



Stony Brook University

Committees on Research Involving Human Subjects
Established 1971

RESEARCH PATIENT CONSENT/ PARENTAL PERMISSION FORM DIGESTIVE SYSTEM RESEARCH INVOLVING CODED TISSUE AND/OR DATA

Project Title: Stony Brook Digestive Diseases Research Tissue Procurement Facility (also termed GI Clinical Resource Core)

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Department: Medicine

Please Note: The word "you" in this consent form, means you or your child. "We" means the doctors and other staff. If you are a parent or legal guardian of a child who may take part in this study, permission from you (on this form) and separate assent from your child (if between 7-17 years old) will be required.

You are being asked to be a volunteer in a research study.

You are eligible for this study because you have been diagnosed with, or your doctor thinks you may have, a digestive disease, and you are here for related tests and/or procedures.

We want you to know that:

- Taking part in this research project is entirely voluntary.
- You may choose not to volunteer and it will not affect your care here in any way.
- You will not benefit from taking part in the project. The research is very early stage, so it may only give us knowledge that will help people in the future.
- There is much more information below. If you are thinking about volunteering, please take as much time as you need to read this form, ask questions of our staff and your doctor, discuss the project with anyone, and think about it before answering.
- If you are signing for a minor child, "you" refers to "your child" throughout this form.

You may have already signed a consent form for this study when you were under the age of 18 years old.

PURPOSE

The purpose of this study is:

To develop a bank of blood, saliva, stool and tissue samples and information from people to help us better understand problems of the digestive system.

Some of the tissue may be used to make a working copy of your tissue (a model) that will continually grow in a laboratory dish. To make this copy, we would take some of the extra tissue remaining from the surgical removal procedure you are about to have and treat it with certain chemicals and nutrients. Or, if you are undergoing biopsy procedure, we will ask your permission to take extra research biopsies during the procedure you are about to have and treat it with certain chemicals and nutrients, after we have insured that the biopsies taken previously for clinical care are sufficient. Sometimes this treatment can turn tissue (normal or diseased) into a "cell line/model", which means the tissue will continue to grow outside of the body. Because these models are designed to be an accurate copy of the original tissue, they can be very useful to scientists who want to understand how digestive diseases such as cancer work, what causes disease, and can also be used to test new drugs. The models are most useful when they are connected to your clinical information, which includes information about you, your disease, how you were treated, and how you responded to that treatment. This clinical information will be collected, but all obvious identifiers (like your name, social security number, medical record number, address and phone number) will be removed.

The Stony Brook University GI Clinical Resource Core, previously termed the Stony Brook Digestive Diseases Research Tissue Procurement Facility, is an administratively dependent facility of the SBU BioBank, which is collecting these samples and information, and will provide them in a coded form (so you cannot be identified) to approved researchers for the study of human digestive diseases. By consenting to this tissue collection, you are consenting to allow your samples to be stored at the GI Clinical Resource Core or within the main SBU BioBank facility or both. Some of the samples, once de-identified in the GI Clinical Resource Core may be provided to outside facilities involved in the Human Cancer Models Initiative (HCMI). HCMI is an international collaboration between the National Cancer Institute (NCI), part of the National Institutes of Health, Cancer Research UK, Wellcome Sanger Institute, and foundation Hubrecht Organoid Technology. NCI supports Cancer Model Development Centers (CMDCs) to generate HCMI models. One of the CMDCs includes Cold Spring Harbor Laboratory. For more information visit: ocg.cancer.gov/programs/HCMI. The goal of this project is to make a large library of many different cancer models connected to the clinical information from each cancer patient who donated tissue. The library of models and information will be kept at central locations, and then made available to cancer researchers worldwide through a distributor.

We expect to have approximately 3,000 patients agree to donate samples and medical information to this facility.

BACKGROUND INFORMATION

Tissues in your body are made up of many cells that contain genetic material, for example DNA. DNA is the genetic material that provides a code of instructions that tell your body's cells how to develop and function. Changes in this genetic code can lead to cancer, a disease where cells stop following their normal biological instructions and start to grow out of control. In recent years, researchers have discovered many genetic changes, and are working to understand how some of them lead to cancer. If a model can be successfully made from your tissue, researchers can use that model to study cancer, including the genetic changes that occurred. In the future, when researchers better understand cancer and other digestive diseases, doctors may use these models to customize treatments based on each patient's unique genetic make-up or test different drugs on these models made from a patient's diseased tissue before giving those drugs to that patient. Sharing the models developed by this early research project is the first step in making that kind of progress.

