

Official Title:	Randomized Comparison of Combination Azithromycin and Hydroxychloroquine vs. Hydroxychloroquine Alone for the Treatment of Confirmed COVID-19
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[REDACTED]

If I Say Yes Now, Can I Change My Mind And Take Away My Permission Later?

Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use

[REDACTED]

How Long Will My Permission Last?

There is no set date when your permission will end. Your health information may be studied for many years unless you have not agreed to allow your data and leftover specimens to be utilized for future use.

AGREEMENT TO PARTICIPATE

Subject Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name (Print): _____

Subject Signature: _____ Date: _____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent Name (Print): _____

Signature: _____ Date: _____

[REDACTED]

CONSENT ADDENDA:

Request to Store Tissue and/or Health Information for Future Research Use

This section of the informed consent form is about additional research that is being done with people who are taking part in the main study. You may take part in this additional research if you want to. You can still be a part of the main study even if you say 'no' to taking part in this additional research.

We ask your permission to store samples and health information collected from you during the main study "**Randomized Comparison of Combination Azithromycin and Hydroxychloroquine vs. Hydroxychloroquine Alone for the Treatment of Confirmed COVID-19**" for future research. You may still participate in the main study even if you say no to this request to store your samples and information for future research.

The types of research that may be performed on specimens obtained from this include analysis of genetic information (DNA or genes), proteins, and/or cell behavior in a test tube. Observations made on genes, proteins, or cells will be linked to clinical information to make associations with risk of developing cancer, response to therapy, side effects of therapy, or with specific cancer outcomes. DNA is the material that makes up your genes or genetic information that you inherit from your parents. Genes are also important in determining the occurrence of cancer and how they respond to cancer treatments. Other types of analyses done on specimens may include measuring the levels of proteins or RNA (a material that helps form the template from which proteins are made) in cells, in body fluids or in tissues. Cells may be processed so that they can be kept in culture short term, injected into animals to observe cell behavior, or kept in culture indefinitely. Cells kept in culture allow for a renewable source of DNA, RNA, proteins and cells that can be used to test response to therapies in a test tube.

HOW AND WHERE WILL MY BIOSPECIMENS BE STORED AND BY WHOM?

[REDACTED]
[REDACTED] to be conducted by the Principal Investigator and the research staff. The goal of the research is to better understand and develop better means to prevent, diagnose and treat disease.

All of the subjects in this study will be asked to allow leftover blood to be stored and used for future use in the repository.

There is no set limit to the number of individuals that may provide samples and information to the repository. The more samples and health information available in storage, the more useful the repository will be for medical research.

HOW WILL TISSUE SAMPLES AND INFORMATION BE COLLECTED?

We use the term "tissue" to refer to specimens such as blood, saliva and throat specimens that were collected as part of this research study. We ask your permission to store left over tissue samples and health information that was collected during this research study for future research.

Please know that you may still participate in the main study even if you say no to this request to store tissue for future research. We will also collect information about you from this study reports for future research. Only the leftover tissue that was collected [REDACTED]

[REDACTED]

study for future research would be stored and used for future use.

Psychological or Social Risks Associated with Loss of Privacy:

While the databases developed for this project will be coded to protect your personal information, people may develop ways in the future that would allow someone to link your medical information back to you. It is also possible that there could be violations to the security of the computer systems.

Although your genetic information is unique to you, you do share some genetic information with your children, parents, brothers, sisters, and other blood relatives. Consequently, it may be possible that genetic information from them could be used to identify you. Similarly, it may be possible that genetic information from you could be used to help identify them. Further, patterns of genetic variation also can be used by agencies to identify a person or his/her blood relatives (for example, to establish relationships between parents and their children).

There also may be other privacy risks that we have not foreseen.

Economic Risks of Harm

Since some genetic variations can help to predict the future health problems of you and your relatives, this information might be of interest to health providers, life insurance companies, and others. Therefore, your genetic information potentially could be used in ways that could cause you or your family economic distress.

There are state and federal laws that protect against genetic discrimination:

There is a federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways: (1) health insurance companies and group health plans may not request your genetic information that we get from this research; (2) health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums; and (3) employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

WHAT ARE THE BENEFITS OF PARTICIPATION?

You will not benefit personally from providing biospecimens and health information for this Repository because research usually takes a long time to produce meaningful results. However, your participation may help investigators understand, prevent, or treat the diseases and conditions studied in the future.

HOW WILL INFORMATION ABOUT ME BE KEPT PRIVATE AND CONFIDENTIAL?

[REDACTED]

IS THERE OTHER IMPORTANT INFORMATION TO CONSIDER?

[REDACTED]

Yes. There is no cost to you to take part in the Research Repository. Nor will you be paid to take part in the Repository. It is possible that future research using your biospecimens may lead to the development of new tests, techniques, drugs or other commercial products. Should any products or services result from future research, there is no plan to share any of the profits with you.

[REDACTED]

Your Rights If I Agree To Take Part In The Research Repository?

You have the right to ask questions about any part of our storage and future research at any time. You should not sign this form unless you have a chance to ask questions and have been given answers to all of your questions. Your participation in the Research Repository is voluntary. You do not have to participate. If you do, you can change your mind at any time.

If I Say Yes Now, Can I Change My Mind And Take Away My Permission Later?

[REDACTED]

[REDACTED]

Please tell us if and how you wish your [biospecimens and information to be used for future research. Please add your Initials to indicate the ways you permit your samples and information to be used:

My blood specimen and health information may be used for future research as follows:

_____ only on Disease related to cancer, infectious diseases, cardiology
_____ on any research topic important to researchers

WHO CAN I CONTACT IF I HAVE QUESTIONS?



AGREEMENT TO PARTICIPATE

Subject Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this Research Repository.

Subject Name (Print): _____

Subject Signature: _____ Date: _____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent Name (Print): _____

Signature: _____ Date: _____