

COMIRB
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Consent and Authorization Form

Principal Investigator: Thomas Flaig, MD

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Study Title: COVID-19 Prospective Observational Cohort Study and Biobank of Health Care Workers and Other Populations

Study Team Contact: 303-724-0945 and e-mail: hcwcovidresearch@cuanschutz.edu

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Summary of this research project

- This project is being conducted to collect data and blood samples to be used to study COVID-19.
- Study participation will be for up to approximately 12 months and include typically 4 visits (but up to 5) in-person visits with blood draws and questionnaires, and shortly weekly questionnaires.
- Data will be analyzed to identify factors associated with COVID-19 prevalence, and disease course and outcomes, and response to SARS-CoV-2 vaccines.
- Blood will be tested for SARS-CoV-2 IgG antibody and results will be reported to each subject.
- Data and samples will be stored in a biobank and made available to research for COVID-19.

Why is this study being done?

This study plans to learn more about SARS-CoV-2 virus ("coronavirus") and COVID-19 by collecting data and banking samples for researchers to use to answer questions related to this disease and its impact on health. These samples as well as your health data will be used to better understand the virus by developing new, experimental tests for diagnosis and antibody identification of the virus, as well as to identify potential prevention or treatment opportunities. In addition, if you agree, your data and samples will be placed in a biobank and be made available for researchers to investigate COVID-19 and other conditions.

Other people in this study

Up to 7500 people from your area will participate in the study.

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What happens if I join this study?

If you join this study, you will participate in typically 4 visits (but up to 5) in-person study visits as well as complete weekly questionnaires on-line. The data and samples that are collected will be to learn more about you and your health, your occupation and exposures to COVID-19 as well as the severity and course of illness if you develop COVID-19.

At your Baseline visit, you will undergo the consent process, and we will collect questionnaires and a blood sample of up to 50 mL (about 10 teaspoons). We will test your blood from that Baseline visit for antibody to SARS-CoV-2 and report those results to you (see below for more details about this test). The results of that test will determine your follow-up:

- If you are negative at your Baseline visit (or future visits) for the antibody to SARS-CoV-2, you have not reported having COVID-19 and you have not received a SARS-CoV-2 vaccine, at your next visit, we will collect questionnaires but only 5 mL (about 1 teaspoon) of blood. We will test that new sample for the antibody to SARS-CoV-2 and give the results to you. If you are negative for that test and you do not report new COVID-19 or get a SARS-CoV-2 vaccine then at your next visit, we will still only collect 5 mL of blood for testing for the antibody to SARS-CoV-2. However, if you are positive for the antibody to SARS-CoV-2, you develop new COVID-19, or you get a SARS-CoV-2 vaccine then we will invite you back for another visit within several weeks to get a larger blood collection (up to 50 mLs of blood).
- If you are positive for the antibody to SARS-CoV-2 at your Baseline visit, you report having COVID-19, and/or you report receiving a SARS-CoV-2 vaccine, then for all of your additional visits, we will collect data and up to 50 mLs of blood although in some cases we still may only collect 5 mL of blood.
- You will also complete weekly questionnaires on-line and will also have the option to complete daily questionnaires if you become ill from COVID19 during the study.
- Depending on the timing that you may have had an infection and/or vaccine to SARS-CoV-2, study personnel may ask you participate in fewer than 4 visits. If this is the case, it will be explained to you.

The details of what will happen at each study visit how your visits may vary based on the results of your blood testing for antibody to SARS-CoV-2, if you report new COVID-19 infection and/or if you receive a vaccine. The overview of the study visits are included in the Schedule of Study Participation table below.

