Accelerating COVID-19 Therapeutic Interventions and Vaccines 4 ACUTE (ACTIV-4A)

NCT04505774

10/22/2021

IRB Approved Template
MUST BE APPROVED
FOR SITES BEFORE USE
AS MODIFIED
Oct 22, 2021

CONSENT FOR A PARTICIPANT IN A RESEARCH STUDY
MAIN CONSENT

TITLE: A Multicenter, Adaptive, Randomized Controlled Platform Trial of the Safety and Efficacy of Antithrombotic and Additional Strategies in Hospitalized Adults with COVID-19

SHORT TITLE: ACTIV-4 ACUTE

PROTOCOL NO.: None
IRB Protocol #20202415

SPONSOR: University of Pittsburgh

<<CF-Main Header Block - Investigator>>
INVESTIGATOR: Name
Address
City, State Zip
Country

SOURCE OF SUPPORT: National Heart Lung and Blood Institute (NHLBI), National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health (NIH), Biomedical Advanced Research and Development Authority (BARDA), Operation Warp Speed (OWS), U.S. Department of Health & Human Services (HHS)

STUDY-RELATED PHONE NUMBER(S): <<CF-Main User Defined #1>>Phone Number

You are being invited to take part in a research study. Your participation is voluntary, which means you can choose whether or not you want to take part in this study.

RESEARCH CONSENT SUMMARY

Purpose of the Research Study

Some people with COVID-19 are hospitalized and are at higher risk for progression of disease and complications related to inflammation and thrombosis (also known as blood clots). Most patients in the hospital for COVID-19 disease receive blood thinners called heparin to prevent blood clots as standard of care. The purpose of this study is to determine if adding other medications to standard care may be better at reducing the risk of worsening COVID-19. We do not currently know the best combination of these drugs to speed recovery in people hospitalized with COVID-19.

Other Key Information

The study could involve several thousand participants. There are several different treatments in the ACTIV-4a study. This form describes the study in general. Consent form supplements for this study describe specific study treatments. The assigned study treatment will be given while you are in the hospital, and could be given just once or more than once depending on the treatment type. After you leave the hospital, you will be contacted by a study representative from time to time, including at approximately 90 days from when you enter into the study. Also, it is likely that researchers will want to contact you to get information about how you are doing after recovering from this illness (up to a year from the time you enter the study). We will not ask you to return in person for research visits.

Foreseeable Risk and Benefits

There may or may not be any direct benefits from participation in this trial.

Risks will be covered in the supplement you will also review and sign

Alternatives to Participation

If you do not wish to participate in this study, you may continue your standard treatment for COVID-19 or participate in other research studies for COVID-19 patients.

For questions and concerns regarding any of this information, contact <<CF-Main Investigator Name>> [INSERT PI NAME] at the phone numbers listed above.

RESEARCH CONSENT

Some of the people who may be able to take part in this study may not be able to give consent because of their medical condition. In this case, we will ask the person's authorized representative, called their Legal Authorized Representative, to give consent for them. However, throughout the consent form, "you" always refers to the "subject" or person who takes part in the study.

Who is being asked to take part in this research study?
You are being asked to participate in this study because you are in the hospital for coronavirus disease-19 (COVID-19).

What is the purpose of this research study?
The purpose of this study is to determine the types of medications that may be helpful for patients in the hospital with COVID-19 when added to the standard of care. The medications that are tested in this research study are commonly given by doctors to people for other reasons.

Patients with COVID-19 disease are at risk for progression of disease and complications which may affect many parts of the body. Doctors are already giving most patients in the hospital for COVID-19 blood thinners called heparins at different doses and this is the standard of care.

Right now, we do not know if adding other medications is better for COVID-19 patients than using standard care alone.

