#0000000000000000000000000000000000000		
From:	Gustafson, Lindsey (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP	
Country	(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5BCC895932D544E4A2F36EB6F9388ADB- <b>b6</b>	
Sent: To:	6/7/2021 7:14:52 PM <b>b6</b>	
10.	<u>L</u>	
Subject:	NIH Post COVID Vaccine Research	
Start:	6/10/2021 5:00:00 PM	
End:	6/10/2021 5:30:00 PM	
Show Time As:	Busy	
Recurrence:	(none)	
5		
Required Attendees:	b6	
Microsc	oft Teams meeting	
IVIICIOSC	increams inceang	
	computer or mobile app	
Click here to	join the meeting	
Or call in (au	idio only)	
+1 240-800-7	7959 <b>b6</b> United States, Bethesda	
Phone Confe	Phone Conference ID: <b>b6</b>	
	Find a local number   Reset PIN	
Lagra More I	Meeting options	
reministric	wiecung Opiono	

From:	Gustafson, Lindsey (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5BCC895932D544E4A2F36EB6F9388ADB- b6		
Sent:	5/19/2021 9:02:45 PM		
To:	h.C		
CC:	<b>b6</b>		
Subject:	NIH Post COVID Vaccination Interview		
Start:	5/20/2021 6:30:00 PM		
End:	5/20/2021 7:30:00 PM		
Show Time As:	Busy		
Recurrence:	(none)		
Attendees:			
Optional	b6		
Attendees:			
NIH Post CC	OVID Vaccine Interview/Screening for May 20, 2021 at 14:30 EST over MS Teams with <b>b6</b>		
b6			
Microso	ft Teams meeting		
100	computer or mobile app join the meeting		
Or call in (au	dio only)		
	959 <b>b6</b> United States, Bethesda		
Phone Conference ID: b6			
Find a local n	umber   Reset PIN		
Learn More	Meeting options		

From:	Gustafson, Lindsey (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP			
	(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5BCC895932D544E4A2F36EB6F9388ADB <b>b6</b>			
Sent:	5/19/2021 9:07:11 PM			
To:	Box Tolomodicing Appointment Schoduling			
Subject:	Subject: Re: Telemedicine Appointment Scheduling			
b	6			
	ou for your quick response. I have emailed you an invitation to join the meeting in MS Teams tomorrow. Please now if you did not receive the invitation.			
I look fo	rward to meeting with you tomorrow at 11:30 PCT over MS Teams.			
Thank y	ou,			
Lindsey	Gustafson, FNP-BC, MSN, CCRN, CNRN			
Nurse P	ractitioner for the Neurology Consult Service			
Nationa	l Institute of Neurological Disorders and Stroke			
	er Drive, Building 10/2A23			
Bethese	la, Maryland 20814			
Office:	b6 b6			
Email:[				
From:	b6			
	Vednesday, May 19, 2021 at 4:14 PM			
	stafson, Lindsey (NIH/NINDS) [E] <b>b6</b>			
Subjec	:: Re: Telemedicine Appointment Scheduling			
Tomorr	ow works at 1130 PCT. thank you			
Sent fro	m my iPhone			
	On May 19, 2021, at 12:40 PM, Gustafson, Lindsey (NIH/NINDS) [E] <b>b6</b> wrote:			
	b6			
	Does Thursday (May 20, 2021) at 14:30 EST (11:30 am pacific time) or Monday (May 24, 2021) at 14:00 EST (11:00 am pacific time) work best for you? Please let me know and I will send you an MS Teams invitation.			
	I look forward to meeting with you.			
	Thank you,			
	Lee			
	Lindsey Gustafson, FNP-BC, MSN, CCRN, CNRN			
	Nurse Practitioner for the Neurology Consult Service			
	National Institute of Neurological Disorders and Stroke			

10 Center Drive, Building 10/2A23	
Bethesda, Maryland 20814	
Office: b6	
Email: b6	
From: b6	
Date: Wednesday, May 19, 2021 at 3:14 PM	
To: Gustafson, Lindsey (NIH/NINDS) [E] <u>b6</u>	
Subject: Re: Telemedicine Appointment Scheduling	
Hi yes, I can do most days after 830am pacific time.	
Sent from my iPhone	
On May 19, 2021, at 10:47 AM, Gustafson, Lindsey (NIH/NINDS) [E]	
b6   wrote:	
\(\frac{1}{2}\)	
, market	
<u> </u>	
Good afternoon. My name is Lee and I am a nurse practitioner at the National Institutes	
of Health who works with Dr. Safavi on the post-COVID vaccine protocol.	
Dr. Safavi forwarded me your email to inquire if you would like to make a telemedicine	
appointment for later this week or next week to discuss your post-COVID vaccine	
symptoms. Availability is best from noon until 4pm EST on Monday, Wednesday,	
Thursdays, and Fridays. Please let me know what dates/times work best for you.	
I look forward to meeting you and appreciate your willingness to contribute to the post-	
COVID vaccine protocol research.	
Thank you,	
Lee	
b6	

From: Sent:	Safavi, Farinaz (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=94807CE146E045D4B61655DA26A0C246- b6 5/18/2021 11:35:12 PM		
То:	Gustafson, Lindsey (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bcc895932d544e4a2f36eb6f9388adb b6		
Subject:	Re: Treatment for Post Vaccine Patient		
Hi <b>b6</b>			
	orry about what you have been going through. I understand you are frustrated and distressed with tion and we are doing our best to help as much as possible.		
I cc our grea	t NP(Lee) to schedule a televisit with you in a convenient time.		
	d Amanda your medical release form and signed consent? without those papeworks I even can not medical records.		
Please let me	e know when you hear back from your neurologist to find out the best way forward.		
Best Regard Farinaz Safa			
Subject: Re: 7	rinaz (NIH/NINDS) [E] <b>b6</b> reatment for Post Vaccine Patient		
Sent from m	y iPhone		
On N	May 18, 2021, at 11:34 AM, Wiebold, Amanda (NIH/NINDS) [E]  b6 wrote:		
Hi Dı	. Safavi,		
	I spoke to <b>b6</b> this afternoon (copied on this email) and she has some outstanding questions for you regarding follow up with her local neurologist and treatment options.		
Than	ks,		
Resea NIND 10 Ce Bethe	unda Wiebold, BSN, RN, CNRN  Irch Nurse Specialist S Section of Infections of the Nervous System Inter Drive, Building 10/7C107, MSC 1430 Ischa, Maryland 20892 Ischa D6		

Cell: **b6**Fax: 301-480-5594

Email: **b6** 

From:	b6	
Sent:	6/7/2021 8:30:17 PM	
То:	Gustafson, Lindsey (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bcc895932d544e4a2f36eb6f9388adb <b>b6</b>	
Subject:	Accepted: NIH Post COVID Vaccine Research	
Start:	6/10/2021 5:00:00 PM	
End:	6/10/2021 5:30:00 PM	
Show Time As:	ow Time As: Busy	
Recurrence:	(none)	
recipient(s) a or distributio	ity Notice: This e-mail message, including any attachments, is for the sole use of the intended and may contain confidential and privileged information. Any unauthorized review, use, disclosure in is prohibited. If you are not the intended recipient, please contact the sender by reply e-mail and opies of the original message.	

From:	66 6/17/2021 12:26:00 PM
Sent: To:	6/17/2021 12:36:00 PM Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
10.	(FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 b6 ; Gustafson, Lindsey
	(NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bcc895932d544e4a2f36eb6f9388adb b6
Subject:	RE: labs
Thanks for	asking –
	b6
	b6
	<b>b6</b>
	absolutely experience an increase in symptoms when I am more physically active. Even something like a an trigger symptoms.
Thank you	so much,
b6	
F	vi, Farinaz (NIH/NINDS) [E] <b>b6</b>
From: Sara	vi, Farinaz (NIH/NINDS) [E] [
	son, Lindsey (NIH/NINDS) [E] <b>b6</b>
l Gustan	b6
Subject: Re	
Hi b6	The results What treatments have you taken for your illiness?
thanks	r the results.What treatments have you taken for your illness?
HIGHNS	
Farinaz	
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
From:	b6
Sent: Thur	sday, June 17, 2021 1:08:13 AM

To: Safavi, Farinaz (NIH/NINDS) [E] b6 Gustafson, Lindsey (NIH/NINDS) [E]
Subject: labs
Julyett. laus
Hello Dr. Safavi and Gustafson,
As promised, here is the summary of my labs for the past several months. As a guick timeline, my first moderna vaccine
<b>b6</b>
DO
I have also sent these documents through the confidential NIH portal.
Thank you so much,
b6
<b>b6</b>
NU
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destroy all copies of the original message.
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recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure
or distribution is prohibited. If you are not the intended recipient, please contact the sender by reply e-mail and destroy all copies of the original message.

From: b6 Sent: 6/7/2021 2:19:53 PM To: Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 b6 Gustafson, Lindsey (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bcc895932d544e4a2f36eb6f9388adb b6 Subject: RE: Inquiry re Post COVID vaccine reactions  Wonderful. Thank you so much. I will discuss with Lee. I really appreciate your help.  b6			
	, Farinaz (NIH/NINDS) [E] <b>b6</b> June 04, 2021 12:58 PM		
To:	b6 Gustafson, Lindsey (NIH/NINDS) [E]		
	b6		
Subject: Re:	Inquiry re Post COVID vaccine reactions		
Hi b6 I am out of town for next couple of weeks.I cc our great nurse practitioner Lee who has been seeing post vaccine complications with ne.Hopefully she can set a time with you and perform a televisit to help us having a better idea about your condition and we can discuss when I will be back. Hope it helps			
Farinaz			
From:	b6		
857	June 4, 2021 9:22:04 PM		
To: Safavi, Farinaz (NIH/NINDS) [E] b6 Subject: RE: Inquiry re Post COVID vaccine reactions			
Subject. NL.	inquiry re rost covid vaccine reactions		
Hi again, Dr.	Safavi,		
Unfortunately, it seems my neurologists are not responding to my request to collaborate with you.  Are there any other options we could explore? I would be willing and able to work with you directly or one of your colleagues if this is a possibility.			
Additionally, connection.	my primary provider <b>b6</b> is quite interested in collaborating and I hope we can make that		
Thank you so	o much,		
b6			
From: Safavi	, Farinaz (NIH/NINDS) [E] <b>b6</b>		
	ny, June 01, 2021 8:20 AM		
То:	b6		
Subject: Re:	Inquiry re Post COVID vaccine reactions		

Hi b6 I am sorry to hear about your symptoms.I would be happy understanding about vaccine neurological adverse reaction Please share my email address with your neurologist and Best Farinaz	ons.
From: b6	
Sent: Tuesday, June 1, 2021 5:00:50 PM	
To: Safavi, Farinaz (NIH/NINDS) [E] b6	
Subject: Inquiry re Post COVID vaccine reactions	
Halla Da Cafari	
Hello Dr. Safavi,	
I received your name through a resource group with other phy- post-COVID vaccine reactions. I have heard such wonderful thi the pieces together on this set of symptoms. I wonder if you w panel? I would, of course, be willing to participate in follow-up well.	ings about your responsiveness, and your ability to put vould consider including me in your patient/participant
I have had severe neurological symptoms since my second Mod	derna vaccine on <b>b6</b>
	the best route of treatment and maintain hope for
recovery. While I believe my doctors here have the best intent issue at hand. This is most likely due to just how new this is to be happy to collaborate, if appropriate.	
I would so appreciate your consideration. I feel quite desperat reassured that you are the right person to be connecting with. but of course am happy to provide more information as needed	I am including the "short-list" of my symptoms below,
Thank you so much,  b6	

Symptoms (onset within 48 hours of second vaccine):

Involuntary muscle movements (nocturnal) best described as "Parkinson's-like" Intense tremors (nocturnal) Insomnia related to the above

Widespread muscle fasciculations
Weakness
Intense fatigue
Neuralgias and parasthesias
Pin prick or hot poker sensations on extremities
Periods of reactive hyper- and hypoglycemia (seems to have resolved)
Periods of increased salivation/difficulty swallowing (intermittent)

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From: Sent:	<b>b6</b> 6/7/2021 8:31:38 PM
To: Subject:	Gustafson, Lindsey (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bcc895932d544e4a2f36eb6f9388adb <b>b6</b> RE: Inquiry re Post COVID vaccine reactions
Thank you s	o much! I just accepted the MS teams invite and look forward to meeting you then.
	afson, Lindsey (NIH/NINDS) [E] <b>b6</b> ay, June 07, 2021 2:13 PM
To: Subject: Re:	b6 Inquiry re Post COVID vaccine reactions
b6	
mandates th	or your follow-up. 1pm on Thursday (6/10) will work great. I will send you a MS teams invitation today. NIH nat we use this platform (MS Teams) for all our telemedicine visits to protect your privacy. Please let me do not receive the link.
I look forwa	rd to meeting with you on Thursday (6/10) at 1pm.
Thank you, Lee	
Nurse Practi National Ins 10 Center D	tafson, FNP-BC, MSN, CCRN, CNRN itioner for the Neurology Consult Service titute of Neurological Disorders and Stroke rive, Building 10/2A23 flaryland 20814 b6 b6
From:	b6
To: Gustafs	day, June 7, 2021 at 10:19 AM son, Lindsey (NIH/NINDS) [E] b6 Safavi, Farinaz (NIH/NINDS) [E]
Subject: RE	: Inquiry re Post COVID vaccine reactions
	o much, Lee – / much appreciate that.
Wed 6/9 7	ollowing times available on those days: am – 10am Central time 10am – 2pm Central
Please let m Thanks agai <b>b6</b>	ne know if you need more options – happy to accommodate your schedule.  n!



From: Gustafson, Lindsey (NIH/NINDS) [E]	b6	
<b>Sent:</b> Friday, June 04, 2021 3:32 PM		
To: Safavi, Farinaz (NIH/NINDS) [E]	b6	
<b>To:</b> Safavi, Farinaz (NIH/NINDS) [E] <b>Subject:</b> RE: Inquiry re Post COVID vaccine react	ions	
Hello b6		
telehealth visit to see you next week. Do you ha	OVID vaccine complication research. I would be happy to set up a ve availability on Wednesday (6/9) or Thursday afternoon (6/10)? I am know what time works best for you and I would be happy to send a MS	
Thank you,		
Lee Gustafson		
NINDS Nurse Practitioner		
From: Safavi, Farinaz (NIH/NINDS) [E] Sent: Friday, June 4, 2021 1:58 PM		
To:   b6	Gustafson, Lindsey (NIH/NINDS) [E]	
b6		
Subject: Re: Inquiry re Post COVID vaccine react	ions	
	cc our great nurse practitioner Lee who has been seeing post can set a time with you and perform a televisit to help us having a discuss when I will be back.	
Farinaz		

From: b6
<b>Sent:</b> Friday, June 4, 2021 9:22:04 PM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: RE: Inquiry re Post COVID vaccine reactions
Hi again, Dr. Safavi,
Unfortunately, it seems my neurologists are not responding to my request to collaborate with you. Are there any other options we could explore? I would be willing and able to work with you directly or one of your colleagues if this is a possibility.
Additionally, my primary provider <b>b6</b> is quite interested in collaborating and I hope we can make that connection.
Thank you so much,  b6
From: Safavi, Farinaz (NIH/NINDS) [E] b6
Sent: Tuesday, June 01, 2021 8:20 AM  To: b6
Subject: Re: Inquiry re Post COVID vaccine reactions
Hi b6 I am sorry to hear about your symptoms.I would be happy to speak with your providers and share our understanding about vaccine neurological adverse reactions. Please share my email address with your neurologist and we can connect. Best
Farinaz
From: b6
<b>Sent:</b> Tuesday, June 1, 2021 5:00:50 PM
To: Safavi, Farinaz (NIH/NINDS) [E] b6 Subject: Inquiry re Post COVID vaccine reactions
Hello Dr. Safavi,
I received your name through a resource group with other physicians and individuals, some of whom you've treated for post-COVID vaccine reactions. I have heard such wonderful things about your responsiveness, and your ability to put the pieces together on this set of symptoms. I wonder if you would consider including me in your patient/participant panel? I would, of course, be willing to participate in follow-up and provide all information needed for your work as well.
I have had severe neurological symptoms since my second Moderna vaccine on <b>b6</b>
b6 still attempting to figure out the best route of treatment and maintain hope for recovery. While I believe my doctors here have the best intentions, the evaluation thus far has failed to fully capture the issue at hand. This is most likely due to just how new this is to all of us. I am confident that my existing providers would be happy to collaborate, if appropriate.

I would so appreciate your consideration. I feel quite desperate to find solutions for these symptoms, and have been reassured that you are the right person to be connecting with. I am including the "short-list" of my symptoms below, but of course am happy to provide more information as needed.

Thank you so much,  b6
b6
Symptoms (onset within 48 hours of second vaccine): Involuntary muscle movements (nocturnal) best described as "Parkinson's-like" Intense tremors (nocturnal) Insomnia related to the above Widespread muscle fasciculations Weakness Intense fatigue Neuralgias and parasthesias Pin prick or hot poker sensations on extremities Periods of reactive hyper- and hypoglycemia (seems to have resolved) Periods of increased salivation/difficulty swallowing (intermittent)
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From:	b6
Sent:	6/16/2021 8:38:13 PM
То:	Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 b6 Gustafson, Lindsey (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bcc895932d544e4a2f36eb6f9388adb b6
Subject:	labs
Attachments:	<b>b6</b>
	here is the summary of my labs for the past several months. As a quick timeline, my first moderna vaccine
As promised,	here is the summary of my labs for the past several months. As a quick timeline, my first moderna vaccine
	DO
T. I	nt these documents through the confidential NIH portal.
I have also se	The stresse descention in a defit the serimaential ritin portain
Thank you so	
Thank you so	

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**b6** 





From: Sent: To: Subject:	Walitt, Brian (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5B9339AB4CD1422AAF4669C64CA85914 b6 1/13/2022 3:12:34 PM Gavin, Angelique (NIH/NINDS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6e97392e947e4f7ebb17eeb8ac87c5d5 b6 RE: Need current NIH Director's email address-Re: Tomorrow 9am will work- will email if I am up all night tonight-Re: Status of care for Pfizer covid vaccine brain, etc injuries- Fwd: [EXTERNAL] Status? Re: Covid vaccine brain injury-are there studies y
b6	
Here are the	contacts for all of the offices at NIH: Contacts   National Institutes of Health (NIH)
patrice.allen-	In tell, the contact for the Office of the Director — Executive Secretariat is Patrice Allen-Gifford: <a href="mailto:gifford@nih.gov">gifford@nih.gov</a> be the person I would reach out to if I wanted to contact the NIH Director.
Thanks,	
Brian	
To: Gavin, And Cc: Walitt, Bri Subject: Need	b6 y, January 13, 2022 9:00 AM gelique (NIH/NINDS) [C] b6 an (NIH/NINDS) [E] b6 I current NIH Director's email address-Re: Tomorrow 9am will work- will email if I am up all night tonight-care for Pfizer covid vaccine brain, etc injuries- Fwd: [EXTERNAL] Status? Re: Covid vaccine brain injury- are yo
	email originated from outside of the organization. Do not click links or open attachments unless you recognize the confident the content is safe.
Angelique,	
Could you ple	ase get me the NIH Director's email address. I did not hear from anyone yesterday as I requested.
Thank you.	
b6	
	1, 2022, 2:59 PM <b>b6</b> wrote: too. And stay safe!
On Tue, Jan :	11, 2022, 2:55 PM Gavin, Angelique (NIH/NINDS) [C] b6 wrote:
Thank you[	<b>b6</b> Fingers crossed it all works out. Best wishes for a good night's sleep.

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)
(cell)
(301) 480-5368 (efax)
https://clinicaltrials.gov - study number 000089-N
-
From: b6
Sent: Tuesday, January 11, 2022 3:53 PM  To: Gavin, Angelique (NIH/NINDS) [C] b6 Walitt, Brian (NIH/NINDS) [E]
<b>Subject:</b> Tomorrow 9am will work- will email if I am up all night tonight- Re: Status of care for Pfizer covid vaccine
brain, etc injuries- Fwd: [EXTERNAL] Status? Re: Covid vaccine brain injury- are there studies you all are doing? What is being done to help us
being done to help ds
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Tomorrow at 9am EST will work. If I cannot sleep tonight and am not doing well- I have a LOT of trouble sleeping more than 1 or 2 hours at a time and am often up most of the night and just miserable then- I will email y'all and we can reschedule.
The number is b6 Sometimes my phone has issues with incoming calls, so if I don't answer, I will call you right back.
Thanks and hopefully we will talk tomorrow.
Take care-
On Tue, Jan 11, 2022, 2:46 PM Gavin, Angelique (NIH/NINDS) [C] <b>b6</b> wrote:  Hi <b>b6</b>
Dr. Walitt has availability tomorrow, January 12 at 9 am or next week, January 17 a 9 or 10 am Eastern Time. Let me know your preference and a good telephone number for him to call.
Thank you,
Angelique
Angelique Gavin, MS
Clinical Operations Manager
Contractor, PSG
National institutes of Health
10 Center Drive, Building 10
Room 3B19, MSC 1251

Bethesda, MD 20814
b6 phone
301-451-7352-fax
From: b6 Sent: Tuesday, January 11, 2022 3:00 PM
To: Walitt Brian (NIH/NINDS) [F1]
To: Walitt, Brian (NIH/NINDS) [E] b6 Cc: Gavin, Angelique (NIH/NINDS) [C] b6
Subject: Re: Status of care for Pfizer covid vaccine brain, etc injuries- Fwd: [EXTERNAL] Status? Re: Covid vaccine
brain injury- are there studies you all are doing? What is being done to help us? Doctors have no idea
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.
Thank you. And thank you for your prompt response.
mank you. And thank you for your prompt response.
We can try to schedule that- it really depends upon if it is a (relatively) good day for me. You all were on my calendar
for yesterday and I was too sick to follow up. I also have more energy in the morning, but I understand if your schedule isn't open for that this week and appreciate you working me in.
schedule isn't open for that this week and appreciate you working me in.
Let me know what a good time is for you and we can pencil something in, and I can let you know tomorrow if I think I
can make it when I wake up if that will work.
Thanks again-
<u>b6</u>
On Tue, Jan 11, 2022, 1:08 PM Walitt, Brian (NIH/NINDS) [E] <b>b6</b> wrote:
b6

Thanks for your interest and advocacy. Having now worked with patients here at NIH with post-vaccine neuropathic complications and hearing their stories, I can understand your frustration.
I would be happy to find some time to chat with you about your concerns. Let me know if you have time tomorrow evening to schedule a phone call.
Thanks,
Brian
From: b6  Sent: Tuesday, January 11, 2022 1:49 PM  To: Walitt, Brian (NIH/NINDS) [E] b6  Subject: Status of care for Pfizer covid vaccine brain, etc injuries- Fwd: [EXTERNAL] Status? Re: Covid vaccine brain injury- are there studies you all are doing? What is being done to help us? Doctors have no idea
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.
Please let me know why nothing is being done to help all of us who were injured by the Pfizer (and Moderna, etc., if applicable) covid vaccine.
Press reports (that were effectively buried, because I had never heard of vax fog until I was in a panic trying to google what the hell was happening to me 9 hours after my first Pfizer vaccine) state you all have known about this for well over a year now and there isn't even a "survey" (which is ridiculous anyway) up and running?!
Who is responsible for this and when and how is it going to be rectifed and care provided?
Thank you.
b6



Angelique Gavin, MS (Contractor)

Forwarded message			
From: Gavin, Angelique (NIH/NINDS) [C]	b6		
Date: Tue, Jan 11, 2022, 12:29 PM			
Subject: RE: [EXTERNAL] Status? Re: Covid vacc	cine brain injury- are	there studies you all ar	e doing? What is being
done to help us? Doctors have no idea			
To: <b>b6</b>			
(			
<u>,</u>			
Hello <b>b6</b>			
Diaman Malitana hC		h  -  -     +	
Please contact Dr. Brian Walitt at <b>b6</b>	wno snould	be able to respond to	your concerns.
Thank you,			
Thank you,			
Angelique			
, ii.geiique			

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)
https://clinicaltrials.gov - study number 000089-N
From: b6
Sent: Tuesday, January 11, 2022 12:22 PM  To: Gavin, Angelique (NIH/NINDS) [C] b6
<b>Subject:</b> [EXTERNAL] Status? Re: Covid vaccine brain injury- are there studies you all are doing? What is being done to help us? Doctors have no idea
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.
Angelique,
Good morning. I hope you are well. I am checking on the status of this. If it is still not "approved", please get me the contact email of whoever is responsible for not providing care for us and not researching what is happening to us.
This is not ok.

Thanks.
On Thu, Nov 4, 2021, 2:27 PM Gavin, Angelique (NIH/NINDS) [C] <b>b6</b> wrote:
Thank you <b>b6</b> for touching base with us! The study has not yet been approved by our review board. Once underway, I will forward your information to the study team and they will contact you directly. All my best to you.
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)
b6 (cell)
(301) 480-5368 (efax)
<b>b6</b>
https://clinicaltrials.gov - study number 000089-N

From: b6 Sent: Thursday, November 4, 2021 10:55 AM To: Gavin, Angelique (NHI/NINDS) [C] Subject: Re: Covid vaccine brain injury- are there studies you all are doing? What is being done to help us? Doctors have no idea  Sorry I am just getting back to you. I was shocked there is only a survey being done and between being sick and trying to get more help for us with the little energy and brain power I have, this has been delayed.  Of course, please contact me over anything you all are doing for this. I have also been keeping documentation of my symptoms, so hopefully that will help.  When will this all start?  Thanks.  b6  b6	
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Thanks.  b6  b6	my symptoms, so hopefully that will help.
Thanks.  b6  b6	
Thanks.  b6  b6	
Thanks.  b6  b6	
b6 b6	When will this all start?
<b>b6</b>	
<b>b6</b>	
b6 b6	
b6	Thanks.
b6	
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b6	
b6	
	b6
<b>b6</b>	<b>b6</b>

### **b6**

On Thu, Sep 23, 2021, 8:59 AM Gavin, Angelique (NIH/NINDS) [C]	b6	wrote:
Dear b6		
Thank you for your interest in our research. I received your informati	ion from Dr. Avindra	Nath We are
currently developing an online survey system to collect stories about p	eople's complication	s after receiving COVID
vaccines. At this time, if you are willing, we can take your name and co to you when the survey system is completed to see if you are willing to		
looking forward to your reply.		
Thanks,		
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		
<b>L</b> (office)		
b6 (cell)		
(301) 480-5368 (efax)		
b6		
https://clinicaltrials.gov - study number 000089-N		

From: b6	
Sent: Thursday, September 23, 2021 8:40 AM	
To: Nath, Avindra (NIH/NINDS) [E] <b>b6</b>	
Cc: NINDSPostCovid19 < nindspostcovid19@ninds.nih.gov >	
<b>Subject:</b> Re: Covid vaccine brain injury- are there studies you all are doing? What is being done to help us?	
Doctors have no idea	
Thank you!	
On Wed, Sep 22, 2021, 3:14 PM Nath, Avindra (NIH/NINDS) [E] <b>b6</b> wrote:	
Dear <b>b6</b>	
Sorry to hear of your illness. At the moment we are collecting data on such complications. I have copied our research team who can guide you on how to help us do so.	ır
Best wishes.	
Avi	
AVI	
From: b6	
Date: Wednesday Sentember 22, 2021 at 3:10 PM	
To: Nath, Avindra (NIH/NINDS) [E] b6	
Subject: Covid vaccine brain injury- are there studies you all are doing? What is being done to hel	nıı
Doctors have no idea	γu
Doctors have no idea	
Dr. Nath-	
I am writing because I was injured from a first dose of the Pfizer vaccine on <b>b6</b> and have horr	ific
"vax fog" that is not going away and press reports list you as working on this- thank you.	
I received the Pfizer vaccine at 11am and felt great all day- so happy, feeling like I may be somewhat more	fre
the next few weeks, etc and just took it easy and rested all day. I was feeling completely fine- my arm was	
even that sore, as I had been moving it, etc., and at 8pm I was lying down and got up to get a drink and go	
restroom and had such violent dizziness that I didn't stop when I was vertical and ran into the wall, and the	

thought I needed to get on the ground and crawl so I wouldn't fall. And the symptoms expanded and none of them have stopped since.

I have brain fog so bad I cannot remember bank pins I have had for decades- this is taking me forever to write, etc, violent dizziness, constant nauseousness, light and sound sensitivity, ear ringing, low grade fever on and off, no energy, most nights can only sleep 2 or 3 hours at a time waking up all night long, horrible pain including eye pain when trying to work or do anything on digital devices, cannot get upset at all- feel it vestibularly and get really sick, lack of sleep makes me super sick, etc. And I have had 2 slight heart issue incidents and "covid arm" of just 3 small bumps like a blemish that felt weird a few weeks into this that oddly went away in a few hours and made me feel so sick that night I actually thought I might not make it through the night and then my head was a bit better the next day (a lot of the head actual pain went away- pain that is not a headache) so that I could then get out of bed- but it is still very, very VERY bad.

