Clinical Investigation Consent Form

IRB Rev 2019

The Rockefeller University Hospital
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New York, New York 10065
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Title of the research study: Entrance into the International Fanconi Anemia Registry (IFAR)

If you are a parent or legal guardian who is giving permission for a child, please note that the word "you" refers to you/your child.

Informed consent is the first step in deciding whether you want to join this research study. Informed consent is a process of sharing information and having your questions answered. This information will include: the purpose of the research study, what will happen in the study and possible risks and benefits. All this information will be explained to you in detail. You should keep asking questions until you understand what the study is about and what is being asked of you. You may then want to enroll, or you may decide not to join the study. The decision to participate is entirely up to you. You can always ask additional questions at any time during the study. You have the right to withdraw from the study and you can change your mind about participating in the study at any time.

Summary of Key Information:

You are being asked to join a research study, which will take place at The Rockefeller University Hospital and in the associated centers that see Fanconi anemia patients. Taking part in a research study is voluntary. This form tells you about the research. You should ask questions of the person who is explaining this form to you. You may take an unsigned copy of this form home with you to read again. After you feel that you understand the research, if you want to be part of the study, you will be asked to sign the form. You can always ask more questions and can later change your mind about staying in the study. Being in a research study is not part of your routine medical care. You can decide not to be in this study.

The purpose of this study is to study the nature, diagnosis and treatment of individuals affected with the genetic disease Fanconi anemia, an inherited disorder that leads to bone marrow failure, inability to make blood cells, and increased likelihood of cancer development. The International Fanconi Anemia Registry (IFAR) was established at the Rockefeller University Hospital in May 1982, to learn if a large number of people with this rare disease show signs of its many various features. This registry has proven to be a very valuable repository for clinical, hematologic and genetic information on FA patients and their families as well as a source of cells for studies.

The study procedures may include blood sample (about 2 tablespoons of blood will be obtained), skin sample, saliva, sample of cheek cells collected with small brushes rubbed on the inside of your mouth or from a mouthwash sample, or tissue samples from surgeries and medical procedures performed for clinical care. The sample will be used to obtain cells or chemical components such as DNA and RNA to further research. Tumor cells may be grown in animals to further understand tumor development and test potential treatments.

By participating in this study, you agree to publications of our findings and to the deposition of the information we gathered in databases. The information published or deposited will be de-identified which means that your name or any identifying information that may be linked to you will not be included.

Before you continue reading, it is important for you to know that you may experience slight pain and/or a bruise from having your blood drawn and you may have a small scar from the skin biopsy. There could be a risk to your privacy and confidentiality as we do not know how your genetic information may be used in the future.

There is no direct benefit to you for participating in this study, but the information that researchers get may help to treat this condition for others who suffer with this problem.

Important Information If You Choose to Participate:

Length of time you will be asked to be in this study: If you join the research study, you will take part indefinitely unless you request that you be withdrawn. The research study as a whole will last indefinitely.

About 10,000 people will take part in the research study.

Researchers contact number: Agata Smogorzewska, MD, PhD Phone: 212-327-7850

More detailed information follows below.

I. What this research study is about, and the reason for doing this research.

The reason for doing this research is to study the nature, diagnosis and treatment of individuals affected with the genetic disease Fanconi anemia, an inherited disorder that leads to bone marrow failure (aplastic anemia). In most cases it is a recessive disorder: if both parents carry a defect (mutation) in the same FA gene, each of their children has a 25% chance of inheriting the defective gene from both parents. When this happens, the child will have FA. Patients may have a variety of birth defects, and may eventually develop acute myelogenous leukemia (AML), head and neck, gynecological, skin, and/or gastrointestinal squamous cell carcinomas. The researchers doing the study will collect information about the medical history, genetics, clinical course, blood test results, treatment, complications and social issues of Fanconi anemia. Information about relatives of Fanconi anemia patients will also be collected. A purpose of this project is to develop a detailed listing, or "registry" of people who may have Fanconi anemia, and their close family members. Normal and tumor tissues will be collected and studied to understand how the disease develops. The ultimate goal of our studies is to identify prevention and treatment strategies for Fanconi Anemia patients.

