Protection of Human Subjects and Ethical Treatment of Research Participants

Policy Owner: Rebecca Collins, Chair, Human Subjects Protection Committee (x7247)

Purpose	This policy describes the appropriate means for acquiring and safeguarding Human Subjects Information and describes the role of the Human Subjects Protection Committee in ensuring the ethical treatment of Research Participants. The Health Insurance Portability and Accountability Act ("HIPAA") also imposes restrictions on the nature and content of private health information that may be provided by health care providers. Guidance on the acquisition and use of such Protected Health Information is provided here.
Scope	All research and support operations conducted by RAND U.S.
Policy	RAND is committed to the ethical and respectful treatment of Research Participants and compliance with applicable regulations. All Research Participants deserve to be treated with respect, beneficence, and justice, as described in the Belmont Report. The decision to acquire information from Research Participants includes taking responsibility for safeguarding the acquired information in ways that respect and protect its confidentiality. RAND Associates must fully carry out our commitment to protecting such information and associated data consistent with the standards of ethical behavior and as required by law, including adherence to each of the following: (1) U.S. federal, state, and local laws, regulations, and requirements that affect the acquisition and safeguarding of information obtained from Human Subjects, (2) any foreign laws applicable to the research, and (3) any requirements from the Human Subjects Protection Committee regarding the ethical treatment of Research Participants.
Contents	
References	▪ Electronic Storage and Transfer of Unclassified Sensitive Information policy ▪ RAND Human Subjects Protection Committee website ▪ Guidance on Acquisition and Use of Protected Health Information (PHI) for Research Purposes

1. Definitions

Associate means all RAND U.S. Regular and Term Employees, Adjunct or Affiliated Adjunct staff, Pardee RAND Graduate School students, and Sponsored Fellows, and RAND Europe and RAND Australia Associates when they are working on RAND U.S. research projects.

The Belmont Report means the document, first drafted in 1978 by the National Commission for the Protection of Human Services of Biomedical and Behavioral Research, that summarizes ethical principles and guidelines for research involving Human Subjects. The principles of respect for persons, beneficence, and justice that it outlines form the basis of the U.S. Department of Health and Human Services' Human Subject protection regulations. It may be found here.

The Common Rule means the Federal Policy for the Protection of Human Subjects, codified at Title 45, Part 46, of the Code of Federal Regulations (45 CFR 46), which outlines the basic provisions for Institutional Review Boards (such as RAND's HSPC), informed consent, and Assurances of Compliance.

Data Safeguarding Plan means the document approved by the HSPC for a specific project that outlines what Human Subjects Information will be obtained and defines the ways specific projects will safeguard it, from initial acquisition through publication to final data destruction.

Human Subject, as defined in the Common Rule, means a living individual about whom an investigator (professional or student) conducting research (1) obtains information through intervention or interaction with the individual and uses, studies, or analyzes information, or (2) obtains, uses, studies, analyzes or generates identifiable private information.

Human Subjects Protection Committee (HSPC) means RAND's institutional review board for Human Subjects research, as authorized by RAND's Federalwide Assurance (FWA) for the Protection of Human Subjects. The HSPC is concerned with both ethical and regulatory issues associated with the protection of Human Subjects and their identifiable private information.

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

Principal Investigator/Project Director means the RAND Associate identified as having primary responsibility for the design and conduct of a specific RAND research project or task. The Principal Investigator/Project Director for a research project is generally the Associate identified in RAND's financial information system as the "Project Leader."

Research, as defined in the Common Rule, means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge. Activities that meet this definition constitute research whether or not they are conducted or supported under a program which is considered research for other purposes.[1]

Research Participant means an individual about whom, or from whom, RAND, or persons acting on behalf of RAND, obtains data for use in a RAND project. Such data may include factual information, opinions, and attitudes, whether or not Human Subjects Information.

2. Acquiring and Safeguarding Human Subjects Information

2.1 Requirements. RAND research projects that involve interaction with Human Subjects or the acquisition of Identifiable Private Information are subject to two fundamental requirements:

[1] This definition applies throughout this policy, even where the term "research" is not capitalized.