I have to educate my doctors as they haven't even heard of the term- which I hadn't either until I was frantically googling what was happening to me, Pfizer lied to me and told me no one has had these symptoms and to speak to my doctor and the FDA and CDC have been zero help, and are part of the problem as usual. How are our local doctors supposed to help us if Pfizer, etc and the FDA and CDC won't even admit this is happening, so the doctors cannot get any info?!

The one doctor I do trust wants to see me in person vs on video, but being in the covid fire that is Texas, I am afraid to go into a healthcare facility without being fully vaccinated. Especially if I am just going to be told no one knows what is happening and have the experiences I am seeing all over these forums, examples below.

I have NEVER taken my mask off this whole time and I do not even go to the grocery store because of how horrible Texas is with no mask mandates. I have been b6 and was telling people to stay home in Feb 2020 because I could see what was coming.

Have you all started researching this, if not why not, and how are we to get help? I am being told I have to pay for everything, which even if I could do so, would not. This is not my responsibility in any way, shape or form. And that this is being covered up by Pfizer and the FDA and CDC is unconscionable.

I would have been better off not getting the vaccine and taking the Regeneron antibodies therapy if I got covid. And I'm not getting the second dose until someone tells me what is going on, <u>so someone is going to have to figure this out.</u>

Please advise. And thank you again for your work.

b6 There are hundreds and hundreds of pages of people having these side effects on this site:

Covid-19 Vaccine side effects - Page 123 - Patient: Dizziness - VeDA Forum

https://vestibular.org/forum/dizziness/covid-19-vaccine-side-effects/paged/123/

April 25, 2021 7:59 am

It's now 2.5 weeks after first Phizer vaccine and still dealing with disabling Vertigo. Saw a neurologist, had MRI, CAT scan, ENT doctor exam, bloodwork and am still taking meclazine & diazepam just to stop the nausea and vomiting.

Neurologist told me that anyone that has any brain problems or autoimmune disease of the brain (I have MS), and any brain injury history should NOT be vaccinated and that he keeps seeing patients with this dizziness problem.

#### **BIAA IS RECOMMENDING THE VACCINES(?!)**

BIAA Issues Guidance on COVID-19 Vaccines for Persons with Brain Injury

https://www.biausa.org/public-affairs/public-awareness/news/biaa-issues-guidance-on-covid-19-vaccines-for-persons-with-brain-injury

"When one is infected with COVID-19, the virus attacks the 'weakest link' it finds in the body, which is why individuals with longstanding chronic medical issues are at greatest risk for infection, complications, and even death," explained BIAA National Medical Director Brent E. Masel, M.D. "Studies have shown that traumatic brain injury triggers an inflammatory process in the brain that causes an individual to experience chronic issues. This process places those individuals at far greater risk of developing complications from COVID-19, which itself is well known to cause chronic neuroinflammatory issues."

Woman suffers 'life-altering injuries' after COVID-19 vaccine, teams up with Utah senator to demand answers | NewsNation Now

https://www.newsnationnow.com/us-news/west/woman-suffers-life-altering-injuries-after-covid-19-vaccine-teams-up-with-utah-senator-to-demand-answers/

A 'black hole' for COVID vaccine injury claims | Reuters

https://www.reuters.com/legal/government/black-hole-covid-vaccine-injury-claims-2021-06-29/

Except historically, almost no one gets anything. Since the program's inception in 2010, only 29 claims have been paid, with an average payout of around \$200,000. (Ten additional claims won approval but were deemed ineligible for compensation.)

Gentry is not optimistic that any will be approved. Because the vaccine is so new, there's no definitive research on injuries caused by the vaccine, she said. Which means that when the claims land on someone's desk at HRSA, that person "can do their job and look at the 'research' and everyone loses."

....Our law firm has concluded that there is nothing our attorneys can do to significantly assist you," the firm states.

Maglio told me his Sarasota, Florida-based firm has been "contacted by at least a couple hundred people" about suspected COVID vaccine-related injuries, including blood clots and cardiac inflammation.

It's not that his firm doesn't want to help. Representing people who've had (rare) major adverse reactions to vaccines for tetanus, measles, hepatitis, influenza and a dozen other shots is its bread and butter.

**b6** 

000000000000000000000000000000000000000	
From:	b6
Sent:	8/16/2021 3:11:40 PM
То:	Walitt, Brian (NIH/NINR) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5b9339ab4cd1422aaf4669c64ca85914 b6
CC:	Gavin, Angelique (NIH/NINDS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6e97392e947e4f7ebb17eeb8ac87c5d5 b6
Subject:	Re: NIH COVID-19 vaccine study
Hi Dr Wal	litt
I understa	nd and won't share this information publicly. I may be wrong, but I don't think that most people in the
ME comm	nunity who have experienced downturns are clamoring as much to personally participate in studies as
they are to	have the potential for longer-lasting side effects acknowledged/researched. I of course understand
•	ssing risks in a nuanced way is a public health challenge and appreciate that Dr Nath mentioned cal side effects in a Body Politic webinar.
On a pers	sonal note, the main lingering effects I'm experiencing are easy to measure (daily fevers and
hyperadr	energic POTS w/ worrisome blood pressure spikes) so it's not hard for me to get medical
support a	ind I'm optimistic something will eventually help. I'd just like to know which vaccine type may
	t for people w/ ME since multiple doctors have told me not to get a second shot and I hate
_	stly unprotected. I realize that "which vaccine has the fewest risk of side effects for people
	is too specific for NIH to study and for now I'm crossing fingers for Novavax to get approved
soon.	
It's the pe	eople I know who are done with their shots and have lost significant functionality that I'm
	ried about. Most people with ME seem to be getting back to baseline after a few weeks but
	that aren't are really struggling.
If there is	anything I can share at some point please let me know.
Thanks,	
b6	
On Mon,	Aug 16, 2021, 3:52 AM Walitt, Brian (NIH/NINR) [E] <b>b6</b> wrote:
	\
b6	<u></u> l
Пото	Il is viall. A most igner shound your small below with man. I would sale you not to show with the bused
	Il is well. Angelique shared your email below with me. I would ask you not to share with the broad ity the sentiment noted below until we are ready to start recruiting. We will let you know when the
	/exclusion criteria are clear and we are ready to go. It is not fair to make people wait for a study they
	oing to be eligible for.
are not go	ong to be ongible for.
Thanks,	

From: b6
Sent: Friday, August 13, 2021 4:34 PM
To: Gavin, Angelique (NIH/NINDS) [C] b6
Subject: Re: NIH COVID-19 vaccine study

ha, thank you!:)

Is it ok for me to share this publicly?

"Dr Nath's team is planning on studying people who have had extended neurological or other symptoms after getting a Covid vaccine. The study plans are not finalized yet but you can get on the wait list by emailing b6

Thanks,

Brian

From: b6

Sent: 1/12/2022 2:25:57 PM

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

(FYDIBOHF23SPDLT)/cn=Recipients/cn=5b9339ab4cd1422aaf4669c64ca85914 b6

Subject: Re: Status of care for Pfizer covid vaccine brain, etc injuries- Fwd: [EXTERNAL] Status? Re: Covid vaccine brain injury-

are there studies you all are doing? What is being done to help us? Doctors have no idea

Flag: Follow up

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.

Below is the email I sent you yesterday explaining exactly what I was contacting you over and the gaslighting that you didn't know why I was contacting you- and from a medical doctor and a neurologist at that- is more than absolutely unacceptable.

Below are the definitions and statutes from the lawsuit draft- and none of you are immune. Immunity is part of the prosecution. I am exercising all rights under the 9th and 10th amendments to oversee all prosecutions, especially since the entire government has all sectors that are compromised by guilty parties within their ranks.

I suggest you pass this on to the people you claim are in charge, since "you're just a doctor"- wasting my time with that outrageous phone call- and I expect an answer with a solution and that solution given in a time frame that meets the urgency of the situation.

#### Democide definition:

https://www.hawaii.edu/powerkills/DBG.CHAP2.HTM

(2.5) a famine or epidemic during which government authorities withhold aid, or knowingly act in a way to make it more deadly

Democide definition and meaning | Collins English Dictionary https://www.collinsdictionary.com/dictionary/english/democide

the killing of members of a country's civilian population as a result of its government's policy, including by direct action, indifference, and neglect

19. Genocide (18 U.S.C. 1091) | JM | Department of Justice https://www.justice.gov/archives/jm/criminal-resource-manual-19-genocide-18-usc-1091

United Nations Office on Genocide Prevention and the Responsibility to Protect <a href="https://www.un.org/en/genocideprevention/genocide-convention.shtml">https://www.un.org/en/genocideprevention/genocide-convention.shtml</a>

United Nations Human Rights Committee's General Comment on the Right to Life <a href="https://www.ohchr.org/Documents/HRBodies/CCPR/CCPR">https://www.ohchr.org/Documents/HRBodies/CCPR/CCPR</a> C GC 36.pdf

- 2. Article 6 recognizes and protects the right to life of all human beings. It is the Supreme right from which no derogation is permitted even in situations of armed conflict And other public emergencies which threatens the life of the nation.[1] The right to life has Crucial importance both for individuals and for society as a whole. It is most precious for its Own sake as a right that inheres in every human being, but it also constitutes a fundamental Right [2] whose effective protection is the prerequisite for the enjoyment of all other human Rights and whose content can be informed by other human rights.
- 3. The right to life is a right which should not be interpreted narrowly. It concerns the Entitlement of individuals to be free from acts and omissions that are intended or may be Expected to cause their unnatural or premature

death, as well as to enjoy a life with dignity. Article 6 guarantees this right for all human beings, without distinction of any kind....

4. Paragraph 1 of article 6 of the Covenant provides that no one shall be arbitrarily Deprived of his life and that the right shall be protected by law. It lays the foundation for the Obligation of States parties to respect and to ensure the right to life, to give effect to it Through legislative and other measures, and to provide effective remedies and reparation to All victims of violations of the right to life.

Crime Against Humanity | Wex | US Law | LII / Legal Information Institute https://www.law.cornell.edu/wex/crime against humanity

1536. Murder -- Definition And Degrees | JM | Department of Justice

https://www.justice.gov/archives/jm/criminal-resource-manual-1536-murder-definition-and-degrees

### 18 U.S. Code Chapter 51 - HOMICIDE | U.S. Code | US Law | LII / Legal Information Institute https://www.law.cornell.edu/uscode/text/18/part-I/chapter-51

§ 1111. Murder

§ 1112. Manslaughter

§ 1113. Attempt to commit murder or manslaughter

§ 1117. Conspiracy to murder

§ 1122. Protection against the human immunodeficiency virus (precedence for covid-19 transmission- which shouldn't be needed)

#### [USC02] 18 USC Ch. 113B: TERRORISM

https://uscode.house.gov/view.xhtml?path=/prelim@title18/part1/chapter113B&edition=prelim

#### U.S.C. Title 18 - CRIMES AND CRIMINAL PROCEDURE

 $\frac{https://www.govinfo.gov/content/pkg/USCODE-2009-title18/html/USCODE-2009-title18-partI-chap113B-sec2331.htm}{}$ 

"domestic terrorism" means activities that—

- (A) involve acts dangerous to human life that are a violation of the criminal laws of the United States or of any State;
- (B) appear to be intended—
- (i) to intimidate or coerce a civilian population;
- (ii) to influence the policy of a government by intimidation or coercion; or
- (iii) to affect the conduct of a government by mass destruction, assassination...and
- (C) occur primarily within the territorial jurisdiction of the United States.

(Added Pub. L. 102–572, title X, §1003(a)(3), Oct. 29, 1992, 106 Stat. 4521; amended Pub. L. 107–56, title VIII, §802(a), Oct. 26, 2001, 115 Stat. 376.)

### 18 U.S.C. § 2331 - U.S. Code Title 18. Crimes and Criminal Procedure § 2331 | FindLaw https://codes.findlaw.com/us/title-18-crimes-and-criminal-procedure/18-usc-sect-2331.html

Universal Declaration of Human Rights | United Nations

https://www.un.org/en/about-us/universal-declaration-of-human-rights

Article 8

Everyone has the right to an effective remedy by the competent national tribunals for acts violating the fundamental rights granted him by the constitution or by law.

#### U.S.C. Title 18 - CRIMES AND CRIMINAL PROCEDURE

https://www.govinfo.gov/content/pkg/USCODE-2009-title18/html/USCODE-2009-title18-partI-chap113B-sec2331.htm

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(A) involve acts dangerous to human life that are a violation of the criminal laws of the United States or of any State; (B) appear to be intended— (i) to intimidate or coerce a civilian population; (C) occur primarily within the territorial jurisdiction of the United States. (Added Pub. L. 102–572, title X, §1003(a)(3), Oct. 29, 1992, 106 Stat. 4521; amended Pub. L. 107–56, title VIII, §802(a), Oct. 26, 2001, 115 Stat. 376.)
42 U.S. Code § 12101 - Findings and purpose   U.S. Code   US Law   LII / Legal Information Institute <a href="https://www.law.cornell.edu/uscode/text/42/12101">https://www.law.cornell.edu/uscode/text/42/12101</a>
Americans with Disabilities Act of 1990, AS AMENDED with ADA Amendments Act of 2008 <a href="https://www.ada.gov/pubs/adastatute08.htm">https://www.ada.gov/pubs/adastatute08.htm</a>
Universal Declaration of Human Rights   United Nations (UDHR) <a href="https://www.un.org/en/about-us/universal-declaration-of-human-rights">https://www.un.org/en/about-us/universal-declaration-of-human-rights</a> Article 25.1
Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.  Article 5
No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment.
Ninth Amendment   U.S. Constitution   US Law   LII / Legal Information Institute https://www.law.cornell.edu/constitution/ninth_amendment#:~:text=Amendment%20IX,others%20retained%20 by%20the%20people.  Amendment IX The enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people.
Tenth Amendment   U.S. Constitution   US Law   LII / Legal Information Institute <a href="https://www.law.cornell.edu/constitution/tenth_amendment">https://www.law.cornell.edu/constitution/tenth_amendment</a> Amendment X The powers not delegated are reservedto the people.
On Tue, Jan 11, 2022, 12:49 PM b6 wrote: Please let me know why nothing is being done to help all of us who were injured by the Pfizer (and Moderna, etc., if applicable) covid vaccine.
Press reports (that were effectively buried, because I had never heard of vax fog until I was in a panic trying to google what the hell was happening to me 9 hours after my first Pfizer vaccine) state you all have known about this for well over a year now and there isn't even a "survey" (which is ridiculous anyway) up and running?!
Who is responsible for this and when and how is it going to be rectifed and care provided?
Thank you.



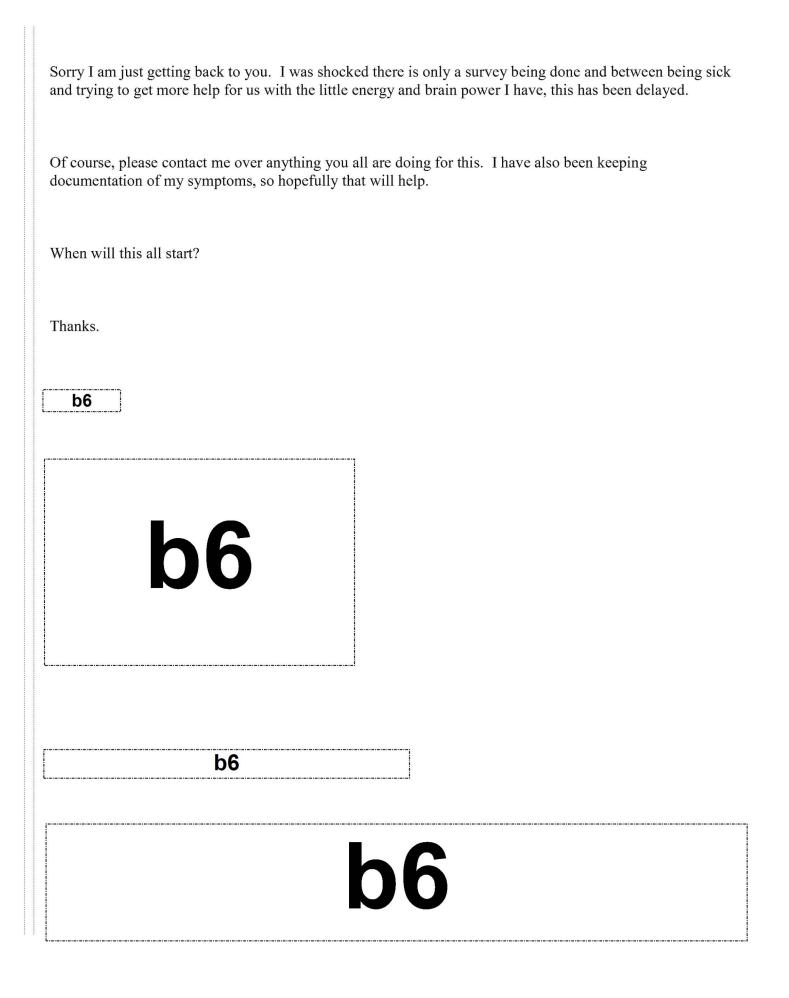
10 Center Drive

Forwarded massage		
Forwarded message From: Gavin, Angelique (NIH/NINDS) [C]	b6	
Date: Tue, Jan 11, 2022, 12:29 PM	!	
Subject: RE: [EXTERNAL] Status? Re: Covid	I vaccine brain injury- are the	re studies you all are doing? Wha
is being done to help us? Doctors have no idea		
To: <b>b6</b>		
Hello <b>b6</b> Please contact Dr. Brian Walitt at <b>b6</b>	who should be able	to respond to your concerns
Thank you,		
Thunk you,		
Angelique		
Angelique Gavin, MS (Contractor)		
NIH/NINDS Clinical Operations Manager		
Contractor Preferred Solutions Group		
National Institutes of Health		

Building 10, Room 3B19, MSC 1251
Bethesda, MD 20814-9692
b6 (office)
(cell)
(301) 480-5368 (efax)
b6
https://clinicaltrials.gov - study number 000089-N
-
From: b6 Sent: Tuesday, January 11, 2022 12:22 PM To: Gavin, Angelique (NIH/NINDS) [C] b6 Subject: [EXTERNAL] Status? Re: Covid vaccine brain injury- are there studies you all are doing? What is being done to help us? Doctors have no idea
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.
Angelique,
Good morning. I hope you are well. I am checking on the status of this. If it is still not "approved", please get me the contact email of whoever is responsible for not providing care for us and not researching what is happening to us.
This is not ok.
Thanks.

b6		
On Thu, Nov 4, 2021, 2:27 PM Gavin, Angelique (NIH/NINDS) [C]	b6	wrote:
Thank you <b>b6</b> for touching base with us! The study has not yet been ap underway, I will forward your information to the study team and they will to you.		
Sincerely,		
Angelique		
Quality Quity MS (Contractor)		
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		
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(301) 480-5368 (efax)		
b6		
https://clinicaltrials.gov - study number 000089-N		
-		

From: b6
Sent: Thursday, November 4, 2021 10:55 AM
To: Gavin, Angelique (NIH/NINDS) [C] b6
Subject: Re: Covid vaccine brain injury- are there studies you all are doing? What is being done to help us? Doctors have no idea



n	h
u	u

On Thu, Sep 23, 2021, 8:59 AM Gavin, Angelique (NIH/NINDS) [C] b6 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 online study. I am looking forward to your reply. Thanks, 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) (301) 480-5368 (efax) b6

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

wrote:

From: b6 Sent: Thursday, September 23, 2021 8:40 AM To: Nath, Avindra (NIH/NINDS) [E] b6 Cc: NINDSPostCovid19 < nindspostcovid19@ninds.nih.gov> Subject: Re: Covid vaccine brain injury- are there studies you all are doing? What is being done to help us? Doctors have no idea
Thank you!
On Wed, Sep 22, 2021, 3:14 PM Nath, Avindra (NIH/NINDS) [E] <b>b6</b> wrote:  Dear <b>b6</b> Sorry to hear of your illness. At the moment we are collecting data on such complications. I have copied our research team who can guide you on how to help us do so.
Best wishes.  Avi
From: b6  Date: Wednesday, September 22, 2021 at 3:10 PM  To: Nath, Avindra (NIH/NINDS) [E] b6  Subject: Covid vaccine brain injury- are there studies you all are doing? What is being done to help us? Doctors have no idea  Dr. Nath-
I am writing because I was injured from a first dose of the Pfizer vaccine on b6 and have horrific "vax fog" that is not going away and press reports list you as working on this- thank you.
I received the Pfizer vaccine at 11am and felt great all day- so happy, feeling like I may be somewhat more free in the next few weeks, etc and just took it easy and rested all day. I was feeling completely fine- my arm wasn't even that sore, as I had been moving it, etc., and at 8pm I was lying down and got up to get a drink and go to the restroom and had such violent dizziness that I didn't stop when I was vertical and ran into the wall, and then thought I needed to get on the ground and crawl so I wouldn't fall. And the

symptoms expanded and none of them have stopped since.

I have brain fog so bad I cannot remember bank pins I have had for decades- this is taking me forever to write, etc, violent dizziness, constant nauseousness, light and sound sensitivity, ear ringing, low grade fever on and off, no energy, most nights can only sleep 2 or 3 hours at a time waking up all night long, horrible pain including eye pain when trying to work or do anything on digital devices, cannot get upset at all-feel it vestibularly and get really sick, lack of sleep makes me super sick, etc. And I have had 2 slight heart issue incidents and "covid arm" of just 3 small bumps like a blemish that felt weird a few weeks into this that oddly went away in a few hours and made me feel so sick that night I actually thought I might not make it through the night and then my head was a bit better the next day (a lot of the head actual pain went away-pain that is not a headache) so that I could then get out of bed- but it is still very, very VERY bad.

I have to educate my doctors as they haven't even heard of the term- which I hadn't either until I was frantically googling what was happening to me, Pfizer lied to me and told me no one has had these symptoms and to speak to my doctor and the FDA and CDC have been zero help, and are part of the problem as usual. How are our local doctors supposed to help us if Pfizer, etc and the FDA and CDC won't even admit this is happening, so the doctors cannot get any info?!

The one doctor I do trust wants to see me in person vs on video, but being in the covid fire that is Texas, I am afraid to go into a healthcare facility without being fully vaccinated. Especially if I am just going to be told no one knows what is happening and have the experiences I am seeing all over these forums, examples below.

I have NEVER taken my mask off this whole time and I	I do not even go to the grocery store because of how
horrible Texas is with no mask mandates. I have been	b6
and was telling people to stay home in Feb 2020 because	e I could see what was coming.

Have you all started researching this, if not why not, and how are we to get help? I am being told I have to pay for everything, which even if I could do so, would not. This is not my responsibility in any way, shape or form. And that this is being covered up by Pfizer and the FDA and CDC is unconscionable.

I would have been better off not getting the vaccine and taking the Regeneron antibodies therapy if I got covid. And I'm not getting the second dose until someone tells me what is going on, so someone is going to have to figure this out.

Please advise. And thank you again for your work.

b6 There are hundreds and hundreds of pages of people having these side effects on this site:

Covid-19 Vaccine side effects - Page 123 - Patient: Dizziness - VeDA Forum

https://vestibular.org/forum/dizziness/covid-19-vaccine-side-effects/paged/123/

April 25, 2021 7:59 am

It's now 2.5 weeks after first Phizer vaccine and still dealing with disabling Vertigo. Saw a neurologist, had MRI, CAT scan, ENT doctor exam, bloodwork and am still taking meclazine & diazepam just to stop the nausea and vomiting.

Neurologist told me that anyone that has any brain problems or autoimmune disease of the brain (I have MS), and any brain injury history should NOT be vaccinated and that he keeps seeing patients with this dizziness problem.

#### **BIAA IS RECOMMENDING THE VACCINES(?!)**

BIAA Issues Guidance on COVID-19 Vaccines for Persons with Brain Injury

https://www.biausa.org/public-affairs/public-awareness/news/biaa-issues-guidance-on-covid-19-vaccines-for-persons-with-brain-injury

"When one is infected with COVID-19, the virus attacks the 'weakest link' it finds in the body, which is why individuals with longstanding chronic medical issues are at greatest risk for infection, complications, and even death," explained BIAA National Medical Director Brent E. Masel, M.D. "Studies have shown that traumatic brain injury triggers an inflammatory process in the brain that causes an individual to experience chronic issues. This process places those individuals at far greater risk of developing complications from COVID-19, which itself is well known to cause chronic neuroinflammatory issues."

Woman suffers 'life-altering injuries' after COVID-19 vaccine, teams up with Utah senator to demand answers | NewsNation Now

https://www.newsnationnow.com/us-news/west/woman-suffers-life-altering-injuries-after-covid-19-vaccine-teams-up-with-utah-senator-to-demand-answers/

A 'black hole' for COVID vaccine injury claims | Reuters

https://www.reuters.com/legal/government/black-hole-covid-vaccine-injury-claims-2021-06-29/

Except historically, almost no one gets anything. Since the program's inception in 2010, only 29 claims have been paid, with an average payout of around \$200,000. (Ten additional claims won approval but were deemed ineligible for compensation.)

Gentry is not optimistic that any will be approved. Because the vaccine is so new, there's no definitive research on injuries caused by the vaccine, she said. Which means that when the claims land on someone's desk at HRSA, that person "can do their job and look at the 'research' and everyone loses."

....Our law firm has concluded that there is nothing our attorneys can do to significantly assist you," the firm states.

Maglio told me his Sarasota, Florida-based firm has been "contacted by at least a couple hundred people" about suspected COVID vaccine-related injuries, including blood clots and cardiac inflammation.

It's not that his firm doesn't want to help. Representing people who've had (rare) major adverse reactions to vaccines for tetanus, measles, hepatitis, influenza and a dozen other shots is its bread and butter.

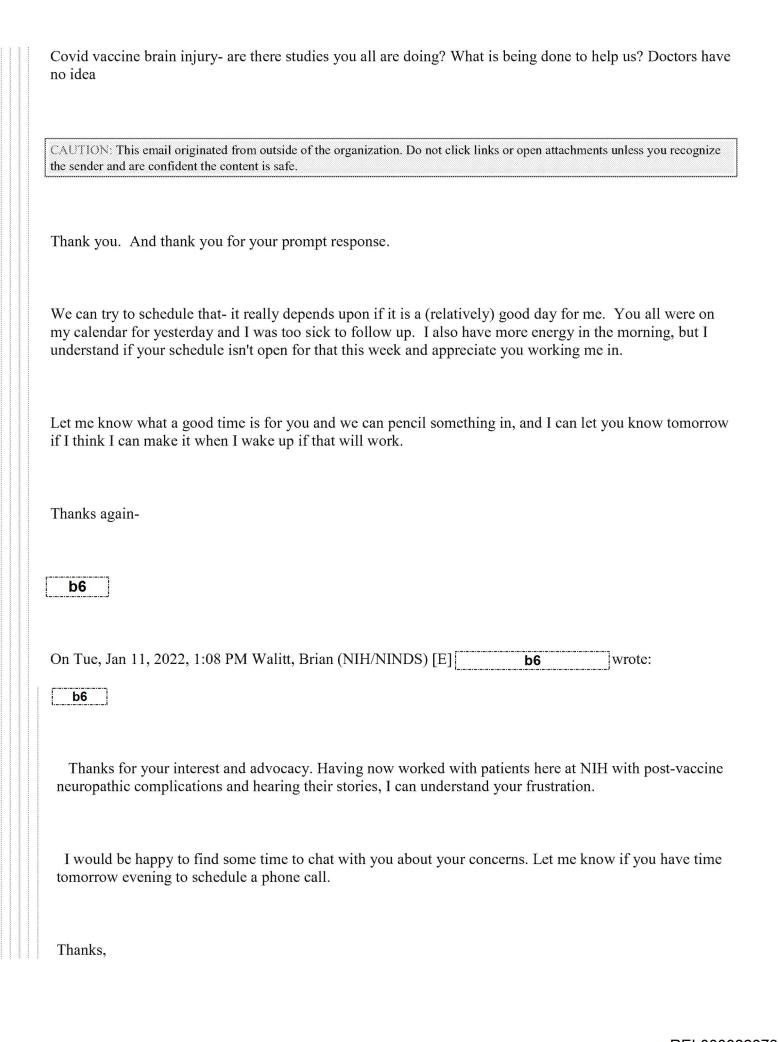
**b6** 

From: Sent: To: Subject:	b6  1/12/2022 2:41:36 PM  Walitt, Brian (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5b9339ab4cd1422aaf4669c64ca85914 b6  WHY ARE YOU TELLING ME COLLINS IS WHO TO CONTACT?! AND BTW- ITS *YOUR* FUCKING JOBS TO "ADVOCATE* FOR US! WHAT IS WRONG WITH ALL OF YOU?! GET. ME. THE. HEAD. OF. THIS. DAMN. AGENCY. Francis Collins to step down as director of the National Institutes of
	email originated from outside of the organization. Do not click links or open attachments unless you recognize the confident the content is safe.
WHY ARE Y JOBS TO "A THIS. DAM National Inst https://www. Re: Good to tonight- Re:	YOU TELLING ME COLLINS IS WHO TO CONTACT?! AND BTW- ITS *YOUR* FUCKING DVOCATE* FOR US! WHAT IS WRONG WITH ALL OF YOU?! GET. ME. THE. HEAD. OF. N. AGENCY. Francis Collins to step down as director of the National Institutes of Health   itutes of Health (NIH) nih.gov/news-events/news-releases/francis-collins-step-down-director-national-institutes-health go whenever y'all are- thanks- Re: Tomorrow 9am will work- will email if I am up all night Status of care for Pfizer covid vaccine brain, etc injuries- Fwd: [EXTERNAL] Status? Re: Covid in injury- are there studies you
On Wed, Jan	12, 2022, 8:21 AM Walitt, Brian (NIH/NINDS) [E] <b>b6</b> wrote:
b6	
Thanks fo	r taking the time to chat. Some links for you to consider as you advocate for yourself:
The Recove	er Initiative: RECOVER (recovercovid.org)
	leading the RECOVER Initiative: <u>RECOVER Builds Large Nationwide Study Population for Long Covid' NIH Record</u>
	egrams in Texas that deal with the types of symptoms you have reported: Post COVID Care Centers vivor Corps
	bout HIV/AIDS advocacy and how they were successful: How '80s AIDS Activist Group ACT UP the Face Of Medicine: Shots - Health News: NPR
Thanks,	

From: b6 Sent: Wednesday, January 12, 2022 8:47 AM
To: Gavin, Angelique (NIH/NINDS) [C] b6  Cc: Walitt, Brian (NIH/NINDS) [E] b6  Subject: Good to go whenever y'all are- thanks- Re: Tomorrow 9am will work- will email if I am up all night tonight- Re: Status of care for Pfizer covid vaccine brain, etc injuries- Fwd: [EXTERNAL] Status? Re: Covid vaccine brain injury- are there studies you a
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.
The number again is <b>b6</b> Thanks again.
On Tue, Jan 11, 2022, 2:59 PM b6 wrote: Thanks. Y'all too. And stay safe!
On Tue, Jan 11, 2022, 2:55 PM Gavin, Angelique (NIH/NINDS) [C] <b>b6</b> wrote:  Thank you <b>b6</b> Fingers crossed it all works out. Best wishes for a good night's sleep.
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
b6 (office) (cell)
(301) 480-5368 (efax)
b6
https://clinicaltrials.gov - study number 000089-N
-
From: b6 Sent: Tuesday, January 11, 2022 3:53 PM To: Gavin, Angelique (NIH/NINDS) [C] b6 Walitt, Brian (NIH/NINDS) [E]  b6 Subject: Tomorrow 9am will work- will email if I am up all night tonight- Re: Status of care for Pfizer covid vaccine brain, etc injuries- Fwd: [EXTERNAL] Status? Re: Covid vaccine brain injury- are there studies you all are doing? What is being done to help us
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.
Tomorrow at 9am EST will work. If I cannot sleep tonight and am not doing well- I have a LOT of trouble sleeping more than 1 or 2 hours at a time and am often up most of the night and just miserable then- I will email y'all and we can reschedule.
The number is Sometimes my phone has issues with incoming calls, so if I don't answer, I will call you right back.
Thanks and hopefully we will talk tomorrow.

