INFORMED CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title: **National Institute of Allergy and Infectious Diseases / "A Randomized, Double-blind, Placebo-controlled Trial to Evaluate the Efficacy of Hydroxychloroquine and Azithromycin to Prevent Hospitalization or Death in Persons with COVID-19"**

Protocol Number: **A5395 Final Version 2.0 April 24, 2020**

Principal Investigator: (Study Doctor) [redacted]

Telephone: [redacted]

Address: [redacted]

SUMMARY

PURPOSE

This is a research study and your participation in this study is voluntary. The purpose of this study is to evaluate the ability **of** hydroxychloroquine (HCQ) and azithromycin (Azithro) compared to placebo **to** prevent hospitalization or death in persons with COVID-19.

STUDY TREATMENT

There will be study treatment provided and required in this study. It is not known whether this study treatment will help your COVID-19 or not. You will be randomized to either Group A or Group B. Randomized means that your assignment will be random, like rolling dice. In this study, you will have a 50/50 chance of receiving either **hydroxychloroquine** and Azithro or Placebos. You and the study doctor will not know what group you are in, and therefore, will not know which study treatment you are taking (this is also referred to as "double-blinded"). You will take **hydroxychloroquine**/Placebo **two** (**2**00 mg each) capsules by mouth **twice a day on the first day, followed by one 200 mg capsule twice a day for 6 days. Hydroxychloroquine**/Placebo should be taken with food or milk. You will also take Azithro/Placebo two (250 mg each) capsules by mouth **once on** the first day and then **one** capsule (250 mg) every day for 4 additional days.

NUMBER OF PARTICIPANTS

There will be 2 study treatment groups of 1000 people, for a total of 2000 participants.

LENGTH OF STUDY

The study will last for about 6 months (7 days on study treatment)

REQUIRED ACTIVITIES

Sample collections

You will report your symptoms and temperature (if you have a thermometer at home) and how often you took study drugs and at what time throughout the study.

Some study sites will be collecting additional samples. If your study site is participating in this portion of the study, you will be asked to sign and date a separate consent form that provides more detail about these activities. At the start of the study you may have some blood collected from a vein in your arm, perform a self-collect nose swab, and, in addition, have study staff do a nasopharyngeal swab of your nose. You will have both types of nose swabs at Day 6 and 20 and blood collected again at Days 6 and 20. All blood will be stored.

Even if your study site is participating in the additional sample collection, you do not have to take part in this portion. You can still be in the main part of the study and receive study treatment even if you decide not to provide additional samples.

RISKS

The following are possible:

- **Hydroxychloroquine** side effects
  - Nausea
  - Diarrhea
  - Vomiting
  - Headache
  - Tiredness
  - Stomach (abdominal) pain
  - Muscle weakness

- Possible **hydroxychloroquine** side effects that are uncommon but potentially serious:
  - Serious (including fatal) allergic and skin reaction
  - Fast heart rate or pulse
  - Prolongation of QT interval (heart takes longer than normal to recharge between beats) and cases of “torsades de pointes” (dangerous fast heart beats)
  - Ventricular tachycardia or fibrillation, a condition of the heart that can cause a fast heart rate and increase the risk of stroke and heart attack

  - Hypoglycemia (blood sugar is low)
  - Blurry vision
  - Muscle pain
  - Death

- Azithro side effects
  - Diarrhea
  - Nausea
  - Abdominal pain
  - Vomiting

- Possible Azithro side effects that are uncommon but potentially serious:
  - Serious (including fatal) allergic and skin reaction
  - Pseudomembranous colitis (swelling or inflammation of the large intestine due to overgrowth of *Clostridium difficile*)
  - New onset of myasthenia gravis (long-term neuromuscular disease that leads to skeletal muscle weakness)
  - Exacerbation of myasthenia gravis (weakness in skeletal muscles)
  - Ventricular arrhythmias (occurs more frequently in people with heart disease)
  - Severe, and sometimes fatal, hepatotoxicity (liver damage)
  - Prolongation of QT interval (heart takes longer than normal to recharge between beats) and cases of “torsades de pointes” (heart beats faster than usual)
  - *Clostridium difficile* (bacteria)-associated diarrhea
  - Death

BENEFITS

If you take part in this study, there may be a direct benefit to you, but no guarantee can be made. It is also possible that you may receive no benefit from being in this study. Information learned from this study may help others who have SARS-CoV-2 infection.

