



ST. JOSEPH MERCY OAKLAND CONSENT FORM with HIPAA

- Instructional text appears in red and should be removed prior to submission to the IRB.
- Red text in parentheses () should be replaced by information for your study, (e.g.: your name here) .
- The consent should read at a 5th grade reading level
- Footer information is required on consent forms for studies conducted at SJMO

INTRODUCTION TO RESEARCH STUDIES

A research study is designed to answer specific questions, sometimes about a drug's or device's safety and effectiveness. Being in a research study is different from being a patient. When you are a patient, you and your doctor have a great deal of freedom in making decisions about your health care. When you are a research participant, the Principal Investigator and the research staff will follow the rules of the research study (protocol) as closely as possible, without compromising your health.

PURPOSE OF RESEARCH

You are invited to participate in a research study of (state what is being studied). We hope to learn (state what the study is designed to discover or establish). You were selected as a possible participant in this study because (state why the participant was selected).

Your participation in this study is entirely voluntary.

Your decision whether or not to participate will not prejudice you or your medical care. If you decide to participate, you are free to withdraw your consent, and to discontinue participation at any time without prejudice to you or effect on your medical care. If you decide to terminate your participation in this study, you should notify (name) at (telephone number).

This research study is looking for (state number of people) with (disease or condition). Clarify if enrollment will occur throughout the United States or internationally. St. Joseph Mercy Oakland expects to enroll (state number) research study participants.

DURATION OF STUDY INVOLVEMENT

This research study is expected to take approximately (x days, weeks, months, etc.) e.g.: this is a 2 year study; 28 days of active participation by each participant; and 180 days collection of medical information for each participant.

- If there is a follow-up period, state so and the expected length of time.

(Protocol Title)

(Principal Investigator)

IRB Approval Date: _____

Participant Identifier: _____

PROCEDURES

If you choose to participate, (Principal Investigator) and (his/her) research study staff will (describe all procedures to be followed). Consider inserting a chart or calendar; these images can be very helpful to participants. Chronological descriptions are also helpful.

Include the following, as applicable, in this section of the consent:

- (Clearly identify what is experimental in this study.)
- (State the purpose(s) of the procedures.) Suggestion: refer to your protocol to assist you in identifying all protocol-related procedures.
- (State how often each procedure will be done and how long it is expected to take.)
- (Identify invasive procedures, where applicable.)
- If contraception is recommended: (include specifics for both women AND men).
- For labs: (state what specimens will be obtained and the estimated amount) The total amount should be calculated and presented to the participant in lay terms, e.g., the number of tablespoons of blood drawn.
- If samples will be sent out for analysis, include a statement: *Your samples will be sent outside of St. Joseph Mercy Oakland for analysis.
- If samples, such as tissues or blood, will be destroyed at the end of the study add the following: *Any samples left over after analysis will be destroyed when the study is completed.

Use the following subsections below if applicable to your study:

- MRI
- Women of Childbearing Potential
- Storage of samples for future research and/or banking
- Genetic testing (current study or future research)
- Gene transfer

If your protocol uses MRI, insert the following MRI paragraphs, as applicable.

MRI (Magnetic Resonance Imaging)

MRI machines use a strong magnet and radiofrequency magnetic fields to make images of the body interior. The scanning procedure is very much like an X-ray or CT scan. You will be asked to lie on a long narrow couch for a certain amount of time (state how long) while the machine gathers data. During this time you will not be exposed to x-rays, but rather a strong magnetic field and radiofrequency magnetic fields, which you will not feel. You will, however, hear repetitive tapping noises that arise from the Magnetic Resonance scanner. We will provide earplugs or headphones that you will be required to wear. The space within the large magnet in which you lie is somewhat confined, although we have taken many steps to relieve the "claustrophobic" feeling.

(Protocol Title)

(Principal Investigator)

IRB Approval Date: _____

Participant Identifier: _____

Risks:

Magnetic fields do not cause harmful effects at the levels used in the MRI machine. However, the MR scanner uses a very strong magnet that will attract some metals and affect some electronic devices. If you have a cardiac pacemaker or any other biomedical device in or on your body, it is very important that you tell the operator/investigator immediately. As metallic objects may experience a strong attraction to the magnet, it is also very important that you notify the operator of any metal objects (especially surgical clips), devices, or implants that are in or on your body before entering the magnet room. All such objects must be removed (if possible) before entering the magnet room. In some cases, having those devices means you should not have an MRI scan performed. In addition, watches and credit cards should also be removed as these could be damaged. You will be provided a way to secure these items. If you have any history of head or eye injury involving metal fragments, if you have ever worked in a metal shop, or if you could be pregnant, you should notify the operator/investigator. If you have kidney problems, please tell the operator.

