Institutional Review Board
Informed Consent Document for Research
STUDY SITE INFORMATION

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 2 of 2: STUDY SITE INFORMATION

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

Site Name:	Vanderbilt University Medical Center
Site Principal Investigator:	
Site Principal Investigator Contact:	
Site Study Coordinator *(if applicable)*:	
Site Study Coordinator Contact *(if applicable)*:	

This part of the consent form includes information about the site that is asking you to participate in this study and is specific to participation at your site only. Before making your decision, both the site-specific information and the general study information should be reviewed with you. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Site specific procedures and risks:
This research study may involve exposure to radiation from up to 1 CT scan of the chest. This radiation exposure is not necessary for your medical care and is for research purposes only. The total amount of radiation that you may receive by participating in this study is equal to your body receiving 9 months of radiation from your natural surroundings, or about 4% of the amount allowed in a year for people who are exposed to radiation as part of their work.

Payments for your time spent taking part in this study or expenses:
You will be reimbursed $200 for participation in the 3-month and 6-month in-person visits and $250 for participation in the 12-month study visit.

You are not allowed to accept any money for taking part in this study if you are not eligible to receive money from a U.S. person or company or the U.S. government because of U.S. national security and/or foreign policy laws. You can still take part in the study however, you will not be paid if you are a resident of a country restricted by the U.S. government's comprehensive territorial sanctions or if you are listed on the U.S. Treasury Department's Office of Foreign Assets Control's Specially Designated Nationals (SDN) list of prohibited individuals. You do not have to say why you choose not to be paid.

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Costs to you if you take part in this study:
There is no cost to you for taking part in this study.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and study doctor that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.

There are no plans for Vanderbilt or the Sponsor to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt or the Sponsor to give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact:

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the Vanderbilt University Medical Center Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Confidentiality:

The sponsors (National Heart, Lung, and Blood Institute (NHLBI) and National Institute of General Medical Sciences (NIGMS), which are both part of the National Institutes of Health (NIH)) and the Coordinating Center (Vanderbilt University Medical Center) may share your information and/or samples, without identifiers, to others or use it for other research projects not listed in this form. The sponsor, Vanderbilt University Medical Center, Dr. Ware, and her staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

It is the intent of the study doctor, study staff, and Sponsor that the health data that is sent to the Sponsor will not identify you.

You will not be identified by name in any published reports about this study or in any other scientific publication or presentation. If you think that you were harmed from being in the study, the study team may also share health data about you with the Sponsor's insurer to resolve your claim.

The Sponsor and Coordinating Center may use the health data and/or samples sent to them:

- To develop new tests
- For other activities (such as development and regulatory)
- As part of research activities related to the study of diseases and the development of drugs and tests used to treat diseases.
- To allow outside researchers to use clinical data that does not identify you.

For these uses, the Sponsor and Coordinating Center may share this health data and/or samples with others involved in these activities, as long as they agree to only use the health data as described here. The Sponsor may transfer health data about you from your country to other countries where the privacy laws may not be as strict. Once the research team shares health data about you with others, it may no longer be protected by privacy laws.

There is a risk that if people outside the study get your health data they could misuse it for purposes other than those outlined in this consent. The study team has strict privacy and confidentiality protection procedures in place to prevent this from occurring so the chance of this happening to you is extremely small.

This study is supported from the National Institutes of Health (NIH). Your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

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Authorization to Use/Disclose Protected Health Information

What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

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To cancel authorization for participation in this study, please contact:

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

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STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date _____ Signature of patient/volunteer _____

Consent obtained by:

Date _____ Signature _____

Printed Name and Title _____

Time: _____

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Signature Form for a Health Care Decision-Maker/Surrogate

I, _____ [name of decision-maker/surrogate], am the _____ [state relationship to participant] of _____ [state participant's name]. I have read the informed consent document or it has been explained to me. I have had the opportunity to ask any questions and all of my questions have been answered. I have been informed that _____ [participant's name] will be entering into a research study. I believe participating in this study would be in the interests of _____ [participant's name] and is consistent with what he/she would have decided had he/she been able to do so.

Your decision to allow your family member/friend to participate in this research study is voluntary. You may choose not to allow his/her participation without affecting his/her healthcare/services or other rights. You are also free to withdraw him/her from this study at any time. In the event new information becomes available that may affect the risks or benefits associated with this research study or your willingness to allow continued participation in this research study, you will be notified so that you can make an informed decision whether or not to continue your family member/friend's participation in this study.

Your family member/friend will periodically be re-evaluated for the capacity to give consent. If he/she is found to be capable, continued participation in this study would only occur with his/her consent.

_____ _____/_____/_____
Signature of Health Care Decision-Maker/Surrogate Date

_____ _____/_____/_____
Signature of Witness Date

_____ _____/_____/_____
Name and Signature of person obtaining consent Date