RESEARCH SUBJECT
INFORMED CONSENT FORM

TITLE:	Efficacy of Hydroxychloroquine for Post-exposure Prophylaxis (PEP) to Prevent Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Infection Among Adults Exposed to Coronavirus Disease (COVID-19): a Blinded, Randomized Study
PROTOCOL NO.:	UW-ICRC Protocol #36 WIRB® Protocol #20200659 20-00408
SPONSOR:	University of Washington
INVESTIGATOR:	Anna Bershteyn, PhD Assistant Professor, Dept. Population Health NYU Grossman School of Medicine 227 E 30th St, New York, NY 10016 United States
STUDY COORDINATOR:	Jane Coates 227 E 30th St, New York, NY 10016; E-mail: jane.coates@nyulangone.org
STUDY-RELATED PHONE NUMBER(S):	347-829-7309 (24 hours)
SITE(S):	NYU Grossman School of Medicine 227 E 30th St, New York, NY 10016

We are asking you to be in a research study. This study is being conducted by NYU Grossman School of Medicine, based here in New York City, and the University of Washington, which is based in Seattle, Washington. This form describes the study procedures and gives you information to decide whether you wish to be in the study. Being in the study is entirely your choice.

What should I do?

1. Read this form, or have it read to you.
2. Make sure the study doctor or study staff explains the study to you.
3. Ask questions (e.g., time commitment, unfamiliar words, specific procedures, etc.)
4. Take time to consider this, and talk about it with your family and friends.

The first part of this consent form gives you a **summary of this study**.

The second part of this consent form gives you more details about the study procedures and any risks to you.

PURPOSE OF THE STUDY

The purpose of this study is to understand if taking a malaria, autoimmunity, and arthritis medication called hydroxychloroquine can reduce the risk of becoming infected with the virus that causes COVID-19 or developing symptoms of COVID-19 after having contact with an infected person. Taking a medication to prevent becoming sick after exposure to an infected person is called "post-exposure prophylaxis" or "PEP." The current standard of care is no treatment for people who had contact with a known or suspected case of COVID-19.

If you choose to be in the study, you will be assigned by chance (chance is like flipping a coin) to either take hydroxychloroquine PEP or vitamin C. You will take 2 pills by mouth for 3 days, followed by one pill by mouth for 11 days, for a total of 14 days of treatment.

STUDY PROCEDURES

We are testing adults who might have been exposed to a suspected or confirmed case of COVID-19. We are inviting you to participate because you have been referred as a possible contact of such a case. Here is what the study involves:

- You will be contacted by our research team and asked to join this study. You will be in this study for approximately 28 days and no in-person visits are necessary – every interaction will occur via telephone, internet, or mail.
- We will ask you to complete a brief enrollment survey about medical history, current symptoms, current use of medicines, encounters with a person suspected or confirmed to have COVID-19, travel history and other behaviors, and demographics. These questions will be asked either by telephone or answering questions in an online survey.
- You will be asked to self-test for COVID-19 by swabbing the inside of your nose with a special swab called a nasal swab. We will ask you to repeat this procedure with a new swab either daily or weekly while in the study. Once you have swabbed the inside of your nose, you will put your swab in a special tube for storage.
- You may also be asked to prick your finger to collect drops of blood called dried blood spots on a special card. We may ask you to collect these blood spots at enrollment, partway through the study, and at the end of the study.
- We will provide you with all of the supplies you need to collect your samples. The supplies will arrive in a mailed package, and we will give you envelopes and postage to either mail them back or a courier will come collect them.
- To test for novel coronavirus, the swab may be sent to a public or private health laboratory for testing. The laboratory may use a test that is authorized for research purposes only, but you will have access to your test results. You may need a second test from your doctor or health department to confirm for certain whether you have COVID-19. If the test is positive, you also will be contacted by your local health department. The health department will ask you to restrict your movement, depending on current local policy. This would be unrelated to the study.

This study does not replace or affect any care you might receive from your doctor.