Why are we asking if you will volunteer for donating to the Stony Brook GI Clinical Resource Core?

You are being asked to donate samples, because, as part of your planned medical procedure, you are having your tissues biopsied or are undergoing surgery to have a portion of your gut, liver or pancreas removed. Normally, any extra tissue from surgical removal would be thrown away. If you are undergoing a procedure to biopsy tissues, we would ascertain that sufficient material has been obtained for your clinical care, prior to obtaining additional biopsies for research. We are also requesting permission to collect samples of bodily fluids (blood, saliva or stool) and information from your medical records. The following sections describe how your tissue samples and information will be collected and studied if you give us this permission.

CONFIDENTIALITY

Protecting your privacy and keeping your information confidential.

We will take steps to help make sure that all the information we get about you is kept private. Your name will not be used wherever possible. We will use a code instead. All the study data that we get from you will be kept locked up. The code will be locked up too. If any papers and talks are given about this research, your name will not be used. Once information and samples are de-identified and assigned a random code, they may be used and shared for other purposes, besides the HCMI, not discussed in this consent form. Specifically, information assembled from a group of patients rather than an individual patient may be released to public on-line databases. Coded clinical information and genetic information that relates to you individually will be released only to qualified researchers who have received prior approval from the NIH Data Access Committee. Because of the steps we are taking to protect your privacy, it will be very hard for anyone who looks at any of the Internet databases to know which information came from you, or even that any information came from you. Also, when scientists publish research results in papers or books or discuss them at scientific meetings, nobody should be able to tell that you were a participant.

Removing your identity from your tissue samples and medical information.

Your tissues and information will be de-identified, which means that all your obvious identifiers (like name, social security number, medical record number, address, phone number, and others) will be stripped away. Once information and samples are assigned a code, they may be used and shared for other purposes not discussed in this consent form. Your samples and information will only be labeled with a patient code and sample code. Dr. Li at Stony Brook University will keep a link between the code and your ID in a secure database. Only authorized people who have specifically agreed to protect your identity at Stony Brook University reporting to Dr. Li, will have access to that database, and the link will not be shared with anyone outside of Stony Brook University. Once models are successfully created from your cancer by the HCMI facility, your deidentified information has been collected and the models are stored in the HCMI designated distribution biobank, the link will be permanently broken with the distribution HCMI designated biobank code and the institution assigned code. Only the HCMI facility code will be attached to the models and your information, and it will not be possible to link you back to those models by the HCMI distribution biobank facility. Sometimes making a model at the HCMI facility doesn't work, in which case the HCMI distribution biobank facility will also break the link and throw away your tissues and information.

While you are in this study, we will get data about your health from your medical record. We will also get health data from the results of the tests you will have done in this study. You have a right to privacy but the data we get about your health in this study can be shared with the study team, Stony Brook University's Committee on Research Involving Human Subjects, applicable institutional officials, and certain federal offices.

You have the right to stop allowing us to use or give out your health data. You can do this at any time by writing to Dr. Ellen Li. If you do this, we will stop collecting any new health data from you. We will use any data we collected before you wrote your letter. If you want to remove the specimens we collected from the tissue bank, write a letter stating this, and any remaining tissues that have not been distributed and/or posted online for sharing with other researchers will be destroyed. With respect to tissues and information sent to the HCMI facility, you may choose to stop being part of this HCMI research project for any reason, but only up to a certain point in the future. We can't know how long it will take to work with your samples to successfully make a model at the HCMI facility. If you withdraw soon enough, we will stop working with your tissue samples and stop trying to make models, and we will stop collecting any of your medical information. Your information will be deleted, and your tissue will be thrown away. However, if we have passed the point of creating models from your tissue and put your information in the database, and broken the link to your identity, it will no longer be possible to discard your samples, the models, or remove your information from this project. This means that if you agree to let us use your tissues and information, and cancer models are successfully grown from your samples, the models and your associated information could be used forever. In addition, any cancer models or cell lines that have been developed by other researchers from your tissues will not be destroyed once we have distributed the tissues and associated deidentified clinical information to these researchers.

