The University of New Mexico Health Sciences Center
Consent and Authorization to Participate in a Research Study

Key Information for Hydroxychloroquine Prophylaxis for UNM HEALTH SYSTEM healthcare workers at high risk for SARS-COV-2 infection

You are being invited to take part in a research study about using hydroxychloroquine prophylaxis for UNM Health System healthcare workers at high risk for SARS-COV-2 infection (also called COVID-19).

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THE STUDY?

By doing this study, we hope to learn if this drug can help prevent respiratory infections caused by SARS-CoV-2. Your participation in this research will last about 90 days.

The purpose of this research is to evaluate the efficacy of hydroxychloroquine (HCQ) to prevent severe acute respiratory syndrome due to SARS-CoV-2 infection among health care workers at high risk of occupational exposure to SARS-CoV-2

This drug is approved by the FDA for other conditions, but not for respiratory infections caused by SARS-CoV-2. There are currently no drugs approved by the FDA for this condition and the FDA has issued an "emergency use authorization" for HCQ use https://wwwfda.gov/medical/136537/download.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You may want to participate in this study because you work in a high risk unit with potential exposure to SARS-CoV-2 and this drug may help prevent severe acute respiratory infections.. You may also want to participate in order to help find a treatment for this condition. For a complete description of benefits, refer to the Detailed Consent section.

WHAT ARE THE KEY REASONS YOU MIGHT NOT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You might choose not to volunteer for this study because this drug may not help prevent a respiratory infection due to SARS-CoV-2, or because you might lose privacy and/or confidentiality. For a complete description of the risks, refer to the Detailed Consent and to the Appendix.

Alternate treatments or procedures would include having access to the study medications without taking part in this study. There is currently no standard of care treatment for treating the SARS-CoV-2 viral infection.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of this study is Dr. Walter Dehority in collaboration with co-investigators Drs. Jens Langsjoen, Renee Mercier, and Jon Femling of the University of New Mexico Health Sciences Center.

Their names, Departments and contact phone numbers are listed at the end of this consent document. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, you can call any of the co-investigators.

If you have any questions or concerns about your rights as a volunteer in this research, contact staff in the University of New Mexico Health Sciences (UNMHSC) Human Research Review Committee (HRRC) between the business hours of 8AM and 5PM, Mountain Standard Time (MST), Monday-Friday at 505-272-1129.

DETAILED CONSENT

Version April 27, 2020

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

You would not qualify to be in this study for the following reasons:

- You are under the age of 18.
- You have an allergy to hydroxychloroquine or have contraindication to treatment with study drugs.
- Currently hospitalized.
- Symptomatic with subjective fever, cough, or sore throat
- Are currently using hydroxychloroquine
- Are currently using anti-malarial drugs or chemoprophylaxis
- Have retinopathy
- Have severe or uncontrolled psoriasis
- Have porphyria
- Known bone marrow disorders with significant neutropenia (polymorphonuclear leukocytes <1500) or thrombocytopenia (<100K)
- Are currently using medicines as follows: anti-arrhythmic agents, digoxin, cyclosporin, cimetidine, or tamoxifen
- Known liver disease
- Known long QT syndrome
- Use of any investigational or non-registered drug or vaccine within 30 days preceding the first dose of the study drugs or planned use during the study period. There may be some exceptions that will be evaluated by the Co-Investigators on a case by case basis.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research procedures will be conducted at University of New Mexico Hospital. The total amount of time you will be asked to volunteer for this study is over the next 90 days.

WHAT WILL YOU BE ASKED TO DO?

This drug will be given once daily by mouth. We will collect the research specimen using a nose swab at screening and on day 30, 60 and 90.

The study will have two groups of participants, Group A and Group B.

- Group A will be participants who choose to take hydroxychloroquine
- Group B will be participants who choose to opt out of taking hydroxychloroquine.

If you choose to take hydroxychloroquine, the study team will need to assess your medical history to determine if you are eligible to be in Group A. This is to minimize the potential risks that may occur with taking hydroxychloroquine.

If you are eligible to participate in study and decide to take part, you will be asked to perform tests and procedures listed below.

Screening/Enrollment Visit (Group A and Group B)

A study team member will coordinate an initial pre-screening visit or phone call to determine eligibility based on the following:

- Going over your medical history and medications you are currently taking
- If you are a woman of childbearing potential, we will ask you to confirm whether you are pregnant and the date of your last menses. Pregnancy is not a contraindication to receiving HCQ.
- Going over inclusion and exclusion criteria

If you are deemed eligible and have given consent, you will then be asked to:

- Complete questionnaires through REDcap, an online data capture system
- You will then take your first dose of hydroxychloroquine (Group A subjects only) This visit may occur in one day or over the span of a couple of days.

