VASCULAR ANOMALIES Registry Consent

Minor < 7yr

University of North Carolina at Chapel Hill
Parental Permission for a Minor Child to Participate in a Research Study

Consent Form Version Date: 8/16/19
IRB Study # 19-1672
Title of Study: Vascular Anomalies Patient Registry, Tissue and Serum Bank
Principal Investigator: Julie Blatt
Principal Investigator Department: Pediatrics - Hematology/Oncology
Principal Investigator Phone number: (919) 966-0590
Principal Investigator Email Address: jblat@med.unc.edu

Concise Summary

Vascular anomalies are rare disorders which we would like to understand more about in order to better treat patients. The purpose of this research study is to keep a list or registry of affected individuals, as well as blood and tissue samples. This will help us track just how common various types of vascular anomalies are, as well as help us to design or participate in future research projects about certain vascular anomalies. Participation is ongoing since the registry and tissue bank are intended to be maintained indefinitely, and participants will be asked to consent for blood draws at multiple times when they are having blood drawn at the hospital. Although individuals are not likely to benefit, we believe that such registries will help patients with vascular anomalies in the future. Risks are minimal since blood and tissue samples will only be collected when they are being collected for patient care anyway, and we will use "left over" material.

What are some general things you and you child should know about research studies?

You are being asked to allow your child to take part in a research study. To join the study is voluntary.

You may decide to not allow your child to participate, or you may withdraw your permission for your child to be in the study, for any reason, without penalty. Even if you give your permission, your child can decide not to be in the study or to leave the study early. Research studies are designed to obtain new knowledge. This new information may help people in the future. Your child may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your or your child's relationship with the researcher, the health care provider, or the University of North Carolina-Chapel Hill. If your child is a patient with an illness, your child does not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you and your child understand this information so that you and your child can make an informed choice about being in this research study.

You will be given a copy of this consent form. You and your child should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this research study is to collect one or more blood samples and a piece of vascular anomalies such as vascular malformations or hemangiomas from patients who are having blood drawn or are having their vascular anomaly taken out or biopsied. We may use these samples for research in the future. In addition, we hope to include your child's information in a registry (listing) of all patients seen at UNC with vascular anomalies in order to help us take care of patients and do research in the future.

You are being asked allow your child to be in the study because he/she has a vascular anomaly and is being seen at UNC. He/She also may be having blood drawn and/or having surgery to biopsy or remove it.

Are there any reasons your child should not be in this study?
Your child should not be in this study if you or he/she does not want to be in the study.

How many people will take part in this study?
We are guessing that there will be approximately10-20 people in this research study a year (both adults and children) who have tissue sampled and more than 100 who will have blood saved. There may be many more than that.

How long will your child's part in this study last?
Once your child has donated a blood sample and had his/her surgery, his/her participation in this study may be complete. We plan to freeze serum (the liquid part of blood) and a piece of your child's vascular anomaly indefinitely (possibly forever). In addition, we want to continue to keep deidentified information about your child on our research registry (database). Therefore, his/her participation may go on indefinitely (possibly forever).

What will happen if your child takes part in the study?
If you give your consent (and your child, if 7-17 years old, gives his/her assent), at a time when your child is having blood drawn to help his/her doctors care for him/her, or at a time when he/she is having an iv (intravenous needle) placed, we will take an additional 10 mL of blood (2 teaspoons) to save. At the time of surgery, if there is a small piece (1gm) of your child's vascular malformation or other anomaly that is extra and not needed by the pathologist, we will freeze that tissue and save it as well. These samples will be frozen indefinitely for as-yet-unknown research to learn about vascular anomalies.

In addition, we are keeping a research registry (list) of all patients with vascular anomalies seen at UNC. We would like to add your child to the registry.

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. Your child will not benefit personally from being in this.

What are the possible risks or discomforts involved from being in this study?
Because your child will have blood drawn and a sample of your child's vascular anomaly taken at a time when this is to be done anyway in order to care for him/her, there are no discomforts specifically related to this research. The amount of extra blood we are taking is small and not medically significant.

There is a small potential risk of loss of confidentiality. We have taken several steps to minimize this (see below).