Certificate of Confidentiality

This study requires that we collect very private information about you. Therefore, we had the National Institutes of Health give us a Certificate of Confidentiality (COC). With this Certificate, we cannot be forced to reveal information that may identify you, even by a court order, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. We will use this Certificate to resist any demands for information that would identify you, with the following exceptions:

- The Certificate cannot be used to stop a request for your information from the United States Government when the information is to be used for auditing or evaluation of federally funded projects or for information that must be disclosed to meet the requirements of the federal Food and Drug Administration (FDA).
- The Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this project. Also, if you have given written permission to an insurer, employer, or other person to receive research information, then we may not use the Certificate to withhold that information.

This piece of paper says that nobody can force the researchers to give out your information, even if a court of law asks for it. This will give you more protection. The only time information about you can be given out is:

- If you are going to hurt yourself,
- If you are going to hurt someone else
- If we believe the safety of a child is at risk.

We will get health data from the results of the tests you will have done in this study. You have a right to privacy but the data we get about your health in this study can be shared with the study team, Stony Brook University's Committee on Research Involving Human Subjects, applicable institutional officials, and certain federal offices.

When you sign the consent form at the end, it means that:

- You have read this section.
- You will allow the use and reporting of your health data as described above.
- You have received a form from the University Hospital. It is called the Notice of Privacy Practices form.

COLLECTION OF SAMPLES & MEDICAL INFORMATION

Participation in this study involves, in part, the donation of samples such as blood, saliva, stool, and tissue from your body. Whenever possible, these samples will be collected at the time of your regular GI clinic or surgical visit. In addition to left-over clinical samples, we may ask you to provide additional samples at this and/or future GI clinic or surgical visits.

You will always have the option to refuse a specific donation without affecting your future participation of your medical care. You will also have the option to withdraw from the study at any time.

If you agree to participate in this activity, the following samples and procedures may be asked of you. At the end of this consent form, you will have an opportunity to provide consent for some or all of the following:

Blood Sample: You may be asked to donate blood. The 40 mL (approximately eight teaspoons) of blood drawn is in addition to blood drawn for any routine purposes that your doctor deems necessary. The blood may be drawn at the same time as your routine blood work so an extra needle stick may not be necessary. If drawn separately (not from the routine blood work draw or IV), blood collection may take up to five minutes of your time.

Saliva Sample: You may be asked to submit a saliva sample by spitting into a plastic container.

Stool Sample: You may be asked to provide a stool sample. We may request a small amount of stool from you when you have a bowel movement, as well as permission to take some stool from inside your colon or small bowel, if and when we do a clinical procedure. If you are unable to provide a stool sample, we may ask permission for our staff to obtain a rectal swab, or for a sample collection kit to be mailed to you, and you will be asked to mail the stool sample back to us in a prepaid container. If you are a patient in the hospital and tests have been ordered on your stool, we may collect any stool left over after the tests have been completed.

Endoscopy Sample:

For Adults (18 years old or older): If you are scheduled for a routine, clinically-indicated (not for research) endoscopic procedure such as a colonoscopy, we may collect up to 10 additional pieces of the tissue (biopsies) to be stored and used for research. The pieces of tissue that we take are each about the size of a grain of rice. Taking extra biopsies may increase the length of the procedure by five minutes. These biopsies will be taken only if the doctor performs biopsies as part of your routine care.

For Children (7-17 years old): If your child is scheduled for a routine, clinically indicated (not for research) endoscopic procedure such as a colonoscopy, we may collect up to 2 additional pieces of tissue during your child's clinical procedure. The pieces of tissue that we take are each about the size of a grain of rice. Taking extra biopsies may increase the length of the procedure by five minutes. These biopsies will be taken only if the doctor performs biopsies as part of your routine care.

In addition to providing these extra biopsies, you may also be asked for permission for us to grow cells we obtain from the endoscopy: This means that cells from your sample could be continuously grown in the research laboratory, producing what is called a "cell model". These models can provide an endless source of your cells and DNA with the sole purpose of using them in research and testing for many years. The laboratories growing the cells may be outside Stony Brook University. For example, we are participating in the HCMI, an international

collaboration between the National Cancer Institute (NCI), which is part of the US government agency known as the National Institutes of Health (NIH), Wellcome Sanger Institute Cancer Research UK and Hubrecht Organoid Technology. NCI funds Cancer Model Development Centers at Cold Spring Harbor Laboratory. All of those institutions will donate the models to the central library for distribution.

