Human Participants Research

- The concepts and information provided here is based upon materials developed by the Office of Human Research Protections (OHRP) and the National Institute of Health (NIH).
- All research involving human participants must receive approval from the Institutional Review Board (IRB) for the Protection of Human Subjects.

- Persons planning research with human participants 1) must complete the following orientation; 2) submit an application for the use of human participants in research, and 3) wait for approval from the IRB.
- Some class projects are exempt.

- Exemption is determined by the IRB, not the student, staff, or faculty conducting the project, even if it is a class project.
- For clarification, contact the Chair of the IRB Committee.

- Research is a systematic investigation designed to develop or contribute to general or practical knowledge.
- A human subject is a living individual about whom an investigator obtains either 1) data through intervention or interaction with the individual; or 2) identifiable private information.

- Northwestern policy requires that all key personnel involved with human participant research complete this training before a protocol will be reviewed by the IRB for the Protection of Human Participants.
- It is important for Northwestern to have documentation that you completed this training. When you have completed the entire course, you will be given instructions on how to certify that you have completed this program.

- This training is designed for all faculty, staff, and students whose research involves human participants, as well as the Northwestern IRB.

- In the 1950s and 1960s, as federal funding for biomedical research increased dramatically, ethical safeguards and legal requirements were imposed on research activities involving human subjects.
- Thus, U.S. Government, in dialogue with the research community, gradually designed one of the most comprehensive systems in the world for protecting human subjects.

- By Congressional mandate, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was established in 1974 to make recommendations for the conduct of research involving humans.

- Oversight for the system was assigned by law to the Secretary of the Department of Health and Human Services (DHHS).

- This training provides an introduction to the Federal Policy (Common Rule) for the Protection of Research Subjects.
- The Federal regulations are intended to implement the basic ethical principles governing the conduct of human subjects research.

- These ethical principles are set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the "Belmont Report").
- No one should be involved in human participants research without being familiar with these ethical principles.

Basic Principles

- The Belmont Report sets forth three basic ethical principles:
- Respect for Persons
  - Respect individual autonomy
  - Protect individuals with reduced autonomy
- Beneficence
  - Maximize benefits and minimize harms
- Justice
  - Equitable distribution of research burdens and benefits

Application of the Principles

- Application of the general ethical principles to the conduct of human subjects research leads to the following requirements:
- Informed Consent
- Risk/Benefit Analysis
- Review of Subject Selection

- Information: Participants must be able to control what shall and shall not happen to them.
- Information generally includes: research procedure, purposes, risks and benefits, alternative procedures, and a statement giving the subject the chance to ask questions and withdrawal at any time.

- Comprehension: Information must be presented in a way that is comprehended by the subject.
- Free Will: Agreement to participate is valid only if voluntarily given. Informed consent requires conditions free of coercion and undue influence.

Assessment of Risks and Benefits

- “Risk” refers to the possibility of harm.
- “Benefit” refers to positive value related to health or welfare.
- Research must be justified on the basis of a favorable risk/benefit assessment.
- Research must be properly designed.

- IRB must determine if risks presented to the participants are justified.
- Risks should be reduced to those necessary to achieve the research objective.
- Risks and benefits must be thoroughly listed in informed consent.

Selection of Participants

- Should not offer potentially beneficial research to only some persons who are favored.
- Distinction should be made between classes of participants who should and should not participate in certain research (e.g., adults vs children).
- The principle of justice should dictate procedures in participant selection.

- The human participant is a living person about whom a researcher obtains either 1) data through intervention or interaction with the person or 2) identifiable private information.
- Third parties may be participants under certain conditions.

Human Participant Protection

- Protection of participants applies in research which involves tissue specimens, medical records, genetic material, behavioral and/or biomedical assessments, and treatments.

- The Federal Policy for the Protection of Human Subjects (Common Rule) was adopted on June 18, 1991.
- The provisions of the Common Rule are identical to Regulations (45 CFR 46, Subpart A).

- Certain low-risk research is exempt from the requirements of the Federal regulations.
- These exemptions do not imply that investigators have no ethical responsibilities to participants in such research. They mean only that IRB review and approval of the research is not required by Federal regulations.

- In no case should investigators make the final determination of exemption from applicable Federal regulations.
- Institutions should have clear procedures under which the IRB determines whether proposed research is exempt from the human subjects regulations.

Researcher Responsibility

- Proper study design that is scientifically sound and yields valid results.
- Participants meet selection and eligibility requirements.
- Study is approved by the IRB and conducted according to protocol.

- Protocol changes and adverse events are reported to appropriate boards and authorities.
- Rights and welfare of participants are monitored throughout the trial.
- All members of the research team are qualified and trained in research methods and human participant protection.

Privacy and Confidentiality

- Privacy refers to control regarding extent, time, and circumstances of disclosing oneself physically, behaviorally, or intellectually with others.
- Participants have a trust relationship with the researcher regarding the former's privilege of privacy.

- The researcher must protect the confidentiality of the research information.
- Breaches of confidentiality are disclosures of information to third parties with the consent of participant.
- Disclosure can be oral or written.

- Confidentiality relates to information obtained in a trust relationship under the expectation that such information will not be revealed to others without permission.
- Appropriate confidentiality of research data should be maintained.

- This is done by substituting codes for identifiers or encrypting identifiable data.
- Removing face sheets from survey instruments containing data.
- Properly disposing of computer sheets and other documents.
- Limit access to identifiable data.