OTHER CHOICES

Instead of being in this study, you have the option of:

- Treatment with prescription drugs available to you by your medical provider.
- Treatment with experimental drugs, if you qualify, treatment with “off-label” treatment with hydroxychloroquine and/or azithromycin if prescribed by your medical provider.
- No treatment.

This form is for use in a research study that may involve subjects who may or may not have the capacity to consent to take part in the study. When the subject cannot legally consent to take part, pronouns "you" and "your" should be read as referring to the subject rather than the person (legally authorized representative) who is signing and dating this form for the subject. In cases where the subject's representative gives consent, the subject should be informed about the study to the extent possible given his/her understanding. During the course of the study, if the subject regains the capacity to consent, informed consent will be obtained from the subject and the subject offered the ability to leave the study if desired.

INTRODUCTION

You are being asked to take part in this research study because you have been diagnosed with SARS-CoV-2 (a new virus that can cause severe pneumonia and death) and have symptoms of this infection, commonly known as COVID-19. This study is sponsored by the National Institutes of Health (NIH). The study doctor listed on page one of this form is in charge of this study at this site. Before you decide if you want to be a part of this study, we want you to know about the study.

This is a consent form. It gives you information about this study. The study staff will talk with you about this information. You are free to ask questions about this study at any time. If you agree to take part in this study, you will be asked to sign this consent form. You will get a copy to keep.

WHY IS THIS STUDY BEING DONE?

SARS-CoV-2 is a new virus that has caused a widespread outbreak of an illness called COVID-19. In most people it causes a mild to moderate upper respiratory infection, like a "cold". In others, this virus can cause a pneumonia, which can be serious and life-threatening.
There is no proven therapy for COVID-19.

The investigators of this study would like to know if the medication hydroxychloroquine (HCQ) combined with azithromycin (Azithro) can protect people from becoming sick enough from SARS-CoV-2 infection to require hospitalization or from dying. This study will gather data on the effectiveness of **hydroxychloroquine** and Azithro to prevent hospitalization and death in adults with SARS-CoV-2 infection when compared to Placebo (sugar capsule). Another purpose of this study is to see if **hydroxychloroquine** and Azithro is safe for people who are infected with SARS-CoV-2 and have symptoms consistent with COVID-19.

Hydroxychloroquine is currently approved by the Food and Drug Administration (FDA) for prevention and treatment of malaria infection and treatment of disease in individuals with rheumatoid arthritis, porphyria cutanea tarda (blood disorder that affects the skin), and lupus (an autoimmune disease). Azithromycin is currently FDA approved for treating bacterial infections. **Hydroxychloroquine** and Azithro have not previously been tested in a randomized controlled trial (where people are assigned randomly to study treatment and compared to people not taking study treatment) to see if they can prevent severe disease from SARS-CoV-2 infection.

If you are an employee or relative of an employee of this research center, you are under no obligation to participate in this study. You/your family member may withdraw from the study at any time and for any reason, and neither you/your family member's decision to participate in the study, nor any decision on your/their part to withdraw, will have any effect on your/your family member's performance appraisal or employment at this clinical research center.

You/your family member may refuse to participate, or you/your family member may withdraw from the study at any time without penalty or anyone blaming you.

WHAT DO I HAVE TO DO IF I AM IN THIS STUDY?

Information Collected at Screening
If you decide to take part in this study, you will be screened to determine if you qualify for the study.

There is some information that we collect on everyone who is screened for an **AIDS Clinical Trials Group (ACTG)** study. As part of the screening, some demographic (such as, age, sex/gender, race), clinical (such as disease condition, diagnosis), and laboratory (such as, inflammation and SARS-CoV-2 levels) information will be collected from you. We also collect information on whether you use (or have used) IV drugs or smoke marijuana or have smoked tobacco or other nicotine products.

