Colorado State University

Institutional Review Board (IRB)

Human Subjects Research Policy

The Colorado State University (CSU) Institutional Review Board (IRB), under the supervision of the Vice President for Research (VPR), serves as the review board for human research and operates in accordance with federal regulations 45 CFR 46 and 21 CFR 50, 56; state and local regulations; other federal regulations specific to funding sources and related to protection of participants in human research; and the Belmont Principles.

The Institutional Review Board (IRB) assists researchers, staff, and faculty, and provides oversight in maintaining an ethical environment for human subjects research activities. Colorado State University complies with the federal regulations governing review of research that involves human subjects. Accordingly, CSU applies the same standards for oversight to all projects involving human subjects, regardless of funding or funding source.

The review of research at CSU is conducted in accordance with our Federalwide Assurance (FWA) policy, an agreement between CSU and the federal government, approved by the Office for Human Research Protection (OHRP). The FWA stipulates that CSU will protect the rights and welfare of human research participants through a review process detailed in 45 CFR 46 and according to the Belmont Report. Through the FWA, the IRB retains sole authority at CSU for the oversight of human research conducted at CSU and by CSU researchers.

The IRB works to protect the rights and welfare of research subjects, to provide guidance on research integrity issues, and to assist the research community in conducting and promoting responsible and ethical research. All personnel using humans for research are required to comply with applicable federal regulations. The IRB considers the federally mandated regulations may, in some instances, provide minimal requirements for ethical use of human subjects, and believes that the ethical values of CSU may require higher standards. In this context, "Policies" are those practices to which faculty and staff must adhere to in their use of humans for research; whereas, "Guidelines" are considered best practices which should be adhered to in the use of humans.

Monday, August 04, 2014
The Code of Federal Regulations (CFR) includes two definitions critical to identifying whether a project must be reviewed:

**Research**: A systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to generalizable knowledge. (46.102(d)) [Click here for more information.](#)

**Human Subject**: Individuals whose physiologic or behavioral characteristics or responses are the object of a study in a research project. Under the federal regulations, human subjects are defined as: living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information. (46.102(e)) [Click here for more information.](#)

The regulations then necessarily apply to evaluations, providing services, demonstration projects, and other activities not typically thought of as “research.” These projects are a systematic collection of data and they, by virtue of publication, public presentation, thesis, dissertation, or project report, contribute to the generalizable knowledge. It is immaterial whether the project is funded by commercial entities, funded by governmental agencies, or unfunded. Any activity involving human subjects at CSU is subject to review, including soliciting questionnaires and surveys, videotaping activities, audio taping, observing behavior, and obtaining individually identifiable data about a person.

The implications of engaging in activities that qualify as research that is subject to IRB review without obtaining such review are significant. Results from such studies may not be published unless IRB approval has been obtained prior to collecting the data; to do so is in violation of federal and Institutional policy, and also violates the editorial expectations of many journals. It is also against Institutional policy to use those data to satisfy thesis or dissertation requirements. If an investigator begins a project and later finds that the data gathered could contribute to the existing knowledge base or that he or she may wish to publish the results, the investigator should submit a protocol to the IRB for review as soon as possible. If the IRB does not approve the research, data collected cannot be used as part of a thesis or dissertation, and/or the results of the research cannot be published.

If any member of the campus community has questions or concerns about these policies or guidelines, or human subjects in general, they are urged to contact an IRB Coordinator or the Chair of the IRB.

*Monday, August 04, 2014*
The Human Subjects Research Policy at Colorado State University was approved by the IRB on August 1, 2014 for recommendation to the Institutional Official, supports the research mission of Colorado State University, and ensures that the welfare of human subjects used therein will be protected. Therefore, as the Institutional Official, I declare the IRB-recommended policy to be the institutional policy of the Colorado State University human subjects' research.

Alan S. Rudolph, Ph.D., MBA
Vice President for Research and Institutional Official

8/4/2014 Date