**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 CREATIING 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.

Orange text boxes contain instructions for studies subject to Good Clinical Practice (**GCP**) standards developed by the International Conference on Harmonization (**ICH**).

If your research is not subject to **ICH GCP** requirements, the information contained within orange text boxes **does not** apply to your study.

**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 staff 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 subjects, 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 friends, family, 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 child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

[copy/paste the appropriate study descriptor below that describes the phases or the nature of the study and the role of the participant in the research. 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 research is studying the use of a new [DRUG/DEVICE] in small numbers of people to learn about its safety as a treatment for [DISEASE/CONDITION]. Researchers want to understand how the [DRUG/DEVICE] works in your body and how your body will react to it. This study will [PROVIDE A BRIEF EXPLANATION OF THE PURPOSE AND THE PROCEDURES OF THE STUDY]. Your health-related information [INDICATE ANY BIOSPECIMEN COLLECTION] will be collected for this research study.

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

This research is studying a new [DRUG/DEVICE] in small numbers of people to learn about its safety and its effect on your body at certain doses [DELETE DOSE LANGUAGE IF STUDY IS A DEVICE] as a treatment for [DISEASE/CONDITION]. This study will [PROVIDE A BRIEF EXPLANATION OF THE PURPOSE AND THE PROCEDURES OF THE STUDY]. Your health-related information [INDICATE ANY BIOSPECIMEN COLLECTION] will be collected for this research study.

**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]. Your health-related information [INDICATE ANY BIOSPECIMEN COLLECTION] will be collected for this research 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]. Your health-related information [INDICATE ANY BIOSPECIMEN COLLECTION] will be collected for this research 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/ ONDITION]. This research will [PROVIDE A BRIEF EXPLANATION OF THE PURPOSE AND THE PROCEDURES OF THE STUDY]. Your health-related information [INDICATE ANY OTHER DATA OR BIOSPECIMEN COLLECTION] will be collected for this research 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].

[ADD ANY SPECIAL CIRCUMSTANCES AS LISTED BELOW FOR RANDOMIZATION OR WASHOUT (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; SEE EXAMPLES BELOW.] More detailed information will be provided later in this document.

serious health complications of your current [DISEASE/CONDITION] such as [BRIEFLY DESCRIBE]

no improvement of your current [DISEASE/CONDITION]

new symptoms from use of the [drug/device] such as [BRIEFLY DESCRIBE]

[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 the amount of time you will participate in the study will be [INDICATE HOW LONG SUBJECTS 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". For 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 subjects 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 subjects 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 subjects are expected to participate, 25 at the University of Michigan and 275 at other sites around the United States." If the study includes different subject pools (control group/affected group), note that also. For example: "100 total subjects (25 subjects with Alzheimer’s disease and 75 healthy subjects)".

**4. information about study participation**

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

**A — General study procedures**

**The instructions within this box pertain to all studies.**

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 or 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 [section12])
* 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.

Per ICH GCP 4.8.10(c), add information about the trial treatments and the **probability for random assignment** to each treatment *(e.g., flip of a coin, one-in-three chance, etc.)*.

Per ICH GCP 4.8.10(e), 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 of your scheduled appointments, take your study medication as directed, and report any adverse reactions you may have during the study.

**Required language for blinded studies:**

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.

**B — Genomic data sharing — Part 1 of 2**

**The instructions within this box pertain to genomic data sharing. If your study does not involve the collection and 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 language may include the following:

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 to be used for scientific purposes. A repository contains information from many people. Some repositories are maintained by the University of Michigan, some are maintained by the federal government, and some are maintained by private companies.

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.

**Genomic data sharing (continued) — Part 2 of 2**

The instructions that follow are divided to reflect two different scenarios: non-NIH-funded research and NIH-funded research. Select the instructions applicable to your genomic study, based on whether your research is NIH-funded and therefore subject to the [NIH Genomic Data Sharing Policy](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html).

**Scenario 1: Genomic research *not* receiving NIH funding**

For non-NIH-funded research, insert the following language:

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 us to remove it. Keep in mind, however, that we cannot take back information that other researchers have already obtained from the repository.

**Scenario 2: Genomic research receiving NIH funding and subject to the GDS Policy**

As of January 25, 2015, 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 data. [Click here](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html) 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.

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.

*Select: 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.

