



Local Context Consent & HIPAA Language for External IRB Submissions (IRB version 02/2020) (FOR USE WHEN WSU IS NOT THE REVIEWING IRB)

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, including local ancillary reviews and restrictions on use and disclosure of PHI, and federal laws and regulations other than human subjects protection regulations that are relevant to a research study for which review is being ceded under a reliance agreement. Reviewing IRBs generally have a “local context form” or survey to capture this information. For additional information on this topic, please see WSU IRB Policy 4-17 and <https://research.wayne.edu/irb/reliance-agreements>.

Local Context Sections & Language Required

- | | |
|--|---|
| <input type="checkbox"/> Study Costs (WIRB, Advarra, Other) | <input type="checkbox"/> WSU Compensation for Injury Policy/Research Related Injury |
| <input type="checkbox"/> Confidentiality | <input type="checkbox"/> Questions |
| <input type="checkbox"/> Signature Page | <input type="checkbox"/> HIPAA Authorization |
| <input type="checkbox"/> Consent version date and space for participant initials provided (footer) | |

INSTRUCTIONS

- **Note: The template language contains only the WSU and affiliate required wording for local context language sections. See Sponsor/Reviewing IRB template for wording and headings encompassing all required elements of consent.**
- This local context language may be copied from this document and inserted into the Sponsor/Reviewing IRB template or provided as an appendix to the consent, depending on the Reviewing IRB's policies.
- Please follow italicized instructions listed in brackets and highlighted areas.
- **Delete all instructional text.**
- Make sure that formatting is correct and delete all colored fonts and hanging headers.
- Only a size 12 font or larger may be used.
- **No letterhead or logos** are allowed.
- **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:

Study Costs

There are two separate instructions for costs for this institution. The first is for cancer research, the second is for all other research submissions. This language should be included in addition to the sponsor language. The study team will need to submit the site-specific appropriate text.

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.

STUDY COSTS FOR OTHER THAN KARMANOS CANCER INSTITUTE PROTOCOLS (e.g. Detroit Medical Center, University Physicians Group), choose only the applicable statement(s) from the following list.

Step 1: [CHOOSE EITHER NON-INTERVENTION OR INTERVENTION PATH]

[FOR NON-INTERVENTION STUDIES ONLY] (ex. blood draw only, saliva sample, questionnaire studies)

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

[FOR INTERVENTION STUDIES ONLY]

You will not be charged for [study drug or device] (*select one*)

THEN

[Step 2: *select only the applicable statement(s) below*]

- The study sponsor will pay for all costs and charges from your participation in this research study.

OR

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

AND/OR

- 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.***

Research Related Injuries

Please note the language in this section must match the Clinical Trial Agreement (CTA)/Contract. The following paragraph(s), when applicable, should be added after the sponsor's or IRB of Record's compensation for injury language.

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, University Pediatricians, University Physician Group, 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 on page one of this form.

Detroit Medical Center/Tenet's Compensation for Injury Policy:

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

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 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 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- 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.

Confidentiality

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*), 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, 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.

Questions (*Note – The following text should be provided in addition to the Reviewing IRB's contact information*)

If you have any questions about this study now or in the future, you may contact [*insert name of PI*] or one of his or her research team members at the phone number listed on the first page of this form. If you have questions or concerns about your rights as a research participant, the Chair of the Institutional Review Board can be contacted at (313) 577-1628. If you are unable to contact the research staff, or if you want to talk to someone other than the research staff, you may also call the Wayne State Research Subject Advocate at (313) 577-1628 to ask questions or voice concerns or complaints.

[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 Health Care Human Research Protections Program at (248) 484-4950, Fax (248) 276-9732, or e-mail hrpp@mcclaren.org or regular mail at 2701 Cambridge Court, Suite 110, Auburn Hills, MI 48326.

Footer (*Note – The following text should be in the footer of each page of the consent/HIPAA Authorization and footer date should be revised when making changes to the document.*)

Consent version date:

Participant Initials _____

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

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. Your signature indicates that you have read, or had read to you, this entire consent form, including the risks and benefits and have had all of your questions answered. You will be given a copy of this consent form.

Signature of Participant/Parent/Legally Authorized Representative (LAR) (*)

Date

Printed Name of Participant/Parent/Legally Authorized Representative (*)

(*) For participants unable to give consent the following individual is acting on behalf of the research participant (e.g., children, mentally impaired, etc.). *Remove LAR reference if you don't intend to consent participants that have or may have LAR.*

I observed the above (or his/her LAR, if applicable) sign this Informed consent form.

Signature of Person Obtaining Consent

Date

Printed Name of Person Obtaining Consent

Remove Translator and Witness wording when these sections are not applicable;

Signature of Translator (**)

Date

Printed Name of Translator (**)

(**) If a Translator is used, this person should be fluent both in English and the language that is understandable to the participant or legal representative. The translator gives an oral presentation to the participant or legal representative that is understandable to the participant that describes the entire content of the English version of Informed Consent.

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

Signature of Witness (***)

Date

Printed Name of Witness (***)

(***) The witness must be impartial (someone not connected with the research or the study team). Use when participant has had this consent form read to them (i.e., illiterate, legally blind, translated into foreign language.)

Delete if not applicable Continue to HIPAA Authorization on next page

[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, "HIPAA in Research" available on the IRB website. 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.]



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 protected health information 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 his or her 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 his or her 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 entities 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 (or initials), address (street address, city, state and zip code), elements of dates, telephone numbers, email address, 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), elements of dates, telephone numbers, email address, 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.

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-- entities that are acceptable include Detroit Medical Center,**

Karmanos Cancer Institute, McLaren Health Care, University Physician Group, etc.]:

- The PI, co-investigators, and key personnel of WSU [enter additional locations as needed] associated with the research project. - **Do not delete**
- WSU's Institutional Review Boards (IRB) and (List the External Reviewing IRB here). - **Do not delete**
- Authorized members of WSU's, KCI's, DMC's, and McLaren's [Delete if not using the KCI at McLaren Sites] 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].
- [Delete if not using the KCI at McLaren Sites] The McLaren Health Care (MHC) Institutional Review Board
- [Delete if not using the KCI at McLaren Sites] The McLaren Health Care Office of Research Compliance and Quality Improvement
- [Delete if not using the KCI at McLaren Sites] 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, NCI, OHRP, OCR, etc.) may review your records. - **Do not delete**

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. 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.

[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. This will be done to prevent the knowledge of the research results from affecting the reliability of the project. Your information will be available to the treating physician should an emergency arise that would require for him/her to know this information to best treat you. 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 withdraw (take back) your permission for the **use** and **disclosure** of your PHI for this research at any time, 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 Detroit Medical Center, Karmanos Cancer Institute, and/or the WSU School of Medicine Practice Plans and/or McLaren Health Care. *[Delete if not using McLaren Sites]*.

Authorization to Use and Disclose PHI

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

Signature of Participant/Parent/Legally Authorized Representative (*)

Date

Printed Name of Participant/Parent/Legally Authorized Representative (*)

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