April 22, 2021 3:19 PM
To: Wiebold, Amanda (NIH/NINDS) [E]
Subject: RE: COVID-19 Vaccine and be
Dear Amanda, thank you for your interest in my medical condition. Except for Monday Apr. 26 10am-1pm  b6 I will be available at anytime for a phone conversation with you. My phone number is b6
b6   Thanks again b6   Original Message
From: Wiebold, Amanda (NIH/NINDS) [E] b6
b6
Sent: Thu, 22 Apr 2021 10:07:02 -0400 (EDT) Subject: RE: COVID-19 Vaccine and b6
b6
I wanted to let you know that I requested records and imaging on Monday. Would it be possible to schedule a telephone call to review the consent? If you give me a few times that work for you next week I can probably make one of the work!
Thanks, Amanda
From: Wiebold, Amanda (NIH/NINDS) [E] Sent: Monday, April 19, 2021 1:03 PM
To: b6 Subject: RE: COVID-19 Vaccine and b6
Thank you. I will track down a fax number.
Thanks, Amanda
From: b6
Sent: Monday, April 19, 2021 12:57 PM To: Wiebold, Amanda (NIH/NINDS) [E]
b6
Cc: Subject: Re: COVID-19 Vaccine and b6
Amanda Please find the executed document. I do not have a FAX # for the hospital or b6 All of his treatment has been at b6  b6
From: Wiebold, Amanda (NIH/NINDS) [E]
b6

Sent: Friday, April 16, 2021 4:18 PM To:   b6
D6
Cc:   b6
Subject: COVID-19 Vaccine and b6
Hello. I work with Dr. Nath and Dr. Safavi at the National Institutes of Health in Bethesda Maryland. I understand b6 is interested in participating in our research study. I will help get him enrolled.
Attached you will find two forms.
A release of medical records. This form gives us permission to request and review medical records. Please have b6 fill out the sections highlighted in yellow and return to me by secure email or fax. If he has not had any tissue collection please write "NA" in that section. Please fill out one form for each facility.
The protocol consent form. Please only review this form at this time and write down any questions you have. Do not sign until we talk on the phone. After you have reviewed the consent form we will schedule a time to talk by phone. We will go over the consent form together and then you can sign it and send it back to me by secure email or fax.
If you need to send any medical records to us directly you can attach them to this secure email. If you personally have any imaging scans you can upload them directly to our radiology department using this link:
<b>b6</b>
Please let me know if you have any questions.
Thank you,
Amanda Wiebold, BSN, RN, CNRN
Research Nurse Specialist

NIH/NINDS/Section of Infections of the Nervous System

10 Center Drive, Building 10/Room 7C107/MSC 1430

Bethesda, Maryland 20892

Office: b6

Cell: b6

Fax: 301-408-5594

REL0000231120

Email:
<b>b6</b>
From: Nath, Avindra (NIH/NINDS) [E]
b6 Sent: Wednesday, April 14, 2021 10:30 PM
To:   b6
[ b6   Safavi, Farinaz (NIH/NINDS) [E]
b6 b6 Wiebold, Amanda (NIH/NINDS) [E]
b6
Subject: Re: Fwd: COVID-19 Vaccine and b6
Yes, we would be interested in b6 We would need to consent him and enroll him to our research study for that purpose. Yes, b6 is an excellent rehab center, however, early rehab is important and am not sure how long a waiting list they have. Since these places require prolonged treatment, it is often best to get the rehab closest to home. In the end there is not much of a difference between most institutions.
Avi
From: 66
b6
Date: Wednesday, April 14, 2021 at 1:56 PM To: Nath, Avindra (NIH/NINDS) [E]
b6   Safavi, Farinaz (NIH/NINDS) [E]
b6
Subject: Re: Fwd: COVID-19 Vaccine and <b>b6</b>
Dear Dr Nath,
Thank you for speaking with b6 you agreed with b6 and you recommended b6 Is that correct? In regards to next steps after b6 they plan to move him to rehab. In your experience, is there a difference in potential outcome based on location and expertise of the rehab facility? I heard that b6 is premier for this type of rehabilitation.
I appreciate all of your help and insights.
b6
From: Nath, Avindra (NIH/NINDS) [E] <b>b6</b>
To: b6
[
<b>b6</b>
Subject: Re: Fwd: COVID-19 Vaccine and b6
Thanks. Would it also be possible for b6 to provide that information directly to b6 Also please share my contact information with b6 so that he is not surprised when we contact him.

Avi

From:   b6
Date: Monday, April 12, 2021 at 3:43 PM To: Nath, Avindra (NIH/NINDS) [E]
b6   Safavi, Farinaz (NIH/NINDS) [E]
b6
Subject: Fw: Fwd: COVID-19 Vaccine and <b>b6</b>
Dear Drs. Nath and Safavi,
b6 has provided the permission (email below) to contact his neurologist at b6
<b>b6</b>
Thank you for all of your help!
Best regards,
From: b6 b6
Sent: Monday, April 12, 2021 2:37 PM To:   b6
b6
Subject: Re: Fwd: COVID-19 Vaccine and be
I b6 give permission to b6 to provide and share any medical information pertaining to myself with Dr. Nath. signed b6 Original Message
From: b6 b6
To:
Sent: Mon, 12 Apr 2021 13:57:26 -0400 (EDT) Subject: Fwd: COVID-19 Vaccine and <b>b6</b>
Get Outlook for
Get Outlook for iOS  b6
<b>b6</b>

From: Nath, Avindra (NIH/NINDS) [E]
<b>b6</b> Sent: Monday, April 12, 2021 12:55:26 PM
To: b6   b6   b6
CC:
<b>b</b> 6
b6   Safavi, Farinaz (NIH/NINDS) [E]   b6   b6   b6   b6   b6   b6   b6   b
Subject: Re: COVID-19 Vaccine and b6
Dear <b>b6</b>
Terribly sorry to hear of b6 illness. With b6 permission, we would be interested in talking to the neurologists taking care of him to see if there is anything we can do to help. I have copied Dr. Safavi who is a neurologist working with me and interested in these issues.
Avi
Avindra Nath MD
Chief, Section of Infections of the Nervous System
Clinical Director,
National Institute of Neurological Disorders and Stroke
National Institutes of Health, Bethesda, MD
h6 (office)
(cell)
b6
From: b6   b6
Date: Monday, April 12, 2021 at 1:45 PM To: Nath, Avindra (NIH/NINDS) [E]
Date: Monday, April 12, 2021 at 1:45 PM
Date: Monday, April 12, 2021 at 1:45 PM To: Nath, Avindra (NIH/NINDS) [E]  b6  CC:
Date: Monday, April 12, 2021 at 1:45 PM To: Nath, Avindra (NIH/NINDS) [E]
Date: Monday, April 12, 2021 at 1:45 PM To: Nath, Avindra (NIH/NINDS) [E]  b6  CC:
Date: Monday, April 12, 2021 at 1:45 PM To: Nath, Avindra (NIH/NINDS) [E]  b6  Cc:  b6  Cc:
Date: Monday, April 12, 2021 at 1:45 PM To: Nath, Avindra (NIH/NINDS) [E]  b6  CC:  b6  Subject: COVID-19 Vaccine and b6
Date: Monday, April 12, 2021 at 1:45 PM  To: Nath, Avindra (NIH/NINDS) [E]    b6

PRINCIPAL INVESTIGATOR: Avindra Nath, MD

STUDY TITLE: Natural History Study of Inflammatory and Infectious Diseases of the

Nervous System

STUDY SITE: NIH Clinical Center

Cohort: Biological Samples Only Consent

Consent Version: 03/17/2020

## WHO DO YOU CONTACT ABOUT THIS STUDY?

Principal Investigator: Avindra Nath, MD,

Study Coordinator: Amanda Wiebold, RN,

b6

This consent form describes a research study and is designed to help you decide if you would like to be a part of the research study.

You are being asked to take part in a research study at the National Institutes of Health (NIH). Members of the study team will talk with you about the information described in this document. Some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). Take the time needed to ask any questions and discuss this study with NIH staff, and with your family, friends, and personal health care providers. Taking part in research at the NIH is your choice.

If the individual being enrolled is a minor then the term "you" refers to "you and/or your child" throughout the remainder of this document.

If the individual being asked to participate in this research study is not able to give consent to be in this study, you are being asked to give permission for this person as their decision-maker. The term "you" refers to you as the decision-maker and/or the individual being asked to participate in this research, throughout the remainder of this document.

## IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

You may choose not to take part in this study for any reason. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. In either case, you will not lose any benefits to which you are otherwise entitled. However, to be seen at the NIH, you must be taking part in a study or are being considered for a study. If you do choose to leave the study, please inform your study team to ensure a safe withdrawal from the research.

## WHY IS THIS STUDY BEING DONE?

The purpose of this study is to learn more about how inflammation and infections hurt the brain and nervous system so we can develop better tests and treatments for them.

## PATIENT IDENTIFICATION

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Consent to Participate in a Clinical Research Study

NIH-2977 (4-17)

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## BACKGROUND

Inflammation is the way your body reacts to infection or injury. Signs of inflammation can include swelling, pain, redness or heat. Infections and/or inflammation in the brain can cause major health problems. Brain infections can be hard to find sometimes because we do not always have good tests for them. Sometimes inflammation in the brain can happen and doctors do not know what caused it. We would like to learn more about how diseases work and affect the brain, so we can figure out better ways to test for them and treat them. We hope that with better and earlier testing and treatment, we can help people avoid serious health problems and death.

This consent form describes the participation of those who are sending biological samples (such as blood or spinal fluid) collected during care procedures to NIH for analysis.

#### STUDY POPULATION

Up to 1000 people will take part in this study.

#### PROCEDURES/STUDY OVERVIEW

Your own clinician outside of NIH will collect blood, tissue, and/or other samples from you, such as cerebrospinal fluid (CSF) as part of the care for your condition. These samples will be sent to the NIH. We may ask you to send us additional blood, urine, and/or saliva for research. We will analyze your samples using research tests to try to give you and your own clinicians more information about your illness. Your samples may be processed in new ways that cannot currently be done by your own clinicians.

## Induced Pluripotent Stem Cells (iPS)

We may use your skin or blood cells to create adult stem cells, also called iPS (induced pluripotent stem) cells. Stem cells can be turned into different cell types. Studying different cell types from the iPS cells may help us better understand the conditions we are studying. The iPS cells will not be used for cloning. iPS cells cannot currently be used to grow artificial organs or organisms, but this may change in the future.

## Genetic Testing

Your blood may be used for genetic research purposes. The genetic material, DNA, will be taken from the sample. Different types of genetic testing may be done, depending on your condition:

- It may be analyzed to identify the genes that might be causing your condition. This will
  help us understand how changes in the genes may cause symptoms. Genetic testing can
  be helpful in establishing a diagnosis. It may eventually lead to improved treatment or
  prevention.
- 2. To try to identify genetic changes that may be associated with your condition we may sequence the part of the DNA that provides instructions for making proteins, called the "exome." The exome makes up about 1% of your DNA.

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3. We may analyze the DNA and do "whole genome" sequencing. Whole genome sequencing provides information on most of your DNA. Sequencing takes months to complete. It may take even longer for us to analyze the results of the sequencing and to understand which genes might be involved in your condition.

After the genetic sequencing and analysis are complete, you may meet again with the study team and the genetic counselor to discuss the results. Results about known or likely disease-causing gene variations will be given to you as part of genetic counseling.

The genetic testing for this study will not detect all gene changes that are associated with known diseases. However, we will tell you if we find gene changes in your DNA that are known to have major and direct medical significance and are associated with illnesses or conditions that could benefit from early treatment. We call these "reportable gene changes." We suggest you share this information with your own doctors and that you have a clinical laboratory confirm the "reportable gene change" before you take any action on this information.

We will find individual DNA variations in everyone. We will not inform you of all gene variations, as not all of them have health implications. For example, we will not tell you about gene changes that only predispose to a particular disease—like a gene change that influences the risk for heart disease, but where the development of heart disease depends on other factors (such as diet and smoking). We will also not tell you if you are a carrier of a recessive mutation, which means that you have one copy of a recessive mutation and one copy of the normal gene, if being a carrier causes no known health problems for you.

The results from this research study will be preliminary. Further research may be necessary before they are fully understood. We do not plan to provide you with research results. However, if we obtain information that may be important for your health, we will share it with you. By participating in this study, you do not waive any rights that you may have regarding access to and

## Banking and Sharing

disclosure of your records.

Your blood, saliva, urine, tissue sample, spinal fluid or blood cells samples and MRI and other clinical data will be stored securely on the NIH campus. Your data and samples may be sent to a repository for storage and may be released for research purposes. Your name and identifying information will not be on the samples and data. A code will be assigned. The key to the code will

be kept at NIH in a separate, secure area.

If you withdraw from this research study before it is complete, you may ask that your remaining samples be destroyed. Results obtained before you withdraw will be kept. Your privacy will be protected as much as possible.

Your blood, saliva, urine, tissue sample, spinal fluid or blood cells samples and MRI and other clinical data may be used for other research projects, including those not related to your current condition. If you do not want your samples and data used for other projects, you should not participate in this study.

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## RISKS, INCONVENIENCES AND DISCOMFORTS

There are minimal risks to you from sharing your samples collected by your outside clinician with us.

## Genetic Testing

Genetic testing can provide information about how illness is passed on within a family. This knowledge may affect your emotional wellbeing. You might feel differently about your life if you learned that you or your children were at increased risk of a disease, especially if there were no treatment. Your children, brothers or sisters may find out that they are at risk for health problems because of your genetic information. This might affect your relationships. Other family members may also be affected by uncovering risks they did not want to know about. This information can cause stress, anxiety, or depression.

Some genetic testing shows if people are directly related. Some genetic tests can show that people were adopted or that their biological parent is someone other than their legal parent. If these facts were not known previously, they could be troubling. Genetic counseling is available at NIH to help you understand the implications of your genetic testing.

Because of the emotional risk, some people do not want to know the results of genetic testing. It is our policy to not disclose the results of research genetic testing unless it may have direct medical implications for you or your family.

Results of the research genetic testing in this study are often difficult to interpret because the testing is being done for research purposes only and the laboratories are not clinically certified.

You may be referred to a CLIA certified laboratory, possibly outside of NIH, for additional testing or confirmation of the research results. NIH will not cover the cost of the additional testing. You or your insurer will be responsible for the cost.

The results from this research study will be preliminary. Further research may be necessary before they are fully understood. We do not plan to provide you with research results. However, if we obtain information that may be important for your health, we will share it with you. By participating in this study, you do not waive any rights that you may have regarding access to and disclosure of your records.

Your genetic information will be kept confidential to the extent possible. The results of your genetic testing will be kept in a locked and secured manner at the NIH.

## Banking and Sharing

We will remove any information that could identify you from data and samples that are sent to repositories or shared. Data and samples will be sent with a code. This linking code will be kept at NIH. However, there is a very small chance that the data or samples could be identified as yours.

Research using data or samples from this study may lead to new tests, drugs, or devices with commercial value. You will not receive any payment for any product developed from research using your data or samples.

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h6

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IRB MCMBER: ESCOLUS
IRB APPROVIC DATE: 04-09/2020

## ANTICIPATED BENEFITS

There are no expected direct benefits for you in this study. This study will likely increase our general knowledge of how infections and immune conditions affect the brain and will probably help us to diagnose brain infections and immune disorders earlier and manage patients better. The study results may help to develop new treatments in the future.

#### RIGHT OF WITHDRAWAL AND CONDITIONS FOR EARLY WITHDRAWAL

You may withdraw from the study at any time and for any reason without loss of benefits or privileges to which you are otherwise entitled. If you withdraw from this research project before it is complete, any remaining samples you have contributed will be discarded. Results obtained before you withdraw will be kept and your privacy will be protected.

## CONFLICT OF INTEREST

The National Institutes of Health reviews NIH staff researchers at least yearly for conflicts of interest. The following link contains details on this process <a href="http://ethics.od.nih.gov/forms/Protocol-Review-Guide.pdf">http://ethics.od.nih.gov/forms/Protocol-Review-Guide.pdf</a>. You may ask your research team for additional information or a copy of the Protocol Review Guide.

## RESULTS FROM THIS STUDY

We will share the results of the tests performed in this study with you. With your written permission, we will discuss and/or send test results and a letter to your doctors.

