



Guidance for Human Subjects Research Protection

This guidance document is intended to assist Recipients of Digital Equity Act Grant Program awards to understand and to navigate the Human Subjects Research Protection requirements applicable to such awards. This document does not and is not intended to supersede, modify, or otherwise alter applicable statutory or regulatory requirements pertaining to Human Subjects Research Protection. In all cases, statutory and regulatory mandates, and the requirements set forth in the terms and conditions of a NTIA award, shall prevail over any inconsistencies or inaccuracies contained in this document.



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HUMAN SUBJECTS RESEARCH PROTECTION REQUIREMENTS FOR THE DIGITAL EQUITY ACT GRANT PROGRAMS

All Recipients of the Digital Equity Act Grant Programs (“Programs”) must comply with Department of Commerce (DOC or Department) regulations relating to the protection of human subjects for all research conducted or supported pursuant to a NTIA grant award. The Department’s policies related to the protection of human subjects are found in 15 C.F.R. Part 27.¹

As the requirements in 15 C.F.R. Part 27 apply to NTIA grants, Recipients must review the following information and make an independent assessment of their planned activities and act in accordance with the Human Subjects Research (HSR) protection requirements.

Below are two key concepts that apply to HSR:

Research: The systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge.

Examples of systematic investigations include surveys, interviews, observations, research development of testing and evaluations that are designed to develop or contribute to generalized knowledge. Factors that may be used to evaluate whether research will develop or contribute to generalized knowledge include:

- The information collected will be applied beyond a particular program or individual.
- The activity is conducted to examine whether the program had the desired effect on program participants, **and** that evaluation can inform other programs.
- The activity is conducted with the intent to replicate the program.
- The activity is designed to draw general conclusions.

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

¹ 15 C.F.R. Part 27, available at <https://www.ecfr.gov/current/title-15/subtitle-A/part-27>.



- (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.*

For the purposes of the HSR policy, NTIA is particularly concerned about protecting certain populations from being subject to research without their informed consent and that human subjects should not incur increased risk of harm from their research involvement, beyond the normal risks inherent in everyday life. To that end, NTIA requires grant Recipients to take special precautions if HSR involves certain populations. These populations include pregnant women, children, fetuses, and prisoners as set forth in the regulations at Part 46, Subparts B, C, D of Title 45 of the Code of Federal Regulations.²

PROGRAM OFFICE EXPECTATIONS

Some Recipients may conduct surveys of individuals as part of their Digital Equity-funded activities. NTIA must ensure that all Recipients understand and comply with the appropriate HSR protection classifications, policies, and requirements by obtaining written assurances from and certifying that any Recipient research activities comply with the requirements set forth in 15 C.F.R. Part 27 (Protection of Human Subjects), as incorporated into every award through a Specific Award Condition and the Department of Commerce Standard Terms and Conditions:

1. All proposed research involving human subjects must be conducted in accordance with 15 C.F.R. Part 27. **No research involving human subjects is permitted under this award unless expressly authorized by specific award conditions, or otherwise approved in writing by the Grants Officer.**
2. Federal policy defines a human subject as a living individual about whom an investigator (whether professional or student) conducting research: (1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. Research

² 45 C.F.R. Part 46, Subparts B, C, and D, *available at* <https://www.ecfr.gov/current/title45/subtitle-A/subchapter-A/part-46>.