Study Treatment Assignment(s)
This study is designed to have many parts. In each part, different medications may be added to the standard of care treatment chosen by your doctor. You may be eligible for all of them or only some of them, depending on your individual clinical condition. For each different part a consent form supplement is given to you to read and consider. The supplement lists the research procedures, background information and any risks from the medications used in this research study. You will need to sign this consent and the supplement or supplements that apply to you. Participation in the study and in any supplement with specific medications is your choice.

How long will you be in this research study?
The length of the assigned study treatment depends on the different medications that you are eligible for. The supplements provided will have more specific information. You will be checked on by the study team while you are in the hospital. After you leave the hospital, you will be

contacted by a study representative to check on your health from time to time in the first 90 days, and may be contacted again up to 1 year from when you entered into the study. We will not ask you to return in person for research visits. Even after the study is over, researchers may want to contact you to get information about how you are doing after recovering from this illness, and your interest in other studies about COVID-19 (long term follow up).

STUDY VISITS
SCREENING/ENROLLMENT, HOSPITALIZATION

If you are a woman who could get pregnant, you will have a pregnancy test if you did not already. If you are pregnant or breastfeeding, we will not include you in the study because there may be unknown risks to a fetus or embryo. If you agree to take part in the study and sign this consent form, the first step is to ask you a few questions about your medical history and read your medical chart (medical record). Most information will be obtained from your chart.

Then, you will be randomly assigned (assigned by chance, like rolling dice) to one of the study treatment groups by a computer and you will start the assigned treatment or treatments. You will receive the assigned treatment for the amount of time written in the supplement describing each study treatment. If there are any major problems, the treatment may be stopped by your care team.

We will check and collect information from medical records or from your care team to learn about your health status, treatments received, and test results during the hospitalization. When you enter the study, you will be asked how you were doing before being hospitalized, including your ability to perform activities and how you were feeling emotionally.

If you decide to take part in this research study, certain research procedures may occur while you are in the hospital. The following research procedures will take place while you are admitted to the hospital.

- Collection of medical record information from standard of care interactions, including, but not limited to:
  - demographics (such as your name and date of birth)
  - medical history (such as information about medications you may take or illnesses you have had in the past)
  - results of procedures/testing
  - results for testing for COVID-19
  - medications taken while hospitalized
  - treatments while hospitalized
  - hospital and ICU admission and discharge
  - questions about quality of life, general well-being and thinking and memory
  - side effects

AFTER THE HOSPITAL

After you leave the hospital, you may be contacted by a study representative to check on your health from time to time, including at 90 days from when you enter into the study. We will ask how you are doing, how well you are able to do different activities and how you are feeling emotionally. If you are transferred to another care facility or admitted back to a hospital within 90 days, we will record information about your health and test results. Also, it is likely that researchers will want to contact you to get information about how you are doing after recovering from this illness (up to a year from when you entered into the study).

Information from this study may be used for future research studies or shared with other researchers. We will not request additional informed consent from you to use the information. You may be contacted about future studies.

What are the possible risks, side effects and discomforts of this research study?

The risks of being part of this study are different depending on which study treatment or treatments you agree to receive. . The details of the risks, side effects and discomforts of being in this study are written into each supplement on later pages. Please read them carefully and ask any questions you may have.

Other Risks

Breach of confidentiality. The information from your medical record will be stored and there is a small chance that your private health information could be unintentionally shared as a result of participation in this study. Professional standards for protecting confidential information are used to minimize this risk. These will be discussed further under the 'Safeguarding Your Health Information' section of this document.

Participation in this study does not prevent you from being part of other research. If you are participating or thinking of joining other research studies tell you doctor. You will need to discuss any possible safety concerns of being in two studies at the same time.

What are possible benefits from taking part in this study?

There might or might not be any direct benefits from participation in this study. We hope to learn about the best treatment to prevent COVID-19 related problems.

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

Taking part in this study is your choice. If you do not wish to participate in this study, you may continue your current treatment for COVID-19, or participate in other research studies for COVID-19 patients. If you do not participate, your doctor will choose your standard treatment. You will receive the same standard treatments for COVID-19 whether or not you choose to be in the study.

