**University of Michigan**

**Consent To Be Part Of A Research Study**

**Do not place anything in the header at the top of the page.**

The information will be completed when the IRBMED approves the document in eResearch.

**THIS INFORMED CONSENT TEMPLATE IS THE ‘WORKING’ VERSION, WHICH CONTAINS ADDITIONAL INSTRUCTIONS AND REQUIRED LANGUAGE IN BLUE AND ORANGE BOXES.**

**IRBMED’S RECOMMENDATION IS TO USE THIS VERSION AS THE TEMPLATE FOR CREATING THE CONSENT DOCUMENT.**

**PRIOR TO SUBMITTING THE INFORMED CONSENT DOCUMENT FOR IRBMED REVIEW, REMOVE ALL BLUE AND ORANGE TEXT BOXES. TO DO THIS, SIMPLY CLICK ON THE BORDER OF THE BOX AND HIT DELETE.**

Blue text boxes contain instructions for all studies.

**Before uploading your informed consent form in eResearch:**

**Be certain to proofread the document(s) for spelling, grammar, and formatting errors.**

New Consents:

Delete all instruction boxes, comments, and headers from the original template.

* Amendments to Consents (see [Version Control of Informed Consent Documents](https://research.medicine.umich.edu/sites/default/files/res_irbmed_SP%20VersionControlInformedConsent%202014%2010%2021.pdf) statement of practice):
  + Edit the most recent version of the **clean** informed consent document found in 10-1.1.
  + Use the **Upload Revision** button to stack the new **tracked-changes** document on top of the tracked-changes stack.
  + Use the **standard naming conventions** for stacks

Consents no longer in use:

In eResearch 10-1.1 add the phrase “X-Not in use” to the beginning of the document name. Do not delete these documents from the eResearch application.

**1. Key Information About the RESEARCHERS and This Study**

**Study title:**

The study title must match on all documents (application, protocol, consent document, etc.). If applicable, add a local identifier code after the title (e.g., MCRU #### or UMCCC ####).

NOTE: The footer of the informed consent document template includes a **“Consent Subtitle”** section to designate the subtitle and version of each consent document used in the study (e.g., Main, Genetic, Screening, Treatment Group, etc.). Abbreviate lengthy subtitles. When a study uses only a single consent document, this item in the footer may be deleted. The **"Consent Version"** MUST be completed and is utilized as a document tracking system for **any** change to the document. The version designation can take the form of a date or alphanumeric code (e.g., 06/01/2003, 1.1, 1.2, 1a, 1b, etc.).

**Company or agency sponsoring the study:**

Provide the name(s) of the sponsor(s) of the study. If the study is not sponsored, state or otherwise explain that there is no sponsor.

**Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):**

List the names and degrees of the PI and study coordinator (if applicable), along with their respective affiliation (i.e., Department and Institution). For example: "Ima Researcher, M.D., Department of Internal Medicine, University of Michigan".

**Do not list other study personnel (such as co-investigators) in this document. Utilize a delegation of authority log to provide a comprehensive list of study team members and the duties that have been delegated to them by the PI.**

**Principal Investigator:**

**Study Coordinator:** [OPTIONAL]

**1.1 Key Study Information**

For studies that use the same informed consent document for both adult and pediatric participants, the following text may be substituted for the first paragraph. While this alternate text has been endorsed by the IRBMED, it may not be appropriate for all studies. On study-specific basis, the IRBMED may require a different approach. Investigators may also propose a different approach, subject to IRBMED approval.

You, or your child, may be eligible to take part in a research study. Parents or legal guardians who are giving permission for a child’s participation in the research, note that in the sections that follow the word ‘you’ refers to ‘your child’. This form contains information that will help you decide whether to join the study. All of the information in this form is important. Take time to carefully review this information. After you finish, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about your possible participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you do, be sure you understand what the study is about.

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find childcare, or make other plans. In your decision to participate in this study, consider all these matters carefully.

The language in the section below, broken down into different common trial types, is provided as an example of how specific trial phases may be described in this section. Investigators are not required to use this language verbatim but should know that this language has been acceptable in other consent documents. Add detail as indicated in each [ ] and include any special circumstances such as randomization or ‘wash-out’. Create a new study descriptor as needed.

**DELETE THE BOLDED HEADER THAT NAMES THE CLINICAL TRIAL DESCRIPTOR.**

**Phase I drug study; feasibility device study**

This is a Phase I study, which means the goal is to find the highest dose of drug that does not cause severe side effects (often called the maximum tolerated dose, or MTD), and to identify the most common side effects. This is determined by giving participants different doses of the study treatment and carefully monitoring for side effects as well as how the body handles the study treatment. [Optional: This is the first time that this study treatment has been given to people with your kind of cancer.] As this is an early investigation, it is not known whether the study treatment will benefit people with your kind of cancer. [Optional for phase Ib or dose expansion: This study also includes a part (sometimes called an expansion cohort) intended to get preliminary information on the safety and effectiveness of the study treatment.]

**Phase II drug study; feasibility/pivotal device study**

This is a Phase II study, which means that the goal is to test the safety and effectiveness of the study treatment, i.e., does it work against your [DISEASE], and do the benefits outweigh the risks and side effects. This is usually done by comparing the outcomes of participants in the study to those of people who received standard treatment.

**Phase III drug study; pivotal device study**

This research is studying a new [DRUG/DEVICE] in a large group of people to learn about its safety and how well it works as a treatment for [DISEASE/CONDITION]. Researchers want to see how your body will react to the [DRUG/DEVICE] and if it is helpful for people with [DISEASE/CONDITION]. This research will [PROVIDE A BRIEF EXPLANATION OF THE PURPOSE AND THE PROCEDURES OF THE STUDY].

**Phase IV drug study; post-approval device study**

This research is studying a [DRUG/DEVICE] already approved by the Food and Drug Administration (FDA) to treat [DISEASE/CONDITION]. Researchers are studying a large group of people to continue to learn information about the safety of the [DRUG/DEVICE] and how people’s bodies react to using it over a long period of time. This research will [PROVIDE A BRIEF EXPLANATION OF THE PURPOSE AND THE PROCEDURES OF THE STUDY].

**Behavioral intervention study**

This research is studying whether changing an individual’s behaviors may have an impact as a treatment or outcome for [DISEASE/CONDITION]. This research will [PROVIDE A BRIEF EXPLANATION OF THE PURPOSE AND THE PROCEDURES OF THE STUDY].

**Data and biospecimen collection**

This research collects health-related information and a [INDICATE THE NATURE OF THE BIOSPECIMEN] to better understand [DISEASE/CONDITION]. This research will [PROVIDE A BRIEF EXPLANATION OF THE PURPOSE AND THE PROCEDURES OF THE STUDY].

**Data collection only**

This research collects health-related information to better understand [DISEASE/CONDITION]. This research will [PROVIDE A BRIEF EXPLANATION OF THE PURPOSE AND THE PROCEDURES OF THE STUDY].

The statement of risks should be designed to orient potential participants to the nature of the study and to highlight significant risks. Simply copying and pasting risk language from elsewhere in the document may not be adequate.

Given the nature of the study and its risks, consider whether the most common or serious should appear, or whether a general statement about study risk would be more valuable to potential participants than a list of risks. A statement such as “Participation in this study involves serious risks, some of which could be painful, require hospitalization, or be life threatening” may be sufficient.

Examples of significant/serious risks may include:

* serious health complications of your current [DISEASE/CONDITION] such as [BRIEFLY DESCRIBE]
* participation in this study may be less effective for your condition than other options
* new symptoms from use of the [drug/device] such as [BRIEFLY DESCRIBE]

[ADD ANY SPECIAL CIRCUMSTANCES SUCH AS THOSE LISTED BELOW (DO NOT INCLUDE THE BOLDED HEADER)].

**Randomization**

This study involves a process called randomization. This means that the [DRUG, DEVICE, OR PROCEDURE] you receive in the study is not chosen by you or the researcher. The study design divides study participants into separate groups, based on chance (like the flip of a coin), to compare different treatments or procedures. If you decide to be in the study, you need to be comfortable not knowing which study group you will be in.

**Washout**

This study may require you to stop taking certain medications before and possibly during the research study. If you decide to be in the study, you should understand that some symptoms that were controlled by that medication may worsen.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include [INDICATE REASONABLY FORSEEABLE RISKS; CONSULT WITH THE PI OR OTHER STUDY TEAM MEMBERS TO DETERMINE WHICH RISKS ARE SIGNIFICANT ENOUGH TO BE PRESENTED IN THE KEY INFORMATION SECTION.] More detailed information will be provided later in this document.

[SELECT ONE OF THE OPTIONS BELOW THAT DESCRIBES THE POTENTIAL BENEFITS FOR PARTICIPANTS. DELETE THE OTHER OPTION.]

[This study may offer some benefit to you now or others in the future by [BRIEFLY SUMMARIZE POTENTIAL BENEFITS]]. [This study may not offer any benefit to you now but may benefit others in the future by [BRIEFLY SUMMARIZE POTENTIAL BENEFITS]]. More information will be provided later in this document.

We expect that you will be receiving study interventions and study follow-up for [INDICATE HOW LONG PARTICIPANTS WILL BE IN THE STUDY].

You can decide not to be in this study. Alternatives to joining this study include [BRIEFLY ADDRESS ALTERNATIVES SUCH AS STANDARD OF CARE ALTERNATIVES OR OTHER CLINICAL TRIALS].

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

**2. PURPOSE OF THis STUDY**

**2.1 Study purpose:**

Briefly, in one paragraph, explain in lay terms the scientific reason for doing this study. Do not describe the details of the protocol here – that will be done in Section 4 "Information About Study Participation". Lay terminology example: “Disease Z is known to be caused by increased levels of a particular protein, called Y, in the bloodstream. Research in animals has shown that a new drug, called X, can lower the levels of the Y protein. We do not know, however, whether Drug X is safe for use in humans, and if so whether it will lower levels of Y protein in people as well as it has in animals. This research study is being done to learn what effect 3 months of treatment with Drug X will have on the levels of Protein Y in the bloodstream of patients with Disease Z."

**3. Who May Participate in the study**

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

**3.1 Who can take part in this study?**

List important eligibility criteria in **lay terms**. Also include a discussion of important exclusion criteria, if applicable. For some studies, investigators may wish to remind potential participants of the importance of providing complete and accurate information about their health condition/history in order to ensure that they are safe and appropriate candidates for participation.