Surgical Waste:

If you are scheduled to have tissue removed in surgery on your digestive system, many times there ends up being more tissue than is needed for your diagnosis, which is normally thrown away. After the pathology department takes the tissue they need for your medical care, we are asking your permission to get some of that extra tissue and to grow your cells in the laboratory. This means that cells we get from your sample could be continuously grown in the research laboratory, producing what is called a "cell model". These models can provide an endless source of your cells and DNA with the sole purpose of using them in research and testing for many years. The laboratories growing the cells may be outside Stony Brook University including the HCFI Cancer Model Development Center (CMDC) Cold Spring Harbor Laboratory. Once the Cancer Model Development Center successfully creates a model from a tumor sample, one vial of each model will be sent to the laboratory which provided the tissues. The remaining vials of models generated will be sent to the distributor for expansion, storage, and downstream distribution to the scientific community. These organoid cultures will be only identified by a code from the HCFI CMDC, which is not linked to identifiable information that can link the organoid culture back to you. Thus the tissues and biopsies sent to other investigators are linked to a patient code and all identifying information is stripped prior to releasing the samples to any investigator or facility including the HCFI. However, there is a rare possibility that confidential information about you may be accidentally disclosed.

Pathology Specimen(s): We are requesting permission to use tissues stored in Stony Brook University Hospital that may have been previously removed from you, or that might be removed in the future, from you for clinical (non-research) reasons.

Questionnaires: Depending on your diagnosis you may be asked to complete some questionnaires about your current health and health history, your eating habits, and symptoms in your digestive system.

Longitudinal Database: We are also asking to collect information from your medical records at Stony Brook University Hospital and associated outpatient clinics, including your age, ethnic background, diagnosis, disease history, medical treatments, and response to treatments. We will also collect some information about your social history, such as whether or not you smoke cigarettes and drink alcohol. We will not collect your name, address, phone number, medical record number or any other obvious identifiers. Information may be collected from your medical record that is on file at Stony Brook University Medical Center and its clinics. This information will be stored with a study code so that your identity is protected. The key to the code that would identify you will be stored in a way so that it is only accessible to the Principal Investigator

above, Dr. Li, and her staff.

The coded medical/clinical information will be placed in a scientific database that will be available to scientists who have received approval from the federal National Institutes of Health (NIH) Data Access Committee. Your coded information may also be grouped together with information from other patients with conditions like yours and released to public online databases. Our research team will update this information periodically (yearly) from your medical records indefinitely. This way, we can update your information on medicines, surgeries, smoking history, family history, disease activity, etc. In the event that the medical record does not contain all the information that is needed, you may be contacted by the GI Clinical Resource Core staff to obtain that information directly from you. Please note that clinical data sent from the GI Resource Core to HCMI will be limited to 9 months after model generation

Genetic research

We will also provide some of your samples and information labeled with a study code to authorized researchers. Your samples may be used to study changes in genetic material (DNA) that are passed on in families, or that are not passed on in families but are influenced by environment and lifestyle. DNA is the material that makes up your genes. Genes are the part of cells that contain the instructions, which tell our bodies how to grow and work, and determine physical characteristics such as hair and eye color. Researchers may perform tests that focus on a section of genetic material, genetic material packaged into chromosomes, or examine all of the genetic material called whole genome analysis. In whole genome studies, all or most of your genes will be analyzed and used by researchers to study links to cancer and related disorders. The results can then be studied to identify changes in genetic material that influence the development of cancer or the effectiveness of specific treatments. Reports of this research done on your specimens will not be given to you or your doctor, or be put in your health record.

NIH Genomic Data Sharing:

In this study we collect information about your health and your individual genes. Researchers can do studies that are more powerful when they share with each other the data or information they get from studying human samples. We will remove direct identifiers (such as your name) from your samples/information and instead code your information. Information from analyses of your coded samples and your coded medical information will then be put into one of the National Institutes of Health (NIH) databases or repositories along with information from the other research participants and will be used for future research. Stony Brook will retain the master list that links your code number to your identifying information here at Stony Brook and only certain Stony Brook research staff members will ever have access to this master list. We will not know what types of health-related research will be done with the data that are sent to the repository. There are two different kinds of databases or repositories.