What if new information becomes available about this research study?
During the study we may find new 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 notify you as soon as possible if such information becomes available.

It is possible that one of the study groups is better than the other. The study is being closely watched by an independent group of doctors and scientists. The study will be stopped or adjusted if they find that one group is doing better than another. You will be notified of any findings that may change your mind about continuing in the study.

Who will know about your participation in this research study?
Any information we store from this research will be kept as confidential as possible. All records related to your involvement will be stored in a locked file cabinet or secure computer. Your identity on some of your records will contain your name or month and year of birth when necessary (such as your consent form or lab results) and others will be indicated by an ID number rather than by your name. The information linking these ID numbers with your name will be kept separate from the research records. You will not be identified by name in any report of the research results.

Will this research study involve the use or disclosure of your identifiable medical information?
The health information we collect for this study is listed below.

- Medical history and examinations
- Information that identifies you, such as your name, address, telephone number, month and year of birth, race, ethnicity, and sex
- Reports from your hospital stay including what treatments were given to you.
- Laboratory and other hospital test results
- X-ray and other images and reports
- Lists of medications you are taking

This information will be stored in locked filing cabinets or on computer servers with secure passwords or encrypted storage devices. Participation in this study will result in data that will become part of your research record and will be kept indefinitely at the research office.

Will my information be kept private?
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 at <<CF-Main User Defined #2>> [INSERT SITE NAME]. In compliance with <<CF-Main User Defined #2>> [INSERT SITE NAME] policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

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 <<CF-Main User Defined #2>> [INSERT SITE NAME] 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 <<CF-Main User Defined #2>> [INSERT SITE NAME] policies and applicable law.

Your privacy is very important to us. The study doctors will make every effort to protect it.

This study has support from the National Institutes of Health (NIH) and 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 must 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.

We will do our best to protect your privacy and keep your information safe by:

- Using a number code to label your samples and other information.
- Keeping your number code separate from your name, address, and other personal information, except where needed. Information that is collected for research will only be identified using your number code and not your personal information.
- Keeping your test results and other information in a secure computer database.

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as “health information.” In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so. Data will be shared per the NIH Policy (including, but not limited to, both BioLINCC and BioData Catalyst being used as repositories for NHLBI-CONNECTS

research specimens and data). Shared data are deidentified and can be accessed by researchers outside this study. For more information see the https://biolincc.nhlbi.nih.gov/home/ and https://biodatacatalyst.nhlbi.nih.gov/ websites

In this study, we may collect health information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable health information and why they may need to do so:

- The research staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform or oversee this research, such as the National Heart, Lung and Blood Institute Collaborating Network of Networks for Evaluating COVID-19 and Therapeutic Strategies (NHLBI-CONNECTS)
- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research including monitoring of the data by an outside agency
- Non-research staff who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The IRB that oversees the research and the research quality improvement programs
- People from organizations that provide independent accreditation and oversight of hospitals and research
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research)
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law) <<CF-Main SMO Company 1>> <<CF-Main Affiliated IN Language 1>>

Some people or groups who get your health information might not have to follow the same privacy rules that we follow and might use or share your health information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your health information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your health

information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your information for any mailing or marketing list. However, once your information is shared outside this institution, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

The results of this research study may be published in a medical book or journal or used to teach others. However, your name or other identifying information **will not** be used for these purposes without your specific permission.

How long will the investigators be permitted to use and share identifiable information related to your participation?

The investigators may continue to use and share, for the purposes described above, identifiable information (which may include your identifiable medical information) related to your participation in this research study for a minimum of seven years and for as long (indefinite) as it may take to complete this research study. It is University of Pittsburgh policy to maintain research data for seven years after final reporting or publication of a project.

Can you withdraw your consent for participation in this research study?

