

Informed Consent/Assent Form requirements *:

1. Must include **ALL** required elements of consent (see below). It is recommended that you use the NSU IRB Consent Templates as they have all the required elements of consent.
2. Use the NSU IRB template that can be found on the “IRB Templates” page of our website.
 - **CEME – Use the NSU IRB template unless your institution has a consent template they mandate.**
3. All forms must have 1.25" or greater margin at the top of each page to allow for electronic approval stamping.
4. The first page of each consent form must be on the official Letterhead of your College or academic unit. Contact your College Representative to obtain a copy.
 - **CEME – Use the NSU IRB CEME College of Osteopathic Medicine letterhead unless your institution has a letterhead they mandate.**
5. If your Informed Consent Form does not meet these requirements, it will be sent back to you for revision.

Elements of Consent: The following eight items must be included in the consent form as documentation that the consent process covered these essential principles of Informed Consent:

1. A description of the research, including that the study is research, the purpose of the research, the duration and nature of the procedures associated with participation, and which, if any, procedures are experimental.
2. Reasonable foreseeable risks associated with participation.
3. A description of benefits to participants as a result of the research.
4. Appropriate alternative procedures or courses of treatment that may be deemed beneficial to the participant, as applicable.
5. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained.
6. If the study is greater than minimal risk, an explanation of possible compensation for injuries, availability of medical treatments and further information on obtaining such treatment.
7. Contact information for questions about the research, participants’ rights, and research-related injuries.
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

Additional Elements of Consent: The following six items must be included when appropriate, but are not required under federal regulations. The IRB may determine that some, or all, of these additional elements are required during the IRB review process:

1. A statement that a particular treatment or procedure involves unforeseeable risks to the participant (including embryos or fetuses, if the participant or their partner may become pregnant)
2. A description of when the researcher may terminate participation without the participant's consent
3. Any additional costs to the participant that may result from participation in the research
4. A description of how a participant may withdraw from a study and in any potential consequences from early withdrawal
5. A statement indicating how significant new findings, developed during the course of the research, will be communicated to participants.
6. The approximate number of participants involved in the study.

Elements Required by Other States or Federal Agencies:

1. For research involving FDA-regulated drugs or devices to be used in clinical trials, the following statement is required: "A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."
2. Other statements required by state law and regulation, depending on where the study will be conducted.
3. Other statements required by non-NSU Institutional Review Boards that may be responsible for reviewing and approving the study.
4. Other statements required as required by sponsored, funding agencies, or other entities with authority over the conduct of the study.