If the study will use contrast media, insert the following: If you have had a previous reaction to Gadolinium-based contrast agents or a history of severe allergies, please notify the operator/investigator.

If you are operating at 3.0T or above, include the following statement:
Dizziness or nausea may occur if you move your head rapidly within the magnet.

IF YOU FEEL DISCOMFORT AT ANY TIME, NOTIFY THE OPERATOR AND YOU CAN DISCONTINUE THE EXAM AT ANY TIME.

The following language is recommended when women of childbearing potential (non-pregnant) will be enrolled in an investigational study:

Women of Childbearing Potential

If you are a woman who is able to become pregnant, it is expected that you will use an effective method of birth control to prevent exposing a fetus to a potentially dangerous agent with unknown risk. If you are pregnant or currently breast feeding, you may not participate in this study. You understand that if you are pregnant, if you become pregnant, or if you are breast-feeding during this study, you or your child may be exposed to an unknown risk (or state specific risk).

To confirm to the extent medically possible that you are not pregnant, you agree to have a pregnancy test done before beginning this research study or to begin the study after the onset of your next menstrual period.

You must agree to avoid sexual intercourse or use a birth control method judged to be effective by the investigator and which will not interfere with the proposed investigation.

(Protocol Title)

(Principal Investigator)

IRB Approval Date: _____

Participant Identifier: _____

You must accept the risk that pregnancy could still result despite the responsible use of reliable method of birth control. You agree to notify the investigator as soon as possible of any failure of proper use of your birth control method, or if you become pregnant, either of which may result in your being withdrawn from the study.

If there are risks associated with men fathering a child, add appropriate language. [e.g., If you are a man participating in this study and your partner is able to become pregnant, you and your partner must use adequate contraception while you are participating in the study and for at least [insert time after last dose of study drug, e.g., 12 weeks after taking your last dose of study medication.] Your doctor will discuss with you what methods of birth control are considered adequate. You should inform your study doctor if your partner becomes pregnant.]

The following language is recommended when samples of tissues, cells, blood, or body fluids (hereafter referred to as tissues) will be taken or banked for use in current or future research. This includes testing the sample for purposes of collecting genetic or other information. Investigators should choose the appropriate provisions to be included in their informed consent form and may vary any of the following language as appropriate.

Tissue Sampling for Future Research

Research using tissues is an important way to try to understand human disease. You have been given this information because the investigators want to include your tissues in a research project and because they want to save the samples for future research. There are several things you should know before allowing your tissues to be studied.

Your tissues will be stored (insert how samples will be stored - and if appropriate how samples will be linked) e.g., under diagnosis and medical record or code number and unlinked.

If linked: You have the right to refuse to allow your tissues to be studied now or saved for future study. You may withdraw from this study at any time. The investigators might retain the identified samples, e.g., as part of your routine clinical care, but not for additional research.

If unlinked: Because your samples will not be linked to your name after they are stored, you cannot withdraw your consent to the use of the samples after they are taken.

Optional:

The results of the study of your samples will be used for research purposes only and you will not be told the results of the tests.

Or

You will be told the results of tests that are part of your clinical care, but you will not be told the results of the research tests, including any future research tests.

(Protocol Title)

(Principal Investigator)

IRB Approval Date: _____

Participant Identifier: _____

Any tissues you have donated which are used in research may result in new products, tests or discoveries. In some instances, these may have potential commercial value and may be developed and owned by the Investigators, Stanford University and/or others. However, donors of tissues do not retain any property rights to the materials. Therefore, you would not share in any financial benefits from these products, tests or discoveries.

_____ I consent to my samples being saved for future research

_____ I do not consent to my samples being saved for future research

Include the following language if samples in study will be used for genetic testing or if future research on samples will include genetic testing.

