



Activities That Are NOT Human Participant Research

The regulatory requirement for IRB review, under the Common Rule applies to research that is “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” Only research meeting this definition (definition of Human Participant Research or HPR) or research for which the FDA regulations apply requires IRB review and IRB oversight.

This guidance describes activities that are not human participant research according to the federal regulations.

NOTE: The intent to publish is an insufficient criterion for determining whether a project involves activity that requires IRB review.

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- **Case Report:** The project consists of a case report or series (up to three cases) which describe an interesting treatment, presentation or outcome. A critical component is that nothing was done to the patient(s) with prior “research” intent.

NOTE: For case reports, HIPAA requires that the disclosure of an individual’s protected health information must be authorized by that individual. If a case report contains any of the [18 Protected Health Information Elements](#), per the HIPAA regulations, a signed authorization (using the authorization form from the entity that holds the record) to disclose this information must be obtained from the individual(s) whose information is being disclosed. Investigators are responsible for complying with HIPAA regulations and the covered entity’s HIPAA policies. Any breach of confidentiality in this context is the responsibility of the covered entity. It is also important to note that written permission should be obtained from the individual(s) whenever possible.

- **Course-Related Activities:** The project is limited to course-related activities designed specifically for educational or teaching purposes where data are collected from and about students as part of a routine class exercise or assignment and is not intended for use outside of the classroom.

NOTE: IRB approval is required if a student is involved in an activity designed to teach research methodologies and the instructor or student wishes to conduct further investigation and analyses in order to contribute to scholarly knowledge.

- **Decedents:** The project involves research that is limited to death records, autopsy materials, or cadaver specimens. If the project involves the use and/or collection of Protected Health

Information (PHI), HIPAA regulations apply to decedent research. As the Privacy Board, the IRB Office requires that you confirm the following conditions as set forth in the Privacy Rule at 45 CFR 164.512(i)(ii)(iii), have been met.

1. The use will be solely for research on the information of a decedent; and
2. The Principal Investigator has documentation of the death of the individual about whom information is being sought, and
3. Information sought is for the purposes of the research

NOTE: This exception may not be available for decedent Information that contains Psychotherapy Notes or Information relating to HIV, mental health, genetic testing, or drug or alcohol abuse or when information will be gathered from or about living individuals (e.g., relatives). Consult with the IRB office in any of these circumstances.

➤ **Journalism/Documentary/Oral History Activities:** The activities are limited to investigations and interviews that focus on specific events, views, recounting of a specific historical event, or experiences of individuals etc., and that lead to publication in any medium (including electronic), documentary production, or are part of training that is explicitly linked to journalism. There is no intent to test a hypothesis, or contribute to draw conclusions or generalize findings.

NOTE: IRB approval may be required when activities conducted which are normally considered scientific research are intended to produce generalizable knowledge (e.g., systematic research, surveys, and/or interviews that are intended to test theories or develop models).

- “Studies using methods such as participant observation and ethnographic studies in which investigators gather information from individuals in order to understand their beliefs, customs and practices, and the findings apply to the studied community or group, and not just the individuals from whom the information was obtained, fall within the scope of the definition of research in the” Common Rule (Protection of Human Subjects 45 CFR § 46, 2017).

➤ **Program evaluation /Quality Improvement/Quality Assurance Activities:** The project is limited to program evaluation, quality improvement or quality assurance activities designed specifically to assess or improve performance within the department, hospital or classroom setting. The intention of the project is not to generate conclusions that can be applied universally, outside of the immediate environment where the project occurred.

NOTE: Investigators, who plan to conduct a QI/QA project, should ensure that they have received approval from any applicable committees within their department or the site in which the activity will occur.

Note: Activities that involve the implementation or evaluation of a new, modified, or previously untested intervention, service, or program to determine whether it is effective and to exclude the systematic comparison of interventions in an experimental-type design are considered human participant research, and require IRB review. In these cases, the knowledge gained

may be applicable beyond the individual, specific program (unless the results are dependent on a set of unique characteristics).

Note: Program evaluation activities that meet the description above and involve the collection of private identifiable health information (PHI) or individually identifiable data:

While the collection of PHI and individually identifiable data meets the definition of a human participant, it still does not meet the definition of research, and therefore does not require IRB review. It is important to note that written permission should be obtained from the individual(s) whenever possible.

- HIPAA requires that the disclosure of an individual's protected health information must be authorized by that individual. If a case report contains any of the [18 Protected Health Information Elements](#), per the HIPAA regulations, a signed authorization (using the authorization form from the entity that holds the record) to disclose this information must be obtained from the individual(s) whose information is being disclosed. Investigators are responsible for complying with HIPAA regulations and the covered entity's HIPAA policies. Any breach of confidentiality in this context is the responsibility of the covered entity.

- **Public Use Datasets:** The project is limited to analyzing de-identified data contained within a publicly available dataset. The research will NOT involve merging any of the data sets or comparing/combining the data set with other data sources in such a way that individuals might be identified, and the researcher will NOT enhance the public data set with identifiable or potentially identifiable data.

NOTE: IRB approval is required for the use of restricted use data, if a proposal is required to obtain the dataset, or if a data use agreement is involved.

- **Public Health Surveillance Activities:** Activities that 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). The collection and testing of information or bio-specimens conducted, supported, requested, ordered, required, or authorized by a public health authority is permitted only under these limitations.

Public health surveillance 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)

- **Authorized Operational Activities (as determined by each agency):** Activities conducted in support of intelligence, homeland security, defense, or other national security missions.
- **Coded* or De-Identified Private Information or Human Biological Specimens:** The project is limited to the use of existing and/or prospectively collected de-identified private information and/or human biological specimens (hereafter referred to as "specimens"). IRB Approval is not required if you can confirm **all** of the following:

1. The private information or specimens were/are not collected specifically for the currently proposed research project through an interaction or intervention with living individuals;
2. The investigator can confirm that the use of the private information or specimens is not in violation of the terms of use under which the information or specimens were/will be collected;
3. The investigator will only receive information or specimens that are fully de-identified. De-identified means that the materials to be studied are devoid of any of the 18 Protected Health Information elements set forth in the Privacy Rule, as well as any codes that would enable linkage of the information or specimens to individual identifiers and does not contain information or detail such that identities may readily be ascertained (for example, demographics and the existence of a rare disease or condition).

Note: To be considered de-identified, nobody, including individuals who are not involved in the conduct of the project, should be able to link the information or specimens back to identifiers.

4. The investigator(s)** do not know and cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:
 - a. the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased (note that the HHS regulations do not require the IRB to review and approve this agreement);
 - b. there are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; or
 - c. there are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased, **and**
5. Drugs and/or specimens are not being used to test the effectiveness of a medical device or as a control in an investigation of an investigational device and the results of the activity are to be submitted to the FDA or held for inspection by the FDA;

From the Office for Human Research Protections (OHRP) guidance document dated October 16, 2008:

Coded* means that: (1) identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and (2) a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens. **The code cannot be derived from or related to the information about the individual.

****Investigator** includes anyone involved in conducting the research. The act of solely providing coded private information or specimens (for example, by a tissue repository) does not constitute involvement in the conduct of the research. If the individuals who provide coded information or specimens collaborate on other activities related to the conduct of this research with the investigators who receive such information or specimens, then the IRB would consider such additional activities to constitute involvement in the conduct of the research. Examples of such additional activities include, but are not limited to: (1) the study, interpretation, or analysis of the data resulting from the coded information or specimens; and (2) authorship of presentations or manuscripts related to the research.