Institutional Review Board
Informed Consent Document for Research
MASTER CONSENT

Study Title: The ARDS, Pneumonia, and Sepsis (APS) Consortium: A Prospective Observational Study to Evaluate Phenotypes (Protocol A – Full Protocol)
Version Date: April 13, 2024

Part 1 of 2: MASTER CONSENT

This informed consent document applies to the APS Study In-person Long-term Outcome Visits.

Name of participant: _____ Age: _____

You are being invited to take part in a research study. This study is a multi-site study, meaning it will take place at several different locations. Because this is a multi-site study this consent form includes two parts. Part 1 of this consent form is the Master Consent and includes information that applies to all study sites. Part 2 of the consent form is the Study Site Information and includes information specific to the study site where you are being asked to enroll. Both parts together are the legal consent form and must be provided to you.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:
In this study, we are trying to learn more about the long-term effects of Acute Respiratory Distress Syndrome (ARDS), Pneumonia, and Sepsis by collecting information and samples from people who have recently been in the hospital. This consent form describes long-term outcome study visits that will be completed for a subset of patients in the APS Phenotyping Study. Only patients participating in the APS Phenotyping Study are eligible for these long-term outcome visits. This document is designed to help participants learn about the long-term outcome visits that are part of the study and decide whether they would like to participate in this part of the study.

This is an observational study. This means that if you participate, we will collect information from you but will not influence the treatment that you receive. If you agree to be in this study, we will collect information and samples from you that are described in detail below. We will ask you some questions and will take information from your medical chart. There are no direct benefits to you for being in the study. A potential benefit to society is understanding how to better treat ARDS, pneumonia, and sepsis. The risks of being in this study are small and include the possibility of your medical information accidentally getting released, discomfort from the sample collections and cognitive tests, and exposure to radiation while getting a CT scan. Participation in this study is voluntary, meaning that you do not have to be in the study if you do not want to be.

Study Title: The ARDS, Pneumonia, and Sepsis (APS) Consortium: A Prospective Observational Study to Evaluate Phenotypes (Protocol A – Full Protocol)
Version Date: April 13, 2024

Detailed Information:
The rest of this document includes detailed information about this study.

This document provides information for a special component of the APS Phenotyping Study that focuses on in-person follow-up visits at 3-months, 6-months, and 12-months. You have the option of joining this part of the study or not joining this part of the study.

You are being asked to take part in this research study because you were recently diagnosed ARDS, pneumonia, and/or sepsis, and you participated in the APS Phenotyping Study. The purpose of long-term outcome visits at 3-months, 6-months, and 12-months in this study is to collect information and samples from you to study the long-term effects of these illnesses. The results obtained may help us better understand how to treat and prevent ARDS, pneumonia, and sepsis in the future. This study will also create a biorepository of the information and samples collected for other researchers to use to answer important questions about ARDS, pneumonia, and sepsis.

The APS cohort study is paid for by the National Heart, Lung and Blood Institute (NHLBI) and the National Institute of General Medical Sciences (NIGMS) of the National Institutes of Health (NIH) which is part of the United States government. Long term storage and access to the information and samples collected in this study will be maintained by NHLBI. There will be up to 1000 people in this study at different hospitals.

You do not have to be in this research study. You may choose not to be in this study without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

Side effects and risks that you can expect if you take part in this study:
The specific side effects and risks related to study procedures are described below under "Procedures to be followed."

Good effects that might result from this study:
You will not directly benefit from this study. A potential benefit to society that may result from this study is understanding how to better treat and prevent ARDS, sepsis, and pneumonia.

Study Title: The ARDS, Pneumonia, and Sepsis (APS) Consortium: A Prospective Observational Study to Evaluate Phenotypes (Protocol A – Full Protocol)
Version Date: April 13, 2024

Procedures to be followed:
If you agree to be in this study, you will attend study visits approximately 3, 6, and 12 months after your initial enrollment in the APS Phenotyping Study. We will contact you by phone, text message, or email to schedule these visits. You may opt out of any of the procedures listed below if you do not feel comfortable completing them.

