

3. WHAT IS SUBJECT TO REVIEW?

3.1 Definition of Research

Research is defined by the federal regulations as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” [45 CFR 46.102(d)] This definition may include qualitative and quantitative research studies, surveys, case studies, experiments, interventions, analysis of specimens, demographic and epidemiological research, program evaluations, oral histories, secondary analyses of documents and records, and other methods associated with biomedical, behavioral and social sciences. Research is characterized by the intent to share knowledge with others in professional, scholarly, or scientific publications and/or forums.

3.2 Definition of a Human Subject

A human subject is defined in the federal regulations as a “living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.” Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject’s environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. 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. [45 CFR 46.102(f)]

a. Third Parties – In the course of their research, investigators sometimes collect information about persons other than the participant who has provided informed consent to be part of a study. For example, medical histories often collect information about conditions and diseases among a person’s relatives or sociological, anthropological, or psychological research may obtain information about people’s experiences and perspectives on others in their lives. Persons who are not primary subjects of research, but about whom information is collected are sometimes referred to as “third parties” or “secondary subjects.” Many CPHSs and the OHRP have examined the issue of: when do third parties become “human subjects” from whom informed consent must be obtained?

Investigators have an ethical responsibility to avoid exposing any persons to unnecessary risks or undue harms, whether or not they are research subjects. Information collected about third parties generally should be recorded in a manner that protects their identities, and special steps must be taken to safeguard confidentiality in the case of sensitive information that could cause harm to persons unless this jeopardizes the rights and welfare of the research participants.

The CPHS will consider on a case-by-case basis the circumstances under which third parties should be considered research subjects. In reaching this determination, the CPHS will consider the following factors: (1) the amount of private information collected about third parties; (2) the sensitivity of that information; (3) the ability of investigators to maintain the confidentiality of third parties; (4) the welfare of the originally designated research subjects; and (5) the right of the originally designated research subjects to provide information on their personal life experiences. Third parties normally are not considered research subjects from whom consent must be obtained unless information obtained about them pertains to their personal behavior unrelated to the interests and experiences of the originally designated research subjects.

b. Expert Opinion – Faculty, staff and students sometimes solicit the opinions of experts through phone or face-to-face interviews, surveys, and panel discussions. Experts are persons who, by virtue of their training or expertise, have information and knowledge in a substantive area beyond that of the average person and who regularly share this information and knowledge through consultation,

teaching or public speaking, or publications and written reports. For CPHS purposes, experts are not human subjects when asked to provide information and opinions within their areas of expertise. Communications with experts on non-private information do not require CPHS approval.

c. Autobiography or “Auto-ethnography” – In sociology, anthropology and related disciplines, postmodern ethnography, autobiography, or auto-ethnography is a narrative method in which the investigator and “subject” are one and the same. That is, the investigator reports on his or her own experiences and perspectives. In this form of narrative reporting, the investigator is not considered a research subject, and CPHS approval is not required.

3.3 Scope of Review

CPHS review and approval is required for any research involving human subjects that:

- is conducted by University faculty, staff, or students;
- is performed on the premises of the University;
- involves University students, faculty, or staff;
- satisfies a requirement imposed by the University for a degree program;
- is performed with, or involves the use of, facilities or equipment belonging to the University.

3.4 Research Conducted by “Affiliated Faculty”

Research conducted by “affiliated faculty” – faculty members who hold clinical appointments – is subject to the University’s guidelines for research on human subjects and must be submitted for CPHS review. Any research project that is conducted by or under the direction of any employee or agent of this institution, in connection with his or her institutional responsibilities, requires CPHS approval.

3.5 Research Projects in which the Researcher is a Consultant

University CPHS review is required as stated above unless the researcher has a strict consulting relationship in which:

- the researcher is hired on his or her own time; OR
- the researcher holds no rights in the work; AND
- neither the researcher nor the University retains any data; AND
- the researcher does not utilize University space, materials and supplies, and secretarial and staff support.

3.6 Research Conducted by Students – The Faculty Sponsor’s Responsibility

Theses/dissertation projects, senior honor theses, independent study research projects, and other similar projects must be submitted independently to the CPHS by the student-researcher. Faculty sponsors must instruct students on the ethical conduct of research and help them prepare the application for CPHS approval. Students should:

- understand the elements of informed consent;
- develop a readable consent form following the samples (www.research.uh.edu, click on “Human Subjects”);
- plan appropriate recruitment strategies for identifying potential subjects;
- establish and maintain strict guidelines for protecting anonymity or confidentiality; and

- allow sufficient time for CPHS review and completion of the project.

To ensure that the University's guidelines will be followed, the faculty sponsor is required to sign the student's application for CPHS approval. The faculty sponsor's certification section of the application states, "I hereby certify the accuracy of this application and attest to the scientific merit of the proposed project. I accept the responsibility for the conduct of this research and for the protection of human subjects as required by law and institutional policy." After CPHS approval, faculty sponsors must take an active role in ensuring that projects are conducted in accordance with the CPHS's requirements.

