From: (b) (6)
To: Gavin, Angelique (NIH/NINDS) [C]
Cc: (b) (6)
Subject: Re: NIH COVID-19 Vaccine Study
Date: Thursday, August 11, 2022 2:55:16 AM
Attachments: (b) (6)

Hello,

Here is the picture of the positive Covid-19 test, with the date and time.

(b) (6)

From: Gavin, Angelique (NIH/NINDS) [C] <(b) (6)
Sent: Tuesday, August 9, 2022 7:13:25 AM
To: (b) (6) <(b) (6)
Subject: RE: NIH COVID-19 Vaccine Study

Thank you (b) (6) for your quick reply! We need a time and date stamp on your COVID-19 test result. Please resend. Once received, we will review your documents and get back to you regarding eligibility. Have a great day!

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
(b) (6) (office)
(b) (6) (cell)
(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089-N

-

From: (b) (6) <(b) (6)

Sent: Monday, August 8, 2022 9:04 PM
To: Gavin, Angelique (NIH/NINDS) [C] < (b) (6)
Subject: RE: NIH COVID-19 Vaccine Study

Hello,

Here is the information needed for the study.

1. What is your full name? (b) (6)

2. What is your preferred phone number? (b) (6)

3. How old are you? (b) (6)

4. Are you fluent in speaking, reading and writing English? Yes

5. Do you live in the United States? Yes
a. If yes, please provide the city, state and zip code where you live. (b) (6)

6. Are you an NIH employee, contractor, trainee or otherwise affiliated with the NIH? No

7. Have you had a COVID-19 infection? (b) (6)
a. If yes, how many COVID-19 infections have you had? (b) (6)
b. What is the date of your first COVID-19 infection? (b) (6)
c. Are you having persistent side effects after your first COVID-19 infection? (b) (6)
d. Do you have test results confirming your COVID 19 infection? (b) (6)
e. If you responded yes, please provide a copy of your COVID 19 test results with your email response.
For tests performed at a laboratory or by a medical provider, results need to include your name, date of test result, type of test, and result of test. If you do not have a copy of your test result, please let us know and we can assist you in obtaining your records from your medical lab or provider.
For tests performed using a home testing kit, a photograph of the results with time and date are required.

8. Have you received a COVID-19 vaccine? Yes
a. *If you responded yes, please provide a copy of your COVID 19 vaccination card with your email response*.
b. If yes, do you have persistent side effects after receiving a COVID-19 vaccination?
Yes, on (b) (6) I had an immediate reaction within 30 min. throat tightness, facial tingling, heart rate increase, dizziness, and nausea. I had to get picked up. I kept feeling sharp pains in my chest but shrugged it off and 11 days later I ended up in ER after getting a sharp pain in my neck and intense

palpitations. My bp was [redacted] and hr [redacted] when EMT's came. [redacted] Since that day [redacted] my body hasn't been the same. I started having chest tightness, palpitations, tachycardia, blood pressure spikes, headaches/ head pressure, noise and light sensitivity, ringing in ears, blurry vision, muscle twitching, internal vibration/buzzing, tingling sensation, adrenaline surges, dizziness, fatigue. I also still have swollen lymph nodes in neck and armpit at [redacted] out. My injection arm had a swollen ball around injection site, and I have a few issues with that arm like tingling and pain. I still have these symptoms the first 3 months were horrible. I literally was in bed most of those months. I couldn't even handle going to stores or my dogs barking. Around 6-8 months I felt like the tachycardia got better and I can do a lot more, but my heart still feels like it's being squeezed, and I get sharp stabbing pains in collar bone area. After 10 months the constant tingling in my lower limbs improved. I still haven't recovered from all my symptoms. My symptoms vary throughout the day. [redacted] The tingling turned into a burning sensation, and I also had worsening tachycardia.

Currently I am waiting to see a [redacted] since [redacted]. I am also waiting to get [redacted]. My cardiologist said I had [redacted].

Thank you for your time and consideration, [redacted]

From: Gavin, Angelique (NIH/NINDS) [C] <[redacted]
Sent: Monday, August 8, 2022 1:15 PM
To: [redacted] <[redacted]
Subject: NIH COVID-19 Vaccine Study

Good Day [redacted]:

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

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

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

1. What is your full name?

2. What is your preferred phone number?

3. How old are you?

4. Are you fluent in speaking, reading and writing English? Yes /No

5. Do you live in the United States? Yes/No

a. If yes, please provide the city, state and zip code where you live.

6. Are you an NIH employee, contractor, trainee or otherwise affiliated with the NIH? Yes/No

7. Have you had a COVID-19 infection? Yes/No/Unsure

a. If yes, how many COVID-19 infections have you had?

b. What is the date of your first COVID-19 infection?

c. Are you having persistent side effects after your first COVID-19 infection? Yes No

d. Do you have test results confirming your COVID 19 infection? Yes No

e. If you responded yes, please provide a copy of your COVID 19 test results with your email response.

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

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

8. Have you received a COVID-19 vaccine? Yes No

a. ***If you responded yes, please provide a copy of your COVID 19 vaccination card with your email response***.

b. If yes, do you have persistent side effects after receiving a COVID-19 vaccination? Yes No

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

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

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

Thank you,

Angelique Gavin
COVID 19 Convalescence Study Team

Angelique Gavin, MS (Contractor)
NIH/NINDS Clinical Operations Manager
Contractor Preferred Solutions Group
National Institutes of Health
10 Center Drive
Building 10, Room 3B19, MSC 1251
Bethesda, MD 20814-9692
(b) (6) (office)
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(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089-N

(b) (6

From: (b) (6)
To: Gavin, Angelique (NIH/NINDS) [C]
Cc: (b) (6)
Subject: Re: [EXTERNAL] Re: NIH COVID-19 Vaccine Study
Date: Thursday, August 25, 2022 4:16:46 AM
Attachments: HIPAA Medical Record Release (b) (6)
(b) (6)
(b) (6)

Hello,

I attached the picture with the time stamp. I also attached my records for this year (b) (6) and the HIPAA release form. I filled it out to be sent to (b) (6) medical records department. Please let me know if I need to correct anything.

Thank you, (b) (6)

From: Gavin, Angelique (NIH/NINDS) [C] <(b) (6)
Sent: Wednesday, August 24, 2022 12:07:33 PM
To: (b) (6) <(b) (6)
Subject: RE: [EXTERNAL] Re: NIH COVID-19 Vaccine Study

Hi (b):

I have good news and bad news. I greatly appreciate your efforts in resending the test result. Sadly, we need the year of the result on that time stamp. Is this possible for you to resend it? In the meantime, to determine if you are eligible to proceed to the next phase of the study, we need medical records to confirm that symptom onset was after your COVID vaccination. Please complete the attached medical record release form for a medical provider who managed your care at the onset of symptoms after vaccination. Return the form to me using this secure email and I will obtain records on your behalf.

Once we have received and reviewed your records, if you are eligible to proceed, we will schedule the phone interview. Please let me know if you have any additional questions. I am looking forward to speaking with you soon.

Sincerely,
Angelique

Angelique Gavin, MS (Contractor)
NIH/NINDS Clinical Operations Manager
Contractor Preferred Solutions Group
National Institutes of Health
10 Center Drive
Building 10, Room 3B19, MSC 1251
Bethesda, MD 20814-9692
(b) (6) (office)
(b) (6) (cell)
(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089-N

-

From: (b) (6) <(b) (6)
Sent: Tuesday, August 23, 2022 3:24 PM
To: Gavin, Angelique (NIH/NINDS) [C] <(b) (6)
Subject: [EXTERNAL] Re: NIH COVID-19 Vaccine Study

Hello,

Sorry for the delayed response. Here is the picture with the time stamp.

On Mon, Aug 15, 2022 at 8:59 AM Gavin, Angelique (NIH/NINDS) [C] <[redacted] (b) (6)> wrote:

Hello [redacted] (b):

Thank you for providing your test result with the time stamp. Typically we ask for the phone's date/time stamp, not one the participant puts on the picture. If you can re-send the test result with the phone's stamp, it would be appreciated. So sorry to make you go through so much effort.

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
(b) (6) (office)
(b) (6) (cell)
(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089-N

-

(b) (6)

From: (b) (6)
To: Gavin, Angelique (NIH/NINDS) [C]
Cc: (b) (6)
Subject: Re: [EXTERNAL] Re: NIH COVID-19 Vaccine Study
Date: Monday, August 29, 2022 7:03:37 PM
Attachments: HIPAA Medical Record Release Blank (b) (6) .pdf
(b) (6)
(b) (6)
(b) (6)

Hello,

I recent them again a few different ways. Hopefully it works if not can I fax them?

Thank you, (b) (6)

From: Gavin, Angelique (NIH/NINDS) [C] <(b) (6)
Sent: Friday, August 26, 2022 6:20:50 AM
To: (b) (6) <(b) (6)
Subject: RE: [EXTERNAL] Re: NIH COVID-19 Vaccine Study

Hi (b) (6):

I just tried to open the HIPAA and SHDS files you attached but they are protected files. Can you resend in another format please?

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
(b) (6) (office)
(b) (6) (cell)
(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089-N

-

From: (b) (6) <Office365@messaging.microsoft.com>

Sent: Thursday, August 25, 2022 4:16 AM
To: Gavin, Angelique (NIH/NINDS) [C] < (b) (6)
Cc: (b) (6)
Subject: Re: [EXTERNAL] Re: NIH COVID-19 Vaccine Study

Hello,

I attached the picture with the time stamp. I also attached my records for this year at (b) (6) and the HIPAA release form. I filled it out to be sent to (b) (6) medical records department. Please let me know if I need to correct anything.

Thank you, (b) (6)

From: Gavin, Angelique (NIH/NINDS) [C] < (b) (6)
Sent: Wednesday, August 24, 2022 12:07:33 PM
To: (b) (6) < (b) (6)
Subject: RE: [EXTERNAL] Re: NIH COVID-19 Vaccine Study

Hi (b) (6)

I have good news and bad news. I greatly appreciate your efforts in resending the test result. Sadly, we need the year of the result on that time stamp. Is this possible for you to resend it? In the meantime, to determine if you are eligible to proceed to the next phase of the study, we need medical records to confirm that symptom onset was after your COVID vaccination. Please complete the attached medical record release form for a medical provider who managed your care at the onset of symptoms after vaccination. Return the form to me using this secure email and I will obtain records on your behalf.

Once we have received and reviewed your records, if you are eligible to proceed, we will schedule the phone interview. Please let me know if you have any additional questions. I am looking forward to speaking with you soon.

Sincerely,
Angelique

Angelique Gavin, MS (Contractor)
NIH/NINDS Clinical Operations Manager
Contractor Preferred Solutions Group
National Institutes of Health
10 Center Drive

Building 10, Room 3B19, MSC 1251
Bethesda, MD 20814-9692
(b) (6) (office)
(b) (6) (cell)
(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089-N

-

From: (b) (6) <(b) (6)
Sent: Tuesday, August 23, 2022 3:24 PM
To: Gavin, Angelique (NIH/NINDS) [C] <(b) (6)
Subject: [EXTERNAL] Re: NIH COVID-19 Vaccine Study

Hello,

Sorry for the delayed response. Here is the picture with the time stamp.

On Mon, Aug 15, 2022 at 8:59 AM Gavin, Angelique (NIH/NINDS) [C] <(b) (6) wrote:

> Hello (b) (6):
>
> Thank you for providing your test result with the time stamp. Typically we ask for the phone's date/time stamp, not one the participant puts on the picture. If you can re-send the test result with the phone's stamp, it would be appreciated. So sorry to make you go through so much effort.
>
> 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
> (b) (6) (office)
> (b) (6) (cell)

(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089-N

-

HIPAA COMPLIANT AUTHORIZATION FOR THE RELEASE OF PATIENT INFORMATION PURSUANT TO 45 CFR 164.508

TO: (b) (6)

Name of Healthcare Provider/Physician/Facility/Medicare Contractor

(b) (6)

Street Address

(b) (6)

City, State and Zip Code

RE: Patient Name: (b) (6)

Date of Birth: (b) (6) Social Security Number: (b) (6)

I authorize and request the disclosure of all protected information for the purpose of review and evaluation in connection with a legal claim. I expressly request that the designated record custodian of all covered entities under HIPAA identified above disclose full and complete protected medical information including the following:

- [x] All medical records, meaning every page in my record, including but not limited to: office notes, face sheets, history and physical, consultation notes, inpatient, outpatient and emergency room treatment, all clinical charts, r ports, order sheets, progress notes, nurse's notes, social worker records, clinic records, treatment plans, admission records, discharge summaries, requests for and reports of consultations, documents, correspondence, test results, statements, questionnaires/histories, correspondence, photographs, videotapes, telephone messages, and records received by other medical providers.
- [ ] All physical, occupational and rehab requests, consultations and progress notes.
- [ ] All disability, Medicaid or Medicare records including claim forms and record of denial of benefits.
- [ ] All employment, personnel or wage records.
- [ ] All autopsy, laboratory, histology, cytology, pathology, immunohistochemistry records and specimens; radiology records and films including CT scan, MRI, MRA, EMG, bone scan, myleogram; nerve conduction study, echocardiogram and cardiac catheterization results, videos/CDs/films/reels and reports.
- [ ] All pharmacy/prescription records including NDC numbers and drug information handouts/monographs.
- [ ] All billing records including all statements, insurance claim forms, itemized bills, and records of billing to third party payers and payment or denial of benefits for the period _____ to _____.

I understand the information to be released or disclosed may include information relating to sexually transmitted diseases, acquired immunodeficiency syndrome (AIDS), or human

immunodeficiency virus (HIV), and alcohol and drug abuse. I authorize the release or disclosure of this type of information.

This protected health information is disclosed for the following purposes: _____

Research Study Participation

This authorization is given in compliance with the federal consent requirements for release of alcohol or substance abuse records of 42 CFR 2.31, the restrictions of which have been specifically considered and expressly waived.

You are authorized to release the above records to the following representatives of defendants in the above-entitled matter who have agreed to pay reasonable charges made by you to supply copies of such records:

Brian Walitt, MD MPH

Name of Representative

Physician

Representative Capacity (e.g. attorney, records requestor, agent, etc.)

National Institutes of Health
10 Center Drive, Building 10, Room 3B19, MSC 1251

Street Address

Bethesda, MD 20814

City, State and Zip Code

I understand the following: See CFR §164.508(c)(2)(i-iii)

a. I have a right to revoke this authorization in writing at any time, except to the extent information has been released in reliance upon this authorization.
b. The information released in response to this authorization may be re-disclosed to other parties.
c. My treatment or payment for my treatment cannot be conditioned on the signing of this authorization.

Any facsimile, copy or photocopy of the authorization shall authorize you to release the records requested herein. This authorization shall be in force and effect until two years from date of execution at which time this authorization expires.

(b) (6)

Signature of Patient or Legally Authorized Representative
(See 45CFR § 164.508(c)(1)(vi))

08/25/2022

Date

Name and Relationship of Legally Authorized Representative to Patient
(See 45CFR §164.508(c)(1)(iv))

Witness Signature

Date

From: (b) (6)
To: Gavin, Angelique (NIH/NINDS) [C]; Espinoza, Claudia (NIH/NINDS) [C]
Subject: Re: COVID-19 Study at NIH
Date: Tuesday, July 26, 2022 11:36:13 PM
Attachments: HIPAA Medical Record Release Blank 1.5.pdf
HIPAA Medical Record Release Blank 2.5.pdf

Good Evening Ms. Gavin and Ms. Espinoza,

Attached is the requested HIPPA release form. I had to send it in two separate PDFs. Please let me know if these documents come over ok.

Thank you so much and I look forward to participating in your study.

Sincerely,

(b) (6)
(b) (6)

From: Bartrum, Elizabeth (NIH/NINDS) [E] <(b) (6)
Sent: Friday, July 22, 2022 10:37:27 AM
To: (b) (6) <(b) (6)
Cc: Gavin, Angelique (NIH/NINDS) [C] <(b) (6) Espinoza, Claudia (NIH/NINDS) [C] <(b) (6)
Subject: RE: COVID-19 Study at NIH

Good afternoon (b) (6) -
Thank you for your responses. To determine if you are eligible to proceed we need medical records to confirm that the symptom onset was after COVID vaccination.

Please complete the attached medical record release form for a medical provider whom managed your care at the onset of symptoms after vaccination. Return the form to Ms. Gavin and Ms. Espinoza and we will obtain the records on your behalf.

Once we have received the records and reviewed them, if you are eligible to proceed we will schedule the phone interview.

Please let me know if you have any additional questions. I look forward to speaking with you soon.

Sincerely-
Elizabeth A Bartrum, FNP-BC

From: (b) (6) <Office365@messaging.microsoft.com>

Sent: Wednesday, July 20, 2022 1:19 PM
To: Bartrum, Elizabeth (NIH/NINDS) [E] <(b) (6)
Subject: Re: COVID-19 Study at NIH

Dear Elizabeth,

Thank you so much for this opportunity to participate in your study. My daughter (b) (6) and I have been suffering with persistent neurological issues since our vaccinations in the (b) (6). I have been diagnosed with (b) (6) after one dose of Pfizer, and (b) (6). She had both doses of Moderna. Neither of us has had the virus.

