**MHC INFORMED CONSENT TEMPLATE v6.5.2018**

**NOTE TO THE WRITER**

**The goal of the informed consent process is to provide potential subjects sufficient information for making informed choices about participating in research. The consent form provides a summary of the study and individual's rights as a study participant; and documents their willingness to participate.**

**Keep in mind that the consent form is only one piece of an ongoing exchange of information between the investigator and study participant.**

*NOTE: Sample or draft consent documents developed by a sponsor or cooperative study group may be used in lieu of this template with proper IRB review / approval.*

**HOW TO USE THIS TEMPLATE**

This document is a **template** to assist you in developing an informed consent form (ICF) specific to your research study; it should be **tailored according to your study procedures / specifications.**

General instructional text is provided in blue text boxes throughout this document. Some provide simple guidance in completing a particular section, and some will contain language for you to copy and paste into the corresponding section of your consent form:

* When you see this symbol some instructions may also be here , click on it an enter text as directed.
* When you see this symbol Choose an item., click on it and use the down arrow that appears to select an option from the drop down list as instructed
* You will see text within a blue box that is in Times New Roman font (and in black). This indicates that language is being provided for you to copy and paste into your document*, if it is applicable to your study*.

**Language that is NOT in a blue box is language that MUST be present in ALL consent forms, and must remain in your document as is.**

**PRIOR TO SUBMITTING THE INFORMED CONSENT DOCUMENT FOR MHC IRB REVIEW, REMOVE ALL INSTRUCTIONAL TEXT. TO DO SO:**

**Click on the border of the box and hit the delete button**

**GUIDELINES FOR PREPARING YOUR CONSENT DOCUMENT**

* Use simple, direct lay language. If it is necessary to use technical and/or scientific terms, ensure they are defined or substituted with [commonly understood terms](http://www.mclaren.org/uploads/Public/Documents/Corporate/lay_language_1.pdf).
* Ensure the headings and content remain in the order provided in this template. Edit the information after each header to accurately reflect your project.
* Focus on what makes the study different from the care a patient would typically receive, limiting the information to the research issues.
* A 10th grade reading level is often suggested for an ICF, however, the reading level should correspond with your targeted population.
* To clearly explain lengthy topics, and make the ICF easier to read, it is best to present information in tables or in a bulleted format, whenever possible.
* Be mindful of redundancy and repetitive language, as this can lead to an unnecessarily lengthy document.
* If your study includes randomization, a simplified study schema should be included in the consent form. This is optional for all other studies.
* Federal regulations dictate that the informed consent document contain required [elements](http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116).

**NOTE**: In order to alter or omit any of the required elements, you must apply for an alteration of informed consent in the Informed Consent section of your eProtocol application and provide the rationale for the request.

* Use second person writing style (you / your) throughout the ICF, with the exception of the signature section. It is appropriate to use the term “I” in this section to document the subject’s understanding.
* The term “study doctor” is used throughout this template. If the local investigator is not a physician, please replace it with an appropriate term (i.e. the “researcher”).
* Ensure no exculpatory language is included in the ICF.
* Ensure the informed consent document does not contain unproven claims of effectiveness or certainty of benefit, either explicit or implicit, that may unduly influence potential subjects.
* Ensure final ICF document is in Times New Roman, 12 pt. font; and in black
* Prior to submitting, carefully review the ICF to ensure ALL information regarding your project is relayed accurately.

**PROOFREAD YOUR DOCUMENT FOR SPELLING, GRAMMAR, AND FORMATTING ERRORS!**

**INFORMED CONSENT FORM**

**Study Title for Study Participants: Use brief, easily understood, general terms.**

**Official Study Title:** **The study title must match on all documents (application, protocol document, informed consent document, etc.)**

**Principal Investigator:** PI Name

**Address:** PI Address

**Phone:** PI Phone #

This is a research study. You are being asked to take part because (i.e. you have been diagnosed with…). Choose an item. will explain the study to you. Please take your time to make your decision about taking part. You may discuss this with your family members or friends. You may also discuss it with your health care team. If you have any questions, you can ask your study doctor or the study staff for more explanation.

**For MCRI studies- Complete the following, then copy and paste into this section:**

 Name is the sponsor of the study and provides support for the costs of conducting the research. In addition, study investigators are compensated for their time and effort conducting the study.

**For all studies -**  **Copy and paste into your document, any of the following that apply to your study:**

None of the study investigators at this site benefit financially from this study.

**OR**

None of the study investigators at this site benefit financially from this study. However, one or more of the investigators receives other compensation that is not a part of this study, from Name for activities such as consulting, giving speeches, honorariums, attending meetings or conferences. The McLaren Health Care (MHC) Institutional Review Board (IRB), along with the Corporate Conflict of Interest Committee in Research, has reviewed the financial benefit.

**OR**

One or more of the study investigators at this site benefit financially from this study. The McLaren Health Care (MHC) Institutional Review Board (IRB), along with the Corporate Conflict of Interest Committee in Research, has reviewed the financial benefit.

**ONCE YOU HAVE COPIED AND PASTED ALL NECESSARY VERBIAGE - DELETE THIS BOX**

**WHY IS THIS STUDY BEING DONE?**

Briefly describe the reason the study is being conducted. Ensure that any drugs, devices, biologics, or procedures are named and defined; specifying any other name(s) by which the subject might recognize the agent, test, or device. You should also describe the extent to which humans have been exposed to the experimental agent or procedure.

