**Policy Title:** Human Subject Research  
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**Category:** 7. Research  
**Policy Owner:** Vice President for Research  
**Contact(s):** Research Integrity & Compliance Review Board (RICRO)  
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**PURPOSE OF THIS POLICY**

The purpose of this policy is to define the activities that meet the regulatory definition of research involving human subjects or clinical investigation involving human subjects and conducted under the auspices of CSU that require prospective IRB review and approval prior to any human research activity.

**APPLICATION OF THIS POLICY**

This policy applies to all CSU employees, including faculty, staff, and student employees, students, and all others engaged in activities that meet the regulatory definition of research involving human subjects or clinical investigation involving human subjects and conducted under the auspices of CSU.

**DEFINITIONS USED IN THIS POLICY**

*Clinical Investigation* (21 CFR 56.102): Any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. 321-392 (“act”), or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that must meet the provisions of 21 CFR Part 58, regarding nonclinical laboratory studies. The terms research, clinical
research, clinical study, study, and clinical investigation are deemed synonymous for purposes of this part.

*Clinical Trial (45 CFR 46.102)*: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

*Cooperative Research*: those projects covered by 45 CFR 46 that involve more than one institution. Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The Office for Human Research Protection (OHRP) has published guidance on defining “engagement” entitled “Engagement of Institutions in Human Subjects Research (2008).” The link to this guidance is set forth below.

*Federalwide Assurance (FWA)*: The only type of assurance currently accepted and approved by Office for Human Research Protections (OHRP). Through the FWA, an institution commits to HHS that it will comply with the requirements in the HHS Protection of Human Subjects regulations at 45 CFR Part 46.

*Human Subject*: A living individual about whom an investigator (whether professional or student) conducting research: (1) Obtains information or biospecimens through intervention or interaction and uses, studies, or analyzes the information or biospecimens; or (2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. An individual who is or becomes a participant in research, either as a recipient of the test article or as a control and/or an individual on whose specimen an investigational device is used. A subject may be either a healthy human or a patient (21 CFR 50). When medical device research involves in vitro diagnostics and unidentified tissue specimens, the FDA defines the unidentified tissue specimens as human subjects. (21 CFR 812.3(p)) Note that the FDA has identified instances where use of leftover specimens that are not individually identifiable for medical device research will not trigger the informed consent requirement. The link to this guidance is set forth below.

*Identifiable Biospecimen*: A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

*Identifiable Private Information*: Private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

*Interaction*: Includes communication or interpersonal contact between investigator and subject.

*Intervention*: Includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.
Institutional Review Board (IRB): A faculty-led group that reviews and approves research with the primary focus on the rights and welfare of the participants.

Investigator: An individual performing various tasks related to the conduct of human subjects research activities, such as obtaining informed consent from subjects, interacting with subjects, and communicating with the IRB.

Multi-site study (NIH): Uses the protocol to conduct non-exempt human subjects research at more than one site.

Office for Human Research Protections (OHRP): Federal office that provides leadership in the protection of the rights, welfare, and wellbeing of participants involved in research conducted or supported by the Department of Health and Human Services (DHHS). This office provides training, regulatory oversight, advice on ethical and regulatory issues in biomedical and social-behavioral research not under the oversight of the Food and Drug Administration (FDA).

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy (45 CFR 46), whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. For the purposes of this part, the following activities are deemed not to be research:

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

- Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.

- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities by law or court order solely for criminal justice or criminal investigative purposes.

- Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Research subject to regulation: those research activities for which a federal department or agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by
a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non–research in nature (for example, Wage and Hour requirements administered by the Department of Labor).

*The “Common Rule: This is a term used for 45 CFR 46 Subpart A.*

**POLICY STATEMENT**

Research involving human subjects at CSU is subject to the policies, procedures and oversight of the Research Integrity & Compliance Review Office (RICRO), under the Vice President for Research. All human subject research must undergo prior review and approval by the Institutional Review Board (IRB).

**POLICY PROVISIONS**

The Vice President for Research at Colorado State University has established two internal IRBs and has agreements with external IRBs to review all human subjects research conducted at or sponsored by CSU. CSU's IRB Panel 1 and Panel 2 and other IRBs through institutional agreements review research protocols in a range of social, behavioral, and biomedical research activities. Institutional oversight of the internal IRB panels is the responsibility of the Vice President for Research who is CSU's Institutional Official.

All research activities that meet the federal definition of both “research” and “human subject” or meets any definitions above that are regulated by FDA must be reviewed and approved by an IRB* if:

- The research is sponsored by CSU, or
- The research is conducted by or under the direction of any employee or agent of CSU in connection with their institutional responsibilities, or
- The research is conducted by or under the direction of any employee or agent of CSU using any property or facility of this institution, or
- The research involves the use of this institution’s non-public information to identify or contact human research participants or prospective participants.

*Social, Behavioral, and Educational Research (SBER) IRB reviews all research conducted by the faculty, staff, students, or other trainees with primary appointment at CSU schools, colleges, units, or programs not subject to FDA regulations. or
*Biomedical (BMR) IRB reviews all research conducted by the faculty, staff, students, or other trainees with primary appointment at CSU schools, colleges, units, or programs that may involve clinical activities and FDA regulated research activities.

Researchers at Colorado State University frequently interact with entities or individuals outside the University with relation to research activities involving human participants. These interactions can be varied, but the University’s (and its researchers’) regulatory obligations and alternatives for addressing them may differ depending on the relationship with the entity or individual outside CSU in the context of the research.

A research site becomes “engaged” in human research when its employees or agents intervene or interact with living individuals for research purposes, including obtaining informed consent, or obtaining individually identifiable private information for the purposes of non-exempt research activities. A research site is always considered engaged in human research when it receives a direct grant or other award to support research involving human subjects, even if the human subject portion of the research is carried out by another institution.

**University’s Position on Outside Entities Engaged in University Research**

CSU’s position on research performed at multiple locations is that each may review and approve its own participation in the research, but, when possible, an IRB Authorization Agreement should be used to avoid duplicate review. When the overall Principal Investigator (PI) of research conducted at multiple locations is affiliated with the University, or the University is otherwise involved as a primary or coordinating center, the PI must assure the CSU IRB reviewing the research that each performance location involved in the research has requested an Authorization Agreement or that the research has been properly approved at that location prior to the human subjects research activity is initiated there and must notify the CSU IRB of any lapse or change in approval status.

If the outside entity is engaged in federally-funded collaborative research activities, the outside entity must demonstrate they hold a Federalwide Assurance (FWA) with OHRP.

If the other organization is engaged in the research activities and does not hold a FWA, and the research activities are not federally-funded, then a letter of cooperation or email is required acknowledging the research activities.

As the designated Institutional Official, the Vice President for Research, has authority to review decisions of the IRB. The Vice President for Research can conclude that a research protocol with CSU IRB approval does not fully comply with the policies or obligations of...
CSU and may disapprove, suspend, or terminate a project on behalf of the institution. Should the IRB disapprove, suspend, or terminate a project, no person or entity, including the Vice President for Research may reverse that decision.

COMPLIANCE WITH THIS POLICY

Compliance with this policy is required. For assistance with interpretation or application of this policy, contact Research Integrity and Compliance Review Office at RICRO Information reply@mail.colostate.edu.

REFERENCES

- Protection of Human Participants – Institutional Review Board
- Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are not Individually Identifiable
- The Belmont Report, Ethical Principles and Guidelines for the Protection of Human Subjects of Research
- Revised Common Rule 45 CFR 46
- 21 CFR Part 56
- Research Integrity and Compliance Review Office (RICRO)