#### ALTERNATIVES TO PARTICIPATION

This study does not provide treatment and you do not have to stop any treatment in order to participate. You may choose not to participate in this study, but to receive diagnostic and treatment care from your own physicians. The alternative is not to participate.

## COMPENSATION, REIMBURSEMENT, AND PAYMENT

## Will you receive compensation for participation in the study?

Some NIH Clinical Center studies offer compensation for participation in research. The amount of compensation, if any, is guided by NIH policies and guidelines.

You will not receive compensation for participation in this study.

## Will you receive reimbursement or direct payment by NIH as part of your participation?

Some NIH Clinical Center studies offer reimbursement or payment for travel, lodging or meals while participating in the research. The amount, if any, is guided by NIH policies and guidelines.

This study does not offer reimbursement for, or payment of, travel, lodging or meals.

## Will taking part in this research study cost you anything?

NIH does not bill health insurance companies or participants for any research or related clinical care that you receive at the NIH Clinical Center.

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## CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

## Will your medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The NIH and other government agencies, like the Food and Drug Administration (FDA), which are involved in keeping research safe for people.
- National Institutes of Health Intramural Institutional Review Board

When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

If we share your specimens or data with other researchers, in most circumstances we will remove your identifiers before sharing your specimens or data. You should be aware that there is a slight possibility that someone could figure out the information is about you.

Further, the information collected for this study is protected by NIH under a Certificate of Confidentiality and the Privacy Act.

## Certificate of Confidentiality

To help us protect your privacy, the NIH Intramural Program has received a Certificate of Confidentiality (Certificate). With this certificate, researchers may not release or use data or information about you except in certain circumstances.

NIH researchers must not share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if requested by a court.

The Certificate does not protect your information when it:

- 1. is disclosed to people connected with the research, for example, information may be used for auditing or program evaluation internally by the NIH; or
- is required to be disclosed by Federal, State, or local laws, for example, when information
  must be disclosed to meet the legal requirements of the federal Food and Drug
  Administration (FDA);
- 3. is for other research;
- is disclosed with your consent.

The Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing below you consent to those

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disclosures. Other permissions for release may be made by signing NIH forms, such as the Notice and Acknowledgement of Information Practices consent.

## Privacy Act

The Federal Privacy Act generally protects the confidentiality of your NIH medical records we collect under the authority of the Public Health Service Act. In some cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act allows release of information from your medical record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to those engaged by the agency for research purposes, to certain federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to tumor registries, for quality assessment and medical audits, or when the NIH is involved in a lawsuit. However, NIH will only release information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act.

## POLICY REGARDING RESEARCH-RELATED INJURIES

The NIH Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH, the NIH Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

## PROBLEMS OR QUESTIONS

If you have any	problems or o	questions	about	this	study,	or	about	your	rights	as a	research
participant, or abo	ut any researc	h-related	injury,	cont	act the	Pri	ncipal	Invest	tigator	Avin	dra Nath,
MD,	b6		You	ı ma	y also	call	the N	IH C	inical	Cent	er Patient
Representative at	301-496-2626	, or the N	IIH Of	fice	of IRB	Op	eration	ns at 3	301-40	2-37	13, if you
Representative at 301-496-2626, or the NIH Office of IRB Operations at 301-402-3713, if you have a research-related complaint or concern.											

## CONSENT DOCUMENT

Please keep a copy of this document in case you want to read it again.

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b6

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MEDICAL RECORD

CONSENT TO PARTICIPATE IN AN NIH CLINICAL RESEARCH STUDY

Adult Research Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to participate in this study. **b**6 **b6** Print Name of Research Participant Date Legally Authorized Representative (LAR) for an Adult Unable to Consent: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I am legally authorized to make research decisions on behalf of the adult participant unable to consent and have the authority to provide consent to this study. As applicable, the information in the above consent was described to the adult participant unable to consent who agrees to participate in the study. Signature of LAR Print Name of LAR Date Parent/Guardian of a Minor Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I give permission for my child to take part in this study. Signature of Parent/Guardian Print Name of Parent/Guardian Date Signature of Parent/Guardian (as applicable) Print Name of Parent/Guardian Date Assent: (Use this section only when this process is approved by an IRB for older minors. Do not use if an IRB requires a separate assent form for this population.) Il have had this study explained to me in a way that I understand, I have been given the opportunity to discuss it, and I have had the chance to ask questions. I agree to take part in this study. Assent of Minor: (as applicable) Signature of Minor Print Name of Minor Date signature of Investigator Print Name of Investigator Witness to the oral short-form consent process only: This section is only required if you are doing the oral hort-consent process and this English consent form has been approved by the IRB for use as the basis of translation. PATIENT IDENTIFICATION Consent to Participate in a Clinical Research Study NIH-2977 (4-17) File in Section 4: Protocol Consent (2) Version Date: 3/17/2020 IRB NEMBER: 15M0125 Page 8 of 9 IRB APPROVAL DATE: 04/09/2020

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18.78	84 8 20 8	8 1	. 8	22	84	8 28 28	2.0	8 8

CONSENT TO PARTICIPATE IN AN NIH CLINICAL RESEARCH STUDY

Witness:

**b6** 

**b6** 

Print Name of Witness

**b6** 

# NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER:

An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent and served as a witness. The investigator obtaining consent may not also serve as the witness.

	An interpreter, or other individual, who speaks English and the participant's preferred language facilitate	ted
t	ne administration of informed consent but did not serve as a witness. The name or ID code of the person	
r	roviding interpretive support is:	

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**b6** 

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IRB NUMBER-15NGCS

IRB APEROVAL DATE: 04/09/2020

From: b6

**Sent**: 4/29/2021 1:52:26 PM

To: Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 b6

Subject: Re: Medical Records

These?

#### MEDICAL RECORD General Admission Consent CONDITIONS GOVERNING ADMISSION. The primary purpose of the NIH Clinical Center is the conduct of teginedical research concerning has the and disease. You will be evaluated, as an inpution or outpatient, for consideration as a participant under a character concerning the state of protocol. Your admission may be for general screening, diagnosic procedures, or specific treatment. You may be asked to undergo a number of fests to evaluate your suitability for a study. All of these activities are done for research our occasions. Before you are smalled on a specific protocol, or undergo any experimental tests or treatments, you will be asked to read and sign a separate informed consent document. The study and the status of your health determine the duration of your realment at the full Clinical segarate months of the seen as an inpatient or outsalient. You are not obligated to stay and may leave at any time, if you have Center and whether you may really shall be seen and the street of medical treatment (such as blood transfusions) that you would agree to receive (or would want your child to renerve), these insues should be discussed in detail with your Nith physicians. Adults may choose to record restrictions on their own medical care in a separate advance directive document. If you have any questions about preparation of an apvance directive nocument, contact a member of your health care team. If you have healthcare insurance, that information will be: or an appendix maintained in your modical record so that, in the unlikely event that you must be transferred emergently to an outside. nealthouse institution, the Clinical Centur can make arrangements with the outside healthouse institution, the ambusines transport company, and your insurance company, as needed. you may be enrolled in more than one study. While you are enrolled in any study, the Nills will provide study related care at the Nill. Charact Center, including the evaluation of any complications that may be study-related. Your admission to the Niel Clinical Center does not mean that you are automatically eligible for long-term care at the NIH. When your NIH physicians determine that your participation in clinical research at the NIH has been completed, you will be so nothled and returned to the care of your primary physician. Your NIH physicians will provide your primary physician with a complete written summary of your gare at the NiH, and will do their best to provide additional information, if necessary Medical records are maintained at the NIH Clinical Center in accordance with the Privacy Act of 1974 and the Public Health Service Act. as amended. Much of the medical information obtained about you will be stored in a computer system. The information is used partly for the same purposes as a typical medical record, that is, for your personal benefit, it is also used for research by NiH scientists, some of whom may have no personal contact with you. Much of the information will eventually be used in publications, but your identity will not be revealed. In addition, contain diseases or conditions, including infectious diseases, may be reported to appropriate representatives of the State of Federal Government as required by law. For further explanation regarding information practices at the NIH Clinical Center. prease refer to NIH-2753 (Notice and Acknowledgment of Information Practices') and the "Potients' Rights, informed Consent. Confedentiality "Patient Handbook Conical Center CONSENT TO ADMISSION. consent to admission to the NiH Clinical Cemer and understand that, prior to entering the research protocol(s) selected for me, I will be provided with additional information and my consonl will be sought for participation in each study further consent to such routine hospital care, diagnostic procedures, and modicul healment which the medical and professional staff of the AGH Contract Center may down necessary Contraction - I further consent to the preservation of any specimens taken for taboratory or pathology examination for the purpose of medical research and/or education, or to the disposal of such specimens in a manner determined appropriate by the staff Nurther consent to the use of medical information obtained about me as specified above and in NiH 2753 (Notice and Acknowledgment of information insulties ( # Supy 0 ) Further consent to NiH staff (as appropriate) making photographic makes or other recordings that document my condition/realment in order to provide, coordinate, or manage my care. These images will be maintained as NIH records until destroyed. This form has been fully explained to me and Cunderstand its Coments. Truther understand that no guarantees have been made to me as to the results of requireuts or examinations done of the NiH Clinical Center 4470000 **b6** 0200 Relationship to minor Relationship to minor per se decord l'aventit egal Guardian (l'equired) Date 04/20/2021 **b6** Date These interpreted to the best of my ability all items on the General Admission Consent (NIH 1225-1). These also asked and translate are questions and answers asset of me by the NIH Staff and research participant to the best of my ability.

Care

**b6** 

	MEDICAL RECORD  Clinical Center (CC), strive in provide priv	sov for all our nationts and in	eledgment of Information Practices maintain the confidentality of the sensitive
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	rance and use of patient information in the	dice records or other cate on e President of the record of thing requisions, employees	rage systems at the CC is governed by laws and applicable provisions of the Public Health of the Nint and the Department of Health and
	sent care activities, the CC may need to re		of record information outside of NIH and HHS.
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information regard with consultants		scientific value, or in order to a	accomplish research purposes may be shared
activities			nizations conducting established accreditation.  Nuenza, HIV or suspected abuse and neglect.
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Communication with Outside Healthcare Providers	ters to receive regular ongoing medical updates about the Contact information for these ourside health care providens					Peditor of the second	Section Control	Portal Called Follow Shiftween Daileria Sorreston Managur Israil information from								
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	As spekely in the first of the	I authorize the NHI Climical Center to provide my designated outside heathcare providers ongoing modical updates about the care in receive at the NHI Climical Center.  I do not wish to designate outside heathcare providers to receive oursides outside.	88	Fleese <u>20, not</u> sultimeficially send to be sent to my provided nome address.	b6	Signature of ParentiLegal Guardian	Signature of Second Pareot/Legal Guarden of required)	Electronic Communication & NIH Clinical Center Patient Portal  The NIH Clinical Center is offent; a secure, internet-increasible communication system and patient parial called FollowMyteath?  provided by Allacipia L.C.* This secure electronic communication system enables communications between patients, their NIH hearn strent providers and/or other authoritical NIH still (for example). Substants, Admissions, or Hearth Information Managuisment Department staff). The FollowMyteritify patient point also enables patients in consciously Admissions or Hearth Information Managuisment Department Critical Center electronic medical record for enables patients in consciously regions related medical information from those NiH-	Authorize the use of secure electronic communications and the shaing of printing of your medical record in identifiable form with Allscripts LLC® to populate your followint/health portal accounts and	Acknowledge that you will be able to access selected motion information from your NiH Clinical Center electronic medical record induces the Followskythscittle painent protoi	Lagree to the use of stource electronic communications and the sharing of portions of my modical record in identifiable form with Alliebraich. L.C. for the guippose of popularing my Pollonskyr-earth focus in an understand that had be able to posthered through Entered the purpose of popularing my Pollonskyr-earth forms and understand that had be able to posthered through Entered the email and resolved to which electronic popularing communications can be directed. (Specify only the email additions that you requirely says and monthly).		b6		b	6
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	wrote:	s one									OS) [E]			b6		

Here is my consent form with signature - I also have my consent form for all my scans which I have been calling b6 to see next steps with.

<image0.jpeg>

On Apr 29, 2021, at 9:32 AM, Safavi, Farinaz (NIH/NINDS) [E]
On Apr 29, 2021, at 9:32 AM, Safavi, Farinaz (NIH/NINDS) [E]  b6 wrote:
Hi <u>b6</u> Can you please send me a pic from signature page of your consent form? Thank you
Farinaz
From: b6
Sent: Friday, April 23, 2021 6:25:28 AM  To: Safavi, Farinaz (NIH/NINDS) [E] b6  Cc: Wiebold, Amanda (NIH/NINDS) [E] b6
Cc: Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: Re: Medical Records
It won't be a problem, I will get them and send as soon as I have them! I'll be in touch as soon as I have them.
Thanks!
Thanks.
On Apr 23, 2021, at 5:45 AM, Safavi, Farinaz (NIH/NINDS) [E]  b6 wrote:
<b>b6</b> wrote:
Thank you very much b6
If getting the CDs alone are easier and cheaper without medical
records, you can request just CDs and we request records from
<b>b6</b> directly.I will leave the decision to you.
Best
Farinaz
Farinaz
From: b6
From:
To: Safavi, Farinaz (NIH/NINDS) [E] b6 Wiebold,
Amanda (NIH/NINDS) [E] b6
Subject: Medical Records
Hi Dr. Safavi and Amanda,
I just wanted to let you both know, I am trying to obtain my
medical records to send forward. It sounds like in order to get the
discs b6

**b6** I will need to go to both locations (or wait for them to be delivered to my home) and at each pay a \$25 fee. I am going to fill out all of my forms today and submit them - and as soon as I have them, I will be sure to touch base with where to forward them to.

Thanks,

b6

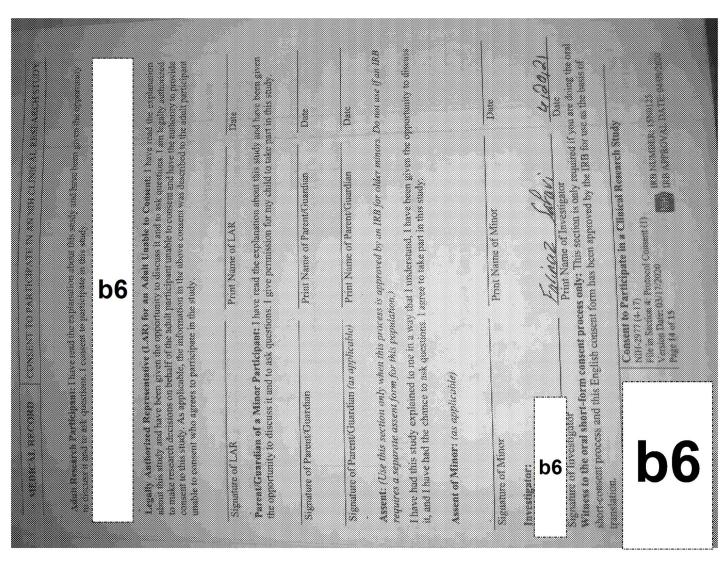
From: b6 Sent: 4/29/2021 1:55:00 PM

To: Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246

Subject: Re: Medical Records

I think you may need this one too!