**3.2 How many people are expected to take part in this study?**

Insert the total number of participants you expect to enroll. If this is a multi-site study, include the total number over all sites as well as the number at UM. For example: "300 participants are expected to participate, 25 at the University of Michigan and 275 at other sites around the United States." If the study includes different participant pools (control group/affected group), note that also. For example: "100 total participants (25 participants with Alzheimer’s disease and 75 healthy participants)".

**4. information about study participation**

**4.1 What will happen to me in this study?**

**Differentiating between research and non-research procedures by use of the “[Not research]” marker**

Typically, research informed consent documents should address and describe only procedures conducted as part of the proposed research; information about standard clinical care should appear, if at all, only where there is a compelling reason to include it in research consent materials.

In some clinical trials, however, in which participants will already be undergoing treatment for the condition relevant to the research, it may be necessary to differentiate between procedures, risks, and other elements associated with study participation and those associated with clinical treatment.

For example, a study may involve increasing the dose or frequency of a medication that participants are already receiving as patients. Or participants already undergoing clinical MRI scans as patients may undergo additional MRIs for study purposes.

Use of the marker “[Not research]” to identify procedures that are not part of the study, but would take place as part of clinical care even if an individual opted not to participate in research, can be useful in the design of calendars and other tables and charts, where a simple designation will help the reader identify which instances of the same type of test (e.g., MRI) are research-driven and which represent ordinary clinical care.

In cases where this type of distinction is appropriate, insert the following recommended language at the beginning of this section.

Some tests and procedures you undergo while taking part in the research would be performed as part of your regular medical care even if you decided not to take part in the study. These will be identified below as “[Not research].”

Costs of all procedures designated in the document as research are expected to be covered by the study, except where information in section 8.1 indicates otherwise.

Keep in mind that some research procedures involve analysis or review of data generated in clinical care procedures. For example, a study may involve no additional MRI scanning but may involve analysis of images produced in the course of MRI scanning conducted as clinical care. In this scenario, only access to and analysis of the images from the clinical MRI scanning process should be addressed in this document, not the clinical scanning procedure itself.

**A — General study procedures**

**The instructions within this box pertain to all studies and sub-studies in this document.**

Explain in lay terms, usually in chronological order, what will happen to subjects during the study. If appropriate, describe medical care or other procedures that would be performed whether or not the subject participated in the study. In this case, be sure to distinguish the research-only or experimental procedures from routine or regular care.

ALL research-only/experimental procedures and treatments must be listed in this section, including any clinical tests or procedures that may have to be repeated in order to conform to the study protocol (e.g., repeat CT scan that was done 6 months ago because protocol requires CT scan within last 4 weeks). The following should always be addressed, as applicable:

* Eligibility Testing (e.g., blood tests, CT scan, office visit, EKG, HIV etc.),
* Experimental intervention/interaction (e.g., study drug or device, experimental neuropsychological test, etc.)
* Randomization (explain probability of random assignment, e.g., *flip of a coin, one-in-three chance, etc.)*
* Blinding procedures
* Data collection (e.g., blood samples, CT scan, office visit, EKG, survey, etc.)
* Use of medical records information
* Photography or video/audio recording (obtain subject signature at Sig-B [section13])
* Other research procedures or activities
* HIV testing (also include the state-mandated HIV informational language included in section 11.2 of this template)

Be sure to describe:

* Any wash-out periods or other deviations from the subjects' regular regimen.
* If research-only tests will not be analyzed or assessed in a timely manner for clinical care purposes.
* **Subject responsibilities** – Sponsor-provided language is permitted or the language suggested below (“As a subject participating in this research study,” etc.) may be used

Add a general sentence on **subject responsibilities** – Sponsor-provided language is permitted or the following suggested language may be used:

As a subject participating in this research study, you have certain responsibilities that may apply to this study, such as ensuring that you arrive at all your scheduled appointments, take your study medication as directed, and report any adverse reactions you may have during the study.

**Optional language for blinded studies, for use only if eResearch section 1-2.9 (“Would the integrity of this research study be compromised if the subject were able to view results of their research tests or medications in the Patient Portal of MyUofMHealth.org?”) is answered yes:**

Introductory sentence (modifiable to reflect study design):

For some research studies, such as the one you are being asked to join, it is important that you do not learn the results of certain tests. Whether you intend it or not, sometimes learning this information may make you change your actions and behaviors in ways that could impact the outcome of the study.

Secondary sentences (Not modifiable FOR BLINDED STUDIES that would be compromised by subjects viewing results in the MiChart Patient Portal):

For this study, you will not be able to see your research test results and you agree to have temporary, limited access placed on your Patient Portal in MyUofMHealth.org. You will not be able to see any laboratory test results (for example, results of cholesterol or glucose tests) or radiology test results (for example, results of x-rays, MRIs, or CT scans). While you are on this study, you will still be able to see and use other parts of the Patient Portal in MyUofMHealth.org to refill prescriptions, set up appointments with your doctor, or pay your medical bills on-line. When this study is over with, full access to the Patient Portal in MyUofMHealth.org will be returned to you.

**Additional information about HIV testing**

Insert the following language if your study involves HIV testing as a necessary condition for participation. Michigan law no longer requires you to provide potential participants with the state’s HIV testing information pamphlet or to offer detailed information about HIV and HIV testing within the informed consent document.

**Additional information about HIV testing**

This study involves HIV testing. HIV infection is a long-term illness that damages the body’s immune system or its ability to fight off diseases. HIV spreads through blood, semen, vaginal fluids, and breast milk. An HIV test is a simple test done by taking blood or fluid from cells in the mouth that shows if you have been infected with HIV. [INCLUDE IF MINORS WILL RECEIVE HIV TESTING: Minors, age 13 and older, have the right to take the test for HIV without their parents’ knowledge or consent.]

In Michigan, all HIV test information is confidential by law. This means that there are very strict rules about who is allowed to see that information. Health care workers that are involved in your care may see your test results. Health insurance companies, Medicare, and Medicaid, if they are paying all or part of the cost of your health care, will also see your test results. All positive HIV tests are reported to the health department. If you have HIV, Michigan law requires that your doctor or someone from the local health department notify all of your known sexual and/or needle-sharing partners that they may have been exposed to HIV. They do this without using your name or sharing any information about you. Keep in mind that if you agree to receive an HIV test as a participant in this study, we may be legally required to report information about your test to government agencies. Michigan law also imposes requirements on individuals whose HIV tests come back positive, and not complying with these requirements may result in criminal charges.

If you have questions about HIV, call the Michigan statewide HIV/AIDS information hotline (English 1-800-872-AIDS; Español 1-800-862-SIDA; TDD 1-800-332-0849). You can also view an online pamphlet from the State of Michigan (<https://www.michigan.gov/documents/mdch/What_you_need_to_know_about_HIV_438247_7.pdf>) or visit the CDC’s HIV/AIDS website for more information (<http://www.cdc.gov/hiv/>).

You can change your mind about HIV testing at any time before the lab runs the test. Tell a member of our study team if you no longer wish to receive the test. Not taking an HIV test may mean that you cannot take part in the study.

**B — Sub-studies with specified designs**

**Obtain subject signature at box Sig-C (section 13).**

**NOTE:** *If your sub-study involves no interventions or invasive procedures that are not already conducted as part of the main study, use the guidance in this blue box and the next to summarize your sub-study in this portion of the document (section 4.1). If your sub-study is more complex, introducing additional interventions and/or risks not part of the main study (such as an additional biopsy), address your sub-study instead in Appendix A, found at the end of this document.*

**The instructions within this box pertain to optional sub-studies that you have already designed; if you expect to use subjects’ data/specimens in future research but have not yet determined how they will be used, use “Collection for unspecified future research”.**

**If your study does not offer subjects the option to participate in a sub-study, these instructions do not apply. Sub-studies included in this manner are usually very limited in the scope of new interventions and/or data collection.**

For research studies that include related sub-studies, the subject must opt-in to the sub-study (meaning give consent).  You may still allow a subject who decides not to take part in the sub-study to take part in the main study.

Explain in lay terms, usually in chronological order, what will happen to subjects during the sub-study. If appropriate, describe medical care or other procedures that would be performed whether or not the subject participated in the sub-study. Use the format required for the main study. Be sure to distinguish the research-only or experimental procedures from routine or regular care.

The researcher must obtain a separate signature from the subject for the sub-study. See below for more information.

For a *sub-study with a specified design*, language should include, as applicable:

**Optional sub-study information**

Besides the information about the main study, the following information is specific to an optional sub-study. We/The sponsor would like your permission to study your [BLOOD/SPECIMEN] and medical information to find out [SPECIFIC PURPOSE]. You can take part in this study even if you decide not to let us analyze your [BLOOD/SPECIMEN] to find out [SPECIFIC PURPOSE].

Even if you give us/them permission now to keep some of your [BLOOD/SPECIMEN] and medical information, you can change your mind later and ask us/them to destroy it. Keep in mind, however, that once we/they have analyzed your [BLOOD/SPECIMEN], we/they may not be able to take the information out of our research. Also, if we/they have shared some of your BLOOD/SPECIMEN and medical information with other researchers, we/they will not be able to get it back.

[INDICATE ADDITIONAL RISKS SUB-STUDY POSES AND DESCRIBE EFFORTS TO MINIMIZE THEM (E.G., THE GINA LAW).]

You [WILL/WILL NOT] receive the results of the analysis of your [BLOOD/SPECIMEN]. Allowing us/they sponsor to study your [BLOOD/SPECIMEN] and medical information to find out [SPECIFIC PURPOSE] will not benefit you directly.

PATIENT PORTAL COMMUNICATION AS PART OF THE RESEARCH

If communication with subjects will occur through the patient portal and subjects *cannot opt to receive communication by other means instead,* insert the following statement:

We’ll communicate with you about the study via the MyUofMHealth.com patient portal. Please speak with our study team for help using the portal and accessing patient study-related information.

**4.2 How much of my time will be needed to take part in this study?**

Explain as needed, describing time in hours, number of visits, amount of time each visit will entail, etc. Include expectations for long-term follow-up visits, if applicable. For example: "Each subject will receive Drug X for **6 months,** then have at least **3 follow-up visits** with the researcher over the next **6 months**. Each visit is expected to last about **1 hour**." Be liberal in the estimations of time.

