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: October 23, 2024

Part 1 of 2: MASTER CONSENT

This informed consent document applies to the primary APS Study.

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 about Acute Respiratory Distress Syndrome (ARDS), Pneumonia, and Sepsis by collecting information and samples from people who have or are at risk for one of these conditions. We want to understand more about what causes these illnesses, why some people get sicker than others, and why some people continue to suffer for a long time after having one of these conditions. There are no experimental treatments involved in the study.

If you agree to be in this study, we will ask you some questions and will take information from your medical chart. We will also plan to take several samples of what are called "biospecimens," which include blood, urine, fluid from the lung, stool, and swabs of your nose, mouth, and rectum. We will also send you brief surveys by email, text message, or phone in about 3, 6, and 12 months. There are no direct benefits to you for being in the study. A potential benefit to society is understanding how to better diagnose and treat these illnesses, which could improve treatments in the future. The risks of being in this study are small and include the possibility of your medical information accidentally getting released and discomfort from collecting the samples.

Participation in this study is voluntary, meaning that you do not have to be in the study if you do not want to be and you can withdraw at any time.

Study Title: The ARDS, Pneumonia, and Sepsis (APS) Consortium: A Prospective Observational Study to Evaluate Phenotypes (Protocol A – Full Protocol)
Version Date: October 23, 2024

For People who Started the Study with Alteration of Informed Consent:
If you were not able to provide consent for this study when you were first eligible for the study, the research team may have collected some information and biospecimens from you using what is called "alteration of informed consent." This means that low risk study procedures may have already been started. This was done because understanding the early stages of ARDS, pneumonia, and sepsis while patients are very sick is important, and the information and biospecimens collected would not have affected your medical care. If study procedures were started earlier, we are now asking for your consent to continue the study and perform the study procedures outlined in this document. If you do not want to continue with the study, you may leave the information and biospecimens already collected as part of the study or have them removed from the study.

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

Overview of the Study:
You are being asked to take part in this study because you have been diagnosed with Acute Respiratory Distress Syndrome (ARDS), pneumonia, and/or sepsis, or you are at risk for having one of these conditions. The purpose of this study is to collect information and samples and run tests on them that will improve the understanding of theses illnesses. The results obtained from these tests may help us better understand how to diagnose, treat, and prevent ARDS, pneumonia, and sepsis. This study will also create a repository of the information and samples collected for other researchers to use to answer important questions about ARDS, pneumonia, and sepsis.

This study, called the APS Phenotyping 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 approximately 4000 people in this study at different hospitals.

This is an observational study. This means that the study will not affect the treatment you receive.

You do not have to be in this study. You may choose not to be in this study and continue to get medical care 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.

Study Title: The ARDS, Pneumonia, and Sepsis (APS) Consortium: A Prospective Observational Study to Evaluate Phenotypes (Protocol A – Full Protocol)
Version Date: October 23, 2024

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 diagnose, treat, and prevent ARDS, sepsis, and pneumonia. These diseases cause a lot of people to die and suffer. This study is being done to try to figure out how to treat people with ARDS, pneumonia, and sepsis better in the future so fewer people die and suffer.

Procedures to be followed:
There are 2 parts of this study. The first part will take place while you are hospitalized. Procedures done during this part of the study are described below under "In -hospital Procedures." In the second part of the study, you will also be asked to answer questions about your health after you are released from the hospital in the form of surveys that do not require you to come back to the hospital. Procedures to be completed during this portion of the study are described under "Post-hospital Procedures."

In-hospital Procedures
Procedures to be done while you are in the hospital:

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: October 23, 2024

Study Procedure 2: Participant (or Surrogate) interview	
Timing	Today or at the earliest time that is convenient
Explanation	The interview includes questions about your current illness and your medical history. If the patient is unable to answer the questions, we will ask a surrogate, who is usually a family member, these questions.
Risks or Discomforts	You may feel uncomfortable answering personal questions. You do not have to answer questions that make you too uncomfortable.
What you will do	You should answer the questions as completely and truthfully as possible.
What we will do	We will record your answers in a secure database.

