**Revised – March 01, 2021**

TEMPLATE: Information Sheet (Waiver of Obtaining a Signed Consent Form)

***Instructions:***

*“Italicized red writing” provides instructions and guidance on how to complete this template; it should be removed from the final documents*. *All studies should start with this template. If a sponsor or another entity has provided a template for multiple sites, the content is to be merged into this form and carefully revised/written for ease in reading, reading level, and comprehension. Do not duplicate content and all header sections are to be included in the final consent form(s).*

*This form is to be used for minimal risk studies in which a signature on a form will be waived. It may also be used for exempt research in which participants will be recruited and asked to participate.*

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

**Title of Research Study:** ***(****insert title of study)*

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

**Sponsor:** *(insert the organization sponsoring the research, if applicable)*

**“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 a research study for which you might qualify. Research studies help us learn more about conditions and develop new treatments. Taking part in a research study is voluntary.

You are being asked to take part in this study because *state why persons/groups are being included.* This study will help us learn more about *briefly describe the purpose of the research*.

If you decide to take part in the study, we will *describe the study procedures – e.g. surveys, focus groups, etc. Include the duration of the participation and how many subjects will be enrolled. If you are collecting information directly from the medical record include:* We will also look at your medical record and collect information on *describe what will be collected for the study*.

There are no direct benefits to participating in this study. However, we hope to learn more about *describe what you hope to learn here or describe how this study has the potential to help future patients.*

The risk of participating in this study is *describe risk, i.e. the possibility of loss of confidentiality of your health information*. However, to minimize the risk *describe all measures to protect confidentiality of records i.e. we will not store your identifying information with the information we record for the study. We will keep all our study records in secure area limited to the research team, etc.*

You will not be paid for taking part in this study. *[Alternately, “*You will be paid $XX for taking part in this study”*.*] There will be no cost to you to take part in this study *[or, if there are costs to the subject, provide a description of these costs]*.

Participation is voluntary. You will receive the same care whether or not you decide to participate in the study. You may decide not to take part in the research, or change your mind at any time, and it will not be held against you. A refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. We will tell you if we learn new information that may make you change your mind about being in this study.

If you have questions about this study, you may contact the Principal Investigator at *insert contact information.*

You may also talk to the Spectrum Health Institutional Review Board at (616) 486-2031 or irbassist@spectrumhealth.org if 1) your questions, concerns, or complaints are not being answered by the investigator or research team, 2) you have questions about your rights as a research participant, or 3) you want to get information or provide input about this research.

***Must include the following section verbatim if PHI will accessed, used and/or shared for this research:***

HIPAA Authorization for Release of Health Information for Research Purposes

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.

You have been asked to participate in this research study. By agreeing to participate, you agree to the use and disclosure (release) of your health information for the research study, as described in this Information Sheet 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.

**Consent Statement**

I agree to take part in this study as explained in this consent form and give permission to use and share my personal information.