I have included a copy of my vaccine card and will answer your questions below. Again, please know how much this means to us and I know your research will mean much to many others, too. I keep hopeful we will get to the bottom of what has happened to those of us hurt so we can avoid these problems in the future. I hope a mother/daughter pair is helpful to you, also. Sincerely, (b) (6)

What is your full name? (b) (6)

What is your preferred phone number? (b) (6)

How old are you? (b) (6)

Are you fluent in speaking, reading and writing English? YES

Do you live in the United States? YES

If yes, please provide the city, state and zip code where you live. (b) (6)

Are you an NIH employee, contractor, trainee or otherwise affiliated with the NIH? NO

Have you had a COVID-19 infection? (b) (6)

8a. If yes, how many COVID-19 infections have you had? (b) (6)

8b. What is the date of your first COVID-19 infection? (b) (6)

8c. Are you having persistent side effects after your first COVID-19 infection? (b) (6)

8d. Do you have test results confirming your COVID 19 infection? (b) (6)

8e. If you responded yes, please provide a copy of your COVID 19 test results with your email response. (b) (6)

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

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

Have you received a COVID-19 vaccine? YES

9a. *If you responded yes, please provide a copy of your COVID 19 vaccination card with your email response*.

9b. If yes, do you have persistent side effects after receiving a COVID-19 vaccination? YES

From: Bartrum, Elizabeth (NIH/NINDS) [E] < (b) (6)
Sent: Wednesday, July 13, 2022 6:27:15 PM
To: (b) (6) < (b) (6)
Cc: Bartrum, Elizabeth (NIH/NINDS) [E] < (b) (6)
Subject: COVID-19 Study at NIH

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

Our study is looking at the experience of recovery for individuals after a COVID-19 infection or after

COVID-19 vaccination. The attached consent form provides more information about our study, which
involves a phone interview and online questionnaires.

In order to be considered for the study, please respond to this email with answers to the following
questions:
What is your full name?

What is your preferred phone number?

How old are you?

Are you fluent in speaking, reading and writing English? Yes /No

Do you live in the United States? Yes/No

If yes, please provide the city, state and zip code where you live.

Are you an NIH employee, contractor, trainee or otherwise affiliated with the NIH? Yes/No

Have you had a COVID-19 infection? Yes/No/Unsure

8a. If yes, how many COVID-19 infections have you had?

8b. What is the date of your first COVID-19 infection?

8c. Are you having persistent side effects after your first COVID-19 infection? Yes No

8d. Do you have test results confirming your COVID 19 infection? Yes No

*8e. If you responded yes, please provide a copy of your COVID 19 test results with your email
response.*

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

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

Have you received a COVID-19 vaccine? Yes No

9a. *If you responded yes, please provide a copy of your COVID 19 vaccination card with your email response*.

9b. If yes, do you have persistent side effects after receiving a COVID-19 vaccination? Yes No

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

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

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

Thank you-
Elizabeth A Bartrum, FNP-BC
COVID 19 Convalescence Study Team

HIPAA COMPLIANT AUTHORIZATION FOR THE RELEASE OF PATIENT INFORMATION PURSUANT TO 45 CFR 164.508

TO: (b) (6)

City, State and Zip Code

RE: Patient Name: (b) (6) _____

Date of Birth: (b) (6) Social Security Number: (b) (6)

I authorize and request the disclosure of all protected information for the purpose of review and evaluation in connection with a legal claim. I expressly request that the designated record custodian of all covered entities under HIPAA identified above disclose full and complete protected medical information including the following:

☑ All medical records, meaning every page in my record, including but not limited to: office notes, face sheets, history and physical, consultation notes, inpatient, outpatient and emergency room treatment, all clinical charts, r ports, order sheets, progress notes, nurse's notes, social worker records, clinic records, treatment plans, admission records, discharge summaries, requests for and reports of consultations, documents, correspondence, test results, statements, questionnaires/histories, correspondence, photographs, videotapes, telephone messages, and records received by other medical providers.

☐ All physical, occupational and rehab requests, consultations and progress notes.

☐ All disability, Medicaid or Medicare records including claim forms and record of denial of benefits.

☐ All employment, personnel or wage records.

☐ All autopsy, laboratory, histology, cytology, pathology, immunohistochemistry records and specimens; radiology records and films including CT scan, MRI, MRA, EMG, bone scan, myleogram; nerve conduction study, echocardiogram and cardiac catheterization results, videos/CDs/films/reels and reports.

☐ All pharmacy/prescription records including NDC numbers and drug information handouts/monographs.

☐ All billing records including all statements, insurance claim forms, itemized bills, and records of billing to third party payers and payment or denial of benefits for the period _____ to _____.

I understand the information to be released or disclosed may include information relating to sexually transmitted diseases, acquired immunodeficiency syndrome (AIDS), or human

immunodeficiency virus (HIV), and alcohol and drug abuse. I authorize the release or disclosure of this type of information.

This protected health information is disclosed for the following purposes: _____

Research Study Participation

This authorization is given in compliance with the federal consent requirements for release of alcohol or substance abuse records of 42 CFR 2.31, the restrictions of which have been specifically considered and expressly waived.

You are authorized to release the above records to the following representatives of defendants in the above-entitled matter who have agreed to pay reasonable charges made by you to supply copies of such records:

Brian Walitt, MD MPH

Name of Representative

Physician

Representative Capacity (e.g. attorney, records requestor, agent, etc.)

National Institutes of Health
10 Center Drive, Building 10, Room 3B19, MSC 1251

Street Address

Bethesda, MD 20814

City, State and Zip Code

I understand the following: See CFR §164.508(c)(2)(i-iii)

a. I have a right to revoke this authorization in writing at any time, except to the extent information has been released in reliance upon this authorization.
b. The information released in response to this authorization may be re-disclosed to other parties.
c. My treatment or payment for my treatment cannot be conditioned on the signing of this authorization.

Any facsimile, copy or photocopy of the authorization shall authorize you to release the records requested herein. This authorization shall be in force and effect until two years from date of execution at which time this authorization expires.

(b) (6)

_____ 7-26-22

Signature of Patient or Legally Authorized Representative — Date

(See 45CFR § 164.508(c)(1)(vi))

_____

Name and Relationship of Legally Authorized Representative to Patient
(See 45CFR §164.508(c)(1)(iv))

_____ _____

Witness Signature — Date

From: (b) (6)
To: Gavin, Angelique (NIH/NINDS) [C]
Subject: RE: NIH COVID-19 Vaccine Study
Date: Monday, August 8, 2022 9:04:46 PM
Attachments: (b) (6)_Vaccine_Card_Front.jpg
(b) (6)_Vaccine_Card_Back.jpg
(b) (6)

Hello,

Here is the information needed for the study.

 What is your full name? (b) (6)

 What is your preferred phone number? (b) (6)

 How old are you? (b) (6)

 Are you fluent in speaking, reading and writing English? Yes

5. Do you live in the United States? Yes
a. If yes, please provide the city, state and zip code where you live. (b) (6)

 Are you an NIH employee, contractor, trainee or otherwise affiliated with the NIH? No

7. Have you had a COVID-19 infection? (b) (6)
a. If yes, how many COVID-19 infections have you had? (b) (6)
b. What is the date of your first COVID-19 infection? (b) (6)
c. Are you having persistent side effects after your first COVID-19 infection? (b) (6)
d. Do you have test results confirming your COVID 19 infection? (b) (6)
e. If you responded yes, please provide a copy of your COVID 19 test results with your email response.
For tests performed at a laboratory or by a medical provider, results need to include your name, date of test result, type of test, and result of test. If you do not have a copy of your test result, please let us know and we can assist you in obtaining your records from your medical lab or provider.
For tests performed using a home testing kit, a photograph of the results with time and date are required.

8. Have you received a COVID-19 vaccine? Yes
a. *If you responded yes, please provide a copy of your COVID 19 vaccination card with your email response*.
b. If yes, do you have persistent side effects after receiving a COVID-19 vaccination?
Yes, on (b) (6) I had an immediate reaction within 30 min. throat tightness, facial tingling, heart

rate increase, dizziness, and nausea. I had to get picked up. I kept feeling sharp pains in my chest but shrugged it off and (b) (6) I ended up in ER after getting a sharp pain in my neck and intense palpitations. My bp was (b) (6) and hr (b) (6) when EMT's came. MY (b) (6) . Since that day (b) (6) my body hasn't been the same. I started having chest tightness, palpitations, tachycardia, blood pressure spikes, headaches/ head pressure, noise and light sensitivity, ringing in ears, blurry vision, muscle twitching, internal vibration/buzzing, tingling sensation, adrenaline surges, dizziness, fatigue. I also still have swollen lymph nodes in neck and armpit at (b) (6). My injection arm had a swollen ball around injection site, and I have a few issues with that arm like tingling and pain. I still have these symptoms the first 3 months were horrible. I literally was in bed most of those months. I couldn't even handle going to stores or my dogs barking. Around 6-8 months I felt like the tachycardia got better and I can do a lot more, but my heart still feels like it's being squeezed, and I get sharp stabbing pains in collar bone area. After 10 months the constant tingling in my lower limbs improved. I still haven't recovered from all my symptoms. My symptoms vary throughout the day. (b) (6) . The tingling turned into a burning sensation, and I also had worsening tachycardia.

Currently I am waiting to see (b) (6). I am also waiting to get (b) (6). My cardiologist said I had (b) (6) .

Thank you for your time and consideration, (b) (6)

From: Gavin, Angelique (NIH/NINDS) [C] < (b) (6)
Sent: Monday, August 8, 2022 1:15 PM
To: (b) (6) < (b) (6)
Subject: NIH COVID-19 Vaccine Study

Good Day (b) (6):

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

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

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

□□□ What is your full name?

□□□ What is your preferred phone number?

□□□ How old are you?

□□□ Are you fluent in speaking, reading and writing English? Yes /No

5. Do you live in the United States? Yes/No
a. If yes, please provide the city, state and zip code where you live.

□□□ Are you an NIH employee, contractor, trainee or otherwise affiliated with the NIH? Yes/No

7. Have you had a COVID-19 infection? Yes/No/Unsure
a. If yes, how many COVID-19 infections have you had?
b. What is the date of your first COVID-19 infection?
c. Are you having persistent side effects after your first COVID-19 infection? Yes No
d. Do you have test results confirming your COVID 19 infection? Yes No
e. If you responded yes, please provide a copy of your COVID 19 test results with your email response.
For tests performed at a laboratory or by a medical provider, results need to include your name, date of test result, type of test, and result of test. If you do not have a copy of your test result, please let us know and we can assist you in obtaining your records from your medical lab or provider.
For tests performed using a home testing kit, a photograph of the results with time and date are required.

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

When you respond to this email, please provide answers to each question above, as well as a Copy of your COVID-19 test results and/or the front and back of your COVID-19 vaccination card, if applicable.
Your responses and documentation will allow us to determine if you are eligible for our research study. If you do not answer all questions or provide the requested documentation, you will not be considered for the study. If you wish to provide a short summary of your condition, we invite you to.

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

Thank you,
Angelique Gavin
COVID 19 Convalescence Study Team

Angelique Gavin, MS (Contractor)
NIH/NINDS Clinical Operations Manager
Contractor Preferred Solutions Group
National Institutes of Health
10 Center Drive
Building 10, Room 3B19, MSC 1251
Bethesda, MD 20814-9692
(b) (6) (office)
(b) (6) (cell)
(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089-N

(b) (6

From: (b) (6)
To: Gavin, Angelique (NIH/NINDS) [C]
Cc: (b) (6)
Subject: Re: NIH COVID-19 study
Date: Monday, December 14, 2020 2:06:59 PM
Attachments: OrganizationLogo.png
(b) (6)

Hi Angelique,

Here's the list of providers I've seen or talked to this year:

(b) (6)
)

All except (b) (6) were through (b) (6) so the records may be included with my primary doctor, but I listed the others in case.

Would they also want dental records from this year? Here's the information for my dentist:

(b) (6)

Thank you,
(b) (6)

From: Gavin, Angelique (NIH/NINDS) [C] <(b) (6)
Sent: Friday, December 11, 2020 11:52:36 AM
To: (b) (6) <(b) (6)
Subject: RE: NIH COVID-19 study

Thank you (b) (6)! I have attached the medical record request form. Please complete and return to me via secure email. You do not need a witness. If we are sending to more than one medical provider, you can leave the "To" section blank and send me the list of who to send to. I will copy the form and send it out to all.

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
(b) (6) (office)
(b) (6) (cell)
(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089

-

From: (b) (6) <Office365@messaging.microsoft.com>
Sent: Thursday, December 10, 2020 2:02 PM
To: Gavin, Angelique (NIH/NINDS) [C] <(b) (6)
Cc: (b) (6) <(b) (6)
Subject: Re: NIH COVID-19 study

Hi Angelique,

I have attached a copy of a negative COVID PCR test as well a copy of my records from my pulmonologist. I am having trouble accessing my records from my primary doctor and neurologist as they recently switched systems and after several attempts with the IT department I've decided it may be easier for you to request them. Can you please send me the form?

Thank you,
(b) (6)

PS. My records will be under my full name (b) (6)

From: Gavin, Angelique (NIH/NINDS) [C] <(b) (6)
Sent: Monday, December 7, 2020 2:17:47 PM
To: (b) (6) <(b) (6)
Subject: NIH COVID-19 study

Hi (b) (6):

Thank you for taking the time to speak with me today. It was such good news to hear that you're feeling better.

To be eligible to proceed to the next phase of the study, our team will need medical documentation of :

- a negative COVID PCR test (typically a nasal swab),
- negative COVID antibody test (typically a blood test), and
- medical documentation that your medical provider attributes the symptoms you have to COVID 19 infection. This should be a diagnosis in a medical note signed by your provider. Problem lists without medical signatures are not considered adequate medical documentation.

When you obtain these 3 items, you may send them to me either via attaching to this encrypted email, or by faxing them to me at the efax number below. If you decide obtaining the medical records is too cumbersome, then let me know and I will send a medical records release form and we will obtain the results on your behalf.

If you have any additional questions, please let me know. When we receive these forms and validate, then I will set up the next interview with you.

In addition, I have attached our study consent form for you review. Please read it over prior to our second interview and let me know if you have any questions.

Thank you, and have a nice day.

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
(b) (6) (office)
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(b) (6)
https://clinicaltrials.gov - study number 000089

-


NIH
National Institutes of Health

HIPAA COMPLIANT AUTHORIZATION FOR THE RELEASE OF PATIENT INFORMATION PURSUANT TO 45 CFR 164.508

TO: _____

Name of Healthcare Provider/Physician/Facility/Medicare Contractor

_____

Street Address

_____

City, State and Zip Code

RE: Patient Name: [redacted] (b) (6)

Date of Birth: [redacted] (b) (6) Social Security Number: [redacted] (b) (6)

I authorize and request the disclosure of all protected information for the purpose of review and evaluation in connection with a legal claim. I expressly request that the designated record custodian of all covered entities under HIPAA identified above disclose full and complete protected medical information including the following:

- [x] All medical records, meaning every page in my record, including but not limited to: office notes, face sheets, history and physical, consultation notes, inpatient, outpatient and emergency room treatment, all clinical charts, r ports, order sheets, progress notes, nurse's notes, social worker records, clinic records, treatment plans, admission records, discharge summaries, requests for and reports of consultations, documents, correspondence, test results, statements, questionnaires/histories, correspondence, photographs, videotapes, telephone messages, and records received by other medical providers.
- [ ] All physical, occupational and rehab requests, consultations and progress notes.
- [ ] All disability, Medicaid or Medicare records including claim forms and record of denial of benefits.
- [ ] All employment, personnel or wage records.
- [ ] All autopsy, laboratory, histology, cytology, pathology, immunohistochemistry records and specimens; radiology records and films including CT scan, MRI, MRA, EMG, bone scan, myleogram; nerve conduction study, echocardiogram and cardiac catheterization results, videos/CDs/films/reels and reports.
- [ ] All pharmacy/prescription records including NDC numbers and drug information handouts/monographs.
- [ ] All billing records including all statements, insurance claim forms, itemized bills, and records of billing to third party payers and payment or denial of benefits for the period _____ to _____.

I understand the information to be released or disclosed may include information relating to sexually transmitted diseases, acquired immunodeficiency syndrome (AIDS), or human

immunodeficiency virus (HIV), and alcohol and drug abuse. I authorize the release or disclosure of this type of information.

This protected health information is disclosed for the following purposes: _____

Research Study Participation

This authorization is given in compliance with the federal consent requirements for release of alcohol or substance abuse records of 42 CFR 2.31, the restrictions of which have been specifically considered and expressly waived.

You are authorized to release the above records to the following representatives of defendants in the above-entitled matter who have agreed to pay reasonable charges made by you to supply copies of such records:

Brian Walitt, MD MPH

Name of Representative

Physician

Representative Capacity (e.g. attorney, records requestor, agent, etc.)

National Institutes of Health
10 Center Drive, Building 10, Room 3B19, MSC 1251

Street Address

Bethesda, MD 20814

City, State and Zip Code

I understand the following: See CFR §164.508(c)(2)(i-iii)

a. I have a right to revoke this authorization in writing at any time, except to the extent information has been released in reliance upon this authorization.
b. The information released in response to this authorization may be re-disclosed to other parties.
c. My treatment or payment for my treatment cannot be conditioned on the signing of this authorization.

