Faculty Handbook 6.5 POLICY ON RESEARCH WITH HUMAN PARTICIPANTS

Guidelines for the protection of human beings that participate in research are established by federal government regulations established in the Belmont Commission Report. The Report sets out three basic ethical principles for all research involving humans.

**Respect for persons.** Individuals are to be treated as autonomous persons capable of making decisions. Persons entering research projects as subjects should do so voluntarily and with adequate information beforehand to make an informed choice regarding participation. Special provisions are required for persons with diminished decision-making capacity.

**Beneficence.** Researchers are required to, “Do No Harm;” and to maximize possible benefits and minimize possible harms.

**Justice.** All persons must be treated equally, and research must not be focused on those who can be exploited.

The essential component that must be part of all human subject research is informed consent. The Belmont Report guidelines require that human subjects must be provided with adequate information regarding the project and their participation, the subjects must agree to participate voluntarily, and researchers have properly assessed the risks and benefits of the research to be carried out.

The federal policy, enacted as the Common Rule by sixteen government agencies is administered by the Office of Human Research Protections of HHS. It applies to all research conducted under federal government support. Claremont McKenna College has, like most institutions of higher education, extended the coverage of the Common Rule to include all human research projects regardless of the source of funding. Exceptions to the Common Rule include: research involving educational practices; testing; surveying, so long as human subjects cannot be identified; research involving existing data or specimens; research conducted subject to the approval of federal agencies and intended to examine federal programs or benefits; and taste and food quality evaluation and consumer acceptance studies.

All faculty, administration, and student research involving human participants not exempted by the above exceptions must be presented to the Claremont McKenna College Institutional Review Board (IRB) for its prior authorization to conduct the research. The IRB has the authority to approve, require modifications to, or disapprove the research project according to the guidelines of the Common Rule. The IRB has the authority to utilize an expedited review procedure for certain categories of research. The IRB will carefully review the informed consent elements of the intended research project and must approve an informed consent document to be signed by the subjects of the project. The IRB will also review any potential conflicts of interest involving research.