(a) *The Belmont Report.* Human Subjects must be treated with respect, beneficence, and justice. These concepts are detailed within the "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," more commonly known as the Belmont Report.

(b) *The Common Rule.* The Federal Policy for the Protection of Human Subjects (the "Common Rule"), codified at Title 45, Part 46, of the Code of Federal Regulations (45 CFR 46), outlines the basic provisions for Institutional Review Boards (such as RAND's HSPC), informed consent, and Assurances of Compliance. These guidelines are also spelled out in RAND's Federalwide Assurance (FWA) for the Protection of Human Subjects. More information is available on the Human Subjects Protection Committee Intranet site.

All institutions must adhere to the Common Rule to be eligible for federal research support, and many, including RAND, also agree to extend the same policies and procedures to all research they undertake, regardless of the funding source. Policies and procedures for protecting private, individual-level data apply to all RAND U.S. projects, including those funded by civilian or military agencies, foreign governments, private foundations, and for-profit firms, whether the research is conducted in the United States or not.

2.2 Prohibitions on Use or Disclosure of Human Subjects Information.

(a) Individual-level Identifiable Private Information from or about Human Subjects to which any RAND Associate gains access during his or her association with RAND shall not be used, published, disclosed, or disseminated (collectively a "disclosure") in any form to any person, agency (governmental or other), corporation, or other entity, unless: (1) the Human Subjects Protection Committee first approves the disclosure as part of the research plan or (2) RAND's Office of the General Counsel determines that such disclosure is required by law. (See also Section 7 below.)

(b) The restrictions and conditions governing use and disclosure of individual-level Identifiable Private Information concerning Human Subjects continue to apply even after (1) termination of the project to which any such information relates, (2) termination of a RAND Associate's involvement with any such project, or (3) termination of an Associate's employment by or association with RAND.

2.3 Responsibilities.

(a) *All RAND Associates* are required to protect, and prevent improper disclosure of, Identifiable Private Information from or about Human Subjects.

(b) *Principal Investigators/Project Directors* are responsible for ensuring that:

- all projects are screened for potential Human Subjects participation as set forth in this policy;
- any project involving Human Subjects or other Research Participants is properly submitted for review by the HSPC, including additional research tasks planned after the initial review takes place;
- guidance from the HSPC is fully implemented by the project prior to the acquisition of Identifiable Private Information about, or activities involving, Human Subjects or Research Participants;
- any breaches of procedure or adverse events that increase risks to Human Subjects or Research Participants are promptly reported to the HSPC; and

- each RAND Associate working on the project completes the Human Subjects online training offered by the Collaborative Institutional Training Initiative (CITI) program before initiating any work involving Human Subjects or Research Participants.

(c) *The HSPC* has responsibility for screening all projects and making determinations with respect to the proper procedures for acquisition and protection of information from or about Research Participants, including Human Subjects.

(d) *The HSPC Chair* provides leadership and policy guidance on ethical treatment of Human Subjects, Identifiable Private Information involving Human Subjects, and related regulatory and ethical requirements.

(e) *The Director of Procurement and Subcontractor Compliance* is responsible for ensuring that all subcontractors and subgrantees of RAND projects that involve Human Subjects research have agreed to comply with the Common Rule and all applicable RAND policies.

(f) *The Office of General Counsel* provides legal oversight and guidance on laws and regulations pertaining to the protection of the Identifiable Private Information of Human Subjects.

(g) *The Senior Vice President, Research and Analysis* is responsible for ensuring that research divisions are in compliance with this policy, regulatory requirements, and ethical guidelines.

(h) *The Senior Vice President, Research and Analysis* is the Signatory Official for RAND's Federalwide Assurance and is the official legally authorized to represent RAND in relation to Human Subjects research.

3. Screening and Designation of Projects

3.1 Mandatory Screening of All Projects. Except as provided in subsection 3.1(c) below, all new research at RAND must be screened by the HSPC for the involvement of Human Subjects before any data collection begins (including data from individuals or acquisition of data sets), regardless of whether the Principal Investigator/Project Director believes the project is Human Subjects Research. Data collection for a project may not commence prior to receipt of the HSPC's determination regarding the involvement of Human Subjects. NOTE: Only the HSPC can make a final determination that a project is "Not Human Subjects Research," regardless of the designation made by the Principal Investigator/Project Director at the proposal stage.

