

Informed Consent Template: General

**** Do not use for collection of biospecimens or research involving genetic analyses****

Informed consent is required to provide potential subjects or their legally authorized representatives with the information necessary for them to make a decision about participating in research.

Information in the consent document must be organized to facilitate comprehension. Consent documents should be written in plain language, generally at the 8th grade reading level. The reading level can be higher if the target population tends to have a higher literacy rate than the general population. For child assent documents, the reading level and complexity of the information provided should be appropriate for the age level of the child.

We recommend the use of this template to create the informed consent document(s) for your study. Please note:

1. Regulations now require that federally-sponsored research projects contain a concise and focused presentation of the key information that is most likely to help potential subjects understand why they might or might not want to participate in the study. The key information must be presented first and must include the following:
 - a. Identification of the project as a research study and that participation is voluntary
 - b. Purpose of the research, duration of participation, and a description of research procedures
Foreseeable risks or discomforts, if any
 - c. Expected benefits to subjects or others, if any
 - d. Alternative procedures or treatments that might benefit the subject
(Note: applies primarily to clinical research)

Many IRB-HSBS studies have brief consent documents (2 or 3 pages) that meet this new requirement without the need for a separate key information section. However, if your project is complex or involves numerous research procedures, this summary is required for federally-sponsored projects and strongly recommended for all others.

2. Text in [brackets] represents information about your study that you must add (in plain text).
3. A backslash indicates that you must make a selection depending on the procedures for your study (e.g., “will/will not” or “I/we”).
4. Additional instructions or sample text are provided in boxes.

For questions about informed consent, please contact the René Muñoz at 717-871-4457 or rene.munoz@millersville.edu

For more information on plain language go to <http://www.plainlanguage.gov/>.

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Consent to be Part of a Research Study

Title of the Project:

Principal Investigator: [Name, credentials, institutional affiliation]

Co-investigator: [Name, credentials, institutional affiliation]

Faculty Advisor: [Name, credentials, institutional affiliation]

Study Sponsor: [If any]

Include Faculty Advisor information only if you are a student PI.

Invitation to be Part of a Research Study

You are invited to participate in a research study. In order to participate, you must be [eligibility criteria; e.g., age, gender, language, etc.]. Taking part in this research project is voluntary.

Important Information about the Research Study

Things you should know:

- The purpose of the study is to [briefly describe study purpose]. If you choose to participate, you will be asked to [do what, when, where, and how]. This will take approximately [period of time].
- Risks or discomforts from this research include [briefly describe].
- The study will [description of potential direct benefits to subjects – or no benefits].
- Taking part in this research project is voluntary. You don't have to participate and you can stop at any time.

Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

For research projects that involve numerous research procedures that will require more than a 2-3 page consent document, provide a concise and focused presentation of key information that is most likely to help potential subjects understand why they might or might not want to participate in the study. Organize information to facilitate comprehension.

Delete this section if not necessary for the study.

What is the study about and why are we doing it?

The purpose of the study is [describe the study purpose].

If you have used the summary above, provide additional details in this section.

What will happen if you take part in this study?

If you agree to take part in this study, you will be asked to [provide a detailed description of what the subject will be asked to do in chronological order (what, when, where, how)]. We expect this to take about [duration, number of interactions]. [Indicate if information

collected will be linked to other data (e.g., research data, protected health information, or administrative data such as US Census data).]

For projects involving the collection of sensitive information or the inclusion of questions that might be upsetting, include examples of the type of questions that will be asked or describe the sensitive topic areas that are involved.

If applicable, include a statement about whether clinically relevant research results will be shared with the subject and under what conditions. For example: "We may learn information about your health as part of the research. We will/will not share this information with you [how/why not]."

How could you benefit from this study?

Although you will not directly benefit from being in this study, others might benefit because [insert details]. **[OR]** You might benefit from being in this study because [insert details].

What risks might result from being in this study?

There are some risks you might experience from being in this study. They are [describe specific risks, and indicate what the study team will do to minimize those risks.]. **[OR]** We don't believe there are any risks from participating in this research.

Primary risks include physical, psychological, or informational risks. For informational risks (e.g., those involving breach of confidentiality), describe what you will do to protect the data during collection, while stored or during transmission of the data in the section below. Psychological risks (e.g., those associated with the completion of a particularly sensitive survey or interview) could be mitigated by providing subjects with contact information for counseling resources.

For research posing more than minimal risk to subjects include the following text: "Please tell the researchers if you have any injuries or other problems related to your participation in the study. The University may be able to assist you with obtaining emergency treatment, if appropriate, but you or your insurance company will be responsible for the cost. 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."

How will we protect your information?

I/We plan to publish the results of this study. To protect your privacy, I/we will/will not include any information that could directly identify you.

If you wish to use identifying information in a publication or presentation, including photographs, audio or video recordings, include the following, as appropriate:

The results of this study may be published or presented at a scientific meeting. The researchers will ask for separate written permission to include your name [or pictures, recordings] or other information that could identify you.

