Consent to Participate in Research
RECOVER – Initial Consent

Study Title: NIH RECOVER: A Multi-site Observational Study of Post-Acute Sequelae of SARS-CoV-2 Infection in Adults

Principal Investigator: Janko Nikolich-Zugich (520-626-6065)

Sponsor and/or Funder: National Institutes of Health (National Heart Lung and Blood Institute)

Summary of the Research

This is a consent form for participation in a research study. Your participation in this research study is voluntary. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether to participate.

The purpose of the RECOVER research study is to better understand the long-term effects of COVID-19, and who is at greatest risk of having long-term effects. We will do this by studying people with, and without, a history of COVID-19 over several years.

If you take part, we will ask you to complete questionnaires, have brief medical exams, provide blood and urine for testing, and provide saliva, nasal swabs, blood, and stool for research. This study will last up to four years and will involve doing a questionnaire every 3 months and coming for an in person visit up to three times in the first year and once a year after that. You may be asked to have additional medical tests, explained later as Tier 2 and Tier 3 tests.

At the first study visit, if you agree, you will:

- Complete a series of questions about who you are (such as age, sex, or race), medical conditions that may affect the chances of having long-term effects of COVID-19, whether you have been vaccinated against COVID-19, and any symptoms you currently have. There will also be questions about your mental health, social determinants of health, discrimination, disability, and substance use. The questionnaire you are asked to complete will depend on whether you were diagnosed with COVID-19 and when you were diagnosed.
- Have a brief medical exam.
- Allow us to collect samples of your blood, saliva, stool, nasal swab and urine. Some of the blood and urine will be sent to a clinical lab to run some laboratory tests. These tests are explained in more detail later in this consent form.
- Based on the results of the questionnaire and the tests, you may be asked to complete more tests.

At follow-up visits you will be asked to:

- Answer a shorter series of questions that will ask about how you are doing. We will ask you to do this at every three months
- Have a brief medical exam. This will happen at six months and then yearly.
- Allow us to collect a nasal swab and blood every three months during the first year, and then yearly after that.
- You may be asked if we can repeat some of the tests you completed at the first visit.

There are possible risks to taking part in this research. A complete list of all possible risks and discomforts related to this research is described in detail later in this consent form.

Answering the questionnaires poses no physical risk but there may be a risk that some of the questions may cause you emotional stress, and there is a small risk of breach of confidentiality. Most of the exam and tests like weight, height, and blood pressure measurements pose no risk. The risks of genetic testing are discussed in detail later in this form.

Having blood taken pose minimal risks like lightheadedness or feeling faint. Redness, pain, bruising, bleeding, or infection may occur at the site of a puncture during blood collection.

During this study, you may have exposure to radiation from CT scans and X-rays, and if you have an MRI scan there may be risks with that too.

You will not benefit personally from being in this study. However, we hope that in the future, other people might benefit from this study by improving the understanding of how to meet the needs of COVID-19 patients and survivors more effectively.

Taking part in this study is optional. If you decide not to participate, your decision will not interfere with your care, payment for your health care, or your eligibility for health care benefits.

The University receives compensation from the sponsor of this study for the conduct of this study. If you have any questions, please discuss this with your study doctor.

The following pages have detailed information about this research study.

Title of Study: **NIH RECOVER: A Multi-site Observational Study of Post-Acute Sequelae of SARS-CoV-2 Infection in Adults (**Study Number: S21-01226)

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For questions or concerns about the study, please call the study team at 520-621-8354 or email uahs-recover@arizona.edu.

Why is this study being done?

This study is part of a research project paid for by the National Institutes of Health (NIH) called RECOVER (Researching COVID to Enhance Recovery). We are doing this study to understand how COVID affects the body, and why some people who got COVID are still sick many months after being infected. This condition is called "Long COVID" or "PASC," which stands for Post-Acute Sequelae of SARS-CoV-2. Sequelae means a long-term effect of an illness or injury.

The people in this study will be 18 years or older. Both adults who have had COVID and those who have not will be part of the study.

How long will I be in this study?

This study will last up to four years. During that time, you will answer survey questions every three months for up to four years and will have in-person visits up to three times in the first year and once a year after that.

How many people will take part in this study?