On Tue, Jan 11, 2022, 2:46 PM Gavin, Angelique (NIH/NINDS) [C]	b6	wrote:
Hi <b>b6</b>		
Dr. Walitt has availability tomorrow, January 12 at 9 am or next week, Time. Let me know your preference and a good telephone number for I		· 10 am Eastern
Thank you,		
Angelique		
Angelique Gavin, MS		
Clinical Operations Manager		
Contractor, PSG		
National institutes of Health		
10 Center Drive, Building 10		
Room 3B19, MSC 1251		
Bethesda, MD 20814		
<b>b6</b> phone		
301-451-7352-fax		
From: b6		
Sent: Tuesday, January 11, 2022 3:00 PM  To: Walitt, Brian (NIH/NINDS) [E] b6		



Brian	
To: Walitt, Brian (N Subject: Status of ca	ary 11, 2022 1:49 PM  IH/NINDS) [E] b6  are for Pfizer covid vaccine brain, etc injuries- Fwd: [EXTERNAL] Status? Re: Covid-are there studies you all are doing? What is being done to help us? Doctors have no
CAUTION: This email of the sender and are confid	originated from outside of the organization. Do not click links or open attachments unless you recogniz lent the content is safe.
	why nothing is being done to help all of us who were injured by the Pfizer (and blicable) covid vaccine.
trying to google wha	rere effectively buried, because I had never heard of vax fog until I was in a panic at the hell was happening to me 9 hours after my first Pfizer vaccine) state you all have well over a year now and there isn't even a "survey" (which is ridiculous anyway) up
Who is responsible f	for this and when and how is it going to be rectifed and care provided?
Thank you.	
b6	

b

Forwarded message From: Gavin, Angelique (NIH/NINDS) [C] b6  Date: Tue, Jan 11, 2022, 12:29 PM Subject: RE: [EXTERNAL] Status? Re: Covid vaccine brain injury- are there studies you all are doing? What is being done to help us? Doctors have no idea To: b6
Hello b6
Please contact Dr. Brian Walitt at <b>b6</b> who should be able to respond to your concerns.
Thank you,
Angelique
Angelique Gavin, MS (Contractor)
NIH/NINDS Clinical Operations Manager
Contractor Preferred Solutions Group
National Institutes of Health
10 Center Drive

Bethesda, MD 20814-9692
b6 (office)
(cell)
(301) 480-5368 (efax)
b6
https://clinicaltrials.gov - study number 000089-N
From: b6 Sent: Tuesday, January 11, 2022 12:22 PM
To: Gavin, Angelique (NIH/NINDS) [C] b6
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On Thu, Nov 4, 2021, 2:27 PM Gavin, Angelique (NIH/NINDS) [C] wrote: Thank you **b6** for touching base with us! The study has not yet been approved by our review board. Once underway, I will forward your information to the study team and they will contact you directly. All my best to you. 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) (301) 480-5368 (efax) b<sub>6</sub> https://clinicaltrials.gov - study number 000089-N From: Sent: Thursday, November 4, 2021 10:55 AM To: Gavin, Angelique (NIH/NINDS) [C] b6 Subject: Re: Covid vaccine brain injury- are there studies you all are doing? What is being done to help us? Doctors have no idea

Sorry I am just getting back to you. I was shocked there is only a survey being done and between being sick and trying to get more help for us with the little energy and brain power I have, this has been delayed. Of course, please contact me over anything you all are doing for this. I have also been keeping documentation of my symptoms, so hopefully that will help. When will this all start? Thanks. b6 **b6** b6 **b6** 

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	6
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On Thu, Sep 23, 2021, 8:59 AM Gavin, Angelique (NIH/NINDS) [C] **b6** wrote:

Dear **b6** 

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Thanks,

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



(301) 480-5368 (efax)

b6

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1			
From:  Sent: Thursday, September 23, 2021 8:40 AM  To: Nath, Avindra (NIH/NINDS) [E]  Cc: NINDSPostCovid19 < nindspostcovid19@ninds.nih.gov >  Subject: Re: Covid vaccine brain injury- are there studies you all are doing? What is being done to help us? Doctors have no idea			
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The one doctor I do trust wants to see me in person vs on video, but being in the covid fire that is Texas, I am afraid to go into a healthcare facility without being fully vaccinated. Especially if I am just going to be told no one knows what is happening and have the experiences I am seeing all over these forums, examples below.

I have	NEVER taken my mask off this whole time and I do not e	even go to the grocery store because of
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Please advise. And thank you again for your work.

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There are hundreds and hundreds of pages of

Covid-19 Vaccine side effects - Page 123 – Patient: Dizziness – VeDA Forum

https://vestibular.org/forum/dizziness/covid-19-vaccine-side-effects/paged/123/

April 25, 2021 7:59 am

It's now 2.5 weeks after first Phizer vaccine and still dealing with disabling Vertigo. Saw a neurologist, had MRI, CAT scan, ENT doctor exam, bloodwork and am still taking meclazine & diazepam just to stop the nausea and vomiting.

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## **BIAA IS RECOMMENDING THE VACCINES(?!)**

BIAA Issues Guidance on COVID-19 Vaccines for Persons with Brain Injury

https://www.biausa.org/public-affairs/public-awareness/news/biaa-issues-guidance-on-covid-19vaccines-for-persons-with-brain-injury

"When one is infected with COVID-19, the virus attacks the 'weakest link' it finds in the body, which is why individuals with longstanding chronic medical issues are at greatest risk for infection, complications, and even death," explained BIAA National Medical Director Brent E. Masel, M.D. "Studies have shown that traumatic brain injury triggers an inflammatory process in the brain that causes an individual to experience chronic issues. This process places those individuals at far greater risk of developing complications from COVID-19, which itself is well known to cause chronic neuroinflammatory issues."

Woman suffers 'life-altering injuries' after COVID-19 vaccine, teams up with Utah senator to demand answers | NewsNation Now

https://www.newsnationnow.com/us-news/west/woman-suffers-life-altering-injuries-after-covid-19-vaccine-teams-up-with-utah-senator-to-demand-answers/

A 'black hole' for COVID vaccine injury claims | Reuters

https://www.reuters.com/legal/government/black-hole-covid-vaccine-injury-claims-2021-06-29/

Except historically, almost no one gets anything. Since the program's inception in 2010, only 29 claims have been paid, with an average payout of around \$200,000. (Ten additional claims won approval but were deemed ineligible for compensation.) Gentry is not optimistic that any will be approved. Because the vaccine is so new, there's no definitive research on injuries caused by the vaccine, she said. Which means that when the claims land on someone's desk at HRSA, that person "can do their job and look at the 'research' and everyone loses." ....Our law firm has concluded that there is nothing our attorneys can do to significantly assist you," the firm states. Maglio told me his Sarasota, Florida-based firm has been "contacted by at least a couple hundred people" about suspected COVID vaccine-related injuries, including blood clots and cardiac inflammation. It's not that his firm doesn't want to help. Representing people who've had (rare) major adverse reactions to vaccines for tetanus, measles, hepatitis, influenza and a dozen other shots is its bread and butter.

From: Sent: To: Subject:	b6  1/12/2022 2:28:22 PM  Walitt, Brian (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5b9339ab4cd1422aaf4669c64ca85914 b6 I said I need NIH Csuite contact info AND YOU ALL EXPECT PEOPLE WITH GD MF BRAIN DAMAGE TO ADVOCATE FOR OURSELVES?! HAVE YOU ALL LOST YOUR FUCKING MINDS?! GET ME THE HEAD OF THIS AGENCY IMMEDIATELY- Re: Good to go whenever y'all are- thanks- Re: Tomorr
	email originated from outside of the organization. Do not click links or open attachments unless you recognize the confident the content is safe.
On Wed, Jan	n 12, 2022, 8:21 AM Walitt, Brian (NIH/NINDS) [E] <b>b6</b> wrote:
Thanks fo	or taking the time to chat. Some links for you to consider as you advocate for yourself:
The Recove	er Initiative: RECOVER (recovercovid.org)
	leading the RECOVER Initiative: RECOVER Builds Large Nationwide Study Population for h 'Long Covid'   NIH Record
	ograms in Texas that deal with the types of symptoms you have reported: <u>Post COVID Care Centers</u> rvivor Corps
	about HIV/AIDS advocacy and how they were successful: How '80s AIDS Activist Group ACT UP he Face Of Medicine: Shots - Health News: NPR
Thanks,	
Brian	

From: b6 Sent: Wednesday, January 12, 2022 8:47 AM
From: b6 Sent: Wednesday, January 12, 2022 8:47 AM To: Gavin, Angelique (NIH/NINDS) [C] b6 Cc: Walitt, Brian (NIH/NINDS) [E] b6 Subject: Good to go whenever y'all are- thanks- Re: Tomorrow 9am will work- will email if I am up all night
tonight- Re: Status of care for Pfizer covid vaccine brain, etc injuries- Fwd: [EXTERNAL] Status? Re: Covid vaccine brain injury- are there studies you a
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.
The number again is <b>b6</b> Thanks again.
On Tue, Jan 11, 2022, 2:59 PM <b>b6</b> wrote:
Thanks. Y'all too. And stay safe!
O T - 1 - 11 2022 2 55 PM C - ' - 1 - 1' - O M M A I PM C   ' - 1 - 1' - 1' - O M M A I PM C   ' - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -
On Tue, Jan 11, 2022, 2:55 PM Gavin, Angelique (NIH/NINDS) [C] <b>b6</b> wrote:
Thank you b6 Fingers crossed it all works out. Best wishes for a good night's sleep.
Sincerely,
Angelique
Angelique Gavin, MS (Contractor)
NIH/NINDS Clinical Operations Manager
Contractor Preferred Solutions Group
National Institutes of Health
National Institutes of Health  10 Center Drive

h6 (office)	
(cell)	
(301) 480-5368 (efax)	
b6	
https://clinicaltrials.gov - study number 000089-N	
-	
From: b6	
Sent: Tuesday, January 11, 2022 3:53 PM	
To: Gavin, Angelique (NIH/NINDS) [C] b6 Walitt, Brian (NIH/NINDS) [E] b6	
Subject: Tomorrow 9am will work- will email if I am up all night tonight- Re: Status of care for Pfizer co	
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	**********
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	2
the sender and are confident the content is safe.	
Tomorrow at 9am EST will work. If I cannot sleep tonight and am not doing well- I have a LOT of trouble	le
the sender and are confident the content is safe.	e
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On Tue, Jan 11, 2022, 2:46 PM Gavin, Angelique (NIH/NINDS) [C]	b6	wrote:
Hi <b>b6</b>		
Du Welitt has availability to many January 12 at 0 am an avet week Jan		) and Eastern
Dr. Walitt has availability tomorrow, January 12 at 9 am or next week, Jan Time. Let me know your preference and a good telephone number for him		am Eastern
Thank you,		
Angelique		
Angelique Gavin, MS		
Clinical Operations Manager		
Contractor, PSG		
National institutes of Health		
10 Center Drive, Building 10		
Room 3B19, MSC 1251		
Bethesda, MD 20814		
<b>b6</b> phone		
301-451-7352-fax		
From: b6 Sent: Tuesday, January 11, 2022 3:00 PM		
To: Walitt, Brian (NIH/NINDS) [E] b6		
Cc: Gavin, Angelique (NIH/NINDS) [C] <b>b6</b> Subject: Re: Status of care for Pfizer covid vaccine brain, etc injuries- Fwo	A. FEYTEDNIA I	1 Status? Da
Covid vaccine brain injury- are there studies you all are doing? What is being no idea		

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Thank you. And thank you for your prompt response.
We can try to schedule that- it really depends upon if it is a (relatively) good day for me. You all were on my calendar for yesterday and I was too sick to follow up. I also have more energy in the morning, but I understand if your schedule isn't open for that this week and appreciate you working me in.
Let me know what a good time is for you and we can pencil something in, and I can let you know tomorrow if I think I can make it when I wake up if that will work.
Thanks again-
On Tue, Jan 11, 2022, 1:08 PM Walitt, Brian (NIH/NINDS) [E] <b>b6</b> wrote: <b>b6</b>
Thanks for your interest and advocacy. Having now worked with patients here at NIH with post-vaccine neuropathic complications and hearing their stories, I can understand your frustration.
I would be happy to find some time to chat with you about your concerns. Let me know if you have time tomorrow evening to schedule a phone call.
Thanks,
Brian
From: b6 Sent: Tuesday, January 11, 2022 1:49 PM

To: Walitt, Brian (NIH/NINDS) [E] Subject: Status of care for Pfizer covid vaccine brain, etc injuries- Fwd: [EXTERNAL] Status? Re: Covid vaccine brain injury- are there studies you all are doing? What is being done to help us? Doctors have no idea 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. Please let me know why nothing is being done to help all of us who were injured by the Pfizer (and Moderna, etc., if applicable) covid vaccine. Press reports (that were effectively buried, because I had never heard of vax fog until I was in a panic trying to google what the hell was happening to me 9 hours after my first Pfizer vaccine) state you all have known about this for well over a year now and there isn't even a "survey" (which is ridiculous anyway) up and running?! Who is responsible for this and when and how is it going to be rectifed and care provided? Thank you. b6

6
•

From: Gavin, Angelique (NIH/NINDS) [C] b6  Date: Tue, Jan 11, 2022, 12:29 PM Subject: RE: [EXTERNAL] Status? Re: Covid vaccine brain injury- are there studies you all are doing? What is being done to help us? Doctors have no idea To: b6
Hello b6
Please contact Dr. Brian Walitt at <b>b6</b> who should be able to respond to your concerns.
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)	
b6	
https://clinicaltrials.gov - study number 000089-N	
-	
From: b6	
Sent: Tuesday, January 11, 2022 12:22 PM  To: Gavin, Angelique (NIH/NINDS) [C] b6	
<b>Subject:</b> [EXTERNAL] Status? Re: Covid vaccine brain injury- are there studies you all are doing? Wh is being done to help us? Doctors have no idea	at
CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recogn	
the sender and are confident the content is safe.	
Angelique,	
Good morning. I hope you are well. I am checking on the status of this. If it is still not "approved", ple	ase
get me the contact email of whoever is responsible for not providing care for us and not researching what is happening to us.	ıt
This is not ok.	
Thanks.	
<b>b6</b>	
On Thu, Nov 4, 2021, 2:27 PM Gavin, Angelique (NIH/NINDS) [C] b6 wrote	
	•
Thank you be for touching base with us! The study has not yet been approved by our review board. Once underway, I will forward your information to the study team and they will contact you directly. All my best to you.	

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) (301) 480-5368 (efax) https://clinicaltrials.gov - study number 000089-N From: Sent: Thursday, November 4, 2021 10:55 AM To: Gavin, Angelique (NIH/NINDS) [C] **b6**Subject: Re: Covid vaccine brain injury- are there studies you all are doing? What is being done to help us? Doctors have no idea Sorry I am just getting back to you. I was shocked there is only a survey being done and between being sick and trying to get more help for us with the little energy and brain power I have, this has been delayed. Of course, please contact me over anything you all are doing for this. I have also been keeping documentation of my symptoms, so hopefully that will help. When will this all start? Thanks. b6 **b6 b6** On Thu, Sep 23, 2021, 8:59 AM 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. I am looking forward to your reply.

Thanks,

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)

be

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

From: b6

Sent: Thursday, September 23, 2021 8:40 AM

To: Nath, Avindra (NIH/NINDS) [E] **b6** 

 Cc: NINDSPostCovid19 < nindspostcovid19(a)ninds.nih.gov > Subject: Re: Covid vaccine brain injury- are there studies you all are doing? What is being done to help us? Doctors have no idea
 Thank you!
 On Wed, Sep 22, 2021, 3:14 PM Nath, Avindra (NIH/NINDS) [E] <b>b6</b> wrote:  Dear <b>b6</b>
 Sorry to hear of your illness. At the moment we are collecting data on such complications. I have copied our research team who can guide you on how to help us do so.
 Best wishes.  Avi
From: b6  Date: Wednesday, September 22, 2021 at 3:10 PM  To: Nath, Avindra (NIH/NINDS) [E] b6  Subject: Covid vaccine brain injury- are there studies you all are doing? What is being done to help us? Doctors have no idea  Dr. Nath-
I am writing because I was injured from a first dose of the Pfizer vaccine on b6 horrific "vax fog" that is not going away and press reports list you as working on this- thank you.
 I received the Pfizer vaccine at 11am and felt great all day- so happy, feeling like I may be somewhat more free in the next few weeks, etc and just took it easy and rested all day. I was feeling completely fine- my arm wasn't even that sore, as I had been moving it, etc., and at 8pm I was lying down and got up to get a drink and go to the restroom and had such violent dizziness that I didn't stop when I was vertical and ran into the wall, and then thought I needed to get on the ground and crawl so I wouldn't fall. And the symptoms expanded and none of them have stopped since.
I have brain fog so bad I cannot remember bank pins I have had for decades- this is taking me forever to write, etc, violent dizziness, constant nauseousness, light and sound sensitivity, ear ringing, low grade fever on and off, no energy, most nights can only sleep 2 or 3 hours at a time waking up all night long, horrible pain including eye pain when trying to work or do anything on digital devices, cannot get upset

at all- feel it vestibularly and get really sick, lack of sleep makes me super sick, etc. And I have had 2 slight heart issue incidents and "covid arm" of just 3 small bumps like a blemish that felt weird a few weeks into this that oddly went away in a few hours and made me feel so sick that night I actually thought I might not make it through the night and then my head was a bit better the next day (a lot of the head actual pain went away- pain that is not a headache) so that I could then get out of bed- but it is still very, very VERY bad.
I have to educate my doctors as they haven't even heard of the term- which I hadn't either until I was frantically googling what was happening to me, Pfizer lied to me and told me no one has had these symptoms and to speak to my doctor and the FDA and CDC have been zero help, and are part of the problem as usual. How are our local doctors supposed to help us if Pfizer, etc and the FDA and CDC won't even admit this is happening, so the doctors cannot get any info?!
The one doctor I do trust wants to see me in person vs on video, but being in the covid fire that is Texas, I am afraid to go into a healthcare facility without being fully vaccinated. Especially if I am just going to be told no one knows what is happening and have the experiences I am seeing all over these forums, examples below.
I have NEVER taken my mask off this whole time and I do not even go to the grocery store because of how horrible Texas is with no mask mandates. I have been b6 and was telling people to stay home in Feb 2020 because I could see what was coming.
Have you all started researching this, if not why not, and how are we to get help? I am being told I have to pay for everything, which even if I could do so, would not. This is not my responsibility in any way, shape or form. And that this is being covered up by Pfizer and the FDA and CDC is unconscionable.
I would have been better off not getting the vaccine and taking the Regeneron antibodies therapy if I got covid. And I'm not getting the second dose until someone tells me what is going on, so someone is going to have to figure this out.
Please advise. And thank you again for your work.
p
b6 There are hundreds and hundreds of pages of people having these side effects on this site:
people naving these side effects on this site:

Covid-19 Vaccine side effects - Page 123 – Patient: Dizziness – VeDA Forum

https://vestibular.org/forum/dizziness/covid-19-vaccine-side-effects/paged/123/

April 25, 2021 7:59 am

It's now 2.5 weeks after first Phizer vaccine and still dealing with disabling Vertigo. Saw a neurologist, had MRI, CAT scan, ENT doctor exam, bloodwork and am still taking meclazine & diazepam just to stop the nausea and vomiting.

Neurologist told me that anyone that has any brain problems or autoimmune disease of the brain (I have MS), and any brain injury history should NOT be vaccinated and that he keeps seeing patients with this dizziness problem.

## **BIAA IS RECOMMENDING THE VACCINES(?!)**

BIAA Issues Guidance on COVID-19 Vaccines for Persons with Brain Injury

https://www.biausa.org/public-affairs/public-awareness/news/biaa-issues-guidance-on-covid-19-vaccines-for-persons-with-brain-injury

"When one is infected with COVID-19, the virus attacks the 'weakest link' it finds in the body, which is why individuals with longstanding chronic medical issues are at greatest risk for infection, complications, and even death," explained BIAA National Medical Director Brent E. Masel, M.D. "Studies have shown that traumatic brain injury triggers an inflammatory process in the brain that causes an individual to experience chronic issues. This process places those individuals at far greater risk of developing complications from COVID-19, which itself is well known to cause chronic neuroinflammatory issues."

Woman suffers 'life-altering injuries' after COVID-19 vaccine, teams up with Utah senator to demand answers | NewsNation Now

https://www.newsnationnow.com/us-news/west/woman-suffers-life-altering-injuries-after-covid-19-yaccine-teams-up-with-utah-senator-to-demand-answers/

A 'black hole' for COVID vaccine injury claims | Reuters

https://www.reuters.com/legal/government/black-hole-covid-vaccine-injury-claims-2021-06-29/

Except historically, almost no one gets anything. Since the program's inception in 2010, only 29 claims have been paid, with an average payout of around \$200,000. (Ten additional claims won approval but were deemed ineligible for compensation.)

Gentry is not optimistic that any will be approved. Because the vaccine is so new, there's no definitive research on injuries caused by the vaccine, she said. Which means that when the claims land on someone's desk at HRSA, that person "can do their job and look at the 'research' and everyone loses." ....Our law firm has concluded that there is nothing our attorneys can do to significantly assist you," the firm states. Maglio told me his Sarasota, Florida-based firm has been "contacted by at least a couple hundred people" about suspected COVID vaccine-related injuries, including blood clots and cardiac inflammation. It's not that his firm doesn't want to help. Representing people who've had (rare) major adverse reactions to vaccines for tetanus, measles, hepatitis, influenza and a dozen other shots is its bread and butter.

000000000000000000000000000000000000000	
From:	b6
Sent:	1/11/2022 8:45:47 PM
To:	Walitt, Brian (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
10 may 201	(FYDIBOHF23SPDLT)/cn=Recipients/cn=5b9339ab4cd1422aaf4669c64ca85914 b6
CC:	Gavin, Angelique (NIH/NINDS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
CC.	
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=6e97392e947e4f7ebb17eeb8ac87c5d5 <b>b6</b>
Subject:	Re: Status of care for Pfizer covid vaccine brain, etc injuries- Fwd: [EXTERNAL] Status? Re: Covid vaccine brain injury-
	are there studies you all are doing? What is being done to help us? Doctors have no idea
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.
If we can try	to do it tomorrow, that would be better. Those of us injured by this cannot keep waiting and
waiting and	waiting.
0	<u> </u>
Iftomorrow	is a had day for me, we can then schedule something next week. Will that work?
II tomorrow	is a bad day for me, we can then schedule something next week. Will that work?
On Tue, Jan	11, 2022, 2:14 PM Walitt, Brian (NIH/NINDS) [E] <b>b6</b> wrote:
	(1.1.2.1.1.1.2.)
[	
b6	
No worrie	es. We can find some time to chat when you typically have more energy. Angelique can help us
	ome time in morning during the next week or so if that works for you.
schedule so	the time in morning during the next week of so it that works for you.
GE1 1	
Thanks,	
Brian	
	1.6
From:	b6
Sent: Tueso	day, January 11, 2022 3:00 PM
	Brian (NIH/NINDS) [E] <b>b6</b>
Cc: Gavin,	Angelique (NIH/NINDS) [C] b6
Subject: Re	e: Status of care for Pfizer covid vaccine brain, etc injuries- Fwd: [EXTERNAL] Status? Re: Covid
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I would be happy to find some time to chat with you about your concerns. Let me know if you have time tomorrow evening to schedule a phone call.
Thanks,
Brian
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Subject: RE: [EXTERNAL] Status? Re: Covid vaccine brain injury- are there studies you all are doing? What is being done to help us? Doctors have no idea
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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
LG (office)
b6 (cell)
(301) 480-5368 (efax)

b6
https://clinicaltrials.gov - study number 000089-N
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From: b6
Sent: Tuesday, January 11, 2022 12:22 PM
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5
Angelique,
Good morning. I hope you are well. I am checking on the status of this. If it is still not "approved", please
get me the contact email of whoever is responsible for not providing care for us and not researching what is
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This is not ok.
Thanks.
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directly. All my best to you.

