UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT
COMBINED INFORMED CONSENT AND HIPAA AUTHORIZATION

Protocol Title:	**CARDIOVASCULAR, PULMONARY, AND RENAL PHENOTYPES IN COVID-19 SURVIVORS (CAPRICORN-19 STUDY)**
ClinicalTrials.gov ID	NCT05080192
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Summary
You are being invited to participate in a research study. Your participation is voluntary and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

The research study is being conducted to better understand the consequences of COVID-19 infection in various organs (such as the liver, kidneys, muscles in the body, and lungs). We plan to measure markers in blood, urine and from a breath collection.

If you agree to join the study, you will be asked to complete the following research procedures:
1. A brief set of surveys;
2. A brief non-invasive ultrasound scan to take pictures of your arteries, liver, kidney, heart, lung, and some of your muscles, and collection of blood, breath air and urine.
3. Tests of blood vessel and lung function.

4. Blood pressure monitoring for 24-hours, including during daily activities
5. Physical function assessment

Your participation will last ~24 hours, followed by a 5-year follow-up period which involves medical record review and 1-2 phone calls per year.
This study does not carry major risks since all procedures are non-invasive (except for a blood draw). The alternative is to not participate in this study.

Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, costs, and other possible risks not discussed here. If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

Why am I being asked to volunteer?
You are being invited to participate in a research study because you were diagnosed with COVID-19 in the past or because you did not previously have known symptomatic COVID-19. Your participation is voluntary, which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the investigator and/or the research team about anything you do not understand. If you decide to participate, you will be asked to sign this form. Your doctor may be an investigator in this research study. As an investigator, your doctor is interested both in your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may want to ask for a second opinion about your care from another doctor who is not an investigator in this study. You do not have to participate in any research study offered by your doctor.

What is the purpose of this research study?
The overall goal of this study is to better understand the consequences of COVID-19 on various organs and how the health status of these other organs may impact the risk of future heart disease compared to people who did not have known symptomatic COVID-19. To better understand this problem, we will measure markers in blood, urine, breath, and will also characterize various organs using non-invasive tests. The information we obtain from this study will be used to study patterns of substances carried in the blood that may help us understand how the heart interacts with other organs and how this relates to the presence of heart disease.

How long will I be in the study?
Your participation in this study will last for approximately 5 years. The study typically involves an initial visit that lasts ~4 hours plus blood pressure monitoring for 24-hours,

including during daily activities, with follow up visits in which the same measurements are performed about every year and a half, for a total of three visits. We expect to enroll 280 participants in this study, all of whom will be enrolled at the University of Pennsylvania.

What am I being asked to do?
If you decide to participate in this study, you will asked to do the following:

- We will perform a brief (~20 minute) non-invasive imaging exam, in which a probe will be placed on your neck, arm, leg, abdomen, and chest to take pictures that will allow us to see your arteries, liver, kidney, heart, lung, and some of your muscles (called ultrasound images). These pictures will provide information about the structure and function of these parts of your body and will help us understand if you have any evidence of scarring in these organs.
- We will collect your blood, urine and breath using a mouthpiece connected to breath collection equipment over ~10 minutes.
- You will be asked to complete a brief survey that asks questions about your symptoms and how you feel you are functioning in your day-to-day life, which will take you about 10 minutes.
- We will perform lung function testing, in which you will blow and breathe into a tube attached to a machine. You will also be asked to perform some breath holds (for about 8-10 seconds). A clip will be placed on your nose to keep your nostrils closed. The test takes ~20 minutes.
- Depending on time and equipment availability, we will perform Impedance cardiography, which is a non-invasive test that records the amount of blood that your heart pumps and the function of your blood vessels. You will be asked to lie on your back on a table, breathing normally and trying not to move or talk. Sticker-like electrodes will be placed on your skin in the neck and the chest. These electrodes are connected to a special device that stores and prints the information. This test takes approximately 3-5 minutes.
- Depending on time availability, we will perform a Short Physical Performance Battery (SPPB) test, during which you will be asked to stand for up to 10 seconds with feet positioned in three ways (together side-by-side, semi-tandem and tandem), walk 4 meters, and rise from a chair and return to the seated position (chair-stand test) 5 times.
- Depending on availability of equipment, personnel, and funding, we may ask you to perform an exercise test using a stationary bicycle while lying on your back. This will typically need to occur on a separate day and location from the rest of the study procedures. The test will begin with a low level of resistance that will then increase every 3 minutes. If you are asked to do this, we would like you to exercise for as long as you possibly can, as the goal is to push yourself to your peak. We will be monitoring you throughout this period and will stop you if we see anything unsafe. When you stop exercising, we will ask you to remain lying in the same position for about 6 minutes while we continue to collect information about your recovery. The total length of this bicycle exercise test will depend on you.