You can decide not to participate in this study. You are also free to leave the study at any time, and withdraw your approval for us to use your identifiable medical information for the purposes described above. This means that you will also be withdrawn from further participation in this research study. Any identifiable research or medical information obtained as part of this research study prior to the date that you withdrew your consent will continue to be used and shared by the investigators for the purposes described above. If you decide not to join the study or if you join the study and leave the study at any time, you will not be penalized in any way and you will not lose any benefits to which you are otherwise entitled. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

To formally withdraw your consent for participation in this research study, you should provide a written and dated notice of this decision to the principal investigator of this research study. If you cannot provide a written notice, then contact a study team member.

Can you be withdrawn from this research study without your consent?
You may be withdrawn from the study without your consent at the discretion of the principal investigator or your physician due to unanticipated circumstances. The investigators reserve the right to terminate the study and discontinue your participation at any time for any reason in order to ensure your safety. Some of the possible reasons for withdrawing a participant include:

- Failure to follow study instructions;
- An investigator determines that continuation could be harmful to you;
- Termination of the study;
- Other unanticipated circumstances.

Any identifiable research or medical information recorded for, or resulting from, your participation in this research study prior to the date that you were withdrawn from participation may continue to be used and shared by the investigators for the purposes described.

Will you be paid for being in this study?
<<CF-Main Payment for Part. Paragraph>>You will not receive any payment for participation in this study.
<<CF-Main Financial Disclosure>>
Will you have to pay for anything?
You and/or your health insurance may be billed for the costs of medical care during this study if these expenses would have happened even if you were not in the study, or if your insurance agrees in advance to pay. If you have health insurance, the cost of these services will be billed to your insurance company. If your insurance does not cover these costs or you do not have insurance, these costs will be your responsibility.

Who will pay if you are injured as a result of taking part in this research study?
If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the <<CF-Main User Defined #3>>[INSERT HOSPITAL NAME HERE]. Your insurance provider may be billed for the costs of this emergency treatment. If you do not have insurance, these costs will be your responsibility. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care.

This study does not provide financial help for medical or other injury-related costs. You do not give up any rights to seek payment via the legal system for personal injury by signing this form.

Due to the coronavirus public health crisis (COVID-19), the federal government has issued an order that may limit your right to bring a claim if you are injured or harmed while participating in this COVID-19 clinical research study. If the order applies to this study, it limits your right to bring a claim against the researchers, healthcare providers, and any study sponsor, manufacturer, and/or distributor involved with the study. However, the federal government has a program that may provide compensation to you or your family if you experience serious physical injuries or death. To find out more about this "Countermeasures Injury Compensation Program" go to https://www.hrsa.gov/cicp/about/index.html or call 1-855-266-2427.

Is your participation in this research study voluntary?
Your participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above, is completely voluntary. (Note, however, that if you do not provide your consent for the use and disclosure of your identifiable information for the purposes described above, you will not be allowed, in general, to participate in the research study.) You may want to discuss this study with your family and friends and your personal physician before agreeing to participate. If there are any words you do not understand, feel free to ask us. The investigators will be available to answer your current and future questions.

Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the <<CF-Main User Defined #2>> [INSERT SITE NAME HERE]. Whether or not you provide your consent for participation will have no effect on your current or future medical care at a <<CF-Main User Defined #2>> [INSERT SITE NAME HERE] or affiliated health care provider or your current or future relationship with a health care insurance provider.

Who can you contact about your rights as a research participant?
If you have questions, concerns or complaints regarding your participation in this research study or if you think you have been injured by this study, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study about your rights as a research subject, or if you have questions, concerns or complaints about the study, you may contact the Institutional Review Board (IRB) at 855-818-2289, researchquestions@wcgirb.com. The IRB is a group of scientists and non-scientists who review the ethics of research. The goal of the IRB is to protect the rights and welfare of study subjects <<CF-Main User Defined #7>>

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

VOLUNTARY CONSENT

- All subjects unable to consent are required to assent, unless the investigator determines that the capability of the subject is so limited that the subject cannot reasonably be consulted.
- If assent is obtained, have the person obtaining assent document assent on the consent form.

