**Revised – June 1, 2022**

Patient name:

DOB:

MRN:

Physician:

TEMPLATE: Informed Consent Document - Greater than Minimal Risk; Biomedical Studies

***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).*

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

# **Permission to Take Part in a Research Study and HIPAA Authorization for Release 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)*

*(Key Information – The intent of this section is to provide a concise and focused summary of the key information that is most likely to assist in understanding the research and the reasons why one might or might not want to participate in the research. This section is required for all more than minimal risk clinical trials/studies and this section must not exceed two pages)*

**Key Information:**

The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

***What are the purpose and main procedures for this study?***

*Describe the purpose and explain the main goals of the research study.*

We invite you to take part in a research study because *(fill in the circumstance or condition that makes participants eligible for the research.)*

You will be asked to *(include a high-level summary of the research-only procedures that will be done. For example: You will be given an investigational drug and asked to come for 3 study visits. You will give a total of 3 blood samples and fill out questionnaires asking about how you feel.)*

More detailed information about the study procedures can be found under “*What happens if I say yes, I want to be in the research?”* on page *(insert page number)*

***What are the possible benefits from this study? Will being in this study help me in any way?***

***State the potential benefit(s) of being a part of this study (****i.e., associated with the investigational agent and/or research intervention).*

***If no direct benefit to the participant is expected, include the following:*** There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from taking part in this research. However, possible benefits to others include *(describe any benefits to others. If benefits from participation may not continue after the research has ended, describe them here. Monetary reimbursement for participation is not a benefit and should be described in a later section)*.

***What are reasons I might choose not to volunteer for this study?***

*State the most important/main reason(s)/risks why a participant may NOT want to volunteer for this study considering the participant’s perspective.*

If you take part in this study, you will be exposed to some risks. A risk is a possibility of something going wrong. The main risks of this study are *(describe the main, specific risks that are key to understanding this study and indicate what the study team will do to minimize these main risks. Note the full list of risks are to be included later in this form. This section is to present the key information.)*

For a complete description of risks, refer to “*What are the possible risks and discomforts I may have if I take part in this study?”* on page *(insert page number)*

***Do I have to take part in this study?***

No. Participation in research is completely voluntary. You can decide to participate or not to participate. If you decide not to participate, you can/will still receive your regular care.

**Details of Taking Part in this Study**

*In the sections below, describe additional details on what is involved in participating in this study. Avoid repeating information that has been provided in the above Key Summary section.*

***What are some general things to know about research studies?***

* Someone will explain this research study to you.
* You volunteer to be in a research study.
* Whether or not you take part is up to you.
* You can choose not to take part in the research study.
* You can agree to take part now and later change your mind.
* Whatever you decide it will not be held against you.
* Feel free to ask all the questions you want before you decide.

***Whom do I call if I have questions or problems?***

If you have questions about this study, contact the study doctor *(insert name, telephone)* or *(insert name, telephone number of staff)* during a workday or *(telephone)* at night.

This research has been reviewed and approved by the Spectrum Health Institutional Review Board (IRB). You may talk to them at (616) 486-2031 or irbassist@spectrumhealth.org for any of the following:

* Your questions, concerns, or complaints are not being answered by the study doctor or research team.
* You cannot reach the study doctor or research team.
* You want to talk to someone besides the study doctor or research team.
* You have questions about your rights as a research participant.
* You think that you may have been harmed by the research.

You may also contact our anonymous hotline at: (855) 613-2262 or (616) 391-2624

***Why are we doing this research?***

*Tell the participant additional details of the purpose of the research that was not included in the Key Summary section. For example, explain the background of the research problem and/or describe current therapies for their disease and explain why these are not satisfactory. For non-therapeutic studies, explain the scientific problem. Describe how this research will attempt to solve the problem.*

***How long will I be in the study?***

We expect that you will be in this research study for *(Months/weeks/years/until a certain event. Duration of follow-up/data collection should be included as well)*.