**Remember to use simple, concise, ‘lay language’ that can be easily understood by the subject.**

Investigational drugs, biologics, or devices MUST be clearly identified as “investigational". Do not simply label them as “new”. You should also provide a definition of what “investigational” means. For example:

The word “investigational” means the study drug or device or biologic is still being tested in research studies and is not approved for this use by the U.S. Food and Drug Administration (FDA).

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The purpose of this study is Include background information for the drug/device/treatment; phase of study (ie. phase I, II, or III) and what information is known to date about drug/device/treatment.

There will be about # of subjects people taking part in this study.

**WHAT ARE MY CHOICES IF I DON’T TAKE PART IN THIS STUDY?**

**IF THE ONLY ALTERNATIVE IS NOT TO PARTICIPATE, YOU MAY OMIT THIS SECTION**

List, explain, and describe appropriate alternative courses of treatment or procedures that might be beneficial to the subject (i.e. explain the “standard of care”; or options for routine management of the subject’s disease/condition outside of a clinical trial). This section should include the study treatment(s) the subject would receive if they were not participating in the study. For example:

If you decide not to take part in this study, you have other choices. For example:

* Getting treatment or care for without being in a study
* Taking part in a different study, if one is available
* You can decide not to be treated.
*

Please talk with your Choose an item., about your options before you decide if you will take part in this study.

You may ask your Choose an item., about these options at any time while you are taking part in this study.

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**STUDY GROUPS**

Group 1

Hormone Therapy

(Usual Approach Group

Group 2

Hormone Therapy + Chemotherapy

(Study group)

Randomize (the computer will randomly put you in a study group)

You agree to take part in the study

**IF NONE OF THE FOLLOWING APPLY TO YOUR STUDY, YOU MAY OMIT THIS SECTION**

**FOR RANDOMIZED, PLACEBO CONTROLLED, AND BLINDED STUDIES:**

Complete any of the following statements that are applicable to you study, then copy and paste into your consent document:

**For randomized studies:**

There will be Click here to enter text. groups in the study. You will be randomly placed (by chance, rather than by choice) in one of the study groups (described below). Include a statement indicating the likelihood of being enrolled in each (i.e. You have an equal chance of being in any of the three arms in the study) Neither you nor your doctor can choose which group you will be in.

**For placebo controlled studies, include a definition:**

…placebo (a Choose an item. that looks like Drug, but has no drug in it).

**For blinded studies:**

Neither you nor your doctor will know which study treatment you are receiving; but this information is available to your study doctor in case of an emergency.

Another way to find out what will happen to you during this study is to read the chart below. Start reading at the left side and read across to the right, following the lines and arrows.

**(NOTE: This study chart is optional if there is no randomization.)**

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**WHAT EXTRA TESTS AND PROCEDURES WILL I HAVE IF I TAKE PART IN THIS STUDY?**

**IF THE ONLY EXAMS, TESTS, OR PROCEDURES IN A STUDY ARE THOSE PERFORMED USING THE USUAL APPROACH/CARE, YOU MAY OMIT THIS SECTION FROM THE CONSENT FORM.**

This section should provide a list of research-related exams, tests, and procedures that are **not part of standard care;** or that will be done more frequently than usual. Specify the frequency of each, if applicable. Exams, tests, and/or procedures that are part of the usual approach / standard care should not be listed in this section. To make this list easier to read, present in a bulleted format as shown:

Most of the exams, tests, and procedures you will have are part of the usual care for your <(i.e. cancer, diabetes, etc.)>. However, there are some extra Choose an item. that you will need to have if you take part in this study.

**For studies that require eligibility testing, the following must be included:**

Before you begin the study:

You will need to have the following extra Choose an item. to find out if you can be in the study:

Here you will list exams, tests, and procedures that will be done only for the purpose of the study; or done more frequently than usual. For example:

1. MUGA scan
2. Blood tests for studies of drug levels
3. CT scan of abdomen
4. Bone scan

If the exams, tests, and procedures show that you can take part in the study, and you choose to do so, then you will need the following extra Choose an item.. They are not part of the usual approach for <(i.e. cancer, diabetes, etc.)>.

During the study:

For example:

1. Blood tests every month for 1 year
2. CT scan of abdomen every 3 months for 2 years
3. Bone scan every 3 months for 2 years
4. Bone marrow biopsy immediately after study treatment is completed; and 1 year later
5. Echocardiogram or MUGA scan every 3 months to see how your heart is working

**If a study calendar is provided in or with the ICF, this statement may be used instead of a bulleted list:**

 A study calendar that shows how often these Choose an item. will be done is attached.

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**HOW LONG WILL I BE IN THE STUDY?**

Subject must be informed of how long they will be expected to participate in the study. Below are two examples of verbiage for you to choose from:

It is expected that your participation in this study will last < length of time>.

**OR**

After you finish the study treatment, we will continue to watch you for side effect and follow your condition for up to < length of time>.

**ONCE YOU HAVE COPIED AND PASTED ALL NECESSARY VERBIAGE - DELETE THIS BOX**

**WHAT RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?**

You are required to identify any risks associated with your study; or to inform subjects that there are **no known risks** associated with study participation. Review the verbiage below. Copy and paste all applicable statements into your consent form.

**If there are no known risks from study participation, the following statement is required:**

There are no expected risks associated with being in this study. However, it is important that you tell the research team about any problems you may be having while taking part in this study.

