**Multi-Site Research: Participant Local Site Consent:**

**Local Context & HIPAA Language for External IRB Submissions:**

For multi-site research requiring a reliance agreement in which WSU is NOT the reviewing IRB.

**NCI-CIRB Studies: DO NOT USE THIS TEMPLATE!**

* All studies involving a reliance agreement with the NCI-CIRB must use the NCI-CIRB consent template available on the [WSU IRB Website for NCI-CIRB Reliance Agreements](https://research.wayne.edu/irb/cirb).

It is important to read this entire instruction page before you begin preparing this template.

A Relying Institution is required to identify, interpret, and communicate to the Reviewing IRB the requirements of any applicable state or local laws, regulations, institutional policies, standards, or other local factors. For additional information please see WSU IRB Policy 4-17 and the [WSU IRB Reliance Agreements website.](https://research.wayne.edu/irb/reliance-agreements)

**INSTRUCTIONS:**

**Note:** The template language contains only the WSU and affiliate required wording for local context language sections. It is not a complete template. See Sponsor/Reviewing IRB template for all other required consent information, instructions, and formatting requirements.

* Prepare the local context consent language in this WSU Site Information Consent addendum template.
* Add this completed addendum/WSU Site Information at the end of the Sponsor/Reviewing IRB’s main consent template as an appendix.
* Signature information can be combined with the sponsor’s signature instructions or used as a separate signature page.
* Please follow italicized instructions listed in brackets and highlighted areas.
* **Delete all instructions from the WSU Site Information template when finished- including this page.**
* Font size must be 12 or larger.
* Letterheads & logos are NOT permitted.
* **The following information must be included, in the Sponsor/Reviewing IRB’s template language:**
	+ Title of Study
	+ Principal Investigator (PI) Name, Address, Phone
	+ Location(s): [*Where study will have services rendered*]
	+ Sponsor/funding source

**Required Local Context WSU Site Information:**

* Study Costs
* WSU Compensation for injury/research related injury
* Confidentiality
* Questions
* Signature page
* HIPAA Authorization
* Consent version date and space for participant initials provided (footer)

**LOCAL SITE CONSENT ADDENDUM: PARTICIPANT INFORMATION ABOUT THE LOCAL SITE**

*This part of the consent form includes additional information about being a research participant at your enrolling site: Wayne State University/Detroit Medical Center/Karmanos Cancer Institute. Before making your decision to join the study, review both the General study information and this Site information.*

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| --- | --- |
| **Study title:**  | Can be removed if repeated on the page’s header.  |
| **Site Name:**  | Wayne State University/Detroit Medical Center/Karmanos Cancer Institute/Karmanos Cancer Institute- McLaren/John. D. Dingell VAMC [Select all applicable sites] |

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| **Who can I contact locally about this study?**  |

Please contact the Principal Investigator & study team listed below if you have any questions about the study now or in the future to:

* Obtain more information about the study
* Ask a question about the study procedures or treatments
* Talk about study-related costs to you or your health plan
* Report an illness, injury, or other problem (you may also need to tell your regular doctors)
* Leave the study before it is finished
* Express a complaint or concern about the study

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| Local Site Principal Investigator (PI):  |  |
| Local Contact Information for PI & Study Team | Phone: |
| Email: |
| Local Site Address: |  |

If you would like to speak with someone locally other than a member of the research staff or wish to share feedback privately, you can also contact the Wayne State University IRB about your research experience, call the Research Participants’ Advocate at (313)577-1628 or email irbquestions@wayne.edu . You are encouraged to contact the IRB if:

Your questions, concerns, or complaints are not being answered by the research team.

You cannot reach the research team.

You want to talk to someone besides the research team.

You have questions about your rights as a research participant.

You want to get information or provide input about this research.

*[Delete if not using McLaren Sites]* If you are a McLaren patient and 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 research that you do not feel you can discuss with your study team, contact the McLaren Heath Care Institutional Review Board (IRB) at (248) 484-4950, Fax (248) 276-9732, or e- mail hrpp@mclaren.org or regular mail at 2701 Cambridge Court, Suite 110, Auburn Hills, MI 48326.

