

PROTECTING HUMAN SUBJECTS IN RESEARCH

ETHICAL ISSUES

Research involving human subjects poses complex ethical issues. As a researcher, it is your responsibility to educate the participants about risks and benefits, obtain their consent before involving them in your research, and keep them informed. This is called the "informed consent process." To discern the key components of informed consent, you need to understand three ethical issues of research involving human subjects:

Autonomy means that each person should be given the respect, time, and opportunity necessary to make his or her own decisions. Prospective participants must be given the information they will need to decide to enter a study or not to participate. There should not be pressure to participate. Special protection must be given to potentially vulnerable populations such as children, the elderly, the mentally ill, or prisoners. If the person is deemed to be incompetent, the investigator must seek the consent of a proxy. A parent or guardian must act as the proxy for the child and complete a parental permission form. Children also need to give their "assent." Assent is the affirmative agreement to participate in the study if the child is able to comprehend aspects of the research. The researcher must use a "consent document" that explains the nature of the research and any risks and benefits to the participant. A copy of the consent document is reviewed by the IRB before it is presented to prospective participants.

Beneficence obligates the researcher to secure the well-being of all study participants. It is your responsibility to protect participants from harm, as well as ensure that they experience the possible benefits of involvement.

The ethical considerations of risks versus benefits raise the question of **justice**. Who should bear the risk of a study and who should receive its benefits? Convenience should not be the sole factor in the selection of participants. Keep the following tips in mind when selecting prospective participants: (1) Participants should not be selected due to gender, class, socioeconomic status, or race unless justified by study objectives. (2) Teacher-student relationships always carry a perception of inequality in roles. The informed consent process should reflect the precautions taken to balance the relationship and guard against even the perception of coercion.

RESEARCH THAT MUST HAVE APPROVAL FROM THE INSTITUTIONAL REVIEW BOARD (IRB)

Nearly all research at EIU that involves humans, human tissue, or records gathered on human subjects requires IRB review. This is true regardless of its funding source or area of research. Even courses in research methods and class assignments involving research with human subjects require IRB approval if the research results will be publicized.

Interviews by journalists conducted solely for the purpose of writing an article in a newspaper, magazine, or other media outlet are not considered research and do not require IRB review.

The IRB conducts both an initial review and continuing review of research. The initial IRB approval is based on the researcher's best estimate of the anticipated risks and benefits to the subjects. It is only after research has begun that the real risk is established and the actual risk/benefit ratio can be calculated. Responsible researchers stay involved in continuous reevaluation of a project since risks and benefits are always better understood after the research has begun.

IRB REVIEW CRITERIA

The IRB uses the following criteria to review your research: (1) Risks to the subjects are minimized. (2) Risks to the subjects are reasonable in relation to anticipated benefits. (3) Selection of subjects is equitable. (4) Informed consent is sought from each prospective participant or his or her legally authorized representative and is properly documented. (5) Adequate preparation is taken to protect the privacy and confidentiality of subjects. (6) Adequate provisions are made for the ongoing monitoring of the subjects' welfare.

OBTAINING INFORMED CONSENT

You should use an informed consent document to make your participants aware of the following information: (1) *Research Purpose* (2) *Research Procedures* (including time commitment and why the individual is eligible to participate) (3) *Risks* (including common risks such as inconvenience, pain, and

embarrassment). (4) *Benefits* (such as feeling good, monetary compensation, or free access to an experimental drug. Be careful not to oversell any benefits.) (4) *Alternatives* (State alternative procedures or courses of treatment, if any, that might be advantageous and available to the subject. In nontherapeutic studies, the alternative may simply be nonparticipation.) (5) *Confidentiality* (Describe the steps that will be taken to protect the participant's privacy. Also describe under what circumstances records will be made available and to whom. Include any techniques you may use for identifying data, such as creation of a numeric code. Subjects should be assured that their identity will not be disclosed.) (6) *Disclosure of Potential Conflict of Interest* (Researchers must inform their participants of any conflicts of interest they have in the research, such as a stake in a company that might benefit from the research.) (7) *Contact Information* (Give the names of people who can answer questions about the research; include the principal investigator. If the researcher is a student, also include the name and phone number of the faculty supervisor.) (8) *Withdrawal*: Always stress the fact that participation is voluntary. State that refusing to participate will involve no penalty or decrease in benefits to which the participant is otherwise entitled. Emphasize that the individual may discontinue participation at any time without penalty or loss of benefits.

A consent document must be made readable but without compromising the content. Direct it at an eighth-grade reading level. Use simple, straightforward sentences. Use commonly recognizable terms and measurement amounts. Avoid the use of jargon or technical language, and explain terms that may not be easily understood. When you have finished writing the consent document, ask a lay person to read and explain it to you. If your document is not understandable, a claim could be made that the participant did not understand what was signed

Obtaining informed consent is not merely disclosing information. The process should include time for both discussion and reflection. Participants may need time to think about their decision or to discuss their involvement with family, friends, or religious advisors. In your discussion, use open-ended and nondirective questions. Open-ended questions often begin with words such as "what," "where," "how often," "when," and "please describe." The goal is to foster an open exchange of information, rather than to quiz the participants. A few of the questions you may want to ask are: "Describe in your own words the purpose of the study." "What more would you like to know?" "Would you please explain to me what you think we're going to ask you to do?" "What are your concerns?"

EXCEPTIONS

The IRB may approve a waiver of some or all of the informed consent requirements provided that: (1) the research involves no more than minimal risk; (2) the waiver or alteration will not adversely affect the subjects; (3) the research could not practically be carried out without the waiver or alteration; and (4) whenever appropriate, the subjects will be provided with additional information after participation.

The IRB may waive the requirement to obtain a signed informed consent if the IRB finds either of the following: (1) the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality; or (2) the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. Additionally, the IRB may decide to waive signature of subjects for research that falls within one or more exemption categories.

UNEXPECTED FINDINGS, NEW KNOWLEDGE, AND ADVERSE EVENTS

Unexpected results can affect the research project itself. The researcher is responsible for informing the IRB of unexpected findings (or new knowledge attributable to other research projects) that can affect the risk/benefit ratio. Adverse events are unexpected problems whose nature, severity, or frequency are not described accurately in the study protocol. It is the researcher's responsibility to analyze the impact of an adverse event. Incidents where subjects have been seriously harmed should be reported to the IRB immediately. The IRB should always be informed of any problems or accidents in the study. The death of a participant, whether related to the study or not, should also be reported to the IRB immediately.

New findings, new knowledge, and adverse effects may need to be communicated to the participants to determine whether their effects will change the subjects' willingness to participate. This may require a revised consent document.