I/We will protect the confidentiality of your research records by [explain]. Your name and any other information that can directly identify you will be stored separately from the data collected as part of the project. **[OR]** [Describe limitations to confidentiality, if any.]

It is possible that other people may need to see the information we collect about you. These people work for the University of Michigan, [the study sponsor, if any], and government offices that are responsible for making sure the research is done safely and properly.

If your project is NIH-funded and collects identifiable, sensitive information, it will be covered by a **Certificate of Confidentiality (CoC)** –or– if you will apply for a CoC for non-NIH-sponsored research collecting health-related, identifiable, sensitive information, insert the following language:

“This project [is funded by the NIH and] holds a Certificate of Confidentiality (CoC) that offers additional protections for your identifiable research information, [biospecimens], and records. The most important protection is that members of the research team cannot be forced to disclose or provide any of your private identifiable information, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding unless you provide permission. Disclosure of your research information may only occur in limited specific instances. [For mandatory reporters, include this statement: “For this study, the researchers may share your information with appropriate authorities if we learn about [include any legal requirements for abuse or public health reporting].” For the full detailed description of the CoC protections and exceptions to those protections, please refer to CoC Summary attachment at the end of this document.”

For projects not involving a CoC, if you are a **mandatory abuse** reporter and it seems likely you will encounter reportable events as part of the study, insert the following: “If you tell us something that makes us believe that you or others have been or may be physically harmed, we may report that information to the appropriate agencies.”

If your project meets the definition of an **NIH clinical trial**, include the following: “A description of this study will be posted on a public website, <http://ClinicalTrials.gov>, and summary results of this study will be posted on this website at the conclusion of the research, as required by the National Institutes of Health (NIH), the study sponsor. No information that can identify you will be posted.”

If you will **register your project on ClinicalTrials.gov** voluntarily or in order to meet journal or other sponsor requirements, include the following: “A description of this study will be posted on <http://ClinicalTrials.gov>, and summary results of this study may be

posted on this website at the conclusion of the research. No information that can identify you will be posted.”

What will happen to the information we collect about you after the study is over?

I/We will/will not keep your research data to use for [future research or other purpose]. Your name and other information that can directly identify you will be kept secure and stored separately from the research data collected as part of the project. **[OR]** Your name and other information that can directly identify you will be deleted from the research data collected as part of the project.

I/We may share your research data with other investigators without asking for your consent again, but it will not contain information that could directly identify you. [If data must or will be deposited in a public or other repository, briefly describe.] **[OR]** [We will not share your research data with other investigators.]

Sample text:

Data collected as part of this research will be provided to the XXX repository for future use by other researchers. This data will not contain information that could directly identify you.

How will we compensate you for being part of the study?

You will receive [nature and total amount of incentive/compensation] for your participation in this study. [Describe how compensation will be determined if the subject withdraws from the research before the end of the study.]

If compensation is more than \$100 in a calendar year, include the following text:

“Because this study pays more than \$100, the University of Michigan will collect your name, address, social security number, and payment amount. This information will be safely stored and used for income tax reporting purposes only if your total payments from the University of Michigan are greater than \$600 in a calendar year (January through December). If you receive more than \$600 in payments from the University of Michigan in a calendar year, this information will be submitted to the Internal Revenue Service (IRS) for tax reporting purposes and an extra tax form (Form 1099) will be sent to your home. If you are a University of Michigan employee, your research payments are tracked separately and are not included as part of your payroll.”

Delete this section if not applicable to the study.

What are the costs to you to be part of the study?

To participate in the research, you will need to pay for [Indicate what costs, if any, subjects will have to pay (such as parking)].

Delete this section if not applicable to the study.

Who can profit from study results?

Where a potential Conflict of Interest (COI) for a member of the study team (or the University of Michigan) has been identified, subjects must be informed about the nature of the conflict. Examples include:

- Investigators have an ownership, consulting, or similar financial relationship with a sponsor.
- 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 whose product is being studied, particularly if the company/organization is also the sponsor of the study or has a financial interest with the investigators.
- The University of Michigan may be paid licensing fees for the investigational technology, or could be paid in the future. Contact the Office of Technology Transfer if you are uncertain.

When a conflict may exist, the UMOR COI or MEDCOI review committees may recommend required language to be included in the consent documents.

Sample text:

“[Name of conflicted individual] is a named inventor on patents or patent applications or is the creator of copyrighted material that is licensed or optioned to company name] that will be used in this research. This means [conflicted individual] could gain financially from this study.”

Delete this section if not applicable to the study.

What other choices do I have if I don't take part in this study?

For projects that involve an intervention that might treat or improve a condition or a disease, describe alternatives to participation in the research study. These could include intervention or treatment available outside the research context.

Sample text:

“There may be other ways of treating your condition if you don't wish to be in this research. Check with your health care provider to discuss other options.”

Delete this section if not applicable to the study.