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| Schedule of Study Participation | | | | | | | |
|--|-------------|---------------------------|------------------------------|-------------------------------|--------------------|------------------|-----------------|
| | Baseline | 6-week visit (+/-42 days) | 4-8-month visit (+/-30 days) | 8-12-month visit (+/-30 days) | Weekly (+/-2 days) | Daily (optional) | One-time visit* |
| In-person or on-line visit | In-person | In-person | In-person | In-person | On-line | On-line | In-person |
| Consent | X | | | | | | |
| Blood draw* | X | X | X | X | | | X |
| Full Questionnaires | X (on-line) | X (on-line) | X (on-line) | X (on-line) | | | |
| Short Symptom Questionnaire | | | | | X (on-line) | | |
| COVID19 Symptom Course Questionnaire (optional) | | | | | | X (on-line) | |
| One time visit to obtain 'full' blood sample if you have become positive for antibody to SARS-CoV-2 or develop new COVID-19* | | | | | | | X |
| Estimated time to complete each visit | 45 minutes | 30 minutes | 30 minutes | 30 minutes | 5 minutes | 5 minutes | |

*The amount of blood drawn depends on the type of visit and also whether you are positive or negative for antibody to SARS-CoV-2 develop new COVID-19, or had a vaccine. For Baseline visits and at follow-up visits if you were positive at your prior research visit for antibody to SARS-CoV-2, or developed new COVID-19, we will collect up to 50 mL at each visit, although the blood volume collected may be less. If you are negative for antibody to SARS-CoV-2 and you did not develop new COVID-19 or get a vaccine, at your follow-up visits, we will only collect 5 mL of blood.

We will also collect information from your health records. By providing consent you will give permission for the study team to collect and store clinical and demographic information related to your health and COVID-19.

After the consent and collection of samples, and the completion of the '8-12-month study visit' there is no plan for further follow up for this study. However, if we decide to extend this study, we will notify you and you will be required to sign a new consent for that extension.

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After the consent and collection of samples, we will continue to access your medical records to collect your health information related to the treatment of this virus and your condition. We will use your samples and health data to support future research. We may also contact you to discuss future research opportunities.

Optional study procedures:

Fingerstick

An optional procedure is for the study to perform a fingerstick to obtain a spot of blood for research purposes.

I agree to the collection of an optional finger stick blood spot

YES _____ NO _____ Initials

Daily symptom questionnaire

If you develop new or suspected COVID-19, we would like to have you complete a short questionnaire daily to track your symptoms and their resolution.

I agree to the collection of daily symptom questionnaire if I develop new or suspected COVID19.

YES _____ NO _____ Initials

Scientists at the University and the health systems involved in this study work to find the causes and cures of disease. The data, blood and specimens collected from you during this study are important to this study and to future research. If you agree, we intend to put your data and any samples that remain after the SARS-CoV-2 IgG test mentioned above, including genetic samples, into the COVID-19 Biobank at the University of Colorado for future studies related to COVID-19 or other conditions (for example, diabetes). Types of research that may be done include looking for medically important differences in people and finding information on genetic ancestry. We may also do additional analysis of your biological specimen, such as looking at how the cells in your body work.

As part of this COVID-19 Biobank, your health information will be linked to your biological sample and your genetic information. The code linking this information will be kept secure and will only be available to restricted members of the study team. All this information will be stored so that it is available for future research. The use of your data and samples will be overseen by the study Principal Investigator as well as Steering Committee. Researchers will only be able to access your data and samples that are in the biobank with permission of the Principal Investigator of this study, the Steering Committee and Institutional Review Board (IRB) approval. We may use your biological samples and data for commercial profit in partnership with other organizations. You will not share in any financial benefit from the creation, use, or sale of such a product or idea.

I agree to the use of my data and samples in the COVID-19 Biobank as described above

YES _____ NO _____ Initials

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I give my permission for my study doctor (or someone he or she chooses) to contact me in the future to ask me to take part in more research.

YES _____ NO _____ Initials _____

Genetic Information Nondiscrimination Act (GINA)

It is possible your biological sample will be analyzed to collect genetic information and perform genetic research. Genetic research means we will study your DNA. We will get your DNA from your biological sample. DNA carries genetic information that is the "instruction book" for the cells in your body and determines what color skin, hair, and eyes you have, and influences health and disease. When we do genetic research, we may only look at small parts of your DNA, or we may look at all of your genetic information, known as your genome. These genetic tests may:

- Predict your risk of diseases such as some cancers, heart diseases, and muscle diseases.
- Predict how you respond to medications. This may help a healthcare provider understand if you need a different medication or a different dose of a medication.
- Identify you as being a 'carrier' for a disease. Carriers usually remain healthy and do not develop disease but there may be a higher risk of a genetic disease in their blood relatives including their children.