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 (301) 480-5368 (efax) b6 https://clinicaltrials.gov - study number 000089-N From: **b**6 Sent: Thursday, November 4, 2021 10:55 AM To: Gavin, Angelique (NIH/NINDS) [C] **b6**Subject: Re: Covid vaccine brain injury- are there studies you all are doing? What is being done to help us? Doctors have no idea Sorry I am just getting back to you. I was shocked there is only a survey being done and between being sick and trying to get more help for us with the little energy and brain power I have, this has been delayed. Of course, please contact me over anything you all are doing for this. I have also been keeping

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When will this all start? Thanks. b6 **b6** b6 **b6** b6 On Thu, Sep 23, 2021, 8:59 AM Gavin, Angelique (NIH/NINDS) [C] wrote: Dear **b6** 

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Cc: NINDSPostCovid19 < nindspostcovid19@ninds.nih.gov> Subject: Re: Covid vaccine brain injury- are there studies you all are doing? What is being done to help us? Doctors have no idea

Thank you for your interest in our research. I received your information from Dr. Avindra Nath. We are

Thank you!
On Wed, Sep 22, 2021, 3:14 PM Nath, Avindra (NIH/NINDS) [E] <b>b6</b> wrote:
 Dear <b>b6</b>
Sorry to hear of your illness. At the moment we are collecting data on such complications. I have copied our research team who can guide you on how to help us do so.
Best wishes.
Avi
From: b6  Date: Wednesday, September 22, 2021 at 3:10 PM  To: Nath, Avindra (NIH/NINDS) [E] b6  Subject: Covid vaccine brain injury- are there studies you all are doing? What is being done to help us? Doctors have no idea  Dr. Nath-
I am writing because I was injured from a first dose of the Pfizer vaccine on (b)(6) and have horrific "vax fog" that is not going away and press reports list you as working on this- thank you.
I received the Pfizer vaccine at 11am and felt great all day- so happy, feeling like I may be somewhat more free in the next few weeks, etc and just took it easy and rested all day. I was feeling completely fine- my arm wasn't even that sore, as I had been moving it, etc., and at 8pm I was lying down and got up to get a drink and go to the restroom and had such violent dizziness that I didn't stop when I was vertical and ran into the wall, and then thought I needed to get on the ground and crawl so I wouldn't fall. And the symptoms expanded and none of them have stopped since.
I have brain fog so bad I cannot remember bank pins I have had for decades- this is taking me forever to write, etc, violent dizziness, constant nauseousness, light and sound sensitivity, ear ringing, low grade fever on and off, no energy, most nights can only sleep 2 or 3 hours at a time waking up all night long, horrible pain including eye pain when trying to work or do anything on digital devices, cannot get upset at all- feel it vestibularly and get really sick, lack of sleep makes me super sick, etc. And I have had 2 slight heart issue incidents and "covid arm" of just 3 small bumps like a blemish that felt weird a few weeks into this that oddly went away in a few hours and made me feel so sick that night I actually thought I might not

make it through the night and then my head was a bit better the next day (a lot of the head actual pain went away- pain that is not a headache) so that I could then get out of bed- but it is still very, very VERY bad. I have to educate my doctors as they haven't even heard of the term- which I hadn't either until I was frantically googling what was happening to me, Pfizer lied to me and told me no one has had these symptoms and to speak to my doctor and the FDA and CDC have been zero help, and are part of the problem as usual. How are our local doctors supposed to help us if Pfizer, etc and the FDA and CDC won't even admit this is happening, so the doctors cannot get any info?! The one doctor I do trust wants to see me in person vs on video, but being in the covid fire that is Texas, I am afraid to go into a healthcare facility without being fully vaccinated. Especially if I am just going to be told no one knows what is happening and have the experiences I am seeing all over these forums, examples below. I have NEVER taken my mask off this whole time and I do not even go to the grocery store because of how horrible Texas is with no mask mandates. I have been **b6** and was telling people to stay home in Feb 2020 because I could see what was coming. Have you all started researching this, if not why not, and how are we to get help? I am being told I have to pay for everything, which even if I could do so, would not. This is not my responsibility in any way, shape or form. And that this is being covered up by Pfizer and the FDA and CDC is unconscionable. I would have been better off not getting the vaccine and taking the Regeneron antibodies therapy if I got covid. And I'm not getting the second dose until someone tells me what is going on, so someone is going to have to figure this out. Please advise. And thank you again for your work. There are hundreds and hundreds of pages of people having these side effects on this site: Covid-19 Vaccine side effects - Page 123 - Patient: Dizziness - VeDA Forum https://vestibular.org/forum/dizziness/covid-19-vaccine-side-effects/paged/123/

April 25, 2021 7:59 am

It's now 2.5 weeks after first Phizer vaccine and still dealing with disabling Vertigo. Saw a neurologist, had MRI, CAT scan, ENT doctor exam, bloodwork and am still taking meclazine & diazepam just to stop the nausea and vomiting.

Neurologist told me that anyone that has any brain problems or autoimmune disease of the brain (I have MS), and any brain injury history should NOT be vaccinated and that he keeps seeing patients with this dizziness problem.

## BIAA IS RECOMMENDING THE VACCINES(?!)

BIAA Issues Guidance on COVID-19 Vaccines for Persons with Brain Injury

https://www.biausa.org/public-affairs/public-awareness/news/biaa-issues-guidance-on-covid-19-vaccines-for-persons-with-brain-injury

"When one is infected with COVID-19, the virus attacks the 'weakest link' it finds in the body, which is why individuals with longstanding chronic medical issues are at greatest risk for infection, complications, and even death," explained BIAA National Medical Director Brent E. Masel, M.D. "Studies have shown that traumatic brain injury triggers an inflammatory process in the brain that causes an individual to experience chronic issues. This process places those individuals at far greater risk of developing complications from COVID-19, which itself is well known to cause chronic neuroinflammatory issues."

Woman suffers 'life-altering injuries' after COVID-19 vaccine, teams up with Utah senator to demand answers | NewsNation Now

https://www.newsnationnow.com/us-news/west/woman-suffers-life-altering-injuries-after-covid-19-vaccine-teams-up-with-utah-senator-to-demand-answers/

A 'black hole' for COVID vaccine injury claims | Reuters

https://www.reuters.com/legal/government/black-hole-covid-vaccine-injury-claims-2021-06-29/

Except historically, almost no one gets anything. Since the program's inception in 2010, only 29 claims have been paid, with an average payout of around \$200,000. (Ten additional claims won approval but were deemed ineligible for compensation.)

Gentry is not optimistic that any will be approved. Because the vaccine is so new, there's no definitive research on injuries caused by the vaccine, she said. Which means that when the claims land on someone's desk at HRSA, that person "can do their job and look at the 'research' and everyone loses."

....Our law firm has concluded that there is nothing our attorneys can do to significantly assist you," the firm states.

Maglio told me his Sarasota, Florida-based firm has been "contacted by at least a couple hundred people" about suspected COVID vaccine-related injuries, including blood clots and cardiac inflammation. It's not that his firm doesn't want to help. Representing people who've had (rare) major adverse reactions to vaccines for tetanus, measles, hepatitis, influenza and a dozen other shots is its bread and butter.

From:	b6		
Sent:	5/31/2022 10:58:24 PM		
То:	Walitt, Brian (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administration (FYDIBOHF23SPDLT)/cn=Recipients/cn=5b9339ab4cd1422aaf4669c64ca	,	"]
CC:	Smith, Bryan (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administ	<u> </u>	<u>!</u>
CC.	(FYDIBOHF23SPDLT)/cn=Recipients/cn=de7bf3d6ad0046288fd8c35f33d		<del></del>
Subject:	Re: [EXTERNAL] <b>b6</b>	L	!
	National Control of the Control of t		
		_	
	s - thank you Brian! That whole experience is a little fuzzy fo	r me so I appi	reciate the help. Have a
great week a	nead.		
On Tue Ma	w 21 2022 of 12:52 DM Woliff Brian (NIH/NINDS) [E]	h6	wrote:
b6	y 31, 2022 at 12:52 PM Walitt, Brian (NIH/NINDS) [E]	b6	wrote.
Sorry to l	ear about your issues. <b>b6</b>	<b>.</b>	
b6	I have attached him to this email. Hope you feel better soon		j
Thanks			
Brian (Wal	itt)		
·			
From:	b6		
	day, May 31, 2022 at 6:14:51 PM		
	, Brian (NIH/NINDS) [E]" b6		
Subject: [E	EXTERNAL] <b>b6</b>		
Hi Brian,			
III DITaii,			
I am a patie	ent with Dr. Nath and Dr. Safavi for post-vaccine complication	ıs.	b6
[			
	nn		
Thank you,			
b6			
	s email originated from outside of the organization. Do not click links or c	ppen attachmen	ts unless you recognize the
sender and a	e confident the content is safe.		

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.

From: Sent: To: Subject:	(FYDIBOHF23S (NIH/NINDS) [I	inda (NIH/NINDS SPDLT)/cn=Recip E] [/o=Exchange SPDLT)/cn=Recip	ients/cn=449 Labs/ou=Excl	)1ee2ae980461 hange Administ	0899c7411001 rative Group	50540 <b>b6</b>	Safavi, Fa	rinaz
To whom it r	nay concern							
I was given y 19 vaccine.	our email an	nd asked to se	nd you a m	essage regard	ling the react	tion I have	had to the M	Ioderna covid
I had the vac	cine on	<b>b6</b> on	b6	was taken t	o the ER due	e to swellin	ng of my tong	gue and throat
I was given	be	<b>3</b> a	nd sent hor	ne to treat my	symptoms.	after 5 day	s of	b6
home had dir having full so the whole ep night I have of to go into a d relief for more what else to of	nner and wen eizure type co isode. The ho continued wi leep sleep. I l re than a few do. Nothing lo be able to g	as able to go	pack to wo prmal night had no confole to get the over my be other ER's imary care on an EEG	rk on be dy routine arc trol over my e convulsions ody on a daily s trying to fin doctor has no b, MRI or any	pund 9pm I varms or my les to stop with y basis the order an answer ow referred to for the blooder.	yas getting in a yas getting egs I was f of the second of	ready for be fully conscious b6 ey stop is whosen unable to because she doctors have	d and started us throughout Since that nen I am able to get any e has no idea
Thank you in	ı advance,							
b6								

From: Sent: To: Subject:	Wiebold, Amanda (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4491EE2AE9804610899C741100150540 b6 3/10/2021 10:54:44 AM Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 b6 RE: Covid vaccine reaction			
Good morni	ng,			
until you cor the same tim pending. Th	Is you question about the consent form? The version you have is just for you to review. It does not get signed until you come to the Clinical Center. The study team will review the consent with you and everyone signs at the same time. I have requested your medical records including your MRIs from <b>b6</b> is still pending. The fax wouldn't go through yesterday and I wasn't able to get someone on the phone. They were apparently having "system problems" according to the messages I got. I will try again today.			
Let me know	v if you have a question I didn't answer.			
Thanks, Amanda				
Sent: Tuesday To: Cc: Wiebold, Subject: RE: C  Dear     b6 I copy Amand Best,  Farinaz Safavi	euroimmunology and Neurovirology			
To: Safavi, Fa	y, March 8, 2021 8:28 PM rinaz (NIH/NINDS) [E] Covid vaccine reaction			
Good evening	5,			
if you got it. I request a CD	read the consent form-however I did not see a place to sign it. I will go tomorrow to medical records to for the rest of my MRIs b6 I had my first MRI b6 done but will sign the medical s that the nurse sent so they can send it to you. Otherwise b6 did all of the other MRIs.			

magings in

From: b6 Sent: Saturday, March 6, 2021 11:18 AM To: Safavi, Farinaz (NIH/NINDS) [E] Subject: Re: Covid vaccine reaction
Apologies, Dr. Safavi (I just realized I was putting Dr. Safazi- I'm so sorry)
I just added two other lab values in and updated it- this should be everything as of now.
I'll see you Monday.
On Sat, Mar 6, 2021 at 10:09 AM <b>b6</b> wrote:  Good morning Dr. Safazi,
I did a brief synopsis, can discuss further during visit. Have placed all results that I have in the Word document. I hope this helps, please let me know if you need anything else. I have access to all my medical records online.
Thanks,
<b>b6</b>
On Sat, Mar 6, 2021 at 7:33 AM Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b> wrote:
perfect.
Can you please send me a summary of your disease course,work ups and treatments you have had so far?
You will receive MS teams for Monday.

Thank you
Farinaz
Farinaz
From: b6 Sent: Saturday, March 6, 2021 6:52:47 AM To: Safavi, Farinaz (NIH/NINDS) [E] b6 Subject: Re: Covid vaccine reaction
Dear Dr. Safazi,
Thank you so much for your response-it means a lot. Yes, I will take the Monday 3/8 spot at 10am ET.
Sincerely,
b6
On Fri, Mar 5, 2021, 10:55 PM Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b> wrote:
Dear b6
I am really sorry to hear about your illness. We certainly can meet through televisit and go over your post vaccine issues.
I have an available spot on Monday 3/8 at 10am ET.Please let me know if this time works for you and I will send you a link.
Best Regards,
Farinaz Safavi MD, PhD
Division of Neuroimmunology and Neurovirology

From: b6 Sent: Friday, March 5, 2021 5:38 PM To: Safavi, Farinaz (NIH/NINDS) [E] Subject: Covid vaccine reaction
Hello Dr. Safazi,
I am part of the group that b6 is in and was wanting to see if I can get a consultation or I do not know if there is a research study to join with you all. I live here in b6 so can come in if needed. I am a b6 here in b6
A quick summary:  I developed a reaction after my 2nd moderna vaccine b6 I am b6 I got my injection on right side. Within an hour I developed RUE/RLE weakness (I couldn't even eat with spoon and fork and was walking with a limp) it progressively got worse the more activity I did and about a month later I developed LUE/LLE weakness additionally. I also experience injection site/deltoid muscle burning sensation with prolonged activity. I am unable to do some of my ADLs and have not been back to work yet. I am able to ambulate with a limp. I have had MRIs and blood test done and they are unable to find
What is causing my weakness.  I appreciate that you all are looking into this!
I hope to hear from you soon! Thank you.
<b>b6</b>

NINDS, NIH, Bethesda, MD

From:	b6
Sent:	4/5/2021 1:21:22 PM
То:	Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540 <b>b6</b>
Subject:	vaccine reactions follow up <b>b6</b>
Hi Amanda,	
wednesday o	well. I just wanted to follow up with you, I had a virtual meeting with <b>b6</b> this past on 3/31 regarding post COVID 19 vaccination reactions. She mentioned her assistant will request work perhaps and other things from me. Please let me know what you may need from me, because I getting you those things this week!
Thank you!	
Sincerely,	,
h6	

From: Sent: To: Subject:	Safavi, Farinaz (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=94807CE146E045D4B61655DA26A0C246 b6 5/17/2021 11:19:38 PM Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540 b6 Re: Moderna Vaccine neurological injury
go ocer you	search nurse Amanda to send you medical release form and sample only consent which help us to medical records and receive you CSF samples.  any documents from your medical records u can send us by email.
Farinaz	
<b>To:</b> Safavi, Fa	b6 , May 16, 2021 11:35:55 PM rinaz (NIH/NINDS) [E] b6 Moderna Vaccine neurological injury
Hi Dr Safav	i,
willing to traget an email  b6  the ER seve  me I was ma	to much for responding! I would love to have you collaborate with my local doctors and I'm always avel to see you as well! I will contact my current neurologist first thing Monday morning to try and or the best way to contact her. Her name is <b>b6</b> she is a neurologist out of <b>b6</b> Up until now it's been very difficult for me to even have them take me seriously. I've had to go to ral times just get someone to examine me and run tests. One of the associates even tried to convince aking it happen from anxiety since my MRIs, CT and LP were all normal. Although I should say cently started seeing <b>b6</b> and she does seem to accept it's "likely" from the vaccine.
vaccine inju frustrating. As far as my unfortunatel records fron system here since, it's cr definitely w online and a Please let m	peen in the middle of getting a second opinion at b6 I thought they may be more open to ry issues and treatments. Doctors here really are in the dark and some very skeptical, it's very a CSF goes, I'm happy to have it sent if possible. It was taken at b6 and y my healthcare system is caught up in the b6 All my medical b6 have been offline for 2 weeks including the referral process. b6 and they were (b)(6) and have been off-line ever eated major problems for a lot of us one of which me being unable to get my biopsy done. But I ant to get the ball rolling and at least all my records from my 2 hospital visits to b6 are still coessible including my neurologists office notes.  e know what else I can do. I will contact you as soon as I'm able to get a response from my Feel free to call me at b6
L	i
Sent from m	y iPhone

- ---- ---- ---- *----* -- -----

On May 14, 2021, at 8:23 PM, Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b> wrote:
Dear b6 I am sorry to hear about your illness. If you connect me with your neurologist I would ve happt to speak and share our understanding with him/her and discuss possible work up and treatment plan. Do you think you can send us your CSF from your lumbar puncture for further research tests?please let me know and our team can coordinate the next step.
Thank you
Farinaz
From: b6 Sent: Friday, May 14, 2021 3:31:47 PM To: Safavi, Farinaz (NIH/NINDS) [E] b6 Subject: Moderna Vaccine neurological injury Hello Dr. Safavi,
My name is b6 Before the vaccine I was a b6 and was working as a b6 b6 With only a history of b6 I haven't had to take any
I received my first dose of the Moderna vaccine on b6 Approximately five days later I began getting headaches at the back of my head which became more intense the following week. The pain was so bad I thought I had a brain tumor it felt like someone had hit me on the back of the head with a bat. I had an MRI which was unremarkable. After a couple of weeks I started getting electrical shocks at the back of my head which I was then diagnosed with b6 I dealt with the painful neuralgia 24/7 through the end of March upon which I began a b6 On March 30th after b6 the neuralgia went around my head to my ear and cheek I woke up at 4 AM with the most intense pain yet, it was presumed I now had b6 By April 2, I began to get muscle twitches through my entire body. That's when the wheels fell off. Since April 2 I began to get neuralgia on body parts starting with my calf and it has now Spread over my entire body from head to toe. I've been hospitalized 3 times in the last month. I have gotten multiple MRIs CT scans, lumbar puncture and labs due to neuropathy and weakness. Everything comes back unremarkable. I have experienced SOB, intolerance to heat/cold, I've woken up in the middle of the night with limbs completely "asleep" for no reason, trouble walking up my stairs, fatigue, irregular heart beat, BP spikes, nerve pain and I still deal with b6 I recently had an EMG which came back normal so now my neurologist is suspecting b6 The problem I'm having is no
one is willing to treat me as someone who is having an immune response to the vaccine. I'm looking for treatment, all I am being offered is b6 at the moment. I am desperate to get my life back!! I am disabled now,, is there anything you or someone else at the NIH can do to help me.
Thank you,  b6

Sent from my iPhone

From:	Nath, Avindra (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B81CA051950B4D458D74037A6A86EAD6 <b>b6</b>
Sent:	8/10/2021 1:37:01 PM
То:	Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 <b>b6</b>
	b6
CC:	Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540 <b>b6</b>
Subject:	b6
I agree with [	Dr. Safavi. b6
Avi	<u> </u>
F	: F
	i, Farinaz (NIH/NINDS) [E] <u>b6</u>
Date: Tuesd	ay, August 10, 2021 at 9:29 AM
To:	b6
Cc: Wiebold	, Amanda (NIH/NINDS) [E] b6 Nath, Avindra (NIH/NINDS) [E]
,	o6
i	
Subject:	b6
Dear Staci,	
Thank you ve	ry much for the medical records. I cc Amanda in this email to help me store them in your file here.
Regarding yo	ur questions, b6
b6	I suggest you discuss it with your local physicians. I also cc Dr.Nath in this email in case he can provide
us with furth	er information.
i also ericoura	age you to speak with your neurologist about b6
l also encoura	b6
	b6
l appreciate i	f you can send us <b>b6</b> as soon as possible.
l appreciate i	b6
l appreciate i	f you can send us <b>b6</b> as soon as possible. for participating in our research.
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l appreciate i Thanks again Best Regards	f you can send us <b>b6</b> as soon as possible. for participating in our research.
I appreciate i Thanks again Best Regards Farinaz	f you can send us b6 as soon as possible.  for participating in our research.  b6
I appreciate i Thanks again Best Regards Farinaz From: Sent: Monda	f you can send us b6 as soon as possible. for participating in our research.  b6 y, August 9, 2021 5:22 PM
I appreciate i Thanks again Best Regards Farinaz From: Sent: Monda To: Safavi, Fa	f you can send us b6 as soon as possible. for participating in our research.  b6 y, August 9, 2021 5:22 PM arinaz (NIH/NINDS) [E]
I appreciate i Thanks again Best Regards Farinaz From: Sent: Monda	f you can send us b6 as soon as possible. for participating in our research.  b6 y, August 9, 2021 5:22 PM arinaz (NIH/NINDS) [E]
I appreciate i Thanks again Best Regards Farinaz  From: Sent: Monda To: Safavi, Fa Subject:	b6  f you can send us b6 as soon as possible.  for participating in our research.  b6  y, August 9, 2021 5:22 PM  rinaz (NIH/NINDS) [E]  b6
I appreciate i Thanks again Best Regards Farinaz From: Sent: Monda To: Safavi, Fa	b6  f you can send us b6 as soon as possible.  for participating in our research.  b6  y, August 9, 2021 5:22 PM  rinaz (NIH/NINDS) [E]  b6
I appreciate i Thanks again Best Regards Farinaz  From: Sent: Monda To: Safavi, Fa Subject: Hello Dr Safav	b6  f you can send us b6 as soon as possible.  for participating in our research.  b6  y, August 9, 2021 5:22 PM rinaz (NIH/NINDS) [E] b6  vi,
I appreciate i Thanks again Best Regards Farinaz  From: Sent: Monda To: Safavi, Fa Subject: Hello Dr Safav	b6  f you can send us b6 as soon as possible.  for participating in our research.  b6  y, August 9, 2021 5:22 PM  rinaz (NIH/NINDS) [E]  b6
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I appreciate i Thanks again Best Regards Farinaz  From: Sent: Monda To: Safavi, Fa Subject: Hello Dr Safav	f you can send us b6 as soon as possible.  for participating in our research.   b6 y, August 9, 2021 5:22 PM rinaz (NIH/NINDS) [E] b6 vi,  ove contain information about b6

# **b6**

Thank you

b6

Sent from  $\underline{\text{Mail}}$  for Windows 10

From: Sent:	Wiebold, Amanda (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4491EE2AE9804610899C741100150540 b6 4/3/2021 1:01:00 AM
To: Subject:	RE: Fwd:post caccine
Thank you	b6
Our schedule	er will reach out to you next week.
Have a good Amanda	weekend,
To: Wiebold,	b6 April 2, 2021 8:42 PM Amanda (NIH/NINDS) [E] b6 wd:post caccine
Hello, I have attache	ed the request for medical information. <b>b6</b>
you need anyt Thank you, <b>b6</b>	<b>b6</b> The scheduler can reach me at <b>b6</b> Please let me know if
On Fri, Apr 2,	2021, 6:39 PM Wiebold, Amanda (NIH/NINDS) [E] <b>b6</b> wrote:
b6	
	Dr. Nath and Dr. Safavi at the National Institutes of Health in Bethesda Maryland. Dr. Safavi has t you are interested in participating in our research study. I will help get you enrolled.
Attached yo	ou will find two forms.
records. Ple not had any	medical records. This form gives us permission to request and review your medical ease fill out the sections highlighted in yellow and return to me by secure email or fax. If you have scans or tissue collection please write "NA" in those sections. If you have been seen at multiple ase fill out one form for each facility.
	ol consent form. This is for your review only. You do not need to sign anything at this time. This assed with you when you come in to the Clinical Center in person and you will sign then.

Please let me know if you have any questions. I will have our scheduler reach out to you also. What is the best number for her to reach you?
Thanks,
Amanda Wiebold, BSN, RN, CNRN
Research Nurse Specialist
NINDS Section of Infections of the Nervous System
10 Center Drive, Building 10/7C107, MSC 1430
Bethesda, Maryland 20892
Office: b6
Cell: b6
Fax: 301-402-1137
Email: <b>b6</b>
From: Safavi, Farinaz (NIH/NINDS) [E] b6 Sent: Thursday, April 1, 2021 3:22:03 PM To: b6 Subject: RE: Re:

Farinaz Safavi MD, PhD
Division of Neuroimmunology and Neurovirology
NINDS, NIH, Bethesda, MD
From: b6 Sent: Thursday, April 1, 2021 3:21 PM
To: Safavi, Farinaz (NIH/NINDS) [E] Subject: Re: Re:
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Thank you,
b6
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I can speak with you tomorrow at 10am ET.Does this time work for you?
Farings Cafari MD DLD
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Division of Neuroimmunology and Neurovirology
NINDS, NIH, Bethesda, MD

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b6 If you need anything further please don't hesitate to ask!
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Thanks
Farinaz
Failidz
From: b6
Sent: Wednesday, March 31, 2021 7:30:22 PM  To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject:
Dr. Safavi,
Hello, I have received your email from b6 I will preface it by saying I am a b6 and my only underlying conditions are b6 no prior
neuro issues. I have been also having neurological symptoms starting shortly after my second dose of the Moderna vaccine. I received my first dose on b6 and my second on b6 The first dose was fine, just was a

From: Sent: To: Subject: Attachments:	b6  4/3/2021 12:42:19 AM Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741 Re: Fwd:post caccine s: CamScanner 04-02-2021 20.38_1.jpg		
	ne know if you need anything further!	<b>b6</b> eduler can reach me at	<b>b6</b>
On Fri, Apr	or 2, 2021, 6:39 PM Wiebold, Amanda (NIH/NINDS) [E]	b6	wrote:
	th Dr. Nath and Dr. Safavi at the National Institutes of he stold me that you are interested in participating in our		•
Attached y	l you will find two forms.		
records. F you have i	e of medical records. This form gives us permission to re Please fill out the sections highlighted in yellow and re not had any scans or tissue collection please write "NA nultiple facilities please fill out one form for each facility	turn to me by secure en A" in those sections. If y	mail or fax. If
	ocol consent form. This is for your review only. You do is will be discussed with you when you come in to the C n.		=
you perso	ed to send any medical records to us directly you can a onally have any imaging scans you can upload them di s link: https://www.cc.nih.gov/dcri/imaginglibrary.html		

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From: Safavi, Farinaz (NIH/NINDS) [E] b6 Sent: Thursday, April 1, 2021 3:22:03 PM To: b6 Subject: RE: Re:
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hours and just didn't feel quite right and like I wasn't quite with it. Then shortly after I started with dizziness
and headaches that ran across my forehead, I then had my eyes checked and all was normal. My eyes are sensitive to light and are just plain weird. Then the dizziness continued but I started to have burning in my

my PCP who gave me
elief from that, so the
elief from symptoms
less, but the tingling
lpitations, I contacted
d all bloodwork came
They did the
I have an appointment
1



***************************************	
From:	Wiebold, Amanda (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4491EE2AE9804610899C741100150540- <b>b6</b>
Sent:	4/2/2021 10:39:09 PM
To:	b6 Nahar, Kymani (NIH/NINDS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f432f899337490ea7cbde0a4b52effb b6
Subject: Attachments:	RE: Fwd:post caccine 15N0125 Standard Consent.pdf; NIH-1208 Authorization for the Release of Medical Information modified.pdf
b6	
	Dr. Nath and Dr. Safavi at the National Institutes of Health in Bethesda Maryland. Dr. Safavi has you are interested in participating in our research study. I will help get you enrolled.
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personally h	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
	e know if you have any questions. I will have our scheduler reach out to you also. What is the best her to reach you?
Research Nur NINDS Sectio 10 Center Driv Bethesda, Ma	n of Infections of the Nervous System ve, Building 10/7C107, MSC 1430 ryland 20892 o6
	Farinaz (NIH/NINDS) [E] <b>b6</b> av. April 1. 2021 3:22:03 PM
bent: Inursa	IV. AUTILIT, ZUZI D.ZZ.UD MVI

To: b6
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Farinaz Safavi MD, PhD Division of Neuroimmunology and Neurovirology NINDS, NIH, Bethesda, MD

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shortly after I started with dizziness and	d headaches tha	at ran across my	forehead, I then h	nad my eyes chec	ked and all
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burning in my temple area that spread	around my eye:	s/sinuses and ac	ross my forehead.	I went to see my	PCP who
gave me	b6		I had	d no relief from tl	hat, so the
gave me following week he put me on	b6	and I had	d about a 2 day rel	ief from symptor	ns while on
b6 The symptoms continue, a					
there, and within the past 2 weeks I have	e had what fee	els like heart pal	oitations, I contact	ed my doctor ag	ain who
wanted me to go to the ER, so I did, and	the EKG, ches	t x ray and all blo	oodwork came bad	ck normal except	for <b>b6</b>
b6		They did t	he normal quick n	euro tests and all	l were
normal. My PCP referred me to an ENT,	which I have a	n appointment \	with on Monday, n	ext I would like t	o see a
neurologist.			•		
Thank you,					
LO					
<b>D</b> 6					

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: Adult/Guardian 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. Therefore, 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.

PATIENT IDENTIFICATION

Consent to Participate in a Clinical Research Study

NIH-2977 (4-17)

File in Section 4: Protocol Consent (1)

Version Date: 02/24/2020

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#### 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.

#### BACKGROUND

Inflammation is the way your body reacts to infection or injury. Signs of inflammation can include swelling, pain, redness or heat. Infections or inflammation in the brain can cause major health problems. Brain and nerve infections can be hard to find 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 affect the brain and nerves 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.

#### STUDY POPULATION

Up to 1000 people will take part in this study.

#### VISIT SCHEDULE

For this study, you may have several visits to the NIH Clinical Center in Bethesda, MD. The number of visits and the visit schedule depends on your individual case. In general, there will

be an initial evaluation period where we may see you as often as every week for the first weeks or months. The frequency of visits during this period depends on how much testing you will need at the beginning and if you agree to the extra visits. After this initial evaluation period, we may ask to see you again, regularly or occasionally, depending on your condition and the research needs of this study.

During one or more of your visits, you may have a brief interview with a Clinical Research Advocate (CRA) from the Human Subjects Protection Unit. The interview will see whether you understand about being in this research study. It will help decide whether you need to have someone else give consent for you to be in the study. The CRA will talk to you and the research team about the interview results.

#### **OVERVIEW**

During your study visits we will ask you about your history and do a physical exam. You will have a variety of tests. These tests are explained below. We may ask you to do additional research tests if we think that they would help us better understand your disease processes. This could include additional MRI testing, a special eye exam called optical coherence tomography (OCT), or a brain wave test called an electroencephalogram (EEG). You do not have to do these optional research tests if you do not want to. You can still be part of the study. There are no experimental drugs or devices used in this study.

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#### **BASELINE STUDY PROCEDURES:**

The following procedures will be required for all adults in the study. The research team may decide some of these procedures are not required based on your health status. For children, these studies will be done only if they are tolerated easily.

# **History and Physical Exam:**

We will ask you for your medical, social, and family history. We will ask you about your medications. You will also have a thorough physical and neurological exam. This physical exam is for research purposes only and does not replace any examination you may receive from you own doctors.

#### **Blood Draw**

Blood will be drawn through a needle in your arm. We will draw no more than 2.3 cups of blood over 8 weeks for adults and no more than 2 cups of blood over 8 weeks for children.

#### **HIV Test**

As part of this study, we may test you for infection with the human immunodeficiency virus (HIV), the virus that causes AIDS. If you are infected with HIV you will still be able to participate in this study.

# **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.
- 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

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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.