The International Fanconi Anemia Registry (IFAR) was established at the Rockefeller University Hospital in 1982 and has proven to be a very valuable repository for clinical, hematologic and genetic information on FA patients and their families as well as a source of cells for studies.

We are asking you (your child) to take part in this research study because you (your child) may be affected with Fanconi anemia or may have symptoms found in those affected with Fanconi anemia or you may be a relative of person affected with Fanconi anemia (or Fanconi anemia-like symptoms).

Memorial Sloan Kettering Cancer Center, Weill Cornell Medical Center, the University of Minnesota, the University of Cincinnati, and other clinical sites will be providing medical information for this study. You will be required to sign additional documents that allow us to gather medical information from physicians who you have seen and are currently seeing.

II. What is going to happen in this research study?

Consent Process: Informed consent is a process to help you understand the purpose of the research study, what will happen in the study, possible risks and benefits, and your right to withdraw from the study at any time. All of this information will be explained to you in detail. You should ask any questions you have until you feel that you understand what is asked of you to participate. You may then want to enroll, or you may decide not to join the study. The decision to participate is entirely up to you. Even after the study has started, you may at any time ask more questions, or decide to withdraw from the study.

Chaperones: The Rockefeller University Hospital has a policy to ensure that you and your child feel comfortable during your child's physical exam. A research doctor will explain the purpose and scope of all exams to you. Usually, a parent or guardian will be present during their young child's exam. If you prefer, you may request that a chaperone be present. A chaperone is a person not conducting the research who is present during the exam. Typically, family members are not present for adolescents' exams. The investigator may decide to provide a chaperone for your child. In some cases, having a chaperone present may be a requirement for participating in the study.

Medical information: If you (your child) agree(s) to join the study, you will be asked questions about your medical history, and the history of your family. The information about you (your child) will be entered on a questionnaire form by your (your child's) doctor. The form along with your (your child's) medical records will be submitted to the International Fanconi Anemia Registry (IFAR). In addition to the information collected when you first join the study, your (your child's) doctor will be contacted regularly for updates about your (your child's) medical condition. You may be asked to sign a release form giving us permission to request some of your (your child's) medical records. In addition, the study coordinator at the Rockefeller University may contact you to ask for medical updates about you (your child). We will maintain a Facebook page (search with "Fanconi Anemia Registry" or "Agata Smogorzewska") to update you on the progress of the studies and to keep in touch with families affected by FA. Lastly, a physical exam may be performed on you/your child to look for any physical features typically associated with Fanconi anemia.

If you participate in an online platform, https://www.ciitizen.com, in which your health data is collected from your medical records, we would like you to consider sharing these data with our study team by giving Dr. Smogorzewska access to these records. These records will have your identity on them and will be stored securely at Rockefeller University for the study team to access. There would be no cost to you to use this platform. We may also use other platforms to collect medical records. One of them will be Ciox Health, a HIPAA-compliant health information

management company that provides a health record request and retrieval service that allows patients to securely share these records with doctors and researchers. If Ciox Health is used, you will be asked to sign a "release of information form." There would be no cost to you to use this platform.

The information will be entered into a secure password protected, web-based database, which will hold similar information about many other Fanconi anemia patients and their relatives.

You (your child) will be given a code such that your (your child's) identity will never be revealed publicly.

In this part, we explain the meaning of words that we are going to use to describe this study:

> "Substances drawn from your body" refer to liquids such as blood, urine, or saliva. It can also mean tissues such as skin, and cheek cells. Cells make up all parts of your body. DNA and RNA are inside all the cells of your body and carries your genetic or inherited information. When we draw blood, take tissue, or take other substances from your body, we are taking a "sample."
>
> "Cell line" means a group of cells that can live and grow outside of the body. They can also be frozen and can be used for future research.

As part of the study of Fanconi anemia, you are being asked to give a blood sample (less than four tablespoons), skin sample, saliva or a sample of cheek cells collected with small brushes rubbed on the inside of your mouth or from a mouthwash sample. The sample will be used to obtain cells or chemical components such as DNA and RNA to further research.

The researchers will try to turn your donated cells into "cell lines," which are a group of cells that can live and grow outside of the body forever. A cell line can be created from living cells such as those taken from a tissue biopsy or a blood sample. Cell lines may be useful because of the characteristics of the cells and/or the products they may produce. Cell lines can be grown in the laboratory. This allows researchers to have an unlimited supply of your cells in the future without asking for more samples from you.