RISKS, STRESS, OR DISCOMFORT

We do not expect any serious side effects from this study. Because there are always some risks to taking part in a research study, we have listed some of the most likely risks of participation in this study here:

Possible Risks related to PEP treatment

- Nausea
- Diarrhea
- Skin pigmentation

There are also rare but serious risks of participation, like:

- Serious allergic reaction, including a severe skin rash
- Retinopathy (eye problems)
- Neuropathy (nerve problem causing numbness or weakness)
- Skeletal myopathy (damage to muscle tissue)
- Cardiomyopathy (problems with the heart muscle)

Fetal death and malformations have been reported when pregnant rats received large doses of the study drug. Human pregnancies have been reported with no increase in birth defects.

Possible Risks related to Nasal Swabs or Fingerprick:

- Swabbing your nose may cause mild discomfort, watery eyes, or sneezing.
- Drawing a few drops of blood from your finger for the dry blood test may cause temporary discomfort from the needle stick, bruising, and infection.

Some questions we might ask you are sensitive and may make you feel uncomfortable. You do not have to answer any question you do not want to. There is a risk that your privacy could be breached. We will do everything we can to make sure that this does not happen.

BENEFITS OF THE STUDY

Possible Benefits:
If you are in the group that receives hydroxychloroquine PEP, and if it proves to reduce your chances of developing COVID-19 disease, you may benefit from participating in the study, but this cannot be guaranteed.

Your Other Options:
There are currently no approved treatments to prevent infection or COVID-19 symptoms for people who have had contact with an infected person. You do not have to participate in this study.

Your other choices may include:

- Taking part in another study.
- Getting no PEP after contact with a suspected or confirmed case of COVID-19.

Please talk to your doctor about your choices before agreeing to participate in this study.

SOURCE OF FUNDING

NYU Grossman School of Medicine and/or the University of Washington is receiving financial support from the Bill & Melinda Gates Foundation.

DETAILED STUDY INFORMATION

The following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will offer you a copy of this form to keep for future reference.

Research studies include only people who choose to take part. Please take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask your study doctor.

You are being asked to take part in this study because you are a contact who had direct contact with a suspected or confirmed case of COVID-19 infection.

Why is this study being done?
The purpose of this study is to understand if a malaria, autoimmunity, and arthritis medication called hydroxychloroquine, taken by mouth as soon as possible after contact with a suspected or confirmed case of COVID-19, can reduce infection. The study will also look at the safety of hydroxychloroquine PEP. While hydroxychloroquine is approved by the Food and Drug Administration (FDA), taking hydroxychloroquine immediately after contact to prevent infection is investigational and is not approved by the FDA for prevention of COVID-19.

The manufacturer of the drug hydroxychloroquine that is being used in this study is not involved in this study. The study will provide this drug at no cost to the research participant.

How many people will take part in this study?
About 4000 people will take part in this study.

What will happen if I take part in this research study?
If you are eligible to be in the study and you choose to take part, then you will need the following tests and procedures:

- You will be asked to complete surveys by telephone, web, or video chat.
    - You will be asked a series of questions about your health, including if you have any current symptoms of a respiratory infection, including shortness of breath, fever, and cough.
    - You will be asked if you have any symptoms that can be associated with taking hydroxychloroquine
    - You will also be asked other questions about your medical history, current symptoms, current use of medicines, encounters with a person suspected or confirmed to have COVID-19, travel history and other behaviors, and demographics.
    - If we do not have information on the person with COVID-19 that you have been exposed to, we may ask you to invite them to contact our study team to provide confirmation of their test.
- You will self-test for COVID-19. This will be done by swabbing the inside of your nose.
- You may be asked to collect a few drops of blood by pricking your finger and collecting it on a piece of filter paper we provide you. This blood will be used to test you for evidence of coronavirus exposure.
- You will receive an email daily with a link to a survey to document when you take the treatment (either hydroxychloroquine or vitamin C), how you are feeling, and if you have collected a nasal swab. We would like you to complete this every day while you are taking your medication.
- You will be asked to complete a final brief survey by telephone or internet at completion of the study. Some of these questions may include how you are feeling, if you thought you were taking hydroxychloroquine or vitamin C, and your thoughts on participating in the study.

The study does not provide smart phones or computers nor does it pay for cellular data or internet required for web use. If you don’t have a smart phone or computer, the study staff will help you complete the questionnaires by telephone.

You will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance, like flipping a coin. A computer program will place you in one of the groups. You will have an equal or 50% chance (one in two) of being placed in the hydroxychloroquine PEP group vs. the vitamin group. You will not know which group you are assigned to.

