HUMAN SUBJECTS RESEARCH (HSR) PROTECTION REQUIREMENTS

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Policy Disclaimer

This document is intended solely to assist recipients in better understanding the Digital Equity Act Grant Programs and the requirements set forth in the Notice of Funding Opportunity (NOFO) for these programs. This document does not and is not intended to supersede, modify, or otherwise alter applicable statutory or regulatory requirements, the terms and conditions of the award, or the specific application requirements set forth in the NOFOs. In all cases, statutory and regulatory mandates, the terms and conditions of the award, the requirements set forth in the NOFOs, and follow-on policies and guidance, shall prevail over any inconsistencies contained in this document.

OVERVIEW OF HSR

Human Subjects Research (HSR) Protection Requirements

No work involving human subjects may be undertaken, conducted, or costs incurred and/or charged for HSR unless expressly authorized by Specific Award Condition (SAC), or otherwise approved in writing by the Grants Officer, via an Administrative Letter.

All Recipients and subrecipients must comply with the appropriate HSR protection categories, policies, and requirements and make an independent assessment of their funded activities, including those implemented directly by the Recipient and subrecipient activities.

Recipients may conduct research with human subjects as part of their grant-funded activities. 15 CFR Part 27 requires that Recipients of federal grants maintain appropriate policies and procedures for the protection of human subjects.

Restriction on HSR Work and Costs Incurred

A Specific Award Condition (SAC) may be placed on the award, providing Human Subjects Research (HSR) requirements must be met before the work involving HSR can be done.

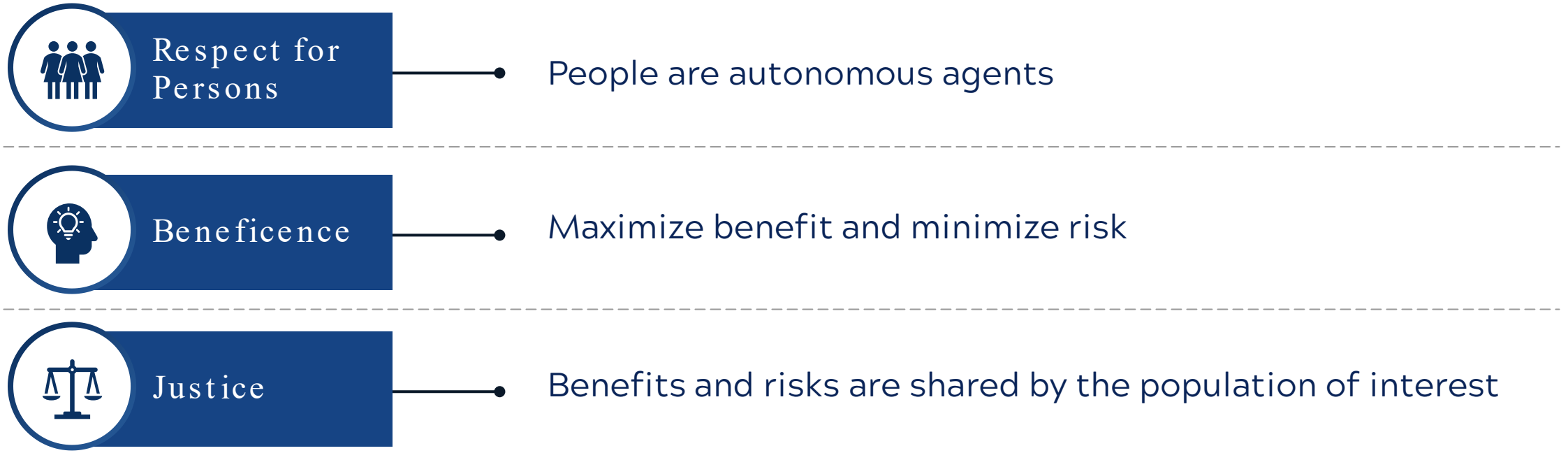
HSR Restrictions:

- The DOC regulations related to the protection of human subjects are found in 15 CFR Part 27. The Recipient is responsible for ensuring that any of its subrecipients are also in compliance with the regulations related to protecting human subjects in 15 CFR Part 27 and in the HSR Guidance for Digital Equity.

Takeaway: Recipients must comply with regulations relating to protection of human subjects for research and the applicable award condition before funds can be spent on HSR.

