**CIRB Submissions ONLY**

**Please maintain the formatting, signature page, and structure of this document**

**The HIPAA Authorization is submitted as a separate document please remove these instructions /highlighted text.**

***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.*** *Delete highlighted text*

**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)]
* (*List the sponsor’s name and name of its affiliated companies*-do not include any additional language)
* (*List the name of the drug company supporting the study*-do not include any additional language)
* 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/Legally Authorized Representative (\*) Date

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

(**\***) *For participants unable to give Authorization 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 authorization form.

Signature of Person Obtaining Authorization Date

Printed Name of Person Obtaining Authorization

 Signature of Translator (\*\*) Date

 Printed Name of Translator (\*\*)

As an impartial third party, I witnessed the authorization 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.)

If a Translator, 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.