Tissue Sampling for Genetic Testing

As part of the analysis on your samples, the investigators (**may/will**) do genetic testing. Genetic research is research that studies genes, including gene characteristics and gene versions that are transmitted by parents to children. Genetic research may include looking at information, such as personal appearance and biochemistry, gene sequences, genetic landmarks, individual and family medical histories, reactions to medications and responses to treatment. Genetic research raises certain questions about informing you of any results. Possible risks of knowing results include: anxiety; other psychological distress; and the possibility of insurance and job discrimination. A possible risk of not knowing includes being unaware of the need for treatment. These risks can change depending on the results of the research and whether there is a treatment or cure for a particular disease.

Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. A Federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information.

If investigators will not share the research results with the participant, the following language can be added:

The results of the study of your samples from this project will be used for research purposes only, and you will not be told the results of the tests.

If investigators will allow participants to choose whether they want to receive test results and/or will contact participants in the future, the following language (two choices of language) can be added:

(Protocol Title)

(Principal Investigator)

IRB Approval Date: _____

Participant Identifier: _____

Regarding informing you of the test results, you should understand the following:

- The information may be too limited to give you particular details or consequences;
- You may be determined to carry a gene for a particular disease that can be treated;
- You may be determined to carry a gene for a particular disease for which there is no current treatment;
- You carry a gene for a disease and might consider informing relatives that they, too, might carry the gene.

Please circle [yes or no] as to whether you wish to be told the test results.

Please circle [yes or no] as to whether you wish your family members to be told the test results.

Or

Investigators in this study may try to re-contact you in the future. If you are re-contacted and want to know what the investigators have learned about your tissue samples, you should understand the following:

- The information may be too limited to give you particular details or consequences;
- You may be determined to carry a gene for a particular disease that can be treated;
- You may be determined to carry a gene for a particular disease for which there is no current treatment;
- You carry a gene for a disease and might consider informing relatives that they, too, might carry the gene.

If the protocol involves gene transfer the following paragraph must be included:

(The approximate number of people who have previously received the genetic material under the study.)

Gene Transfer Studies

To obtain vital information about the safety and effectiveness of gene transfer, at the time of death, no matter what the cause, permission for an autopsy will be requested of your family. Please advise your family of this request and of its scientific and medical importance. Neither you nor your family will be liable for any costs associated with the autopsy procedure.

(Protocol Title)

(Principal Investigator)

IRB Approval Date: _____

Participant Identifier: _____

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include: **Choose applicable points; refer to your protocol to ensure participants know what is expected of them:**

- Follow the instructions of the Principal Investigator and study staff.
- Take the study drug as instructed (**if device, explain what is required for study compliance**).
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Principal Investigator or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Principal Investigator or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Tell the Principle Investigator or research staff if you believe you might be pregnant or gotten your partner pregnant.
- Keep the study drug in a safe place, away from children and for your use only.
- Keep your diaries as instructed.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Tell the Principle Investigator or research staff if you change your mind about staying in the study.

While participating in this research study, you should not take part in any other research project without approval from the Principle Investigator of each study. **Add the following as applicable:** This is to protect you from possible injury arising from such things **as extra blood drawing, extra x-rays, the possible interaction(s) of research drugs, or other similar hazards.**

WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

Clearly outline the study withdrawal procedures (Suggestion: check your protocol).

If you withdraw from the study, or the study medication is stopped for any reason,

- **add anticipated consequences, if any, of discontinuing the study drug or device.**
- **Clearly state the protocol-specific termination procedures.**

- Instruct participants that they must return all study-related supplies, including unused study drug.

The Principle Investigator may also withdraw you from the study **and the study medication may be stopped [if applicable]**, without your consent for one or more of the following reasons: (Note to investigator: check your protocol; you may use these reasons and/or add some of your own).

- Failure to follow the instructions of the Principle Investigator and study staff.
- The Principle Investigator decides that continuing your participation could be harmful to you.
- Pregnancy
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Principle Investigator if you have any questions.

- Describe the discomforts and inconveniences reasonably expected; include the inconvenience of travel.
- If there is a washout period, describe the risks of discontinuing medications.
- Describe any reasonably foreseeable risks - include for example
 - Physical risks – from study medications and procedures (e.g., venipuncture, exposure to radiation, allergic reaction when treatment includes medication)
 - If this is a placebo-controlled study, there may exist the risk that the disease/condition may go untreated and the subject's condition may worsen
- Include a statement that the particular treatment or procedure may involve risks to the subject, which are currently unforeseeable.