Sent from my iPhone

On Apr 29, 2021, at 9:53 AM, Safavi, Farinaz (NIH/NINDS) [E]	b6
wrote:	
yes,Thank you!	
Farinaz	

From:	b6
Sent: T	hursday, April 29, 2021 9:52:26 AM
To: Saf	hursday, April 29, 2021 9:52:26 AM avi, Farinaz (NIH/NINDS) [E] <b>b6</b>
Subjec	t: Re: Medical Records
These	?
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Sent fi	rom my iPhone
	On Apr 29, 2021, at 9:43 AM, Safavi, Farinaz (NIH/NINDS) [E]  b6 wrote:
	b6
	not this one the one I gave you when you were here.
	Tarinas
	Farinaz
	From: b6
	Sent: Thursday, April 29, 2021 9:40:30 AM  To: Safavi, Farinaz (NIH/NINDS) [E] b6
	Subject: Re: Medical Records
	Subject: No. Medical Necords
	Here is my consent form with signature - I also have my consent form for all my
	Here is my consent form with signature - I also have my consent form for all my scans which I have been calling b6 to see next steps with.
	jes see new steps with
	<image0.jpeg></image0.jpeg>
	200 Jf 20
	Sent from my iPhone
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	Hi <b>b6</b>
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	consent form?
	Thank you
	Farinaz
	From: b6
	<b>Sent:</b> Friday, April 23, 2021 6:25:28 AM

To: Safavi, Farinaz (NIH/NINDS) [E] b6  Cc: Wiebold, Amanda (NIH/NINDS) [E] b6  Subject: Re: Medical Records
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Farinaz
From: b6 Sent: Thursday, April 22, 2021 10:54:13 AM To: Safavi, Farinaz (NIH/NINDS) [E] b6 Wiebold, Amanda
(NIH/NINDS) [E] b6 Subject: Medical Records
Hi Dr. Safavi and Amanda,
I just wanted to let you both know, I am trying to obtain my medical records to send forward. It sounds like in order to get the discs of <b>b6</b> I will need to go to both leastings (or weit for them to
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Thanks, <b>b6</b>

***************************************	
From: Sent:	<b>b6</b> 7/14/2021 2:46:38 PM
To:	Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 <b>b6</b>
Subject:	Re: My history of events.
Attachments:	b6
Sent from m	y iPhone
į	<b>b6</b>
<u> </u>	
On Jul 14 2	021, at 9:44 AM, <b>b6</b> wrote:
On Jul 14, 2	021, at 9:44 AM, wrote:
Hi Lam sen	ding 2 emails for you to review to get some idea.
	16
Sent from m	y iPhone
İ	h6
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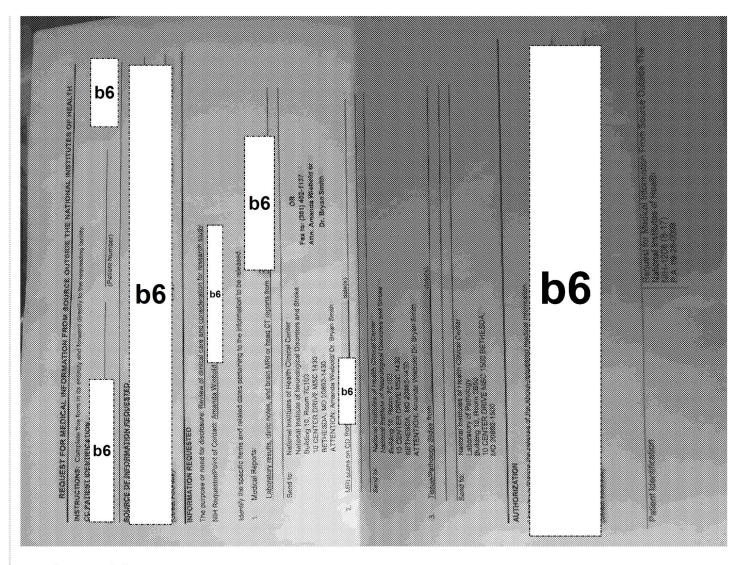




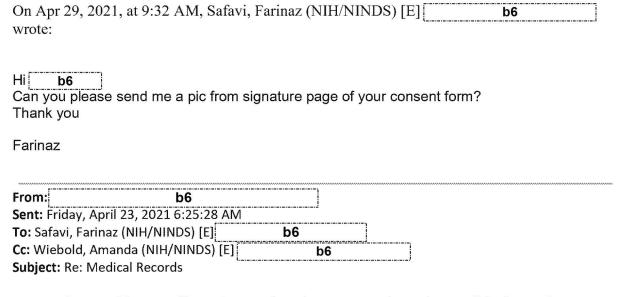




From:	<b>b6</b> 4/29/2021 1:53:37 PM					
Sent: To:	Safavi, Farinaz (NIH/NINDS)	[E] [/o=Evch	angol ahs/ou=Evshango	Administrativo	Group	
10.	(FYDIBOHF23SPDLT)/cn=Re				,	
Subject:	Re: Medical Records	cipients/cri-:	54607Ce146e04304b616.	33Ua20aUC240	b6	
Sorry, I kno	w which one you need.	aking a pi	c of it now.			
b6	or 29, 2021 at 9:43 AM S e the one I gave you whe			][	b6	wrote:
Farinaz						
From:	b6					
	day, April 29, 2021 9:40:30					
To: Safavi, F	arinaz (NIH/NINDS) [E]	b6				
Subject: Re	: Medical Records					
	consent form with signa		o have my consent fo	orm for all m	y scans w	hich I have been



Sent from my iPhone



It won't be a problem, I will get them and send as soon as I have them! I'll be in touch as soon as I have them.

On Apr 23, 2021, at 5:45	5 AM, Safavi, Far	inaz (NIH/N	INDS) [E]
b6	wrote:		
Thank you very much If getting the CDs alone can request just CDs an leave the decision to you Best Farinaz	are easier and ch d we request reco	neaper witho ords from	ut medical records ,you  b6 directly.I will
Farinaz			
From:	<b>b6</b>		
Sent: Thursday, April 22, 2		i	
To: Safavi, Farinaz (NIH/NI	NDC) [F] [	b6	Wiebold, Amanda
(NIH/NINDS) [E]	h6	7	Wiebold, Allialida
Subject: Medical Records	b6	ز.	
Justice: Medical Necords			
Hi Dr. Safavi and Aman	da,		
I just wanted to let you b	ooth know, I am tr	ying to obta	in my medical records to
send forward. It sounds l			
b6			both locations (or wait
for them to be delivered	to my home) and	at each pay	a \$25 fee. I am going to
fill out all of my forms to	oday and submit t	them - and as	s soon as I have them, I
will be sure to touch base	e with where to fo	orward them	to.
Thanks,			

From:	b6	
Sent:	7/14/2021 3:07:58 PM	
То:	Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group	
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 <b>b6</b>	
Subject:	Fwd: vasculitis events	
Attachments:	b6	
Hi		
Here is even	its and some pictures as background	
Sent from m	y iPhone	
	<b>b6</b>	
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D : C		
Begin forwa	arded message:	
From:	b6	
	3, 2021 at 12:42:16 AM CDT	
To:	<b>b6</b>	
Subject: vas	sculitis to be printed color	
· ·		
	<b>b</b> 6	
<u> </u>		













From: Sent: To: Subject:	b6 9/21/2021 7:37:12 PM Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/c (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca0519 Re: Paralyzed after J &J Covid Vaccine		Company and the Company and th
Dear Dr. Na	ath,		
Thank you.	I will be reaching to your research team.		
Kind regard	·		
On Tue, Sep	p 21, 2021 at 12:54 PM Nath, Avindra (NIH/	NINDS) [E]	<b>b6</b> wrote:
Dear <b>b</b>	<b>56</b>		
	ied our research team. They can guide you or us to gather information on these conditions.	how to provide us info	ormation on your illness. This
Thanks for	your help.		
Avi			
To: Nath, A Subject: R	b6 sday, September 21, 2021 at 12:06 AM Avindra (NIH/NINDS) [E] b6 Re: Paralyzed after J &J Covid Vaccine  7the article link is from the LA timesnot the	b6 e New York Times.	
On Mon, S	Sep 20, 2021, 9:51 PM <b>k</b>	16	wrote:
Dear Dr. N	Nath,		
who exper	o disrespect when I share with you the New Y crienced very similar adverse reactions, as I, to uring the trials.		
Sir, I am n	not the gentleman you were very concerned a	bout in the article, so the	nat would make me case #2.
I, too, am	very concerned. Concerned about me and the	e possibility of more lik	te me.

https://www.latimes.com/science/story/2020-09-15/nih-concerned-side-effect-in-astrazeneca-coronavirus-vaccine-trial
Kind regards,
b6
On Mon, Sep 20, 2021, 8:04 PM Nath, Avindra (NIH/NINDS) [E] <b>b6</b> wrote:
Dear <b>b6</b>
Sorry. I agree that a blood clot as a cause of your paralysis would make the most sense, however, proving cause and effect related to the vaccine in a single patient is virtually impossible.
Avi
From: b6  Date: Monday, September 20, 2021 at 9:39 PM  To: Nath, Avindra (NIH/NINDS) [E] b6  Subject: Re: Paralyzed after J &J Covid Vaccine b6
Dear Doctor Nath,
Thank for your prompt response.
First, it is myself, <b>b6</b> who has written to you and the one who has been injured by the vaccine. <b>b6</b>

I thought that your title with the NIH was Senior Investigator and Clinical Director so, I thought you might like to investigate further as to the connection of my paralysis and blood clot with the Johnson and Johnson Covid vaccine. Yes, it is true that I questioned the practice of not treating Covid until it requires hospitalization. And possibly, that is for someone else to figure out. However, my medical records will be available to you, should you choose to investigate this. Kind regards, **b6** On Mon, Sep 20, 2021, 6:00 PM Nath, Avindra (NIH/NINDS) [E] wrote: Dear b6 I am terribly sorry to hear of your illness and the difficulty you are having to navigate the system. The temporal association of the symptoms with the vaccine does make is suspect, but I do not know of any way how to sort it out. You have identified flaws in our health care system, which I think are problems that way

beyond what I can do to change. Wish there was something I could do, but this way out my area of

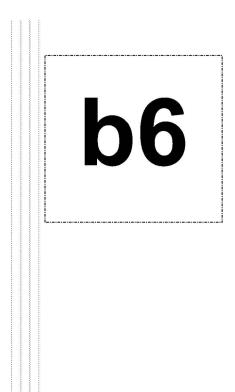
expertise.

Avi

REL0000231424

From: b6
Date: Monday, September 20, 2021 at 7:14 PM
To: Nath, Avindra (NIH/NINDS) [E] b6
Subject: Paralyzed after J &J Covid Vaccine b6
0.20.2021
9-20-2021
Dear Doctor Avindra Nath,
Dear Doctor Avindra Natil,
My name is <b>b6</b> I am a healthy but paralyzed <b>b6</b> male who lives in <b>b6</b>
<u> </u>
I am writing to you for help. My doctors and most of <b>b6</b> politicians seem not to care what happened to
me. They are afraid to admit the truth of my ordeal. There have been assumptions made as to why this
happened. Gravitating towards these assumptions has only delayed in preventing others injury.
It has been assumed that I was asymmtometic with Covid 10 miles to vaccination and/or I already had an
It has been assumed that I was asymptomatic with Covid-19 prior to vaccination and/or I already had an autoimmune defect which was the trigger for my reaction to the Covid vaccine. To my knowledge, every
possible test the doctors performed to try and pin my adverse reaction on me came back negative.
possible test the doctors performed to try and pin my deverse reaction on the came back negative.
I received the Johnson and Johnson Covid vaccine on <b>b6</b> Less than 24 hours after vaccination, I
lost bladder control. From there my legs and hips felt very heavy and odd. I experienced erectile
dysfunction. It felt like there was a belt strapped around my hips being cinched tighter and tighter. There
was no relief, regardless of what I tried. I continued to work through all of this.
I went to the ER on <b>b6</b> The doctors initially began working at trying to figure it out until <b>b6</b>
b6 That was enough for them b6not the vaccine. I was sent home, even though my discharge paper said b6 Four days later I was
even though my discharge paper said b6 Four days later I was paralyzed. I had a blood clot in my calf, my spinal cord hemorrhaged from the inflammation, and I was
intubated for 2 weeks after aspirating on water. I am still paralyzed <b>b6</b>
intubated for 2 weeks after aspirating on water. I am still paratyzed:
<b>b6</b>
NU

b6
The blood clot in my calf muscle was found after b6 I believe that a blood clot was present upon my paralysis. b6 the doctors only treated me with that in mind. There was very little, if any consideration, given to the possibility of vaccination induced problems, even with medical evidence of blood clots associated with the J & J vaccine.
After my hospitalization on b6 several diagnoses were tossed around, simply because they would not consider the vaccine as the problem. The final diagnosis was b6
People are suffering long term health problems and dying from Covid because no one is focused on treating Covid. The doctors are sending people home who are sick, telling them it's a virus that will run its course. Why are doctors not focused on treating Covid prior to hospitalization?
With the White House threatening loss of federal dollars to medical institutions and medical institutions threatening to strip away doctor's medical licensing for treating patients, the cause of my diagnosis is documented as and not Covid-19 vaccination. This documentation is going to be difficult for me to receive any monetary compensation from the federally funded Countermeasures Injury Compensation Program and National Vaccine Injury Compensation Program.
I was a before this
happened to me. b6  My employer did not want me to return to work for him since I could not walk and be a b6
Due to my family's insistence, and not the doctors, my case has been reported to the VAERS reporting agency.
I would gladly share my medical records with you, if they have not already been shared with you by my b6 doctors. I am available to visit about this anytime with you.
Kind regards,



From: b6
Sent: 12/15/2021 4:04:09 PM
To: Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6 b6 Brown, Warren (NIH/NINDS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bef0730648434bb69542199fca79f67e b6
Subject: [EXTERNAL] Re: Post Covid19 Vaccine reaction Research

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Hi Dr. Nath,

That would be so appreciated. I am very flexible on availability.

Thank you.

b6

**b6** 

					000000000000000000000000000000000000000
From: Nath, Av	vindra (NIH/NINDS) [E]	b6			
Sent: Tuesday,	December 14, 2021 8:41 P	M			
То:	b6	Brown, Warre	n (NIH/NINDS) [C]	b6	]
Subject: [EXTER	RNAL] Re: Post Covid19 Vac	cine reaction Research	·		·-·-··I
Dear <b>b6</b>					
I am sorry to he	ear of your illness. I will eb	glad to talk to you to see	if there is anything tha	at can be done to he	lp. I have
copied Warren	who can set up a phone ca	ll/virtual meeting			
Avi		_			
Avindra Nath M	ИD				
Chief, Section f	or Infections of the Nervou	s System			
Clinical Directo	r,	•			
National Institu	ute of Neurological Disorde	rs and Stroke			
	utes of Health, Bethesda, M				
	(Office)				
b6	<u></u>				

p
From: b6
Date: Monday, December 13, 2021 at 11:30 AM
To: Nath, Avindra (NIH/NINDS) [E] b6
Subject: [EXTERNAL] Post Covid19 Vaccine reaction Research
CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.
Dear Dr. Nath,
l am a b6 male b6 at b6
I am reaching out to you today in desperation as I am seeking any research studies at NIH that might be able to me help understand my progressive symptomatology and identify any possible interventions.
l experienced paresthesia after dose 1 on
I received the second dose of Pfizer on b6 and by b6 I ended up in the ED with severe headache, labile BP, tachycardia, tinnitus and mesenteric inflammation. As a b6 I tried to convey that I was having some type of reaction but was dismissed and sent home with b6
Symptoms continued to progress over months to include severe tinnitus, intractable insomnia, facial tingling, right eye irritation, autonomic nervous system dysfunction (POTs-like symptoms) and polyneuropathies.
I have been diligent and determined in seeking care near and far, but have continued to face skepticism, half-interest, and an inability to know how best to treat.
I am currently b6
<b>b6</b>
It is worth noting that I was healthy prior to vaccination. I work on b6 but due to my worsening symptoms I have had to take leave. I am desperate to get my health and life back on track so I can return to the work I love.
If you should know of any current studies, I kindly as that you please keep me in mind.
Med Hx:
<b>b6</b>

b6		
Significant testing results:		
	b6	
~	and care at my own expense	e. I thank you for your time and attention.
Regards,		
b6		
b6		

**b6** 

From: Sent: 12/20/2021 5:51:45 PM To: Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6 **b6** Subject: [EXTERNAL] Re: Post Covid19 Vaccine reaction Research Attachments: **b6** CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe. **b6** From: Nath, Avindra (NIH/NINDS) [E] Sent: Tuesday, December 14, 2021 8:41 PM Brown, Warren (NIH/NINDS) [C] Subject: [EXTERNAL] Re: Post Covid19 Vaccine reaction Research Dear **b6** I am sorry to hear of your illness. I will eb glad to talk to you to see if there is anything that can be done to help. I have copied Warren who can set up a phone call/virtual meeting Avi Avindra Nath MD Chief, Section for Infections of the Nervous System Clinical Director, National Institute of Neurological Disorders and Stroke National Institutes of Health, Bethesda, MD (Office) **b6** From: Date: Monday, December 13, 2021 at 11:30 AM To: Nath, Avindra (NIH/NINDS) [E] Subject: [EXTERNAL] Post Covid19 Vaccine reaction Research

CAUTION: This email originated from outside of the orgal sender and are confident the content is safe.	nization. Do not click link	s or open attachments	unless you recognize the
Dear Dr. Nath,			
l am a <b>b6</b> male <b>b6</b>	at	b6	
I am reaching out to you today in desperation be able to me help understand my progress interventions.			
l experienced paresthesia after dose 1 on saw a neurologist at <b>b6</b> who advis subsided. Things calmed down after about	sed at the time to g	tly affecting right a et the second dos	ırm, face eye, axilla. I e if things
I received the second dose of Pfizer on bheadache, labile BP, tachycardia, tinnitus a b6 I tried to convey that I was ha home with b6	nd mesenteric infla	mmation. As a	b6
Symptoms continued to progress over montaingling, right eye irritation, autonomic nervo polyneuropathies.			
I have been diligent and determined in seek skepticism, half-interest, and an inability to	_		nued to face
I am currently	b6		
	b6		
It is worth noting that I was healthy prior to vacuue to my worsening symptoms I have had to ta so I can return to the work I love.			
If you should know of any current studies, I kind	dly as that you pleaso	keep me in mind.	
Med Hx:	b6		
<b>b6</b>			
Significant testing results:	6		

I am willing to travel for studies and care at my own expense. I thank you for your time and attention.

