Creighton University

Creighton University Institutional Review Board
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Guidelines for

Identifying Studies That Are Not Human Subjects Research (Do Not Need IRB Review)

The following examples describe activities that are Not Human Subjects Research (NHSR):

1. **Data collection** for internal departmental, school, or other university administrative purposes. Examples: teaching evaluations, customer service surveys.

2. **Service surveys** issued or completed by University personnel for the intent and purpose of improving services and programs of the University or for developing new services or programs for students, employees, or alumni, as long as the privacy of the subjects is protected, the confidentiality of individual responses is maintained, and survey participation is voluntary. This would include surveys by professional societies or University consortia.

   Note: If at a future date an opportunity arises to contribute previously collected identifiable or coded survey data to a new study producing generalizable knowledge, IRB review may be required before the data may be released to the new project.

3. **Information-gathering interviews** in which questions focus on things, products, or policies rather than people or their thoughts regarding themselves. Example: canvassing librarians about inter-library loan policies or rising journal costs.

4. **Course-related activities** designed specifically for educational or teaching purposes, in which data is collected from and about human subjects as part of a class exercise or assignment, but are **not** intended for use outside of the classroom. Example: instruction on research methods and techniques.

   Note: The IRB is only required to review studies that meet the Federal definitions of research and human subject, or "engaged in research".
   http://answers.hhs.gov/ohrp/categories/1562
   http://www.hhs.gov/ohrp/policy/engage08.html

5. **Biography or oral history** research involving a living individual in which the information is not generalizable beyond that individual.

6. **Independent contracts for procedures** carried out for an external agency. Examples: personnel studies, cost-benefit analyses, customer satisfaction studies, biological sample processing (for a fee and not authorship or other credit), public park usage, IT usage, and software development.

7. **Research involving cadavers,** autopsy material, or biospecimens from now deceased individuals.

   Note: Some research in this category, such as genetic studies providing private or medical information about live relatives, may need IRB review. Please contact the IRB for further information.

8. **Innovative therapies,** except when they involve "research" as defined by the above criteria. (An innovative clinical practice is an intervention designed solely to enhance the well-being of an individual patient or client. The purpose of an innovative clinical practice is to provide diagnosis, preventive treatment, or therapy to particular individuals.)

9. **Quality improvement** projects are generally **not** considered research unless there is a clear intent to contribute to generalizable knowledge ***and*** use the data derived from the project to improve or alter the quality of care or the efficiency of an institutional practice. Any individual who is unsure whether a proposed quality improvement project should be classified as research should contact the IRB for guidance. If the data is re-examined or re-analyzed and new information surfaces that would contribute to generalizable knowledge, an application must be submitted to the IRB.

10. **Case histories** that are published and/or presented at national or regional meetings are **not** considered research if the case is limited to a description of the clinical features and/or outcome of a single patient and do not contribute to generalizable knowledge.

11. **Publicly available data do not** require IRB review. Examples: census data, labor statistics. Note: Investigators should contact the IRB if they are uncertain as to whether the data qualifies as “publicly available.”

12. **Coded private information or biological specimens** that were **not** collected for the currently proposed projects do not need IRB review as long as the investigator cannot link the data/specimens back to individual subjects. If the data/specimen provider has access to the identity of the subjects (e.g., subjects’ names, addresses, etc.), the investigator must enter into an agreement with the data/specimen provider that states that under no circumstances will the identity of the subjects be released to the investigator.

Note: Investigators are not allowed to make this determination. These projects require verification from the IRB.
See the OHRP Guidance on Research Involving Coded Private Information or Biological Specimens for more information (http://www.hhs.gov/ohrp/policy/cdebiol.html)