There may be uncommon or previously unknown risks. You or your child should report any problems to the researcher.

What if we learn about new findings or information during the study?
This is not applicable, though if we have problems with confidentiality, we will let you know.

How will information about you be protected?
Frozen samples will not have your child's name or medical record number, but will be labeled with a number and kept in a locked freezer which only the investigators on this study can access. The registry will not have your child's name or medical record number, and will only list his/her date of birth, the type of vascular anomaly, where it is located in his/her body, and that we have a sample of blood and tissue frozen from him/her. A master list with your child's name, date of birth, and medical record number will be kept locked in a password-protected file on the principal investigator's and coordinator's computers.

Participants will not be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your child's information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

What if you or your child wants to stop before your child's part in the study is complete?
You can withdraw your child from this study at any time, without penalty. The investigators also have the right to stop your child's participation at any time. This could be because your has failed to follow instructions, or because the entire study has been stopped.

Will your child receive anything for being in this study?
Neither you nor your child will receive anything for being in this study.

Will it cost you anything for your child to be in this study?
It will not cost anything to be in this study.

Who is sponsoring this study?
This research is not funded and members of the team to not receive money for doing the study. .

What if you or your child has questions about this study?
You and your child have the right to ask, and have answered, any questions you may have about this research. If there are questions about the study, complaints, concerns, or if a research-related injury occurs, contact the researchers listed on the first page of this form.

What if there are questions about your child's rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your child's rights and welfare. If there are questions or concerns about your child's rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Parent's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily give permission to allow my child to participate in this research study.

_____

Printed Name of Research Participant (child)

_____ _____

Signature of Parent Date

_____

Printed Name of Parent

Julie Blatt _____

Signature of Research Team Member Obtaining Permission Date

Julie Blatt MD

Printed Name of Research Team Member Obtaining Permission

University of North Carolina at Chapel Hill
HIPAA Authorization for Use and Disclosure of Health Information for Research Purposes

---

IRB Study # 19-1672

Title of Study: Vascular Anomalies Patient Registry, Tissue and Serum Bank

Principal Investigator: Julie Blatt
Mailing Address for UNC-Chapel Hill Department: CB:7236 170 Manning Dr 1106 POB , CB 7236 , Chapel Hill, NC 27599-7236 , USA

This is a permission called a "HIPAA authorization." It is required by the "Health Insurance Portability and Accountability Act of 1996" (known as "HIPAA") in order for us to get information from your medical records or health insurance records to use in this research study.

---

1. If you sign this HIPAA authorization form, you are giving your permission for the following people or groups to give the researchers certain information about you (described below):

   Any health care providers or health care professionals or health plans that have provided health services, treatment, or payment for you such as physicians, clinics, hospitals, home health agencies, diagnostics centers, laboratories, treatment or surgical centers, including but not limited to the UNC Health Care System and its members and affiliates (collectively, "UNCHCS"), health insurance plans, and government health agencies.

   1. If you sign this HIPAA authorization form, you are giving your permission for the following people or groups to give the researchers certain information about you (described below):

   Any health care providers or health care professionals or health plans that have provided health services, treatment, or payment for you such as physicians, clinics, hospitals, home health agencies, diagnostics centers, laboratories, treatment or surgical centers, including but not limited to the UNC Health Care System, health insurance plans, and government health agencies.

   2. If you sign this form, this is the health information about you that the people or groups listed in #1 may give to the researchers to use in this research study:

   Any information in your medical records that relates to your participation in this research. These records might include information such as genetic testing. Other

information includes: date of birth, surgical pathology results, imaging results, progress notes.

3. The HIPAA protections that apply to your medical records will not apply to your information when it is in the research study records. Your information in the research study records may also be shared with, used by or seen by collaborating researchers, the sponsor of the research study, the sponsor's representatives, and certain employees of the university or government agencies (like the FDA) if needed to oversee the research study. HIPAA rules do not usually apply to those people or groups. If any of these people or groups reviews your research record, they may also need to review portions of your original medical record relevant to the situation. The informed consent document describes the procedures in this research study that will be used to protect your personal information. You can also ask the researchers any questions about what they will do with your personal information and how they will protect your personal information in this research study.

