

***INSTRUCTIONS:***

*This template includes shaded areas providing instruction and required or suggested language, when applicable to the research study protocol. Please read these shaded areas to ensure all applicable language is included appropriately in your consent form.*

*Use lay language. Avoid long or complex sentences and excessive technical language. Define any words or terms that may be unfamiliar to lay persons and always define acronyms or abbreviations the first time they are used.*

*Please delete all shaded areas (including these instructions) prior to submitting this form to the IRB.*

**RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM**

**Title of Research Study**

The title is the only place where technical language may be used.

**Who is conducting this study?**

Principal Investigator: [Insert name here]

Sub-Investigators: [Insert names here]

Hackensack Meridian Health Sites: [Insert HMH sites here]

Sponsor: [List study sponsor(s) here]

**Concise Summary**

Federal regulations require that consent forms contain a concise presentation of key information in the beginning of the consent form. The intention of this section is to provide potential research participants with a better understanding of the project’s scope, including major risks and benefits, so they can make a more fully informed decision about whether to participate.

This section should include a summary of the purpose of the study, duration of participation, major requirements of the study and any potential benefits. This section should also contain any significant risks of participating in the study. The information presented in this section may be discussed in greater detail later in the consent form.

**Why is this research being conducted and why have I been asked to take part?**

You have been asked to take part in this study because you have [state disease here and list why they are being asked, be concise and avoid technical language]. This form gives you important information about the research study. It describes the purpose of this research study, and the risks and possible benefits of participating.

If there is anything in this form you do not understand, please ask questions. Please take your time.

Taking part in this research study is voluntary. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time.

The purpose of this research study is to [Describe study purpose; See sample language below to complete this section].

Sample language: The purpose of this research is to study an experimental drug called “drug x”. “Experimental” means that the study drug is currently being tested and is not approved for sale in the United States by the Food and Drug Administration (FDA). This testing includes an evaluation of the safety of “drug x”. “Drug x” is an investigational drug for the treatment of “y”. “Y”, commonly known as “xxx”, is [insert lay language; short description]. This study is being conducted to find out how well the experimental “drug x” works for treating “y” compared to “drug z”, marketed as “brand name®.” “Brand name” is a prescription medication that can be given by your doctor to treat “y” in patients who are not hospitalized.

**How many people will take part in this study?**

Approximately \_\_\_ people will take part in this study at Hackensack Meridian Health.

Sample language, if multi-site:

Approximately \_\_\_ people will take part in this study at Hackensack Meridian Health, with about \_\_\_ subjects total across all sites for this multi-site study.

**What is involved in this study?**

* Describe the study related procedures chronologically using lay language, short sentences and short paragraphs.
* The use of subheadings will help to organize this section and increase readability.
* Indicate exactly what will happen to each subject during screening procedures, where the study will take place, approximately how long each visit will take, and how many visits are required.
* Include procedures to monitor subjects for safety. Specify eligibility examinations, lab assessments, pregnancy testing and medical history review, along with any drug washout period.
* For studies with many visits, a flowchart or table (see example below) may help to clarify the sequence of events. The table below provides a brief description of the purpose and duration of each study visit. If there are multiple visits that involve different procedures using a table can help provide a clearer overview of the study. If there is a single visit or the procedures are simple, the table is usually unnecessary.
* Distinguish which procedures are experimental (e.g., investigational drug or device) and which are standard clinical treatments, if necessary in describing the research. Clarify the difference in procedures for those who participate in the research study versus those who do not participate (and instead continue the standard of care). If a drug, device, test or procedure employed in the course of the research study is considered part of routine clinical practice outside or standard patient care, this should be noted.

As applicable, include the following:

* Route of how the drug will be administered.
* If certain foods must be avoided, if specific medications are contra-indicated, if extra spinal tap, endoscopy, EKG, chest x-ray, blood drawing, etc. will occur.
* If the research includes extending surgery beyond the standard of care, explain how much longer surgery/anesthesia will occur for research purposes.
* Identify all hospitalizations, outpatient visits, and telephone or written follow-ups.
* If blood will be drawn, indicate how often, the amount in tablespoons or teaspoons, and whether draw will be done at time of clinical blood draws or separately.
* Identify all questionnaires/surveys and explain what they involve and how long and how often they will need to be completed.
* Any audio/videotaping should be noted; If participant is expected to keep a diary, wear a monitor, respond to telephone queries, this information should appear.
* Describe any planned future research (extension study, follow-up study, analysis of specimens). Describe the future use and whether subjects will be asked to sign a separate consent form.