**Non-physical risks:**

Non-physical (psychological, social, or financial) risks that could affect an individual’s decision to participate should be included in your consent document. List reasonably foreseeable risks and discomforts that are not physical side effects. For example:

If you choose to take part in this study, there is a risk that you may:

* Lose time at work or home and spend more time in the hospital or doctor’s office than usual
* Be asked sensitive or private questions which you normally do not discuss.

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Any reasonably foreseeable physical risks, side effects, or discomforts of participation must be included in your consent document. Keep in mind that the examples below are not a comprehensive list. You must review your study and adjust risks / side effects to meet your study design. For example:

The used in this study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. The study doctor will be testing your blood and will let you know if changes occur that may affect your health.

There is also a risk that you could have side effects. Here are important points about side effects:

* The study doctors do not know who will or will not have side effects.
* Some side effects may go away soon, some may last a long time, or some may never go away.
* Some side effects may interfere with your ability to have children.
* Some side effects may be serious and may even result in death.

Here are important points about how you and the study doctor can make side effects less of a problem:

* Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.
* The study doctor may be able to treat some side effects.
* The study doctor may adjust the study drugs to try to reduce side effects.

As with any part of the consent document that lists a large amount of important information, risks / side effects should be presented in a bulleted format, in language that can be easily understood by subjects. If medical terms are used, substitute them with more commonly understood terms. If this is not possible, ensure medical terms are defined. Because side effects may be complicated and difficult to explain, it is best to provide them in tables to ensure they are separated and can be easily read. For example:

The tables below show the most common and the most serious side effects that researchers know about. There might be other side effects that researchers do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

**SEE THE NEXT PAGE FOR NOTES REGARDING HOW TO PRESENT SUCH A TABLE TO THE SUBJECT.**

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1. **Side effects of study group(s):**
	* + 1. For single-arm studies, list all possible side effects of the study drugs according to the recommendations given in items 2-6 below.
			2. For multiple-arm studies with a control, the Table(s) of Possible Side Effects for the control arm should appear first and be followed by the Tables of Possible Side Effects for the drugs/agents used in the experimental arm(s).
			3. If the experimental arm consists of the usual treatment drugs/regimens (the control arm) plus experimental agent(s)/drug(s), the Table of Possible Side Effects for the usual treatment should not be repeated. The following statement should appear before the Table of Possible Side Effects for the investigational drugs/agents: “In addition to side effects outlined above for Group 1 and Group 2, people in this study who are in Group 2 may also experience the possible side effects of (insert name of research drug) listed below.”
2. **Side effects of procedures**:
	* + 1. When describing risks for procedures, describe risks only for procedures that are beyond what would be considered as occurring during the usual treatment approach. The determination of deeming a procedure as part or not part of the usual treatment approach is left to the discretion of the investigator.
			2. Examples of procedures that are not part of the usual treatment approach could include an unusually large amount of blood to be drawn for PK, central line placement to administer the investigational agent, etc.
3. **Side effects of supportive drugs named in the consent form**:
	1. Non-experimental supportive drugs need not have their side effects listed unless the treatment they support is the research question tested in the study. For example, side effects of Bactrim need not be listed when transplant is part of a study unless transplant is the actual study question in the trial.
4. **Side effects of classes of medications**:
	1. If general classes of approved medications, such as a hormonal therapy or anti-emetics – where no specific drug is named – are required by the protocol, these do not need to be listed, nor their possible side effects included, in the consent form.
5. **Extremely specific possible side effects** which are not perceived by the study participant, such as minor changes in lab values, should not be included in the consent form. Lab value changes that could be perceived by the study participant, or could be indicative of harm, should be listed, for example, the phrase “you could have liver damage,” would be much more understandable to the study participant than “you could have elevated liver enzymes” or “you could have an elevation in (such-and-such lab value).”
6. **Definitions of frequency categories**:
	* + - 1. “Common, some may be serious” - There is no standard definition of the frequency of risks included in this category however, as a guideline, “Common, some may be serious” can be viewed as “In 100 people receiving XXXXX, more than 20 may have:”.
				2. “Occasional, some may be serious”- There is no standard definition of the frequency of risks included in this category however, as a guideline, “Occasional, some may be serious” can be viewed as “In 100 people receiving XXXXX, from 4 to 20 may have:”.
				3. “Rare, and serious” - Side effects that occur in less than 3% of patients are not considered ‘reasonably foreseeable’ therefore do not have to be listed unless they are serious, in which case they should appear in the “Rare, and serious” category i.e. “In 100 people receiving XXXXX, from 3 or fewer may have:”. This categorization will need to be modified for prevention studies.
				4. “Serious” is defined as side effects that may require hospitalization or may be irreversible, long-term, or life-threatening.
				5. “Possible, some may be serious” – This is a unique frequency category and may be used, when appropriate, for informing study participants of possible side effects related to IND agents for which the frequency of individual side effects has not yet been determined.

**ONCE YOU HAVE GATHERED ALL NECESSARY INFORMATION - DELETE THIS BOX**

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1. **Note on stating possible side effects for imaging agents:** Certain FDA regulations will need to be considered when imaging agents are used depending on the imaging agent (IND vs. commercial) and the protocol. For more information, please refer to: FDA's draft guidance for industry standards for clinical trial imaging endpoints, found at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM268555.pdf>, and FDA’s final guidance: “Developing Medical Imaging Drug and Biological Products” found at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm092895.htm>. Radiation Safety Committees may also require the mention of certain radiation-related information in the informed consent form.