Medication Administration (Group A only)

You will be asked to take 600mg of hydroxychloroquine on the first day (screening/enrollment day) and 200mg everyday thereafter.

Group A and Group B

You will be asked to complete questionnaires through REDcap daily. A nasal swab for COVID-19 and plasma/serum sample will be collected at screening, day 30, day 60 and 90 and at any early termination/switch over day. If SARS-CoV-2 is detected, the virus will undergo whole genome sequencing at UNM. Your DNA/RNA will not be sequenced, only the virus. You will not be notified of these sequencing results. Serology testing will be done on the blood several months after collection. If desired, you can be notified of these results when they become available.

Visit for Switching from Group B to Group A

If you were originally in Group B (not taking HCQ) and want to switch to Group A (start taking HCQ), you can do so at any time during the study. You will be re-screened to join Group A and begin taking HCQ.

Questionnaires (Group A and Group B)

At each study time point, Screen, 30, 60, and 90 days, you will be asked to complete questionnaires regarding current medications and symptoms. The survey will include information about any potential exposures you many have had participating in aerosol generating procedures (AGP's).

Early Termination Visit

If you have to stop taking the study medication (Group A), or if you decide to leave the study (Group B) you will be asked to complete questionnaires, blood collection and nasal swab collection as part of the study termination visit. However, you may still stop enrollment in the study at any time and will not be required to do this.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

NOTE: The US Food and Drug Administration (FDA) released a safety warning in April 2020 regarding reports of serious heart rhythm problems in some patients with COVID-19 treated with hydroxychloroquine or chloroquine, often in combination with other medications that can also lead to heart rhythm problems. The FDA cautioned against use of hydroxychloroquine outside the hospital or outside clinical trials, and the FDA recommended close supervision. In light of this new safety warning, it is particularly important that you tell one of the investigators about any history of heart rhythm problems you may have and about all medications that you are taking, and that you discuss this warning with one of the investigators or another physician you see before you begin any new medications. It is currently unclear how long such risks would persist (if at all) after discontinuation of the drug.

In addition, taking macrolide antibiotics (azithromycin, clarithromycin, erythromycin, spiramycin, telithromoycin) while receiving hydroxychloroquine may increase the risk of serious heart rhythm problems (e.g. torsades de pointes). You may wish to consult with your physician before participating in the trial because you may be predisposed to these problems.

HCQ is currently FDA approved for rheumatoid arthritis and malaria. It is generally well tolerated in patients for many years with little toxicity. However, we do not know all the side effects that may happen when HCQ is taken for this study purpose. All participants of this study will be monitored for any side effects you report during participation. Side effects can 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. As with any experimental treatment for specific diseases, there may be unknown or unforeseeable side effects.

Below is a list of possible adverse reactions that may occur while taking hydroxychloroquine. Although none of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur while taking hydroxychloroquine:

Incidence not known:

- Blistering, peeling, loosening of the skin
- Blurred vision or other vision changes

- Chest discomfort, pain, or tightness
- Cough or hoarseness
- Dark urine
- Decreased urination
- Defective color vision
- Diarrhea
- Difficulty breathing
- Difficulty seeing at night
- Dizziness or fainting
- Fast, pounding, uneven heartbeat
- Feeling that others are watching you or controlling your behavior
- Feeling that others can hear your thoughts
- Feeling, seeing, or hearing things that are not there
- Fever with or without chills
- General feeling of tiredness or weakness
- Headache
- Inability to move the eyes
- Increased blinking or spasms of the eyelid
- Joint or muscle pain
- Large, hive-like swelling on the face, eyelids, lips, tongue, throat, hands, legs, feet, and sex organs
- Loss of hearing
- Lower back or side pain
- Noisy breathing
- Painful or difficult urination
- Red irritated eyes
- Red skin lesions, often with a purple center
- Severe mood or mental changes
- Sore throat, sores, ulcers, or white spots on the lips or in the mouth
- Sticking out of the tongue
- Stomach pain
- Swelling of the feet or lower legs
- Swollen or painful glands
- Trouble with breathing, speaking, or swallowing
- Uncontrolled twisting movements of the neck, trunk, arms, or legs
- Unusual behavior
- Unusual bleeding or bruising
- Unusual facial expressions
- Unusual tiredness or weakness
- Yellow eyes or skin

Some side effects of hydroxychloroquine may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects. Check with your health care professional if any of the following side effects continue or are bothersome or if you have any questions about them:

Side effects that may go away, incidence not known

- Continuing ringing or buzzing or other unexplained noise in the ears
- Feeling of constant movement of self or surroundings
- Irritability
- Nausea
- Nervousness
- Nightmares
- Sensation of spinning
- Shakiness and unsteady walk
- Uncontrolled eye movements
- Unsteadiness, trembling, or other problems with muscle control or coordination
- Vomiting

The most common risk we anticipate in this study is allergic reaction to the study drug that will be in the form of a skin rash. If you experience a rash, tell the study team right away. You may be asked to discontinue the study drug.