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| **Will there be any cost to me?** |

*There are two separate instructions for costs for this institution. There are 2 steps to preparing this section.*

***[Step 1:*** *Select ONE of the statements that applies to the study.]*

***Option 1*** *must be used for cancer research.*

***Option 2*** *must be used for all other research submissions.*

**Option 1: Study Costs for Karmanos Cancer Institute Protocols:**

You and/or your insurance company will be charged for the following items and procedures that are considered routine care for your disease. These include *[insert items]*

The study sponsor will provide *[list items to be covered by sponsor per funding information]* at no cost to you and/or your insurance company during your participation in this research study.

You and/or your health plan/insurance company will need to pay for the costs of treating your cancer in this study. Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment. You will be responsible for any charges that your insurance does not cover, including co-payments, coinsurance, and deductibles.

For more information on clinical trials, you can call the National Cancer Institute at 1-800-4-CANCER (1- 800-422-6237) and talk to an Information Specialist.

**Option 2: Study Costs for all other institutions** (e.g., Detroit Medical Center, Wayne Health). **Choose only the applicable statement(s) from the following list:**

**Statement 1**: Use this statement when the study involves only minimal risk interventions with participants (ex. Blood draw only, saliva sample, questionnaire studies)

Participation in this study will be of no cost to you.

**Statement 2:** Use this statement when the study involves investigational drugs or devices:

You will not be charged for [*study drug or device*]

**Step 2: select only the applicable statement(s) below.** Delete any statement that does not apply.

**Statement 1:** The study sponsor will pay for all costs and charges from your participation in this research study.

OR

**Statement 2:** Your participation in this study could result in increased costs to you and/or your insurance company for additional monitoring and tests.

AND/OR

**Statement 3:** You will not be charged for any tests specifically required for this research study, but you or your insurance company will be billed for tests or procedures that are considered “standard of care” and would have been part of your medical treatment if you did not participate in this study. These treatment costs include but are not limited to drugs, routine laboratory tests, x-rays, scans, surgeries, routine medical care, and physician charges.

Your health insurance company may not pay for these “standard of care” charges because you are in a research study. If your insurance company does not pay for costs associated with this research study that are considered standard care for your medical treatment, then you will be billed for these costs. You are responsible for paying for any insurance co-pays and any deductibles due under your insurance policy, and any charges your insurance company does not pay.

So that you do not have unexpected expenses from being in this study, ask your study doctor for a list of the tests or procedures that will be paid by the sponsor of the study.

**[*Please provide a separate list to the IRB or include the items in the consent.]***

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| **What if I am injured?** |

*Please note the language in this section must match the Clinical Trial Agreement (CTA)/Contract****.***

***Select the applicable statements.***

**Statement 1: Wayne State University’s Compensation for Injury Policy:**

In the event that this research-related activity results in an injury, treatment will be made available including first aid, emergency treatment, and follow-up care as needed. Cost for such care will be billed in the ordinary manner to you or your insurance company. No reimbursement, compensation, or free medical care is offered by Wayne State University *[or (insert as applicable, the name(s) of the Detroit Medical Center, Karmanos Cancer Institute, McLaren Health Care, Wayne Health, sponsor, and any other facility involved with this study)].* If you think that you have suffered a research-related injury, contact the PI right away at *the phone number listed on the first page of the consent form.*

**Statement 2: For Detroit Medical Center/Tenet’s Compensation for Injury Policy Only:**

PICK THE FIRST PARAGRAPH OR SECOND SET OF PARAGRAPHS BELOW DEPENDING ON WHO IS RESPONSIBLE FOR PAYMENT

**If the sponsor will pay for medical treatment of research-related injuries:**

If a “research-related-injury” results from your participation in this research study, medical treatment will be provided at no cost to you and paid by the sponsor of the study. A “research-related-injury” means injury caused by the product or procedures required by the research which you would not have experienced if you had not participated in the research study. You, or your medical insurance, will be responsible for other medical expenses resulting from your medical condition.

OR

**If medical treatment of research-related injuries will be billed to participant and/or their insurance:**

If a “research related injury” results from your participation in this research study, medical treatment will be provided. The costs for all your medical treatment will be billed to you and/or your insurance. A “research related-injury” means injury caused by the product or procedures required by the research which you would not have experienced if you had not participated in the research.

