From: Wiebold, Amanda (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4491EE2AE9804610899C741100150540 b6]
Sent: 5/4/2021 6:05:24 PM
To: b6
Subject: Consent Form
Attachments: 15N0125 Samples Only Consent.pdf

Amanda Wiebold, BSN, RN, CNRN
Research Nurse Specialist
NINDS Section of Infections of the Nervous System
10 Center Drive, Building 10/7C107, MSC 1430
Bethesda, Maryland 20892
Office: b6
Cell: b6
Fax: 301-480-5594
Email: b6

PRINCIPAL INVESTIGATOR: Avindra Nath, MD

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

STUDY SITE: NIH Clinical Center

Cohort: Biological Samples Only Consent

Consent Version: 03/17/2020

WHO DO YOU CONTACT ABOUT THIS STUDY?

Principal Investigator: Avindra Nath, MD, b6

Study Coordinator: Amanda Wiebold, RN,

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

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

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

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

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

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

WHY IS THIS STUDY BEING DONE?

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

BACKGROUND

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

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

STUDY POPULATION

Up to 1000 people will take part in this study.

•

PROCEDURES/STUDY OVERVIEW

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

Induced Pluripotent Stem Cells (iPS)

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

Genetic Testing

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

1. It may be analyzed to identify the genes that might be causing your condition. This will help us understand how changes in the genes may cause symptoms. Genetic testing can be helpful in establishing a diagnosis. It may eventually lead to improved treatment or prevention.

2. To try to identify genetic changes that may be associated with your condition we may sequence the part of the DNA that provides instructions for making proteins, called the "exome." The exome makes up about 1% of your DNA.

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

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

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

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

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

Banking and Sharing

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

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

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

RISKS, INCONVENIENCES AND DISCOMFORTS

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

Genetic Testing

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

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

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

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

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

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

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

Banking and Sharing

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

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

ANTICIPATED BENEFITS

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

RIGHT OF WITHDRAWAL AND CONDITIONS FOR EARLY WITHDRAWAL

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

CONFLICT OF INTEREST

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

RESULTS FROM THIS STUDY

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

ALTERNATIVES TO PARTICIPATION

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

COMPENSATION, REIMBURSEMENT, AND PAYMENT

Will you receive compensation for participation in the study?

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

You will not receive compensation for participation in this study.

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

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

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

Will taking part in this research study cost you anything?

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

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Will your medical information be kept private?

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

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

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

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

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

Certificate of Confidentiality

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

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

The Certificate does not protect your information when it:

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

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

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

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

Privacy Act

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

POLICY REGARDING RESEARCH-RELATED INJURIES

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

PROBLEMS OR QUESTIONS

If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator Avindra Nath, MD, b6 You may also call the NIH Clinical Center Patient Representative at 301-496-2626, or the NIH Office of IRB Operations at 301-402-3713, if you have a research-related complaint or concern.

CONSENT DOCUMENT

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

Adult Research Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to participate in this study.

Signature of Research Participant	Print Name of Research Participant	Date

Legally Authorized Representative (LAR) for an Adult Unable to Consent: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I am legally authorized to make research decisions on behalf of the adult participant unable to consent and have the authority to provide consent to this study. As applicable, the information in the above consent was described to the adult participant unable to consent who agrees to participate in the study.

Signature of LAR	Print Name of LAR	Date

Parent/Guardian of a Minor Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I give permission for my child to take part in this study.

Signature of Parent/Guardian	Print Name of Parent/Guardian	Date
Signature of Parent/Guardian *(as applicable)*	Print Name of Parent/Guardian	Date

Assent: *(Use this section only when this process is approved by an IRB for older minors. Do not use if an IRB requires a separate assent form for this population.)*

I have had this study explained to me in a way that I understand, I have been given the opportunity to discuss it, and I have had the chance to ask questions. I agree to take part in this study.

Assent of Minor: *(as applicable)*

Signature of Minor	Print Name of Minor	Date

Investigator:

Signature of Investigator	Print Name of Investigator	Date

Witness to the oral short-form consent process only: This section is only required if you are doing the oral short-consent process and this English consent form has been approved by the IRB for use as the basis of translation.

Witness:

Signature of Witness*	Print Name of Witness	Date

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

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

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

From: Safavi, Farinaz (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=94807CE146E045D4B61655DA26A0C246 b6

Sent: 9/29/2021 3:13:32 PM

To: b6 Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540 b6

Subject: question

Hello b6

I discussed your case in our team again. b6

b6

Hope it helps.

Best Regards

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

From: b6
Sent: 1/6/2022 10:51:34 PM
To: Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540 b6
Subject: [EXTERNAL] Re: b6

Thanks

Sent from my iPhone

On Jan 6, 2022, at 4:50 PM, Wiebold, Amanda (NIH/NINDS) [E] b6 wrote:

Happy New Year b6

I have sent them your request. If you don't hear back from anyone in the next couple of days just let me know and I will follow up.

Thanks,
Amanda

From: b6
Sent: Thursday, January 6, 2022 3:04 PM
To: Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: [EXTERNAL] b6

Hello Ms. Amanda
Happy New Year
Hope everything is fine with you.

b6

Wish you well.

b6

Thank you

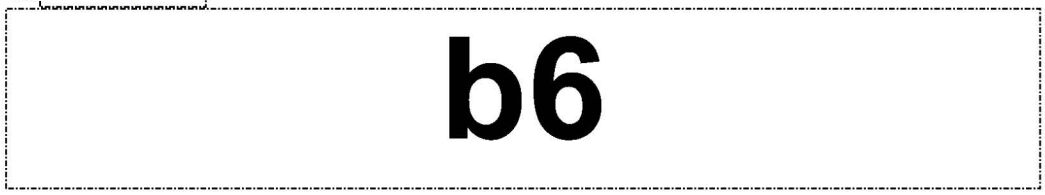
From: b6
Sent: Monday, November 29, 2021 6:41 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Cc: Wiebold, Amanda (NIH/NINDS) [E]
Subject: Re: née Question

Thank you very much

Sent from my iPhone

On Nov 29, 2021, at 6:38 PM, Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Hi b6



Farinaz

From: Wiebold, Amanda (NIH/NINDS) [E] b6
Sent: Wednesday, November 24, 2021 12:44:22 PM
To: b6
Subject: RE: née Question

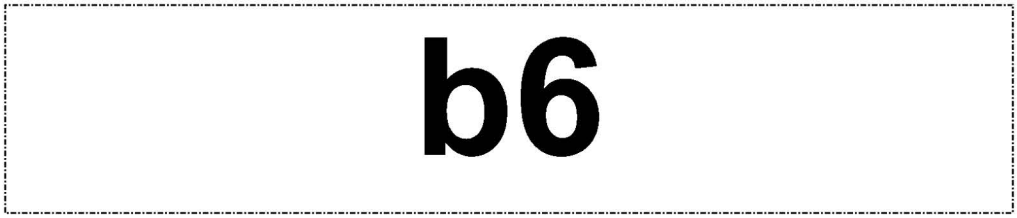
Hello b6

Happy Thanksgiving to you as well! I am sending your questions to Dr. Safavi for her to follow up on.

Thank you,
Amanda

From: b6
Sent: Wednesday, November 24, 2021 11:12 AM
To: Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: Re: née Question

Hi Dear Amanda
Good morning.
I have two questions for Dr. Safavi



Thank you for time and effort.
Happy Thanksgiving

b6

From: b6
Sent: Monday, September 27, 2021 12:11 PM
To: Wiebold, Amanda (NIH/NINDS) [E]
Subject: Re: Question

Great, thank you so much!

From: Wiebold, Amanda (NIH/NINDS) [E] b6
Sent: Monday, September 27, 2021 11:58:42 AM
To: b6
Subject: RE: Question

Good afternoon b6

I have passed along your question to our study doctors as they would be better able to answer your questions. Please let me know if you need anything else.

Thank you,
Amanda

From: b6
Sent: Monday, September 27, 2021 12:41 PM
To: Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: Question

Hello Ms. Amanda
Good afternoon
b6
Thank you
b6

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Sent: 5/5/2021 8:33:35 PM
To: b6
Subject: RE: Consent Form b6
Attachments: b6

b6

Your kit should arrive tomorrow. Please make sure to have your blood collected before 11:00 am on a Monday, Tuesday, Wednesday, or Thursday not before a holiday in order for us to receive the blood the following morning. We are not in the lab to receive the blood on weekends or holidays. Since the pandemic not all Quest locations allow for walk-ins. Please go to https://appointment.questdiagnostics.com/patient/confirmation to see if you need to make an appointment for the one closest to you. Please review the instructions below and let me know if you have any questions.

Patient Instructions

1) When you receive the box, open it and remove the cold packs from the box and place them inside of your freezer.
2) Do Not Discard the Cardboard Box. You will need everything sent to you. Please make sure to remove all shipping labels before giving to Quest.
3) On the day of collection, remove the cold packs from your freezer and place them back in the bottom of the box.
4) Take the box with all the contents inside to the collection center.
5) Give the kit along with the green sheet and the orange sheet(s) to Quest.
6) If you have any questions, contact Amanda Wiebold at b6

Please let me know when you are scheduled for your blood draw so we can make arrangements with our lab to receive it the next morning.

I have also attached a copy of your countersigned consent form for your records.

Thank you,
Amanda

From: b6
Sent: Tuesday, May 4, 2021 2:38 PM
To: Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: Re: Consent Form b6

b6

From: Wiebold, Amanda (NIH/NINDS) [E] b6
Sent: Tuesday, May 4, 2021 1:05 PM
To: b6
Subject: Consent Form

Amanda Wiebold, BSN, RN, CNRN
Research Nurse Specialist
NINDS Section of Infections of the Nervous System
10 Center Drive, Building 10/7C107, MSC 1430
Bethesda, Maryland 20892
Office: b6
Cell: b6
Fax: 301-480-5594
Email: b6

PRINCIPAL INVESTIGATOR: Avindra Nath, MD

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

STUDY SITE: NIH Clinical Center

Cohort: Biological Samples Only Consent

Consent Version: 03/17/2020

WHO DO YOU CONTACT ABOUT THIS STUDY?

Principal Investigator: Avindra Nath, MD, b6

Study Coordinator: Amanda Wiebold, RN,

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

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BACKGROUND

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STUDY POPULATION

Up to 1000 people will take part in this study.

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PROCEDURES/STUDY OVERVIEW

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

Induced Pluripotent Stem Cells (iPS)

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

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

Banking and Sharing

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

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

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

RISKS, INCONVENIENCES AND DISCOMFORTS

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

Genetic Testing

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

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

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

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

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

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

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

Banking and Sharing

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

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

ANTICIPATED BENEFITS

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

RIGHT OF WITHDRAWAL AND CONDITIONS FOR EARLY WITHDRAWAL

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

CONFLICT OF INTEREST

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

RESULTS FROM THIS STUDY

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

ALTERNATIVES TO PARTICIPATION

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

COMPENSATION, REIMBURSEMENT, AND PAYMENT

Will you receive compensation for participation in the study?

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

You will not receive compensation for participation in this study.

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

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

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

Will taking part in this research study cost you anything?

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

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Will your medical information be kept private?

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

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

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

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

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

Certificate of Confidentiality

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

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

The Certificate does not protect your information when it:

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

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

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

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

Privacy Act

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

POLICY REGARDING RESEARCH-RELATED INJURIES

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

PROBLEMS OR QUESTIONS

If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator Avindra Nath, MD, b6 You may also call the NIH Clinical Center Patient Representative at 301-496-2626, or the NIH Office of IRB Operations at 301-402-3713, if you have a research-related complaint or concern.

CONSENT DOCUMENT

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

MEDICAL RECORD	CONSENT TO PARTICIPATE IN AN NIH CLINICAL RESEARCH STUDY

Adult Research Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to participate in this study.

b6 | b6 | May 5/4/2021

Signature of Research Participant | Print Name of Research Participant | Date

Legally Authorized Representative (LAR) for an Adult Unable to Consent: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I am legally authorized to make research decisions on behalf of the adult participant unable to consent and have the authority to provide consent to this study. As applicable, the information in the above consent was described to the adult participant unable to consent who agrees to participate in the study.

Signature of LAR | Print Name of LAR | Date

Parent/Guardian of a Minor Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I give permission for my child to take part in this study.

Signature of Parent/Guardian | Print Name of Parent/Guardian | Date

Signature of Parent/Guardian *(as applicable)* | Print Name of Parent/Guardian | Date

Assent: *(Use this section only when this process is approved by an IRB for older minors. Do not use if an IRB requires a separate assent form for this population.)*

I have had this study explained to me in a way that I understand. I have been given the opportunity to discuss it, and I have had the chance to ask questions. I agree to take part in this study.

Assent of Minor: *(as applicable)*

Signature of Minor | Print Name of Minor | Date

Investigator:

b6 | Amanda Niebaad | 5/4/21

Print Name of Investigator | Date

Witness to the oral short-form consent process only: This section is only required if you are doing the oral short-consent process and this English consent form has been approved by the IRB for use as the basis of translation.

Witness:

Signature of Witness*	Print Name of Witness	Date

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

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

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

From: b6
Sent: 5/4/2021 6:37:40 PM
To: Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540 b6
Subject: Re: Consent Form b6
Attachments: NIH Research 001.jpg

b6

From: Wiebold, Amanda (NIH/NINDS) [E] b6
Sent: Tuesday, May 4, 2021 1:05 PM
To: b6
Subject: Consent Form

Amanda Wiebold, BSN, RN, CNRN
Research Nurse Specialist
NINDS Section of Infections of the Nervous System
10 Center Drive, Building 10/7C107, MSC 1430
Bethesda, Maryland 20892
Office: b6
Cell: b6
Fax: 301-480-5594
Email: b6

MEDICAL RECORD	CONSENT TO PARTICIPATE IN AN NIH CLINICAL RESEARCH STUDY

Adult Research Participant: I have read the explanation about this study and have been given the opportunity [illegible] to participate in this study.

b6 b6 May 4 2021

Signature of Research Participant | Print Name of Research Participant | Date

Legally Authorized Representative (LAR) for an Adult Unable to Consent: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I am legally authorized to make research decisions on behalf of the adult participant unable to consent and have the authority to provide consent to this study. As applicable, the information in the above consent was described to the adult participant unable to consent who agrees to participate in the study.

Signature of LAR | Print Name of LAR | Date

Parent/Guardian of a Minor Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I give permission for my child to take part in this study.

Signature of Parent/Guardian | Print Name of Parent/Guardian | Date

Signature of Parent/Guardian *(as applicable)* | Print Name of Parent/Guardian | Date

Assent: *(Use this section only when this process is approved by an IRB for older minors. Do not use if an IRB requires a separate assent form for this population.)*

I have had this study explained to me in a way that I understand, I have been given the opportunity to discuss it, and I have had the chance to ask questions. I agree to take part in this study.

Assent of Minor: *(as applicable)*

Signature of Minor | Print Name of Minor | Date

Investigator:

Signature of Investigator | Print Name of Investigator | Date

Witness to the oral short-form consent process only: This section is only required if you are doing the oral short-consent process and this English consent form has been approved by the IRB for use as the basis of translation.

From: b6
Sent: 1/10/2022 2:15:45 PM
To: Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540 b6
Subject: [EXTERNAL] Re: b6
Attachments: b6

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

Thank you very much

Sent from my iPhone

On Jan 10, 2022, at 8:00 AM, Wiebold, Amanda (NIH/NINDS) [E] b6 wrote:

b6

Please see the attached letter.

Thank you,
Amanda

From: b6
Sent: Thursday, January 6, 2022 7:16 PM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Cc: Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: [EXTERNAL] Re: b6

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

Hello Dr. Safavi
Thank you for your quick response.

b6

Sent from my iPhone

On Jan 6, 2022, at 6:09 PM, Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Hi b6
We can give you a letter. Can you please confirm b6
b6

Thank you

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

b6

From: b6
Sent: 2/23/2022 1:07:09 AM
To: Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540-b6
Subject: Re: [EXTERNAL] b6

Thank you

On Tue, Feb 22, 2022 at 7:54 PM Wiebold, Amanda (NIH/NINDS) [E] b6 wrote:

Of course. Her MD license number is b6

Thanks,

Amanda

From: b6
Sent: Tuesday, February 22, 2022 2:23 PM
To: Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: [EXTERNAL] b6

Hi,

I have to submit Dr. Safavi's licence number with b6 I have tried to google her public license number but cannot find it. Can you please send it to me? I have also emailed her.

Thanks

b6

From: b6
Sent: 3/2/2022 2:35:22 PM
To: Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540-b6
Subject: Re: [EXTERNAL] b6

Thank you.
b6

On Wed, Mar 2, 2022 at 8:41 AM Wiebold, Amanda (NIH/NINDS) [E] b6 wrote:

Hi b6

The form you needed signed is attached. Let me know if you need anything else.

Thank you,

Amanda

From: b6
Sent: Monday, February 28, 2022 10:10 PM
To: Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: Re: [EXTERNAL] b6

Hi Amanda,

b6

Thank you

b6

On Tue, Feb 22, 2022 at 7:54 PM Wiebold, Amanda (NIH/NINDS) [E] b6 wrote:

Of course. Her MD license number is b6

Thanks,

Amanda

From: b6
Sent: Tuesday, February 22, 2022 2:23 PM
To: Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: [EXTERNAL] b6

Hi,

I have to submit Dr. Safavi's licence number with b6 I have tried to google her public license number but cannot find it. Can you please send it to me? I have also emailed her.

Thanks

b6

From: Wiebold, Amanda (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4491EE2AE9804610899C741100150540-b6]
Sent: 3/2/2022 1:41:47 PM
To: b6
Subject: RE: [EXTERNAL] b6
Attachments: b6

Hi b6

The form you needed signed is attached. Let me know if you need anything else.

Thank you,
Amanda

From: b6
Sent: Monday, February 28, 2022 10:10 PM
To: Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: Re: [EXTERNAL] b6

Hi Amanda,

b6

Thank you
b6

On Tue, Feb 22, 2022 at 7:54 PM Wiebold, Amanda (NIH/NINDS) [E] b6 wrote:

> Of course. Her MD license number is b6
>
> Thanks,
>
> Amanda

From: b6
Sent: Tuesday, February 22, 2022 2:23 PM
To: Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: [EXTERNAL] b6

Hi,

I have to submit Dr. Safavi's licence number with b6 I have tried to google her public license number but cannot find it. Can you please send it to me? I have also emailed her.

Thanks

b6

b6

From: Wiebold, Amanda (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4491EE2AE9804610899C741100150540 b6
Sent: 1/26/2022 6:23:25 PM
To: Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 b6
b6
Subject: RE: [EXTERNAL] b6
Attachments: b6

Hello b6

Please see the attached letter.

Thanks,
Amanda

From: Safavi, Farinaz (NIH/NINDS) [E] b6
Sent: Friday, January 21, 2022 3:04 PM
To: b6 Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: RE: [EXTERNAL] b6

Hi b6
We can give you that letter.I will draft it and get approval from Dr.Nath and Amanda will send you the final version.
Hope it helps.
Best
Farinaz

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

From: b6
Sent: Wednesday, January 19, 2022 10:14 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: [EXTERNAL] b6

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

Hi,

b6

If you have any question, please let me know.

Thanks!

b6

b6

From: Nath, Avindra (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B81CA051950B4D458D74037A6A86EAD6 b6
Sent: 2/25/2021 7:33:47 PM
To: b6 Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 b6 Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540 b6
Subject: FW: Your offer to see b6 experiencing long term post-vaccination symptoms
Attachments: b6

Dear b6
Sorry to hear of your illness. Dr. Safavi and I will be glad to meet with you to see how we can help. I have copied other members of our team who can help set up a virtual meeting.
All the best.
Avi
Avindra Nath MD
Chief, Section of Infections of the Nervous System
Clinical Director,
National Institute of Neurological Disorders and Stroke
National Institutes of Health, Bethesda, MD
b6 (Office)
(cell)
b6

From: b6
Date: Thursday, February 25, 2021 at 2:14 PM
To: "Nath, Avindra (NIH/NINDS) [E]" b6
Cc: b6
Subject: Your offer to see b6 experiencing long term post-vaccination symptoms

Dr. Nath,

b6 was nice enough to share with me your kind offer to meet with b6 who is having persistent symptoms after her vaccination. She saw our allergy and immunologist on Wednesday, and in follow up today I learned that she is still having symptoms, so we would like to take you up on this opportunity. Per your suggestion, I'll share your contact information with the patient.