Study Procedure 1: Consent for study participation	
Timing	Today
Explanation	Consent includes reading through this form, asking questions, and receiving answers
Risks or Discomforts	You may not understand all the information in this form. Please be sure to ask questions so you understand.
What you will do	After reading this form and asking questions, if you agree to be in this research study, you will sign this form.
What we will do	We will go through this form with you, answer any questions you have, and give you a copy of the signed form.

Study Title: The ARDS, Pneumonia, and Sepsis (APS) Consortium: A Prospective Observational Study to Evaluate Phenotypes (Protocol A – Full Protocol)
Version Date: April 13, 2024

Study Procedure 2: Medical Record Review	
Timing	Throughout the duration of the study
Explanation	Data will be collected from your medical record. These data will include: demographics like age, race, and sex; chronic medical conditions; the reasons why you are in the hospital; treatments; laboratory test results; medications; how well you respond to treatment; whether you returned to the hospital after initial discharge; and medical images, including x-rays and CT scans.
Risks or Discomforts	There is a small risk that some of your personal health information will be exposed.
What you will do	Nothing for you to do.
What we will do	We will take information from your medical record and enter it into a secure study database. This will include storing electronic medical images, including x-ray and CT images. We will take steps to prevent your data from being improperly exposed. These steps include: only researchers involved with this study will have access to the information about your identity, and long-term use of the information will be deidentified, meaning it will not be linked to you as the person whose information this is. De-identified information will be transferred to NHLBI's secure database called BioData Catalyst for indefinite storage. BioData Catalyst will provide other researchers with access to this de-identified information so they can do research.

Study Procedure 3: Blood collection	
Timing	At approximately 3 months, 6 months, and 12 months after initial study enrollment.
Explanation	We will obtain blood using a needle stick into a vein unless you already have a catheter ("IV") in place. If you have a catheter in place, we may be able to obtain blood from the catheter.
Risks or Discomforts	Pain, redness, soreness, bruising, or rarely infection may occur at the needle stick site. Rarely some people feel lightheaded or faint.
What you will do	There is nothing for you to do other than attend your study visits.
What we will do	The most blood we plan to take is shown below by study visit: - 3 months: 28.5 ml (about 2 tablespoons) - 6 months: 12.5 ml (about 1 tablespoon) - 12 months: 12.5 ml (about 1 tablespoon) - Total maximum: 53.5 ml (about 4 tablespoons)

Study Title: The ARDS, Pneumonia, and Sepsis (APS) Consortium: A Prospective Observational Study to Evaluate Phenotypes (Protocol A – Full Protocol)
Version Date: April 13, 2024

Study Procedure 4: Nasal swab	
Timing	At approximately 3 months, 6 months, and 12 months after initial study enrollment.
Explanation	Nasal swabbing involves putting a swab (like a Q-tip) to into your nose and rubbing the inside of your nose.
Risks or Discomforts	Some patients have brief irritation, pain, or bleeding.
What you will do	You will tilt your head back for the swab.
What we will do	We will insert a swab into your nostril, rotate it around while touching the inside of your nose, and then remove the swab.

Study Procedure 5: Oral swab	
Timing	At approximately 3 months, 6 months, and 12 months after initial study enrollment.
Explanation	Oral swabbing involves putting a swab (like a Q-tip) to into your mouth and rubbing the inside of your mouth.
Risks or Discomforts	Some patients have brief irritation, pain, bleeding, or gagging.
What you will do	You will open your mouth for the swab.
What we will do	We will insert a swab into your mouth, rub the inside of your cheek, and remove the swab.

Study Procedure 6: Stool collection	
Timing	At approximately 3 months, 6 months, and 12 months after initial study enrollment.
Explanation	We will collect stool in a cup after you defecate.
Risks or Discomforts	There are no common risks or discomforts associated with stool collection.
What you will do	You will provide a stool sample in cup.
What we will do	We will take stool from the cup you provide us.