During bicycle exercise testing, you will breathe through a mouthpiece that is connected to a machine that monitors the air that you breathe in and out. Specifically, the machine tells us about how much oxygen you are using, and how much carbon dioxide your body is making during exercise. We will also continuously monitor your heart rate and rhythm, and we will be checking your blood pressure frequently during the study. We will also monitor the oxygen levels in your blood using a finger probe and will perform arterial tonometry. This information will allow us to determine how much oxygen your body is using during exercise, the electrical conduction of your heart, how fast your heart is beating during exercise, how much pressure there is in your arteries, and how stiff your arteries are during exercise.

We will also do the following measures of blood vessel function which will take ~60 minutes:

- We will use a pencil-like device (called an arterial tonometer) to examine the pressure in your blood vessels. This test will allow us to determine the stiffness of your blood vessels and to estimate your blood pressure in the blood vessels closest to your heart. You may experience minor discomfort due to pressure when the device is placed against your neck, arm, and groin. We will also use adhesive electrodes attached to your skin.
- A blood pressure cuff will be inflated on your forearm for 5 minutes so that blood flow into the forearm will be blocked. We will then deflate the cuff and your blood flow will be restored. The way your blood vessels respond to this pressure (called flow-mediated dilation) is a marker of your heart and blood vessel health.
- We will take pictures of your mouth under your tongue using a special hand-held microscope (called sublingual microscopy) to visualize blood flow in smaller vessels.
- We will place special devices (called near-infrared spectrometers) on your head, forearm, and calf which are the size an iPhone and use light to measure the amount of oxygen in your brain and muscle.
- We will take images of your face and both hands using a thermal imaging camera. This device is able to show us heat patterns on your skin.
- You will be asked to do a six-minute walking test. The goal of this test is to walk as quickly as you can for six minutes in a hallway track (up and down the corridor) so that you cover as much ground as possible. You may slow down if necessary. If you stop, we ask that you to continue to walk again as soon as you are able to. You will be kept informed of the time and you will be encouraged to do your best. During the walk test, you will wear special oxygen sensors that will be placed on top of your calf, forearm and scalp. The calf and forearm sensors are smaller than a mobile phone and will be secured with a band around your calf and forearm. The scalp sensors are mounted in a special head cap. These sensors will transmit data wirelessly to our computer.
- A blood pressure cuff will be placed on your non-dominant arm. Your blood pressure will be measured every 20 minutes during the day (from 7AM to 10PM) and every 30 minutes at night (from 10PM to 7AM) for 24-hours. The machine

takes about 30 seconds to 1 minute for each blood pressure measurement. We ask that you engage in your usual daily activities while the blood pressure monitor is in place, but that you avoid strenuous exercise. You may remove the blood pressure cuff for a few minutes to change your clothing or take a shower, however we ask that you otherwise keep in on for the full 24-hour period. We also ask that you write down what time you went to sleep, what time you woke up, and what time you took any medications while wearing the monitor, and that you provide this information upon returning the monitor at the end of the 24-hour period.

