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|  | **Instructions for Developing the Informed Consent Document**  3/01/2022 |

The informed consent template has been revised to accommodate different kinds of research and changes in regulations.

This template contains 3 different kinds of language, distinguished by color:

* Language in black font is required and should (usually) appear in all informed consent documents.
* Language in green font provides instructions about what should be stated in various sections. Green font should **not** appear in the final document.
* Blue hyperlinks lead to sections that must be inserted depending on the nature of the research. These sections should be copied and pasted into the template. It is possible that you will not need to insert any language in this category. ScreenTips. Hovering the mouse pointer over a hyperlink reveals a small balloon with information about when to follow the hyperlink.

All fonts should appear black when you have finished constructing the document. Delete this page when you have finished developing the document.

# We anticipate that this template will be revised frequently.

**Be sure to use the most recent version.**

# Please send us feedback about the template: [cmuirb@cmich.edu](mailto:cmuirb@cmich.edu) Other Forms

Certain kinds of research require authorizations or releases in addition to a consent to participate in research. The following forms are available on IRBNet.

**HIPAA**. If you intend to access, collect, or disseminate protected health information (PHI) from research participants, you will have to use a separate *Authorization Form* in addition to the *Consent Form*.

**FERPA**. If you intend to access, collect, or disseminate information from education records of adult participants, you will have to use a separate *Authorization Form* in addition to the Consent Form.

**Informed Consent to Participate in Research**

|  |  |
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| **Study Title:** | Title as shown on IRB application |
| **Research Investigator(s):** | Names and Departments.  Principal Investigator MUST be a faculty member |
| **Investigator(s) Contact Information** | Office phone and cmich.edu address. Do not supply home phone number; it is not advisable to list a personal cell phone number or a personal email address. |

# Key Information.

Required if the consent from exceeds 3 pages in length, then it must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

# Introductory statement.

Introduce the study, inviting the person’s participation and explaining that details are provided in this consent document. State that investigator(s) is(are) available to answer any questions the participant may have about the project.

# What is the purpose of this study?

State that the study involves research and explain the purpose of the research in non- technical language.

# What will I do in this study?

Describe the procedures to be followed and their purpose. Identify any procedures that are experimental.

[Recordings](#_bookmark2).

# How long will it take me to do this?

Describe the expected duration of the subject’s participation.

# Are there any risks to me for participating in the study?

Describe any risks and/or discomforts that can reasonably be expected as a result of participating in this study. Avoid saying there are no risks. For minimal risk study, it is acceptable to state “This study poses no risks beyond the risks encountered in daily

life.“

[Injury Clause](#_bookmark3)

# What are the potential benefits of participating in the study?

Describe any potential benefits to the participants, society, or both that can reasonably be expected from the research. If there are no benefits to an individual, state so.

Note: Compensation is not a benefit of the study.

# Is there a different way for me to receive the benefits of this study?

Describe any alternate procedures that may provide benefits without participating in this research. [Usually applicable in medical or behavioral studies for which standard therapies are available. *Delete this section if it is not relevant to your study*.]

# Who beside the research team will know what I will do or say in this study (Confidentiality)?

Staff of Central Michigan University and government agencies who ensure the protection of human subjects in research may examine your records.

Identify any other persons or agencies, including the sponsor, to whom confidential information will be disclosed.

State the nature of the information to be disclosed, and the purpose of the disclosure.

State that in all other instances, any data under the investigator’s control will, if

disclosed, be presented in a manner that does not reveal the subject’s identity, except

as may be required by law.

Avoid guaranteeing anonymity or describing the study as “anonymous”.

# Additional information about confidentiality

Delete this section if none of the following items apply [Focus Groups](#_bookmark5)

[Mandatory Reporting](#_bookmark5)

[Research Exception to Requirement to Report Sexual Misconduct](#_bookmark7) [Certificate of Confidentiality](#_bookmark6)

# What will happen to my data after the study?

The consent document MUST include one of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

1. Identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
2. Your information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies. [Recordings](#_bookmark4)

Note: This form MAY NOT be used to obtain consent to store IDENTIFIABLE private

information or identifiable biospecimens for future studies. (“Broad Consent”) Consult

IRB office for further information on this point.

# Additional information about this research.

Delete this section if none of the following items apply [Compensation](#_bookmark11)

[Financial support](#_bookmark0) [Financial interest](#_bookmark1) [Commercialization.](#_bookmark8)

[Returning results of clinical tests](#_bookmark9). [Genomic sequencing.](#_bookmark10)

# How can I contact a member of the research team?

To talk to someone on the research team about the research, research subjects’ rights, or to report a research-related injury, please call [name and telephone number of a specific office or person].

# How can I contact someone outside the research team for information about this study?

To talk to someone other than the researcher(s) about your rights as a research participant; obtain information; report a research-related injury; ask questions or discuss any concerns about this study; or you wish to offer input about this study, please contact (anonymously if you wish):

Central Michigan University Institutional Review Board 600 East Preston Street, Foust Hall 104

Mount Pleasant, MI 48859 Phone: (989) 774-6401

Email: [researchconcern@cmich.edu](mailto:researchconcern@cmich.edu)

# What happens if I refuse to participate or want to stop being in the study?

You are free to refuse to participate in this research project or to withdraw your consent and discontinue participation in the project at any time without penalty or loss of benefits to which you are otherwise entitled. Your decision not to participate will not affect your relationship with the institution(s) involved in this research project.

