Risks

- **Risk/Benefit:** in order to approve research covered by this policy, the IRB shall determine that the following requirements are satisfied:
  
  o Risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk.
  o Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result from the research.
  o In evaluating risks and benefits the IRB will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits that may result from therapies participants would receive even if not participating in the research). The IRB will not consider long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility. The IRB will examine study design or scientific merit of a proposed study within the context of its risk/benefit analysis.

The review of human participant research is confined solely to procedures affecting the rights and welfare of human participants. No evaluation is made of the scientific merit of the project unless participants are found to be “at risk,” at which time the risk/benefit ratio of the project will be evaluated. Review of protocol focuses on issues of:

- **Risk/Benefit ratio:**
  - Risks to participants are minimized by using procedures which are consistent with sound research design and do not unnecessarily expose participants to risk;
  - Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and to the importance of the knowledge that may reasonably be expected to result from the research. The IRB will examine study design or scientific merit only within the context of its risk/benefit analysis.

- **Equitable selection of participants and recruitment:** Selection criteria should consider all populations that might potentially benefit from the research, not just those readily available. The IRB will take into account the purposes of the search and setting in which the research will be conducted. The IRB ensures that the recruitment of participants is equitable and free of coercion.

- **Informed consent process:** Informed consent will be sought from each prospective participant or the participant’s legally authorized representative and will be appropriately documented in accordance with 45 CFR 46.116 and 46.117 (Code of Federal Regulations). The reviewers will look for the process used to obtain informed consent not just the information regarding the study that would be relevant to participants’ ability to make an informed decision to participate has been provided. A written signature is documentation of consent and is required for all Category 3 proposals. Proposals that
fall into an exempt (Category 1) or expedited (Category 2) category do not require a signed informed consent. A cover page including the following consent information must accompany the research protocol:

- Identify the researcher and institutional affiliation,
- Description of the project,
- What is expected of participants,
- Length of time required for participation,
- Location of study,
- State participation is “voluntary,”
- Indicate “subject can withdraw at any time without penalty,”
- Indicate “subject does not have to answer any questions(s) they do not want to,”
- Payment (if applicable and procedures for distributing payment),
- Taping (if applicable) must include information about what will be done with the tapes for storage and disposal,
- Include referrals (if applicable),
- Include a risk/benefit statement-if there are no anticipated risks, so indicate,
- The study is confidential or anonymous and how the data will be disseminated,
- Contact information for investigator and/or faculty advisor with phone number and email.

- Privacy and confidentiality: the IRB will determine that adequate provisions have been taken to protect the privacy of participants and for ensuring confidentiality of participants and of study data as appropriate.

- Special populations: when some or all of the participants are likely to be vulnerable to coercion or undue influence (such as minors, prisoners, pregnant women, physically or mentally disable persons, or economically or educationally disadvantaged persons), additional safeguards must be included in the study to protect the rights and welfare of these participants.