***How many people will be studied?***

We expect about *(insert enrollment number)* people here will be in this research study out of *(insert national/international enrollment number)* people in the entire study nationally *(or internationally). (If single site study, adjust accordingly) (If registry, indicate approximate prospective/retrospective enrollment)*

***What happens if I say yes, I want to be in this study?***

*Tell the participant what to expect using lay language and simple terms. Whenever appropriate include the following items:*

* *A time-line description of the procedures that will be performed. If practical, prepare a time-line chart or schematic to accompany descriptions of procedures and tests for studies that require more than 1 or 2 steps/visits.*
* *The drugs or biologics that will be given to the participant.*
* *If a placebo is used consider describing as “substance, such as a sugar pill, that does not contain active ingredients such as medicine”*
* *All devices that will be used.*
* *All hospitalizations, outpatient visits, and telephone or written follow-up*
* *The length and duration of visits and procedures*
* *If blood or other samples will be taken, indicate the amount and frequency*
* *With whom the participant will interact*
* *Where the research will be done*
* *When the research will be done*
* *List experimental procedures and therapies and identify them as such*
* *How often procedures will be performed*
* *What is being performed as part of the research study*
* *What is being performed as part of standard of care*
* *What procedures are part of regular medical care that will be done even if the participant does not take part in the research*
* *If their primary physician will be informed of participation in the research study*

*For studies that include randomization to a specific treatment, describe how participants are assigned to each treatment group/arm:*

The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have an *(equal/one in three/etc.)* chance of being given each treatment. *For double-blinded studies, add the following:* Neither you nor the study doctor will know which treatment you are getting. *For single-blinded studies add the following:*You will not be told which treatment you are getting, however your study doctor will know.

*Describe any responsibilities of the participant during the study.*

If you wish to take part in this study, we expect that you will *(add or remove items from the list below as necessary)*:

* Keep your study appointments. If you cannot keep an appointment, contact your study doctor or research study team to reschedule as soon as you know that you will miss the appointment.
* Tell your study doctor or research study team about any medications you are taking so they can check how the drug being studied and your medications may interact. If you have to start on any new medications while you are in the study, please check with your study doctor before you do so.
* Tell your study doctor or research study staff about any side effects, doctor visits, or hospitalization that you may have whether or not you think they are related to the research study.

*If this study will include genetic research as a study outcome, describe the genetic testing here. If genetic testing is only “future research” do not add that information here; add it to the new section “****What will be done with my study information and samples collected as a part of this research?****”*

***Example language to explain “genes”:***

Like all tissues and cells in your body, these tissues/cells have genes. Genes make up the “instruction book” for how to build a cell. These genes are spelled out in the DNA in your cells. Your genes determine your physical characteristics, such as your height and hair and eye color. Your genes can also help determine whether you have a chance of developing a certain illness or medical condition.

***Example language to explain “genetic research”:***

Many diseases can come from changes in a person’s genes that cause cells to not work properly. researchers and doctors know some of these gene changes that can cause disease, but they do not know all the gene changes that can cause disease. Efforts to figure out which genes are involved in diseases is called “genetic research”.

We would like to study your genes as part of this research. We will compare the DNA from people with certain diseases to the DNA from people without those diseases to find the differences that exist. By combining this information with information from your medical records, it may be possible to identify the gene changes that are associated with different diseases. We will perform this same process with other people who have agreed to participate in this research project. This research could lead to more knowledge about why certain people respond differently to treatment. This knowledge could lead to future treatments customized to a patient’s unique genetic make-up.

***What happens if I say no, I do not want to be in this study?***

You may decide not to take part in the research, 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.

*If there are no alternatives other than not participating, add the following:* Your alternative to participating in this research study is to not participate.

Instead of being in this research study, your choices may include: *(List alterative procedures to taking part in this study. Be sure to describe other treatment options that you would normally offer a patient, including supportive care if applicable. If there are alternative treatments that may be more advantageous to the participant, it is required to include this information.)*

*Describe the important risks and potential benefits of the alternative procedures and courses of treatment.* Talk to your study doctor about the important risks and benefits of these alternatives. ***OR*** The important risks and benefits of these alternatives are listed below:

***What happens if I say yes, but I want to stop before my part of the study is complete?***

You can agree to take part in the research now and stop at any time. It will not be held against you. Stopping your participation will not result in penalty or loss of benefits to which you are otherwise entitled.

*(Describe the circumstances under which participation may be ended by the investigator and/or the participant. Outline the procedures for safe withdrawal from the study. If additional monitoring for stopping the study (e.g. end of study visits, continued follow-up etc.) are necessary, the consent must include the following information: justification, schedule, procedures and tests necessary for the additional monitoring.)*

[If there are adverse consequences to withdrawing from the research, add] If you decide to leave the research, you may experience [Describe primary adverse consequences such as worsening symptoms/disease, or need for substitute treatment plan]

***For FDA regulated clinical trials - include the following verbatim:*** If you choose to withdraw from the study early, the data collected for you up until the point you withdraw will remain in the study database per U.S. Food & Drug Administration (FDA) policy. This is so the FDA can have accurate information regarding any possible safety concerns about the drug or device being studied.