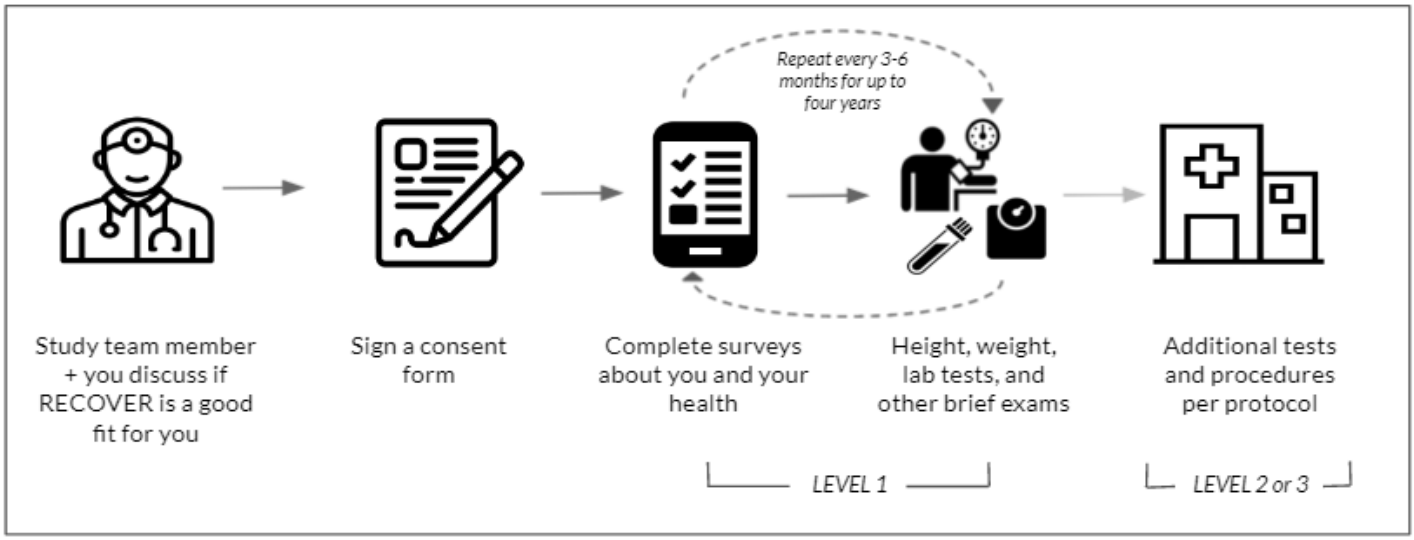
Researchers plan to include about 17,680 people at multiple sites across the United States. We hope to include about 909 people across Arizona.

What will happen if I take part in this study?

If you choose to take part in the study, we will first ask you to sign this consent form before you do any other parts of the study. We will ask you to either sign a paper version of this consent form, or we can use a computer, tablet or smart phone to sign the form electronically. The study staff will help you with this.

There are three types of study visits: Tier 1, Tier 2, and Tier 3

Everyone who takes part in the study will complete the Tier 1 surveys and tests. Only some participants will be asked to do Tier 2 or Tier 3 surveys and tests. This consent form talks about the surveys and tests for Tier 1 and Tier 2, and about the surveys and tests for Tier 3 that are low risk (very low chance of hurting you). By agreeing to be a part of this study, you are agreeing to do any of the low-risk tests that are appropriate for you. Some Tier 3 tests are higher risk, and we will separately ask your permission to do those tests later if we request that you to do them.



Tier 1 surveys and tests for all research participants

Tier 1 Surveys can take place either in person at the study office or at home. When you start the study, the surveys will take about 2 hours. After that, the surveys will take about 45 minutes. The number of questions you will be asked and the amount of time the surveys will take depends on your answers to the questions.

At the first visit, we will ask you questions about you, your health, behaviors, medical problems, and medications. We will also ask some questions about your home, and the neighborhood you live in. In addition, we will also ask about COVID related items including any testing, COVID vaccine status, and any related health problems you have had. We will look at your hospital records if you had to stay in the hospital because of COVID. If we can't access your health records, we will ask you some of these questions instead.

Every three months after you start the study, we will ask you about how you are currently feeling, and about any new diagnoses (illnesses) your doctors have found or new medicines you are taking.

While you are in the study, we will check national registries (places where information about people across the country is kept) and your medical records to find out about your health and about any tests you have had outside the research study. Your medical records may be included in the study to help the team fully understand your condition.

If you have Long COVID when you start this study, we will let your primary care physician know that you are part of this study. If you join the study while you are still in the hospital, we will reach out to your doctors and nurses to learn about your treatment plans.

Tier 1 tests

At the first visit, we will do the tests listed below, numbered 1 through 5. For people who had COVID-19 we will do them again at 6 months after your infection, if you enroll in the study before that time. If you are a participant who did not have COVID-19, we will repeat the tests 6 months after your enrollment in the study. If your tests are normal at 6 months, we won't do them again. If your tests are not normal, we may do these tests once a year for the rest of the study or until they turn normal.

If you agree, **we will sometimes collect a total of 6 ½ tablespoons (95.5mL) of blood**. Some of the blood is for lab tests and some is for banking for future research. This will not happen at every visit. This amount of blood is safe to collect, but you may choose to have the blood collected on two separate days.

1. Laboratory tests: We will draw about **3 (44 mL) tablespoons of blood** from a vein in your arm at each visit, and up to 21 tablespoons (308 mL) over 4 years. The blood will be used to check blood sugar tiers, cholesterol tiers, vitamins, protein tiers, hormone tiers and other compounds found in the blood. We will also collect urine for a urinalysis test.

See next page for the second set of blood that may be collected

2. Samples for future testing: We will also take samples to store for testing in the future, explained in this table below.