I'm attaching a timeline summary of the workup that has occurred so far, for your reference, also including b6 contact information. I did not give her your cellphone but I gave her your office number and email. Let me know if I should do differently, and if easier I'm sure she'd be fine if your office reached out to her as well.

This is a big relief to us, that we have another avenue for further workup for b6 You have my deep personal appreciation for this- I hope we can do something to help you in the future. You were independently recommended by both b6

Here is the patient's contact information:
b6

b6

With Appreciation,
b6

PS- we're so honored to be working with b6 –she comes with such a rich background from b6

b6

b6

b6

b6

From: b6
Sent: 3/1/2022 9:52:19 PM
To: Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540 b6
Subject: Re: [EXTERNAL] b6

Thank you for the update.
b6

On Tue, Mar 1, 2022 at 4:50 PM Wiebold, Amanda (NIH/NINDS) [E] b6 wrote:

Hi b6

I forwarded to Dr. Nath today for him to complete. I know he has been in meetings all day today and I expect him to return it to me this evening. Dr. Safavi is out of town.

Thanks,

Amanda

From: b6
Sent: Tuesday, March 1, 2022 4:42 PM
To: Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: Re: [EXTERNAL] b6

Hi Amanda,

My email above is extremely time sensitive. Can you please let me know the status of this form? It is due in 2 days.

Thank you.

b6

On Mon, Feb 28, 2022 at 10:10 PM b6 wrote:

Hi Amanda,

b6

Can you please give this form to Dr. Safavi and send it back to me.

Thank you

b6

On Tue, Feb 22, 2022 at 7:54 PM Wiebold, Amanda (NIH/NINDS) [E] b6 wrote:

Of course. Her MD license number is b6

Thanks,

Amanda

From: b6
Sent: Tuesday, February 22, 2022 2:23 PM
To: Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: [EXTERNAL] b6

Hi,

I have to submit Dr. Safavi's licence number with b6 I have tried to google her public license number but cannot find it. Can you please send it to me? I have also emailed her.

Thanks

b6

From: b6
Sent: 3/1/2022 3:10:09 AM
To: Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540 b6
Subject: Re: [EXTERNAL] b6
Attachments: b6

Hi Amanda,

b6

Can you please give this form to Dr. Safavi and send it back to me.

Thank you
b6

On Tue, Feb 22, 2022 at 7:54 PM Wiebold, Amanda (NIH/NINDS) [E] b6 wrote:

Of course. Her MD license number is b6

Thanks,

Amanda

From: b6
Sent: Tuesday, February 22, 2022 2:23 PM
To: Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: [EXTERNAL] b6

Hi,

I have to submit Dr. Safavi's licence number with b6 I have tried to google her public license number but cannot find it. Can you please send it to me? I have also emailed her.

Thanks

b6

b6

From: b6
Sent: 3/1/2021 2:06:22 PM
To: Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540 b6
Subject: Re: Your offer to see b6 experiencing long term post-vaccination symptoms

Hi Amanda,
I am so sorry. Can we please switch the day to March 3, 2021 at 4:30 PM? I can do any time that day.
Thank you.
b6

On Thu, Feb 25, 2021 at 6:39 PM b6 wrote:

Hi,
Let's do March 2nd @12:30.
Thank you
b6

Sent from my iPhone

> On Feb 25, 2021, at 5:59 PM, Wiebold, Amanda (NIH/NINDS) [E] b6 wrote:
>
> Hello b6
>
> I am happy to schedule a virtual meeting. Which time below would work for you?
>
> March 2, 2021 at 12:30 PM?
>
> March 3, 2021 at 4:30 PM?
>
> March 11, 2021 at 3:00 PM?
>
> March 12, 2021 at 1:00 PM?
>
> Thank you,
>
> Amanda

From: Nath, Avindra (NIH/NINDS) [E] b6
Sent: Thursday, February 25, 2021 2:34 PM
To: b6 Safavi, Farinaz (NIH/NINDS) [E] b6
Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: FW: Your offer to see b6 experiencing long term post-vaccination symptoms

Dear b6

Sorry to hear of your illness. Dr. Safavi and I will be glad to meet with you to see how we can help. I have copied other members of our team who can help set up a virtual meeting.

All the best.

Avi

Avindra Nath MD

Chief, Section of Infections of the Nervous System

Clinical Director,

National Institute of Neurological Disorders and Stroke

National Institutes of Health, Bethesda, MD

b6 (Office)

(cell)

b6

From: b6
Date: Thursday, February 25, 2021 at 2:14 PM
To: "Nath, Avindra (NIH/NINDS) [E]" b6
Cc: b6
Subject: Your offer to see b6 experiencing long term post-vaccination symptoms

Dr. Nath,

b6 was nice enough to share with me your kind offer to meet with b6 who is having persistent symptoms after her vaccination. She saw our allergy and immunologist on Wednesday, and in follow up today I learned that she is still having symptoms, so we would like to take you up on this opportunity. Per your suggestion, I'll share your contact information with the patient.

I'm attaching a timeline summary of the workup that has occurred so far, for your reference, also including b6 contact information. I did not give her your cellphone but I gave her your office number and email. Let me know if I should do differently, and if easier I'm sure she'd be fine if your office reached out to her as well.

This is a big relief to us, that we have another avenue for further workup for b6 You have my deep personal appreciation for this- I hope we can do something to help you in the future. You were independently recommended by both b6
b6

Here is the patient's contact information:

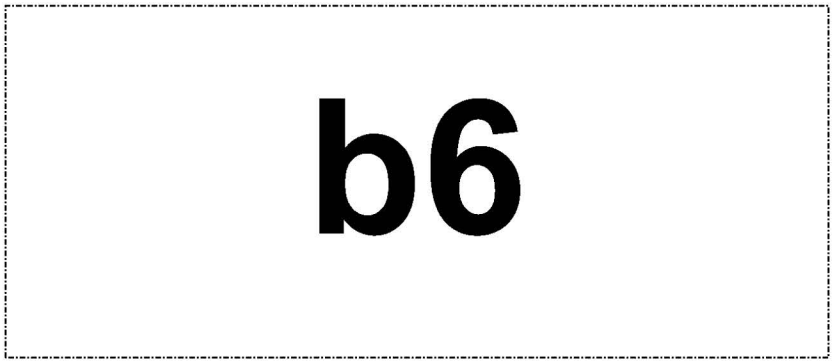
b6

With Appreciation,

b6

PS- we're so honored to be working with b6 –she comes with such a rich background from
b6

b6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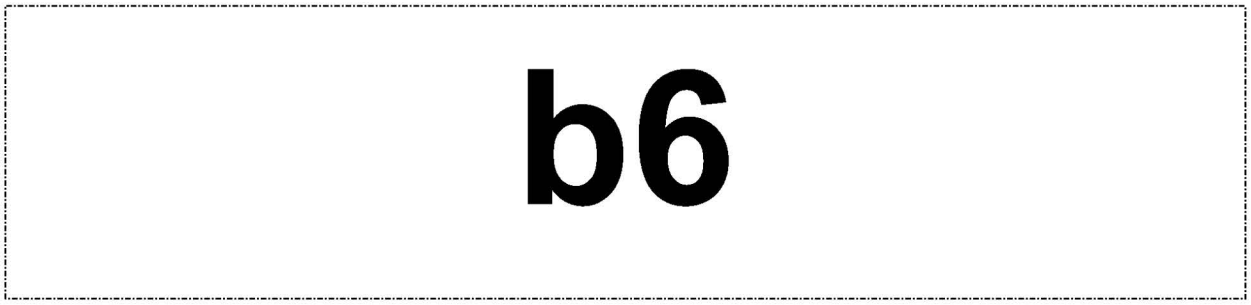
b6

From: b6
Sent: 2/27/2021 7:49:38 PM
To: Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540-b6
Subject: Re: Your offer to see b6 experiencing long term post-vaccination symptoms

Hi Amanda,
I am so sorry. Can we please switch the day to March 3, 2021 at 4:30 PM? I can do any time that day.
Thank you.

b6

On Thu, Feb 25, 2021 at 6:39 PM b6 wrote:

Hi,
Let's do March 2nd @12:30.
Thank you
b6

Sent from my iPhone

> On Feb 25, 2021, at 5:59 PM, Wiebold, Amanda (NIH/NINDS) [E]
> b6 wrote:
>
> Hello b6
>
> I am happy to schedule a virtual meeting. Which time below would work for you?
>
> March 2, 2021 at 12:30 PM?
>
> March 3, 2021 at 4:30 PM?
>
> March 11, 2021 at 3:00 PM?
>
> March 12, 2021 at 1:00 PM?
>
> Thank you,
>
> Amanda

From: Nath, Avindra (NIH/NINDS) [E] b6
Sent: Thursday, February 25, 2021 2:34 PM
To: b6 Safavi, Farinaz (NIH/NINDS) [E] b6
Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: FW: Your offer to see b6 experiencing long term post-vaccination symptoms

Dear b6

Sorry to hear of your illness. Dr. Safavi and I will be glad to meet with you to see how we can help. I have copied other members of our team who can help set up a virtual meeting.

All the best.

Avi

Avindra Nath MD

Chief, Section of Infections of the Nervous System

Clinical Director,

National Institute of Neurological Disorders and Stroke

National Institutes of Health, Bethesda, MD

b6 (Office)

(cell)

b6

From: b6
Date: Thursday, February 25, 2021 at 2:14 PM
To: "Nath, Avindra (NIH/NINDS) [E]" b6
Cc: b6
Subject: Your offer to see b6 experiencing long term post-vaccination symptoms

Dr. Nath,

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I'm attaching a timeline summary of the workup that has occurred so far, for your reference, also including b6 contact information. I did not give her your cellphone but I gave her your office number and email. Let me know if I should do differently, and if easier I'm sure she'd be fine if your office reached out to her as well.

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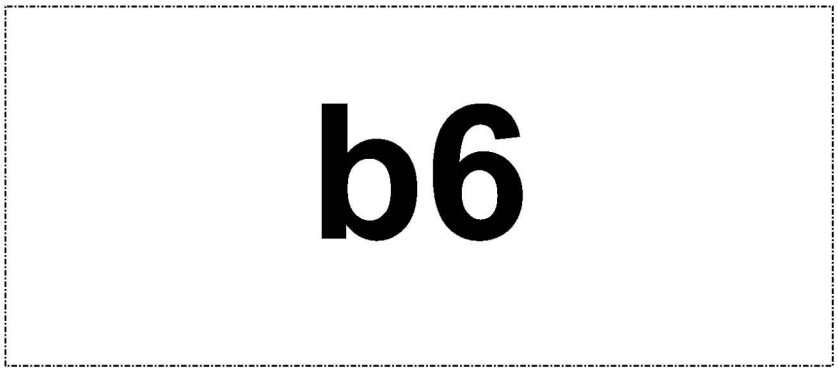
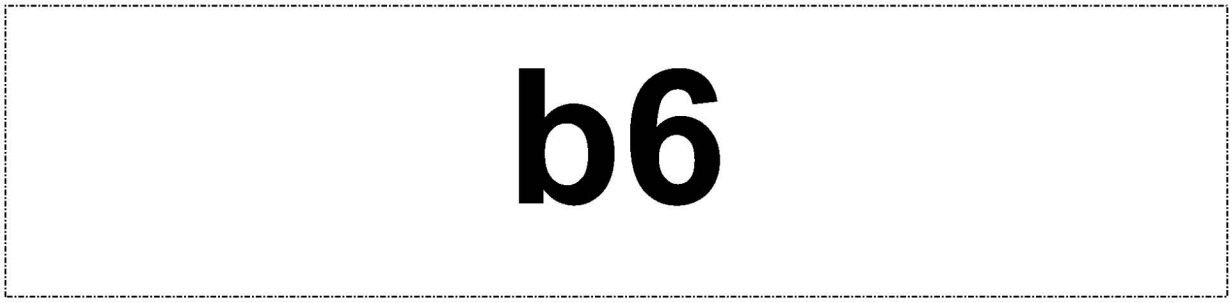
b6


b6


b6

From: Wiebold, Amanda (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4491EE2AE9804610899C741100150540-b6]
Sent: 10/14/2021 4:17:38 PM
To: b6
CC: Nahar, Kymani (NIH/NINDS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f432f899337490ea7cbde0a4b52effb-b6]
Subject: RE: Referral from b6
Attachments: 15N0125 Standard Consent.pdf

b6

As Dr. Safavi has mentioned she would like to evaluate you here at the NIH under our natural history protocol 15N0125. I have attached a copy of the consent form just for your review. The studies that she would like you to do include consent, exam, blood work, brain MRI with contrast, lumbar puncture done under x-ray, skin biopsy, EMG, and autonomic testing. Please let Dr. Safavi or myself know if you have any questions.

Kymani (copied here) will be the one to get you scheduled.

Thank you,
Amanda Wiebold, BSN, RN, CNRN
Research Nurse Specialist
NINDS Section of Infections of the Nervous System
10 Center Drive, Building 10/7C107, MSC 1430
Bethesda, Maryland 20892
Office: b6
Cell: b6
Fax: 301-480-5594
Email: b6

From: b6
Sent: Thursday, October 14, 2021 11:59 AM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Cc: Smith, Bryan (NIH/NINDS) [E] b6
b6 Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: Re: Referral from b6

Thank you so much, Farinaz! I appreciate it enormously.

Amanda - I look forward to hearing from you on next steps.

On Thu, Oct 14, 2021 at 11:57 AM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

> Hi b6
>
> I spoke with the team and we can bring you to NIH under our neuroinflammatory research protocol.I cc Amanda(our research nurse) for further information.
>
> Best

Farinaz Safavi MD, PhD

Division of Neuroimmunology and Neurovirology

NINDS, NIH, Bethesda, MD

From: b6
Sent: Thursday, October 14, 2021 11:53 AM
To: Safavi, Farinaz (NIH/NINDS) [E]
Cc: Smith, Bryan (NIH/NINDS) [E]; b6
Subject: Re: Referral from b6

Hi Farinaz,

I just wanted to share that my PCP and I went ahead and submitted bloodwork for b6 b6 I thought it may be relevant as you and Dr. Nath consider my case.

Please let me know once you have had a chance to speak with him.

Thank you very much,

b6

On Tue, Oct 12, 2021 at 4:39 PM b6 wrote:

> Thank you so much, Farinaz. I really appreciate it.
>
> This is truly the most difficult situation I have ever been in and I have little hope because the issues keep presenting. I am happy to come to NIH anytime as addressing this is the most important thing in my life. My state is preventing me from working to my best ability, let alone engaging in any exercise or social activities.

Please let me know if there's anything else I can do at all.

Thank you again,

b6

On Tue, Oct 12, 2021 at 4:31 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Dear b6

I am really sorry that your symptoms have aggravated recently.

Since there was a federal holiday yesterday we did not have our usual meeting to discuss your case. Additionally Bryan is out of office for next afew weeks.

The questions you asked are all legit ones and we really do not know the exact underlying cause of your symptoms but we have some clues to say it might be immune mediated however the exact nature of it is still unknown.

Please give me a couple of days to discuss with Dr.Nath and will get back to you about how we can proceed.

Thank you

Farinaz

From: b6
Sent: Tuesday, October 12, 2021 1:02 PM
To: Safavi, Farinaz (NIH/NINDS) [E]; Smith, Bryan (NIH/NINDS) [E]; b6
Subject: Re: Referral from b6

Hi Farinaz and Bryan,

Thank you for taking the time to talk to me last Tuesday. I wanted to check-in and see if you had a chance to discuss my case and if there were any next steps. I am going through another pretty bad flare up with my skin rash becoming painful, fever, weakness and night sweats. In addition, my joint and muscle pain is getting worse and I am seeing bruises on my body for an unknown reason. As you can imagine, it's extremely disruptive to my life especially as I have been dealing with it for almost 6 months now. I am very desperate.

Is it possible to at least begin testing to verify our hypotheses? Is it autoimmune? Is it vascular or multi-system inflammation? Is it long-COVID if I had a prior infection in Feb 2020? Is it hormonal? As you know, it has been very difficult to work with my PCP and specialists because they don't understand what's going on.

Again, I really appreciate you working with me - it gives me hope every day.

Thank you,

b6

On Mon, Oct 4, 2021 at 2:01 PM b6 wrote:

> Hi Farinaz,
>
> Thank you very much for your reply. Tomorrow from 3-4pm would work great for me.
>
> I look forward to receiving the link and speaking with you,
>
> b6
>
> On Mon, Oct 4, 2021 at 10:51 AM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:
>
> > Dear b6
> >
> > Thank you very much for your email and history. We would like to schedule a televisit with you to gain more information from you. I will be available tomorrow from 11-1pm and from 3-4pm or Wednesday in the morning before noon.
> >
> > Please let me know and I can send you the link.
> >
> > Thank you

Farinaz Safavi MD, PhD

Division of Neuroimmunology and Neurovirology

NINDS, NIH, Bethesda, MD

From: b6
Sent: Saturday, October 2, 2021 10:48 AM
To: Nath, Avindra (NIH/NINDS) [E]; Wiebold, Amanda (NIH/NINDS) [E]
Cc: Smith, Bryan (NIH/NINDS) [E]; Safavi, Farinaz (NIH/NINDS) [E]; b6
Subject: Referral from b6

Hello Dr. Nath and Team,

My sincerest thank you for your willingness to help. Please see below for a more specific description of my case and applicable medical records. Amanda - let me know if you would like to discuss or any other next steps. I am incredibly grateful for your consideration of my case.

Thank you,

b6

Narrative of events:

I received the first dose of the Pfizer vaccine on b6 and the second on b6 I began to experience extreme weakness, a low grade fever and a sore throat shortly after and went to the ER on b6 Since then, a lot of other issues have emerged that are on the list below. I have seen my primary care physician, an infectious diseases specialist, an allergy specialist, and gynecologists. However, the cause of my symptoms has not been identified while the symptoms persist. I did not have any medical concerns before.

Bloodwork (attached):

b6

Tests completed that came back negative:

b6

Lastly, I had a CT scan done - no acute abnormality within the chest, abdomen, or pelvis to explain symptoms. When I saw the allergist, she said some of my symptoms (stuffiness, sore throat, tonsil pain) could be due to allergies. The test showed I experienced an allergic reaction to every category of allergens. However, I have never had allergies despite living in b6 for a very long time.

List of Symptoms:

Extreme weakness, fatigue and malaise since vaccine
Low grade fever of 37.3
Sore throat and tonsils, chest pain, feeling of inflammation in lungs, stuffiness
Heart palpitations
Prolonged menstrual periods (14 days), change in cycle, bleeding and spotting outside of period
Rash of small red dots on arms, legs and torso, skin sensitivity and feeling of heat
Severe night sweats
Dizziness and tinnitus
Joint, muscle and back pain
Weight loss and muscle degeneration
Loss of appetite
Twitching all over body

Veins protruding
Brain fog
New allergies

PRINCIPAL INVESTIGATOR: Avindra Nath, MD

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

STUDY SITE: NIH Clinical Center

Cohort: Adult/Guardian Consent

Consent Version: 03/17/2020

WHO DO YOU CONTACT ABOUT THIS STUDY?

Principal Investigator: Avindra Nath, MD, b6

Study Coordinator: Amanda Wiebold, RN,

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

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

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

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

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

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

WHY IS THIS STUDY BEING DONE?

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

BACKGROUND

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

STUDY POPULATION

Up to 1000 people will take part in this study.

VISIT SCHEDULE

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

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

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

OVERVIEW

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

BASELINE STUDY PROCEDURES:

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

History and Physical Exam:

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

Blood Draw

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

HIV Test

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

Genetic Testing

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

1. It may be analyzed to identify the genes that might be causing your condition. This will help us understand how changes in the genes may cause symptoms. Genetic testing can be helpful in establishing a diagnosis. It may eventually lead to improved treatment or prevention.

2. To try to identify genetic changes that may be associated with your condition we may sequence the part of the DNA that provides instructions for making proteins, called the "exome." The exome makes up about 1% of your DNA.