(a) *Timing of HSPC Screening.* HSPC screening is generally conducted once a project has been funded and must be completed before any individual-level data collection activities may commence. However, certain RAND clients require Human Subjects approval before funds will be released (e.g., a National Institutes of Health "just-in-time review"). In such cases, approval must be obtained, including satisfaction of all contingencies, before Human Subjects research activities may commence.

(b) *Submissions Through RHINO.* All submissions of new projects for HSPC screening must use the RAND HSPC Information Online (RHINO) system. It is the specific responsibility of the Principal Investigator/Project Director to ensure that the RHINO submission is complete and accurate. These procedures help assure careful attention to potentially high-risk projects, while avoiding prolonged review of low-risk projects. The first step in the review process is to make the distinction between the

two. For many projects, the only potential risks to Human Subjects are those associated with potential breaches of confidentiality (unintentional or not).

- A Data Safeguarding Plan (see Section 4 below) is required for most individual-level research projects that either collect primary data or acquire existing individual-level data.
- Addition of new Human Subjects research activities to an existing project requires filing an amendment/modification in RHINO and obtaining approval before the activity can begin.
- Projects under HSPC review, where a continuing review was determined to be required at the time of initial or modification review, are required to submit an annual continuing review through RHINO at least 60 days before the expiration of their approval. Projects that have not obtained approval in continuing annual review may be required to cease all Human Subjects activities until the approval is obtained.

(c) *Initial Screening by Research Divisions.* With prior approval from the HSPC, specific RAND research divisions may be authorized to conduct an initial screening for the purpose of determining whether or not submission to the HSPC is required. Research divisions given such permission must maintain complete records of these determinations, including a clear description of the basis for the determination, and make such records available for review by the HSPC and federal agencies with audit responsibilities. All other RAND research projects must be screened by the HSPC as described above.

3.2 U.S. Department of Defense (DoD) Secondary Review. Most projects that involve Human Subjects and/or their Identifiable Private Information, that are funded by DoD also require a secondary review by a designated agency of DoD. Information about this requirement is available on the HSPC web page. Division directors or their designated representatives are responsible for determining whether a secondary review is required and identifying the agency that will conduct the review.

3.3 Delegation of Responsibilities of Principal Investigator/Project Director. The Principal Investigator/Project Director retains responsibility for any activities delegated to other RAND Associates under this policy and is therefore responsible for ensuring that the individual assigned any such activity has sufficient training, knowledge, experience, resources, and judgment to successfully undertake such activities in compliance with RAND policies and HSPC directives. No Principal Investigator/Project Director responsibilities may be delegated to any individual other than a qualified RAND Associate without prior HSPC approval.

3.4 Project Participants Who Are Not Human Subjects. The HSPC may, in its discretion, determine that although a particular project does not meet the Common Rule definition of Human Subjects Research, fulfillment of the principles of The Belmont Report (respect, beneficence, and justice) or RAND's Institutional Principles requires implementation of certain protections and procedures associated with Human Subjects Research.

4. Data Safeguarding Plans

4.1 Requirement for Data Safeguarding Plan. All research projects involving Human Subjects are required to have a Data Safeguarding Plan, which must be approved by the HSPC prior to the commencement of individual-level data collection. The Data Safeguarding Plan is the document that outlines what Human Subjects' information will be obtained and defines how the project will safeguard and use such information, from initial acquisition through publication to final data destruction.

4.2 Preparation of Data Safeguarding Plan. It is the responsibility of Principal Investigators/Project Directors to (1) prepare the Data Safeguarding Plan, (2) ensure that the Plan is communicated to the relevant project staff members, and (3) ensure compliance with the plan. Preparation and communication of the Data Safeguarding Plan may be delegated to a qualified RAND Associate consistent with Section 3.3 above. More information about Data Safeguarding Plans is available on the HSPC intranet site. Compliance with Data Safeguarding Plans is monitored by HSPC administrators.