- We will measure your heart rate and blood pressure while sitting, and subsequently after 3 minutes of standing. This will be done with a blood pressure cuff around your arm and via palpation of the pulse in your wrist.
- We will collect some cells from the blood vessel in your arm. To do this, we will pass a flexible, very thin, j-shaped wire (see image) through the intravenous catheter and gently move it back and forth. This will pick up a sample of some cells from the sides of the blood vessels. We will then make measurements of different chemicals (proteins, gene expression) in these cells that we collect. We may or may not do this procedure depending on the availability, at the time of your study visit, of a nurse and laboratory personnel needed to process the cells.

In order to better interpret your results, we will collect information about your past medical history, heart studies, physical exams, imaging, laboratory values, and medications. We will gather this information from your University of Pennsylvania Health System medical record.

What are the possible risks or discomforts?
There are risks to consider when deciding to participate in this study.

Risks of the Intravenous Catheter and Blood Draw
We will draw a small amount of blood (~2-3 tablespoons). Local pain, bruising, bleeding, blood clot formation, and in rare instances, an infection might occur at the site of the intravenous catheter or needle stick where blood is drawn. There is also the possibility of dizziness or fainting while your blood is being drawn. Multiple needle-sticks may be necessary if a vein cannot be properly accessed and this will be carried out upon your permission.

Risks of Collection of Endothelial Cells from the Antecubital Vein
We will pass a very thin wire through the intravenous catheter to gently collect cells from your blood vessel. The risks are similar to the intravenous catheter and blood draw, including local pain, bruising, bleeding, blood clot formation, and in rare instances, an infection might occur at the site of the intravenous catheter.

Risks of Ultrasound, Breath Collection, Thermal Imaging and Sublingual Microscopy
These tests are painless and non-invasive tests that do not carry any known risks.

Risk of Lung Testing
These tests are associated with minimal risk, but you may feel some dizziness, lightheadedness, shortness of breath or slight soreness of your chest muscles due to your effort involved with the testing. During the test, some people cough. Rarely, pulmonary function testing may result in a collapsed lung. You may feel lightheaded due to the deep breathing.

Risks of Vascular Function Tests
Arterial tonometry and impedance cardiography are not associated with known risks. The adhesive electrodes attached to your skin may occasionally cause itching and irritation. Flow mediated dilation is safe and is not associated with any significant risks, but you will feel tingling and experience some discoloration of your forearm during cuff inflation. This will go away shortly after the procedure. Rarely, this test may lead to minor bruising around your arm, which goes away on its own. Near-infrared spectroscopy has no known risks.

Risks of Blood Pressure Measurements and Monitoring
There is minimal physical risk from non-invasive blood pressure monitoring. A potential discomfort will be the squeezing from inflation of the blood pressure cuff, which may cause sleep disturbance for some people.

Risks of Genetic Testing
We may perform genetic testing in stored samples in the future. Even without your name or other identifiable information, your genetic information is unique to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information.

There can be a risk in knowing genetic information. New health information about inherited traits that might affect you or your blood relatives could be found during a research study. Even though your genes are unique, you share some of the same genes with your blood relatives. Although we are not able to know all of the risks from taking part in research on inherited traits, we believe that the risks to you and your family are very low, because your samples will be coded. Research results will not be returned to you or your doctor.

Very rarely health or genetic information could be misused by employers, insurance companies, and others. For example, it could make it harder for you to get or keep a job or insurance, or life insurance companies may charge a higher rate based on this

information. We believe the chance these things will happen is very small, but we cannot make guarantees.

A federal law (Genetic Information Non-Discrimination Act, GINA) helps reduce the risk from health insurance or employment discrimination. The law does not include other types of misuse by life insurance or long-term care insurance. If you want to learn more about GINA, you can find information about it on the internet or ask the study staff.

Risks of the 6-minute walk tests: In general, the risks of this tests are the same as those from taking a brisk walk for 6 minutes at home or in the street. The 6-minute walk test has been performed in thousands of older persons and thousands of patients with heart failure or heart disease without serious negative effects. However, if you routinely experience chest pain on exertion, or have worsening chest pain over the last month or a history of recent heart attack (within a month), a fast heart rate (120 beats per minute) or a very high blood pressure, we will not perform this test, since people with these factors may be at increased risk for arrhythmias or cardiovascular collapse during testing.

