Vanderbilt University Institutional Review Board
Proposal for Research Using Human Participants
**Assent Document for Research Study**

**PI: Jonathan Schoenecker, MD, PhD** **Version Date: 4/12/2021**
**Title of Study: Disorders of the Acute Phase Response Accelerated by Plasmin Activation Following Trauma and Invasive Surgery: A Prospective Study**
**Institution/Hospital: Vanderbilt University Medical Center, Vanderbilt Children's Hospital**

This assent document applies to: children ages 16-17

Name of participant _____ Age___

**Below are the answers to some of the questions you may have. If you have any questions about what is written below or have any other questions about this research, please ask them. You will be given a copy of this consent form.**

1. **Why are you doing this research?**

   We are doing this study to learn more about how your injury affects your body's ability to protect itself (inflammation), the way your blood clots (coagulation), how your body cleans up those clots (fibrinolysis), and the way your body heals an injury.

   We are enrolling 150 trauma patients in this study.

2. **What will I do and how long will it take?**

   Blood sample from your vein:
   As part of your routine care, you will have blood taken from your vein and drawn into a tube. Any blood that is left over from your routine care blood tests will be used for study tests. In most cases you will not need to have any additional blood taken from your vein for this study. If additional blood from your vein is needed, it will be a very small amount, around a teaspoon per blood draw. The additional blood draws would occur at the following time points, if needed:
   - Day you enter the hospital
   - Every 12 hours until discharge

   If you have to undergo surgery for your injury, additional blood draws would occur at the following time points, if needed:
   - Immediately prior to your surgery
   - Every 30 minutes while you are in surgery
   - Every 6 hours for the first 3 days following surgery
   - Every 12 hours from 3 days following surgery until your discharge

   Our study team will also record information from your medical record. This will include information about: you (date of birth, gender, height, weight), your injury/injuries (diagnosis), and your treatment (wound healing).

   Your participation in the study will last as long as you are in the hospital for your injuries and when you return to the hospital for your routine care (up to 2 years). If you come back to the hospital for a routine care visit related to your injuries within the next 2 years we will record any problems you have had with your injury and recovery.

3. **Do I have to be in this research study and can I stop if I want to?**

   You do not have to be in this project. You may stop any time that you want to. If you would like to stop, tell your parents or the study doctor. Any data that has been collected on you will be kept, but no additional data will be recorded.

4. **Could it make me sick [or sicker]?**

   **Blood Draw Side Effects:** You may experience pain and discomfort at the site where the blood is drawn (vein). This is a chance you may develop a bruise at the site of the blood draw.

**PI: Jonathan Schoenecker, MD, PhD** **Version Date: 4/12/2021**
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5. **Will anyone know that I am in this research study?**

   The only people who will know are your nurses, doctor, study doctor, and study staff.

6. **How will this research help me or other people?**

   This research will not help you, but this research may help trauma patients in the future. We hope this study will help us learn more about why certain trauma patients develop conditions that make them very sick and make it harder for them to heal. By doing so, we hope to stop future trauma patients from becoming so sick and help them heal faster.

7. **Can I do something else instead of this research?**

   You do not have to participate in this research project if you do not want to.

8. **Who do I talk to if I have questions?**

   The study doctor or your parents.

_____ _____
Date Signature of patient/volunteer

Consent obtained by:

_____ _____
Date Signature

_____
Printed Name and Title

# Arm 1 Assent 16-17yo (Version Date: 5/13/21)

**VUMC Institutional Review Board**
**Assent Document for Research Study Principal Investigator: Jonathan Schoenecker, MD, PhD**

**Study Title: Disorders of the Acute Phase Response Accelerated by Plasmin Activation Following Trauma and Invasive Surgery: A Prospective Study**

**Institution/Hospital: Vanderbilt University Medical Center**

**Version Date: 5/13/2021**
**IRB Approval Date:**
**Expiration Date:**

**This assent document applies to: children ages 16-17**

1) Name of Participant:

_____
(First Last)

2) Age of Participant:

_____

Below are the answers to some of the questions you may have. If you have any questions about what is written below or have any other questions about this research, please ask them. You will be given a copy of this consent form.

1. Why are you doing this research?

We are doing this study to learn more about how your injury affects your body's ability to protect itself (inflammation), the way your blood clots (coagulation), how your body cleans up those clots (fibrinolysis), and the way your body heals an injury.

We are enrolling 150 trauma patients in this study.

2. What will I do and how long will it take?

Blood sample from your vein:

As part of your routine care, you will have blood taken from your vein and drawn into a tube. Any blood that is left over from your routine care blood tests will be used for study tests. In most cases you will not need to have any additional blood taken from your vein for this study. If additional blood from your vein is needed, it will be a very small amount, around a teaspoon per blood draw. The additional blood draws would occur at the following time points, if needed:

- Day you enter the hospital
- Every 12 hours until discharge

If you have to undergo surgery for your injury, additional blood draws would occur at the following time points, if needed:

- Immediately prior to your surgery
- Every 30 minutes while you are in surgery
- Every 6 hours for the first 3 days following surgery
- Every 12 hours from 3 days following surgery until your discharge

Our study team will also record information from your medical record. This will include information about: you (date of birth, gender, height, weight), your injury/injuries (diagnosis), and your treatment (wound healing).

Your participation in the study will last as long as you are in the hospital for your injuries and when you return to the hospital for your routine care (up to 2 years). If you come back to the hospital for a routine care visit related to your injuries within the next 2 years we will record any problems you have had with your injury and recovery.

3. Do I have to be in this research study and can I stop if I want to?

You do not have to be in this project. You may stop any time that you want to. If you would like to stop, tell your parents or the study doctor. Any data that has been collected on you will be kept, but no additional data will be recorded.

4. Could it make me sick [or sicker]?

Blood Draw Side Effects: You may experience pain and discomfort at the site where the blood is drawn (vein). This is a chance you may develop a bruise at the site of the blood draw.

5. Will anyone know that I am in this research study?

The only people who will know are your nurses, doctor, study doctor, and study staff.

6. How will this research help me or other people?

This research will not help you, but this research may help trauma patients in the future. We hope this study will help us learn more about why certain trauma patients develop conditions that make them very sick and make it harder for them to heal. By doing so, we hope to stop future trauma patients from becoming so sick and help them heal faster.

7. Can I do something else instead of this research?

You do not have to participate in this research project if you do not want to.

8. Who do I talk to if I have questions?

The study doctor or your parents.

## Signature

3) Signature of Patient/Volunteer

_____

(Click "Add signature" and use your mouse (or finger on a touchscreen device) to sign your first and last name.)

4) Date and time signed:

_____

(Date/time of Patient/Volunteer Signature)

## Copy for patient/volunteer records

You may save or print a blank copy of this consent form for your records if you wish. After you submit this form, you will be offered the opportunity to save or print a signed copy of this consent form. If you don't have a PDF reader installed, please click here to install one for free and access this document (link will open in new tab or window): Get Adobe Reader

## Study personnel only

5) Assent obtained by (please enter full name and title):

_____

(Completed by study personnel at time of consent.)

6) Date and time assented

_____

**Vanderbilt University Institutional Review Board**
**Informed Consent Document for Research**

**Principal Investigator: Jonathan Schoenecker, MD, PhD** **Revision Date: 5/27/2021**
**Study Title: Disorders of the Acute Phase Response Accelerated by Plasmin Activation Following Trauma and Invasive Surgery: A Prospective Study**
**Institution/Hospital: Vanderbilt University Medical Center**

This informed consent applies to: adults 18 or older who are trauma patients

Name of participant: _____ Age: _____

**The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.**

You do not have to be in this research study. 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.

1. **What is the purpose of this study?**

   You are being asked to take part in this research study because you have a major injury. Researchers at Vanderbilt University Medical Center are attempting to determine how these injuries affect a patient's blood clotting, inflammation, and tissue healing systems. We believe that some patients' response to these injuries cause them to develop serious conditions that can lead to poor wound healing, infection, organ failure. By understanding how a traumatic injury affects these body systems, we hope to be able to identify future trauma patients that may be at risk for developing these serious conditions through routine blood tests and treating them early.

   We are enrolling 150 trauma patients.

2. **What will happen and how long will you be in the study?**

   Blood sample from your vein:
   As part of your routine care, you will have blood taken from your vein and drawn into a tube. Any blood that is left over from your routine care blood tests will be used for study tests. In most cases you will not need to have any additional blood taken from your vein for this study. If additional blood from your vein is needed, it will be a very small amount, around a teaspoon per blood draw. The additional blood draws would occur at the following time points, if needed:
   - Day you enter the hospital
   - Every 12 hours until discharge

   If you have to undergo surgery for your injury, additional blood draws would occur at the following time points, if needed:
   - Immediately prior to your surgery
   - Every 30 minutes while you are in surgery
   - Every 6 hours for the first 3 days following surgery
   - Every 12 hours from 3 days following surgery until your discharge

   Blood sample from your finger:
   In addition to the blood taken from your vein and drawn into a tube, you may have blood taken from your finger. This will be done for research purposes only. The amount of blood taken from your finger will be a very small amount, around 2 drops. The reason we are taking blood from you using two different methods, vein and finger stick, is to determine if blood taken from a finger stick can provide us with all the data we need so we don't have to take blood from patient veins in the future.

   You may have blood taken from your finger at the following time points:
   - Day you enter the hospital
   - Every 24 hours until discharge

Our study team will also record information from your medical record. This will include information about: you (date of birth, gender, height, weight), your injury/injuries (diagnosis), and your treatment (wound healing).

Your participation in the study will last as long as you are in the hospital for your injuries and when you return to the hospital for your routine care (up to 2 years). If you come back to the hospital for a routine care visit related to your injuries within the next 2 years we will record any problems you have had with your injury and recovery.

3. **Costs to you if you take part in this study:**

   There is no cost to you for taking part in this study.

4. **Side effects and risks that you can expect if you take part in this study:**

   **Blood Draw Side Effects**
   You may experience pain and discomfort at the site where their blood is drawn (vein or finger). There is a chance you may develop a bruise at the site of the blood draw.

   **Breach of Confidentiality (Rare)**
   There is a rare chance that the confidentiality of the data we collect about you may be breached by taking part in this study. To lower this risk, all study data will be kept in a secure, password-protected database, where only research staff will have access to it.

5. **Risks that are not known:**

   If we discover an unknown risk to this study not listed in Item# 4 we will let you know about it.

6. **Payment in case you are injured because of this research study:**

   If it is determined by Vanderbilt and the Investigator 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 to pay for the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

7. **Good effects that might result from this study:**

   a) The benefits to science and humankind that might result from this study: Ability to identify and treat patient who are at risk for developing serious or life-threatening conditions (infection, organ failure, death) through the use of routine blood tests.

   b) There are no benefits to you for your part in this study.

8. **Other treatments you could get if you decide not to be in this study:**

   You can receive your routine care without taking part in this study.

9. **Payments for your time spent taking part in this study or expenses:**

None

**10. Reasons why the study doctor may take you out of this study:**

You may be taken out of this study if it is determined that you no longer meet inclusion criteria. If you are taken out of this study you will be told why.

**11. 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 the research investigator or research coordinator.

**12. 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 **Jonathan Schoenecker, MD, PhD** at **615-936-3080.** If you cannot reach the research staff, please page the study doctor at **615-835-8211.**

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 Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

**13. Confidentiality:**

During this study every attempt will be made to keep your protected health information (PHI) private. All data obtained from this study will be stored in a password-protected excel file on a secure server and a Vanderbilt REDCap database. REDCap is a secure, web-based application for building and managing online databases. Only research personnel will have access to your study information to ensure confidentiality.

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Schoenecker and his 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.

This study may have some support from the National Institutes of Health (NIH). If so, 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.

**14. Authorization to Use/Disclose Protected Health Information**

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing (“disclosure”) such data must follow

federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Dr. Schoenecker and his study team may share the results of your study, as well as parts of your medical record, to the groups named below. These groups may include people from the: Federal Government Office for Human Research Protections and the Vanderbilt University Institutional Review Board. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data in the study database will be destroyed.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Schoenecker in writing and let him know that you withdraw your consent. His mailing address is 4202 Doctors Office Tower, 2200 Children's Way, Nashville, TN 37212. The health data we stored before you withdrew your consent may still be used for reporting and research quality.

**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.**

**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 Volunteer |

Consent obtained by:

| | |
|---|---|
| Date | Signature |
| | Printed Name and Title |

Time

Surrogate Consent:

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 an investigational treatment may be administered to _____ [participant's name]. I believe receiving such treatment 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 and he/she will receive alternative treatments 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

## Consent for Genetic Research

The purpose of this study is to look at genes (DNA) and how they affect health and disease. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body behaves. They can also tell us a person's risk for certain diseases and how they will respond to treatment.

You are being asked to give a blood sample for genetic research. What we learn about you from this sample 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.

A single blood sample of 1 teaspoon will be drawn from a vein in your arm using a needle. This will take about 5 minutes of your time.

You may feel bothered or pained from the needle stick. You may have a bruise or the site may get infected. It is rare, but some people faint.

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 key study personnel will have access to your name.

Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers with 15 or more employees may not use your genetic information that comes from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Your sample will be used to make 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.

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

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Your samples and information about you may be shared with others to use for research. To protect your privacy, we will not release your name.

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You will not receive any benefit as a result of the tests done on your samples. These tests may help us learn more about the causes, risks, treatments, or how to prevent this and other health problems.

At any time, you may ask to have your sample destroyed. You should contact study staff at Vanderbilt University Medical Center (615) 936-3080 to have your sample destroyed and no longer used for research. 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.