Regards,

b6

**b6** 

**b6** 













, LC
1/25/2022 12:30:26 AM
Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6 <b>b6</b> :: Re: [EXTERNAL] I need your help!
Re. [EXTERNAL] Theed your help:
IN: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the
and are confident the content is safe.
n't the NIH doing research on this? There are so many COVID vaccine injured, we need help.
om my iPhone
on my n none
On Jan 24, 2022, at 6:22 PM, Nath, Avindra (NIH/NINDS) [E] <b>b6</b> wrote:
Dear b6
I am terribly sorry to hear of your illness. We have limited experience with
b6
Best wishes.
Avi
AVI
From: b6
Date: Monday, January 24, 2022 at 5:32 PM
Date: Monday, January 24, 2022 at 5:32 PM  To: "Nath, Avindra (NIH/NINDS) [E]" b6
Date: Monday, January 24, 2022 at 5:32 PM
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I have seen the best doctors loca	ited in <u>b6</u>	ithey all agree that the vaccine has caused some		
		no idea or direction on how to help me.		
I have had b6	but doctors	s have not been told how to help us or what to look		
for. They are waiting for direction				
My neighbor who lives on the str	eet behind me also h	has the same symptoms due to the Pfizer vaccine.		
Our reaction is not rare. I have connected with thousands of other people who are also feeling many of				
the same symptoms that I am ha	ving. I am not anti-va	ax, I got the vaccine, I believed in the vaccine. I'm		
injured and I need help. I want to	know what my doct	ors need to do to help me get back to my normal		
healthy self.				
_				
There are so many people that are hurting, they are in so much pain. Some even talk about suicide, they				
need your help. They took the vaccine because they thought it was safe, but everything has risks.				
		nad a bad reaction but with your help we can get		
	3. No. 10 March 10 Ma	elp us! Are there any studies that we can be part		
		lp guide them on how to treat me? I've heard		
people talk about	D6	What do you think will help?		
Thank you,				
Thank you,				
<b>b6</b>				

From:	b6
Sent:	2/14/2022 3:08:08 PM
То:	Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
6.1.	(FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6 <b>b6</b>
Subject:	Re: [EXTERNAL] I need your help!
CAUTION: <b>Th</b>	is email originated from outside of the organization. Do not click links or open attachments unless you recognize the
sender and a	re confident the content is safe.
-	o. Let them know they can contact me with any information. I'm desperate for help, I was healthy before this ny life back.
Sent from m	ny iPhone
On	Feb 13, 2022, at 10:52 PM, Nath, Avindra (NIH/NINDS) [E] <b>b6</b> wrote:
	the NIH provides funding to researchers who study these and other diseases. I will forward to email he officials who would know a lot more than I do about these issues.
Fro	m: b6
	e: Sunday, February 13, 2022 at 11:37 PM
	"Nath, Avindra (NIH/NINDS) [E]" b6
Sun	iject: Re: [EXTERNAL] I need your help!
\$	TION: This email originated from outside of the organization. Do not click links or open attachments unless you gnize the sender and are confident the content is safe.
had	es the government have a place or organization that's studying how to help people like me who have an adverse reaction to the vaccine?
	an adverse reaction to the vaccine?

From: Date: Sunday, February 13, 2022 at 10:39 PM To: "Nath, Avindra (NIH/NINDS) [E]" b6 Subject: Re: [EXTERNAL] I need your help! CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe. I have full body skin burning from the vaccine along with awful muscle pains and unbearable tinnitus. Are you treating the neuropathy at the NIH? My neurologist needs direction, he's not sure how to proceed, no doctor is. Sent from my iPhone On Jan 24, 2022, at 6:22 PM, Nath, Avindra (NIH/NINDS) [E] wrote: Dear I am terribly sorry to hear of your illness. We have limited experience Best wishes. Avi b6 From: Date: Monday, January 24, 2022 at 5:32 PM To: "Nath, Avindra (NIH/NINDS) [E]" b6 Subject: [EXTERNAL] I need your help! CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe. Hello Dr Nath, woman who was completely healthy before taking the Pfizer vaccines. I walked into that pharmacy the strongest and healthiest I've ever been. I didn't have a bad reaction to the first shot, only a sore arm. I didn't have flu-like symptoms. I received the second Pfizer vaccine shot on b6 my arm was achy and I noticed my spine was also achy. I went to sleep and woke up the next day with wrist pains, which I never have. Later that week they progressed to arm muscle pains which I continued having for a few weeks.

Then, the neurological symptoms started, I woke up one day and scratched my face but it felt like my hands weren't getting the full

the command, it was like a numbness. My symptoms then progressed to weakness in my legs, severe sensitivity to sound, tinnitus, tremors, twitches, insomnia, brain fog, head fullness and burning neuropathy to name a few. My life went from wonderful to horrific because of the vaccine. I can't tell you how awful the last **b6** have been for me. b6 I have seen the best doctors located in they all agree that the vaccine has caused some sort of neurological inflammatory response but have no idea or direction on how to help me. I have had but doctors have not been told how to help us or what to look for. They are waiting for direction on how to help us. My neighbor who lives on the street behind me also has the same symptoms due to the Pfizer vaccine. Our reaction is not rare. I have connected with thousands of other people who are also feeling many of the same symptoms that I am having. I am not anti-vax, I got the vaccine, I believed in the vaccine. I'm injured and I need help. I want to know what my doctors need to do to help me get back to my normal healthy self. There are so many people that are hurting, they are in so much pain. Some even talk about suicide, they need your help. They took the vaccine because they thought it was safe, but everything has risks. Unfortunately we are part of the unlucky group that had a bad reaction but with your help we can get better. We need research and we need help. Please help us! Are there any studies that we can be part of? Is there anything I can tell my doctors that will help guide them on how to treat me? I've heard people talk about **b6** What do you think will help? Thank you, **b6** 

message from my brain. As if they were only receiving about 60-70% of

To:   ( Subject:	b6 3/4/2022 11:35:39 PM Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6 b6 Re: [EXTERNAL] I need your help! Video.MOV
	email originated from outside of the organization. Do not click links or open attachments unless you recognize the confident the content is safe.
Do you think	b6
Sent from my	iPhone
On Ma	ar 2, 2022, at 10:37 AM, <b>b6</b> wrote:
don't l	b6 Here's a video of how my hands shake now. Doctors know how to treat me because they have no studies to reference. Please, I'm begging you lude vaccine injured in your studies
Sent fr	rom my iPhone
	On Mar 2, 2022, at 9:45 AM, <b>b6</b> wrote:
	I came across your new published article, why aren't you including vaccine injured in your studies?    b6
	https://nn.neurology.org/content/9/3/e1146 b6 b6
	Sent from my iPhone
	On Feb 13, 2022, at 10:52 PM, Nath, Avindra (NIH/NINDS) [E]  b6 wrote:
	Yes, the NIH provides funding to researchers who study these and other diseases. I will forward to email to the officials who would know a lot more than I do about these issues.

Avi

REL0000231492

From:	b6
L	Sunday, February 13, 2022 at 11:37 PM
To: "N	ath, Avindra (NIH/NINDS) [E]" b6 t: Re: [EXTERNAL] I need your help!
links or	N: This email originated from outside of the organization. Do not click open attachments unless you recognize the sender and are confident tent is safe.
	ne government have a place or organization that's studying how people like me who have had an adverse reaction to the?
Sent fro	om my iPhone
	On Feb 13, 2022, at 10:09 PM, Nath, Avindra (NIH/NINDS) [E]
	Dear b6  Sorry, we are not a treatment facility, we do not have any patient care clinics like you have in other institutions. I understand the challenges. We are all struggling to figure out how to manage patients like you.  Best wishes.  Avi
	From: b6  Date: Sunday, February 13, 2022 at 10:39 PM  To: "Nath, Avindra (NIH/NINDS) [E]"  b6  Subject: Re: [EXTERNAL] I need your help!
	CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.
	I have full body skin burning from the vaccine along with awful muscle pains and unbearable tinnitus. Are you treating the neuropathy at the NIH? My neurologist needs direction, he's not sure how to proceed, no doctor is.
	Sent from my iPhone

On Jan 24, 2022, at 6:22 PM, Nath, Avindra (NIH/NINDS) [E] b6 wrote:

Dear b6 I am terribly sorry to hear of your illness. We have limited experience with
Best wishes. Avi
From: b6  b6  Date: Monday, January 24, 2022 at 5:32 PM  To: "Nath, Avindra (NIH/NINDS) [E]"  b6  Subject: [EXTERNAL] I need your help!
CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.
Hello Dr Nath, I'm a b6 woman who was completely healthy before taking the Pfizer vaccines. I walked into that pharmacy the strongest and healthiest I've ever been. I didn't have a bad reaction to the first shot, only a sore arm. I didn't have flu-like symptoms.
I received the second Pfizer vaccine shot on b6 That night my arm was achy and I noticed my spine was also achy. I went to sleep and woke up the next day with wrist pains, which I never have. Later that week they progressed to arm muscle pains which I continued having for a few weeks.
Then, the neurological symptoms started, I woke up one day and scratched my face but it felt like my hands weren't getting the full message from my brain. As if they were only receiving about 60-70% of

the command, it was like a numbness.

My symptoms then progressed to weakness in my legs, severe sensitivity to sound, tinnitus, tremors, twitches, insomnia, brain fog, head fullness and burning neuropathy to name a few. My life went from wonderful to horrific because of the vaccine. I can't tell you how awful the last have been for me. I have seen the best doctors located in b6 they all agree that the vaccine has caused some sort of neurological inflammatory response but have no idea or direction on how to help me. I have had **b6** but doctors have not been told how to help us or what to look for. They are waiting for direction on how to help

My neighbor who lives on the street behind me also has the same symptoms due to the Pfizer vaccine. Our reaction is not rare. I have connected with thousands of other people who are also feeling many of the same symptoms that I am having. I am not anti-vax, I got the vaccine, I believed in the vaccine. I'm injured and I need help. I want to know what my doctors need to do to help me get back to my normal healthy self.

There are so many people that are hurting, they are in so much pain. Some even talk about suicide, they need your help. They took the vaccine because they thought it was safe, but everything has risks. Unfortunately we are part of the unlucky group that had a bad reaction but with your help we can get better. We need research and we need help. Please help us! Are there any studies that we can be part of? Is there anything I can tell my doctors that will help guide them on how to treat me? I've heard people talk about b6 What b6

Thank you,

do you think will help?

_	p-1
From:	
Sent: To:	4/30/2022 2:21:34 PM Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
10.	(FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6 b6
Subject:	
	N: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the and are confident the content is safe.
_	y research yielded any ideas on how to treat the vaccine injured? I continue having weakness in my legs, burning athy, tinnitus, muscle aches, tremors, internal shaking, etc. I was completely healthy before the vaccine, it's been of this hell. Are they making any progress on how to treat us? I'm willing to try anything, really feeling ate.
	eting more and more people with similar side effects from the vaccine, lots of people who just aren't reporting it e they feel there's no point.
Sent fro	om my iPhone
	On Feb 13, 2022, at 10:52 PM, Nath, Avindra (NIH/NINDS) [E] <b>b6</b> wrote:
	Yes, the NIH provides funding to researchers who study these and other diseases. I will forward to email to the officials who would know a lot more than I do about these issues.  Avi
	From: b6
	Date: Sunday, February 13, 2022 at 11:37 PM
	To: "Nath, Avindra (NIH/NINDS) [E]" b6
	Subject: Re: [EXTERNAL] I need your help!
	CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.
	Does the government have a place or organization that's studying how to help people like me who have had an adverse reaction to the vaccine?
	Sent from my iPhone
	On Feb 13, 2022, at 10:09 PM, Nath, Avindra (NIH/NINDS) [E] <b>b6</b>
	wrote:
	Dear <b>b6</b>
	Sorry, we are not a treatment facility, we do not have any patient care clinics like you
	have in other institutions. I understand the challenges. We are all struggling to figure
	out how to manage patients like you.
	Best wishes.

From: b6	
Date: Sunday, February 13, 2022 at 10:39 PM	
F HALLI A 1 1 (AULI/AUAIDC) [C]III	
Subject: Re: [EXTERNAL] I need your help!	
CAUTION: This email originated from outside of the organization. Do not click links or open	20000
attachments unless you recognize the sender and are confident the content is safe.	
have full body skin burning from the vaccine along with awful muscle pains and unbearable tinnitus. Are you treating the neuropathy at the NIH? My neurologist need direction, he's not sure how to proceed, no doctor is.	S
Sent from my iPhone	
On Jan 24, 2022, at 6:22 PM, Nath, Avindra (NIH/NINDS) [E]	
<b>b6</b> wrote:	
wrote.	
Dear <b>b6</b>	
I am terribly sorry to hear of your illness. We have limited experience	
<b>b6</b>	
Best wishes.	
Avi	
7.00	
From: b6	
Date: Monday, January 24, 2022 at 5:32 PM	
To: "Nath, Avindra (NIH/NINDS) [E]" b6	
Subject: [EXTERNAL] I need your help!	
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the content is sale.	
will be as all	
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healthiest I've ever been. I didn't have a bad reaction to the first shot,	
only a sore arm. I didn't have flu-like symptoms.	
I received the second Pfizer vaccine shot on <b>b6</b> That night	
my arm was achy and I noticed my spine was also achy. I went to sleep	
and woke up the next day with wrist pains, which I never have. Later	
that week they progressed to arm muscle pains which I continued	
having for a few weeks.	

message from my brain. As if they were only receiving about 60-70% of the command, it was like a numbness. My symptoms then progressed to weakness in my legs, severe sensitivity to sound, tinnitus, tremors, twitches, insomnia, brain fog, head fullness and burning neuropathy to name a few. My life went from wonderful to horrific because of the vaccine. I can't tell you how awful the last **b6** have been for me. I have seen the best doctors located in **b6** they all agree that the vaccine has caused some sort of neurological inflammatory response but have no idea or direction on how to help me. I have had \_\_\_\_\_but doctors have not been told how to help us or what to look for. They are waiting for direction on how to help us. My neighbor who lives on the street behind me also has the same symptoms due to the Pfizer vaccine. Our reaction is not rare. I have connected with thousands of other people who are also feeling many of the same symptoms that I am having. I am not anti-vax, I got the vaccine, I believed in the vaccine. I'm injured and I need help. I want to know what my doctors need to do to help me get back to my normal healthy self. There are so many people that are hurting, they are in so much pain. Some even talk about suicide, they need your help. They took the vaccine because they thought it was safe, but everything has risks. Unfortunately we are part of the unlucky group that had a bad reaction but with your help we can get better. We need research and we need help. Please help us! Are there any studies that we can be part of? Is there anything I can tell my doctors that will help guide them on how to treat me? I've heard people talk about **b6** What do you think will help?

Thank you,

**b6** 

Then, the neurological symptoms started, I woke up one day and scratched my face but it felt like my hands weren't getting the full

 Sent:
 8/8/2022 8:17:19 PM

 To:
 b6

 Subject:
 NIH COVID-19 Vaccine Study

Attachments: Vaccination\_Consent\_Clean\_05.17.22.pdf

Good Day **b6** 

Thank you for your patience and your interest in the COVID-19 Convalescence study at the National Institutes of Health. I am emailing you because you had previously contacted the NIH about participating in this study. To ensure that your information and communication remains secure, you are receiving this via encrypted email. Please respond using encrypted email.

