Criteria for Institutional Review Board (IRB) Approval of Research Involving Human Subjects

A research project that has received an Exempt designation is **not** exempt from protection of the human subjects**. All** of the following criteria to protect human subjects must be met:

1. Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonable be expected to result.

3. Selection of subjects is equitable.

4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

5. Informed consent will be appropriately documented or appropriately waived in accordance with §46.117.

6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of the subjects.

7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.