Sample language, if investigational drug or device is included:

This study involves testing an investigational drug (or device), meaning it is being used in a manner not approved by the Food and Drug Administration (FDA) and has not yet been proven safe and effective. This research study may help determine whether this drug (or device) should be approved by the FDA.

Sample language, if drug or device is approved for another indication:

Drug (or device) name is approved by the Food and Drug Administration (FDA) for \_\_\_, but for purposes of this study it is being used in an experimental, non-FDA approved manner, studying the treatment of \_\_\_.

Sample language, if study includes randomization:

You will be ‘randomized’ into one of X study groups. Randomized means you will be put into a study group by chance (like a coin toss). One group will receive the study drug and one group will receive a placebo (an inactive pill that contains no medicine). or One group will receive drug X while the other group will receive drug Y. You have a X out of X chance of being placed in each group. You cannot choose your study group.

Sample language, if the study includes a placebo:

You may be assigned to receive a placebo, an inactive pill that contains no medicine. We use placebos to compare the effects of the study drug versus not using the study drug.

Sample language, if the study includes blinding:

Results of research studies can be influenced by the expectations of patients (and doctors, if study is double blind). Therefore, you (or you and the study doctor) will not know which study group you are assigned to. Your study doctor can find out in case of emergency.

Sample language, if the study involves collection of medical information for research purposes:

This research study involves the collection of medical information from the standard of care you are receiving. If you agree to participate in the study, we will collect data from your medical record that includes (specify medical information to be obtained for research purposes).

Procedures Table example:

|  |  |  |  |
| --- | --- | --- | --- |
| **Visit** | **Purpose** | **Main Procedures** | **Duration** |
| Visit 1 | Screening visit  | Blood tests, MRI scan | 2 hours |
| Visit 2, Day 0 | Start study drug | Distribute study drug  | 30 minutes |
| Visit 3, Day 28 | Routine Visit | Lab tests, distribute study drug | 1 hour |
| Visit 4, Day 56 | End of Study | Return unused drug and Quality-of-Life Survey | 1 hour |

**How long will I be in this study?**

Please state the length of time the subject’s participation in this study is expected to last, including any post-study follow up. Please indicate the length of their participation in months, years, etc. as appropriate.

Sample language:

The study will take one year, including follow-up visits.

**What are the risks involved in this study?**

* Identify each intervention with a subheading and then describe any reasonably foreseeable risks, discomforts, or inconveniences and how these will be managed.
* In general, list side effects or complications from most to least severe. When available from the Sponsor, quantify the risks involved (e.g., frequent (> 25%), common (10-25%), uncommon (1-10%), or rare (<1%).
* **Please note:** The risk section should only contain the risks associated with research study procedures. Risks of standard of care procedures should not be included in the research consent form.
* In addition to physiological risks/discomforts, describe any psychological, social, legal, or financial risks that might result from participating in the research, including risks related to breach of confidentiality.
* For minimal risk studies (such as questionnaires/surveys), loss of confidentiality or psychological stress should be listed, if applicable.

Sample language for risk of confidentiality loss: There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

Sample language for psychological stress: Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

* Required language for greater than minimal risk studies:

All side effects can be different from person to person. It is important that you tell the study staff right away if you have any side effects or any other problems with your health, even if you do not think they are related to the study.

The risks or discomforts described may happen more often or be more severe than has been seen before. Your health and safety will always be the first concern of your study doctor. If you notice anything unusual, you should inform your study doctor or the nurse immediately. In the event of any serious unexpected events, all necessary medical action will be taken.

**What are the risks to a pregnancy or fetus?**

This section should only be included if applicable.

* Address the precautions that should be taken by women of childbearing potential and their sexual partners during participation. In some cases you will need to include additional language to cover men and their sexual partners when appropriate.
* List the specific acceptable methods of birth control for participants involved in the study.