Our study is looking at the experience of recovery for individuals after a COVID-19 infection or after COVID 19 vaccination. The attached consent form provides more information about our study, which involves a phone interview and online questionnaires.

In order to be considered for the study, please respond to this email with answers to the following questions:

- 1. What is your full name?
- 2. What is your preferred phone number?
- 3. How old are you?
- Are you fluent in speaking, reading and writing English? Yes /No
- 5. Do you live in the United States? Yes/No
- a. If yes, please provide the city, state and zip code where you live.
- 6. Are you an NIH employee, contractor, trainee or otherwise affiliated with the NIH? Yes/No
- 7. Have you had a COVID-19 infection? Yes/No/Unsure
- a. If yes, how many COVID-19 infections have you had?
- b. What is the date of your first COVID-19 infection?
- c. Are you having persistent side effects after your first COVID-19 infection? Yes No
- d. Do you have test results confirming your COVID 19 infection? Yes No
- e. If you responded yes, please provide a copy of your COVID 19 test results with your email response.

For tests performed at a laboratory or by a medical provider, results need to include your name, date of test result, type of test, and result of test. If you do not have a copy of your test result, please let us know and we can assist you in obtaining your records from your medical lab or provider.

For tests performed using a home testing kit, a photograph of the results with time and date are required.

- 8. Have you received a COVID-19 vaccine? Yes No
- a. If you responded yes, please provide a copy of your COVID 19 vaccination card with your email response.
- b. If yes, do you have persistent side effects after receiving a COVID-19 vaccination? Yes No

When you respond to this email, please provide answers to each question above, as well as a Copy of your COVID-19 test results and/or the front and back of your COVID-19 vaccination card, if applicable.

Your responses and documentation will allow us to determine if you are eligible for our research study. If you do not answer all questions or provide the requested documentation, you will not be considered for the study. If you wish to provide a short summary of your condition, we invite you to.

If you are eligible, then we will email you within 10 business days to schedule a time to obtain verbal consent and perform a study interview. Please let me know if you have any additional questions. I look forward to hearing from you.

Thank you, Angelique Gavin COVID 19 Convalescence Study Team

# Angelique Gavin, MS (Contractor)

NIH/NINDS Clinical Operations Manager **Contractor Preferred Solutions Group** National Institutes of Health 10 Center Drive Building 10, Room 3B19, MSC 1251 Bethesda, MD 20814-9692

(office) **b6** (cell) (301) 480-5368 (efax)

https://clinicaltrials.gov - study number 000089-N

### Angelique Gavin, MS (Contractor)

NIH/NINDS Clinical Operations Manager **Contractor Preferred Solutions Group** National Institutes of Health 10 Center Drive Building 10, Room 3B19, MSC 1251

Bethesda, MD 20814-9692

(office) **b6** (cell)

(301) 480-5368 (efax)

https://clinicaltrials.gov - study number 000089-N

REL0000231599

# Informed Consent: Protocol 00089 Phase A Surveying COVID vaccinations Version 05/17/2022

PRINCIPAL INVESTIGATOR: Avi Nath, MD

STUDY TITLE: Natural History of Post-Coronavirus Disease 19 Convalescence at the National Institutes of Health

You are being asked to take part in a research study at the National Institutes of Health (NIH).

### IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

This study is entirely voluntary, and you are not required to participate. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. In either case, you will not lose any benefits to which you are otherwise entitled. If you do choose to leave the study, please inform the study team.

### WHY IS THIS STUDY BEING DONE?

This consent form is being used for the first phase of a multi-phase study. We are only asking you to consent to participate in procedures in this phase of the study. The purpose of this study is to learn more about the range and timing of symptoms individuals have experienced before, during, and after COVID -19 infection. It also strives to learn more about the range and timing of symptoms in individuals whom have documented adverse effects from COVID 19 vaccination. We hope to use this information to describe the differentways people recover from COVID-19 and help us develop future studies to understand why some people do not fully recover. This study is also being used to help identify participants for other research studies taking place at NIH.

### WHAT WILL HAPPEN DURING THE STUDY?

If you are found to be eligible for this study, we will ask you to complete a telephone survey interview and on-line questionnaires. The survey interview and optional on-line questionnaires will include questions about your health prior to receiving your COVID-19 vaccine. The survey interview typically takes between 30 and 60 minutes. English speaking participants with email and internet access will be provided with computer log-in information in order to access the online questionnaires. You will receive a link with log-in information to access follow up questionnaires every 3 months for 3 years. The follow up questionnaires will ask you follow up information on your recovery from COVID-19 vaccination. Completing all of the questionnaires the first time may take up to 3 hours and follow up questionnaires will take up to 30 minutes. We do not expect you to complete the questionnaires at a single session. You will be able to save your progress and return to them at your convenience. You should answer the questions the best you can.

We will also collect your COVID-19 vaccination record and related medical records as part of this study. We will retain this data and use it as part of the study.

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IRB APPROVAL DATE: 05/23/2022

### HOW LONG WILL THE STUDY TAKE?

You will also be offered the opportunity to complete additional questionnaires about your COVID-19 vaccine related symptoms every three months for up to 3 years. These follow-up questionnaires willtake less than 30 minutes to complete. With your permission, we will reach out every three months to remind you that there are questionnaires available to be completed. If you agree to take part in this study, we will ask you to complete optional follow-up questionnaires for up tothree years.

We may also re-contact you after you have participated in this study. We may need to clarify answers or collect additional medical record. We may re-contact you to offer you opportunities to participate in these other research studies. With your approval, we will facilitate getting these other researchers in touch with you. Some individuals who continue to have symptoms or have had a unique presentation may also be re-contacted for further evaluation and follow up as part of this study.

### HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

We plan to have approximately 1590 people participate in this study.

### WHAT ARE THE RISKS AND DISCOMFORTS OF BEING IN THE STUDY?

The primary risk to subjects for this study would be a breach of confidentiality. We plan to take extensive precautions to protect the confidentiality of your data.

You may find it difficult to answer questions about the impact of COVID-19 vaccination on yourself andyour life. You may refuse to answer any question or stop at any time.

### WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

There is no direct benefit to you from participating in this research study; however, we hope to learn more about COVID -19 infection and vaccinations and how people recover afterwards. There is no alternative treatment or procedure to being in the study. Therefore, if you do not wish to be in the study, do not participate.

# STORAGE, SHARING AND FUTURE RESEARCH USING YOUR DATA

As part of this study, we are obtaining data from you. We will remove all the identifiers, such as your name, date of birth, address, or medical record number and label your data with a code so that you cannot easily be identified. However, the code will be linked through a key to information that can identify you. We plan to store and use these data for studies other than the ones described in this consent form that are going on right now, as well as studies that may be conducted in the future.

Our research team is also performing additional research studies at NIH, including "Neurological Complications of COVID-19" (Protocol 000094) and "Post-Infectious Myalgic Encephalomyelitis/Chronic Fatigue Syndrome at NIH" (Protocol 16-N-0058). We are also collaborating with investigators on the studies for 20CC0113: "Cardiopulmonary Inflammation

000089 Phase A Vaccination Informed Consent 05.17.2022

IRB NUMBER: 000089

IRB APPROVAL DATE: 05/23/2022

and Multi-System Imaging During the Clinical Course of COVID-19 Infection in Asymptomatic and Symptomatic Persons", protocol 000102-CC: "COVID-19, Chronic Adaptation, and Response to Exercise (COVID-CARE)", 000711 "Immunotherapy for Neurological Post-Acute Sequelae of SARS-CoV-2 (IN-PASC)", and 000466 "Procedural Motor Memory in Long Haul COVID-19".

If you consent to participate in any of these studies, we may share identifiable information with members of those research teams.

We may share your coded data with other researchers. These researchers may be at NIH, other research centers and institutions, or commercial entities. If we do this, while we will maintain the code key, we will not share it, so the other researchers will not be able to identify you. The future studies may provide additional information that will be helpful in understanding COVID-19, or other diseases or conditions. This could include studies to develop other research tests, treatments, drugs, or devices, that may lead to development of a commercial product by the NIH and/or its research or commercial partners. There are no plans to provide financial compensation to you if this happens. Also, it is unlikely that we will learn anything from these studies that may directly benefit you.

If you change your mind and do not want us to store and use your data for future research, you should contact the research team member identified at the bottom of this document. We will do our best to comply with your request but cannot guarantee that we will always be able to destroy your data. For example, if some research with your data has already been completed, the information from that research may still be used. Also, for example, if the data have been shared already with other researchers, it might not be possible to withdraw them.

In addition to the planned use and sharing described above, we might remove all identifiers and codes from your data and use or share them with other researchers for future research at the NIH or other places. When we or the other researchers access your anonymized data, there will be no way to link the data back to you. If we do this, we would not be able to remove your data to prevent their use in future research studies, even if you asked, because we will not be able to tell which are your data.

# How long will your data be stored by the NIH?

Your data may be stored by the NIH indefinitely.

# Risks of storage and sharing of data

When we store your data, we take precautions to protect your information from others that should not have access to it. Even with the safeguards we put in place, we cannot guarantee that your identity will never become known or someone may gain unauthorized access to your information. New methods may be created in the future that could make it possible to re-identify you and your data.

### **COMPENSATION**

There is no compensation for completing the phone interview or questionnaires.

### CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

# Will your information be kept private?

We will protect your confidentiality and privacy if you decide to participate. Personal information, such as your birth date and address, will be collected during the telephone interview. We will assign you a Study ID number and remove your name from your responses (de-identify) when we enter your information into our database. Your de-identified responses will be stored securely. De-identifying your responses makes the risk of having your confidentiality breached very low but not zero.

### CERTIFICATE OF CONFIDENTIALITY

To help us protect your privacy, the NIH Intramural Program has received a Certificate of Confidentiality (Certificate). With this certificate, researchers may not release or use data or information about you except in certain circumstances.

NIH researchers must not share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if requested by a court.

The Certificate does not protect your information when it:

- 1. is disclosed to people connected with the research, for example, information may be used for auditing or program evaluation internally by the NIH; or
- 2. is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA);
- 3. is for other research;
- 4. is disclosed with your consent.

The Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing below you consent to those disclosures. Other permissions for release may be made by signing NIH forms, such as the Notice and Acknowledgement of Information Practices consent.

### **Privacy Act**

The Federal Privacy Act generally protects the confidentiality of your NIH research information that we collect under the authority of the Public Health Service Act during your participation in this research study. This study's data will be stored under system 09-25-0200, Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH). In some

cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act allows release of information from your record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to NIH staff (such as contractors and volunteers), to those engaged by the agency for research purposes, to certain federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to morbidity, mortality, disease, or tumor registries, when authorized by the Secretary of HHS, or when the NIH is involved in a lawsuit. However, NIH will only release information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act. If you do not want to share your information with us, then you cannot participate in this study.

# PROBLEMS OR QUESTIONS

Before the telephone survey interview, you will be given an opportunity to ask questions about the research study and the impact it may have on you and your privacy. Please let us know your questions and concerns.

If you have any problems or questions about this study or about your rights as a research participant, you may contact:

Study Coordinator: Angelique Gavin, Building/room Building 10/3B19, b6 email-
b6
Lead Associate Investigator: Brian Walitt M.D, M.P.H, Building/room Building 10/3B19, <b>b6</b>
b6 email- b6
Principal Investigator:, Avindra Nath, M.D., Building/Room 10/7C-103, Telephone <b>b6</b>
b6 email- b6

You may also call the NIH Clinical Center Patient Representative at 301-496-2626, or the NIH Office of IRB Operations at 301-402-3713, if you have a research-related complaint or concern.

By agreeing to this acknowledgment, you affirm that you are at least 18 years old and agree to participate in this research study.

b6 To: Subject: NIH COVID-19 Vaccine Study Attachments: Vaccination\_Consent\_Clean\_05.17.22.pdf Hello b6 I hope all is well. We have reviewed your medical records and they are sufficient for our needs. I'd like to arrange our next interview which I anticipate will take approximately 45 minutes of your time. Angelique Gavin, MS (Contractor) NIH/NINDS Clinical Operations Manager **Contractor Preferred Solutions Group** National Institutes of Health 10 Center Drive Building 10, Room 3B19, MSC 1251 Bethesda, MD 20814-9692 (office) b6 (cell) (301) 480-5368 (efax)

https://clinicaltrials.gov - study number 000089-N

REL0000231618

# Informed Consent: Protocol 00089 Phase A Surveying COVID vaccinations Version 05/17/2022

PRINCIPAL INVESTIGATOR: Avi Nath, MD

STUDY TITLE: Natural History of Post-Coronavirus Disease 19 Convalescence at the National Institutes of Health

You are being asked to take part in a research study at the National Institutes of Health (NIH).

### IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

This study is entirely voluntary, and you are not required to participate. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. In either case, you will not lose any benefits to which you are otherwise entitled. If you do choose to leave the study, please inform the study team.

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IRB NUMBER: 000089
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### HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

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000089 Phase A Vaccination Informed Consent 05.17.2022

IRB NUMBER: 000089

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and Multi-System Imaging During the Clinical Course of COVID-19 Infection in Asymptomatic and Symptomatic Persons", protocol 000102-CC: "COVID-19, Chronic Adaptation, and Response to Exercise (COVID-CARE)", 000711 "Immunotherapy for Neurological Post-Acute Sequelae of SARS-CoV-2 (IN-PASC)", and 000466 "Procedural Motor Memory in Long Haul COVID-19".

If you consent to participate in any of these studies, we may share identifiable information with members of those research teams.

We may share your coded data with other researchers. These researchers may be at NIH, other research centers and institutions, or commercial entities. If we do this, while we will maintain the code key, we will not share it, so the other researchers will not be able to identify you. The future studies may provide additional information that will be helpful in understanding COVID-19, or other diseases or conditions. This could include studies to develop other research tests, treatments, drugs, or devices, that may lead to development of a commercial product by the NIH and/or its research or commercial partners. There are no plans to provide financial compensation to you if this happens. Also, it is unlikely that we will learn anything from these studies that may directly benefit you.

If you change your mind and do not want us to store and use your data for future research, you should contact the research team member identified at the bottom of this document. We will do our best to comply with your request but cannot guarantee that we will always be able to destroy your data. For example, if some research with your data has already been completed, the information from that research may still be used. Also, for example, if the data have been shared already with other researchers, it might not be possible to withdraw them.

In addition to the planned use and sharing described above, we might remove all identifiers and codes from your data and use or share them with other researchers for future research at the NIH or other places. When we or the other researchers access your anonymized data, there will be no way to link the data back to you. If we do this, we would not be able to remove your data to prevent their use in future research studies, even if you asked, because we will not be able to tell which are your data.

# How long will your data be stored by the NIH?

Your data may be stored by the NIH indefinitely.

# Risks of storage and sharing of data

When we store your data, we take precautions to protect your information from others that should not have access to it. Even with the safeguards we put in place, we cannot guarantee that your identity will never become known or someone may gain unauthorized access to your information. New methods may be created in the future that could make it possible to re-identify you and your data.

### **COMPENSATION**

There is no compensation for completing the phone interview or questionnaires.

### CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

# Will your information be kept private?

We will protect your confidentiality and privacy if you decide to participate. Personal information, such as your birth date and address, will be collected during the telephone interview. We will assign you a Study ID number and remove your name from your responses (de-identify) when we enter your information into our database. Your de-identified responses will be stored securely. De-identifying your responses makes the risk of having your confidentiality breached very low but not zero.

### CERTIFICATE OF CONFIDENTIALITY

To help us protect your privacy, the NIH Intramural Program has received a Certificate of Confidentiality (Certificate). With this certificate, researchers may not release or use data or information about you except in certain circumstances.

NIH researchers must not share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if requested by a court.

The Certificate does not protect your information when it:

- 1. is disclosed to people connected with the research, for example, information may be used for auditing or program evaluation internally by the NIH; or
- 2. is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA);
- 3. is for other research;
- 4. is disclosed with your consent.

The Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing below you consent to those disclosures. Other permissions for release may be made by signing NIH forms, such as the Notice and Acknowledgement of Information Practices consent.

### Privacy Act

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cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act allows release of information from your record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to NIH staff (such as contractors and volunteers), to those engaged by the agency for research purposes, to certain federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to morbidity, mortality, disease, or tumor registries, when authorized by the Secretary of HHS, or when the NIH is involved in a lawsuit. However, NIH will only release information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act. If you do not want to share your information with us, then you cannot participate in this study.