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

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

The genetic testing for this study will not detect all gene changes that are associated with known diseases. However, we will tell you if we find gene changes in your DNA that are known to have major and direct medical significance and are associated with illnesses or conditions that could benefit from early treatment. We call these "reportable gene changes." We suggest you share this

information with your own doctors and that you have a clinical laboratory confirm the "reportable gene change" before you take any action on this information.

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

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

MRI

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

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

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

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

Lumbar puncture

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

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

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

Banking and Sharing

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

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

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

OPTIONAL STUDY PROCEDURES

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

Optical coherence tomography (OCT)

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

Evoked Potentials

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

Electromyogram (EMG) and Nerve Conduction Study (NCS)

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

Neuropsychological Testing

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

Electroencephalogram (EEG)

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

Skin biopsy (adults only)

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

Urine Collection

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

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

Saliva Collection

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

RISKS, INCONVENIENCES AND DISCOMFORTS OF MAIN STUDY PROCEDURES:

History and Physical Exam

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

Blood Draw

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

Genetic Testing

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

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

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

Results of the research genetic testing in this study are often difficult to interpret because the testing is being done for research purposes only and the laboratories are not clinically certified. You may be referred to a CLIA certified laboratory, possibly outside of NIH, for additional testing or confirmation of the research results. NIH will not cover the cost of the additional testing. You or your insurer will be responsible for the cost.

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

HIV Testing

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

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

Urine Collection

There are no risks associated with urine collection.

Saliva Collection

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

MRI

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

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

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

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

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

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

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

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

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

Lumbar Puncture

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

Radiation Risk

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

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

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

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

Banking and Sharing

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

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

RISKS, INCONVENIENCES AND DISCOMFORTS OF ADDITIONAL STUDY PROCEDURES:

OCT

There are no known risks of OCT.

Evoked Potentials

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

EMG and NCS

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

Neuropsychological Testing

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

EEG

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

Skin Biopsy

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

INDUCED PLURIPOTENT STEM CELLS (IPS)

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

ADDITIONAL RISKS

Sedation

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

ANTICIPATED BENEFITS

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

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

For both adults and children, this study will likely increase our general knowledge of how infections and immune conditions affect the brain, and will probably help us to diagnose brain infections and immune disorders earlier and manage patients better. The study results may help to develop new treatments in the future.

RIGHT OF WITHDRAWAL AND CONDITIONS FOR EARLY WITHDRAWAL

You may withdraw from the study at any time and for any reason without loss of benefits or privileges to which you are otherwise entitled. The investigator can remove you from the study at any time if she or he believes that continuation is not in your best medical interest or if you are unable to comply with the requirements of the study.

ALTERNATIVES TO PARTICIPATION OR TREATMENT

The alternative is not to participate.

COMPENSATION, REIMBURSEMENT, AND PAYMENT

Will you receive compensation for participation in the study?

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

You will not receive compensation for participation in this study.

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

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

Reimbursement of travel will be offered consistent with NIH guidelines.

Will taking part in this research study cost you anything?

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

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Will your medical information be kept private?

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

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

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

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

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

Certificate of Confidentiality

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

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

The Certificate does not protect your information when it:

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

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

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

Privacy Act

The Federal Privacy Act generally protects the confidentiality of your NIH medical records we collect under the authority of the Public Health Service Act. In some cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act allows release of information from your medical record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to those engaged by the agency for research purposes, to certain

federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to tumor registries, for quality assessment and medical audits, or when the NIH is involved in a lawsuit. However, NIH will only release information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act.

POLICY REGARDING RESEARCH-RELATED INJURIES

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

PROBLEMS OR QUESTIONS

If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Avindra Nath, MD, b6 You may also call the NIH Clinical Center Patient Representative at 301-496-2626, or the NIH Office of IRB Operations at 301-402-3713, if you have a research-related complaint or concern.

CONSENT DOCUMENT

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

From: b6
Sent: 1/22/2021 2:13:00 AM
To: Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540 b6
Subject: Re: NIH Study
Attachments: NIH-1208 Authorization for the Release of Medical Information modified (1).pdf

Dear Amanda:

Attached you will find my authorization form. Thank you so much for reaching out to me. Do you know when the phone call will be? Let me know and I will put it on my calendar.

Thank you again

On Thu, Jan 21, 2021 at 1:39 PM Wiebold, Amanda (NIH/NINDS) [E] b6 wrote:

> Hello b6
>
> I am the research nurse that works with Dr. Nath. I would be happy to go over the consent with you. Let me know when a good time to talk on the phone would be.
>
> I am attaching two forms.
>
> 1. The consent form. Please review prior to our telephone call. **Do not sign** it until after we talk on the phone. This will give us permission to receive specimens.
> 2. Medical Records Release form. Please fill out the sections highlighted in yellow and return to me. This gives us permission to request and to review your medical records.
>
> If you have any additional (other than what you have already sent to Dr. Nath) medical records you can fax them to us directly or I can provide you with secure email access. If you have any imaging you can upload them directly following the instructions here https://www.cc.nih.gov/dcri/imaginglibrary.html.
>
> Let me know if you have any questions.
>
> Thanks,

Amanda Wiebold, BSN, RN, CNRN

Research Nurse Specialist

NINDS Section of Infections of the Nervous System

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

Bethesda, Maryland 20892

Office: b6

Cell: b6

Fax: 301-402-1137

Email: b6

b6

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

INSTRUCTIONS: Complete this form in its entirety and forward directly to the requesting facility.

CC PATIENT IDENTIFICATION

b6		b6
(Patient Name)	(Patient Number)	(Date of Birth)

SOURCE OF INFORMATION REQUESTED

b6

(Name of Health Care Organization or Physician) (Phone Number) (Fax Number)

b6

(Street Address) (City) (State) (Zip Code)

INFORMATION REQUESTED

The purpose or need for disclosure: Review of clinical care and consideration for research study

NIH Requestor/Point of Contact: Amanda Wiebold b6

Identify the specific items and related dates pertaining to the information to be released.

1. Medical Reports:

   Laboratory results, clinic notes, and brain MRI or head CT reports from any and all date(s).

   Send to: National Institutes of Health Clinical Center
   National Institute of Neurological Disorders and Stroke
   Building 10, Room 7C103
   10 CENTER DRIVE MSC 1430
   BETHESDA, MD 20892-1430
   ATTENTION: Amanda Wiebold/ Dr. Bryan Smith

   OR
   Fax to: (301) 402-1137
   Attn: Amanda Wiebold or
   Dr. Bryan Smith

2. MRI scans on CD from any and all date(s).

   Send to: National Institutes of Health Clinical Center
   National Institute of Neurological Disorders and Stroke
   Building 10, Room 7C103
   10 CENTER DRIVE MSC 1430
   BETHESDA, MD 20892-1430
   ATTENTION: Amanda Wiebold/ Dr. Bryan Smith

3. Tissue/Pathology Slides from any and all date(s).

   Send to: National Institutes of Health Clinical Center
   Laboratory of Pathology
   Building 10, Room 2B50
   10 CENTER DRIVE MSC 1500 BETHESDA,
   MD 20892-1500

AUTHORIZATION

I hereby authorize the release of the above-requested medical information.

b6	b6	1/21/2021
(Signature of Patient/Legal Guardian)	(Printed Name of Patient)	(Date Signed)

b6

(Street Address) (City) (State) (Zip Code)

From: Wiebold, Amanda (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4491EE2AE9804610899C741100150540 b6]
Sent: 1/21/2021 6:39:18 PM
To: b6
Subject: NIH Study
Attachments: 15-N-0125.2.Consent.200422.pdf; NIH-1208 Authorization for the Release of Medical Information modified.pdf

Hello b6

I am the research nurse that works with Dr. Nath. I would be happy to go over the consent with you. Let me know when a good time to talk on the phone would be.

I am attaching two forms.

1. The consent form. Please review prior to our telephone call. **Do not sign** it until after we talk on the phone. This will give us permission to receive specimens.
2. Medical Records Release form. Please fill out the sections highlighted in yellow and return to me. This gives us permission to request and to review your medical records.

If you have any additional (other than what you have already sent to Dr. Nath) medical records you can fax them to us directly or I can provide you with secure email access. If you have any imaging you can upload them directly following the instructions here https://www.cc.nih.gov/dcri/imaginglibrary.html.

Let me know if you have any questions.

Thanks,

Amanda Wiebold, BSN, RN, CNRN
Research Nurse Specialist
NINDS Section of Infections of the Nervous System
10 Center Drive, Building 10/7C107, MSC 1430
Bethesda, Maryland 20892
Office: b6
Cell: b6
Fax: 301-402-1137
Email: b6

PRINCIPAL INVESTIGATOR: Avindra Nath, MD

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

STUDY SITE: NIH Clinical Center

Cohort: Biological Samples Only Consent

Consent Version: 03/17/2020

WHO DO YOU CONTACT ABOUT THIS STUDY?

Principal Investigator: Avindra Nath, MD, b6

Study Coordinator: Amanda Wiebold, RN,

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

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

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

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

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

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

WHY IS THIS STUDY BEING DONE?

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

BACKGROUND

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

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

STUDY POPULATION

Up to 1000 people will take part in this study.

-

PROCEDURES/STUDY OVERVIEW

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

Induced Pluripotent Stem Cells (iPS)

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

Genetic Testing

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

1. It may be analyzed to identify the genes that might be causing your condition. This will help us understand how changes in the genes may cause symptoms. Genetic testing can be helpful in establishing a diagnosis. It may eventually lead to improved treatment or prevention.

2. To try to identify genetic changes that may be associated with your condition we may sequence the part of the DNA that provides instructions for making proteins, called the "exome." The exome makes up about 1% of your DNA.

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

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

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

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

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

Banking and Sharing

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

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

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

RISKS, INCONVENIENCES AND DISCOMFORTS

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

Genetic Testing

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

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

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

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

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

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

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

Banking and Sharing

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

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

ANTICIPATED BENEFITS

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

RIGHT OF WITHDRAWAL AND CONDITIONS FOR EARLY WITHDRAWAL

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

CONFLICT OF INTEREST

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

RESULTS FROM THIS STUDY

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

ALTERNATIVES TO PARTICIPATION

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

COMPENSATION, REIMBURSEMENT, AND PAYMENT

Will you receive compensation for participation in the study?

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

You will not receive compensation for participation in this study.

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

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

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

Will taking part in this research study cost you anything?

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

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Will your medical information be kept private?

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

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

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

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

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

Certificate of Confidentiality

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

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

The Certificate does not protect your information when it:

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

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

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

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

Privacy Act

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

POLICY REGARDING RESEARCH-RELATED INJURIES

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

PROBLEMS OR QUESTIONS

If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator Avindra Nath, MD, b6 You may also call the NIH Clinical Center Patient Representative at 301-496-2626, or the NIH Office of IRB Operations at 301-402-3713, if you have a research-related complaint or concern.

CONSENT DOCUMENT

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

Adult Research Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to participate in this study.

Signature of Research Participant	Print Name of Research Participant	Date

Legally Authorized Representative (LAR) for an Adult Unable to Consent: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I am legally authorized to make research decisions on behalf of the adult participant unable to consent and have the authority to provide consent to this study. As applicable, the information in the above consent was described to the adult participant unable to consent who agrees to participate in the study.

Signature of LAR	Print Name of LAR	Date

Parent/Guardian of a Minor Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I give permission for my child to take part in this study.

Signature of Parent/Guardian	Print Name of Parent/Guardian	Date
Signature of Parent/Guardian *(as applicable)*	Print Name of Parent/Guardian	Date

Assent: *(Use this section only when this process is approved by an IRB for older minors. Do not use if an IRB requires a separate assent form for this population.)*

I have had this study explained to me in a way that I understand, I have been given the opportunity to discuss it, and I have had the chance to ask questions. I agree to take part in this study.

Assent of Minor: *(as applicable)*

Signature of Minor	Print Name of Minor	Date

Investigator:

Signature of Investigator	Print Name of Investigator	Date

Witness to the oral short-form consent process only: This section is only required if you are doing the oral short-consent process and this English consent form has been approved by the IRB for use as the basis of translation.

Witness:

Signature of Witness*	Print Name of Witness	Date

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

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

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

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

INSTRUCTIONS: Complete this form in its entirety and forward directly to the requesting facility.

CC PATIENT IDENTIFICATION

(Patient Name) (Patient Number) (Date of Birth)

SOURCE OF INFORMATION REQUESTED

(Name of Health Care Organization or Physician) (Phone Number) (Fax Number)

(Street Address) (City) (State) (Zip Code)

INFORMATION REQUESTED

The purpose or need for disclosure: Review of clinical care and consideration for research study

NIH Requestor/Point of Contact: Amanda Wiebold b6

Identify the specific items and related dates pertaining to the information to be released.

1. Medical Reports:

   Laboratory results, clinic notes, and brain MRI or head CT reports from _____ date(s).

   Send to: National Institutes of Health Clinical Center
   National Institute of Neurological Disorders and Stroke
   Building 10, Room 7C103
   10 CENTER DRIVE MSC 1430
   BETHESDA, MD 20892-1430
   ATTENTION: Amanda Wiebold/ Dr. Bryan Smith

   OR
   Fax to: (301) 402-1137
   Attn: Amanda Wiebold or
   Dr. Bryan Smith

2. MRI scans on CD from _____ date(s).

   Send to: National Institutes of Health Clinical Center
   National Institute of Neurological Disorders and Stroke
   Building 10, Room 7C103
   10 CENTER DRIVE MSC 1430
   BETHESDA, MD 20892-1430
   ATTENTION: Amanda Wiebold/ Dr. Bryan Smith

3. Tissue/Pathology Slides from _____ date(s).

   Send to: National Institutes of Health Clinical Center
   Laboratory of Pathology
   Building 10, Room 2B50
   10 CENTER DRIVE MSC 1500 BETHESDA,
   MD 20892-1500

AUTHORIZATION

I hereby authorize the release of the above-requested medical information.

(Signature of Patient/Legal Guardian) (Printed Name of Patient) (Date Signed)

(Street Address) (City) (State) (Zip Code)

From: b6
Sent: 1/26/2021 7:41:12 PM
To: Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540b6
Subject: Re: NIH Study
Attachments: 15-N-0125.2.Consent.200422 (1).pdf

On Thu, Jan 21, 2021 at 1:39 PM Wiebold, Amanda (NIH/NINDS) [E] b6 wrote:

Hello b6

I am the research nurse that works with Dr. Nath. I would be happy to go over the consent with you. Let me know when a good time to talk on the phone would be.

I am attaching two forms.

1. The consent form. Please review prior to our telephone call. **Do not sign** it until after we talk on the phone. This will give us permission to receive specimens.
2. Medical Records Release form. Please fill out the sections highlighted in yellow and return to me. This gives us permission to request and to review your medical records.

If you have any additional (other than what you have already sent to Dr. Nath) medical records you can fax them to us directly or I can provide you with secure email access. If you have any imaging you can upload them directly following the instructions here https://www.cc.nih.gov/dcri/imaginglibrary.html.

Let me know if you have any questions.

Thanks,

Amanda Wiebold, BSN, RN, CNRN

Research Nurse Specialist

NINDS Section of Infections of the Nervous System

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

Bethesda, Maryland 20892

Office: b6

Cell: b6

Fax: 301-402-1137

Email: b6

b6

PRINCIPAL INVESTIGATOR: Avindra Nath, MD

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

STUDY SITE: NIH Clinical Center

Cohort: Biological Samples Only Consent

Consent Version: 03/17/2020

WHO DO YOU CONTACT ABOUT THIS STUDY?

Principal Investigator: Avindra Nath, MD, b6

Study Coordinator: Amanda Wiebold, RN,

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

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

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

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

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

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

WHY IS THIS STUDY BEING DONE?

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

BACKGROUND

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

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

STUDY POPULATION

Up to 1000 people will take part in this study.

•

PROCEDURES/STUDY OVERVIEW

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

Induced Pluripotent Stem Cells (iPS)

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

Genetic Testing

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

1. It may be analyzed to identify the genes that might be causing your condition. This will help us understand how changes in the genes may cause symptoms. Genetic testing can be helpful in establishing a diagnosis. It may eventually lead to improved treatment or prevention.

2. To try to identify genetic changes that may be associated with your condition we may sequence the part of the DNA that provides instructions for making proteins, called the "exome." The exome makes up about 1% of your DNA.

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

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

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

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

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

Banking and Sharing

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

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

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

RISKS, INCONVENIENCES AND DISCOMFORTS

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

Genetic Testing

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

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

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

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

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

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

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

Banking and Sharing

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

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

ANTICIPATED BENEFITS

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

RIGHT OF WITHDRAWAL AND CONDITIONS FOR EARLY WITHDRAWAL

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

CONFLICT OF INTEREST

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

RESULTS FROM THIS STUDY

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

ALTERNATIVES TO PARTICIPATION

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

COMPENSATION, REIMBURSEMENT, AND PAYMENT

Will you receive compensation for participation in the study?

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

You will not receive compensation for participation in this study.

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

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

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

Will taking part in this research study cost you anything?

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

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Will your medical information be kept private?

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

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

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

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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.

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CONSENT DOCUMENT

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

Adult Research Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to participate in this study.

b6	b6	1/26/21
Signature of Research Participant	Print Name of Research Participant	Date

Legally Authorized Representative (LAR) for an Adult Unable to Consent: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I am legally authorized to make research decisions on behalf of the adult participant unable to consent and have the authority to provide consent to this study. As applicable, the information in the above consent was described to the adult participant unable to consent who agrees to participate in the study.

Signature of LAR	Print Name of LAR	Date

Parent/Guardian of a Minor Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I give permission for my child to take part in this study.

Signature of Parent/Guardian	Print Name of Parent/Guardian	Date
Signature of Parent/Guardian *(as applicable)*	Print Name of Parent/Guardian	Date

Assent: *(Use this section only when this process is approved by an IRB for older minors. Do not use if an IRB requires a separate assent form for this population.)*

I have had this study explained to me in a way that I understand, I have been given the opportunity to discuss it, and I have had the chance to ask questions. I agree to take part in this study.

Assent of Minor: *(as applicable)*

Signature of Minor	Print Name of Minor	Date

Investigator:

Signature of Investigator	Print Name of Investigator	Date

Witness to the oral short-form consent process only: This section is only required if you are doing the oral short-consent process and this English consent form has been approved by the IRB for use as the basis of translation.

Witness:

Signature of Witness*	Print Name of Witness	Date

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

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

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

From: b6
Sent: 1/27/2021 4:07:57 PM
To: Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540 b6
Subject: Re: NIH Study

Great, thank you so much!

On Tue, Jan 26, 2021 at 2:55 PM Wiebold, Amanda (NIH/NINDS) [E] b6 wrote:

> Thank you! It was very nice talking with you. I will reach out to you next week regarding the kit for the blood draw.
>
> Sincerely,
>
> Amanda
>
> **From:** b6
> **Sent:** Tuesday, January 26, 2021 2:41 PM
> **To:** Wiebold, Amanda (NIH/NINDS) [E] b6
> **Subject:** Re: NIH Study
>
> On Thu, Jan 21, 2021 at 1:39 PM Wiebold, Amanda (NIH/NINDS) [E] b6 wrote:
>
> > Hello b6
> >
> > I am the research nurse that works with Dr. Nath. I would be happy to go over the consent with you. Let me know when a good time to talk on the phone would be.
> >
> > I am attaching two forms.
> >
> > 1. The consent form. Please review prior to our telephone call. **Do not sign** it until after we talk on the phone. This will give us permission to receive specimens.

2. Medical Records Release form. Please fill out the sections highlighted in yellow and return to me. This gives us permission to request and to review your medical records.

If you have any additional (other than what you have already sent to Dr. Nath) medical records you can fax them to us directly or I can provide you with secure email access. If you have any imaging you can upload them directly following the instructions here https://www.cc.nih.gov/dcri/imaginglibrary.html.

Let me know if you have any questions.