If you have a surgery and tissue is/was removed, we may request a sample of that surgical specimen to be sent to us for further studies. We may work with your surgeon to obtain fresh tumor tissue which will be used to grow tumor cells in animals as patient-derived xenografts or PDXs. PDXs are invaluable for studying how tumors develop and to test new treatments.

The samples that you have donated for this research study will be stored in our repository where it can be used by researchers at Rockefeller and elsewhere for future research projects to study the genetic and biochemical changes seen in Fanconi anemia and clinically related diseases.

In this study, you will not receive care for any related medical problems you may have.
In this study, you will not receive care for any other medical problems you may have.

If you are seen at the Rockefeller University Hospital, your medical information and test results will be written in your Hospital chart. The researchers will also keep separate records with information about you and your study tests. If you are not seen at the Rockefeller University Hospital but participate in this study, there will be no Rockefeller University Hospital chart with your medical history. The researchers will keep the records with information about you and your study tests. Sometimes we will need to look at your earlier medical records. We will ask you to sign a form that will let health care providers share your records with us. This could be your doctor, a clinic or another hospital where you have been treated before. All of this information will also be entered into a secure password protected web- based database.

Returning results of genetic testing performed in this study:

- If testing was performed in our licensed laboratory before the start of 2008, the researcher may tell your doctor the test results that may affect your health. You will need to sign an "Authorization to Release Clinical Results" form if you want the genetic test results for you (your child) released to the physician that provided the sample or to some other health care provider.

- All testing as of 2008 has been performed in our research laboratory. As such, these results need to be confirmed in a clinical "CLIA" laboratory before results could be shared with you or your doctor. We can help your doctor order the necessary testing for confirmation, but it is likely that there will be a cost associated and testing will require a new DNA sample. This confirmation step is optional and you do not have to pursue it, but it is important to realize that without confirming the results, we cannot share this information with you or your doctor.

III. What are the risks of taking part in this research study?

There may be some risks and discomforts in taking part in this study. We know that these risks and discomforts may happen during this study:

The possible risks and discomforts associated with a blood draw are slight pain, and possibly a bruise. Occasionally there may be a temporary faintness or an infection at the needle entry site.

The risks of a skin biopsy are slight pain and slight bleeding. The skin biopsy will produce a small, permanent scar in the skin; however biopsy sites will be chosen to minimize their appearance. These skin biopsy sites heal in a variety of ways. The final appearance will depend in part on the area of the body biopsied, the reason for the biopsy, and the underlying skin appearance before the biopsy. Scars may continue to change for many years after the sutures are removed. In addition, everyone heals differently, and it is possible that the scars may be red for some time, or become raised, darker or lighter than the surrounding skin. You will most likely have a permanent scar of some kind and looking at your prior scars may give the best prediction

of your long-term healing. An occasional person may develop a superficial, temporary wound infection at the site of the biopsy.

The possible risks and discomforts associated with a cheek cell collection are slight irritation at the site of the brushing. The appearance of any of these complications after these procedures is rare.

While the risk is more theoretical at this time, as we do not know how genetic information will be used in the future, there is a potential risk to your privacy and confidentiality through participation in this study. When a large amount of genetic sequencing is done (called whole exome or whole genome sequencing), that information is stored in a secure web-based database. Only certain researchers will have access to this database and the information in the database is not connected to your name, date of birth, or any other information that could identify you. However, your genetic information is like a fingerprint and is unique to you, so it is possible that someone in the future could identify you based on this information. It is important to note that there is a federal law in place to prevent discrimination based on genetic information called Genetic Information Nondiscrimination Act (GINA) (see below).

Privacy Risks: There is the risk that there could be computer security breaches which could reveal your identity. There may be the risk that data about you may become public and could be used by employers or law enforcement agencies. These privacy risks are described in greater detail below.

There may be other risks and discomforts that we do not know about now, but we will tell you any new information discovered which might affect your decision to participate or remain in the study.

The risks of participating in this study which involves genetic testing include:

- You may be upset to learn that you have a greater chance of having a disease or condition. Even if genetic tests show that you do not have a greater risk of disease, you may still be upset if you know that others in your family have that higher risk of disease. When genetic tests become available, you may want to have genetic counseling or a talk with your own doctor.