**4.3 When will my participation in the study be over?**

Explain as needed the overall amount of time, including on-going examination of medical or other records, if applicable. For example: "In addition to the time above, we will collect information from your medical records for another **3 years** after your participation. Most subjects will complete their part in the study within about **4 years.** The entire study is expected to last about **5 years**."

You should also include a description of any plan to enable participant post-trial access to beneficial interventions; if there is no such plan it should be disclosed that access to the intervention being tested may not be available after the close of the trial.

**5. information about Study RISKS and benefits**

**5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?**

It is **not**necessary to list risks associated with non-research procedures.

Explain the **research** risks and discomforts in clear, simple, concise terms (consider using bulleted format). Please note that "none" or "not applicable" are not considered appropriate for this section, since even studies involving minimal risks do have foreseeable risks, such as discomfort or inconvenience, or risk to confidentiality.

Note that federal regulations require that research consent documents list **ALL** reasonably foreseeable risks, stresses, and discomforts of **ALL** aspects of participation in a study, not just the most serious or common side effects of a research intervention or procedure (e.g., study drug or device). Avoid statements like "The main risks are…" or "Side effects include…" as these statements would not comply with the federal requirement to list all foreseeable risks. However, investigators **are** encouraged to stratify the risks by categories such as

"The most common side effects (occurring in more than 10% of patients) are:"

"Less common side effects (1% - 10% of patients) are:"

"Rare side effects (less than 1% of patients) are:"

Remember to include the risks of any research-related monitoring procedures such as biopsies, blood draws, or radiological tests, as well as the risks of allergic reactions and adverse drug-drug interactions, as applicable. Include reproductive risks and/or risks to a fetus if women of child-bearing potential take part in the study.

**MRI risk language**

*For use only where the MRI scanning procedure itself—not simply the analysis of MRI images generated in the clinical context—is a research procedure.*

In most cases, the risk of hearing damage in standard MRI scanning is considered low. For these typical instances, insert the following risk language:

The MRI scanner makes loud, vibrating noises. You [Your child] will wear hearing protection (for example, properly fitted foam earplugs or noise muffs) to reduce the loud noises made by the scanner and to reduce the risk of hearing damage. When properly fitted hearing protection is used, the likelihood of hearing damage from the MRI scan(s) in this study is low.

In rare instance in which the risk of hearing damage is higher than described above, adjust the passage to convey the appropriate likelihood of hearing damage. eResearch offers the following system of expressing frequency of occurrence:

* "Common" (i.e., approximate incidence > 25%)
* "Likely" (i.e., approximate incidence of 10-25%)
* "Infrequent" (i.e., approximate incidence of 1-10%)
* "Rare" (i.e., approximate incidence < 1%)

In these instances, which IRBMED expects to be rare, provide the rationale within the eResearch application for characterizing the risk as higher than usual.

The known or expected risks are:

The researchers will try to minimize these risks by:

Add additional language to explain efforts to mitigate study-specific risks. Consult with the PI or other study team member as needed for help addressing these mitigation efforts.

USE THE FOLLOWING LANGUAGE ONLY IF YOUR STUDY INVOLVES PREMEDICATION ASSOCIATED WITH RESEARCH PROCEDURES:

As explained in section 4.1, you will take some medications before beginning certain study procedures. The risks of these medications are as follows:

* [LIST PREMEDICATIONS, THEIR ATTENDANT RISKS, AND HOW THOSE RISKS WILL BE MINIMIZED.]

Additionally, there may be a risk involving loss of confidentiality or privacy. For example, if individuals outside this study were to discover that you were a participant in this research, or if any collected identifiable genetic or health information were disclosed to unauthorized persons, there is a risk of discrimination by employers or insurance providers. The researchers have adopted privacy and confidentiality procedures to help prevent such disclosures. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

Keep in mind, as well, that the committee (IRBMED) that reviews this study does not review risks associated with procedures that are conducted as part of your regular medical care and are not part of the research, including those marked “[Not research]” in section 4.1, above. Risks associated with your regular medical treatment should be discussed with your regular doctor.

**5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?**

**For Internally Funded or Investigator-Initiated (Non-Sponsored) Projects**

Study teams should direct questions to your designated CRAO analyst for guidance on completing section 5.2 and/or section 8.1 of the informed consent with regard to injury language and potential business risk.

Delete the following sentence if the statement does not apply to this study.

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors or any other provider or hospital you visit**.**

Explain how risks are monitored and reduced. For example, explain that the subject will receive a physical examination and blood test once a week after beginning treatment with the new drug or device. Also explain what steps will be taken if complications or adverse effects are detected (e.g., "first aid will be provided" or "the drug dose will be lowered or stopped altogether").

**Information about payment for first aid or emergency care should be provided in Section 8 "Financial Information" and not here in Section 5 "Risks and Benefits."**

**5.3 If I take part in this study, can I also participate in other studies?**

*Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies*. You should not take part in more than one study without approval from the researchers involved in each study.

If applicable, include a description of any relevant potential risks associated with participation in multiple studies (e.g., drug interactions, excessive radiation exposure, etc.).

**5.4 How could I benefit if I take part in this study? How could others benefit?**

You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study.

If applicable, the required sentence can be followed with language that describes **possible** benefits to subjects or to society. For example: “However, some subjects may [describe potential benefit to subjects]” and/or “Possible benefits of the research for society (or for future patients with this disease) include [describe potential benefit to society]”. Do not describe payments or other compensation to subjects here; utilize Section 8 on "Financial Information".

Add a statement of **no benefit** when applicable.

**5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?**

If new information might affect the eligibility of subjects to continue to participate in the study, address that possibility here and also in answer to Question 7.3. For studies in which a subject's participation is limited to a single experimental session (e.g., a single survey study, or study that collects all data at a single time point), investigators may choose to delete this question from the template.

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

**6. Alternatives to Participating in the study**

**6.1 If I decide not to take part in this study, what other options do I have?**

Describe alternatives to participation in the research study, including what is usually done to treat the condition or disease. Be sure to include information, when appropriate, about all alternative treatments.

Examples of alternatives may include, but are not limited to: treatment or intervention utilized outside of the research context (e.g., clinical care on-label or off‑label use), over-the counter (OTC) medications, and additional research studies (e.g., [www.clinicaltrials.gov](file:///\\MEDINFO\WEB\WEBDOCS\irbmed\ict\www.clinicaltrials.gov)). All alternative treatment options suggested to research subjects should warn that use of alternatives should be undertaken with appropriate continued medical supervision.

If an investigational drug/device used in the study is approved for another indication, inform subjects that the agent may be available outside the research project.

If the FDA approval status of an investigational drug/device is mentioned in the description of the research (section 4.1), then it need not be repeated here. Otherwise, it should be described here.

Possible language includes:

There may be other ways of treating your condition. These include: [list alternative treatments and/or interventions, as well as how they may be available (standard treatment, different study, over-the-counter)]. Although [investigational product] is available as part of this clinical study, you should check with the researcher and/or your primary care physician to discuss your options including how to obtain any alternative treatments and whether they must be obtained through a physician or require medical supervision.

For non-therapeutic studies, in which there is no “alternative” or standard treatment, reiterate the voluntary nature of participation.

Add a statement about **alternative treatments** – Sponsor-provided language is permitted or the following suggested language may be used:

There may be other ways to treat your \_\_\_\_\_\_\_\_\_\_\_\_, including treatment with \_\_\_\_\_\_\_\_\_\_\_\_, alternative treatments such as \_\_\_\_\_\_\_\_\_\_\_\_, or other experimental treatments. Your doctor can tell you more about these other treatments, their risks and their possible benefits.  You should have this discussion about the risks and benefits or other alternatives prior to making your decision about whether you wish to take part in this research study.

**7. ENDING THE STUDY**

**7.1 If I want to stop participating in the study, what should I do?**

As applicable, investigators should use this section to reassure subjects that their standard medical treatment does not depend on their continued participation in this study. If the study involves special procedures for termination of treatment (e.g., orderly withdrawal from drug treatment) or potential dangers of terminating treatment (e.g., on implanted device studies), investigators should edit the boilerplate text under Question 7.1 as appropriate, and be sure to describe the termination risks and procedures under Question 7.2. Please note that subjects always have the right to end their participation in research for any reason, so be careful not to imply that subjects should remain in the study against their will or should stop participating only for certain reasons.

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information”.

**7.2 Could there be any harm to me if I decide to leave the study before it is finished?**

Let the subject know about any termination procedures that might exist for this study (e.g., exit interviews, laboratory tests), and any dangers of terminating treatment abruptly or completely, particularly without consulting with the researchers or another doctor.

Tell us if you are thinking about stopping or decide to stop. It is important to tell us if you are thinking about stopping so any risks can be evaluated by the researchers. We will also tell you how to stop safely and discuss what follow-up care and testing could be most helpful for you. If you decide to leave the study before it is finished, please tell one of the researchers listed in Section 10 “Contact Information” (below).

You are free to end your participation partially or completely in the study. An example of partially ending your participation would be to discontinue receiving study intervention, while still allowing continuation of study follow-up procedures.

Please note that any information collected before you withdraw will be kept and used to complete the research.

Please note that even if you withdraw consent for further follow-up or contacts, if the study doctor becomes aware of additional safety information this will be reported to the sponsor to comply with legal or regulatory requirements.

**7.3 Could the researchers take me out of the study even if I want to continue to participate?**

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

* The researchers believe that it is not in your best interest to stay in the study.
* You become ineligible to participate.
* Your condition changes and you need treatment that is not allowed while you are taking part in the study.
* You do not follow instructions from the researchers.
* The study is suspended or canceled.

**8. Financial Information**

**8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?**

If there is no cost for the study, delete all of the language under 8.1 EXCEPT FOR THE LAST PARAGRAPH and state “There are no costs or billing for this study.”

The study will pay for research-related items or services that are provided only because you are in the study. The procedures described in section 4.1 may include some non-research procedures. Those designated as “[Not research]” will not be paid for by the study. If you are not sure which procedures or services the study will pay for, ask the researchers for a list. If you get a bill you think is wrong, call the researcher’s telephone number listed in Section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

* Health care given during the study as part of your regular care
* Items or services needed to give you study drugs or devices
* Monitoring for side effects or other problems
* Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan’s medical reviewer.