Samples To be Collected	When They will Be Collected	How Much Will Be Collected Each Time
Blood	1st Visit, 3 months, 6 months, year 1, year 2, year 3, year 4	**51.5mL (about 3 ½ tablespoons)**
Urine	1st visit, year 2	10mL (about 2 teaspoons)
Nasal Swab	1st Visit, 3 months, 6 months, year 1, year 2, year 3, year 4	1 swab
Stool	1st Visit, year 2	25mL (about 1 ½ tablespoons)

3. Exam (Check-up): We will measure your weight, height, waist, blood pressure, heart rate, and oxygen tier.
4. 30 second sit-stand test: You will be asked to sit in a straight-back chair without arm rests, rise to a full standing position, and sit back down. We will count how many times you can do this in 30 seconds.
5. Active Standing Test: This is a blood pressure test where we will measure your blood pressure at different times while you are lying down and standing up.

Tier 2 surveys and tests for some research participants

About 1 in 3 of the people completing Tier 1 tests will be asked to do Tier 2 tests. Those with certain symptoms or findings in Tier 1 tests will be triggered to have Tier 2 tests that are specific to their signs or symptoms. For example, if a person has an abnormal result on one of the lab tests they may be asked to have an additional test. We will also choose some people without symptoms randomly (like by flipping a coin) to do Tier 2 tests. You may be asked to complete these tests up to 4 times over the course of the study, but not more often than once a year.

Tier 2 tests may include the following:

Blood tests	Blood tests are done to follow up on findings in Tier 1.
EKG	An electrocardiogram is a test that records the electrical signal from your heart by placing electrodes on your chest to record your heartbeat.
6 minute walk test	We will see how far you can walk in 6 minutes. We will set-up cones in a long hallway and count how many laps you can do.
Vision Screening	This vision test uses an eye chart on the wall. You will be asked to read the rows of letters that get smaller.
Smell Test	A smell test uses cards with smell strips on them. We will activate a smell and ask you to identify it. There are 40 strips to smell.
More tests on next page	

Home sleep study	The test measures how you sleep using a monitor. This test is done at home with a NOX T3 home sleep device.
Examinations by a physician or other health care specialist	These include testing your feeling in your legs or artery function; testing your vision (how well you can see); examining your nose, throat and ears; checking your sense of smell; or testing how well you can do basic activities like walking or using your hands.
Cognitive (thinking) tests	This tests your memory, attention, mood, and thinking. This takes about 20 minutes.
Pulmonary function tests	You will be asked to breathe in different ways (fast, slow, deep, shallow) through a plastic tube in your mouth to measure how well the lungs are working.
Ultrasounds	These tests use sound waves to get a picture of your heart, kidneys or liver.
CT scan of lungs	CT scans use X rays to get a picture of your lungs.
Glucose Tolerance Test	You will be asked to drink a sugary drink and we will collect blood samples to check your blood glucose tiers.

Tier 3 Tests

About 1 in 5 people will be asked to do some tier 3 tests. You would only do each Tier 3 test once. Below is a list of low risk Tier 3 tests. You will be asked to sign a separate consent form that describes the procedures and risks for any Tier 3 test that has more than very low (minimal) risk.

Low risk Tier 3 tests may include the following:

Blood tests	Blood tests are done to follow up on findings in Tier 1 or Tier 2.
Sleep study	This test measures how you sleep using a monitor. This test is done overnight at the sleep center.
Examinations	These include testing your hearing and testing how your blood vessels work with a sensor on your finger
Cognitive (thinking) and mood tests	Tier 3 has more detailed tests of memory, attention, mood and thinking than Tier 2. These may take 1-2 hours.
Eye exam	This includes tests of your vision, eye pressure, and movement. We would use drops to dilate your eyes.
Exercise testing	While you exercise on a treadmill or bike, we will monitor your heart and breathing through a tube in your mouth.

What benefits can I expect from being in this study?

We do not expect for you to benefit directly from taking part in this study, and we also do not expect that your health will get better from being a part of this study. Being part of the study may help you and your doctor better understand problems that are due to COVID. The results of the study will be important in helping patients, caregivers, and parents understand how COVID affects the body's long-term reaction to COVID.

Can I be in the study if I am pregnant or breast-feeding?

Arizona sites are not part of the pregnancy cohort, so we are not enrolling pregnant people.

What risks, side effects or discomforts can I expect from being in the study?

Being in this study may involve some risks or discomforts from study procedures. In addition to the risks listed below, there may be risks that have not been seen before. You should contact the Study Site Leader if you are concerned about anything while you are a part of the study.

Possible loss of privacy or confidentiality

When we share your information and study samples, there is a small risk that people may get to see it who are not supposed to. Researchers will do their best to protect your privacy by keeping identifying information about who you are in a different place from the other information you are giving us and any results. We will keep your study information and study samples as securely as possible. Researchers using your information and study samples must agree not to try to find out who you are. However, there is a small chance they may be able to find out who you are.

