University of Michigan

Consent to Be Screened for Eligibility in 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 eligibility screening and *only* if screening procedures pose no more than minimal risk to subjects.

You *may not* use this template if

you plan to conduct genetic analysis of subjects’ blood or tissue samples

you plan to submit subjects’ material or data to a biorepository or data repository

### 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].

Before you can join the study, we’ll need to make sure you qualify. To find out whether you qualify, [DESCRIBE PROCEDURES, FOR EXAMPLE: “we’ll ask you some questions about (BRIEFLY DESCRIBE QUESTIONS). These questions will take about (TIME) to answer”].

Insert other procedures here. Possible additional language includes:

We’ll use a needle to take about [QUANTITY (USE STANDARD UNITS)] of blood from [LOCATION]. This usually takes less than a minute.

There is a small chance of infection with any blood draw. We will use a sterile needle and will clean your skin with alcohol where the needle goes in. The needle may sting a little and may leave a bruise. Some people may feel dizzy or faint. If you do, you may lie down during the blood draw. We’ll give you first aid if you need it.

We’ll label your blood sample with a code, rather than your name or any other details that someone could use to identify you. That way, only members of our study team will know whose blood it is.

After we finish analyzing your blood, we’ll destroy what’s left of your blood sample.

If accessing medical records in addition to other screening procedures:

We’ll look at your medical records to find out more about your [CONDITION] and how your doctors have treated it in the past.

If you qualify to be in the study and you are interested in joining, we’ll give you another consent form to read and sign. That form will explain the rest of the study.

[SPECIFY SCREENING PROCEDURES, e.g., having this blood draw, taking this survey] to find out whether you qualify for our study is voluntary. You don’t have to take part if you don’t want to. Choosing not to take part won’t affect your medical care in any way. Even if you do qualify for the study and decide to join, you can change your mind later and leave the study.

Determining whether you qualify for the study won’t benefit you directly.

Distinguish between screening procedures that are solely part of research and any screening procedures that are part of the subject’s standard clinical care. Explain that the study will pay only for screening procedures that occur solely as part of research and that the subject or their health insurance will be responsible for the costs of clinical procedures.

Like the information in your medical record, the records we create in this study will remain confidential and protected.

The following section (Authorization to Release Protected Health Information) is for eligibility screening procedures that involve accessing, using, or disclosing subjects’ protected health information (PHI). If your screening procedures 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 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.
* 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).

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.

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):

### 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): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_