“The study will pay for” means the internal or external sponsor. The discussion in Section 4 will have made clear what items or services are research-related. The final approved billing plan may serve as a good list to provide to subjects. *Note:* Change the text in this paragraph if study-related items or services are NOT paid for by the study (e.g., “the study does not pay for the cost of the drug or device.”)

**Some sponsors may require the following CMS language:**

If you are treated for a research injury that is paid for by the study sponsor, then the study sponsor may need to collect certain information about you, such as your name, date of birth, and Medicare Health Insurance Claim Number, or if you do not have one, your Social Security Number. This information will be used only to check to see if you receive Medicare, and, if you do, to report the payment made by the study sponsor to the Centers for Medicare & Medicaid Services, or “CMS,” which administers the Medicare program. The study sponsor will not use this information for any other purpose.

By signing this form, you specifically authorize the study sponsor to disclose your personal identifiable information to CMS for the purpose of complying with these Medicare reporting requirements.

**EXTERNAL INDUSTRY SPONSOR**

If any complication, injury, or illness requiring medical treatment is paid for by the external **INDUSTRY** sponsor, **the STUDY TEAM MUST INSERT THE FOLLOWING LANGUAGE**:

The study team has given you instructions about this research study. It is important that you follow these instructions carefully. If you get sick, have a medical complication, or are injured as a result of your being in the study, call Dr. [XXX] immediately, at [XXX-XXX-XXXX]. The doctor will either treat you or send you to another doctor for treatment. You will get free medical care for any complication, injury, or illness caused by the study drug, device, or procedure. The study sponsor and the study doctor are responsible for determining whether your condition was the result of your participation in the study. The study sponsor will pay for your treatment only if the need for treatment has been caused by the study drug, device or procedure. This means that you or your health plan must pay for any treatment that is part of your usual medical care or that is related to a medical condition you had before participating in the study.

**Internally Funded or Investigator-Initiated (Non-Sponsored)**

If you are injured or in the event of a medical emergency, dial 911 or visit your nearest Emergency Room. If you believe the study has made you sick or caused you injury, contact one of the people listed in section 10 of this document (Contact Information). If taking part in the study makes you sick or causes you injury, you or your insurance provider will be billed for all costs of treatment as the study does not provide compensation for sickness or injury caused by the study. It is possible that your insurance will not cover these costs.

**FEDERAL GOVERNMENT SPONSOR**

If any complication, injury, or illness requiring medical treatments is paid for by a **GOVERNMENT** (Federal) sponsor, **the STUDY TEAM MUST INSERT THE FOLLOWING LANGUAGE**:

If you are injured or in the event of a medical emergency, dial 911 or visit your nearest Emergency Room. If you believe the study has made you sick or caused you injury, contact one of the people listed in section 10 of this document (Contact Information). If taking part in the study makes you sick or causes you injury, you or your insurance provider will be billed for all costs of treatment as the study does not provide compensation for sickness or injury caused by the study. It is possible that your insurance will not cover these costs.

If appropriate, identify any specific known or expected insurance coverage problems for this study, and modify the boilerplate at “…if you think your health plan may not cover…” to provide additional important information. For example, research subjects participating in certain Phase I trials may jeopardize their insurance coverage for the "standard" or "routine" care of their disease or condition. The billing specialist in your department may be able to help you determine if this is applicable to this study.

There is no need to identify in the consent form every single item or service that might be provided in connection with the study, the cost of the item or service, and who will be responsible for payment. However, the subject should be provided with contact information for a person who can provide that information in case it is relevant to the subject’s decision (likely the study coordinator or other identified administrator). Make sure there is no promise for the UM to pay if insurance does not. Reference any sponsor promise to pay (e.g., sponsor will pay for items or services if insurance does not; or sponsor will pay for costs associated with complications that sponsor determines are sponsor’s responsibility). Contact the Calendar Review & Analysis Office (CRAO) if you have any questions.

**DO NOT DELETE** the statement below: "By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.”

By signing this form, you do not give up your right to seek payment if you are harmed because of being in this study.

**8.2 Will I be paid or given anything for taking part in this study?**

Provide clear, concise information. For example: “No. You will not be paid for taking part in this study.” or “You will receive $20 for completing the study questionnaire.” Include the amounts and conditions of payment. Investigators are advised that payments to subjects should be prorated (when the study has a long duration and/or involves multiple interactions or interventions). The prorated amount should be paid even when subjects withdraw from the study prematurely. Incentive payments for completing the study, or disproportionately high levels of payments, might constitute enticement and should not be offered. Investigators are advised to explain prorated payment when applicable.

**8.3 Who could profit or financially benefit from the study results?**

Delete any of the sub-headings under this question that are not applicable to this study.

If no person or organization has a financial interest in the outcome of the study, so state in answer to this question and delete all sub-headings.

If a person or organization involved in the conduct of this study may have a conflict of interest, address any of the following issues that may apply:

How is the research supported or financed?

Where and by whom was the study designed (i.e., industry-sponsored versus investigator-initiated)?

Do individuals or the institution receive any compensation that is affected by the study outcome?

Do individuals or the institution

have any proprietary interests in the product (including patents and licensing agreements);

have an equity interest in the sponsor;

receive significant payments of other sorts (e.g., grants or consultant retainers); and/or

receive payment per participant or incentive payments?

The company whose product is being studied:

Disclose under this sub-heading if a company or other organization has an ownership or other financial interest in the product or technology under study, and might profit or otherwise benefit from the outcome of the study, particularly if the company/organization is also the sponsor of the study or has a financial relationship with the investigators (as described under the next sub-heading). Delete this sub-heading if it does not apply.

The researchers conducting the study:

**Information regarding suggested language for this section:**

If any of the investigators on the study have an ownership, consulting, or similar financial relationship with the sponsor, they should disclose it here in accordance with the management plan approved by the [Medical School’s Conflict of Interest Committee](http://msa.med.umich.edu/regulatory-affairs/across-missions/conflict-interest#MECOI). If your plan is reviewed and approved by the Institutional Conflict of Interest Committee (ICOC), your plan may include suggested language. Please review your plan accordingly. Delete this sub-heading if it does not apply.

**Suggested Language if there is involvement with U-M Innovation Partnerships or a U-M Financial Interest:**

The University of Michigan is an owner and [CONFLICTED INDIVIDUAL’S NAME HERE] is a named inventor on patents or patent applications or is a creator of copyrighted material that is licensed or optioned to [STATE COMPANY NAME]. This means, the University of Michigan and [CONFLICTED INDIVIDUAL’S NAME HERE] could gain financially from this study.

**Suggested Language if there is Stock Ownership:**

[STATE CONFLICTED INDIVIDUAL’S NAME HERE] owns stock or stock options in [COMPANY NAME] who is the [SPONSOR/MANUFACTURER] of the [DRUG/DEVICE] being studied.

**Suggested Language if there is Other Financial (Paid):**

[STATE CONFLICTED INDIVIDUAL’S NAME] serves as a paid [STATE POSITION] for [COMPANY NAME] on topics [RELATED/UNRELATED] to this study. [COMPANY NAME] is the [SPONSOR/MANUFACTURER] of the [DRUG/DEVICE] being studied.

**Suggested Language if there is Other Non-financial (Unpaid):**

[STATE CONFLICTED INDIVIDUAL’S NAME] serves as an unpaid [STATE POSITION] for [COMPANY NAME] on topics [RELATED/UNRELATED] to this study. [COMPANY NAME] is the [SPONSOR/MANUFACTURER] of the [DRUG/DEVICE] being studied.

**Suggested Language if there is a Relative/Family-Related Conflict of Interest:**

[STATE CONFLICTED INDIVIDUAL’S NAME, STATE RELATIONSHIP TO YOU.]

The University of Michigan:

If the UM intends to be paid licensing fees for the investigational technology, **or could in the future**, so disclose under this sub-heading (e.g., when there is a technology transfer agreement in place or anticipated, or if there are tissues collected or cell lines developed for which the University and/or creators could be paid licensing fees). Contact [Innovation Partnerships](https://innovationpartnerships.umich.edu/) if you are uncertain. Delete this sub-heading if you are certain it does not apply.

The University of Michigan is receiving payments from [INDICATE PAYMENT SOURCE] to support the activities that are required to conduct the study.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

**9. confidentiality of participant records and authorization to release your protected health information**

If this study does not involve Protected Health Information (PHI) (e.g., medical or billing records) and is not subject to the HIPAA privacy rule, investigators may choose to delete “…**AND AUTHORIZATION TO RELEASE PROTECTED HEALTH INFORMATION**" from this section heading.

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

**9.1 How will the researchers protect my information?**

Your participation will occur at Michigan Medicine. Your data will be kept confidential, to the extent permitted by applicable laws, in the following manner:

* Your name will not be used in any reports about the study
* You will be identified only by a study code
* Your identifying information will be kept secure

Despite these protections, some study data may contain information that could be used (perhaps in combination with other information) to identify you (e.g., initials, date of birth).

Describe procedures that will be followed to keep subject information, specimens, and tissues secure and confidential. For example: “Your research information will be stored in a locked cabinet and will not be made a part of your regular medical record. However, if the researcher orders any tests, the order and results may become part of your regular medical record. {REGARDING ELECTRONIC STORAGE; REVISE AS REFLECTS YOUR DATA STORAGE PLAN:] Your research information will be stored electronically in encrypted, password-protected computers. It will also be stored on the cloud; the term “cloud” refers to large computers located in different parts of the world where individuals may keep and remotely access their personal and professional files. Each cloud service has its own policies and methods for preventing unauthorized individuals from accessing files stored on their cloud servers. The cloud service used to store files associated with this study meets University of Michigan protection standards. Only members of the study team will have access to your study information.”

[Genetic Information Nondiscrimination Act (GINA)](http://www.ginahelp.org/GINA_you.pdf) -- If the research involves analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes, insert the following two paragraphs:

The federal Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Under this law:

* Health insurance companies and group health plans may not request your genetic information that we obtain from this research
* Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums
* Employers with 15 or more employees may not use your genetic information that we obtain from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment

GINA does not apply to the following groups; however, these groups have policies in place that provide similar protections against discrimination:

* Members of the US Military receiving care through Tricare
* Veterans receiving care through the Veteran’s Administration (VA)
* The Indian Health Service
* Federal employees receiving care through the Federal Employees Health Benefits Plans

If your study is NIH-funded or you have or plan to obtain a Certificate of Confidentiality, insert the following:

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that we cannot release or use information, documents, or samples that may identify you in any action or suit except as described below. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other legal proceedings. An example of a situation in which the Certificate would apply would be a court subpoena for research records.

