

Conducting Research with Incarcerated Individuals for NTIA Grant Programs

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CONDUCTING RESEARCH WITH INCARCERATED INDIVIDUALS



Requirements for Human Subjects Research (HSR)

All NTIA grant recipients of programs established by the Bipartisan Infrastructure Law must comply with Department of Commerce award terms and conditions and the relevant regulations relating to the protection of human subjects for all research conducted or supported pursuant to a federal grant award. This resource highlights some of the additional protections required for human subjects research with incarcerated individuals.

WHAT REGULATIONS APPLY TO HSR WITH INCARCERATED INDIVIDUALS?

Recipients and subrecipients intending to use federal funds to conduct HSR are subject to regulatory requirements in <u>15 C.F.R. Part 27 Protection of Human Subjects</u>.

As cited in <u>15 C.F.R. Part 27</u>, research that involves **incarcerated individuals** (referred to as "prisoners" in the Common Rule (<u>15 C.F.R. § 27.104(b)(2)</u>) is subject to **additional regulatory requirements** which provide safeguards to involuntarily detained or confined research participants in a penal institution, as described in <u>45 C.F.R. § 46.300</u>, <u>Subpart C — Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects</u>.



Recipients and subrecipients intending to work with or conduct research with incarcerated individuals using federal funds must receive the appropriate Institutional Review Board (IRB) approval. All project activities, including measurement and evaluation activities, must demonstrate compliance with applicable law and NOFO requirements.

DEFINITIONS

Human Subject: A living individual about whom an investigator (whether professional or student) conducting research:

- (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; **or**
- (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. (15 C.F.R. § 27.102(e)(1))

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. (15 C.F.R. § 27.102(I))

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INCLUDING INCARCERATED INDIVIDUALS IN RESEARCH

Research that involves incarcerated individuals is subject to both <u>15 C.F.R. Part 27</u> and <u>45 C.F.R. § 46.300, Subpart C</u>. There are two ways in which incarcerated individuals may be included in a research study.

1. Research fits into permissible categories and is reviewed by an appropriate IRB.

Permissible categories in Subpart C include:

Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;



Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;



Research on conditions particularly affecting prisoners as a class provided that the study may proceed only after the Secretary of Health and Human Services has consulted with appropriate experts including experts in penology medicine and ethics, and published notice, in the Federal Register, of his intent to approve such research; or



Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.

2. Research may be exempt if it only incidentally includes some incarcerated individuals.

Some research with incarcerated individuals may be eligible for one of the exempt categories listed in 45 C.F.R. § 46.104 only if the research is aimed at involving a broader subject population that only incidentally includes prisoners (15 CFR 27.104(b)(2)).

Note: If incarcerated individuals are intentionally included in the survey design, this does not apply.



For example, a federal grant recipient designs a survey sent to residents of a state using random sampling, where every person in the state has an equal chance of being sent the survey.

Subsequently, inclusion of incarcerated individuals in this example study is incidental to the larger study population and would be allowed as exempt under 15 CFR 27.104(b)(2) and 104.(d)(2).