Thanks,

Amanda Wiebold, BSN, RN, CNRN

Research Nurse Specialist

NINDS Section of Infections of the Nervous System

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

Bethesda, Maryland 20892

Office: b6

Cell: b6

Fax: 301-402-1137

Email: b6

b6

b6

b6

From: b6
Sent: 1/26/2021 3:30:24 PM
To: Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540 b6
Subject: Re: NIH Study

yes 2:30 works for me. You can call me at that number for sure

On Mon, Jan 25, 2021 at 12:52 PM Wiebold, Amanda (NIH/NINDS) [E] b6 wrote:

> Yes! That works for me. How about 2:30 PM? Is b6 the best number to reach you at?
>
> Thanks,
>
> Amanda

From: b6
Sent: Monday, January 25, 2021 12:01 PM
To: Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: Re: NIH Study

It is all good..

Today is full of meetings and classes to teach. Can we do tomorrow? I am available from 1030 am till 1 pm and from 230-3 and from 4pm on....

On Mon, Jan 25, 2021 at 9:58 AM Wiebold, Amanda (NIH/NINDS) [E] b6 wrote:

> Hi b6
>
> Sorry we missed each other last Friday. What is your availability today?
>
> Thank you,

Amanda

From: b6
Sent: Friday, January 22, 2021 4:47 PM
To: Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: Re: NIH Study

Yes, I have time this evening, anytime after 6:30pm you may call me. b6

On Fri, Jan 22, 2021 at 9:34 AM Wiebold, Amanda (NIH/NINDS) [E] b6 wrote:

Hi b6

Thank you for responding. Actually, that was the intent of my email – to see when you are available for a phone call. Let me know if you have time today. If not we can look at next week.

Thanks,

Amanda

From: b6
Sent: Thursday, January 21, 2021 9:13 PM
To: Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: Re: NIH Study

Dear Amanda:

Attached you will find my authorization form. Thank you so much for reaching out to me. Do you know when the phone call will be? Let me know and I will put it on my calendar.

Thank you again

On Thu, Jan 21, 2021 at 1:39 PM Wiebold, Amanda (NIH/NINDS) [E] b6 wrote:

Hello b6

I am the research nurse that works with Dr. Nath. I would be happy to go over the consent with you. Let me know when a good time to talk on the phone would be.

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Let me know if you have any questions.

Thanks,

Amanda Wiebold, BSN, RN, CNRN

Research Nurse Specialist

NINDS Section of Infections of the Nervous System

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

Bethesda, Maryland 20892

Office: b6

Cell: b6

Fax: 301-402-1137

Email: b6

b6

b6

b6

b6

From: Wiebold, Amanda (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4491EE2AE9804610899C741100150540-b6]
Sent: 2/8/2021 8:33:56 PM
To: b6
Subject: RE: NIH Study

Oh, I see. Ok, keep us posted.

Thanks,
Amanda

From: b6
Sent: Monday, February 8, 2021 3:19 PM
To: Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: Re: NIH Study

They have not set a date, but when they do i will let you know...

On Mon, Feb 8, 2021, 9:54 AM Wiebold, Amanda (NIH/NINDS) [E] b6 wrote:

b6

Thank you for the information. Quest will not bill your insurance. They will bill our account. Do you know the date and place of your lumbar puncture so I can request the results from the testing?

Thanks,

Amanda

From: b6
Sent: Saturday, February 6, 2021 7:08 AM
To: Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: Re: NIH Study

The only other test I can think of is possible spinal tap for testing.

On Sat, Feb 6, 2021 at 7:03 AM b6 wrote:

Also, will this be billed to my insurance? Or covered by NIH?

On Sat, Feb 6, 2021 at 7:02 AM b6 wrote:

Thank you so much, my lab appointment confirmation is attached.

On Wed, Feb 3, 2021 at 8:09 PM Wiebold, Amanda (NIH/NINDS) [E] b6 wrote:

b6

Your kit should arrive tomorrow. Please make sure to have your blood collected before 11:00 am on a Monday, Tuesday, Wednesday, or Thursday not before a holiday in order for us to receive the blood the following morning. We are not in the lab to receive the blood on weekends or holidays. Since the pandemic not all Quest locations allow for walk-ins. Please go to https://appointment.questdiagnostics.com/patient/confirmation to see if you need to make an appointment for the one closest to you. Please review the instructions below and let me know if you have any questions.

Patient Instructions

1) When you receive the box, open it and remove the cold packs from the box and place them inside of your freezer.

2) Do Not Discard the Cardboard Box. You will need everything sent to you. Please make sure to remove all shipping labels before giving to Quest.

3) On the day of collection, remove the cold packs from your freezer and place them back in the bottom of the box.

4) Take the box with all the contents inside to the collection center.

5) Give the kit along with the green sheet and the orange sheet(s) to Quest.

6) If you have any questions, contact Amanda Wiebold at b6

Please let me know when you are scheduled for your blood draw so we can make arrangements with our lab to receive it the next morning.

Thank you,

Amanda Wiebold, BSN, RN, CNRN

Research Nurse Specialist

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

Bethesda, Maryland 20892

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Cell: b6

Fax: 301-402-1137

Email: b6

From: Wiebold, Amanda (NIH/NINDS) [E]
Sent: Monday, February 1, 2021 4:59 PM
To: b6
Subject: RE: NIH Study

Hello b6

I meant to ask you...you sent us several medical records. Is there any additional ones that I need to request or any imaging or biopsies?

Thank you,

Amanda

From: b6
Sent: Thursday, January 21, 2021 9:13 PM
To: Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: Re: NIH Study

Dear Amanda:

Attached you will find my authorization form. Thank you so much for reaching out to me. Do you know when the phone call will be? Let me know and I will put it on my calendar.

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On Thu, Jan 21, 2021 at 1:39 PM Wiebold, Amanda (NIH/NINDS) [E] b6 wrote:

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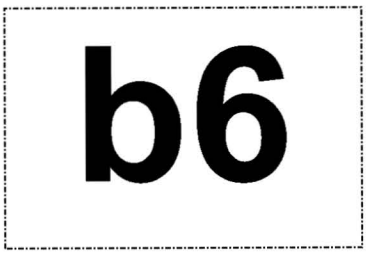

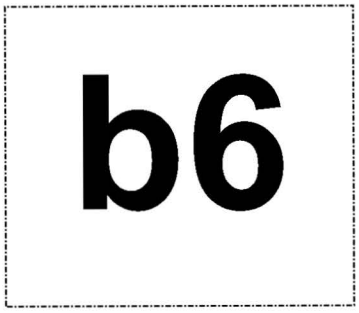

From: b6
Sent: 2/6/2021 12:02:58 PM
To: Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540b6
Subject: Re: NIH Study
Attachments: lab appointment confirmation.pdf

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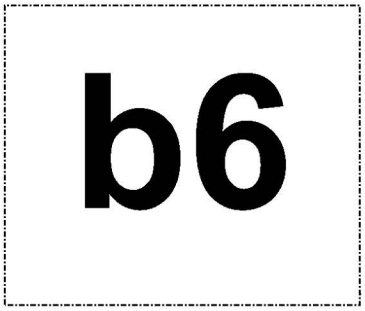

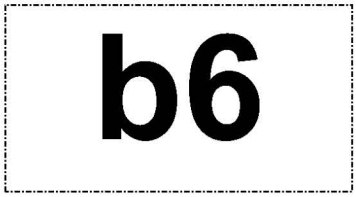

b6

b6

From: b6
Sent: 2/6/2021 11:29:18 AM
To: Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540-b6
Subject: Re: NIH Study
Attachments: b6

Dear Amanda

Here are the results of several tests I had performed this past week. b6

b6

On Mon, Feb 1, 2021 at 4:58 PM Wiebold, Amanda (NIH/NINDS) [E] b6 wrote:

Hello b6

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Sent: 3/10/2022 6:45:59 PM
To: b6
Subject: RE: NIH Study
Attachments: b6 Samples Only Consent (L) 03.08.22.pdf

b6

Please find your countersigned consent form attached for your records. Please let me know if you have any questions.

Thank you,
Amanda

From: Wiebold, Amanda (NIH/NINDS) [E]
Sent: Tuesday, March 8, 2022 1:15 PM
To: b6
Subject: NIH Study

Hello b6

It was a pleasure speaking with you. My contact information is below if you need to reach out to me.

Was b6 going to fax me the forms? If not, I can send you a secure email to send them back to me or you can fax them to me.

Thank you,

Amanda Wiebold, BSN, RN, CNRN
Research Nurse Specialist
NINDS Section of Infections of the Nervous System
10 Center Drive, Building 10/7C107, MSC 1430
Bethesda, Maryland 20892
Office: b6
Cell: b6
Fax: 301-480-5594
Email: b6

aft Amanda

b6

PRINCIPAL INVESTIGATOR: Avindra Nath, MD

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

STUDY SITE: NIH Clinical Center

Cohort: Biological Samples Only Consent

Consent Version: 10/06/2021

WHO DO YOU CONTACT ABOUT THIS STUDY?

Principal Investigator: Avindra Nath, MD, b6

Study Coordinator: Amanda Wiebold, RN,

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

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

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

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

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

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

WHY IS THIS STUDY BEING DONE?

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

BACKGROUND

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

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

STUDY POPULATION

Up to 1000 people will take part in this study.

PROCEDURES/STUDY OVERVIEW

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

Induced Pluripotent Stem Cells (iPS)

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

Genetic Testing

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

1. It may be analyzed to identify the genes that might be causing your condition. This will help us understand how changes in the genes may cause symptoms. Genetic testing can be helpful in establishing a diagnosis. It may eventually lead to improved treatment or prevention.

2. To try to identify genetic changes that may be associated with your condition we may sequence the part of the DNA that provides instructions for making proteins, called the "exome." The exome makes up about 1% of your DNA.

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

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

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

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

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

Banking and Sharing

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

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

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

RISKS, INCONVENIENCES AND DISCOMFORTS

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

Genetic Testing

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

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

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

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

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

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

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

Banking and Sharing

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

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

ANTICIPATED BENEFITS

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

RIGHT OF WITHDRAWAL AND CONDITIONS FOR EARLY WITHDRAWAL

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

CONFLICT OF INTEREST

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

RESULTS FROM THIS STUDY

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

ALTERNATIVES TO PARTICIPATION

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

COMPENSATION, REIMBURSEMENT, AND PAYMENT

Will you receive compensation for participation in the study?

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

You will not receive compensation for participation in this study.

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

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

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

Will taking part in this research study cost you anything?

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

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Will your medical information be kept private?

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

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

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

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

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

Certificate of Confidentiality

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

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

The Certificate does not protect your information when it:

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

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

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

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.

POLICY REGARDING RESEARCH-RELATED INJURIES

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

PROBLEMS OR QUESTIONS

If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator Avindra Nath, MD, b6 You may also call the NIH Clinical Center Patient Representative at 301-496-2626, or the NIH Office of IRB Operations at 301-402-3713, if you have a research-related complaint or concern.

CONSENT DOCUMENT

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

Adult Research Participant: I have read the explanation about this study and have been given the opportunity participate in this study.

b6

b6

Print Name of Research Participant

03-08-22

Date

Legally Authorized Representative (LAR) for an Adult Unable to Consent: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I am legally authorized to make research decisions on behalf of the adult participant unable to consent and have the authority to provide consent to this study. As applicable, the information in the above consent was described to the adult participant unable to consent who agrees to participate in the study.

Signature of LAR | Print Name of LAR | Date

Parent/Guardian of a Minor Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I give permission for my child to take part in this study.

Signature of Parent/Guardian | Print Name of Parent/Guardian | Date

Signature of Parent/Guardian *(as applicable)* | Print Name of Parent/Guardian | Date

Assent: *(Use this section only when this process is approved by an IRB for older minors. Do not use if an IRB requires a separate assent form for this population.)*

I have had this study explained to me in a way that I understand, I have been given the opportunity to discuss it, and I have had the chance to ask questions. I agree to take part in this study.

Assent of Minor: *(as applicable)*

Signature of Minor | Print Name of Minor | Date

Investigator:

b6

Amanda Wiebold, RN

3/9/2022

Signature of Investigator | Print Name of Investigator | Date

Witness to the oral short-form consent process only: This section is only required if you are doing the oral short-consent process and this English consent form has been approved by the IRB for use as the basis of translation.

Witness:

b6

b6

3/8/2022
Date

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

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

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

From: Wiebold, Amanda (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4491EE2AE9804610899C741100150540-b6
Sent: 3/4/2021 6:59:16 PM
To: Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246-b6
b6
Subject: RE: Myself

A secure email has been sent.

Thank you,
Amanda

From: Safavi, Farinaz (NIH/NINDS) [E] b6
Sent: Thursday, March 4, 2021 1:43 PM
To: b6 Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: RE: Myself

Dear Amanda,
Can you please provide b6 the link for sending us his medical records.
Thank you
Farinaz

From: b6
Sent: Wednesday, March 3, 2021 5:47 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Myself

Hi Farinaz,
Friday 3/5 from 3-5 will work.
I am in b6
I can gather some records if you like. Do you have access to Epic emr?
Thanks so much,
b6

Sent from my iPhone

> On Mar 3, 2021, at 2:41 PM, Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:
>
> b6
> Please kindly let me know which of the following dates/ times works for you to meet? I will send you the MS teams link accordingly.
> Friday 3/5 3-5 ET
> Tues 3/9 3-5 ET
> Thurs 3/11 3-5 ET
>
> Thank you

Farinaz

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

From: b6
Sent: Wednesday, March 3, 2021 4:24 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Myself

Please let me know when I can have a visit. Thanks,
b6

Sent from my iPhone

> On Mar 2, 2021, at 8:03 PM, Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:
>
> b6
> I am really sorry to hear about your symptoms. We definitely can schedule a televisit in mutually convenient time to go over the details. I will coordinate with our team and get back to you tomorrow.
> Best Regards,
> Farinaz
>
> Farinaz Safavi MD, PhD
> Section of Infections of the Nervous System
> Division of Neuroimmunology and Neurovirology
> NINDS, NIH
>
> **From:** Nath, Avindra (NIH/NINDS) [E]
> **Sent:** Tuesday, March 2, 2021 9:04 PM
> **To:** b6
> **Cc:** Safavi, Farinaz (NIH/NINDS) [E]; Wiebold, Amanda (NIH/NINDS) [E]; Smith, Bryan (NIH/NINDS) [E]
> **Subject:** Re: Myself
>
> Dear b6
> I am terribly sorry to hear of your illness. We are following several patients with neurological symptoms from the COVID vaccines I have copied members of my research team who will get in touch with you. Dr. Safavi is leading the effort and will do a televisit and then we will like to obtain some medical records and blood samples. You would need to be enrolled on to our research study for this purpose. Our hope to try and

identify if there is some kind of molecular mimicry between vaccine and the antigens in the nervous system.
With best wishes.
Avi

Avindra Nath MD
Chief, Section of Infections of the Nervous System
Clinical Director,
National Institute of Neurological Disorders and Stroke
National Institutes of Health, Bethesda, MD
b6 (Office)
(cell)
b6

On 3/2/21, 4:54 PM, b6 wrote:

Hi Dr. Nath,

My name is b6 I was given your name by b6

I am a b6 in b6 who had a severe reaction to the Pfizer Covid Vaccine b6. I was previously healthy and 30 minutes after receiving the vaccine developed burning in my face, had a pre-syncopal event and my blood pressure spiked very high. I initially became bedridden for one week with severe malaise and paresthesias in my face and tongue. I also felt a tight band like constriction around my chest. I was treated with b6 b6 Since that time, energy has improved but I have severe paresthesias in my face, head, tongue and mouth, chest, abdomen and limbs. At times they are incapacitating. I feel a vibration in my head and hands. The tight band around my chest persists. I have had extensive negative neurological and rheumatological work up and have seen several doctors in b6 who have no clue what has happened to me. b6 b6 at b6 found b6 b6 and b6 at b6 put me on b6

Are you aware of these reactions and what is causing them? Is there anything that can help me? I am quite incapacitated. I have collected a group of people whom I met through the internet with similar reactions to mine. Several are physicians as far away as France and Argentina. Pfizer, the FDA and CDC have been unhelpful.

Any help or insight you can give me would be most appreciated.

Sincerely,

b6

Sent from my iPhone

From: b6
Sent: 11/30/2021 2:20:36 PM
To: Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540 b6
Subject: Re: Per conversation with b6

Hi Amanda,

Thank you! I received the email and will set up today.

Best,
b6

On Tue, Nov 30, 2021 at 7:44 AM Wiebold, Amanda (NIH/NINDS) [E] b6 wrote:

> Good morning b6
>
> Ladi and I are the research nurses with Dr. Nath. I have just sent you a secure email letting you know what we need in order to review your recent health issues. It is a secure email platform which allows us to exchange sensitive or identifying information. You will be walked through a couple of steps to set up an account. Please do not send medical records through this email exchange. If you prefer to fax your records or mail them you may use the contact information below to do so. We do not recommend sending anything by USPS as it can take several weeks for us to receive items.
>
> Please reach out to us if you have any questions.
>
> Thank you,
>
> *Amanda Wiebold, BSN, RN, CNRN*
>
> Research Nurse Specialist
>
> NINDS Section of Infections of the Nervous System
>
> 10 Center Drive, Building 10/7C107, MSC 1430
>
> Bethesda, Maryland 20892
>
> Office: b6
>
> Cell: b6
>
> Fax: 301-480-5594

Email: b6

From: Nath, Avindra (NIH/NINDS) [E] b6
Sent: Tuesday, November 30, 2021 2:47 AM
To: b6 Kwan, Justin (NIH/NINDS) [E] b6 Safavi, Farinaz (NIH/NINDS) [E] b6 Wiebold, Amanda (NIH/NINDS) [E] b6 Smith, Bryan (NIH/NINDS) [E] b6
Subject: Re: Per conversation with b6

Dear b6

I am terribly sorry of hear of your illness. Yes, we would be glad to review all your medical records to determine if you would be eligible for one of our studies. I have copied several key members of our research team who will help review them with me.

Best wishes.

Avi

Avindra Nath MD

Chief, Section of Infections of the Nervous System

Clinical Director,

National Institute of Neurological Disorders and Stroke

National Institutes of Health, Bethesda, MD

b6 (Office)

(cell)

b6

From: b6
Date: Monday, November 29, 2021 at 9:57 AM
To: Nath, Avindra (NIH/NINDS) [E] b6
Subject: Fwd: Per conversation with b6

Dear Dr. Nath,

I recently spoke with b6 about my post COVID vaccine and post-COVID infection disease course. She suggested I write to you directly. In a brief summary, b6 had COVID in b6 Although I was around him, I never tested positive but was exposed. On b6 I had the first Pfizer vaccine. Around this time, I developed a mild foot drop in my right foot. On b6 I received my second shot and within two weeks, had developed full foot drop in my right foot. I was worked up extensively with EMG showing b6 however, MRI found b6 I also developed a rash on my face and Raynauds on my right foot. My history is notable for b6

b6 I became ill with COVID. Although the cold was mild I have developed partial foot drop on the left side and progressive weakness up my right leg and signs of weakness in my left leg. I have been given the diagnosis of b6

I am writing to ask if this could be related to COVID and if I could be eligible to participate in research at the NIH. I would be willing to travel and am willing to provide test results to you via email prior to speaking with you if needed.

Thank you for your time.

Please feel free to reach out to set up a time to talk.

All the best.

b6

From: b6
Sent: 12/13/2021 5:18:22 PM
To: Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540 b6
CC: Smith, Bryan (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=de7bf3d6ad0046288fd8c35f33de3e57 b6 Farren, Jennifer (NIH/NINDS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0288f67595eb447bb14c29e872fbe4ba b6
Subject: [EXTERNAL] Re: Per conversation with b6

Hi Amanda,

No thanks, I am not interested at this time!

Take care,
b6

On Mon, Dec 13, 2021 at 11:12 AM Wiebold, Amanda (NIH/NINDS) [E] b6 wrote:

Hello b6

I was just following up on Dr. Smith's email below b6

b6

Please let us know.