There are some important things that you need to know:

* The Certificate does not stop reporting or information-sharing that you agreed to in this consent document. For example, [Cite examples as apply to your research] we may share information with appropriate authorities if we think you may harm yourself or others. We may also share your information with other researchers.
* [Insert this statement only if applicable] The Certificate does not stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse and of some communicable diseases.
* The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs.
* The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA).
* We may also release information about you to others when you say it is okay. For example, you may give us permission to release information to insurers, medical providers, or anyone else.
* The Certificate of Confidentiality does not stop you from personally releasing information about your involvement in this research if you wish.

More information about Certificates of Confidentiality and the protections they provide is available at <https://www.era.nih.gov/erahelp/CoC_Ext/Content/A-Introduction/Introduction.htm>

**Adult Abuse -** Michigan law requires the reporting by certain persons of actual or suspected adult abuse, neglect, or exploitation. Required reporters include physicians, nurses, therapists, and other persons employed by healthcare institutions. More information about required reporting is available [here](http://www.legislature.mi.gov/(S(05je2555daxqvkmg2xxdpsfh))/mileg.aspx?page=GetObject&objectname=mcl-400-11a).

A study team may consist entirely of required reporters, a combination of required and non-required reporters, or entirely of non-required reporters.

The following language should be inserted if actual or suspected adult abuse, neglect, or exploitation may be revealed during this study:

* If you tell us or we learn something that makes us believe that you or others have been or may be abused, neglected, or exploited, we may, and in some cases must, report that information to the appropriate agencies.

**Child Abuse –** The University of Children on Campus policy requires all study team members (including university employees, students, and volunteers) who interact with minors participating as subjects in university-sponsored research to adhere to the policy, including reporting actual or suspected child abuse or neglect of any adult responsible for the child’s health and welfare. Additional information may be found [here](https://childrenoncampus.umich.edu/researchers/).

In addition, Michigan law requires the reporting of actual or suspected child abuse or neglect by certain persons (called mandated reporters). Mandated reporters include physicians, nurses, therapists, and other medical professionals. A complete list may be found [here](https://www.michigan.gov/mdhhs/adult-child-serv/abuse-neglect/childrens/mandated-reporters/mandated-reporters-list).

A study team may consist entirely of mandated reporters, a combination of mandated and non-mandated reporters, or entirely of non-mandated reporters.

The following language should be inserted if actual or suspected child abuse may be revealed during this study:

* For the parental permission form: If you tell us or we learn something that makes us believe that your child or others have been or may be abused or neglected, we may, and in some cases must, report that information to the appropriate agencies.
* For the child assent form: If you tell us or we learn something that makes us believe that you or others have been or may be abused or neglected, we may, and in some cases must, report that information to the appropriate agencies.

If you encounter actual or suspected child abuse or neglect, contact the UHMS Child Protection Team for assistance: 734.763.0215 or <http://www.mottchildren.org/conditions-treatments/ped-cpt>.

**ClinicalTrials.Gov**

**Required Registration and Reporting for ACTs**

[Applicable Clinical Trials](https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf) (ACTs) are required **by federal law** to be registered and to report results in [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov).  The federal [checklist](https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf) for evaluating whether a clinical study is an ACT under 42 CFR 11.22(b) should be consulted with careful attention to the pages associated with the initial checklist.  ACTs must use the **unaltered** consent template language provided below in the template.

**NIH and other Sponsor Requirements for Registration and Reporting**

Many sponsors require registration and some (such as NIH) also require results reporting. NIH funded clinical trials that began on or after 1/18/2017 must refer to ClinicalTrials.gov in their informed consent document (unless they are conducted under a grant submitted prior to that date, with no competing renewals on or after 1/18/2017). If the trial is an NIH funded ACT, it must use the unaltered template language for ACTs. If the trial is NIH funded but is not an ACT, use the language listed in the next paragraph for Non-ACTs.

**Registration for Non-ACTs (including for purposes of publication)**

All clinical trials should be registered to preserve the right to publish as per ICMJE requirements.

Note that this indication of registration constitutes a “promise” to participants that the trial will be registered, so it must meet that obligation. Thus, if you plan to register a trial that is not an ACT, whether because a sponsor requires it or to preserve the right to publish, replace the template statement below with the following:

“This trial will be registered and may report results on [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov), a publicly available registry of clinical trials.”

**Registries and observational studies**

Check to see if the funding agency requires it, but if the study is NOT a clinical trial (e.g., an observational study) and you do not plan to register it, you do not need to include any statement about [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) and should delete the consent template language below.

**Questions?** Contact the Medical School’s Office of Regulatory Affairs by emailing [UMMS-RegAffairs@med.umich.edu](mailto:UMMS-RegAffairs@med.umich.edu) or calling 734-647-1576.

A description of this clinical trial will be available on <http://www.clinicaltrials.gov/>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

**9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?**

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required for you to take part in the study.

If the study does not involve PHI and is not subject to HIPAA, edit or delete the following paragraph and bulleted list accordingly.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

Anything not selected in the eResearch application should be removed from the list below.

* Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
* Mental health care records (except psychotherapy notes not kept with your medical records)

If psychotherapy notes that are not part of the regular medical record will be used or disclosed for the study, separate permission is required from the subject. Investigators are advised to contact the [Health System Legal Office](http://www.med.umich.edu/u/attorney/index.html) for guidance.

* Alcohol/substance abuse treatment records
* HIV/AIDS status
* Sexually transmitted disease and/or other communicable disease status
* Genetic counseling/genetic testing records
* Health plan/health insurance records
* All records relating to your condition, the treatment you have received, and your response to the treatment
* Billing information
* Demographic information
* Personal identifiers
* Other information

The sentence below applies to all studies and should not be deleted. Delete or add examples in the bullets below as appropriate for this study unless the instructions specifically prohibit deletion. For example, delete the bullet about reporting subject payments if subjects do not receive payment for participation. Do NOT delete the bullet about University and Government officials.

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

* The researchers may need the information to make sure you can take part in the study.
* The researchers may need the information to check your test results or look for side effects.

**DO NOT DELETE** the bullet below.

* University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner and for quality improvement purposes.
* Study sponsors or funders, or safety monitors or committees, may need the information to:
  + Make sure the study is done safely and properly
  + Learn more about side effects
  + Analyze the results of the study
* Insurance companies or other organizations may need the information to pay your medical bills or other costs of your participation in the study.

Do not delete the bullet below unless you are certain that the data or specimens will **not** be used for:

future IRB-approved research studies

a technology transfer or licensing agreement.

Contact [Innovation Partnerships](https://innovationpartnerships.umich.edu/) if you are uncertain.

* The researchers may need to use the information to create a databank of information about your condition or its treatment.

**Do not delete the first bullet below** unless you are certain information will not be included in the medical record.

* Information about your study participation may be included in your regular Michigan Medicine medical record.
* If you receive any payments for taking part in this study, the University of Michigan finance department will need your name and address for tax reporting purposes. In a calendar year if: 1) your payments total greater than $400 for this study or 2) if you receive payments of greater than $400 for being in more than one study, the University of Michigan finance department will also require your Social Security Number for tax reporting purposes. If you do not wish to provide your Social Security Number, you may continue to participate in research studies, but you will not be able to receive payment for the remainder of the calendar year.
* Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

Alternate language for use when identifying information will be used in publications or presentations: "The results of this study may be published or presented at a scientific meeting. If your name or other information that might identify you will be used in the publications or presentations, the researchers will ask for your separate written permission." Likewise, if video or audio recordings or photographs of the subject will be used: "If your name and pictures will be used in any publications or presentations, the researchers will ask for your separate written permission." If the study involves photography or video/audio recording, obtain subject signature at Sig-B.

**9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?**

Alternate language for non-PHI/HIPAA-regulated studies: "…leave the study before it is finished…"

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Alternate language for non-PHI/HIPAA-regulated studies: "…even after you have left the study…"

Examples of reasons for this include:

* To avoid losing study results that have already included your information
* To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
* To help University and government officials make sure that the study was conducted properly

If your information is kept within the University of Michigan Health System, it is protected by the Health System’s privacy policies. For more information about these policies, ask for a copy of the University of Michigan “Notice of Privacy Practices”. This information is also available on the web at <http://www.uofmhealth.org/patient+and+visitor+guide/hipaa>. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

If the study does not involve PHI and is not subject to HIPAA, and this statement does not otherwise apply, investigators should edit or delete this paragraph accordingly.

**9.4 When does my permission to use my PHI expire?**

Your permission does not expire unless you cancel it. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

Alternate language, if applicable: "Your permission expires at the end of the study, unless you cancel it sooner.”

**10. Contact Information**

**10.1 Who can I contact about this study?**

Please contact the researchers listed below to:

* Obtain more information about the study
* Ask a question about the study procedures or treatments
* Talk about study-related costs to you or your health plan
* Report an illness, injury, or other problem (you may also need to tell your regular doctors)
* Leave the study before it is finished
* Express a concern about the study

Principal Investigator:  
Mailing Address:  
Telephone:

Study Coordinator:  
Mailing Address:  
Telephone:

**INTERNATIONAL STUDIES**:

For research projects conducted outside the US, IRBMED will require the [US Country Code](http://www.countrycodes.com/international-dialing-codes.php) be included. **For example, calling the US from Australia the number would be 0011 +1 + XXX-XXX-XXXX.**

If a local IRB or ethics committee has reviewed the project, IRBMED will require that the contact information (email, telephone number (including Country Code) and address as applicable) for the local IRB or ethics committee be included in the consent document. IRBMED may require that investigators provide contact information for a local individual or organization that can assist subjects in relaying questions or complaints to IRBMED, particularly for projects involving more than minimal risk to subjects.