Female

Being part of this study while pregnant may expose an unborn child to significant risks, some of which may be currently unforeseeable. Therefore, pregnant women will be excluded from the study. If you are a woman of childbearing potential (capable of becoming pregnant), a blood pregnancy test will be done (using 1 teaspoon of blood drawn from a vein by needle-stick), and it must be negative before you can continue in this study. If sexually active with a man, you must agree to use appropriate contraceptive measures for the duration of the study and for (specify if applicable) months afterwards. Medically acceptable contraceptives include: (1) surgical sterilization (such as the tying of fallopian tubes or removal of uterus), (2) approved hormonal contraceptives (such as birth control pills, patches, implants or injections), (3) barrier methods (such as a condom or diaphragm) used with a spermicide, or (4) an intrauterine device (IUD). Contraceptive measures such as Plan B™ sold for emergency use after unprotected sex are not acceptable methods for routine use. If you do become pregnant during this study or if there’s a chance you are pregnant, you must inform your study doctor immediately.

Male

The effects of the research drug on the reproductive system (including sperm) are unknown and could cause harm to a child that you may father while on this study. Such harm may be currently unforeseeable. If you are sexually active with a woman of childbearing potential, you must agree to use a medically acceptable form of birth control in order to be in this study and for (specify if applicable) months afterward. Medically acceptable contraceptives include: (1) surgical sterilization (such as a vasectomy), or (2) a condom used with a spermicide. Contraceptive measures such as Plan B™ sold for emergency use after unprotected sex are not acceptable methods for routine use. You should inform your partner of the potential for harm to an unborn child. She should know that if pregnancy occurs, you will need to report it to the study doctor, and she should promptly notify her doctor.

Required Language for Georgetown studies only – delete if not applicable.

**Avoidance of Pregnancy:** The medicines and procedures used in this study may be unsafe for fetus/unborn baby, an infant, sperm, and eggs.  If you, as a subject of study, are a woman of child bearing potential, you must agree to avoid pregnancy during your participation in this study and for three months after the completion of the study (include when appropriate); if you, as a subject, are a man, you must agree to not conceive a child during your participation in this study and for three months after the completion of the study (include when appropriate).  If you do become pregnant during the study or if you father a child during the study, you should immediately notify Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  at 202-\_\_\_\_\_\_\_\_\_\_\_\_\_\_.  In addition, if you are already pregnant or are breast feeding, you cannot participate in this study.

**Are there benefits to taking part in the study?**

* State any potential benefits to the participant or to others that may reasonably be expected from the research.
* If there is no potential for direct benefit to the participant, that should also be stated.
* No unproven claims of effectiveness or certainty of benefit, either implicit or explicit, may be included.
* **Do not include** medication, treatment, devices, or compensation as these are not considered to be benefits.

Sample language for direct benefit: Based on experience with this [drug, procedure, device, etc.] in [animals, patients with similar disorders], researchers believe it may be of benefit to subjects with your condition [or, it may be as good as standard therapy but with fewer side effects]. Of course, because individuals respond differently to therapy, no one can know in advance if it will be helpful in your particular case. The potential benefits may include: [Describe the anticipated benefits to subjects resulting from their participation in the research. Note: If the research includes a placebo condition, indicate if the benefits do/do not apply to subjects in the placebo group].

Sample language if no direct benefit: There are no benefits for participating in this study other than the scientific knowledge gained. However, this research may help others in the future.

**What other treatment options are there?**

* Describe any appropriate alternative therapeutic, diagnostic, or preventive procedures that should be considered before the subject decides whether or not to consent/give permission for participation in the study.
* If prospective subjects have a chronic, progressive disorder, for which no treatment had been demonstrated to be safe and effective, indicate that as well. But also describe opportunities for managing symptoms, improving ability to function, etc. so that it does not appear that the patient will be abandoned if he/she does not agree to consent for participation in the research. If there are no efficacious alternatives, state that an alternative is not to participate in the study.

Sample Language: You do not have to participate in this study to get help for your condition. Alternatives to this study for the treatment of your [insert condition] may include drugs already approved or being used for the treatment of your disease. Your study doctor can discuss the risks and advantages of these alternative treatment methods with you. In addition, you may discuss your options with your regular healthcare provider.