***For FDA regulated clinical trials requesting to collect further clinical outcome data if the participant discontinues participation in the study, include the following verbatim:*** At the time of withdrawal, the study doctor will ask you to consider allowing the study doctor to continue to collect follow-up data from your medical record regarding your routine medical care for your condition. If you agree, this data will be handled the same as research data and entered into a study database to evaluate outcomes.

If you decide to leave the research, contact the study doctor so that they can tell you how to stop safely.

***What are the possible risks and discomforts I may have if I take part in this study?***

*Group the risks into those that are expected, occasional, or rare and describe them as such.*

*List all side effects, no matter how rare, that are life altering or potentially life altering (i.e. - vision loss, anaphylaxis, paralysis, and aplastic anemia. Explain the ramifications of the significant risks (i.e. What will happen to the participant if liver enzyme testing indicates an abnormality?)*

*Describe each of the following risks/discomforts, if appropriate*

* *Physical risks (for example, medical side effects)*
* *Psychological risks/discomforts (for example, embarrassment, fear or guilt)*
* *Legal risks (for example, legal prosecution or being reported for child abuse)*
* *Social risks (for example, social ostracization or discrimination*

*If there are risks to participation in the research, describe them for each relevant procedure (for example, blood drawing, computerized tomography, survey procedure, etc.) and for each investigational article (for example, drug, device, or biologic)*

*Drugs - list any/all potential drug allergies that may be caused by the investigational and other drugs used in the research.*

*Devices - if the research involves use of an investigational device with a potential for malfunction, list “device malfunction” as one of the device risks.*

***For clinical trials that involve risks to an embryo, fetus, or nursing infant, include:*** You should not become pregnant, nurse a baby, or father a baby while on the research study. This drug may harm a pregnancy/unborn child or nursing infant in the following ways: *insert known and unknown risks to an embryo, fetus, or nursing infant.*

***For research that requires a blood draw, include:*** You may experience discomfort, pain, swelling and/or bruising where the blood is taken from your vein. Sometimes bleeding can occur at the place where blood is drawn. Fainting and infection can also occur, but they are rare.

***For research that exposes a study team member to blood draw or other bodily fluids the following must to be included for Michigan law:*** Under Michigan law, an HIV and hepatitis test may be done on you without your consent if a healthcare worker is exposed to your blood or other bodily fluids. If the results of a HIV or hepatitis test indicate that you are HIV or hepatitis positive, you will be told about these results and given information about the disease, treatment, resources, and other options.

***For research involving pregnant women or a person of child-bearing potential and an investigational product or procedures whose risk profile in pregnancy is not well known, include:*** If you think you are pregnant or if you become pregnant during the study, you must tell the study doctor right away. It is important to tell your doctor because there may be risks to you or your baby if you continue in the study. Some of these risks may be known, but some risks may not be known and may not be foreseeable. Because the risks to embryo/fetus/unborn babies and babies who are breast feeding may not be known or foreseeable, pregnant women and nursing mothers are not allowed to join this study. If you are a person who can get pregnant, you should not become pregnant during this study.

***If applicable, include:*** Participants who can get pregnant must have a negative pregnancy test before being allowed to join in this study. *Specify type if pregnancy test needs to be blood or urine as defined by the protocol. Specify any requirements for birth control to participate in the research. If risks will be accrued to a participant’s partner, explain what will happen in the case of pregnancy (i.e., will the partner’s pregnancy be followed, etc.). Refer to the IRB Guidance: Pregnancy During Participation in Research.*

***For research the involves genetic testing, profiling, or sequencing, include:*** A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information. However, you should be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

***For research that involves an investigational product or procedures where the risk profile is not well known, include:*** In addition to these risks, this research may hurt you in ways that are unknown.

***For research involving the collection of sensitive PHI (e.g. sexual practices, sexually transmitted diseases, alcohol addiction, illegal drug use, controlled substance addiction, illegal conduct, mental health diagnoses and corresponding medications, HIV status), include:*** In this study, we will collect sensitive information about *(specify).* This information is necessary to conduct the research. We will keep this information as confidential as possible, but we cannot guarantee complete confidentiality.

***Required Statement for Breach of Privacy and Confidentiality, include verbatim:*** As with all health care related information, there is a risk of breach of privacy and confidentiality when taking part in this research. Every precaution will be taken to secure your personal information to ensure privacy and confidentiality.