Any facsimile, copy or photocopy of the authorization shall authorize you to release the records requested herein. This authorization shall be in force and effect until two years from date of execution at which time this authorization expires.

(b) (6)

Signature of Patient or Legally Authorized Representative

12/14/20

Date

(See 45CFR § 164.508(c)(1)(vi))

Name and Relationship of Legally Authorized Representative to Patient
(See 45CFR §164.508(c)(1)(iv))

Witness Signature

Date

From: Gavin, Angelique (NIH/NINDS) [C]
To: (b) (6)
Subject: NIH COVID-19 Vaccine Study
Date: Wednesday, August 3, 2022 11:11:00 AM
Attachments: Vaccination_Consent_Clean_05.17.22.pdf

Good morning (b) (6):

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

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

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

1. What is your full name?

2. What is your preferred phone number?

3. How old are you?

4. Are you fluent in speaking, reading and writing English? Yes /No

5. Do you live in the United States? Yes/No
a. If yes, please provide the city, state and zip code where you live.

6. Are you an NIH employee, contractor, trainee or otherwise affiliated with the NIH? Yes/No

7. Have you had a COVID-19 infection? Yes/No/Unsure
a. If yes, how many COVID-19 infections have you had?
b. What is the date of your first COVID-19 infection?
c. Are you having persistent side effects after your first COVID-19 infection? Yes No
d. Do you have test results confirming your COVID 19 infection? Yes No
e. If you responded yes, please provide a copy of your COVID 19 test results with your email response.
For tests performed at a laboratory or by a medical provider, results need to include your name, date of test result, type of test, and result of test. If you do not have a copy of your test result, please let us know and we can assist you in obtaining your records from your medical lab or provider.

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

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

When you respond to this email, please provide answers to each question above, as well as a Copy of your COVID-19 test results and/or the front and back of your COVID-19 vaccination card, if applicable.
Your responses and documentation will allow us to determine if you are eligible for our research study. If you do not answer all questions or provide the requested documentation, you will not be considered for the study. If you wish to provide a short summary of your condition, we invite you to.

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

Thank you,
Angelique Gavin
COVID 19 Convalescence Study Team

Angelique Gavin, MS (Contractor)
NIH/NINDS Clinical Operations Manager
Contractor Preferred Solutions Group
National Institutes of Health
10 Center Drive
Building 10, Room 3B19, MSC 1251
Bethesda, MD 20814-9692
(b) (6) (office)
(b) (6) (cell)
(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089-N

-

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

PRINCIPAL INVESTIGATOR: Avi Nath, MD

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

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

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

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

WHY IS THIS STUDY BEING DONE?

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

WHAT WILL HAPPEN DURING THE STUDY?

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

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

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

HOW LONG WILL THE STUDY TAKE?

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

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

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

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

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

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

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

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

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

STORAGE, SHARING AND FUTURE RESEARCH USING YOUR DATA

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

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

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

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

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

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

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

How long will your data be stored by the NIH?

Your data may be stored by the NIH indefinitely.

Risks of storage and sharing of data

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

COMPENSATION

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

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Will your information be kept private?

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

CERTIFICATE OF CONFIDENTIALITY

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

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

The Certificate does not protect your information when it:

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

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

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

Privacy Act

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

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

PROBLEMS OR QUESTIONS

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

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

Study Coordinator: Angelique Gavin , Building/room Building 10/3B19, (b) (6), email- (b) (6)
Lead Associate Investigator: Brian Walitt M.D, M.P.H, Building/room Building 10/3B19, (b) (6) (b) (6), email- (b) (6)
Principal Investigator:, Avindra Nath, M.D., Building/Room 10/7C-103, Telephone (b) (6) (b) (6), email- (b) (6)

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

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

From: Gavin, Angelique (NIH/NINDS) [C]
To: (b) (6)
Subject: NIH COVID-19 study
Date: Friday, May 7, 2021 12:42:00 PM
Attachments: NIH_000089_Phase_A_Informed_Consentclean_13Nov_2020 (003).pdf

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Hi (b) (6):

Thank you for volunteering for our COVID-19 study here at the NIH. It was good speaking with you today! I have attached our study consent form for your review. Please read it over prior to our next interview. Please use this secure email to attach your positive COVID-19 test result. Once reviewed, I will arrange our next interview which I anticipate will take approximately 45 minutes to one hour of your time. Feel free to contact me with any questions you may have.

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
(b) (6) (office)
(b) (6) (cell)
(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089

-

Informed Consent: Protocol 00089 Phase A Surveying

PRINCIPAL INVESTIGATOR: Avi Nath, MD

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

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

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

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

WHY IS THIS STUDY BEING DONE?

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

WHAT WILL HAPPEN DURING THE STUDY?

If you are found to be eligible for this study, we will ask you to complete a telephone survey interview and on-line questionnaires. The survey interview and optional on-line questionnaires will include questions about your health prior to being infected with COVID-19, what happened during the COVID-19 infection, and what recovering from COVID-19 has been like for you. The survey interview typically takes between 30 and 60 minutes. We will provide you with computer log-in information in order to access the on-line questionnaires. You will use the same log-in information to access follow up questionnaires every 3 months for 3 years. The follow up questionnaires will ask you follow up information on your recovery from COVID-19. Completing all of the questionnaires the first time may take up to 3 hours and follow up questionnaires will take up to 30 minutes. We do not expect you to complete the questionnaires at a single session. You will be able to save your progress and return to them at your convenience. You should answer the questions the best you can.

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

HOW LONG WILL THE STUDY TAKE?

IRB NUMBER: 000089
IRB APPROVAL DATE: 11/20/2020

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

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

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

We plan to have approximately 1200 people participate in this study.

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

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

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

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

There is no direct benefit to you from participating in this research study; however, we hope to learn more about COVID -19 infection and how people recover from infection.

STORAGE, SHARING AND FUTURE RESEARCH USING YOUR DATA

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

Our research team is also performing additional research studies at NIH, including “Neurological Complications of COVID-19” (Protocol 000094) and “Post-Infectious Myalgic Encephalomyelitis/Chronic Fatigue Syndrome at NIH” (Protocol 16-N-0058). If you consent to participate in either of these studies, we may share identifiable information with members of those research teams.

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

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

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

How long will your data be stored by the NIH?

Your data may be stored by the NIH indefinitely.

Risks of storage and sharing of data

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

COMPENSATION

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

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Will your information be kept private?

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

CERTIFICATE OF CONFIDENTIALITY

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

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

The Certificate does not protect your information when it:

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

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

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

Privacy Act

The Federal Privacy Act generally protects the confidentiality of your NIH research information that we collect under the authority of the Public Health Service Act during your participation in this research study. This study's data will be stored under system 09-25-0200, Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH). In some cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act allows release of information from your record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to NIH staff (such as contractors and volunteers), to those engaged by the agency for research purposes, to certain federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to morbidity, mortality, disease, or tumor registries, when authorized by the Secretary of HHS, or when the NIH is involved in a lawsuit. However, NIH will only release

information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act. If you do not want to share your information with us, then you cannot participate in this study.

PROBLEMS OR QUESTIONS

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

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

Study Coordinator: Angelique Gavin, Building/room Building 10/3B19, (b) (6), email- (b) (6)
Lead Associate Investigator: Brian Walitt M.D, M.P.H, Building/room Building 10/3B19, (b) (6) (b) (6), email- (b) (6)
Principal Investigator: Avindra Nath, M.D., Building/Room 10/7C-103, Telephone (b) (6) (b) (6), email- (b) (6)

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

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

IRB NUMBER: 000089
IRB APPROVAL DATE: 11/20/2020

From: Gavin, Angelique (NIH/NINDS) [C]
To: (b) (6)
Subject: NIH COVID-19 study
Date: Monday, December 7, 2020 2:17:00 PM
Attachments: NIH_000089_Phase_A_Informed_Consentclean_13Nov_2020.pdf

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Hi (b) (6):

Thank you for taking the time to speak with me today. It was such good news to hear that you're feeling better.

To be eligible to proceed to the next phase of the study, our team will need medical documentation of :

1. a negative COVID PCR test (typically a nasal swab),
2. negative COVID antibody test (typically a blood test), and
3. medical documentation that your medical provider attributes the symptoms you have to COVID 19 infection. This should be a diagnosis in a medical note signed by your provider. Problem lists without medical signatures are not considered adequate medical documentation.

When you obtain these 3 items, you may send them to me either via attaching to this encrypted email, or by faxing them to me at the efax number below. If you decide obtaining the medical records is too cumbersome, then let me know and I will send a medical records release form and we will obtain the results on your behalf.

If you have any additional questions, please let me know. When we receive these forms and validate, then I will set up the next interview with you.

In addition, I have attached our study consent form for you review. Please read it over prior to our second interview and let me know if you have any questions.

Thank you, and have a nice day.

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
(b) (6) (office)

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IRB NUMBER: 000089
IRB APPROVAL DATE: 11/20/2020

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HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

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COMPENSATION

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

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Will your information be kept private?

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

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

The Certificate does not protect your information when it:

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

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

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

Privacy Act

The Federal Privacy Act generally protects the confidentiality of your NIH research information that we collect under the authority of the Public Health Service Act during your participation in this research study. This study's data will be stored under system 09-25-0200, Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH). In some cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act allows release of information from your record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to NIH staff (such as contractors and volunteers), to those engaged by the agency for research purposes, to certain federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to morbidity, mortality, disease, or tumor registries, when authorized by the Secretary of HHS, or when the NIH is involved in a lawsuit. However, NIH will only release

information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act. If you do not want to share your information with us, then you cannot participate in this study.

PROBLEMS OR QUESTIONS

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

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

Study Coordinator: Angelique Gavin, Building/room Building 10/3B19, (b) (6), email- (b) (6)
Lead Associate Investigator: Brian Walitt M.D, M.P.H, Building/room Building 10/3B19, (b) (6) (b) (6), email- (b) (6)
Principal Investigator: Avindra Nath, M.D., Building/Room 10/7C-103, Telephone (b) (6) (b) (6), email- (b) (6)

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

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

IRB NUMBER: 000089
IRB APPROVAL DATE: 11/20/2020

From: Gavin, Angelique (NIH/NINDS) [C]
To: (b) (6)
Subject: RE: NIH COVID-19 study
Date: Friday, December 11, 2020 11:52:00 AM
Attachments: HIPAA Medical Record Release Blank.pdf

Thank you (b) (6)! I have attached the medical record request form. Please complete and return to me via secure email. You do not need a witness. If we are sending to more than one medical provider, you can leave the "To" section blank and send me the list of who to send to. I will copy the form and send it out to all.

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
(b) (6) (office)
(b) (6) (cell)
(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089

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From: (b) (6) <Office365@messaging.microsoft.com>
Sent: Thursday, December 10, 2020 2:02 PM
To: Gavin, Angelique (NIH/NINDS) [C] <(b) (6)
Cc: Betty Graham <(b) (6)
Subject: Re: NIH COVID-19 study

Hi Angelique,

I have attached a copy of a negative COVID PCR test as well a copy of my records from my pulmonologist. I am having trouble accessing my records from my primary doctor and neurologist as they recently switched systems and after several attempts with the IT department I've decided it may be easier for you to request them. Can you please send me the form?

Thank you,

(b) (6)

PS. My records will be under my full name (b) (6)

From: Gavin, Angelique (NIH/NINDS) [C] < (b) (6)
Sent: Monday, December 7, 2020 2:17:47 PM
To: (b) (6) < (b) (6)
Subject: NIH COVID-19 study

Hi (b) (6):

Thank you for taking the time to speak with me today. It was such good news to hear that you're feeling better.

To be eligible to proceed to the next phase of the study, our team will need medical documentation of :

1. a negative COVID PCR test (typically a nasal swab),
2. negative COVID antibody test (typically a blood test), and
3. medical documentation that your medical provider attributes the symptoms you have to COVID 19 infection. This should be a diagnosis in a medical note signed by your provider. Problem lists without medical signatures are not considered adequate medical documentation.

When you obtain these 3 items, you may send them to me either via attaching to this encrypted email, or by faxing them to me at the efax number below. If you decide obtaining the medical records is too cumbersome, then let me know and I will send a medical records release form and we will obtain the results on your behalf.

If you have any additional questions, please let me know. When we receive these forms and validate, then I will set up the next interview with you.

In addition, I have attached our study consent form for you review. Please read it over prior to

our second interview and let me know if you have any questions.

Thank you, and have a nice day.

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

(b) (6) (office)

(b) (6) (cell)

(301) 480-5368 (efax)

(b) (6)

https://clinicaltrials.gov - study number 000089

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HIPAA COMPLIANT AUTHORIZATION FOR THE RELEASE OF PATIENT INFORMATION PURSUANT TO 45 CFR 164.508

TO: _____
Name of Healthcare Provider/Physician/Facility/Medicare Contractor

_____
Street Address

_____
City, State and Zip Code

RE: Patient Name: _____

Date of Birth: _____ Social Security Number: _____

I authorize and request the disclosure of all protected information for the purpose of review and evaluation in connection with a legal claim. I expressly request that the designated record custodian of all covered entities under HIPAA identified above disclose full and complete protected medical information including the following:

- [x] All medical records, meaning every page in my record, including but not limited to: office notes, face sheets, history and physical, consultation notes, inpatient, outpatient and emergency room treatment, all clinical charts, r ports, order sheets, progress notes, nurse's notes, social worker records, clinic records, treatment plans, admission records, discharge summaries, requests for and reports of consultations, documents, correspondence, test results, statements, questionnaires/histories, correspondence, photographs, videotapes, telephone messages, and records received by other medical providers.
- [ ] All physical, occupational and rehab requests, consultations and progress notes.
- [ ] All disability, Medicaid or Medicare records including claim forms and record of denial of benefits.
- [ ] All employment, personnel or wage records.
- [ ] All autopsy, laboratory, histology, cytology, pathology, immunohistochemistry records and specimens; radiology records and films including CT scan, MRI, MRA, EMG, bone scan, myleogram; nerve conduction study, echocardiogram and cardiac catheterization results, videos/CDs/films/reels and reports.
- [ ] All pharmacy/prescription records including NDC numbers and drug information handouts/monographs.
- [ ] All billing records including all statements, insurance claim forms, itemized bills, and records of billing to third party payers and payment or denial of benefits for the period _____ to _____.

I understand the information to be released or disclosed may include information relating to sexually transmitted diseases, acquired immunodeficiency syndrome (AIDS), or human

immunodeficiency virus (HIV), and alcohol and drug abuse. I authorize the release or disclosure of this type of information.

This protected health information is disclosed for the following purposes: _____

Research Study Participation

This authorization is given in compliance with the federal consent requirements for release of alcohol or substance abuse records of 42 CFR 2.31, the restrictions of which have been specifically considered and expressly waived.

You are authorized to release the above records to the following representatives of defendants in the above-entitled matter who have agreed to pay reasonable charges made by you to supply copies of such records:

Brian Walitt, MD MPH

Name of Representative

Physician

Representative Capacity (e.g. attorney, records requestor, agent, etc.)

National Institutes of Health
10 Center Drive, Building 10, Room 3B19, MSC 1251

Street Address

Bethesda, MD 20814

City, State and Zip Code

I understand the following: See CFR §164.508(c)(2)(i-iii)

a. I have a right to revoke this authorization in writing at any time, except to the extent information has been released in reliance upon this authorization.
b. The information released in response to this authorization may be re-disclosed to other parties.
c. My treatment or payment for my treatment cannot be conditioned on the signing of this authorization.

Any facsimile, copy or photocopy of the authorization shall authorize you to release the records requested herein. This authorization shall be in force and effect until two years from date of execution at which time this authorization expires.

_____ _____

Signature of Patient or Legally Authorized Representative Date
(See 45CFR § 164.508(c)(1)(vi))

_____

Name and Relationship of Legally Authorized Representative to Patient
(See 45CFR §164.508(c)(1)(iv))

_____ _____

Witness Signature Date

From: Gavin, Angelique (NIH/NINDS) [C]
To: (b) (6)
Subject: NIH Vaccine Study
Date: Saturday, September 24, 2022 2:42:00 PM
Attachments: Vaccination_Consent_Clean_05.17.22 (002).pdf

Good Day (b) (6):

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

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

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

1. What is your full name?

2. What is your preferred phone number?

3. How old are you?

4. Are you fluent in speaking, reading and writing English? Yes /No

5. Do you live in the United States? Yes/No

a. If yes, please provide the city, state and zip code where you live.

6. Are you an NIH employee, contractor, trainee or otherwise affiliated with the NIH? Yes/No

7. Have you had a COVID-19 infection? Yes/No/Unsure

a. If yes, how many COVID-19 infections have you had?

b. What is the date of your first COVID-19 infection?

c. Are you having persistent side effects after your first COVID-19 infection? Yes No

d. Do you have test results confirming your COVID 19 infection? Yes No

e. If you responded yes, please provide a copy of your COVID 19 test results with your email response.

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

from your medical lab or provider.
For tests performed using a home testing kit, a photograph of the results with time and date are required.