Human Subjects Research Protections

Sometimes referred to as the "Common Rule" (15 CFR Part 27), HSR regulations are intended to implement the basic ethical principles[1] governing the conduct of human subjects research.



There are additional protections for some groups, such as pregnant women, fetuses, neonates[2], incarcerated individuals[3], and children[4].

1. The Belmont Report
2. 45 CFR Part 46 Subpart B
3. 45 CFR Part 46 Subpart C
4. 45 CFR Part 46 Subpart D

What Is Considered Research?

Recipients should understand what project activities are considered research and must comply with HSR requirements.

What is considered research?

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Examples:

- Surveys
- Interviews
- Observations
- Research development of testing
- Evaluations that are designed to develop or contribute to generalized knowledge.

What is not considered research?

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literacy 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
- Collection and analysis of information solely for criminal justice or criminal investigative purposes
- Authorized operational activities in support of national security

15 CFR § 27.102(l)

Human Subjects Definition

A human subject is a living individual about whom an investigator (whether professional or student) conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; **or**
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Human subjects research is not just clinical research. These are examples of other types of work that are potentially human subjects research:

- Surveys
- Focused interviews
- Use of social media data
- Use of videos or other images that likely include people
- Use of data from or about people that is publicly available
- Use of biospecimens
- Use of data collected for another reason, such as human resources, training, etc.

15 CFR § 27.102(e)(1)

Institutional Review Board

For certain Category determinations, recipients **must** engage an IRB to review their human subject research activities. If a Recipient is unable to make a category determination, they may engage an IRB to review their activities to inform their Category Determination Letter. In all cases, the IRB documentation must be consistent with the Category Determination Letter.

IRB Definition

- An IRB is an appropriately constituted group that has been formally designated to review and monitor research, established in accord with and for the purposes of 15 CFR § 27.102(g).
- Many IRBs are affiliated with universities and there are also private IRB companies
- Recipients may use an internal, as applicable, or external IRB

Choosing an IRB:

- Recipients can reach out to IRBs to get information about their specific requirements and processes.
- Recipients must use an established IRB, whether university affiliated or private.
  - Visit the **Office for Human Research Protections website** for registered IRBs.
- NTIA will accept the approval and requirements set by that IRB.

HSR CATEGORIES

Category 1

It is the responsibility of the Recipient to make a category determination based on whether the grant funded activities are research[1] and to what extent those activities involve human subjects[2]. Category 1 is Not Conducting Human Subjects Research.

Category 1: Not Conducting Human Subjects Research

$ FUNDED ACTIVITIES

- Category 1A: Not research per 15 CFR § 27.102(l)

OR

- Category 1B: Not human subject research per 15 CFR § 27.102(e)

REQUIREMENTS

- No IRB required
- Submit Category Determination Letter to FPO
- No other documentation is required
- If an IRB makes the Category Determination, submit all IRB documents
- If the recipient has an IRB, the IRB should confirm the determination

1. 15 CFR 27.102(l)
2. 15 CFR § 27.102(e)

Category 2

It is the responsibility of the Recipient to make a category determination based on whether the grant funded activities are research[1] and to what extent those activities involve human subjects[2]. Category 2 is Exemption Request.

Category 2: Exemption Request

$ FUNDED ACTIVITIES

- Research per 15 CFR § 27.102(l)
- With human subjects per 15 CFR § 27.102(e)
- However, activities fit one of the categories that are statutorily exempt per 15 CFR § 27.104(d)

REQUIREMENTS

- External IRB not required
- Submit Category Determination Letter to FPO
- Submit all other documentation, including all research tools (such as finalized surveys) and protocols
- If an IRB makes the Category Determination, submit all IRB documents
- If the recipient has an IRB or IRB office the IRB should confirm the determination

1. 15 CFR 27.102(l)
2. 15 CFR § 27.102(e)

Category 3

It is the responsibility of the Recipient to make a category determination based on whether the grant funded activities are research[1] and to what extent those activities involve human subjects[2]. Category 3 is Human Subjects Research Non-Exempt.