You will be provided with a supply of pills. You will be asked to take 2 pills per day for the first 3 days, starting as soon as possible, within 24 hours of receiving them. Then, you will take 1 pill per day for the next 11 days (days 4 to 14).

- **If you are assigned to the group receiving hydroxychloroquine,** you will be taking 400 mg hydroxychloroquine (2 pills) daily for three days, and then 200mg of hydroxychloroquine (1 pill) daily for 11 days.

- **If you are assigned to the group receiving the vitamin C pill,** you will be taking 500 mg of vitamin C daily for three days, and then 250 mg of vitamin C (1 pill) daily for 11 days.

Timing of study visits and procedures:
- The initial enrollment survey will take approximately 15 minutes.
- The follow-up survey at the end of the study will take approximately 10 minutes.

Study location: All study procedures will be at your own home.

Dry blood spot: A self-test dry blood spot test sample will be drawn by pricking one of your fingers with a lancet. You may be asked to collect your blood on multiple days.

Swabs for nasal and oral bacteria: The study will ask you to swab theinside of your nose every day from day 1 until day 14, and then a final swab on day 28. Swabbing will take approximately 5 minutes.

Results of testing done for research only will not be available to you or your providers, just to the researchers in the study. You will be able to contact the study to find out your results, if you wish.

How long will I be in the study? You will be in the study for 28 days.

Can I stop being in the study?
Yes. You can decide not to participate in the study or to stop your participation in the study at any time. Your decision will not lead to any penalties or loss of benefits to which you are otherwise entitled. Tell the study team if you are thinking about stopping or if you decide to stop. He or she will tell you how to stop your participation safely.

It is important to tell the study team if you are thinking about stopping so any risks from the hydroxychloroquine can be evaluated and the study team can discuss what follow-up care and testing could be most helpful for you.

The study team may stop you from taking part in this study at any time if we believe it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from the treatment?
Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Many side effects go away soon after you stop taking the hydroxychloroquine. In some rare cases, side effects can be serious, long lasting, or may never go away.

You should talk to your study doctor about any side effects you experience while taking part in the study.

For participants assigned to the hydroxychloroquine PEP group, risks and side effects include:

Likely
- Nausea
- Diarrhea
- Skin pigmentation

Less likely

- Serious allergic reaction, including a severe skin rash
- Retinopathy

Rare but serious

- Serious allergic reaction, which may include trouble breathing, hives, and involvement of skin and other organs in the body
- Serious skin reaction
- Neuropathy
- Skeletal myopathy
- Cardiomyopathy

For participants assigned to the vitamin C group, risks and side effects include nausea, diarrhea, and stomach cramps.

Randomization risks: You will be assigned to receive hydroxychloroquine or vitamin C, and the group to which you are assigned may prove to be less effective or to have more side effects than the other study treatment or other available treatments.

Dry Blood Spot: Drawing a dry blood test may cause temporary discomfort from the needle stick, bruising, and rarely, infection.

Privacy and confidentiality risks: We will make every effort to protect your confidentiality during the study. However, it is possible that others may learn that you are part of this study and they may think that you are infected with COVID-19 or are at high risk for infection with COVID-19. The most common risks we know about are family or friends worrying, getting upset or angry, or assuming that you are infected and treating you unfairly as a result.

You should think very carefully before deciding to tell anyone about your participation in this study.

Although every reasonable effort has been taken, confidentiality during online communication procedures cannot be guaranteed and it is possible that additional information beyond that collected for research purposes may be viewed by others not associated with this study for unauthorized purposes.

Unknown Risks: Although hydroxychloroquine is well studied and widely used, use of hydroxychloroquine for post-exposure prophylaxis (PEP) to prevent COVID-19 may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

For more information about risks and side effects, ask your study team.

Are there benefits to taking part in the study?
If you are in the group that receives hydroxychloroquine PEP, and if it proves to reduce your chances of getting infected after contact with a suspected or confirmed case of COVID-19 without causing side effects that you cannot tolerate, you may benefit from participating in the study, but this cannot be guaranteed.

If you are in the group that does not receive hydroxychloroquine PEP, you may have the same or fewer side effects associated with hydroxychloroquine compared to those who do take hydroxychloroquine, but this cannot be guaranteed.