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

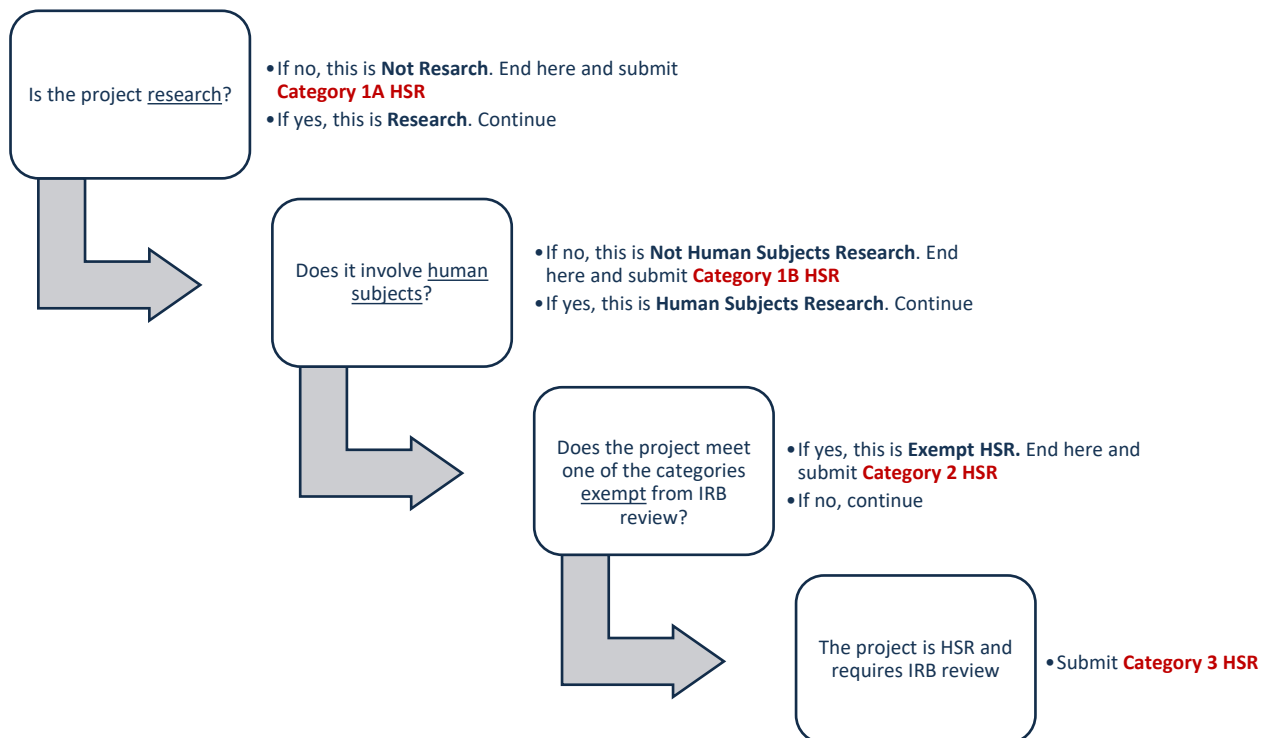
3. 15 C.F.R. Part 27 requires that non-Federal entities maintain appropriate policies and procedures for the protection of human subjects. In the event it becomes evident that human subjects may be involved in this project, the non-Federal entity (generally through the Recipient) must submit appropriate documentation to the Federal Program Officer for approval by the appropriate DOC officials. As applicable, this documentation must include:
 - i. Documentation establishing approval of an activity in the project by an Institutional Review Board (IRB) under a Federal wide Assurance issued by Department of Health and Human Services or other Federal agency guidelines (see also 15 C.F.R. § 27.103);
 - ii. Documentation to support an exemption for an activity in the project under 15 C.F.R. § 27.104(d);
 - iii. Documentation of IRB approval of any modification to a prior approved protocol or to an informed consent form;
 - iv. Documentation of an IRB approval of continuing review approved prior to the expiration date of the previous IRB determination; and
 - v. Documentation of any reportable events, such as serious adverse events, unanticipated problems resulting in risk to subjects or others, and instances of noncompliance.
4. **No work involving human subjects may be undertaken, conducted, or costs incurred and/or charged for human subjects research, until the appropriate documentation is approved in writing by the Grants Officer.** In accordance with 15 C.F.R. § 27.118, if research involving human subjects is proposed after an award is made, the non-Federal entity must contact the Federal Program Officer and provide the required documentation. Notwithstanding this prohibition, work may be initiated, or costs incurred and/or charged to the project for protocol or instrument development related to human subjects research.