- You could face discrimination in your job, in getting a job or getting insurance if it were known that you have an increased genetic risk for a disease or condition. The researchers will keep your genetic test information confidential as allowed by federal and state law.

- Genetic tests may show information that has nothing to do with the research study. For example, when parents and children are both tested, the tests may show if the parents are the biological parents of the child. If we learn this information from these tests, you will not be told.

IV. What are the alternatives to participating in this research study?

The alternative is not to participate in this registry.

V. What are the benefits of taking part in this research study?

There may be no direct benefit from your participation in this research program. Rather, the benefits that you (your child) might reasonably expect from this research program are indirect. The Registry is expected to improve understanding about diagnosis, genetic basis, course, and treatment of Fanconi anemia, and this could potentially benefit you (your child). In some cases, the study may be able to identify the specific gene that Fanconi anemia is due to in your family. If this happens, the results would need to be confirmed by a clinical laboratory before they could be released to you. To do this clinical testing, your doctor would likely need to take another blood, buccal (sample of cheek cells collected with small brushes rubbed on the inside of your mouth), or skin sample from you (your child). This knowledge may be a direct help to some patients by allowing their doctors to know better whether a bone marrow transplant will be needed soon. In addition, the PI or the study coordinator who has a medical genetics background is available to speak with you or your child's physician should questions be raised about FA, FA testing, or our research study. We can also direct you to a genetic counselor in your area. However, it is important to know that this study is not intended to provide medical care and as such we cannot provide any recommendations about you or your child's medical care.

VI. Who will be able to see the information learned about you in this research study?

We will keep your personal information private and will do our best to keep this information confidential. We will listen to what you say we may do with this information, and we will follow the law. For example, by New York State law, hospitals must inform the New York State Department of Health if we find that you have a reportable communicable disease, such as a viral disease like COVID-19, or a sexually transmittable disease, like chlamydia, hepatitis, gonorrhea, syphilis and HIV-1. Also, the researchers must report to the authorities if they believe that child abuse or neglect has happened, or to prevent serious harm to you or others.

During the research study, the scientists in the Laboratory of Genome Maintenance at Rockefeller University and doctors who provided the information/sample to us will know that you are participating in the study. No one can have access to your identifiable information without specific permission of our regulatory board called the Institutional Review Board (IRB). In addition, these individuals cannot share your information with anyone else without your permission. Other researchers will have access to the information in the database, but will not be able to identify you, because your information will have a code instead of a name attached to it. These other researchers who study your samples will not know that they came from you and will not be able to figure out that they came from you.

Whenever possible, data about you will be unlinked from your name and identified by a code. However, auditors and regulators from government agencies that oversee research, and people at the Rockefeller University Hospital and at Rockefeller University may see your information in the course of their duties.

Your privacy is very important to us and we will use many safety measures to protect your privacy. However, in spite of all of the safety measures that we will use, we cannot guarantee that your

identity will never become known. Although your genetic information is unique to you, you do share some genetic information with your children, parents, brothers, sisters, and other blood relatives. Therefore, it is possible that genetic information from them could be used to help identify you. Similarly, it may be possible that genetic information from you could be used to help identify them. We may deposit your genetic data to databases/repositories available to others for research. While neither the public nor the controlled-access databases/repositories developed for this project will contain information that is traditionally used to identify you, such as your name, address, telephone number, or social security number, people may develop ways in the future that would allow someone to link your genetic or medical information in a database/repository back to you. For example, someone could compare information in one database/repository with information from you (or a blood relative) in another database and be able to identify you (or your blood relative). It also is possible that there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information to you. Since some genetic variations can help to predict the future health problems of you and your relatives, this information might be of interest to health providers, life insurance companies, and others. Patterns of genetic variation also can be used by law enforcement agencies to identify a person or his/her blood relatives. Therefore, your genetic information potentially could be used in ways that could cause you or your family distress, such as by revealing that you (or a blood relative) carry a genetic disease. If concerns over non-paternity or non-maternity arise, they will not be divulged under any circumstances.

There also may be other privacy risks that we have not foreseen.