Currently, there are no controlled studies to support efficacy and data is limited at this point. It is possible that the study drug may increase risk of acquiring COVID-19.

Unknown Risks

Although hydroxychloroquine is well studied and widely used, use of hydroxychloroquine for pre-exposure prophylaxis 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.

WHAT ABOUT MY EMPLOYEE STATUS?

Employees recruited as research subjects are more vulnerable to undue influence or coercion because of the possibility that they may perceive employment or other benefits as dependent upon their participation in research. In addition, UNMHSC employees may experience increased risk of invasion of privacy or loss of confidentiality.

To minimize these risks, you will be contacted and consented to enroll in this study by a member of the study team who does not have any direct supervisory responsibilities or role in your performance evaluation. We will remove identifiers from your data and label it instead with a unique code. The link to your identifiable information will be stored separately from your coded data and available to members of the study team. However, this link will not be made available to your direct supervisor(s).

Your decision to participate, refuse participation, or to later withdraw from the study will have no impact on your employment, salary, or performance evaluation.

CAN I BE IN THE STUDY IF I AM PREGNANT OR BREASTFEEDING?

You can participate in this study if you are pregnant. Hydroxychloroquine is used as a standard of care medication in pregnant lupus patients without increase in miscarriages or birth defects. Additionally, there is consensus in the scientific community that the drug does not have adverse effects on the fetus. One of the Investigators will answer questions to help you with this decision.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

We do not know if you will get any benefit from participating in this study. It is possible that pre-exposure HCQ will prevent symptoms or reduce severity of infection with SARS-CoV-2. Additionally, the medical community and general public may benefit from the information collected from this study.

WHAT WILL IT COST YOU TO PARTICIPATE?

You and/or your insurance company, Medicare, or Medicaid will be responsible for the costs of all care and treatment that you would normally receive for any conditions you may already have. These are costs that are considered medically necessary and will be part of the care you receive even if you do not take part in this study.

The University of New Mexico may not be allowed to bill your insurance company, Medicare, or Medicaid for the medical procedures done strictly for research. This means you may have to pay out-of-pocket for these costs.

If a health insurance company insures you, your insurer may pay the costs. You should ask your insurer if you have any questions regarding your insurer's willingness to pay these costs.

If Medicare or Medicaid covers you, Medicare or Medicaid may cover these costs. For questions regarding Medicare coverage, call 1-800-MEDICARE (1-800-633-4227). For questions regarding Medicaid coverage, call 1-800-2570. Your insurer, Medicare, or Medicaid, may agree to pay for the costs. If you are required to expend a co-payment or deductible, the amount of this co-payment or deductible may be costly.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

Each person participating in this Study will be assigned a randomly generated study ID that will be linked to identifiers (MRN, DOB) in a linking table to be kept separate from the research data. Data and specimens will be labelled with the study ID only. Only HRRC-approved members of the study team who have the appropriate training will have access to the data and identifiers. All data that we collect in this study will be entered into REDcap, a secure database, on a password-protected computer using a secure network. Any hard copy records/data will be kept in a locked file cabinet in the locked office of a designated member of the Study team. The specimens will be kept and stored in the Clinical and Translational Science Center at the UNM HSC and can only be accessed by the members of the study team. We will transport the specimens to TriCore Reference Laboratories for lab analysis through standard transport hospital procedures. After testing, any left-over samples, including serum or blood will be destroyed after the study is completed. Once data collection is complete, data will be de-identified by destruction of the linking table. Study records will be kept for 6 years past study closure.

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave information, or what the information is.

You should know there are some circumstances in which we may have to show your information to other people. For example, the law may require us to share your information with the following agencies and for the following reasons:

- The law requires us to share your information with authorities if you report information about a child being abused
- If you pose a danger to yourself or someone else.
- A court or agencies, if you have a reportable disease or condition.
- Authorities, if you report information about a child being abused, if you pose a danger to yourself or someone else.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. The study intervention, medication will no longer be provided to you and may not be available for purchase. This may occur for a number of reasons. You may be removed from the study if you are not able to follow the direction, they find that your participation in the study is more risk than benefit to you, or if the Co-investigators choose to stop the study early for a number of scientific reasons.

You may be removed from the study if:

- You are not able to follow the directions.
- They find that your participation in the study is more risk than benefit to you.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEACH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may not take part in this study if you are currently involved in another research study. It is important to let the investigator and your doctor know if you are in another research study. It will be up to them to determine if you can participate in more than one study. You should discuss this with the investigator and your doctor before you agree to participate in another research study while you are in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call or email one of the Co-investigators immediately. Their contact information is listed at the end of this document. If you need to reach someone outside of business hours, please call (505) 272-2121.

