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.

PRIOR TO SUBMITTING THE INFORMED CONSENT DOCUMENT FOR IRBMED REVIEW, REMOVE ALL BLUE AND YELLOW TEXT BOXES. TO DO THIS, SIMPLY CLICK ON THE BORDER OF THE BOX AND HIT DELETE. OR YOU CAN USE THE ‘CLEAN’ COPY OF THE FORM WITHOUT TEXT BOXES.

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.

When uploading your informed consent form in eResearch:

- New Applications: Please make sure to delete all instruction boxes, comments, and headers from the original template. Also be sure to proofread the document for spelling, grammar, and formatting errors.
- Amendments: Per the IRBMED Version Control of Informed Consent Documents statement of practice, as part of an amendment modifying the consent(s)
  - 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.
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INFORMATION ABOUT THIS FORM
You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

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:

You, or your child, may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study. Parents or legal guardians, who are giving permission for a child, please note: in the sections that follow the word ‘you’ refers to ‘your child’.

While this alternate text has been endorsed by the IRBMED, it may not be appropriate for all studies. As appropriate, on an individual basis, the IRBMED may require a different approach. Investigators may also propose a different approach, subject to IRBMED approval.
Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 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 spaces for the investigator to designate the subtitle and version of each consent document used in the study. The "Consent Subtitle" uniquely identifies a consent document when a study uses multiple consents (e.g., Main, Genetic, Screening, Treatment Group, etc.). Lengthy subtitles may need to be abbreviated to fit into the footer space. 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. The version designation can take the form of a date or alphanumeric code, and is created and used by the investigator to distinguish this consent document version from previous versions and/or future revisions of the document (e.g., 06/01/2003, 1.1, 1.2, 1a, 1b, etc.). Each consent document revision, whether administrative or substantive, should trigger a change to this code.

1.2 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.

1.3 Names, degrees, and affiliations of the researchers conducting the study:

List the names and degrees of the PI and Co-Is and their respective affiliations (i.e., Department and Institution). For example: "Ima Researcher, M.D., Department of Internal Medicine, University of Michigan".

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 "Study Procedures". 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. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

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.

If applicable, investigators should consider using this section to reassure subjects that their standard medical treatment does not depend on their participation in this study.

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 (subjects) 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, 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.

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.
B — Genomic data sharing

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.

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 public repository. A repository contains many people’s information. There are many different kinds of scientific repositories; some 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.

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 above.

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.
**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 to 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 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 to take back information that other researchers have already obtained from the repository.

The NIH policy on genomic data sharing recommends that researchers submitting genomic data to an NIH-designated repository obtain a Certificate of Confidentiality. If you plan to obtain a Certificate, see help text in Section 9 for recommended language.
C — Sub-studies

The instructions within this box pertain to optional sub-studies. If your study does not offer subjects the option to participate in a sub-study, these instructions do not apply.

For research studies that include sub-studies to collect specimens and/or information for future research, the subject must opt in to the sub-study. 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 the following information:

- How long and where the specimen and any resulting information will be stored
- Whether the subject can withdraw the 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 specimen and whether the specimen will be shared, and with whom
- Whether shared specimens will be identifiable, coded, or deidentified
- 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.

For a specific use, language must include:

We would also 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].

We will keep your [BLOOD/SPECIMEN] [DESCRIBE CIRCUMSTANCES OF STORAGE AND SHARING FOR THIS SPECIFIC 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. Also, once 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.

[PARTY/-IES may benefit financially from future research on your BLOOD/SPECIMEN and medical information.]
4.2 How much of my time will be needed to take part in this study?

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

5. INFORMATION ABOUT 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?

For unspecified future use of subjects’ samples, language must include:

We would also like your permission to keep some of your [BLOOD/SPECIMEN] and medical information, 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 this 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 SUB-STUDY POSES AND DESCRIBE EFFORTS TO MINIMIZE THEM (E.G., THE GINA LAW).]

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.

[PARTY/IES may benefit financially from future research on your BLOOD/SPECIMEN and medical information.]
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."

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

**Genetic Information Nondiscrimination Act (GINA)** – If the research involves genetic analysis of biological samples, 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
5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

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.

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

Explain how risks are monitored and reduced. For example, explain that the subject will receive a physical examination and blood test once a week after beginning treatment with the new drug or device. Also explain what steps will be taken if complications or adverse effects are detected (e.g., "first aid will be provided" or "the drug dose will be lowered or stopped altogether"). Information about payment for first aid or emergency care should be provided in Section 8 "Financial Information" and not here in Section 5 "Risks and Benefits."

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

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

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

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

You may not receive any personal benefits from being in this study.

This should always be the first sentence. If applicable, it 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 compensations to subjects here. That information belongs in Section 8 on "Financial Information" (below).

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. OTHER OPTIONS

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 that may be of interest.

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). 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?
If applicable, investigators should consider using 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” (below).

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, tests, etc.), and any dangers of terminating treatment abruptly or completely, particularly without consulting with the researchers or another doctor, etc.

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 researchers’ 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 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.
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.”

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.

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.
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.

