

# 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 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.**

### 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: Please upload a "tracked changes" version as well as a "clean" version of the informed consent. For each consent and child assent document, there should be two documents uploaded: 1 labeled as the "tracked" changes version with all changes highlighted, and 1 labeled as the "clean" version that has all of the tracked changes accepted. This will be essential for the document review and finalization process. Otherwise, the IRB will not be able to provide you with finalized documents for the study. Also be sure to proofread the document for spelling, grammar, and formatting errors.
- For informed consent documents that are uploaded in eResearch but are no longer in use, please simply change the document file name by adding the phrase "Not in use" to the file name. Do not delete these documents from the eResearch application.

### 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?

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.

### 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?

Explain the 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 risks to a fetus if women of child-bearing potential may participate in the study. It is **not** necessary to list risks associated with non-research procedures.

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."

Insert (if applicable) the following language into Section 5.1 if the research involves genetic analysis of samples:

A new Federal law, called the 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 generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get 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 get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009.

Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

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?

Delete this sentence if it 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."**

### 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).

### 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 (e.g., what is usually done to treat the condition or disease). If appropriate, consider informing subjects of alternative studies, either specifically or by reference to a central source (e.g., [www.clinicaltrials.gov](http://www.clinicaltrials.gov)). For non-therapeutic studies, in which there is no "alternative" or standard treatment, reiterate the voluntary nature of participation and state that the alternative is to not participate, in which case there will be no penalty. A suitable last sentence for this section is: "Ask the researchers or your doctors about other options you may have." ("...or your doctors..." should be deleted if it is not applicable for this 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.”)

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."

STUDY TEAMS - for guidance on informed consent language and potential business risk for UM Investigator Initiated Internally Funded Projects please contact Dr. Samuel Silver, Assistant Dean for Research and Medical Director or Gina Vuocolo-Branch of the Calendar Review and Analysis Office (CRAO) prior to the completion of the informed consent document. The consent form should not include the names of these individuals.

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.

## 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
  - (1) have any proprietary interests in the product (including patents and licensing agreements);
  - (2) have an equity interest in the sponsor;
  - (3) receive significant payments of other sorts (e.g., grants or consultant retainers); and/or
  - (4) 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.

**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. Two committees made sure that both your safety and the quality of the study will not be affected by the possible financial benefit.

**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. Two committees made sure that both your safety and the quality of the study will not be affected by any possible financial benefit.

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

{State conflicted individuals 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. Two committees made sure that both your safety and the quality of the study will not be affected by any possible financial benefit.

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

{State conflicted individuals 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. Two committees made sure that both your safety and the quality of the study will not be affected by any possible financial benefit.

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

{State conflicted individuals name, state relationship to you} [Insert conflict of interest related wording from above here]. Two committees made sure that both your safety and the quality of the study will not be affected by any possible financial benefit.

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](#) if you are uncertain. Delete this sub-heading if you are certain it does not apply.

**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." This would be the place to mention a Certificate of Confidentiality, if applicable. 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.

- Alcohol/substance abuse treatment records
- Your AIDS/HIV status
- All records relating to your condition, the treatment you have received, and your response to the treatment

Specify the "condition" or disease (e.g., arthritis, cancer, etc.)

- Billing 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:

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.

- 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 may need the information to make sure that the study is done in a safe and proper manner.

**DO NOT DELETE** this 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 this 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.
- 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."

### **FDA Mandated Changes in Consent Form Language**

The FDA has added a new element of consent that is required for "applicable" clinical trials: These are [clinical trials](#) that are registered on [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) AND are conducted under a US Investigational New Drug (IND) or are otherwise subject to FDA regulations. All applicable clinical trials are required to include this new element of consent by March 7, 2012. Subjects who were consented before March 7, 2012 will NOT have to be re-consented or otherwise sign addendum consent with this language.

This requirement is a federal regulation, and for that reason, the required language **cannot be altered in any way**. You must incorporate the following statement verbatim: **"A description of this clinical trial will be available on [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov), as required by US law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time."**

For more information or questions, contact the IRBMED office or the Medical School's [Office of Regulatory Affairs](#).

A description of this clinical trial will be available on [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov), as required by US law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

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

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>. 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 200, Room 2086  
 Ann Arbor, MI 48109-2800  
 Telephone: 734-763-4768 (For International Studies: US Country Code: 001)  
 Fax: 734-763-1234  
 e-mail: [irbmed@umich.edu](mailto:irbmed@umich.edu)

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

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

## **11. RECORD OF INFORMATION PROVIDED**

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

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.

## 12. SIGNATURES

### Research Subject:

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 for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Name (print legal name): \_\_\_\_\_

Signature of Subject: \_\_\_\_\_

Date of signature: \_\_\_\_\_

Patient ID: \_\_\_\_\_ Date of Birth (mm/dd/yyyy): \_\_\_\_\_

This signature block may also be used to document the assent of children or others unable to fully give their own consent. If used for assent, the following signature block should be used to document the consent of the person serving as the legal representative of the assenting subject. The person(s) responsible for consenting the subject and answering questions should fill in their name(s) in the yellow area.

The subject signs to consent or assent (in the case of minors or others unable to fully consent for themselves) to participate in the study using the signature line. For assenting subjects, investigators may choose to insert the word "Assenting" before the word "Subject" in the signature line label for clarity (although this is not required). Investigators are reminded that the consent of the Legally Authorized Representative (see the next signature block) is always required for assenting subjects.

Delete the labels and spaces for Patient ID (hospital registration number, etc. – NOT social security number) and Date of Birth if not applicable for this study.

### Legal Representative (if applicable):

Signature of Person Legally Authorized to Give Consent \_\_\_\_\_

Date of signature: \_\_\_\_\_

Name of Person Legally Authorized to Give Consent (print legal name): \_\_\_\_\_

Address of Legal Representative: \_\_\_\_\_

Relationship to Subject (check):  Parent  Spouse  Child  Sibling  
 Legal Guardian  Other: \_\_\_\_\_

**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 the IRBMED.**

Reason subject is unable to sign for self: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

If the study will enroll minors or others unable to fully consent for themselves, this signature block should be used to document the consent of the minor's parent(s) or other person serving as the legal representative of the assenting subject. **Special note for studies involving minor subjects: If there is no direct benefit to the minor subject, and the risks are assessed by the IRBMED to be more than minimal, the consent of both parents (or of the legal guardian) will be required.**

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

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. If the study is in eResearch, section 33.4 indicates what regulation(s) the study is approved under.

**Principal Investigator (or Designee):**

I have given this research subject (or his/her legally authorized representative, if applicable) information about this study that I believe is accurate and complete. The subject has indicated that he or she understands the nature of the study and the risks and benefits of participating.

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

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

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

Date of Signature: \_\_\_\_\_

The purpose of this section is not to witness the subject's signature, but rather to ensure that the subject was given sufficient information to be able to freely consent to participate in the trial. This section should be filled out and signed by the person who conducted the informed consent interview with the research subject. In most cases, this should be the PI, Co-Investigator, Study Coordinator, or other qualified and knowledgeable member of the research team. The name(s) of the person(s) signing in this signature block should match the name(s) indicated in the introduction to the subject's signature block at the beginning of the signature section. Indicate the title or role of the person(s) responsible for consenting the subject and answering questions. Examples include: Principal Investigator, Co-Investigator, Study Coordinator, Research Nurse, or other functional titles.

***Witness (optional):***

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

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

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

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

*Date of Signature:* \_\_\_\_\_

A witness signature and date is optional, but may be required by some sponsors. If not required for your study, DELETE this section.