Preparing Informed Consent Documents

This document contains guidance for principal investigators (PI) and faculty sponsors (of student PIs) in creating informed consent documents (ICDs). The IRB has prepared this guidance, based on the observation that approval of projects is often delayed because the ICD does not meet the requirements of ISU policy and Federal regulations. It is important to emphasize that informed consent is not just a form; it is a process of informing subjects of their rights, responsibilities, and risks that continues throughout the study. **If the PI is a student, the faculty sponsor must be actively involved in developing the informed consent process and in creating the ICD.**

We recognize that writing an informed ICD is not straightforward, so we have prepared templates to follow when preparing your ICD, along with examples of ICDs that meet the requirements of ISU's policy and Federal regulations. For more information, refer to the discussion of the informed consent process in ISU policy on ISU's IRB website (IRB Policy). An Informed Consent Checklist is available to help you make certain that you have covered all required areas of the consent process (Informed Consent Checklist).

If you have any questions, contact the IRB before creating the ICD (x8217 or irb@indstate.edu).

This document is not intended to cover all possible types of studies, but rather focuses on the most common types of studies conducted at ISU.

Guidelines

Basics of Preparing Informed Consent Documents

Regulations recognize two broad categories of research: socio-behavioral and biomedical. The nature of the specific study, rather than the researcher's academic discipline, determines whether the research is considered biomedical or socio-behavioral.

Socio-behavioral studies include methodologies such as surveys, interviews, focus groups, observations of children in classrooms, educational tests, and evaluation of nonmedical treatment programs. Biomedical research includes methodologies such as medical tests (e.g., drawing blood), physical interventions (e.g., exercise, induction of muscle cramp), or medical or surgical procedures. Some studies contain aspects of both types of research. Either type of study can be of "no more than minimal risk" or of "greater than minimal risk."