Thank you,

Amanda Wiebold, BSN, RN, CNRN

Research Nurse Specialist

NINDS Section of Infections of the Nervous System

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

Bethesda, Maryland 20892

Office: b6

Cell: b6

Fax: 301-480-5594

Email: b6

From: Smith, Bryan (NIH/NINDS) [E] b6
Sent: Monday, December 6, 2021 11:27 AM
To: b6
Cc: Farren, Jennifer (NIH/NINDS) [C] b6 Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: Re: Per conversation with b6

Hi b6

Thank you for sharing your story and records, and our team is heartbroken to hear of your story. Based on the records, b6

b6

Best,

Bryan

--

Bryan Smith, MD

Staff Clinician, NINDS Section of Infections of the Nervous System

From: b6
Date: Tuesday, November 30, 2021 at 9:27 AM

To: "Nath, Avindra (NIH/NINDS) [E]" b6
Cc: "Kwan, Justin (NIH/NINDS) [E]" b6 "Safavi, Farinaz (NIH/NINDS) [E]" b6 "Wiebold, Amanda (NIH/NINDS) [E]" b6 "Smith, Bryan (NIH/NINDS) [E]" b6
Subject: Re: Per conversation with b6

Hi Dr. Nath,

Thanks so much for the quick reply! I have already heard from your team about how to send over records and will get started with that today.

Thank you.

b6

On Tue, Nov 30, 2021 at 1:47 AM Nath, Avindra (NIH/NINDS) [E] b6 wrote:

> Dear b6
>
> I am terribly sorry of hear of your illness. Yes, we would be glad to review all your medical records to determine if you would be eligible for one of our studies. I have copied several key members of our research team who will help review them with me.
>
> Best wishes.
>
> Avi
>
> Avindra Nath MD
>
> Chief, Section of Infections of the Nervous System
>
> Clinical Director,
>
> National Institute of Neurological Disorders and Stroke
>
> National Institutes of Health, Bethesda, MD
>
> b6 (Office)
>
> (cell)
>
> b6

From: b6
Date: Monday, November 29, 2021 at 9:57 AM
To: Nath, Avindra (NIH/NINDS) [E] b6
Subject: Fwd: Per conversation with b6

Dear Dr. Nath,

I recently spoke with b6 about my post COVID vaccine and post-COVID infection disease course. She suggested I write to you directly. In a brief summary, b6 had COVID in b6 Although I was around him, I never tested positive but was exposed. On b6 I had the first Pfizer vaccine. Around this time, I developed a mild foot drop in my right foot. On b6 I received my second shot and within two weeks, had developed full foot drop in my right foot. I was worked up extensively with EMG showing b6 however, MRI found b6 I also developed a rash on my face and Raynauds on my right foot. My history is notable for b6

b6 I became ill with COVID. Although the cold was mild I have developed partial foot drop on the left side and progressive weakness up my right leg and signs of weakness in my left leg. I have been given the diagnosis of b6

I am writing to ask if this could be related to COVID and if I could be eligible to participate in research at the NIH. I would be willing to travel and am willing to provide test results to you via email prior to speaking with you if needed.

Thank you for your time.

Please feel free to reach out to set up a time to talk.

All the best.

b6

From: b6
Sent: 4/1/2021 6:03:25 AM
To: Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540 b6
Subject: Re: Follow up from vaccine effects with Dr Safavi

I found it in my junk mailbox!! Let me know if either of those times work for you!!

Thanks

Sent from my iPhone

On Mar 31, 2021, at 10:59 PM, b6 wrote:

Hello Amanda

I have open 10:10 am on April 1st or 1:10pm
All on pacific standard time! Let me know what works for you. I also am not sure what email I should be looking for to receive the secured document?! I didn't see it but could search my email for it.

Thanks

b6

Sent from my iPhone

On Mar 30, 2021, at 1:59 PM, Wiebold, Amanda (NIH/NINDS) [E]
b6 wrote:

Hello b6

I have sent you a secure email with documents for your to review and instructions. Please review and let me know when you are available to talk by phone. My schedule is very flexible on Thursday.

Thanks,
Amanda

From: b6
Sent: Tuesday, March 30, 2021 4:18 PM
To: Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: Fwd: Follow up from vaccine effects with Dr Safavi

Sent from my iPhone

Begin forwarded message:

From: b6
Date: March 30, 2021 at 1:12:43 PM PDT
To: b6
Subject: Follow up from vaccine effects with Dr Safavi

I give my consent for the serum kit. Not sure what you need me to do. I also need to know where to send my results of all my tests. Thanks.

b6

Hi b6
How is everything? Hope your symptoms have improved.
Our research nurse did not receive any call from you for consent.Can you please contact her and schedule the consent which helps us to complete our paperwork.(her email address is b6
I also think at this moment bringing you to NIH is not easily possible but if you give us the consent we can send you a kit and information to send us your serum sample.

Please let me know if you have any questions/concerns
Thank you
Farinaz

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

Sent from my iPhone

From: b6
Sent: 4/1/2021 4:57:07 PM
To: Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540-b6
Subject: Re: Follow up from vaccine effects with Dr Safavi

Will you be calling me then?!

Sent from my iPhone

On Apr 1, 2021, at 7:11 AM, Wiebold, Amanda (NIH/NINDS) [E] b6 wrote:

b6

Let's do 10:10 AM PST (1:10 PM EST).

Thanks,
Amanda

From: b6
Sent: Thursday, April 1, 2021 1:59 AM
To: Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: Re: Follow up from vaccine effects with Dr Safavi

Hello Amanda

I have open 10:10 am on April 1st or 1:10pm
All on pacific standard time! Let me know what works for you. I also am not sure what email I should be looking for to receive the secured document?! I didn't see it but could search my email for it.

Thanks

b6

Sent from my iPhone

On Mar 30, 2021, at 1:59 PM, Wiebold, Amanda (NIH/NINDS) [E]
b6 wrote:

Hello b6

I have sent you a secure email with documents for your to review and instructions. Please review and let me know when you are available to talk by phone. My schedule is very flexible on Thursday.

Thanks,
Amanda

From: b6
Sent: Tuesday, March 30, 2021 4:18 PM
To: Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: Fwd: Follow up from vaccine effects with Dr Safavi

Sent from my iPhone

Begin forwarded message:

From: b6
Date: March 30, 2021 at 1:12:43 PM PDT
To: b6
Subject: Follow up from vaccine effects with Dr Safavi

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b6

Hi b6
How is everything? Hope your symptoms have improved.
Our research nurse did not receive any call from you for consent.Can you please contact her and schedule the consent which helps us to complete our paperwork.(her email address is b6
I also think at this moment bringing you to NIH is not easily possible but if you give us the consent we can send you a kit and information to send us your serum sample.

Please let me know if you have any questions/concerns
Thank you
Farinaz

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

Sent from my iPhone

From: b6
Sent: 4/14/2021 10:05:31 PM
To: Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540 b6
Subject: Re: Medical Records

Thanks!

On Apr 14, 2021, at 5:52 PM, Wiebold, Amanda (NIH/NINDS) [E]
b6 wrote:

Yes of course. Please see the attached.

Thanks,
Amanda

From: b6
Sent: Wednesday, April 14, 2021 5:43 PM
To: Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: Re: Medical Records

Per our phone conversation earlier today, could you please send me a protocol that I can access and read that's not in a secure message?

On Apr 12, 2021, at 12:39 PM, Wiebold, Amanda (NIH/NINDS) [E]
b6 wrote:

You have been sent a secure message/file(s).

To access the secure message/file(s), click on the following link or copy and paste the link into the browser.

Sender : Wiebold, Amanda (NIH/NINDS) [E]
Link : https://medicalsecureemail.nih.gov/ b6
b6

Sent To : b6
Expires : 4/17/24, 12:00:00 AM EDT

NIH SecureEmail Service, brought to you by the NIH Central Email Service.
*Proven*Trusted*

<15-N-0125.1.Consent.210402.pdf><NIH-1208 Authorization for the Release of Medical Information modified.pdf>

From: Wiebold, Amanda (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4491EE2AE9804610899C741100150540 b6
Sent: 4/14/2021 9:52:56 PM
To: b6
Subject: RE: Medical Records
Attachments: 15-N-0125.1.Consent.210402.pdf; NIH-1208 Authorization for the Release of Medical Information modified.pdf

Yes of course. Please see the attached.

Thanks,
Amanda

From: b6
Sent: Wednesday, April 14, 2021 5:43 PM
To: Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: Re: Medical Records

Per our phone conversation earlier today, could you please send me a protocol that I can access and read that's not in a secure message?

On Apr 12, 2021, at 12:39 PM, Wiebold, Amanda (NIH/NINDS) [E] b6 wrote:

You have been sent a secure message/file(s).

To access the secure message/file(s), click on the following link or copy and paste the link into the browser.

Sender : Wiebold, Amanda (NIH/NINDS) [E]
Link : https://medicalsecureemail.nih.gov/ b6
b6

Sent To : b6
Expires : 4/17/24, 12:00:00 AM EDT

NIH SecureEmail Service, brought to you by the NIH Central Email Service.
*Proven*Trusted*

PRINCIPAL INVESTIGATOR: Avindra Nath, MD

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

STUDY SITE: NIH Clinical Center

Cohort: Adult/Guardian Consent

Consent Version: 03/17/2020

WHO DO YOU CONTACT ABOUT THIS STUDY?

Principal Investigator: Avindra Nath, MD, b6

Study Coordinator: Amanda Wiebold, RN

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

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

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

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

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

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

WHY IS THIS STUDY BEING DONE?

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

BACKGROUND

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

STUDY POPULATION

Up to 1000 people will take part in this study.

VISIT SCHEDULE

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

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

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

OVERVIEW

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

BASELINE STUDY PROCEDURES:

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

History and Physical Exam:

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

Blood Draw

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

HIV Test

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

Genetic Testing

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

1. It may be analyzed to identify the genes that might be causing your condition. This will help us understand how changes in the genes may cause symptoms. Genetic testing can be helpful in establishing a diagnosis. It may eventually lead to improved treatment or prevention.

2. To try to identify genetic changes that may be associated with your condition we may sequence the part of the DNA that provides instructions for making proteins, called the "exome." The exome makes up about 1% of your DNA.

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

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

The genetic testing for this study will not detect all gene changes that are associated with known diseases. However, we will tell you if we find gene changes in your DNA that are known to have major and direct medical significance and are associated with illnesses or conditions that could benefit from early treatment. We call these "reportable gene changes." We suggest you share this

information with your own doctors and that you have a clinical laboratory confirm the "reportable gene change" before you take any action on this information.

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

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

MRI

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

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

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

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

Lumbar puncture

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

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

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

Banking and Sharing

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

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

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

OPTIONAL STUDY PROCEDURES

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

Optical coherence tomography (OCT)

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

Evoked Potentials

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

Electromyogram (EMG) and Nerve Conduction Study (NCS)

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

Neuropsychological Testing

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

Electroencephalogram (EEG)

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

Skin biopsy (adults only)

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

Urine Collection

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

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

Saliva Collection

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

RISKS, INCONVENIENCES AND DISCOMFORTS OF MAIN STUDY PROCEDURES:

History and Physical Exam

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

Blood Draw

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

Genetic Testing

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

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

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

Results of the research genetic testing in this study are often difficult to interpret because the testing is being done for research purposes only and the laboratories are not clinically certified. You may be referred to a CLIA certified laboratory, possibly outside of NIH, for additional testing or confirmation of the research results. NIH will not cover the cost of the additional testing. You or your insurer will be responsible for the cost.

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

HIV Testing

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

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

Urine Collection

There are no risks associated with urine collection.

Saliva Collection

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

MRI

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

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

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

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

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

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

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

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

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

Lumbar Puncture

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

Radiation Risk

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

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

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

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

Banking and Sharing

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

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

RISKS, INCONVENIENCES AND DISCOMFORTS OF ADDITIONAL STUDY PROCEDURES:

OCT

There are no known risks of OCT.

Evoked Potentials

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

EMG and NCS

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

Neuropsychological Testing

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

EEG

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

Skin Biopsy

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

INDUCED PLURIPOTENT STEM CELLS (IPS)

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

ADDITIONAL RISKS

Sedation

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

ANTICIPATED BENEFITS

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

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

For both adults and children, this study will likely increase our general knowledge of how infections and immune conditions affect the brain, and will probably help us to diagnose brain infections and immune disorders earlier and manage patients better. The study results may help to develop new treatments in the future.

RIGHT OF WITHDRAWAL AND CONDITIONS FOR EARLY WITHDRAWAL

You may withdraw from the study at any time and for any reason without loss of benefits or privileges to which you are otherwise entitled. The investigator can remove you from the study at any time if she or he believes that continuation is not in your best medical interest or if you are unable to comply with the requirements of the study.

ALTERNATIVES TO PARTICIPATION OR TREATMENT

The alternative is not to participate.

COMPENSATION, REIMBURSEMENT, AND PAYMENT

Will you receive compensation for participation in the study?

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

You will not receive compensation for participation in this study.

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

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

Reimbursement of travel will be offered consistent with NIH guidelines.

Will taking part in this research study cost you anything?

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

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Will your medical information be kept private?

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

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

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

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

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

Certificate of Confidentiality

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

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

The Certificate does not protect your information when it:

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

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

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

Privacy Act

The Federal Privacy Act generally protects the confidentiality of your NIH medical records we collect under the authority of the Public Health Service Act. In some cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act allows release of information from your medical record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to those engaged by the agency for research purposes, to certain

federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to tumor registries, for quality assessment and medical audits, or when the NIH is involved in a lawsuit. However, NIH will only release information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act.

POLICY REGARDING RESEARCH-RELATED INJURIES

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

PROBLEMS OR QUESTIONS

If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Avindra Nath, MD, b6 You may also call the NIH Clinical Center Patient Representative at 301-496-2626, or the NIH Office of IRB Operations at 301-402-3713, if you have a research-related complaint or concern.

CONSENT DOCUMENT

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

Adult Research Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to participate in this study.

Signature of Research Participant	Print Name of Research Participant	Date

Legally Authorized Representative (LAR) for an Adult Unable to Consent: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I am legally authorized to make research decisions on behalf of the adult participant unable to consent and have the authority to provide consent to this study. As applicable, the information in the above consent was described to the adult participant unable to consent who agrees to participate in the study.

Signature of LAR	Print Name of LAR	Date

Parent/Guardian of a Minor Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I give permission for my child to take part in this study.

Signature of Parent/Guardian	Print Name of Parent/Guardian	Date
Signature of Parent/Guardian *(as applicable)*	Print Name of Parent/Guardian	Date

Assent: *(Use this section only when this process is approved by an IRB for older minors. Do not use if an IRB requires a separate assent form for this population.)*

I have had this study explained to me in a way that I understand, I have been given the opportunity to discuss it, and I have had the chance to ask questions. I agree to take part in this study.

Assent of Minor: *(as applicable)*

Signature of Minor	Print Name of Minor	Date

Investigator:

Signature of Investigator	Print Name of Investigator	Date

Witness to the oral short-form consent process only: This section is only required if you are doing the oral short-consent process and this English consent form has been approved by the IRB for use as the basis of translation.

Witness:

Signature of Witness*	Print Name of Witness	Date

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

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

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

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

INSTRUCTIONS: Complete this form in its entirety and forward directly to the requesting facility.

CC PATIENT IDENTIFICATION

(Patient Name) (Patient Number) (Date of Birth)

SOURCE OF INFORMATION REQUESTED

(Name of Health Care Organization or Physician) (Phone Number) (Fax Number)

(Street Address) (City) (State) (Zip Code)

INFORMATION REQUESTED

The purpose or need for disclosure: Review of clinical care and consideration for research study

NIH Requestor/Point of Contact: Amanda Wiebold b6

Identify the specific items and related dates pertaining to the information to be released.

1. Medical Reports:

   Laboratory results, clinic notes, and brain MRI or head CT reports from _____ date(s).

   Send to: National Institutes of Health Clinical Center
   National Institute of Neurological Disorders and Stroke
   Building 10, Room 7C103
   10 CENTER DRIVE MSC 1430
   BETHESDA, MD 20892-1430
   ATTENTION: Amanda Wiebold/ Dr. Bryan Smith

   OR
   Fax to: (301) 480-5594
   Attn: Amanda Wiebold or
   Dr. Bryan Smith

2. MRI scans on CD from _____ date(s).

   Send to: National Institutes of Health Clinical Center
   National Institute of Neurological Disorders and Stroke
   Building 10, Room 7C103
   10 CENTER DRIVE MSC 1430
   BETHESDA, MD 20892-1430
   ATTENTION: Amanda Wiebold/ Dr. Bryan Smith

3. Tissue/Pathology Slides from _____ date(s).

   Send to: National Institutes of Health Clinical Center
   Laboratory of Pathology
   Building 10, Room 2B50
   10 CENTER DRIVE MSC 1500 BETHESDA,
   MD 20892-1500

AUTHORIZATION

I hereby authorize the release of the above-requested medical information.

(Signature of Patient/Legal Guardian) (Printed Name of Patient) (Date Signed)

(Street Address) (City) (State) (Zip Code)

From: Nath, Avindra (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B81CA051950B4D458D74037A6A86EAD6-b6]
Sent: 7/20/2021 2:22:03 PM
To: b6

Subject: Meet w/ b6 to discuss post Pfizer Covid vaccine issues
Location: Zoom

Start: 7/23/2021 9:00:00 PM
End: 7/23/2021 9:30:00 PM
Show Time As: Busy

Recurrence: (none)

Required Attendees: b6

Topic: Meet w/ b6 to discuss post Pfizer Covid vaccine issues
Time: Jul 23, 2021 05:00 PM Eastern Time (US and Canada)

Join ZoomGov Meeting
b6

Meeting ID: b6
Passcode: b6
One tap mobile
+16692545252 b6 US (San Jose)
+16468287666 US (New York)

Dial by your location
+1 669 254 5252 US (San Jose)
+1 646 828 7666 US (New York)
+1 551 285 1373 US
+1 669 216 1590 US (San Jose)
Meeting ID: b6
Passcode: b6
Find your local number: https://nih.zoomgov.com/u/adHNpa8y7v

Sent: 7/30/2021 6:21:19 PM
To: Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6-b6 Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246-b6
CC: b6
Subject: Update on 0125 Patient b6

Dr. Nath and Dr. Safavi,

b6 copied here, reached out to me to provide some updates on her care since she enrolled on the samples only arm of 15N0125 and was hoping for information/recommendations.

b6

Her concerns/questions:

b6

I told b6 that I would share her updates with you and ask that if you have any recommendations you could reach out to her for follow up. Her number is b6

Amanda Wiebold, BSN, RN, CNRN
Research Nurse Specialist
NINDS Section of Infections of the Nervous System
10 Center Drive, Building 10/7C107, MSC 1430
Bethesda, Maryland 20892
Office: b6
Cell: b6
Fax: 301-480-5594
Email: b6

From: Nath, Avindra (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B81CA051950B4D458D74037A6A86EAD6 b6
Sent: 7/23/2021 9:16:32 PM
To: b6

Subject: Meeting w/ b6 to discuss COVID Vaccine Allergic Reaction
Location: Zoom

Start: 7/30/2021 3:00:00 PM
End: 7/30/2021 3:30:00 PM
Show Time As: Busy

Recurrence: (none)

Required Attendees: b6

Topic: Meeting w/ b6 to discuss COVID Vaccine Allergic Reaction
Time: Jul 30, 2021 11:00 AM Eastern Time (US and Canada)

Join ZoomGov Meeting
b6

Meeting ID: b6
Passcode: b6
One tap mobile
+16692545252 b6 US (San Jose)
+16468287666 US (New York)

Dial by your location
+1 669 254 5252 US (San Jose)
+1 646 828 7666 US (New York)
+1 551 285 1373 US
+1 669 216 1590 US (San Jose)
Meeting ID: b6
Passcode: b6
Find your local number: https://nih.zoomgov.com/u/ae3D0njKJ

From: Jones, Antoinette (NIH/CC/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=668563213D304055953D974BCD8A269D b6
Sent: 8/30/2021 2:35:48 PM
To: Jones, Antoinette (NIH/CC/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=668563213d304055953d974bcd8a269d b6 b6 Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6 b6

Subject: 15-N-0125
Location: Microsoft Teams Meeting

Start: 8/30/2021 7:00:00 PM
End: 8/30/2021 7:30:00 PM
Show Time As: Busy

Required Attendees: b6 ; Nath, Avindra (NIH/NINDS) [E]

Microsoft Teams meeting

Join on your computer or mobile app
Click here to join the meeting

Or call in (audio only)
b6 United States, Bethesda
Phone Conference ID: b6
Find a local number | Reset PIN

Learn More | Meeting options

From: Wiebold, Amanda (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4491EE2AE9804610899C741100150540 b6]
Sent: 10/7/2022 8:13:02 PM
To: b6
Subject: RE: Thank you / b6

Great! Thank you for letting me know!
Have a great weekend and hope you have a speedy recovery.
Amanda

From: b6
Sent: Friday, October 7, 2022 4:12 PM
To: Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: [EXTERNAL] Re: Thank you / b6

Dear Amanda
Thank you very much for your effort.
For your info. both Dr. Safavi and Dr. Nath responded to my question. b6
Once again thank you and will the best.
Regards
b6

From: Wiebold, Amanda (NIH/NINDS) [E] b6
Sent: Thursday, October 6, 2022 6:39 PM
To: b6
Cc: Safavi, Farinaz (NIH/NIAID) [E] b6 Nath, Avindra (NIH/NINDS) [E] b6
Subject: RE: Urgent Question / b6

Hello b6

I am so sorry. I can imagine this is extremely concerning for you! I am copying Dr. Nath and Dr. Safavi so they can both see you question and respond to you.