Study Title: The ARDS, Pneumonia, and Sepsis (APS) Consortium: A Prospective Observational Study to Evaluate Phenotypes (Protocol A – Full Protocol)
Version Date: April 13, 2024

Study Procedure 7: Short physical performance battery	
Timing	At approximately 3 months, 6 months, and 12 months after initial study enrollment.
Explanation	A short physical performance battery is used to evaluate how well your legs and lower body are functioning.
Risks or Discomforts	You may experience fatigue or shortness of breath. There is a small risk of falling.
What you will do	• Chair Stand Test: For this test you will sit in a chair. You will then stand as quickly as possible without using your upper body to assist you. • Balance Test: For this test you will stand unsupported for 10 seconds with your feet in 3 different positions. • 4-meter walk: For this test you will walk 4 meters as quickly as possible.
What we will do	• Chair Stand Test: We will time how long it takes for you to move from seated to standing. • Balance Test: We will time how long you are able to stand unassisted with your feet in 3 different positions. • 4-meter walk: We will time how long it takes for you to walk 4 meters.

Study Procedure 8: Hand grip strength	
Timing	At approximately 3 months, 6 months, and 12 months after initial study enrollment.
Explanation	Hand grip strength is used to measure the strength in your hand and forearm.
Risks or Discomforts	You may experience fatigue, shortness of breath, or temporary discomfort in your hand and forearm.
What you will do	Using your dominant hand, you will squeeze a machine called a hand-held dynamometer 3 times with all your strength.
What we will do	We will record the measurements on the dynamometer.

Study Title: The ARDS, Pneumonia, and Sepsis (APS) Consortium: A Prospective Observational Study to Evaluate Phenotypes (Protocol A – Full Protocol)
Version Date: April 13, 2024

Study Procedure 9: CNS-Vital Signs	
Timing	At approximately 3 months, 6 months, and 12 months after initial study enrollment.
Explanation	CNS Vital Signs is a computer test that measures different types of brain activity including memory and attention.
Risks or Discomforts	No plausible physical risks. You may experience embarrassment or emotional discomfort.
What you will do	You will sit at a computer and follow the prompts on the screen. This test takes about 45 minutes.
What we will do	We will set up the computer.

Study Procedure 10: Muscle Ultrasound	
Timing	At approximately 3 months, 6 months, and 12 months after initial study enrollment.
Explanation	Muscle ultrasound can be used to determine how well your body is healing following hospitalization.
Risks or Discomforts	There may be slight pressure or discomfort at the area where the ultrasound is being conducted.
What you will do	You will lay or sit on a table and remove any clothing from the quadricep (upper leg) on the dominant side of your body.
What we will do	We will rub gel on your leg and use an ultrasound machine to look at your quadricep muscle and capture images.

Study Procedure 11: Muscle Strength	
Timing	At approximately 3 months, 6 months, and 12 months after initial study enrollment.
Explanation	Muscle strength testing is used to measure strength in the lower body.
Risks or Discomforts	You may experience fatigue, shortness of breath, or temporary discomfort in your leg.
What you will do	You will sit or lay on a table and raise the leg on the dominant side of your body 3 times.
What we will do	We will put a machine called a dynamometer on your leg to measure the strength. We will record the measurements.

Study Title: The ARDS, Pneumonia, and Sepsis (APS) Consortium: A Prospective Observational Study to Evaluate Phenotypes (Protocol A – Full Protocol)
Version Date: April 13, 2024

Study Procedure 12: Spirometry (12 month visit only)	
Timing	At approximately 12 months after initial study enrollment. Participants who have had recent spirometry for clinical purposes will not have it repeated.
Explanation	Spirometry measures your lung function. It determines the amount and/or speed of air that can be inhaled or exhaled.
Risks or Discomforts	You may feel dizzy, faint, shaky, or tired after the spirometry test.
What you will do	You will sit upright in a chair. You will have a clip placed on your nose, and you will be given a plastic mouthpiece that is connected to a machine called a spirometer. You will place your lips tightly around the mouthpiece and take in as big and deep of a breath as possible and then blow out as hard and fast as you can.
What we will do	We will record the information captured by the spirometer.