- Educate research assistants on importance of confidentiality.
- Store paper records in locked cabinets or assign security codes to computerized documents.

Investigator Responsibilities & Informed Consent

- Researchers have the primary responsibility for protecting the rights and welfare of research participants.
- Conduct their research according to the IRB approved protocol and comply with all IRB requirements.
- Researchers must know the requirements of the Federal regulations, applicable state law, and institutional rules for the protection of research participants.

- Ensure that each potential participant understands the nature of the research and of their participation and take steps to achieve that comprehension.
- Provide a copy of the IRB-approved informed consent document to each participant at the time of consent, unless the IRB has specifically waived this requirement. All signed consent documents are to be retained in a manner approved by the institution.

- Prompt reporting of proposed changes in previously approved human participant research activities to the IRB. Changes may not be initiated without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to participants.
- Report progress of research to the IRB per approval conditions.
- Report to the IRB problems involving risks to participants or others.

Informed Consent

- Informed consent refers to the voluntary choice of an individual to participate in research based on an accurate and complete understanding of its purposes, procedures, risks, benefits, alternatives, and any other factors that may affect a person's decision to participate.
- Informed consent is process that takes place between the investigator and the prospective participant.

- Informed consent must be obtained from the participant or legally authorized representative of the participant (if allowed by state law).
- Information must be conveyed in understandable language.
- Participants must be given sufficient opportunity to consider whether they want to participate.

- Only legally competent adults can give consent.
- In most cases, minors cannot give consent. Parents or legal guardians can give permission for minors to participate in research.

- The evaluation of competence must be made on a case-by-case basis.
- In addition to obtaining permission from parents or legal guardians, provisions must be made for soliciting the assent of the children or incompetent adults.

- The following areas must be disclosed to potential participants:
- Description of the research and participants' role; identification of experimental procedures;
- Description of reasonably foreseeable risks; description of expected benefits;
- Potentially advantageous alternatives to participation;

- Explanation of confidentiality protections;
- Explanation of compensation for injuries policy;
- Whom to contact with questions about the research and research participant's rights;
- Explanation that participation is voluntary.

- Appropriate alternatives to participating in the research project, particularly alternatives that might be advantageous to the participant, should be described. For example, in drug studies, the medication(s) may be available through their family doctor or clinic without the need to volunteer for the research activity.
- Investigators should be reasonably specific about describing the nature and type of available alternatives. It is not sufficient simply to state that "the researcher will discuss alternative treatments" with the subject.

- Regulations require that participants be told the extent to which their personally identifiable, private information will be held in confidence. For example, sponsors, funding agencies, regulatory agencies, and the IRB may review research records.
- Some studies may need sophisticated encryption techniques to prevent confidentiality breaches or a Certificate of Confidentiality to protect the investigator from involuntary release (e.g., under subpoena).

- If research related injury (i.e., physical, psychological, social, financial, or otherwise) is possible in research that is more than minimal risk, an explanation is required of whatever voluntary compensation and treatment will be provided. Regulations do not limit injury to "physical injury."

- Consent language regarding compensation for injury must be selected carefully so that participants are not given the impression that they have no recourse to seek satisfaction beyond the institution's voluntary chosen limits.
- The regulations prohibit requiring participants to waive any of their legal rights and leading them to believe they are waiving their rights.

- A single contact person is not likely to be appropriate to answer questions in all areas. This is because of real or apparent conflicts of interest. Questions about the research are frequently best answered by the investigator(s). However, questions about the rights of research subjects may best be referred to persons not on the research team. These questions could be addressed to the IRB, an ombudsperson, an ethics committee, or other informed individual or committee. Each consent document can be expected to have at least two names with local telephone numbers for contacts to answer questions in these specified areas.

- The regulations require statements regarding voluntary participation and the right to withdraw at any time. Participants must be informed that their participation is voluntary and they may discontinue participation at any time.
- Also, no penalty or loss of benefits for not participating or discontinuing participation.

- Informed consent is verified by use of an IRB approved consent form. It is signed by the participant or participant's legally authorized representative. A copy is given to the person signing the form.
- The information that is given to the prospective participant or his/her representative must be understandable to the participant or representative.

- The Office for Human Research Protections (OHRP) strongly discourages use of the "first person" in consent documents (e.g., "I have been fully informed about..."). Such statements unfairly ask subjects to make statements that the subject is not in a position to verify (e.g., the subject has no way to verify that the investigator has provided full and complete information).

- The IRB may waive the requirement for written documentation of consent in cases where:
- The principal risks are those associated with a breach of confidentiality concerning the participants involvement in the research; and the consent documentation is the only record linking the him/her 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.

IRB Responsibilities

- All assured institutions should have a Human Protections Administration (HPA) program in place to ensure that human participants involved in research are adequately protected and that the institution remains in compliance with the regulations.

- The IRB is a committee established to protect the rights and welfare of human research participants recruited to participate in research activities.

- IRBs must have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.
- The IRB must be sufficiently qualified through the experience and expertise of its members and the diversity of their backgrounds, including considerations of their racial and cultural heritage and the sensitivity to issues such as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

- The IRB reviews, and has the authority to approve or disapprove, require modification in all research activities.
- The IRB reviews approved research at intervals appropriate to the degree of risk, but not less than once per year.

- The IRB can suspend or terminate research that is not being conducted in compliance with the IRB's conditions. Research that results in unexpected serious harm to participants may be terminated.

- Northwestern Human Participants Training Certification
- Please go to the certification link, complete the certification and send to the Chair of the IRB.