***For NIH funded research and any other research with a Certification of Confidentiality, include:***

To help keep information about you confidential, we have obtained a certificate of confidentiality (CC) from the Department of Health and Human Services (HHS). This CC adds special protection for the research information about you. This CC does not imply that the Secretary, HHS, approves or disapproves of the project. The CC will protect the study doctor from being forced, even under a court order or subpoena, to release information that could identify you. We may release identifying information in some circumstances, however. For example, we may disclose medical information in cases of medical necessity or take steps (including notifying authorities) to protect you or someone else from serious harm, including child abuse or neglect. Also, because this research is sponsored by HHS, staff from HHS may review records that identify you during an audit.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The CC does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

It also does not prevent Spectrum Health from using and disclosing your health information for permitted purposes, such as treatment and payment activities.

***Will I be told about new information that may affect my decision to participate?***

*Insert the following:*

During this study, you will be informed of any new findings that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study may be re-obtained.

*If incidental findings will be returned that may affect a participant’s willingness to continue in the study, or may affect their care, include this information here. Indicate the plan for continued care, referral or counseling as necessary.*

***How will my study information and samples be kept confidential?***

*Describe how the study data will be kept confidential, include:*

Efforts will be made to keep your personal information private and secure. This includes limiting access to your research study *(insert if applicable)* and medical records to people who have a need to review this information.

*Include if information from medical records will be included in the study records:* In addition to the study doctor, nurses and study team, others may need to have access to your study information and may be granted direct access to your medical records. Representatives from government agencies, including the U.S. Food and Drug Administration (“FDA”), institutional review boards, the sponsor and/or the sponsor’s authorized representatives may need access to your original medical records and study records for the purpose of checking data collected for the study. By signing this consent form, you authorize this access.

*Insert if data and samples will be coded:* You will be assigned a study identification number at the start of this study. This number will be used on *include items as applicable* data collection forms, blood samples, tissue specimens and in the database instead of your names and other private information. A separate list will be kept by the study doctor that will link your name to the study identification number for future reference and communication*.* This link will not be shared with other entities involved in this study.

*Describe any limitations on confidentiality based on possible legal issues. For example, if the research team is likely to uncover abuse, neglect, or reportable diseases, explain that this information may be disclosed to appropriate authorities.*

***Include if there is a risk of death related to the investigational drug/device:***In the unfortunate event of your death, it may be necessary for your study doctor to collect medical records leading up to and/or related to your death. Such information may include information about the study *device/drug/intervention*, or information that may be saved in a study device.  In addition, a copy of the death certificate and a copy of the autopsy report (if an autopsy is performed) will be requested.  *(Include for drug studies)* The obtained information would be reported to study sponsors and other reviewers if necessary.  The study staff may ask for return of the remaining study drug so it may be sent back to the study sponsor and/or manufacturer.  *(Include for devices studies)* If there is a research device that is explanted (removed), the study staff may ask for the device to be sent back to the study sponsor and/or manufacturer. Please discuss with your family and caregivers the potential for obtaining your medical records, the remaining, unused study *drug and any medical device* that was used during the course of this research in the event of your death during this study.

***What will be done with my study information and samples collected as a part of this study?***

*Explain where the data or specimens will be stored, who will have access to the data or specimens, and how long it will be retained* ***during the study.***

*If data or specimens* ***will be shared, describe the planned sharing of study information and/or specimens****. Include the* ***purpose*** *of this sharing.*

*Select* ***one of the three*** *paragraphs below. Delete the paragraphs that do not apply.*

*(Not sharing for future research)* Your study data and samples collected for this research study will not be used for future research studies nor shared with other researchers for future research.

*Or*

*(Sharing only de-identified data/samples*) Your study information and samples collected for this research may be used for future research studies and/or shared with other researchers for future research. We will remove all identifying information about you before the study information and samples are shared. Once this identifiable information is removed, the study information and samples cannot be withdrawn from further use. You will not be asked for additional consent for this future research.

*Or*

*(When sharing a Limited Data Set)* Your study information and samples collected for this research may be used for future research studies and/or shared with other researchers for future research. We will share a limited set of identifiable information along with your study information and samples. This identifiable information is limited to *(insert all that apply)* dates linked to treatment, admission, and/or service, date of birth, zip code, or your age in years.

 *If re-identification for future research is possible (i.e., more than a theoretical risk), insert a statement to that effect and describe any risks.*

*For gene therapy studies that include NIH/IBC for long term follow-up:*

The US federal government has established guidelines for gene therapy studies. One such guideline is that if you receive a gene therapy study drug, such as *(insert name of study drug),* you will be expected to cooperate in long-term follow-up after you have received study drug. The Sponsor is currently asking *(include details of what the follow-up might include i.e. visits to clinic and for how long)*.