If you allow us to put your genomic information in the repository, you can change your mind later and ask us to remove it. Keep in mind, however, that we cannot take back information that other researchers have already obtained from the repository.

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

**Obtain subject signature at box Sig-C (section 12).**

**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 box D instead (“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. 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 sub-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, etc.),
* Experimental intervention/interaction (e.g., study drug or device, experimental neuropsychological test, etc.)
* Data collection (e.g., blood samples, CT scan, office visit, EKG, survey, etc.)
* Other research procedures or activities

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.

If data or specimens are being collected, describe:

* How long and where the data/specimen and any resulting information will be stored
* Whether the subject can withdraw the data/specimen and any resulting information from the sub-study
* Whether the subject will be told the results of future analysis
* Who exercises control over the data/specimen and whether the data/specimen will be shared, and with whom
* Whether shared data/specimens will be identifiable or coded
* Whether the subject, PI/study team, or the University of Michigan will obtain any financial benefits from the sub-study
* Whether there are any additional risks to participating in the sub-study, as well as efforts to minimize the risk, such as the GINA statute

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 must include:

Besides the information about the main study, the following information is specific to an optional sub-study. We 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 permission now to keep some of your [BLOOD/SPECIMEN] and medical information, you can change your mind later and ask us to destroy it. Keep in mind, however, that once we have analyzed your [BLOOD/SPECIMEN], we may not be able to take the information out of our research. Also, if we have shared some of your BLOOD/SPECIMEN and medical information with other researchers, we 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).]

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

As part of this study, your samples and collected information may 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.

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.

**D – Collection for unspecified future research**

**Obtain subject signature at box Sig-D (section 12).**

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.

Besides the information about the main study, the following information is specific to unspecified future use of identifiable data and/or biospecimens. We would also like your permission to keep some of your [BLOOD/SPECIMEN] and medical information collected in the main study, so that we may study 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 [BLOOD/SPECIMEN] and medical information for future research.

If you give us your permission, we will use your [BLOOD/SPECIMEN] and medical information for future research. Even if you give us permission now to keep some of your [BLOOD/SPECIMEN] and medical information, you can change your mind later and ask us to destroy it. Keep in mind, however, that once we have analyzed your [BLOOD/SPECIMEN], we may not be able to take the information out of our research.

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]. 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 of future research on your [BLOOD/SPECIMEN]. Allowing us to do future research on your [BLOOD/SPECIMEN] and medical information will not benefit you directly.

With appropriate permissions, your samples and collected information may also be shared with other researchers here, around the world, and with companies.

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.

**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.

**4.4 What will happen with my information and/or biospecimens used in this study?**

Your biospecimens and collected information may be shared with [PROVIDE SPONSOR NAME, OR DELETE THIS SENTENCE IF THERE IS NO SPONSOR].

With appropriate permissions, your biospecimens and collected information may also be shared with other researchers, here, around the world, and with companies.

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.

**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.

The known or expected risks are:

The researchers will try to minimize these risks by:

When appropriate, also note here that in order to minimize risk, those procedures already being performed on subjects for diagnostic or treatment purposes will be used for the research. List the procedures these include. This list can be general or specific, as appropriate. For example: "To avoid extra blood tests we will use the results of blood tests you are having for your clinical care."

Additionally, there may be a risk of loss to confidentiality or privacy. 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.

**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**.**

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."**

**Additional language for COVID-19 projects or projects with COVID-19-related components**

On March 10, 2020, the Secretary of Health and Human Services (“HHS”) published the Notice of Declaration Under the Federal Government’s 2005 Public Readiness and Emergency Preparedness Act (PREP Act) for Medical Countermeasures against COVID-19. The PREP Act covers studies with any products that are approved, cleared, or licensed by FDA; authorized for investigational use under IND or IDE; or used for emergency use.

If your project involves any COVID-19-related procedures and fall under above categories, insert the following:

Due to the coronavirus public health emergency, the federal government has issued an order that may limit your right to sue if you are injured or harmed while participating in this COVID-19 study.

If the order applies, it limits your right to sue researchers, healthcare providers, any study sponsor, manufacturer, distributor or any other official involved with the study. However, the federal government has a program that may provide compensation to you or your family if you experience serious physical injuries or death. To find out more about this “Countermeasures Injury Compensation Program” please go to <https://www.hrsa.gov/cicp/about/index.html>or call 1-855-266-2427.