Study Procedure 13: Lung Diffusion Testing (DLCO, 12-month visit only)	
Timing	At approximately 12 months after initial study enrollment. Participants who have had recent DLCO for clinical purposes will not have it repeated.
Explanation	Lung diffusion testing is used to determine how well your lungs are working by measuring how much oxygen moves from your lungs to your blood when you inhale.
Risks or Discomforts	You may feel dizzy, faint, shaky, or tired after the DLCO test.
What you will do	You will have a clip on your nose. You will put your mouth over a mouthpiece that is attached to a machine. This machine will deliver a small amount of carbon dioxide when you breathe in and will also record the results of the test. You will then take a few normal breaths. Next you will inhale deeply and exhale completely. You will breathe in quickly through your mouth and hold your breath for 10 seconds or as long as you can. Then you will breathe out.
What we will do	We will record the measurements on the machine.

Study Title: The ARDS, Pneumonia, and Sepsis (APS) Consortium: A Prospective Observational Study to Evaluate Phenotypes (Protocol A – Full Protocol)
Version Date: April 13, 2024

Study Procedure 14: Chest CT scan (12-month visit only)	
Timing	At approximately 12 months after initial study enrollment. Participants who have had recent Chest CT scan for clinical purposes will not have it repeated.
Explanation	A Chest Computed Tomography (CT) scan uses special X-ray equipment to take detailed pictures of the lungs.
Risks or Discomforts	Chest CT involves exposure to radiation. The risks of this radiation are described in part 2 of this informed consent document.
What you will do	You will lie flat on your back on a CT table. A pillow will be placed under your head. The CT table will slide under the scanner. The scanner will move over and around your chest, between your neck and your abdomen.
What we will do	We will take you to the lab where the CT is performed. We will make sure that you are comfortable. We will step out of the room during the CT scan. The CT scan will be read by a radiologist. We will give you the results of this CT scan.

Study Procedure 15: Testing and storing your samples	
Timing	Your samples may be stored indefinitely.
Explanation	Your samples (blood, stool, nasal swab, oral swab) will be stored indefinitely. Your samples will be tested by researchers in the future, including genetic tests (tests on genes).
Risks or Discomforts	We do not expect risk or discomfort for you. Your samples will be stored in a deidentified manner (without your name on it). Even though we will protect against it, someone figuring out that the samples came from you could happen.
What you will do	Nothing for you to do.
What we will do	We will store your samples in freezers. We will ship the samples to research who would like to run tests on them. For long-term storage, the samples will be sent to NHLBI's specimen repository called BioLINCC for indefinite storage. BioLINCC will provide other researchers with access to your samples for testing. Results of research tests will be used to understand human disease better. These results will not be returned to you.

Reasons why the study doctor may take you out of this study:
The study doctor may take you out of the study if he or she thinks it is not in your best interest. If you are taken out of this study, you will be given a reason why.

Study Title: The ARDS, Pneumonia, and Sepsis (APS) Consortium: A Prospective Observational Study to Evaluate Phenotypes (Protocol A – Full Protocol)
Version Date: April 13, 2024

What will happen if you decide to stop being in this study?
If you decide to stop being part of the study, you should tell your study doctor or study staff. These people will talk to you about the study and will remove you from the study if you would like to be removed.

Clinical Trials Registry.
A description of this clinical study will be available on www.clinicaltrials.gov. 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 Web site at any time.

Privacy:
Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name, birth date or other identifying information. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent ARDS, sepsis, pneumonia, and other health problems.

Your samples and information collected as a part of this study will be available to the doctors and researchers leading this study and will also be made available to others to use for future research. This will help researchers answer additional important questions about the causes, risks, treatments, or how to prevent health problems.

Your samples may be used to make new products or tests. These may have value and may be developed and owned by the study staff, participating Universities, and/or others. If this happens, there are no plans to provide money to you.

Study Results:
Other than the Chest CT scan at the 12-month visit, the are no plans to inform you of the results of research testing done in this study. The overall study results will be shared with NHLBI and NIGMS, which are part of the United States government. You will not be identified. Study results may be made public once the study is completed using methods such as scientific publications, press releases, social media advertisements, and advertisements in local newspapers. Your identity will not be revealed.