You will be asked to provide a list of people to contact in case the study team cannot reach you. You will be asked to provide your new address and telephone number to the study doctor or study staff if you move.

The Sponsor would like to obtain information about the long-term safety and effects of the gene transfer. In order to meet the National Institute of Health (NIH) guidelines for gene therapy studies, if you were to pass away during the duration of the study for any reason, study doctor would request an autopsy from your family or next-of-kin. Signing this consent does not mean that you are giving permission for an autopsy. You are encouraged to discuss this with your family in advance.

***Genetic Research:***

*If specimens are retained for future genetic research, attempt to describe what genetic research will be conducted; indicate if the future testing is broad, targeted, or unknown. Indicate whether the research will or might include whole genome sequencing (i.e. sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).*

*If genetic “terms” such as DNA, RNA, Gene, Genetic Testing, Whole Genome Sequencing, etc., have not yet been defined; include that definition here.*

*Explain how and where the specimens and genetic information will be stored, and who owns the specimens and related genetic information.*

***Sharing Study Information in Scientific Databases:***

In addition to the information sharing described above, we may also share information about you and/or your samples by putting the information into scientific databases. These databases store information from many studies conducted in many different places, including Spectrum Health. Researchers study the combined information in these databases to learn even more about health and many different diseases.

There are many scientific databases and they are maintained by institutions, the federal government, and/or private companies. There are also different kinds of databases—controlled access and open access. Controlled access databases are only available to researchers who apply and are approved to access the information in them. Open access databases and the information in them are available to anyone on the Internet.

No matter which kind of database your information is put into, your name and other information that could easily identify you (such as your address or social security number) will not be placed into any scientific database.

As a part of this research, your information about you and/or your samples will be shared in a *<insert one or both>* controlled and open access database. *Insert the name(s) of the databases if know (e.g. dbGAP, etc.)*

*If this research is collecting or analyzing genetic information (such as genomic sequencing), also include the following statement that is applicable, based on the type of database. Note: some NIH databases include both types of access and if open-access is an option, the NIH requires that consent is explicitly obtained from the participant prior to adding their data to allow open-access:*

If you take part in this research, we may place some of your genetic and health information into controlled access databases. Your genetic information is unique to you so there is a possibility that someone using controlled access could trace the information back to you. Researchers who are approved to access the information in controlled access databases have a professional duty to protect your privacy and to keep your information confidential.

-and/or-

If you agree, we may also place some of your genetic and health information into open access databases.

Your genetic information is unique to you so there is a possibility that someone using open access databases could trace the information back to you. The risk of being identified may be greater with an open access database because anybody can access the information.

*Insert if data will be shared in an open-access database:*

The decision to allow your genetic and health information to be put into open access databases is completely yours. There will be no penalty to you if you decide not to allow release of your information to open access databases, and your decision will not affect your participation in this research.

|  |  |
| --- | --- |
|  | YES – I consent to release of my genetic and health information to open access databases. |
| Initials |

|  |  |
| --- | --- |
|  | NO – I do not consent to release of my genetic and health information to open access databases*.*  |
| Initials |

***Will my samples be used for commercial purposes?*** *This section may be deleted only if it is known that the samples collected as a part of this study* ***will not be used now, or in the future****, for commercial purposes.*

*There may be situations where a patient or a research participant is known to possess biologic materials with unique characteristics thought to have potential commercial value. In this case, if specimens are to be collected for research and the investigator expects that the specimens may be commercialized into a marketable product or sent to a commercial sponsor for research or development, the consent form must state the possibility. The following is language to be included in this section if there is a possibility of commercial profit.*

Your samples may be used for development of a marketable product or for research and development. The samples may be used for commercial profit (even if the identifiers are removed). You will notreceive any financial proprietary interest in the samples or in any products or processes that may results from research on the samples.

***Can I be removed from the research without my permission?***

The study doctor or the sponsor can remove you from the research study without your approval. Possible reasons for removal include *(add additional reasons why the participant may be withdrawn, if appropriate. For example, failure to follow instructions of the research staff, if the person in charge decides that the research study is no longer your best interest)* The sponsor can also end the research study early.