**DO NOT DELETE** the last paragraph: "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, and the amount earned to date 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, consider addressing under this question 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?

If applicable to this study, include the following language under this heading: "You will not receive any proceeds, profits, or other benefits from any commercial product that may result from this study."

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. 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.
The information below describes how your privacy and the confidentiality of your research records will be protected in this study.

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 your privacy and the confidentiality of your research records will be protected in this study.
9.1 How will the researchers protect my privacy?

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 you have obtained or plan to obtain an NIH Certificate of Confidentiality for the study, insert the following language; be sure in paragraph one to indicate whether you have already obtained the Certificate or plan to obtain it in the future.

<table>
<thead>
<tr>
<th>Language</th>
</tr>
</thead>
<tbody>
<tr>
<td>To help us protect your privacy, we [SELECT ONE: have obtained / plan to obtain] a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, [except as explained below].</td>
</tr>
</tbody>
</table>

Use the following language as applicable:

<table>
<thead>
<tr>
<th>Language</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects 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 or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.</td>
</tr>
</tbody>
</table>

Language such as the following should be included if researcher intends to make voluntary disclosure about information obtained in the research such as child abuse, or intent to hurt self or others:

<table>
<thead>
<tr>
<th>Language</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of [list what will be reported, such as child abuse and neglect, or harm to self or others].</td>
</tr>
</tbody>
</table>

Please check the IRBMED website for additional information on Certificates of Confidentiality if your study involves use or disclosure of extremely sensitive information (e.g., illegal drug use).

9.2 What information 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. Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- 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 for guidance.

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

- 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

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

This paragraph should apply 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.

- DO NOT DELETE the above bullet.

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

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

- future IRB-approved research studies
- a tech transfer or licensing agreement.

Contact Office of Technology Transfer if you are uncertain.

- Information about your study participation may be included in your regular UMHS medical record.

If you don’t use this bullet, make sure you can reliably keep the information out of the 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.

**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://www.med.umich.edu/mott cpt/).

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.med.umich.edu/mott cpt/](http://www.med.umich.edu/mott 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.med.umich.edu/mott cpt/).

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.

- 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.
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.

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

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.

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. 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 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).

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:

Insert PI and study coordinator names, addresses, and phone numbers. Duplicate and/or edit the contact information headings as necessary to include all appropriate contact personnel.

INTERNATIONAL STUDIES:
For research projects conducted outside the US, IRBMED will require the US Country Code. 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 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
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?

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.)

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. 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.

- Other (specify): _______

If you provide the subject with other information, such as a study calendar, study diary, Notice of Privacy Practices or information about advance directives for research, etc., list the documents here. Otherwise, you may delete this bullet.

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

12. SIGNATURES
**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).

---

**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 [Study Team Member Name/s]. 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.

Legal Name: _________________________________________________________________

Signature: ____________________________________________________________________

Date of Signature (mm/dd/yy): ________________________

For use only if required by sponsor:

Date of Birth (mm/dd/yy): ____________________________

ID Number: ________________________________________

---

**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).
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.

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.
Legally Authorized Representative or Parent Permission

Subject Name:
__________________________________________________________________________________

Parent/Legally Authorized Representative:

Name: _______________________________________________________________________________

Signature: ____________________________________________________________________________

Address: ______________________________________________________________________________

Date of Signature (mm/dd/yy): ________________________________

Relationship to subject: ☐ Parent ☐ Spouse ☐ Child ☐ Sibling ☐ Legal guardian ☐ Other

If “Other,” explain: ______________________________________________________________________

Reason subject is unable to consent: ___________________________________________________________________

For use only if required by sponsor:

Date of Birth (mm/dd/yy): ________________________________

ID Number: ____________________________________________

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 - If the study involves minor subjects and the permission of one parent is sufficient or if the study involves adults unable to consent and requires the permission of one legally authorized representative, 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).

Second Parent Permission

Legal Name: ________________________________________________________________________

Signature: _________________________________________________________________________

Address: ___________________________________________________________________________

Date of Signature (mm/dd/yy): ________________________

Reason second parent permission was not collected:

☐ Parent is deceased ☐ Parent is unknown
☐ Parent is incompetent ☐ Only one parent has legal responsibility for care and custody
☐ Prospect of direct benefit solely to the fetus and pregnancy resulted from rape or incest
☐ Parent is not reasonably available*; explain:

__________________________________________________________________________________

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

For use only if required by sponsor:

Date of Birth (mm/dd/yy): __________________________

ID Number: _______________________________________
**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.

**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.

Legal Name: ________________________________________________________________

Title: ______________________________________________________________________

Signature: __________________________________________________________________

Date of Signature (mm/dd/yy): _______________________

**Witness** – The witness signature is optional, unless required by the study sponsor. If you do not plan on using the Witness signature block, you should delete it.

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.

**Witness**

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

Legal Name: ________________________________________________________________

Title: ______________________________________________________________________

Signature: __________________________________________________________________

Date of Signature (mm/dd/yy): _______________________

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Consent Subtitle: ______________________

Consent Version: ______________________