Section 320 - Use of Human Subjects

It is the policy of the College to act in an ethically responsible manner when conducting research involving human subjects. To that end, an Institutional Review Board has been established to provide a process to ensure that the normal and prudent policies established for the protection of human subjects is followed at Lower Columbia College.

This policy applies to any and all research (i.e., activities that are procedures, demonstrations, and/or experiments which use human subjects) conducted by College faculty, staff, or students as well as to any non-College entities performing research upon College faculty, staff, or students with the expressed consent of the College. Persons conducting such research are known, for the purpose of this document, as investigators.

320.1 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. 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 subject, the College requires a signed informed consent form from each participant in the study unless the study meets the exception criteria outlined in the section on exemptions.
2. Beneficence: The investigator has an obligation to each participant to attempt to maximize benefits for each participant and/or society, while minimizing the risk of harm to each participant.
3. Participants (i.e. avoiding unfair coercion). The investigator is also obligated to provide for equitable distribution of benefits and burdens among the selected population.

320.2 Specific Requirements

The investigator shall present to the Institutional Review Board (IRB) a description of his or her research project's goals, objectives, and procedures to (Lower Columbia College: Institutional Review Board), along with documentation addressing each of the following (taken from the Ethics in Medicine at U of W.)

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, and 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. There should also be a statement that describes procedures in place to ensure the confidentiality or anonymity of the participant. The informed consent document must also disclose what compensation and medical treatment are available in the case of a research-related injury. The document 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 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 lay language, avoiding any technical jargon.
3. Voluntariness: The participant's consent to participate in the research must be voluntary, free of any coercion or promises of benefits unlikely to result from participation.
4. Competence: The participant must be competent to give consent. If the participant is not competent due to mental status, disease, or emergency, a designated surrogate 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, preferably in writing

320.3 Exemptions

Some research with human subjects is exempt from the requirements of this document if it meets the following criteria (taken from **Belmont Report** referenced above in 320.1).

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.

Investigators must **request approval** for all proposed projects from the **Institutional Review Board (IRB)**. The Institutional Review Board will consider all requests and may approve the project, decline to approve the project, or grant a **Certificate of Exemption** indicating that the criteria detailed in 320.3 has been met.

Historic Information

- 3-4-20 – Reviewed by the Executive Leadership Team
- Nov. 2008 - Reviewed by the Cabinet and Leadership Team
- ADOPTED 2/23/09
  - Replaces policy 408 adopted - June 2005

Resource/Reference/Procedure	Title	Unit Responsibility
Institutional Review Board		