

Study No.: «ID»
IRB: «IRB»

Consent Approved On: «ApprovalDate»

Project Approval Expires On: «ExpirationDate»

UNIVERSITY OF MICHIGAN CONSENT TO BE PART OF A RESEARCH STUDY

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.

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.*

Comment [IRBMED1]: GENERAL INFORMATION ON ALTERING THE INFORMED CONSENT DOCUMENT LANGUAGE

The template wording may be altered to suit a particular study except as noted throughout the instructions that are embedded as comments within each section of the template.

•Federal regulations for informed consent documents require the elements listed in the chart available on the IRBMED's website at [http://www.med.umich.edu/irbmed/ict/Informed Consent Checklist.pdf](http://www.med.umich.edu/irbmed/ict/Informed%20Consent%20Checklist.pdf). **If necessary elements are not included, the IRBMED will require revision of the consent document prior to approval.**

•SECTIONS 1-8 and 10-12: You may delete questions/passages that do not apply to your study UNLESS THE INSTRUCTIONS EMBEDDED IN THOSE SECTIONS PROHIBIT DELETION.

○You may alter the suggested 'questions' and 'answers' to conform to your study unless the embedded directions below specifically state a particular phrase a particular phrase must be included.

○Suggested answers work with most, but not all studies.

○If a passage that is indicated as one that cannot be deleted does not make sense in the context of your study, please contact the IRB staff for assistance.

•SECTION 9: Section nine provides required information for HIPAA compliance. Suggested "answers" may be altered to conform to the study unless the embedded directions specifically state a particular phrase must be included. For detailed HIPAA guidance, refer to this page:

<http://www.med.umich.edu/irbmed/HIPAA/ICD-HIPAA-REQS.pdf>

Comment [IRBMED2]: eResearch Users: Do not alter the header at the top of the page. The information will be completed when the IRBMED approves the document in eResearch. Legacy (paper applicants) Users: Enter the IRBMED study number, approval and expiration dates (if known at the time submitting).

Comment [IRBMED3]: 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.

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study title:

1.2 Company or agency sponsoring the study:

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

Comment [IRBMED4]: 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., GCRC ##### or UMCC #####). 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.

Comment [IRBMED5]: 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.

Comment [IRBMED6]: 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., Ph.D., Department of Internal Medicine, University of Michigan."

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

Comment [IRBMED7]: Briefly (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 on "Study Procedures" (below). 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.

Comment [IRBMED8]: 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?

Comment [IRBMED9]: 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?

Comment [IRBMED10]: 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?

Comment [UpdateCRB11]: 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.

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

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

4.3 When will my participation in the study be over?

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 (for examples see the text modules at <http://www.med.umich.edu/irbmed/ict/Modules/modules.htm>)

Comment [UpdateCRB12]: 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!

Comment [UpdateCRB13]: 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?

The known or expected risks are:

The researchers will try to minimize these risks by:

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?

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.

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.

Comment [IRBMED14]: 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.

Comment [UpdateCRB15]: 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."

Comment [UpdateCRB16]: •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."** Make sure there is no promise for the University of Michigan to pay if insurance does not.

Comment [IRBMED17]: Delete this sentence if it does not apply to this study.

Comment [IRBMED18]: If applicable, follow this sentence with 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.

Comment [IRBMED19]: 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?

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.

Comment [IRBMED20]: 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.

6. OTHER OPTIONS

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

Comment [IRBMED21]: 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). 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?

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).

Comment [IRBMED22]: 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.

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

Comment [IRBMED23]: 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?

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.

Comment [UpdateCRB24]: 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."

Comment [UpdateCRB25]: "The study will pay for" means the internal or external sponsor.

Comment [UpdateCRB26]: 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.")

Comment [UpdateCRB27]: If complications are paid for by the internal or external sponsor, you should say so here. For example, "the sponsor will pay for treatment of complications it believes were caused by the study."

Comment [UpdateCRB28]: If the internal or external sponsor has explicitly agreed to pay for any of the items or services in this list edit this section accordingly.

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
- Treatment of complications
- 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**.

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?

Comment [UpdateCRB29]: If the internal or external sponsor has agreed to provide limited payment for complications that occur as a result of participation in the study, say so in the paragraph above (under what the study will pay for), and add to the end of this bullet [Treatment of complications] "not covered by the sponsor".