***What if I am injured or made sick from the study?***

*The below options are provided for general reference. The injury compensation language must coincide with the terms and conditions of the contract between Spectrum Health and the sponsor. Contact the individual handling contract negotiations at Spectrum Health on the investigator’s behalf for guidance and review of this section. They will be able to determine if the sponsor is paying (has funds set aside) for medical care costs incurred as a result of the research-related injury/adverse reaction.*

***Option 1 – Funds set aside***

If you are injured or become sick as a result of taking part in this research study and need medical care, please tell your study doctor right away. Medical care will be made available to you just as it is to the general community.

The sponsor will pay for medical expenses for illnesses or injuries caused that are a direct result of your participation in the study. The sponsor will only pay for medical expenses for research-related illnesses or injuries and will not pay for expenses related to a pre-existing disease or underlying condition, nor will the sponsor pay for any lost wages, disability, discomfort, or inconvenience you may have from a research-related injury or illness.

***Option 2 – No funds set aside***

If you are injured or become sick as a result of taking part in this research study and need medical care, please tell your study doctor right away. Medical care will be made available to you just as it is to the general community.

The Sponsor, nor Spectrum Health, will pay for research-related injuries or illnesses, for medical expenses for research-related injuries or illnesses, or for any lost wages, disability, discomfort, or inconvenience you may have from a research-related injury or illness. Medical care for any research-related injury or illness you experience will be billed to you and/or your insurance. Your insurance may not pay for all of the costs of treating a research-related injury or illness. If your insurance does not cover the entire cost, you may be responsible for the rest of the cost for this treatment. If you have no insurance, you may be responsible for all costs of the medical care you receive for a research-related injury or illness.

***For both option 1 and 2 include the following:***

Contact the study doctor for more information. By signing this consent form you will not be waiving any of your legal rights which you otherwise would have if you were not participating in a research study.

***Will I need to pay for any of the tests or procedures in the study?***

*If the research will result in additional costs to the participant, include the following:* Taking part in this research study will lead to added costs to you. *List the study-related procedures, tests, etc. that will be charged to the participant.*

***The following language is required if the procedure will be billed to insurance:*** You or your health insurance will be billed for these study-related procedures/tests. If your insurance company requires any co-payment or deductible, you will be responsible for making that payment.

***The following language is required for all adult DRUG (not device) clinical trial studies:*** If your insurance is through Medicare Advantage, any routine care that is part of this study and not being paid for by the sponsor will be directed to traditional Medicare for payment. The traditional Medicare deductibles will be waived, but you will be responsible for any co-payments. Please talk to the study doctor if you have any questions about this.

*If there are* ***no*** *additional costs to the participant, include the following:* Taking part in this research study will not result in any added costs to you. You may still be responsible for the costs of your regular care while you are in this study. Talk to your study doctor about any costs related to your care.

***Will I receive any study results or information about this research after my participation?***

*Indicate if research results will be returned to participants, this includes general or aggregate research findings and individual results (this does not relate to accessing tests/procedures that are used for clinical care). In addition, participants should be informed of the possibility that they might not receive research results.*

*If research results will not be returned:*

In general, we will not give you any individual results from the study. *(Insert if the study may have clinically relevant findings)*If we find something of medical importance to you, we will inform you, *(or explain another method of communicating the information)* although we expect that this will be a very rare occurrence.

*If research results will be returned, describe the mechanism of return, to whom the results will be returned to, when this will occur and the service that will be provided to help with interpretation of the results, if applicable. For the return of general, aggregate results only, include:* Once the study has been completed, we may send you a summary of all of the results of the study and what they mean.

***Will I receive payment for taking part in this research?***

*If participants will be paid, include*: If you agree to take part in this research study, you will receive *(indicate amount and method of payment)* for your time and effort. *(Indicate if the amount is pro-rated for research visit completion.)* To receive payment, you must agree to complete a W-9 form which requires you to provide an address and social security number to the Spectrum Health Finance Department. This payment to you may be considered taxable income by the IRS. Should the payment exceed $600 for all studies in which you are participating in a single year, you will be issued an IRS 1099-Misc Form.

***If Greenphire will be used for payments, include the following and be sure to complete a separate HIPAA Authorization for Reimbursement:*** Payments will be made using ClinCard, a secure, reloadable debit card supported by Greenphire. Greenphire is a company working with Spectrum Health to manage the reimbursement process. We will give you a ClinCard on the day you sign the consent form. ClinCard is a MasterCard debit card that your funds are loaded onto, to be used however you wish. When a visit is completed, funds will be approved and loaded onto your card. Funds will typically be available within two business days of study visit completion. You will be given one card for the duration of our participation in the study. All information is stored in a secure fashion and is deleted from Greenphire’s system once the research has been completed. Your information will not be shared with any third parties and will be completely confidential.