#### **MRI**

Magnetic resonance imaging (MRI) uses a strong magnetic field and radio waves to take pictures of your brain. The MRI scanner is a metal cylinder surrounded by a strong magnetic field. During the MRI, you will lie on a table that can slide in and out of the cylinder. You will be in the scanner about 60-90 minutes. You may be asked to lie still for up to eight minutes at a time. While in the scanner you will hear loud knocking noises, and you will be fitted with earplugs or earmuffs to muffle the sound. You will be able to communicate with the MRI staff at all times during your scan, and you may ask to be moved out of the machine at anytime.

During the MRI scan you will receive gadolinium, a contrast agent, through an intravenous (IV) catheter. A needle will be used to guide a thin plastic tube (catheter) into one of your arm veins. The needle will be removed, leaving only the catheter in the vein. The catheter will be taped to the skin to hold it in place.

During part of the MRI you will receive gadolinium, a contrast agent, through an intravenous (IV) catheter. It will be done for both research and medical purposes.

It is not known if MRI with contrast is completely safe for a developing fetus. Therefore, all women of childbearing potential will have a pregnancy test performed no more than 24 hours before each MRI scan with contrast. The scan will not be done if the pregnancy test is positive.

#### Lumbar puncture

For the lumbar puncture, you will lie on your side, curled up with your knees at your chest, or you will sit upright. Your lower back will be washed and a local anesthetic will be injected into your back to make it numb, which may sting for a few seconds. A needle will be inserted through the numbed skin and into the space between the bones in your back.

You may feel a sensation of pressure. About 1.5 tablespoons of cerebrospinal fluid (CSF) will be removed. It usually takes 5 to 20 minutes to collect the CSF. After the fluid is collected, the needle will be removed and you may get up and move around as soon as your doctor says you may.

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If we cannot safely do your lumbar puncture without the help of an x-ray, your lumbar puncture will be done in the Radiology Department. If you are under 18 years of age the lumbar puncture (either at the bedside or in the Radiology Department) will only be done if it is needed for your clinical care.

# **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.

#### **OPTIONAL STUDY PROCEDURES**

# The following procedures will be done depending on your symptoms and diagnosis:

# **Optical coherence tomography (OCT)**

OCT is short for optical coherence tomography. It is a test that measures the thickness of the nerve in the eye. This works similarly to an ultrasound, but instead of measuring sound, it measures the reflection of infrared light. It takes about 15 to 30 minutes. This test is optional. You don't have to have to do this test to take part in this study.

#### **Evoked Potentials**

You may be asked to have evoked potential testing. Evoked potentials measure the how fast signals travel along pathways of sensation, hearing or vision. You will have a few electrodes placed on top of the skin your head and you will receive sensory stimulation, listen to clicks or look at pattern. No hair is removed for this testing. The electrodes will be removed after the study. Evoked potentials typically take 1 hour.

# Electromyogram (EMG) and Nerve Conduction Study (NCS)

You may be asked to have an EMG and NCS done to study how the muscles and nerves in your arms or legs work. During the EMG a small needle will be inserted into the muscles or an arm and/or leg and the activity of the muscle will be measured. NCS is a test during which small electric shocks are applied to the nerves in your arms or legs and the ability of your nerves to conduct signals is measured. EMG and NCS take 30 minutes to 1 hour.

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# **Neuropsychological Testing**

Neuropsychological testing may include tests of your memory, attention, concentration, and thinking. This may include an interview, questionnaires, and a pen-and-paper or a computerized test. It takes 2-4 hours.

# Electroencephalogram (EEG)

During an EEG, the electrical activity of your brain ("brain waves") will be recorded by placing small metal disc electrodes on your scalp with either glue, paste or an electrode cap. A conductive gel will be placed in the space between the electrodes and your scalp to make sure there is good contact between them. Your brain waves will be recorded while you are lying quietly, breathing deeply, watching bright flashes of light, or sleeping. The EEG usually takes 1 to 2 hours. The electrodes will be taken off once the EEG is completed.

# Skin biopsy (adults only)

A small area of skin will be washed with iodine and alcohol. We will inject a local anesthetic to numb the area. Then we will remove a 1/4-inch piece of skin with a biopsy tool. After the biopsy, the site will be covered by a dressing. You will receive instructions on how to care for area.

#### **Urine Collection**

We will collect urine to look for viruses or other signs of infection. We will also do a urine

pregnancy test for women and girls who are able to get pregnant. If you are a minor and have a positive pregnancy test, we will inform both you and your parents. If you object to having this required pregnancy test, you should not participate in this study.

#### Saliva Collection

We would like to see if certain viruses are found in the saliva of people with inflammation in the brain and nervous system. You will need to chew on a piece of sterile cotton for one minute.

#### RISKS, INCONVENIENCES AND DISCOMFORTS OF MAIN STUDY PROCEDURES:

# **History and Physical Exam**

There is minimal risk with doing history and physical exam; there could be minimal discomfort.

# **Blood Draw**

You may have some discomfort and bruising at the site of needle entry. There is a very small risk of fainting. Infection in the area of the needle insertion is rare.

# **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.

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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.

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.

# **HIV Testing**

If you test positive for HIV, this could be distressing news for you and your partner. We will tell

you what the results mean and how we report newly diagnosed HIV infection. We will also tell you how to find care. We will tell you how to avoid infecting others and the importance of informing your partners at possible risk because of your HIV infection.

#### **Urine Collection**

There are no risks associated with urine collection.

#### Saliva Collection

There are no medical risks and minimal discomfort with saliva testing.

#### **MRI**

People are at risk for injury from the MRI magnet if they have pacemakers or other implanted electrical devices, brain stimulators, some types of dental implants, aneurysm clips (metal clips on the wall of a large artery), metallic prostheses (including metal pins and rods, heart valves, and cochlear implants), permanent eyeliner, implanted delivery pump, or shrapnel fragments. Welders and metal workers are also at risk for injury because of possible small metal fragments in the eye of which they may be unaware. You will be screened for these conditions before having any scan, and if you have any, you will not receive an MRI scan. If you have a question about any metal objects being present in your body, you should inform the staff. In addition, all magnetic objects (for example, watches, coins, jewelry, and credit cards) must be removed before entering the MRI scan room.

It is not known if MRI is completely safe for a developing fetus. Therefore, all women of childbearing potential will have a pregnancy test performed no more than 24 hours before each MRI scan. The scan will not be done if the pregnancy test is positive.

People with fear of confined spaces may become anxious during an MRI. Those with back problems may have back pain or discomfort from lying in the scanner. The noise from the scanner

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is loud enough to damage hearing, especially in people who already have hearing loss. Everyone having a research MRI scan will be fitted with hearing protection. If the hearing protection comes loose during the scan, you should let us know right away. Please notify the investigators if you have hearing or ear problems. You will be asked to complete an MRI screening form for each MRI scan you have. There are no known long-term risks of MRI scans.

The risks of an IV catheter include bleeding, infection, or inflammation of the skin and vein with pain and swelling.

Mild symptoms from gadolinium infusion occur in fewer than 1% of those who receive it and usually go away quickly. Mild symptoms may include coldness in the arm during the injection, a metallic taste, headache, and nausea. In an extremely small number, fewer than one in 300,000 people, more severe symptoms have been reported including shortness of breath, wheezing, hives, and lowering of blood pressure. You should not receive gadolinium if you previously had an allergic reaction to it. You will be asked about such allergic reactions before gadolinium is given.

People with kidney disease are at risk for a serious reaction to gadolinium contrast called "nephrogenic systemic fibrosis" which has resulted in a very small number of deaths. A blood test of your kidney function may be done within the month before an MRI scan with gadolinium contrast. You will not receive gadolinium for a research MRI scan if your kidney function is not normal or if you received gadolinium within the previous month.

Most of the gadolinium contrast leaves the body in the urine. However, the FDA recently issued a safety alert that indicates small amounts of gadolinium may remain in the body for months to years. The effects of the retained gadolinium are not clear. At this time, retained gadolinium has not been linked to health risks in people whose kidneys work well. Some types of gadolinium contrast drugs are less likely to remain than others. In this study, we will use the gadolinium contrast drugs that are less likely to remain, whenever possible.

Please tell your research team if you have had any MRI scans in the past 12 months. We will also give you additional information called a "Medication Guide." Upon request, we will give you individual information about retained gadolinium we see on your studies

#### **Lumbar Puncture**

You may feel a brief pain or tingling sensation in your legs during the LP if the needle brushes against a nerve. If this happens, please let the doctor or nurse practitioner know right away. They will adjust the needle. You may have a mild backache after the LP at the place the needle was inserted. About one- third of people have a headache for a few days after a lumbar puncture. Usually the headache is not severe and improves without treatment other than a mild pain reliever. Headaches that last longer than 7 days happen with one in 50 to 200 lumbar punctures. They usually improve gradually over 2 weeks. In rare cases headaches have lasted longer. Prolonged headaches may be due to continued leakage of CSF from the area of the LP. You and your clinician may decide to perform a "blood patch" if your headache is prolonged. A blood patch requires removing blood with a needle from a vein in your arm and then injecting it into the area of your back where the lumbar puncture was done to seal off the leak of CSF. If you have your LP with an x-ray, you will be exposed to a small amount of radiation.

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#### **Radiation Risk**

This research study may involve exposure to radiation from up to 2 lumbar punctures under X-ray. This radiation exposure is not required for your medical care and is for research purposes only. The amount of radiation you will receive in this study is 0.026 rem which is below the guideline of 5 rem per year allowed for research subjects by the NIH Radiation Safety Committee. The average person in the United States receives a radiation exposure of 0.3 rem per year from natural sources, such as the sun, outer space, and the earth's air and soil. If you would like more information about radiation, please ask the investigator for a copy of the pamphlet, <u>An Introduction to Radiation for NIH Research Subjects.</u>

While there is no direct evidence that the amount of exposure received from participating in this study is harmful, there is indirect evidence it may not be completely safe. There may be a very slight increase in the risk of cancer.

Please tell your doctor if you have had any radiation exposure in the past year, either from other research studies or from medical tests or care, so we can make sure that you will not receive too much radiation. Radiation exposure includes x-rays taken in radiology departments, cardiac catheterization, and fluoroscopy as well as nuclear medicine scans in which radioactive materials were injected into your body.

If you are pregnant or breast feeding, you may not undergo LP under X-ray. It is best to avoid radiation exposure to unborn or nursing infants since they are more sensitive to radiation than adults.

# **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.

# RISKS, INCONVENIENCES AND DISCOMFORTS OF ADDITIONAL STUDY PROCEDURES:

#### OCT

There are no known risks of OCT.

#### **Evoked Potentials**

The skin needs to be lightly rubbed to place the electrodes, which may cause mild irritation. You may also have slight discomfort of pain from the shock stimulation. If it is too uncomfortable, let us know and we will try to turn down the stimulus intensity. You may stop the test at any time.

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#### EMG and NCS

You may have pain when the needles are inserted. There is a very small risk of infection or bleeding. The nerve stimulation may cause discomfort or pain. If it is too uncomfortable, you can ask to have the test stopped.

# **Neuropsychological Testing**

The neuropsychological tests are not harmful but may be frustrating or stressful. We only ask that you try your best. No one performs perfectly on these tasks. You may refuse to answer any question or to stop a test at any time and for any reason.

#### EEG

There is no risk associated with having an EEG. You may feel uncomfortable while the electrodes are attached to your scalp. The conductive gel sometimes causes some mild irritation You may not like the smell of the paste or the glue remover, but they are not harmful. If an electrode cap is used instead of the glue or paste, the cap may be uncomfortably tight and cause a headache.

# **Skin Biopsy**

Pain at the biopsy site is usually minimal; bleeding and infection are rare. The biopsy site usually heals with a very small, nearly unnoticeable scar, but may leave a raised scar or visible lump.

# 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.

#### ADDITIONAL RISKS

Sedation

You may request medicine to help relax you during your MRI or lumbar puncture. This medicine may have side effects. These side effects include upset stomach, vomiting, headache, dizziness, and mild allergic reactions. Some people may stay sedated (groggy, disoriented) for a longer time than others. Some people may not feel relaxed even after taking the medicine. You may feel irritable or restless. More serious risks are rare. These rare risks include slowed breathing, drop in blood pressure, change in your heart rate or rhythm, or death. We will ask you questions about your medical history to try to pick the best medicine to give you if you request it for your MRI or LP. We will watch you closely during your test if you are given a sedating medicine.

#### ANTICIPATED BENEFITS

If you are an adult, all procedures will be done for research purposes and there are no expected direct benefits for you in this study.

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If you are a child, some procedures will be done only if it will help to diagnose your condition. This information may help your doctor treat your illness better.

For both adults and children, 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. The investigator can remove you from the study at any time if she or he believes that continuation is not in your best medical interest or if you are unable to comply with the requirements of the study.

#### ALTERNATIVES TO PARTICIPATION OR TREATMENT

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.

Reimbursement of travel will be offered consistent with NIH guidelines.

# 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.

#### 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

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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 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

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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 questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Avindra Nath, MD, 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.

#### CONSENT DOCUMENT

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

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

		: Complete this form in its entirety and forw ENTIFICATION	ard directly to the requ	lesting facility.		
Pat	ient Name)		(Patier	nt Number)	(Date of Birth)	
SOL	JRCE OF INF	FORMATION REQUESTED				
Nar	ne of Health	Care Organization or Physician)		(Phone Number)	(Fax Number)	
Stre	eet Address)		(City)	(State)	(Zip Code)	
NF	DRMATION F	REQUESTED				
he	purpose or n	eed for disclosure: Review of clinical care a	nd consideration for re	search study		
ИH	Requestor/Po	oint of Contact: <u>Amanda Wiebold</u>	b6			
don	tify the specif	fic items and related dates pertaining to the	information to be releas	hose		
uen I.	Medical Re		information to be relea	seu.		
		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 Building 10, Room 7C103 10 CENTER DRIVE MSC 1430 BETHESDA, MD 20892-1430	0.00	OR Fax to: (301) 402-1137 Attn: Amanda Wiebold or Dr. Bryan Smith		
		ATTENTION: Amanda Wiebold/ Dr. Brya	an Smith	Di. Diyan Olman		
2.	MRI scans	on CD from	date(s).			
3.	Send to:  Tissue/Pat	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 hology Slides from	ers and Stroke			
	Send to:	National Institutes of Health Clinical Cer Laboratory of Pathology Building 10, Room 2B50 10 CENTER DRIVE MSC 1500 BETHE: MD 20892-1500				
\UT	HORIZATIO	N				
hei	eby authorize	e the release of the above-requested medic	al information.			
Sig	nature of Pati	ient/Legal Guardian)	(Printe	d Name of Patient)	(Date Signed)	
Stre	eet Address)		(City)	(State)	(Zip Code)	
Pa	tient Identif	fication	Nationa NIH-12	st for Medical Information From S al Institutes of Health 08 (8-17) 25-0099	ource Outside The	

From:	Wiebold, Amanda (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4491EE2AE9804610899C741100150540 <b>b6</b>
Sent:	3/22/2021 8:08:33 PM
То:	b6
CC:	Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
Subject:	(FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 <b>b6</b> RE: Symptoms following Pfizer vaccine
Subject:	RE. Symptoms following Prizer vaccine
D ( ( ;	
	ill work with your doctor <b>b6</b> to arrange a blood sample. We usually collect 8 ml on patients
	e up to Dr. Safavi. Before you can get your blood collected we need to discuss the consent and I
will need th	e forms I sent you to be returned.
Thanks	
Thanks, Amanda	
Amanua	
From:	b6
	ay, March 22, 2021 3:58 PM
	, Amanda (NIH/NINDS) [E] <b>b6</b>
Subject: Re:	Symptoms following Pfizer vaccine
Hello,	you let make any what values of blood is required for the blood analysis and is there a special container
	you let me know what volume of blood is required for the blood analysis and is there a special container.  I live in <b>b6</b>
	od have to be transported at any particular temperature etc?
Many thanks	
b6	
Sent from m	y iPad
On 20 Mar 2	021, at 01:36, Wiebold, Amanda (NIH/NINDS) [E] <b>b6</b> wrote:
C	al acception of
G00	d evening,
l hav	ve sent you a secure email with all the information. You will be walked through setting up
	ccount. If you have any difficulty, there is a helpdesk number on the website. Please let me
	w if you have any questions.
KIIO	will you have any questions.
Thai	nk you,
	<b>yy</b>
Am	anda Wiebold, BSN, RN, CNRN
	arch Nurse Specialist
	OS Section of Infections of the Nervous System
	enter Drive, Building 10/7C107, MSC 1430
Beth Offic	esda, Maryland 20892
Cell:	
Emai	

From: b6 Sent: Wednesday, March 17, 2021 12:29 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: RE: Symptoms following Pfizer vaccine
Dear Farinaz,
It was a pleasure to meet you virtually yesterday and for your help. I hope I am able to make a
contribution to your research at the NIH and look forward to receiving any further information.  I am most grateful for the opportunity to discuss my symptoms with you and hopefully they will resolve
in the not too distant future however at the moment they seem to be getting more intense rather than
subsiding.
Thank you once again .
Kind regards,
b6
From: Safavi, Farinaz (NIH/NINDS) [E] b6 Sent: 15 March 2021 19:54
To: b6
Subject: RE: Symptoms following Pfizer vaccine
, , , , , , , , , , , , , , , , , , , ,
Dear b6
I can not send you the link.Do you have any other email address like gmail or general generic ones?
Thank you
Farinaz Safavi MD, PhD
Division of Neuroimmunology and Neurovirology
NINDS, NIH, Bethesda, MD
From: b6
Sent: Monday, March 15, 2021 3:42 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Symptoms following Pfizer vaccine
Dear Farinaz,
Thank you for getting back to me I am most grateful.
Tomorrow 12.30 ET time is perfect.
I have not had any lab tests or imaging as the neurologist at <b>b6</b> who
examined me said that they would show nothing. Also the neurologist with whom I had a video
consultation was convinced it was functional neurological symptoms and unrelated to the vaccine.
I really look forward to our conversation tomorrow.
Kind regards,
<u>b6</u>

Sent from my iPhone

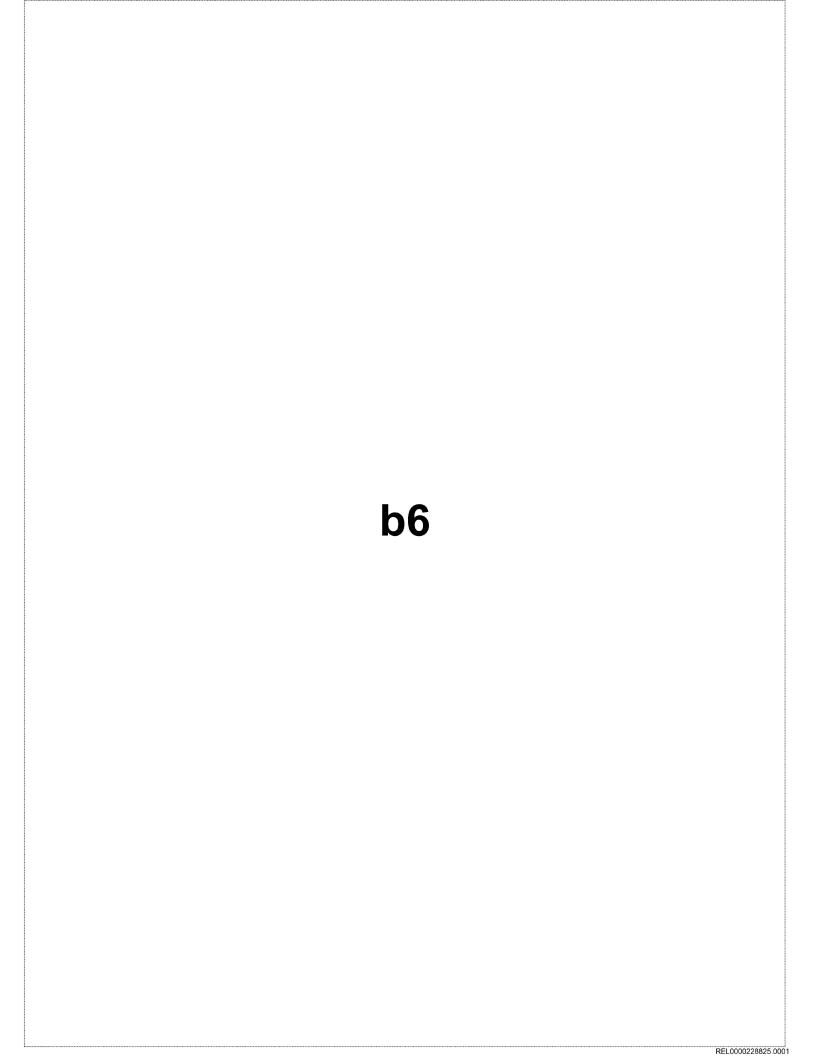
On 15 Mar 2021, at 18:37, Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b> wrote:
Dear b6 I am really sorry to hear about your illness. yes, we started an effort to evaluate post covid vaccine reactions and I would be happy to speak with you through televisit and go over your symptoms and discuss it.  Did you have any imaging or lab work at all? I have an spot at 12:30pm ET(US) tomorrow.If it works for you I can send you a link. Please let me know
Farinaz Farinaz Safavi MD, PhD Division of Neuroimmunology and Neurovirology NINDS, NIH, Bethesda, MD
From: b6  Sent: Sunday, March 14, 2021 12:42 PM  To: Safavi, Farinaz (NIH/NINDS) [E]  Subject: Symptoms following Pfizer vaccine
Dear Dr Safavi,
I have been given you email by b6 as I have experience severe symptoms following the 1st dose of the Pfizer vaccine and was informed that you may be able to shed some light on what has happened and provide me with some information or a virtual consultation if possible.
Prior to vaccination I had no symptoms with no known health conditions and was taking no medications only Vitamin D and cod liver oil. b6  b6 I considered myself healthy b6 exercising, walking 10k 5 times a week and aerobics 2- 3 times a week
I received the vaccine at b6 on b6 I had no hesitation about receiving the vaccine, only anxious about going into an indoor environment for any length of time. I was given the vaccine without any problems, but three hours later developed a sudden cold sensation in my lower legs. This turned into a sensation of ants crawling in both lower legs. This improved when walking but recurred when sitting or lying down.
On day 5 post vaccine, I experienced <b>mild numbness and tightness on the left side of my face.</b> I noticed that there was no difference in the sensation when I touched my face.
On day 11, I developed bad <b>nausea and light-headedness</b> for 2 days and this has fluctuated and intermittently but less severe than initially for 3 to 4 weeks.
By day 12, the (ant) paresthesia spread to my upper legs. On day 14, this also developed into a <b>burning</b> sensation in my upper legs and, to a lesser extent, the front of my lower legs. On day 15, the (burning) <b>dyesthesia</b> spread to the upper

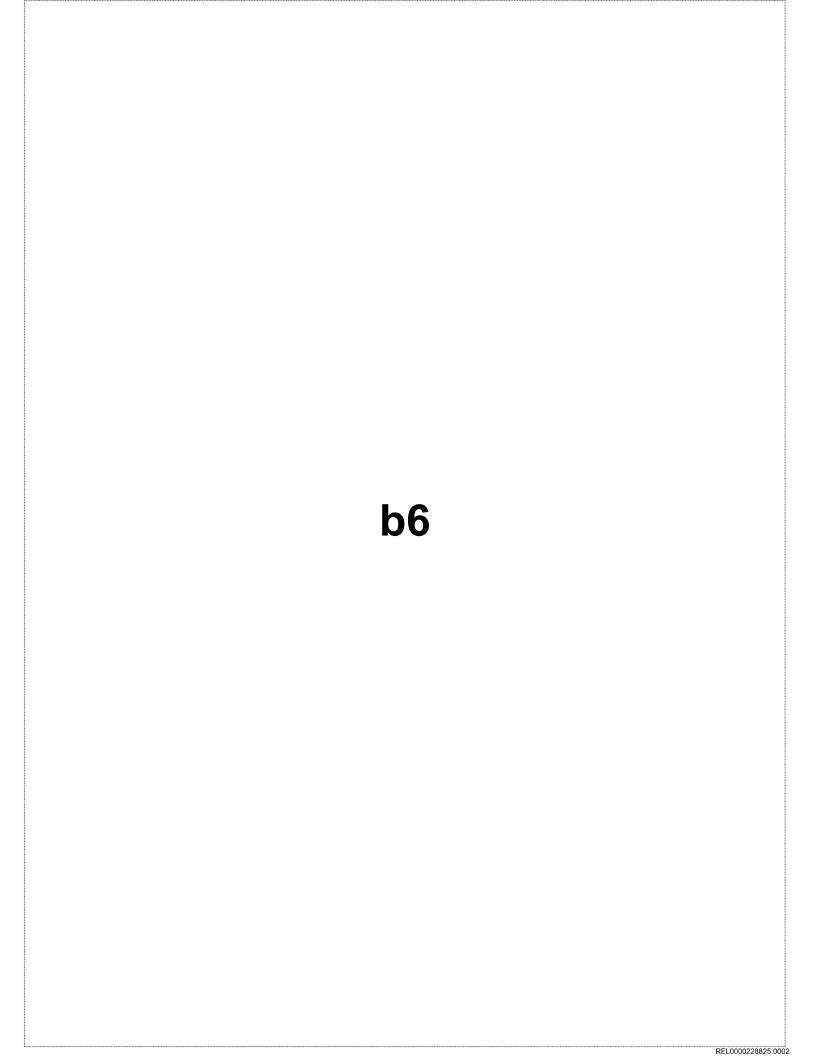
and then lower arms. On day 21, the symptoms spread to my chest parallel, I developed some numbness on my face. The sensations h intermittently since then. I am aware of these sensations for a few hours at a time and the intensity varies. Over the last week or so sensation has become more painful particularly the legs. I have no motor weakness.	ave persisted or for several o the burning
I have been examined by a top neurologist at <b>b6</b>	in
I have been examined by a top neurologist at b6 and he has found nothing and says if I have loads of test	s they will be
negative. Also stating that my symptoms could be anxiety related and	d coincidental
and that it is unlikely that they are vaccine related and that he sees n	
I should not go ahead with the 2 <sup>nd</sup> dose.	,
Also I had a video consultation with another neurologist at the local	hospital who
said my symptoms were functional, (that is her speciality), and not	
vaccine. She initially said there is no reason not to go ahead with the	2nd dose but
later said maybe I should delay the 2 <sup>nd</sup> dose a few more weeks.	
My 2 <sup>nd</sup> dose is due in approximately a week as here in the	e 2 <sup>nd</sup> dose is
delayed up to 12 weeks.	
I do associate my symptoms directly to the vaccine and am really cor	
my symptoms. Will they progress and to what? Should I have the 2 <sup>nd</sup>	
My GP has not come across anyone with these symptoms post vac	<u>cine. He</u> has
entered the details on the government b6	and
has had no response.	
I really would welcome your opinion re what may have caused these	
I find it difficult to believe that they are coincidental or functional sense	ory symptoms
and whether to go ahead with 2 <sup>nd</sup> dose. Many thanks.	
I look forward to hearing from you.	
Kind regards	
Kind regards, b6	

i	Wiebold, Amanda (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4491EE2AE9804610899C741100150540 b6 4/22/2021 3:42:04 PM b6 Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 b6 RE: signed consent forms for Dr Safavi's research  b6
To: Wiebold, Cc: Safavi, Fa Subject: Re: s Hi Amanda,	b6 ay, April 22, 2021 10:22 AM Amanda (NIH/NINDS) [E] b6 rinaz (NIH/NINDS) [E] b6 signed consent forms for Dr Safavi's research
research. On	either my GP nor I have received any information regarding sending my blood sample to Dr Safavi for her the consent form I did include my GPs b6 email address for you to be able to contact him. elpful If you please could also cc me to the email you send him. In advance,
Sent from my	<i>t</i> iPad
On 8	Apr 2021, at 13:24, Wiebold, Amanda (NIH/NINDS) [E] <b>b6</b> wrote:
Exce	llent.
Thar Ama	nk you, nda
From	ı: b6
	Monday, April 5, 2021 5:34 AM Viebold, Amanda (NIH/NINDS) [E] <b>b6</b> Safavi, Farinaz (NIH/NINDS) [E]
Subje	b6ect: signed consent forms for Dr Safavi's research
Furth Pleas	Amanda, neer to our conversation last week I am sending the requested signed consent forms for research. See let me know if these is any further information that you need or may be helpful.