You need to know that if you choose to communicate with the investigators using Facebook, we cannot guarantee the confidentiality of the private messages exchanged.

If the researchers publish the results of this study, they will not mention your name or other information that could identify you. However, FA is a rare disease so when you read a published study, you may identify your family from the description. By participating in this study, you give us a permission to publish our research findings.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). This means that the researchers cannot release or use information, documents, or samples that may identify you in any legal action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop

disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Genetic Information Nondiscrimination Act

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal in the United States of America for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Additional information is available in the Rockefeller University Outpatient or Inpatient Information Handbook.

There may also be privacy risks that we have not foreseen.

Sharing of the results

In order to allow researchers to share test results, the National Institutes of Health (NIH) and other central repositories have developed special data (information) banks that collect the results of whole genome studies. The NIH or other data banks will store your genetic information and give it to other researchers to do more studies. We do not think that there will be further risks to your privacy and confidentiality by sharing your whole genome analysis with these databanks; however, we cannot predict how genetic information will be used in the future. The information will be sent with only your code number attached, and your name or other identifiable information will never be given to them. There are many safeguards in place to protect your information while it is stored in repositories and used for research. Research using your whole genome information is important for the study of virtually all diseases and conditions. Therefore, the databank will provide study data for researchers working on any disease, which could include conditions such as HIV/AIDS, cancer, mental illness, and others.

VII. <u>What are the payment arrangements?</u>

There is no cost to you for being in this research study.

If research using your samples helps develop a drug or another product that is sold to the public, the drug company, the University and the researcher may share in some of the profits. For example, a cell line from your samples could be used to make a product for sale. There are no plans to pay you any money resulting from such discoveries. However, by signing this form, you do not give up any rights you may have.

VIII. What happens if you don't want to stay in this study or your participation is ended?

You can choose if you want or do not want to be part of this study. If you do not join, there is no penalty, and no one will hold this against you. You may change your mind and stop taking part in this study at any time, and this will not be held against you. Information about you up to the time you stop participating in the study may remain a part of the study.

During this study, the researchers may learn new information that might make you change your mind about whether you want to stay in the study. You will be given that information promptly.

If you decide to join the study now but later want to stop, you should let the researcher know. You can contact the head of the study, Agata Smogorzewska (all contact information on page 8) and share that you no longer want to be part of the study.

If you no longer wish to be part of the repository the researchers will anonymize the sample by removing and destroying all identifiers and links to identifiers so that it cannot be associated with you, but the researchers will not destroy the sample.

IX. Whom do you call if a medical problem results from this research study?

If you believe that this study has led to a medical problem, you should call the researcher listed below right away. The researcher will help you get appropriate, available medical care.

Name: Jeanne Walker, DNP, ANP-BC
Phone No.: 212-327-7270
Fax No.: 212-327-8449
After 5pm and weekends: 212-327-8448 (inpatient unit)
Email: walkerj@rockefeller.edu

The Rockefeller University does not plan to pay for medical care that you may have as a result of taking part in this study at The Rockefeller University Hospital. However, you do not give up any rights you may have to seek compensation by signing and dating this consent form.

X. Whom do you contact if you have questions about the research study?

Please ask as many questions as you want about this research study and this consent form. If you agree to take part in this study and have questions later on, contact the following researchers:

Study Coordinator	212-327-8613	fanconiregistry@rockefeller.edu
Agata Smogorzewska, MD, PhD	212-327-7850	asmogorzewska@rockefeller.edu

These individuals can also be reached at:

The Rockefeller University
1230 York Avenue, Box 182

New York, NY 10065
Fax: 212-327-8262

If you have any concerns about your experience while taking part in this research study, you may contact The Rockefeller University Institutional Review Board (IRB) Office at (212) 327-8410, or the Office of Clinical Research at (212) 327-8408.