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

When you respond to this email, please provide answers to each question above, as well as a Copy of your COVID-19 test results and/or the front and back of your COVID-19 vaccination card, if applicable.
Your responses and documentation will allow us to determine if you are eligible for our research study. If you do not answer all questions or provide the requested documentation, you will not be considered for the study. If you wish to provide a short summary of your condition, we invite you to.

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

Thank you,
Angelique Gavin
COVID 19 Convalescence Study Team

Angelique Gavin, MS (Contractor)
NIH/NINDS Clinical Operations Manager
Contractor Preferred Solutions Group
National Institutes of Health
10 Center Drive
Building 10, Room 3B19, MSC 1251
Bethesda, MD 20814-9692
(b) (6) (office)
(b) (6) (cell)
(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089-N

-

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

PRINCIPAL INVESTIGATOR: Avi Nath, MD

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

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

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

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

WHY IS THIS STUDY BEING DONE?

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

WHAT WILL HAPPEN DURING THE STUDY?

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

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

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

HOW LONG WILL THE STUDY TAKE?

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

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

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

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

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

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

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

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

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

STORAGE, SHARING AND FUTURE RESEARCH USING YOUR DATA

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

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

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

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

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

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

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

How long will your data be stored by the NIH?

Your data may be stored by the NIH indefinitely.

Risks of storage and sharing of data

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

COMPENSATION

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

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Will your information be kept private?

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

CERTIFICATE OF CONFIDENTIALITY

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

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

The Certificate does not protect your information when it:

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

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

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

Privacy Act

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

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

PROBLEMS OR QUESTIONS

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

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

Study Coordinator: Angelique Gavin , Building/room Building 10/3B19, (b) (6), email- (b) (6)
Lead Associate Investigator: Brian Walitt M.D, M.P.H, Building/room Building 10/3B19, (b) (6) (b) (6), email- (b) (6)
Principal Investigator:, Avindra Nath, M.D., Building/Room 10/7C-103, Telephone (b) (6) (b) (6), email- (b) (6)

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

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

From: Gavin, Angelique (NIH/NINDS) [C]
To: (b) (6)
Subject: NIH Vaccine Study
Date: Thursday, October 20, 2022 12:46:00 PM
Attachments: HIPAA COVID test Medical Record Release Blank (002) (002).pdf

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Thank you (b) (6) for the information you've provided thus far. To determine if you are eligible to proceed, we need medical records to confirm that the symptom onset was after COVID vaccination.

Please complete the attached medical record release form for a medical provider whom managed your care at the onset of symptoms after vaccination. Please return the form to me using this encrypted email and I will obtain the records on your behalf.

Once we have received and reviewed the records, if you are eligible to proceed, we will schedule a telephone interview. Please let me know if you have any additional questions. I look forward to speaking with you very soon.

Sincerely,
Angelique Gavin

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) (6) (office)
(b) (6) (cell)
(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089-N

-

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

PRINCIPAL INVESTIGATOR: Avi Nath, MD

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

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

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

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

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

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

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

HOW LONG WILL THE STUDY TAKE?

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

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

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

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

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Your data may be stored by the NIH indefinitely.

Risks of storage and sharing of data

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COMPENSATION

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

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Will your information be kept private?

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

CERTIFICATE OF CONFIDENTIALITY

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

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

The Certificate does not protect your information when it:

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

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

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

Privacy Act

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

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

PROBLEMS OR QUESTIONS

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

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

Study Coordinator: Angelique Gavin , Building/room Building 10/3B19, (b) (6), email- (b) (6)
Lead Associate Investigator: Brian Walitt M.D, M.P.H, Building/room Building 10/3B19, (b) (6) (b) (6), email- (b) (6)
Principal Investigator:, Avindra Nath, M.D., Building/Room 10/7C-103, Telephone (b) (6) (b) (6), email- (b) (6)

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

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

From: Gavin, Angelique (NIH/NINDS) [C]
To: (b) (6)
Subject: FW: NIH Vaccine Study
Date: Thursday, October 27, 2022 1:43:00 PM
Attachments: HIPAA COVID test Medical Record Release Blank (002) (002).pdf

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Thank you (b) (6) for the information you've provided thus far. To determine if you are eligible to proceed, we need medical records to confirm that the symptom onset was after COVID vaccination.

Please complete the attached medical record release form for a medical provider whom managed your care at the onset of symptoms after vaccination. Please return the form to me using this encrypted email and I will obtain the records on your behalf.

Once we have received and reviewed the records, if you are eligible to proceed, we will schedule a telephone interview. Please let me know if you have any additional questions. I look forward to speaking with you very soon.

Sincerely,
Angelique Gavin

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) (6) (office)
(b) (6) (cell)
(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089-N

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From: Gavin, Angelique (NIH/NINDS) [C]
Sent: Thursday, October 20, 2022 12:47 PM
To: (b) (6) < (b) (6)
Subject: NIH Vaccine Study

Thank you (b) (6) for the information you've provided thus far. To determine if you are eligible to proceed, we need medical records to confirm that the symptom onset was after COVID vaccination.

Please complete the attached medical record release form for a medical provider whom managed

your care at the onset of symptoms after vaccination. Please return the form to me using this encrypted email and I will obtain the records on your behalf.

Once we have received and reviewed the records, if you are eligible to proceed, we will schedule a telephone interview. Please let me know if you have any additional questions. I look forward to speaking with you very soon.

Sincerely,
Angelique Gavin

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) (6) (office)
(b) (6) (cell)
(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089-N

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HIPAA COMPLIANT AUTHORIZATION FOR THE RELEASE OF PATIENT INFORMATION PURSUANT TO 45 CFR 164.508

TO: _____
Name of Healthcare Provider/Physician/Facility/Medicare Contractor

_____
Street Address

_____
City, State and Zip Code

RE: Patient Name: _____

Date of Birth: _____ Social Security Number: _____

I authorize and request the disclosure of all protected information for the purpose of review and evaluation in connection with a legal claim. I expressly request that the designated record custodian of all covered entities under HIPAA identified above disclose full and complete protected medical information including the following:

- [x] COVID-19 PCR and/or Antibody Results
- [ ] All medical records, meaning every page in my record, including but not limited to: office notes, face sheets, history and physical, consultation notes, inpatient, outpatient and emergency room treatment, all clinical charts, r ports, order sheets, progress notes, nurse's notes, social worker records, clinic records, treatment plans, admission records, discharge summaries, requests for and reports of consultations, documents, correspondence, test results, statements, questionnaires/histories, correspondence, photographs, videotapes, telephone messages, and records received by other medical providers.
- [ ] All physical, occupational and rehab requests, consultations and progress notes.
- [ ] All disability, Medicaid or Medicare records including claim forms and record of denial of benefits.
- [ ] All autopsy, laboratory, histology, cytology, pathology, immunohistochemistry records and specimens; radiology records and films including CT scan, MRI, MRA, EMG, bone scan, myleogram; nerve conduction study, echocardiogram and cardiac catheterization results, videos/CDs/films/reels and reports.
- [ ] All pharmacy/prescription records including NDC numbers and drug information handouts/monographs.
- [ ] All billing records including all statements, insurance claim forms, itemized bills, and records of billing to third party payers and payment or denial of benefits for the period _____ to _____.

I understand the information to be released or disclosed may include information relating to sexually transmitted diseases, acquired immunodeficiency syndrome (AIDS), or human

immunodeficiency virus (HIV), and alcohol and drug abuse. I authorize the release or disclosure of this type of information.

This protected health information is disclosed for the following purposes: _____

Research Study Participation

This authorization is given in compliance with the federal consent requirements for release of alcohol or substance abuse records of 42 CFR 2.31, the restrictions of which have been specifically considered and expressly waived.

You are authorized to release the above records to the following representatives of defendants in the above-entitled matter who have agreed to pay reasonable charges made by you to supply copies of such records:

Brian Walitt, MD MPH

Name of Representative

Physician

Representative Capacity (e.g. attorney, records requestor, agent, etc.)

National Institutes of Health
10 Center Drive, Building 10, Room 3B19, MSC 1251

Street Address

Bethesda, MD 20814

City, State and Zip Code

I understand the following: See CFR §164.508(c)(2)(i-iii)

a. I have a right to revoke this authorization in writing at any time, except to the extent information has been released in reliance upon this authorization.
b. The information released in response to this authorization may be re-disclosed to other parties.
c. My treatment or payment for my treatment cannot be conditioned on the signing of this authorization.

Any facsimile, copy or photocopy of the authorization shall authorize you to release the records requested herein. This authorization shall be in force and effect until two years from date of execution at which time this authorization expires.

_____ _____

Signature of Patient or Legally Authorized Representative Date
(See 45CFR § 164.508(c)(1)(vi))

_____

Name and Relationship of Legally Authorized Representative to Patient
(See 45CFR §164.508(c)(1)(iv))

_____ _____

Witness Signature Date

From: Gavin, Angelique (NIH/NINDS) [C]
To: (b) (6)
Subject: RE: [EXTERNAL] Re: NIH COVID-19 Vaccine Study
Date: Wednesday, August 24, 2022 3:07:00 PM
Attachments: image001.jpg
HIPAA Medical Record Release Blank.pdf

Hi (b) :

I have good news and bad news. I greatly appreciate your efforts in resending the test result. Sadly, we need the year of the result on that time stamp. Is this possible for you to resend it? In the meantime, to determine if you are eligible to proceed to the next phase of the study, we need medical records to confirm that symptom onset was after your COVID vaccination. Please complete the attached medical record release form for a medical provider who managed your care at the onset of symptoms after vaccination. Return the form to me using this secure email and I will obtain records on your behalf.

Once we have received and reviewed your records, if you are eligible to proceed, we will schedule the phone interview. Please let me know if you have any additional questions. I am looking forward to speaking with you soon.

Sincerely,
Angelique

Angelique Gavin, MS (Contractor)
NIH/NINDS Clinical Operations Manager
Contractor Preferred Solutions Group
National Institutes of Health
10 Center Drive
Building 10, Room 3B19, MSC 1251
Bethesda, MD 20814-9692
(b) (6) (office)
(b) (6) (cell)
(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089-N

-

From: (b) (6) <(b) (6)
Sent: Tuesday, August 23, 2022 3:24 PM
To: Gavin, Angelique (NIH/NINDS) [C] <(b) (6)
Subject: [EXTERNAL] Re: NIH COVID-19 Vaccine Study

Hello,

Sorry for the delayed response. Here is the picture with the time stamp.

On Mon, Aug 15, 2022 at 8:59 AM Gavin, Angelique (NIH/NINDS) [C] <(b) (6)> wrote:

Hello (b):

Thank you for providing your test result with the time stamp. Typically we ask for the phone's date/time stamp, not one the participant puts on the picture. If you can re-send the test result with the phone's stamp, it would be appreciated. So sorry to make you go through so much effort.

Sincerely,
Angelique

Angelique Gavin, MS (Contractor)
NIH/NINDS Clinical Operations Manager
Contractor Preferred Solutions Group
National Institutes of Health
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Building 10, Room 3B19, MSC 1251
Bethesda, MD 20814-9692
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-

(b) (6)

HIPAA COMPLIANT AUTHORIZATION FOR THE RELEASE OF PATIENT INFORMATION PURSUANT TO 45 CFR 164.508

TO: _____
Name of Healthcare Provider/Physician/Facility/Medicare Contractor

_____
Street Address

_____
City, State and Zip Code

RE: Patient Name: _____

Date of Birth: _____ Social Security Number: _____

I authorize and request the disclosure of all protected information for the purpose of review and evaluation in connection with a legal claim. I expressly request that the designated record custodian of all covered entities under HIPAA identified above disclose full and complete protected medical information including the following:

- [x] All medical records, meaning every page in my record, including but not limited to: office notes, face sheets, history and physical, consultation notes, inpatient, outpatient and emergency room treatment, all clinical charts, r ports, order sheets, progress notes, nurse's notes, social worker records, clinic records, treatment plans, admission records, discharge summaries, requests for and reports of consultations, documents, correspondence, test results, statements, questionnaires/histories, correspondence, photographs, videotapes, telephone messages, and records received by other medical providers.
- [ ] All physical, occupational and rehab requests, consultations and progress notes.
- [ ] All disability, Medicaid or Medicare records including claim forms and record of denial of benefits.
- [ ] All employment, personnel or wage records.
- [ ] All autopsy, laboratory, histology, cytology, pathology, immunohistochemistry records and specimens; radiology records and films including CT scan, MRI, MRA, EMG, bone scan, myleogram; nerve conduction study, echocardiogram and cardiac catheterization results, videos/CDs/films/reels and reports.
- [ ] All pharmacy/prescription records including NDC numbers and drug information handouts/monographs.
- [ ] All billing records including all statements, insurance claim forms, itemized bills, and records of billing to third party payers and payment or denial of benefits for the period _____ to _____.

I understand the information to be released or disclosed may include information relating to sexually transmitted diseases, acquired immunodeficiency syndrome (AIDS), or human

immunodeficiency virus (HIV), and alcohol and drug abuse. I authorize the release or disclosure of this type of information.

This protected health information is disclosed for the following purposes: _____

Research Study Participation

This authorization is given in compliance with the federal consent requirements for release of alcohol or substance abuse records of 42 CFR 2.31, the restrictions of which have been specifically considered and expressly waived.

You are authorized to release the above records to the following representatives of defendants in the above-entitled matter who have agreed to pay reasonable charges made by you to supply copies of such records:

Brian Walitt, MD MPH

Name of Representative

Physician

Representative Capacity (e.g. attorney, records requestor, agent, etc.)

National Institutes of Health
10 Center Drive, Building 10, Room 3B19, MSC 1251

Street Address

Bethesda, MD 20814

City, State and Zip Code

I understand the following: See CFR §164.508(c)(2)(i-iii)

a. I have a right to revoke this authorization in writing at any time, except to the extent information has been released in reliance upon this authorization.
b. The information released in response to this authorization may be re-disclosed to other parties.
c. My treatment or payment for my treatment cannot be conditioned on the signing of this authorization.

Any facsimile, copy or photocopy of the authorization shall authorize you to release the records requested herein. This authorization shall be in force and effect until two years from date of execution at which time this authorization expires.

_____ _____

Signature of Patient or Legally Authorized Representative Date
(See 45CFR § 164.508(c)(1)(vi))

_____

Name and Relationship of Legally Authorized Representative to Patient
(See 45CFR §164.508(c)(1)(iv))

_____ _____

Witness Signature Date

From: Gavin, Angelique (NIH/NINDS) [C]
To: (b) (6)
Subject: RE: Information Request: Clinical Center Study PI000089-N
Date: Thursday, November 10, 2022 9:21:00 AM
Attachments: HIPAA Medical Record Release Blank.pdf

Thank you (b) (6) for the information you've provided thus far. To determine if you are eligible to proceed, we need medical records to confirm that the symptom onset was after COVID vaccination.

Please complete the attached medical record release form for a medical provider whom managed your care at the onset of symptoms after vaccination. Please return the form to me using this encrypted email and I will obtain the records on your behalf.

Once we have received and reviewed the records, if you are eligible to proceed, we will schedule a telephone interview. Please let me know if you have any additional questions. I look forward to speaking with you very soon.

Sincerely,
Angelique Gavin

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) (6) (office)
(b) (6) (cell)
(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089-N

-

From: (b) (6) <Office365@messaging.microsoft.com>
Sent: Wednesday, November 9, 2022 4:18 PM
To: Gavin, Angelique (NIH/NINDS) [C] <(b) (6)
Cc: (b) (6)
Subject: Re: Information Request: Clinical Center Study PI000089-N

Thank You for your quick response. I have contacted NIH several times and spoken with Dr. Nath.

I am interested in participating in any and all ongoing research at NIH.

(b) (6)

Questions are answered below; marked in **RED**.

From: Gavin, Angelique (NIH/NINDS) [C] <(b) (6)
Sent: Wednesday, November 9, 2022 2:24:37 PM
To: (b) (6) <(b) (6)
Subject: RE: Information Request: Clinical Center Study PI000089-N

Good Day (b) (6):

Thank you for your interest in the COVID-19 Convalescence study at the National Institutes of Health. I am emailing you because you had previously contacted the NIH about participating

in this study. To ensure that your information and communication remains secure, you are receiving this via encrypted email. Please respond using encrypted email.

Our study is looking at the experience of recovery for individuals after a COVID-19 infection or after

COVID 19 vaccination. The attached consent form provides more information about our study, which

involves a phone interview and online questionnaires.

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

questions:

1. What is your full name? (b) (6)

2. What is your preferred phone number? (b) (6)

3. How old are you? (b) (6)

4. Are you fluent in speaking, reading and writing English? **Yes** /No

5. Do you live in the United States? **Yes**/No

a. If yes, please provide the city, state and zip code where you live. (b) (6)

6. Are you an NIH employee, contractor, trainee or otherwise affiliated with the NIH? Yes/**No**

7. Have you had a COVID-19 infection? (b) (6)

a. If yes, how many COVID-19 infections have you had?

b. What is the date of your first COVID-19 infection?

c. Are you having persistent side effects after your first COVID-19 infection? Yes No

d. Do you have test results confirming your COVID 19 infection? Yes No

e. If you responded yes, please provide a copy of your COVID 19 test results with your email

response.

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

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

8. Have you received a COVID-19 vaccine? **Yes** No

a. *If you responded yes, please provide a copy of your COVID 19 vaccination card with your*

email response.

b. If yes, do you have persistent side effects after receiving a COVID-19 vaccination?