**ONCE YOU HAVE GATHERED ALL NECESSARY INFORMATION - DELETE THIS BOX**

**If applicable, you must include the following statement in the consent to further guarantee the subject’s safety:**

You should tell the person obtaining your consent about any other medical research studies you are involved in right now. If applicable, it is also very important that you tell the study doctor or study staff about all the prescription drugs, herbal products, over-the-counter (OTC) drugs, vitamins and natural remedies that you are taking before you start the study and before taking any of these products while you are on the study.

Let your study doctor know of any questions you have about possible side effects. You can ask the study doctor questions about side effects at any time.

**Reproductive Risks, include the following statement if your study involves reproductive risks:**

You should not get pregnant, breastfeed, or father a baby while in this study. The used in this study could be very damaging to an unborn baby. Check with the study doctor about what types of birth control, or pregnancy prevention, to use while in this study.

**If applicable, include the following statement regarding further information about risks:**

For more information about risks and side effects, ask Choose an item..

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**WILL I BENEFIT FROM THIS STUDY?**

Subjects must be informed of any way they may directly benefit from taking part in the study; or if there is expected to be no direct benefit to participants.

Explain in what way(s) they might benefit. Ensure that study participants are given information regarding the type and duration of the likely benefit, if possible. If you are conducting a study that has multiple arms, make sure you specify if different arms of the study have different possible benefits.

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**Financial or other compensation is not considered a benefit** of being in the research. Information regarding compensation should be listed under “**WILL I BE PAID TO PARTICIPATE?**”

**NOTE:** The statements below are generic and should be modified to fit the study question.

**If it can be reasonably expected that the subject may directly benefit from his/her participation:**

This study may or may not help you because researchers do not know <(i.e. how the study drugs will compare to the usual approach)> However, this study may help us learn things that may help people in the future.

**If your study has no direct benefit to the subjects:**

This study is unlikely to help you. However, this study may help us learn things that may help people in the future.

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**CAN I STOP TAKING PART IN THIS STUDY?**

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

It must be clear to subjects that any new information regarding the study that might change their decision to participate will be relayed to them. You must also inform them of any circumstances under which they may be removed from the study. **If any of the following information applies to your study, copy and paste into your document:**

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

**OR**

The study doctor may take you out of the study:

* If your health changes and the study is no longer in your best interest
* If new information becomes available
* If you do not follow the study rules
* If the study is stopped by the sponsor

If the research (a) is FDA-regulated; or (b) is not subject to FDA regulations but is covered by the HIPAA Privacy Rule; and you intend to retain and analyze already collected data about the subject after they choose to withdraw, the following statement **must** be included:

It is important for you to know, however, that information collected about you up to the point of your withdrawal will be kept as part of the study data and may continue to be analyzed.

If the study is **NOT** subject to FDA regulations or the HIPAA Privacy Rule, you must inform subjects whether you intend to:

(1) Keep and analyze already collected data relating to the subject up to the time of their withdrawal; **OR**

(2) Honor a subject’s request to destroy their data or have it excluded from any analysis.

**ONCE YOU HAVE COPIED AND PASTED ALL NECESSARY VERBIAGE - DELETE THIS BOX**

**WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?**

Subjects must be informed of any and all costs they will (or will not) incur as a part of their participation in research. When completing this section:

1. State which study agent(s) or procedure(s) is/are provided free of charge (when applicable).
2. Indicate if the study participant and/or their health plan are likely to be billed for any charges associated with these tests or procedures.
3. Outline any other pertinent financial support.

**If there will be no cost to subjects in your study:**

Taking part in this study will not involve any extra costs to you or your health plan.

OR

The Choose an item.will be supplied at no charge while you take part in this study.

**If applicable to your study:**

The cost of getting the ready and giving it to you *<* indicate if study agent is being given to subject free of charge; OR if the subject / insurance company are responsible for paying*>*. It is possible that the may not continue to be supplied free while you are on the study. Although not likely, if this occurs, your study doctor will talk to you about your options.

You and/or your health plan/insurance company will need to pay for all of the other costs of Choose an item. your while in this study, including the cost of managing any side effects.

Before you decide to be in the study, you should check with your health plan or insurance company to find out exactly what they will pay for.

OR

You and/or your health plan/insurance company will need to pay for all the costs of treating your <insert disease> in this study. Some health plans do not pay for these costs for people taking part in studies. Check with your health plan or insurance company.

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**WILL I BE PAID TO TAKE PART IN THIS STUDY?**

Subjects must be clearly informed if they will be paid to participate in a research study. Conversely, they must also be made aware if they will receive no payment for their participation. You must describe all incentives being offered for participation, as well as the conditions under which they will be offered.

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**If subjects WILL be paid to take part, include the following in your document:**

You will be paid $ per Choose an item.*.* You will be paid at Choose an item. . If you complete the study, you will be paid a total of $ . If you do not finish the study, you will be paid for the part(s) that you did complete.

**If subjects will NOT be paid to take part, include the following in your document:**

You will not be paid for taking part in this study.

**If the incentive is monetary, the informed consent must include:**

1 – The amount of each payment to be made to subjects, as well as the total amount subjects will receive (i.e. $25 per visit, up to a maximum of $XXX)

2 –Schedule of payments

3 – Method by which compensation will be received (i.e. check, gift card, cash)

Although payments are usually monetary, participants may be offered rewards other than money. The incentive, and the conditions under which they are to be provided, must not be coercive. Incentives should not unduly influence a subject’s participation / continued participation in this study.