Category 3: Human Subjects Research Non-Exempt

$ FUNDED ACTIVITIES

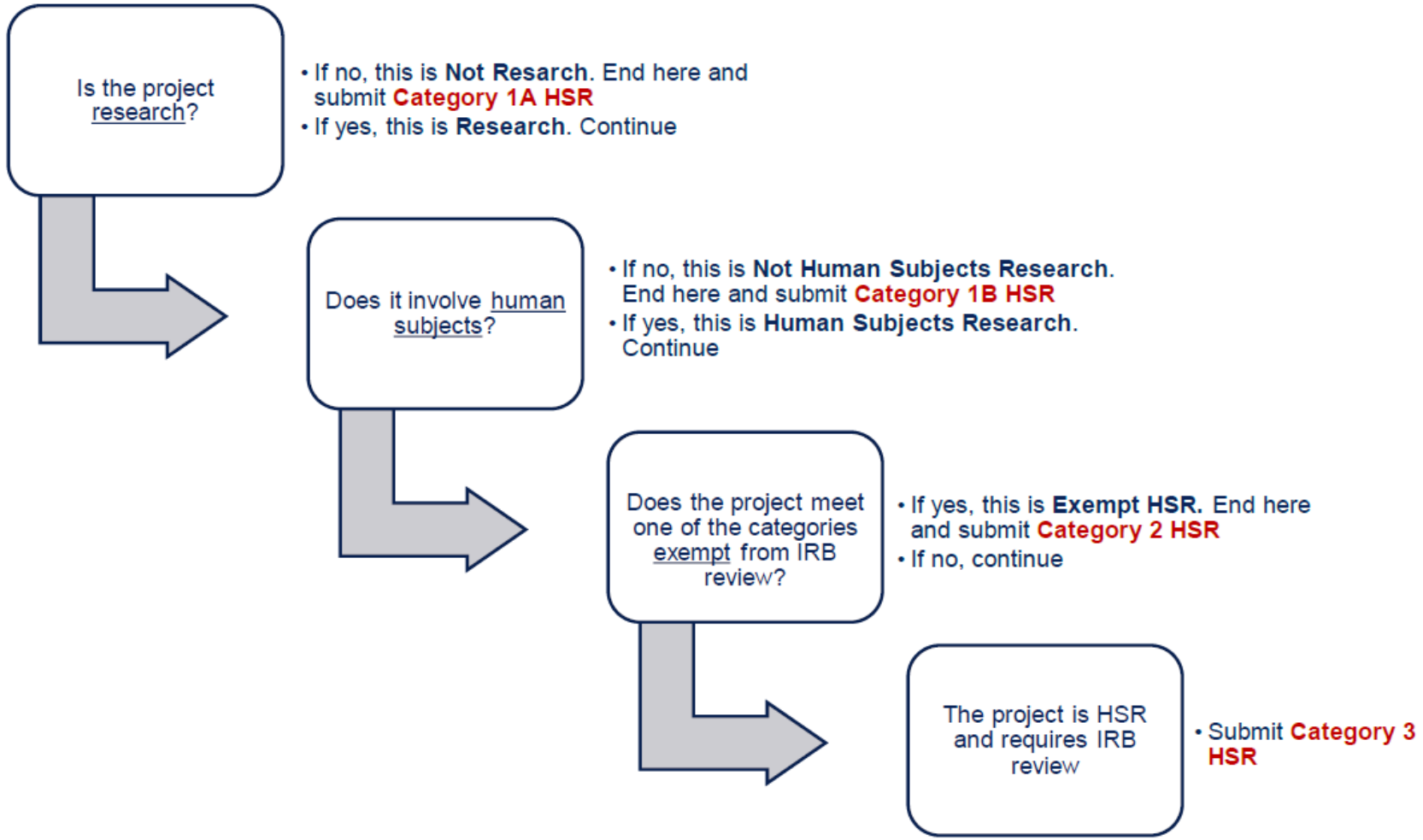
- Research per 15 CFR § 27.102(l)
- With human subjects per 15 CFR § 27.102(e)
- And are non-exempt or do not meet one of the categories exempt from further IRB review

REQUIREMENTS

- IRB required
- Submit Category Determination Letter to FPO
- Submit all IRB documentation