Yes No

When you respond to this email, please provide answers to each question above, as well as a

Copy of your COVID-19 test results and/or the front and back of your COVID-19 vaccination card,

if applicable. Copy of vaccination card front attached. Back has nothing marked. Copy of vaccination confirmation from Health Department attached.

Your responses and documentation will allow us to determine if you are eligible for our research

study. If you do not answer all questions or provide the requested documentation, you will not

be considered for the study. If you wish to provide a short summary of your condition, we invite

you to.

If you are eligible, then we will email you within 10 business days to schedule a time to obtain

verbal consent and perform a study interview. Please let me know if you have any additional

questions. I look forward to hearing from you.

Thank you,

Angelique Gavin

COVID 19 Convalescence Study Team

Angelique Gavin, MS (Contractor)

NIH/NINDS Clinical Operations Manager

Contractor Preferred Solutions Group

National Institutes of Health

10 Center Drive

Building 10, Room 3B19, MSC 1251

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(b) (6)

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

Angelique Gavin, MS (Contractor)

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(b) (6) (office)

(b) (6) (cell)

(301) 480-5368 (efax)

(b) (6)

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

-

From: (b) (6) < (b) (6)
Sent: Tuesday, November 8, 2022 4:26 PM
To: Gavin, Angelique (NIH/NINDS) [C] < (b) (6)
Subject: Information Request: Clinical Center Study PI000089-N

LastName :	(b) (6)
FirstName :	
Organization :	
Building Mail Stop:	
Street Addresss:	
City/State/Zip:	
Phone:	
Fax:	
Patient's First Name(if different from sender name):	
Patient's Last Name((if different from sender name):	
Comments :	Is NIH doing any data gathering or clinical research on post-COVID vaccine adverse responses? I am interesting in participating.

HIPAA COMPLIANT AUTHORIZATION FOR THE RELEASE OF PATIENT INFORMATION PURSUANT TO 45 CFR 164.508

TO: _____
Name of Healthcare Provider/Physician/Facility/Medicare Contractor

_____
Street Address

_____
City, State and Zip Code

RE: Patient Name: _____

Date of Birth: _____ Social Security Number: _____

I authorize and request the disclosure of all protected information for the purpose of review and evaluation in connection with a legal claim. I expressly request that the designated record custodian of all covered entities under HIPAA identified above disclose full and complete protected medical information including the following:

- [x] All medical records, meaning every page in my record, including but not limited to: office notes, face sheets, history and physical, consultation notes, inpatient, outpatient and emergency room treatment, all clinical charts, r ports, order sheets, progress notes, nurse's notes, social worker records, clinic records, treatment plans, admission records, discharge summaries, requests for and reports of consultations, documents, correspondence, test results, statements, questionnaires/histories, correspondence, photographs, videotapes, telephone messages, and records received by other medical providers.
- [ ] All physical, occupational and rehab requests, consultations and progress notes.
- [ ] All disability, Medicaid or Medicare records including claim forms and record of denial of benefits.
- [ ] All employment, personnel or wage records.
- [ ] All autopsy, laboratory, histology, cytology, pathology, immunohistochemistry records and specimens; radiology records and films including CT scan, MRI, MRA, EMG, bone scan, myleogram; nerve conduction study, echocardiogram and cardiac catheterization results, videos/CDs/films/reels and reports.
- [ ] All pharmacy/prescription records including NDC numbers and drug information handouts/monographs.
- [ ] All billing records including all statements, insurance claim forms, itemized bills, and records of billing to third party payers and payment or denial of benefits for the period _____ to _____.

I understand the information to be released or disclosed may include information relating to sexually transmitted diseases, acquired immunodeficiency syndrome (AIDS), or human

immunodeficiency virus (HIV), and alcohol and drug abuse. I authorize the release or disclosure of this type of information.

This protected health information is disclosed for the following purposes: _____

Research Study Participation

This authorization is given in compliance with the federal consent requirements for release of alcohol or substance abuse records of 42 CFR 2.31, the restrictions of which have been specifically considered and expressly waived.

You are authorized to release the above records to the following representatives of defendants in the above-entitled matter who have agreed to pay reasonable charges made by you to supply copies of such records:

Brian Walitt, MD MPH

Name of Representative

Physician

Representative Capacity (e.g. attorney, records requestor, agent, etc.)

National Institutes of Health
10 Center Drive, Building 10, Room 3B19, MSC 1251

Street Address

Bethesda, MD 20814

City, State and Zip Code

I understand the following: See CFR §164.508(c)(2)(i-iii)

a. I have a right to revoke this authorization in writing at any time, except to the extent information has been released in reliance upon this authorization.
b. The information released in response to this authorization may be re-disclosed to other parties.
c. My treatment or payment for my treatment cannot be conditioned on the signing of this authorization.

Any facsimile, copy or photocopy of the authorization shall authorize you to release the records requested herein. This authorization shall be in force and effect until two years from date of execution at which time this authorization expires.

_____ _____

Signature of Patient or Legally Authorized Representative Date
(See 45CFR § 164.508(c)(1)(vi))

_____

Name and Relationship of Legally Authorized Representative to Patient
(See 45CFR §164.508(c)(1)(iv))

_____ _____

Witness Signature Date

From: Gavin, Angelique (NIH/NINDS) [C]
To: (b) (6)
Subject: RE: Information Request: Clinical Center Study PI000089-N
Date: Wednesday, November 9, 2022 2:24:00 PM
Attachments: Vaccination_Consent_Clean_05.17.22 (002).pdf

Good Day (b) (6):

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

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

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

1. What is your full name?

2. What is your preferred phone number?

3. How old are you?

4. Are you fluent in speaking, reading and writing English? Yes /No

5. Do you live in the United States? Yes/No

a. If yes, please provide the city, state and zip code where you live.

6. Are you an NIH employee, contractor, trainee or otherwise affiliated with the NIH? Yes/No

7. Have you had a COVID-19 infection? Yes/No/Unsure

a. If yes, how many COVID-19 infections have you had?

b. What is the date of your first COVID-19 infection?

c. Are you having persistent side effects after your first COVID-19 infection? Yes No

d. Do you have test results confirming your COVID 19 infection? Yes No

e. If you responded yes, please provide a copy of your COVID 19 test results with your email response.

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

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

8. Have you received a COVID-19 vaccine? Yes No

a. ***If you responded yes, please provide a copy of your COVID 19 vaccination card with your email response***.

b. If yes, do you have persistent side effects after receiving a COVID-19 vaccination? Yes No

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

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

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

Thank you,
Angelique Gavin
COVID 19 Convalescence Study Team

Angelique Gavin, MS (Contractor)
NIH/NINDS Clinical Operations Manager
Contractor Preferred Solutions Group
National Institutes of Health
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Building 10, Room 3B19, MSC 1251
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Angelique Gavin, MS (Contractor)
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(b) (6) (office)
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(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089-N

-

From: (b) (6) < (b) (6)
Sent: Tuesday, November 8, 2022 4:26 PM
To: Gavin, Angelique (NIH/NINDS) [C] < (b) (6)
Subject: Information Request: Clinical Center Study PI000089-N

LastName :	(b) (6)
FirstName :	
Organization :	
Building Mail Stop:	
Street Addresss:	
City/State/Zip:	
Phone:	
Fax:	
Patient's First Name(if different from sender name):	
Patient's Last Name((if different from sender name):	
Comments :	Is NIH doing any data gathering or clinical research on post-COVID vaccine adverse responses? I am interesting in participating.

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

PRINCIPAL INVESTIGATOR: Avi Nath, MD

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

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

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

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

WHY IS THIS STUDY BEING DONE?

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

WHAT WILL HAPPEN DURING THE STUDY?

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

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

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

HOW LONG WILL THE STUDY TAKE?

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

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

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

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

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

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

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

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

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

STORAGE, SHARING AND FUTURE RESEARCH USING YOUR DATA

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

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

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

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

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

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

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

How long will your data be stored by the NIH?

Your data may be stored by the NIH indefinitely.

Risks of storage and sharing of data

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

COMPENSATION

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

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Will your information be kept private?

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

CERTIFICATE OF CONFIDENTIALITY

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

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

The Certificate does not protect your information when it:

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

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

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

Privacy Act

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

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

PROBLEMS OR QUESTIONS

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

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

Study Coordinator: Angelique Gavin , Building/room Building 10/3B19, (b) (6), email- (b) (6)
Lead Associate Investigator: Brian Walitt M.D, M.P.H, Building/room Building 10/3B19, (b) (6) (b) (6), email- (b) (6)
Principal Investigator:, Avindra Nath, M.D., Building/Room 10/7C-103, Telephone (b) (6) (b) (6), email- (b) (6)

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

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

From: (b) (6)
To: Bartrum, Elizabeth (NIH/NINDS) [E]
Cc: Gavin, Angelique (NIH/NINDS) [C]; Ashade, Adedamola (NIH/NINDS) [F]; (b) (6); Walitt, Brian (NIH/NINDS) [E]
Subject: Re: COVID 19 Research Study at NIH
Date: Tuesday, October 25, 2022 1:39:04 PM
Attachments: (b) (6)

Hello Elizabeth,

I have sent the medical release forms out and you should be getting the information shortly. You will be getting records from:

(b) (6)

Attached to this email:
1)vaccination notes from (b) (6) plus all the records they gleamed from the system after I notified them of my adverse reaction.
2) (b) (6) notes from ambulance trips (b) (6). I have included this to show my health status at the time of transport.

Please let me know if you do not receive the medical records.

(b) (6)

From: Bartrum, Elizabeth (NIH/NINDS) [E] <(b) (6)
Sent: Tuesday, October 18, 2022 10:44:58 AM
To: (b) (6) <(b) (6)
Cc: Gavin, Angelique (NIH/NINDS) [C] <(b) (6) Ashade, Adedamola (NIH/NINDS) [F] <(b) (6)
Subject: RE: COVID 19 Research Study at NIH

(b) (6)
Thanks so much, and I appreciate you reaching out to our team.

The records you describe will likely be sufficient for what we need. Once we review them, then we can address next steps.

Thanks very much, and I look forward to understanding more about what you have suffered in the past year.

Kind regards-
Elizabeth

From: (b) (6) <Office365@messaging.microsoft.com>
Sent: Tuesday, October 18, 2022 10:31 AM
To: Bartrum, Elizabeth (NIH/NINDS) [E] <(b) (6)
Cc: Gavin, Angelique (NIH/NINDS) [C] <(b) (6) Ashade, Adedamola (NIH/NINDS) [F] <(b) (6) (b) (6) <(b) (6)
Subject: Re: COVID 19 Research Study at NIH

Elizabeth,

Thank you for your kind words. It has been challenging, for sure.

I will get the records release completed and sent in. I did not have a primary doctor prior to this happening to me. I was a healthy man and not on any medications. I may of had (b) (6) (b) (6) (b) (6) Other than that I can not recall anything that was not out of the ordinary.

I will have my records from both facilities sent.

Hope this works,

(b) (6)

From: Bartrum, Elizabeth (NIH/NINDS) [E] <(b) (6)
Sent: Monday, October 17, 2022 9:49:04 AM
To: (b) (6) <(b) (6)
Cc: Gavin, Angelique (NIH/NINDS) [C] <(b) (6) Ashade, Adedamola (NIH/NINDS) [F] <(b) (6)
Subject: COVID 19 Research Study at NIH

Hi (b) (6)-

I'm so sorry to hear of this devastating experience. There are no words to convey how difficult your life has been for over a year. I'm very sorry.

Thank you for your interest in our study. The next step will be to obtain medical records from you. The records ideally are from a primary medical provider who can document your health

in the year prior to vaccination, as well as document your health after vaccination. To begin, we will review from your primary provider, and then if we need additional detail we will request additional records.

I've attached a copy of the medical records release form. Please complete this, sign it and return to me and Angelique Gavin. Once it is completed and we receive the records then we can proceed to the interview and questionnaire portions of the study.

If you have additional questions, please let me know.

My best to you-
Elizabeth

From: (b) (6)
To: Gavin, Angelique (NIH/NINDS) [C]
Subject: Re: NIH COVID-19 Vaccine Study
Date: Thursday, August 25, 2022 3:50:00 PM
Attachments: Medical Release NIH.pdf

Hi Angelique,

Please see the attached forms.

(b) (6)

From: Gavin, Angelique (NIH/NINDS) [C] <(b) (6)
Sent: Wednesday, August 24, 2022 2:34 PM
To: (b) (6) <(b) (6)
Subject: [EXTERNAL] FW: NIH COVID-19 Vaccine Study

Thank you (b) (6) for the information you've provided thus far. To determine if you are eligible to proceed, we need medical records to confirm that the symptom onset was after COVID vaccination.

Please complete the attached medical record release form for a medical provider whom managed your care at the onset of symptoms after vaccination. Please return the form to me using this encrypted email and I will obtain the records on your behalf.

Once we have received and reviewed the records, if you are eligible to proceed, we will schedule a telephone interview. Please let me know if you have any additional questions. I look forward to speaking with you very soon.

Sincerely,
Angelique Gavin

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) (6) (office)
(b) (6) (cell)
(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089-N

-

From: NINDSPostCovid19
Sent: Monday, August 15, 2022 2:15 PM
To: (b) (6) < (b) (6)
Subject: RE: NIH COVID-19 Vaccine Study

Thank you (b) (6) for the information you've provided thus far. To determine if you are eligible to proceed, we need medical records to confirm that the symptom onset was after COVID vaccination.

Please complete the attached medical record release form for a medical provider whom managed your care at the onset of symptoms after vaccination. Please return the form to me using this encrypted email and I will obtain the records on your behalf.

Once we have received and reviewed the records, if you are eligible to proceed, we will schedule a telephone interview. Please let me know if you have any additional questions. I look forward to speaking with you very soon.

Sincerely,
Angelique Gavin

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) (6) (office)
(b) (6) (cell)
(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089-N

-

From: (b) (6) < (b) (6)

Sent: Monday, August 15, 2022 1:50 PM
To: Gavin, Angelique (NIH/NINDS) [C] <(b) (6)
Subject: Re: NIH COVID-19 Vaccine Study

Please see vaccine card photos attached.

From: Gavin, Angelique (NIH/NINDS) [C] <(b) (6)
Sent: Monday, August 15, 2022 11:11 AM
To: (b) (6) <(b) (6)
Subject: [EXTERNAL] RE: NIH COVID-19 Vaccine Study

Thank you (b) (6) for your response. Please send me a copy of your vaccine card, front and back. Once received, we can determine if you are eligible to move forward in the study.

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) (6) (office)
(b) (6) (cell)
(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089-N

-

From: (b) (6) <(b) (6)
Sent: Friday, August 12, 2022 3:25 PM

To: Gavin, Angelique (NIH/NINDS) [C] <(b) (6)
Subject: Re: NIH COVID-19 Vaccine Study

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

1. What is your full name?
2. (b) (6)

3. What is your preferred phone number?

(b) (6)

4. How old are you?

(b) (6)

5. Are you fluent in speaking, reading and writing English? Yes /No

Yes

5. Do you live in the United States? Yes/No

Yes

a. If yes, please provide the city, state and zip code where you live.

(b) (6)

1. Are you an NIH employee, contractor, trainee or otherwise affiliated with the NIH? Yes/No

No

7. Have you had a COVID-19 infection? Yes/No/Unsure

(b) (6)

a. If yes, how many COVID-19 infections have you had?

(b) (6)

b. What is the date of your first COVID-19 infection?

(b) (6)

c. Are you having persistent side effects after your first COVID-19 infection? Yes No

(b) (6)

d. Do you have test results confirming your COVID 19 infection? Yes No

e. If you responded yes, please provide a copy of your COVID 19 test results with your email response.
For tests performed at a laboratory or by a medical provider, results need to include your name, date of test result, type of test, and result of test. If you do not have a copy of your test result, please let us know and we can assist you in obtaining your records from your medical lab or provider.
For tests performed using a home testing kit, a photograph of the results with time and date are required.

8. Have you received a COVID-19 vaccine? Yes No

YES

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

YES

From: Gavin, Angelique (NIH/NINDS) [C] < (b) (6)
Sent: Monday, August 8, 2022 4:17 PM

To: (b) (6) < (b) (6)
Subject: [EXTERNAL] NIH COVID-19 Vaccine Study

Good Day (b) (6):

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

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

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

1. What is your full name?

2. What is your preferred phone number?

3. How old are you?

4. Are you fluent in speaking, reading and writing English? Yes /No

5. Do you live in the United States? Yes/No
a. If yes, please provide the city, state and zip code where you live.

6. Are you an NIH employee, contractor, trainee or otherwise affiliated with the NIH? Yes/No

7. Have you had a COVID-19 infection? Yes/No/Unsure
a. If yes, how many COVID-19 infections have you had?
b. What is the date of your first COVID-19 infection?
c. Are you having persistent side effects after your first COVID-19 infection? Yes No
d. Do you have test results confirming your COVID 19 infection? Yes No
e. If you responded yes, please provide a copy of your COVID 19 test results with your email response.
For tests performed at a laboratory or by a medical provider, results need to include your name, date of test result, type of test, and result of test. If you do not have a copy of your test result, please let us know and we can assist you in obtaining your records from your medical lab or provider.
For tests performed using a home testing kit, a photograph of the results with time and date are required.