We will collect this information even if you do not enroll in this study. This information is collected so that researchers can determine whether there are patterns and/or common reasons why people do not join a study.

Study Visits
The schedule of visits and study procedures are explained in Attachment B.

You will most likely be screened over the phone, but you also could be screened in person. If you qualify for the study, you will have an in-person entry visit to get your study treatment for the duration of the study, or a remote (i.e., by telephone or video) visit in which your study treatment for the duration of the study will be mailed or delivered to you. The screening and entry visit may occur on the same day. You will be randomized to receive either **hydroxychloroquine** and Azithro (Group A) or Placebos (Group B). Randomized means that your assignment will be random, like rolling dice. In this study, you will have a 50/50 chance of receiving either **hydroxychloroquine** and Azithro or Placebos. You and the study doctor will not know what study **group you are in**.

If you are in Group A, you will take two **hydroxychloroquine capsules (200 mg each) by mouth twice a day on the first day**, **followed by one 200 mg capsule twice a day for 6 days**. **Hydroxychloroquine** should be taken with food or milk. You will also take two Azithro capsules (250 mg each) by mouth **once on** the first day and then **one** capsule (250 mg) every day for 4 additional days.

If you are in Group B, you will take **two** Placebo **hydroxychloroquine capsules (200 mg each) by mouth twice a day on the first day**, **followed by one 200 mg capsule twice a day for 6 days**. Placebo **hydroxychloroquine** should be taken with food or milk. You will also take two Placebo Azithro capsules **(250 mg each)** by mouth **once on** the first day and then **one** capsule **(250 mg each)** every day for 4 additional days. Study staff will counsel you on how to take these study drugs. Both study groups are important to the study to answer the study questions.

After entry, you will be followed-up by telephone or video a few times. These phone calls will take between 30 and 60 minutes to complete. During the study, you will take your temperature if you have a thermometer at home and complete a symptom diary.

If you need medical help at any time during the study, please contact the study staff right away.

Screening Visit (in-person or remote)
You will be asked for your medical and medication history. You will be asked about your symptoms.

Study Entry (in-person or remote)
Following the screening visit **(if not combined with the entry visit)**, if you qualify for the study, you will be asked for your medical and medication history again, be given your study treatment and be given a Study Diary packet and complete the Study Diary for that day (if remote visit, these items will be mailed or delivered to you). You will be asked to provide contact information for people close to you in case study staff cannot reach you during the study. We would like you to tell these contacts that you are in the study, so they know they may receive a call from study staff. You will also be asked to provide your health care provider's contact information along with the name(s) of the hospital you would likely go to if you get really sick (see consent below under "WHAT IF THE SITE CAN NO LONGER REACH ME DURING THE STUDY?"). You will also be asked to provide your home address. You will take your study treatment on this day. If you have an in-person visit, study staff will observe you taking the study treatment. If you have a remote visit, you will need to tell study staff when you have taken the study drug.

Follow-up Visits
You will be contacted by phone by study staff on Days 2, **4**, 6, 9, 13, and 17, and at 3 and 6 months after you enter the study. During the study, you will complete a symptom diary. You will also be asked questions about how you are taking the study treatment and health care that you have accessed. Site staff will also ask you to update your secondary contact information. These visits will take between 30 and 60 minutes.

You will have an in-person visit **or remote visit** on Day 20 to see how you are feeling and for you to turn in your Study Diary. If your Day 20 visit **is not done** in person, you will be called by study staff to do the visit over the phone or by video. Arrangements will be made for you to send the symptom diary to the clinic. This visit will take between 30 and 60 minutes.

If you cannot be reached, the study staff will contact your alternative contacts or your health care provider. If you become hospitalized, the study staff will ask your contacts for information about you being in the hospital. The study staff will also ask your contacts about death, should that occur (see consent below under "WHAT IF THE SITE CAN NO LONGER REACH ME DURING THE STUDY?").

Early discontinuation
If at any point in the study you want to stop study treatment or stop participating in the study, you must contact the site immediately **and will be asked to come to the clinic for an extra visit**.

