**Purpose:** This document is intended to serve as a checklist for consent, minor assent, and parental permission forms. In this document, the requirements from the Revised Common Rule, university policy, and other applicable State/Federal laws are listed as individual elements. Parental permission forms require the same information as consent forms. [Click here to skip to assent requirements.](#Assent) New Federal requirements are emphasized with the placement of the “” icon at the beginning of the item.

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| **Yes** | **No** | **N/A** | **General Informed Consent Requirements**  *As specified under Federal regulation 45 CFR 46.116(a) of the Revised Common Rule.* |
|  |  |  | (1) Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative. |
|  |  |  | (2) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence. |
|  |  |  | (3) The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative. |
|  |  |  |  (4) The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information. |
|  |  |  |  (5) (i) Informed consent must begin with a concise and focused presentation of the key information 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. |
|  |  |  |  (ii) 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 prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate. |
|  |  |  | (6) No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence. |

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| **Yes** | **No** | **N/A** | **Basic elements of informed consent**  *As specified under Federal regulation 45 CFR 46.116(b) of the Revised Common Rule.* |
|  |  |  | (1)  The following elements are required under *45 CFR 46.116(b)(1)*   * A statement that the study involves research * An explanation of the purposes of the research * The expected duration of the subject's participation * A description of the procedures to be followed * Identification of any procedures that are experimental |
|  |  |  | (2) A description of any reasonably foreseeable risks or discomforts to the subject |
|  |  |  | (3) A description of any benefits to the subject/others that may reasonably be expected from the research |
|  |  |  | (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject |
|  |  |  | (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained |
|  |  |  | (6) 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 |
|  |  |  | (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject |
|  |  |  | (8) 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 |
|  |  |  | (9) **One** of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:   1. 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** 2. 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. |

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| **Yes** | **No** | **N/A** | **Additional elements of informed consent**  *As specified under Federal regulation 45 CFR 46.116(c) of the Revised Common Rule these may be required if they are applicable* |
|  |  |  | (1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable |
|  |  |  | (2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent |
|  |  |  | (3) Any additional costs to the subject that may result from participation in the research |
|  |  |  | (4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject |
|  |  |  | (5) A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject |
|  |  |  | (6) The approximate number of subjects involved in the study |
|  |  |  |  (7) 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 |
|  |  |  |  (8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions |
|  |  |  |  (9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen) |

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| **Yes** | **No** | **N/A** | **Elements of Informed Consent Required by University Policy or other Federal/State Laws** (These must be included in the consent form if applicable) |
|  |  |  | (1) The consent form must state any criteria that would make the potential participant either ineligible or eligible to participate.   * Example: If only adults will be eligible and a minor could be recruited, a statement that the participant must be 18 or older to be eligible to participate must be in the form. * This is related to ***45 CFR 46.116(a)(4)*** |
|  |  |  | (2)  Language regarding the GDPR must be in the consent form if identifiable private information could be collected from individuals when they are in the European Economic Area at the time of data collection. |
|  |  |  | (3) The consent form must either state that a copy of the consent form will be provided to the participant or instruct them to print a copy of the consent form for their records. |
|  |  |  | (4) If research incentives are being provided, language regarding the compensation must be in the consent form.   * [Click here for additional information on research incentives](https://research.illinoisstate.edu/ethics/human/payments/) |
|  |  |  | (5) If mandated reporting of criminal activity or child abuse/neglect may be required, language indicating that the researcher is a mandated reporter needs to be included in the consent form. **Suggested Template Language** *(Note: Text within brackets must be edited by PI*)  “We need to make you aware that in certain research studies, it is our legal and ethical responsibility to report [situations of child abuse, child neglect, or any life-threatening situation] [illegal activity on the ISU campus, campus-controlled locations, or involving ISU students] to appropriate authorities. However, we are not seeking this type of information in our study nor will you be asked questions about these issues.” |
|  |  |  | (6) If recordings (i.e. audio, video & image) will be collected and the collection of these recordings are optional, a separate signature must be obtained from the participant to indicate that agree to be recorded. This can either be a separate signature line or separate page. |

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| **Yes** | **No** | **N/A** | **Assent** (if applicable) |
|  |  |  | Note: Parental permission is usually required before the child is approached for assent. |
|  |  |  | For studies involving children capable of assent, the assent process must incorporate oral and/or written communication; illustrate respect for the child; convey voluntary nature of decision; and include information the child requires, in a manner he/she can understand, in order to make a decision about participating in the research. |
|  |  |  | If young children (typically ages 3-8) are involved who are yet unable to read, develop an assent script, which provides the children with information in a format that facilitates a voluntary decision whether or not to assent. Documentation should take a form that is appropriate for the purpose of recording that assent took place. |
|  |  |  | For children at an age, maturity, and degree of literacy capable of understanding a written form, develop a simplified Assent Form using format and language appropriate for the study population, including a signature unless documentation has been waived. |