From: b6 Sent: 4/5/2021 9:33:32 AM To: Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540 **b6** Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 Subject: signed consent forms for Dr Safavi's research Attachments: Scan\_20210405.pdf; Scan\_20210405 (2).pdf Hello Amanda, Further to our conversation last week I am sending the requested signed consent forms for research. Please let me know if these is any further information that you need or may be helpful. Best regards,

b6





From:	Wiebold, Amanda (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP
Sent:	(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4491EE2AE9804610899C741100150540 <b>b6</b> 3/15/2021 5:46:09 PM
To:	Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 <b>b6</b>
Subject:	RE: post vaccine reaction
Good afterno	pon b6
	nave sent you a secure email with all information. You will be walked through setting up an ou have any difficulty, there is a helpdesk number on the website.
Thank you,	
Research Nurs NINDS Section	n of Infections of the Nervous System ve, Building 10/7C107, MSC 1430 ryland 20892
From: Safavi,	Farinaz (NIH/NINDS) [E] <b>b6</b>
Sent: Monday	, March 15, 2021 1:05 PM
То:	<b>b6</b> Wiebold, Amanda (NIH/NINDS) [E] <b>b6</b>
Subject: post	vaccine reaction
Dear Amanda	
	b6 this morning. Can you please send her medical record release form and consent her for sample only?
<u>-</u> .	b6 and will get b6 next week when she can upload the imaging for us as well.
Thank you for	your help
Farinaz	

From: Sent:	<b>b6</b> 4/16/2021 11:16:50 AM
To:	Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540 <b>b6</b>
Subject:	Re: NIH
Hi Amanda, Sorry for the His cell phon	delayed response. It would be best for you to call him directly e is
b6	
L	
Sent from m	y iPhone
On A	pr 13, 2021, at 7:46 AM, Wiebold, Amanda (NIH/NINDS) [E] <b>b6</b> wrote:
Goo	d morning,
he c	nk you for the medical records release form. However, I need to talk with your father before an sign the consent form. I apologize for any inconvenience. Please give me a couple lable times so I can get him on my schedule.
Thar	nks,
Ama	
	n: b6  : Monday, April 12, 2021 3:28 PM  Gafavi, Farinaz (NIH/NINDS) [E] b6 Wiebold, Amanda (NIH/NINDS) [E]  b6
Subj	ect: Fwd: NIH
My o revie	d afternoon, dad uploaded the paperwork using his phone last night i am in clinic and have not had a chance to ew the documents that he signed but they are attached below. se let me know if anything additional is needed.
Rega	nrds,  b6
Fron Date	: Sun, Apr 11, 2021 at 11:27 PM
Subj To:	ect: NIH  b6
	b6
CC	b6

OBJ

[OBJ]

OBJ

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OBJ

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From:	b6			
Sent:	4/12/2021 7:27:59 PM			
To:	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			
Subject:	Fwd: NIH			
Attachments:	<b>b6</b>			

# Good afternoon,

My dad uploaded the paperwork using his phone last night -- i am in clinic and have not had a chance to review the documents that he signed but they are attached below. Please let me know if anything additional is needed.

b6	
Forwarded message From: <b>b6</b> Date: Sun, Apr 11, 2021 at 11:27 PM Subject: NIH	
To:	b6
Cc: <b>b6</b>	
[OBJ]	
[OBJ]	
[08]	
[OBJ]	
(OB)	
[OBJ]	
[OBJ]	
[OBJ]	

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 questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator Avindra Nath, MD, avindra.nath@nih.gov. 301-496-1561. 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.

#### CONSENT DOCUMENT

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

PATIENT IDENTIFICATION

Consent to Participate in a Clinical Research Study

NIH-2977 (4-17)

File in Section 4: Protocol Consent (2)

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MEDICAL RECORD	CONSENT TO PARTICIPATE IN AN 1	NIH CLINICAL RESEARCH STUD
Witness:		
Signature of Witness*	Print Name of Witness	Date
*NIH ADMINISTRATIVE INTERPRETER:	SECTION TO BE COMPLETED R	EGARDING THE USE OF AN
An interpreter, or other in the administration of information serve as the witness.	ndividual, who speaks English and the particed consent and served as a witness. The inv	ipant's preferred language facilitated restigator obtaining consent may not

An interpreter, or other individual, who speaks 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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# 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

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

#### PATIENT IDENTIFICATION

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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**

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 Parent/Guardian of a Minor Parent the opportunity to discuss it and the opportunity theorem is the opportunity the op	articipant: I hav o ask questions.	e read the explanation about this I give permission for my child to	study and have been given 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 wi requires a separate assent form)	hen this process for this populatio	is approved by an IRB for older n n.)	ninors. Do not use if an Ib
I have had this study explained t	a main a may th	at Lundauerand Thatta boan aive	n the apparentity to discu
it, and I have had the chance to a	sk questions. I a	gree to take part in this study.	n ac opportunity to asses
it, and I have had the chance to a  Assent of Minor: (as applicable	sk questions. I a	gree to take part in this study.	n an opportunity to show
it, and I have had the chance to a	sk questions. I a	Print Name of Minor	Date
it, and I have had the chance to a  Assent of Minor: (as applicable)	sk questions. I a	gree to take part in this study.	
it, and I have had the chance to a  Assent of Minor: (as applicable  Signature of Minor	sk questions. [ a	Print Name of Investigator only: This section is only requir	Date  Date  red if you are doing the o

**\*** \*

#### 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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IRB NUMBER: 15N0125

IRB APPROVAL DATE: 04/09/2020

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

Consent to Participate in a Clinical Research Study

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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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🕽 IRB APPROVAL DATE: 04/09/2020

From: Sent: To:	Safavi, Farinaz (NIH/NINDS) [E] [/O=EXCHANGELABS, (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=94807CE143/22/2021 1:49:33 AM     b6     b7     b7     b8     b8     b8     b9     b9	46E045D4B61655DA26A0C246 <b>b6</b> Wiebold, Amanda (NIH/NINDS) [E]  up
Subject:	RE: [EXTERNAL] Post covid vaccine neurological com	plications
Amanda, Can you pleas Best Regards Farinaz	arch nurse in this email. se send medical release form to <b>b6</b> and g	et a consent for sample?
To: Safavi, Fa Subject: Re: [ I am interest	r, March 21, 2021 8:27 PM  arinaz (NIH/NINDS) [E]  [EXTERNAL] Post covid vaccine neurological comp  ted in participating.	lications
	, Farinaz (NIH/NINDS) [E] <b>b6</b>	]
Sent: Thursda	ay, March 18, 2021 3:41 PM <b>b6</b>	
L	[EXTERNAL] Post covid vaccine neurological comp	lications
Basically for t team coordin a study with r potentially pr	ery much for your respond.  This research we just need to meet with you through this research we just need to meet with you through the get consent to receive your medical record many long questionnaire and mainly we are trying ropose the pathogenesis.  The paper is apply to answer any questions and really appreciated to the pathogenesis.	ugh televisit once talking about your issue and our research ds and possibility of sending us serum samples. This is not g to characterize COVID vaccine side effects and te if you kindly let me know are you interested to proceed
Farinaz Safav	i MD, PhD euroimmunology and Neurovirology	
	Bethesda, MD	

REL0000228905

From: b6
Sent: Wednesday, March 17, 2021 9:17 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: [EXTERNAL] Post covid vaccine neurological complications
Dear Dr. Safavi,
I would be happy to participate in your study as long as it isnt too burdensome.
As regards my symptoms: They gradually improved and in early February there was very little residual mostly
or only consisting of right hand ulnar sided mild paresthesia. As of early March all symptoms are resolved. I
had a <b>b6</b> which began 9 days after symptom onset.
Please feel free to contact me and I can provide more information as needed.
Best
<b>b6</b>
From: Safavi, Farinaz (NIH/NINDS) [E] b6
Sent: Wednesday, March 17, 2021 1:24 PM  To:    b6     Cubicot   EVTERNALL Desired Label   EVTERNALL DESIRED   EVER   EVER
To: b6
Subject: [EXTERNAL] Post covid vaccine neurological complications
Dear <b>b6</b>

My name is Farinaz and I am one of Dr.Nath's team member at NINDS. We started an effort to study post covid vaccine neurological complications here and Dr.Nath informed me about your brachial plexopathy post 1<sup>st</sup> dose of vaccine. I am writing to ask you how your symptoms are going currently and are you interested in providing us with more information about your disease or contribute in our study?

Thank you very much for your consideration and look forward to hearing from you. Best Regards,

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

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this email, you are hereby notified that any unauthorized use, dissemination or copying of this email or the information contained in it or attached to it is strictly prohibited. If you have received this email in error, please delete it and immediately notify the person named above by reply email. Thank you.

NOTICE: This email may contain PRIVILEGED and CONFIDENTIAL information and is intended only for the use of the specific individual(s) to which it is addressed. It may contain Protected Health Information or Personally Identifiable Information that is privileged and confidential. Protected Health Information and Personally Identifiable Information may only be used or disclosed in accordance with law and you may be subject to penalties under law for improper use or further disclosure of the Protected Health Information or Personally Identifiable Information in this email. If you are not an intended recipient of this email, you are hereby notified that any unauthorized use, dissemination or copying of this email or the information contained in it or attached to it is strictly prohibited. If you have received this email in error, please delete it and immediately notify the person named above by reply email. Thank you. NOTICE: This email may contain PRIVILEGED and CONFIDENTIAL information and is intended only for the use of the specific individual(s) to which it is addressed. It may contain Protected Health Information or Personally Identifiable Information that is privileged and confidential. Protected Health Information and Personally Identifiable Information may only be used or disclosed in accordance with law and you may be subject to penalties under law for improper use or further disclosure of the Protected Health Information or Personally Identifiable Information in this email. If you are not an intended recipient of this email, you are hereby notified that any unauthorized use, dissemination or copying of this email or the information contained in it or attached to it is strictly prohibited. If you have received this email in error, please delete it and immediately notify the person named above by reply email. Thank you.

E68000000000000000000000000000000000000	
F	h6
From: Sent:	j <b>b6</b> 5/31/2022 11:16:01 PM
To:	Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 <b>b6</b> Nath, Avindra (NIH/NINDS)
	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6 <b>b6</b>
Subject:	Re: [EXTERNAL] <b>b6</b>
Hi Dr. Sat	favi and Dr. Nath,
	b6
If this info	ormation provides any clues for you in terms of how I can get back to pre-vaccine health, I would e it.
Thank you b6	<u>1,</u>
On Tue, N	May 31, 2022 at 1:08 PM Smith, Bryan (NIH/NINDS) [E] <b>b6</b> wrote:
I'm so so	orry to hear about the long-standing issues. <b>b6</b>
1 111 30 30	b6 I'm cc'ing Drs. Nath
and Safar thoughts.	vi here who know your case better and would be better able to help offer some suggestions and
Doot	
Best,	
Bryan	
Bryan Sn	with MD
•	
MINDS	Section of Infections of the Nervous System
	alitt, Brian (NIH/NINDS) [E] <b>b6</b> esday, May 31, 2022 18:52
То:	<b>b6</b> Smith, Bryan (NIH/NINDS) [E]
	b6
Subject:	Re: [EXTERNAL] b6
b6	
Sorry to	o hear about your issues. <b>b6</b>
<b>b6</b>	I have attached him to this email. Hope you feel better soon
טט	1 Have actualled filling to till attitude. Hope you took book

Thanks
Brian (Walitt)
From: b6
<b>Date:</b> Tuesday, May 31, 2022 at 6:14:51 PM
To: "Walitt, Brian (NIH/NINDS) [E]" b6 Subject: [EXTERNAL] b6
Subject: [EXTERNAL] D6
Hi Brian,
I am a patient with Dr. Nath and Dr. Safavi for post-vaccine complications.
<b>b6</b>
NO I
Thank you,  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.

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.

800000000000000000000000000000000000000	
From: Sent:	Nath, Avindra (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B81CA051950B4D458D74037A6A86EAD6 <b>b6</b> 10/6/2021 4:59:01 AM
To:	b6
Subject:	Re: Receive this? Re: Having trouble getting support for clinical research? Re: Covid vaccine brain injury- are there studies you all are doing? What is being done to help us? Doctors have no idea
most of the massive und	rson to address this issue would be Dr. Gary Gibbons who in the Director of NHLBI. His institute received funds for COVID research. I have not received a single penny and do not have any resources for such a dertaking. May the companies who make the vaccines should be putting some their monies towards his is all about my pay grade. I am just a neurologist with no authority to make such decisions.
From:	b6
Date: Mon	day, October 4, 2021 at 9:14 AM
To: Nath, A	Avindra (NIH/NINDS) [E] b6
	eceive this? Re: Having trouble getting support for clinical research? Re: Covid vaccine brain injury-tudies you all are doing? What is being done to help us? Doctors have no idea
Checking to this? Thank	see if you received this last week. Is clinical care and hands on research and care going to be done on ss.
On Mon, Se	p 27, 2021, 9:05 AM <b>b6</b> wrote:
and the su	ning. I just wanted to follow up because I am shocked there is no clinical in person patient research going on rvey you all are doing isn't set up yet and this has been going on since the vax trials last year. Are you all uble getting support to address this? I ask because that would track with Pfizer, CDC and FDA denying this is ng.
vaccines us in the new	society are missing out on important information if this is not being seriously studied- especially for future sing mRNA technology. It reminds me of forever now lost data from Havana syndrome, which was again just is last week and the report made me look up the symptoms which are pretty consistent with my symptoms, here is no directed attack obviously. My symptoms are also very similar to long covid symptoms I am
to doctors people are	we to turn for healthcare? Because I am not getting the 2nd Pfizer shot until this is figured out, and turning who haven't even heard of it only exposes me to covid risk. I can't even find any information on whether getting better after the 2nd shot to know what to even consider- which all the research I am forced to do digital devices is making my symptoms worse, of course.
What help	do you need from us to get clinical, hands on care and research set up?
Thanks.	
b6	
On Wed, S	ep 22, 2021, 3:14 PM Nath, Avindra (NIH/NINDS) [E] <b>b6</b> wrote:
Dear <b>k</b>	p6 ]
2	hear of your illness. At the moment we are collecting data on such complications. I have copied our research o can guide you on how to help us do so.

Best wishes.
Avi
From: b6  Date: Wednesday, September 22, 2021 at 3:10 PM  To: Nath, Avindra (NIH/NINDS) [E] b6  Subject: Covid vaccine brain injury- are there studies you all are doing? What is being done to help us?  Doctors have no idea  Dr. Nath-
Dr. Natri-
I am writing because I was injured from a first dose of the Pfizer vaccine on <b>b6</b> and have horrific "vax fog" that is not going away and press reports list you as working on this- thank you.
I received the Pfizer vaccine at 11am and felt great all day- so happy, feeling like I may be somewhat more free in the next few weeks, etc and just took it easy and rested all day. I was feeling completely fine- my arm wasn't even that sore, as I had been moving it, etc., and at 8pm I was lying down and got up to get a drink and go to the restroom and had such violent dizziness that I didn't stop when I was vertical and ran into the wall, and then thought I needed to get on the ground and crawl so I wouldn't fall. And the symptoms expanded and none of them have stopped since.
I have brain fog so bad I cannot remember bank pins I have had for decades- this is taking me forever to write, etc, violent dizziness, constant nauseousness, light and sound sensitivity, ear ringing, low grade fever on and off, no energy, most nights can only sleep 2 or 3 hours at a time waking up all night long, horrible pain including eye pain when trying to work or do anything on digital devices, cannot get upset at all- feel it vestibularly and get really sick, lack of sleep makes me super sick, etc. And I have had 2 slight heart issue incidents and "covid arm" of just 3 small bumps like a blemish that felt weird a few weeks into this that oddly went away in a few hours and made me feel so sick that night I actually thought I might not make it through the night and then my head was a bit better the next day (a lot of the head actual pain went away- pain that is not a headache) so that I could then get out of bed- but it is still very, very VERY bad.
I have to educate my doctors as they haven't even heard of the term- which I hadn't either until I was frantically googling what was happening to me, Pfizer lied to me and told me no one has had these symptoms and to speak to my doctor and the FDA and CDC have been zero help, and are part of the problem as usual. How are our local doctors supposed to help us if Pfizer, etc and the FDA and CDC won't even admit this is happening, so the doctors cannot get any info?!
The one doctor I do trust wants to see me in person vs on video, but being in the covid fire that is Texas, I am afraid to go into a healthcare facility without being fully vaccinated. Especially if I am just going to be told no one knows what is happening and have the experiences I am seeing all over these forums, examples below.

I have NEVER taken my mask off this whole time a	and I do not even go t	o the grocery store b	ecause of how horrible
I have NEVER taken my mask off this whole time a Texas is with no mask mandates. I have been	b	6	and was telling people
to stay home in Feb 2020 because I could see wha	at was coming.		
Have you all started researching this, if not why neeverything, which even if I could do so, would not this is being covered up by Pfizer and the FDA and	. This is not my respo	onsibility in any way,	
I would have been better off not getting the vacci	ine and taking the Reg	eneron antibodies th	nerapy if I got covid. And
I'm not getting the second dose until someone tel	1000		2 (A) (T)
Please advise. And thank you again for your work	ζ.		
he to the total control of the	'horo aro hundrods a	ad hundrade of nagar	s of noonlo having those
b6 T side effects on this site:	nere are nunureus ai	id ildildreds of pages	or people having these
Covid-19 Vaccine side effects - Page 123 — Patient	: Dizziness – VeDA Fo	rum	
https://vestibular.org/forum/dizziness/covid-19-v	accine-side-effects/pa	nged/123/	
April 25, 2021 7:59 am			
It's now 2.5 weeks after first Phizer vaccine and st scan, ENT doctor exam, bloodwork and am still ta	( <del>7</del> )	7	_
Neurologist told me that anyone that has any brany brain injury history should NOT be vaccinate	***************************************	000000000000000000000000000000000000000	
BIAA IS RECOMMENDING THE VACCINES(?!)			

https://www.biausa.org/public-affairs/public-awareness/news/biaa-issues-guidance-on-covid-19-vaccines-for-

"When one is infected with COVID-19, the virus attacks the 'weakest link' it finds in the body, which is why individuals with longstanding chronic medical issues are at greatest risk for infection, complications, and even death," explained

BIAA Issues Guidance on COVID-19 Vaccines for Persons with Brain Injury

persons-with-brain-injury

REL0000229471

BIAA National Medical Director Brent E. Masel, M.D. "Studies have shown that traumatic brain injury triggers an inflammatory process in the brain that causes an individual to experience chronic issues. This process places those individuals at far greater risk of developing complications from COVID-19, which itself is well known to cause chronic neuroinflammatory issues."

Woman suffers 'life-altering injuries' after COVID-19 vaccine, teams up with Utah senator to demand answers | NewsNation Now

https://www.newsnationnow.com/us-news/west/woman-suffers-life-altering-injuries-after-covid-19-vaccine-teams-up-with-utah-senator-to-demand-answers/

A 'black hole' for COVID vaccine injury claims | Reuters

https://www.reuters.com/legal/government/black-hole-covid-vaccine-injury-claims-2021-06-29/

Except historically, almost no one gets anything. Since the program's inception in 2010, only 29 claims have been paid, with an average payout of around \$200,000. (Ten additional claims won approval but were deemed ineligible for compensation.)

Gentry is not optimistic that any will be approved. Because the vaccine is so new, there's no definitive research on injuries caused by the vaccine, she said. Which means that when the claims land on someone's desk at HRSA, that person "can do their job and look at the 'research' and everyone loses."

....Our law firm has concluded that there is nothing our attorneys can do to significantly assist you," the firm states.

Maglio told me his Sarasota, Florida-based firm has been "contacted by at least a couple hundred people" about suspected COVID vaccine-related injuries, including blood clots and cardiac inflammation.

It's not that his firm doesn't want to help. Representing people who've had (rare) major adverse reactions to vaccines for tetanus, measles, hepatitis, influenza and a dozen other shots is its bread and butter.



b6 b6

·			***************************************
From:	b6		
Sent: To:	1/13/2022 2:09:31 PM Gavin, Angelique (NIH/NINDS) [C] [/o=ExchangeLabs/ou=Exchange Admin		
Subject:	(FYDIBOHF23SPDLT)/cn=Recipients/cn=6e97392e947e4f7ebb17eeb8ac87 Re: Need current NIH Director's email address-Re: Tomorrow 9am will wo		up all night tonight-
,	Re: Status of care for Pfizer covid vaccine brain, etc injuries- Fwd: [EXTERN		
	are there studies y		
	s email originated from outside of the organization. Do not click links or ope e confident the content is safe.	n attachments unle	ss you recognize the
Thanks.			
On Thu, Jai	n 13, 2022, 8:09 AM Gavin, Angelique (NIH/NINDS) [C]	b6	wrote:
Hello I	b6		
Our acting	director is Larry Tabak at <b>b6</b>		
	L		
Thank you	ı,		
Angelique			
8 1			
Angeliaue	Gavin, MS (Contractor)		
	OS Clinical Operations Manager		
	Preferred Solutions Group		
	nstitutes of Health		
10 Center	Drive		
Building 1	0, Room 3B19, MSC 1251		
Bethesda,	MD 20814-9692		
h	(office)		
	(cell)		
(301) 480-	5368 (efax)		
	b6		

From:	b6
	anuary 13, 2022 9:00 AM
	ique (NIH/NINDS) [C] b6
	(NIH/NINDS) [E] <b>b6</b> rent NIH Director's email address-Re: Tomorrow 9am will work- will email if I am up all
	Status of care for Pfizer covid vaccine brain, etc injuries- Fwd: [EXTERNAL] Status? Re
	in injury- are there studies yo
TARITANI TL:	Il minimated from outside of the consciention Do not alight limbs on some attachment and account of
	il originated from outside of the organization. Do not click links or open attachments unless you recognize t ent the content is safe.
Angelique,	
Could you please	get me the NIH Director's email address. I did not hear from anyone yesterday as I
requested.	
Thank you.	
mank you.	
b6	
On Tue Jan 11 20	022, 2:59 PM <b>b6</b> wrote:
311 1 de, 3dff 11, 2	722, 2.35 TH
Thereby Miller	o. And stay safe!
manks. Yan too	•
Thanks. Y'all too	
Thanks. Y'all too	
	2022, 2:55 PM Gavin, Angelique (NIH/NINDS) [C] <b>b6</b> wrote:

 $\underline{https:/\!/clinicaltrials.gov-study\ number\ 000089\text{-}N}$ 

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) (301) 480-5368 (efax) b6 https://clinicaltrials.gov - study number 000089-N From: Sent: Tuesday, January 11, 2022 3:53 PM b6 To: Gavin, Angelique (NIH/NINDS) [C] Walitt, Brian (NIH/NINDS) [E] Subject: Tomorrow 9am will work- will email if I am up all night tonight- Re: Status of care for Pfizer covid vaccine brain, etc injuries- Fwd: [EXTERNAL] Status? Re: Covid vaccine brain injury- are there studies you all are doing? What is being done to help us...

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.

sleeping more than 1 or 2 hours at a time and am often up most of the night and just miserable then- I we email y'all and we can reschedule.	
The number is Sometimes my phone has issues with incoming calls, so if I don't answer will call you right back.	, I
Thanks and hopefully we will talk tomorrow.	
Take care-	
b6	
On Tue, Jan 11, 2022, 2:46 PM Gavin, Angelique (NIH/NINDS) [C] <b>b6</b> wrote Hi <b>b6</b>	<b>:</b> :
Dr. Walitt has availability tomorrow, January 12 at 9 am or next week, January 17 a 9 or 10 am Easterr Time. Let me know your preference and a good telephone number for him to call.	1
Thank you,	
Angelique	
Angelique Gavin, MS	
Clinical Operations Manager	
Contractor, PSG	
National institutes of Health	
10 Center Drive, Building 10	
Room 3B19, MSC 1251	

Dethesda, MD 20814
<b>b6</b> phone
301-451-7352-fax
From: b6 Sent: Tuesday, January 11, 2022 3:00 PM To: Walitt, Brian (NIH/NINDS) [E] b6 Cc: Gavin, Angelique (NIH/NINDS) [C] b6 Subject: Re: Status of care for Pfizer covid vaccine brain, etc injuries- Fwd: [EXTERNAL] Status? Re: Covid vaccine brain injury- are there studies you all are doing? What is being done to help us? Doctors have no idea
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.
Thank you. And thank you for your prompt response.
We can try to schedule that- it really depends upon if it is a (relatively) good day for me. You all were on my calendar for yesterday and I was too sick to follow up. I also have more energy in the morning, but I understand if your schedule isn't open for that this week and appreciate you working me in.
Let me know what a good time is for you and we can pencil something in, and I can let you know tomorrow if I think I can make it when I wake up if that will work.
Thanks again-
b6
On Tue, Jan 11, 2022, 1:08 PM Walitt, Brian (NIH/NINDS) [E] <b>b6</b> wrote:
<u> </u>

Thanks for your interest and advocacy. Having now worked with patients here at NIH with post-vaccine neuropathic complications and hearing their stories, I can understand your frustration.
I would be happy to find some time to chat with you about your concerns. Let me know if you have time tomorrow evening to schedule a phone call.
Thanks,
Brian
From: b6 Sent: Tuesday, January 11, 2022 1:49 PM To: Walitt, Brian (NIH/NINDS) [E] b6 Subject: Status of care for Pfizer covid vaccine brain, etc injuries- Fwd: [EXTERNAL] Status? Re: Covid vaccine brain injury- are there studies you all are doing? What is being done to help us? Doctors have no idea
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.
Please let me know why nothing is being done to help all of us who were injured by the Pfizer (and Moderna, etc., if applicable) covid vaccine.
Press reports (that were effectively buried, because I had never heard of vax fog until I was in a panic trying to google what the hell was happening to me 9 hours after my first Pfizer vaccine) state you all have known about this for well over a year now and there isn't even a "survey" (which is ridiculous anyway) up and running?!
Who is responsible for this and when and how is it going to be rectifed and care provided?
Thank you.

**b6** 

# **b6**

Forwarded message			
From: Gavin, Angelique (NIH/NINDS) [C	2]	b6	
Date: Tue, Jan 11, 2022, 12:29 PM			, <del>-</del>
Subject: RE: [EXTERNAL] Status? Re:	Covid vaco	cine brain inju	ıry- are th
What is being done to help us? Doctors l	have no ide	a	
To: <b>b6</b>			
77 11			
Hello <b>b6</b>			
Please contact Dr. Brian Walitt at	b6	who shou	uld be able
L			
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)
b6
https://clinicaltrials.gov - study number 000089-N
_
From: b6 Sent: Tuesday, January 11, 2022 12:22 PM To: Gavin, Angelique (NIH/NINDS) [C] b6 Subject: [EXTERNAL] Status? Re: Covid vaccine brain injury- are there studies you all are doing? What is being done to help us? Doctors have no idea
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.
Angelique,

Good morning. I hope you are well. I am checking on the status of this. If i get me the contact email of whoever is responsible for not providing care for is happening to us.		
This is not ok.		
Thanks.		
<b>b6</b>		
On Thu, Nov 4, 2021, 2:27 PM Gavin, Angelique (NIH/NINDS) [C]	b6	wrote:
Thank you b6 for touching base with us! The study has not yet been app board. Once underway, I will forward your information to the study team and directly. All my best to you.		
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		
b6 (office) (cell)		
(301) 480-5368 (efax)		
<b>b6</b>		

-		
Fron Sent: To: ( Subj us? D	m: b6 t: Thursday, November 4, 2021 10:55 AM Gavin, Angelique (NIH/NINDS) [C] b6 ject: Re: Covid vaccine brain injury- are there studies you all are doing? What is being done to Doctors have no idea	to help
	y I am just getting back to you. I was shocked there is only a survey being done and between and trying to get more help for us with the little energy and brain power I have, this has been	
	ourse, please contact me over anything you all are doing for this. I have also been keeping amentation of my symptoms, so hopefully that will help.	
Whei	en will this all start?	
Than	nks.	
b6		
	b6	

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

1.0	
ph	
20	

### **b6**

On Thu, Sep 23, 2021, 8:59 AM 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. I am looking forward to your reply.

Thanks,

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)
b6
https://clinicaltrials.gov - study number 000089-N
-
From: b6 Sent: Thursday, September 23, 2021 8:40 AM To: Nath, Avindra (NIH/NINDS) [E] b6 Cc: NINDSPostCovid19 < nindspostcovid19@ninds.nih.gov> Subject: Re: Covid vaccine brain injury- are there studies you all are doing? What is being done to help us? Doctors have no idea
Thank you!
On Wed, Sep 22, 2021, 3:14 PM Nath, Avindra (NIH/NINDS) [E] <b>b6</b> wrote:
Dear b6
Sorry to hear of your illness. At the moment we are collecting data on such complications. I have copied our research team who can guide you on how to help us do so.
Best wishes.
Avi
From: b6  Date: Wednesday, September 22, 2021 at 3:10 PM  To: Nath, Avindra (NIH/NINDS) [E] b6  Subject: Covid vaccine brain injury- are there studies you all are doing? What is being done to help us? Doctors have no idea
Dr. Nath-

 I am writing because I was injured from a first dose of the Pfizer vaccine on b6 and have horrific "vax fog" that is not going away and press reports list you as working on this- thank you.
I received the Pfizer vaccine at 11am and felt great all day- so happy, feeling like I may be somewhat more free in the next few weeks, etc and just took it easy and rested all day. I was feeling completely fine- my arm wasn't even that sore, as I had been moving it, etc., and at 8pm I was lying down and got up to get a drink and go to the restroom and had such violent dizziness that I didn't stop when I was vertical and ran into the wall, and then thought I needed to get on the ground and crawl so I wouldn't fall. And the symptoms expanded and none of them have stopped since.
I have brain fog so bad I cannot remember bank pins I have had for decades- this is taking me forever to write, etc, violent dizziness, constant nauseousness, light and sound sensitivity, ear ringing, low grade fever on and off, no energy, most nights can only sleep 2 or 3 hours at a time waking up all night long, horrible pain including eye pain when trying to work or do anything on digital devices, cannot get upset at all- feel it vestibularly and get really sick, lack of sleep makes me super sick, etc. And I have had 2 slight heart issue incidents and "covid arm" of just 3 small bumps like a blemish that felt weird a few weeks into this that oddly went away in a few hours and made me feel so sick that night I actually thought I might not make it through the night and then my head was a bit better the next day (a lot of the head actual pain went away- pain that is not a headache) so that I could then get out of bed- but it is still very, very VERY bad.
I have to educate my doctors as they haven't even heard of the term- which I hadn't either until I was frantically googling what was happening to me, Pfizer lied to me and told me no one has had these symptoms and to speak to my doctor and the FDA and CDC have been zero help, and are part of the problem as usual. How are our local doctors supposed to help us if Pfizer, etc and the FDA and CDC won't even admit this is happening, so the doctors cannot get any info?!
The one doctor I do trust wants to see me in person vs on video, but being in the covid fire that is Texas, I am afraid to go into a healthcare facility without being fully vaccinated. Especially if I am just going to be told no one knows what is happening and have the experiences I am seeing all over these forums, examples below.
I have NEVER taken my mask off this whole time and I do not even go to the grocery store because of how horrible Texas is with no mask mandates. I have been b6 and was telling people to stay home in Feb 2020 because I could see what was coming.
Have you all started researching this, if not why not, and how are we to get help? I am being told I have

to pay for everything, which even if I could do so, would not. This is not my responsibility in any way, shape or form. And that this is being covered up by Pfizer and the FDA and CDC is unconscionable.