Study Procedure 3: Medical Record Review (in-hospital and post-hospital)	
Timing	Throughout the duration of the study
Explanation	Information will be collected from your medical record including: age, race, sex, chronic medical conditions, the reasons why you are in the hospital, treatments, laboratory test results, medications, how long you are in the hospital, how well you respond to treatment, whether you returned to the hospital after initial discharge, and medical images (radiology), 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 and radiology images from your medical record and enter them into secure study databases. To prevent your data from being improperly exposed, only researchers involved with this study will have access to the information about your identity. Your information will be deidentified, meaning it will not be linked to you as the person who provided the information. 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 Title: The ARDS, Pneumonia, and Sepsis (APS) Consortium: A Prospective Observational Study to Evaluate Phenotypes (Protocol A – Full Protocol)
Version Date: October 23, 2024

Study Procedure 4: Blood collection	
Timing	Today and about every other day for one week or until you leave the hospital. If you are still in the hospital in two weeks, we will do one additional blood draw then. Blood draws are scheduled for the following study days while you are in the hospital: 0 (today), 2, 4, 6, 14. Additionally, blood may also be drawn after you are placed on a breathing machine.
Explanation	We will attempt to collect blood from a catheter ("IV") that you already have in place. If we are unable to obtain blood from one of these catheters, we will obtain blood using a needle stick into a vein.
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.
What we will do	When possible, we will collect blood at the same time as your regular blood samples through an existing catheter. The most blood we plan to take is shown below by day: - Day 0 (today): 33 ml (about 2 tablespoons) - After being put on a breathing tube: 16 ml (about 1 tablespoon) - Day 2: 15 ml (about 1 tablespoon) - Day 4: 6 ml (about half a tablespoon) - Day 6: 27 ml (about 2 tablespoons) - Day 14: 8 ml (about half tablespoon) - Total maximum: 106 ml (about 8 tablespoons)

Study Procedure 5: Urine collection	
Timing	Today or at the earliest time that is convenient
Explanation	We will attempt to collect urine through a urinary catheter if you already have one in place. If you do not have a urinary catheter in place, your urine will be collected by your urinating into a cup.
Risks or Discomforts	There are no common risks or discomforts associated with urine collection.
What you will do	If you have a urinary catheter there is nothing for you to do. If you do not have a urinary catheter, you will urinate into a cup provided by the research staff.
What we will do	We will collect urine through your catheter, or we will provide a cup and ask you to provide a urine sample in the cup.

Study Title: The ARDS, Pneumonia, and Sepsis (APS) Consortium: A Prospective Observational Study to Evaluate Phenotypes (Protocol A – Full Protocol)
Version Date: October 23, 2024

Study Procedure 6: Nasal, oral, and rectal swabs	
Timing	Today and in about 2 days and 6 days. Nasal, oral, and rectal swab collection is scheduled for the following study days while you are in the hospital: 0 (today), 2, 6.
Explanation	Swabbing involves putting a swab (like a Q-tip) to into your nose, mouth, or rectum and briefly rubbing the inside.
Risks or Discomforts	Some patients have brief irritation, pain, or bleeding.
What you will do	You will tilt your head back for the nasal swab, open your mouth for the oral swab, and roll on to your side or stomach for the rectal swab.
What we will do	We will insert different swabs into your nose, mouth and rectum, rubbing the inside and then removing the swab.

Study Procedure 7: Stool collection	
Timing	Today and in about 2 days and 6 days. Stool collection is scheduled for the following study days while you are in the hospital: 0 (today), 2, 6.
Explanation	We will collect stool either in a cup after you defecate or by collecting it from a tube or bag that you may already have in place that is catching stool.
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, or if you already have a tube or bag connected to your body that is collecting stool, there is nothing for you to do.
What we will do	We will take the stool sample and store it for future research studies. for laboratory examination.

Study Title: The ARDS, Pneumonia, and Sepsis (APS) Consortium: A Prospective Observational Study to Evaluate Phenotypes (Protocol A – Full Protocol)
Version Date: October 23, 2024

Study Procedure 8: Heat Moisture Exchange Filter collection (only patients on a breathing machine)	
Timing	Heat Moisture Exchange (HME) filters will be collected while patients are on a breathing machine in the hospital. These filters will be collected on the following study days if the participant is on a breathing machine during that day: Day 0 (today) 2, 4, 6, 14.
Explanation	An HME filter is a sponge that is placed in the tubing between a patient and breathing machine. It reduces the amount of heat and moisture a patient loses when on a breathing machine. Moisture from your breath is collected in this filter. The filter is changed every few hours. The moisture from your breath contained in this filter may have information about your lungs. When the filter is changed, we will save the filter to collect the moisture that it contains and run tests on it.
Risks or Discomforts	HME filters are regularly used and changed even when patients are not in research studies. When the filters are being changed, if the tubing is disconnected for longer than intended, your oxygen levels might drop. Using the removed filter for research does not pose any risk to you.
What you will do	Nothing for you to do.
What we will do	We will collect some of the HME filters that are removed from the breathing machine tubing during your care and drain the fluid from the filter for testing.