Recipients should review the *NTIA HSR Classification - Decision Tree* below and consider the planned activities to determine which HSR category applies to their grants.

DE ACT GRANT PROGRAMS HSR CLASSIFICATION - DECISION TREE

The decision tree included below can be used by Recipients to determine if human subjects are involved in their research, and, if the research does involve human subjects, whether it may be exempt under current Department of Commerce (DOC) regulations for the Protection of Human Subjects, 15 CFR 27. For Recipients that engage in research that requires a review and approval by an Institutional Review Board (IRB), additional resources will detail the IRB review approval process. Definitions for research and human subjects are noted above. Exempt categories may be found at 15 CFR 27.104(d).

FIGURE 1: HSR CLASSIFICATION DECISION TREE



DE ACT GRANT PROGRAMS HSR CLASSIFICATION CATEGORIES & DETERMINATION CRITERIA

After completing the decision tree, all Recipients should be able to determine their HSR classification categories (defined below). Recipients should contact their Federal Program Officer (FPO) if they have questions about the categories.

TABLE 1: HSR CLASSIFICATION CATEGORIES & DETERMINATION CRITERIA

HSR Classification Category	Determination Criteria ³
Category 1: Not Conducting Research/Human Subjects Research	<ul style="list-style-type: none"> • 1A. The activity does not qualify as research, as defined in 15 C.F.R. § 27.102(I), because it does not follow a systematic investigation designed to develop or contribute to generalizable knowledge. OR • 1B. The research activity does not involve human subjects as defined in 15 C.F.R. § 27.102 (e)(1).
Category 2: Exempt Human Subjects Research ⁴	<ul style="list-style-type: none"> • The research meets the criteria for one or more of the exempt categories at 15 CFR 27.104(d)
Category 3: Human Subjects Research (Non-Exempt)	<ul style="list-style-type: none"> • The activities qualify as research as defined in 15 C.F.R. § 27.102(I) • The activities do involve human subjects as defined in 15 C.F.R. § 27.102 (e)(1) • The activities do not meet the criteria for exempt HSR • The activities will require review and approval by an Institutional Review Board

³ Determinations only remain valid so long as the activities on which the determination is based remain unchanged.

⁴ For the full list of exempt research categories, grant recipients should review 15 C.F.R. § 27.104(d).



REQUIRED GRANT RECIPIENT ACTION

No research involving human subjects is permitted under this award unless expressly authorized by specific award condition, or otherwise in writing by the Grants Officer. Further, no work involving human subjects may be undertaken under this award, until the appropriate documentation is approved in writing by the Grants Officer.

Recipients must provide an HSR memo to their FPO and the Grants Office prior to conducting any research or administration of any surveys funded with NTIA funds. To satisfy the HSR requirements, Recipients must submit, per the deadline listed in the Notice of Award, a letter or memorandum addressed to the Grants Officer that provides the following information:

- a. Which HSR classification category is applicable; and
- b. A detailed description of project activities that justify inclusion in that category.

Recipients must provide final study plans and documents.

If the Recipient engages an IRB to review their research materials, the Recipient must provide the letter from the IRB that details the outcome of the review and all documents submitted to the IRB for the review. The outcome of the IRB must support the HSR category selected by the Recipient in the HSR Memo to NTIA.

The Recipient may not conduct any activities in any HSR category until expressly approved in writing by the Grants Officer. If a Recipient conducts research before receiving Grants Office approval, Recipients will be considered in material non-compliance with award terms and conditions, and any costs incurred to conduct the research could be disallowed.

The templates provided below are samples that may help Recipients complete an HSR memo.