**NOTE: Compensation information must correspond with information provided in the eProtocol application.**

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**WHAT HAPPENS IF I AM INJURED OR HURT BECAUSE I TOOK PART IN THIS STUDY?**

**IF YOUR STUDY INVOLVES NO MORE THAN MININIMAL RISK, YOU MAY OMIT THIS SECTION FROM THE CONSENT FORM.**

If your study involves **more than minimal risk**, you MUST explain whether any compensation and / or medical treatments are available if injury occurs. You must describe what they consist of, or where further information may be obtained. When completing this section, keep in mind that the consent form must not include any exculpatory language through which the participant or the representative is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the researcher, the sponsor, the institution or its agents from liability for negligence. (You may reference 45 CFR 46.116, 21 CFR 50.20 for further information)

**If no costs will be paid, copy and paste the following into your document:**

If you feel you have been injured or hurt as a result of taking part in the study, it is important that you tell the study doctor. You will get medical treatment if you are injured or hurt as a result of taking part in this study.

You and/or your health plan will be charged for this treatment. The study will not pay for medical treatment.

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##### **If costs will be covered, copy and paste the following into your document:**

If you feel you have been injured or hurt as a result of taking part in the study, it is important that you tell the study doctor. You will get medical treatment if you are injured or hurt as a result of taking part in this study.

Your health plan will be charged for this treatment. The study will not pay for medical treatment. Any costs that are not covered or in excess of those paid by your health plan, including deductibles, shall be paid by .

##### When completing this section, ensure that the extent of injury compensation is described; and use language that is simple and easy to understand. Also, keep in mind that this section should reflect the information in the contract with the sponsor (if applicable).

##### **Alternative Injury Clause Language for projects that are funded**:

If the sponsor has requirements different or in addition to the statements above, language should be negotiated with the appropriate individuals (e.g., responsible project researcher, department, sponsor, legal counsel); and will be subsequently reviewed by the IRB.

**WILL MY INFORMATION BE KEPT PRIVATE?**

Your privacy is very important to us and the researchers will make every effort to protect it. We will do our best to make sure that the personal information in your medical record and research file will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

**If participants will be identified:** You must insert the following language, as specific permission for identification must be obtained.

I agree to allow my identity to be disclosed in reports and presentations

\_\_\_\_ YES \_\_\_\_ NO Initials \_\_\_\_\_\_\_\_

There are persons and organizations that may look at your records. These organizations are required to make sure your information is kept private. Some of these organizations are:

**Insert any of the following that apply to your study:**

* + - U.S. government officials who oversee research, including but not limited to the Food and Drug Administration (FDA). Choose an item.
* The study sponsor, , and its representatives
	+ - Researchers at other institutions participating in the research.
		- AChoose an item. that meets regularly to monitor safety and other data related to the study
		- The insurance company may need the information in order to pay for your medical bills or other costs of your participation in this study

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* + - McLaren Choose an item.
* The Principal Project Investigator and his/her associates who work on, or oversee the research activities.
	+ - The McLaren Health Care (MHC) Institutional Review Board (a group of people who review the research with the goal of protecting the people who take part in the study)
		- The McLaren Health Care Office of Research Compliance and Quality Improvement

**If any of the following points apply to your study, copy and paste into your document:**

* The data for this study is being collected anonymously. Neither the researchers nor anyone else will be able to link data to you.
* The data collected about you for this study that is sent to the sponsor will include < (i.e. a unique ID number assigned to you when you joined the study)*>*.

**If the data are being coded and a key maintained separately:**

* Your study doctor will maintain a confidential list linking your name to the code and only authorized persons will have access to this list.

This section should also include information regarding how you will maintain the participant’s privacy throughout the project.

**If participants will be audiotaped and/or videotaped** – it must be clearly stated in the consent. You must also indicate whether this is a requirement for participating in the study, or if they are able to opt out.

**If audio / video taping is optional:** Provide a section to document the participant’s choice:

I agree to allow audiotaping of the interview

\_\_\_\_ YES \_\_\_\_ NO Initials \_\_\_\_\_\_\_\_

I agree to allow videotaping of the interview

\_\_\_\_ YES \_\_\_\_ NO Initials \_\_\_\_\_\_\_\_

Ensure that you also include the following information regarding confidentiality:

* Where will the data be stored and how will it be protected
* If data is being sent elsewhere (i.e. central data base, another institution), ensure it is clear who will have access to it

**ONCE YOU HAVE COPIED AND PASTED ALL NECESSARY VERBIAGE - DELETE THIS BOX**

**GENETIC TESTING -** If your study involves genetic testing, the following MUST be included:

A federal law, called the Genetic Information Nondiscrimination Act (GINA), makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

* Health insurance companies and group health plans may not request your genetic information that we get from this research.
* Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
* Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

You can learn more about the federal law at the following web site:

<http://www.genome.gov/Pages/PolicyEthics/GeneticDiscrimination/GINAInfoDoc.pdf>.

Michigan also has laws which prohibit discrimination on the basis of genetic information in employment and in health insurance under the Medicare program or supplemental to the Medicare program.

If you have questions about this subject, please contact: the McLaren IRB at (248) 484-4950.

**ClinTrials.gov** – If your study is listed on ClinTrials.gov, the following must be included, AS IS:

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. At most, the Web site will include a summary of the results. You can search this Web site at any time.