**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".

Per ICH GCP 4.8.10(h), 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:///%5C%5CMEDINFO%5CWEB%5CWEBDOCS%5Cirbmed%5Cict%5Cwww.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.

Per ICH GCP 4.8.10(i), 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 or not 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.

**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 researcher believes 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. If you are not sure what these are, see Section 4.1 above or 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.

“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)**

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.

**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**: "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 at the UMHS for any complication, injury, or illness caused by the study drug, device, or procedure. The UMHS and the study doctor are responsible for determining whether your condition was the result of your participation in the study. The UMHS 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. It is not the general policy of the federal funding agencies to compensate or provide medical treatment for human subjects in federally funded studies."

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.

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 as a result 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 involves a long duration of time and/or 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.

Per ICH GCP 4.8.10(k), add **pro-rated** payment information 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 a Tech Transfer/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 RELTIONSHIP 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 tech 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 the [*Office of Technology Transfer*](http://www.techtransfer.umich.edu) if you are uncertain. Delete this sub-heading if you are certain it does not apply.

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 subject 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?**

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." Or: “Research records will be kept in a separate research file that does not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you.”

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

This research [is/will be] covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the SPONSOR which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of [list what will be reported, such as child abuse and neglect, or harm to self or others].

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

[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

**Child Abuse -** 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](http://michigan.gov/dhs/0%2C4562%2C7-124-7119_50648_44443-157836--%2C00.html).

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 physically harmed, we may be required to 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 physically harmed, we may be required to report that information to the appropriate agencies.

A study team may consist entirely of mandated reporters, a combination of mandated and non-mandated reporters, or entirely of non-mandated reporters. The above language accommodates each of these scenarios.

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>.

**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/%28S%2805je2555daxqvkmg2xxdpsfh%29%29/mileg.aspx?page=GetObject&objectname=mcl-400-11a).

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 harmed, we may be required to report that information to the appropriate agencies.

A study team may consist entirely of required reporters, a combination of required and non-required reporters, or entirely of non-required reporters. The above language accommodates each of these scenarios.

**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 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 Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site 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 in order 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 eResearch 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.
* 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 in order 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 [*Office of Technology Transfer*](http://www.techtransfer.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 UMHS medical record.
* If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
* 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

As long as 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](http://www.uofmhealth.org/patient%2Band%2Bvisitor%2Bguide/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 expires at the end of the study, unless you cancel it sooner. 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 will not expire unless you cancel it.”

**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

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.

Per ICH GCP 4.8.11, add a statement that the subject ***will receive a copy of the signed and dated informed consent***.

Your signature in the next section means that you have received copies of all of the following documents:

* 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.

**Additional information about HIV testing — Part 1 of 3**

The State of Michigan requires providers give information to patients prior to administering an HIV test. If your study procedures include HIV testing, copy all of the text from the 3 boxes and paste it into the body of the consent document. You will not need to provide a separate pamphlet to subjects when including this information.

**11.2 Additional required information**

Because this study requires you to receive an HIV test in order to be a part of the study, the State of Michigan requires information about HIV to be provided to you.

**HIV testing information**

What is HIV (human immunodeficiency virus) and how is it spread?

* 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. You can get or give HIV infection by:
	+ Having vaginal, anal, or oral sex without a condom.
	+ Sharing needles or works when injecting drugs.
	+ HIV can be passed from mother to child during pregnancy, birth or breastfeeding.
	+ You cannot get HIV by donating blood or through casual contact such as hugging or shaking hands.

What is AIDS?

* AIDS (Acquired Immunodeficiency Syndrome) is the stage of HIV infection when the body is weakened and less able to fight off germs.

What is an HIV test?

* It is a simple test, done by taking blood or fluid from cells in the mouth, that shows if you have been infected with HIV, the virus that causes AIDS.

 Who should have an HIV test?

* The CDC (Centers for Disease Control and Prevention) recommends that everyone between the ages of 13 and 64 get tested for HIV.
* Whatever your age, you should have an HIV test if you are sexually active or have shared needles or works for injecting drugs.
* Women who are pregnant or considering pregnancy should also get an HIV test.

Can anyone make me take an HIV test?