# PROBLEMS OR QUESTIONS

Before the telephone survey interview, you will be given an opportunity to ask questions about the research study and the impact it may have on you and your privacy. Please let us know your questions and concerns.

If you have any problems or questions about this study or about your rights as a research participant, you may contact:

Study	Coordina	tor: Angeliq	jue Gavin,	Build	ding/room	Building	10/3B19,	b	6	]email-	
	b6										
Lead A	Associate	Investigator	: Brian W	alitt I	M.D, M.P.	H, Buildin	ng/room l	Building	10/3B	19, <b>b6</b>	,
b6	emai	l-[	b6								
Princip	oal Invest	igator:, Avi	ndra Nath,	M.D.	., Building	/Room 10	/7C-103,	Telepho	ne	b6	j
b6 6	email-	b6									

You may also call the NIH Clinical Center Patient Representative at 301-496-2626, or the NIH Office of IRB Operations at 301-402-3713, if you have a research-related complaint or concern.

By agreeing to this acknowledgment, you affirm that you are at least 18 years old and agree to participate in this research study.

From:	Gavin, Angelique (NIH/NINDS) [C] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6E97392E947E4F7EBB17EEB8AC87C5D5 b6
Sent:	8/29/2022 2:57:41 PM
То:	b6
Subject:	RE: NIH COVID-19 Vaccine Study
Thanks <b>b6</b>	What we have is fine for now!
Angelique	
	awin, MS (Contractor)  Inical Operations Manager
	eferred Solutions Group
	tutes of Health
10 Center Dri	ve
Building 10, R	toom 3B19, MSC 1251
Bethesda, ME	
	(office)
<b>b6</b>	(cell)
(301) 480-536	58 (efax)
b6	
https://clinica	altrials.gov - study number 000089-N
From:	b6
L	y, August 29, 2022 10:48 AM
	gelique (NIH/NINDS) [C] <b>b6</b>
	ERNAL] Re: NIH COVID-19 Vaccine Study
Subject. [EXT	ENVAL NET COVID 13 vaccine study
Hi,	
Yes that work	ss. I also have medical records at <u>b6</u> Not sure if you need them,
b6	
Get <u>Outlook f</u>	For iOS
From: Gavin	Angelique (NIH/NINDS) [C] <b>b6</b>
	y, August 29, 2022 10:25:11 AM
To:	b6
	ERNAL] RE: NIH COVID-19 Vaccine Study
Thank you	of for your quick reply! Would Wednesday, August 31 at 11 am work for you?
Angelique	
Angeliane C.	avin, MS (Contractor)
	linical Operations Manager
	eferred Solutions Group

National Institutes of Health

10 Center Drive Building 10, Room 3B19, MSC 1251
Bethesda, MD 20814-9692
b6 (cell) (cell)
(301) 480-5368 (efax)
https://clinicaltrials.gov - study number 000089-N
From: b6
Sent: Monday, August 29, 2022 10:09 AM  To: Gavin, Angelique (NIH/NINDS) [C] b6
Subject: [EXTERNAL] Re: NIH COVID-19 Vaccine Study
Hi,
I am available this week from tomorrow onward between 10-5 pm EST.
Get <u>Outlook for iOS</u>
From: Gavin, Angelique (NIH/NINDS) [C] b6
Sent: Monday, August 29, 2022 9:51:42 AM
To:   b6 Subject: [EXTERNAL] NIH COVID-19 Vaccine Study
Hello b6 I hope all is well. We have reviewed your medical records and they are sufficient for our needs. I'd like to arrange our next interview which I anticipate will take approximately 45 minutes of your time. Please send me some good days and times that will work for you and I will get back to you with an option that works for us both. Please send me options for this week. I am leaving for vacation next week and will return September 20. If this week is not good for you, please send options for the week of my return.
Additionally, please read over the study consent form prior to our next interview. Let me know if you have any questions.
I am looking forward to speaking with you soon!
Sincerely, Angelique
Angelique Gavin, MS (Contractor)
NIH/NINDS Clinical Operations Manager Contractor Preferred Solutions Group
National Institutes of Health
10 Center Drive
Building 10, Room 3B19, MSC 1251 Bethesda, MD 20814-9692
h6 (office)
(301) 480-5368 (efax)

### b6

https://clinicaltrials.gov - study number 000089-N

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CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

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From: Gavin, Angelique (NIH/NINDS) [C] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6E97392E947E4F7EBB17EEB8AC87C5D5 Sent: 8/29/2022 1:51:42 PM To: b6 Subject: NIH COVID-19 Vaccine Study Attachments: Vaccination\_Consent\_Clean\_05.17.22.pdf Hello **b6** I hope all is well. We have reviewed your medical records and they are sufficient for our needs. I'd like to arrange our next interview which I anticipate will take approximately 45 minutes of your time. Please send me some good days and times that will work for you and I will get back to you with an option that works for us both. Please send me options for this week. I am leaving for vacation next week and will return September 20. If this week is not good for you, please send options for the week of my return. Additionally, please read over the study consent form prior to our next interview. Let me know if you have any questions. I am looking forward to speaking with you soon! Sincerely, Angelique Angelique Gavin, MS (Contractor) NIH/NINDS Clinical Operations Manager **Contractor Preferred Solutions Group** National Institutes of Health 10 Center Drive Building 10, Room 3B19, MSC 1251 Bethesda, MD 20814-9692 (office) **b6** (cell) (301) 480-5368 (efax)

b6

https://clinicaltrials.gov - study number 000089-N

REL0000231711

# Informed Consent: Protocol 00089 Phase A Surveying COVID vaccinations Version 05/17/2022

PRINCIPAL INVESTIGATOR: Avi Nath, MD

STUDY TITLE: Natural History of Post-Coronavirus Disease 19 Convalescence at the National Institutes of Health

You are being asked to take part in a research study at the National Institutes of Health (NIH).

### IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

This study is entirely voluntary, and you are not required to participate. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. In either case, you will not lose any benefits to which you are otherwise entitled. If you do choose to leave the study, please inform the study team.

### WHY IS THIS STUDY BEING DONE?

This consent form is being used for the first phase of a multi-phase study. We are only asking you to consent to participate in procedures in this phase of the study. The purpose of this study is to learn more about the range and timing of symptoms individuals have experienced before, during, and after COVID -19 infection. It also strives to learn more about the range and timing of symptoms in individuals whom have documented adverse effects from COVID 19 vaccination. We hope to use this information to describe the differentways people recover from COVID-19 and help us develop future studies to understand why some people do not fully recover. This study is also being used to help identify participants for other research studies taking place at NIH.

### WHAT WILL HAPPEN DURING THE STUDY?

If you are found to be eligible for this study, we will ask you to complete a telephone survey interview and on-line questionnaires. The survey interview and optional on-line questionnaires will include questions about your health prior to receiving your COVID-19 vaccine. The survey interview typically takes between 30 and 60 minutes. English speaking participants with email and internet access will be provided with computer log-in information in order to access the online questionnaires. You will receive a link with log-in information to access follow up questionnaires every 3 months for 3 years. The follow up questionnaires will ask you follow up information on your recovery from COVID-19 vaccination. Completing all of the questionnaires the first time may take up to 3 hours and follow up questionnaires will take up to 30 minutes. We do not expect you to complete the questionnaires at a single session. You will be able to save your progress and return to them at your convenience. You should answer the questions the best you can.

We will also collect your COVID-19 vaccination record and related medical records as part of this study. We will retain this data and use it as part of the study.

IRB NUMBER: 000089
IRB APPROVAL DATE: 05/23/2022

### HOW LONG WILL THE STUDY TAKE?

You will also be offered the opportunity to complete additional questionnaires about your COVID-19 vaccine related symptoms every three months for up to 3 years. These follow-up questionnaires willtake less than 30 minutes to complete. With your permission, we will reach out every three months to remind you that there are questionnaires available to be completed. If you agree to take part in this study, we will ask you to complete optional follow-up questionnaires for up tothree years.

We may also re-contact you after you have participated in this study. We may need to clarify answers or collect additional medical record. We may re-contact you to offer you opportunities to participate in these other research studies. With your approval, we will facilitate getting these other researchers in touch with you. Some individuals who continue to have symptoms or have had a unique presentation may also be re-contacted for further evaluation and follow up as part of this study.

### HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

We plan to have approximately 1590 people participate in this study.

### WHAT ARE THE RISKS AND DISCOMFORTS OF BEING IN THE STUDY?

The primary risk to subjects for this study would be a breach of confidentiality. We plan to take extensive precautions to protect the confidentiality of your data.

You may find it difficult to answer questions about the impact of COVID-19 vaccination on yourself andyour life. You may refuse to answer any question or stop at any time.

### WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

There is no direct benefit to you from participating in this research study; however, we hope to learn more about COVID -19 infection and vaccinations and how people recover afterwards. There is no alternative treatment or procedure to being in the study. Therefore, if you do not wish to be in the study, do not participate.

# STORAGE, SHARING AND FUTURE RESEARCH USING YOUR DATA

As part of this study, we are obtaining data from you. We will remove all the identifiers, such as your name, date of birth, address, or medical record number and label your data with a code so that you cannot easily be identified. However, the code will be linked through a key to information that can identify you. We plan to store and use these data for studies other than the ones described in this consent form that are going on right now, as well as studies that may be conducted in the future.

Our research team is also performing additional research studies at NIH, including "Neurological Complications of COVID-19" (Protocol 000094) and "Post-Infectious Myalgic Encephalomyelitis/Chronic Fatigue Syndrome at NIH" (Protocol 16-N-0058). We are also collaborating with investigators on the studies for 20CC0113: "Cardiopulmonary Inflammation

000089 Phase A Vaccination Informed Consent 05.17.2022

and Multi-System Imaging During the Clinical Course of COVID-19 Infection in Asymptomatic and Symptomatic Persons", protocol 000102-CC: "COVID-19, Chronic Adaptation, and Response to Exercise (COVID-CARE)", 000711 "Immunotherapy for Neurological Post-Acute Sequelae of SARS-CoV-2 (IN-PASC)", and 000466 "Procedural Motor Memory in Long Haul COVID-19".

If you consent to participate in any of these studies, we may share identifiable information with members of those research teams.

We may share your coded data with other researchers. These researchers may be at NIH, other research centers and institutions, or commercial entities. If we do this, while we will maintain the code key, we will not share it, so the other researchers will not be able to identify you. The future studies may provide additional information that will be helpful in understanding COVID-19, or other diseases or conditions. This could include studies to develop other research tests, treatments, drugs, or devices, that may lead to development of a commercial product by the NIH and/or its research or commercial partners. There are no plans to provide financial compensation to you if this happens. Also, it is unlikely that we will learn anything from these studies that may directly benefit you.

If you change your mind and do not want us to store and use your data for future research, you should contact the research team member identified at the bottom of this document. We will do our best to comply with your request but cannot guarantee that we will always be able to destroy your data. For example, if some research with your data has already been completed, the information from that research may still be used. Also, for example, if the data have been shared already with other researchers, it might not be possible to withdraw them.

In addition to the planned use and sharing described above, we might remove all identifiers and codes from your data and use or share them with other researchers for future research at the NIH or other places. When we or the other researchers access your anonymized data, there will be no way to link the data back to you. If we do this, we would not be able to remove your data to prevent their use in future research studies, even if you asked, because we will not be able to tell which are your data.

# How long will your data be stored by the NIH?

Your data may be stored by the NIH indefinitely.

# Risks of storage and sharing of data

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# PROBLEMS OR QUESTIONS

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If you have any problems or questions about this study or about your rights as a research participant, you may contact:

Study Coordinator: Angelique Gavin, Building/room Building 10/3B19, <b>b6</b> email-
b6
Lead Associate Investigator: Brian Walitt M.D, M.P.H, Building/room Building 10/3B19, <b>b6</b>
b6 email- b6
Principal Investigator:, Avindra Nath, M.D., Building/Room 10/7C-103, Telephone <b>b6</b>
b6 email- b6

You may also call the NIH Clinical Center Patient Representative at 301-496-2626, or the NIH Office of IRB Operations at 301-402-3713, if you have a research-related complaint or concern.

By agreeing to this acknowledgment, you affirm that you are at least 18 years old and agree to participate in this research study.

Sent:	
	1/10/2022 3:12:05 PM
To:	Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6 b6
Subject:	[EXTERNAL] Fwd: Followup Jan 4th Meeting
Attachments:	Covid Vaccine Case Reports.xlsx
CAUTION: This s	email originated from outside of the organization. Do not click links or open attachments unless you recognize the

### Dr Nath.

Please see my notes below. The FDA has asked once again for us to provide any input from those who have experience with this disease. Very prompt responses and more active engagement on their part lead me to believe they will now examine these problems with some effort.

Please review concerns we have on reporting issues, neuropathy with gender/age, approaches with PASC vs post-vaccine, correlation/causation.

If there are any researchers you know who could fill in the gaps would you kindly be willing to discuss with Peter Marks?

The gov has conveniently absolved the drug companies of any liability, and the federal government is now saddled with the responsibility of figuring out this mess. As such it would only make sense that resources be allocated for further examination and investigation, and open dialogue be initiated by those who are credible sources. I am happy to orchestrate a meeting of the minds with NDR agreements if that would get the discussion started in a way that is similar to how previous new diseases have been investigated. No I don't need to be in attendance.

In our own talks with germany, france, us, and elsewhere it appears this is immune dysfunction that leads to inflammation, auto-immunity, and allergic(mcas).

It has been insanely challenging for these people suffering to have to walk this path alone. They grow more and more desperate by the day. Knowing there is someone, somewhere looking into this makes a big difference for these people to just hang on.

Thoughts?
b6

# Begin forwarded message:

From:		b6		
Date: J	anuary 9, 202	2 at 9:58:05 PM MST		
<b>To:</b> "M	arks, Peter"[	b6		
Cc: Loi	rie McNeill	b6	"Woodcock, Janet"	
	b6	"Richards, Paul"	b6	
	<b>b6</b>			
Subject	· Followin I	Ian 4th Meeting		

Dr Marks.

I appreciate you taking the time to meet with us last week. Below, find the contact for a few researchers examining the persistent symptoms following the Covid vaccines. Along with a brief description of the area of focus.

### 1) Dysautonomia -

As we mentioned in the call last week, there likely are issues with identifying this syndrome if only looking through VAERS or similarly reported databases.

- 1- even in typical circumstances dysautonomia is grossly under diagnosed
- 2- Dysautonomia is not diagnosed in ERs or ICUs, this is found through autonomic specialty labs. Hospital settings are far more likely to file VAERS reports than an autonomic specialist, which take months to for a patient to get into, and proper dx many months after the onset of the vaccination injury.

So, it would be reasonable to approach autonomic specialists / long covid specialists about their observations.

# Stanford - Autonomic Neurology Lab

Dr. Safwan Jaradeh - Autonomic Specialist

**b6** 

https://stanfordhealthcare.org/doctors/j/safwan-jaradeh.html

Dr Jaradeh says this is a conversation for their entire department to discuss with you. They have more post vax coming in than long-haulers and one MD is working on getting a vax trial setup now.

### 2) Neuropathy -

\*\*Please review with your data team: Historically, neuropathy presents in the predominantly male population aged 59+. However as discussed previous, neuropathy in our case is predominantly female, aged 29-40. I am curious if the reporting databases would bring up this signal if it isn't queried by straight population numbers, but rather gender or age. Neuropathy is likely to be inadequately reported through the VAERS and BEST systems because of the circumstances previously mentioned for dysautonomia.

### Wagar Waheed, MD

Professor of Neurological Sciences Vice Chair, Department of Neurological Sciences, University of Vermont College of Medicine

**b6** 

Waheed's Small Fiber Neuropathy Case Report:

Post COVID-19 vaccine small fiber neuropathy - Waheed - 2021 - Muscle & Delivery - Wiley Online Library

He is expanding this for a review of 100 participants with neuropathy, post covid vaccine. His initial findings lead him to realize the strong potential tie.

\_\_\_\_\_

# 3) Tinnitus -

Our findings are that this is not just J&J... not by a long shot. This symptom is more proportionate to the general neuro symptoms by brand as previously reported in our patient led survey of 500 participants.