Risk of Short Physical Performance Battery: These tests are associated with minimal risk. They have been administered to thousands of older persons in a home setting without any adverse outcome. You may lose balance during the gait and balance tests which can lead to a fall. The repeat chair-stand test requires some effort so you may become tired or short of breath.

Bicycle exercise test: For those who participate in the bicycle exercise test, pushing yourself hard during the test may make you uncomfortable. It is expected that you will become tired and short of breath, and that your blood pressure, heart rate, and other vital signs will change as a result of exercise. We ask that you push yourself, and do the most that you can possibly do. You may feel nauseous, lightheaded, or develop aches and pains as a result of the exercise study and pushing yourself hard. This exercise testing protocol is considered safe. Extremely rarely, people without symptomatic heart disease have a serious adverse event during exercise. The risk of this happening is the same in our lab as it would be if you heavily exerted yourself elsewhere. You will be closely monitored throughout the entire period by individuals who are trained to respond to situations that might develop. This part of the study is not required in all participants. Please let us know if you are unable to exercise for any reason and you will not be asked to perform this test.

Other Risks

Although breach of confidentiality is a potential risk, we have implemented various measures to minimize the possibility of a breach in confidentiality. If you decide to participate in the study, you will be assigned a unique identifier number and all of your data will be handled in a way that cannot link your name to other personal information. Only the investigator and study staff will have access to the list that connects your name to your data.

What if new information becomes available about the study?
During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?
You are not expected to get any benefit from being in this research study. While there may be no benefit to you from this study, your participation may provide new information about long-term consequences of COVID-19 and may help develop new ways to diagnose, treat, or prevent potential negative consequences of COVID-19. This may be of value to future patients and to society.

What other choices do I have if I do not participate?
There is no penalty if you choose not to participate in this research study. The alternative to this study is to not participate.

Will I be paid for being in this study?

You will receive $250 of financial compensation for your participation in this study in the form of a ClinCard. For those who perform the bicycle testing, you will receive an additional $150 for your participation, which will also be provided via ClinCard.

Please note: In order to be compensated for your participation in this study, you must provide your Social Security Number. Additionally, please note that the University of Pennsylvania is required to report to the IRS any cumulative payments for participation in research studies that exceed a total of $600 in a calendar year.

Will I have to pay for anything?
You will not have to pay for any research blood draws or tests that result from participating in this study. You are still responsible for any deductibles or applicable co-pays for routine office visits, scans, and blood work not related to this study. Please talk to your doctor and study team about putting you in touch with a financial counselor to determine exactly what the deductible and co-pay will be for you; this is highly variable depending on your type of insurance.

Will I receive the results of research testing?
Most tests done in research studies are only for research and have no clear meaning for health care. Research results will not be returned to you because they would not be relevant to your health care.

However, if you are not a current patient within the Penn Medicine system, we may ask for a release of your medical records to determine study eligibility. If you do not have recent laboratory tests as part of your standard of care, we may need to ask you to

come to our research center (located at the University of Pennsylvania) to perform bloodwork and/or a pregnancy test as part of the study. You would receive the results of these tests performed as part of the study.

What if something unexpected is discovered during my participation?
It is possible that during the course of the research study, the research staff may notice an unexpected finding(s) or information related to your health. Should this occur, the finding(s) will be considered by the appropriate personnel and the PI will inform you if necessary. These possible finding(s) may or may not be significant and may lead to anxiety. You may need to meet with professionals who have the expertise to help you learn more about these results. You can decide whether you want this information to be provided to you. The study team/study will not cover the costs of any follow-up consultations or actions.

What happens if I am injured from being in the study?
We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form. If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed in the consent form.

When is the study over? Can I leave the study before it ends?
This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time by the Investigator without your consent because:

- The Principal Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The Principal Investigator has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Withdrawal will not interfere with your future care.

How will my personal information be protected during the study?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other

personal information will not be used. The Institutional Review Board (IRB) at the University of Pennsylvania will have access to your records.

