Use of consent templates is strongly encouraged.
Consent templates for social science and biomedical research are available at the Human Research Protection Program (HRPP) website. Investigators are strongly encouraged to utilize the consent templates. The templates provide standard language that investigators may copy and paste directly into their consent form or the template may be modified directly to create a consent form.

Informed consent is a process, not just a form.
Information must be presented to enable potential subjects to decide voluntarily whether or not to participate in a research study. It is a fundamental mechanism to ensure respect for persons who may be willing to offer their bodies and experiences to assist investigators in research without promise of benefit.

The procedures used in obtaining informed consent should be designed to educate the subject population in easily understood terms. The process should include information regarding the study’s purpose, duration, experimental procedures, alternative treatments (if applicable), risks, and benefits.

When developing an informed consent process, investigators should consider the following criteria as appropriate:
- the person who will conduct the consent interview
- the person who will provide consent or permission
- any waiting period between informing the prospective subject and obtaining consent
- steps taken to minimize the possibility of coercion or undue influence
- language used by those obtaining consent
- language understood by the prospective subject or legally authorized representative
- information to be communicated to the prospective subject or legally authorized representative

See HRPP Manual 6-4 “Informed Consent” for regulatory informed consent requirements, e.g., provide subject with sufficient opportunity to consider whether participate, minimization of coercion, or undue influence.
Consent form should be written in “lay terms.”
Informed consent language must be written in "lay language" (i.e., understandable to the individuals being asked to participate). Use of scientific terms and legalese is not appropriate. Simple declarative sentences are most appropriate.

Consent forms should be written in the second person.
The U.S. Office for Human Research Protections (OHRP) says that the use of the first person (e.g., “I will view seven videos,” “I give permission to…”) can be interpreted “as suggestive … and can constitute coercive influence over a subject.” The second person pronoun (e.g., "you are being asked to participate in a study because....") is preferred because it is more open and conversational with subjects. Use of first person may also be interpreted as presumption of subject consent, i.e., the subject has no choice. The second person writing style helps to communicate that there is a choice to be made by the prospective subject. Simple declarative sentences are best using the second person pronoun written just as the investigator would give an oral explanation to the subject, that is, the subject is addressed as "you" and the investigator as "I/we."

The use of the word “understand” in consent forms is strongly discouraged.
Use of the wording, "I/you understand..." in informed consent documents is also inappropriate, as some prospective subjects may not "understand" all the statements. Also, the tone of the first person "I/you understand" style seems to misplace emphasis on legal statements rather than on explanatory wording enhancing the subject's comprehension. Subjects simply agree to participate following a detailed explanation and discussion of the research study and its potential risks.

Consent form may not indicate or imply Institutional Review Board (IRB) endorsement.
The consent form should not indicate or imply that the IRB has endorsed the research study.

Permission to be audio/video recorded should be included in the consent form.
A researcher’s intent to tape and/or film subjects should be indicated in the consent form, and there should be signed permission by the subject to be taped/filmed. The consent form should indicate how the recorded materials will be used. Will tapes be kept or destroyed at the end of the study? What will the investigator do if the subject withdraws?

Permission to use tissue, blood, fluids, or genetic material should be included in the consent form.
See the biomedical research consent template for suggested language regarding use of genetic and other materials for future use.

Compensation should be described in the consent form.
A description of any compensation (e.g., payment, services, course credit) that encourages subject participation should be included in the consent form. See HRPP Manual 6-5 “Selection of Subjects” for policies and procedures related to compensation.

Any conflict of interest should be disclosed in consent form.
Any potential for real or perceived conflict of interest should be disclosed in the consent form.

The recommended contact language for questions, concerns, and complaints should be included in the consent form.
The consent form should include contact information for the researcher and the MSU IRBs. The following language is recommended:

“If you have concerns or questions about this study, such as scientific issues, how to do any part of it, or to report an injury, please contact the researcher (name and complete contact information: mailing address, e-mail address, phone number).

If you have problems, questions or concerns about your role and rights as a research participant, would like to obtain information or offer input, or would like to register a complaint about this study, you may contact, anonymously if you wish, the Michigan State University’s Human Research Protection Program at 517-355-2180, Fax 517-432-4503, or e-mail irb@msu.edu or regular mail at 202 Olds Hall, MSU, East Lansing, MI 48824.”

The subject must be able to contact the researcher at the contact information provided.

Language immediately before signature should be concise and simple.
Language immediately before the subject’s signature should simply say “I voluntarily agree to participate in this study.” or “Your signature below indicates your voluntary agreement to participate in this study.” It is not necessary to reiterate information presented earlier in the consent document.

A date line should be included next to the signature line in the consent form.
A date line is typically required in all consent forms and must be included in consent forms for research studies regulated by the U.S. Food and Drug Administration (FDA).

Multi-page consent documents should include pagination.
If you have a multi-page consent form it is helpful to include pagination (e.g., 1 of 3).

Consent forms should include specific formatting.
Investigators must format their consent form in Microsoft Word. The footer of the document should remain blank. The document should include a 1 inch margin at the bottom of the document for the IRB office to insert the IRB approval footer.

Additional Considerations
For policies and procedures related to informed consent, see the following sections of the HRPP Manual:
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<thead>
<tr>
<th>6-4</th>
<th>Informed Consent</th>
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<td>6-4-A</td>
<td>Documentation of Informed Consent</td>
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<tr>
<td>6-4-B</td>
<td>Waiver or Alteration of Informed Consent</td>
</tr>
<tr>
<td>6-4-C</td>
<td>Parental Consent and Child Assent</td>
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<tr>
<td>6-4-D</td>
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