POTENTIAL BENEFITS

- Describe any benefits that may be reasonably expected (key word-“reasonably”). If none can be expected, state so.
- After describing any potential benefits, state:

WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS FROM THIS STUDY.

ALTERNATIVES

Describe (in lay terms) the known appropriate alternative procedures that might be advantageous to the participant, including their important risks and benefits.

- Any standard treatment that may be withheld must be disclosed.
- If there is no alternative treatment state: "the alternative is not to participate".
- If there is no alternative other than not participating, (e.g., some cancer research) indicate that there may be alternate palliative treatments that are not curative.

PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction.

If you decide not to participate, tell the Principle Investigator. You will still receive care for your disease and will not lose any benefits to which you would otherwise be entitled.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

CONFIDENTIALITY

Your identity will be kept as confidential as possible as required by law. Except as required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Your research records may be disclosed outside of St. Joseph Mercy Oakland, but in this case, you will be identified only by a unique code number. Information about the code will be kept in a secure location and access limited to research study personnel.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed.



Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

If this study falls within the jurisdiction of the Food and Drug Administration, include following:

The purpose of this research study is to obtain data or information on the safety and effectiveness of **(insert name of drug, device, etc.)**; the results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

(Protocol Title)

(Principal Investigator)

IRB Approval Date: _____

Participant Identifier: _____

Authorization To Use Your Health Information For Research Purposes

State law requires that the HIPAA text be in at least 14-point type.

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

(Provide a description of the study, such as its purpose, and describe how the individual's health information will generally be used in the study, including any publication. If this is a clinical trial, also explain that the information in some form will be submitted to the sponsor and the FDA.)

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study. **If the study includes any treatment, add:** *including receiving any research-related treatment. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: **(researcher's name and contact information)**.

What Personal Information Will Be Obtained, Used or Disclosed?

Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to, (List or describe the protected health (medical) information that will be collected in this study. The information should be limited to the least amount of information needed to accomplish the purpose of the research (i.e., information relating to a particular medical condition, specific blood tests, specific physical examination measures, specific x-rays or MRI imaging information, including any reports such as radiology or pathology reports.))

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Principle Investigator (Insert Name of PD)
- The St. Joseph Mercy Oakland Institutional Review Board and any other unit of St. Joseph Mercy Oakland as necessary
- Research Staff

(List every other class of persons or organization affiliated with SJMO who might need to use and/or disclose the participant's information in connection with this study.)

Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- (Sponsor, funding agency or collaborators who may receive information)

If the study is a clinical investigation involving a test article (drug, device, biologic) that is subject to FDA regulations, add:

- * The Food and Drug Administration

List every other class of persons or organization not affiliated with SJMO -- e.g., a sponsor, data safety monitoring board, collaborators at other

institutions, outside data analysts, the National Institutes of Health, etc. -- to whom the participant's information might be disclosed.

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?

Your authorization for the use and/or disclosure of your health information will end on (date) or when the research project ends, whichever is earlier. List a specific date on which the authorization will expire, e.g., “will end on December 31, 2015”). If you are uncertain, choose a date that provides plenty of time for your work to be completed.

If the research involves treatment include:

Will access to my medical record be limited during the study?

To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (e.g., if included in your official medical record).

Signature of Participant

Date

If consent is to be obtained from a legally authorized representative -- e.g., parent(s), legal guardian or conservator - signature line(s) for representative(s) must be included on the consent form, as well as a description of his/her authority to act for the participant:

Signature of Legally Authorized Representative

Date

Description of Representative's Authority to Act for Subject

FINANCIAL CONSIDERATIONS

Payment

Clearly state if the participant will be paid for participating in the research study.

#Include the **amount of payment**, if any, and the schedule of payment. A statement of any anticipated prorated payments to the participant is required.

If participants will be paid, add the following:

Payments may only be made to U.S. citizens, legal resident aliens, and those who have a work eligible visa.

If the patient will not be paid, use the following statement: You will not be paid to participate in this research study.