**How will information about me be kept private?**

What information do researchers want to use?

As part of this research study, personal information about you will be collected. This will include information from [include all that apply: medical records, procedures, samples, surveys, interviews and tests, etc.]. Information related to your medical care will go in your medical record. This could include physical exams, imaging studies (x-rays or MRI scans) or tests done in the clinical lab. Research staff will view your records only when required as part of their jobs and are required to keep your information private.

Who can see my information?

Information may be shared with the following:

* Members of the research team and other authorized staff at Hackensack Meridian Health (HMH);
* People at HMH who oversee and evaluate research, including the Institutional Review Board and Compliance programs.
* People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the US Department of Health and Human Services (DHHS), Office for Human Research Protections (OHRP);

[Include the following only if applicable]

* Representatives of [insert sponsor name] who is the study sponsor funding this research;
* [list lab names who receive identifiable specimens], who is testing your blood/urine/tissue sample(s);
* The Data Coordinating Center at [for multi-center research studies – include the data coordinating center];
* Groups monitoring the safety of this study; the study’s Data Safety Monitoring Board;
* The Food and Drug Administration;
* Public health authorities that are required by law to receive information for the prevention or control of disease, injury or disability. [Only include this statement when applicable – i.e., tests for sexually transmitted diseases, HIV, AIDS, child abuse, etc.]

Information that could identify you will not be shared with anyone outside of the research team unless you provide your written consent on this form, or it is required or allowed by law. Laboratory test results will appear in your medical record with the exception of [list any exceptions, e.g. genetic tests, non-CLIA approved test results, confidential data which must be protected] which are performed only for this research study. The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. No publication or presentation will include any information that could identify you.

How will my information be protected?

* Give a brief description of how personal information, research data, and related records will be coded, stored, etc. to prevent access by unauthorized personnel by editing the below language. Only include and edit applicable language below.
* If any other uses are anticipated, explain how specific consent will be obtained.
* If applicable, state when individual identifiable data will be destroyed.
* If a Certificate of Confidentiality is required, the language provided by the agency regarding the certificate should be inserted in this section.

In addition to the data security description, include: We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Data or specimens collected in this study might be used for future research or distributed to another investigator for future research without your consent. If used for future purposes, the data and/or specimens will not include any information that could identify you, such as your name, medical record number or date of birth.

If applicable: Your samples and/or data will be shared with outside laboratories, including [insert lab names] for analysis (and storage, if applicable) but they will not know who you are. Instead, your samples and/or data will be labeled with a [insert whatever is appropriate; e.g. study number, code, etc.]. Identifying information such as your name, birth date or medical record number will not be shared with them.

If applicable, include the following for NIH-funded studies that generate large-scale human genomic data such as GWAS, SNP, genome sequence, gene expression:

Your data will be shared through databases that may be publicly available to anyone. The data will not include any identifying information. To use your data, researchers must promise not to try to re-identify you.

**If the protocol includes use/access of protected health information (PHI), the following HIPAA language is required:**

Any of your health information used in this research study is protected by a law called the Health Information Portability and Accountability Act (HIPAA). Anyone involved in this research as indicated above may have access to that information.

Some people or groups outside of HMH might not have to follow the same privacy rules. Once any information is shared outside of HMH and given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

Your permission to use and share the information and data from this study will not expire. You may cancel this Authorization at any time by notifying the research team in writing. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the health information that was provided before you cancelled your authorization.

Not signing this form or later canceling your permission will not affect your health care treatment outside the study, payment for health care from a health plan, or ability to get health plan benefits. However, if you do not give permission to use your health information, you may not take part in this study because your health information is needed in order to conduct the research.

**What should you know about the collection of genetic information?**

Insert the following section for all studies in which **genetic information** will be collected or studied. If this section is not applicable, please delete.

The risks related to genetic analyses can be to individuals or to groups. These harms include social and economic disadvantages associated with genetic information. To reduce this risk, only coded samples will be stored and used for future research. Information about this study will not be recorded in your medical record.

