**Eastern Illinois University**

**Institutional Review Board for Review of Research Involving Human Subjects**

**Informed Consent Form Checklist**

For further guidance and phrasing assistance, see the [Informed Consent Template](https://www.eiu.edu/grants/COMP_IRB_Forms.php) at the EIU IRB website.

Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a subject 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.

Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the subject’s understanding of the reasons why one might or might not want to participate.

Informed consent/assent forms should be written in second person (e.g., You are being asked to participate…).

**Basic elements to include:**

[ ]  A statement that the study involves research

[ ]  An explanation of the purpose(s) of the research

[ ]  Optional: An explanation as to why subject is eligible to participate

**Procedures**:

[ ]  A chronological description of the procedures to be followed. Use language appropriate to the population

[ ]  The expected duration of the subject’s participation
If applicable, state the length of time for participation in each procedure or activity, the total length of time for participation, frequency of procedures and location of the procedures.

[ ]  If subjects will be recorded (audiotaped, videotaped, digitally), describe the procedures to be used.

[ ]  If any study procedures are experimental, clearly identify which ones.

[ ]  If applicable, describe any appropriate alternative therapeutic, diagnostic, or preventive procedures that might be advantageous to the subjects and should be considered before the subjects decide whether to participate in the study.

**Risk or Discomfort**:

[ ]  A description of any reasonably foreseeable risks or discomforts to the subject, an estimate of their likelihood, and a description of what steps will be taken to prevent or minimize them

[ ]  For research involving more than minimal risk: an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained

[ ]  If there are circumstances in which the researcher may terminate the study without regard to the subject’s consent, include a description of those circumstances.

**Potential Benefits**:

[ ]  A description of any benefits to the subject or to others which may reasonably be expected from the research. *Monetary compensation is not a benefit*.

[ ]  If the subject will not benefit directly from participation, clearly state this fact.

**Incentives for Participation** (Provided only if subject will receive incentive to participate):

[ ]  If subject will receive incentives, describe type and amount, and when incentives (e.g., money, extra credit, gift certificate) are scheduled for distribution
If compensation is prorated in the event the subject does not complete the study, this must be indicated as well.

**Confidentiality**:

[ ]  A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. Include a description of whom may have access to research records

[ ]  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 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 research involves the collection of identifiable private information or identifiable biospecimens, one of the following statements:

* 1. That identifiers might be removed from the identifiable private information or biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another PI for future research studies without additional informed consent from the subject, IF this might be a possibility, or
	2. 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.

**Participation and Withdrawal**:

[ ]  A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled

[ ]  Optional: a statement that the subject may also refuse to answer any questions they do not want to answer.

[ ]  If applicable, a statement that the subject may be withdrawn from the research by the investigator if circumstances warrant it.

**Identification of Investigators**:

Note: When a student is the PI, **the Faculty Sponsor or EAP must be identified**. Student researchers (whether PI’s or Co-PI’s) can, but are not required to be identified.

[ ]  An explanation of whom to contact for answers to questions about the research. Identify faculty/staff research personnel including Principal Investigator, Faculty Sponsor (if student is the P.I.), Co-Investigator(s), if any. Include daytime phone numbers, and email addresses for all listed individuals.
For studies of greater than minimal risk, it may be necessary to include night/emergency phone numbers.

**Rights of Research Subjects**:

[ ]  A statement that the subject may contact the Institutional Review Board (IRB) with any questions or concerns they may have regarding the treatment of human participants in the study.

[ ]  A description of the IRB

[ ]  Contact information for the IRB

[ ]  A statement that the IRB has reviewed and approved the study

**Signatures**:

Note: If informed consent or documentation of informed consent is being waived, this section will not need to appear

[ ]  A statement that the participant is voluntarily agreeing to participate in the study, and understands that they are free to withdraw or discontinue participation

[ ]  Area for Participant printed name, signature, and date

[ ]  If study involves minors and/or disabled subjects who cannot otherwise consent, include an area for signature of subject parent or guardian

[ ]  Statement that the investigator has defined and explained the study to the participant, along with an area for investigator signature and date.

**Additional elements, as appropriate**:

[ ]  The approximate number of subjects involved in the study

[ ]  Any additional costs to the subject that may result from participation in the research

[ ]  The consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject

[ ]  When appropriate, a statement concerning an investigator’s potential financial or other conflict of interest in the conduct of the study

[ ]  A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to the subjects, and if so, under what conditions

[ ]  A statement that significant new findings developed during the course of the research, which may relate to the subject’s willingness to continue participation, will be provided to the subject

[ ]  A statement that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable (or to the embryo or fetus if the subjects is or my become pregnant)

[ ]  For research involving biospecimens, whether the research will (if known) or might include genome sequencing

[ ]  A statement that the subject’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