**HIPAA AUTHORIZATION-** If subjects will be signing a HIPAA Authorization form, include the following:

In addition to your consent to take part in this research study, you will also be asked to sign a separate form to give your permission for the use and release of your personal health information for this research.

**ONCE YOU HAVE COPIED AND PASTED ALL NECESSARY VERBIAGE - DELETE THIS BOX**

 **WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?**

You can talk with your study doctor about any questions or concerns or complaints you may have about the study. Please contact  at .

If you have questions about your rights while taking part in this study, if the study staff cannot be reached, or if you have questions, complaints or concerns about the study that you do not feel you can discuss with your study team, contact the McLaren Health Care IRB at (248) 484-4950, Fax (248) 276-9732, or e-mail hrpp@mclaren.org or regular mail at 2701 Cambridge Ct., Suite 110, Auburn Hills, MI 48326.

**SHARING OF INFORMATION**:If subjects will be given the opportunity to choose whether or not to share information with their PCP, copy and paste the following into your document:

**Notification of Primary Care Physician**

**Please check one of the boxes below, and initial, to indicate whether or not you would like your study doctor to let your primary care physician know that you are taking part of this study:**

* I do not have a primary care physician (PCP). Subject’s Initials\_\_\_\_\_\_\_\_\_
* I give my permission for my study doctor to notify my PCP, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, of my participation in this research. Subject’s Initials \_\_\_\_\_\_\_\_\_
* I do not give my permission for my study doctor to notify my PCP of my participation in this research. Subject’s Initials \_\_\_\_\_\_\_\_\_

**ONCE YOU HAVE COPIED AND PASTED ALL NECESSARY VERBIAGE - DELETE THIS BOX**

**OPTIONAL RESEARCH TESTING: RESEARCH INVOLVING THE USE OF BIOLOGICAL SPECIMENS**

**IF YOUR STUDY INVOLVES NO OPTIONAL TESTING, YOU MAY OMIT THIS SECTION**

If your study involves the optional collection of tissue, blood, fluid, or genetic material; or collection of these specimens for future research, subjects must be informed of their options for participation. This section is in the main informed consent document to eliminate the need for subjects to sign two separate documents. The following information must be included:

* Purpose of the sub-study.
* Procedures involved (this would include blood tests, biopsies, etc.)
* Risks to subjects agreeing to participate in sub-study
* Whether or not the subject’s decision to participate / not participate in the optional study will have an impact on their participation in the main study
* Information regarding how subjects may withdraw consent for the sub-study
* For studies involving specimens to be stored for future use, indicate where they will be stored, and how long they will be kept
* Choices for the subject in regards to the use / storage of specimens

**For example:**

If you decide now that your Choose an item. can be used now/kept for research, you can change your mind at any time. Just contact your study doctor and let him or her know that you do not want us to use your Choose an item.. The Choose an item. will no longer be used for research; tissue specimens will be returned to the laboratory from which they were obtained, and blood and body fluids specimens will be destroyed.

(CONTINUED ON NEXT PAGE)

**Check one of the boxes below, and initial to indicate whether or not you agree to participate in the part of this study:**

 I agree to allow my Choose an item. to be stored with identifiers and used for . I may be contacted for future studies with my samples. If future work is done on my samples beyond the scope of this project, the researchers will present the research to an Institutional Review Board (IRB) to review and approve, and determine if my further consent is needed. Initials\_\_\_\_\_\_\_\_\_

 I agree to allow my Choose an item. to be stored without any identifiers and used for . I will not be contacted for future studies with my samples since my samples are stored without any identifiers or linking codes; no further IRB approval is needed for future research on these samples. Initials\_\_\_\_\_\_\_\_\_

 I do not want my Choose an item. to be stored and used for . My samples are to be destroyed after this study is over. Initials\_\_\_\_\_\_\_\_\_

**Provide a consent section specifically for the sub-study:**

**OPTIONAL SUB-STUDY CONSENT**

I have read the description of this <optional research / testing *>*, or it has been read to me. The study doctor and/or study staff have explained this information and answered all of my questions, so far, to my satisfaction. I have been given time and opportunity to read the information carefully, to discuss it with others and to decide whether or not to take part in this study. My signature below indicates my voluntary agreement to participate in this *<*optional research / testing >.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Participant Date**1**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Participant

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Person Conducting the Informed Consent Discussion

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person Conducting Date**1**

the Informed Consent Discussion

**ONCE YOU HAVE COPIED AND PASTED ALL NECESSARY VERBIAGE - DELETE THIS BOX**

**CONSENT**

**Signatures are a required element of informed consent.** The consent document must be signed by the subject and a member of the study team. Investigators may choose to delegate the task of obtaining informed consent to another individual listed on the study**.** However, the investigator always remains **ultimately responsible**.

**While completing this section, keep the following in mind:**

If subjects will not be signing an informed consent document, you must apply for a “waiver of documentation of informed consent”. This can be done in the Informed Consent section of your eProtocol application. When requesting such a waiver, it is important to ensure that all requested information is provided**.**

I have read this consent form or had it read to me. I have discussed it with the Choose an item., and my questions have been answered. I have been told that I will be given a fully signed and dated copy of this form. I agree to take part in the Choose an item..

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Participant Date**1**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Participant

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Person Conducting the Informed Consent Discussion

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person Conducting Date**1**

the Informed Consent Discussion

Previous IRB-Approved Consent Version(s): Click here to enter text.