The research team may communicate with you electronically, such as over email or text message. While the researchers will take steps to protect your privacy and confidentiality, text messages are not encrypted and not a secure mode of communication, and there is a risk that people may see the messages who are not supposed to. The researchers will only send limited information in these messages.

When you use apps or software made by companies, such as wearable fitness trackers, wearable sleep monitors, or other mobile or web apps, there is a small risk that people outside the research study may get to see your information who are not supposed to.

Risk of surveys, office tests and ultrasounds, including:

- Surveys and tests of thinking
- Physical examinations
- Tests of smelling, vision, hearing and sleep
- Blood tests
- Ultrasounds

Answering the survey questions can take a long time. This may make you tired, uncomfortable, or frustrated. You can stop or take a break if you need to. The other tests listed are routine medical procedures with minimal risk.

Risk of COVID nasal swab (COVID test using liquid from your nose)
The nasal swab test may be uncomfortable and may cause a small number of people to gag, cough or have a nosebleed.

Risk of having blood taken
Blood will be drawn through a needle placed into a vein in your arm. Having blood taken may be uncomfortable or make you feel dizzy or faint (pass out) or lightheaded. Tell the staff right away if you feel like you might pass out. Redness, pain, bruising, bleeding, or infection may also happen where the needle goes into the skin during blood collection.

Tests of how well you see (Vision testing)
There is a very low (minimal) risk from vision tests. The eye drops used to dilate your eyes (open the pupils to see in the eye) may sting. You may have glare and blurry vision for several hours while your eyes are dilated. Some people are allergic to eye drops. Some people have an increase in eye pressure which would make your eye red or painful that goes away with time. These problems will be treated if they occur.

6-minute walk test and breathing tests (pulmonary function tests)
You may get tired, lightheaded or dizzy during these tests. There is minimal medical risk from these tests.

Sleep Study monitoring at home
The sleep study needs straps around your chest and abdomen, a small clip on your finger, sensors on your chest for heart monitoring (electrocardiogram) and small plastic prongs in your nose. These may cause local skin irritation or allergies and can disrupt your sleep. The sleep study monitoring in the sleep center will include 8 electrodes on your scalp and chin and two electrodes on the legs that may also cause local skin irritation or disrupt your sleep.

Electrocardiogram (ECG)
There is minimal medical risk from ECG. The sticky pads (electrodes) that are put on your chest can sometimes cause discomfort such as redness or itching. We may need to shave your chest before we put the pads on. Shaving may also bother the skin.

Exercise testing
The main risks of exercise testing are abnormal heart beats (arrhythmias), change in blood pressure (too high or too low), heart attack (myocardial infarction), muscle, bone, or joint injury, or death. However, these problems are very rare: they happen in less than 1 in every 5,000 to 10,000 tests, with death estimated at 1 in every 20,000 tests. You can stop the test at any time if you do not feel well.

Radiation Exposure from CT scan

Your participation in this study may involve exposure to radiation from CT scans. You may receive a chest CT in your first year and no more than one chest CT each subsequent year for up to four years. This exposure is not necessary for your medical care, is for research purposes only, and is necessary to obtain the desired research information.

Radiation has been shown to cause cancer from exposures that are significantly higher than the additional radiation dose you will receive by participating in this study. According to the International Commission on Radiological Protection (ICRP), the increased risk of health effects, such as cancer, from radiation doses of this amount is either too small to be observed or nonexistent. The effective radiation dose you will receive in your first year from these research scans is approximately 6 milliSieverts mSv. A Sievert is a measure of the amount of ionizing radiation. The total effective dose you will receive from all combined x-ray and CT scans is approximately 22 mSv. The organ receiving the highest dose in this study is the thymus. The effective dose you will receive from your participation is comparable to 7 times the yearly dose from natural environmental radiation in the US (3.1 mSv) and within the limits of 50 mSV, which is set by the FDA for individuals participating in basic research studies.

Please inform your study team if you have been exposed to radiation as a result of any other research studies or part of your clinical care. If you participate in future studies that involve the use of radiation, you should discuss it with the researchers performing those studies.

CT Scan Dye

Some of the CT scans in this study use dye in the veins (“contrast”). Some people are allergic to this dye; if you are, we will not do the study. For this reason, we will ask you about allergies to contrast or shellfish in advance. There is a potential risk the contrast dye may cause kidney damage, especially in people who already have kidney problems or are dehydrated (have not drunk enough water). For this reason, we will check how your kidneys are working first and will not do the test if your kidneys are not working right.

Risks of Genetic Research

It is possible that during the study, we may find out things about your genes. You can decide whether you want to be told about these things. There can be a risk in knowing these results. For example, in the future, researchers may look at the full set of genes in your body, including looking at the exact order of DNA. This is called whole genome sequencing. New information may be found that show that you have genes that make it more likely that you will have certain health problems. Knowing this information can be stressful, lead to worry and affect your relationship with your family. There may also be benefits in knowing about genetic risks of disease; sometimes you can change your habits or have screening tests that will help you avoid disease or treat a disease earlier.