**You may also express a question or concern about a study by contacting the Institutional Review Board listed below:**

University of Michigan Medical School Institutional Review Board (IRBMED)  
2800 Plymouth Road  
Building 520, Room 3214  
Ann Arbor, MI 48109-2800  
Telephone: 734-763-4768 (For International Studies, include the appropriate [calling codes](http://www.countrycodes.com/international-dialing-codes.php).)  
Fax: 734-763-1234  
e-mail: [irbmed@umich.edu](mailto:irbmed@umich.edu)

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

*When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.*

**11. record of Information provided**

**11.1 What documents will be given to me?**

If you provide the subject with other information such as a study calendar/diary, Notice of Privacy Practices or information about advance directives for research list the documents in the bullet labeled “Other”.

Otherwise, you may delete only that bullet.

You will receive a copy of the signed and dated informed consent document.

Your signature in the next section means that you have received a copy of the following document(s):

* This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*
* Other (specify):

A copy of the complete (every page) signed consent form should be placed in the UM medical record of subjects, particularly when the research intervention may affect other treatment or care (use the “Scan Informed Consent into MiChart” process described at the [MiChart Research Tip Sheets](http://www.med.umich.edu/i/michart/training/tips_Research.html)). ***However***, doing so may **not** be appropriate in all cases (for example if identification of the subject as a study participant might put the subject at risk of criminal prosecution or harm to reputation). If that is the case, replace "…and may…" with "…but will **not**…" If more appropriate for this study, the portion of the sentence after "…separate research file…" may be deleted altogether.

**12. Storage, Use, and sharing of specimens and information collected or generated in the study described above**

If your study includes one or more sub-studies and/or unspecified future use, insert the following statement, after modifying it to accurately reflect your circumstance:

The information that follows applies to information and/or specimens collected and/or used in both the main study and the sub-study/-ies, as well as to unspecified future use of your information and/or samples.

**12.1 What is meant by the storage, future research use, and sharing of study participants’ medical information and leftover samples (sometimes referred to as biospecimens) taken from me?**

Individual researchers, the University of Michigan, and companies that design and sponsor studies often want to keep subjects’ medical information and leftover samples such as blood, tissue, saliva, and cells to use in future research. These future research uses take different basic forms, which are described below. The medical information and leftover samples may also be shared with other researchers so that they can use it in their studies.

The purpose of storing, using, and sharing participants’ medical information and leftover samples is to promote more research that might lead to useful medical discoveries.

In some cases, researchers need your consent to store, use, and share your medical information and leftover samples; in other cases, they can store, use and/or share it without your consent. Whether or not researchers need your consent depends on if the stored information and samples would still be identifiable as yours or whether the researchers would first remove all information connecting them back to you.

**12.2 Types of storage, future research use, and sharing in this study**

The help text boxes labeled **12.2-A** through **12.2-E** in this section address different storage, use, and sharing scenarios. Whether the information in each box applies to your research depends on your study design, funding source, and other factors. In some cases, the information within a help text box is designed to satisfy federal or other requirements. Carefully consider the information in each of these five help text boxes to determine whether it applies to your research.

* **12.2-A:** Storage, use, and sharing of data in all research subject to the Common Rule (45 CFR 46 Subpart A)
  + The language provided in this box satisfies a requirement in OHRP’s 2018 revised Common Rule that potential subjects be informed as to whether their deidentified data may be used and shared in the future without their additional consent. Every consent document submitted to IRBMED must contain one of the two passages contained in this box, depending on sponsorship type.
* **12.2-B:** NIH policies and requirements
  + This box addresses NIH’s data sharing requirements for all research that receives NIH funding. These requirements correspond to two NIH policies, both of which are addressed within box 12.2-B:
    - NIH data management and sharing (DMS) policy
    - NIH genomic data sharing (GDS) policy

If your research receives NIH funding, one or both of these policies apply.

* **12.2-C:** Nonoptional unspecified future use and sharing of information and samples
  + This information applies to research in which storage, use, and sharing of subject data are built into the study design and in which subjects may not participate unless they permit these uses of their data.
* **12.2-D:** Genomic data sharing in non-NIH-funded research
  + This box is for use by researchers whose genomic research is not funded by NIH, and therefore not subject to the GDS policy, but who nevertheless choose to share genomic data.
* **12.2-E:** Optional unspecified future use and sharing of identifiable information and samples
  + This information applies to studies in which subjects are asked for consent to the storage, use, and sharing of their data but may participate in the research even if they do not consent to these optional uses of their data.

**12.2-A — Storage, future use, and sharing of data in all research subject to the Common Rule (45 CFR 46 Subpart A)**

In all instances of research subject IRBMED oversight, one of the following two passages will apply. The two passages correspond to two sponsorship scenarios:

* Industry-sponsored research
* Investigator-initiated or -sponsored research

Choose the pertinent passage and paste it into the body of this consent document.

*Investigator-initiated research*

For purposes of this research study, your collected private information and any biospecimens will be shared with the study sponsor, [PROVIDE SPONSOR NAME INCLUDING U-M IF ACTING AS SPONSOR], its collaborators, and associated research partners.

With appropriate institutional and regulatory permissions, your collected private information and identifiable biospecimens could be used for future research with other researchers and companies, including those in other countries, with or without your consent.

In addition, after identifiers are removed from your private information and any biospecimens, the information and biospecimens could be used for future research studies by U-M and shared with other researchers or companies, including those in other countries, without your additional informed consent.

Or:

*Industry-initiated or -sponsored research*

For purposes of this research study, your coded private information and any coded biospecimens will be shared with the study sponsor, [PROVIDE SPONSOR NAME], its collaborators, and associated research partners.

In addition, after any remaining identifiers are removed from your coded private information and any biospecimens, the information and biospecimens could be used for future research studies and shared with other researchers without your additional informed consent.

In most instances of storage, use, and sharing of subject data, subjects may, after consenting to storage, use, and/or sharing, later change their minds and rescind their consent to this activity.

Insert here a statement like the following, modifying the text to correspond to which types of storage, use, and sharing apply to your plans.

In each of the situations described below, you may later change your mind and withdraw your consent to the storage, use, and sharing of your information even if you give consent now, provided that the information can still be identified as yours, has not already been used or shared, or has not been added to your medical record. Keep in mind, however, that any information that has already been used or shared with other researchers, as well as any information that has been added to your medical record, cannot be recovered, or deleted.

[IF ANY STORAGE, USE, AND SHARING WILL BE NONOPTIONAL] Keep in mind, too, that in cases where giving us your permission to store, use, or share your information is necessary in order for you to participate in this study, changing your mind later and withdrawing your consent to that storage, use, or sharing will also mean that you can no longer take part in the study, and we will remove you unless your participation has already ended.

**12.2-B — NIH policies and requirements**

If your research does not receive NIH funding, no NIH policy requirements apply to your study.

If your research does receive NIH funding, select the appropriate passage(s) to reflect your study and its compliance with these NIH policies. In this series of help text boxes, the National Institutes of Health’s various policies and requirements are addressed. These include:

* NIH’s data management and sharing (DMS) policy
* NIH’s genomic data sharing (GDS) policy

**NIH data management and sharing (DMS) policy**

The National Institutes of Health (NIH)’s Data Management and Sharing (DMS) policy, which took effect in January 2023, requires researchers receiving NIH funding to develop plans for making research data available to other researchers, in accordance with criteria and definitions outlined in the policy, which can be viewed here.

NIH’s policy does not forbid what it refers to as the “open sharing” of data, meaning utilization of sharing mechanisms that are publicly available without securing special authorization from the data’s holders. Open sharing is permitted provided that it occur “in ways that are consistent with consent practices [this includes compliance with all federal and institutional consent requirements], established norms, and applicable law” and “as long as participants are appropriately informed and prospectively agree to them.”

Within the language offered in the following blue box, select where indicated the statement that reflects whether you plan to make data available through open access or plan to use sharing mechanisms that require special authorization before data are shared.

Likewise, select the appropriate statement, where indicated, that reflects whether data sharing is a necessary condition of study participation or an optional component that subjects may choose not to allow.

*(DMS policy information continues in the next blue box.)*

**12.2-B — NIH policies and requirements (continued)**

*(DMS policy information continues here.)*

If your research receives NIH funding and the accepted funding proposal includes a DMS plan, insert the following:

**NIH data management and sharing (DMS) policy**

This study receives funding from the National Institutes of Health (NIH). NIH requires us to develop a plan regarding how we may share some information about you with other researchers so that they can use it in their studies. Their research may be similar to this study or may be completely different. Once we have shared information about you with other researchers, we will not be able to get it back.

Although we will do our best to protect your information, both during storage and when sharing it with others, it’s possible that unauthorized people might gain access to your information.

Select the statement that reflects the **identifiability of data** according to your sharing plan:

[IF DATA WILL BE CODED] We will assign your information a random code, rather than your name or any other details that others could use to identify you, before sharing it with other researchers. [PARTY IN POSSESSION OF CODE KEY] will securely store the code key that links your coded information to you.

[IF DATA WILL BE DEIDENTIFIED] We will remove all details from your information that identify you individually and assign it a random code before sharing it with other researchers. Once we have removed and destroyed those identifying details, it will be impossible for others to know the information came from you.

[IF DATA WILL BE FULLY IDENTIFIABLE, THE STUDY TEAM SHOULD CONTACT THE IRBMED OFFICE FOR GUIDANCE AS TO CONTENT.].

Select the statement that reflects your **data sharing plan**:

[Controlled access plan] Researchers who wish to access your information must obtain permission to access your information.

[Open access plan] Your information will be openly available to the public. Researchers who wish to access and use your information in their studies will not be required to obtain permission.

You will not find out the results or directly benefit from future research utilizing your information. Sharing your information may contribute to research that helps others in the future.

Select the paragraph that reflects your **data sharing plan**:

[Optional data sharing plan] You do not have to agree to storage and sharing of your information if you do not wish to. You may take part in this study even if you do not want us to share your information with other researchers. You will indicate your choice regarding storage and sharing of your information in a signature box at near the end of this document.

[Nonoptional data sharing plan] Permitting us to store and share your information is a condition of participating in this study. If you do not want us to share your information with other researchers, you should not take part in this study.

**12.2-B — NIH policies and requirements (continued)**

*NIH genomic data sharing (GDS) policy*

**The instructions within this box pertain to genomic data collection and sharing. If your NIH-funded study does not involve the collection and/or sharing of genomic data, these instructions do not apply.** If you have explained DNA, genomics, and/or repositories elsewhere within this document, it may be unnecessary to insert some or all of the sample text below.