Thank you,
Amanda

From: b6
Sent: Thursday, October 6, 2022 2:58 PM
To: Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: [EXTERNAL] Urgent Question / b6

Good afternoon, Amanda,

I have a question from Dr. Safavi,

b6

b6

please send my regards to her.
Thank you.

b6

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

From: b6
Sent: 4/13/2021 12:18:46 PM
To: Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6 b6
Subject: Re: Re:

Thank you!
b6

From: Nath, Avindra (NIH/NINDS) [E] b6
Sent: Tuesday, April 13, 2021 8:14 AM
To: b6
Subject: Re:

Agree. Good to pre-treat and to observe her. Some can develop a mast cell reaction but is transient.
Avi

From: b6
Date: Tuesday, April 13, 2021 at 7:55 AM
To: Nath, Avindra (NIH/NINDS) [E] b6
Subject: Re:

Sorry,
I forgot to tell you she had an event of b6 I am going to pretreat her with b6
b6

From: b6
Sent: Tuesday, April 13, 2021 7:49 AM
To: Nath, Avindra (NIH/NINDS) [E] b6
Subject:

Dear Avi,
Hope you are well.
I have a question about the vaccine. Your recommendations are important. b6 has the pfizer vaccine today. Do you think is safe? Do I need to observe her? Sorry but after my reaction I am overprotective.
Best,

b6

From: b6
Sent: 5/14/2021 12:08:17 PM
To: Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6 b6
Subject: Re: Moderna Vaccine Reaction (Ongoing since b6

Okay, thank you.
I have seen another Neurologist at b6 and they weren't able to find anything.
Should I mention that I have spoken with you and you recommended her?
Thank you so much for your quick response. I greatly appreciate it.
b6

On May 14, 2021, at 7:48 AM, Nath, Avindra (NIH/NINDS) [E] b6 wrote:

Sorry to hear of your illness. You might want to reach out to b6 in Neurology at b6 to see if she might be willing to investigate you for POTS and consider b6 She had treated another patient with similar symptoms from the vaccine.
Avi

From: b6
Date: Friday, May 14, 2021 at 2:14 AM
To: Nath, Avindra (NIH/NINDS) [E] b6
Subject: Moderna Vaccine Reaction (Ongoing since b6

Hello,

My name is b6 I belong to the CO-19 VASE Family on Facebook. It is from this group page that I got your email contact information. I hope that you don't mind me reaching out to you.

I am a b6 at b6 I'm b6 highly active, and healthy (no underlying conditions except b6 . Here is the timeline of what happened after I was inoculated with the Moderna Covid-19 Vaccine:

b6 1st Moderna Covid Vaccine: presented with Raynaud's Syndrome 4.5 hrs afterwards for 15-30 minute episodes (never had this occur before the vaccine). Followed up with my primary care provider, and now am being seen by a rheumatologist. Provided counsel that being administered 2nd dose of Moderna COVID-19 Vaccine benefits outweighed the risks.
b6 2nd Moderna Covid Vaccine: Started getting itchy bumps on bilateral front of neck about a week later. Then had what seemed like a pimple appear above my right eyebrow on b6 my right eye was swollen. By b6 I was diagnosed with b6 On b6 , I was sent to the ER to rule out b6 (I did not have this), but was not given diagnosis. Had bilateral lower leg muscle weakness, and upper neck/shoulder muscle weakness pain/fatigue. By b6 muscle/joint pain, muscle weakness, paresthesia in various areas of my body at various intervals, nausea, dizziness, constant headache, blurred vision, muscle twitching. I was seen by b6 Neurology and order MRI c b6 b6 . On b6 , seen by b6 Dermatology to have herpes like rash swabbed for b6 . b6 On b6 , b6 Neurology did EMG/NCS testing. b6 even though my toes were numb the entire time & they had difficulty regulating my body temperature in my extremities to perform the testing. b6 Neurology was unable to provide me with any explanation as to why my body is reacting to the vaccine with these

"complicated" symptoms. The best explanation I was given is that b6
b6
b6 and I may never find out the diagnosis or why my body is responding this way, but doctors are "positive" that my body will go back to normal within 6 months. Seen by rheumatology, unable to find diagnosis. Seen yesterday in b6 ER for 4 episodes of sudden Shortness of Breath, near Syncope, chest pain, left sided arm weakness, left arm numbness/pain, heart palpitations. EKG showed b6 Unable to find emergent findings and disposition was discharge home with referral to another specialist (cardiology). Previous EKG's prior to vaccine were b6

I have been thoroughly evaluated by some of the top Neurologists at b6 and referred to numerous specialists throughout b6 plus Rheumatology for extensive bloodwork. These different specialities are unable to find a clear diagnosis to explain any of these symptoms that are happening in my body.

I went from being a highly active, healthy b6 woman to a woman who is easily fatigued, has herpes like rashes on her face and different painful, rashes appearing on her body, dry mouth, red eyes, muscle weakness, muscle twitching, numbness in various body parts in different times of the day, vertigo, blurred vision, joint pain, brain fog. Doctors are unable to give me a diagnosis.

I have copies of all my medical records. I did inform my PCP that I was reaching out to you about my interest in the study you are conducting on others who have found me that seem to be experiencing similar symptoms.

Thank you,

b6

From: b6
Sent: 10/2/2021 2:47:48 PM
To: Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6-b6] Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540-b6]
CC: Smith, Bryan (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=de7bf3d6ad0046288fd8c35f33de3e57-b6] Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246-b6] (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=768f87322a624968841b8b6310e51174-b6]
Subject: Referral from b6
Attachments: b6

Hello Dr. Nath and Team,

My sincerest thank you for your willingness to help. Please see below for a more specific description of my case and applicable medical records. Amanda - let me know if you would like to discuss or any other next steps. I am incredibly grateful for your consideration of my case.

Thank you,
b6

Narrative of events:
I received the first dose of the Pfizer vaccine on b6 and the second on b6. I began to experience extreme weakness, a low grade fever and a sore throat shortly after and went to the ER on b6. Since then, a lot of other issues have emerged that are on the list below. I have seen my primary care physician, an infectious diseases specialist, an allergy specialist, and gynecologists. However, the cause of my symptoms has not been identified while the symptoms persist. I did not have any medical concerns before.

Bloodwork (attached):

b6

Tests completed that came back negative:

b6

Lastly, I had a CT scan done - no acute abnormality within the chest, abdomen, or pelvis to explain symptoms. When I saw the allergist, she said some of my symptoms (stuffiness, sore throat, tonsil pain) could be due to allergies. The test showed I experienced an allergic reaction to every category of allergens. However, I have never had allergies despite living in b6 for a very long time.

List of Symptoms:
Extreme weakness, fatigue and malaise since vaccine
Low grade fever of 37.3
Sore throat and tonsils, chest pain, feeling of inflammation in lungs, stuffiness
Heart palpitations
Prolonged menstrual periods (14 days), change in cycle, bleeding and spotting outside of period
Rash of small red dots on arms, legs and torso, skin sensitivity and feeling of heat
Severe night sweats
Dizziness and tinnitus
Joint, muscle and back pain
Weight loss and muscle degeneration
Loss of appetite
Twitching all over body
Veins protruding
Brain fog
New allergies

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From: b6
Sent: 10/7/2022 2:54:59 AM
To: Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6b6 Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540b6
CC: Safavi, Farinaz (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246b6
Subject: [EXTERNAL] Re: Urgent Question /b6

Thank you. I appreciate that.

From: Nath, Avindra (NIH/NINDS) [E] b6
Sent: Thursday, October 6, 2022 9:22:29 PM
To: Wiebold, Amanda (NIH/NINDS) [E] b6
Cc: Safavi, Farinaz (NIH/NIAID) [E] b6
Subject: Re: Urgent Question /b6

Dear b6
b6 But your physician would be the best person to guide you.
Best.
Avi
Avindra Nath MD

From: Wiebold, Amanda (NIH/NINDS) [E] b6
Date: Thursday, October 6, 2022 at 7:39 PM
To: b6
Cc: Safavi, Farinaz (NIH/NIAID) [E] b6 Nath, Avindra (NIH/NINDS) [E] b6
Subject: RE: Urgent Question /b6

Hello b6

I am so sorry. I can imagine this is extremely concerning for you! I am copying Dr. Nath and Dr. Safavi so they can both see you question and respond to you.

Thank you,
Amanda

From: b6
Sent: Thursday, October 6, 2022 2:58 PM
To: Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: [EXTERNAL] Urgent Question /b6

Good afternoon, Amanda,

I have a question from Dr. Safavi,

b6

b6

please send my regards to her.
Thank you.

b6

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

From: b6
Sent: 2/25/2021 9:32:42 PM
To: Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6 b6
Subject: Re: FW: Your offer to see b6 experiencing long term post-vaccination symptoms

Hi Dr. Nath,
Thank you for fitting me in your busy schedule. I am very excited to meet with you and to see how you can possibly help me. Please let me know how we can set up an appointment. Feel free to call me.
Thank you.

b6

On Thu, Feb 25, 2021 at 2:34 PM Nath, Avindra (NIH/NINDS) [E] b6 wrote:

Dear b6

Sorry to hear of your illness. Dr. Safavi and I will be glad to meet with you to see how we can help. I have copied other members of our team who can help set up a virtual meeting.

All the best.

Avi

Avindra Nath MD

Chief, Section of Infections of the Nervous System

Clinical Director,

National Institute of Neurological Disorders and Stroke

National Institutes of Health, Bethesda, MD

b6 (Office)

(cell)

b6

From: b6
Date: Thursday, February 25, 2021 at 2:14 PM

To: "Nath, Avindra (NIH/NINDS) [E]" b6
Cc: b6
Subject: Your offer to see b6 experiencing long term post-vaccination symptoms

Dr. Nath,

b6 was nice enough to share with me your kind offer to meet with b6 who is having persistent symptoms after her vaccination. She saw our allergy and immunologist on Wednesday, and in follow up today I learned that she is still having symptoms, so we would like to take you up on this opportunity. Per your suggestion, I'll share your contact information with the patient.

I'm attaching a timeline summary of the workup that has occurred so far, for your reference, also including b6 contact information. I did not give her your cellphone but I gave her your office number and email. Let me know if I should do differently, and if easier I'm sure she'd be fine if your office reached out to her as well.

This is a big relief to us, that we have another avenue for further workup for b6 You have my deep personal appreciation for this- I hope we can do something to help you in the future. You were independently recommended by both b6

Here is the patient's contact information:

b6

With Appreciation,

b6

PS- we're so honored to be working with b6 —she comes with such a rich background from b6

b6

b6

b6

From: Nath, Avindra (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B81CA051950B4D458D74037A6A86EAD6 b6
Sent: 9/5/2021 10:25:21 PM
To: b6
Subject: Re: Inquiry b6 Covid + b6 Adverse Reaction to Moderna Vaccine (Ongoing since b6

Dear b6
Terribly sorry to hear of your illness. b6 Depending on where you live you might want to call the emergency room of one of the major hospitals and see if they might be able to give it to you. It is possible that b6
Best wishes.
Avi

From: b6
Date: Sunday, September 5, 2021 at 12:58 PM
To: Nath, Avindra (NIH/NINDS) [E] b6
Subject: Inquiry b6 - Covid - b6 Adverse Reaction to Moderna Vaccine (Ongoing since b6

Good Afternoon,

Hope you are doing well. My name is b6 I emailed you back in May about the numerous adverse effects I was experiencing from Moderna Vaccine (Was provided your contact from Co-19 Vase group on FB).
Thank you for the recommendation to see b6 for POTS, and b6 Unfortunately, b6 is leaving b6 but I was able to get an appointment in December with b6 POTS clinic.

I am inquiring today because b6 b6 and I was her caretaker (since I am b6 and vaccinated).
However, b6 and am concerned because I still am experiencing the adverse effects from the vaccine.

I am curious about receiving b6 and how to obtain these quickly, as it is a holiday weekend.

I do have information about b6 but will not be able to contact doctors until Tuesday.
Is there any reccomemdations that you suggest?
Unfortunately, I have not been able to make any progress on treatment for the vaccine reaction, other than what your suggested.

Thank you so much,

b6

On May 14, 2021, at 12:15 PM, b6 wrote:

I see b6

He has a fellow of the name b6 who I reached o it to via MyChart this morning asking if I could see b6 since I am being followed by them. I also gave them your contact info.
b6 told me that b6 was leaving b6 in a month or so, and she gave me a referral to the POTS clinic here at b6 I called to make an appointment, earliest was December.
I asked b6 if anyone at b6 Neurology was like b6 and was willing to contact you and follow treatment recommendations.
No response.

Thank you so much again for your response ,

b6

On May 14, 2021, at 11:00 AM, Nath, Avindra (NIH/NINDS) [E] b6 wrote:

Who did you see?

From: b6
Date: Friday, May 14, 2021 at 8:34 AM
To: Nath, Avindra (NIH/NINDS) [E] b6
Subject: Re: Moderna Vaccine Reaction (Ongoing since b6

One more thing.. I work for b6 and am a b6
I can attempt to go around the Neurologist I've already seen, but it's going to be tricky since they've already "ruled out everything dangerous".
Thank you again,
b6

On May 14, 2021, at 7:48 AM, Nath, Avindra (NIH/NINDS) [E]
b6 wrote:

Sorry to hear of your illness. You might want to reach out to b6 in Neurology at b6 to see if she might be willing to investigate you for POTS and consider b6 She had treated another patient with similar symptoms from the vaccine.
Avi

From: b6
Date: Friday, May 14, 2021 at 2:14 AM
To: Nath, Avindra (NIH/NINDS) [E] b6
Subject: Moderna Vaccine Reaction (Ongoing since b6

Hello,

My name is b6 I belong to the CO-19 VASE Family on Facebook. It is from this group page that I got your email contact information. I hope that you don't mind me reaching out to you.

I am a b6 at b6 I'm b6 highly active, and healthy (no underlying conditions except b6 b6 Here is the timeline of what happened after I was inoculated with the Moderna Covid-19 Vaccine:

b6 1st Moderna Covid Vaccine: presented with Raynaud's Syndrome 4.5 hrs afterwards for 15-30 minute episodes (never had this occur before the vaccine). Followed up with my primary care provider, and now am being seen by a rheumatologist. Provided counsel that being administered 2nd dose of Moderna COVID-19 Vaccine benefits outweighed the risks.

b6 2nd Moderna Covid Vaccine: Started getting itchy bumps on bilateral front of neck about a week later. Then had what seemed like a pimple appear above my right eyebrow or b6 , by b6 my right eye was swollen. B b6 , I was diagnosed with b6 On b6 I was sent to the ER to rule out b6 (I did not have this), but was not given diagnosis. Had bilateral lower leg muscle weakness, and upper neck/shoulder muscle weakness pain/fatigue. By b6 muscle/joint pain, muscle weakness, paresthesia in various areas of my body at various intervals, nausea, dizziness, constant headache, blurred vision, muscle twitching. I was seen by b6 Neurology and order MRI b6 On b6 seen by b6 Dermatology to have herpes like rash swabbed for b6 b6 b6 On b6 b6 Neurology did EMG/NCS testing. b6 even though my toes were numb the entire time & they had difficulty regulating my body temperature in my extremities to perform the testing. b6 Neurology was unable to provide me with any explanation as to why my body is reacting to the vaccine with these "complicated" symptoms. The best explanation I was given is that b6 b6 b6 and I may never find out the diagnosis or why my body is responding this way, but doctors are "positive" that my body will go back to normal within 6 months. Seen by rheumatology, unable to find diagnosis. Seen yesterday in b6 ER for 4 episodes of sudden Shortness of Breath, near Syncope, chest pain, left sided arm weakness, left arm numbness/pain, heart palpitations. EKG showed b6 b6 Unable to find emergent findings and disposition was discharge home with referral to another specialist (cardiology). Previous EKG's prior to vaccine were b6

I have been thoroughly evaluated by some of the top Neurologists at b6 and referred to numerous specialists throughout b6 b6 plus Rheumatology for extensive bloodwork. These different specialities are unable to find a clear diagnosis to explain any of these symptoms that are happening in my body.

I went from being a highly active, healthy b6 woman to a woman who is easily fatigued, has herpes like rashes on her face and different painful, rashes appearing on her body, dry mouth, red eyes, muscle weakness, muscle twitching, numbness in various body parts in different times of the day, vertigo, blurred vision, joint pain, brain fog.

Doctors are unable to give me a diagnosis.

I have copies of all my medical records. I did inform my PCP that I was reaching out to you about my interest in the study you are conducting on others who have found me that seem to be experiencing similar symptoms.

Thank you,

b6

From: b6
Sent: 3/3/2021 4:34:32 AM
To: Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246-b6
Subject: Re: Myself

Thank you Farinaz. I will await your call.

Sent from my iPhone

On Mar 2, 2021, at 8:03 PM, Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Dear b6
I am really sorry to hear about your symptoms. We definitely can schedule a televisit in mutually convenient time to go over the details. I will coordinate with our team and get back to you tomorrow.
Best Regards,
Farinaz

Farinaz Safavi MD, PhD
Section of Infections of the Nervous System
Division of Neuroimmunology and Neurovirology
NINDS, NIH

From: Nath, Avindra (NIH/NINDS) [E]
Sent: Tuesday, March 2, 2021 9:04 PM
To: b6
Cc: Safavi, Farinaz (NIH/NINDS) [E]; Wiebold, Amanda (NIH/NINDS) [E]; Smith, Bryan (NIH/NINDS) [E]
Subject: Re: Myself

Dear b6
I am terribly sorry to hear of your illness. We are following several patients with neurological symptoms from the COVID vaccines I have copied members of my research team who will get in touch with you. Dr. Safavi is leading the effort and will do a televisit and then we will like to obtain some medical records and blood samples. You would need to be enrolled on to our research study for this purpose. Our hope to try and identify if there is some kind of molecular mimicry between vaccine and the antigens in the nervous system.
With best wishes.
Avi
Avindra Nath MD
Chief, Section of Infections of the Nervous System
Clinical Director,
National Institute of Neurological Disorders and Stroke
National Institutes of Health, Bethesda, MD
b6 (Office)
(cell)
b6

On 3/2/21, 4:54 PM, b6 wrote:

Hi Dr. Nath,

My name is b6 I was given your name by b6

I am a b6 in b6 who had a severe reaction to the Pfizer Covid Vaccine b6 I was previously healthy and 30 minutes after receiving the vaccine developed burning in my face, had a pre-syncopal event and my blood pressure spiked very high. I initially became bedridden for one week with severe malaise and paresthesias in my face and tongue. I also felt a tight band like constriction around my chest. I was treated with b6 b6 Since that time, energy has improved but I have severe paresthesias in my face, head, tongue and mouth, chest, abdomen and limbs. At times they are incapacitating. I feel a vibration in my head and hands. The tight band around my chest persists. I have had extensive negative neurological and rheumatological work up and have seen several doctors in b6 who have no clue what has happened to me. b6 at b6 found b6 b6 and b6 at b6 put me on b6 b6

Are you aware of these reactions and what is causing them? Is there anything that can help me? I am quite incapacitated. I have collected a group of people whom I met through the internet with similar reactions to mine. Several are physicians as far away as France and Argentina. Pfizer, the FDA and CDC have been unhelpful.