There will be no costs to you for any of the tests done on your samples. You will not be paid for the use of your samples.

**Principal Investigator: Jonathan Schoenecker, MD, PhD** **Revision Date: 5/27/2021**
**Study Title: Disorders of the Acute Phase Response Accelerated by Plasmin Activation Following Trauma and Invasive Surgery: A Prospective Study**
**Institution/Hospital: Vanderbilt University Medical Center**

Please check Yes or No to the questions below:

My blood/tissue sample may be used for gene research in this study.

☐ Yes ☐ No

Signature: _____ Date: _____

# Arm 1 Adult Consent (Version Date: 5/27/21)

**VUMC Institutional Review Board**
**Informed Consent Document for Research Principal Investigator: Jonathan Schoenecker, MD, PhD**

**Study Title: Disorders of the Acute Phase Response Accelerated by Plasmin Activation Following Trauma and Invasive Surgery: A Prospective Study**

**Institution/Hospital: Vanderbilt University Medical Center**

**Version Date: 5/27/2021**
**IRB Approval Date:**
**Expiration Date:**

**This informed consent applies to: adults 18 or older who are trauma patients**

Name of Participant: _____
(First Last)

Age of Participant: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

You do not have to be in this research study. 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.

1. What is the purpose of this study?

You are being asked to take part in this research study because you have a major injury. Researchers at Vanderbilt University Medical Center are attempting to determine how these injuries affect a patient's blood clotting, inflammation, and tissue healing systems. We believe that some patients' response to these injuries cause them to develop serious conditions that can lead to poor wound healing, infection, organ failure. By understanding how a traumatic injury affects these body systems, we hope to be able to identify future trauma patients that may be at risk for developing these serious conditions through routine blood tests and treating them early.

We are enrolling 150 trauma patients.

2. What will happen and how long will you be in the study?

Blood sample from your vein:
As part of your routine care, you will have blood taken from your vein and drawn into a tube. Any blood that is left over from your routine care blood tests will be used for study tests. In most cases you will not need to have any additional blood taken from your vein for this study. If additional blood from your vein is needed, it will be a very small amount, around a teaspoon per blood draw. The additional blood draws would occur at the following time points, if needed:

- Day you enter the hospital
- Every 12 hours until discharge

If you have to undergo surgery for your injury, additional blood draws would occur at the following time points, if needed:

- Immediately prior to your surgery
- Every 30 minutes while you are in surgery
- Every 6 hours for the first 3 days following surgery
- Every 12 hours from 3 days following surgery until your discharge

Blood sample from your finger:
In addition to the blood taken from your vein and drawn into a tube, you may have blood taken from your finger. This will be done for research purposes only. The amount of blood taken from your finger will be a very small amount, around 2 drops. The reason we are taking blood from you using two different methods, vein and finger stick, is to determine if blood taken from a finger stick can provide us with all the data we need so we don't have to take blood from patient veins in the future.

You may have blood taken from your finger at the following time points:

- Day you enter the hospital
- Every 24 hours until discharge

Our study team will also record information from your medical record. This will include information about: you (date of birth, gender, height, weight), your injury/injuries (diagnosis), and your treatment (wound healing).

Your participation in the study will last as long as you are in the hospital for your injuries and when you return to the hospital for your routine care (up to 2 years). If you come back to the hospital for a routine care visit related to your injuries within the next 2 years we will record any problems you have had with your injury and recovery.

3. Costs to you if you take part in this study:

There is no cost to you for taking part in this study.

4. Side effects and risks that you can expect if you take part in this study:

Blood Draw Side Effects
You may experience pain and discomfort at the site where their blood is drawn (vein or finger). There is a chance you may develop a bruise at the site of the blood draw.

Breach of Confidentiality (Rare)
There is a rare chance that the confidentiality of the data we collect about you may be breached by taking part in this study. To lower this risk, all study data will be kept in a secure, password protected database, where only research staff will have access to it.

5. Risks that are not known:

If we discover an unknown risk to this study not listed in Item# 4 we will let you know about it.

6. Payment in case you are injured because of this research study:

If it is determined by Vanderbilt and the Investigator 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 to pay for the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

7. Good effects that might result from this study:

a) The benefits to science and humankind that might result from this study: Ability to identify and treat patient who are at risk for developing serious or life-threatening conditions (infection, organ failure, death) through the use of routine blood tests.

b) There are no benefits to you for your part in this study.

8. Other treatments you could get if you decide not to be in this study:

You can receive your routine care without taking part in this study.

9. Payments for your time spent taking part in this study or expenses:

None

10. Reasons why the study doctor may take you out of this study:

You may be taken out of this study if it is determined that you no longer meet inclusion criteria. If you are taken out of this study you will be told why.

11. 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 the research investigator or research coordinator.

12. 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 Jonathan Schoenecker, MD, PhD at 615-936-3080. If you cannot reach the research staff, please page the study doctor at 615-835-8211.

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 Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

13. Confidentiality:

During this study every attempt will be made to keep your protected health information (PHI) private. All data obtained from this study will be stored in a password-protected excel file on a secure server and in a Vanderbilt REDCap database. REDCap is a secure, web-based application for building and managing online databases. Only research personnel will have access to your study information to ensure confidentiality.

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Schoenecker and his 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.

This study may have some support from the National Institutes of Health (NIH). If so, 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.

14. Authorization to Use/Disclose Protected Health Information

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Dr. Schoenecker and his study team may share the results of your study, as well as parts of your medical record, to the groups named below. These groups may include people from the: Federal Government Office for Human Research Protections and the Vanderbilt University Institutional Review Board. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data in the study database will be destroyed.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Schoenecker in writing and let him know that you withdraw your consent. His mailing address is 4202 Doctors Office Tower, 2200 Children's Way, Nashville, TN 37212. The health data we stored before you withdrew your consent may still be used for reporting and research quality.

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.

## 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.

◯ Yes ◯ No

---

Signature of Patient/Volunteer

_____
(Click "Add signature" and use your mouse (or finger on a touchscreen device) to sign your first and last name.)

---

Date and time signed:

_____
(Date/time of Patient/Volunteer Signature)

---

Surrogate Consent

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 an investigational treatment may be administered to _____ [participant's name]. I believe receiving such treatment 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 and he/she will receive alternative treatments 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 this study and if found to be capable, continued participation in this study would only occur with his/her consent.

Full Name of Health Care Decision-Maker/Surrogate

_____
(First and Last Name)

Relationship of Health Care Decision-Maker/Surrogate

_____
(First and Last Name)

Signature of Health Care Decision-Maker/Surrogate

_____

Date and time surrogate signed:

_____
(Date/time of Patient/Volunteer Signature)

Signature of Witness

_____

Date and time witness signed:

_____
(Date/time of Patient/Volunteer Signature)

## Consent for Genetic Research

The purpose of this study is to look at genes (DNA) and how they affect health and disease. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body behaves. They can also tell us a person's risk for certain diseases and how they will respond to treatment.

You are being asked to give a blood sample for genetic research. What we learn about you from this sample 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.

A single blood sample of 1 teaspoon will be drawn from a vein in your arm using a needle. This will take about 5 minutes of your time.

You may feel bothered or pained from the needle stick. You may have a bruise or the site may get infected. It is rare, but some people faint.

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 key study personnel will have access to your name.

Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers with 15 or more employees may not use your genetic information that comes from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Your sample will be used to make 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.

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

Your samples and information about you may be shared with others to use for research. To protect your privacy, we will not release your name.



You will not receive any benefit as a result of the tests done on your samples. These tests may help us learn more about the causes, risks, treatments, or how to prevent this and other health problems.

At any time, you may ask to have your sample destroyed. You should contact study staff at Vanderbilt University Medical Center (615) 936-3080 to have your sample destroyed and no longer used for research. 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.

There will be no costs to you for any of the tests done on your samples. You will not be paid for the use of your samples.

Please check Yes or No to the questions below:

My blood/tissue sample may be used for gene research in this study. ◯ Yes ◯ No

Signature of patient/volunteer regarding Genetic Rider

_____
(Click "Add signature" and use your mouse (or finger on a touchscreen device) to sign your first and last name.)

Date and time genetic rider signed:

_____
(Date/time of Patient/Volunteer Signature)

## Copy for patient/volunteer records

You may save or print a blank copy of this consent form for your records if you wish. After you submit this form, you will be offered the opportunity to save or print a signed copy of this consent form. If you don't have a PDF reader installed, please click here to install one for free and access this document (link will open in new tab or window): Get Adobe Reader

## Study personnel only

Consent obtained by (please enter full name and title):

_____
(Completed by study personnel at time of consent.)

Date and time consented

_____

**Vanderbilt University Institutional Review Board**
**Informed Consent Document for Research**

**Principal Investigator: Jonathan Schoenecker, MD, PhD** **Version Date: 5/27/2021**
**Study Title: Disorders of the Acute Phase Response Accelerated by Plasmin Activation Following Trauma and Invasive Surgery: A Prospective Study**
**Institution/Hospital: Vanderbilt University Medical Center**

This informed consent applies to: parents or legal guardians of children who are trauma patients

Name of participant: _____ Age: _____

**The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.**

Your child does not have to be in this research study. Your child 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 your child to be in this study. Your child's medical record will contain a note saying your child is in a research study. Anyone you authorize to receive your child's medical record will also get this note.

1. **What is the purpose of this study?**

   Your child is being asked to take part in this research study because he/she has a major injury. Researchers at Vanderbilt University Medical Center are attempting to determine how these injuries affect a patient's blood clotting, inflammation, and tissue healing systems. We believe that some patients' response to these injuries cause them to develop serious conditions that can lead to poor wound healing, infection, organ failure. By understanding how a traumatic injury affects these body systems, we hope to be able to identify future trauma patients that may be at risk for developing these serious conditions through routine blood tests and treating them early.

   We are enrolling 150 trauma patients.

2. **What will happen and how long will your child be in the study?**

   Blood sample from your child's vein:
   As part of your child's routine care, your child will have blood taken from their vein and drawn into a tube. Any blood that is leftover from your child's routine care blood tests will be used for study tests. In most cases your child will not need to have any additional blood taken from their vein for this study. If additional blood from their vein is needed, it will be a very small amount, around ½ a teaspoon per blood draw. The additional blood draws would occur at the following time points, if needed:
   - Day your child entered the hospital
   - Every 12 hours until your child is discharged

   If your child has to undergo surgery for their injury, additional blood draws would occur at the following time points, if needed:
   - Immediately prior to their surgery
   - Every 30 minutes while they are in surgery
   - Every 6 hours for the first 3 days following their surgery
   - Every 12 hours from 3 days following surgery until their discharge

   Our study team will also record information from your child's medical record. This will include information about: your child (date of birth, gender, height, weight), your child's surgical procedure, and notes regarding your child's treatment and recovery (healing).

   Your child's participation in this study will last as long as your child is in the hospital for their injuries and when they return to the hospital for their routine care (up to 2 years). If your child comes back to the hospital for a routine care visit related to their injuries within the next 2 years we will record any problems your child has had related to their injuries.

3. **Costs to you if your child takes part in this study:**

   There is no cost to you/your child for taking part in this study.

   However, you are still responsible for paying for the usual care your child would normally receive for the treatment of their illness. This includes treatments and tests they would need even if they were not in this study. These costs will be billed to you and/or your child's insurance.

   You have the right to ask what it may cost for your child to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your child's insurance company to discuss the costs of their routine care (non-research) further before choosing to be in the study. You may choose for your child not to be in this study if their insurance does not pay for their routine care (non-research) costs and your child's doctor will discuss other treatment plans with you.

4. **Side effects and risks that you can expect if your child take parts in this study:**

   **Blood Draw Side Effects**
   Your child may experience pain and discomfort at the site where their blood is drawn (vein). There is a chance they may develop a bruise at the site of the blood draw.

   **Breach of Confidentiality (Rare)**
   There is a rare chance that the confidentiality of the data we collect about your child may be breached by taking part in this study. To lower this risk, all study data will be kept in a secure, password-protected database, where only research staff will have access to it.

5. **Risks that are not known:**

   There may be risks that we do not know about at this time.

6. **Payment in case your child is injured because of this research study:**

   If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your child's 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 to pay for the costs of any additional care. There are no plans for Vanderbilt to give you/your child money for the injury.

7. **Good effects that might result from this study:**

   a) The benefits to science and humankind that might result from this study- Ability to identify and treat patient who are at risk for developing serious or life-threatening conditions (infection, organ failure, death) through the use of routine blood tests.

   b) There are no benefits to your child for taking part in this study.

8. **Other treatments your child could get if you decide not to allow them to be in this study:**

This is not a treatment study. Your child will receive routine care for their surgery. Participation or non-participation will not affect their care.

9. **Payments for your/your child's time spent taking part in this study or expenses:**

   Your child will not be paid for taking part in this study.

10. **Reasons why the study doctor may take your child out of this study:**

    There is no expected reason why the study doctor will take your child out of this study. However, if your child is removed from the study, the doctor will give you a reason from removing your child.

11. **What will happen if you decide your child should stop being in this study?**

    You may decide to withdraw your child from the study at any time. If you decide for your child to stop being part of the study, you should tell your child's study doctor.

12. **Who to call for any questions or in case your child is injured:**

    If you should have any questions about this research study or if you feel your child has been hurt by being a part of this study, please feel free to contact **Jonathan Schonecker, MD, PhD** at **615-936-3080**. If you cannot reach the research staff, please page the study doctor at **615-835-8211.**

    For additional information about giving consent or your child's 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 Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

13. **Confidentiality:**

    During this study every attempt will be made to keep your child's protected health information (PHI) private. All data obtained from this study will be stored in a password-protected excel file on a secure server and in a Vanderbilt REDCap database. REDCap is a secure, web-based application for building and managing online databases. Only research personnel will have access to your child's study information to ensure confidentiality.

