

Indiana University Kokomo
Institutional Review Board for the Protection of Human Subjects
Guidelines for Preparing Informed Consents

Informed consent is a hallmark of ethical research practice. Expedited and Full Review Studies will be required to use informed consent, except in very limited circumstances that meet strict exclusion criteria. Researchers conducting Exempt Studies should use informed consent in most circumstances, as well. If the informed consent document in the exempt study would be the only personal identifier gathered by the researcher, then an informational statement that is not signed may be reasonably substituted.

Here is a checklist that the researcher may use to help prepare a complete informed consent statement:

- Wording understandable to the subject population (explain technical/medical terminology).
- Use of “understand” language.
- Heading: “Indiana University Kokomo Informed Consent Statement,” Title of Research, Number the Pages.
- Invitation to participate: “*You are invited to participate in a research study...*”
- Explanation of the purpose of the study.
- Expected duration of the subject’s participation.
- Approximate number of subjects involved in the study.
- Description of procedures to be followed in lay terms. Identification of any *experimental* procedures.
- Description of any reasonable foreseeable risks, discomforts or side effects to the subject.
- Safeguards to be used to minimize the risks, discomforts or side effects.
- Statement of anticipated benefits to the subject. SEPARATE STATEMENT re compensation for participation and terms (e.g. if subject withdraws, when compensation is earned etc).
- Disclosure of appropriate alternative procedures or courses of treatment if applicable.
- Statement describing the extent to which confidentiality of records identifying the subject will be maintained, including subject’s identity to be held in confidence in reports in which the results of the study may be published and that the IRB or its designees may review research records.
- Standard Injury Compensation Statement and/or explanation of compensation available if injury occurs.
- Statement of additional costs to the subject that may result from participation in the research.

- Investigator's name and telephone number and statement that subject's may call and ask questions about the study or a research-related injury.
- Statement of whom to contact about subjects' rights as a research participant.
- 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 refuse or discontinue participation at any time without jeopardizing the investigator's interest in the subject.
- Statement of consent to participate in the study.
- Include appropriate signature and date lines.

ADDITIONAL ELEMENTS, AS APPROPRIATE (these will not apply in every study)

- 24-hour emergency telephone number – this only applies to certain medical studies.
 - HIPAA checklist and Recruitment Checklist for studies dealing with health information
 - Compare amount of radiation exposure in this study to that which the subject would be exposed to in everyday living.
 - 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) which are currently unforeseeable.
 - Statement of circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
 - Statement of the consequences of the subject's decision to withdraw and procedures for orderly termination of participation by the subject.
 - Statement that new findings developed during research that may relate to the subject's willingness to continue participation, will be provided.
 - Total amount of blood to be withdrawn for the entire study in common measurement terms, (e.g. teaspoons/tablespoons).
 - If a subject's participation is contingent upon another person's involvement in the research procedures (e.g. caregiver), a statement must be included to inform the subject regarding what will be expected of the other participant.