5. Disposing of Human Subjects' Information

5.1 Retention and Destruction of Human Subjects Information. Principal Investigators/Project Directors must document the retention and destruction procedures applicable to the project in the Data Safeguarding Plan (see Section 4 above) and ensure compliance with all applicable retention and destruction procedures. Procedures for retention and destruction of Human Subjects' information differ depending on the original terms under which data are acquired, as well as agreements related to disclosure and return or destruction of the information.

(a) In most instances, identifying information should be destroyed as soon as possible. However, there may be circumstances in which it may be necessary or appropriate to securely retain such information. Retention of identifying data beyond the life of a project involving Identifiable Private Information requires prior approval of the HSPC.

(b) Data that is not individually identifiable may be retained indefinitely. When such data are made available for public use after project completion, it is critically important to ensure that all direct identifiers have been eliminated and that data enabling identification by inference have been removed or sufficiently altered so as to preclude identification.

(c) Signed participant consent forms must be retained for at least three years (or longer, if required by the client or HSPC) in a secure location approved by the HSPC. For studies that were approved in Full Committee review, the signed consent forms must be retained for 7 years after the end of the study.

5.2 Responsibilities of Terminating Associates. When terminating from RAND, Principal Investigators/Project Directors, and all other Associates who are custodians of Identifiable Private Information must consult with the appropriate division director(s) to determine whether the information for which they are responsible should be archived for future use or designated for disposal. If identifiable data are to be retained, the HSPC will determine the manner in which they must be archived. The HSPC Chair can offer guidance on this procedure. Terminating Associates will be required to acknowledge that they have met these requirements in the sign-out process with RAND's Human Resources Department. Information that is designated for disposal must be handled in in accordance with the procedures outlined on the Data Protection website.

6. Reporting Data Compromises and Adverse Events and Audit of Procedures

6.1 Reporting Requirement. The Principal Investigator/Project Director is responsible for reporting any actual or potential Data Compromises or Adverse Events to the HSPC within one working day of any such incident.

(a) *Data Compromise* means disclosure of Identifiable Private Information to any individual not specifically authorized to receive or possess such information, or any unplanned loss of possession or control of Identifiable Private Information.

(b) *Adverse Event* means an incident occurring in the course of research that deviates from the existing approved research plan; that may be unanticipated or surprising; and/or that may have potentially negative consequences for the research subject(s) involved (including consequences associated with intentional or inadvertent breaches of confidentiality).

6.2 Auditing. The HSPC and other entities designated by RAND may conduct periodic audits of compliance with Human Subjects protection procedures such as administration of informed consent, storage and retention of consent materials and other required records, and data safeguarding procedures. Outside agencies, such as DoD or the Office for Human Research Protections ("OHRP"), an office of the United States Department of Health and Human Services, may also audit RAND from time to time for compliance with Human Subjects regulations. The Principal Investigator/Project Director is responsible for facilitating compliance with any such audits in cooperation with the HSPC.

7. Subpoenas and Other Requests for Disclosure of Human Subjects Information

7.1 Associates Contacted by Government Agencies or Officials. A RAND Associate who has been or has reason to believe that he or she may be, called on to make a disclosure of Identifiable Private Information to any court or governmental agency shall immediately notify the HSPC Chair and the Office of the General Counsel. Following such notice, the Associate shall cooperate in responding to the request.

7.2 Subpoenas. All subpoenas addressed to RAND or a RAND Associate relating to Human Subjects information must be immediately directed to the Office of the General Counsel for review and preparation of an appropriate response. The Office of the General Counsel will inform the HSPC Chair of any subpoenas served on RAND pertaining to Human Subjects information.

8. Sanctions

8.1 Adherence to this policy is a condition of employment at RAND. Violation may result in disciplinary action, up to and including termination of employment.

Policy Review	The Chair of the HSPC will review this policy at least every three years.
Policy Last Reviewed	February 14, 2025
Policy Last Revised	February 14, 2025
Intranet Address	https://randus.sharepoint.com/pp/Pages/hspc.aspx