Any help or insight you can give me would be most appreciated.

Sincerely,

b6

Sent from my iPhone

From: b6
Sent: 4/1/2021 1:37:03 PM
To: Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 b6
Subject: Re: [EXTERNAL] Post covid vaccine neurological complications
Attachments: b6

Here are the attachments
Forgot to send on previous

From: b6
Sent: Thursday, April 1, 2021 9:32 AM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Re: [EXTERNAL] Post covid vaccine neurological complications

Hi Dr. Safavi,

I have sent signed consent forms to Anna Wiebold (nurse assisting on research)

Attached are office notes and b6 from my neurologist. Also attached are reports from the b6 b6

CD copies of the imaging is a little more difficult to get to you. You could try calling the neurology office or the MRI imaging secretary's directly- b6

Thanks
b6

From: Safavi, Farinaz (NIH/NINDS) [E] b6
Sent: Monday, March 29, 2021 5:20 PM
To: b6
Subject: Re: [EXTERNAL] Post covid vaccine neurological complications

Dure,I will send you MS teams link for the televist.
Thank you very much!
Best Regards,

Farinaz

From: b6
Sent: Monday, March 29, 2021 5:17:32 PM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Re: [EXTERNAL] Post covid vaccine neurological complications

OK. 10am is ok.
I will complete the consent forms after we talk. I do plan on participating.

b6

From: Safavi, Farinaz (NIH/NINDS) [E] b6
Sent: Monday, March 29, 2021 12:10 PM
To: b6 Wiebold, Amanda (NIH/NINDS) [E]
b6
Subject: RE: [EXTERNAL] Post covid vaccine neurological complications

Sure,Is tomorrow at 10am work for you? If so I will send you televisit link.
I also would like to follow up with you regarding consent and medical release form.Have you received them. Please kindly let us know.
Thank you
Farinaz

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

From: b6
Sent: Sunday, March 28, 2021 8:56 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: [EXTERNAL] Post covid vaccine neurological complications

This week I could do a televisit:
Monday Afternoon
Tuesday Morning
Thursday or Friday- Flexible

b6

From: Safavi, Farinaz (NIH/NINDS) [E] b6
Sent: Friday, March 26, 2021 9:52 AM
To: b6
Subject: RE: [EXTERNAL] Post covid vaccine neurological complications

Dear b6
Hope all is well.I would like to follow up with you to find a mutual convenient time to schedule a televisit.
Please let me know what days work the best for you?
Thank you
Farinaz

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

From: b6
Sent: Sunday, March 21, 2021 8:27 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: [EXTERNAL] Post covid vaccine neurological complications

I am interested in participating.

b6

From: Safavi, Farinaz (NIH/NINDS) [E] b6
Sent: Thursday, March 18, 2021 3:41 PM
To: b6
Subject: RE: [EXTERNAL] Post covid vaccine neurological complications

Dear b6
Thank you very much for your respond.
Basically for this research we just need to meet with you through televisit once talking about your issue and our research team coordinate to get consent to receive your medical records and possibility of sending us serum samples. This is not a study with many long questionnaire and mainly we are trying to characterize COVID vaccine side effects and potentially propose the pathogenesis.
I would be happy to answer any questions and really appreciate if you kindly let me know are you interested to proceed with our protocol.
Best Regards,
Farinaz

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

From: b6
Sent: Wednesday, March 17, 2021 9:17 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: [EXTERNAL] Post covid vaccine neurological complications

Dear Dr. Safavi,

I would be happy to participate in your study as long as it isnt too burdensome.
As regards my symptoms: They gradually improved and in early February there was very little residual mostly or only consisting of right hand ulnar sided mild paresthesia. As of early March all symptoms are resolved. I had a b6 which began 9 days after symptom onset.

Please feel free to contact me and I can provide more information as needed.

Best
b6

From: Safavi, Farinaz (NIH/NINDS) [E] b6
Sent: Wednesday, March 17, 2021 1:24 PM

To: b6
Subject: [EXTERNAL] Post covid vaccine neurological complications

Dear b6

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

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

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

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

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

received this email in error, please delete it and immediately notify the person named above by reply email. Thank you.

b6

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From: b6
Sent: 10/14/2021 3:53:23 PM
To: Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 b6
CC: Smith, Bryan (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=de7bf3d6ad0046288fd8c35f33de3e57 b6
b6 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=768f87322a624968841b8b6310e51174 b6
Subject: Re: Referral from b6
Attachments: b6

Hi Farinaz,

I just wanted to share that my PCP and I went ahead and submitted bloodwork for b6 b6 I thought it may be relevant as you and Dr. Nath consider my case.

Please let me know once you have had a chance to speak with him.

Thank you very much,
b6

On Tue, Oct 12, 2021 at 4:39 PM b6 wrote:

> Thank you so much, Farinaz. I really appreciate it.
>
> This is truly the most difficult situation I have ever been in and I have little hope because the issues keep presenting. I am happy to come to NIH anytime as addressing this is the most important thing in my life. My state is preventing me from working to my best ability, let alone engaging in any exercise or social activities.
>
> Please let me know if there's anything else I can do at all.
>
> Thank you again,
> b6

On Tue, Oct 12, 2021 at 4:31 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

> Dear b6
>
> I am really sorry that your symptoms have aggravated recently.
>
> Since there was a federal holiday yesterday we did not have our usual meeting to discuss your case. Additionally Bryan is out of office for next afew weeks.
>
> The questions you asked are all legit ones and we really do not know the exact underlying cause of your symptoms but we have some clues to say it might be immune mediated however the exact nature of it is still unknown.

Please give me a couple of days to discuss with Dr.Nath and will get back to you about how we can proceed.

Thank you

Farinaz

From: b6
Sent: Tuesday, October 12, 2021 1:02 PM
To: Safavi, Farinaz (NIH/NINDS) [E]; Smith, Bryan (NIH/NINDS) [E] b6
b6
Subject: Re: Referral from b6

Hi Farinaz and Bryan,

Thank you for taking the time to talk to me last Tuesday. I wanted to check-in and see if you had a chance to discuss my case and if there were any next steps. I am going through another pretty bad flare up with my skin rash becoming painful, fever, weakness and night sweats. In addition, my joint and muscle pain is getting worse and I am seeing bruises on my body for an unknown reason. As you can imagine, it's extremely disruptive to my life especially as I have been dealing with it for almost 6 months now. I am very desperate.

Is it possible to at least begin testing to verify our hypotheses? Is it autoimmune? Is it vascular or multi-system inflammation? Is it long-COVID if I had a prior infection in Feb 2020? Is it hormonal? As you know, it has been very difficult to work with my PCP and specialists because they don't understand what's going on.

Again, I really appreciate you working with me - it gives me hope every day.

Thank you,

b6

On Mon, Oct 4, 2021 at 2:01 PM b6 wrote:

> Hi Farinaz,

Thank you very much for your reply. Tomorrow from 3-4pm would work great for me.

I look forward to receiving the link and speaking with you,

b6

On Mon, Oct 4, 2021 at 10:51 AM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Dear b6

Thank you very much for your email and history. We would like to schedule a televisit with you to gain more information from you. I will be available tomorrow from 11-1pm and from 3-4pm or Wednesday in the morning before noon.

Please let me know and I can send you the link.

Thank you

Farinaz Safavi MD, PhD

Division of Neuroimmunology and Neurovirology

NINDS, NIH, Bethesda, MD

From: b6
Sent: Saturday, October 2, 2021 10:48 AM
To: Nath, Avindra (NIH/NINDS) [E]; Wiebold, Amanda (NIH/NINDS) [E]
Cc: Smith, Bryan (NIH/NINDS) [E]; Safavi, Farinaz (NIH/NINDS) [E]; b6
b6
Subject: Referral from b6

Hello Dr. Nath and Team,

My sincerest thank you for your willingness to help. Please see below for a more specific description of my case and applicable medical records. Amanda - let me know if you would like to discuss or any other next steps. I am incredibly grateful for your consideration of my case.

Thank you,

b6

Narrative of events:

I received the first dose of the Pfizer vaccine on b6 and the second on b6 . I began to experience extreme weakness, a low grade fever and a sore throat shortly after and went to the ER on b6 . Since then, a lot of other issues have emerged that are on the list below. I have seen my primary care physician, an infectious diseases specialist, an allergy specialist, and gynecologists. However, the cause of my symptoms has not been identified while the symptoms persist. I did not have any medical concerns before.

Bloodwork (attached):

b6

Tests completed that came back negative:

b6

Lastly, I had a CT scan done - no acute abnormality within the chest, abdomen, or pelvis to explain symptoms. When I saw the allergist, she said some of my symptoms (stuffiness, sore throat, tonsil pain) could be due to allergies. The test showed I experienced an allergic reaction to every category of allergens. However, I have never had allergies despite living in b6 for a very long time.

List of Symptoms:

Extreme weakness, fatigue and malaise since vaccine
Low grade fever of 37.3
Sore throat and tonsils, chest pain, feeling of inflammation in lungs, stuffiness
Heart palpitations
Prolonged menstrual periods (14 days), change in cycle, bleeding and spotting outside of period
Rash of small red dots on arms, legs and torso, skin sensitivity and feeling of heat
Severe night sweats
Dizziness and tinnitus
Joint, muscle and back pain
Weight loss and muscle degeneration
Loss of appetite
Twitching all over body

Veins protruding
Brain fog
New allergies

b6

From: b6
Sent: 10/20/2021 2:42:20 PM
To: Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 b6
CC: Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540- b6 Nahar, Kymani (NIH/NINDS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f432f899337490ea7cbde0a4b52effb b6
Subject: Re: Referral from b6

Hi Farinaz,

Thank you very much. That sounds like a very good way to proceed.

Amanda and Nahar - please let me know how to schedule my first appointment and anything I need to do. I appreciate your help!

Wishing everyone a great day,
b6

On Wed, Oct 20, 2021 at 10:40 AM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Hi b6

We definitely can schedule the LP for different time than 1st visit. We also have the option to schedule it under X-RAY that neuro-radiologist can see the space and perform it.

CSF study will help us to find the footprint of inflammation in nervous system and can be helpful to provide more information for potential treatment.

As you may already read in consent form, the purpose of our research is to perform very comprehensive evaluation to gain as much as information about your and people like you who suffer from the disease. of course if in this process we find enough evidence ,we definitely discuss our understanding, test results and potential treatment with you and your outside physicians to help proceeding for next step.

Hope I answered all your questions.

Farinaz

From: b6
Sent: Tuesday, October 19, 2021 11:13 AM
To: Safavi, Farinaz (NIH/NINDS) [E]
Cc: Wiebold, Amanda (NIH/NINDS) [E]; Nahar, Kymani (NIH/NINDS) [C]
Subject: Re: Referral from b6

Hi Dr. Safavi,

Thank you very much for elaborating on the process. I am fine with all the tests but the lumbar puncture makes me very nervous - is it possible to start with the other tests and then see if the LP is necessary? Can I still participate if I forgo that test?

And lastly, I assume the purpose of the tests is to come up with a better understanding of what is causing my symptoms and a potential diagnosis. Does the team at NIH also help identify treatment options?

Thank you very much,

b6

On Mon, Oct 18, 2021 at 8:53 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Hi b6

The typical process is our team meet you first for consent,history and exam. The protocol has some basic tests including Blood draw,MRI and LP which are necessary work up for neuroinflammatory diseases and the most important ones that can help to determine any footprint of inflammation in nervous system.

It also includes other tests that we may decide to do for example the autonomic testing based on your symptoms.

MRI is not xray based imaging. In terms of lab tests we have a list of labs(very comprehensive work up) to exclude a lot if underlying autoinflammatory diseases that we have been sending for patients with post vaccine adverse events.Regarding LP, cerebrospinal fluid analysis may help us to

evaluate whether there is inflammatory process in brain and guide us through the cause of your symptoms.

Finally,this is a research protocol to evaluate neuroinflammatory diseases and as you may know the participation is completely voluntarly so that please let us know how you would like to proceed.

Regarding testing timeline,Amanda and Kymani are great and try to coordinate several tests on the same day to save your time.

Amanda,please add further information if I miss anything here.

Hope I answered your questions.Please let us know if you have further questions.

Best

Farinaz

From: b6
Sent: Monday, October 18, 2021 2:57:56 PM
To: Safavi, Farinaz (NIH/NINDS) [E] b6 Wiebold, Amanda (NIH/NINDS) [E] b6
Cc: Nahar, Kymani (NIH/NINDS) [C] b6
Subject: Re: Referral from b6

Hi Amanda and Dr. Safavi,

Thank you for the information. I have taken the weekend to review the tests and have a few questions:

- What is the typical process for this protocol and testing? Would I first meet with the doctors to discuss hypotheses, what the test is for, etc.?
- Is it possible to forego a test? I have done a lot of tests this year that involved radiology and would like to limit further exposure. I am specifically concerned about the lumbar puncture.
- What does the testing timeline look like typically? Is it possible to have multiple tests done in one visit?

I appreciate you providing extra context for the protocol.

Thank you,

b6

On Thu, Oct 14, 2021 at 12:18 PM Wiebold, Amanda (NIH/NINDS) [E] b6 wrote:

b6

As Dr. Safavi has mentioned she would like to evaluate you here at the NIH under our natural history protocol 15N0125. I have attached a copy of the consent form just for your review. The studies that she would like you to do include consent, exam, blood work, brain MRI with contrast, lumbar puncture done under x-ray, skin biopsy, EMG, and autonomic testing. Please let Dr. Safavi or myself know if you have any questions.

Kymani (copied here) will be the one to get you scheduled.

Thank you,

Amanda Wiebold, BSN, RN, CNRN

Research Nurse Specialist

NINDS Section of Infections of the Nervous System

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

Bethesda, Maryland 20892

Office: b6

Cell: b6

Fax: 301-480-5594

Email: b6

From: b6
Sent: Thursday, October 14, 2021 11:59 AM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Cc: Smith, Bryan (NIH/NINDS) [E] b6
b6 Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: Re: Referral from b6

Thank you so much, Farinaz! I appreciate it enormously.

Amanda - I look forward to hearing from you on next steps.

On Thu, Oct 14, 2021 at 11:57 AM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Hi b6

I spoke with the team and we can bring you to NIH under our neuroinflammatory research protocol.I cc Amanda(our research nurse) for further information.

Best

Farinaz Safavi MD, PhD

Division of Neuroimmunology and Neurovirology

NINDS, NIH, Bethesda, MD

From: b6
Sent: Thursday, October 14, 2021 11:53 AM
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Cc: Smith, Bryan (NIH/NINDS) [E] b6
Subject: Re: Referral from b6

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Please let me know once you have had a chance to speak with him.

Thank you very much,

[b6]

On Tue, Oct 12, 2021 at 4:39 PM [b6] wrote:

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> This is truly the most difficult situation I have ever been in and I have little hope because the issues keep presenting. I am happy to come to NIH anytime as addressing this is the most important thing in my life. My state is preventing me from working to my best ability, let alone engaging in any exercise or social activities.
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> Please let me know if there's anything else I can do at all.
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> Thank you again,
>
> [b6]
>
> On Tue, Oct 12, 2021 at 4:31 PM Safavi, Farinaz (NIH/NINDS) [E] [b6] wrote:
>
> > Dear [b6]

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The questions you asked are all legit ones and we really do not know the exact underlying cause of your symptoms but we have some clues to say it might be immune mediated however the exact nature of it is still unknown.

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Thank you

Farinaz

From: b6
Sent: Tuesday, October 12, 2021 1:02 PM
To: Safavi, Farinaz (NIH/NINDS) [E]; Smith, Bryan (NIH/NINDS) [E]; b6
b6
Subject: Re: Referral from b6

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Thank you,

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> b6
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> > Dear b6
> >
> > Thank you very much for your email and history. We would like to schedule a televisit with you to gain more information from you. I will be available tomorrow from 11-1pm and from 3-4pm or Wednesday in the morning before noon.
> >
> > Please let me know and I can send you the link.
> >
> > Thank you
> >
> > Farinaz Safavi MD, PhD
> >
> > Division of Neuroimmunology and Neurovirology
> >
> > NINDS, NIH, Bethesda, MD

From: b6
Sent: Saturday, October 2, 2021 10:48 AM
To: Nath, Avindra (NIH/NINDS) [E]; Wiebold, Amanda (NIH/NINDS) [E]
Cc: Smith, Bryan (NIH/NINDS) [E]; Safavi, Farinaz (NIH/NINDS) [E]; b6
b6
Subject: Referral from b6

Hello Dr. Nath and Team,

My sincerest thank you for your willingness to help. Please see below for a more specific description of my case and applicable medical records. Amanda - let me know if you would like to discuss or any other next steps. I am incredibly grateful for your consideration of my case.

Thank you,

b6

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Bloodwork (attached):

b6

Tests completed that came back negative:

b6

b6

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List of Symptoms:

Extreme weakness, fatigue and malaise since vaccine
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Sore throat and tonsils, chest pain, feeling of inflammation in lungs, stuffiness
Heart palpitations
Prolonged menstrual periods (14 days), change in cycle, bleeding and spotting outside of period
Rash of small red dots on arms, legs and torso, skin sensitivity and feeling of heat
Severe night sweats
Dizziness and tinnitus
Joint, muscle and back pain
Weight loss and muscle degeneration
Loss of appetite
Twitching all over body

Veins protruding
Brain fog
New allergies

From: b6
Sent: 10/18/2021 7:00:40 PM
To: Smith, Bryan (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=de7bf3d6ad0046288fd8c35f33de3e57b6 Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246b6
CC: b6 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=768f87322a624968841b8b6310e51174b6
Subject: Re: Referral from b6
Attachments: b6

Hi Bryan and Farinaz,

I wanted to share two additional tests results that I have received. The first is b6
b6

The second is b6

b6

I thought these may be relevant as you consider my case.

Thank you,
b6

On Sat, Oct 2, 2021 at 10:47 AM b6 wrote:

> Hello Dr. Nath and Team,
>
> My sincerest thank you for your willingness to help. Please see below for a more specific description of my case and applicable medical records. Amanda - let me know if you would like to discuss or any other next steps. I am incredibly grateful for your consideration of my case.
>
> Thank you,
> b6
>
> **Narrative of events:**
> I received the first dose of the Pfizer vaccine on b6 and the second on b6 . I began to experience extreme weakness, a low grade fever and a sore throat shortly after and went to the ER on b6 . Since then, a lot of other issues have emerged that are on the list below. I have seen my primary care physician, an

infectious diseases specialist, an allergy specialist, and gynecologists. However, the cause of my symptoms has not been identified while the symptoms persist. I did not have any medical concerns before.

Bloodwork (attached):

b6

Tests completed that came back negative:

b6

Lastly, I had a CT scan done - no acute abnormality within the chest, abdomen, or pelvis to explain symptoms. When I saw the allergist, she said some of my symptoms (stuffiness, sore throat, tonsil pain) could be due to allergies. The test showed I experienced an allergic reaction to every category of allergens. However, I have never had allergies despite living in b6 for a very long time.

List of Symptoms:
Extreme weakness, fatigue and malaise since vaccine
Low grade fever of 37.3
Sore throat and tonsils, chest pain, feeling of inflammation in lungs, stuffiness
Heart palpitations
Prolonged menstrual periods (14 days), change in cycle, bleeding and spotting outside of period
Rash of small red dots on arms, legs and torso, skin sensitivity and feeling of heat
Severe night sweats
Dizziness and tinnitus
Joint, muscle and back pain
Weight loss and muscle degeneration
Loss of appetite
Twitching all over body
Veins protruding
Brain fog
New allergies

b6

b6

b6

b6

b6

b6

From: b6
Sent: 12/20/2021 1:37:43 PM
To: Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 b6
CC: Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6 b6
Subject: Re: [EXTERNAL] Re: Per conversation with b6

Hi Farinaz,

Yes, works for me!