I would have been better off not getting the vaccine and taking the Regeneron antibodies therapy if I got covid. And I'm not getting the second dose until someone tells me what is going on, so someone is going to have to figure this out.

Please advise. And thank you again for your work.

b6 There are hundreds and hundreds of pages of people having these side effects on this site:

Covid-19 Vaccine side effects - Page 123 - Patient: Dizziness - VeDA Forum

https://vestibular.org/forum/dizziness/covid-19-vaccine-side-effects/paged/123/

April 25, 2021 7:59 am

It's now 2.5 weeks after first Phizer vaccine and still dealing with disabling Vertigo. Saw a neurologist, had MRI, CAT scan, ENT doctor exam, bloodwork and am still taking meclazine & diazepam just to stop the nausea and vomiting.

Neurologist told me that anyone that has any brain problems or autoimmune disease of the brain (I have MS), and any brain injury history should NOT be vaccinated and that he keeps seeing patients with this dizziness problem.

### **BIAA IS RECOMMENDING THE VACCINES(?!)**

BIAA Issues Guidance on COVID-19 Vaccines for Persons with Brain Injury

https://www.biausa.org/public-affairs/public-awareness/news/biaa-issues-guidance-on-covid-19-vaccines-for-persons-with-brain-injury

"When one is infected with COVID-19, the virus attacks the 'weakest link' it finds in the body, which is why individuals with longstanding chronic medical issues are at greatest risk for infection, complications, and even death," explained BIAA National Medical Director Brent E. Masel, M.D. "Studies have shown that traumatic brain injury triggers an inflammatory process in the brain that causes an individual to experience chronic issues. This process places those individuals at far greater risk of developing complications from COVID-19, which itself is well known to cause chronic neuroinflammatory issues."

Woman suffers 'life-altering injuries' after COVID-19 vaccine, teams up with Utah senator to demand answers | NewsNation Now

https://www.newsnationnow.com/us-news/west/woman-suffers-life-altering-injuries-after-covid-19-vaccine-teams-up-with-utah-senator-to-demand-answers/

A 'black hole' for COVID vaccine injury claims | Reuters

https://www.reuters.com/legal/government/black-hole-covid-vaccine-injury-claims-2021-06-29/

Except historically, almost no one gets anything. Since the program's inception in 2010, only 29 claims have been paid, with an average payout of around \$200,000. (Ten additional claims won approval but were deemed ineligible for compensation.)

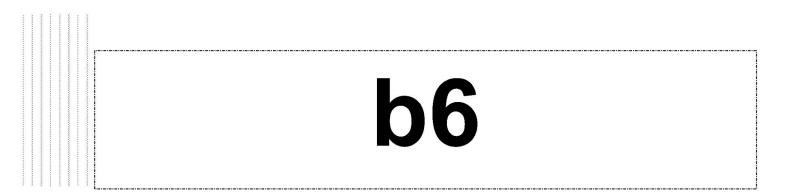
Gentry is not optimistic that any will be approved. Because the vaccine is so new, there's no definitive research on injuries caused by the vaccine, she said. Which means that when the claims land on someone's desk at HRSA, that person "can do their job and look at the 'research' and everyone loses."

....Our law firm has concluded that there is nothing our attorneys can do to significantly assist you," the firm states.

Maglio told me his Sarasota, Florida-based firm has been "contacted by at least a couple hundred people" about suspected COVID vaccine-related injuries, including blood clots and cardiac inflammation.

It's not that his firm doesn't want to help. Representing people who've had (rare) major adverse reactions to vaccines for tetanus, measles, hepatitis, influenza and a dozen other shots is its bread and butter.





From: Sent: To: Subject:	b6 8/13/2021 8:34:21 PM Gavin, Angelique (NIH/NINDS) [C] [/o=ExchangeLabs/ou=Exchange Administ (FYDIBOHF23SPDLT)/cn=Recipients/cn=6e97392e947e4f7ebb17eeb8ac87c5Re: NIH COVID-19 vaccine study		
ha, thank yo	u! :)		
Is it ok for m	ne to share this publicly?		
	eam is planning on studying people who have had extended neurovid vaccine. The study plans are not finalized yet but you can get		
Thanks, <b>b6</b>			
On Tue, Aug	g 10, 2021 at 4:14 AM Gavin, Angelique (NIH/NINDS) [C]	b6	wrote:
who are inq	thing yet! It is too soon. The study has not yet been approved. I uiring and will contact them as soon as we are giving the go-aher checking in with us and keeping us on our toes!		t list for those
Angelique G	Pavin, MS (Contractor)		
NIH/NIND	S Clinical Operations Manager		
Contractor	Preferred Solutions Group		
National In	stitutes of Health		
10 Center I	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
-
From: b6 Sent: Monday, August 9, 2021 4:40 PM
To: Gavin, Angelique (NIH/NINDS) [C] b6
Subject: Re: NIH COVID-19 vaccine study
Thanks Angelique. I didn't even know there was a study! Is there a link that describes the vaccination study?
The link at the bottom doesn't work. I know many people who would be reassured to know that different reactions to the vaccines are being studied at NIH.
Thanks again
Thanks again,
<b>b6</b>
On Fri, Jul 23, 2021, 5:41 AM Gavin, Angelique (NIH/NINDS) [C] <b>b6</b> wrote:
Hi b6
Thank you <b>b6</b> for your interest in our COVID-19 studies here at the NIH. I received your inquiry from Dr.
Nath. We are currently not recruiting participants for the vaccination study. We can place you on our wait
list and would be happy to contact you when we are up and running. Let me know if you are interested. In addition, can recommend you contact <a href="https://researchmatch.org">https://researchmatch.org</a> which is a great site for enrolment in research
studies taking place all over the USA.
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

b6 (office) (cell)

(301) 480-5368 (efax)

b6

https://clinicaltrials.gov - study number 000089

REL0000229816

From: Sent: To: Subject:	Gavin, Angelique (NIH/NINDS) [C] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6E97392E947E4F7EBB17EEB8AC87C5D5 b6 1/11/2022 6:53:12 PM b6 RE: [EXTERNAL] Status? Re: Covid vaccine brain injury- are there studies you all are doing? What is being done to help us? Doctors have no idea
You are very	welcome. All my best to you!
Sincerely, Angelique	
NIH/NINDS CI Contractor Pr National Insti 10 Center Dri Building 10, R Bethesda, MI <b>b6</b> (301) 480-536	toom 3B19, MSC 1251 D 20814-9692 (office) (cell) 58 (efax)
To: Gavin, An Subject: Re: [	b6 y, January 11, 2022 1:34 PM gelique (NIH/NINDS) [C] b6 EXTERNAL] Status? Re: Covid vaccine brain injury- are there studies you all are doing? What is being done octors have no idea
	email originated from outside of the organization. Do not click links or open attachments unless you recognize the confident the content is safe.
Great. Thank	you.
On Tue, Jan 1 Hello <b>b6</b>	1, 2022, 12:29 PM Gavin, Angelique (NIH/NINDS) [C] <b>b6</b> wrote:
Please conta	oct Dr. Brian Walitt at <b>b6</b> who should be able to respond to your concerns.
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
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b6 (office) (cell)
(301) 480-5368 (efax)
b6
https://clinicaltrials.gov - study number 000089-N
-
From: b6  Sent: Tuesday, January 11, 2022 12:22 PM  To: Gavin, Angelique (NIH/NINDS) [C] b6  Subject: [EXTERNAL] Status? Re: Covid vaccine brain injury- are there studies you all are doing? What is being done to help us? Doctors have no idea
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.
Angelique,
Good morning. I hope you are well. I am checking on the status of this. If it is still not "approved", please get me the contact email of whoever is responsible for not providing care for us and not researching what is happening to us.

This is not ok.
Thanks.
b6
On Thu, Nov 4, 2021, 2:27 PM Gavin, Angelique (NIH/NINDS) [C] <b>b6</b> wrote:  Thank you <b>b6</b> for touching base with us! The study has not yet been approved by our review board. Once underway, I will forward your information to the study team and they will contact you directly. All my best to you.
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
he (office)
b6 (cell)
(301) 480-5368 (efax)
b6
https://clinicaltrials.gov - study number 000089-N

From: b6 Sent: Thursday, November 4, 2021 10:55 AM To: Gavin, Angelique (NIH/NINDS) [C] b6 Subject: Re: Covid vaccine brain injury- are there studies you all are doing? What is being done to help us? Doctors have no idea
Sorry I am just getting back to you. I was shocked there is only a survey being done and between being sick and trying to get more help for us with the little energy and brain power I have, this has been delayed.
Of course, please contact me over anything you all are doing for this. I have also been keeping documentation of my symptoms, so hopefully that will help.
When will this all start?
Thanks.
b6
<b>b6</b>

## **b6**

On Thu, Sep 23, 2021, 8:59 AM Gavin, Angelique (NIH/NINDS) [C] <b>b6</b> wrote:
Dear <b>b6</b>
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. I am looking forward to your reply.
Thanks,
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>

From: b6 Sent: Thursday, September 23, 2021 8:40 AM	
To: Nath, Avindra (NIH/NINDS) [E] b6	
Cc: NINDSPostCovid19 < nindspostcovid19@ninds.nih.gov>	
<b>Subject:</b> Re: Covid vaccine brain injury- are there studies you all are doing? What is being done to help	us? Doctors
have no idea	
Thank you!	
On Wed, Sep 22, 2021, 3:14 PM Nath, Avindra (NIH/NINDS) [E] <b>b6</b> wrote:	
Dear <b>b6</b>	
Sorry to hear of your illness. At the moment we are collecting data on such complications. I have copie research team who can guide you on how to help us do so.	ed our
Best wishes.	
Avi	
From: b6	
Date: Wednesday, September 22, 2021 at 3:10 PM	
To: Nath, Avindra (NIH/NINDS) [E] b6	
<b>Subject:</b> Covid vaccine brain injury- are there studies you all are doing? What is being done to	help us?
Doctors have no idea	
Dr. Nath-	
	horrific "vax
fog" that is not going away and press reports list you as working on this- thank you.	
I received the Pfizer vaccine at 11am and felt great all day- so happy, feeling like I may be somewhat n the next few weeks, etc and just took it easy and rested all day. I was feeling completely fine- my arm	

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

that sore, as I had been moving it, etc., and at 8pm I was lying down and got up to get a drink and go to the restroom and had such violent dizziness that I didn't stop when I was vertical and ran into the wall, and then thought I needed to get on the ground and crawl so I wouldn't fall. And the symptoms expanded and none of them have stopped since. I have brain fog so bad I cannot remember bank pins I have had for decades- this is taking me forever to write, etc, violent dizziness, constant nauseousness, light and sound sensitivity, ear ringing, low grade fever on and off, no energy, most nights can only sleep 2 or 3 hours at a time waking up all night long, horrible pain including eye pain when trying to work or do anything on digital devices, cannot get upset at all-feel it vestibularly and get really sick, lack of sleep makes me super sick, etc. And I have had 2 slight heart issue incidents and "covid arm" of just 3 small bumps like a blemish that felt weird a few weeks into this that oddly went away in a few hours and made me feel so sick that night I actually thought I might not make it through the night and then my head was a bit better the next day (a lot of the head actual pain went away- pain that is not a headache) so that I could then get out of bed- but it is still very, very VERY bad. I have to educate my doctors as they haven't even heard of the term- which I hadn't either until I was frantically googling what was happening to me, Pfizer lied to me and told me no one has had these symptoms and to speak to my doctor and the FDA and CDC have been zero help, and are part of the problem as usual. How are our local doctors supposed to help us if Pfizer, etc and the FDA and CDC won't even admit this is happening, so the doctors cannot get any info?! The one doctor I do trust wants to see me in person vs on video, but being in the covid fire that is Texas, I am afraid to go into a healthcare facility without being fully vaccinated. Especially if I am just going to be told no one knows what is happening and have the experiences I am seeing all over these forums, examples below. I have NEVER taken my mask off this whole time and I do not even go to the grocery store because of how horrible Texas is with no mask mandates. I have been and was telling people to stay home in Feb 2020 because I could see what was coming. Have you all started researching this, if not why not, and how are we to get help? I am being told I have to pay for everything, which even if I could do so, would not. This is not my responsibility in any way, shape or form. And that this is being covered up by Pfizer and the FDA and CDC is unconscionable. I would have been better off not getting the vaccine and taking the Regeneron antibodies therapy if I got covid. And I'm not getting the second dose until someone tells me what is going on, so someone is going to have to figure this

Please advise. And thank you again for your work.

out.

b6 side effects on this site:

There are hundreds and hundreds of pages of people having these

Covid-19 Vaccine side effects - Page 123 – Patient: Dizziness – VeDA Forum

https://vestibular.org/forum/dizziness/covid-19-vaccine-side-effects/paged/123/

April 25, 2021 7:59 am

It's now 2.5 weeks after first Phizer vaccine and still dealing with disabling Vertigo. Saw a neurologist, had MRI, CAT scan, ENT doctor exam, bloodwork and am still taking meclazine & diazepam just to stop the nausea and vomiting.

Neurologist told me that anyone that has any brain problems or autoimmune disease of the brain (I have MS), and any brain injury history should NOT be vaccinated and that he keeps seeing patients with this dizziness problem.

### **BIAA IS RECOMMENDING THE VACCINES(?!)**

BIAA Issues Guidance on COVID-19 Vaccines for Persons with Brain Injury

https://www.biausa.org/public-affairs/public-awareness/news/biaa-issues-guidance-on-covid-19-vaccines-for-persons-with-brain-injury

"When one is infected with COVID-19, the virus attacks the 'weakest link' it finds in the body, which is why individuals with longstanding chronic medical issues are at greatest risk for infection, complications, and even death," explained BIAA National Medical Director Brent E. Masel, M.D. "Studies have shown that traumatic brain injury triggers an inflammatory process in the brain that causes an individual to experience chronic issues. This process places those individuals at far greater risk of developing complications from COVID-19, which itself is well known to cause chronic neuroinflammatory issues."

Woman suffers 'life-altering injuries' after COVID-19 vaccine, teams up with Utah senator to demand answers | NewsNation Now

https://www.newsnationnow.com/us-news/west/woman-suffers-life-altering-injuries-after-covid-19-vaccine-teams-up-with-utah-senator-to-demand-answers/

A 'black hole' for COVID vaccine injury claims | Reuters

https://www.reuters.com/legal/government/black-hole-covid-vaccine-injury-claims-2021-06-29/

Except historically, almost no one gets anything. Since the program's inception in 2010, only 29 claims have been paid, with an average payout of around \$200,000. (Ten additional claims won approval but were deemed ineligible for compensation.)

Gentry is not optimistic that any will be approved. Because the vaccine is so new, there's no definitive research on injuries caused by the vaccine, she said. Which means that when the claims land on someone's desk at HRSA, that person "can do their job and look at the 'research' and everyone loses."

....Our law firm has concluded that there is nothing our attorneys can do to significantly assist you," the firm states.

Maglio told me his Sarasota, Florida-based firm has been "contacted by at least a couple hundred people" about suspected COVID vaccine-related injuries, including blood clots and cardiac inflammation.

It's not that his firm doesn't want to help. Representing people who've had (rare) major adverse reactions to vaccines for tetanus, measles, hepatitis, influenza and a dozen other shots is its bread and butter.

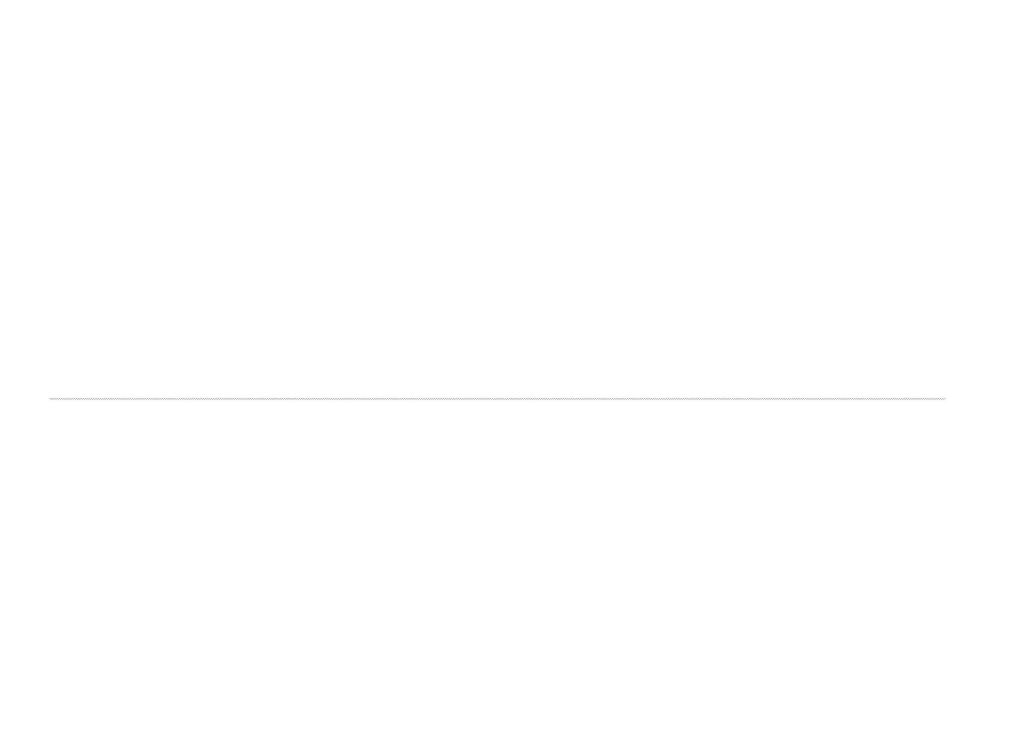
**b6** 

**b6** 

From: Sent: To: Subject: Attachments:	b6 4/1/2021 7:21:00 PM Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246  Re: Re: D77FF158DDD14C23820B27D71FEE8443.png	
Yes, that is particular Thank you,	perfect! Will you call my phone number?	
On Thu, Ap	r 1, 2021, 3:14 PM Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b> wrote:	
Ні,		
I can speak	with you tomorrow at 10am ET.Does this time work for you?	
Farinaz Saf	avi MD, PhD	
Division of	Neuroimmunology and Neurovirology	
NINDS, NI	H, Bethesda, MD	
	sday, April 1, 2021 8:21 AM Farinaz (NIH/NINDS) [E] e:	
Hello,		
	for your quick response! I see an ENT on Monday, April 5th. My PCP wanted me to see the ENT ring me to a neurologist, unfortunately she has been less than helpful. I live in <b>b6</b> If you need anything further please don't hesitate to ask!	
Thank you,		

b6	
On Thu, Apr 1, 2021, 8:10 AM Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b>	wrote:
Hi b6	
I am sorry about your illness.	
I would like to know bellow information.	
When you are supposed to see your ENT?and neurologist.	
Where do you live?	
Thanks	
Farinaz	
From: b6 Sent: Wednesday, March 31, 2021 7:30:22 PM To: Safavi, Farinaz (NIH/NINDS) [E] b6 Subject:	
Dr. Safavi,	
b6 The first dose was fine, just was a little tired. The second one, I had brain fog within a just didn't feel quite right and like I wasn't quite with it. Then shortly after I started with dizheadaches that ran across my forehead, I then had my eyes checked and all was normal. My to light and are just plain weird. Then the dizziness continued but I started to have burning it that spread around my eyes/sinuses and across my forehead. I went to see my PCP who gave b6 I had no relief from that, so week he put me on b6 and I had about a 2 day relief from symposic b6 The symptoms continue, although I will say that the dizziness is less, but the tinglistill there, and within the past 2 weeks I have had what feels like heart palpitations, I contact again who wanted me to go to the ER, so I did, and the EKG, chest x ray and all bloodwork normal except b6 The quick neuro tests and all were normal. My PCP referred me to an ENT, which I have an approach the second one, I had brain fog within a just didn't feel suited with its didn't feel suited with dizziness in the started with dizziness is less.	econd on b6  a few hours and ziness and y eyes are sensitive in my temple area to the following ottoms while on b6  and my face is seted my doctor to came back ey did the normal
normal except b6 The	ey did the normal

Thank you,



<b>r</b>	L.C.			
From:	b6			
Sent:	4/4/2021 8:38:37 AM Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group			
То:	(FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 b6			
CC:	Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group			
Cubicati	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c74110015054( <b>b6</b>			
Subject:	Re: Planned Analysis			
Hi Farinaz, Thank you f Best wishes <b>b6</b>	For the information. I look forward to the telehealth.			
Sent from n	ny iPad			
Hi	b6 wrote:  b6 wrote:  b6 ically we use the serum in research type assays to look at immunological foot print of inflammation			
	possible antibodies reactive to nerves. Regarding scheduling another telehealth, I will get back to			
Divi	inaz Safavi MD, PhD ision of Neuroimmunology and Neurovirology IDS, NIH, Bethesda, MD			
Sen To:	m: <u>Wiebold, Amanda (NIH/NINDS) [E]</u> it: Wednesday, March 31, 2021 2:04 PM Safavi, Farinaz (NIH/NINDS) [E]; b6 ject: Planned Analysis			
Dr.	Safavi,			
her sym	st spoke to b6 and she would like to know what testing you plan on doing with sample and what kind of results can she expect to get back. She also has had a change in appropriate since she spoke to you last and would like to schedule another telehealth visit to cuss.			
Tha	ank you,			
Res NIN 10 G Betl Offi Cell	earch Nurse Specialist  IDS Section of Infections of the Nervous System Center Drive, Building 10/7C107, MSC 1430 hesda, Maryland 20892 ice: b6 : b6 : 301-402-1137			

Email: **b6** 

From:	<b>b6</b>		
Sent:	3/6/2021 3:09:06 PM		
То:	Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 b6		
Subject:	Re: Covid vaccine reaction		
Attachments:	post vaccine medical.docx		
Good morni	ng Dr. Safazi,		
	synopsis, can discuss further during visit. Have placed all results that I have in the Word document elps, please let me know if you need anything else. I have access to all my medical records online.		
Thanks,			
b6			
	6, 2021 at 7:33 AM Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b> wrote:		
perfect.			
and the control of th	ease send me a summary of your disease course,work ups and treatments you have had so far?		
Thank you	one we team of monday.		
Farinaz			
Farinaz			
1 Gilliaz			
From:	b6		
	ay, March 6, 2021 6:52:47 AM arinaz (NIH/NINDS) [E] <b>b6</b>		
	Covid vaccine reaction		
Dear Dr. Sa	ıfazi,		
Thank you	so much for your response-it means a lot. Yes, I will take the Monday 3/8 spot at 10am ET.		
Sincerely,			
b6			
On Fri, Ma	r 5, 2021, 10:55 PM Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b> wrote:		
Dear l	<b>06</b>		
I am really vaccine iss	sorry to hear about your illness. We certainly can meet through televisit and go over your post sues.		
I have an a send you a	available spot on Monday 3/8 at 10am ET.Please let me know if this time works for you and I will link.		
1			

best Regards,
Farinaz Safavi MD, PhD
Division of Neuroimmunology and Neurovirology
NINDS, NIH, Bethesda, MD
From: b6 Sent: Friday, March 5, 2021 5:38 PM To: Safavi, Farinaz (NIH/NINDS) [E] Subject: Covid vaccine reaction
Hello Dr. Safazi,
I am part of the group that b6 is in and was wanting to see if I can get a consultation or I do not know if there is a research study to join with you all. I live here in b6 so can come in if needed. I am a b6 here in b6
A quick summary:
I developed a reaction after my 2nd moderna vaccine b6 I am b6 I got my injection
on right side. Within an hour I developed RUE/RLE weakness (I couldn't even eat with spoon and fork and was walking with a limp) it progressively got worse the more activity I did and about a month later I developed LUE/LLE weakness additionally. I also experience injection site/deltoid muscle burning sensation with prolonged activity. I am unable to do some of my ADLs and have not been back to work yet. I am able to ambulate with a limp. I have had MRIs and blood test done and they are unable to find what is causing my weakness.
I appreciate that you all are looking into this!