8. Have you received a COVID-19 vaccine? Yes No

a. ***If you responded yes, please provide a copy of your COVID 19 vaccination card with your email response***.

b. If yes, do you have persistent side effects after receiving a COVID-19 vaccination? Yes No

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

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

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

Thank you,
Angelique Gavin
COVID 19 Convalescence Study Team

Angelique Gavin, MS (Contractor)
NIH/NINDS Clinical Operations Manager
Contractor Preferred Solutions Group
National Institutes of Health
10 Center Drive
Building 10, Room 3B19, MSC 1251
Bethesda, MD 20814-9692
(b) (6) (office)
(b) (6) (cell)
(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089-N

HIPAA COMPLIANT AUTHORIZATION FOR THE RELEASE OF PATIENT INFORMATION PURSUANT TO 45 CFR 164.508

TO: (b) (6)
Name of Healthcare Provider/Physician/Facility/Medicare Contractor

(b) (6)
Street Address

(b) (6)
City, State and Zip Code

RE: Patient Name: (b) (6)

Date of Birth: (b) (6) Social Security Number: (b) (6)

I authorize and request the disclosure of all protected information for the purpose of review and evaluation in connection with a legal claim. I expressly request that the designated record custodian of all covered entities under HIPAA identified above disclose full and complete protected medical information including the following:

- [x] All medical records, meaning every page in my record, including but not limited to: office notes, face sheets, history and physical, consultation notes, inpatient, outpatient and emergency room treatment, all clinical charts, r ports, order sheets, progress notes, nurse's notes, social worker records, clinic records, treatment plans, admission records, discharge summaries, requests for and reports of consultations, documents, correspondence, test results, statements, questionnaires/histories, correspondence, photographs, videotapes, telephone messages, and records received by other medical providers.
- [ ] All physical, occupational and rehab requests, consultations and progress notes.
- [ ] All disability, Medicaid or Medicare records including claim forms and record of denial of benefits.
- [ ] All employment, personnel or wage records.
- [ ] All autopsy, laboratory, histology, cytology, pathology, immunohistochemistry records and specimens; radiology records and films including CT scan, MRI, MRA, EMG, bone scan, myleogram; nerve conduction study, echocardiogram and cardiac catheterization results, videos/CDs/films/reels and reports.
- [ ] All pharmacy/prescription records including NDC numbers and drug information handouts/monographs.
- [ ] All billing records including all statements, insurance claim forms, itemized bills, and records of billing to third party payers and payment or denial of benefits for the period _____ to _____.

I understand the information to be released or disclosed may include information relating to sexually transmitted diseases, acquired immunodeficiency syndrome (AIDS), or human

immunodeficiency virus (HIV), and alcohol and drug abuse. I authorize the release or disclosure of this type of information.

This protected health information is disclosed for the following purposes: _____

Research Study Participation

This authorization is given in compliance with the federal consent requirements for release of alcohol or substance abuse records of 42 CFR 2.31, the restrictions of which have been specifically considered and expressly waived.

You are authorized to release the above records to the following representatives of defendants in the above-entitled matter who have agreed to pay reasonable charges made by you to supply copies of such records:

Brian Walitt, MD MPH

Name of Representative

Physician

Representative Capacity (e.g. attorney, records requestor, agent, etc.)

National Institutes of Health
10 Center Drive, Building 10, Room 3B19, MSC 1251

Street Address

Bethesda, MD 20814

City, State and Zip Code

I understand the following: See CFR §164.508(c)(2)(i-iii)

a. I have a right to revoke this authorization in writing at any time, except to the extent information has been released in reliance upon this authorization.
b. The information released in response to this authorization may be re-disclosed to other parties.
c. My treatment or payment for my treatment cannot be conditioned on the signing of this authorization.

Any facsimile, copy or photocopy of the authorization shall authorize you to release the records requested herein. This authorization shall be in force and effect until two years from date of execution at which time this authorization expires.

(b) (6)

8/25/2022

Signature of Patient or Legally Authorized Representative — Date

(See 45CFR § 164.508(c)(1)(vi))

Name and Relationship of Legally Authorized Representative to Patient
(See 45CFR §164.508(c)(1)(iv))

Witness Signature — Date

From: Gavin, Angelique (NIH/NINDS) [C]
To: (b) (6)
Subject: NIH COVID-19 Vaccine Study
Date: Monday, August 8, 2022 4:17:00 PM
Attachments: Vaccination_Consent_Clean_05.17.22.pdf

Good Day (b) (6):

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

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

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

1. What is your full name?

2. What is your preferred phone number?

3. How old are you?

4. Are you fluent in speaking, reading and writing English? Yes /No

5. Do you live in the United States? Yes/No
a. If yes, please provide the city, state and zip code where you live.

6. Are you an NIH employee, contractor, trainee or otherwise affiliated with the NIH? Yes/No

7. Have you had a COVID-19 infection? Yes/No/Unsure
a. If yes, how many COVID-19 infections have you had?
b. What is the date of your first COVID-19 infection?
c. Are you having persistent side effects after your first COVID-19 infection? Yes No
d. Do you have test results confirming your COVID 19 infection? Yes No
e. If you responded yes, please provide a copy of your COVID 19 test results with your email response.
For tests performed at a laboratory or by a medical provider, results need to include your name, date of test result, type of test, and result of test. If you do not have a copy of your test result, please let us know and we can assist you in obtaining your records from your medical lab or provider.

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

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

When you respond to this email, please provide answers to each question above, as well as a Copy of your COVID-19 test results and/or the front and back of your COVID-19 vaccination card, if applicable.
Your responses and documentation will allow us to determine if you are eligible for our research study. If you do not answer all questions or provide the requested documentation, you will not be considered for the study. If you wish to provide a short summary of your condition, we invite you to.

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

Thank you,
Angelique Gavin
COVID 19 Convalescence Study Team

Angelique Gavin, MS (Contractor)
NIH/NINDS Clinical Operations Manager
Contractor Preferred Solutions Group
National Institutes of Health
10 Center Drive
Building 10, Room 3B19, MSC 1251
Bethesda, MD 20814-9692
(b) (6) (office)
(b) (6) (cell)
(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089-N

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

PRINCIPAL INVESTIGATOR: Avi Nath, MD

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

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

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

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

WHY IS THIS STUDY BEING DONE?

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

WHAT WILL HAPPEN DURING THE STUDY?

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

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

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

HOW LONG WILL THE STUDY TAKE?

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

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

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

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

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

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

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

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

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

STORAGE, SHARING AND FUTURE RESEARCH USING YOUR DATA

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

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

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

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

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

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

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

How long will your data be stored by the NIH?

Your data may be stored by the NIH indefinitely.

Risks of storage and sharing of data

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

COMPENSATION

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

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Will your information be kept private?

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

CERTIFICATE OF CONFIDENTIALITY

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

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

The Certificate does not protect your information when it:

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

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

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

Privacy Act

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

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

PROBLEMS OR QUESTIONS

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

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

Study Coordinator: Angelique Gavin , Building/room Building 10/3B19, (b) (6), email- (b) (6)
Lead Associate Investigator: Brian Walitt M.D, M.P.H, Building/room Building 10/3B19, (b) (6) (b) (6), email- (b) (6)
Principal Investigator:, Avindra Nath, M.D., Building/Room 10/7C-103, Telephone (b) (6) (b) (6), email- (b) (6)

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

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

From: NINDSPostCovid19
To: (b) (6)
Subject: RE: NIH COVID-19 Vaccine Study
Date: Monday, August 15, 2022 2:14:00 PM
Attachments: HIPAA Medical Record Release Blank.pdf

Thank you (b) (6) for the information you've provided thus far. To determine if you are eligible to proceed, we need medical records to confirm that the symptom onset was after COVID vaccination.

Please complete the attached medical record release form for a medical provider whom managed your care at the onset of symptoms after vaccination. Please return the form to me using this encrypted email and I will obtain the records on your behalf.

Once we have received and reviewed the records, if you are eligible to proceed, we will schedule a telephone interview. Please let me know if you have any additional questions. I look forward to speaking with you very soon.

Sincerely,
Angelique Gavin

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) (6) (office)
(b) (6) (cell)
(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089-N

-

From: (b) (6) < (b) (6)
Sent: Monday, August 15, 2022 1:50 PM
To: Gavin, Angelique (NIH/NINDS) [C] < (b) (6)
Subject: Re: NIH COVID-19 Vaccine Study

Please see vaccine card photos attached.

(b) (6)

(b) (6)

From: Gavin, Angelique (NIH/NINDS) [C] <(b) (6)
Sent: Monday, August 15, 2022 11:11 AM
To: (b) (6) <(b) (6)
Subject: [EXTERNAL] RE: NIH COVID-19 Vaccine Study

Thank you (b) (6) for your response. Please send me a copy of your vaccine card, front and back. Once received, we can determine if you are eligible to move forward in the study.

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) (6) (office)
(b) (6) (cell)
(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089-N

-

From: (b) (6) <(b) (6)
Sent: Friday, August 12, 2022 3:25 PM
To: Gavin, Angelique (NIH/NINDS) [C] <(b) (6)
Subject: Re: NIH COVID-19 Vaccine Study

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

□□□ What is your full name?
□□□
(b) (6)

□□□ What is your preferred phone number?

(b) (6)

□□□ How old are you?

(b) (6)

□□□ Are you fluent in speaking, reading and writing English? Yes /No

Yes

5. Do you live in the United States? Yes/No

Yes

a. If yes, please provide the city, state and zip code where you live.

(b) (6)

□□□ Are you an NIH employee, contractor, trainee or otherwise affiliated with the NIH? Yes/No

No

7. Have you had a COVID-19 infection? Yes/No/Unsure

(b) (6)

a. If yes, how many COVID-19 infections have you had?

(b) (6)

b. What is the date of your first COVID-19 infection?

(b) (6)

c. Are you having persistent side effects after your first COVID-19 infection? Yes No

(b) (6)

d. Do you have test results confirming your COVID 19 infection? Yes No

e. If you responded yes, please provide a copy of your COVID 19 test results with your email response.
For tests performed at a laboratory or by a medical provider, results need to include your name, date of test result, type of test, and result of test. If you do not have a copy of your test result, please let us know and we can assist you in obtaining your records from your medical lab or provider.
For tests performed using a home testing kit, a photograph of the results with time and date are required.

8. Have you received a COVID-19 vaccine? Yes No

YES

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

YES

From: Gavin, Angelique (NIH/NINDS) [C] < (b) (6)
Sent: Monday, August 8, 2022 4:17 PM
To: (b) (6) < (b) (6)
Subject: [EXTERNAL] NIH COVID-19 Vaccine Study

Good Day (b) (6):

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

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

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

□□□ What is your full name?

□□□ What is your preferred phone number?

□□□ How old are you?

□□□ Are you fluent in speaking, reading and writing English? Yes /No

5. Do you live in the United States? Yes/No
a. If yes, please provide the city, state and zip code where you live.

□□□ Are you an NIH employee, contractor, trainee or otherwise affiliated with the NIH? Yes/No

7. Have you had a COVID-19 infection? Yes/No/Unsure
a. If yes, how many COVID-19 infections have you had?
b. What is the date of your first COVID-19 infection?
c. Are you having persistent side effects after your first COVID-19 infection? Yes No
d. Do you have test results confirming your COVID 19 infection? Yes No
e. If you responded yes, please provide a copy of your COVID 19 test results with your email response.
For tests performed at a laboratory or by a medical provider, results need to include your name, date of test result, type of test, and result of test. If you do not have a copy of your test result, please let us know and we can assist you in obtaining your records from your medical lab or provider.
For tests performed using a home testing kit, a photograph of the results with time and date are required.

8. Have you received a COVID-19 vaccine? Yes No

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

When you respond to this email, please provide answers to each question above, as well as a Copy of your COVID-19 test results and/or the front and back of your COVID-19 vaccination card, if applicable.
Your responses and documentation will allow us to determine if you are eligible for our research study. If you do not answer all questions or provide the requested documentation, you will not be considered for the study. If you wish to provide a short summary of your condition, we invite you to.

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

Thank you,
Angelique Gavin
COVID 19 Convalescence Study Team

Angelique Gavin, MS (Contractor)
NIH/NINDS Clinical Operations Manager
Contractor Preferred Solutions Group
National Institutes of Health
10 Center Drive
Building 10, Room 3B19, MSC 1251
Bethesda, MD 20814-9692
(b) (6) (office)
(b) (6) (cell)
(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089-N

HIPAA COMPLIANT AUTHORIZATION FOR THE RELEASE OF PATIENT INFORMATION PURSUANT TO 45 CFR 164.508

TO: _____
Name of Healthcare Provider/Physician/Facility/Medicare Contractor

_____
Street Address

_____
City, State and Zip Code

RE: Patient Name: _____

Date of Birth: _____ Social Security Number: _____

I authorize and request the disclosure of all protected information for the purpose of review and evaluation in connection with a legal claim. I expressly request that the designated record custodian of all covered entities under HIPAA identified above disclose full and complete protected medical information including the following:

- [x] All medical records, meaning every page in my record, including but not limited to: office notes, face sheets, history and physical, consultation notes, inpatient, outpatient and emergency room treatment, all clinical charts, r ports, order sheets, progress notes, nurse's notes, social worker records, clinic records, treatment plans, admission records, discharge summaries, requests for and reports of consultations, documents, correspondence, test results, statements, questionnaires/histories, correspondence, photographs, videotapes, telephone messages, and records received by other medical providers.
- [ ] All physical, occupational and rehab requests, consultations and progress notes.
- [ ] All disability, Medicaid or Medicare records including claim forms and record of denial of benefits.
- [ ] All employment, personnel or wage records.
- [ ] All autopsy, laboratory, histology, cytology, pathology, immunohistochemistry records and specimens; radiology records and films including CT scan, MRI, MRA, EMG, bone scan, myleogram; nerve conduction study, echocardiogram and cardiac catheterization results, videos/CDs/films/reels and reports.
- [ ] All pharmacy/prescription records including NDC numbers and drug information handouts/monographs.
- [ ] All billing records including all statements, insurance claim forms, itemized bills, and records of billing to third party payers and payment or denial of benefits for the period _____ to _____.

I understand the information to be released or disclosed may include information relating to sexually transmitted diseases, acquired immunodeficiency syndrome (AIDS), or human

immunodeficiency virus (HIV), and alcohol and drug abuse. I authorize the release or disclosure of this type of information.

This protected health information is disclosed for the following purposes: _____

Research Study Participation

This authorization is given in compliance with the federal consent requirements for release of alcohol or substance abuse records of 42 CFR 2.31, the restrictions of which have been specifically considered and expressly waived.

You are authorized to release the above records to the following representatives of defendants in the above-entitled matter who have agreed to pay reasonable charges made by you to supply copies of such records:

Brian Walitt, MD MPH

Name of Representative

Physician

Representative Capacity (e.g. attorney, records requestor, agent, etc.)

National Institutes of Health
10 Center Drive, Building 10, Room 3B19, MSC 1251

Street Address

Bethesda, MD 20814

City, State and Zip Code

I understand the following: See CFR §164.508(c)(2)(i-iii)

a. I have a right to revoke this authorization in writing at any time, except to the extent information has been released in reliance upon this authorization.
b. The information released in response to this authorization may be re-disclosed to other parties.
c. My treatment or payment for my treatment cannot be conditioned on the signing of this authorization.

Any facsimile, copy or photocopy of the authorization shall authorize you to release the records requested herein. This authorization shall be in force and effect until two years from date of execution at which time this authorization expires.

_____ _____

Signature of Patient or Legally Authorized Representative Date
(See 45CFR § 164.508(c)(1)(vi))

_____

Name and Relationship of Legally Authorized Representative to Patient
(See 45CFR §164.508(c)(1)(iv))

_____ _____

Witness Signature Date

From: Gavin, Angelique (NIH/NINDS) [C]
To: (b) (6)
Subject: NIH COVID-19 Vaccine Study
Date: Wednesday, August 3, 2022 11:14:00 AM
Attachments: Vaccination_Consent_Clean_05.17.22.pdf

Hello (b) (6):

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

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

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

1. What is your full name?

2. What is your preferred phone number?

3. How old are you?

4. Are you fluent in speaking, reading and writing English? Yes /No

5. Do you live in the United States? Yes/No
a. If yes, please provide the city, state and zip code where you live.

6. Are you an NIH employee, contractor, trainee or otherwise affiliated with the NIH? Yes/No

7. Have you had a COVID-19 infection? Yes/No/Unsure
a. If yes, how many COVID-19 infections have you had?
b. What is the date of your first COVID-19 infection?
c. Are you having persistent side effects after your first COVID-19 infection? Yes No
d. Do you have test results confirming your COVID 19 infection? Yes No
e. If you responded yes, please provide a copy of your COVID 19 test results with your email response.
For tests performed at a laboratory or by a medical provider, results need to include your name, date of test result, type of test, and result of test. If you do not have a copy of your test result, please let us know and we can assist you in obtaining your records from your medical lab or provider.