There are repositories that are called controlled-access repositories. These are only available to researchers and companies who apply to the NIH. The NIH will review data requests for scientific merit and for methods to protect data and methods to ensure coded data will be used

for the approved purpose. The information stored in these databases or repositories will not include any identifying information and will be coded as mentioned above. Our research team will update this information periodically (yearly) from your medical records indefinitely. This way, we can update your information on medicines, surgeries, smoking history, family history, disease activity, etc. In the event that the medical record does not contain all the information that is needed, you may be contacted by the GI Clinical Resource Core staff to obtain that information directly from you. Please note that clinical data from this study sent to the HCMi will be limited to 9 months after model generation start.

RISKS / DISCOMFORTS

The following risks/discomforts may occur as a result of you being in this study:

Risks if information about you is accidentally released:

Keeping your information confidential is very important to us and we use many safety measures to protect that information. However, some of this information may still be traceable to you and we cannot guarantee that your identity will never become known. It is possible, for example, that there could be violations to the security of the computer systems used to store the link between the random number code and your name or other identifiers. It is also possible that, in the future, someone could compare information in our databases with information from you (or a relative) in another database and be able to identify you (or your relative). While we believe that the risks to you and your family are low if your identity became known, we are unable to tell you exactly what all of the risks are. There are some laws that protect you against genetic discrimination by employers or insurance companies. In 2008, the US federal government passed the Genetic Information Nondiscrimination Act (GINA), a law that prohibits genetic discrimination in employment and health insurance. It is important to note that while this law protects you from certain kinds of genetic discrimination, there are exceptions. For example, GINA does not apply to employers with fewer than 15 employees. Additionally, this law does not protect you from genetic discrimination in life, disability, or long-term care insurance.

If your identity became known, here are some of the possible risks:

- There could be psychological or social risks associated with loss of privacy. For example, your genetic information could potentially be used in ways that could cause you or your family distress by revealing that you (or a relative) carry a genetic disease. This could lead to the denial of life insurance for you (or a relative).
- Patterns of genetic information are shared by relatives. If your identity became known, it is possible that the identity of your relatives could also become known.
- Patterns of genetic variation also can be used by law enforcement agencies to identify a person or his/her relatives.
- There may also be other privacy risks that we have not foreseen.

NIH Genomic Data Sharing: There are no physical risks to you for donating and storing your specimens for use in future research studies. The data will be transmitted associated with

patient code or sample code and stripped of any identifying information. However, there is as rare risk that information about you may be accidentally released.

Risk of Blood Draw:

The risks of blood drawing include temporary pain and bruising where the needle enters the skin, and sometimes, fainting and/or infection.

Risk of Endoscopy or Colonoscopy (For patients already undergoing procedure for clinical reasons):

Taking the additional biopsies for research may result in:

- A rare risk (1 in 100 patients) of a hole in the colon, bleeding and/or infection.
- A slightly increased risk of bleeding. In the vast majority of cases, the bleeding will stop on its own, or the doctor can stop it during the test.
- Very rare risk of infection.

BENEFITS

There is no benefit to you expected as a result of being in this study.

The tissue and medical/clinical information you provide will be used for research purposes only. The research that may be done with your specimens is not designed specifically to help you, but it may help others with digestive and other diseases in the future. Reports about research done with your specimens will not be given to you or your doctor, and will not be put in your medical record. The research will not have an effect on your medical care.

There is no direct benefit to you from placing your genetic information in the NIH repository. Allowing researchers to study your genetic information may lead to a better understanding of how genes affect health. This may help other people in the future.

PAYMENT TO YOU

You will not be paid for your participation in this study.

Your specimens will be shared with approved researchers. The research done on your specimens may help to develop new products and therapies in the future, however there is no intent to share any profits with you that may result from those possible products or therapies.

PAYMENT TO THE INSTITUTION

This project is funded by National Institute of Health/ National Institute of Cancer and the internal funds from Department of Medicine, Division of Gastroenterology.

COSTS TO YOU

There will be no cost to you for participating in this study.

ALTERNATIVES

Your alternative to being in this study is to simply not participate.

IN CASE OF INJURY

If you are injured as a result of being in this study, please contact Dr. Ellen Li at telephone # (631) 444-2119. The services of Stony Brook University Hospital will be open to you in case of such injury. However, you and/or your insurance company will be responsible for payment of any resulting treatment and/or hospital stay.