    Vanderbilt may share your child's information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Schoenecker, and their staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you/your child for the use or transfer of this de-identified information.

    This study may have some support from the National Institutes of Health (NIH). If so, 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.

**14. Authorization to Use/Disclose Protected Health Information**

All efforts, within reason, will be made to keep your child's protected health information (PHI) private. PHI is your child's health information that is, or has been gathered or kept by Vanderbilt as a result of their healthcare. This includes data gathered for research studies that can be traced back to your child. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your child's PHI. If you decide for your child to be in this research study, you are also agreeing to let the study team use and share their PHI as described below.

As part of the study, Dr. Schoenecker and his study team may share the results of your child's study and/or non-study linked laboratory tests, as well as parts of their medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections and the Vanderbilt University Institutional Review Board. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your child's PHI private.

The study results will be kept in your child's research record for at least six years after the study is finished. At that time, the research data in the study database will be destroyed. Any research data that has been put into their medical record will be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your child's PHI does not expire. If you change your mind, we ask that you contact Dr. Schoenecker in writing and let him know that you withdraw your consent. His mailing address is 4202 Doctors Office Tower, 2200 Children's Way, Nashville, TN 37212. At that time, we will stop collecting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

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

**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 for my child to take part in this study.**

| | |
|---|---|
| Date | Signature of parent/legal guardian |
| Date | Signature of parent/legal guardian |

Consent obtained by:

| | |
|---|---|
| Date | Signature |
| | Printed Name and Title |

**STUDY PERSONNEL CONSENT INSTRUCTIONS**

Consent must be obtained from both parents or legal guardians of the study participant unless one parent or legal guardian is deceased, unknown, incompetent, or not reasonably available, or when only one parent or legal guardian has legal responsibility for the care and custody of the child.

☐ Obtaining a signature from the second parent or legal guardian **IS NOT** possible for one of the above reasons noted above. Please document reason for not obtaining second parent or legal guardian signature in REDCap study database or provide documentation to research coordinator for filing.

## Consent for Genetic Research

The purpose of this study is to look at genes (DNA) and how they affect health and disease. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body behaves. They can also tell us a person's risk for certain diseases and how they will respond to treatment.

You are being asked to give a blood sample for genetic research. What we learn about you from this sample 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.

A single blood sample of 1 teaspoon will be drawn from a vein in your arm using a needle. This will take about 5 minutes of your time.

You may feel bothered or pained from the needle stick. You may have a bruise or the site may get infected. It is rare, but some people faint.

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 key study personnel will have access to your name.

Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers with 15 or more employees may not use your genetic information that comes from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Your sample will be used to make 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.

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

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Your samples and information about you may be shared with others to use for research. To protect your privacy, we will not release your name.

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You will not receive any benefit as a result of the tests done on your samples. These tests may help us learn more about the causes, risks, treatments, or how to prevent this and other health problems.

At any time, you may ask to have your sample destroyed. You should contact study staff at Vanderbilt University Medical Center (615) 936-3080 to have your sample destroyed and no longer used for research. 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.

There will be no costs to you for any of the tests done on your samples. You will not be paid for the use of your samples.

Please check Yes or No to the questions below:

My blood/tissue sample may be used for gene research in this study.

☐ Yes ☐ No

Parent/Legal Guardian 1 Signature: _____ Date: _____

Parent/Legal Guardian 2 Signature: _____ Date: _____

**STUDY PERSONNEL CONSENT INSTRUCTIONS**

Consent must be obtained from both parents or legal guardians of the study participant unless one parent or legal guardian is deceased, unknown, incompetent, or not reasonably available, or when only one parent or legal guardian has legal responsibility for the care and custody of the child.

☐ Obtaining a signature from the second parent or legal guardian **IS NOT** possible for one of the above reasons noted above. Please document reason for not obtaining second parent or legal guardian signature in REDCap study database or provide documentation to research coordinator for filing.

# Arm 1 Parent Consent (Version Date: 5/27/21)

**VUMC Institutional Review Board**
**Informed Consent Document for Research Principal Investigator: Jonathan Schoenecker, MD, PhD**

**Study Title: Disorders of the Acute Phase Response Accelerated by Plasmin Activation Following Trauma and Invasive Surgery: A Prospective Study**

**Institution/Hospital: Vanderbilt University Medical Center**

**Version Date: 5/27/2021**
**IRB Approval Date:**
**Expiration Date:**

**This informed consent applies to: parents or legal guardians of children who are trauma patients**

Name of Participant: _____
(First Last)

Age of Participant: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Your child does not have to be in this research study. Your child 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 your child to be in this study. Your child's medical record will contain a note saying your child is in a research study. Anyone you authorize to receive your child's medical record will also get this note.

1. What is the purpose of this study?

Your child is being asked to take part in this research study because he/she has a major injury. Researchers at Vanderbilt University Medical Center are attempting to determine how these injuries affect a patient's blood clotting, inflammation, and tissue healing systems. We believe that some patients' response to these injuries cause them to develop serious conditions that can lead to poor wound healing, infection, organ failure. By understanding how a traumatic injury affects these body systems, we hope to be able to identify future trauma patients that may be at risk for developing these serious conditions through routine blood tests and treating them early.

We are enrolling 150 trauma patients.

2. What will happen and how long will your child be in the study?

Blood sample from your child's vein:
As part of your child's routine care, your child will have blood taken from their vein and drawn into a tube. Any blood that is leftover from your child's routine care blood tests will be used for study tests. In most cases your child will not need to have any additional blood taken from their vein for this study. If additional blood from their vein is needed, it will be a very small amount, around ½ a teaspoon per blood draw. The additional blood draws would occur at the following time points, if needed:

- Day your child entered the hospital
- Every 12 hours until your child is discharged

If your child has to undergo surgery for their injury, additional blood draws would occur at the following time points, if needed:

- Immediately prior to their surgery
- Every 30 minutes while they are in surgery
- Every 6 hours for the first 3 days following their surgery
- Every 12 hours from 3 days following surgery until their discharge

Our study team will also record information from your child's medical record. This will include information about: your child (date of birth, gender, height, weight), your child's surgical procedure, and notes regarding your child's treatment and recovery (healing).

Your child's participation in this study will last as long as your child is in the hospital for their injuries and when they return to the hospital for their routine care (up to 2 years). If your child comes back to the hospital for a routine care visit related to their injuries within the next 2 years we will record any problems your child has had related to their injuries.

3. Costs to you if your child takes part in this study:

There is no cost to you/your child for taking part in this study.

However, you are still responsible for paying for the usual care your child would normally receive for the treatment of their illness. This includes treatments and tests they would need even if they were not in this study. These costs will be billed to you and/or your child's insurance.

You have the right to ask what it may cost for your child to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your child's insurance company to discuss the costs of their routine care (non-research) further before choosing to be in the study. You may choose for your child not to be in this study if their insurance does not pay for their routine care (non-research) costs and your child's doctor will discuss other treatment plans with you.

4. Side effects and risks that you can expect if your child take parts in this study:

Blood Draw Side Effects
Your child may experience pain and discomfort at the site where their blood is drawn (vein). There is a chance they may develop a bruise at the site of the blood draw.



Breach of Confidentiality (Rare)

There is a rare chance that the confidentiality of the data we collect about your child may be breached by taking part in this study. To lower this risk, all study data will be kept in a secure, password-protected database, where only research staff will have access to it.

5. Risks that are not known:

There may be risks that we do not know about at this time.

6. Payment in case your child is injured because of this research study:

If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your child's 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 to pay for the costs of any additional care. There are no plans for Vanderbilt to give you/your child money for the injury.

7. Good effects that might result from this study:

a) The benefits to science and humankind that might result from this study- Ability to identify and treat patient who are at risk for developing serious or life-threatening conditions (infection, organ failure, death) through the use of routine blood tests.

b) There are no benefits to your child for taking part in this study.

8. Other treatments your child could get if you decide not to allow them to be in this study:

This is not a treatment study. Your child will receive routine care for their surgery. Participation or non-participation will not affect their care.

9. Payments for your/your child's time spent taking part in this study or expenses:

Your child will not be paid for taking part in this study.

10. Reasons why the study doctor may take your child out of this study:

There is no expected reason why the study doctor will take your child out of this study. However, if your child is removed from the study, the doctor will give you a reason from removing your child.

11. What will happen if you decide your child should stop being in this study?

You may decide to withdraw your child from the study at any time. If you decide for your child to stop being part of the study, you should tell your child's study doctor.

12. Who to call for any questions or in case your child is injured:

If you should have any questions about this research study or if you feel your child has been hurt by being a part of this study, please feel free to contact Jonathan Schonecker, MD, PhD at 615-936-3080. If you cannot reach the research staff, please page the study doctor at 615-835-8211.

For additional information about giving consent or your child's 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 Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

13. Confidentiality:

During this study every attempt will be made to keep your child's protected health information (PHI) private. All data obtained from this study will be stored in a password-protected excel file on a secure server and in a Vanderbilt REDCap database. REDCap is a secure, web-based application for building and managing online databases. Only research personnel will have access to your child's study information to ensure confidentiality.

Vanderbilt may share your child's information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Schoenecker, and their staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you/your child for the use or transfer of this de-identified information.

This study may have some support from the National Institutes of Health (NIH). If so, 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.

14. Authorization to Use/Disclose Protected Health Information

All efforts, within reason, will be made to keep your child's protected health information (PHI) private. PHI is your child's health information that is, or has been gathered or kept by Vanderbilt as a result of their healthcare. This includes data gathered for research studies that can be traced back to your child. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your child's PHI. If you decide for your child to be in this research study, you are also agreeing to let the study team use and share their PHI as described below.

As part of the study, Dr. Schoenecker and his study team may share the results of your child's study and/or non-study linked laboratory tests, as well as parts of their medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections and the Vanderbilt University Institutional Review Board. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your child's PHI private.

The study results will be kept in your child's research record for at least six years after the study is finished. At that time, the research data in the study database will be destroyed. Any research data that has been put into their medical record will be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your child's PHI does not expire. If you change your mind, we ask that you contact Dr. Schoenecker in writing and let him know that you withdraw your consent. His mailing address is 4202 Doctors Office Tower, 2200 Children's Way, Nashville, TN 37212. At that time, we will stop collecting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

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

**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.

◯ Yes ◯ No

Signature of First Parent/Legal Guardian

_____
(Click "Add signature" and use your mouse (or finger on a touchscreen device) to sign your first and last name.)

Date and time First parent/guardian signed:

_____
(Date/time of Patient/Volunteer Signature)

Signature of Second Parent/Legal Guardian

_____
(Click "Add signature" and use your mouse (or finger on a touchscreen device) to sign your first and last name.)

Date and time Second parent/guardian signed:

_____
(Date/time of Patient/Volunteer Signature)

## Consent for Genetic Research

The purpose of this study is to look at genes (DNA) and how they affect health and disease. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body behaves. They can also tell us a person's risk for certain diseases and how they will respond to treatment.

You are being asked to give a blood sample for genetic research. What we learn about you from this sample 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.

A single blood sample of 1 teaspoon will be drawn from a vein in your arm using a needle. This will take about 5 minutes of your time.

You may feel bothered or pained from the needle stick. You may have a bruise or the site may get infected. It is rare, but some people faint.

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 key study personnel will have access to your name.

Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers with 15 or more employees may not use your genetic information that comes from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Your sample will be used to make 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.

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

Your samples and information about you may be shared with others to use for research. To protect your privacy, we will not release your name.

You will not receive any benefit as a result of the tests done on your samples. These tests may help us learn more about the causes, risks, treatments, or how to prevent this and other health problems.

At any time, you may ask to have your sample destroyed. You should contact study staff at Vanderbilt University Medical Center (615) 936-3080 to have your sample destroyed and no longer used for research. 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.

There will be no costs to you for any of the tests done on your samples. You will not be paid for the use of your samples.

Please check Yes or No to the questions below:

My blood/tissue sample may be used for gene research in this study. ◯ Yes ◯ No

Signature of parent/guardian 1 regarding Genetic Rider

_____
(Click "Add signature" and use your mouse (or finger on a touchscreen device) to sign your first and last name.)

Date and time parent/guardian 1 signed Genetic Rider

_____
(Date/time of Patient/Volunteer Signature)

Signature of parent/guardian 2 regarding Genetic Rider

_____
(Click "Add signature" and use your mouse (or finger on a touchscreen device) to sign your first and last name.)

Date and time parent/guardian 2 signed Genetic Rider

_____
(Date/time of Patient/Volunteer Signature)

## Copy for patient/volunteer records

You may save or print a blank copy of this consent form for your records if you wish. After you submit this form, you will be offered the opportunity to save or print a signed copy of this consent form. If you don't have a PDF reader installed, please click here to install one for free and access this document (link will open in new tab or window): Get Adobe Reader

## Study personnel only

Consent obtained by (please enter full name and title):

_____
(Completed by study personnel at time of consent.)

Date and time consented

_____

Vanderbilt University Institutional Review Board
Proposal for Research Using Human Participants
**Assent Document for Research Study**

Principal Investigator: Jonathan Schoenecker, MD, PhD Version Date: 10/15/2020
Study Title: Disorders of the Acute Phase Response Accelerated by Plasmin Activation Following Trauma and Invasive Surgery: A Prospective Study
Institution/Hospital: Vanderbilt University Medical Center, Vanderbilt Children's Hospital

This assent document applies to: children ages 7-12 undergoing invasive elective surgery

Name of participant _____ Age___

**Below are the answers to some of the questions you may have. If you have any questions about what is written below or have any other questions about this research, please ask them. You will be given a copy of this consent form.**

1. **Why are you doing this research?**

   We are doing a study to learn more about how your surgery affects your body.