NIH‐funded research that generates large‐scale human or non‐human genomic data is subject to NIH’s policy on broad sharing of genomic and phenotypic (observable physical characteristics) data. Click here to review the NIH policy.

For research that is subject to the NIH policy, insert the following language. Be certain to specify at paragraph 3 whether researchers will have *controlled* or *unrestricted* access to repository data.

**NIH genomic data sharing (GDS) policy**

As part of this study, we will collect and store information about your genes. The DNA contained in your genes holds the instructions that your body uses to grow and function. Your genes are responsible for your physical features such as eye color, blood type, and how your body breaks down medications. Genes can also be responsible for some medical conditions.

*Genomic* information relates to the structure and function of all of the genetic material in the body.

We will submit your genomic information to a repository [managed by the University of Michigan/federal government/external sponsor] to be used for scientific purposes. A repository contains information from many people.

OPTIONAL, IF APPLICABLE: Researchers all over the world can take information from the repository and use it in their studies. Their studies may be similar to this one or may be completely different (NIH, GWAS, etc.).

Because this research receives funding from the National Institutes of Health (NIH), we will submit your genomic information to a public repository approved by NIH. NIH is a national research agency and is part of the federal government.

We will label your genomic information with a code, instead of your name or other information that people could use to directly identify you. Even so, there is a possibility that when your genomic information is combined with other information available to researchers, either now or in the future, they may be able to identify a group you belong to (like an ethnic group or a disease population) or, less likely, you personally. NIH prohibits people from trying to identify individuals whose genomic information is in an NIH-designated repository.

Researchers will have *controlled access* to your specific genomic information. Controlled access means that researchers will need approval from NIH in order to obtain genomic information from the repository.

*Or:*

Researchers will have *unrestricted access* to your specific genomic information. Unrestricted access means that researchers may obtain genomic information from the repository without special approval from NIH.

[INCLUDE THIS STATEMENT IF GENOMIC SUMMARY RESULTS WILL HAVE UNRESTRICTED ACCESS: Summarized information about you and others may be shared in scientific literature or made publicly available. This summarized information does not contain individual-level information about specific people, but summarizes information about a group of people.]

**12.2-C — Nonoptional unspecified future use and sharing of identifiable information and biospecimens**

**NOTE:**

* If your study is *UM investigator-initiated* and has no external sponsor, use the prewritten language below in the blue box.
* If your study is *industry sponsored*, do not use the below language; rather, use unspecified future use consent language provided by the company sponsoring the research.
* If your study is part of a multi-site project in which another institution will maintain specimens and data for unspecified future use, do not use the language below; rather, use unspecified future use language consent prepared by the site maintaining the specimens and data.
* In most instances, storage, future use, and/or sharing should be optional, meaning that potential subjects should be asked for separate consent to those purposes. Although making consent to those purposes a necessary condition of study participation is not categorically prohibited, IRBMED strongly discourages nonoptional storage, use, and sharing in all cases of research that offer potential for direct benefit, as the value of this hoped-for benefit may exert undue influence over potential subjects’ willingness to permit storage, future use, and sharing.

*(Nonoptional unspecified future use information continues in the next blue box.)*

**12.2-C — Nonoptional unspecified future use and sharing of identifiable information and biospecimens (continued)**

*(Nonoptional unspecified future use information continues here.)*

*The following language is for collection* *for* *unspecified future use* of subjects’ identifiable data and/or biospecimens. *Prior to use* of these identifiable data and/or biospecimens, you must submit an application to the IRB for review and approval.

**Collection and use of your biospecimens and/or information for future research**

We will also keep some of your identifiable [BLOOD/BIOSPECIMEN] and medical information collected in the main study, so that it may be studied in future research. The future research may be similar to this study or may be completely different.

This storage and use of your [BLOOD/BIOSPECIMEN] and medical information is a necessary condition of your participation in this study. If you do not wish to allow us to store, use, and share your information and samples in the future, you should not take part in this study.

We will use your [BLOOD/BIOSPECIMEN] and medical information for future research. Even if you give us permission now to keep some of your [BLOOD/BIOSPECIMEN] and medical information, you can change your mind later and ask us to destroy it. If you do change your mind, you cannot continue participating in the study. We will do our best to get your information and specimens back from the other researchers we’ve shared them with. However, there may be times we cannot. For example, if we are unable to tell which information and specimens came from you, we will not be able to get them back. Additionally, any information that has been added to your medical record cannot be deleted. Also, keep in mind that once we have analyzed your [BLOOD/BIOSPECIMEN], we may not be able to take the information out of our research study.

We may share your [BLOOD/SPECIMEN] and medical information with other researchers, so that they can use it in their research. Their research may be similar to this study or may be completely different. Once we have shared your BLOOD/SPECIMEN and medical information with other researchers, we will not be able to get it back.

[INDICATE ADDITIONAL RISKS THE FUTURE RESEARCH MAY POSE AND DESCRIBE EFFORTS TO MINIMIZE THEM]. Although we will do our best to protect your information and specimens, both during storage and when sharing them with others, it’s possible that someone may be able to identify you from them. It’s also possible that unauthorized people might gain access your information and/or specimens. To try to minimize both of these risks, we will assign your information and specimens a random code before sharing them with other researchers. [PARTY IN POSSESSION OF CODE KEY] will securely store the code key that links your coded information and specimens to you. Future use of your identifiable data and/or specimens will be conducted in compliance with applicable regulatory requirements.

You will not find out the results or directly benefit from future research on your [BLOOD/SPECIMEN]. Sharing your information and specimens may contribute to research that helps others in the future.

**12.2-D — Genomic data sharing in non-NIH-funded research**

**The instructions within this box pertain to genomic data collection and sharing. If your non-NIH-funded study does not involve the collection and/or sharing of genomic data, these instructions do not apply.** If you have explained DNA, genomics, and/or repositories elsewhere within this document, it may be unnecessary to insert some or all of the sample text below.

**Genomic data sharing**

As part of this study, we will collect and store information about your genes. The DNA contained in your genes holds the instructions that your body uses to grow and function. Your genes are responsible for your physical features such as eye color, blood type, and how your body breaks down medications. Genes can also be responsible for some medical conditions.

*Genomic* information relates to the structure and function of all of the genetic material in the body.

We will submit your genomic information to a repository [MANAGED BY THE UNIVERSITY OF MICHIGAN, THE FEDERAL GOVERNMENT, OR THE EXTERNAL SPONSOR] to be used for scientific purposes. A repository contains information from many people.

We will label your genomic information with a code, instead of your name or other information that people could use to directly identify you. Even so, there is a possibility that when your genomic information is combined with other information available to researchers, either now or in the future, they may be able to identify a group you belong to (like an ethnic group or a disease population) or, less likely, you personally.

If you allow us to put your genomic information in the repository, you can change your mind later and ask [THE UNIVERSITY OF MICHIGAN OR EXTERNAL SPONSOR] to remove it. Keep in mind, however, that we cannot take back information that other researchers have already obtained from the repository.

**12.2-E — Optional unspecified future use and sharing of identifiable information and biospecimens**

**Obtain subject signature at box Sig-D (section 13).**

**NOTE:**

* If your study is *UM investigator-initiated* and has no external sponsor, use the prewritten language below in the blue box.
* If your study is *industry sponsored*, do not use the below language; rather, use unspecified future use consent language provided by the company sponsoring the research.
* If your study is part of a multi-site project in which another institution will maintain specimens and data for unspecified future use, do not use the language below; rather, use unspecified future use language consent prepared by the site maintaining the specimens and data.

*The following language is for collection* *for* *unspecified future use* of subjects’ identifiable data and/or biospecimens. *Prior to use* of these identifiable data and/or biospecimens, you must submit an application to the IRB for review and approval.

**Optional collection/use of your specimens and/or information for future research**

We would also like your permission to keep some of your identifiable [BLOOD/SPECIMEN] and medical information collected in the main study, so that it may be studied it in future research. The future research may be similar to this study or may be completely different.

You can take part in the main study even if you decide not to let us keep your identifiable [BLOOD/SPECIMEN] and medical information for future research.

If you give us your permission, we will use your identifiable [BLOOD/SPECIMEN] and medical information for future research. Even if you give us permission now to keep some of your identifiable [BLOOD/SPECIMEN] and study information collected in the study, you can change your mind later and ask us to destroy it. If you do change your mind, we will attempt to get your information and biospecimens back from the other researchers we’ve shared them with. However, there may be times we cannot. For example, if we are unable to tell which information and biospecimens came from you, we will not be able to get them back. Additionally, any information that has been added to your medical record cannot be deleted. Also, keep in mind that once we have analyzed your [BLOOD/BIOSPECIMEN], we may not be able to take the information out of our research study.

We may share your [BLOOD/SPECIMEN] and medical information with other researchers, so that they can use it in their research. Their research may be similar to this study or may be completely different. Once we have shared your BLOOD/SPECIMEN and medical information with other researchers, we will not be able to get it back.

[INDICATE ADDITIONAL RISKS THE FUTURE RESEARCH MAY POSE AND DESCRIBE EFFORTS TO MINIMIZE THEM]. Although we will do our best to protect your information and specimens, both during storage and when sharing them with others, it’s possible that someone may be able to identify you from them. It’s also possible that unauthorized people might gain access your information and/or specimens. To try to minimize both of these risks, we will assign your information and specimens a random code before sharing them with other researchers. [PARTY IN POSSESSION OF CODE KEY] will securely store the code key that links your coded information and specimens to you. Future use of your identifiable data and/or specimens will be conducted in compliance with applicable regulatory requirements.

You will not find out the results or benefit directly from future research on your [BLOOD/SPECIMEN]. Sharing your information and specimens may contribute to research that helps others in the future.

**13. Signatures**

Add this information to the bottom of the Consent/Assent box only if required by sponsor:

Date of Birth (mm/dd/yy): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

ID Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Consent/Assent -** The following signature block may be used to document consent of an adult or the assent of a child or adult unable to fully provide consent. The subject consents or assents to participate in the study by signing on the signature line.

For assenting subjects, investigators may choose to insert the words "Assenting Subject" before the word "Signature" in the signature line. Permission of the Legally Authorized Representative(s) is always required for assenting subjects (see second blue box, below).