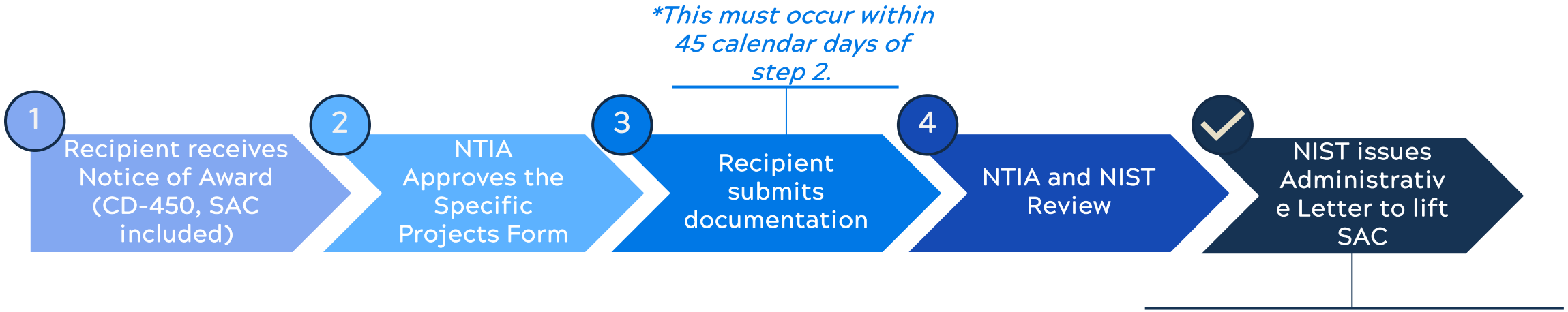
1. 15 CFR 27.102(l)
2. 15 CFR § 27.102(e)

HSR Category Determination Decision Tree



HSR SUBMISSION

HSR SAC Process



Reminders:

- All requirements "pass through" to each subrecipient.
- The category determination must cover all activities (including those directly implemented by recipient and activities by subrecipients).
- This means that if there is even one HSR activity that requires a Category 3 determination then the entire award is a Category 3.
- The recipient and subrecipients can start a project except for the portion that may require the HSR clearance, like standing up software, printing materials, planning, etc., but they cannot start the actual human interaction activities until the SAC is lifted (administrative letter is granted).

Human Subjects Research Checklist

Recipients may use the following checklist to ensure they submit the necessary HSR information

Information required:

- ❑ Title of study: [Grant request name or name used for DE Plan or unique name]
- ❑ Award number: [Can be found on CD-450/Notice of Award]
- ❑ If awardee has an in-house IRB [yes/no] If yes, provide the IRB name
- ❑ If awardee has an ongoing relationship with an external IRB [yes/no] If yes, provide the IRB name
- ❑ HSR Classification [Category 1, 2, 3; must be consistent with Category Determination Letter]
- ❑ List of attachments - some attachments are required depending on the Category Determination

Attachments

HSR Category Determination Letter

Recipients must submit a Category Determination Letter that must contain:

The Category Determination
- Must explicitly identify Category 1, 2, or 3

A description of the planned project activities that justify inclusion in that Category.

The letter should be on letterhead or conform to the standards and policies of the recipient and Category 2 and 3 Letters must be signed by the AOR

Reminder: The Recipient must determine their Category based on all funded activities, including those the Recipient is implementing directly and all subrecipient activities.

IRB Documentation

If the Recipient engages an IRB they must submit all documentation from the IRB.

Categories 1 and 2:
- These categories do not require an IRB; however, if there is an in-house IRB, the IRB should endorse Category 1 (funded activities do not constitute research with human subjects) and make the determination/approval for Category 2 (Activities are exempt). The IRB documentation must be submitted to NTIA.

Category 3:
- Approval letter from in-house IRB, or
- Approval letter from external IRB
- Any other documents provided by the IRB to the Recipient regarding grant funded activities

Study Documents

As applicable, attach all final versions of documents related to the HSR aspects of this award:
- Protocol or proposals, including all data to be collected
- Surveys
- Consent forms
- Other relevant forms or documents, including those submitted to an IRB (if applicable)

Note

If an IRB is engaged, submit the Category Determination Letter to UGAM@NTIA.gov to satisfy the deadline. Once the IRB completes its review, send all IRB documentation and final study documents to your FPO.

ADDITIONAL PROTECTIONS

Additional Protections for Pregnant Women & Children

Some populations, including pregnant women and children, are subject to additional HSR protections per 15 CFR Part 27 and 45 CFR § 46 Subpart B and Subpart D. Recipients must conform to both regulations if planning to do HSR activities with either group.

Pregnant Women

Pregnant women or fetuses may be involved in research if all of the conditions at 15 CFR § 46.204 are met, including:

- Any risk is the least possible for achieving the objectives of the research;
- No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
- Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
- Individuals engaged in the research will have no part in determining the viability of a neonate.

