Division of RESEARCH Research Compliance

Glossary of Institutional Review Board (IRB) Terms

This document defines and describes the terms used throughout the IRB policies and procedures.

Term	Definition/Description
45 CFR 46	Title 45 Code of Federal Regulations Part 46, Protection of Human Subjects, http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
Adverse Event (AE)	An adverse event is defined as any untoward physical or psychological occurrence in a human subject participating in research. An AE can be any unfavorable or unintended event including abnormal laboratory finding, symptom or disease associated with the research or the use of a medical investigational test article.
Anonymity	No identifiers (e.g., name, address, telephone number, IP addresses) are collected that link information/records/samples, either individually or when combined with other variables, to the individual from whom they were obtained. It is extremely difficult for data to be anonymous.
Assent	"A child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent" [45 CFR 46.402(b)].
The Belmont Report	The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research report titled Ethical Principles and Guidelines for the Protection of Human Subjects of Research, https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html
Child/Minor	Individuals who have not attained the age of majority (18 in most states) in the jurisdiction where the research will take place. CU students who are under 18 are considered minors.
Clinical Trial	"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." [45 CFR 46.102(b)].
Confidentiality	The treatment of information (data) disclosed in a trust relationship and with the expectation that it will not be divulged without permission to others in ways inconsistent with the understanding of the original disclosure.
Consent	The agreement of an individual 18 years of age or older to participate in a research study.
Cooperative research projects	Projects that involve more than one institution using the same protocol to conduct research involving human subjects at more than one site.
External IRB	The IRB of another institution or organization, or an independent (commercial) IRB.

Federalwide Assurance (FWA)	CU's assurance with the U.S. Department of Health and Human Services (HHS) to comply with the requirements in the HHS Protection of Human Subjects regulations at 45 CFR part 46. The FWA is the only type of assurance currently accepted and approved by Office for Human Research Protections (OHRP).
HIPAA	The Health Insurance Portability and Accountability Act of 1996. Includes the Privacy Rule found at 45 CFR 160, and 164 subparts A and E, which establishes national standards for protection of individuals' medical records and other personal health information; applies to covered entities.
Human Subject	"Human subject means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens." [45 CFR 46.102(e)(1)].
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." [45 CFR 46.102(e)(5)].
Institutional Official (IO)	The individual designated by the CU President to ensure that research involving human subjects conducted under the purview of CU follows all applicable laws and regulations. This individual is the Vice President for Research.
Institutional Review Board for the Protection of Human Subjects in Research (IRB)	The federally mandated committee established by the CU President to oversee the use of human subjects in research conducted under the purview of CU.
IRB of Record	The IRB that conducts the initial review of the protocol and has primary oversight of the study throughout its life. For multi-site studies, this is the single IRB (sIRB).
Minimal Risk	"The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily living or during the performance of routine physical or psychological examinations or tests" [45 CFR 46.102(j)].
Multi-Site Study	A multi-site study uses the same protocol to conduct research involving human subjects at more than one site.
Non-federally Funded Research	Research sponsored by Clemson University or private entities.
Participant	See Human Subject
Participating Site	In a multi-site study a participating site is a domestic entity that will rely on the sIRB to carry out the site's IRB review of human research for the study.
Principal Investigator (PI)	Responsible leader of a team of research personnel who has the ultimate responsibility for the conduct of the research.

Prisoner	"Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing" [45 CFR. 46.303(c)].
Privacy	Refers to persons and their interest in controlling the access of others to themselves.
Related Problems	There is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research.
Relying IRB	An IRB designating an agreement to rely on an external IRB for a particular study.
Research	A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" [45 CFR 46.102(l)]. The regulations state that the following activities are not deemed 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. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters). • Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized 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." [45 CFR 46.102(l)].
Researcher	CU affiliated Individuals engaged in human subjects research; specifically, individuals who interact or intervene with human subjects or access identifiable information for research purposes. May also be called principal investigator (PI), investigators, co-investigators, primary or other research personnel, or other research staff.
Risk	The probability of harm or injury (physical, psychological, social, legal, or economic) occurring because of participation in a research study.
Single-IRB (sIRB)	The selected IRB of record that conducts the review for participating sites of the multi-site study.

Sponsor	An agency, company, individual, or organization funding the research study.
Unanticipated Problems Involving Risk to Participants or Others	Unanticipated problems involving risks to participants or others refer to any incident, experience, outcome, or new information that: 1. Is unexpected 2. Is related or possibly related to participation in the research, and 3. Indicates that subjects or others are at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.
Unexpected Problems	The incident, experience or outcome is not expected (in terms of nature, severity, or frequency) given the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent documents; and the characteristics of the subject population being studied.
Written, or In Writing	Refers to writing on a tangible medium (e.g., paper) or in an electronic format [45 CFR 46.102(m)].