NEW – April 21, 2021

Patient name:

DOB:

MRN:

Physician:

TEMPLATE: HIPAA Authorization for Release of Health Information for Research Purposes

***Instructions:***

*“Italicized red writing” provides instructions and guidance on how to complete this template; it should be removed from the final documents*.

*This template is provided for use when it is required to have a separate HIPAA Authorization that is not combined with an Consent form. The SH IRB will advise if a separate form is required.*

“Black writing**”** *is required language to be included in final documents.*

*The following HIPAA Authorization is to be used verbatim, making the needed additions as instructed in the applicable sections below. Avoid adding in duplicative information that may be included in a sponsor-provided template.*

# **HIPAA Authorization for the Use and Disclosure of Health Information for Research Purposes**

## (Leave title as is. Required by medical records for recognition scanning.)

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

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

**Sponsor:** *(insert the organization sponsoring this research)*

**Funding Source:** *(insert the name of the funding source, if this is different from the Sponsor; for studies supported with internal funds, list Spectrum Health as the funding source. This may be deleted if the funding source and sponsor are the same entity.)*

**“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*(include organizations affiliated with the research, for example, Spectrum Health and Michigan State University)*

This form describes the way that Spectrum Health can share your health information 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, we cannot use or share your health information 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 Consent and 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?**

Your health information may be ***accessed (used)*** for this research study by Spectrum Health, the Principal Investigator, and their representatives. ***Include if applicable:*** The study team may also include students who are approved to perform research activities at Spectrum Health.

To collect study data, we will need access (see) to your identifiable health information in your medical records. *(Include any other applicable HIPAA protected source documents(s) which will be accessed to collect the study data, e.g., medical insurance records, billing records, etc.)*

**What information about me will be collected and disclosed as part of the research?**

The following health information about you 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****. Add to the list below any additional elements, as applicable. Delete from the list any elements that do not apply.).*

* 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 drugs
* Records about study devices
* Billing information

*If the information that is listed above will be de-identified /will not include any direct identifiers before it is disclosed, include the following:* We will remove all identifying information about you before the protected health information listed above is disclosed (shared).

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

*List below the names of the person(s), entities, organizations, or class of persons, to whom Spectrum Health will disclose* ***identifiable*** *study data****.***

The health information listed above that we collect for this study will be ***disclosed (shared)*** to the following people and organizations in order to conduct this research and/or audit/validate the study:

* The Sponsor(s) of the research ***(must insert name of sponsor here)*** or its agents (monitors, auditors)
* *List any other collaborating entity not under contract with the sponsor that will receive identifiable data or specimens.*
* The Spectrum Health Institutional Review Board (IRB)
* 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 Institute of Health (NIH)
* Spectrum Health offices that have the responsibility to oversee the conduct of research
* Agencies that accredit the hospital or the research program

In addition to disclosing the study data, as listed above, there may also be instances when certain information may be accessed by both Spectrum Health and non-Spectrum Health personnel for study-related purposes. For example, the sponsor of the study or an outside company or government agency may need to review the study information (including your medical record and other study data) for purposes of monitoring, auditing or validating the study. In those instances, these outside parties may see your identifiable health information (e.g., information in your medical record). However, we will take steps to make sure that these outside parties do not copy or record any information that identifies you.

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 these 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 once it leaves Spectrum Health. Therefore, we will share your information only if necessary for the study or required by law, and we use all reasonable efforts 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 and until 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, *Spectrum Health, 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).***

You may also write to the Spectrum Health Privacy Department at privacy@spectrumhealth.org to revoke this authorization.

**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 take allow the use and disclosure of your protected health information. You will receive a signed copy of this completed form. |
|  |  |  |
| Signature of participant/ Legally Authorized Representative (LAR) |  | Date |
|  |  |
| Printed name of participant / Legally Authorized Representative (LAR) |
|  |  |  |
| Signature of person obtaining authorization |  | Date |
|  |  |  |
| Printed name of person obtaining authorization |  |  |