This is more likely to be reported appropriately. However, many suffering neuro problems will not list this as a symptom (e.g., in my case yes, I have tinnitus now and it was a freight train in my head for the first four months. I didn't report because it was not high on my list of complaints, I had way too many other problems going on that were concerning for my quality of life.)

# Bowen Sao, PhD

Assoc, Professor, Nueroscience

**b6** 

He has been conducting research for most of last year on tinnitus after the covid vaccines. I suspect it may be in peer review process now.

# **Mayo Clinic**

Gregory Poland, MD

Vaccine researcher and vaccine reaction sufferer (tinnitus)

**b6** 

Greg Vanichkachorn, MD, MPH

Co-Authored a case series with Poland

b6

\_\_\_\_

# 4) Immunology

# Dr Yogendra

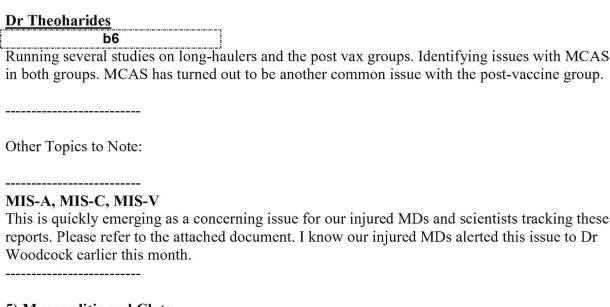
b6

Like the researchers above, this long-hauler researcher found these post-vax symptoms mirror Covid PASC. So much so that their same testing and methods to identify abnormalities in the immune cells of long-haulers, has also worked for us as well. Not only are the post vax injured group coming back with the same issues in our immune cells as the long haulers (spike protein in the monocytes, the control group has none), but it is in much higher levels than long-haulers. (With the high level of resources, focus and funds allotted to long-haulers research and collaboration, and the many similarities between PASC and post Covid vaccine injury, it would make sense to encourage exploration of these similarities. It would lead to clues and eventual healing for both groups.)

They also have potentially identified that the proper inflammatory response that should engage when vaccinated, does not engage in the typical fashion in those suffering problems after the vaccines. In some cases, the pro-inflammatory markers don't increase at all.

The long-hauler portion of their study has been accepted by "Frontiers in Immunology". Their subsequent paper using the same methods with the post vaccine injured cohort is going through peer review now, data is collected and analyzed.

https://www.frontiersin.org/articles/10.3389/fimmu.2021.746021/full?&utm\_source=Email\_to\_authors\_&utm\_medium=Email&utm\_content=T1\_11.5e1\_author&utm\_campaign=Email\_publication&field=&journalName=Frontiers in Immunology&id=746021



# 5) Myocarditis and Clots

Side note on myocarditis and clotting currently acknowledged by the FDA and CDC. Every person in our groups that have one of these two conditions, also have accompanying neuro issues like those of us who are not currently acknowledged by the FDA and CDC. Namely POTS, brain fog/memory loss, and inflammation (MCAS). Even the perfectly healthy very fit young males with the lasting myocarditis are struggling with the POTS and inflammation/brain fog/memory loss. Makes me suspect that somehow these all are a result of the same mechanism of action.

# 6) Parasthesias

Added to the package insert for Pfizer in the EU. We request the US follow suit. (but with all brands) doctors are much more receptive to recognize this side effect if it is communicated through the proper channels.

# 7) Correlation vs Causation

While we understand that correlation does not equal causation, we also find a strong correlation with the change in our blood that mirrors long-haul, and symptomology that mirrors long-haul. Because of this, I have to ask what is the process by which Covid PASC symptoms have been so readily tied back to Covid, whereas the same symptoms due to the Covid vaccines have not?

Also, while it may be coincidental to have one or maybe two strange symptoms pop up, is it reasonable to dismiss 10, 15, 20, new symptoms that occur in a single person post vaccine. Then

for this same pattern to ensue in tens of thousands of others? Yet, this same timeline and symptoms are easily tied to long-covid?

In conclusion, I appreciate your time and look forward to hearing from you soon.

Attached, find our latest collection of peer-reviewed case reports/research articles about Covid vaccine reactions. This collection has about 850 reports, which provides many more potential contacts for you with those who are/have looked into these issues.

Regards,

b6

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CC: b6   Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 b6
Subject: Re: COVID-19 Vaccine and b6
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Thanks for your quick response. I will immediately reach out to <b>b6</b> to obtain his permission <b>b6</b> Get Outlook for iOS
From: Nath, Avindra (NIH/NINDS) [E] b6
From: Nath, Avindra (NIH/NINDS) [E] b6 Sent: Monday, April 12, 2021 12:55:26 PM
To: b6
Cc: Safavi, Farinaz (NIH/NINDS) [E]
b6
Subject: Re: COVID-19 Vaccine and b6
Dear <b>b6</b>
Terribly sorry to hear of <b>b6</b> illness. With <b>b6</b> permission, we would be interested in talking to the
neurologists taking care of him to see if there is anything we can do to help. I have copied Dr. Safavi who is a neurologist
working with me and interested in these issues.
Avi
Avindra Nath MD Chief, Section of Infections of the Nervous System Clinical Director, National Institute of Neurological Disorders and Stroke National Institutes of Health, Bethesda, MD  (Office) (cell)
b6
From: b6
<b>Date:</b> Monday, April 12, 2021 at 1:45 PM
To: Nath, Avindra (NIH/NINDS) [E] b6
Cc: b6
Subject: COVID-19 Vaccine and b6
Dear Dr. Nath,
Appreciating your interest and expertise in regards to CNS Adverse events and the COVID-19 vaccines, I am
writing in regards to b6 In short, he is a b6 male who was otherwise healthy. He received his 2nd
dose of the Moderna vaccine on <b>b6</b> On <b>b6</b> he developed low back pain and
numbness in his legs. On b6 he presented to the Emergency Department of b6
b6 due to inability to walk, pain and numbness in his lower extremities. b6

he was told his diagnosis is	b6	He remains hospitalized
with bilateral foot drop, inability to	walk and inability to urinate.	Since this is a very rare adverse event, I
thought it best to reach out to you	or others at NIH to determine i	f there are further tests or treatments that
are appropriate. Any help or referra	als would be greatly appreciate	d.
Thank you for your help.		
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	r your submission, SUDDEN ONSET OF MYELITIS AFTER COVID-19 VACCINATION: AN UNDERED SEVERE RARE ADVERSE EVENT. The following URL links to the abstract page for this submission
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Sudden onset of myelitis after COVID-19 vaccination: An under-recognized severe rare adverse event

William E. Fitzsimmons, Pharm.D., M.S. and Christopher S. Nance, M.D.

## Abstract

Myelitis has been reported as a complication of COVID-19 infection. However, it has rarely been reported as a complication of COVID-19 vaccination, and this may be the first case report following an mRNA vaccine. A 63 yo, otherwise healthy male, received his second dose of the Moderna vaccine on 08 April 2021. He had some initial pain and soreness at the injection site. Seventeen hours post dose, he reported pain and numbness in both calves which progressed to lower back pain, paresthesia in both feet, and pain in lower extremities. Over the day post-vaccination the patient's condition worsened and he was unable to walk and unable to urinate voluntarily. On the second day post-vaccination he presented to the Emergency Department and was admitted to the University of Iowa hospital unable to walk with severe pain in lower back, legs and feet, and numbness in buttocks. Laboratory findings were unremarkable and lumbar puncture was not diagnostic. MRI revealed increased T2 cord signal seen in the distal spinal cord and conus. Initial treatment included IV Immunoglobulin for 2 days, followed by methylprednisolone 1000 mg/day IV for 5 days. Discharge from the hospital occurred on 16 April 2021 to inpatient rehabilitation. Treatment consisted of oral prednisone 60 mg/day with a tapering schedule. The patient slowly improved and was able to ambulate unassisted at 25 days post -vaccination. This case represents one of the first cases of myelitis reported in the literature after COVID-19 mRNA vaccination. As of 27 April 2021 the FDA VAERS system has 45 reports of transverse myelitis after COVID-19 vaccination (21 after Moderna vaccine, 19 were after Pfizer vaccine, and 5 occurred after Janssen vaccine).

Key Words: COVID-19 vaccine, myelitis, transverse myelitis, serious adverse event

Authors:

William E. Fitzsimmons, Pharm.D., M.S. (corresponding author)

University of Illinois at Chicago

College of Pharmacy

833 S. Wood Street

Chicago, IL 60612

wfitzsim@uic.edu

ORCID ID

https://orcid.org/0000-0002-6189-5499

Christopher S. Nance, M.D.

University of Iowa

Carver College of Medicine

Department of Neurology

C22-F General Hospital (GH)

200 Hawkins Dr.

Iowa City, IA 52242

christopher-nance@uiowa.edu

## Introduction

Transverse myelitis has been reported as a complication of COVID 19 infection.<sup>1-5</sup> However, case reports describing myelitis after COVID-19 vaccination have been rare and primarily after vaccination with the AstraZeneca/Oxford ChAdOx1 nCoV-19 vaccine, an adenovirus vector vaccine.<sup>6,7</sup> Goss et al reported that there were 9 cases of transverse myelitis in the Centers for Disease Control (CDC) Vaccine Adverse Event Reporting System (VAERS) database as of March 2, 2021.<sup>8</sup> To our knowledge, this is the first detailed case report of myelitis after the Moderna mRNA-1273 vaccine.

## Case Report

A 63 yo, otherwise healthy male received his first vaccination in left deltoid with Moderna Lot 036A21A on 11 Mar 2021. Soreness at the injection site was the only adverse event. On 8 April 2021 at 1230 he received his 2nd injection in the left deltoid with Moderna 028A21A. 15 minutes after vaccination he noticed low level pain (1 on a 0-10 scale) around the injection site. This persisted throughout the day and evening. On 9 April 2021, 0515 while walking from bedroom to bathroom he noticed aching and slight numbness in calves of both legs, more prominent in left leg. At 0700 he developed lower back pain (3 out of 10) and aching and numbness extended from his calves to ankles. Over the next few hours lower back pain and leg aches persisted. At 1100 he experienced an involuntary erection lasting 5-10 minutes. During the afternoon, pain in the lower back increased to 6 out of 10, pain in lower legs increased (severity 2 out of 10), and he had paresthesias in both feet. At 1800 he had difficulty with ambulation and his feet became increasingly numb. Pain in lower legs and ankles persisted at level 4. At 1900 he noted his last voluntary urination before hospitalization. Over the next several hours he experienced greater difficulty walking and inability to sleep. On 10 April 2021 (day 2 post-vaccination) at 0100 he experienced sharp shooting pain from the buttocks down through the legs into bottoms of the feet lasting several seconds with greater severity in the left leg. The pain in the lower legs and ankles increased to level 5 and numbness in the buttocks and back of thighs started. The shooting pain persisted and at 0600 while attempting to get out of bed, he could not stand. His left calf, both ankles and both feet were completely numb. He was unable to urinate and was constipated. The patient arrived at University of Iowa Hospital Emergency Department at approximately 0830. At that time, his buttocks was completely numb, pain in the lower back, lower legs ankles and feet persisted (level 6). He was admitted to the hospital. At 1300 his pain levels suddenly and severely spiked, pain in lower back, legs, ankles and feet were all at level 10. Approximately 45 minutes after administration of narcotic analgesics pain decreased to level 8 and over the course of the next few hours decreased to 6. Over the next 4 days pain levels diminished. During his hospitalization, the patient continued to experience urinary retention and constipation along with other buttocks and lower extremity symptoms but no symptoms above the waist. He had left foot drop and brisk patellar and Achilles reflexes. The patient was discharged from the hospital to inpatient rehabilitation on 15 Apr 2021 (7 days of hospitalization). At that time the patient was voiding urine on his own with straight catheterization for retention as needed. He continued to experience bilateral lower extremity numbness and was walking with a walker or physical therapist. Inpatient treatment consisted of IVIG 0.5 g/kg on 10 Apr and 11 Apr (2 doses); Methylprednisolone IV

1 G/day 11-15 Apr (5 doses) followed by oral prednisone. He reported sporadic shooting pain in soles of feet and was discharged after 7 days in hospital. Discharge medications included prednisone 60 mg/day on a slow tapering schedule.

After 7 days of inpatient rehabilitation he was discharged to home, ambulating with two canes. He is now able to walk in his home without assistance, canes, or walker and continues to improve but some numbness continues in his feet and ankles. His current prednisone dose is 40 mg/day.

# Laboratory tests

## On admission

CBC and chemistries were within normal limits.

COVID-19 PCR test negative.

ESR 16 mm/hr (normal < 15)

C-reactive protein < 0.5

PTT 23 sec

C3 and C4 complement normal

Rapid plasma reagin titer 1:1

# During hospitalization:

Neuromyelitis Optica/Aquaporin-4-IgG - Serum- Negative

MOG FACS - Serum- Negative

MS screen- negative

SS A antibody 1.9AI (positive)- drawn 12 Apr after two doses of IVIG

SS B antibody negative

ANCA negative

Rheumatoid Factor negative (<10 IU/ml)

ANA <1:80

# <u>Imaging</u>

MRI on 11 Apr 2021 of cervical thoracic and lumbar spine

Cervical and lumbar spines appear within normal limits. Increased T2 cord signal seen in the distal spinal cord and conus with questionable associated enhancement suggestive of myelitis.

MRI on 13 Apr 2021 of brain

Few punctate T2/FLAIR signal hyperintensities in bilateral corona radiata, nonspecific. No enhancing or restricting lesion.

# **CSF**

Lumbar Puncture on 12 Apr 2021

Aerobic and anaerobic cultures negative; meningitis/encephalitis panel negative; glucose 74 mg/dL(40-75); total protein 37 mg/dL (15-45); cell count and differential normal; total nucleated cell count 3

Autoimmune Myelopathy Evaluation performed by Mayo Clinic labs was negative for all autoantibodies tested.

## **EMG**

14 Apr 2021 No clear evidence for demyelinating polyradiculoneuropathy. One positive sharp wave in left gastrocnemius muscle.

## Discussion

Two cases of transverse myelitis were reported with the ChAdOx1n CoV-19 vaccine (AZD1222), a replication-deficient chimpanzee adenoviral vector vaccine, from the four randomized controlled trials in Brazil, South Africa, and the UK which triggered a temporary pause in enrollment. One case was reported 14 days after booster vaccination and one case 10 days after a first vaccination. Additionally Sing Malhotra et al reported a case of a 36 yo male who received the ChAdOx1n CoV-19 vaccine and on the 8<sup>th</sup> day post vaccination presented with abnormal sensations in both lower limbs. MRI on the 13<sup>th</sup> day post vaccination showed a T2-hyperintense lesion in the dorsal aspect of the spinal cord at the C6 and C7 vertebral levels. The patient responded well to IV methylprednisolone 1G/day for 5 days.

As of April 27, 2021, VAERS has 133,321 reports for all adverse events after COVID-19 vaccine. Of these, 45 (0.03%) are reports of transverse myelitis. The ages of the patients with transverse myelitis ranged from 27 to 88 years with a median of 62 years, with symptoms beginning within 14 days for 71% of the reports. Twenty one of the reports were after the Moderna vaccine, 19 were after the Pfizer vaccine, and 5 occurred after the Janssen vaccine. This case report is consistent with those in VAERS given the patient is 63 yo and the

onset was within 14 days of the second vaccine dose. In this case, no other etiology for lumbar spine myelitis was identified and the temporal association to the second dose of the Moderna vaccine was clear. Transverse myelitis is a very rare event in the population and has been reported after other types of vaccines (e.g. hepatitis B virus, measles-mumps-rubella, diphtheria-tetanus-pertussis) but the reports describe very few cases. Baxter et al described 7 cases after nearly 64 million doses of vaccine. Agmon-Levin et al found 37 cases reported in the literature between 1970-2009. Therefore, serious adverse events occurring soon after COVID-19 vaccination should be reported to the VAERS system and formally assessed as a potential safety signal with communication to health care providers. Given that myelitis has been associated with both COVID-19 infection and with COVID-19 vaccination, there may be an immunologic reaction to the spike protein that is misdirected to the spinal cord in these patients.

Ethics approval and consent to participate - Not applicable

Consent for publication - Informed consent obtained.

Competing interests - The author declares no competing interests.

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- M. Roy First, MD, Sef Kurstjens, MD, PhD, and Kenneth Johnson, Pharm.D., for review and editorial assistance with the case report.