***What else do I need to know?***

Additionally, while you are part of this study you will not have access to research records, including through electronic patient portals (such as MyChart), to view lab results, progress notes, or other information related to the treatment you are receiving as part of this research study. When the study concludes, research record access will be available. You still have a right to request a copy of your medical record and tests related to regular medical care that is given during the same time as the study.

If you agree to take part in this study, you are not giving up any of your legal rights. You can stop participating in this study at any time. Your decision will not affect your regular care.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

***The following is a required statement if your study is FDA regulated:*** A description of this clinical trial will be available on <http://www.ClinicalTrials.gov> , as required by U.S. Law. This web site will not include information that can identify you. At most, the website will include a summary of the results. You can search this web site at any time using NCT # *(insert NCT# here).*

*If the Spectrum Health Compliance Department recommends that you disclose a conflict of interest to participants, please include the language recommended by the Compliance Department here so the IRB can review and make a final determination.*

*The following HIPAA Authorization is to be included* ***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 Use and Disclosure 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.

***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 study doctor, 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 as part of the research?***

The following health information about you will be ***collected*** for this research study: ***(****Modify the list below to specify all elements of health information that will be collected for this study. Add to the list any additional elements, as applicable. Delete from the list any elements that do not apply.).*

* Personal identifiers (*specify which personal identifier:* 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

***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 study doctor 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 study doctor’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.

**Optional Research:**

*Include this section for any optional research procedures that are included in the research. If there is no optional research, this section may be deleted. If there are multiple optional testing included, this section and the tables below with the initials may be copy/pasted.* ***NOTE: If PHI will be disclosed*** *as a result of these optional procedures, it must be included in the HIPAA Authorization above.*

*Insert the following:*

You can still take part in the study if you do not agree to the optional research below.

**What are the purpose and procedures of this optional research?**

*Describe the purpose and procedures specific to the optional research, including when and how the procedures will take place.*

**What information or samples will be kept for this optional research?**

*Describe what data/samples will be stored and whether they will be identifiable/coded or de-identified*.

**Who will have access to my information or samples for this optional research and how will it be kept private?**

*Describe who will have access to the identifiers or de-identified data, if applicable.*

*Include if and how data/samples will be shared (e.g. through a central repository, etc.) with other researchers for future research, if applicable, including if the future research will be done without obtaining further consent.*

**What happens if I want to stop, or take back (withdraw) my permission for this optional research?**

*Describe the process for a participant to withdraw consent to use data/specimens in this research. If data/samples cannot be withdrawn after being shared, indicate this here.*

Please initial next to your choice below regarding the optional testing:

|  |  |
| --- | --- |
|  | YES – I agree to …. *Complete this sentence stating the optional testing that the participant is consenting to.*  |
| Initials |

|  |  |
| --- | --- |
|  | NO – I do not agree to …. *Complete this sentence stating the optional testing that the participant is consenting to.*  |
| Initials |

***\*\*\*\*INFORMATION REGARDING SIGNATURE PAGE\*\*\*\****

***There are five signature block examples attached to this template consent. Adapt the signature page for your study based on the study population. Delete the signature blocks that are not applicable.***

***For example: Omit the signature block regarding children (i.e. do not include parent/guardian signature line(s)) if you do not plan to enroll children in the study.***

**Signature Block for Capable Adult: Long Form**

|  |
| --- |
| Your signature below documents your permission to take part in this research and to the use and disclosure of your protected health information. You will receive a signed copy of this completed form. |
|  |  |  |
| Signature of participant |  | Date |
|  |  |
| Printed name of participant |
|  |  |  |
| Signature of person obtaining consent |  | Date |
|  |  |  |
| Printed name of person obtaining consent |  |  |

***The following signature block is to be used when an impartial witness is needed for non-readers or visually impaired participants.***

|  |
| --- |
| I witnessed the entire consent discussion and attest that the information in the consent document and any other written information were accurately read to the participant. I witnessed that all of the participant’s questions were addressed.  I witnessed the participant freely giving consent to take part in this study. |
|  |  |  |
| Signature of Impartial Witness |  | Date |
|  |  |
| Printed name of Impartial Witness |

***The following signature block is to be used when an adult participant is unable to sign their name and date the informed consent form. A witness is required to verify that the participant provided their “mark”.***

|  |
| --- |
| I witnessed the participant providing their “mark” on the above signature line and have identified the participant by documenting his/her name on the above “Printed name of participant” line. |
|  |  |  |
| Signature of Impartial Witness |  | Date |
|  |  |