1. *Stopping the study treatment early*
   You or your doctor may decide to stop the study treatment that you began at entry.

   If you must stop taking the study treatment early, you will continue the study and complete the study visits as described in this form.

2. *Leaving the study early*
   You or your doctor may decide that you will no longer stay in the study or you are notified the study is stopped early. You will be asked to complete some evaluations before being taken off the study.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Up to 2000 people will take part in this study.

HOW LONG WILL I BE IN THIS STUDY?

You will be in this study for about 6 months (7 days on treatment).

WHY WOULD THE DOCTOR TAKE ME OFF THIS STUDY EARLY?

The study doctor may need to take you off the study early without your permission if:
- The study is stopped or cancelled.
- Continuing the study treatment may be harmful to you.
- Your primary care provider requests that you stop participating in the study.
- You do not take your first dose of study treatment when you start the study.

The study doctor may also need to take you off the study drug without your permission if:
- You are taking other medications that should not be taken with the study drug.

If you must stop taking the study treatments before the study is over, the study doctor will ask you to continue to be part of the study and return for study visits and procedures.

WHAT HAPPENS IF I DECIDE TO PERMANENTLY STOP TAKING STUDY DRUGS?

If you must permanently stop taking study-provided **hydroxychloroquine** and Azithro or Placebo before your study participation is over, the study staff will discuss other options that may be of benefit to you.

WHAT HAPPENS WHEN I FINISH THE ONE WEEK STUDY DRUGS?

After you have completed your study participation, the study will not be able to continue to provide you with the **hydroxychloroquine** and Azithro you received on the study. If continuing to take these or similar drugs/agents would be of benefit to you, the study staff will discuss how you may be able to obtain them.

WHAT ARE THE RISKS OF THE STUDY?

There are risks to taking part in any research study. The effectiveness of the study treatments is not known. One risk is that the study treatments may not stop you from becoming sicker, being hospitalized or dying from SARS-CoV-2.

Another risk is that the study treatments used in this study may have side effects, some of which are listed below. Additionally, the study drugs tested in the study may have unknown side-effects in persons with SARS-CoV-2 infection. In a research study, all of the risks or side effects may not be known before you start the study. You need to tell your study doctor or a member of the study team immediately if you experience any side effects.

Please note that these lists do not include all the side effects seen with the study drugs. These lists include the more serious or common side effects with a known or possible relationship to the study drugs. If you have questions concerning the additional side effects, please ask the medical staff at your site.

There is a risk of serious and/or life-threatening side effects when non-study medications are given with the study treatment. For your safety, you must tell the study doctor or nurse about all medications you are taking before you start the study. Medications that are high risk include:

