**Basic Principles**

The basic principles adhered to by the College are drawn from the Belmont Report, written by the

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in

1979.

1. Respect for Persons: Individuals should be treated as autonomous agents. That is, individuals should be treated as capable of deliberation about personal goals and of acting under the direction of such deliberation. To respect autonomy is to give weight to an individual person’s considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show lack of respect for an autonomous agent is to repudiate that person’s considered judgments, to deny an individual the freedom to act on those considered judgments, or to withhold information necessary to make a considered judgment, when there are no compelling reasons to do so.
2. Autonomy: The investigator has an obligation to each participant to treat them as a person fully capable of making an informed decision regarding his or her participation in the research. Each participant must be given a full disclosure of the nature of the study, including any risks or benefits. To ensure the autonomy of the participant, the College requires a signed informed consent form from each participant in the study unless the study meets the exception criteria outlined in the sections on “consent” (i.e., Specific Requirements, subsection (e) - “Consent”) or “exemptions”.
3. Beneficence: The investigator has an obligation to each participant to attempt to maximize benefit for each participant and/or society, while minimizing the risk of harm to each participant.
4. Justice: The investigator has an obligation to provide for equitable selection of participants, i.e., avoiding unfair coercion. The investigator is also obligated to provide for equitable distribution of benefits and burdens among the selected population. An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. As an example, the burdens of serving as research subjects should not fall largely upon the poor, infirm, or upon particular racial or ethnic minorities, while the research benefits likewise should not fall largely and exclusively upon, for example, the rich and/or healthy populations.

**Specific Requirements**

The investigator shall present to the IRB a description of his or her research project’s goals, objectives, and procedures, along with documentation addressing each of the following:

1. Disclosure: The potential participant must be as fully informed as possible of the nature and purpose of the research, the procedures to be used, including any procedures or interventions that are experimental, the purpose of participants in the research, the expected duration of study of individuals participating, the expected benefits to the participant and/or society, the potential of reasonably foreseeable risks, stresses, and discomforts, and alternatives to participating in the research where therapy is involved. When appropriate (e.g., use of investigational drugs or devices) or in use of drugs for a new unapproved condition, a statement that there may be unanticipated side effects should be disclosed. When appropriate, a statement about risks to the participant or fetus if the participant is or becomes pregnant should be disclosed. There should also be a statement that describes procedures in place regarding maintaining the confidentiality or anonymity of the participant within the limits of the law. The disclosure should include a statement offering the participant the opportunity to ask questions and to withdraw at any time from the research. The documents should make it clear whom to contact with questions about the research study, about research subjects’ rights, and in case of injury.
2. Understanding: The participant must understand what has been explained, including the range of risk and must be given the opportunity to ask questions and have them answered by one of the investigators. The informed consent document must be written in the participant’s native language, in plain lay language, at no higher than an 8th grade reading level of understanding, avoiding any technical jargon.
3. Voluntariness: The participant’s consent to participate in the research must be fully informed, understood by the participant, and voluntary, i.e., free of any coercion or promises of benefits unlikely to result from participation. Participants must be advised they are free to withdraw consent and to discontinue participation without penalty or loss of benefits to which the subject is otherwise entitled.
4. Competence: The participant must be competent to give consent. If the participant is not competent because he/she is a minor or due to mental status, disease, or emergency, a designated parent/legal guardian may provide consent if it is in the best interest of the participant.
5. Consent: The potential human subject must authorize his/her participation in the research study, in writing unless the IRB waives written consent. Waiver should be in the form of a “certificate of exemption” and should only be granted where (i) the risk to the subject is minimal; (ii) use of primary procedures for obtaining consent would invalidate important research objectives, (iii) where alternative means would be less advantageous to the subjects, or (iv) as otherwise set forth in the “exemptions” section of this policy.

**Exemptions**

Some research with human subjects is exempt from the requirements of this document, if it meets the following criteria:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostics, aptitude, achievement), survey procedures, interview procedures or observation of public behavior unless (i) information obtained is recorded in such a manner that human subjects can be identified directly or indirectly through identifiers linked to the subjects and (ii) any disclosure of the human subject’s responses outside of the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.

When such exemptions are found, a Certificate of Exemption is issued by the IRB and the written consent of section “e” above is not required. Investigators who believe their research projects qualify for exemption should petition the IRB for a Certificate of Exemption.