The above information has been explained to me and all my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints will be answered by a qualified individual or by the investigators listed on the first page of this consent document at the telephone numbers given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator.

Agreement to Participate in the ACTIV-4 ACUTE Study
I voluntarily agree to participate in this research at <<CF-Main User Defined #2>> [STUDY SITE NAME]

☐ I agree to be approached to consider taking part in other studies related to this one.

☐ I do NOT agree to be approached to consider taking part in other studies related to this one.

By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me<<CF-Main California Bill of Rights>>.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

CERTIFICATION OF INFORMED CONSENT:
I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____	_____
Printed Name of Person Obtaining Consent	Role in Research Study
_____	_____
Signature of Person Obtaining Consent	Date

Witness to Consent Process for Non-English-Speaking Subjects (using a translated consent form OR "Short Form" in Subject's Spoken Language)

Statement of Witness
As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

_____	_____	_____
Name of Witness (Print)	Signature of Witness	Date

Witness to Consent of a Subject Who Cannot Read or Write

Statement of Witness:
I represent that the consent form was presented orally to the subject in the subject's own language, that the subject was given the opportunity to ask questions, and that the subject has indicated his/her consent and authorization for participation by (check box that applies).

☐ Subject making his/her own "X" above in the subject signature line

☐ Subject showed approval for participation in another way; describe:

Name of Witness (Print)	Signature of Witness	Date

For participants unable to give consent, the consent for study participation and authorization to collect and use protected health information is given by the following authorized participant representative:

Name of Authorized Participant Representative (Print)	Signature of Authorized Participant Representative	Date

Select the category that best describes the above Authorized Participant Representative:

☐ Court-appointed guardian
☐ Health care proxy
☐ Durable power of attorney
☐ Family member/next of kin; for this category describe relationship below:
_____

- ❑ I have explained the study to the extent compatible with the subject's capability, and the subject has agreed to be in the study.

OR

- ❑ The subject is not able to assent because the capability of the subject is so limited that the subject cannot reasonably be consulted.

_____ _____

Signature of person obtaining assent Date

ADDITIONAL OPTIONAL RESEARCH – Stored Samples for Future Research

ADDITIONAL OPTIONAL RESEARCH - Stored Samples for Future Research
In addition to the main part of the study, there is optional research you may want to participate in.

What is the purpose of this optional part of the study?
We would like to collect and store a small amount of your blood until future researchers need them. You are being asked to participate to help develop a repository (storage) of samples from persons who are actively infected with COVID-19. Your participation will allow our team to collect blood for the repository.

DNA is the material that makes up your genes. All living things are made of cells. Genes are the part of the cells that contain the instructions that tells our bodies how to grow and work. They also determine physical characteristics such as hair and eye color. Genes are passed from parent to child.

There are many differences in DNA from one person to another and these differences can affect a person's chance of getting a disease or the way a person responds to a drug. Genetic research studies these differences, which may allow researchers to find new ways to find, treat, and maybe prevent or cure health problems, including heart disease.

How will my samples be used?
Your samples will only be used for research and may also be used for research on other health problems.

Any information that can directly identify you will be removed, and labeled only with the code assigned to you in the main ACTIV-4 ACUTE study. After such removal of identifiers, your samples may be used for future research studies or shared with other researchers and we will not request additional informed consent from you to use these specimens as we have noted here. We will let researchers use the stored samples for approved studies. Researchers from universities, governments, and drug- or health-related companies can apply to use the samples. A science committee will review each request. All studies must be approved by the committee in charge of protecting research participants. We will not give researchers your name or any other information that could directly identify you. Your samples may be used for commercial profit. You will not receive any payments for any research done on your stored samples, or for allowing your samples to be collected or stored.