- "Off-label" prescription for hydroxychloroquine, chloroquine, and/or azithromycin
- Cardiac medications
    - Antiarrhythmic drugs: quinidine [Quinidex Extentabs, Quinaglute, Quinalan, Cardioquin], procainamide [Pronestyl], disopyramide [Norpace, Norpace CR], dofetilide [Tikosyn], ibutilide [Corvert], and sotalol [Betapace, Betapace AF, Sorine, Sotylize]
    - Loop diuretics: furosemide [Furocot, Lasix], bumetanide [Bumex], torsemide [Demadex], ethacrynic acid [Edecrin]
- Non-cardiac medications
    - Diphenhydramine [Benadryl, Banophen, Allermax, Genahist, Sominex, Unisom, ZzzQuil]
    - Antiepileptic medications: Carbamazepine (Tegretol, Carbegen), Eslicarbazepine (Aptiom), Ethosuximide, Felbamate (Felbatol), Gabapentin (Neurontin), Lamotrigine (Lamictal), Levetiracetam (Desitrend, Keppra), Oxcarbazepine (Trileptal), Phenobarbital, Phenytoin (Dilantin, Epanutin), Piracetam (Nootropil), Pregabalin (Alzain, Axalid, Lyrica, Rewisca), Rufinamide (Inovelon), Stiripentol (Diacomit), Tiagabine (Gabitril), Topiramate (Topamax), Sodium Valproate (Epilim, Episenta, Epival), Valproic Acid (Convulex, Depakote, Depakene), Zonisamide (Zonegran)
    - Antipsychotic and antidepressant agents: Neuroleptic (haloperidol [Haldol], droperidol [Inapsine], thioridazine [Mellaril, Mellaril-S], chlorpromazine [Thorazine, Ormazine]); Atypical antipsychotics (ziprasidone [Geodon], risperidone [Risperdal M-Tab, RisperiDONE M-Tab], zimeldine [Normud, Zelmid], citalopram [CeleXA]); Antidepressants (amitriptyline [Elavil, Vanatrip], desipramine [Norpramin], imipramine [Tofranil and Tofranil-PM], maprotiline [Ludiomil], doxepin [Silenor, SINEquan], fluoxetine [PROzac, PROzac Weekly, Rapiflux, Sarafem, Selfemra], escitalopram [Lexapro], citalopram [CeleXA])
    - Antibiotics: Quinolone (levofloxacin [Levaquin], moxifloxacin [Moxeza, Vigamox]); Macrolide (erythromycin [EES 200, EES 400, EES Granules, Eryc, Eryped, Eyrped 200, Eyrped 400, Ery-Tab, Erythrocin, Erythrocin Stearate, Ilosone, PCE, PCE Dispertab], clarithromycin [Biaxin, Biaxin Filmtab, Biaxin XL])
    - Antimalarials (quinine [Qualaquin, Quinamm, Quiphile], halofantrine [Halfan])
    - Antiprotozoal (pentamidine [Pentam])
    - Antifungal (azole group [Vfend, Sporanox, Noxafil, Diflucan, Nizoral, Mycelex Troche, Cresemba, Onmel, Oravig, Tolsura])

- Antimotility agents (antidiarrheals)
- Methadone [Diskets Dispersible, Dolophine, Methadone HCl Intensol, Methadose]

Please contact the study doctor or nurse before starting any of these medications while on the study. Also, you must tell the study doctor or nurse before enrolling in any other clinical trials while on this study.

If you enroll in this trial and are randomized to receive active hydroxychloroquine and azithromycin drugs, and you also receive "off-label" prescription for hydroxychloroquine, **chloroquine,** and/or azithromycin, then there is a risk of over-dosing. It is possible to have serious side effects with risk for death. It is important that you do not take **hydroxychloroquine** or Azithro from sources outside of the study, like from your primary doctor. If you do take one or both of these drugs from sources outside the study, please let the study staff know right away.

There is also a risk that these drugs have no benefit for COVID-19, and thus drug exposure would carry more risk than placebo.

Commonly reported side effects of **hydroxychloroquine** are:
- Nausea
- Diarrhea
- Vomiting
- Headache
- Tiredness
- Stomach (abdominal) pain
- Muscle weakness

Less common, but potentially severe and potentially life-threatening side effects of **hydroxychloroquine** in volunteers were:
- Allergic reactions and rash
- Tachycardia (fast heart rate or pulse)
- Prolongation of QT interval (heart takes longer than normal to recharge between beats) and cases of "torsades de pointes" (dangerously fast heart beats)
- Ventricular tachycardia or fibrillation, a condition of the heart that can cause a fast heart rate and increase the risk of stroke and heart attack
- Hypoglycemia (blood sugar is low)
- Blurry vision
- Muscle pain
- Death

If you have psoriasis and are randomized to receive **hydroxychloroquine**, you may experience a psoriasis flare.

Side Effects of Azithro
- Diarrhea
- Nausea
- Abdominal pain
- Vomiting
- Pseudomembranous colitis (swelling or inflammation of the large intestine due to overgrowth of *Clostridium difficile*)

- New onset of myasthenia gravis (long-term neuromuscular disease that leads to skeletal muscle weakness)
- Exacerbation of myasthenia gravis (weakness in skeletal muscles)
- Ventricular arrhythmias (occurs more frequently in people with heart disease)

The following severe and potentially life-threatening side effects have been reported:
- Serious (including fatal) allergic and skin reaction
- Severe, and sometimes fatal, hepatotoxicity (liver damage)
- Prolongation of QT interval (heart takes longer than normal to recharge between beats) and cases of "torsades de pointes" (dangerously fast heart beats)
- *Clostridium difficile* (bacteria)-associated diarrhea
- Death

As with all drugs, you could have an allergic reaction such as a rash or hives. Allergic reactions can be dangerous; if you develop an allergic reaction, you will be given medication (similar to Benadryl) to counter the reaction and be taken off study drug.