**This line and the line directly below this box, must always be the last on your consent form!**

**1** Each person who signs the informed consent form must personally enter the date for his/her signature.

**STOP:**

**THE REMAINDER OF THIS DOCUMENT PERTAINS TO THE FOLLOWING SPECIAL CIRCUMSTANCES:**

* **Decisionally / congnitively impaired subjects**
* **Witness Statement**
* **Non-English speaking subjects**
* **Children**

**IF YOUR PROJECT DOES NOT INVOLVE ANY OF THE ABOVE MENTIONED CIRCUMSTANCES, DELETE THE REMAINDER OF THIS DOCUMENT**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**COGNITIVELY / DECISIONALLY IMPAIRED SUBJECTS**

**If you have indicated in your application that cognitively / decisionally impaired persons will be included in your subject population, insert the following signature section into your document, directly following the signature section for the subject, and before the signature for the person conducting the informed consent discussion:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person Signing For Subject**\*** Date**1**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Person Signing for Subject Relationship to Subject\*

**\***A court-appointed legal guardian (see definition below) may act on behalf of the subject who was found incompetent by a court. Review the guardianship paper (sometimes called letters of authority) from the probate court to assure that it permits the legal guardian to act on behalf of the subject. Make a copy of the guardianship paper and retain it with this consent.

**\*\*\*\*Michigan’s Definition of Legally Authorized Representative (LAR): In Michigan, a Legally Authorized Representative is an individual or body authorized by a court of competent jurisdiction as the Legal Guardian of an incapacitated person, pursuant to a court order that grants the Legal Guardian the authority to approve the ward’s participation in medical research studies. A Legally Authorized Representative is also a properly designated patient advocate, who has been given the authority to approve the patient’s participation in medical research studies.**

**Review the documentation provided by the LAR to ensure that it permits the representative to approve the ward’s participation in medical research studies. Retain a copy of the document with this consent.**

**Whenever possible, the subject should be approached to either assent to, or at least to not dissent from serving as a research subject. The assent process must be presented to the MHC IRB. The wishes of the subject should be respected, regardless of whether surrogate/proxy permission has been provided.**

**ONCE YOU HAVE COPIED AND PASTED ALL NECESSARY VERBIAGE - DELETE THIS BOX**

**WITNESSES**

The MHC IRB does not require a “witness” section on an informed consent form. In the event that either the PI or the sponsor insist on including documentation of a witness:

* The witness must be impartial (someone not connected with the research or the study team).
* The ICF must include the reason why a witness is being used, as well as an explanation as to what the signature of the witness is confirming.

**Only if you are including documentation of a witness, insert the following, directly after the consent section:**

**WITNESS STATEMENT**

* The participant was unable to read or sign this informed consent form because of the following reason(s):
* The participant is illiterate
* The participant is visually impaired
* The participant is physically unable to sign the consent form. Please describe:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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* Other (please specify):

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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As an impartial third party, I witnessed the entire consent discussion for this study and the participant’s signature on this form. I confirm that this entire form was read to the participant named above, and the participant voluntarily agreed to be in this study.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Witness

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Witness Date**1**

**ONCE YOU HAVE COPIED AND PASTED ALL NECESSARY VERBIAGE - DELETE THIS BOX**

**NON-ENGLISH SPEAKING PARTICIPANTS**

**If you have indicated in your application that non-English speaking participants may be included in your subject population, insert the following signature section into your document, directly following the signature section for the subject, and before the signature for the person conducting the informed consent discussion:**

Consent was obtained from the participant using a short form for non-English speakers. The short form is available in the participant’s language and this (long) consent form was read to the participant using an interpreter.

I witnessed the entire oral presentation of this study and the participant’s signature on this form. I confirm that the participant named above was read the information in this consent document in a language he/she understands, and the participant voluntarily agreed to be in this study.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Witness

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Witness Date**1**

**CHILDREN**

**If your research will involve children (persons under the age of 18), federal regulations provide requirements for permission by parents or guardians and for assent by children. You can find more information regarding this requirements on the OHRP** [**website**](http://www.hhs.gov/ohrp/policy/faq/informed-consent/requirements-for-assent-in-research-with-children.html)**.**

**You may also contact IRB office at (248) 484-4950 for further assistance.**

**ONCE YOU HAVE COPIED AND PASTED ALL NECESSARY VERBIAGE - DELETE THIS BOX**

**If a HIPAA Authorization is required for this study, add the following language to this consent document and have the participant or legally authorized representative sign the last page*.***

**Authorization (Permission) to Use or Disclose Identifiable (Personal)**

**Health Information for Research Purposes**

**What is the purpose of this form?**

State and Federal privacy laws protect the use and disclosure of your health information. Protected Health Information (PHI) is any health information that can identify you. To take part in this research study, the research team must obtain your permission to access your health information and to use and share your PHI. The research team will only use and/or share your information as described below and in the research consent form.

**What PHI will be obtained, used or disclosed?**

**The PHI that will be “USED”** for this research includes the following: [*Delete elements of PHI that will NOT be* ***used*** *for this research*]: name, address (street address, city, state and zip code), e-mail address, elements of dates, telephone numbers, fax numbers, social security number, medical record number, health insurance number, account numbers, certificate/license numbers, vehicle and serial numbers, web URLs, internet protocol (IP) addresses, biometric identifiers (voice and fingerprints), full face photographs, and any unique identifying numbers or characteristics or code.