3.7 Research Conducted in University Courses

Many research methods courses at the University of Houston require students to complete projects as a way of teaching research methods and skills. Institutional review boards at institutions of higher education vary according to whether they require student projects to be reviewed and approved. The University of Houston's CPHS does not require student projects conducted in research methods courses to be reviewed if the purpose of these projects is educational in nature and will not be published or used in future research. Activities not intended to provide generalizable knowledge are not subject to CPHS review. However, *the instructor of the course is ultimately responsible for the protection of human subjects.*

Students are not permitted to continue projects conducted for a research methods course after the semester has ended without CPHS approval.

Students in graduate methods courses, in particular, sometimes use projects to refine their research interests and provide a foundation for a thesis or dissertation. This type of research would require CPHS approval if human subjects are involved. A project initially conducted to learn research methods may yield data that the student subsequently wishes to use to contribute to knowledge. In order to use this data for theses, dissertations, or other research purposes, students must either: (1) demonstrate that individuals provided informed consent for the project at the time, through procedures approved by the instructor; or (2) obtain consent from the individuals to use previously collected information according to procedures approved by the CPHS (i.e., an application for exemption, expedited review, or full CPHS review). Instructors of methods courses requiring student projects are required to send a memo to the CPHS administrator listing the students and their research projects and indicating that the projects were conducted under the instructor's supervision and in accord with procedures approved by the instructor. The administrator will provide a memo verifying that the student projects did not require CPHS approval.

Student projects in courses are subject to CPHS review if they are designed at least partially to provide data for research and publication purposes. For example, instructors may enlist students to assist in data collection or analysis for their own research or may design seminars in which a goal is for students to collaborate in research that will be submitted for publication. These projects constitute research and must be submitted to the CPHS for approval before the project can begin.

3.8 Research Conducted at Another Institution

Prior to participation in a research project at another institution, the University-researcher must obtain approval of the project by the relevant CPHS at University of Houston and all relevant institutions. For example, a University researcher engaged in research with Baylor College of Medicine must secure approval from the CPHS at University of Houston and the IRB at Baylor College of Medicine, unless a Memorandum of Understanding recognizing each other's IRB is in place.

Changes in protocol or consent forms required by the IRB at the other institution must be brought to the attention of the CPHS at the University of Houston.

3.9 Research Conducted at UH by Investigators from Other Institutions

University of Houston officials and faculty are sometimes approached by investigators at other institutions for cooperation in their research. For example, department chairs or deans might be asked to assist in the distribution of surveys to faculty or students. This research does not fall under the purview of the CPHS unless: (1) University facilities and resources will be used; (2) University officials are actively engaged in or actively cooperate with or encourage participation in the research; or (3) University officials, faculty, staff, or students intend to use the findings or results of these studies for their own purposes.

Investigators from other institutions are advised to contact the Director of Research Compliance at (713) 743-9204 for additional information on the required procedures.

3.10 Research as Part of Multicenter Clinical Trials

Approval of a proposal document at the national level is not sufficient to bypass approval at the local level. Researchers who conduct multicenter clinical trials sponsored by the National Institutes of Health (NIH) or the National Cancer Institute (NCI), for example, should include protocols and consent forms approved at the national level with their applications to the CPHS. Although the documents should be identified as having been approved by a national CPHS, the local CPHS must review the material as it would any other submission.

Only the local IRB is vested with the authority to review and approve projects to be conducted at a given *institution* familiar with the particular circumstances of its research setting and is able to weigh critical considerations such as state and local laws, professional and community standards, institutional policies, and the needs of different patient and subject populations.

If changes are made to documents approved by the national IRB, the investigator must notify that IRB. The University CPHS will rarely make substantive changes in the protocol or study plan and more likely to request that the wording of a consent form be changed to reflect local standards or to include specific language required by the University.

3.11 Research in Foreign Countries

Research conducted by University investigators in foreign countries remains under the purview and guidelines of the University CPHS. While we cannot impose our standards for written documentation on other cultures, we do not relax our standards for ethical conduct or consent process.

While human subjects in foreign countries merit the same level of protection as subjects in the United States, acceptable practices vary from place to place. Different traditions, mores and institutions may require different research protocols, particularly regarding informed consent, recruitment practices, and documentation. Special attention must be given to local customs, culture, and religious norms in drafting written consent documents.

Documentation of "local approval" is a prerequisite to CPHS approval at the University. This approval should be from the local equivalent of the University CPHS, local experts or community leaders. Researchers should provide sufficient information regarding the language and culture of the country in question. Researchers proposing international research should allow additional time for this review process.

3.12 Research at a Pilot or Feasibility Stage

Investigators sometimes conduct pilot studies designed to develop or refine research procedures and instruments. Although data collected through pilot or feasibility studies (including those involving only one human subject) may not be used in research reports and publications, pilot studies represent part of the research process that leads to the development of or contribution to generalizable knowledge. Therefore, these studies require the same scrutiny as full-scale research projects and must be submitted for CPHS approval. Pilot studies should be identified as such in the "Application to Conduct Research using Human Subjects." Ordinarily, the data collected from subjects as part of a pilot/feasibility study are not used for study findings. The consent document should clearly identify the project as a pilot study.