ARE THERE RISKS RELATED TO PREGNANCY AND BREASTFEEDING?

Pregnancy
The safety of **hydroxychloroquine** during pregnancy is not fully established. However, pregnant women with lupus and arthritis are recommended to continue **hydroxychloroquine** throughout pregnancy. Studies have shown that taking **hydroxychloroquine** during pregnancy does not harm the fetus. It should be noted that **hydroxychloroquine** at the dose used in this study has not been used before during pregnancy and may involve risks.

In animal studies, no evidence of harm to the fetus due to Azithro was found. When given as malaria prevention during pregnancy, Azithro was not shown to harm the fetus.

The study treatment may involve risks to you (or to the embryo or fetus, if you or your partner become pregnant), which are currently unforeseen. Let your study doctor know immediately if you become pregnant. If you become pregnant while on the study, the study staff would like to obtain information from you about the outcome of the pregnancy (even if it is after your participation in the study ends).

If you are pregnant, please discuss study participation with your OB/GYN provider.

Breastfeeding
Hydroxychloroquine is excreted in human breast milk. When given at the dose used in this study the relative amount of **hydroxychloroquine** in breast milk is considered safe for infants. Azithro is excreted in human milk, but considered safe to use during breastfeeding.

It is unknown if SARS-CoV-2 is excreted in human breast milk. If you would like to breastfeed during this study, please talk to your OB/GYN provider.

ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

No direct benefits should be expected from participating in this study. If you take part in this study, there may be a direct benefit to you, but no guarantee can be made. It is also possible that you may receive no benefit from being in this study. Information learned from this study may help others who have SARS-CoV-2 infection.

WHAT OTHER CHOICES DO I HAVE BESIDES THIS STUDY?

Instead of being in this study you have the choice of:

- Treatment with prescription drugs available to you by your medical provider.
- Treatment with experimental drugs, if you qualify, treatment with “off-label” treatment with hydroxychloroquine and/or azithromycin if prescribed by your medical provider.
- No treatment.

Please talk to your doctor about these and other choices available to you. Your doctor will explain the risks and benefits of these choices.

WHAT ABOUT CONFIDENTIALITY?

We will do everything we can to protect your privacy. In addition to the efforts of the study staff to help keep your personal information private, we have gotten a Certificate of Confidentiality from the US Federal Government. This certificate means that researchers cannot be forced to tell people who are not connected with this study, such as the court system, about your participation. Also, any publication of this study will not use your name or identify you personally.

The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use.
Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

Your records may be reviewed by the US Food and Drug Administration (FDA), the ACTG, the US Office for Human Research Protections (OHRP), or other local, US, and international regulatory entities as part of their duties, (insert name of site) institutional review board (IRB) (a committee that protects the rights and safety of participants in research), National Institutes of Health (NIH), study staff, study monitors, drug companies supporting this study, and their designees. Having a Certificate of Confidentiality does not prevent you from releasing information about yourself and your participation in the study.

Even with the Certificate of Confidentiality, if the study staff learns of possible child abuse and/or neglect or a risk of harm to yourself or others, we will be required to tell the proper authorities.

A description of this clinical trial will be available on 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.

WHAT IF THE SITE CAN NO LONGER REACH ME DURING THE STUDY?

In the event you cannot be reached after multiple attempts to contact you, study staff may try to contact you through alternate phone numbers of family, friends, case manager, or acquaintances obtained **from you** at screening and updated at each visit. If you are still unable to be reached, we will attempt to obtain information about you from your designated contacts, clinic records, or by contacting your health care providers (if you agree).

Contacting Your Health Care Providers

With your permission, for which you would need to sign a waiver, study staff may contact your health care providers or hospitals where you might receive care to determine if you have been hospitalized or died while in the study, and the cause of death. Will you allow us to contact your health care provider(s) or hospitals to obtain this information?