**Sig-A**

**Consent/Assent to Participate in the Research Study**

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with [NAME OF STUDY TEAM MEMBER OBTAINING CONSENT] \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Signature (mm/dd/yy): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Sig-B**

**Consent/Assent to video/audio recording/photography solely for purposes of this research project**

This study involves video and/or audio recording and/or photography. If you do not agree to be recorded, you [CAN STILL/CANNOT] take part in the study.

\_\_\_\_\_ Yes, I agree to be video/audio recorded/photographed (signature required below).

\_\_\_\_\_ No, I do not agree to be video/audio recorded/photographed (no signature).

Print Legal Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Signature (mm/dd/yy): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Sig-C**

**Consent/Assent for Participating in an Optional Sub-Study**

This project involves optional participation in a sub-study. I understand that it is my choice whether or not to take part in the sub-study. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

\_\_\_\_\_ Yes, I agree to take part in this optional sub-study (signature required below).

\_\_\_\_\_ No, I do not agree to take part in this optional sub-study (no signature).

Print Legal Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Signature (mm/dd/yy): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Sig-D**

**Consent/Assent to Collect for Unspecified Future Research**

This project involves the option to allow the study team to keep your identifiable specimens/data for use in future research. I understand that it is my choice whether or not to allow future use of my specimens. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

\_\_\_\_\_ Yes, I agree to let the researchers keep my specimens for future research (signature required below).

\_\_\_\_\_ No, I do not agree to let the researchers keep my specimens for future research (no signature).

Print Legal Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Signature (mm/dd/yy): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Legally Authorized Representative(s) -** If the above signature block(s) is/are used for assent, the following signature block(s) should be used to document the permission of the person(s) serving as the legal representative(s). Certain projects involving minors require the permission of both parents (see the second blue box below).

If you are unsure whether a particular person is legally authorized to give consent, contact the Health System Legal Office at (734) 764-2178.

**Wards -** Federal regulations require the IRB to appoint an advocate before a ward of the state is enrolled in a study approved under 45 CFR 46.406 and/or 45 CFR 46.407. Call the IRB office immediately upon considering a ward for such a study. If it is after hours or the weekend page the Pediatric Ethics Committee on-call representative and explain that you need an advocate appointed for a ward to participate in a research study. Section 33.4 of the eResearch application will indicate under which regulation(s) the study is approved.

**Sig-E**

**Legally Authorized Representative or Parent Permission**

Subject Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Parent/Legally Authorized Representative:**

Printed Legal Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Signature (mm/dd/yy): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Relationship to subject: Parent Spouse Child Sibling Legal guardian Other

*If “Other,” explain: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

Reason subject is unable to consent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*If this consent is for a child who is a ward of the state (for example, a foster child), please tell the study team immediately. The researchers may need to contact IRBMED.*

**Two-Parent Signature Requirement for Minor Subjects**

If the study involves minor subjects and the IRBMED has determined that the permission of one parent is sufficient, the Second Parent Permission box below should be deleted.

If the study involves minor subjects with no prospect of direct benefit to the minor subject and the risks are assessed by the IRBMED to be greater than minimal, the consent of both parents (or of the legal guardian) is required.

Research that holds out the prospect of direct benefit solely to the fetus requires the permission of both parents unless the father is unavailable, incompetent, or temporarily incapacitated, or if the pregnancy resulted from rape or incest.

When the second parent’s permission is not documented, indicate the reason (see the end of the Second Parent Permission box).

**Sig-F**

**Second Parent Permission**

Printed Legal Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Signature (mm/dd/yy): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Reason second parent permission was not collected:*

Parent is deceased Parent is unknown

Parent is incompetent Only one parent has legal responsibility for care and custody

Prospect of direct benefit solely to the fetus and pregnancy resulted from rape or incest

Parent is not reasonably available\*; explain: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*\* Note: “Not reasonably available” means the other parent is not able to be contacted by phone, mail, email, or fax, or his or her whereabouts are unknown. It does not mean that the other parent is at work or home, or that he or she lives in another city, state, or country.*

**Principal Investigator or Designee –** The following signature block is to ensure that the participant was given sufficient information to be able to freely consent. This signature, which is required, should be from the person who actually conducted the informed consent and is familiar with the study procedures, such as the PI, Co-I, study coordinator, or other qualified member of the research team designated by the PI.

**Sig-G**

**Principal Investigator or Designee**

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Signature (mm/dd/yy): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Witness –** The witness signature is optional and should be deleted unless required by the study sponsor.

Per ICH GCP 4.8.9, add the word “**Impartial**” to the Witness signature box for instances where an illiterate subject is enrolled in the research or an illiterate LAR is asked to sign the informed consent on behalf of the illiterate subject.

**Sig-H**

**Witness**

I observed the above subject (or his/her legally authorized representative, if applicable) sign this consent document.

Printed Legal Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Signature (mm/dd/yy): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**(OPTIONAL) APPENDIX:**

**INFORMED CONSENT TO A SUB-STUDY**

**NOTE:** *Use this appendix to summarize your sub-study only if it involves different/additional (e.g., additional biopsy) interventions and/or risks from those applicable to the main study. If your sub-study does not involve additional interventions or risks, address it in section 4.1 (above) and delete this entire appendix.*

*Likewise, if your research plan does not include a sub-study at all, delete this entire appendix.*

**C — Sub-studies with specified designs — Part 1 of 2**

Utilize the proper signature box.

The instructions within this box pertain to optional sub-studies that you have already designed; if you expect to use subjects’ data/specimens in future research but have not yet determined how they will be used, do not utilize this appendix. Instead, refer to blue text box D in section 4.4 above (“Collection for unspecified future research”).

If your study does not offer subjects the option to participate in a sub-study, these instructions do not apply. Sub-studies included in this manner are usually very limited in the scope of new interventions and/or data collection.

For research studies that include related sub-studies, the subject must opt-in to the sub-study (meaning give consent).  You may still allow a subject who decides not to take part in the sub-study to take part in the main study.

Explain in lay terms, usually in chronological order, what will happen to subjects during the sub-study. If appropriate, describe medical care or other procedures that would be performed whether or not the subject participated in the sub-study. Use the format required for the main study. Be sure to distinguish the research-only or experimental procedures from routine or regular care.

The researcher must obtain a separate signature from the subject for the sub-study. See below for more information.

**C — Sub-studies with specified designs (continued) — Part 2 of 2**

For a *sub-study with a specified design*, language should include, as applicable:

Besides the information about the main study, the following information is specific to an optional sub-study. We/The sponsor would like your permission to study your [BLOOD/SPECIMEN] and medical information to find out [SPECIFIC PURPOSE]. You can take part in this study even if you decide not to let us/them analyze your [BLOOD/SPECIMEN] to find out [SPECIFIC PURPOSE].

Even if you give us/them permission now to keep some of your [BLOOD/SPECIMEN] and medical information, you can change your mind later and ask us/them to destroy it. Keep in mind, however, that once we/they have analyzed your [BLOOD/SPECIMEN], we/they may not be able to take the information out of our research. Also, if we/they have shared some of your BLOOD/SPECIMEN and medical information with other researchers, we/they will not be able to get it back.

[INDICATE ADDITIONAL RISKS SUB-STUDY POSES AND DESCRIBE EFFORTS TO MINIMIZE THEM (E.G., THE GINA LAW).]

You [WILL/WILL NOT] receive the results of the analysis of your [BLOOD/SPECIMEN]. Allowing us/the sponsor to study your [BLOOD/SPECIMEN] and medical information to find out [SPECIFIC PURPOSE] will not benefit you directly.

As part of this sub-study, your samples and collected information will be shared with [SPONSOR NAME OR DELETE THIS SENTENCE IF THERE IS NO SPONSOR].

With appropriate permissions, your samples and collected information may also be shared with other researchers, here, around the world, and with companies.[DELETE THIS SENTENCE IF THE SPONSOR OR SPONSOR INVESTIGATOR WILL NOT SHARE THE SAMPLES AND COLLECTED INFORMATION.]

Your identifiable private information or identifiable biospecimens may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

**Optional Participation in a Sub-Study -** The following signature block must be used to document consent of an adult or the assent of a child or adult unable to fully provide consent for to participation in an optional sub-study. The subject consents or assents to participate in the sub-study by selecting the YES box and signing on the signature line.

For assenting subjects, investigators may choose to insert the words "Assenting Subject" before the word "Signature" in the signature line. Permission of the Legally Authorized Representative(s) is always required for assenting subjects (see the next blue box, below).

**Sig-C**

**Consent/Assent for Participating in an Optional Sub-Study**

This project involves optional participation in a sub-study. I understand that it is my choice whether to take part in the sub-study. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

\_\_\_\_\_ Yes, I agree to take part in this optional sub-study (signature required below).

\_\_\_\_\_ No, I do not agree to take part in this optional sub-study (no signature).

Print Legal Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Signature (mm/dd/yy): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Sig-B**

**Consent/Assent to video/audio recording/photography solely for purposes of this research**

This study involves video and/or audio recording and/or photography. If you do not agree to be recorded, you [CAN STILL/CANNOT] take part in the study.

\_\_\_\_\_ Yes, I agree to be video/audio recorded/photographed (signature required below).

\_\_\_\_\_ No, I do not agree to be video/audio recorded/photographed (no signature).

Print Legal Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Signature (mm/dd/yy): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Sig-E**

**Legally Authorized Representative or Parent Permission**

Subject Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Parent/Legally Authorized Representative:**

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Signature (mm/dd/yy): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Relationship to subject: Parent Spouse Child Sibling Legal guardian Other

*If “Other,” explain: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

Reason subject is unable to consent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*If this consent is for a child who is a ward of the state (for example, a foster child), please tell the study team immediately. The researchers may need to contact IRBMED.*

**Sig-F**

**Second Parent Permission**

Legal Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Signature (mm/dd/yy): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Reason second parent permission was not collected:*

Parent is deceased Parent is unknown

Parent is incompetent Only one parent has legal responsibility for care and custody

Prospect of direct benefit solely to the fetus and pregnancy resulted from rape or incest

Parent is not reasonably available\*; explain: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*\* Note: Not reasonably available means the other parent is not able to be contacted by phone, mail, email, or fax, or his or her whereabouts are unknown. It does not mean that the other parent is at work or home, or that he or she lives in another city, state, or country.*

**Sig-H**

**Witness**

I observed the above subject (or his/her legally authorized representative, if applicable) sign this consent document.

Legal Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Signature (mm/dd/yy): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_