ILLINOIS
CRIMINAL JUSTICE
INFORMATION AUTHORITY

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DOES MY PROJECT REQUIRE IRB REVIEW?

The Federal Common Rule defines research as "a systematic investigation, including research development, testing, and evaluation, **designed to develop or contribute to generalizable knowledge**."

Under the Common Rule, the following activities are deemed not to be research:

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities 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). Such 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).
- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

It is important to note that just because a project involves humans, it does not mean that the project is considered human subjects research under the Common Rule. Many times, the distinction between human subjects research and similar activities can be hard to distinguish. ICJIA has developed this guidance to assist researchers determining whether or not their project requires IRB review. This guide is not all inclusive and may not accurately reflect all projects. Please see the IRB manager or secretary with any project specific questions.

HUMAN SUBJECTS RESEARCH VS. OTHER PROJECT TYPES

	Human Subjects Research	Program Evaluation	Quality Improvement/Assessment
Purpose	Produce new, generalizable knowledge to contribute to the broader field and/or society	Evaluate and improve a specific program to improve or inform that program	Improve a practice or process within a institution or to ensure it conforms to expected norms
Design	Present a question or hypothesis and systematically collect data to statistically prove/disprove the question or hypothesis	Assess performance through systematic data collection to compare a program to an established set of standards	Assess performance through systematic data collection to compare a practice/process to an established set of standards
Effect on Program/Practice	Findings are not expected to directly affect the institution or program	Findings of the evaluation are expected to directly affect the conduct of the program and identify improvements	Findings are expected to directly affect the practice/process and identify any corrective actions needed
Subject Population	Human subject as defined by the Federal Common Rule	Information on participants receiving a particular treatment or undergoing a particular practice or process expected to be used; exclusion of information from some individuals significantly affects conclusions	Information on all or most receiving a particular treatment or undergoing a particular practice or process expected to be included; exclusion of information from some individuals significantly affects conclusions
Benefits	Participants may or may not benefit directly – benefit, if any, to individuals is likely to be incidental or delayed	No benefit to participants expected; evaluation concentrates on program improvements or whether the program should continue	Participants expected to benefit directly from the activities
Dissemination of Results	Intent to publish or present generally presumed at the outset of project as part of professional expectations, obligations; dissemination of information usually occurs in research/scientific publications, grant proposals, or other research/scientific forum; results expected to develop or contribute to generalizable knowledge by filling a gap in scientific knowledge or supporting, refining, or refuting results from other research studies. Results of the project will be disseminated outside the institution for the purpose of sharing the outcomes or implications of the project, not just the process	Intent to publish or present generally presumed at the outset of the project; dissemination of information to program stakeholders and participants; may be publicly posted (e.g., website) to ensure transparency of results; when published or presented to a wider audience, the intent is to suggest potentially effective models, strategies, assessment tools or provide benchmarks or base rates rather than to develop or contribute to generalizable knowledge	Intent to publish or present generally not presumed at the outset of the project; dissemination of information often does not occur beyond the institution evaluated; dissemination of information may occur in quality improvement publications; when published or presented to a wider audience, the intent is to suggest potentially effective models, strategies, assessment tools or provide benchmarks or base rates rather than to develop or contribute to generalizable knowledge

Adapted from Brown University's Human Research Protection Program (https://bit.ly/2SfwV4F) and Oregon State University's Research Office (https://bit.ly/37SAJQ0).