University of Michigan

Consent To Be Part Of A Research Study

**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.**

This template may be used *only* for studies that

involve a survey and no other procedures

pose minimal risk to subjects

### Name of Study and Researchers

**Title of Project:**

**Principal Investigator:**

### GENERAL Information

We’re doing a study to learn more about [BRIEFLY STATE THE OBJECT OF THE STUDY]. To get information, we’d like [NUMBER] people to answer a survey. We expect it to take about [TIME] to complete the survey.

Answering this survey is voluntary. You don’t have to answer it if you’d rather not. You can skip any questions that you don’t want to answer, whatever the reason, and you don’t have to tell us why. Choosing not to answer our survey won’t affect the medical care you might receive at the University of Michigan Health System.

It’s possible that some of the questions may make you feel uncomfortable. If a question makes you uncomfortable, you can just skip it and go to the next question.

To keep your information confidential, we will [DESCRIBE MEASURES].

Examples of confidentiality measures include *coding*:

We’ll label your survey with a code, rather than your name or any other details that someone could use to identify you. Although we’ll keep a list of all the people who answered our survey, no one outside our study team will be able to figure out who answered the survey or which people gave which answers. We plan to publish what we learn from this study, but we won’t include any personal information that could reveal who answered the survey.

and *anonymous* data collection:

Your survey responses will be completely anonymous. No one, including members of our study team, will know which subjects gave which answers.

Answering our survey won’t benefit you directly. We hope what we learn will help other people in the future.

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

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

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

To thank you for taking part in our study, we’ll send you [COMPENSATION OR INCENTIVE AMOUNT] after you take the survey. The University of Michigan finance department will need your name and address for tax reporting purposes. In a calendar year if: 1) your payments total greater than $400 for this study or 2) if you receive payments of greater than $400 for being in more than one study, the University of Michigan finance department will also require your Social Security Number for tax reporting purposes. If you do not wish to provide your Social Security Number, you may continue to participate in research studies, but you will not be able to receive payment for the remainder of the calendar year.

If you plan to register this study at www.clinical trials.gov, insert the following:

A description of this clinical trial may be available on [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov). 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.

The following section (Authorization to Release Protected Health Information) is for survey studies that involve accessing, using, or disclosing subjects’ protected health information (PHI) from a UMHS or other University of Michigan medical or dental record. If your survey study will in no way involve subjects’ PHI, remove the following section from your informed consent document.

### AUTHORIZATION TO RELEASE PROTECTED HEALTH INFORMATION

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. Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by contacting the researchers listed below (under Contact Information).

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
* HIV/AIDS status
* Sexually transmitted disease and other communicable disease status
* Genetic counseling/genetic testing records
* Health plan/health insurance records
* All records relating to your condition, the treatment you have received, and your response to the treatment
* Billing information
* Demographic information
* Personal identifiers
* Other information

It’s possible that the researchers or others will need access to information about you during or after this study. For example:

* 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.
* The University of Michigan or a government agency 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, or analyze the results of 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.
* Federal or State law may require the study team to give information to the Food and Drug Administration (FDA) or other government agencies. For example, to prevent harm to you or others, or for public health reasons.
* 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.

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.

As a rule, the researchers will continue to use information about you until the study is over and will keep it secure until it is destroyed. Limited information about you may continue to be used after the study is over, for other research, education, or other activities. But use of this information would not reveal your identity.

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 see [http://www.uofmhealth.org/patient+and+visitor+guide/hipaa](http://www.uofmhealth.org/patient%2Band%2Bvisitor%2Bguide/hipaa). Note that once your information has been shared with others, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

### Contact Information

## To find out more about the study, to ask a question or express a concern about the study, or to talk about any problems you may have as a study subject, you may contact one of the following:

|  |  |
| --- | --- |
| Principal Investigator: Mailing Address: Telephone: Email:  | Study Coordinator: Mailing Address: Telephone: Email:  |

**You may also express a concern about a study by contacting the Institutional Review Board:**

University of Michigan Medical School Institutional Review Board (IRBMED)

2800 Plymouth Road

Building 520, Room 3214

Ann Arbor, MI 48109-2800
734-763-4768

E-mail: irbmed@umich.edu

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

### SIGNATURES

**Research Subject:**

I understand the information printed on this form. My questions so far have been answered.

Signature of Subject: Date:

Name (Print legal name):

Patient ID: Date of Birth:

**Legal Representative (if applicable):**

Signature of Person Legally

Authorized to Give Consent 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.]**

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

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**Principal Investigator or Designee –** The following signature block is to ensure that the participant was given sufficient information to be able to freely consent. This signature is optional, unless required by the study sponsor. This signature should be from the person who actually conducted the informed consent and is familiar with the study procedures, such as the PI, Co-I, study coordinator, or other qualified member of the research team.

**Principal Investigator or Designee**

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

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

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

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

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