The Consent Process

1. A Process - not a form

Since subjects retain the right to withdraw from a study, consent is an ongoing process. It starts well before any forms are signed and continues until the subject's participation is complete.

The informed consent process is different from the consent form. It involves meeting with a potential subject, finding out whether he or she is capable of giving consent, and discussing the purpose, risks, and benefits of participation. The consent form formalizes the agreement to participate and should be designed to document the process. Obtaining informed consent is not just giving a prospective subject a consent form and getting it signed.

If consent is to be informed, the subjects must genuinely understand the study. Hence, researchers should strive to convey information to subjects, not merely disclose it to them. Subjects should be able to demonstrate their understanding of the study procedures, risks, and benefits in which they are agreeing to participate.

2. When to discuss participation

To achieve understanding, potential subjects should not be presented information all at once or only at the last minute. People need time to think about whether or not they want to participate. They may wish to discuss the decision with family, close friends, or religious advisors. They should not feel rushed or coerced. They need time, especially if the information is disturbing or particularly complex, to digest the information and come to terms with it.

Consent documents should be written in nontechnical language that can be understood by the proposed participant population-consistent with their educational level, familiarity with research, and cultural views.

Even highly educated people need to have technical information presented in simple terms. How information is best expressed will vary with the population of course. In studies involving nurses as subjects, for example, researchers can explain a project using some medical terminology, but lay persons need to have information presented as simply and straightforwardly as possible. Some of the suggestions offered here for writing readable consent forms are also useful for presenting information in discussions.

3. What must be said about the research

The consent document must make clear that participation in research is voluntary, and it should not include any language waiving or appearing to waive participants' rights. In some cases, the researcher may want to request that the IRB approve a modification or waiver of the elements of informed consent as spelled out in the regulations.

Advertisements, fliers, or brochures prepared to recruit and inform potential participants about a study are considered part of the informed consent process and, as such, also require review and approval by the IRB. **Student investigators** should prepare the ‘Consent Form” with assistance/input from their Research Advisors.

INFORMATION TO BE INCLUDED IN THE CONSENT DOCUMENT
(adapted from 45CFR.46.116)

- A statement that the study involves research;
- An explanation of the purpose of the research, an invitation to participate and explanation of why the participant was selected, and the expected duration of the participant's participation;
- The approximate number of participants involved in the study;
- A description of procedures to be followed and identification of which procedures are investigational and which might be provided as standard care to the participant in another setting. Use of research methods such as randomization and placebo controls should be explained;
- A description of any foreseeable risks or discomforts to the participant, an estimate of their likelihood, and a description of what steps will be taken to prevent or minimize them; as well as acknowledgment of potentially unforeseeable risks;
- A description of any benefits to the participant or to others that may reasonably be expected from the research, and an estimate of their likelihood;
- A statement describing to what extent records will be kept confidential, including examples of who may have access to research records;
- For research involving more than minimal risk, an explanation and description of any compensation and any medical treatments that are available if participants are injured through participation; where further information can be obtained, and whom to contact in the event of research-related injury;
- An explanation of whom to contact for answers to questions about the research and the research participant's rights (including the name and phone number of the Principal Investigator (PI));
- A statement that research is voluntary and that refusal to participate or a decision to withdraw at any time will involve no penalty or loss of benefits to which the participant is otherwise entitled;
- A statement indicating that the participant is making a decision whether or not to participate, and that his/her signature indicates that he/she has decided to participate having read and discussed the information presented.

***The institution has responsibility for all research conducted in its name therefore all records and especially signed Consent Forms must be stored on campus or institutional facility (investigator or Departmental office), such documents may not be kept in homes. Signed Consent forms from student dissertation research may not be stored in student's home or non-university facility. If the research is carried out in other institution (agency, state, federal) copies of the signed consent forms must be stored in university facility. Research/dissertation advisors have responsibility for security and storage of such documents.*