YOUR RIGHTS AS A RESEARCH SUBJECT

- Your participation in this study is voluntary. You do not have to be in this study if you don't want to be.
- You have the right to change your mind and leave the study at any time without giving any reason, and without penalty.
- You will get a copy of this consent form to keep.
- You do not lose any of your legal rights by signing this consent form.

QUESTIONS ABOUT THE STUDY OR YOUR RIGHTS AS A RESEARCH SUBJECT

- If you have any questions, concerns, or complaints about the study, you may contact Dr. Ellen Li at telephone # (631) 444-2119, OR by e-mail, Ellen.Li@stonybrookmedicine.edu.
- If you have any questions about your rights as a research subject or if you would like to obtain information or offer input, you may contact Ms. Lu-Ann Kozlowski, Committee on Research Involving Human Subjects, at telephone # (631) 632-9036, OR by e-mail, Lu-Ann.Kozlowski@stonybrook.edu.
- Visit Stony Brook University's Community Outreach page, <http://research.stonybrook.edu/orc/community.shtml#overview-of-volunteering-inresearch> for more information about participating in research, frequently asked questions, and an opportunity to provide feedback, comments, or ask questions related to your experience as a research subject.

MAKING YOUR CHOICES FOR THIS RESEARCH

The choice to let us collect and store your specimens and data for use in future research is completely up to you. No matter what you decide to do, it will not affect the care you receive

from your doctor.

The person having the discussion with you now about participating will tell you which of the following research procedures are being asked of you, and will cross out the ones that don't apply to you. For the remaining procedures, check **yes** (you want to have the procedure done for research purposes) or **no** (you do not want to have the procedure done for research purposes), and then provide your signature and date next to your choice for each procedure. By consenting to this tissue collection, you are consenting to allow your samples to be stored either in the Stony Brook GI Clinical Resource Core), the main SBU hospital BioBank, or divided between the two.

If you are being asked to participate before your surgery and/or endoscopic procedure, these are the possible choices:

	YES	NO	Your Initials	Date
Blood	✓		[Redacted]	[Redacted]
Saliva				
Stool				
Endoscopy Samples				
Surgical Waste	✓		[Redacted]	[Redacted]
Cell-Line / Model (Permission to grow cells)	✓		[Redacted]	[Redacted]
Pathology Samples	✓		[Redacted]	[Redacted]
Questionnaire	✓		[Redacted]	[Redacted]
Longitudinal Database	✓		[Redacted]	[Redacted]

If you are being asked to participate after your surgery, these are the possible choices:

	YES	NO	Your Initials	Date
Blood				
Saliva				
Stool				
Surgical Waste				
Pathology Samples				
Questionnaire				
Longitudinal Database				

If you are being asked to participate after your surgery/endoscopic procedure and have been discharged from the hospital within the past two weeks, these are the possible choices:

	YES	NO	Your Initials	Date
Surgical Waste				
Pathology Samples				
Questionnaire				
Longitudinal Database				

Incidental Findings

The procedures in this study are being done, and results reviewed, only for research reasons, as explained in the beginning of this consent form. In other words, this study is neither designed nor intended to detect health problems.

Nonetheless, it is possible that during review of results from tissue samples, we may uncover something that may (potentially) have health or reproductive importance to you. Such findings are called 'incidental findings' (IFs).

Because of the possible significance of the IF's that may result from these procedures, your consent to be in this study also includes permitting the researchers to disclose IF's not only to you, but directly to your primary care physician, as necessary. If you do not have one, assistance will be provided in securing one. However no incidental findings or results from your HCM1 models will be provided to you or your primary care physician.

Do you agree to be informed of any incidental findings discovered during the course of this research study? Choose, and sign below one option:

YES, I want to be informed of incidental findings discovered during the course of this research study

[Redacted Signature]

Subject Signature

[Redacted Date]

Date

NO, I do not want to be informed of incidental findings discovered during the course of this research study

Subject Signature

Date

If you sign below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to be a volunteer in this study as indicated above.

[Redacted Name]

Subject Name (Printed)

[Redacted Signature]

Subject Signature (Adults only)

[Redacted Date]

Date

Parent Name (for minor subject)
(Printed)

Parent Signature (for minor subject)

Date

DIMITRI F JOSEPH

Name of Person Obtaining Consent

D. Joseph

Signature of Person Obtaining Consent

3/10/20

Date