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally 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: Health insurance companies and group health plans may not request your genetic information that we get from this research. Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. 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. All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009. Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

COVID-19 related precautions during your study visits

To minimize your risk for exposure to SARS-CoV-2, or for you to transmit an infection to our study personnel, we will follow best practice policies and procedures as recommended by the Centers for Disease Control and the University of Colorado. This may include the following:

- Before each in-person visit you will also undergo a brief set of questions and have your temperature taken to determine if you have an infection at the time of the research visit. If

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you do, you will be asked to reschedule the in-person visit at a time that you are cleared from infection.

- During the in-person research visits, you will be required to wear a face mask that the study will provide to you at no-cost.
- We will schedule your research visit to maintain social distancing
- Our study personnel will be screened for signs and symptoms of infection prior to their visit with you
- The research study rooms will be cleaned before and after your visit.
- We will minimize the time you have to spend in-person by having you complete study questionnaires online.
- Best practices and recommendations from the Centers of Disease Control and the University of Colorado may change and we may ask you to do more or fewer of the procedures to minimize risk for exposure to SARS-CoV-2.

Will I find out my personal results from testing in this study?

As part of this study, we will perform a blood test for the IgG antibody to SARS-CoV-2 virus. This will be done in an approved lab, **and we will provide you with the results of this test.** The results will come in the mail or email depending on how you choose to receive your results, and be on a formal medical lab report and also include a letter explaining the results. More details will be included in the laboratory report and accompanying letter. Briefly, however, if your test for IgG antibody to SARS-CoV-2 is positive/abnormal, it can mean that you have been exposed to the virus and/or vaccine and developed an immune response. While we will be using tests that are approved and validated, it could also be a false-positive meaning that you have not actually been exposed to SARS-CoV-2. Also, it could be false-negative meaning that you have been exposed to SARS-CoV-2 and/or a vaccine, but this test doesn't pick that up. In addition, we do not know at this time if this test means that you are immune to future COVID-19 related illness. As such we recommend you continue to practice activities to minimize your risk for exposure.

If you are a CHCO faculty or staff member and participation in this research project reveals a positive COVID-19 antibody result, it is preferred that you report the positive result to CHCO Occupational Health.

Experimental testing

It is possible that additional testing will be done that is separate from the IgG test mentioned above. This testing may include genetic testing or other immune testing, and potentially include additional testing that could be diagnostic for SARS-CoV-2. At this time, these tests are considered experimental, and therefore we will not tell you the results of these tests. However, if at some point during the study we find information from these experimental tests, including genetic tests, that may be relevant to your health, with your permission, we will tell you so that you can receive that information and, if necessary, follow-up with your health-care provider outside of the study. Notably, it may be months or years before a result that is relevant to your health is identified. You will also have to pay for the cost of follow-up care with your own health-

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care provider.

What are the possible discomforts or risks?

From the needle stick for the blood draw, you may feel mild pain, or experience bruising at the site of blood draw. In addition, rarely, you may experience light-headedness.

For the collection of a blood drop from a finger prick, you will feel pain and may experience bruising. In addition, rarely, you may experience light-headedness.

There is also the risk of loss of confidentiality, which the study team will minimize by labeling samples with barcodes instead of your name and keeping all study records in a locked office accessible only to the investigators and study team members.

There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it cannot be guaranteed.

There may be unknown risks, stresses, or discomforts to you that we do not know about. There may also be unknown risks to groups of individuals like yourself.

What are the possible benefits of the study?

This study is designed for the researchers to learn more about the SARS-CoV-2 virus leading to improved diagnosis and treatment.

This study is not designed to treat any illness or to improve your health.