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. Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Group Risks

Although we will not give researchers your name, we will give them basic information such as your race, ethnic group, and sex. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could help people of the same race, ethnic group, or sex as you. However, they could also be used to support harmful stereotypes, stigmatize, or discriminate against members of a socially defined group such as race or ethnicity.

If you are Native American and agree to participate in this study there may be risks associated with the research that impact your community. Health information, especially genetic information, can be applied to more than just you. Genetic analysis may be able to provide information about a person's parents, siblings, children, or others. Some genetic research can produce new information about entire subpopulations and individual racial or ethnic groups. It is unknown exactly what the researchers will discover because this study involves unspecific future research. Risks may include legal, financial, social, or physical harm. Information may be published that conflicts with your communities' culture, traditions, creation stories, or spiritual beliefs.

What other choices do I have if I do not take part in this study?

This study does not provide treatment and the tests are being done for research purposes, not to provide you with health care. You will have to seek treatment for COVID symptoms apart from being in this study. If you do not take part in this study, you can get any tests you need for COVID care from your own health care providers. Deciding not to be part of the study will not affect your health care now or in the future, how you pay for health care or if you can get health insurance.

Your participation is voluntary. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The University of Arizona or Banner Health.

You do not have to sign this consent form if you do not want to. You do not have to give us permission to use and share your information, but if you do not, you will not be able to be part of this study.

When may participation in the study be stopped?

This study will last for 4 years. This study may be stopped early. It is also possible that you may be taken out of the study early for the following reasons:

- The researchers in charge of the study feel it is important to remove you for your health or safety.
- You have not followed study instructions.

- The group funding the study, the main researchers in charge, or people monitoring the safety of the study decide to stop the study.
- More information about Long COVID is known so that the study is no longer needed.

You may decide to stop participating in this research study at any time. Leaving the study will not affect your care, how your health care is paid for, or what kind of health insurance you can get. If you withdraw (take back) your permission, we will not be able to take back information that has already been used or shared with others. If you want to withdraw (take back) your permission, please talk to a member of the study team.

What happens if I am injured because I took part in this study?

For emergencies, call 911. If you think you have been hurt because of being part of this research study, tell the Study Site Leader as soon as you can. The Study Site Leader's name and phone number are listed at the top of page 1 of this consent form.

If you are hurt because of being part of this research, we will give you treatment if you want. We may ask your insurance company to pay for the costs of the treatment due to your being hurt, but you may also need to pay for some of this cost.

There are no plans to pay you or give you anything else for being hurt. You do not give up the rights you have under the law by signing this form.

The University of Arizona, Banner-University Medical Center, NYU Grossman School of Medicine and NYU Langone Health have no funds set aside for the payment of treatment expenses for this study.

What are the costs of taking part in this study?

Services performed for research only will be provided at no charge to you or your insurance company. You and/or your health insurance will be billed for the costs of regular medical care you receive while participating in this study. If you have health insurance, your insurance company will be asked to pay for these costs. If your insurance does not cover these costs or you do not have insurance, these costs will be up to you to take care of. Please speak with your insurance company to find out what you may be financially liable for.

Will I be paid for taking part in this study?

You will receive a payment for the research visits that you complete. These payments can be used to pay for parking or transportation costs for your visits. For any compensation or reimbursement you receive, we are required to obtain identifiable information such as your name, address, and Social Security number for financial compliance purposes.

Participants who complete Tier 1 assessments will receive the following payments:

Visit	Payment
Baseline (surveys, exam, labs)	$100
Month 3 (surveys and specimens)	$25
Follow-up surveys only	$25
Follow-up visits (surveys, exam, labs)	$75
Additional Acute Infection	$100

Participants who complete Tier 2 and Tier 3 assessments will receive payment based on what procedures they complete. There is a limit of $600 for all Tier 2 procedures, and a limit of $1,000 for all Tier 3 procedures.

Your name, address, and U.S. tax-payer identification number (SSN or ITIN) are required to process payments and/or to report taxable income to the IRS. You must complete a W-9 or other required documentation (for U.S. persons) or W-8BEN and the Foreign Vendor Withholding Assessment with supporting documents (for non-resident aliens), in order to receive payment for participation.

Compensation for participation in a research study is considered taxable income for you. If your compensation for this research study or a combination of research studies is $600 or more in a calendar year (January to December), you will receive an IRS Form 1099 to report on your taxes. Please note, if you are an employee of UArizona, any compensation from a research study is considerable taxable income.

U.S. person participants must complete Form W-9 or other required documentation in order to receive payment for participation. Nonresident alien participants must complete Form W-8BEN and the Foreign Vendor Withholding Assessment with supporting documents in order to receive payment for participation. Payments to nonresident alien participants may be subject to tax withholding and are generally reported to the Internal Revenue Service on Form 1042-S. This information will not be linked to any of the study data and will only be used for payment purposes.

For any compensation or reimbursement you receive, we are required to obtain identifiable information such as your name, address, and Social Security number for financial compliance purposes. Identifiable information collected for financial compliance purposes will not be linked to your research data. If you do not want us to collect this information, you can still participate in this study, but you will not be able to receive any payment for your participation.