Experts reviewing draft research procedures or instruments are not considered human subjects, and CPHS approval is not required for this.

3.13 Quality Improvement/Program Evaluation Research

Quality improvement (QI) activities may, but do not necessarily, constitute human research. QI attempts to measure the effectiveness of programs and services. Such activity *may* constitute human research, if they are designed or intended to contribute to generalizable knowledge. If they are designed solely for internal program evaluation purposes, with no external application or generalization, they do not require CPHS review and approval.

3.14 Research Involving Secondary or Archival Data

Federal regulations extend to the use of existing or "archival" data if it was originally obtained from persons who would meet the definition of a human subject. Exempt category 4 states, "Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects."

This might include (but is not limited to) student test scores, academic achievement scores, attendance and/or discipline records, data previously collected in a research project, census records, etc. The application must indicate that the data is publicly available (with a description of how it is obtained) or provide a letter from the person who is the owner or the keeper of the data indicating that permission has been granted for the use of the data in a research activity. Also, the data must be in existence at the time the application is submitted to the CPHS.

3.15 Research Involving Tissue/Blood Samples

Research that is conducted on "waste" or "extra" human tissue or fluids must be submitted for review. "Waste material" is material that is collected originally for clinical or diagnostic purposes only but is no longer needed. "Extra material" is material that is collected above and beyond what is needed for a clinical or diagnostic procedure. It is collected during the same procedure, but solely for investigational purposes.

The CPHS may determine that research on waste material qualifies as exempt from full review. If the subject's consent to the clinical procedure outlines research use of the material as well, a separate consent form may not be required. Collecting and using "extra material" requires subjects' written consent and full CPHS review.

3.16 Research Involving Deception

The CPHS discourages deception in any form of experimental procedure. If an investigator believes that deception is necessary to conduct the research and is the only way to answer the research question(s), he or she must provide a detailed rationale to the CPHS and ensure that psychological, social, and other risks will be minimized. Before approving deception in research, the CPHS will require a procedure to be put into place that provides for a debriefing process, with the participant being given a statement to sign indicating that debriefing has occurred and that he or she understands that deception occurred and how.

3.17 Research Involving the Internet

For Internet research, investigators must protect the privacy and confidentiality of participants and obtain their informed consent. Investigators may not be required to obtain consent of persons to record information or communications in public Internet forums in which people do not have a reasonable expectation of privacy. For example, an investigator would need to obtain consent of people to record communications in a private listserv, but would not be required to do so in a public chat room with unrestricted access. In communications with persons in public or private Internet forums, investigators must not conceal their identities as investigators or mislead people about their purposes. Investigators must not communicate directly on the Internet with persons whom they believe are minors without their parents' permission.

In electronic surveys or interviews, investigators must take reasonable steps to protect people's privacy and confidentiality, taking into account the sensitivity of questions asked of them. For interviews or surveys on non-sensitive topics, e-mail is generally acceptable. Interviews or surveys on sensitive topics should be conducted on a secure Web site.

3.18 HIPAA and Research

The Health Insurance Portability and Accountability Act of 1996 was adopted with the goal of improving the efficiency and effectiveness of the healthcare system. It also carries with it an associated Privacy Rule that can significantly affect the way researchers obtain, use and disclose protected health information (PHI) in research involving human subjects. The minimum standard necessary requires that only the minimum amount of information needed for any specific purpose be used or disclosed. NOTE: HIPAA IS IN ADDITION TO, NOT INSTEAD OF, UNIVERSITY CPHS POLICIES. WHEN HIPAA AND HUMAN SUBJECT PROTECTION REGULATIONS APPLY, BOTH SETS OF REQUIREMENTS MUST BE FOLLOWED.

Under certain circumstances, the Privacy Rule allows a covered entity to use or disclose PHI for research without an individual's authorization. Therefore, the CPHS's role, under HIPAA, is to act on requests for a waiver or an alteration of the Privacy Rule's Authorization requirement. The CPHS may grant a Waiver of Authorization for studies meeting ALL of the following criteria:

- The use or disclosure involves no more than minimal risk to a subject's privacy, based on at least the following principles:
 - A plan to protect identifiers
 - A plan to destroy identifiers at the earliest opportunity that is consistent with the goals of the study, unless there is a health justification for retaining identifiers or retention is otherwise required by law
 - Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by the study or law enforcement agencies.

- The research could not be practicably conducted without the waiver.
- The research could not be practicably conducted without access to and use of PHI.

If a waiver is obtained, please note that the following procedures must also be in place:

- The investigator must identify and justify what identifiable information is needed.
- Disclosures of PHI outside UH must be tracked. The purpose of this tracking requirement is to provide patients, upon their request, with a list of where information about them was released for research and certain other non-treatment purposes without their knowledge. The following information must be tracked for each disclosure:
 - Name of individual
 - Date of disclosure
 - Name of person/entity that received the information
 - Brief description of PHI disclosed
 - Brief statement about the purpose of the disclosure
 - Disclosures must be made available to the individual upon request for 6 years following the disclosure

Any changes to a waiver (for example, the addition of new sources of PHI) must be approved by the CPHS.