# INFORMED CONSENT TEMPLATE: INSTRUCTIONS

* The following template is an example of how to do a written consent form. The HRPP "Forms and Other Resources" web page discusses informed consent in more detail, including notes on how written forms may have to be adapted when waivers are requested, or when they are used to gain parental permission.
* A consent document should read in at a level appropriate for your target audience**. Layman’s terms!** We highly recommend having a non-scientist or a person not on your research team read your draft consent prior to submitting to the eIRB system. You can then make changes to any section that is not clear to them.
* Areas with red text require modifications specific to your research study project, remove any sample language or optional sections not relevant to your study project.

**CONSENT TO PARTICIPATE IN RESEARCH**

**Title of the study**

**INTRODUCTION**

You are asked to participate in a research study conducted by name of PI, and student if appropriate, from the departmental affiliation at Michigan Technological University. If student, indicate whether study is being conducted as part of undergraduate project, graduate student project, thesis, or dissertation. Your participation in this study is entirely voluntary. Please read the information below and ask questions about anything you do not understand, before deciding whether or not to participate.

You have been asked to participate in this study because…be sure to include the following information in this section:

* Describe who is eligible to participate.
* Communicate the total commitment to participate - duration or length of time.
* List inclusion or exclusion criteria for participation (e.g., medical conditions that would include or exclude a person).
* Approximate number of subjects involved in the study.

**PURPOSE OF THE STUDY**

Briefly state in a couple sentences what the study is designed to examine, assess, or establish.

**PROCEDURES**

If you volunteer to participate in this study, you will be asked to do the following things:

* Reminder keep this information in Layman’s terms! A prospective participant should not have to use the internet to search out medical or scientific terminology.
* Provide clear and thorough information about the procedure or task the person will perform.
* If applicable, specify assignment to study groups, length of time for participation in each procedure or study activity, the total length of time for participation, frequency of procedures and location of the procedures to be done.
* If subjects will be recorded (audio and/or video), describe the procedures to be used.
* If any study procedures are experimental, clearly identify which ones.

**RISKS OR DISCOMFORTS**

Describe any risks and/or discomforts *(physiological, psychological, social, legal, or financial)* that are known or associated with the participating in this research study.

* **Refrain from “minimizing risks”.** State what is currently known (or unknown) about the potential risks. If past research is limited and a part of the reason for the study, tell them that as well.
* Explain how you will manage any risks to lessen the possibility of that risk happening. For example:
  + Is this a procedure the study team (or supervising PI) has performed routinely and on the target population group?
  + Does the procedure require routine certification to perform, if so, who is certified from the research team and state they will be the only one conducting the procedure?
  + Is the research team First Aid/CPR certified?
  + Do you have an AED and/or first aid kit available in the location the research study will be performed?
  + If appropriate for your research, state that 911 will be called in the event of an emergency. Further reassure prospective participants by including information about our MTU Emergency Medical Services (EMS). How quickly can they be deployed to your study location?

If there is a risk of injury, include something like the following:

"In the event of physical and/or mental injury resulting from participation in this research project, Michigan Technological University does not provide any medical, hospitalization or other insurance for participants in this research study, nor will Michigan Technological University provide any medical treatment or compensation for any injury sustained as a result of participation in this research study, except as required by law."

**POTENTIAL BENEFITS TO SUBJECTS AND/OR TO SOCIETY**

Describe benefits to subjects expected from the research. State the potential benefits, if any, to science or society expected from the research.

If the subject will not directly benefit from participation, clearly state this fact. You could write something like: “Although you will not directly benefit by participating in this study, we hope that what we learn will help us to …….”

***Note:*** *Payment or other compensation for participation (e.g., a gift certificate, extra credit) is* ***not*** *a benefit and is not to be discussed in this section. Include a Compensation Section (see below)*

For biomedical studies, include something like the following:

"Based on experience with this drug, procedure, device, etc. in animals, patients with similar disorders, researchers believe it may be of benefit to subjects with your condition or, it may be as good as standard therapy but with fewer side effects. Of course, because individuals respond differently to therapy, no one can know in advance if it will be helpful in your particular case. The potential benefits may include: describe the anticipated benefits to subjects resulting from their participation in the research."

If there is no likelihood that participants will benefit directly from their participation in the research, state in clear terms. For example: “You should not expect your condition to improve as a result of participating in this research” or “This study is not being conducted to improve your condition or health. You have the right to refuse to participate in this study.”

