



## Office of Research Administration

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### **ORA POLICY AND PROCEDURE: Informed Consent & Human Subjects Research**

All human subjects have the right to be fully informed about the research in which they participate. To ensure that the subjects are informed, they must read and sign a consent form. A copy of the consent form should be given to the person signing the form. Below are some important questions about consent that are asked by the Human Subjects Committee when it reviews an application.

#### **Consent Form**

You should be able to answer **yes** to the following questions about your consent form:

- Letterhead.** Is it typed on UM-St. Louis stationery?
- Language.** Is the language written at a level appropriate to the subject?
- Invitation.** Does it begin with an invitation to participate?
- Purpose.** Is there a clear statement that the study involves research and is there a clear description of the purpose and procedures of the study?
- Alternatives.** If applicable, is there a descriptions of appropriate alternative procedures or courses of treatment that might be advantageous to the subject?
- Experimental Procedures.** Are all experimental procedures clearly identified?
- Time.** Is there a reasonable estimate of the total amount of time required on the part of the subject?
- Participation.** Does it state that participation is voluntary and that refusal to participate will involve no penalty or loss of benefits to which the participant would otherwise be entitled?
- Opportunity to Withdraw.** Does it state that the subjects are free to withdraw at any time without penalty or loss of benefits to which they are otherwise entitled? In the case of interviews and questionnaires does it state that the subject is free to choose not to answer individual questions?
- Students.** If applicable, does it explain how participation in the study will affect their grades?

- Risks.** Is there a description of potential risks or discomforts? For research involving more than minimal risk, is there an explanation of whether any compensation or medical treatments will be provided in case of injury.
- Benefits.** Is there a description of potential benefits to the subjects and society?
- Costs.** If applicable, does it explain cost sharing, cost to, or payments to subjects?
- Prisoners.** If applicable, does it state that participation in the study will not affect adjudication of their cases, their applications for parole or other factors affecting their incarceration?
- Confidentiality.** Is there an assurance of confidentiality which clearly describes how it will be maintained?
- Any Questions.** Is there an offer to answer all questions concerning the research now and at a later date?
- Name and Phone Number.** Are the investigator's name and phone number on the form?
- Signatures.** Are there date and signature blanks for both subject and investigator? Any subject unable to read must have the procedure explained verbally and a witness must sign indicating that the research was explained. The signed copy is given to the subject; a copy is held by the investigator.

### **Request for Consent**

The committee recommends the following final request for consent:

“I have read the above statement and have been able to express concerns, which have been satisfactorily responded to by the investigator. I believe I understand the purpose of the study as well as potential benefits and risks that are involved. I hereby give my informed and free consent to be a participant in this study.”

### **IRB Application**

- **Informed Consent**  
In the application, describe how informed consent will be obtained. Who will discuss risks, benefits and alternative treatment with the subjects? When will this occur?
- **Confidentiality**  
In the application, describe how confidentiality or anonymity will be maintained unless consent to divulge this information is obtained. Will records include identifying information? How will records be protected and who will have access to the confidential information?
- **Deception and Debriefing**  
In your application, if deception is used, you must explain why the research could not be

accomplished without it. Describe how the degree of deception has been minimized and what will occur during the debriefing. Who will discuss the actual purpose of this study with the subject and when will this occur? (Attach your debriefing statement.)

- **Special Protection of Minors**

Subjects younger than 18 who can read and comprehend must sign an **assent** in addition to the **consent** obtained from their parents. For older children, the wording of the assent can be the same as the consent. Generally, children under 12 need an assent written more simply. For young children, written informed consent may not be appropriate and a summary of the oral explanation should be included in the application.

When preparing the assent, follow the guidelines for consent, but make sure the language is age appropriate. The signed copy of the assent is given to the minor; a copy is retained by the investigator.

**NOTE:** Other issues and statutory requirements may apply to your particular project. Copies of the federal regulation, the University assurance document, educational video tapes, brochures on the review of Human Subjects protocols and confidentiality, and all necessary forms are available from the ORA; guidelines and forms are also downloadable through this web site. Committee members can also advise you.