Costs

Include the following if there is no treatment involved and there will be no additional costs to the participant due to their participation in the research: There is no cost to you for participating in this study.

Include the following paragraphs if there might be additional costs to the participant due to their participation in the research:

If you participate in this study, there may be additional costs to you. These include the personal time it will take to come to all of the study visits.

The study will pay for those services, supplies, procedures, and care associated with this study that are not a part of your routine medical care. If you would like to review the list of such covered services, supplies, procedures and care, please tell us now or at any time during the study.

Participation in this study is not a substitute for health insurance. You and/or your health insurance must pay for those services, supplies, procedures, and care that you require during this study for routine medical care. **You will be responsible for any co-payments and/or deductibles as required by your insurance.**

Sponsor

Disclose what institution(s) -- e.g., NIH - or companies are involved in the study through funding, cooperative research, or by providing study drugs or equipment. The following generic disclosure is acceptable:

(Name of institution/company) is providing financial support and/or material for this study.

(Protocol Title)

(Principal Investigator)

IRB Approval Date: _____

Participant Identifier: _____

If consultative or financial relationships exist for the Principle Investigator and/or any investigators in a study, disclose in a separate paragraph in the consent form the name and precise nature of the relationship:

#Consultative or Financial Relationships

Examples:

Dr. W is a paid consultant to the company sponsoring this study.

Dr. X is a paid consultant, paid member of the Advisory Board, and receives payment for lectures from the company sponsoring this study.

Dr. Y is an unpaid consultant to the company sponsoring this study.

Dr. Z is a founder of the company, has stock in the company, and is a paid consultant to the company sponsoring this study.

CONTACT INFORMATION

Contact information should include the following as appropriate.

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Principle Investigator, **(name of Principle Investigator)**. You may contact **him/her** now or later at **(Principle Investigator's phone number)**.

Injury Notification: If you feel you have been hurt by being a part of this study, please contact the Protocol Director, **(name of Principle Investigator)** at **(Principle Investigator's phone number)**.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the St. Joseph Mercy Oakland Institutional Review Board (IRB) to speak to someone independent of the research team at (248) 858-3233. You can also write to the St. Joseph Mercy Oakland IRB, 44405 Woodward Ave., Pontiac, MI, 48341.

If applicable:

Appointment Contact: If you need to change your appointment, please contact **(name)** at **(phone number)**.

If applicable:

Alternate Contact: If you cannot reach the Principle Investigator, please contact **(name)** at **(phone number and/or pager number)**.

If the contact person for both the first two paragraphs will be the Principle Investigator, you may combine the two as follows:

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of

(Protocol Title)

(Principal Investigator)

IRB Approval Date: _____

Participant Identifier: _____

treatment, you should ask the Principle Investigator (name and phone number of Principle Investigator). You should also contact him/her at any time if you feel you have been hurt by being a part of this study.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS
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Add the following Bill of Rights to your consent:

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

If you would like to contact participants about future studies, include the following statement:

*May we contact you about future studies that may be of interest to you? Yes
 No

(Protocol Title)

(Principal Investigator)

IRB Approval Date: _____

Participant Identifier: _____



YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTAND THE ABOVE INFORMATION, THAT YOU HAVE DISCUSSED THIS STUDY WITH THE PERSON OBTAINING CONSENT, THAT YOU HAVE DECIDED TO PARTICIPATE BASED ON THE INFORMATION PROVIDED, AND THAT A COPY OF THIS FORM HAS BEEN GIVEN TO YOU.

Signature of Adult Participant

Date

When consent is obtained from a legally authorized representative (LAR) or representatives (e.g., parent(s), guardian or conservator), include signature lines for representatives and a description of their authority to act for the participant.

Signature of LAR (Parent, Guardian or Conservator)

Date

Authority to act for participant

(If available) Signature of Other Parent or Guardian

Date

Authority to act for participant

Person Obtaining Consent

I attest that the requirements for informed consent for the medical research project described in this form have been satisfied – that the subject has been provided with the Experimental Subject’s Bill of Rights, if appropriate, that I have discussed the research project with the subject and explained to him or her in non-technical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the subject to ask questions and that all questions asked were answered.

Signature of Person Obtaining Consent

Date

(Protocol Title)

(Principal Investigator)

IRB Approval Date: _____

Participant Identifier: _____