A member of the Investigator group will determine what type of treatment, if any, is best for you at that time.

It is important for you to understand that the University of New Mexico does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of New Mexico will not pay for any wages you may lose if you are harmed by this study.

Medical costs related to your care and treatment because of study-related harm will be paid by you and/or your insurance

WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?

You will not receive any rewards or payment for taking part in the study.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

You will be informed if the investigators learn new information that could change your mind about staying in the study. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS?

Except for the results of NP swabs for SARS-CoV-2, you and your doctor will not be given individual results from the research tests unless there is a clear potential benefit to your subsequent medical care.

At your request, a member of the study team will contact you using the information you provided. With the help of a member of the study team, they will present possible risks or benefits of receiving the information. At that time, you can choose to receive or refuse the result or finding. If you would like more information about this, please call one of the study Co-investigators. You may also withdraw your consent to be contacted with information about research results by sending a written request to a study Co-investigator.

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

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of up to 350 people at UNM to do so.

FUTURE USE OF YOUR INFORMATION *OR* PROTECTED HEALTH INFORMATION

Identifiable information such as your name, medical record number, or date of birth will be removed from the information or samples collected in this study. After removal, the information or samples may be used for future research or shared with other researchers without your additional informed consent.

In addition to the main study, you are being asked to allow us to keep and use your information for future research.

HIPAA AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATIN (PHI).

As part of this study, we will be collecting health information about you and sharing it with others. This information is "protected" because it is identifiable or "linked" to you.

Protected Health Information (PHI)

By signing this Consent Document, as described in this consent form, you are allowing the investigators and other authorized personnel to use your protected health information for the purposes of this study. This information includes results of tests and exams done for your clinical care, your medical history, and other information related to the treatment of your condition.

In addition to researchers and staff at UNMHS and other groups listed in this form, there is a chance that your health information may be shared (re-disclosed) outside of the research study and no longer be protected by federal privacy laws. Examples of this include health oversight activities and public health measures, safety, monitors, other sites in the study, companies that sponsor this study, government agencies such as Food and Drug Administration (FDA).

Right to Withdraw Your Authorization

Your authorization for the use and disclosure of your health information for this study shall not expire unless you cancel this authorization. This is because the information used and created during the study may be analyzed for many years and it is not possible to know when this will be complete. Your health information will be used or disclosed as long as it is needed for this study. However, you may withdraw your authorization at any time provided you notify the UNM investigators in writing. To do this, please notify them of your wish to withdraw by email.

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or
Renee Mercier, PharmD (Dr. Mercier can answer questions about drug interactions and other issues)
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Please be aware that the research team will not be required to destroy or retrieve any of your health information that has already been used or shared before the date that your withdrawal is received.

If you become pregnant anytime during the study or within 15 days after stopping the study drug, you must inform the study doctor. The study doctor must then report the outcome of your pregnancy to the Sponsor (and/or the FDA).

The researchers agree to only share your health information with the people listed in this document. Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information would still be regulated by applicable federal and state laws.

You may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign this form it will not affect your:

- Current or future healthcare at the University of New Mexico;
- Current or future payments to the University of New Mexico;
- Ability to enroll in any health plans (if applicable); or
- Eligibility for benefits (if applicable).

After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the authorization:

- You will send a written letter to Dr. Dehority to inform him of your decision.
- Researchers may use and release your health information already collected for his research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).

The use and sharing of your information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of New Mexico Health Sciences Privacy Officer between the business hours of 8am and 5pm Mountain Pacific Time, Monday-Friday at (505) 272-1493.

If I am found to be ineligible to receive the study drug (hydroxychloroquine), I am willing to enroll as a control subject (will not take the study drug but will participate in study surveys, nasopharyngeal swabs and blood collection):

□ Yes

□ No

Note: You may sign and fax the consent form to the CTSC at (505) 272-9929 or sign and scan the consent form to the email of the investigator above who consented you.

INFORMED CONSENT SIGNATURE PAGE

You are participating or are authorized to act on behalf of the participant. This consent includes the following:

- Key Information Page
- Detailed Consent

You will receive a copy of this consent form after it has been signed.

_____ _____

Signature of research subject **Date**

_____

Printed name of research subject

_____ _____

Printed name of [authorized] person obtaining informed consent/HIPAA Authorization **Date**

_____

Signature of [authorized] person obtaining informed consent/HIPAA Authorization

At time of consent, after determining Eligibility criteria, patient chooses to be in:	Group A	Group B
Date of Group assignment:		

If participant switches Group:

Original Group assignment	Group A	Group B
New Group assignment	Group A	Group B
Date of Group assignment switch:		