[Can someone else end my participation in this study?](#_bookmark13) [Information for European participants](#_bookmark12)

# Statement of Consent

My signature below indicates that I am 18 years of age or older and all my questions have been answered. I consent to participate in the project as described above.

|  |
| --- |
| Name of Participant: |
| Signature: |
| Date: |

You will be given a copy of this form to keep for your records.

[Legally Authorized Representative (LAR).](#_bookmark13) [Statement of Person Obtaining Consent](#_bookmark14)**.**

**Delete any text that follows.**

# ADDITIONAL ELEMENTS OF CONSENT TO BE ADDED WHEN APPROPRIATE

**Financial Support.**

This work is financially supported by [insert name of sponsor]. Central Michigan University and Dr [insert name of investigator] are being paid to conduct this research.

# Financial Interest in this Research.

Dr [name of investigator] has the following financial interest in this research: [Insert description of interest]... As appropriate, give details of the COI management plan.

# Recordings.

If audio or video recordings will be made, state that the participant’s responses will be recorded. In some situations it may be appropriate to request that the participant initial this section.

# What if I am injured while participating in this study?

If you are injured while participating in the study, CMU personnel will assist you in obtaining emergency care. If you have insurance for medical care, the insurance carrier will be billed in the ordinary manner. As with any medical insurance, any costs that are not covered or in excess of those paid by your insurance, including deductibles, will be your responsibility. CMU does not provide financial compensation for the disability, pain, or discomfort, unless required by law to do so. This does not mean that you are giving up any legal rights you may have. You may contact [Name of Principal Investigator] at (989) 774-XXXX with any questions or to report injury.

If the research is sponsored by a company and presents greater than minimal risk to research subjects, then the sponsor may be contractually required to pay for research- related injury. Consult the Office of Sponsored Projects for specific language.

# Recordings

If the study involves video or audio recording, include a specific statement about what will happen to the recordings when the study is completed or if a subject withdraws before completion.

# Focus Group(s)

If the study involves focus groups, state that all participants are asked to respect the confidentiality of what other participants say, but confidentiality cannot be assured.

# Mandatory Reporting.

If, during your participation in this study, we have reason to believe that elder abuse or child abuse is occurring, or if we have reason to believe that you are at risk for being suicidal or otherwise harming yourself, we must report this to authorities as required by law. We will make every effort to keep your research information confidential.

However, it may be possible that we have to release your research information. If this were to occur, we would not be able to protect your confidentiality.

**Certificate of Confidentiality. *(Only for NIH-supported research)***

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate 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 except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

For further guidance, consult https://humansubjects.nih.gov/coc/suggested-consent- language

# Research Exception to Requirement to Report Sexual Misconduct.

Responsible Employees are not required to report allegations of Sexual Misconduct to the Title IX Coordinator, or designee, when the disclosure is made during the course of a research project approved by the CMU Institutional Review Board.

[Policy Reference](https://www.cmich.edu/office_provost/ORGS/ComplianceandResearchIntegrity/InstitutionalReviewBoard/Documents/Sexual%20Misconduct%20policy%20change%20announcement%20FINAL.pdf)

# Commercialization

A statement that the participant’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.

# Will test results be shared with me?

A statement whether clinically relevant research results, including individual research results, will be disclosed to participants, and if so, under what conditions.

# Will my blood or tissue be used to sequence all or part of my genome?

For research involving biospecimens, a statement whether the research will (if known) or might include whole genome sequencing (ie, sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

# Will I receive any compensation for participating?

Describe the amount and nature of any compensation to be paid for participating in the research. Indicate whether payments will be prorated. (The IRB generally requires prorating compensation.)

**Is there a different way for me to receive this compensation for participating?** Describe alternative procedures, if any, that might be available. Otherwise state there is no other way.

# Can someone else end my participation in this research?

Yes. Under certain circumstances, the researchers or the study sponsor might decide to end your participation in this research study earlier than planned. This might happen because funding for the project has ended.

# Information for European Participants (Members States of the EU, Iceland, Liechtenstein, Norway, or UK)

If you are a resident of one of the Member States of the European Union, or of Iceland, Liechtenstein, Norway, or the UK, then you have additional rights under the General Data Protection Regulations (GDPR). You have the right to withdraw your consent to participate as easily as you gave your consent initially. You may request that data about you collected in the course of this research be erased and we will honor your request or explain why the request cannot be honored. Consult IRB on this matter.

# Statement by Legally Authorized Representative (LAR):

My signature below indicates that I am 18 years of age or older and all my questions have been answered. I agree to allow my charge to participate in the project as described above.

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| --- | --- |
| Name of Participant: |  |
| Name of LAR: |  |
| Signature of LAR: |  |
| Relationship to Participant: |  |
| Date: |  |

# Statement of Person Obtaining Consent

I have discussed with this participant or LAR the procedure(s) described above and the risks involved in this research. I believe he/she understands the contents of this consent document and is competent to give legally effective and informed consent.

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| --- |
| Name: |
| Signature: |
| Date: |