It is important for you to follow your study physician’s instructions including notifying your study physician as soon as you are able of any complication or injuries that you experienced.

You will not be paid for any other injury-related or illness-related costs, such as lost wages. You are not waiving any legal rights and are not freeing the sponsor, Principal Investigator, or hospital of any malpractice, negligence, blame or guilt by participating in this study.

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| **Will my information be confidential?**  |

All information collected about you during the course of this study will be kept confidential to the extent permitted by law. You will be identified in the research records by a code name or number. Information that identifies you personally will not be released without your written permission. However, the study sponsor (*List the sponsor, its representative(s), affiliated companies, CRO’s, etc., as they are listed in the sponsor template consent)*, (*List the Reviewing IRB, i.e., Advarra IRB, WCG,* ), the Institutional Review Board (IRB) at Wayne State University, *[Insert, as applicable; the Institutional Review Board (IRB) at McLaren Health Care (MHC), the McLaren Health Care Office of Research Compliance and Quality Improvement, Karmanos Cancer Institute, McLaren Health Care, other McLaren sites involved in this study**[insert McLaren sites], Detroit Medical Center, Wayne State University),* and federal agencies with appropriate regulatory oversight [e.g., Food and Drug Administration (FDA), National Cancer Institute (NCI), Office for Human Research Protections (OHRP), Office of Civil Rights (OCR), etc.) may review your records.

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| **Signatures** |

**Consent to Participate in a Research Study**

**Signatures are a required element of informed consent.** The consent document must be signed by the participant/legally authorized representative (LAR) 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 approved by the IRB to obtain consent**.** However, the principal investigator always remains **ultimately responsible**.

**Documentation of Informed Consent Steps:**

* **Step 1: Consent to Participate in a Research Study:** Required for all studies using this consent template.
	+ **Step 1.2: Witness Statement:** Required for participants who are unable to read the consent form themselves (i.e., non-English speaking participants, or participants who are illiterate or visually impaired)
	+ **Step 1.3:** **Translator:** Required when consent is obtained from a non-English speaking participant using a short form *(Remove from consent form if you have indicated in your application that non-English speaking participants will not be included in your participant population)*
* **Step 2: HIPAA Authorization:** Required for research that involves the use of Protected Health Information (PHI) subject to HIPAA regulations.

**Step 1: Documentation of Informed Consent:** *(Required for all studies using this template)*

To voluntarily agree to take part in this study, you must sign on the line below. If you choose to take part in this study, you may withdraw at any time. You are not giving up any of your legal rights by signing this form.

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

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Signature of participant / Legally Authorized Representative\* Date

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Printed name of participant / Legally Authorized Representative\*

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Signature of person conducting the informed consent discussion Date

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Printed name of person conducting the informed consent discussion

**\*A Legally Authorized Representative is also a properly designated patient advocate, who has been given the authority to approve the participant’s consent.**

Remove Legally Authorized Representative (LAR) Reference if you don’t intend to consent participants that have or may have a LAR.

**Step 1.2: Witness Statement**

**Remove this box if participation in this study is not likely to require the signature of a witness.**

* *The witness must be impartial (someone not connected with the research or the study team).*

**WITNESS STATEMENT** (if applicable)

The participant was unable to read or sign this informed consent form because of the following reason(s):

* The Participant is non-English speaking and required translation with a short form:
* 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.
* The participant is illiterate.
* The participant is visually impaired.
* 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 in a language he/she understands, and the participant voluntarily agreed to be in this study.

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Printed Name of Witness

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Signature of Witness Date

**Step 1.3 Translator for Non-English-Speaking Participants**

**If you have indicated in your application that non-English speaking participants may be included in your participant population, insert the following signature section into your document.**

The translator must be fluent in both languages, gives oral presentation of consent content, can be anyone including a member of the research team, but cannot also serve as the witness.

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 am fluent both in English and the language that is understandable to the participant or legal representative. I have given the oral presentation of the entire content of this English consent form to the participant or legal representative in the language that is understandable to the

participant that describes the entire content of the English version of Informed Consent.