What other choices do I have if I do not take part in this study?
There are currently no approved treatments for COVID-19, your other choices may include:

- Taking part in another study.
- Getting no post-exposure prophylaxis (PEP) after contact with a suspected or confirmed case of COVID-19.

How will my specimens and information be used?
Researchers will use your specimens and information to conduct this study. Once the study is done using your specimens and information, we may share them with other researchers so they can use them for other studies in the future. We will not share your name or any other personal information that would let the researchers know who you are.

Research results: There may be times when researchers using your information or specimens may learn new information. The researchers may or may not share these results with you, depending on a number of factors.

How will you protect my confidentiality?
Your medical information is protected health information, or "PHI", and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?
All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

Who may use and share information about me?
The following individuals may use, share or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study.
- The study sponsor: University of Washington.
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).
- Western Institutional Review Board (WIRB).
- Health care providers who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.
- Other study sites involved in the research.

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

How long may my information be used or shared?
Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Are there any costs to me for taking part in this study?
There are no costs to you. Any procedures done only for research will not be charged to you or your insurer.

The study will provide hydroxychloroquine at no cost for those assigned to the hydroxychloroquine PEP group.

Will I be paid for taking part in this study?
If you complete all parts of the study, you will be paid $200. You will receive $100 on day 15 if you completed the surveys, nasal swabs and blood spot. You will receive another $100 on day 28 if you complete the final nasal swab and blood spot. Not everyone will be asked to complete a blood spot.

What happens if I am injured because I took part in this study?
For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form.

It is important that you tell study doctors if you feel that you have been injured because of taking part in this study. Study doctors at each site are:

NYU Grossman School of Medicine:
Dr. Angelica Kottkamp (347-829-7309)
Dr. Robert Pitts (347-829-7309)
Dr. Mark Schwartz (646-634-6710)

There are no plans for the NYU School of Medicine or Medical Center to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

Who can answer my questions about the study?
You can talk to your study doctor about any questions, concerns, or complaints you have about this study – see contact information above. If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers, or if you wish to voice any problems, complaints or concerns you may have about the study, please contact the Western Institutional Review Board® (WIRB®) at 800-562-4789, Help@wirb.com.

What are my rights if I take part in this study?
Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care.

During the study, we will tell you about any new information or changes in the study that may affect your health or willingness to continue in the study.

In case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Financial Disclosure
The NYU Langone Health maintains a financial disclosure process by which researchers must disclose any personal financial interest that may be related to the research. This study is being sponsored by the University of Washington and the Bill and Melinda Gates Foundation. One or more of the investigators involved in this study has or has had a financial relationship with Gates Ventures. This may include consulting, advisory board, or writing reports. If you would like more information, please ask the researchers, the study coordinator, or the CIMU at 212-404-4079.

Subject's statement
This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call at 800-562-4789.

Printed name of subject	Signature of subject	Date

Copies to: Researcher
Subject

Optional Consent

Genetic Testing

We do not know yet if a person's genes determine whether or not they are infected with SARS-CoV-2 and whether genetics are associated with disease severity. To help us learn about genes associated with SARS-CoV-2, we may use your DNA to study whether a person's genes may make them more or less likely to get a respiratory virus such as SARS-CoV-2 and/or related infection and more or less likely to have a severe infection, if they get a respiratory virus infection. You can still be a part of this study even if you say "no" to this.

I agree to participate in genetic testing of my samples.

☐ Yes ☐ No

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Signature of subject Date

Collection of Information from Medical Records

Because we may need additional medical information in the future that we don't include in our surveys now, we are asking participants if they are willing to 'opt in' to allowing us to access their medical records, should additional information be needed. You can still be a part of the main study even if you say "no" to this.

I agree that researchers can record information about me from medical charts kept by my doctor and link that information to the results from my interviews, physical exams, and laboratory tests. If I am hospitalized, I agree that the researchers can record medical information from my hospitalization. I will sign a release of medical information form for each chart I choose to release.

☐ Yes ☐ No

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Signature of subject Date

Future Studies

Because future studies that you may be eligible for may become available, we are asking now if you would like to learn about these studies. You can still be a part of the main study even if you say "no" to this.

I agree that I may be contacted in the future to see if I am interested in participating in further research.

☐ Yes ☐ No

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Signature of subject Date