I hope to h	ear from you so	on! Thank you.
b6		
L		















From:	b6
Sent:	3/6/2021 4:17:44 PM
То:	Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
Subject:	(FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 <b>b6</b> Re: Covid vaccine reaction
Subject: Attachments:	post vaccine medical.docx
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
Apologies, I	Dr. Safavi (I just realized I was putting Dr. Safazi- I'm so sorry)
I just added	two other lab values in and updated it- this should be everything as of now.
I'll see you I	Monday.
b6	
On Sat Mar	c 6, 2021 at 10:09 AM <b>b6</b> wrote:
	ning Dr. Safazi,
	f synopsis, can discuss further during visit. Have placed all results that I have in the Word I hope this helps, please let me know if you need anything else. I have access to all my medical line.
Thanks,	
b6	
perfect. Can you p	ar 6, 2021 at 7:33 AM Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b> wrote: blease send me a summary of your disease course, work ups and treatments you have had so far? eceive MS teams for Monday.
Farinaz	
<b>To:</b> Safavi,	b6 rday, March 6, 2021 6:52:47 AM Farinaz (NIH/NINDS) [E] b6 e: Covid vaccine reaction Safazi,
Thank you	u so much for your response-it means a lot. Yes, I will take the Monday 3/8 spot at 10am ET.
Sincerely,	
b6	
On Fri, M	ar 5, 2021, 10:55 PM Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b> wrote:

Dear <b>b6</b>
I am really sorry to hear about your illness. We certainly can meet through televisit and go over your post vaccine issues.
I have an available spot on Monday 3/8 at 10am ET.Please let me know if this time works for you and I will send you a link.
Best Regards,
Farinaz Safavi MD, PhD
Division of Neuroimmunology and Neurovirology
NINDS, NIH, Bethesda, MD
From: b6 Sent: Friday, March 5, 2021 5:38 PM To: Safavi, Farinaz (NIH/NINDS) [E] Subject: Covid vaccine reaction
Hello Dr. Safazi,
I am part of the group that b6 is in and was wanting to see if I can get a consultation or I do not know if there is a research study to join with you all. I live here in b6 so can come in if needed. I am a b6 here in b6
A quick summary:
I developed a reaction after my 2nd moderna vaccine b6 I am b6 I got my injection on right side. Within an hour I developed RUE/RLE weakness (I couldn't even eat with spoon and fork and was walking with a limp) it progressively got worse the more activity I did and about a month later I developed LUE/LLE weakness additionally. I also experience injection site/deltoid muscle burning sensation

with prolonged activity. I am unable to do some of my ADLs and have not been back to work yet. I am able to ambulate with a limp. I have had MRIs and blood test done and they are unable to find what is causing my weakness.
I appreciate that you all are looking into this!
I hope to hear from you soon! Thank you.

















rom: ent: o:	3/15/2021 8:42:02 PM
<b>o</b> :	
	Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 <b>b6</b>
ubject:	Re: Symptoms following Pfizer vaccine
ear Farinaz	
his is my hı	usbands email
	b6
lope this or	
ind regards	s,
b6	
ent from m	ny iPhone
On :	15 Mar 2021, at 19:53, Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b> wrote:
	<u> </u>
Dea	\
I car	n not send you the link.Do you have any other email address like gmail or general generic ones?
	nk you
Thai	nk you
Thai Farii	nk you naz Safavi MD, PhD
Thai Farii Divis	nk you naz Safavi MD, PhD sion of Neuroimmunology and Neurovirology
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Thai Farii Divi: NIN	naz Safavi MD, PhD sion of Neuroimmunology and Neurovirology DS, NIH, Bethesda, MD
Thai Farii Divis NINI Fror	naz Safavi MD, PhD sion of Neuroimmunology and Neurovirology DS, NIH, Bethesda, MD
Thai Farii Divis NINI Fror Sent	naz Safavi MD, PhD sion of Neuroimmunology and Neurovirology DS, NIH, Bethesda, MD  m: b6 t: Monday, March 15, 2021 3:42 PM
Farii Divis NINI Fror Sent To:	naz Safavi MD, PhD sion of Neuroimmunology and Neurovirology DS, NIH, Bethesda, MD  m: b6 t: Monday, March 15, 2021 3:42 PM Safavi, Farinaz (NIH/NINDS) [E]
Farii Divis NINI Fror Sent To:	naz Safavi MD, PhD sion of Neuroimmunology and Neurovirology DS, NIH, Bethesda, MD  m: b6 t: Monday, March 15, 2021 3:42 PM
Faring Division NINI  From Sent To: 5	naz Safavi MD, PhD sion of Neuroimmunology and Neurovirology DS, NIH, Bethesda, MD  m: b6 t: Monday, March 15, 2021 3:42 PM Safavi, Farinaz (NIH/NINDS) [E]
Faring Division NINI  From Sent To: Subj	naz Safavi MD, PhD sion of Neuroimmunology and Neurovirology DS, NIH, Bethesda, MD  m: b6 t: Monday, March 15, 2021 3:42 PM Safavi, Farinaz (NIH/NINDS) [E] ject: Re: Symptoms following Pfizer vaccine
Faring Division NINI  From Sente To: Subject Dear Than	naz Safavi MD, PhD sion of Neuroimmunology and Neurovirology DS, NIH, Bethesda, MD  m: b6 t: Monday, March 15, 2021 3:42 PM Safavi, Farinaz (NIH/NINDS) [E] ject: Re: Symptoms following Pfizer vaccine
From Sent Too: Subj	naz Safavi MD, PhD sion of Neuroimmunology and Neurovirology DS, NIH, Bethesda, MD  m: b6 t: Monday, March 15, 2021 3:42 PM Safavi, Farinaz (NIH/NINDS) [E] ject: Re: Symptoms following Pfizer vaccine  ar Farinaz, nk you for getting back to me I am most grateful. horrow 12.30 ET time is perfect.
Fror Sent To: Subj	naz Safavi MD, PhD sion of Neuroimmunology and Neurovirology DS, NIH, Bethesda, MD  m: b6 tt Monday, March 15, 2021 3:42 PM Safavi, Farinaz (NIH/NINDS) [E] ject: Re: Symptoms following Pfizer vaccine or Farinaz, nk you for getting back to me I am most grateful. horrow 12.30 ET time is perfect.  ve not had any lab tests or imaging as the neurologist at b6 who
Fror Sent To: Subj	naz Safavi MD, PhD sion of Neuroimmunology and Neurovirology DS, NIH, Bethesda, MD   m: b6 tt Monday, March 15, 2021 3:42 PM Safavi, Farinaz (NIH/NINDS) [E] ject: Re: Symptoms following Pfizer vaccine or Farinaz, nk you for getting back to me I am most grateful. horrow 12.30 ET time is perfect.  ve not had any lab tests or imaging as the neurologist at b6 mined me said that they would show nothing. Also the neurologist with whom I had a video
From Sent Too: Subj	naz Safavi MD, PhD sion of Neuroimmunology and Neurovirology DS, NIH, Bethesda, MD   m: b6 t: Monday, March 15, 2021 3:42 PM Safavi, Farinaz (NIH/NINDS) [E] ject: Re: Symptoms following Pfizer vaccine  ar Farinaz, nk you for getting back to me I am most grateful. horrow 12.30 ET time is perfect.  ve not had any lab tests or imaging as the neurologist at b6 who mined me said that they would show nothing. Also the neurologist with whom I had a video sultation was convinced it was functional neurological symptoms and unrelated to the vaccine.
Fror Sent To: Subj	naz Safavi MD, PhD sion of Neuroimmunology and Neurovirology DS, NIH, Bethesda, MD   m: b6 t: Monday, March 15, 2021 3:42 PM Safavi, Farinaz (NIH/NINDS) [E] ject: Re: Symptoms following Pfizer vaccine  ar Farinaz, nk you for getting back to me I am most grateful. horrow 12.30 ET time is perfect.  ve not had any lab tests or imaging as the neurologist at b6 who mined me said that they would show nothing. Also the neurologist with whom I had a video sultation was convinced it was functional neurological symptoms and unrelated to the vaccine. ally look forward to our conversation tomorrow.
Fror Sent To: Subj	naz Safavi MD, PhD sion of Neuroimmunology and Neurovirology DS, NIH, Bethesda, MD   m: b6 t: Monday, March 15, 2021 3:42 PM Safavi, Farinaz (NIH/NINDS) [E] ject: Re: Symptoms following Pfizer vaccine  ar Farinaz, nk you for getting back to me I am most grateful. horrow 12.30 ET time is perfect.  ve not had any lab tests or imaging as the neurologist at b6 who mined me said that they would show nothing. Also the neurologist with whom I had a video sultation was convinced it was functional neurological symptoms and unrelated to the vaccine.

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On 15 Mar 2021, at 18:37, Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b> wrote:
Dear b6 I am really sorry to hear about your illness. yes, we started an effort to evaluate post covid vaccine reactions and I would be happy to speak with you through televisit and go over your symptoms and discuss it.  Did you have any imaging or lab work at all? I have an spot at 12:30pm ET(US) tomorrow.If it works for you I can send you a link. Please let me know
Farinaz Farinaz Safavi MD, PhD Division of Neuroimmunology and Neurovirology NINDS, NIH, Bethesda, MD
From: b6 Sent: Sunday, March 14, 2021 12:42 PM To: Safavi, Farinaz (NIH/NINDS) [E] Subject: Symptoms following Pfizer vaccine
Dear Dr Safavi,
I have been given you email by b6 as I have experience severe symptoms following the 1st dose of the Pfizer vaccine and was informed that you may be able to shed some light on what has happened and provide me with some information or a virtual consultation if possible.
Prior to vaccination I had no symptoms with no known health conditions and was taking no medications only Vitamin D and cod liver oil. b6    b6
I received the vaccine at b6 on b6 I had no hesitation about receiving the vaccine, only anxious about going into an indoor environment for any length of time. I was given the vaccine without any problems, but three hours later developed a sudden cold sensation in my lower legs. This turned into a sensation of ants crawling in both lower legs. This improved when walking but recurred when sitting or lying down.  On day 5 post vaccine, I experienced mild numbness and tightness on the left side of my face. I noticed that there was no difference in the sensation when I touched my face.
On day 11, I developed bad <b>nausea and light-headedness</b> for 2 days and this has fluctuated and intermittently but less severe than initially for 3 to 4 weeks.
By day 12, the (ant) paresthesia spread to my upper legs. On day 14, this also developed into a <b>burning</b> sensation in my upper legs and, to a lesser extent, the front of my lower legs. On day 15, the (burning) <b>dyesthesia</b> spread to the upper and then lower arms. On day 21, the symptoms spread to my chest and neck. In parallel, I developed some numbness on my face. The sensations have persisted

intermittently since then. I am aware of these sens		
hours at a time and the intensity varies. Over the	e last week or so th	re burning
sensation has become more painful particularly the	legs.	
I have no motor weakness.		
I have been examined by a top neurologist at  b6 and he has found nothing and says if I h	b6	in
b6 and he has found nothing and says if I h	ave loads of tests th	iey will be
negative. Also stating that my symptoms could be a	inxiety related and co	oincidental
and that it is unlikely that they are vaccine related a	nd that he sees no re	eason why
I should not go ahead with the 2 <sup>nd</sup> dose.		
Also I had a video consultation with another neuro	logist at the local ho	spital who
said my symptoms were functional, (that is her spe	eciality), and not rela	ated to the
vaccine. She initially said there is no reason not to	go ahead with the 2nd	d dose but
later said maybe I should delay the 2 <sup>nd</sup> dose a few	more weeks.	
My 2 <sup>nd</sup> dose is due in approximately a week as h	nere in <b>b6</b> the 2	<sup>ind</sup> dose is
delayed up to 12 weeks.		
I do associate my symptoms directly to the vaccine	and am really concer	ned about
my symptoms. Will they progress and to what? Sho	ould I have the 2 <sup>nd</sup> do	se?
My GP has not come across anyone with these sy	motoms post vaccin	e. He has
entered the details on the	)6	and
has had no response.		
I really would welcome your opinion re what may ha	ave caused these syn	nptoms as
I find it difficult to believe that they are coincidental of	or functional sensory	symptoms
and whether to go ahead with 2 <sup>nd</sup> dose.		
Many thanks.		
I look forward to hearing from you.		
Kind regards,		
b6		

From:	b6
Sent:	3/18/2021 1:51:31 PM Sofovi Forings (NIH (NINDS) [5] [/a-Evolongs] abs/su-Evolongs Administrative Crown
То:	Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 b6
CC:	Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540 <b>b6</b> Nahar, Kymani
	(NIH/NINDS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4f432f899337490ea7cbde0a4b52effb <b>b6</b>
Subject:	Re: Covid vaccine reaction
Medical reco	ords never got my request so I'm going back in an hour and she will give me all my records to bring
with me tom	iorrow.
On Thu May	r 18 2021 0:20 AM
Good morn	r 18, 2021, 9:20 AM <b>b6</b> wrote:
Good morn	ing,
I am about	to go pick up the CD from b6 that will have b6 I did with them.
I have not h	neard back regarding time of appt for tomorrow and if I need to be fasting.
Thanks!	
b6	
Thank you	Iar 17, 2021, 4:50 PM Safavi, Farinaz (NIH/NINDS) [E]
Farinaz	
From:	b6
	nesday, March 17, 2021 4:48:08 PM
To: Wiebole	d Amanda (NIH/NINDS) [F] <b>h6</b>
Cc: Safavi. F	Farinaz (NIH/NINDS) [F] b6
Subject: Re	d, Amanda (NIH/NINDS) [E] <b>b6</b> Farinaz (NIH/NINDS) [E] <b>b6</b> E: Covid vaccine reaction
	g to try to go tomorrow in person to get the CDs.
1 am gome	to try to go tomorrow in person to get the CDs.
Thanks,	
b6	
On Wed, M	Mar 17, 2021, 3:39 PM Wiebold, Amanda (NIH/NINDS) [E] <b>b6</b> wrote:
Hello	b6

	request everything from	<u> </u>	and	b6	We have not
received anything	g back yet but it usual	ly takes a little while.			
Thank you,					
Amanda					
From:	b6				
Sent: Wednesday	March 17, 2021 3:36 Ph	M	7		
Cc: Wiebold, Am	z (NIH/NINDS) [E] anda (NIH/NINDS) [E][	b6 b6	<u> </u>		
Subject: Re: Covi	d vaccine reaction				
Good afternoon D	c. Safavi,				
	,				
I only have the two	o discs for <b>b6</b> e rest of the CDs- I am r	on hand and I up	ploaded it into	the syste	m. Amanda was
going to request th	e rest of the CDs-1 and 1	iot sure it she got the re	cords yet-1 c	c nor on the	ms cman.
Thanks,					
<b>b</b> 6					
ii					
On Wed Man 17	2021 2:02 BM Sofavi E	Coninger (NULL/NUNIDS) [	D1	L 0	
	2021, 2:02 PM Safavi, F	armaz (Min/MinDS) [	E][	D6	wrote:
Dear <b>b6</b>					
	as informed that you ar u bring CDs of all your				
Please let me kno	w if you have any quest	ions.			
Best					
Farinaz Safavi M	D. PhD				

Division of Neuroimmunology and Neurovirology
NINDS, NIH, Bethesda, MD
From: b6
Sent: Monday, March 8, 2021 8:28 PM To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Covid vaccine reaction
Good evening,
It was a pleasure talking to you this afternoon. I uploaded my <b>b6</b> imaging as zip file-
please let me know if you got it. I read the consent form-however I did not see a place to sign it. I will go
tomorrow to medical records to request a CD for the rest of my MRIs through b6 I had my first MRI done but will sign the medical request forms that the nurse sent so they can send it to you.
Otherwise, b6 did all of the other MRIs.
Thanks,
h6
<b>b6</b>
On Mon, Mar 8, 2021 at 5:58 PM Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b> wrote:
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Farinaz	
From: b6 Sent: Saturday, March 6, 2021 12:54:07 PM To: Safavi, Farinaz (NIH/NINDS) [E] b6 Subject: Re: Covid vaccine reaction	
I will look out for the email-thanks! Yes, 12 noon is good for me.	
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I also would like to know can we change our meeting time to 12pm ET on Monday? Unfortunately I had an overlap on my schedule.	av(
Thank you	
Farinaz Safavi MD, PhD	
Division of Neuroimmunology and Neurovirology	
NINDS, NIH, Bethesda, MD	

From: b6

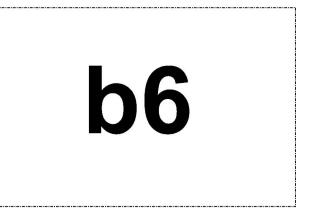
Sent: Saturday, March 6, 2021 11:18 AM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Covid vaccine reaction

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	I just added two other lab values in and updated it- this should be everything as of now.
***************************************	I'll see you Monday.
	b6
	On Sat, Mar 6, 2021 at 10:09 AM <b>b6</b> wrote:
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	perfect.
	Can you please send me a summary of your disease course,work ups and treatments you have had so far?
	You will receive MS teams for Monday.
	Thank you
	Farinaz
	Farinaz

From: b6	
Sent: Saturday, March 6, 2021 6:52:47 AM  To: Safavi, Farinaz (NIH/NINDS) [E] b6	
Subject: Re: Covid vaccine reaction	
Dear Dr. Safazi,	
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Sincerely,	
b6	
On Fri, Mar 5, 2021, 10:55 PM Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b> wr	on Land
WI OH FH, Wal 5, 2021, 10.55 FW Salavi, Falmaz (MH/MINDS) [E]!	
	ote:
Dear b6	ote:
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From: b6	
	ch 5, 2021 5:38 PM
	(NIH/NINDS) [E]
Subject: Covid vac	ceine reaction
Hello Dr. Safazi,	
I am part of the gro do not know if ther come in if needed.	oup that b6 is in and was wanting to see if I can get a consultation or I be is a research study to join with you all. I live here in b6 so can I am a b6 here in b6
A quick summary:	
injection on right s and fork and was w month later I devel muscle burning ser been back to work	ion after my 2nd moderna vaccine b6 I am b6 I got my ide. Within an hour I developed RUE/RLE weakness (I couldn't even eat with spoon valking with a limp) it progressively got worse the more activity I did and about a oped LUE/LLE weakness additionally. I also experience injection site/deltoid isation with prolonged activity. I am unable to do some of my ADLs and have not yet. I am able to ambulate with a limp. I have had MRIs and blood test done and find what is causing my weakness.
I appreciate that yo	ou all are looking into this!
I hope to hear from	you soon! Thank you.
b6	

From: Sent: To: Subject:	b6 6/1/2021 2:47:34 PM Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 b6 RE: Inquiry re Post COVID vaccine reactions
I look forwar	o much - I will do that today. rd to working with you. thing I can be doing in the meantime in terms of paperwork or providing more information?
Sent: Tuesda To:	i, Farinaz (NIH/NINDS) [E] b6 ay, June 01, 2021 8:20 AM b6 Inquiry re Post COVID vaccine reactions
understand	o hear about your symptoms.I would be happy to speak with your providers and share our ing about vaccine neurological adverse reactions. re my email address with your neurologist and we can connect.
Farinaz	
From:	b6
Sent: Tuesda To: Safavi, Fa Subject: Inqu	ay, June 1, 2021 5:00:50 PM arinaz (NIH/NINDS) [E] <b>b6</b> uiry re Post COVID vaccine reactions
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Symptoms (onset within 48 hours of second vaccine):

Involuntary muscle movements (nocturnal) best described as "Parkinson's-like" Intense tremors (nocturnal)
Insomnia related to the above
Widespread muscle fasciculations
Weakness
Intense fatigue
Neuralgias and parasthesias
Pin prick or hot poker sensations on extremities
Periods of reactive hyper- and hypoglycemia (seems to have resolved)
Periods of increased salivation/difficulty swallowing (intermittent)

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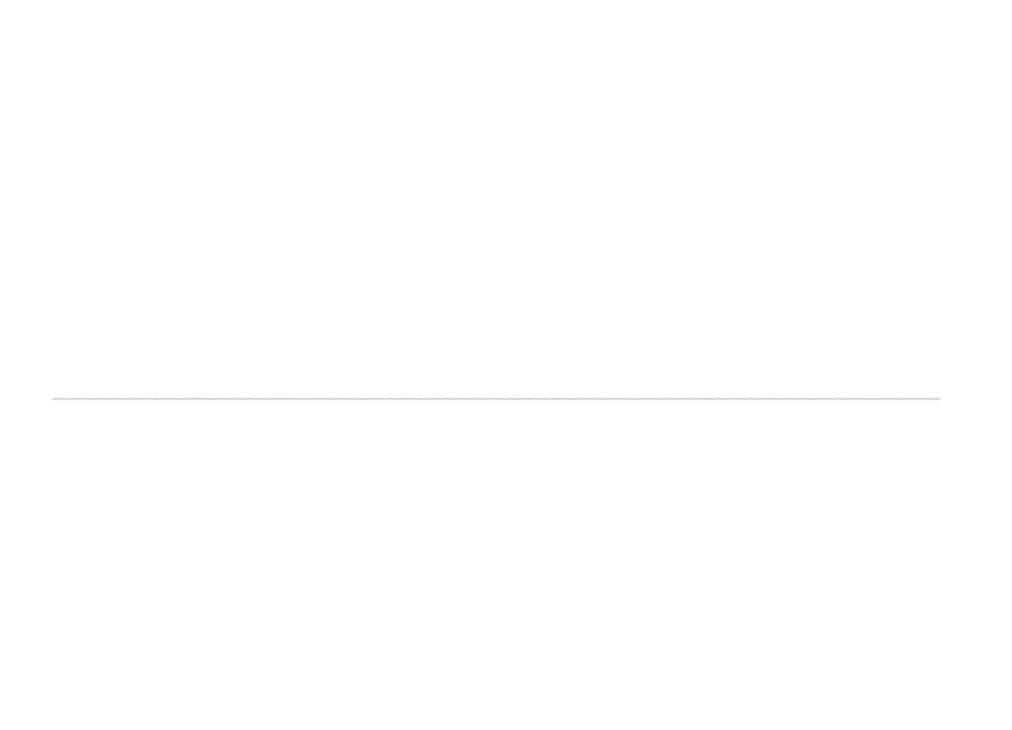
From: Sent: To: Subject: Attachments:	3/6/2021 5:54:07 PM Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 b6 Re: Covid vaccine reaction 7A3C8FA9523F4C829291978CD8E6AF2D.png
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Farinaz Saf	avi MD, PhD
Division of	Neuroimmunology and Neurovirology
NINDS, NI	H, Bethesda, MD
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Subject: Covid vaccine reaction
Hello Dr. Safazi,
I am part of the group that b6 is in and was wanting to see if I can get a consultation or I do not know if there is a research study to join with you all. I live here in b6 so can come in if needed. I am a b6 here in b6
A quick summary:
I developed a reaction after my 2nd moderna vaccine b6 I am b6 I got my injection on right side. Within an hour I developed RUE/RLE weakness (I couldn't even eat with spoon and fork and was walking with a limp) it progressively got worse the more activity I did and about a month later I developed LUE/LLE weakness additionally. I also experience injection site/deltoid muscle burning sensation with prolonged activity. I am unable to do some of my ADLs and have not been back to work yet. I am able to ambulate with a limp. I have had MRIs and blood test done and they are unable to find what is causing my weakness.
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540 <b>b6</b>
Subject:	Re: Covid vaccine reaction
Attachments:	F8827D16798B4AE1B429D81A6272E74D.png
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Best	
Dest	
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Division of	Neuroimmunology and Neurovirology
NINDS NI	H, Bethesda, MD
1111100, 111	11, 100110000, 11110
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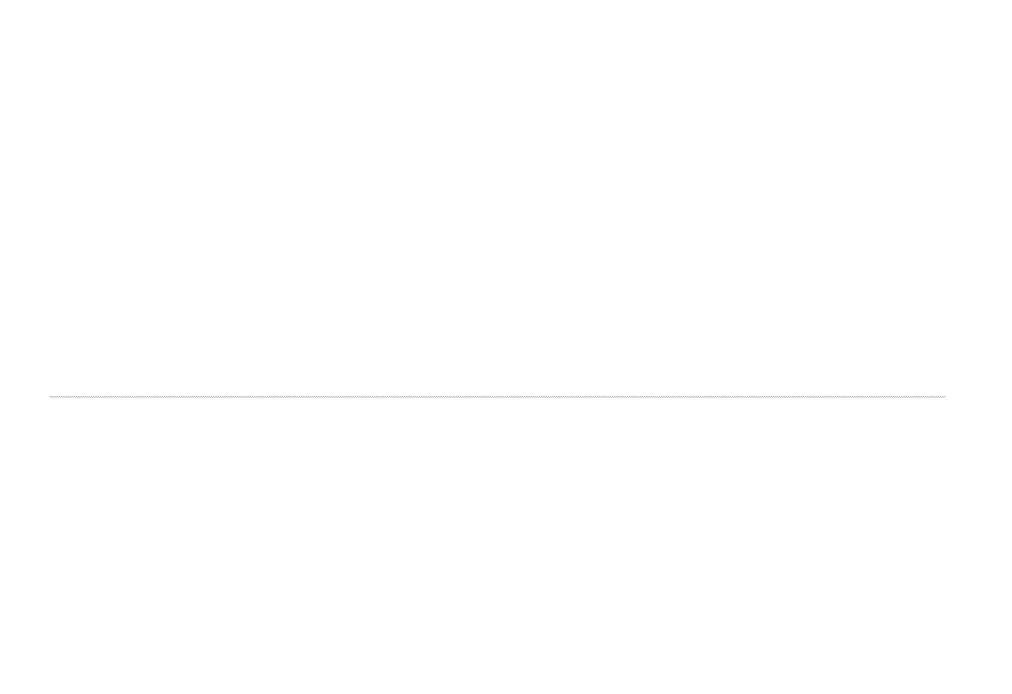
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NI	NDS, NIH, Bethesda, MD
Se To	com: b6  nt: Saturday, March 6, 2021 11:18 AM  o: Safavi, Farinaz (NIH/NINDS) [E]  ubject: Re: Covid vaccine reaction
Aŗ	pologies, Dr. Safavi (I just realized I was putting Dr. Safazi- I'm so sorry)
Ιjι	ust added two other lab values in and updated it- this should be everything as of now.
I'll	see you Monday.
	b6

C	n Sat, Mar 6, 2021 at 10:09 AM <b>b6</b> wrote:
	Good morning Dr. Safazi,
(	did a brief synopsis, can discuss further during visit. Have placed all results that I have in the Word ocument. I hope this helps, please let me know if you need anything else. I have access to all my medical ecords online.
,	Thanks,
	b6
,	On Sat, Mar 6, 2021 at 7:33 AM Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b> wrote:
	perfect.
	Can you please send me a summary of your disease course,work ups and treatments you have had so far?
	You will receive MS teams for Monday.
	Thank you
	Farinaz
	Farinaz
	From: b6 Sent: Saturday, March 6, 2021 6:52:47 AM
	To: Safavi, Farinaz (NIH/NINDS) [E] b6 Subject: Re: Covid vaccine reaction
	Dear Dr. Safazi,
	Thank you so much for your response-it means a lot. Yes, I will take the Monday 3/8 spot at 10am ET.

Sincerely,
b6
On Fri, Mar 5, 2021, 10:55 PM Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b> wrote:
Dear b6
I am really sorry to hear about your illness. We certainly can meet through televisit and go over your post vaccine issues.
I have an available spot on Monday 3/8 at 10am ET.Please let me know if this time works for you and I will send you a link.
Best Regards,
Farinaz Safavi MD, PhD
Division of Neuroimmunology and Neurovirology
NINDS, NIH, Bethesda, MD
From: b6 Sent: Friday, March 5, 2021 5:38 PM To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Covid vaccine reaction
Hello Dr. Safazi,

	I am part of the gr	oup that	b6	is in and	was wan	iting to see	if I can get	a consultation or I do
	not know if there	s a research	study to join	with you	all. I live	here in	b6	so can come in it
	needed. I am a							
000000000								
	A quick summary	:						
	I developed a reac	tion after my	2nd modern	na vaccine	b6 I	am	b6	I got my
	injection on right	side. Within	an nour i dev	velopea K	UE/KLE	weakness (	(1 coulant e	ven eat with spoon
	and fork and was							
								site/deltoid muscle have not been back
								and they are unable
	to find what is cau				1144-1111	and order		und moj uro undero
		11 1	1-1	-1				
	I appreciate that y	ou an are 100	king into thi	S!				
	I hope to hear from	n you soon!	Thank you.					
	b6							



From:	b6							
Sent:	8/9/2021 9:10:55 PM							
To: Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group								
(FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 <b>b6</b>								
Subject:	· · · · · · · · · · · · · · · · · · ·							
Attachments:	: b6							
Hello Dr Safav	avi.							
	,							
The 2 files abo	b6							
<b>b6</b>								
L								
·								
	<b>b6</b>							
i								
Thank you								
b6								

Sent from  $\underline{\text{Mail}}$  for Windows 10



From:	Safavi, Farinaz (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP
	(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=94807CE146E045D4B61655DA26A0C246 <b>b6</b>
Sent:	4/17/2021 12:33:31 PM <b>b6</b>
To: Subject:	Re: Planned Analysis
Jun, 2001.	No. 1 tallings / marysis
Hi b6	<del></del>
	h6
	<b>b6</b>
Hope you feel better and let me know if you have any questions. Best	
Dest	
Farinaz	
From:	b6
Sent: Friday.	April 16, 2021 4:47:15 AM
To: Safavi, Fa	rinaz (NIH/NINDS) [E] b6
Subject: Re: Planned Analysis	
Hi Dr Farinaz,	
I expect you are inundated with people that have these neurological symptoms from the Covid vaccines.	
I have returned the signed consent forms to Amanda and am pleased to be able to contribute to your valuable research.	
There is no one in <b>b6</b> to turn to for any information. <b>b6</b> my GP, was very apologetic because he missed his telehealth call due to <b>b6</b> He is very supportive and would very much like to	
missed his telehealth call due to b6 He is very supportive and would very much like to	
speak to you. I did give your email to the 2 neurologists I saw, but they haven't contacted you. <b>b6</b>	
b6 is a GP and is interested in my case and has been trying to work out how this type of reaction could	
have happened so quickly after vaccination.	
I am still experiencing symptoms <b>b6</b> after 1st dose of Pfizer vaccine. Severe pain and twitching muscles	
in both legs but I have a few good days with more energy and less pain and I think it's over only for it to return	
again. My le	egs are very sensitive to cold which initiates the pain.  I have been taking b6 as one of the consultant neurologists
Refuctantity,	I have been taking b6 as one of the consultant neurologists ust the last couple of days the symptoms have been less severe - I expect this be the b6
	reduce pain? Also, for the last couple of weeks I have had a buzzing in my head which I haven't had
previously.	educe pain. Theo, for the last couple of wooks I have had a suzzing in my head which I haven that
	ave NOT had the 2nd dose of the vaccine. It is <b>b6</b> from 1st dose. I have been called for the
Pfizer for th	is Sunday but am really scared as I don't know what might happen. Still very undecided and
	whether to go for 2nd dose Pfizer or 2nd dose AZ wait for Jensen or Novavax or have no 2nd dose?
I did the Roche SARS Cov 2 spike antibody test at <b>b6</b> and it came back as <b>b6</b> I wonder	
whether this gives a reasonable protection as I believe the scale is 0 - 250 and how quickly the antibodies will decline?	
	ly appreciate to have a telehealth to update you on my symptoms <b>b6</b> and how they
have developed since we last spoke. Also what tests I could have done that would help diagnosis. My	
neurologist, who I saw at the end of February, said that it would be waste of money as the tests would not show	
anything!	
	very much for listening to my story and all your help and reassurance that one day the symptoms
will go.	

I look forward to contributing to your research and to hearing from you.  Kind regards,  b6  Sent from my iPad		
On 1 Apr 2021, at 20:17, Safavi, Farinaz (NIH/NINDS) [E] <b>b6</b> wrote:		
Hi <b>b6</b> Basically we use the serum in research type assays to look at immunological foot print of inflammation and possible antibodies reactive to nerves. Regarding scheduling another telehealth, I will get back to you.		
Farinaz Safavi MD, PhD Division of Neuroimmunology and Neurovirology NINDS, NIH, Bethesda, MD		
From: Wiebold, Amanda (NIH/NINDS) [E]  Sent: Wednesday, March 31, 2021 2:04 PM  To: Safavi, Farinaz (NIH/NINDS) [E]; b6  Subject: Planned Analysis		
Dr. Safavi,		
I just spoke to <b>b6</b> and she would like to know what testing you plan on doing with her sample and what kind of results can she expect to get back. She also has had a change in symptoms since she spoke to you last and would like to schedule another telehealth visit to discuss.		
Thank you,		
Amanda Wiebold, BSN, RN, CNRN  Research Nurse Specialist  NINDS Section of Infections of the Nervous System  10 Center Drive, Building 10/7C107, MSC 1430  Bethesda, Maryland 20892  Office: b6  Cell: b6  Fax: 301-402-1137  Email: b6		