Children

The exemptions at 15 CFR § 27.104(d)(1) and (d)(3) through (d)(6) are applicable to children if the conditions of the exemption are met. The other exemptions do not apply.

For example, the exemption at 15 CFR § 27.104 d(2) regarding educational tests can be applicable to children. However, the exemption for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

Additional Protections for Incarcerated Individuals

Research that involves **incarcerated individuals**[1] is subject to both 15 CFR Part 27 and 45 CFR § 46 Subpart C. There are two ways in which incarcerated individuals may be included in a research study.

Research fits into permissible Subpart C categories, is reviewed by an appropriate IRB and must be certified by HHS/OHRP.

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 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.

1.Referred to as "prisoners" in 15 CFR § 27.104(b)(2)

Additional Protections for Incarcerated Individuals

Research that involves **incarcerated individuals**[1] is subject to both 15 CFR Part 27 and 45 CFR § 46 Subpart C. There are two ways in which incarcerated individuals may be included in a research study.

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 CFR § 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).

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, in this example inclusion of incarcerated individuals in the 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).

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

1. 15 CFR § 27.104(b)(2)

CATEGORY 2
EXEMPTION REQUEST

HSR Exemptions - Category 2

If the funded activities fit one of the exemptions listed at 15 CFR § 27.104, then an IRB review is not required, and the recipient should determine that their activities qualify as Category 2.

Exemptions

	*Research in established or commonly accepted educational settings*
	*Research that only includes educational tests, survey procedures, interviews or observations of public behavior*
	*Research involving benign behavioral interventions*
	*Secondary research of specimens or data under certain circumstances*
	*Taste and food quality evaluation*
	*Storage and maintenance of identifiable data or specimens with limited IRB review*
	*Secondary research of specimens or data collected under broad consent with limited IRB review*

To be clear, **an HSR exemption does not mean that the recipient is exempt from the protection of human subjects**, it means that they are exempt from the same level of IRB review non-exempt activities are subject to per 15 CFR § 27.

If the recipient has an in-house IRB, they should follow their institutional policy for approval of exempt HSR. Documentation of IRB approval and all study documents must be submitted.

Exemptions for Educational Settings or Tests

Research conducted in educational settings or involving educational tests or similar procedures may be exempt under 15 CFR § 27.104, with some exceptions.

EDUCATIONAL RESEARCH, 15 CFR § 27.104(d)(1)

The research is conducted in established or commonly accepted educational settings, involving normal education practices, such as:

(i) research on regular and special education instructional strategies, or

(ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. See 15 C.F.R. § 27.104(d)(1).

EDUCATIONAL TESTS, 15 CFR § 27.104(d)(2)

The research involves the use of educational tests (i.e., cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(1) the information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

(2) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, or reputation.

Exemption for Benign Behavioral Interventions

Research involving benign behavioral interventions may be exempt under 15 CFR § 27.104 under certain conditions.

BENIGN BEHAVIORAL INTERVENTIONS

15 CFR § 27.104(d)(3)

The research will involve benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection.

The information collected is recorded by the investigator in such a manner that **subjects cannot be identified**, directly or through identifiers linked to the subjects, or disclosure of the subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

CHARACTERISTICS

Benign behavioral interventions are:

- ✓ brief in duration,
- ✓ harmless,
- ✓ painless,
- ✓ not physically invasive,
- ✓ not likely to have a significant adverse lasting impact on the subjects,
- ✓ and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.

Exemption for Secondary Research

Secondary research for which consent is not required may be exempt under 15 CFR § 27.104 if certain criteria are met.

SECONDARY RESEARCH FOR WHICH CONSENT IS NOT REQUIRED, 15 CFR § 27.104(d)(4)

Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects.

Exempt Determinations

For all categories, Recipients must provide a description of the proposed activities that justify inclusion in that category. For Category 2 Exemption Request, Recipients must provide the specific exemption, as listed in 15 CFR § 27.104, that applies to their activities to justify the Category 2 determination.

If the Recipient is unable to determine if the exemptions apply to their activities, they can optionally engage an IRB to review their activities.

For more info on exemptions, please refer to 15 CFR § 27.104.

Note: If the research involves: pregnant women and/or fetuses, refer to 45 CFR § 46 Subpart B; incarcerated individuals, refer to 45 CFR § 46 Subpart C; children under 18, refer to 45 CFR § 46 Subpart D before making a Category Determination.

THANK YOU