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## REVIEW ARTICLE



Check for updates

# Neurological side effects of SARS-CoV-2 vaccinations

## Josef Finsterer

Klinik Landstrasse, Vienna, Austria

#### Correspondence

Josef Finsterer, Klinik Landstrasse, Postfach 20, Vienna 1180, Austria. Email: fifigs1@yahoo.de

SARS-CoV-2 and adverse reactions to SARS-CoV-2 vaccinations show a tropism for neuronal structures and tissues. This narrative review was conducted to collect and discuss published data about neurological side effects of SARS-CoV-2 vaccines in order to discover type, frequency, treatment, and outcome of these side effects. The most frequent neurological side effects of SARS-CoV-2 vaccines are headache, Guillain-Barre syndrome (GBS), venous sinus thrombosis (VST), and transverse myelitis. Other neurological side effects occur in a much lower frequency. Neurological side effects occur with any of the approved vaccines but VST particularly occurs after vaccination with vector-based vaccines. Treatment of these side effects is not at variance from similar conditions due to other causes. The worst outcome of these side effects is associated with VST, why it should not be missed and treated appropriately in due time. In conclusion, safety concerns against SARS-CoV-2 vaccines are backed by an increasing number of studies reporting neurological side effects. The most frequent of them are headache, GBS, VST, and transverse myelitis. Healthcare professionals, particularly neurologists involved in the management of patients having undergone SARS-CoV-2 vaccinations, should be aware of these side effects and should stay vigilant to recognize them early and treat them adequately.

## KEYWORDS

adverse reaction, COVID-19, neuropathy, SARS-CoV-2, side effect, vaccination

## INTRODUCTION

Though SARS-CoV-2 vaccinations are usually sold as well tolerated. they can cause mild-to-severe side effects in some patients. Since the benefit for the global population outweighs these adverse reactions, and since political and pecuniary interests create the image of a "safe and indispensable" tool against the currently dominant global burden, there is only moderate reporting and discussion about them.<sup>2</sup> There is also an anti-vaccine movement in the world nowadays that also contributes to the biased assessment of these adverse effects. Usually, single case reports, case series, or registration studies report these side effects but systematic, transnational, multicenter, postmarketing investigations on this matter are infrequently done. This shortage of published information about type, frequency, severity, and therapeutic management of vaccination-related side effects is

in contradiction to the daily experience of healthcare workers and affected probands, and may contribute to the individual or organized resistance and reservations against the vaccination from parts of the populations, the only moderate effect of vaccination campaigns, and the tendency to introduce compulsory vaccination.<sup>3</sup>

Neurological side effects to SARS-CoV-2 vaccinations are usually mild, of short duration, self-limiting, and ambulatorily manageable. However, in some cases, these side effects are severe and require hospitalization or even admission to an intensive care unit (ICU).4 Only, rarely these side effects can be fatal. 5 Since the virus and the adverse reactions to vaccinations show a tropism for neuronal structures and tissues this narrative review about the neurological side effects was conducted to collect and discuss published data in order to discover type, frequency, treatment, and outcome of these side effects and to eventually discover if certain patients are prone to

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experience them, if they can be prevented, and which therapeutic management is the most appropriate.

## 2 | METHODS

A literature search in the databases PubMed and Google Scholar using the search terms "vaccination", "SARS-CoV-2," "anti-covid vaccination," "immunisation" in combination with the terms "side effects," "adverse reactions," "neurological," "brain," and "nerves" was conducted for the period December 2020 to September 2021. Initially detected were 62 titles in PubMed and 4580 in Google Scholar. Most of them were excluded already after having read the title or the abstract. Included were only original articles which convincingly reported a neurological adverse reaction. Excluded were articles which were repetitive and articles in which a causal relation between the vaccination and the complication could not be convincingly established. Additionally, reference lists were checked for further articles meeting the search criteria. All approved vaccines were considered. Lastly, 28 papers were included.

## 3 | RESULTS

Neurological side effects of SARS-CoV-2 vaccines collected from the literature are listed in Table 1. They include headache, Guillain-Barre syndrome (GBS), venous sinus thrombosis (VST), transverse myelitis, facial nerve palsy, small fiber neuropathy, newly developing multiple sclerosis, and some others that have been reported only in a few patients (Table 1). By far the most frequent of the neurological adverse reactions to SARS-CoV-2 vaccinations is headache, followed by GBS, VST, and myelitis (Table 1). Neurological side effects develop after any of the commercially available anti-COVID-19 vaccines but myelitis predominantly after application of the AstraZeneca vaccine (AZV).

In a recent multinational, multicenter observational cohort study by means of a standardized questionnaire, among inhabitants of residential care homes of the elderly and patients from hospitals, 2349 patients reported headache after vaccination with the Pfizer vaccine. 6 Headache started on the average 18 h after the shot and lasted on the average for 14 h.6 In two thirds of these cases, headache manifested with a single episode. In 38% and 32% of the cases, headache occurred in a frontal or temporal distribution, respectively.6 Headache was characterized as dull in 40%, and intensity was very severe in 8.2%, severe in 32.1%, and moderate in 46.2%.6 According to one of the registration studies for the AZV, headache was the most frequent neurological complication of SARS-CoV-2 vaccinations without providing an exact figure of the headache frequency.7 In a study of 1480 healthcare workers from Malta undergoing vaccination with the Pfizer vaccine, 655 probands reported headache after the first or second shot.<sup>8</sup> Several other studies evaluated the frequency of side effects, why the true figure about headache frequency probably exceeds that provided in Table 1.

In a recent review about Guillain-Barre syndrome (GBS) following a SARS-CoV-2 vaccination, 19 cases were collected as per the end of July 2021.<sup>4</sup> Fifteen patients had received the AZV, four patients the Pfizer vaccine, and 2 the Johnson & Johnson vaccine.<sup>4</sup> In six of these patients, respiratory muscles were involved why they required mechanical ventilation. Only in a single patient was complete recovery achieved until the last follow-up under standard GBS therapies.<sup>4</sup> All other patients in whom the outcome was reported achieved only incomplete recovery. One of the 19 patients had a history of a previous GBS from which he had completely recovered.<sup>1</sup> Recently, a further case with post-vaccination GBS after having been vaccinated with the AZV has been reported.<sup>9</sup> This patient remained bedridden by the 4-week follow-up.<sup>9</sup>

Thrombotic events in cerebral veins are another neurological complication of SARS-CoV-2 vaccinations. VST has been most frequently reported after vaccinations with the AZV. <sup>10</sup> In most cases, VST occurred already after the first shot. Patients in whom VST was attributed to immune-mediated thrombocytopenia received IVIGs or steroids in addition to heparin. <sup>10</sup> Notably, sixty-two patients with post-SARS-CoV-2 vaccination VST died. <sup>10</sup> In the study with the highest number of patients experiencing a VST after shots with the AZV (n = 187), Pfizer (n = 25), or Moderna (n = 1) vaccine, concomitant thrombocytopenia was found only among those having received the AZV. <sup>11</sup> Of the 117 patients with a reported outcome, 44 (38%) in the AZV group had died, compared to 20% in the Pfizer/Moderna group. <sup>11</sup>

The fourth most frequent neurological side effect of SARS-CoV-2 vaccinations is transverse myelitis, which has been reported in 11 patients so far (Table 1). In seven of them, transverse myelitis occurred after application of the AZV (Table 1). In the patient having received the Johnson & Johnson vaccine, transverse myelitis was associated with facial palsy. The patient who developed transverse myelitis after vaccination with the Moderna vaccine, additionally had vitamin-B12 deficiency, which may have contributed to the development of the neurological compromise. The same statement of the neurological compromise.

Several other neurological abnormalities occurred after SARS-CoV-2 vaccinations, but the number of reported cases was below 5 (Table 1). Facial palsy, for example, was reported in four patients and usually occurred unilaterally but occasionally bilaterally. 14,15 Among the cases so far reported, facial palsy occurred as an isolated condition without being associated with other neurological compromise. We did not include "myalgia" as it is only a symptom and usually the underlying diagnosis is unknown.

## 4 | DISCUSSION

This narrative review shows that the most frequent neurological side effects of SARS-CoV-2 vaccines are headache, GBS, VST, and transverse myelitis. Other neurological side effects occur in a very low frequency as expressed by a number of published cases <5. The worst outcome of these side effects is associated with VST, why it should not be missed and treated appropriately in due time.

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Neurologica

TABLE 1 Neurological side effects of SARS-CoV-2 vaccines as per the end of September 2021

NAR	NOP	Vaccine type	Outcome	Reference
Headache	3051	AZV, Pfizer	CR	6,7
GBS	389	AZV, Pfizer, JJ	CR, PR	4,9
VST	312	vector-based, AZB, JJ	nr	16,17
Transverse myelitis	11	AZV, Moderna, JJ Sinovac	PR, CR, nr	12,13,19-26
Facial nerve palsy	4	AZV, Pfizer	CR, PR	15,20,27
		Bharat Biotech		14
Small fiber neuropathy	3	Moderna, Pfizer	CRm PR, nr	28
Autoimmune encephalitis	3	ATV	PR	29
RCVS	2	Moderna	CR	[Personal communication]
Multiple sclerosis	2	Moderna, Pfizer	nr	30
Neuromyelitis optica	2	Pfizer, vector based	CR	30,31
Ischemic stroke	1	AZV	PR	20
ICB	1	Pfizer	PR	32
Tolosa-Hunt syndrome	1	nr	PR	33
Hypophysitis	1	Moderna	CR	34
Epilepsy	1	Moderna	CR	35
Hyperactive encephalopathy	1	Moderna	PR	36
ADEM	1	Pfizer	PR	37

Abbreviations: ADEM, acute disseminated encephalomyelitis; AZV, AstraZeneca vaccine; CR, complete recovery; ICB, intracerebral bleeding; JJ, Johnson & Johnson vaccine; NAR, neurological adverse reaction; nr, not reported; PR, partial recovery; RCVS, reversible cerebral vasoconstriction syndrome: VST, venous sinus thrombosis.

Headache is by far the most frequent neurological side effect of SARS-CoV-2 vaccinations and occurs with any of the approved vaccines. In the majority of cases, headache starts within a few hours after the vaccination and resolves spontaneously within 48 h. However, a subacute type of headache has been delineated which occurs on the average 8 days after the shot and is frequently associated with VST. The cause of headache after SARS-CoV-2 vaccinations remains speculative but generally, it can be tension-type headache due to stress, due to intracerebral bleeding (ICB) or subarachnoid bleeding (SAB), due to vasospasms like in SAB or reversible, cerebral vasoconstriction syndrome (RCVS), or due to VST. As VST is frequently associated with ischemic stroke, ICB, or SAB, headache may be multi-causal in patients experiencing VST. Thunderclap headache typically occurs with SAB or RCVS.

The pathophysiological mechanism of GBS post-SARS-CoV-2 vaccination is poorly understood but molecular mimicry is regarded as the most plausible concept. Considering that SARS-CoV-2 vaccines induce immunization against the spike protein and that the SARS-CoV-2 spike protein can bind to sialic acid-containing glycoprotein and gangliosides on cell surfaces, an antibody cross-reaction may be the most likely causal link between GBS and immunization to SARS-CoV-2.<sup>9</sup>

Venous sinus thrombosis is the third most frequent complication of SARS-CoV-2 vaccinations and explained by hypercoagulability. Hypercoagulability after a SARS-CoV-2 vaccination has been attributed to activation of platelets by the virus or to enhancement of the coagulation system by indirect activation of endothelial cells by SARS-CoV-2, shifting endothelium from an anti-thrombotic to a prothrombotic state, and by direct activation of complement pathways, promoting thrombin generation.<sup>18</sup>

A limitation of the review is that not all patients experiencing side effect may have been included. Patients with side effects may have been missed simply because the side effects were mild and not worth to be reported. It is also conceivable that not each patient with a presumed side effect was also published, as publishing is time-consuming and increasingly expensive.

In conclusion, this study shows that safety concerns against SARS-CoV-2 vaccines are backed by an increasing number of studies reporting neurological side effects. The most frequent of them are headache, GBS, VST, and transverse myelitis. Healthcare professionals, particularly neurologists, involved in the management of patients having undergone SARS-CoV-2 vaccinations, should be aware of these side effects and should stay vigilant to recognize them early and treat them efficiently.



## ACKNOWLEDGMENT

None.

## CONFLICT OF INTEREST

None.

## **AUTHOR CONTRIBUTIONS**

JF: literature search, discussion, first draft, critical comments, and final approval.

## ETHICAL APPROVAL

The study was approved by the institutional review board.

#### INFORMED CONSENT

Informed consent was obtained.

## PEER REVIEW

The peer review history for this article is available at https://publo ns.com/publon/10.1111/ane.13550.

## DATA AVAILABILITY STATEMENT

All data used for the review are available from the corresponding author.

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From:	b6	
Sent:	9/7/2021 6:05:13 AM	
То:	Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Adı (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d7403	
CC:	Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Ad (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655	
Subject:	Re: WHO scale 2	tJ
71		
Thank you.	u. I will call my doc in the morning.	
And thanks	ks for the ideas for the survey. I think we can manage those questi	ons. ;) Stay tuned!
Alsoran a	across this study. Was interesting	
	know all of the goings-on already so you probably already have th	is.)
	nk.springer.com/article/10.1007/s00415-021-10780- =IwAR1WIozzELtGyD_DttkLNZFMcl3yW6iBW9C0v8uRyiYtTt	ulzPvKVPE vVko
/ : IDCIIG=N	-IWAKTWIOZZEELGYD_DUKENZFINICISYWOIBW9COVOURYTTU	UIZKVKVFL_X1KU
b6	·	
	i	
On	On Sep 4, 2021, at 7:08 PM, Nath, Avindra (NIH/NINDS) [E]	<b>b6</b> wrote:
	,	
	Dear b6	
	/ery nice work! The survey is very informative. You have asked all t hat several patients are getting better over a period of time. So it w	
	ime period is the improvement occurring. And those that have resi	
	o what they experienced when the symptoms began. This could be	
and	and/or severity of symptoms.	
Sor	forry to hear that your symptoms have recurred.	b6
	\	
Avi	AVÍ	
Fro	rom: b6	
	Date: Thursday, September 2, 2021 at 3:48 PM	
То	o: Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b>	Nath, Avindra (NIH/NINDS) [E]
<u> </u>	b6	
Sul	Subject: RE: WHO scale 2	
Wo	Norking Attachments	
	VHO scale	
Syr	Symptoms Survey	
·		
Ser	ent from <u>Mail</u> for Windows	
Fro	rom: b6	
	Sent: Sunday, August 22, 2021 10:15 PM	

Subject: Re: WHO scale 2
b6
<u> </u>
My brain vibration sensations got really bad and I got suuuuper depressed and ended up full on sobbing every day until I stopped. b6 Felt much better after I stopped.
I went downhilll the week of july 20th. I remember things just going downhill from there.
I continued to go downhill after my call with you both, My husband looked at me last week (still going
downhill and bedridden again, worse than when I went to the NIH) and told me to b6
b6 It definitely made enough of a difference to where I am out of bed again.
in desirately made enough of a unit of the order of an out of the desirate of the order of the o
My new favorite thing is b6 Looks like the last couple weeks things leveled off
<image001.jpg></image001.jpg>
b6
On Aug 20, 2021, at 7:37 AM, Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b>
wrote:
HI b6
Thank you for updating me about your symptoms. Hopefully you can b6
<u>b6</u>
I also would like to ask you is it possible you send me a couple of pieces of information
about your disease course
<b>b</b> 6
Thank you
mank you
Farinaz
From: b6
Sent: Wednesday, August 18, 2021 11:31 AM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: WHO scale 2
Thank you Dr Safavi.
You are SO smart. :)
I got way way sicker after meeting with you both my husband recommended I b6
b6
<b>b6</b> Hopeful that helps too.

To: Safavi, Farinaz (NIH/NINDS) [E]

b6	
On Aug 18, 2021, at 9:19	AM, Safavi, Farinaz (NIH/NINDS) [E] wrote:
Thank you very much for email regarding	updated scale.I think I missed answering <b>b6</b>
	<b>b6</b>
Please let me know if you Best Farinaz	u have any questions or concerns.
Farinaz Safavi MD, PhD Division of Neuroimmun NINDS, NIH, Bethesda, N	
From: b6 Sent: Saturday, August 1	4, 2021 12:24 PM

yet to

Updates to my scores

