

## EXAMPLES OF PROJECTS THAT DO AND DO NOT REQUIRE IRB REVIEW

### STUDIES THAT ARE NOT HUMAN SUBJECTS RESEARCH

Studies that fit any of the categories below do not need IRB review.

- **Data collection** for internal departmental, school, or other University administrative purposes. Examples: teaching evaluations, customer service surveys.
- **Service surveys** issued or completed by University personnel for the intent and purposes 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 are maintained, and survey participation is voluntary. This would include surveys by professional societies or University consortia. *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.*
- **Information-gathering interviews** where 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.
- **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. 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<sup>4</sup>, or "engaged in research".*
- **Biography or oral history** research involving a living individual that is not generalizable beyond that individual.
- **Independent contract 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.
- **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.*
- **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.*
- **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.
- **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.

- **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". NOTE: If ACCESS to data is limited to researchers and NOT publicly available, IRB review is needed.*
- **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 or the IRB liaison/designee. (<http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>)*
- Some examples of **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. (<http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm>)*

#### STUDIES THAT ARE HUMAN SUBJECTS RESEARCH

- Studies that utilize test subjects for new devices, products, drugs, or materials.
- Studies that collect data through intervention or interaction with individuals. Examples of this type of research include drug trials, internet surveys about alcohol consumption, studies that involve deception, research involving risky behaviors or attitudes, and open-ended interviews with minors that contribute to generalizable knowledge.
- Studies using private information that can be readily identified with individuals, even if the information was not collected specifically for the study in question.
- Studies that use bodily materials such as cells, blood, urine, tissues, organs, hair, or nail clippings, even if one did not collect these materials for the study. However, such research may be considered exempt or not human subjects research if the materials/data are coded and the investigator does not have access to the coding systems. Guidance on research involving coded private information or biological specimens is available on the web at: (<http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>.)
- Studies that produce generalizable knowledge about categories or classes of subjects from individually identifiable information.