When your samples are used for research, the researchers may also use your medical information collected from you in the main study, for example, your blood pressure, and the medications you use. This medical information will not identify you because it is labeled only with the code assigned to you in the main ACTIV-4 ACUTE study.

It is not possible to list every research project. We cannot predict all of the research questions that will be important in the future. As we learn more, there are new research questions that will need to be answered. Your samples will never be sold or donated for purposes beyond what has been described here.

Genetics and other forms of research will be conducted on all your samples collected for research or clinical care. We will learn about how genetics influence your health and the health of others. We may also gather other data by conducting other tests as they become available, such as measuring substances that naturally occur in the body or are a sign of other exposures (like medication use, environmental exposures, or biomarkers) or substances that measure the inflammation in response to the infection.

We may do pharmacogenomics testing. Pharmacogenomics is the study of how a person's genes affect their response to medications. We may study your samples using this type of lab test to see if certain medications may or may not work in different individuals or if there is an increased chance of adverse drug reactions based on genetics and other factors. We are not able to give this information, or other information about research tests done on your samples, back to you.

The research may include genetic research on the DNA in your samples like whole genome sequencing and be compared with data from others to see similarities and differences. Whole genome sequencing is a way to study your body's entire genetic instructions.

Other tests may be run on your samples as they become of interest for understanding COVID-19 or other conditions.

Do I have to take part in this optional part of the study?
You may decide not to take part. Your blood will not be stored for future research. This decision will not affect your participation in the main ACTIV-4 ACUTE study.

What are the alternatives to being in this study?
The alternative to participating in the additional optional research is NOT participating.

What will happen to me if I take part and what do I need to do?

You will have blood tests for safety purposes and to determine whether you are eligible for the study. You will have blood drawn at time of enrollment, Day 3, Day 7 and Day 14 while you are in the hospital. No more than 3 tablespoons will be collected each time. We will collect blood samples by drawing blood from a vein in your arm using a needle.

What are the possible disadvantages of taking part in this study?
The possible risks of taking part in this study are described under Confidentiality Risks in main consent above, and below.

Risks of blood draw: You may experience some bleeding, bruising or possible infection at the blood draw site. Some people become dizzy or faint. These risks are lowered by having trained personnel draw your blood. We will have trained professionals draw blood to minimize risks. If you have existing intravenous (IV) access, we may use this site to draw a blood sample.

Risks of genetic studies: The risks associated with genetic studies include the potential for a breach of confidentiality which could affect future insurability, employability, or reproduction plans, or have a negative impact on family relationships and/or result in paternity suits or stigmatization.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), further makes it illegal for some health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, nor does it protect you against genetic discrimination by all employers.

Where will my samples be stored?
After blood is drawn and processed, the resulting samples will be frozen and stored at each clinical site until enough samples have been stored to constitute an efficient shipping batch. The samples will then be shipped on dry ice to the ACTIV-4 Biorepository and Central Lab (BCL) at the University of Vermont for long-term storage.

How long will my samples be stored?
Samples for will be stored for up to 25 years at the BCL; after storage at the BCL, they will be either destroyed, or anonymized and transferred to an NIH Biorepository, at the discretion of the NIH.

What are the advantages of taking part in the study?
It is unlikely that allowing your samples to be stored and used in future research will benefit you directly. We hope that the results of this future research will increase our understanding of human health and lead to better diagnoses and treatments for diseases, including blood clot formation and COVID-19. You may feel good about contributing to medical knowledge, and helping researchers make discoveries that might help people in the future.

What happens if I change my mind later?
You are free to change your mind at any time without penalty or loss of benefits to which you would otherwise be entitled. If you withdraw your permission, it will not affect your participation in the main ACTIV-4 ACUTE study. If you withdraw your consent your study doctor will ensure that any unused samples are destroyed. However, the results of any testing that has already been done using your samples will not be destroyed.