Who is paying for this study?

The following agencies are providing funds for this study:

The University of Colorado School of Medicine, Anschutz Medical Campus

The Boettcher Foundation

Will I be paid for being in the study?

You will not be paid to be in the study.

Will I have to pay for anything?

It will not cost you anything to be in the study.

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Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

Who do I call if I have questions?

The researcher carrying out this study is Dr. Thomas Flaig. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call a research team member at 303-724-0945. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Dr. Flaig with questions at 303-724-8155. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

Certificate of Confidentiality

This study has been issued a Certificate of Confidentiality from the federal government to help protect your privacy. The Certificate prohibits the researchers from disclosing your name, or any identifiable information, document or biospecimen from the research, with the exceptions listed below. A certificate provides protections against disclosing research information in federal, state, or local civil, criminal, administrative, legislative or other proceedings.

These protections apply only to your research records. The protections do not apply to your medical records.

The researchers may disclose your name or identifiable information, document or biospecimen, under the following circumstances:

- To those connected with the research,
- If required by Federal, State or local laws,
- If necessary for your medical treatment, with your consent,
- For other scientific research conducted in compliance with Federal regulations,
- To comply with mandated reporting, such as a possible threat to harm yourself or others, reports of child abuse, and required communicable disease reporting, or
- Under other circumstances with your consent.

A Certificate of Confidentiality does not protect information you or a member of your family voluntarily release.

Who will see my research information?

The University of Colorado Denver | Anschutz Medical Campus (the University) and its affiliated health systems have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:

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- University of Colorado Denver | Anschutz Medical Campus
- University of Colorado Health
- Children's Hospital Colorado

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information, but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Dr. Thomas Flraig
13001 East 17th Place, MS F520
Aurora, CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- The Institutional Review Board that is responsible for overseeing this research
- The study doctor and the rest of the study team.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator.

The investigator (or staff acting on behalf of the investigator) will use your information for the research outlined in this consent form. They will also make *all or some of the following health information about you collected in this study available to:*

- State or Federal authorities who have a right to know certain information such as infectious diseases for public health purposes

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- Commercial companies

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.)
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results, medications, mortality status
- Research Visit and Research Test records
- Alcoholism, Alcohol or Drug abuse
- Testing for or infection with diseases reportable to the Public Health department, including but not limited to: Human Immunodeficiency Virus (HIV), hepatitis (all forms) tuberculosis, or other sexually transmitted diseases.
- Testing for sickle cell
- Tissue samples and the data with the samples.

None of your personal identifying information will be released to commercial companies

What happens to Data, Blood and Specimens that are collected in this study?

Scientists at the University and the health systems involved in this study work to find the causes and cures of disease. The data, tissue, blood and specimens collected from you during this study are important to this study and to future research. If you join this study:

- The data, tissue, blood, or other specimens given by you to the investigators for this research no longer belong to you.
- Both the investigators and any sponsor of this research may study your data, tissue, blood, or other specimens collected from you.
- If data, tissue, blood, or other specimens are in a form that identifies you, the University or the health systems involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

HIPAA Authorization for Optional Additional Study Procedures

In this form, you were given the option to agree to additional, optional research procedures that include fingerstick blood spot and daily symptom questionnaires, and storage of your data and samples in the COVID-19 Biobank for future use in research. You must also give us your permission, under HIPAA rules, to use and disclose the information collected from these optional procedures, as described above. If you decline to give us permission to use and disclose your information, you cannot take part in these optional procedures, but you can still

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participate in the main study. Please **initial** next to your choice:

I give permission for my information, from the optional procedures I have agreed to above, to be used and disclosed as described in this section.

I **do not** give permission for my information for any optional procedures to be used and disclosed; I understand that I will not participate in any optional procedures.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature: _____

Date: _____

Print Name: _____

Consent form explained by: _____

Date: _____

Print Name: _____

A signature of a witness is required for consent of non-reading subjects and consent using a short form.

Witness Signature: _____ Date: _____

Print Name: _____

Witness of Signature Witness of consent process