2. **What will I do and how long will it take?**

   You will not have to do anything extra to participate in the project. You will have blood taken from you as part of your normal hospital stay. You may have to have some extra blood taken from your vein. This study will last as long as you are in the hospital and you will not have to come back to the hospital after you go home for this study. If you come back to the hospital for a routine follow-up or a problem related to your injury in the next 2 years we will record why you returned to the hospital.

3. **Do I have to be in this research study and can I stop if I want to?**

   You do not have to be in this study. You may stop being a part of this study at any time if you want to. If you would like to stop, tell your parents or your study doctor. Any data that has been collected on you will be kept, but no extra data will be recorded.

4. **Could it make me sick [or sicker]?**

   This project will not make you sick or sicker.

5. **Will anyone know that I am in this research study?**

   The only people who will know are your nurses, doctor, study doctor, and study staff.

6. **How will this research help me or other people?**

   This research will not help you, but this research may help patients in the future.

7. **Can I do something else instead of this research?**

   You do not have to participate in this study if you do not want to.

8. **Who do I talk to if I have questions?**

   The study doctor, staff, or your parents.

Vanderbilt University Institutional Review Board
Proposal for Research Using Human Participants
**Assent Document for Research Study**

Principal Investigator: Jonathan Schoenecker, MD, PhD Version Date: 10/15/2020
Study Title: Disorders of the Acute Phase Response Accelerated by Plasmin Activation Following Trauma and Invasive Surgery: A Prospective Study
Institution/Hospital: Vanderbilt University Medical Center, Vanderbilt Children's Hospital

| | |
|---|---|
| Date | Signature of patient |

Consent obtained by:

| | |
|---|---|
| Date | Signature |
| | Printed Name and Title |

# Arm 2 Assent 7-12yo (Version date: 5/13/21)

**VUMC Institutional Review Board**

**Assent Document for Research Study Principal Investigator: Jonathan Schoenecker, MD, PhD**

**Study Title: Disorders of the Acute Phase Response Accelerated by Plasmin Activation Following Trauma and Invasive Surgery: A Prospective Study**

**Institution/Hospital: Vanderbilt University Medical Center**

**Version Date: 5/13/2021**
**IRB Approval Date:**
**Expiration Date:**

**This assent document applies to: children ages 7-12 undergoing invasive elective surgery**

Name of Participant: _____
(First Last)

Age of Participant: _____

Below are the answers to some of the questions you may have. If you have any questions about what is written below or have any other questions about this research, please ask them. You will be given a copy of this consent form.

1. Why are you doing this research?

We are doing a study to learn more about how your surgery affects your body.

2. What will I do and how long will it take?

You will not have to do anything extra to participate in the project. You will have blood taken from you as part of your normal hospital stay. You may have to have some extra blood taken from your vein. This study will last as long as you are in the hospital and you will not have to come back to the hospital after you go home for this study. If you come back to the hospital for a routine follow-up or a problem related to your injury in the next 2 years we will record why you returned to the hospital.

3. Do I have to be in this research study and can I stop if I want to?

You do not have to be in this study. You may stop being a part of this study at any time if you want to. If you would like to stop, tell your parents or your study doctor. Any data that has been collected on you will be kept, but no extra data will be recorded.

4. Could it make me sick [or sicker]?

This project will not make you sick or sicker.

5. Will anyone know that I am in this research study?

The only people who will know are your nurses, doctor, study doctor, and study staff.

6. How will this research help me or other people?

This research will not help you, but this research may help patients in the future.

7. Can I do something else instead of this research?

You do not have to participate in this study if you do not want to.

8. Who do I talk to if I have questions?

The study doctor, staff, or your parents.

## Signature

Signature of Patient/Volunteer

_____
(Click "Add signature" and use your mouse (or finger on a touchscreen device) to sign your first and last name.)

Date and time signed:

_____
(Date/time of Patient/Volunteer Signature)

## Copy for patient/volunteer records

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## Study personnel only

Assent obtained by (please enter full name and title):

_____
(Completed by study personnel at time of consent.)

Date and time assented

_____

Vanderbilt University Institutional Review Board
Proposal for Research Using Human Participants
**Assent Document for Research Study**

**PI: Jonathan Schoenecker, MD, PhD** **Version Date: 10/15/2020**
**Title of Study: Disorders of the Acute Phase Response Accelerated by Plasmin Activation Following Trauma and Invasive Surgery: A Prospective Study**

**Institution/Hospital: Vanderbilt University Medical Center, Vanderbilt Children's Hospital**

This assent document applies to: children ages 13-17 years old undergoing invasive elective surgery

Name of participant _____ Age___

**Below are the answers to some of the questions you may have. If you have any questions about what is written below or have any other questions about this research, please ask them. You will be given a copy of this consent form.**

1. **Why are you doing this research?**

   We are doing this study to learn more about how your surgery affects your body's ability to protect itself (inflammation), the way your blood clots (coagulation), how your body cleans up those clots (fibrinolysis), and the way your body heals after a surgery.

   We are enrolling 150 patients having elective major surgery.

2. **What will I do and how long will it take?**

   Blood sample from your vein:
   As part of your routine care, you will have blood taken from your vein and drawn into a tube. Any blood that is left over from your routine care blood tests will be used for study tests. In most cases you will not need to have any additional blood taken from your vein for this study. If additional blood from your vein is needed, it will be a very small amount, around a teaspoon per blood draw. The additional blood draws would occur at the following time points, if needed:
   - Immediately before surgery
   - Every 30 minutes during surgery
   - Every 6 hours for 3 days after surgery
   - Every 12 hours from 3 days after surgery until discharge

   Our study team will also record information from your medical record. This will include information about: you (date of birth, gender, height, weight), your surgery, and notes about your treatment and recovery your treatment (healing).

   Your participation in the study will last as long as you are in the hospital for your surgery. If you come back to the hospital for a routine care visit we will record any problems you have had after your surgery.

3. **Do I have to be in this research study and can I stop if I want to?**

   You do not have to be in this project. You may stop any time that you want to. If you would like to stop, tell your parents or the study doctor. Any data that has been collected on you will be kept, but no additional data will be recorded.

4. **Could it make me sick [or sicker]?**

   **Blood Draw Side Effects:** You may experience pain and discomfort at the site where the blood is drawn (vein). There is a chance you may develop a bruise at the site of the blood draw.

5. **Will anyone know that I am in this research study?**

   The only people who will know are your nurses, doctor, study doctor, and study staff.

**PI: Jonathan Schoenecker, MD, PhD** **Version Date: 10/15/2020**
**Title of Study: Disorders of the Acute Phase Response Accelerated by Plasmin Activation Following Trauma and Invasive Surgery: A Prospective Study**

**Institution/Hospital: Vanderbilt University Medical Center, Vanderbilt Children's Hospital**

6. **How will this research help me or other people?**

   This research will not help you, but this research may help patients undergoing major surgeries in the future. We hope this study will help us learn more about why certain patients develop conditions after major surgeries that make them very sick and make it harder for them to heal. By doing so, we hope to stop patients from becoming sick after surgery and to help them heal faster.

7. **Can I do something else instead of this research?**

   You do not have to participate in this research project if you do not want to.

8. **Who do I talk to if I have questions?**

   The study doctor or your parents.

_____ _____
Date Signature of patient/volunteer

Consent obtained by:

_____ _____
Date Signature

_____
Printed Name and Title

# Arm 2 Assent 13-17yo (Version date: 5/13/21)

**VUMC Institutional Review Board**
**Assent Document for Research Study Principal Investigator: Jonathan Schoenecker, MD, PhD**

**Study Title: Disorders of the Acute Phase Response Accelerated by Plasmin Activation Following Trauma and Invasive Surgery: A Prospective Study**

**Institution/Hospital: Vanderbilt University Medical Center**

**Version Date: 5/13/2021**
**IRB Approval Date:**
**Expiration Date:**

**This assent document applies to: children ages 13-17 years old undergoing invasive elective surgery**

Name of Participant: _____
(First Last)

Age of Participant: _____

Below are the answers to some of the questions you may have. If you have any questions about what is written below or have any other questions about this research, please ask them. You will be given a copy of this consent form.

1. Why are you doing this research?

We are doing this study to learn more about how your surgery affects your body's ability to protect itself (inflammation), the way your blood clots (coagulation), how your body cleans up those clots (fibrinolysis), and the way your body heals after a surgery.

We are enrolling 150 patients having elective major surgery.

2. What will I do and how long will it take?

Blood sample from your vein:
As part of your routine care, you will have blood taken from your vein and drawn into a tube. Any blood that is left over from your routine care blood tests will be used for study tests. In most cases you will not need to have any additional blood taken from your vein for this study. If additional blood from your vein is needed, it will be a very small amount, around a teaspoon per blood draw. The additional blood draws would occur at the following time points, if needed:

- Immediately before surgery
- Every 30 minutes during surgery
- Every 6 hours for 3 days after surgery
- Every 12 hours from 3 days after surgery until discharge

Our study team will also record information from your medical record. This will include information about: you (date of birth, gender, height, weight), your surgery, and notes about your treatment and recovery your treatment (healing).

Your participation in the study will last as long as you are in the hospital for your surgery. If you come back to the hospital for a routine care visit we will record any problems you have had after your surgery.

3. Do I have to be in this research study and can I stop if I want to?

You do not have to be in this project. You may stop any time that you want to. If you would like to stop, tell your parents or the study doctor. Any data that has been collected on you will be kept, but no additional data will be recorded.

4. Could it make me sick [or sicker]?

Blood Draw Side Effects: You may experience pain and discomfort at the site where the blood is drawn (vein). There is a chance you may develop a bruise at the site of the blood draw.

5. Will anyone know that I am in this research study?

The only people who will know are your nurses, doctor, study doctor, and study staff.

6. How will this research help me or other people?

This research will not help you, but this research may help patients undergoing major surgeries in the future. We hope this study will help us learn more about why certain patients develop conditions after major surgeries that make them very sick and make it harder for them to heal. By doing so, we hope to stop patients from becoming sick after surgery and to help them heal faster.

7. Can I do something else instead of this research?

You do not have to participate in this research project if you do not want to.

8. Who do I talk to if I have questions?

The study doctor or your parents.

## Signature

Signature of Patient/Volunteer

_____

(Click "Add signature" and use your mouse (or finger on a touchscreen device) to sign your first and last name.)

Date and time signed:

_____

(Date/time of Patient/Volunteer Signature)

## Copy for patient/volunteer records

You may save or print a blank copy of this consent form for your records if you wish. After you submit this form, you will be offered the opportunity to save or print a signed copy of this consent form. If you don't have a PDF reader installed, please click here to install one for free and access this document (link will open in new tab or window): Get Adobe Reader

## Study personnel only

Assent obtained by (please enter full name and title):

_____

(Completed by study personnel at time of consent.)

Date and time assented

_____

**Vanderbilt University Institutional Review Board**
**Informed Consent Document for Research**

**Principal Investigator: Jonathan Schoenecker, MD, PhD** **Revision Date: 5/27/2021**
**Study Title: Disorders of the Acute Phase Response Accelerated by Plasmin Activation Following Trauma and Invasive Surgery: A Prospective Study**
**Institution/Hospital: Vanderbilt University Medical Center**

This informed consent applies to: adults 18 or older undergoing invasive elective surgery

Name of participant: _____ Age: _____

**The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.**

You do not have to be in this research study. 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.

1. **What is the purpose of this study?**

   You are being asked to take part in this research study because you are undergoing a major surgery. Researchers at Vanderbilt University Medical Center are attempting to determine how these surgeries affect a patient's blood clotting, inflammation, and tissue healing systems. We believe that some patients' response to major surgeries cause them to develop serious conditions that can lead to poor wound healing, infection, organ failure. By understanding how a major surgery affects these body systems, we hope to be able to identify future patients that may be at risk for developing these serious conditions after surgery through routine blood tests and treating them early.

   We are enrolling 150 patients who will have elective major surgery.

2. **What will happen and how long will you be in the study?**

   Blood sample from your vein:
   As part of your routine care, you will have blood taken from your vein and drawn into a tube. Any blood that is left over from your routine care blood tests will be used for study tests. In most cases you will not need to have any additional blood taken from your vein for this study. If additional blood from your vein is needed, it will be a very small amount, around a teaspoon per blood draw. The additional blood draws would occur at the following time points, if needed:
   - Immediately before surgery
   - Every 30 minutes during surgery
   - Every 6 hours for 3 days after surgery
   - Every 12 hours from 3 days after surgery until discharge

   Blood sample from your finger:
   In addition to the blood taken from your vein and drawn into a tube, you may have blood taken from your finger. This will be done for research purposes only. The amount of blood taken from your finger will be a very small amount, around 2 drops. The reason we are taking blood from you using two different methods, vein and finger stick, is to determine if blood taken from a finger stick can provide us with all the data we need so we don't have to take blood from patient veins in the future.

   You may have blood taken from your finger at the following time points:
   - Every 12 hours after surgery until your discharge

   Our study team will also record information from your medical record. This will include information about: you (date of birth, gender, height, weight), your surgery, and notes about your treatment and recovery your treatment (healing).

Your participation in the study will last as long as you are in the hospital for your surgery and when you return to the hospital for your routine care (up to 2 years). If you come back to the hospital for a routine care visit related to your surgery within the next 2 years we will record any problems you have had after your surgery.

