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

**Health Information for Research Purposes**

Study Title (or IRB Approval Number if study title may breach subject’s privacy):

Principal Investigator (PI):

PI’s Address:

PI’s Phone Number:

# Sponsor/Funding Agency (if applicable):

**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.

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| Printed Name of Participant Signature Date Signed |

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