<u>ClinCard</u>

You will be issued a Greenphire ClinCard, which is a debit card that your funds are loaded onto and can be used at your discretion. When a visit is completed, funds will be approved and loaded onto your card. The funds will be available within 1 business day and can be used at your discretion. In order to

assign a ClinCard to you and load funds onto the ClinCard Greenphire will need your Subject ID, Name, Address, and Date of Birth.

Greenphire has administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of your personal information. Your personal information will be used and disclosed only to support the described activities, including to service providers who assist us in managing, administering or delivering the Services. Your personal information will not be shared by Greenphire with FARAPULSE or sold, used or distributed for any other purpose. Your information will be retained for as long as necessary to provide the described activities and for compliance with applicable laws.

Will my data or specimens be sold for commercial profits?

The use of your information and study samples may lead to new tests or drugs, or other things that may be sold to make money. A patent or license may be received for these things to keep other people from making, using, or selling these things. There are no plans to give any money to you if this was to happen.

What if new information becomes available?

During this study we may find information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will let you know as soon as possible if this kind of information is found.

Will my data or specimens be stored for future research?

Yes, your data will be saved for future research. This includes data collected during the screening process.

If you agree, your specimens will be stored for future research.
Biospecimens (blood, spit (saliva), poop (stool) and pee (urine)) will be sent to a storage place called the RECOVER Research Biorepository at Mayo Clinic, MN to be stored for future research tests.

Blood, saliva, urine, stool and other samples in this storage place will be used mostly for research on COVID and the long-term effects of COVID, but with your permission, they may also be used for research on other health problems. If you agree, future research with your specimens may include genetic analysis or whole genome sequencing.

Your study information and study samples may be shared with researchers around the world, including those with commercial interests. However, leaders of this RECOVER study control who can get your information and study samples. To use your information and study samples, researchers must ask RECOVER leaders if samples can be shared. Your name or other identifying information will not be provided to other researchers. Samples that are stored will be given a code number and only the researchers at the place you signed up to be part of this research (your study site) and the researchers who are in charge of keeping study information will have the key that links, or connects, the code

number given to your study samples with your personal information. Researchers must also agree to not try to figure out who you are. If you change your mind about sharing your samples, you can withdraw your samples from the Biorepository by contacting the Study Leader named at the top of this form.

At the end of the study, your personal information will be completely removed from the RECOVER database, and there will no longer be a key to link your information with the study samples. After taking away the key, the data and study samples you provided may be used for future research studies without your consent because they are no longer linked to you. Note that after the linking key is removed, you will no longer be able to request to take back your study samples.

Findings from Genetic Research

If you agree to future research on your genes, you may choose to be told about any results we find about your genes that increase your risk of a health condition.

If you choose to be told about these results, a study doctor will speak to you in person or over the telephone to explain the information. It is important for you to know that the results may become part of your health record, which means that anybody who is allowed to see your health records (for example your main doctor) will be able to see this information. Based on the genetic results, your health care provider may order more tests or treatments that are not part of the study, and may ask you to meet with a specially trained counselor who is expert at talking to people about the results (genetic counselor). Any additional tests and counseling are not part of the study, so you and/or your health insurance might have to pay for the costs.

Please initial the line below to let us know if you want to allow your samples to be used in future research on COVID and the long-term effects of COVID, and also health research outside the RECOVER study. What you decide will not change whether you can be part of the RECOVER study, and does not mean that you have to have any more tests.

Review and choose one – mark your answer with your initials

Please initial next to your choice below:

_____ **Yes,** I agree to allow my samples to be used for future research as described above, including research on my genes.

WW _____ **Yes**, I agree to allow my samples to be used for future research as described above, but **NOT** for research on my genes.

_____ **No**, I do not agree to allow my samples to be used for future research.

Use of Leftover Samples

If you agreed above for samples to be saved for future research, the samples will be collected and processed at a University of Arizona research lab before they are sent to the Mayo Clinic Biorepository. Sometimes there are leftover amounts of specimens that can not be sent. If you agree, researchers at the University of Arizona would like to save these leftover samples for local research.

Please initial the line below to let us know if you want to allow your leftover samples to be used in future research at the University of Arizona. What you decide will not change whether you can be part of the RECOVER study, and you will not have any extra samples collected.

Review and choose one – mark your answer with your initials

Please initial next to your choice below:

_____ **Not applicable,** I did not agree to the collection of samples for future research above.

_____ **Yes,** I agree to allow my leftover samples to be used for future research at the University of Arizona.

WW **No**, I do not agree to allow my leftover samples to be used for future research at the University of Arizona, and request that any leftover samples are discarded.

Will I hear back on any results that directly impact me?

As part of this study, you will be having tests done using 2 kinds of laboratories: 1) "certified clinical laboratories" and 2) research laboratories. A "certified clinical laboratory" is a laboratory that does medical lab tests, and the results can be used by your doctor or other health care provider to help you take care of your health. A research laboratory does lab tests where the results are just used for research. Research laboratory tests may be done while you are in the study, or in the future after the study is finished.