3. **Costs to you if you take part in this study:**

   There is no cost to you for taking part in this study.

4. **Side effects and risks that you can expect if you take part in this study:**

   **Blood Draw Side Effects**
   You may experience pain and discomfort at the site where their blood is drawn (vein or finger). There is a chance they may develop a bruise at the site of the blood draw.

   **Breach of Confidentiality (Rare)**
   There is a rare chance that the confidentiality of the data we collect about you may be breached by taking part in this study. To lower this risk, all study data will be kept in a secure, password-protected database, where only research staff will have access to it.

5. **Risks that are not known:**

   If we discover an unknown risk to this study not listed in Item# 4 we will let you know about it.

6. **Payment in case you are injured because of this research study:**

   If it is determined by Vanderbilt and the Investigator 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 to pay for the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

7. **Good effects that might result from this study:**

   a) The benefits to science and humankind that might result from this study: May help patients undergoing major surgeries in the future. We hope this study will help us learn more about why certain patients develop conditions after major surgeries that make them very sick and make it harder for them to heal. By doing so, we hope to stop patients from becoming sick after surgery and to help them heal faster.

   b) There are no benefits to you for your part in this study.

8. **Other treatments you could get if you decide not to be in this study:**

   You can receive your routine care surgery without taking part in this study.

9. **Payments for your time spent taking part in this study or expenses:**

   None

**10. Reasons why the study doctor may take you out of this study:**

You may be taken out of this study if it is determined that you no longer meet inclusion criteria. If you are taken out of this study you will be told why.

**11. 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 the research investigator or research coordinator.

**12. 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 **Jonathan Schoenecker, MD, PhD** at **615-936-3080.** If you cannot reach the research staff, please page the study doctor at **615-835-8211.**

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 Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

**13. Confidentiality:**

During this study every attempt will be made to keep your protected health information (PHI) private. All data obtained from this study will be stored in a password-protected excel file on a secure server and in a Vanderbilt REDCap database. REDCap is a secure, web-based application for building and managing online databases. Only research personnel will have access to your study information to ensure confidentiality.

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Schoenecker and his 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.

This study may have some support from the National Institutes of Health (NIH). If so, 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.

**14. Authorization to Use/Disclose Protected Health Information**

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing (“disclosure”) such data must follow federal privacy rules. By signing the consent for this study, you are agreeing (“authorization”) to the uses and likely

sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Dr. Schoenecker and his study team may share the results of your study, as well as parts of your medical record, to the groups named below. These groups may include people from the: Federal Government Office for Human Research Protections, the Vanderbilt University Institutional Review Board, and the National Institutes of Health. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data in the study database will be destroyed.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Schoenecker in writing and let him know that you withdraw your consent. His mailing address is 4202 Doctors Office Tower, 2200 Children's Way, Nashville, TN 37212. The health data we stored before you withdrew your consent may still be used for reporting and research quality.

**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.**

**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 Volunteer |

Consent obtained by:

| | |
|---|---|
| Date | Signature |
| | Printed Name and Title |

Time

## Consent for Genetic Research

The purpose of this study is to look at genes (DNA) and how they affect health and disease. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body behaves. They can also tell us a person's risk for certain diseases and how they will respond to treatment.

You are being asked to give a blood sample for genetic research. What we learn about you from this sample 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.

A single blood sample of 1 teaspoon will be drawn from a vein in your arm using a needle. This will take about 5 minutes of your time.

You may feel bothered or pained from the needle stick. You may have a bruise or the site may get infected. It is rare, but some people faint.

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 key study personnel will have access to your name.

Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers with 15 or more employees may not use your genetic information that comes from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Your sample will be used to make 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.

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

---

Your samples and information about you may be shared with others to use for research. To protect your privacy, we will not release your name.

---

You will not receive any benefit as a result of the tests done on your samples. These tests may help us learn more about the causes, risks, treatments, or how to prevent this and other health problems.

At any time, you may ask to have your sample destroyed. You should contact study staff at Vanderbilt University Medical Center (615) 936-3080 to have your sample destroyed and no longer used for research. 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.

There will be no costs to you for any of the tests done on your samples. You will not be paid for the use of your samples.

**Principal Investigator: Jonathan Schoenecker, MD, PhD** **Revision Date: 5/27/2021**
**Study Title: Disorders of the Acute Phase Response Accelerated by Plasmin Activation Following Trauma and Invasive Surgery: A Prospective Study**
**Institution/Hospital: Vanderbilt University Medical Center**

Please check Yes or No to the questions below:

My blood/tissue sample may be used for gene research in this study.

☐ Yes ☐ No

Signature: _____ Date: _____

# Arm 2 Adult Consent (Version Date: 5/27/21)

**VUMC Institutional Review Board**
**Informed Consent Document for Research Principal Investigator: Jonathan Schoenecker, MD, PhD**

**Study Title: Disorders of the Acute Phase Response Accelerated by Plasmin Activation Following Trauma and Invasive Surgery: A Prospective Study**

**Institution/Hospital: Vanderbilt University Medical Center**

**Version Date: 5/27/2021**
**IRB Approval Date:**
**Expiration Date:**

**This informed consent applies to: adults 18 or older undergoing invasive elective surgery**

Name of Participant: _____
(First Last)

Age of Participant: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

You do not have to be in this research study. 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.

1. What is the purpose of this study?

You are being asked to take part in this research study because you are undergoing a major surgery. Researchers at Vanderbilt University Medical Center are attempting to determine how these surgeries affect a patient's blood clotting, inflammation, and tissue healing systems. We believe that some patients' response to major surgeries cause them to develop serious conditions that can lead to poor wound healing, infection, organ failure. By understanding how a major surgery affects these body systems, we hope to be able to identify future patients that may be at risk for developing these serious conditions after surgery through routine blood tests and treating them early.

We are enrolling 150 patients who will have elective major surgery.

2. What will happen and how long will you be in the study?

Blood sample from your vein:
As part of your routine care, you will have blood taken from your vein and drawn into a tube. Any blood that is left over from your routine care blood tests will be used for study tests. In most cases you will not need to have any additional blood taken from your vein for this study. If additional blood from your vein is needed, it will be a very small amount, around a teaspoon per blood draw. The additional blood draws would occur at the following time points, if needed:

- Immediately before surgery
- Every 30 minutes during surgery
- Every 6 hours for 3 days after surgery
- Every 12 hours from 3 days after surgery until discharge

Blood sample from your finger:
In addition to the blood taken from your vein and drawn into a tube, you may have blood taken from your finger. This will be done for research purposes only. The amount of blood taken from your finger will be a very small amount, around 2 drops. The reason we are taking blood from you using two different methods, vein and finger stick, is to determine if blood taken from a finger stick can provide us with all the data we need so we don't have to take blood from patient veins in the future.

You may have blood taken from your finger at the following time points:

- Every 12 hours after surgery until your discharge

Our study team will also record information from your medical record. This will include information about: you (date of birth, gender, height, weight), your surgery, and notes about your treatment and recovery your treatment (healing).

Your participation in the study will last as long as you are in the hospital for your surgery and when you return to the hospital for your routine care (up to 2 years). If you come back to the hospital for a routine care visit related to your surgery within the next 2 years we will record any problems you have had after your surgery.

3. Costs to you if you take part in this study:

There is no cost to you for taking part in this study.

4. Side effects and risks that you can expect if you take part in this study:

Blood Draw Side Effects
You may experience pain and discomfort at the site where their blood is drawn (vein or finger). There is a chance they may develop a bruise at the site of the blood draw.

Breach of Confidentiality (Rare)
There is a rare chance that the confidentiality of the data we collect about you may be breached by taking part in this study. To lower this risk, all study data will be kept in a secure, password-protected database, where only research staff will have access to it.



5. Risks that are not known:

If we discover an unknown risk to this study not listed in Item # 4 we will let you know about it.

6. Payment in case you are injured because of this research study:

If it is determined by Vanderbilt and the Investigator 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 to pay for the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

7. Good effects that might result from this study:

a) The benefits to science and humankind that might result from this study: May help patients undergoing major surgeries in the future. We hope this study will help us learn more about why certain patients develop conditions after major surgeries that make them very sick and make it harder for them to heal. By doing so, we hope to stop patients from becoming sick after surgery and to help them heal faster.

b) There are no benefits to you for your part in this study.

8. Other treatments you could get if you decide not to be in this study:

You can receive your routine care surgery without taking part in this study.

9. Payments for your time spent taking part in this study or expenses:

None

10. Reasons why the study doctor may take you out of this study:

You may be taken out of this study if it is determined that you no longer meet inclusion criteria. If you are taken out of this study you will be told why.

11. 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 the research investigator or research coordinator.

12. 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 Jonathan Schoenecker, MD, PhD at 615-936-3080. If you cannot reach the research staff, please page the study doctor at 615-835-8211.

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 Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

13. Confidentiality:

During this study every attempt will be made to keep your protected health information (PHI) private. All data obtained from this study will be stored in a password-protected excel file on a secure server and in a Vanderbilt REDCap database. REDCap is a secure, web-based application for building and managing online databases. Only research personnel will have access to your study information to ensure confidentiality.

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Schoenecker and his 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.

This study may have some support from the National Institutes of Health (NIH). If so, 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.



14. Authorization to Use/Disclose Protected Health Information

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Dr. Schoenecker and his study team may share the results of your study, as well as parts of your medical record, to the groups named below. These groups may include people from the: Federal Government Office for Human Research Protections, the Vanderbilt University Institutional Review Board, and the National Institutes of Health. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data in the study database will be destroyed.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Schoenecker in writing and let him know that you withdraw your consent. His mailing address is 4202 Doctors Office Tower, 2200 Children's Way, Nashville, TN 37212. The health data we stored before you withdrew your consent may still be used for reporting and research quality.

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.

## 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.

◯ Yes ◯ No

Signature of Patient/Volunteer

_____
(Click "Add signature" and use your mouse (or finger on a touchscreen device) to sign your first and last name.)

Date and time signed:

_____
(Date/time of Patient/Volunteer Signature)

## Consent for Genetic Research

The purpose of this study is to look at genes (DNA) and how they affect health and disease. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body behaves. They can also tell us a person's risk for certain diseases and how they will respond to treatment.

You are being asked to give a blood sample for genetic research. What we learn about you from this sample 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.

A single blood sample of 1 teaspoon will be drawn from a vein in your arm using a needle. This will take about 5 minutes of your time.

You may feel bothered or pained from the needle stick. You may have a bruise or the site may get infected. It is rare, but some people faint.

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 key study personnel will have access to your name.

Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers with 15 or more employees may not use your genetic information that comes from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Your sample will be used to make 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.

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

Your samples and information about you may be shared with others to use for research. To protect your privacy, we will not release your name.

You will not receive any benefit as a result of the tests done on your samples. These tests may help us learn more about the causes, risks, treatments, or how to prevent this and other health problems.

At any time, you may ask to have your sample destroyed. You should contact study staff at Vanderbilt University Medical Center (615) 936-3080 to have your sample destroyed and no longer used for research. 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.

There will be no costs to you for any of the tests done on your samples. You will not be paid for the use of your samples.

Please check Yes or No to the questions below:

My blood/tissue sample may be used for gene research in this study. ◯ Yes ◯ No

Signature of Patient/Volunteer regarding Genetic Rider

_____
(Click "Add signature" and use your mouse (or finger on a touchscreen device) to sign your first and last name.)

Date and time genetic rider signed:

_____
(Date/time of Patient/Volunteer Signature)

Date of IRB Approval: 05/26/2021
Date of Expiration: 12/30/2021

Institutional Review Board

VANDERBILT

## Copy for patient/volunteer records

You may save or print a blank copy of this consent form for your records if you wish. After you submit this form, you will be offered the opportunity to save or print a signed copy of this consent form. If you don't have a PDF reader installed, please click here to install one for free and access this document (link will open in new tab or window): Get Adobe Reader

## Study personnel only

Consent obtained by (please enter full name and title):

_____

(Completed by study personnel at time of consent.)

Date and time consented

_____

**Vanderbilt University Institutional Review Board**
**Informed Consent Document for Research**

**Principal Investigator: Jonathan Schoenecker, MD, PhD** **Version Date: 5/27/2021**
**Study Title: Disorders of the Acute Phase Response Accelerated by Plasmin Activation Following Trauma and Invasive Surgery: A Prospective Study**
**Institution/Hospital: Vanderbilt University Medical Center**

This informed consent applies to: parents or legal guardians of children undergoing invasive elective surgery

Name of participant: _____ Age: _____

**The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.**

Your child does not have to be in this research study. Your child 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 your child to be in this study. Your child's medical record will contain a note saying your child is in a research study. Anyone you authorize to receive your child's medical record will also get this note.

1. **What is the purpose of this study?**

   Your child is being asked to take part in this research study because he/she is undergoing a major surgery. Researchers at Vanderbilt University Medical Center are attempting to determine how these surgeries affect a patient's blood clotting, inflammation, and tissue healing systems. We believe that some patients' response to major surgeries cause them to develop serious conditions that can lead to poor wound healing, infection, organ failure. By understanding how a major surgery affects these body systems, we hope to be able to identify future patients that may be at risk for developing these serious conditions after surgery through routine blood tests and treating them early.

   We are enrolling 150 patients who are having elective major surgery.