* Under Michigan law, unless you are ordered by a judge, or you are a prisoner entering into a state correctional facility, getting an HIV test is your decision. No one can test you without getting your consent.

Can I change my mind after I consent to the test?

* Yes, you can change your mind at any time before the lab runs the test.
* If you change your mind, you must give the study team a written request saying that you do not want your test to be run. This may mean that you cannot take part in the study.

Can someone under age 18 take the test without their parents’ consent?

* Yes. Minors, age 13 and older, have the right to take the test for HIV without their parents’ knowledge or consent.

**Additional information about HIV testing (continued) — Part 2 of 3**

What is the difference between anonymous and confidential testing?

* Anonymous HIV testing means your name is not used and will not be on the test results. To get your test results, you will be given a code number.
* Confidential HIV testing means that your name will be used on your test results.
* If you get an anonymous HIV test, you will not receive a piece of paper with your name and your test results. If you need a copy of your HIV test results, you should take a confidential test.
* In Michigan, you have the right to request an anonymous HIV test.
* Anonymous HIV testing may not be available if the researchers need to know your HIV status for this study. However, your HIV status will remain confidential.

How is HIV testing done?

* Typical HIV tests are done on blood or oral fluids. Specimens are sent to a lab and you get your results in about one week. When testing blood, a needle will be used to draw blood from a vein in your arm. When testing oral fluids, they are collected on a swab from your mouth.
* Rapid test: Some clinics or testing sites offer rapid testing. This is a test done on a small amount of blood from the tip of your finger or from fluid in your mouth. You will get results in that same visit. If your result is reactive (shows possible signs of infection), you will need more testing.

How will this test help me?

* The test will tell you whether or not you have HIV. People can have HIV for years and not know it unless they get tested.
* If you are infected, it can help you get proper treatment and learn how to avoid spreading HIV to other people.
* If you are not infected, it can help you learn how to reduce your risk of getting HIV.

What does a negative (or “non-reactive”) result mean?

* A negative result means you are not infected with HIV,
* OR you have been infected too recently for it to show up on the test.
* If you recently had sex without a condom or shared needles, you should get another test in about six weeks. This is because sometimes HIV tests cannot detect recent infection.

What does a positive result mean?

* A positive result means that you are living with HIV.
* You should see a doctor as soon as possible. The person who gave you your test results can help you find a doctor if you don’t have one.
* If you have HIV, you can pass your infection to other people through sex, sharing needles, or through birth or breastfeeding if you are or will be a mother.
* You should use condoms every time you have sex, to prevent passing the infection to others. The person who gave you your test results can help you plan ways to keep from passing your infection on to others.

**Additional information about HIV testing (continued) — Part 3 of 3**

Who will know the results of my test?

* 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.
	+ It is illegal to discriminate against people with HIV.

If I have HIV, will I definitely develop AIDS or get sick?

* No. Today there are many treatments for HIV. These treatments can prevent serious illness, including AIDS. If you get care quickly, you have a good chance for a long and healthy life.

Whom should I tell if I have HIV?

* Current, past and future sexual and/or needle-sharing partners should be notified.
* Your local health department can also help to notify partners. They will do this without using your name or sharing any information about you. Your doctor, health care provider or counselor that performed the test can connect you with the local health department.
* Michigan law requires you to tell any current or future sexual partner that you have HIV before having any kind of sex with them.
* The law also requires that your doctor or someone from the local health department talk to you about this.

What if I have more questions?

* Feel free to ask the health professional who gave you this booklet any questions that you might have.
* Call the Michigan statewide HIV/AIDS information hotline (English 1-800-872-AIDS; Español 1-800-862-SIDA; TDD 1-800-332-0849).
* Visit the CDC’s HIV/AIDS website for more information (<http://www.cdc.gov/hiv/>).

**12. Signatures**

Insert and complete the following lines 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**

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.

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

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

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

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

**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 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 the optional sub-study.

\_\_\_\_\_ No, I do not agree to take part in the optional sub-study.

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 study team keep my specimens for future research.

\_\_\_\_\_ No, I do not agree to let the study team keep my specimens for future research.

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

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

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

**Legally Authorized Representative(s) -** If the above signature block is 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 is optional, unless required by the study sponsor. This signature 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.

Per ICH GCP 4.8.8, the person who conducted the informed consent discussion must sign and personally date the consent form.

**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): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_