**HIPAA Authorization to Use and Disclose Health Information for Research Purposes**

**Title of research study:** *(insert title of study)*

**Principal Investigator:** *(insert name of Principal Investigator)*

**Sponsor:** *(insert the organization sponsoring this research; delete if no sponsor)*

**“You”** refers to the participant*(include only if adult study)*

**“You”** refers to you and your child*(include only if pediatric study)*

**“We”** refers to the research team at Grand Valley State University*(update if needed)*

This form describes the way that your health information can be shared with the researchers, research team, sponsor, and people with oversight responsibility for this study. The information we are asking to collect, use, and share is called Protected Health Information (PHI). PHI is protected by a federal law called the Health Insurance Portability and Accountability Act (HIPAA). In general, your health information cannot be used or shared for research without your permission.

**Why am I being asked to sign this form?**

You have been asked to participate in this research study. If you sign this form, you agree to the use and disclosure (release) of your health information for the research study, as described in this Authorization. Your health information will be used to *(describe the purpose of the requested use or release which typically is the objective of the research).*

**What health information will be used and disclosed?**

Your below health information from *(insert name of hospital, medical office, health care provider)* will be ***collected and disclosed*** for this research study. *(Modify the list below to specify all elements of health information that will be collected and disclosed for research purposes.)*

* Personal identifiers (your name, address, phone number, date of birth, social security number, medical record number)
* Demographics (age, gender, race)
* Dates of service, diagnosis and/or treatments
* Results of physical exams, blood tests, X-rays
* Diagnostic and medical procedures
* Medical history
* Certain health information indicating or relating to a particular condition as well diaries and questionnaires
* Records about study medication or study devices
* Billing information

**To whom will my health information be disclosed (shared)?**

*(Modify the list below to specify the names of the person(s), entities, organizations, or class of persons, to whom the* ***identifiable*** *health information will be given****.)***

The health information listed above that is collected for this study will be disclosed (shared)to the following people and organizations in order to conduct this research and audit the study:

* The principal investigator *(insert name of PI here)*and the research team
* The Sponsor of the research *(insert name of sponsor here)* or its agents (monitors, auditors)
* *List any other collaborating entity that will receive identifiable data or specimens.*
* The Grand Valley State University Institutional Review Board (IRB) and its representatives
* Public health agencies and other government agencies (including non-U.S.) as authorized or required by law
* Applicable government and regulatory offices that have oversight of this research such as the Office of Human Research Protections (OHRP), the Food and Drug Administration (FDA), and/or the National Institutes of Health (NIH)

The people who see your health information for this research study might not be required to follow HIPAA. It is also possible that anyone who receives your health information may re-release it. Because some of the individuals who receive your health information for this study may not be required by law to keep your information confidential, we cannot guarantee that your information will not be released or made available to another party. Therefore, your information will be shared only if necessary for the study or required by law, and all reasonable efforts will be used to request that those individuals who receive your information take steps to protect your privacy.

**How long will my health information be used?**

This authorization will remain valid with no expiration date unless you decide to revoke (take back) this authorization.

**Can I stop my health information from being collected and disclosed?**

Yes, you may change your mind and revoke (take back) this authorization at any time. Even if you revoke this authorization in writing, *the Investigator and/or Sponsor*may still use or disclose health information they already have obtained about you. This may be necessary to maintain the integrity or reliability of the research study, ensure the research was done properly, to protect your safety, or if needed to comply with applicable laws.

To revoke this authorization, you must write or email *(list the investigator’s name and address and email).*

**What happens if I do not want you to collect and/or release my health information?**

If you decide not to authorize the collection and release of your health information as part of this study, your decision will in no way affect your medical care or cause you to lose any benefits to which you are entitled. You cannot participate in this research if you do not authorize the use and release of your health information.

**Signature(s):**

Your signature below documents your permission to allow the use and disclosure of your protected health information for this research. You will receive a signed copy of this completed form.

Signature of Participant/Legally Authorized Representative Date

Printed Name of Participant/Legally Authorized Representative

Description of Legally Authorized Representative’s Authority

to Act on Behalf of the Participant