Is my research project considered Human Subjects Research?

The following types of protocols would not constitute human subjects research under current Federal guidelines.

Examples of NOT HUMAN SUBJECTS RESEARCH (Examples):

1. Data collection for internal improvements used to support departmental, school, or other University administrative purposes. Data collection for internal departmental, school or other administrative purposes (e.g., teaching evaluations, "customer service" surveys).

   Examples: teaching evaluations, customer service surveys, policies and procedures from agencies that do not ask for individual opinions, etc.

2. Service surveys issued or completed by University personnel for the intent and sole purpose of improving services and programs within the university or within an agency. This internal evaluation can be used to help develop new services or programs for students, employees, or alumni, as long as the privacy of the subjects is protected, the confidentiality of individual responses are maintained, and survey participation is voluntary. This would include surveys by professional societies or University, agency where INTERNAL improvement is the purpose. These surveys are completed for the intent and purpose of improving services and as long as the privacy of the individuals is protected, the confidentiality of individual responses is maintained, and survey participation is voluntary.

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

3. Information-gathering interviews and recording of existing policies and procedures. In this type of research the questions focus on products, or policies rather than people or their thoughts regarding the service. The reporting is of a policy or factual nature rather than specific opinions of the participants.

   Example: canvassing librarians about inter-library loan policies or rising journal costs. This does not include individual surveys that could affect a participant's employability, reputation or legal standing.

4. Course-related activities designed specifically for educational or teaching purposes, where 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. The information is used specifically for a grade in the class. Also, the data may be presented at local, community or national conferences if is presented as a student class project and not as a formal research study where the information can be "generalized" for future research and publication. Generally this type of activity is described as "**part of the general academic day**." Regardless of the review status, however, it is the

responsibility of the instructor to continue to employ methods that protect human subjects.

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."

5. Biography or oral history research involving a living individual that is not generalizable beyond that individual.

6. Independent contract for procedures carried out for an external agency. This information is not considered generalizable to all agencies and is used for internal purposes.

   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 bio specimens 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, preventative treatment, or therapy to particular individuals.)

   Note: When innovative therapies differ significantly from routine practice it should be viewed and treated as such with appropriate safeguards in place to protect the rights and welfare of the patients.

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 or not 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 which 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.

10. Publicly available data do ***not*** require IRB review and research projects involving certain national data sets that provide researchers with de-identified information.

    Examples: census data, labor statistics. Note: Investigators should contact the IRB if they are uncertain as to whether the data qualifies as "publicly available."

11. 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 coded 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 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.

12. Non-Engagement in Research include: when an institution's employees or agents act as consultants on research but at no time obtain, receive, or possess identifiable private information, perform commercial services for the investigators, or inform prospective subjects about the availability of research.

    Note: the examples above are not an all-inclusive listing.

13. Fact-collecting interviews of individuals where questions focus on things, products, or policies, rather than on people or their opinions or experiences (e.g., canvassing librarians about inter-library loan policies or rising journal costs).

14. Instruction on research methods or Searches of existing literature.

15. Research involving a living individual, such as a biography, that is not generalizable beyond that individual such as case studies.

UCF IRB: The Federal Definition

The IRB is always expected to make the final determination; and, researchers should do so with caution, **when in doubt call the UCF-IRB**. The IRB can also provide a letter supporting this decision if you do a brief protocol in the iRIS system.

- N**ot Human Subjects Research vs. Human Subject Research that needs IRB approval**

Research: "A systematic investigation designed to develop or contribute to generalizable knowledge."

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Human Subjects: "The investigator will gather data about living individuals through intervention or interaction OR the investigator will gather data about living individuals that is private AND identifiable."

If the IRB determines that a submission is "not human subjects research," the IRB sends the PI (and others, as applicable) a determination letter (via iRIS) that the project has been determined by the IRB not to need IRB approval.

INFORMATION PROVIDED FROM THE RESOURCES BELOW:

(https://www.washington.edu/research/hsd/topics/Not+Human+Subjects+Research)

(http://www.hhs.gov/ohrp/humansubjects/commonrule/)

(http://www.hhs.gov/ohrp/)

(http://www.hhs.gov/ohrp/policy/belmont.html)

(http://www.hhs.gov/ohrp/policy/engage08.html)

(http://ors.umkc.edu/research-compliance-(iacuc-ibc-irb-rsc)/institutional-review-board-(irb)/not-human-subjects-research)

(http://www.hhs.gov/ohrp/policy/cdebiol.html)

(http://www.ju.edu/institutionalreviewboard/docs/IRB-Guide-for-Investigators.pdf)

(https://extranet.fhcrc.org/EN/sections/iro/irb/not_human_sub.html)

(https://irb.northwestern.edu/templates-forms/templates-forms-sops)