

Human Research Participant Protection Program

GLOSSARY

Advertising

Any outreach effort intended to be seen and heard by potential human research participants and designed to encourage them to contact the investigator for further information about a specific study.

Allegation

An assertion made by a party which has not yet been proven or supported by evidence.

Anonymized means that data or biospecimens do not contain any identifying information and they cannot be linked to any identifiable person.

Benign Behavioral Intervention

“Low risk behavioral [not biomedical] interventions in conjunction with collecting information from an adult subject through oral or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and certain conditions are met.” Regulations add that benign behavioral interventions are: brief in duration, painless, harmless, and not physically invasive.

Broad Consent

Elements of consent for the storage, maintenance, and secondary research use of private information or identifiable biospecimens. “Seeking prospective consent to unspecified future research.”

Case Studies

In-depth explorations of a particular project, policy, institution, program or system in a 'real life' context. Case studies are sometimes developed for classroom instruction using the 'case method.'

Case Report Form (CRF)

Case report form is the tool that is used to record data collected during a clinical trial. The CRF is submitted to the sponsor.

Clinical Trial NIH

“Clinical trial” means 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.

Children

Persons who have not attained the legal age for consent to treatment or procedures involved in the research, as determined under the applicable law of jurisdiction in which the research will be conducted.

Cognitive Impairment

Having either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders, or dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interest

Confirmed Noncompliance

An allegation of noncompliance that has been verified as a result of an investigation and/or a for-cause audit.

Continuing Noncompliance

A repeated pattern or un-rectified instance of noncompliance by an individual investigator or research staff member either on a single protocol or multiple protocols.

Data and Safety Monitoring Board

A committee of scientists, physicians, statisticians, and others that collects and analyzes data during the course of a clinical trial to monitor for adverse effects and other trends (such as an indication that one treatment is significantly better than another, particularly when one arm of the trial involves a placebo control) that would warrant modification or termination of the trial or notification of subjects about new information that might affect their willingness to continue in the trial.

De-identified means that identifiers have been removed from data biospecimens; a code may link individual records or specimens to identifiable persons. The requirement for IRB review depends on who deidentified the data/biospecimens and who has access to the linking code.

Deception

“Authorized deception would be prospective agreement by the subject to participate in research where the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research”

Engagement in Research

An institution becomes "engaged" in human subjects research when its employees or agents¹ (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes [45 CFR 46.102(d),(f)].

An institution is automatically considered to be "engaged" in human subjects research whenever it receives a direct HHS award to support such research. In such cases, the awardee institution bears ultimate responsibility for protecting human subjects under the award.

For more details, including examples of situations where an institution may or may not be considered engaged, please refer to the [guidance](#) provided by OHRP on this topic.

Essential Documents

Essential documents are defined by ICH (2016) E6 (Section 1.23) as the documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced.

Generalizable Knowledge

Has not been explicitly defined in federal regulations, but can be: a) applied to individuals outside the research sample; b) predictive of future events; or c) widely applied as theories or principles that enhance scientific or academic understanding; or d) create general explanations about all that has happened in the past.

Human Subjects or Human Participants

Living individuals about whom an investigator (whether professional or student) conducting research obtains:

1. information and biospecimens through intervention or interaction with the individual or
2. obtaining, storing, using, studying, analyzing, or generating identifiable private information or identifiable biospecimens as trigger events

Human Subjects Research

'Research' (as defined below) involving 'human subjects' (as defined above).

Informed Consent

A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence.

Institutional Review Board (IRB)

A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research.

Investigator's Brochure (IB)

Investigator brochure is a compilation of the clinical and nonclinical data on the investigational product and serves as a resource for investigators, institutional review boards/independent ethics committees (IRBs/IECs) during the conduct of a clinical trial.

IRB Approval

The determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

Interaction

Includes communication or interpersonal contact between investigator and subject.

Intervention

Includes both physical procedures by which data are gathered and manipulations of the participant or the participant's environment that are performed for research purposes. Intervention includes communication or interpersonal contact between investigator and participant.

Investigator

The individual(s) designated to have the appropriate level of authority and responsibility to direct the research project and/or activity.

Journalism

Includes activities focused on the collection, verification, and reporting of information or facts on current events, trends, newsworthy issues or stories about people or events, with no intent to develop or test a hypothesis.

Key Personnel

Individuals who contribute to the scientific development or execution of the project in a substantive, measurable way, whether or not salaries are requested on the corresponding grant application/contract proposal.

Legally authorized representative (LAR)

Legally authorized representative now adds specific authorization to use institutional policy when there is no applicable law (state statute or regulation, case law, or an opinion of a state Attorney General) that addresses this issue.

Life Histories (or Life Stories)

Include 'any retrospective account by the individual of his [or her] life in whole or part, in written or oral form, that has been elicited or prompted by another person.' Life stories intend 'to show something about the kind of person a speaker is.'

Limited IRB review

Limited IRB review is making and documenting the determination required by 46.111(a)(7), to ensure that there are adequate privacy safeguards for identifiable private information and identifiable biospecimens in the proposed research

Minimal Risk

A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Multiple Relationships (Financial Conflicts of Interest)

a. income: including receiving past, current, or expecting future income in the form of salary, stock or stock option/warranties, equity, dividends, royalties, profit sharing capital gain, forbearance of forgiveness of a loan, interest in real or personal property, or involvement in a legal partnership with the sponsor. b. consultant: receiving past, current, or expecting future income in the form of consulting fees, honoraria, gifts, gifts to the University, or payments resulting from seminars, lectures, or teaching engagements, or service on a non-federal advisory committee or review panel. c. service: serving in a corporate or for-profit leadership position, such as executive officer, board member, fundraiser officer, agent, member of a scientific advisory board, member of a scientific review committee, or member of a data safety monitoring committee, regardless of compensation. d. intellectual property: inventor on a patent or copyright involving technology/processes and/or products licensed or expected to be licensed to the sponsor.