FOR CATEGORY 1 (NOT RESEARCH/NOT HUMAN SUBJECTS RESEARCH)

1A. Provide an email or letter to Grants Office and NTIA FPO certifying the following (*recommended text*) with additional justification as noted:

Based on our review of the policy described in Part 27 of Title 15 of the Code of Federal Regulations, the Common Rule for Protection of Human Subjects, we advise the National Telecommunications and Information Administration (NTIA) that the activities we expect to perform under our Digital Equity project grant number [INCLUDE GRANT NUMBER HERE] are not considered research as defined in 15 C.F.R. § 27.102(l). This project is not research, Category 1A, because [PROVIDE JUSTIFICATION FOR WHY THE ACTIVITIES ARE NOT RESEARCH].

We understand that the protection of human subjects is an ongoing activity. If our planned activities under the grant change, then we will advise our assigned Federal Program Officer (FPO) and seek approval from the Department of Commerce prior to any work involving human subjects research being undertaken under this award. We will also submit appropriate documentation to allow NTIA to certify that the research and evaluation activities we will undertake are either: (1) **exempt** human subjects research under one of the exempt categories listed in 15 C.F.R. § 27.104(d); or (2) **approved** by an outside Institutional Review Board in accordance with 15 C.F.R. § 27.109.

-OR-

1B. Provide an email or letter to Grants Office and [NTIA] FPO certifying the following (*recommended text*) with additional justification as noted:

Based on our review of the policy described in Part 27 of Title 15 of the Code of Federal Regulations, the Common Rule for Protection of Human Subjects, we advise the National Telecommunications and Information Administration (NTIA) that the research activities we expect to perform under our Digital Equity project grant number [INCLUDE GRANT NUMBER HERE] do not include human subjects research as defined in 15 C.F.R. § 27.102(e). This project does not involve human subjects, Category 1B, because [PROVIDE JUSTIFICATION FOR WHY THE ACTIVITIES DO NOT INCLUDE HUMAN SUBJECTS OR MEET THE DEFINITION OF HUMAN SUBJECTS].

We understand that the protection of human subjects is an ongoing activity. If our planned activities under the grant change, then we will advise our assigned Federal Program Officer (FPO) and seek approval from the Department of Commerce prior to any work involving human subjects research being



undertaken under this award. We will also submit appropriate documentation to allow NTIA to certify that the research and evaluation activities we will undertake are either: (1) **exempt** human subjects research under one of the exempt categories listed in 15 C.F.R. § 27.104(d); or (2) **approved** by an outside Institutional Review Board in accordance with 15 C.F.R. § 27.109.

FOR CATEGORY 2 (EXEMPT HSR)

If the Recipient's institution has an IRB Office (or equivalent) or in-house IRB they should follow their institutional policy for approval of exempt HSR. Documentation of IRB or institutional approval must be provided with the HSR letter. If the Recipient does not have an IRB Office (or equivalent) or in-house IRB, they may request approval of their exempt HSR justification.

Recipients requesting a determination that the study meets one of the exempt categories of human subjects research, must submit a letter that resembles in form and substance the sample language set forth below. This letter will be submitted by NTIA to the Grants Office for their review and approval.

In-house IRB Office or IRB:

Based on our review of the policy described in Part 27 of Title 15 of the Code of Federal Regulations, the Common Rule for Protection of Human Subjects, we advise the National Telecommunications and Information Administration (NTIA) that the research activities we expect to perform under our Digital Equity project grant number [INCLUDE GRANT NUMBER HERE] have been approved by [IRB office or IRB name] as exempt human subjects research (15 CFR 27.104(d), Category 2. The approval letter and documents reviewed are attached.

We understand that the protection of human subjects is an ongoing activity. If our planned activities under the grant change, then we will advise our assigned Federal Program Officer (FPO) and seek approval from the Department of Commerce prior to any work involving human subjects research being undertaken under this award. We will also submit appropriate documentation to allow NTIA to certify that the research and evaluation activities we will undertake are either: (1) **exempt** human subjects research under one of the exempt categories listed in 15 C.F.R. § 27.104(d); or (2) **approved** by an outside Institutional Review Board in accordance with 15 C.F.R. § 27.109.