**COMPENSATION FOR PARTICIPATION (if relevant)**

Describe any compensation here, including any details on how it will be affected by dropping out of the study, or being removed from it, before completion.

**Financial compensation:** be sure to follow the compensation policy document found on the HRPP "Compensating Research Subjects" web page.

**Class credit**: If you plan to recruit participants from the Sona Systems Pool, be sure to state the exact amount of class credit received for amount of time for participation. Include whether or not they will receive full credit if they withdraw early or are withdrawn by the investigator. If they withdraw early and would not be eligible for the full class credit stated, include information about amount that will be received or optional assignments to receive the amount of class credit (such as reading an article about the type of research you are conducting). Include a statement that withdrawal from the study will have no effect on the participant’s class grade or class standing.

**CONFIDENTIALITY**

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. Confidentiality will be maintained by means of describe any coding procedures and plans to safeguard data, including where data will be kept, (i.e., locked drawer in researchers office), who will have access to it, and/or disposal of participant’s data or records (you must indicate a minimum of three years retention after the completion of the final report or alternate length of time if it needs to be longer. Federal IRB regulations require the retention of records for three years after the completion of the final report. Research sponsors, the institution, and including you and your project, may need to impose longer retention periods. If that is the case, the period of retention must be stated and adhered to.

If information will be released to any other party for any reason, state the person or agency to whom the information will be furnished, the nature of the information, the purpose of the disclosure, and the conditions under which it will be released.

If identifiable private information or identifiable biospecimens are being collected, one of the following must be included:

A statement that 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

A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

When confidentiality of participant identity is not proposed, such as when participants will be quoted by name, this section must be clear regarding where and how the quotes will be used. Participants should also be told they have the opportunity to review the text or audio/visual which their quotes or identity appear to ensure proper attribution.

If activities are to be audio- or videotaped or digitally recorded, describe who will have access, if the tapes/files will be used for educational purposes, and when they will be erased or destroyed.

If a subject form is used, add “In case of an emergency, injury, or illness that occurs during this study, I hereby authorize the release of any and all health information to allow for medical care and treatment of my condition.”

If biospecimens are involved, include the following:

* A statement that biospecimens may be used for commercial profit, and whether or not the subject will share in that profit.
* A statement regarding whether clinically relevant research results will be returned to subjects, and under what conditions.
* A statement specifically for research involving biospecimens about whether the research will or might include whole genome sequencing.

**PARTICIPATION AND WITHDRAWAL**

You can choose whether or not to be in this study. If you volunteer to be in this study, you may withdraw at any time without consequences of any kind or loss of benefits to which you are otherwise entitled. You may also refuse to answer any questions you do not want to answer. There is no penalty if you withdraw from the study and you will not lose any benefits to which you are otherwise entitled.

Include something like the following paragraph if relevant:

The investigator may withdraw you from this research if circumstances arise which warrant doing so. Describe the anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent. (This also may refer to situations in which the study itself may be terminated. It is not the same thing as circumstances in which a specific subject may be withdrawn).

**ALTERNATIVES TO PARTICIPATION (if relevant, e.g. in clinical trials)**

Describe any appropriate alternative therapeutic, diagnostic, or preventive procedures that should be considered before the subjects decide whether to participate in the study. If applicable, explain why these procedures are being withheld. If there are no efficacious alternatives, state that an alternative is not to participate in the study.

**FURTHER INFORMATION**

If you have any questions or concerns about this research, please contact: identify the research personnel to contact, i.e. the Principal Investigator (PI), or Co-Investigator, and student researcher (if relevant). If not already included at the beginning of the consent form, include contact phone number, mailing address, and email address for listed individuals. For some studies of greater than minimal risk, it may be necessary to include alternate/emergency phone numbers.

The Michigan Technological Institutional Review Board (MTU-IRB) has reviewed my request to conduct this project.  If you have any concerns about your rights in this study, please contact the MTU-IRB at 906-487-2902 or email IRB@mtu.edu.

I understand the information provided above. My questions have been answered to my satisfaction, and I confirm that I am age 18 years or older and I agree to participate in this study. I have been given a copy of this form. If audio/video recording participants, include checkboxes above the signature line with two statements “I agree to participate and be recorded” **or** “I agree to participate but I do not agree to be recorded”.

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Printed Name of Subject

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Signature of Subject Date

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Signature of Witness\* Date

\*Only necessary under certain circumstances.