

UNIVERSITY OF MICHIGAN CONSENT TO BE PART OF A RESEARCH STUDY

[IRBMED1]

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. [IRBMED2]

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:** [IRBMED3]

1.2 **Company or agency sponsoring the study:** [IRBMED4]

1.3 **Names, degrees, and affiliations of the researchers conducting the study:** [IRBMED5]

2. PURPOSE OF THIS STUDY

2.1 **Study purpose:** [IRBMED6]

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. [IRBMED7] You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 **Who can take part in this study?** [IRBMED8]

3.2 How many people (subjects) are expected to take part in this study? [IRBMED9]

4. INFORMATION ABOUT STUDY PARTICIPATION PROCEDURES

4.1 What exactly will happen to me in this study? [UpdateCRB10] What kinds of research procedures will I receive if I agree to take part in this study? [IRBMED11]

4.2 How much of my time will be needed to take part in this study? [UpdateCRB12]

4.3 When will my participation in the study be over? [UpdateCRB13] [IRBMED14]

5. INFORMATION ABOUT RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? [IRBMED15][IRBMED16] What will the researchers do to protect me against these risks? [IRBMED17]

The known or expected risks are:

The researchers will try to minimize these risks by: [UpdateCRB18]

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 known or expected risks of this study. Even so, However, you may still have experience problems or side effects, even when the researchers are careful to avoid them. Please tell If you believe that you have been harmed, notify the researchers listed in Section 10 of this form. The University of Michigan will provide first aid or emergency care. The cost of this first aid or emergency care may be billed to your insurance company, but if it is not covered by your insurance, the University of Michigan will pay for it. Additional medical care will be provided if the University determines that it is responsible to provide such treatment. [IRBMED19] If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

*Please note: It is important that you tell the researchers about any injuries, side effects, or other problems that you **have experience** during this study. You **should** ~~may~~ also **need to** tell your regular doctors.* [UpdateCRB20]-[IRBMED21]

[UpdateCRB22]

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. [IRBMED23] *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.

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. [IRBMED24]

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study? [IRBMED25]

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? [IRBMED26]

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do? [IRBMED27]

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, and 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** ~~notify~~ 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?

[IRBMED28]

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? ~~8.1 Will taking part in this study cost me anything?~~ ~~Will I or my health plan insurance company be billed for any costs of the study?~~ [IRBMED29] [UpdateCRB30]

~~The study will pay~~ [UpdateCRB31] for research-related items or services that are provided only because you are in the study. [UpdateCRB32] 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. [UpdateCRB33]

~~You or your health plan will pay for all the things you would have paid for even if so, which costs?~~ **What happens** if you were not in the study, like: [UpdateCRB34]

- ~~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~~ [UpdateCRB35]
- ~~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~~ **my insurance does** 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.** [IRBMED36]

~~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.~~ [UpdateCRB37] [UpdateCRB38]

8.2 Will I be paid or given anything for taking part in this study? [IRBMED39]

8.3 Who could profit or financially benefit from the study results? [IRBMED40]

The company whose product is being studied: [IRBMED41]

The researchers conducting the study: [IRBMED42]

The University of Michigan: [IRBMED43][IRBMED44]

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION [IRBMED45]

~~University of Michigan policies require that private information about you be protected. This is especially true for your personal health [IRBMED46] information.~~

~~On the other hand, sometimes the law allows or requires others to see your information.~~ The information given 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? [IRBMED47]

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: [IRBMED48]~~

~~Information about you may include information about your health and your medical care before, during, and after the study, even if that information wasn't collected as part of this research study. For example: [IRBMED49]~~

- 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) [IRBMED50]
- Alcohol/substance abuse treatment records
- Your AIDS/HIV status
- All records relating to your condition [IRBMED51], 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: [IRBMED52]

- 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. [UpdateCRB53] properly.
- Study sponsors or funders, or safety monitors or committees, Organizations that are funding the study may need the information to:
 - Make ~~make~~ sure ~~that~~ the study is done safely and properly.
 - Learn more about side effectsAnalyze
 - ~~Safety monitors or committees may need~~ the results of information to ~~make sure that~~ the study is safe.
- 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. [UpdateCRB54]
- Information about your study participation may be included in your regular UMHS medical record. [UpdateCRB55]
- 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. [IRBMED56]
- 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. [IRBMED57]

9.3 What happens to information about me after the study is over or if I cancel my permission [IRBMED58] ?

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 [IRBMED59] or the study is over. Examples of reasons for this include:

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

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System’s privacy policies. For more information about these policies, ask for a copy of the University of Michigan Notice of Privacy Practices. This information is also available on the web at <http://www.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). [IRBMED60]

9.4 When does my permission expire? [IRBMED61]

Your permission expires at the end of the study, unless you cancel it sooner. [IRBMED62] You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below).

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: [IRBMED63]

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.)* [IRBMED64]
- Other (specify): [IRBMED65] _____



12. SIGNATURES

Research Subject: [IRBMED66]

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____ [IRBMED67]. 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: [IRBMED68] _____ Date: _____

Name (Print legal name): _____

Patient ID: _____ Date of Birth: _____ [IRBMED69]

Legal Representative (if applicable): [IRBMED70]

Signature of Person Legally Authorized to Give Consent [IRBMED71] _____ Date: _____

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. [UpdateCRB72]

Reason subject is unable to sign for self: _____

Principal Investigator (or Designee): [IRBMED73]

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: [IRBMED74] _____

Signature: _____ Date of Signature: _____

Witness (optional): [IRBMED75]

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

Study No.: «ID»
IRB: «IRB»

Consent Approved On: «ApprovalDate»

Project Approval Expires On: «ExpirationDate»

Name: _____

Signature: _____ Date of Signature: _____