XI. The use, storage and sharing of your samples and data for separate research studies

The scientific value of your samples and the information obtained from them is greatly increased if we can share them with other scientists at universities and pharmaceutical or technological companies worldwide. Your samples and information will be used for biomedical research including genetic analyses. You will not be provided details of any specific research studies or their purpose. In general identifiers will be removed from the identifiable private information or identifiable biospecimens. Thereafter the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative. The genetic information obtained from your DNA is called genotype. The information about your disease condition and the physiology of your cells is called phenotype. We may:

- store, use, and share for many years your biospecimens and information including genotype and phenotype data, with other investigators at Rockefeller and elsewhere, possibly worldwide, and including pharmaceutical and technology companies, sample and/or data banks/repositories for separate studies for many years. Your biospecimens will either be stripped of information identifying them as yours or coded (we will hold the key to the code) so that they cannot be identified as having come from you. Other data related to your biospecimens, but that does not identify you, may accompany the specimens; and

- put anonymous data information from the analyses in a completely public database, available to anyone on the Internet; and

- put your coded genotype and phenotype medical data information and data information from more detailed analyses of your coded samples in a NIH controlled-access database/repository. The information in this database/repository will be available only to qualified researchers from academic institutions and commercial organizations, both domestic and foreign who have received approval from an NIH Data Access Committee.

Any time in the future, you may withdraw your consent to use any samples that have not already been used in research or shared. If you withdraw your consent, the remaining unused samples will be destroyed, unless the samples cannot be identified as having come from you. Data generated using your samples will continue to be used.

We realize that some people may not want to have their samples and/or data stored and shared with others and if that is your feeling, then you should not participate in this study. You may participate by providing information only but no samples.

XII. May we have permission to contact you about future studies?

May we contact you by phone or email to find out if you are interested in hearing about new research studies? (We will not share your contact information for any other purpose). Contact would be made by the staff of the Rockefeller Clinical Research Support Office for recruitment. If you decide at any time that you no longer want to be contacted, please tell us, and we will no longer attempt to contact you.

Would you like us to contact you about future research studies?

Yes _____ No _____

If you say "no" to this question, this will not affect your participation in this study.

AGREEMENT TO PARTICIPATE -- SIGNATURES REQUIRED

I have read this consent form, and my questions have been answered.

A copy of this consent form will be given to you. Please keep a copy of the form as it contains important information that you may wish to refer to during the research study and thereafter.

I hereby voluntarily consent to take part in this research study.

Name of the Study Participant (Print) _____

_____ _____
Signature of Study Participant **Date (To Be Filled in by Study Participant)**

ALTERNATE SIGNATURE BLOCK

Adult not legally capable of giving consent

Name of the Study Participant (Print) _____

Name of Legal Representative (Print) _____

_____ _____
Signature of Legal Representative **Date (To Be Filled in by Representative)**

- Documentation, such as a health care proxy, showing authorization to act as a legal representative, is attached.

ALTERNATE SIGNATURE BLOCK

Participant requires assistance by a translator

Translation Services Provided by (choose one, by checking one box below):

☐ **Pacific Interpreters**

_____ _____
Language **Translator Identification Number**

Witness to telephone translation:_____
(Print Name)

_____ _____
Signature of witness **Date**

☐ **Other Translator:**

_____ _____
Name of translator **Date**

Witness to oral presentation: _____
(Print Name)

_____ _____
Signature of witness **Date**

ALTERNATE SIGNATURE BLOCK

Protocols Involving Children

I hereby voluntarily consent to have my child take part in this research study.

Name of Child (Print) _____

Name of Mother or Legal Guardian (Print) _____

_____	_____
Signature of the Mother or Legal Guardian	**Date (To Be Filled in by Mother or Legal Guardian)**

Name of Father or Legal Guardian (Print) _____

_____	_____
Signature of the Father or Legal Guardian	**Date (To Be Filled in by Father or Legal Guardian)**

ALTERNATE SIGNATURE BLOCK

Protocols Involving Pregnant Women

I hereby consent, as the pregnant mother of my unborn child, to take part in this research study.

Name of Pregnant Woman (Print) _____

_____ _____
Signature of Pregnant Woman **Date (To Be Filled in by Pregnant Woman)**

I hereby consent to have the pregnant mother of my unborn child take part in this research study.

Name of Male Parent (Print) _____

_____ _____
Signature of Male Parent of Child **Date (To Be Filled in by Male Parent)**

Signature of the Person Conducting the Informed Consent Discussion

I have explained the research protocol and this consent form to the participant and have answered the participant's questions about this research study and/or the consent process.

Name of Person (Print) _____

_____ _____
Signature of Person Discussing Consent **Date (To Be Filled in by Person Discussing Consent)**