_____ YES _____ NO _____Initials

If you said Yes, please list the names of your health care provider and the hospitals you would likely be admitted to, below:

WHAT ARE THE COSTS TO ME?

There will be no cost to you for study-related visits or procedures. If you require medical care as a result of taking study drugs, it is possible that your insurance company will not pay for these costs because you are taking part in a research study. You are more likely to require medical care as a result of having COVID-19. Costs related to acute care/hospitalization will not be covered by the study.

WILL I RECEIVE ANY PAYMENT?

You will be paid $25 at the completion of each visit. If you do not complete the study, for any reason, you will be paid for each study visit you do complete.

WHAT HAPPENS IF I AM INJURED?

If you are injured as a result of being in this study, you will be given immediate treatment for your injuries. The cost for this treatment will be charged to you or your insurance company. There is no program for compensation either through this institution or the National Institutes of Health. You will not be giving up any of your legal rights by signing this consent form.

A new public health declaration, called the Public Readiness and Emergency Preparedness Declaration (PREP), was issued by the Department of Health and Human Services on March 10, 2020. This declaration limits the legal rights of a subject participating in a COVID-19 clinical study that uses a drug, device or vaccine designed to treat, diagnose, cure or prevent COVID-19. This includes the study drug Hydroxychloroquine and Azithromycin used in this study. Subjects using Hydroxychloroquine and Azithromycin in this study will have limits on their right to sue the manufacturers, the study sponsor, healthcare providers and others for significant injuries and adverse reactions.

WHAT ARE MY RIGHTS AS A RESEARCH PARTICIPANT?

Taking part in this study is completely voluntary. You may choose not to take part in this study or leave this study at any time. Your decision will not have any impact on your participation in other studies and will not result in any penalty or loss of benefits to which you are otherwise entitled.

We will tell you about new information from this or other studies that may affect your health, welfare, or willingness to stay in this study. If you want the results of the study, let the study staff know.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:**

- By mail: [redacted]
- or call **toll free**: [redacted]
- or by **email**: [redacted]

Please reference the following number when contacting the Study Subject Adviser: [redacted]

SIGNATURE PAGE

If you have read this consent form (or had it explained to you), all your questions have been answered and you agree to take part in this study, please sign your name and date below.

Participant's Name (print)	Participant's Signature and Date
Participant's Legally Authorized Representative (print) (As appropriate)	Legally Authorized Representative Signature and Date
Study Staff Conducting Consent Discussion (print)	Study Staff's Signature and Date
Witness's Name (print) (As appropriate)	Witness's Signature and Date

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study doctor and study staff will use and share health data about you to conduct the study. Health data may include:

- Your name.
- Address.
- Phone number.
- Date of birth.
- Medical history.
- Information from your study visits, including all test results.

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the study staff may share health data about you with authorized users. Authorized users may include:

- Representatives of the National Institute of Allergy and Infectious Diseases.
- Representatives of the AIDS Clinical Trials Group.
- Representatives of University of California, Los Angeles (UCLA).
- Representatives of Teva Pharmaceuticals Industries Ltd. (the industry sponsor).
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study.
- Other research doctors and medical centers participating in this study, if applicable.
- A data safety monitoring board which oversees this study, if applicable.

Your health data will be used to conduct and oversee the research, including for instance:

- To see if the study drugs work and are safe.
- To compare the study drugs to other drugs.
- For other research activities related to the study drugs.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign and date this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____
Printed Name of Subject

_____ _____
Signature of Subject Date

_____
Printed Name of Legally Authorized Representative

_____ _____
Signature of Legally Authorized Representative Date

_____
Authority of Legally Authorized Representative to act on behalf of Subject

_____
Printed Name of the Person Obtaining the Authorization

_____ _____
Signature of the Person Obtaining the Authorization Date

WITNESS SIGNATURE FOR SUBJECTS WHO CANNOT READ

The study subject has indicated that he/she is unable to read. This Authorization document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.

_____

Printed Name of Impartial Witness

_____ _____

Signature of Impartial Witness Date