Tutorial on Ethics in Research

This tutorial only contains information on human subjects
Material from : http://departments.weber.edu/irb/

You must additionally complete the Informed Consent tutorial (http://69.5.4.33/c01/nih_intro_01.htm).

V. ETHICS
A. Human

- Ethics in research address the legal and moral obligations of a researcher to human participants and/or animal subjects.
- Ethics in research also address the ethical obligations of a researcher to other researchers and to the discipline.
- These will be reviewed briefly in this tutorial.

V. RESEARH AND ITS EVALUTION
A. Human

- Three basic principles of ethics are particularly relevant to the protection of human subjects in biomedical and behavioral research. They are:
  - **Respect for Persons**: recognition of the personal dignity and autonomy of individuals and special protection of those persons with diminished autonomy
  - **Beneficence**: obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm
  - **Justice**: fairness in the distribution of research

V. RESEARH AND ITS EVALUTION
A. Human

- This is not just a good idea, it's the law!
- Title 45/Part 46 (45 CFR 46) contains the Code of Federal Regulations (CFR) regarding the use of human subjects in research and is the law under which the IRB at Weber State University functions.
- The IRB Institutional Review Board assess each study performed at WSU involving human subjects and assesses it for the ethical treatment of participants.

V. RESEARH AND ITS EVALUTION
A. Human

- In fulfilling its purpose, the IRB committee shall:
  - Review each research plan, recruitment procedures and subject consent forms in order to safeguard the rights and welfare of human subjects.
  - Study the background and methodology of each proposed project to determine possible benefits and/or risks, physical, psychological, social or legal.
  - Assess confidentiality, and adequacy of the method for securing informed consent from subjects.

V. RESEARH AND ITS EVALUTION
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- In fulfilling its purpose, the IRB committee shall:
  - Review the scientific design since a poorly designed study can expose the participants to unnecessary risk.
  - Report findings and actions to the investigator and the institution.
  - Review proposed changes in research activities to insure that changes in approved research during the period for which the committee approval has already been given, not be initiated without the review and approval of the

V. RESEARH AND ITS EVALUTION
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- In fulfilling its purpose, the IRB committee shall:
  - Approve research only with the concurrence of the majority of the committee members in attendance.
  - Report to the appropriate administrative officer of Weber State University of continuing or serious non compliance by the investigators, with the requirements and determinations of the committee.

V. RESEARH AND ITS EVALUTION
A. Human

- The IRB Committee shall ensure that:
  - Risks to subjects are minimized by using the safest procedures consistent with sound research design and whenever appropriate, by using procedures already being performed for diagnostic and treatment procedures.
  - Risks to subjects are reasonable in relation to anticipated benefits to subjects and the importance of the knowledge that may reasonably be expected to result. When assessing risk, the committee should not consider the possible long range effects of applying knowledge gained in research;

V. RESEARH AND ITS EVALUTION
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- The IRB Committee shall ensure that:
  - Selection of subjects is equitable, taking into account the purposes of the research.
  - Informed consent will be sought from each subject or the subjects legally authorized representative.
  - Informed consent will be appropriately documented.
  - Where appropriate, the research plan makes provision for monitoring the data collected to insure the safety of the subjects.

V. RESEARH AND ITS EVALUTION
A. Human

- The IRB Committee shall ensure that:
  - Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
  - Additional safeguards are taken when vulnerable subjects are involved in the research, in order to protect against coercion or undue influence.

V. RESEARH AND ITS EVALUTION
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- Perhaps the most important obligation of researchers to the ethical treatment of participants is offering **informed consent**.
- Basic elements of informed consent: In seeking informed consent, the following information shall be provided to each subject:
  - A statement that the study involves research, an explanation of the purposes of the research, and the expected duration of the studies expected participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

V. RESEARH AND ITS EVALUTION
A. Human

- Basic elements of informed consent
  - A description of any foreseeable risks or discomforts to the subject.
  - A description of any benefits to the subject or to others which may reasonably be expected from the research.
  - A disclosure of any alternative procedures or courses of treatment, if any, that might be advantages to the subject.

V. RESEARH AND ITS EVALUTION
A. Human

- Basic elements of informed consent
  - A statement describing the extent, if any to which confidentiality of records is maintained and that notes the possibility that the food and drug administration may inspect the records, if applicable.
  - For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and if so, what they consist of, or where further information may be obtained.

V. RESEARH AND ITS EVALUTION
A. Human

- Basic elements of informed consent
  - An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research - related injury to the subject.
  - A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.