You will receive the results of the tests done by the certified clinical laboratories. These results will be shared with your doctor, and other health care providers who care for you and who can look at your health records. Also, each of the clinical laboratory tests and scans done as part of this study will be looked at by an expert, who may find something that is not normal. If something that could affect your health is found, someone from the study team will talk to you in person or by phone about this new information.

Similarly, if you have any scans done for this study, they may be done by a provider in Banner Health or in a research lab at the University of Arizona. Tests and procedures performed at Banner Health will be part of your medical record and you and your doctor will receive the results.

The results of research laboratory tests and scans, however, will not be put in your medical record. If the research test shows something that is not normal that we know could affect your health, someone from the study team will talk to you in person or by phone about this new information.

The research test or scan might also show a result that is different from others, but whose importance is not known. You can decide whether you would like to know about these results.

Please indicate below your choice about receiving findings from research tests whose importance is unknown. What you decide does not impact whether you can be part of the study and does not mean that you must have any more tests.

Review and choose one – mark your answer with your initials

Please initial next to your choice below:

WW **Yes**, I want to be told about findings from research tests whose importance is unknown

____ **No**, I do not want to be told about findings from research tests whose importance is unknown

Will my study-related information be shared, disclosed, and kept confidential?

Your medical information is protected health information, or "PHI", and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

Who may use and share information in connection with this study?

It is anticipated there will be circumstances where your study related information and Protected Health Information (PHI) will be released to persons and organizations described in this form. If you sign this form, you are giving permission to the research team to use and/or disclose your PHI for this study. Your information may be shared or disclosed with others to conduct the study, to comply with

regulations, and to help ensure that the study has been done correctly. These other groups may include:

- The research team, including the Study Site Leader and other people helping with the study or who are in charge of watching over the study at the University of Arizona.
- The researchers at NYU Grossman School of Medicine, who are in charge of helping with and watching over the study at all the places across the country where the study is happening
- Non-research staff who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The researchers at Massachusetts General Hospital, who are in charge of storing the information for this study, the researchers at Mayo Clinic who are in charge of the research biorepository, and other RECOVER study centers or national centers in charge of storing research information
- The group that funded the study: National Institutes of Health (National Heart Lung and Blood Institute)
- The ethical review board (also called institutional review board or IRB) that oversees the research and the research quality improvement programs.
- The group that is watching over the safety of patients and families in the study (called the observational study safety monitoring board). The National Institutes of Health decides who will be in this group.
- National data repositories such as the National Center for Biotechnology Information or dbGAP
- A company hired to oversee the quality of the RECOVER research information ((Biomedical Research Alliance of New York)
- People or groups that we hire to do work for the study, such as data storage companies, insurers, and lawyers
- Governmental agencies in charge of watching over or overseeing the research (for example, the US Department of Health and Human Services).
- Health care providers, including your doctors and others who care for you related to this study, and laboratories or other people who are looking at your health information as part of this study.
- Other places that are involved in this research

Your information may be re-disclosed (shared) or used for other reasons if the person who gets your information is not required by law to protect the privacy of the information.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence

unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

By agreeing to be in this research and signing below, you are giving your consent to share research information with others. This means that your research information, including lab results, x-rays, MRIs, and medical exams may be included in your electronic medical records. These other groups may include:

- Office for Human Research Protections, Food and Drug Administration, or other federal, state, or international regulatory agencies
- Banner University Medical Group and Banner Health
- The University of Arizona (UA) and the UA Institutional Review Board
- Your primary care physician or a specialist taking care of your health
- The sponsor and/or funder supporting the study, their agents or study monitors
    - New York University, the Clinical Science Core
    - Massachusetts General Hospital, the Data Resource Core
    - The Mayo Clinic, the Biorepository Core

If you agree to take part in this study a copy of this signed informed consent form will be saved into your electronic medical record (EMR) at Banner Health. As a result, healthcare providers and staff who are not working on this study, but who may provide you medical treatment in the future, will know that you are taking part or took part in this study.

Your PHI may no longer be protected under the HIPAA privacy rule once it is disclosed by the research team.

What information may be put in my medical record?

Information related to your being part of the research (like laboratory tests, research-related notes, imaging studies (studies to look at parts of the body), and other study tests, etc.) will be put in your medical record at Banner Health and may be shared with your regular doctor.

This information will be able to be looked at by people who work at Banner Health and your doctor's office who are not part of the research team. Information that is in your medical record may also be shared with others who Banner Health has decided should be able to look at your medical record (for example, health insurance company, disability provider, etc.).

Will I be able to look at research-related information within the Electronic Medical Record?

A law called the "21st Century Cures Act" makes it easier for patients to look at their EMR. However, the law may keep you from getting to certain research information right away when it is important for the research study.

As a person who is part of this research study, some research-related information will be put in your EMR and you will be able to see it right away. You may not be able to see some research-related information until the end of the study.

What study-related information and PHI will be obtained, used or disclosed from my medical record at Banner?