Study Procedure 9: Tracheal Aspirate sample collection (only patients on a breathing machine)	
Timing	Fluid from the trachea (windpipe) will be collected while you are on a breathing machine. This will be done on study Day 0 (today) 2, 4, 6, and 14 if the participant is on a breathing machine that day.
Explanation	Patients on a breathing machine have a breathing tube in their trachea that connects their lungs to the breathing machine. A smaller tube, called a suction catheter, will be placed through the larger tube and fluid will be gently sucked out.
Risks or Discomforts	Tracheal suctioning is regularly done for patients on breathing machines. Complications are rare. These include a drop in oxygen level (hypoxemia), bleeding, and moving the breathing tube out of the trachea. Using the fluid for research instead of throwing it away does not pose any risk to you.
What you will do	Nothing for you to do.
What we will do	We will insert a flexible tube called a suction catheter through the breathing tube in your trachea. Gentle suction will be performed to remove a small amount of fluid for testing.

Study Title: The ARDS, Pneumonia, and Sepsis (APS) Consortium: A Prospective Observational Study to Evaluate Phenotypes (Protocol A – Full Protocol)
Version Date: October 23, 2024

Study Procedure 10: Non-bronchoscopic BAL (only patients on a breathing machine)	
Timing	One time within 4 days of starting on a breathing machine.
Explanation	We will obtain a sample of fluid from your lungs if you are on a breathing machine. The procedure used to collect this fluid is called a non-bronchoscopic bronchoalveolar lavage (NBBAL). The NBBAL procedure involves putting a flexible rubber tube through the breathing tube into the airway of one of the lungs. A small amount of fluid is injected into the lung and then a gentle suction is used to collect fluid. Only patients who pass a safety screen showing that they are not at high risk for complications will have the NBBAL procedure performed. Some patients may have had bronchial fluid collected for clinical purposes in the hospital. If there is left over bronchial fluid available from one of these prior procedures, we may use that fluid for research instead of collecting more bronchial fluid.
Risks or Discomforts	Complications from NBBAL sample collection are rare. Risks include bleeding, moving the breathing tube, and drop in oxygen level (hypoxemia).
What you will do	Nothing for you to do.
What we will do	We will insert a small suction tube through the breathing tube into your lungs, insert a small amount of fluid, and then gently suction the fluid back. This fluid will be used for research testing.

Study Procedure 11: Testing and storing your samples	
Timing	Your samples may be stored indefinitely.
Explanation	Your samples (blood, urine, stool, nasal swab, oral swab, rectal swab, HME filter fluid, tracheal aspirate fluid, and NBBAL fluid) 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 researchers 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.

Study Title: The ARDS, Pneumonia, and Sepsis (APS) Consortium: A Prospective Observational Study to Evaluate Phenotypes (Protocol A – Full Protocol)
Version Date: October 23, 2024

Post-hospital Procedures:
Procedures to be completed after you are released from the hospital:

Study Procedure 12: Surveys	
Timing	At 3, 6, and 12 months after you begin the study
Explanation	You will be contacted by email, text, and /or phone to give updates about your health. These surveys will ask questions about quality of life, mental health, return to work, and if you have been re-admitted to the hospital.
Risks or Discomforts	You may feel uncomfortable sharing your health information. You do not need to answer any questions that make you feel too uncomfortable. There is a small risk of your answers being improperly disclosed (seen by people not part of the study), resulting in loss of privacy.
What you will do	You will answer questions in the survey to the best of your ability.
What we will do	We will send you the surveys at 3, 6, and 12 months. We will follow-up with you if we have not received a response to the surveys. This follow-up may be by researchers at the institution where you were enrolled or another institution.

Genetic Research that will be Performed on your Samples:
Genes are the instruction manual for your body. The genes you get from your parents partially decide what you look like and how your body behaves. Genes can also tell us about a person's risk for certain diseases and how they will respond to treatment. Biospecimens, such as blood samples, collected as part of this study may be used for genetic testing. What researchers learn about you from testing these samples will not be put in your health record. Your test results will not be shared with you or your doctor. No one else (like a relative, boss, or insurance company) will be given your test results. Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

One risk of giving samples for this research may be the release of your name that could link you to the stored samples and/or the results of the tests run on your samples. This may cause problems with insurance or getting a job. To prevent this, these samples will be given a code. Only the study staff will know the code. The name that belongs to the code will be kept in a locked file or in a computer with a password. Only study personnel will have access to your name.

Your sample will provide DNA that will be kept for an unknown length of time (maybe years) for future research. The sample will be destroyed when it is no longer needed. At any time, you may ask to have your samples destroyed. We will not be able to destroy research data that has already been gathered using your sample. Also, if your identity was removed from the samples, we will not be able to locate and destroy them.

Study Title: The ARDS, Pneumonia, and Sepsis (APS) Consortium: A Prospective Observational Study to Evaluate Phenotypes (Protocol A – Full Protocol)
Version Date: October 23, 2024

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.

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 contact information may be used by researchers who are part of the study at other institutions to contact you for follow-up questions.

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:
The are no plans to inform you of the results of research testing done on your samples 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.