The research team will make every effort to keep all the information you tell us during the study strictly confidential, as required by law. Any documents you sign where you can be identified by name will be kept in a locked file cabinet in Dr. Chirinos' research offices. All of your electronic information will be kept in a secure server and the file that contains your health information will not be the same as the file that contains your name. Only the investigators will have access to the codes that link your health information with your personal data. These documents will be kept confidential.

Will information about this study be available to the public?
Information collected as part of this study may be published or presented at scientific meetings. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

What may happen to my information and samples collected on this study?
Collection of Identifiable Specimens
Samples and data will be analyzed by the investigators for scientific purposes. Knowledge derived from this study may be used to create products for diagnosis or treatment of diseases, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

Future Use of Data and/or Specimens
Your identifiable information and samples will be stored for future research purposes. The future use of your information and samples only applies to the information and samples collected in this study.

Your identifiable information and samples will be stored for future research purposes for an indefinite amount of time. The following identifiers will be retained with your information: your name and medical record number. Research with your identifiable information and samples may help others by improving our understanding of health and disease, improving health care and making safer or more effective medical therapies, and developing new scientific knowledge.

There are no plans to tell you about the specific future research that will be done. Possible future research may include measurement of new biomarkers in blood that are not yet known or are not currently known to be important. Whole genome sequencing may be conducted on your samples. Whole genome sequencing involves analyzing your entire personal genetic code.

Your information may be shared with other investigators or outside entities (other research institutions, drug or biotechnology companies) for scientific collaborations, but any shared data with other investigators will **not** contain any identifiable information (such as age, name, date of birth, or procedure date) that would allow them to trace the

data to you. This can be done without again seeking your consent in the future, as permitted by law.

We will not give you any results from these future research studies. It is possible that you may have chosen not to participate in these future research studies, had you been approached for participation.

There is a risk of breach of confidentiality (unintentional release of your information). We will do our best to make sure that this doesn't happen. However, we cannot guarantee total privacy. We will protect your confidentiality during storage by keeping the study files in a secure server; the file that contains your research information will not be the same as the file that contains your name or medical record number. Only the investigators will have access to the research files. You will likely not directly benefit from future research with your information and samples. If you have questions about the storage of your information and samples, or have changed your mind, you can contact Dr. Chirinos at (215) 200-7779. If you change your mind, we will dispose of your samples and exclude your samples information from future research.

What information about me may be collected, used or shared with others?
Name, telephone number, elements of dates, medical record number, social security number, current medications, and medical history including imaging, laboratory values, results of physical exams, vital signs, hemodynamic values, and other test results.

Why is my information being used?
Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research;
- oversee the research;
- to see if the research was done right;
- to evaluate and manage research functions.

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

- The investigator for the study and the study team;
- Other authorized personnel at Penn, including offices that support research operations;
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB.

Who, outside of the School of Medicine, might receive my information?
<u>Oversight organizations</u>

- The Food and Drug Administration
- The Office of Human Research Protections

We may also share your data or specimens with scientists from other institutions with whom we collaborate to accelerate or promote scientific discoveries.

Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may the School of Medicine use or disclose my personal health information?
Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization;
- The University of Pennsylvania's Institutional Review Board grants permission;
- As permitted by law.

Can I change my mind about giving permission for use of my information?
Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document, you are permitting the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

Electronic Medical Records and Research Results

What is an Electronic Medical Record and/or a Clinical Trial Management System?
An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

A clinical trial management system (CTMS) is used to register your information as a participant in a study and to allow for your research data to be entered/stored for the

purposes of data analysis and any other required activity for the purpose of the conduct of the research.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, information related to your participation in the research (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS. Information related to your participation in clinical research will also be contained in the CTMS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any information produced from your participation in this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Information related to your participation in the study (i.e. laboratory tests, imaging studies, and clinical procedures) may be placed in this EMR.

Once placed in your EMR or in the CTMS, your information may be accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns, or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns, or complaints at the University of Pennsylvania by calling (215) 898-2614.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

_____	_____	
Name of Subject (Please Print)	Signature of Subject	Date
_____	_____	
Name of Person Obtaining Consent (Please Print)	Signature	Date