

## Guidelines for Obtaining Informed Consent

Informed consent is one of the basic ethical obligations for researchers. Informed consent is not just a form. It is a process of information exchange that takes place between the prospective subject and the investigator, before, during and sometimes after the experiment. The amount of information that needs to be presented both in writing (i.e., the consent document and related materials) and verbally is directly related to the risk that the study presents and the complexity of the procedures.

The manner and context in which information is conveyed is as important as the information itself. There must be no coercion or undue influence. Subjects must have sufficient time to decide and should be allowed to consult with family and/or others if needed.

The informed consent process is not a single event, but continues as the study progresses. Subjects should feel free to ask questions at any time.

The purpose of a consent form is to provide a written source of information and a place to document that a subject's consent has been given before the start of the study. Consent forms must be signed and dated by the subject before any research procedures are begun. The form serves as a baseline of information for initial presentation and a reference source during the study as well as documentation of voluntary participation.

This guideline contains explanations and examples of text that may be used in preparing consent forms for research studies. Due to the wide variety of research projects conducted at the University, several types of consent forms are acceptable to the IRB. For 'bio-medical' research that poses more than minimal risk to subjects, a consent document that follows a 'standard' format with detailed information is usually required. For research that poses minimal risk to subjects, a less formal document may be approved, as long as it contains necessary elements of consent.

The IRB reviews each form to determine that it contains required information in sufficient detail to protect the rights and welfare of human research subjects.

To speed the approval of consent forms, the following are general suggestions:

- All consent forms must be understandable to the subject population.
- Use short sentences and non-technical terms.
- An eighth-grade reading level is usually desirable for studies of the general population. [Most word processors can generate 'reading level scores.']
- Use second person (i.e., write the consent form as if you are talking to the subject).
- The project title may be a repeat of the 'official' title as submitted to the IRB and sponsor agency, or it may be simplified to assist subject understanding.
- Use element headings and 'white-space' to improve readability in long forms. (If headings are not used, send the IRB an extra copy of the form with the required elements marked.)
- All scientific, medical and technical terms should be defined or explained.
- Use listings, tables and charts to show complex schedules and study designs.

- Use type no smaller than 12 point.
- Use letterhead stationery for the first page.
- Number the pages of the consent form, e.g., 1 of 3, 2 of 3, 3 of 3.
- The version date of the consent form should appear on the bottom of the last page.
- Provide translated versions if non-English speaking populations are a target population.

Although each research study involving human subjects is unique, the federal regulations and the Institutional Review Board (IRB) require that all consent forms contain the following information elements:

Introduction (with statement that this is a research project)  
 Purpose of Study  
 Description of Study Procedures (identifying any that are experimental)  
 Duration of Subject Involvement  
 Risks or Discomforts of Participation  
 Benefits of Participation  
 Confidentiality of Records Statement  
 Contact Persons  
 Statement of Voluntary Participation

Federal regulations and the IRB require several other elements of information to be included if they apply to the study and are important for subjects to know. These include:

Compensation for Injury Statement (for more than minimal risk studies)  
 Alternatives (medical treatments or other courses of action, if any)  
 Unforeseen Risks Statement (if applicable)  
 Reasons for Involuntary Termination of Participation (if applicable)  
 Additional Costs to Participant (if any)  
 Consequences for Withdrawal (adverse health/welfare effects if any)  
 New Findings Statement (to be provided if relevant)  
 Number of Subjects (if it may impact on the decision to participate)  
 Payments (incentives and/or expense reimbursements if any)