2. **What will happen and how long will your child be in the study?**

   Blood sample from your child's vein:
   As part of your child's routine care, your child will have blood taken from their vein and drawn into a tube. Any blood that is leftover from your child's routine care blood tests will be used for study tests. In most cases your child will not need to have any additional blood taken from their vein for this study. If additional blood from their vein is needed, it will be a very small amount, around a teaspoon per blood draw. The additional blood draws would occur at the following time points, if needed:
   - One hour before surgery
   - Every 30 minutes during surgery
   - Every 6 hours for 3 days after surgery
   - Every 12 hours from 3 days after surgery until discharge

   Our study team will also record information from your child's medical record. This will include information about: your child (date of birth, gender, height, weight), your child's surgical procedure, and notes regarding your child's treatment and recovery (healing).

   Your child's participation in this study will last as long as your child is in the hospital for their surgery and when they return to the hospital for their routine care (up to 2 years). If your child comes back to the hospital for a routine care visit related to their surgery within the next 2 years we will record any problems your child has had related to their surgery.

3. **Costs to you if your child takes part in this study:**

   There is no cost to you/your child for taking part in this study.

However, you are still responsible for paying for the usual care your child would normally receive for the treatment of their illness. This includes treatments and tests they would need even if they were not in this study. These costs will be billed to you and/or your child's insurance.

You have the right to ask what it may cost for your child to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your child's insurance company to discuss the costs of their routine care (non-research) further before choosing to be in the study. You may choose for your child not to be in this study if their insurance does not pay for their routine care (non-research) costs and your child's doctor will discuss other treatment plans with you.

**4. Side effects and risks that you can expect if your child take parts in this study:**

**Blood Draw Side Effects**
Your child may experience pain and discomfort at the site where their blood is drawn (vein). There is a chance they may develop a bruise at the site of the blood draw.

**Breach of Confidentiality (Rare)**
There is a rare chance that the confidentiality of the data we collect about your child may be breached by taking part in this study. To lower this risk, all study data will be kept in a secure, password-protected database, where only research staff will have access to it.

**5. Risks that are not known:**

There may be risks that we do not know about at this time.

**6. Payment in case your child is injured because of this research study:**

If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your child's 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 to pay for the costs of any additional care. There are no plans for Vanderbilt to give you/your child money for the injury.

**7. Good effects that might result from this study:**

a) The benefits to science and humankind that might result from this study- Ability to identify and treat patient who are at risk for developing serious or life-threatening conditions (infection, organ failure, death) through the use of routine blood tests.

b) There are no benefits to your child for taking part in this study.

**8. Other treatments your child could get if you decide not to allow them to be in this study:**

This is not a treatment study. Your child will receive routine care for their surgery. Participation or non-participation will not affect their care.

**9. Payments for your/your child's time spent taking part in this study or expenses:**

Your child will not be paid for taking part in this study.

**10. Reasons why the study doctor may take your child out of this study:**

There is no expected reason why the study doctor will take your child out of this study. However, if your child is removed from the study, the doctor will give you a reason from removing your child.

**11. What will happen if you decide your child should stop being in this study?**

You may decide to withdraw your child from the study at any time. If you decide for your child to stop being part of the study, you should tell your child's study doctor.

**12. Who to call for any questions or in case your child is injured:**

If you should have any questions about this research study or if you feel your child has been hurt by being a part of this study, please feel free to contact **Jonathan Schonecker, MD, PhD** at **615-936-3080**. If you cannot reach the research staff, please page the study doctor at **615-835-8211.**

For additional information about giving consent or your child's 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 Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

**13. Confidentiality:**

During this study every attempt will be made to keep your child's protected health information (PHI) private. All data obtained from this study will be stored in a password-protected excel file on a secure server and in a Vanderbilt REDCap database. REDCap is a secure, web-based application for building and managing online databases. Only research personnel will have access to your child's study information to ensure confidentiality.

Vanderbilt may share your child's information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Schoenecker, and their staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you/your child for the use or transfer of this de-identified information.

This study may have some support from the National Institutes of Health (NIH). If so, 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.

**14. Authorization to Use/Disclose Protected Health Information**

All efforts, within reason, will be made to keep your child's protected health information (PHI) private. PHI is your child's health information that is, or has been gathered or kept by Vanderbilt as a result of their healthcare. This includes data gathered for research studies that can be traced back to your child. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your child's PHI. If you decide for your child to be in this research study, you are also agreeing to let the study team use and share their PHI as described below.

As part of the study, Dr. Schoenecker and his study team may share the results of your child's study and/or non-study linked laboratory tests, as well as parts of their medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections and the Vanderbilt University Institutional Review Board. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your child's PHI private.

The study results will be kept in your child's research record for at least six years after the study is finished. At that time, the research data in the study database will be destroyed. Any research data that has been put into their medical record will be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your child's PHI does not expire. If you change your mind, we ask that you contact Dr. Schoenecker in writing and let him know that you withdraw your consent. His mailing address is 4202 Doctors Office Tower, 2200 Children's Way, Nashville, TN 37212. At that time, we will stop collecting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

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

**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 for my child to take part in this study.**

| | |
|---|---|
| Date | Signature of parent/legal guardian |
| Date | Signature of parent/legal guardian |

Consent obtained by:

| | |
|---|---|
| Date | Signature |
| | Printed Name and Title |

**STUDY PERSONNEL CONSENT INSTRUCTIONS**

Consent must be obtained from both parents or legal guardians of the study participant unless one parent or legal guardian is deceased, unknown, incompetent, or not reasonably available, or when only one parent or legal guardian has legal responsibility for the care and custody of the child.

☐ Obtaining a signature from the second parent or legal guardian **IS NOT** possible for one of the above reasons noted above. Please document reason for not obtaining second parent or legal guardian signature in REDCap study database or provide documentation to research coordinator for filing.

## Consent for Genetic Research

The purpose of this study is to look at genes (DNA) and how they affect health and disease. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body behaves. They can also tell us a person's risk for certain diseases and how they will respond to treatment.

You are being asked to give a blood sample for genetic research. What we learn about you from this sample 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.

A single blood sample of 1 teaspoon will be drawn from a vein in your arm using a needle. This will take about 5 minutes of your time.

You may feel bothered or pained from the needle stick. You may have a bruise or the site may get infected. It is rare, but some people faint.

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 key study personnel will have access to your name.

Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers with 15 or more employees may not use your genetic information that comes from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Your sample will be used to make 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.

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

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Your samples and information about you may be shared with others to use for research. To protect your privacy, we will not release your name.

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You will not receive any benefit as a result of the tests done on your samples. These tests may help us learn more about the causes, risks, treatments, or how to prevent this and other health problems.

At any time, you may ask to have your sample destroyed. You should contact study staff at Vanderbilt University Medical Center (615) 936-3080 to have your sample destroyed and no longer used for research. 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.

There will be no costs to you for any of the tests done on your samples. You will not be paid for the use of your samples.

Please check Yes or No to the questions below:

My blood/tissue sample may be used for gene research in this study.

☐ Yes ☐ No

Parent/Legal Guardian 1 Signature: _____ Date: _____

Parent/Legal Guardian 2 Signature: _____ Date: _____

**STUDY PERSONNEL CONSENT INSTRUCTIONS**

Consent must be obtained from both parents or legal guardians of the study participant unless one parent or legal guardian is deceased, unknown, incompetent, or not reasonably available, or when only one parent or legal guardian has legal responsibility for the care and custody of the child.

☐ Obtaining a signature from the second parent or legal guardian **IS NOT** possible for one of the above reasons noted above. Please document reason for not obtaining second parent or legal guardian signature in REDCap study database or provide documentation to research coordinator for filing.

# Arm 2 Parent 1 Consent (Version Date 5/27/21)

**VUMC Institutional Review Board**
**Informed Consent Document for Research Principal Investigator: Jonathan Schoenecker, MD, PhD**

**Study Title: Disorders of the Acute Phase Response Accelerated by Plasmin Activation Following Trauma and Invasive Surgery: A Prospective Study**

**Institution/Hospital: Vanderbilt University Medical Center**

**Version Date: 5/27/2021**
**IRB Approval Date:**
**Expiration Date:**

**This informed consent applies to: parents or legal guardians of children undergoing invasive elective surgery**

Name of Participant:

_____
(First and Last Name of Child)

Age of Participant:

_____
(Age of child)

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Your child does not have to be in this research study. Your child 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 your child to be in this study. Your child's medical record will contain a note saying your child is in a research study. Anyone you authorize to receive your child's medical record will also get this note.

1. What is the purpose of this study?

Your child is being asked to take part in this research study because he/she is undergoing a major surgery. Researchers at Vanderbilt University Medical Center are attempting to determine how these surgeries affect a patient's blood clotting, inflammation, and tissue healing systems. We believe that some patients' response to major surgeries cause them to develop serious conditions that can lead to poor wound healing, infection, organ failure. By understanding how a major surgery affects these body systems, we hope to be able to identify future patients that may be at risk for developing these serious conditions after surgery through routine blood tests and treating them early.

We are enrolling 150 patients who are having elective major surgery.

2. What will happen and how long will your child be in the study?

Blood sample from your child's vein:
As part of your child's routine care, your child will have blood taken from their vein and drawn into a tube. Any blood that is leftover from your child's routine care blood tests will be used for study tests. In most cases your child will not need to have any additional blood taken from their vein for this study. If additional blood from their vein is needed, it will be a very small amount, around a teaspoon per blood draw. The additional blood draws would occur at the following time points, if needed:

- One hour before surgery
- Every 30 minutes during surgery
- Every 6 hours for 3 days after surgery
- Every 12 hours from 3 days after surgery until discharge

Our study team will also record information from your child's medical record. This will include information about: your child (date of birth, gender, height, weight), your child's surgical procedure, and notes regarding your child's treatment and recovery (healing).

Your child's participation in this study will last as long as your child is in the hospital for their surgery and when they return to the hospital for their routine care (up to 2 years). If your child comes back to the hospital for a routine care visit related to their surgery within the next 2 years we will record any problems your child has had related to their surgery.

3. Costs to you if your child takes part in this study:

There is no cost to you/your child for taking part in this study.

However, you are still responsible for paying for the usual care your child would normally receive for the treatment of their illness. This includes treatments and tests they would need even if they were not in this study. These costs will be billed to you and/or your child's insurance.

You have the right to ask what it may cost for your child to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your child's insurance company to discuss the costs of their routine care (non-research) further before choosing to be in the study. You may choose for your child not to be in this study if their insurance does not pay for their routine care (non-research) costs and your child's doctor will discuss other treatment plans with you.

4. Side effects and risks that you can expect if your child take parts in this study:

Blood Draw Side Effects
Your child may experience pain and discomfort at the site where their blood is drawn (vein). There is a chance they may develop a bruise at the site of the blood draw.

Breach of Confidentiality (Rare)
There is a rare chance that the confidentiality of the data we collect about your child may be breached by taking part in this study. To lower this risk, all study data will be kept in a secure, password-protected database, where only research staff will have access to it.

5. Risks that are not known:

There may be risks that we do not know about at this time.

6. Payment in case your child is injured because of this research study:

If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your child's 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 to pay for the costs of any additional care. There are no plans for Vanderbilt to give you/your child money for the injury.

7. Good effects that might result from this study:

a) The benefits to science and humankind that might result from this study- Ability to identify and treat patient who are at risk for developing serious or life-threatening conditions (infection, organ failure, death) through the use of routine blood tests.

b) There are no benefits to your child for taking part in this study.

8. Other treatments your child could get if you decide not to allow them to be in this study:

This is not a treatment study. Your child will receive routine care for their surgery. Participation or non-participation will not affect their care.

9. Payments for your/your child's time spent taking part in this study or expenses:

Your child will not be paid for taking part in this study.

10. Reasons why the study doctor may take your child out of this study:

There is no expected reason why the study doctor will take your child out of this study. However, if your child is removed from the study, the doctor will give you a reason from removing your child.

11. What will happen if you decide your child should stop being in this study?

You may decide to withdraw your child from the study at any time. If you decide for your child to stop being part of the study, you should tell your child's study doctor.

12. Who to call for any questions or in case your child is injured:

If you should have any questions about this research study or if you feel your child has been hurt by being a part of this study, please feel free to contact Jonathan Schonecker, MD, PhD at 615-936-3080. If you cannot reach the research staff, please page the study doctor at 615-835-8211.

For additional information about giving consent or your child's 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 Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

13. Confidentiality:

During this study every attempt will be made to keep your child's protected health information (PHI) private. All data obtained from this study will be stored in a password-protected excel file on a secure server and in a Vanderbilt REDCap database. REDCap is a secure, web-based application for building and managing online databases. Only research personnel will have access to your child's study information to ensure confidentiality.

Vanderbilt may share your child's information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Schoenecker, and their staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you/your child for the use or transfer of this de-identified information.

This study may have some support from the National Institutes of Health (NIH). If so, 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.

14. Authorization to Use/Disclose Protected Health Information

All efforts, within reason, will be made to keep your child's protected health information (PHI) private. PHI is your child's health information that is, or has been gathered or kept by Vanderbilt as a result of their healthcare. This includes data gathered for research studies that can be traced back to your child. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your child's PHI. If you decide for your child to be in this research study, you are also agreeing to let the study team use and share their PHI as described below.

As part of the study, Dr. Schoenecker and his study team may share the results of your child's study and/or non-study linked laboratory tests, as well as parts of their medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections and the Vanderbilt University Institutional Review Board. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your child's PHI private.