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Printed Name of Witness

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Signature of Witness Date

***For McLaren Sites:*** *When an ICF is revised, McLaren requires the following at the end of the ICF:*

* Previous IRB-Approved Consent Version(s): [Version(s)]

**Continue to HIPAA Authorization on next page. *[remove this line if not applicable]***

[*DELETE the following pages if not applicable*]

**[*If any research activities involve accessing a medical record, electronic or hard copy, in- or out-patient, retrospective or prospective, or involve databases or tissue banks outside of normal health care activities, please refer to the IRB Policy/Procedure, “10-1 HIPAA in Research” available on the***[***IRB Policies and Procedures website***](https://research.wayne.edu/irb/policies-human-research#S10)***. 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.*]**

**Step 2: HIPAA Authorization**

A federal regulation, known as the “Health Insurance Portability and Accountability Act (HIPAA)” gives you certain rights concerning the use and disclosure (sharing with others) of your Protected Health Information (PHI). This regulation provides safeguards for the privacy and security of your information. Your permission (authorization) is required for the use and sharing of any PHI collected as part of this research study. 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.

The principal investigator (PI) and the research team will use your medical records and information created or collected as part of this research study. Your PHI is important for the PI and the research team in order to collect information about you during the study, to be able to contact you if needed, and to provide treatments to you during the study, if required. The PI may send out your study related health information to the sponsor or other groups involved in this study.

Your medical records, which may contain information that directly identifies you, may be reviewed by representatives from groups identified below. The purpose of these reviews is to assure the study is being conducted properly, that data is being obtained correctly or for other uses authorized by law. These reviews occur at the study site or in the PI’s research office and can take place anytime during the study or after the study has ended.

**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 (all geographic subdivisions smaller than state including street address, city, county, precinct, 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,
* 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 (all geographic subdivisions smaller than state including street address, city, county, precinct, 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,
* any unique identifying numbers or characteristics or code.

Your study information may be **used** or **shared/disclosed** with the following people or groups: [*Delete bullet points that do not apply and/or add others who will have access to the PHI*]:

* The PI, co-investigators, and key personnel of WSU associated with the research project. *[Do not delete this bullet]*
* Advarra IRB and WSU’s Institutional Review Boards (IRBs). *[Do not delete this bullet]*
* Authorized members of WSU’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.*]
* Authorized members of McLaren Health Care’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 academic research institutions, which include: [*list all academic centers that have key personnel participating in this research project*].
* The McLaren Health Care (MHC) Institutional Review Board
* The McLaren Health Care Office of Research Compliance and Quality Improvement KCI at McLaren *[SITE NAME(S)]*
* 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 *this bullet*.

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.

This Authorization does not expire *[Or as appropriate, insert expiration date or event such as “the end of the research study”]*. The research team may need to correct it or provide missing information about you even after the study has ended, and your medical records may be needed to assist in this process.

*[Please select* ***ONLY ONE*** *of the, following statements]*:

* **Statement 1:** 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.
* **Statement 2:** During your participation in this research project, you will not be able to access that part of your medical record involved in the research. This will be done to prevent the knowledge of the research results from affecting the results of the project. Your information will be available to the treating physician to allow them to provide medical treatment in case of an emergency. 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.

You may take back your permission for the **use** and **sharing/disclosure** of your PHI for this research at anytime, by **writing** to the PI at the address on the first page of the consent form. Even if you take back 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 take back your permission for use of your PHI, you will also be removed from the research project. This **will not** affect the health care that will be provided by the *Detroit Medical Center and/or the WSU School of Medicine Practice Plans and/or McLaren Health Care.*

**Authorization to use and disclose PHI**

* By signing this document, you are authorizing the PI to **use** and **share/disclose** PHI collected about you for the research purposes as described above.

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Signature of participant Date

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Printed name of participant

* For participants unable to give Authorization, the following individual is acting on behalf of the research participant (e.g., children, mentally impaired, etc.).

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Signature of authorized representative Date

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Printed name of authorized representative Relationship to the participant

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Signature of person obtaining Authorization Date

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Printed name of person obtaining Authorization