Printed name of Impartial Witness

**Signature Block for Adult Unable to Consent**

|  |
| --- |
| Your signature below documents your permission for the participant named below to take part in this research and to the use and disclosure of this person’s protected health information. You will receive a signed copy of this completed form. |
|  |  |  |
| Printed name of participant |  |  |
|  |  |  |
| Signature of legally authorized representative |  | Date |
|  |  |  |
| Printed name of legally authorized representative |  | Relationship to participant |
|  |  |  |
| Signature of person obtaining consent and assent **(Remove latter section if assent will not be obtained)** |  | Date |
|  |  |  |
| Printed name of person obtaining consent and assent **(Remove latter section if assent will not be obtained)** |  |  |

***Add the following block if you will document verbal assent of the participant on this consent form. If you will be documenting written assent add an assent signature line, printed name line and date line to the consent form or have a separate assent form.***

|  |  |
| --- | --- |
| Assent | * Verbal Assent Obtained
* Not obtained because the capability of the participant is so limited that the participant cannot reasonably be consulted.
 |

***The following signature block will be completed if an impartial witness is required for LAR that is a non-reader.***

|  |
| --- |
| I witnessed the entire consent discussion and attest that the information in the consent document and any other written information were accurately read to the participant.  I witnessed that all of the participant’s questions were addressed. I witnessed the participant freely giving consent to take part in this study. |
|  |  |  |
| Signature of Impartial Witness |  | Date |
|  |  |
| Printed name of Impartial Witness |

**Signature Block for Children**

|  |
| --- |
| Your signature below documents your permission for the child named below to take part in this research and to the use and disclosure of this child’s protected health information. You will receive a signed copy of this complete form. |
|  |  |
| Printed name of child |
|  |  |  |
| Signature of parent or guardian |  | Date |
|  | * Parent
* Guardian (See note below)
 |
| Printed name of parent or guardian |
| **Note on permission by guardians:** An individual may provide permission for a child only if that individual can provide a written document indicating that he or she is legally authorized to consent to the child’s general medical care. Attach the documentation to the signed document. |

***The following second parent or guardian block is required if your study is greater than minimal risk with no prospect of direct benefit but likely to yield generalizable knowledge about the child’s disorder or condition*** *45 CFR 46.406 & 21 CFR 50.53.*

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of second parent or guardian |  | Date |
|  | * Second Parent
* Guardian (See note above)
 |
| Printed name of second parent or guardian |
| If signature of second parent not obtained, indicate why: (select one) |
| * Second parent is deceased
* Second parent is unknown
* Second parent is incompetent
 | * Second parent is not reasonably available
* Only one parent has legal responsibility for the care and custody of the child
 |

***Add the following block if you will document verbal assent of children on this consent form. If you will be documenting written assent add an assent signature line, printed name line and date line to the consent form or have a separate assent form.***

|  |  |
| --- | --- |
| Assent | * Verbal Assent Obtained
* Not obtained because the capability of the participant is so limited that the participant cannot reasonably be consulted.
 |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of person obtaining consent and assent **(Remove latter section if assent will not be obtained)** |  | Date |
|  |  |  |
| Printed name of person obtaining consent and assent **(Remove latter section if assent will not be obtained)** |  |  |

**Signature Block for Limited English Speaking: Short Form**

|  |
| --- |
| This English version of the Informed Consent Form is to accompany the Short Form you sign in your stated primary language. You will receive a signed copy of this complete English Informed Consent Form and Short Form together. |
|  |  |
| Printed name of participant |
|  |  |  |
| Signature of person obtaining consent |  | Date |
|  |  |  |
| Printed name of person obtaining consent |  |  |

|  |
| --- |
| I declare that, to the best of my ability, I have accurately interpreted to/from the participant’s stated primary language, \_\_\_\_\_\_\_\_\_ (Specify language), everything said during the informed consent discussion.  |
|  |  |  |
| Signature of Appointed Medical Interpreter |  | Date |
|  |  |  |

Printed name of Appointed Medical Interpreter Time

|  |
| --- |
| I declare that I was present for the entire informed consent discussion and that, to the best of my ability, everything said during the discussion was accurately interpreted by the Spectrum Health-appointed interpreter to/from participant’s stated primary language: \_\_\_\_\_\_\_\_\_ (Specify language).  |
|  |  |  |
| Signature of Witness to Informed Consent Interpretation |  |  Date |
|  |  |  |
| Printed name of Witness to Informed Consent Interpretation |  |  Time |