The Genetic Information Nondiscrimination Act (GINA) is a Federal law that makes it illegal for some groups to discriminate against you based on genetic information. This law applies to all health insurance companies, group health plans, and employers with 15 or more employees. This law does not apply to companies that sell life insurance, disability insurance, or long-term care insurance.

If the research involves whole genome sequencing:

This research includes whole genome sequencing (determining your unique genetic code).

**What are the costs?**

* Participants must be told if costs will increase as a result of their participation, being specific about the differences between ‘standard of care’ vs. research-required testing, procedures office visits, etc. If insurance carriers generally pay/reimburse for the tests, procedures, etc., please indicate that. Wherever possible, be specific; e.g., “the drug will be provided at no charge as well as blood tests to determine drug levels. Office visits, however, will be the responsibility of the participant.” If costs are expected to decrease as a result of participation, this should be stated. If insurance will not pay, the patient must be made aware that they will be responsible for payment.

Sample language if sponsor is paying for all costs (Sponsor might issue their own language): There will be no cost to you from taking part in this study. All drugs, exams, and medical care related to this study will be provided by the Sponsor, at no cost to you, during the study period.

Sample language if some procedures may be billed to insurance: Although research funds will pay for some research-related items and services, we may bill your health insurer for routine items and services you would have received even if you did not take part in this research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the research staff.

Information relating to this study, including your name, medical record number, date of birth and social security number, may be shared with the billing offices of Hackensack Meridian Health and its affiliates so that claims may be appropriately submitted to the study sponsor or to your insurance company for clinical services and procedures provided to you during the course of this study.

**Will I be paid to participate in the study?**

* Specify the amount and type/method (cash, gift card) of compensation a participant will receive for participating, or that there is no compensation for participation.
* Indicate when the subject can expect payment (i.e. at the end of each visit, etc.) If applicable, include the payment schedule.
* Describe prorated payments for participants who withdraw before the end of the study.
* **Note:** Payment may not be based upon successful completion of the protocol.

Sample language: You will be paid [$X] for each study visit, including the placebo phase of the study. If you quit the study, you will be paid [$X] for each study visit made to the clinic. Payments will be made after [X] months and [X] months if you complete the entire study. If you do not finish the entire study, you will be paid at the time you decide to stop taking part in the study. If you complete the entire study, you will receive a total of [$X].

* If a participant is to earn $600 or more in a calendar year from their participation in the research study, the following language should be included in the consent form. If not applicable, please delete*.*

You are responsible for paying any state, federal, Social Security or other taxes on the payments you receive if you earn $600 or more in a calendar year from your participation in this research study. You will receive a form 1099 in January of the year following your participation in this study. This form is also sent to the IRS to report any money paid to you. No taxes are kept from your check.

If any commercial profits are gained from the research: Any commercial profits generated from your samples and/or information collected in this study [will/will not] be shared with you. (If commercial profit will be shared with the participant, provide details.)

**What if you are injured because of the research study?**

* This section is required for greater than minimal risk studies. If the sponsor is willing to provide treatment, compensation, etc., this information should be reflected here. The following paragraph is to be included only if the sponsor is not paying and will replace any other language.

If you are injured as a direct result of your participation in this study, you may seek medical attention at the medical provider of your choice. However, you and/or your insurance company/third party payer will be billed for all routine medical, diagnostic, laboratory and pharmaceutical costs associated with the treatment of your illness or injury. You will be responsible for any deductibles or co-payments that would normally be associated with your insurance coverage. There will be no financial compensation offered by Hackensack Meridian Health.

**What are my rights as a research participant?**

Your decision to take part in this study is voluntary. If you decide not to participate or if you choose to withdraw after beginning the study, you can do so without penalty and you will not lose any benefits to which you are entitled. You are encouraged to ask questions before deciding whether you wish to participate and at any time during the course of the project. You will be told of any new findings that may change your decision to be in this study. If information becomes available that may influence your decision to take part in this study you may be asked to sign a revised consent form or consent form addendum.

* If clinically relevant research results will be shared:

During this research, we may learn information from the study results that could be important for your health or treatment. This information will be made available to (insert recipient: you, your health care provider). The information we may share includes (insert details as to what may be shared and the conditions of how it will be shared).