No in-house IRB office or IRB:

[Federal Program Officer]

[Program Name]

U.S. Department of Commerce

National Telecommunications and Information Administration 1401 Constitution Avenue, NW

Room 4078

Washington, DC 20230

Dear [NAME OF THE FEDERAL PROGRAM OFFICER]:

Based on review of the policy described in Part 27 of Title 15 of the Code of Federal Regulations, the Common Rule for Protection of Human Subjects, we request approval of the justification below for the proposed research for our Digital Equity project grant number [INCLUDE GRANT NUMBER HERE]. Our institution does not have an IRB Office or an in-house IRB.

As described in 15 C.F.R. § 27.104(d), we believe that our activities are Category 2 and the following exemption(s) listed below apply to our proposed evaluation:

[From the exemptions listed below, INCLUDE ONLY THE EXEMPTION(S) THAT APPLY TO YOUR RESEARCH. Please discuss your planned activities with your FPO to decide which exemptions apply to your planned activities.]

- The research is conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. 15 C.F.R. § 27.104(d)(1).
- Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained 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;

(ii) Any disclosure of the human 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. 15 C.F.R. § 27.104(d)(2).

- The research involves 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 and at least one of the following criteria is met: (1) the information obtained 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; or (2) any disclosure of the human 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. 15 C.F.R. § 27.104(d)(3).
- Secondary research for which consent is not required: 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 15 C.F.R. § 27.104(d)(4).

Provide a thorough and complete description of your research study and plan. Include final versions of any surveys, interview questions, or other study instruments.

Our research will involve:

[In this section you should summarize your research plan. Please describe:

- What information do you plan to collect?
- What type of research instrument will you use to collect the information (e.g., survey, focus groups, interviews)?
- Who will participate in the research (e.g., public safety professionals, government officials, individuals who work for utility companies)?
- Who will administer the research (e.g., a contracted vendor, an internal state agency that conducts similar types of surveys/evaluation)?
- How will you use the information that you collect?
- As applicable, how will you ensure that information obtained from subjects is recorded in such a manner that the subjects cannot be readily identified?

There must be sufficient information to determine how the research will be conducted.]

I request an exemption based on the research information submitted at this time. I recognize that we cannot proceed with any research activities that involve human subjects until this exemption is approved. If our planned activities under the grant change, then we will advise our assigned Federal Program Officer (FPO) and seek approval from the Department of Commerce before conducting any work involving human subjects research being undertaken under this award. If applicable, we will also submit appropriate documentation to allow NTIA to certify that the research and evaluation activities we will undertake are either: (1) exempt from Human Subjects Research Protections under one of the exemptions listed in 15 C.F.R. § 27.104(d); or (2) approved by an outside Institutional Review Board in accordance with 15 C.F.R. § 27.109.

[Signed by Authorized Organization Representative, including their title]

FOR CATEGORY 3 (NON-EXEMPT HSR)

Provide an email or letter to the FPO and Grants Office certifying the following (*recommended text*):

Based on our review of the policy described in Part 27 of Title 15 of the Code of Federal Regulations, the Common Rule for Protection of Human Subjects, we

advise the National Telecommunications and Information Administration (NTIA) that the activities we expect to perform under our Digital Equity project grant number [INCLUDE GRANT NUMBER HERE] do include human subjects research, Category 3, and [has been or will be] review[ed] by an IRB. The approval letter and documents will be submitted to NTIA as the IRB makes them available.

We understand that the protection of human subjects is an ongoing activity. If our planned activities under the grant change, then we will advise our assigned Federal Program Officer (FPO) and seek approval from the Department of Commerce prior to any work involving human subjects research being undertaken under this award.

[Signed by Authorized Organization Representative, including their title]