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

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

When you respond to this email, please provide answers to each question above, as well as a Copy of your COVID-19 test results and/or the front and back of your COVID-19 vaccination card, if applicable.
Your responses and documentation will allow us to determine if you are eligible for our research study. If you do not answer all questions or provide the requested documentation, you will not be considered for the study. If you wish to provide a short summary of your condition, we invite you to.

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

Thank you,
Angelique Gavin
COVID 19 Convalescence Study Team

Angelique Gavin, MS (Contractor)
NIH/NINDS Clinical Operations Manager
Contractor Preferred Solutions Group
National Institutes of Health
10 Center Drive
Building 10, Room 3B19, MSC 1251
Bethesda, MD 20814-9692
(b) (6) (office)
(b) (6) (cell)
(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089-N

-

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

PRINCIPAL INVESTIGATOR: Avi Nath, MD

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

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

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

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

WHY IS THIS STUDY BEING DONE?

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

WHAT WILL HAPPEN DURING THE STUDY?

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

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

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

HOW LONG WILL THE STUDY TAKE?

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

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

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

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

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

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

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

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

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

STORAGE, SHARING AND FUTURE RESEARCH USING YOUR DATA

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

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

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

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

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

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

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

How long will your data be stored by the NIH?

Your data may be stored by the NIH indefinitely.

Risks of storage and sharing of data

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

COMPENSATION

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

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Will your information be kept private?

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

CERTIFICATE OF CONFIDENTIALITY

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

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

The Certificate does not protect your information when it:

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

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

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

Privacy Act

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

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

PROBLEMS OR QUESTIONS

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

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

Study Coordinator: Angelique Gavin , Building/room Building 10/3B19, (b) (6), email- (b) (6)
Lead Associate Investigator: Brian Walitt M.D, M.P.H, Building/room Building 10/3B19, (b) (6) (b) (6), email- (b) (6)
Principal Investigator:, Avindra Nath, M.D., Building/Room 10/7C-103, Telephone (b) (6) (b) (6), email- (b) (6)

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

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

From: (b) (6)
To: Gavin, Angelique (NIH/NINDS) [C]
Subject: Re: NIH COVID-19 Vaccine Study
Date: Monday, August 15, 2022 1:49:54 PM
Attachments: image2.jpeg
image3.jpeg

Please see vaccine card photos attached.

From: Gavin, Angelique (NIH/NINDS) [C] < (b) (6)
Sent: Monday, August 15, 2022 11:11 AM
To: (b) (6) < (b) (6)
Subject: [EXTERNAL] RE: NIH COVID-19 Vaccine Study

Thank you (b) (6) for your response. Please send me a copy of your vaccine card, front and back. Once received, we can determine if you are eligible to move forward in the study.

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) (6) (office)
(b) (6) (cell)
(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089-N

-

From: (b) (6) < (b) (6)

Sent: Friday, August 12, 2022 3:25 PM
To: Gavin, Angelique (NIH/NINDS) [C] <(b) (6)
Subject: Re: NIH COVID-19 Vaccine Study

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

 What is your full name?

(b) (6)

 What is your preferred phone number?

(b) (6)

 How old are you?

(b) (6)

 Are you fluent in speaking, reading and writing English? Yes /No

Yes

5. Do you live in the United States? Yes/No

Yes

a. If yes, please provide the city, state and zip code where you live.

(b) (6)

 Are you an NIH employee, contractor, trainee or otherwise affiliated with the NIH? Yes/No

No

7. Have you had a COVID-19 infection? Yes/No/Unsure

(b) (6)

a. If yes, how many COVID-19 infections have you had?

(b) (6)

b. What is the date of your first COVID-19 infection?

(b) (6)

c. Are you having persistent side effects after your first COVID-19 infection? Yes No

(b) (6)

d. Do you have test results confirming your COVID 19 infection? Yes No

e. If you responded yes, please provide a copy of your COVID 19 test results with your email response.
For tests performed at a laboratory or by a medical provider, results need to include your name, date of test result, type of test, and result of test. If you do not have a copy of your test result, please let us know and we can assist you in obtaining your records from your medical lab or provider.
For tests performed using a home testing kit, a photograph of the results with time and date are required.

8. Have you received a COVID-19 vaccine? Yes No

YES

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

YES

(b) (6)

From: Gavin, Angelique (NIH/NINDS) [C] < (b) (6)

Sent: Monday, August 8, 2022 4:17 PM
To: (b) (6) < (b) (6)
Subject: [EXTERNAL] NIH COVID-19 Vaccine Study

Good Day (b) (6):

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

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

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

□□□ What is your full name?

□□□ What is your preferred phone number?

□□□ How old are you?

□□□ Are you fluent in speaking, reading and writing English? Yes /No

5. Do you live in the United States? Yes/No
a. If yes, please provide the city, state and zip code where you live.

□□□ Are you an NIH employee, contractor, trainee or otherwise affiliated with the NIH? Yes/No

7. Have you had a COVID-19 infection? Yes/No/Unsure
a. If yes, how many COVID-19 infections have you had?
b. What is the date of your first COVID-19 infection?
c. Are you having persistent side effects after your first COVID-19 infection? Yes No
d. Do you have test results confirming your COVID 19 infection? Yes No
e. If you responded yes, please provide a copy of your COVID 19 test results with your email response.
For tests performed at a laboratory or by a medical provider, results need to include your name, date of test result, type of test, and result of test. If you do not have a copy of your test result, please let us know and we can assist you in obtaining your records from your medical lab or provider.
For tests performed using a home testing kit, a photograph of the results with time and

date are required.

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

When you respond to this email, please provide answers to each question above, as well as a Copy of your COVID-19 test results and/or the front and back of your COVID-19 vaccination card, if applicable.
Your responses and documentation will allow us to determine if you are eligible for our research study. If you do not answer all questions or provide the requested documentation, you will not be considered for the study. If you wish to provide a short summary of your condition, we invite you to.

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

Thank you,
Angelique Gavin
COVID 19 Convalescence Study Team

Angelique Gavin, MS (Contractor)
NIH/NINDS Clinical Operations Manager
Contractor Preferred Solutions Group
National Institutes of Health
10 Center Drive
Building 10, Room 3B19, MSC 1251
Bethesda, MD 20814-9692
(b) (6) (office)
(b) (6) (cell)
(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089-N

(b) (6)

(b) (6)

From: (b) (6)
To: Gavin, Angelique (NIH/NINDS) [C]
Subject: Re: NIH COVID-19 Vaccine Study
Date: Thursday, August 25, 2022 3:50:00 PM
Attachments: Medical Release NIH.pdf

Hi Angelique,

Please see the attached forms.

(b) (6)

From: Gavin, Angelique (NIH/NINDS) [C] < (b) (6)
Sent: Wednesday, August 24, 2022 2:34 PM
To: (b) (6) < (b) (6)
Subject: [EXTERNAL] FW: NIH COVID-19 Vaccine Study

Thank you (b) (6) for the information you've provided thus far. To determine if you are eligible to proceed, we need medical records to confirm that the symptom onset was after COVID vaccination.

Please complete the attached medical record release form for a medical provider whom managed your care at the onset of symptoms after vaccination. Please return the form to me using this encrypted email and I will obtain the records on your behalf.

Once we have received and reviewed the records, if you are eligible to proceed, we will schedule a telephone interview. Please let me know if you have any additional questions. I look forward to speaking with you very soon.

Sincerely,
Angelique Gavin

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) (6) (office)
(b) (6) (cell)
(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089-N

-

From: NINDSPostCovid19
Sent: Monday, August 15, 2022 2:15 PM
To: (b) (6) < (b) (6)
Subject: RE: NIH COVID-19 Vaccine Study

Thank you (b) (6) for the information you've provided thus far. To determine if you are eligible to proceed, we need medical records to confirm that the symptom onset was after COVID vaccination.

Please complete the attached medical record release form for a medical provider whom managed your care at the onset of symptoms after vaccination. Please return the form to me using this encrypted email and I will obtain the records on your behalf.

Once we have received and reviewed the records, if you are eligible to proceed, we will schedule a telephone interview. Please let me know if you have any additional questions. I look forward to speaking with you very soon.

Sincerely,
Angelique Gavin

Angelique Gavin, MS (Contractor)
NIH/NINDS Clinical Operations Manager
Contractor Preferred Solutions Group
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10 Center Drive
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(b) (6) (office)
(b) (6) (cell)
(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089-N

-

From: (b) (6) < (b) (6)

Sent: Monday, August 15, 2022 1:50 PM
To: Gavin, Angelique (NIH/NINDS) [C] <(b) (6)
Subject: Re: NIH COVID-19 Vaccine Study

Please see vaccine card photos attached.

From: Gavin, Angelique (NIH/NINDS) [C] <(b) (6)
Sent: Monday, August 15, 2022 11:11 AM
To: (b) (6) <(b) (6)
Subject: [EXTERNAL] RE: NIH COVID-19 Vaccine Study

Thank you (b) (6) for your response. Please send me a copy of your vaccine card, front and back. Once received, we can determine if you are eligible to move forward in the study.

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) (6) (office)
(b) (6) (cell)
(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089-N

-

From: (b) (6) <(b) (6)
Sent: Friday, August 12, 2022 3:25 PM

To: Gavin, Angelique (NIH/NINDS) [C] <(b) (6)
Subject: Re: NIH COVID-19 Vaccine Study

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

□□□ What is your full name?
□□□
(b) (6)

□□□ What is your preferred phone number?

(b) (6)

□□□ How old are you?

(b) (6)

□□□ Are you fluent in speaking, reading and writing English? Yes /No

Yes

5. Do you live in the United States? Yes/No

Yes

a. If yes, please provide the city, state and zip code where you live.

(b) (6)

□□□ Are you an NIH employee, contractor, trainee or otherwise affiliated with the NIH? Yes/No

No

7. Have you had a COVID-19 infection? Yes/No/Unsure

(b) (6)

a. If yes, how many COVID-19 infections have you had?

(b) (6)

b. What is the date of your first COVID-19 infection?

(b) (6)

c. Are you having persistent side effects after your first COVID-19 infection? Yes No

(b) (6)

d. Do you have test results confirming your COVID 19 infection? Yes No

e. If you responded yes, please provide a copy of your COVID 19 test results with your email response.
For tests performed at a laboratory or by a medical provider, results need to include your name, date of test result, type of test, and result of test. If you do not have a copy of your test result, please let us know and we can assist you in obtaining your records from your medical lab or provider.
For tests performed using a home testing kit, a photograph of the results with time and date are required.

8. Have you received a COVID-19 vaccine? Yes No

YES

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

YES

(b) (6)

From: Gavin, Angelique (NIH/NINDS) [C] < (b) (6)
Sent: Monday, August 8, 2022 4:17 PM

To: (b) (6) < (b) (6)
Subject: [EXTERNAL] NIH COVID-19 Vaccine Study

Good Day (b) (6):

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

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

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

1. What is your full name?

2. What is your preferred phone number?

3. How old are you?

4. Are you fluent in speaking, reading and writing English? Yes /No

5. Do you live in the United States? Yes/No
a. If yes, please provide the city, state and zip code where you live.

6. Are you an NIH employee, contractor, trainee or otherwise affiliated with the NIH? Yes/No

7. Have you had a COVID-19 infection? Yes/No/Unsure
a. If yes, how many COVID-19 infections have you had?
b. What is the date of your first COVID-19 infection?
c. Are you having persistent side effects after your first COVID-19 infection? Yes No
d. Do you have test results confirming your COVID 19 infection? Yes No
e. If you responded yes, please provide a copy of your COVID 19 test results with your email response.
For tests performed at a laboratory or by a medical provider, results need to include your name, date of test result, type of test, and result of test. If you do not have a copy of your test result, please let us know and we can assist you in obtaining your records from your medical lab or provider.
For tests performed using a home testing kit, a photograph of the results with time and date are required.

8. Have you received a COVID-19 vaccine? Yes No

a. ***If you responded yes, please provide a copy of your COVID 19 vaccination card with your email response***.

b. If yes, do you have persistent side effects after receiving a COVID-19 vaccination? Yes No

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

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

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

Thank you,
Angelique Gavin
COVID 19 Convalescence Study Team

Angelique Gavin, MS (Contractor)
NIH/NINDS Clinical Operations Manager
Contractor Preferred Solutions Group
National Institutes of Health
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(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089-N

HIPAA COMPLIANT AUTHORIZATION FOR THE RELEASE OF PATIENT INFORMATION PURSUANT TO 45 CFR 164.508

TO: (b) (6)
Name of Healthcare Provider/Physician/Facility/Medicare Contractor

(b) (6)
Street Address

(b) (6)
City, State and Zip Code

RE: Patient Name: (b) (6)

Date of Birth: (b) (6) Social Security Number: (b) (6)

I authorize and request the disclosure of all protected information for the purpose of review and evaluation in connection with a legal claim. I expressly request that the designated record custodian of all covered entities under HIPAA identified above disclose full and complete protected medical information including the following:

- [x] All medical records, meaning every page in my record, including but not limited to: office notes, face sheets, history and physical, consultation notes, inpatient, outpatient and emergency room treatment, all clinical charts, r ports, order sheets, progress notes, nurse's notes, social worker records, clinic records, treatment plans, admission records, discharge summaries, requests for and reports of consultations, documents, correspondence, test results, statements, questionnaires/histories, correspondence, photographs, videotapes, telephone messages, and records received by other medical providers.
- [ ] All physical, occupational and rehab requests, consultations and progress notes.
- [ ] All disability, Medicaid or Medicare records including claim forms and record of denial of benefits.
- [ ] All employment, personnel or wage records.
- [ ] All autopsy, laboratory, histology, cytology, pathology, immunohistochemistry records and specimens; radiology records and films including CT scan, MRI, MRA, EMG, bone scan, myleogram; nerve conduction study, echocardiogram and cardiac catheterization results, videos/CDs/films/reels and reports.
- [ ] All pharmacy/prescription records including NDC numbers and drug information handouts/monographs.
- [ ] All billing records including all statements, insurance claim forms, itemized bills, and records of billing to third party payers and payment or denial of benefits for the period _____ to _____.

I understand the information to be released or disclosed may include information relating to sexually transmitted diseases, acquired immunodeficiency syndrome (AIDS), or human

immunodeficiency virus (HIV), and alcohol and drug abuse. I authorize the release or disclosure of this type of information.

This protected health information is disclosed for the following purposes: _____

Research Study Participation

This authorization is given in compliance with the federal consent requirements for release of alcohol or substance abuse records of 42 CFR 2.31, the restrictions of which have been specifically considered and expressly waived.

You are authorized to release the above records to the following representatives of defendants in the above-entitled matter who have agreed to pay reasonable charges made by you to supply copies of such records:

Brian Walitt, MD MPH

Name of Representative

Physician

Representative Capacity (e.g. attorney, records requestor, agent, etc.)

National Institutes of Health
10 Center Drive, Building 10, Room 3B19, MSC 1251

Street Address

Bethesda, MD 20814

City, State and Zip Code

I understand the following: See CFR §164.508(c)(2)(i-iii)

a. I have a right to revoke this authorization in writing at any time, except to the extent information has been released in reliance upon this authorization.
b. The information released in response to this authorization may be re-disclosed to other parties.
c. My treatment or payment for my treatment cannot be conditioned on the signing of this authorization.

Any facsimile, copy or photocopy of the authorization shall authorize you to release the records requested herein. This authorization shall be in force and effect until two years from date of execution at which time this authorization expires.

[redacted] (b) (6)

8/25/2022

Signature of Patient or Legally Authorized Representative — Date

(See 45CFR § 164.508(c)(1)(vi))

_____

Name and Relationship of Legally Authorized Representative to Patient
(See 45CFR §164.508(c)(1)(iv))

_____ _____

Witness Signature — Date

From: Bartrum, Elizabeth (NIH/NINDS) [E]
To: (b) (6)
Cc: Gavin, Angelique (NIH/NINDS) [C]; Ashade, Adedamola (NIH/NINDS) [F]
Subject: COVID 19 Research Study at NIH
Date: Monday, October 17, 2022 11:49:22 AM
Attachments: HIPAA Medical Record Release Blank.pdf

Hi (b) (6) -

I'm so sorry to hear of this devastating experience. There are no words to convey how difficult your life has been for over a year. I'm very sorry.

Thank you for your interest in our study. The next step will be to obtain medical records from you. The records ideally are from a primary medical provider who can document your health in the year prior to vaccination, as well as document your health after vaccination. To begin, we will review from your primary provider, and then if we need additional detail we will request additional records.

I've attached a copy of the medical records release form. Please complete this, sign it and return to me and Angelique Gavin. Once it is completed and we receive the records then we can proceed to the interview and questionnaire portions of the study.

If you have additional questions, please let me know.

