IRB Toolbox

Waiving the Requirement for a Signed Consent Form

Informed consent is one of the primary ethical requirements underpinning research with humans, reflecting the basic principle of **respect** for persons. It can be defined as the voluntary choice of an individual to participate in research based on an accurate understanding of its purposes, the procedures (or methodology), any risks or benefits, and any other factors specific to the research that may affect a person's decision to participate.

Informed consent is an educational process that takes place between the investigator and the prospective subject. It is the responsibility of the researcher to ensure that the full informed consent educational process is fulfilled prior to engaging in research with the subject. This is true whether a signed informed consent form is used or whether the research has used alternate methods of obtaining voluntary informed consent.

Written, signed informed consent is not necessarily appropriate for all research. The federal regulations governing the protection of human subjects in research provide flexibility to the IRB to address these situations. The IRB may waive the requirement for written documentation of consent (a signed consent form) in the following cases:

- The principal risks are those associated with a breach of confidentiality concerning the subject's participation in the research, and the consent document is the only record linking the subject with the research;
  or
- The research presents no more than minimal risk and involves procedures that do not require written consent when performed outside of a research setting.

Waiving the requirement for a signed form does not waive the requirement to insure that the subject provides voluntary informed consent. In such situations, researchers must demonstrate how they will carry out the consent process with participants. This process can be accomplished by providing participants with an **Information Sheet** that contains the elements of an informed consent form, but does not require signature. Alternately, a **script** of proposed oral discussion can be prepared for situations in which personal interaction will not occur (e.g., telephone surveys). Information sheets and scripts should be submitted for IRB review with the application. Examples of information sheets can be found on the IRB website at http://compliance.vpr.okstate.edu/IRB/consent.aspx.

It is advisable to discuss these exceptions with the IRB chair prior to starting the research. These exceptions are evaluated on a case-by-case basis by the IRB.