Non-compliance

Failure to comply with federal regulations; the policies or procedures of the IRB; or institutional policies governing human research. Examples of noncompliance include: (1) conducting human participant research without IRB approval (*e.g.*, before approval; after expiration of approval and in the absence of a continuation application submitted to the IRB; during a suspension of IRB approval; after termination of IRB approval); (2) disregarding or otherwise violating IRB-approved informed consent procedures (*e.g.*, failing to obtain consent/assent, using unapproved or outdated consent, assent, and information sheets, missing signatures, failing to document consent process); (3) deviating from the protocol approved by the IRB; (4) modifying an approved protocol without IRB consent; (5) failing to report or tardily reporting unanticipated problems; (6) failing to maintain adequate records; (7) failing to train research team members in the proper procedures; and (8) failing to follow recommendations by the IRB to ensure the safety of research participants.

Office for Human Research Protections (OHRP)

The Health and Human Services (HHS) office that oversees the regulation of research involving human research participants.

Oral History

The National Oral History Association (OHA) defines oral history as 'a method of gathering and preserving historical information through recorded interviews with participants in past events and ways of life'. Oral history is a recorded conversation about the past with named individuals in which knowledge about specific events and individual lives is narrated in story form and made available to the

public through deposit in archives. Biographical in nature and historical in scope, the scholarly oral history interview is rooted in particular recollections about history based on the individual perspective of the narrator.

Principal Investigator (Protocol)

The scientist or scholar with primary responsibility for the design and conduct of a research project.

Prisoner

An individual involuntarily confined in a penal institution, including persons: (1) sentenced under a criminal or civil statute; (2) detained pending arraignment, trial, or sentencing; and (3) detained in other facilities (e.g. for drug detoxification or treatment of alcoholism) under statutes or commitment procedures providing such alternatives to criminal prosecution or incarceration in a penal institution.

Private Information

Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Private information must be individually identifiable (i.e., the identity of the participant is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human participants.

Protected Health Information (PHI or Identifiable Private Information)

Name; Address, including city and zip code; Telephone number; Fax number; Email address; Social Security Number; Date of birth; Medical record number; Health plan ID number; Dates of treatment; Account number; Certificate/license number; Device identifiers and serial number; Vehicle identifiers and serial number; URL; IP address; Biometric identifiers, including fingerprints; Full face photo and other comparable image

Protocol

Protocol is the study plan that describes how a trial will be conducted including information about the investigational product, the criteria for subject selection, the schedule of procedures, and the plan for data analysis.

Public health authority

Public health authority means an agency or authority that is responsible for public health matters as part of its official mandate.

Quorum

A quorum will be at least 5 members of the IRB but one Non-scientist/non-affiliated (community member) must be present. For reasons other than conflict of interest, abstentions do not alter the quorum, or change the number of votes required.

Research

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, 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 and they would be included in this definition of Research.

Restricted Use or Limited Data Set

Files that have restrictions imposed regarding their use in research and contain data fields such as social security numbers, names, protected health information or other life history markers that might enable an unauthorized user to identify a participant.

Secondary Research Use

Secondary research means conducting research using data or biospecimens originally collected for another purpose, which may or may not have been research. The requirements for IRB review and informed consent depend on the circumstances under which the data were collected and whether the data can be linked to individuals.

Re-using identifiable and non-identifiable information and biospecimens that are collected for some other 'primary' or 'initial' activity"

Secondary Data Set

Data that can be used in research and comes from public or private documents, including medical records, police reports, vital statistic records, student record.

Specimen

A sample, as of human tissue, blood or urine, used for diagnostic or pathological analyses.

Source Data

Source data means all information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies)

Source Document

Source document is the initial documentation of data in a clinical study and includes recorded observations, laboratory reports, medical records, etc.

Suspension

Suspension is defined as a temporary halt to all research activities. It occurs when the Chair of the IRB or the convened IRB places a temporary hold on the previously approved research, such that no research activities can be conducted, including recruitment/enrollment of new participants, further research interventions (unless necessary for the safety and well-being of the enrolled participants), follow-up

(unless it is in the best interests of the participants and approved by the IRB), analysis of data, publications, and presentations.

Termination

Termination is defined as a permanent halt to all research activities, including recruitment/enrollment of new participants, further research interventions, analysis of data, publications, and presentations. It occurs when the convened IRB votes to withdraw approval or stop all research activities permanently.

Unanticipated Problem

An unanticipated problem involving risk to human participants or others, is one that (1) was unforeseen at the time of its occurrence, and (2) indicates that participants or others are at an increased risk of harm.

Vulnerable (to Coercion or Undue Influence)

“Vulnerability” of the subjects in research studies should be considered as a function of the possibility of coercion or undue influence.

Witness is a person who is independent of the research team and cannot be unfairly influenced by people involved with the research, who does not have a coercive relationship with the participant, and who attends the informed consent process. A translator who participated in the informed consent process also may serve as the witness.

Written or in Writing

Writing on a tangible medium (e.g., paper) or in an electronic format.