Thanks,
b6

Sent from my iPhone

On Dec 20, 2021, at 5:45 AM, Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Dear b6
We can meet you at 4pm EST/3pm CST.If it works for you I will send you the link shortly.
Best Regards,

Farinaz

From: b6
Sent: Sunday, December 19, 2021 5:23:56 PM
To: Nath, Avindra (NIH/NINDS) [E] b6
Cc: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: [EXTERNAL] Re: Per conversation with b6

Hi Dr. Nath,

Sure, anytime after 1pm CST/2pm EST will work for me as well. How about 1:30pm CST/2pm EST? Or just let me know whatever time works best for you.

Thanks so much,
b6

On Fri, Dec 17, 2021 at 8:15 PM Nath, Avindra (NIH/NINDS) [E] b6 wrote:

Sorry, just saw your email. How about Monday anytime after 1 pm CST/2 pm EST?

Avi

From: b6
Date: Friday, December 17, 2021 at 8:46 AM
To: Nath, Avindra (NIH/NINDS) [E]
Cc: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Re: [EXTERNAL] Re: Per conversation with b6

Hi Dr. Nath,

Sure, can you let me know 6pm in what time zone? I am in central time zone.

Thanks!

b6

Sent from my iPhone

> On Dec 16, 2021, at 8:57 PM, Nath, Avindra (NIH/NINDS) [E] b6 wrote:
>
> How about 6 pm tomorrow? I have copied Dr. Safavi to see if she can join us.
>
> Thanks
>
> Avi
>
> ---
>
> **From:** b6
> **Date:** Thursday, December 16, 2021 at 12:51 PM

To: Nath, Avindra (NIH/NINDS) [E] b6
Cc: Kwan, Justin (NIH/NINDS) [E] b6 Safavi, Farinaz (NIH/NINDS) [E] b6 Wiebold, Amanda (NIH/NINDS) [E] b6 Smith, Bryan (NIH/NINDS) [E] b6
Subject: [EXTERNAL] Re: Per conversation with b6

Hi Dr. Nath,

Thanks so much for your email. I am free tomorrow (Friday) afternoon. Otherwise, next week I am flexible during the day and can likely work around any day/time you are available.

Thank you!

b6

On Wed, Dec 15, 2021 at 9:45 PM Nath, Avindra (NIH/NINDS) [E] b6 wrote:

> Dear b6
>
> We have reviewed your records and am eager to talk to you further about the possibility of enrolling you on our study. When might be a good time for us to talk?
>
> Best wishes.
>
> Avi
>
> ---
> **From:** Nath, Avindra (NIH/NINDS) [E] b6
> **Date:** Tuesday, November 30, 2021 at 2:47 AM
> **To:** b6 Kwan, Justin (NIH/NINDS) [E] b6 Safavi, Farinaz (NIH/NINDS) [E] b6 Wiebold, Amanda (NIH/NINDS) [E] b6 Smith, Bryan (NIH/NINDS) [E]

b6

Subject: Re: Per conversation with b6

Dear b6

I am terribly sorry of hear of your illness. Yes, we would be glad to review all your medical records to determine if you would be eligible for one of our studies. I have copied several key members of our research team who will help review them with me.

Best wishes.

Avi

Avindra Nath MD

Chief, Section of Infections of the Nervous System

Clinical Director,

National Institute of Neurological Disorders and Stroke

National Institutes of Health, Bethesda, MD

b6 (Office)

(cell)

b6

From: b6

Date: Monday, November 29, 2021 at 9:57 AM

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

Subject: Fwd: Per conversation with b6

Dear Dr. Nath,

I recently spoke with b6 about my post COVID vaccine and post-COVID infection disease course. She suggested I write to you directly. In a brief summary, b6 had COVID in b6 Although I was around him, I never tested positive but was exposed. On b6 I had the

first Pfizer vaccine. Around this time, I developed a mild foot drop in my right foot. On b6 I received my second shot and within two weeks, had developed full foot drop in my right foot. I was worked up extensively with EMG showing b6 b6 however, MRI found b6 I also developed a rash on my face and Raynauds on my right foot. My history is notable for b6

In August I b6 Although the cold was mild I have developed partial foot drop on the left side and progressive weakness up my right leg and signs of weakness in my left leg. I have been given the diagnosis b6

I am writing to ask if this could be related to COVID and if I could be eligible to participate in research at the NIH. I would be willing to travel and am willing to provide test results to you via email prior to speaking with you if needed.

Thank you for your time.

Please feel free to reach out to set up a time to talk.

All the best.

b6

From: b6
Sent: 1/22/2022 1:09:08 PM
To: Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 b6
Subject: Re: FW: [EXTERNAL] b6

Hi,

b6 is the date of my second vaccine when I developed the reactions.

Thank you
b6

On Fri, Jan 21, 2022 at 3:06 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

> Can you please send me the exact date of your vaccination?
>
> Thanks
>
> Farinaz

From: Safavi, Farinaz (NIH/NINDS) [E]
Sent: Friday, January 21, 2022 3:04 PM
To: b6 Wiebold, Amanda (NIH/NINDS) [E]
Subject: RE: [EXTERNAL] b6

Hi b6

We can give you that letter.I will draft it and get approval from Dr.Nath and Amanda will send you the final version.

Hope it helps.

Best

Farinaz

Farinaz Safavi MD, PhD

Division of Neuroimmunology and Neurovirology

NINDS, NIH, Bethesda, MD

From: b6
Sent: Wednesday, January 19, 2022 10:14 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: [EXTERNAL] b6

Hi,

b6

If you have any question, please let me know.

Thanks!

b6

From: Safavi, Farinaz (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=94807CE146E045D4B61655DA26A0C246-b6
Sent: 3/6/2021 2:52:40 PM
To: b6
Subject: Re: Myself

Sure,Let me discuss and we may ask b6 for next step.

Thats a great news that b6
b6
You definietely can upload your imagings and we will review it with our team.

Have a good weekend.

Farinaz

Farinaz

From: b6
Sent: Saturday, March 6, 2021 9:47:06 AM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Re: Myself

Thank you Farinaz. I have been so frightened about this illness. I would prefer not to travel unless it is very important for my recovery. Could you and Dr. Nath speak with b6 and tell her your thoughts and what tests you want me to have. I would be happy to have another MRI and any blood tests. I would be happy to do them here if possible.
Of note is the radiologist who read my MRI told me that b6
b6
Thank you so much,
b6

Sent from my iPhone

> On Mar 6, 2021, at 6:28 AM, Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:
>
> b6
>
> There is not reason to be concerned. Dr.Nath completely agreed with what I already explained to you about potential underlying mechanisms of your symptoms.
>
> The reason we thought it might be be better to bring you here is that we have outstanding resources at NIH including very sensitive MRI and cutting edge research availabilities that are not available in other institutions which may help us to find objective evidence of your problem otherwise we still think your symptoms slowly recover.

I am also aware about b6 conversation with Dr.Nath and if you can not come over due to covid situation which is very understandable we can coordinate with her to see whether she can collect some samples for us.

There is nothing to worry about.The big picture of your issue is exactly the same as we already discussed.

let me know if I can be any of help.

Farinaz

From: b6
Sent: Saturday, March 6, 2021, 9:08 AM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Myself

Hi Farinaz,
I am very nervous to travel due to Covid risks. Is it possible to do these tests in b6
b6 is my neurologist at b6 and knows Dr. Nath. She told me she spoke with him a couple of days ago.
Now I am very frightened. What does Dr. Nath suspect had happened to me? What does he want to look for?
Could we speak on the phone?
My number is b6
Thank you so much,
b6

Sent from my iPhone

On Mar 6, 2021, at 5:01 AM, Safavi, Farinaz (NIH/NINDS) [E]
b6 wrote:

Dear b6
I discussed your case with Dr.Nath(NINDS clinical director) and we are wondering is it feasible for you to travel? We might be able to coordinate bringing you here at NIH and perform several testing including sensitive MRI and lab works to understand underlying mechanism of your symptoms.
Please let me know your thoughts.
Thank you
Farinaz

From: b6
Sent: Wednesday, March 3, 2021, 5:47 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Myself

Hi Farinaz,

Friday 3/5 from 3-5 will work.
I am in b6
I can gather some records if you like. Do you have access to Epic emr?
Thanks so much,
b6

Sent from my iPhone

On Mar 3, 2021, at 2:41 PM, Safavi, Farinaz (NIH/NINDS) [E]
b6 wrote:

b6
Please kindly let me know which of the following dates/ times works for you to meet? I will send you the MS teams link accordingly.
Friday 3/5 3-5 ET
Tues 3/9 3-5 ET
Thurs 3/11 3-5 ET

Thank you
Farinaz

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

From: b6
Sent: Wednesday, March 3, 2021 4:24 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Myself

Please let me know when I can have a visit. Thanks,
b6

Sent from my iPhone

On Mar 2, 2021, at 8:03 PM, Safavi, Farinaz (NIH/NINDS)
[E] b6 wrote:

Dear b6
I am really sorry to hear about your symptoms. We definitely can schedule a televisit in mutually convenient time to go over the details. I will coordinate with our team and get back to you tomorrow.
Best Regards,
Farinaz

Farinaz Safavi MD, PhD
Section of Infections of the Nervous System
Division of Neuroimmunology and Neurovirology
NINDS, NIH

From: Nath, Avindra (NIH/NINDS) [E]
Sent: Tuesday, March 2, 2021 9:04 PM
To: b6
Cc: Safavi, Farinaz (NIH/NINDS) [E]; Wiebold, Amanda (NIH/NINDS) [E]; Smith, Bryan (NIH/NINDS) [E]
Subject: Re: Myself

Dear b6
I am terribly sorry to hear of your illness. We are following several patients with neurological symptoms from the COVID vaccines I have copied members of my research team who will get in touch with you. Dr. Safavi is leading the effort and will do a televisit and then we will like to obtain some medical records and blood samples. You would need to be enrolled on to our research study for this purpose. Our hope to try and identify if there is some kind of molecular mimicry between vaccine and the antigens in the nervous system.
With best wishes.
Avi
Avindra Nath MD
Chief, Section of Infections of the Nervous System
Clinical Director,
National Institute of Neurological Disorders and Stroke
National Institutes of Health, Bethesda, MD
b6 (Office)
(cell)
b6

On 3/2/21, 4:54 PM, b6
b6 wrote:

Hi Dr. Nath,
My name is b6 I was given your name by b6
I am a b6 in b6 who had a severe reaction to the Pfizer Covid Vaccine b6 I was previously healthy and 30 minutes after receiving the vaccine developed burning in my face, had a pre-syncopal event and my blood pressure

spiked very high. I initially became bedridden for one week with severe malaise and paresthesias in my face and tongue. I also felt a tight band like constriction around my chest. I was treated with b6
Since that time, energy has improved but I have severe paresthesias in my face, head, tongue and mouth, chest, abdomen and limbs. At times they are incapacitating. I feel a vibration in my head and hands. The tight band around my chest persists. I have had extensive negative neurological and rheumatological work up and have seen several doctors in b6 who have no clue what has happened to me. b6 b6 at b6 found b6 b6 b6 and b6 at b6 put me on b6

Are you aware of these reactions and what is causing them? Is there anything that can help me? I am quite incapacitated. I have collected a group of people whom I met through the internet with similar reactions to mine. Several are physicians as far away as France and Argentina. Pfizer, the FDA and CDC have been unhelpful.

Any help or insight you can give me would be most appreciated.

Sincerely,

b6

Sent from my iPhone

From: Safavi, Farinaz (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=94807CE146E045D4B61655DA26A0C246 b6
Sent: 3/3/2021 11:54:02 PM
To: b6
Subject: RE: Myself

Thank you. Our research nurse will send you the link.
Farinaz

From: b6
Sent: Wednesday, March 3, 2021 5:47 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Myself

Hi Farinaz,
Friday 3/5 from 3-5 will work.
I am in b6
I can gather some records if you like. Do you have access to Epic emr?
Thanks so much,
b6

Sent from my iPhone

On Mar 3, 2021, at 2:41 PM, Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

b6
Please kindly let me know which of the following dates/ times works for you to meet? I will send you the MS teams link accordingly.
Friday 3/5 3-5 ET
Tues 3/9 3-5 ET
Thurs 3/11 3-5 ET

Thank you
Farinaz

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

From: b6
Sent: Wednesday, March 3, 2021 4:24 PM

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

Please let me know when I can have a visit. Thanks,
b6

Sent from my iPhone

On Mar 2, 2021, at 8:03 PM, Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Dear b6
I am really sorry to hear about your symptoms. We definitely can schedule a televisit in mutually convenient time to go over the details. I will coordinate with our team and get back to you tomorrow.
Best Regards,
Farinaz

Farinaz Safavi MD, PhD
Section of Infections of the Nervous System
Division of Neuroimmunology and Neurovirology
NINDS, NIH

From: Nath, Avindra (NIH/NINDS) [E]
Sent: Tuesday, March 2, 2021 9:04 PM
To: b6
Cc: Safavi, Farinaz (NIH/NINDS) [E]; Wiebold, Amanda (NIH/NINDS) [E]; Smith, Bryan (NIH/NINDS) [E]
Subject: Re: Myself

Dear b6
I am terribly sorry to hear of your illness. We are following several patients with neurological symptoms from the COVID vaccines I have copied members of my research team who will get in touch with you. Dr. Safavi is leading the effort and will do a televisit and then we will like to obtain some medical records and blood samples. You would need to be enrolled on to our research study for this purpose. Our hope to try and identify if there is some kind of molecular mimicry between vaccine and the antigens in the nervous system.
With best wishes.
Avi
Avindra Nath MD
Chief, Section of Infections of the Nervous System
Clinical Director,
National Institute of Neurological Disorders and Stroke
National Institutes of Health, Bethesda, MD
b6 (Office)
(cell)

b6

On 3/2/21, 4:54 PM, b6 wrote:

Hi Dr. Nath,

My name is b6 I was given your name by b6

I am a b6 in b6 who had a severe reaction to the Pfizer Covid Vaccine b6 I was previously healthy and 30 minutes after receiving the vaccine developed burning in my face, had a pre-syncopal event and my blood pressure spiked very high. I initially became bedridden for one week with severe malaise and paresthesias in my face and tongue. I also felt a tight band like constriction around my chest. I was treated with b6 b6 Since that time, energy has improved but I have severe paresthesias in my face, head, tongue and mouth, chest, abdomen and limbs. At times they are incapacitating. I feel a vibration in my head and hands. The tight band around my chest persists. I have had extensive negative neurological and rheumatological work up and have seen several doctors in b6 who have no clue what has happened to me. b6 b6 at b6 found b6 b6 and b6 at b6 put me on b6

Are you aware of these reactions and what is causing them? Is there anything that can help me? I am quite incapacitated. I have collected a group of people whom I met through the internet with similar reactions to mine. Several are physicians as far away as France and Argentina. Pfizer, the FDA and CDC have been unhelpful.

Any help or insight you can give me would be most appreciated.

Sincerely,

b6

Sent from my iPhone

From: Safavi, Farinaz (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=94807CE146E045D4B61655DA26A0C246-b6]
Sent: 1/5/2022 9:58:26 PM
To: b6
Subject: RE: [EXTERNAL] Post covid vaccine neurological complications

Dear b6
Thank you for your email. I am glad you tolerated J&J vaccines.In terms of your question,I would like to clarify that our research at NIH is on molecular/cellular immunopathogenesis causing adverse events to vaccine which is quite different from epidemiological studies that FDA and CDC eventually will answer with large databases.
Sorry that I can not be any of more help.
Please let me know if you have any more questions or concerns.
Best Regards

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

From: b6
Sent: Tuesday, January 4, 2022 12:49 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: [EXTERNAL] Post covid vaccine neurological complications

Hello Dr. Safavi,

As a participant in one of your research projects I was wondering if you have any results regarding neurologic complications post Covid vaccination particularly the mRNA vaccines.

Is there increased incidence of neurologic autoimmune disorder relative to the general population incidence or relative to other vaccinations?

To refresh your memory, I developed b6 shortly after a single dose of the pfizer covid vaccine. I fully recovered and have since taken the J&J vaccine x 2 with no ill effects.
I am carefully considering possibility of future vaccination with one of the mRNA covid vaccines as they are reported to be the most effective. So, I am wondering if you have any results.

Thanks,
b6

From: Safavi, Farinaz (NIH/NINDS) [E] b6
Sent: Thursday, April 1, 2021 9:35 AM

To: b6
Subject: Re: [EXTERNAL] Post covid vaccine neurological complications

Thank you very much b6 Really appreciate it.

Farinaz

From: b6
Sent: Thursday, April 1, 2021 9:32:38 AM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Re: [EXTERNAL] Post covid vaccine neurological complications

Hi Dr. Safavi,

I have sent signed consent forms to Anna Wiebold (nurse assisting on research)

Attached are office notes and b6 from my neurologist. Also attached are reports from the b6 b6

CD copies of the imaging is a little more difficult to get to you. You could try calling the neurology office or the MRI imaging secretary's directly- b6

Thanks
b6

From: Safavi, Farinaz (NIH/NINDS) [E] b6
Sent: Monday, March 29, 2021 5:20 PM
To: b6
Subject: Re: [EXTERNAL] Post covid vaccine neurological complications

Dure,I will send you MS teams link for the televist.
Thank you very much!
Best Regards,

Farinaz

From: b6
Sent: Monday, March 29, 2021 5:17:32 PM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Re: [EXTERNAL] Post covid vaccine neurological complications

OK. 10am is ok.
I will complete the consent forms after we talk. I do plan on participating.

b6

From: Safavi, Farinaz (NIH/NINDS) [E] b6
Sent: Monday, March 29, 2021 12:10 PM
To: b6 Wiebold, Amanda (NIH/NINDS) [E]

b6

Subject: RE: [EXTERNAL] Post covid vaccine neurological complications

Sure,Is tomorrow at 10am work for you? If so I will send you televisit link.
I also would like to follow up with you regarding consent and medical release form.Have you received them. Please kindly let us know.
Thank you
Farinaz

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

From: b6
Sent: Sunday, March 28, 2021 8:56 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: [EXTERNAL] Post covid vaccine neurological complications

This week I could do a televisit:
Monday Afternoon
Tuesday Morning
Thursday or Friday- Flexible

b6

From: Safavi, Farinaz (NIH/NINDS) [E] b6
Sent: Friday, March 26, 2021 9:52 AM
To: b6
Subject: RE: [EXTERNAL] Post covid vaccine neurological complications

Dear b6
Hope all is well.I would like to follow up with you to find a mutual convenient time to schedule a televisit.
Please let me know what days work the best for you?
Thank you
Farinaz

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

From: b6
Sent: Sunday, March 21, 2021 8:27 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: [EXTERNAL] Post covid vaccine neurological complications

I am interested in participating.

b6

From: Safavi, Farinaz (NIH/NINDS) [E] b6
Sent: Thursday, March 18, 2021 3:41 PM
To b6
Subject: RE: [EXTERNAL] Post covid vaccine neurological complications

Dear b6
Thank you very much for your respond.
Basically for this research we just need to meet with you through televisit once talking about your issue and our research team coordinate to get consent to receive your medical records and possibility of sending us serum samples. This is not a study with many long questionnaire and mainly we are trying to characterize COVID vaccine side effects and potentially propose the pathogenesis.
I would be happy to answer any questions and really appreciate if you kindly let me know are you interested to proceed with our protocol.
Best Regards,
Farinaz

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

From: b6
Sent: Wednesday, March 17, 2021 9:17 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: [EXTERNAL] Post covid vaccine neurological complications

Dear Dr. Safavi,

I would be happy to participate in your study as long as it isnt too burdensome.
As regards my symptoms: They gradually improved and in early February there was very little residual mostly or only consisting of right hand ulnar sided mild paresthesia. As of early March all symptoms are resolved. I had a b6 which began 9 days after symptom onset.

Please feel free to contact me and I can provide more information as needed.

Best
b6

From: Safavi, Farinaz (NIH/NINDS) [E] b6
Sent: Wednesday, March 17, 2021 1:24 PM
To: b6
Subject: [EXTERNAL] Post covid vaccine neurological complications

Dear b6

My name is Farinaz and I am one of Dr.Nath's team member at NINDS. We started an effort to study post covid vaccine neurological complications here and Dr.Nath informed me about your b6 post 1st dose of vaccine. I am writing to ask you how your symptoms are going currently and are you interested in providing us with more information about your disease or contribute in our study?

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

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

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