You are not waiving any of your legal rights by signing this informed consent document. As part of the consent process, you will receive a signed copy of this informed consent document.

Can I leave the study before it is finished? Can I be removed from this study without my approval?

* Please edit the below language if your research is not supported by a Sponsor or does not involve biologics or devices. For FDA-regulated clinical trials, the consent document **cannot** give the subject the option of having data removed when a subject withdraws from a study. The data collected on the subject to the point of withdrawal remain part of the study database and may not be removed.

You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this hospital or doctor.

* This section is required in all Hackensack Meridian Health informed consents for greater than minimal risk studies:

If you decide to withdraw before the end of the study, there may be risks associated with this decision that you should discuss with your study doctor. You may need to return to see the study doctor for safety reasons so you can be taken off the study appropriately and referred for follow-up care.

Your study doctor, if applicable study sponsor, or applicable regulatory authorities have the right to stop your participation in the study at any time, with or without your consent.

You may be removed from the study without your consent if the sponsor ends the study, if the [drug or device] is approved by the FDA, if the study doctor decides it is not in the best interest of your health, or if you are not following the study rules. The sponsor may decide to stop the study and your access to the study under certain circumstances even if the study drug appears to be safe and effective.

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal. However, all data that have already been collected for study purposes will remain.

If your research study will be registered on clinicaltrials.gov;

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. You can search this Web site at any time.

**Does the institution or researcher have financial interest in this study?**

(Section can be removed if there’s no sponsor and no investigator financial interest)

If the study is sponsored: Hackensack Meridian Health is receiving financial support from [insert sponsor name] to conduct this research study.

If researcher has financial interest (COI committee may also provide required language): The principal investigator has disclosed a financial interest or other compensation from the study sponsor, [insert name of sponsor]. [Describe the nature of the financial interest].

If HMH has institutional financial interest: Hackensack Meridian Health (HMH) has financial interests relative to this study. HMH has [insert nature of interest here (e.g., intellectual property interests in product under evaluation, business relationship with or equity interests in the company sponsoring the research)]. As a result of these interests, HMH could ultimately potentially benefit, either directly or indirectly, from the outcomes of this research.

If you have questions about this financial disclosure please call the Research Integrity Office 201-880-3669.

**Who can I call if I have questions or problems?**

You are encouraged to ask questions before deciding what you want to do. If you decide to take part, feel free to ask questions at any time during your participation.

For questions about this research project, please contact:

Insert PI contact information (phone number, pager number, etc.)

Insert other Research Team (coordinator, sub-investigators, etc.) contact info.

For questions regarding your rights as a research participant or any research-related concerns, you can call the Hackensack Meridian Health Research Integrity Office at 201-880-3669.

***Participant/Authorized Representative Signature(s)***

*I have read this consent form or it has been read to me. All of the questions that I had were answered to my satisfaction. I have been told that I will receive a signed copy of this consent form for my records. By signing this consent form I have not waived any of the legal rights which I otherwise would have as a participant in a research study.*

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| --- | --- | --- |
|  |  |  |
| Name of Subject (Please Print) |  |  |
|  |  |  |
| Signature of Subject (18 years or older) |  | Date & Time |
|  |  |  |
| Name of Authorized Representative (if different than participant) |  | Relation to Participant:  |
|  |  | [ ]  Parent [ ]  Legal Guardian |
|  |  |  |
| Signature of Authorized Representative |  | Date & Time |

***Institutional Signature(s)***

*I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject (or the subject’s legally authorized representative). The subject (or the subject’s legally authorized representative) freely consented to be in the research study.*

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Person Obtaining Consent |  |  |
|  |  |  |
| Signature of Person Obtaining Consent |  | Date & Time |
|  |  |  |
| Name of Impartial Witness (if applicable) |  |  |
|  |  |  |
| Signature of Impartial Witness (if applicable) |  | Date & Time |

##

## ***Child Assent to Take Part in this Research Study***

### For children capable of providing assent:

I have explained this study and the procedures involved to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ in terms he/she could understand, and he/she freely assented to take part in this study.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Person Obtaining Assent |  |  |
|  |  |  |
| Signature of Person Obtaining Assent |  | Date & Time |