**The PHI that will be “DISCLOSED”** or shared with others for this research includes the following: [*Delete elements of PHI that will NOT be disclosed/or shared with others for this research*]: name (or initials), address (street address, city, state and zip code), e-mail address, elements of dates, telephone numbers, fax numbers, social security number, medical record number, health insurance number, account numbers, certificate/license numbers, vehicle and serial numbers, web URLs, internet protocol (IP) addresses, biometric identifiers (voice and fingerprints), full face photographs, and any unique identifying numbers or characteristics or code.

PHI used or disclosed could come from your medical records or information created or collected during the research. This could include your medical history and dates or results from any physical exams, laboratory tests or other tests.

**Do I have to give my permission for certain information to be released?** [*Delete the types of information that you do not need for your research. If none of the types of information are needed, this section may be removed completely.*]:

Yes. The following information will only be released if you give your specific permission by putting your initials on the line(s). This is your specific permission for release of this information. Federal rules do not allow any use of the information to criminally investigate or prosecute any alcohol or drug abuse.

\_\_\_\_I agree to the release of information pertaining to drug and alcohol abuse, diagnosis or treatment.

\_\_\_\_I agree to the release of HIV/AIDS testing information.

\_\_\_\_I agree to the release of information pertaining to sexually transmitted diseases.

\_\_\_\_I agree to the release of information pertaining to mental health diagnosis or treatment.

\_\_\_\_I agree to the release of genetic testing information.

**Who will my Personal Health Information be used or shared with?**

Your study information may be **used** or **shared** with the following people or groups: [*Delete or add others who will have access to the PHI, ensuring to include each study site*]:

* The PI and research staff associated with the research project Do not delete
* Authorized members of MHC’s workforce who may need to access your information in the performance of their duties. [*For example, to provide treatment and services, ensure integrity of the research, or for accounting and/or billing matters.*]
* Other collaborating research institutions, which include: [*list all other institutions that have key personnel participating in this research project*].
* The McLaren Health Care (MHC) Institutional Review Board Do not delete
* The McLaren Health Care Office of Research Compliance and Quality Improvement Do not delete
* McLaren Center for Research and Innovation Do not delete
* The study Sponsor or representative, including companies it hires to provide study related services, which include: [*list the sponsor, its representative(s), and affiliated companies-CRO’s, etc.*].
* Federal agencies with appropriate regulatory oversight (e.g., FDA, OHRP, OCR, etc.) may review your records Do not delete.

The above groups may use your health information to complete this research, to evaluate the results of this

study, to check that the study is being done properly, or to obtain marketing approval for new products

resulting from this research.

**What happens if I do not sign this permission form?**

Your decision to sign or not sign this authorization will not affect your standard medical care, payment or enrollment in any health plans or affect your eligibility for benefits. However, if you are not willing to sign this authorization to use and/or disclose your PHI by the research team, you will not be eligible to take part in this research study.

**Does my permission (authorization) expire?**

This permission to release your Personal Health Information expires when the research ends and all required study monitoring is over. [or indicate authorization does not have an expiration date, if applicable]

**Can I cancel my permission (revoke my authorization)?**

You may withdraw (take back) your permission for the **use** and **disclosure** of your PHI for this research at anytime, by **writing** to the PI at the address on the first page of this form. Even if you withdraw your permission, the PI for the research project may still use your PHI that was collected prior to your written request if that information is necessary to the study. If you withdraw your permission for use of your PHI, you will also be withdrawn from the research project. Withdrawing your authorization **will not** affect the health care that will be provided by the McLaren Health Care [add others, if applicable].

**Other information I should know about my privacy and who can I call if I have questions regarding my privacy**

We will do our best to protect the privacy of your records. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people listed on this form who are not covered by the HIPAA Privacy Rules, then your information won’t be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

PHI may be used or disclosed for research as “limited or de-identified data sets” which includes removing identifying information from your PHI such as your name, address or other direct identifiers. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study. Once your information has been released according to this Authorization, it could be released again and may no longer be protected by the HIPAA regulations.

If you have questions about your privacy rights contact the McLaren Health Care IRB by telephone at 248-484-4950 or email at hrpp@mclaren.org

**What are my rights regarding access to my personal health information?**

[*Select only one of the next two paragraphs, delete the other*]:

During your participation in this study you will have access to your medical record and any study information that is part of that record. The PI is not required to release research information that is not part of your medical record.

During your participation in this research project you will not be able to access that part of your medical record involved in the research. You will have access to your medical record when the study is ended or earlier, if possible. The PI is not required to release research information that is not part of your medical record.

**Optional research activity** *[if your study contains optional research activities, or if you have specific future research plans that you would like to obtain HIPAA authorization for at this time, please complete and include the following section. Otherwise, delete].*

If the research I am agreeing to participate in has additional optional research activity such as the creation of a database, a tissue repository or other activities, as explained to me in the informed consent process, I understand I can choose to agree to have my information shared for those activities or not.

**[ ]** I agree to allow my information to be disclosed for the additional optional research activities explained in the informed consent process.

**Participant Agreement:**

I have read (or someone has read to me) the information provided above. I have been given the opportunity to ask questions and all of my questions have been answered to my satisfaction. By signing below, I agree that my health information may be used and disclosed as described in this form. I will be given a signed copy of this authorization.

|  |
| --- |
|  |
| Printed Name of Participant Signature Date Signed |

|  |
| --- |
|   |
| Printed Name of Signature Legal Relationship Date SignedLegal Authorized Representative |