The study results will be kept in your child's research record for at least six years after the study is finished. At that time, the research data in the study database will be destroyed. Any research data that has been put into their medical record will be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your child's PHI does not expire. If you change your mind, we ask that you contact Dr. Schoenecker in writing and let him know that you withdraw your consent. His mailing address is 4202 Doctors Office Tower, 2200 Children's Way, Nashville, TN 37212. At that time, we will stop collecting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

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

## 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.

◯ Yes ◯ No

Signature of First Parent/Guardian

_____
(Click "Add signature" and use your mouse (or finger on a touchscreen device) to sign your first and last name.)

Date and time first parent signed:

_____
(Date/time of Patient/Volunteer Signature)

## Consent for Genetic Research

The purpose of this study is to look at genes (DNA) and how they affect health and disease. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body behaves. They can also tell us a person's risk for certain diseases and how they will respond to treatment.

You are being asked to give a blood sample for genetic research. What we learn about you from this sample 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.

A single blood sample of 1 teaspoon will be drawn from a vein in your arm using a needle. This will take about 5 minutes of your time.

You may feel bothered or pained from the needle stick. You may have a bruise or the site may get infected. It is rare, but some people faint.

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 key study personnel will have access to your name.

Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers with 15 or more employees may not use your genetic information that comes from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Your sample will be used to make 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.

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

Your samples and information about you may be shared with others to use for research. To protect your privacy, we will not release your name.

You will not receive any benefit as a result of the tests done on your samples. These tests may help us learn more about the causes, risks, treatments, or how to prevent this and other health problems.

At any time, you may ask to have your sample destroyed. You should contact study staff at Vanderbilt University Medical Center (615) 936-3080 to have your sample destroyed and no longer used for research. 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.

There will be no costs to you for any of the tests done on your samples. You will not be paid for the use of your samples.

Please check Yes or No to the questions below:

My blood/tissue sample may be used for gene research in this study. ◯ Yes ◯ No

Signature of parent/guardian regarding Genetic Rider

_____
(Click "Add signature" and use your mouse (or finger on a touchscreen device) to sign your first and last name.)

Date and time genetic rider signed:

_____
(Date/time of Patient/Volunteer Signature)

Date of IRB Approval: 05/26/2021
Date of Expiration: 12/30/2021

Institutional Review Board

VANDERBILT

## Copy for patient/volunteer records

You may save or print a blank copy of this consent form for your records if you wish. After you submit this form, you will be offered the opportunity to save or print a signed copy of this consent form. If you don't have a PDF reader installed, please click here to install one for free and access this document (link will open in new tab or window): Get Adobe Reader

## STUDY PERSONNEL ONLY

Consent obtained by (please enter full name and title):

_____

(Completed by study personnel at time of consent.)

Date and time consented

_____

Date of IRB Approval: 05/26/2021
Date of Expiration: 12/30/2021

Institutional Review Board

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# Arm 2 Parent 2 Consent (Version Date 5/27/21)

**VUMC Institutional Review Board**
**Informed Consent Document for Research Principal Investigator: Jonathan Schoenecker, MD, PhD**

**Study Title: Disorders of the Acute Phase Response Accelerated by Plasmin Activation Following Trauma and Invasive Surgery: A Prospective Study**

**Institution/Hospital: Vanderbilt University Medical Center**

**Version Date: 5/27/2021**
**IRB Approval Date:**
**Expiration Date:**

**This informed consent applies to: parents or legal guardians of children undergoing invasive elective surgery**

Name of Participant:

_____
(First and Last Name of Child)

Age of Participant:

_____
(Age of child)

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Your child does not have to be in this research study. Your child 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 your child to be in this study. Your child's medical record will contain a note saying your child is in a research study. Anyone you authorize to receive your child's medical record will also get this note.

1. What is the purpose of this study?

Your child is being asked to take part in this research study because he/she is undergoing a major surgery. Researchers at Vanderbilt University Medical Center are attempting to determine how these surgeries affect a patient's blood clotting, inflammation, and tissue healing systems. We believe that some patients' response to major surgeries cause them to develop serious conditions that can lead to poor wound healing, infection, organ failure. By understanding how a major surgery affects these body systems, we hope to be able to identify future patients that may be at risk for developing these serious conditions after surgery through routine blood tests and treating them early.

We are enrolling 150 patients who are having elective major surgery.

2. What will happen and how long will your child be in the study?

Blood sample from your child's vein:
As part of your child's routine care, your child will have blood taken from their vein and drawn into a tube. Any blood that is leftover from your child's routine care blood tests will be used for study tests. In most cases your child will not need to have any additional blood taken from their vein for this study. If additional blood from their vein is needed, it will be a very small amount, around a teaspoon per blood draw. The additional blood draws would occur at the following time points, if needed:

- One hour before surgery
- Every 30 minutes during surgery
- Every 6 hours for 3 days after surgery
- Every 12 hours from 3 days after surgery until discharge

Our study team will also record information from your child's medical record. This will include information about: your child (date of birth, gender, height, weight), your child's surgical procedure, and notes regarding your child's treatment and recovery (healing).

Your child's participation in this study will last as long as your child is in the hospital for their surgery and when they return to the hospital for their routine care (up to 2 years). If your child comes back to the hospital for a routine care visit related to their surgery within the next 2 years we will record any problems your child has had related to their surgery.

3. Costs to you if your child takes part in this study:

There is no cost to you/your child for taking part in this study.

However, you are still responsible for paying for the usual care your child would normally receive for the treatment of their illness. This includes treatments and tests they would need even if they were not in this study. These costs will be billed to you and/or your child's insurance.

You have the right to ask what it may cost for your child to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your child's insurance company to discuss the costs of their routine care (non-research) further before choosing to be in the study. You may choose for your child not to be in this study if their insurance does not pay for their routine care (non-research) costs and your child's doctor will discuss other treatment plans with you.

4. Side effects and risks that you can expect if your child take parts in this study:

Blood Draw Side Effects
Your child may experience pain and discomfort at the site where their blood is drawn (vein). There is a chance they may develop a bruise at the site of the blood draw.

Breach of Confidentiality (Rare)
There is a rare chance that the confidentiality of the data we collect about your child may be breached by taking part in this study. To lower this risk, all study data will be kept in a secure, password-protected database, where only research staff will have access to it.

5. Risks that are not known:

There may be risks that we do not know about at this time.

6. Payment in case your child is injured because of this research study:

If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your child's 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 to pay for the costs of any additional care. There are no plans for Vanderbilt to give you/your child money for the injury.

7. Good effects that might result from this study:

a) The benefits to science and humankind that might result from this study- Ability to identify and treat patient who are at risk for developing serious or life-threatening conditions (infection, organ failure, death) through the use of routine blood tests.

b) There are no benefits to your child for taking part in this study.

8. Other treatments your child could get if you decide not to allow them to be in this study:

This is not a treatment study. Your child will receive routine care for their surgery. Participation or non-participation will not affect their care.

9. Payments for your/your child's time spent taking part in this study or expenses:

Your child will not be paid for taking part in this study.

10. Reasons why the study doctor may take your child out of this study:

There is no expected reason why the study doctor will take your child out of this study. However, if your child is removed from the study, the doctor will give you a reason from removing your child.

11. What will happen if you decide your child should stop being in this study?

You may decide to withdraw your child from the study at any time. If you decide for your child to stop being part of the study, you should tell your child's study doctor.

12. Who to call for any questions or in case your child is injured:

If you should have any questions about this research study or if you feel your child has been hurt by being a part of this study, please feel free to contact Jonathan Schonecker, MD, PhD at 615-936-3080. If you cannot reach the research staff, please page the study doctor at 615-835-8211.

For additional information about giving consent or your child's 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 Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

13. Confidentiality:

During this study every attempt will be made to keep your child's protected health information (PHI) private. All data obtained from this study will be stored in a password-protected excel file on a secure server and in a Vanderbilt REDCap database. REDCap is a secure, web-based application for building and managing online databases. Only research personnel will have access to your child's study information to ensure confidentiality.

Vanderbilt may share your child's information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Schoenecker, and their staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you/your child for the use or transfer of this de-identified information.

This study may have some support from the National Institutes of Health (NIH). If so, 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.

14. Authorization to Use/Disclose Protected Health Information

All efforts, within reason, will be made to keep your child's protected health information (PHI) private. PHI is your child's health information that is, or has been gathered or kept by Vanderbilt as a result of their healthcare. This includes data gathered for research studies that can be traced back to your child. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your child's PHI. If you decide for your child to be in this research study, you are also agreeing to let the study team use and share their PHI as described below.

As part of the study, Dr. Schoenecker and his study team may share the results of your child's study and/or non-study linked laboratory tests, as well as parts of their medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections and the Vanderbilt University Institutional Review Board. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your child's PHI private.

The study results will be kept in your child's research record for at least six years after the study is finished. At that time, the research data in the study database will be destroyed. Any research data that has been put into their medical record will be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your child's PHI does not expire. If you change your mind, we ask that you contact Dr. Schoenecker in writing and let him know that you withdraw your consent. His mailing address is 4202 Doctors Office Tower, 2200 Children's Way, Nashville, TN 37212. At that time, we will stop collecting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

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

## 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.

◯ Yes ◯ No

Signature of Second Parent/Guardian

_____
(Click "Add signature" and use your mouse (or finger on a touchscreen device) to sign your first and last name.)

Date and time second parent signed:

_____
(Date/time of Patient/Volunteer Signature)

## Consent for Genetic Research

The purpose of this study is to look at genes (DNA) and how they affect health and disease. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body behaves. They can also tell us a person's risk for certain diseases and how they will respond to treatment.

You are being asked to give a blood sample for genetic research. What we learn about you from this sample 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.

A single blood sample of 1 teaspoon will be drawn from a vein in your arm using a needle. This will take about 5 minutes of your time.

You may feel bothered or pained from the needle stick. You may have a bruise or the site may get infected. It is rare, but some people faint.

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 key study personnel will have access to your name.

Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers with 15 or more employees may not use your genetic information that comes from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Your sample will be used to make 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.

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

Your samples and information about you may be shared with others to use for research. To protect your privacy, we will not release your name.

You will not receive any benefit as a result of the tests done on your samples. These tests may help us learn more about the causes, risks, treatments, or how to prevent this and other health problems.

At any time, you may ask to have your sample destroyed. You should contact study staff at Vanderbilt University Medical Center (615) 936-3080 to have your sample destroyed and no longer used for research. 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.

There will be no costs to you for any of the tests done on your samples. You will not be paid for the use of your samples.

Please check Yes or No to the questions below:

My blood/tissue sample may be used for gene research in this study. ◯ Yes ◯ No

Signature of parent/guardian regarding Genetic Rider

_____
(Click "Add signature" and use your mouse (or finger on a touchscreen device) to sign your first and last name.)

Date and time genetic rider signed:

_____
(Date/time of Patient/Volunteer Signature)

Date of IRB Approval: 05/26/2021
Date of Expiration: 12/30/2021

Institutional Review Board

VANDERBILT

## Copy for patient/volunteer records

You may save or print a blank copy of this consent form for your records if you wish. After you submit this form, you will be offered the opportunity to save or print a signed copy of this consent form. If you don't have a PDF reader installed, please click here to install one for free and access this document (link will open in new tab or window): Get Adobe Reader

## STUDY PERSONNEL ONLY

Consent obtained by (please enter full name and title):

_____

(Completed by study personnel at time of consent.)

Date and time consented

_____

Date of IRB Approval: 05/26/2021
Date of Expiration: 12/30/2021

Institutional Review Board

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# Arm 3 Healthy Volunteer Consent (Version Date: 5/13/21)

**VUMC Institutional Review Board**
**Informed Consent Document for Research Principal Investigator: Jonathan Schoenecker, MD, PhD**

**Study Title: Disorders of the Acute Phase Response Accelerated by Plasmin Activation Following Trauma and Invasive Surgery: A Prospective Study**

**Institution/Hospital: Vanderbilt University Medical Center**

**Version Date: 5/13/2021**
**IRB Approval Date:**
**Expiration Date:**

**This informed consent applies to: healthy volunteers**

Name of Participant: _____
(First Last)

Age of Participant: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

You do not have to be in this research study. 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.

1. What is the purpose of this study?

You are being asked to take part in this research study because we would like to compare your blood to the blood of patients who have experienced severe injuries or had a major surgery. We are trying to determine the effect of these injuries on a patient's blood clotting, inflammation, and tissue healing systems. We will use your blood as a healthy control to compare with the injured patient's blood.

We are enrolling 20 healthy volunteers to give blood.

2. What will happen and how long will you be in the study?

One-Time Visit
Your participation in this study will include a one-time blood draw of 100ml (slightly less than ½ a cup). This blood draw will conclude your participation in this study.

3. Costs to you if you take part in this study:

There is no cost to you for taking part in this study.

4. Side effects and risks that you can expect if you take part in this study:

Blood Draw Risks:
• pain
• redness
• soreness
• bruising
• infection, which may occur at the needle stick site
• some people faint (rare)

The person drawing your blood may put some cream (called EMLA) on your skin to numb the area so you will not feel the needle stick as much. The numbing cream may make your skin or the area have a change in skin color, but this change is temporary.

5. Risks that are not known:

There may be risks that we do not know about at this time.

6. Payment in case you are injured because of this research study:

If it is determined by Vanderbilt and the Investigator 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 to pay for the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

7. Good effects that might result from this study:

a) The benefits to science and humankind that might result from this study: Ability to identify and treat patients who are at risk for developing serious or life-threatening conditions (infection, organ failure, death) through the use of routine blood tests.

b) There are no benefits to you for your part in this study.

8. Other treatments you could get if you decide not to be in this study:

Not applicable.



9. Payments for your time spent taking part in this study or expenses:

You will be reimbursed $20 for your time. A check will be mailed to you following completion of your blood draw visit.

10. Reasons why the study doctor may take you out of this study:

You may be taken out of this study if it is determined that you no longer meet inclusion criteria. If you are taken out of this study you will be told why.