Comment [UpdateCRB30]: •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 University of Michigan 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).

Comment [UpdateCRB31]: **DO NOT DELETE** THIS last paragraph (i.e., "By signing this form . . .").

Comment [IRBMED32]: 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?

The company whose product is being studied:

The researchers conducting the study:

The University of Michigan:

Comment [IRBMED33]: 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."

Comment [IRBMED34]: 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.

Comment [IRBMED35]: 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 Conflict of Interest Committee (visit: www.med.umich.edu/medschool/orgs/ResearchPolicies/ConflictofInterest.html). Delete this sub-heading if it does not apply.

Comment [IRBMED36]: If the University of Michigan 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 (www.techtransfer.umich.edu). 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

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?

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)
- 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
- 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:

- The researchers may need the information to make sure you can take part in the study.

Comment [IRBMED37]: 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.

Comment [IRBMED38]: 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).

Comment [IRBMED39]: 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.

Comment [IRBMED40]: Specify the "condition" or disease (e.g., arthritis, cancer, etc.)

Comment [IRBMED41]: 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 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.
- 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.
- Information about your study participation may be included in your regular UMHS medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.

Comment [UpdateCRB42]: **DO NOT DELETE** this bullet.

Comment [UpdateCRB43]: 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 the *Office of Technology Transfer* if you are uncertain (www.techtransfer.umich.edu).

Comment [UpdateCRB44]: If you don't use this bullet, make sure you can reliably keep the information out of the medical record.

- 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.

Comment [IRBMED45]: 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."

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:

Comment [IRBMED46]: Alternate language for non-PHI/HIPAA-regulated studies: "...leave the study before it is finished..."

- 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

Comment [IRBMED47]: Alternate language for non-PHI/HIPAA-regulated studies: "...left the study..."

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.med.umich.edu/hipaa/npp.htm>. 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).

Comment [IRBMED48]: 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).

Comment [IRBMED49]: If the study does not involve PHI and is not subject to HIPAA, and this statement does not otherwise apply, investigators may choose to delete this question from the template.

Comment [IRBMED50]: 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:

Comment [IRBMED51]: 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.

You may also express a concern about a study by contacting the Institutional Review Board listed below, or by calling the University of Michigan Compliance Help Line at 1-888-296-2481.

University of Michigan Medical School Institutional Review Board
(IRBMED)
Argus I
517 W. William
Ann Arbor, MI 48103-4943

Telephone: 734-763-4768
Fax: 734-615-1622
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy, contact the University of Michigan Health System Privacy Officer at 1-888-296-2481.

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.)*
- Other (specify): _____

Comment [IRBMED52]: 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.

Comment [IRBMED53]: 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.

Study No.: «ID»
IRB: «IRB»

Consent Approved On: «ApprovalDate»

Project Approval Expires On: «ExpirationDate»



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

_____ *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.*

Signature of Subject:

Name (Print legal name): _____

Patient ID: _____ Date of Birth: _____

Comment [IRBMED54]: 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.

Comment [IRBMED55]: The person(s) responsible for consenting the subject and answering questions should fill in their name(s).

Comment [IRBMED56]: This is where 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. 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.

Comment [IRBMED57]: 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.

Comment [IRBMED58]: 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.

Comment [IRBMED59]: If you are unsure whether a particular person is "legally authorized to give consent," contact the Health System Legal Office at 734-764-2178.

Legal Representative (if applicable):

Signature of Person Legally
Authorized to Give Consent _____

Name (Print legal name): _____ Phone: _____

Address: _____

Check Relationship to Subject:

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.

Comment [UpdateCRB60]: 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. For studies approved in Legacy (the former paper application system) contact the IRB to determine if an advocate is required on the study.

Study No.: «ID»
IRB: «IRB»

Consent Approved On: «ApprovalDate»

Project Approval Expires On: «ExpirationDate»

Reason subject is unable to sign for self:

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: _____

Comment [IRBMED61]: 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.

Comment [IRBMED62]: 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: _____

Signature: _____

Date of Signature: _____

Comment [IRBMED63]: A witness signature and date is optional, but may be required by some sponsors. If not required for your study, DELETE this section.