Information related to this research study that identifies you and your PHI will be collected from your past, present, and future hospital and/or other health care provider medical records.

The PHI you are authorizing to be used and/or disclosed in connection with this research study is:

- Results of any previous and future clinic visits, hospitalizations, and medical procedures.
- Information about any previous or current illnesses and treatments.
- Results from any lab tests, X-ray imaging, CT or MRI scans, or other medical tests used to diagnose medical conditions.
- Results of any previous or future neurocognitive assessments and/or psychiatry evaluations.

Demographic information to be disclosed may include, but is not limited to, your name, date of birth, address and zip code, phone number, and email address. If you receive compensation for participating in this research study, information identifying you may be used or disclosed as necessary to provide that compensation.

Your existing health records may include information related to the diagnosis or treatment of sexually transmitted disease (STD), acquired immunodeficiency syndrome (AIDS), human immunodeficiency virus (HIV), other communicable diseases, genetic information (e.g., genetic testing), and/or alcohol and/or drug abuse. The study staff and study sponsor's monitor may see this information while

reviewing your regular health records for this study, but they WILL NOT create, collect, or disclose this type of information for the purposes of this research study.

When will my authorization expire?

There is no expiration date for your authorization. Therefore, unless you cancel this authorization (as instructed below) this authorization will continue to be in effect.

Do I have to sign this authorization form?

You do not have to sign this authorization. However, if you decide not to sign, you will not be able to participate in this research study; but it will not affect any non-study Banner Health medical treatment or health care, payment, enrollment in any health plans, or benefits.

Also, by signing this form you are authorizing and permitting uses and/or disclosures of your PHI for future research purposes (e.g., future studies) as described in this document.

What do I need to know if I decide to cancel my authorization?

After signing the authorization, you may decide to cancel your previous authorization for the research team to use your PHI. If you cancel the authorization, you will no longer be able to stay in the research study. Please note that any PHI collected before you cancel the authorization may still be used. You may revoke the authorization by contacting the Principal Investigator in writing. Contact information is under "Who can answer my questions about the study" at the end of this document.

Will access be limited to my research study record during this study?

Yes, access to your research records will be limited to the study team. You will not have access to the research information developed as part of this study.

Who can answer my questions about this study?

If at any time you feel you have had a research-related injury, or for questions, concerns, or complaints about the study you may contact any member of the study team. The team leader is Dr. Janko Nikolich-Zurgich, and you can call him at 520-626-6065.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Subjects Protection Program Director at 520-626-8630 or online at https://research.arizona.edu/compliance/human-subjects-protection-program

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact any member of the study team, or Dr. Janko Nikolich-Zurgich at 520-626-6065.

If you have questions, concerns, or complaints about the use or sharing of your health information or would like a copy of the Banner Notice of Privacy Practices, you may contact the Banner Research HIPAA Liaison at 602-839-4583 or BHResearchCompliance@bannerhealth.com

To cancel your authorization for access to PHI you must notify the *Principal Investigator* and/or *Research Team* in writing at the following address:

Dr. Janko Nikolich-Zurgich
1501 N. Campbell St.
PO Box 245221, Tucson, AZ 85724

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

Communicating with the Research Team

The research team will contact you by phone, email or text messages, depending on your preference. When the research team sends email messages that include information about your health that is linked to who you are (identifiable), they will help keep your personal information confidential by "encrypting" the message. There is no way to encrypt the messages sent by text. This means that information you send or receive by text message could be looked at by someone who was not supposed to see it, or by your mobile/cell phone provider or company. Therefore, when text messages are sent, there may be risks related to your privacy. Please indicate whether you agree to receive email and text messages from the research team:

Review and choose one – mark your answer with your initials

Initial next to your choice below:

WW **Yes,** I agree to receive email and/or text messages from this research group.

Cell phone number: 520-123-4567

Email address: wilbur.wildcat@arizona.com

_____**No**, I do not agree to receive texts or emails from this research group.

Please make sure to keep the research team updated if you address, email, or mobile/cell phone number changes during the study.

Permission to Contact for Additional Research Opportunities

Researchers across Arizona are conducting other important research in COVID-19 and other illnesses. Are you willing to be contacted to learn more about other possible research studies? You would be given the opportunity to review the information and decide if you want to take part. Your decision will not affect your participation in this RECOVER study.

Review and choose one – mark your answer with your initials

Please initial next to your choice below:

____ **Yes**, someone may contact me to share information about other possible research studies.

WW **Io**, I do not want to be contacted about other possible research studies.

Signing the consent form

I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study, and I authorize the use and/or disclosure of my PHI. I am not giving up any legal rights by signing this form. I will be given a signed copy of this form**.**

Wilbur Wildcat	Wilbur Wildcat	02/29/2022
Printed name of research participant	**Signature of research participant**	**Date**

Research Staff

I have explained the research to the participant or the participant's representative before requesting the signature(s) above. There are no blanks in this document. A signed copy of this form has been given to the participant or to the participant's representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**	**Date**