11. 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 the research investigator or research coordinator.

12. 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 Jonathan Schoenecker, MD, PhD at 615-936-3080. If you cannot reach the research staff, please page the study doctor at 615-835-8211.

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 Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

13. Confidentiality:

During this study every attempt will be made to keep your protected health information (PHI) private. All data obtained from this study will be stored in a password-protected Excel file on a secure server and in a Vanderbilt REDCap database. REDCap is a secure, web-based application for building and managing online databases. Only research personnel will have access to your study information to ensure confidentiality.

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Schoenecker and his 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.

This study may have some support from the National Institutes of Health (NIH). If so, 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.

14. Authorization to Use/Disclose Protected Health Information

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Dr. Schoenecker and his study team may share the results of your study, as well as parts of your medical record, to the groups named below. These groups may include people from the: Federal Government Office for Human Research Protections and the Vanderbilt University Institutional Review Board. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data in the study database will be destroyed.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Schoenecker in writing and let him know that you withdraw your consent. His mailing address is 4202 Doctors Office Tower, 2200 Children's Way, Nashville, TN 37212. The health data we stored before you withdrew your consent may still be used for reporting and research quality.

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

## 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.

◯ Yes ◯ No

Signature of Volunteer

_____
(Click "Add signature" and use your mouse (or finger on a touchscreen device) to sign your first and last name.)

Date and time signed:

_____
(Date/time of Patient/Volunteer Signature)

## Copy for patient/volunteer records

You may save or print a blank copy of this consent form for your records if you wish. After you submit this form, you will be offered the opportunity to save or print a signed copy of this consent form. If you don't have a PDF reader installed, please click here to install one for free and access this document (link will open in new tab or window): Get Adobe Reader

## Study personnel only

Consent obtained by (please enter full name and title):

_____
(Completed by study personnel at time of consent.)

Date and time consented

_____

**Vanderbilt University Institutional Review Board**
**Informed Consent Document for Research**

**Principal Investigator: Jonathan Schoenecker, MD, PhD** **Revision Date: 3/4/2020**
**Study Title: Disorders of the Acute Phase Response Accelerated by Plasmin Activation Following Trauma and Invasive Surgery: A Prospective Study**
**Institution/Hospital: Vanderbilt University Medical Center**

This informed consent applies to: healthy volunteers

Name of participant: _____ Age: _____

**The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.**

You do not have to be in this research study. 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.

1. **What is the purpose of this study?**

   You are being asked to take part in this research study because we would like to compare your blood to the blood of patients who have experienced severe injuries or had a major surgery. We are trying to determine the effect of these injuries on a patient's blood clotting, inflammation, and tissue healing systems. We will use your blood as a healthy control to compare with the injured patient's blood.

   We are enrolling 20 healthy volunteers to give blood.

2. **What will happen and how long will you be in the study?**

   <u>One-Time Visit</u>
   Your participation in this study will include a one-time blood draw of 100ml (slightly less than ½ a cup). This blood draw will conclude your participation in this study.

3. **Costs to you if you take part in this study:**

   There is no cost to you for taking part in this study.

4. **Side effects and risks that you can expect if you take part in this study:**

   **Blood Draw Risks:**
   - pain
   - redness
   - soreness
   - bruising
   - infection, which may occur at the needle stick site
   - some people faint (rare)

   The person drawing your blood may put some cream (called EMLA) on your skin to numb the area so you will not feel the needle stick as much. The numbing cream may make your skin or the area have a change in skin color, but this change is temporary.

5. **Risks that are not known:**

   There may be risks that we do not know about at this time.

6. **Payment in case you are injured because of this research study:**

If it is determined by Vanderbilt and the Investigator 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 to pay for the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

**7. Good effects that might result from this study:**

a) The benefits to science and humankind that might result from this study: Ability to identify and treat patients who are at risk for developing serious or life-threatening conditions (infection, organ failure, death) through the use of routine blood tests.

b) There are no benefits to you for your part in this study.

**8. Other treatments you could get if you decide not to be in this study:**

Not applicable.

**9. Payments for your time spent taking part in this study or expenses:**

You will be reimbursed $20 for your time. A check will be mailed to you following completion of your blood draw visit.

**10. Reasons why the study doctor may take you out of this study:**

You may be taken out of this study if it is determined that you no longer meet inclusion criteria. If you are taken out of this study you will be told why.

**11. 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 the research investigator or research coordinator.

**12. 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 **Jonathan Schoenecker, MD, PhD** at **615-936-3080.** If you cannot reach the research staff, please page the study doctor at **615-835-8211.**

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 Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

**13. Confidentiality:**

During this study every attempt will be made to keep your protected health information (PHI) private. All data obtained from this study will be stored in a Vanderbilt REDCap database. REDCap is a secure, web-based application for building and managing online databases. Only research personnel will have access to your study information to ensure confidentiality.

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Schoenecker and his 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.

This study may have some support from the National Institutes of Health (NIH). If so, 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.

**14. Authorization to Use/Disclose Protected Health Information**

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Dr. Schoenecker and his study team may share the results of your study, as well as parts of your medical record, to the groups named below. These groups may include people from the: Federal Government Office for Human Research Protections and the Vanderbilt University Institutional Review Board. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data in the study database will be destroyed.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Schoenecker in writing and let him know that you withdraw your consent. His mailing address is 4202 Doctors Office Tower, 2200 Children's Way, Nashville, TN 37212. The health data we stored before you withdrew your consent may still be used for reporting and research quality.

**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.**

**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 Volunteer |

Consent obtained by:

| | | |
|---|---|---|
| _____ | _____ | |
| Date | Signature | |
| | _____ | _____ |
| | Printed Name and Title | Time |

# Arm 1 and 2 Spanish Short Form Consent (Version date: 5/13/21)

Short Form Instructions for KSP

[Attachment: "ICD Short Form Instructions.doc"]

**VUMC Institutional Review Board**

**Consent to Participate in Research Principal Investigator: Jonathan Schoenecker, MD, PhD**

**Study Title: Disorders of the Acute Phase Response Accelerated by Plasmin Activation Following Trauma and Invasive Surgery: A Prospective Study**

**Institution/Hospital: Vanderbilt University Medical Center**

**Version Date: 5/13/2021**
**IRB Approval Date:**
**Expiration Date:**

CONSENTIMIENTO INFORMADO POR ESCRITO- DOCUMENTO CORTO

Este documento debe ser escrito en lenguaje entendible a la persona y debe ser anexado a un resumen escrito de la información que se presenta de manera oral.

Se le pide que tome parte de un estudio de investigación.

Antes de que usted acepte, el médico del estudio debe indicarle acerca de lo siguiente:

La razón para hacer el estudio, las cosas que se van a hacer y cuánto tiempo estará en el estudio; Cualquier prueba o tratamiento que sea experimental; Cualquier riesgo o efecto secundario que usted pueda esperar, y efectos positivos que puedan resultar del estudio; Otros tratamientos que usted puede tomar si decide no participar en este estudio; y Cómo se mantendrán los expedientes del estudio y quién los puede ver. Cuando cualquiera de los siguientes puntos aplique, el médico del estudio también debe hablarle de lo siguiente:

Compensación en caso de que se lastime debido al estudio de investigación; La posibilidad de otros riesgos que no se conocen; Razones por las que el médico del estudio pueda retirarle del estudio; Costos para usted si participa en el estudio; Qué puede suceder si usted decide dejar de participar en el estudio; Cuándo se le dirá acerca de hallazgos nuevos que puedan afectar su decisión de permanecer en el estudio; y Cuántas personas participarán en el estudio. Si usted acepta participar en el estudio, el médico del mismo le debe proporcionar una copia de este documento después de que sea firmada, al igual que un resumen escrito del estudio.

Si tiene cualquier pregunta acerca de este estudio de investigación o si cree que ha sido lesionado a causa de este estudio, por favor tome la libertad de contactar a Jonathan Schoenecker, MD, PhD al 615-936-3080. Si no puede contactar al personal de investigación, por favor use el número de bíper a continuación para que el médico del estudio sea localizado al 615-835-8211.

Para mayor información acerca de otorgar su consentimiento o sus derechos como participante en este estudio, contactar a la Oficina de la Junta Institucional de la Universidad de Vanderbilt al (615) 322-2918 o llame sin costo al (866) 224-8273.

Usted no tiene que participar de este estudio de investigación. Usted puede escoger no participar en este estudio y obtener otros tratamientos sin cambiar su cuidado de salud, servicios u otros derechos. Usted puede dejar de participar en este estudio en cualquier momento.

1) DECLARACIÓN DE LA PERSONA QUE ACEPTA SER PARTE DE ESTE ESTUDIO
El estudio de investigación se me ha explicado de manera verbal. Todas mis preguntas han sido contestadas y yo escojo libre y voluntariamente participar en este estudio.

◯ Si ◯ No

2) Firma del Participante
(Signature of Participant)

_____
(Click "Add signature" and use your mouse (or finger on a touchscreen device) to sign your first and last name.)

3) Fecha y hora firmada por el participante
(Date and time signed by participant)

_____
(Date/time of Participant Signature)

4) Firma del Testigo
(Signature of Witness)

_____
(Click "Add signature" and use your mouse (or finger on a touchscreen device) to sign your first and last name.)

5) Fecha y hora firmadas por el testigo
(Date and time signed by witness)

_____
(Date/time of Participant Signature)

6) Firma del Intérprete (si aplica)
(Interpreter's signature, if applicable)

_____
(Click "Add signature" and use your mouse (or finger on a touchscreen device) to sign your first and last name.)

7) Fecha y hora de la firma del intérprete, si corresponde

_____
(Date/time of Participant Signature)

**Copia para los registros del participante**
**(Copy for patient/volunteer records)**

You may save or print a blank copy of this consent form for your records if you wish. After you submit this form, you will be offered the opportunity to save or print a signed copy of this consent form. If you don't have a PDF reader installed, please click here to install one for free and access this document (link will open in new tab or window): Get Adobe Reader

| | **Solo personal del estudio**<br>**(Study personnel only)** | |
|---|---|---|
| 8) | Consent obtained by (please enter full name and title): | _____<br>(Completed by study personnel at time of consent.) |
| 9) | Date and time consented | _____ |

**Vanderbilt University Institutional Review Board**
**Consent to Participate in Research**

**Principal Investigator: Jonathan Schoenecker, MD, PhD** **Version Date: 10/25/2018**
**Study Title: Disorders of the Acute Phase Response Accelerated by Plasmin Activation Following Trauma and Invasive Surgery: A Prospective Study**
**Institution/Hospital: Vanderbilt University Medical Center**

## CONSENTIMIENTO INFORMADO POR ESCRITO- DOCUMENTO CORTO

***Este documento debe ser escrito en lenguaje entendible a la persona y debe ser anexado a un resumen escrito de la información que se presenta de manera oral.***

Se le pide que tome parte de un estudio de investigación.

Antes de que usted acepte, el médico del estudio debe indicarle acerca de lo siguiente:

(i) La razón para hacer el estudio, las cosas que se van a hacer y cuánto tiempo estará en el estudio;
(ii) Cualquier prueba o tratamiento que sea experimental;
(iii) Cualquier riesgo o efecto secundario que usted pueda esperar, y efectos positivos que puedan resultar del estudio;
(iv) Otros tratamientos que usted puede tomar si decide no participar en este estudio; y
(v) Cómo se mantendrán los expedientes del estudio y quién los puede ver.

Cuando cualquiera de los siguientes puntos aplique, el médico del estudio también debe hablarle de lo siguiente:

(i) Compensación en caso de que se lastime debido al estudio de investigación;
(ii) La posibilidad de otros riesgos que no se conocen;
(iii) Razones por las que el médico del estudio pueda retirarle del estudio;
(iv) Costos para usted si participa en el estudio;
(v) Qué puede suceder si usted decide dejar de participar en el estudio;
(vi) Cuándo se le dirá acerca de hallazgos nuevos que puedan afectar su decisión de permanecer en el estudio; y
(vii) Cuántas personas participarán en el estudio.

Si usted acepta participar en el estudio, el médico del mismo le debe proporcionar una copia de este documento después de que sea firmada, al igual que un resumen escrito del estudio.

Si tiene cualquier pregunta acerca de este estudio de investigación o si cree que ha sido lesionado a causa de este estudio, por favor tome la libertad de contactar a **Jonathan Schoenecker, MD, PhD** al **615-936-3080**. Si no puede contactar al personal de investigación, por favor use el número de bíper a continuación para que el médico del estudio sea localizado al **615-835-8211.**

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Usted no tiene que participar de este estudio de investigación. Usted puede escoger no participar en este estudio y obtener otros tratamientos sin cambiar su cuidado de salud, servicios u otros derechos. Usted puede dejar de participar en este estudio en cualquier momento.

**DECLARACIÓN DE LA PERSONA QUE ACEPTA SER PARTE DE ESTE ESTUDIO**
**El estudio de investigación se me ha explicado de manera verbal. Todas mis preguntas han sido contestadas y yo escojo libre y voluntariamente participar en este estudio.**

**Principal Investigator: Jonathan Schoenecker, MD, PhD** **Version Date: 10/25/2018**
**Study Title: Disorders of the Acute Phase Response Accelerated by Plasmin Activation Following Trauma and Invasive Surgery: A Prospective Study**
**Institution/Hospital: Vanderbilt University Medical Center**

| | |
|---|---|
| _____ | _____ |
| Firma del Participante | Fecha |
| _____ | _____ |
| Firma del Testigo | Fecha |
| _____ | _____ |
| Firma del Intérprete (si aplica) | Fecha |