Your Participation in this Study is Voluntary

It is totally up to you to decide to be in this research study. Participating in this study is voluntary. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to answer any questions you do not want to answer. If you decide to withdraw before this study is completed, [provide details about disposition of data]. [Describe anticipated circumstances, if any, under which the subject's participation may be terminated by the PI without the consent of the subject].

Contact Information for the Study Team and Questions about the Research

If you have questions about this research, you may contact **[PI name, email, phone (and faculty advisor if PI is a student)]**.

The contact information for the study team must be bolded.

For International Studies: List the name, email and phone of the local collaborator, if any, first. Be sure to include the U.S. calling code and exit number for the country of origin. The number will be in the following format: Phone: XXX+1-734-936-0933.

Contact Information for Questions about Your Rights as a Research Participant

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

University of Michigan
Health Sciences and Behavioral Sciences Institutional Review Board
2800 Plymouth Road
Building 520, Room 1169
Ann Arbor, MI 48109-2800
Phone: (734) 936-0933 or toll free, (866) 936-0933
Email: irbhsbs@umich.edu

For International Studies: List information for the local IRB or Ethics Committee, if any, first. Omit the IRB-HSBS local and toll free numbers. Instead, include the U.S. calling code and exit number for the country of origin. The number will be in the following format: Phone: XXX+1-734-936-0933.

Your Consent

Required for projects obtaining a signature only – delete this paragraph for projects that will request a waiver of documentation. The document must be dated by the person signing.

For projects involving a waiver of documentation, include the following statement:

Before agreeing to be part of the research, please be sure that you understand what the study is about. We will give you a copy of this document for your records [or you can print a copy of the document for your records]. If you have any questions about the study later, you can contact the study team using the information provided above.

By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. I/We will give you a copy of this document for your records. I/We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

Printed Subject Name

Signature

Date

Parent or Legally Authorized Representative Permission

Delete this section if not applicable to the study.

For more than minimal risk research involving children, signature by two parents may be required. Contact the IRB-HSBS for more information.

By signing this document, you are agreeing to [your child's **OR** the person's named below] participation in this study. Make sure you understand what the study is about before you sign. I/We will give you a copy of this document for your records. I/We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

*I understand what the study is about and my questions so far have been answered. I agree for [my child **OR** the person named below] to take part in this study.*

Printed Subject Name

Printed Parent/Legally Authorized Representative Name and Relationship to Subject

Signature

Date

Printed Parent Name and Relationship to Subject (when 2 signatures are required)

Signature

Date

You may also need to obtain dated consent for specific activities when those activities are **optional**. Whether an activity is required or optional must be clearly described in the main body of the consent above. Some common optional research activities are included below:

Consent to be Audio/video Recorded

I agree to be audio/video recorded.

YES _____ **NO** _____

Signature

Date

Consent to Use Data for Future Research

I agree that my information may be shared with other researchers for future research studies that may be similar to this study or may be completely different. The information shared with other researchers will not include any information that can directly identify me. Researchers will not contact me for additional permission to use this information.

(Note: This separate consent is not necessary if you will only store and share deidentified data.)

YES _____ **NO** _____

Signature

Date

Consent to be Contacted for Participation in Future Research

I give the researchers permission to keep my contact information and to contact me for future research projects.

YES _____ **NO** _____

Signature

Date

Note 1: *If your research holds a CoC, include Attachment A as the last page of the consent document. If there is no CoC for this research, delete Attachment A from the consent document.*

Note 2: Text in [brackets] is instructional and is not meant to be a part of the Attachment A language. The brackets and text within should be deleted from the final version. **Delete Notes from the final version of document.**

Attachment A

Certificate of Confidentiality (CoC)

This research holds a Certificate of Confidentiality from the National Institutes of Health.

What is a Certificate of Confidentiality?

With this Certificate, the researchers may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research. A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

When are the researchers allowed by the CoC policy to disclose my information?

- If there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).
- If you have consented to the disclosure, including for your medical treatment. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.
- If it is used for other scientific research, as allowed by federal regulations protecting research subjects.

When may the researchers disclose my research information for this study?

- *[Use the following language as applicable; edit as necessary, e.g., if the research is federally funded but isn't subject to the requirements of the FDA, do not include the second phrase.]* If the [name of federal or state agency], the agency funding this research, requests information to audit or evaluate our procedures; or if we must disclose information in order to meet the requirements of the federal Food and Drug Administration (FDA).
- *[Use the following language if you intend to disclose information covered by a Certificate, such as with potential child abuse, or intent to hurt self or others, in response to specific federal, state, or local laws.]* The CoC will not be used to prevent disclosure of *[list what will be reported, such as child abuse and neglect, or harm to self or others]*, as required by federal, state, or local law. *[OR, for non-mandatory reporters]* If the researchers learn about child abuse or anything that leads them to think you might harm yourself or others, we may report this to the appropriate authorities.
- *[Use the following language if you intend to disclose information covered by a Certificate, with the consent of research participants.]* The CoC will not be used to prevent disclosure for any purpose you have consented to, as described in this informed consent document. This includes *[restate what will be disclosed, such as including research data in the medical record]*.