My best to you-
Elizabeth

HIPAA COMPLIANT AUTHORIZATION FOR THE RELEASE OF PATIENT INFORMATION PURSUANT TO 45 CFR 164.508

TO: _____
Name of Healthcare Provider/Physician/Facility/Medicare Contractor

_____
Street Address

_____
City, State and Zip Code

RE: Patient Name: _____

Date of Birth: _____ Social Security Number: _____

I authorize and request the disclosure of all protected information for the purpose of review and evaluation in connection with a legal claim. I expressly request that the designated record custodian of all covered entities under HIPAA identified above disclose full and complete protected medical information including the following:

- [x] All medical records, meaning every page in my record, including but not limited to: office notes, face sheets, history and physical, consultation notes, inpatient, outpatient and emergency room treatment, all clinical charts, r ports, order sheets, progress notes, nurse's notes, social worker records, clinic records, treatment plans, admission records, discharge summaries, requests for and reports of consultations, documents, correspondence, test results, statements, questionnaires/histories, correspondence, photographs, videotapes, telephone messages, and records received by other medical providers.
- [ ] All physical, occupational and rehab requests, consultations and progress notes.
- [ ] All disability, Medicaid or Medicare records including claim forms and record of denial of benefits.
- [ ] All employment, personnel or wage records.
- [ ] All autopsy, laboratory, histology, cytology, pathology, immunohistochemistry records and specimens; radiology records and films including CT scan, MRI, MRA, EMG, bone scan, myleogram; nerve conduction study, echocardiogram and cardiac catheterization results, videos/CDs/films/reels and reports.
- [ ] All pharmacy/prescription records including NDC numbers and drug information handouts/monographs.
- [ ] All billing records including all statements, insurance claim forms, itemized bills, and records of billing to third party payers and payment or denial of benefits for the period _____ to _____.

I understand the information to be released or disclosed may include information relating to sexually transmitted diseases, acquired immunodeficiency syndrome (AIDS), or human

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You are authorized to release the above records to the following representatives of defendants in the above-entitled matter who have agreed to pay reasonable charges made by you to supply copies of such records:

Brian Walitt, MD MPH

Name of Representative

Physician

Representative Capacity (e.g. attorney, records requestor, agent, etc.)

National Institutes of Health
10 Center Drive, Building 10, Room 3B19, MSC 1251

Street Address

Bethesda, MD 20814

City, State and Zip Code

I understand the following: See CFR §164.508(c)(2)(i-iii)

a. I have a right to revoke this authorization in writing at any time, except to the extent information has been released in reliance upon this authorization.
b. The information released in response to this authorization may be re-disclosed to other parties.
c. My treatment or payment for my treatment cannot be conditioned on the signing of this authorization.

Any facsimile, copy or photocopy of the authorization shall authorize you to release the records requested herein. This authorization shall be in force and effect until two years from date of execution at which time this authorization expires.

_____ _____

Signature of Patient or Legally Authorized Representative Date
(See 45CFR § 164.508(c)(1)(vi))

_____

Name and Relationship of Legally Authorized Representative to Patient
(See 45CFR §164.508(c)(1)(iv))

_____ _____

Witness Signature Date

From: Bartrum, Elizabeth (NIH/NINDS) [E]
To: (b) (6)
Cc: Gavin, Angelique (NIH/NINDS) [C]; Ashade, Adedamola (NIH/NINDS) [F]; Walitt, Brian (NIH/NINDS) [E]
Subject: RE: COVID 19 Research Study at NIH
Date: Tuesday, November 1, 2022 8:33:00 PM
Attachments: 000089_Phase_A_Vaccination_Consent_Clean_05.17.22.pdf

---

Hi (b) (6) -

We received your outside records, and I reviewed them this evening. I'm so sorry for all that you have been through.

You are eligible for the next portion of the study, which involves the interview. Please provide some dates and times when you are available over the next two weeks for 30 minutes to an hour. During the call we will discuss your health before and after vaccination and review the attached consent form.

Sincerely-
Elizabeth

From: (b) (6) <Office365@messaging.microsoft.com>
Sent: Tuesday, October 25, 2022 1:37 PM
To: Bartrum, Elizabeth (NIH/NINDS) [E] <(b) (6)
Cc: Gavin, Angelique (NIH/NINDS) [C] <(b) (6) Ashade, Adedamola (NIH/NINDS) [F] <(b) (6) (b) (6) <(b) (6) Walitt, Brian (NIH/NINDS) [E] <(b) (6)
Subject: Re: COVID 19 Research Study at NIH

Hello Elizabeth,

I have sent the medical release forms out and you should be getting the information shortly. You will be getting records from:

(b) (6)

Attached to this email:

1)vaccination notes from [redacted] plus all the records they gleamed from the system after I notified them of my adverse reaction.

2) [redacted] notes from ambulance trips [redacted]. I have included this to show my health status at the time of transport.

Please let me know if you do not receive the medical records.

[redacted]

From: Bartrum, Elizabeth (NIH/NINDS) [E] <[redacted]
Sent: Tuesday, October 18, 2022 10:44:58 AM
To: [redacted] <[redacted]
Cc: Gavin, Angelique (NIH/NINDS) [C] <[redacted] Ashade, Adedamola (NIH/NINDS) [F] <[redacted]
Subject: RE: COVID 19 Research Study at NIH

[redacted]-

Thanks so much, and I appreciate you reaching out to our team.

The records you describe will likely be sufficient for what we need. Once we review them, then we can address next steps.

Thanks very much, and I look forward to understanding more about what you have suffered in the past year.

Kind regards-

Elizabeth

From: [redacted] <Office365@messaging.microsoft.com>
Sent: Tuesday, October 18, 2022 10:31 AM
To: Bartrum, Elizabeth (NIH/NINDS) [E] <[redacted]
Cc: Gavin, Angelique (NIH/NINDS) [C] <[redacted] Ashade, Adedamola

(NIH/NINDS) [F] < (b) (6) (b) (6)
< (b) (6)
Subject: Re: COVID 19 Research Study at NIH

Elizabeth,

Thank you for your kind words. It has been challenging, for sure.

I will get the records release completed and sent in. I did not have a primary doctor prior to this happening to me. I was a healthy man and not on any medications. I may of had (b) (6) (b) (6) (b) (6). Other than that I can not recall anything that was not out of the ordinary.

I will have my records from both facilities sent.

Hope this works,

(b) (6)

From: Bartrum, Elizabeth (NIH/NINDS) [E] < (b) (6)
Sent: Monday, October 17, 2022 9:49:04 AM
To: (b) (6) < (b) (6)
Cc: Gavin, Angelique (NIH/NINDS) [C] < (b) (6) Ashade, Adedamola (NIH/NINDS) [F] < (b) (6)
Subject: COVID 19 Research Study at NIH

Hi (b) (6) -

I'm so sorry to hear of this devastating experience. There are no words to convey how difficult your life has been for over a year. I'm very sorry.

Thank you for your interest in our study. The next step will be to obtain medical records from you. The records ideally are from a primary medical provider who can document your health in the year prior to vaccination, as well as document your health after vaccination. To begin, we will review from your primary provider, and then if we need additional detail we will request additional records.

I've attached a copy of the medical records release form. Please complete this, sign it and return to me and Angelique Gavin. Once it is completed and we receive the records then we can proceed to the interview and questionnaire portions of the study.

If you have additional questions, please let me know.

My best to you-

Elizabeth

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

PRINCIPAL INVESTIGATOR: Avi Nath, MD

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

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

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

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

WHY IS THIS STUDY BEING DONE?

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

WHAT WILL HAPPEN DURING THE STUDY?

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

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

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

HOW LONG WILL THE STUDY TAKE?

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

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

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

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

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

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

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

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

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

STORAGE, SHARING AND FUTURE RESEARCH USING YOUR DATA

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

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

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

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

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

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

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

How long will your data be stored by the NIH?

Your data may be stored by the NIH indefinitely.

Risks of storage and sharing of data

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

COMPENSATION

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

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Will your information be kept private?

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

CERTIFICATE OF CONFIDENTIALITY

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

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

The Certificate does not protect your information when it:

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

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

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

Privacy Act

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

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

PROBLEMS OR QUESTIONS

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

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

Study Coordinator: Angelique Gavin , Building/room Building 10/3B19, (b) (6), email- (b) (6)
Lead Associate Investigator: Brian Walitt M.D, M.P.H, Building/room Building 10/3B19, (b) (6) (b) (6), email- (b) (6)
Principal Investigator:, Avindra Nath, M.D., Building/Room 10/7C-103, Telephone (b) (6) (b) (6), email- (b) (6)

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

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

From: Gavin, Angelique (NIH/NINDS) [C]
To: (b) (6)
Subject: FW: NIH COVID-19 Vaccine Study
Date: Wednesday, August 24, 2022 2:34:00 PM
Attachments: HIPAA Medical Record Release Blank.pdf

Thank you (b) (6) for the information you've provided thus far. To determine if you are eligible to proceed, we need medical records to confirm that the symptom onset was after COVID vaccination.

Please complete the attached medical record release form for a medical provider whom managed your care at the onset of symptoms after vaccination. Please return the form to me using this encrypted email and I will obtain the records on your behalf.

Once we have received and reviewed the records, if you are eligible to proceed, we will schedule a telephone interview. Please let me know if you have any additional questions. I look forward to speaking with you very soon.

Sincerely,
Angelique Gavin

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) (6) (office)
(b) (6) (cell)
(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089-N

-

From: NINDSPostCovid19
Sent: Monday, August 15, 2022 2:15 PM
To: (b) (6) < (b) (6)
Subject: RE: NIH COVID-19 Vaccine Study

Thank you (b) (6) for the information you've provided thus far. To determine if you are eligible to proceed, we need medical records to confirm that the symptom onset was after COVID vaccination.

Please complete the attached medical record release form for a medical provider whom managed

your care at the onset of symptoms after vaccination. Please return the form to me using this encrypted email and I will obtain the records on your behalf.

Once we have received and reviewed the records, if you are eligible to proceed, we will schedule a telephone interview. Please let me know if you have any additional questions. I look forward to speaking with you very soon.

Sincerely,
Angelique Gavin

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) (6) (office)
(b) (6) (cell)
(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089-N

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From: (b) (6) < (b) (6)
Sent: Monday, August 15, 2022 1:50 PM
To: Gavin, Angelique (NIH/NINDS) [C] < (b) (6)
Subject: Re: NIH COVID-19 Vaccine Study

Please see vaccine card photos attached.

(b) (6)

From: Gavin, Angelique (NIH/NINDS) [C] < (b) (6)

Sent: Monday, August 15, 2022 11:11 AM
To: (b) (6) < (b) (6)
Subject: [EXTERNAL] RE: NIH COVID-19 Vaccine Study

Thank you (b) (6) for your response. Please send me a copy of your vaccine card, front and back. Once received, we can determine if you are eligible to move forward in the study.

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) (6) (office)
(b) (6) (cell)
(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089-N

-

From: (b) (6) < (b) (6)
Sent: Friday, August 12, 2022 3:25 PM
To: Gavin, Angelique (NIH/NINDS) [C] < (b) (6)
Subject: Re: NIH COVID-19 Vaccine Study

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

□□□ What is your full name?
□□□
(b) (6)

□□□ What is your preferred phone number?

(b) (6)

□□□ How old are you?

(b) (6)

□□□ Are you fluent in speaking, reading and writing English? Yes /No

Yes

5. Do you live in the United States? Yes/No

Yes

a. If yes, please provide the city, state and zip code where you live.

(b) (6)

□□□ Are you an NIH employee, contractor, trainee or otherwise affiliated with the NIH? Yes/No

No

7. Have you had a COVID-19 infection? Yes/No/Unsure

(b) (6)

a. If yes, how many COVID-19 infections have you had?

(b) (6)

b. What is the date of your first COVID-19 infection?

(b) (6)

c. Are you having persistent side effects after your first COVID-19 infection? Yes No

(b) (6)

d. Do you have test results confirming your COVID 19 infection? Yes No

e. If you responded yes, please provide a copy of your COVID 19 test results with your email response.
For tests performed at a laboratory or by a medical provider, results need to include your name, date of test result, type of test, and result of test. If you do not have a copy

of your test result, please let us know and we can assist you in obtaining your records from your medical lab or provider.
For tests performed using a home testing kit, a photograph of the results with time and date are required.

8. Have you received a COVID-19 vaccine? Yes No

YES

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

YES

(b) (6)

From: Gavin, Angelique (NIH/NINDS) [C] < (b) (6)
Sent: Monday, August 8, 2022 4:17 PM
To: (b) (6) < (b) (6)
Subject: [EXTERNAL] NIH COVID-19 Vaccine Study

Good Day (b) (6):

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

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

involves a phone interview and online questionnaires.

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

□□□ What is your full name?

□□□ What is your preferred phone number?

□□□ How old are you?

□□□ Are you fluent in speaking, reading and writing English? Yes /No

5. Do you live in the United States? Yes/No
a. If yes, please provide the city, state and zip code where you live.

□□□ Are you an NIH employee, contractor, trainee or otherwise affiliated with the NIH? Yes/No

7. Have you had a COVID-19 infection? Yes/No/Unsure
a. If yes, how many COVID-19 infections have you had?
b. What is the date of your first COVID-19 infection?
c. Are you having persistent side effects after your first COVID-19 infection? Yes No
d. Do you have test results confirming your COVID 19 infection? Yes No
e. If you responded yes, please provide a copy of your COVID 19 test results with your email response.
For tests performed at a laboratory or by a medical provider, results need to include your name, date of test result, type of test, and result of test. If you do not have a copy of your test result, please let us know and we can assist you in obtaining your records from your medical lab or provider.
For tests performed using a home testing kit, a photograph of the results with time and date are required.

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

When you respond to this email, please provide answers to each question above, as well as a Copy of your COVID-19 test results and/or the front and back of your COVID-19 vaccination card, if applicable.
Your responses and documentation will allow us to determine if you are eligible for our research

study. If you do not answer all questions or provide the requested documentation, you will not be considered for the study. If you wish to provide a short summary of your condition, we invite you to.

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

Thank you,
Angelique Gavin
COVID 19 Convalescence Study Team

Angelique Gavin, MS (Contractor)
NIH/NINDS Clinical Operations Manager
Contractor Preferred Solutions Group
National Institutes of Health
10 Center Drive
Building 10, Room 3B19, MSC 1251
Bethesda, MD 20814-9692
(b) (6) (office)
(b) (6) (cell)
(301) 480-5368 (efax)
(b) (6)
https://clinicaltrials.gov - study number 000089-N

HIPAA COMPLIANT AUTHORIZATION FOR THE RELEASE OF PATIENT INFORMATION PURSUANT TO 45 CFR 164.508

TO: _____
Name of Healthcare Provider/Physician/Facility/Medicare Contractor

_____
Street Address

_____
City, State and Zip Code

RE: Patient Name: _____

Date of Birth: _____ Social Security Number: _____

I authorize and request the disclosure of all protected information for the purpose of review and evaluation in connection with a legal claim. I expressly request that the designated record custodian of all covered entities under HIPAA identified above disclose full and complete protected medical information including the following:

- [x] All medical records, meaning every page in my record, including but not limited to: office notes, face sheets, history and physical, consultation notes, inpatient, outpatient and emergency room treatment, all clinical charts, r ports, order sheets, progress notes, nurse's notes, social worker records, clinic records, treatment plans, admission records, discharge summaries, requests for and reports of consultations, documents, correspondence, test results, statements, questionnaires/histories, correspondence, photographs, videotapes, telephone messages, and records received by other medical providers.
- [ ] All physical, occupational and rehab requests, consultations and progress notes.
- [ ] All disability, Medicaid or Medicare records including claim forms and record of denial of benefits.
- [ ] All employment, personnel or wage records.
- [ ] All autopsy, laboratory, histology, cytology, pathology, immunohistochemistry records and specimens; radiology records and films including CT scan, MRI, MRA, EMG, bone scan, myleogram; nerve conduction study, echocardiogram and cardiac catheterization results, videos/CDs/films/reels and reports.
- [ ] All pharmacy/prescription records including NDC numbers and drug information handouts/monographs.
- [ ] All billing records including all statements, insurance claim forms, itemized bills, and records of billing to third party payers and payment or denial of benefits for the period _____ to _____.

I understand the information to be released or disclosed may include information relating to sexually transmitted diseases, acquired immunodeficiency syndrome (AIDS), or human

immunodeficiency virus (HIV), and alcohol and drug abuse. I authorize the release or disclosure of this type of information.

This protected health information is disclosed for the following purposes: _____

Research Study Participation

This authorization is given in compliance with the federal consent requirements for release of alcohol or substance abuse records of 42 CFR 2.31, the restrictions of which have been specifically considered and expressly waived.

You are authorized to release the above records to the following representatives of defendants in the above-entitled matter who have agreed to pay reasonable charges made by you to supply copies of such records:

Brian Walitt, MD MPH

Name of Representative

Physician

Representative Capacity (e.g. attorney, records requestor, agent, etc.)

National Institutes of Health
10 Center Drive, Building 10, Room 3B19, MSC 1251

Street Address

Bethesda, MD 20814

City, State and Zip Code

I understand the following: See CFR §164.508(c)(2)(i-iii)

a. I have a right to revoke this authorization in writing at any time, except to the extent information has been released in reliance upon this authorization.
b. The information released in response to this authorization may be re-disclosed to other parties.
c. My treatment or payment for my treatment cannot be conditioned on the signing of this authorization.

Any facsimile, copy or photocopy of the authorization shall authorize you to release the records requested herein. This authorization shall be in force and effect until two years from date of execution at which time this authorization expires.

_____ _____

Signature of Patient or Legally Authorized Representative Date
(See 45CFR § 164.508(c)(1)(vi))

_____

Name and Relationship of Legally Authorized Representative to Patient
(See 45CFR §164.508(c)(1)(iv))

_____ _____

Witness Signature Date