If you decide to withdraw your consent you should contact <<CF-Main Investigator Name>> [INSERT PI NAME] in writing and let him/her know that you are withdrawing from this research. If you cannot provide a written notice, then contact a study team member. At the end of the study, if the link between you and your samples is destroyed at your study center, we will be unable to remove your samples.

How will my privacy be protected and confidentiality maintained?
All information collected will be kept confidential as described above. In addition, we will remove your name and other identifiers from your samples and replace them with a code number that is assigned to you in the main ACTIV-4 ACUTE study. The list linking the code number to your name will be kept in a locked file cabinet and/or password protected computer at your study site. Researchers who will use your samples and information will not know who you are. They must also sign an agreement that they will not try to find out who you are.

What will happen to the results of this study?
Neither you nor your study doctor will receive the results of tests done using your samples in future research, including your individual results. The results will not be put in your health record and will not have an effect on your care.

Will I receive any payments for participating?
<<CF-Main User Defined #4>>You will not receive any payments for allowing your samples to be collected or stored, nor will you receive any payments for any research that is conducted on your stored samples.

AGREEMENT TO PARTICIPATE: Storage of Samples for Future Research (Optional)
Check one below:

☐ I voluntarily agree to have my samples stored for **future research**

☐ I DO NOT agree to have my samples stored for **future research**

I understand that I am entitled to and will get a copy of this consent form.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

CERTIFICATION OF INFORMED CONSENT:

- All subjects unable to consent are required to assent, unless the investigator determines that the capability of the subject is so limited that the subject cannot reasonably be consulted.
- If assent is obtained, have the person obtaining assent document assent on the consent form.

I certify that I have explained the nature and purpose of this optional research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____
Printed Name of Person Obtaining Consent Role in Research Study

_____ _____
Signature of Person Obtaining Consent Date

Witness to Consent Process for Non-English-Speaking Subjects (using a translated consent form OR "Short Form" in Subject's Spoken Language)

Statement of Witness
As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

Name of Witness (Print)	Signature of Witness	Date

Witness to Consent of a Subject Who Cannot Read or Write

Statement of Witness
I represent that the consent form was presented orally to the subject in the subject's own language, that the subject was given the opportunity to ask questions, and that the subject has indicated his/her consent and authorization for participation by (check box that applies).

☐ Subject making his/her own "X" above in the subject signature line

☐ Subject showed approval for participation in another way; describe:

Name of Witness (Print)	Signature of Witness	Date

For participants unable to give consent, the consent for study participation and authorization to collect and use protected health information is given by the following authorized participant representative:

Name of Authorized Participant Representative (Print)	Signature of Authorized Participant Representative	Date

Select the category that best describes the above Authorized Participant Representative:

- ☐ Court-appointed guardian
- ☐ Health care proxy
- ☐ Durable power of attorney
- ☐ Family member/next of kin; for this category describe relationship below:

  _____

❑ I have explained the study to the extent compatible with the subject's capability, and the subject has agreed to be in the study.

OR

❑ The subject is not able to assent because the capability of the subject is so limited that the subject cannot reasonably be consulted.

_____	_____
Signature of person obtaining assent	Date

<<CF-Main California HIPAA>>

****For Sites in California****

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?

The study doctor will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits.

Who may use and give out information about you?

The study doctor and the study staff. [They may also share the research information with [enter SMO company name], an agent for the study doctor. delete if the site does not have an SMO]

Who might get this information?

The sponsor of this research. "Sponsor" means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor.

Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- The institution where the research is being done,
- Governmental agencies to whom certain diseases (reportable diseases) must be reported, and
- Institutional Review Board (IRB).

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to make sure that the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

May I review or copy my information?

Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?

This permission will be good until December 31, 2070.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission.

Authorization:
I have been given the information about the use and disclosure of my health information for this research study. My questions have been answered.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

AUTHORIZATION SIGNATURE:

Signature of Subject	**Date**
Signature of Legally Authorized Representative	**Date**
Relationship to Subject	