4. If this research study creates medical information about you that will go into your medical record, you may not be able to see the research study information in your medical record until the entire research study is over.

5. If you want to participate in this research study, you must sign this HIPAA authorization form to allow the people or groups listed in #1on this form to give access to the information about you that is listed in #2. If you do not want to sign this HIPAA authorization form, you cannot participate in this research study. However, not signing the authorization form will not change your right to treatment, payment, enrollment or eligibility for medical services outside of this research study.

6. This HIPAA authorization will not stop unless you stop it in writing.

7. You have the right to stop this HIPAA authorization at any time. You must do that in writing. You may give your written stop of this HIPAA authorization directly to Principal Investigator or researcher or you may mail it to the department mailing address listed at the top of this form, or you may give it to one of the researchers in this study and tell the researcher to send it to any person or group the researcher has given a copy of this HIPAA authorization. Stopping this HIPAA authorization will not stop information sharing that has already happened.

8. You will be given a copy of this signed HIPAA authorization.

_____ _____

Signature of Research Subject Date

_____

Print Name of Research Subject

For Personal Representative of the Research Participant (if applicable)

Print Name of Personal Representative: _____

Please explain your authority to act on behalf of this Research Subject:

_____

I am giving this permission by signing this HIPAA Authorization on behalf of the Research Participant.

_____ _____

Signature of Personal Representative Date

University of North Carolina at Chapel Hill
Consent for Storing Biological Specimens Without Identifying Information

---

Consent Form Version Date: 8-16-2019
IRB Study # 19-1672
Title of Study: Vascular Anomalies Patient Registry, Tissue and Serum Bank
Principal Investigator: Julie Blatt
Principal Investigator Department: Pediatrics - Hematology/Oncology
Principal Investigator Phone number: (919) 966-0590
Principal Investigator Email Address: jblat@med.unc.edu

If you are a parent or legal guardian of a child who may take part in this study, permission from you is required. The assent (agreement) of your child may also be required. When we say "you" in this consent form, we mean you or your child.

What are some general things you should know about research?
Research is designed to gain scientific information that may help other people in the future. You may not receive any direct benefit from participating. There also may be risks.

You may refuse to take part in research. If you are a patient with an illness, you do not have to be in research in order to receive treatment.

Details are discussed below. It is important that you understand this information so that you can make an informed choice. You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this specimen repository or "biobank?"
Research with blood, tissue or body fluids (specimens) can help researchers understand how the human body works. Research can also answer other questions by using specimens. Researchers may develop new tests to find diseases, or new ways to treat diseases. In the future, research may help to develop new products, such as drugs. Specimens are commonly used for genetic research. Sometimes researchers collect and store many specimens together and use them for different kinds of research, or share them with other scientists; this is called a specimen repository or "biobank."

The purpose of this research study is to collect blood samples and a piece of vascular anomalies such as vascular malformations or hemangiomas from patients who are having blood drawn for routine care and/or are having their vascular anomaly taken out or biopsied. We may use these samples for research in the future.

How will the specimens be collected?

If you give your consent, at a time when you are having blood drawn to help your doctors care for you, or at a time when you are having an iv (intravenous needle) placed, we will take an additional 10 mL of blood (2 teaspoons) to save. At the time of surgery, if there is a small piece (1gm) of your vascular malformation or other anomaly that is extra and not needed by the pathologist, we will freeze and save that as well. These samples will be frozen indefinitely for as-yet-unknown research to learn about vascular anomalies.

What will happen to the specimens?
Samples will be kept in a locked freezer in the Dept of Pathology which only the investigators on this study can access. A master list with your name, date of birth, and medical record number will be kept locked in a password-protected file on the principal investigator's computers in her office.

What are the possible benefits to you?
Benefits to you are unlikely. Studies that use specimens from this repository may provide additional information that will be helpful in understanding what makes normal and abnormal blood vessels grow.

What are the possible risks or discomforts involved with the use of your specimens?
Because you will have blood drawn and/or a sample of your vascular anomaly taken at a time when this is to be done anyway in order to care for you, there are no discomforts specifically related to this research. The amount of extra blood we are taking is small and not medically significant.

There is a risk of breach of confidentiality. If future research involves genetics, there is also a potential risk for some of your relatives and other members of your ethnic group, since they share some of your genetic makeup. We have taken several steps to minimize this (see below).

Will there be any cost to you for storage of the specimens?
There will be no cost to you for the storage and use of the specimens for research purposes.

Will you receive anything for the use of your specimens?
No

Who owns the specimens?
Any blood or tissue specimens obtained for this purpose become the exclusive property of the University of North Carolina at Chapel Hill. This organization may retain, preserve or dispose of these specimens and may use these specimens for research that may result in commercial applications. There are no plans to compensate you for any future commercial use of these specimens.

How will information about you be protected?
Frozen samples will not have your name or medical record number, but will be labeled with a number corresponding to a registry which will also not have your name or medical record number, and will only list your date of birth, the type of vascular anomaly you have, where it is located in your body, and note that we have a sample of blood and tissue frozen from you. A

master list with your name, date of birth, and medical record number will be kept locked in a separate password-protected file on the principal investigator's computer, in order to allow us to correlate information found by studying your body samples with information about your vascular anomaly. You will be asked to sign a separate form ("HIPAA authorization") to allow researchers to review your medical records.

It is possible that the specimens may be shared with researchers at this or other institutions in the future. Research studies may be done at many places at the same time. Your personal identifying information will not be sent to other researchers.

You will not be identified in any report or publication about research using your specimens. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research could be reviewed by representatives of the University, research sponsors, or government agencies for purposes such as quality control or safety.

A Federal law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

Will researchers seek approval from you to do future studies involving the specimens?
By signing this consent form, you are giving your permission for researchers to use your specimens as described above. Current and future research is overseen by a committee called the Institutional Review Board (IRB). The role of the IRB is to protect the rights and welfare of research participants. In some cases, the IRB may require that you be re-contacted and asked for your consent to use your specimens in a specific research study. You have the right, at that future time, not to participate in any research study for which your consent is sought. Refusal to participate will not affect your medical care or result in loss of benefits to which you are entitled.

Will you receive results from research involving your specimens?
Most research with your specimens is not expected to yield new information that would be meaningful to share with you personally. There are no plans to re-contact you or other subjects with information about research results..

Sometimes there are concerns, even if hypothetical, that people may find out things about you (for example, that your genes make you susceptible to a certain disease). These concerns are minimized with this repository, because the specimens themselves will not be labeled with identifying information. Our master list with your identifiers will be kept in locked files accessible only by the investigators.

Will you receive study results of future research involving your specimens?

Most research with your specimens is not expected to yield new information that would be meaningful to share with you personally. In this case that would be impossible, because the researchers have no information that identifies you.

Can you withdraw the specimen from this repository?
If you decide that you no longer wish for the specimens to be stored, you should contact the researchers on the front page of this form. It is best to make your request in writing.

Any analysis in progress at the time of your request or already performed prior to your request being received by the researcher will continue to be used as part of the research study. Once the researchers have been notified, your remaining specimens would be destroyed. If you do not make such a request, the specimens may be stored forever. The researchers may choose to destroy the specimens at any time.

Who is sponsoring this research?
This research is not being paid for and there is no salary to any members of the team for doing the study. The researchers do not have a direct financial interest in the final results of the study.

What if you have questions about this research?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research subject?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, the Institutional Review Board at 919-966-3113 or by e-mail to IRB_ subjects@unc.edu.

Subject's Agreement:

I have read the information provided abov. I have asked all the questions I have at this time. I voluntarily agree to participate or have my minor child participate. I agree to my specimen(s) being stored without identifying code(s).

_____ _____

Signature of Research Subject Date

Printed Name of Research Subject

Parent/Guardian Agreement

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to allow my child to participate by allowing their specimen(s) to be stored without identifying code(s).

Signature of Parent/Guardian Date

Printed Name of Parent/Guardian

Signature of Research Team Member Obtaining Consent Date

Julie Blatt MD

Printed Name of Research Team Member Obtaining Consent