Guidance for Human Subjects Research Protection[1]

Human Subjects Research Protection Requirements for the State Digital Equity Planning Grant Program

All State Digital Equity Planning Grant Program (DE) grant recipients 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.[2]

As the requirements in 15 C.F.R. Part 27 apply to DE 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 a few 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 the 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.

[1] This guidance document is intended to assist recipients of DE 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 DE award, shall prevail over any inconsistencies or inaccuracies contained in this document.

[2] 15 C.F.R. Part 27, *available at* https://www.ecfr.gov/current/title-15/subtitle-A/part-27.

Human Subject: A living individual about whom an investigator (whether professional or student) conducting research obtains: (1) Data through intervention or interaction with the individual; or (2) Identifiable private information.

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.[3]

State Digital Equity Planning Grant Program Office Expectations

Some DE recipients may conduct surveys of individuals as part of their DE-funded activities. NTIA must ensure that all DE recipients understand and comply with the appropriate HSR protection classifications, policies, and requirements by obtaining written assurances from and certifying that any DE recipient research activities comply with the requirements set forth in 15 C.F.R. Part 27 (Protection of Human Subjects), as incorporated into every DE 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 condition, 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 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

[3] 45 C.F.R. Part 46, Subparts B, C, and D, *available at* https://www.ecfr.gov/current/title-45/subtitle-A/subchapter- A/part-46.

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

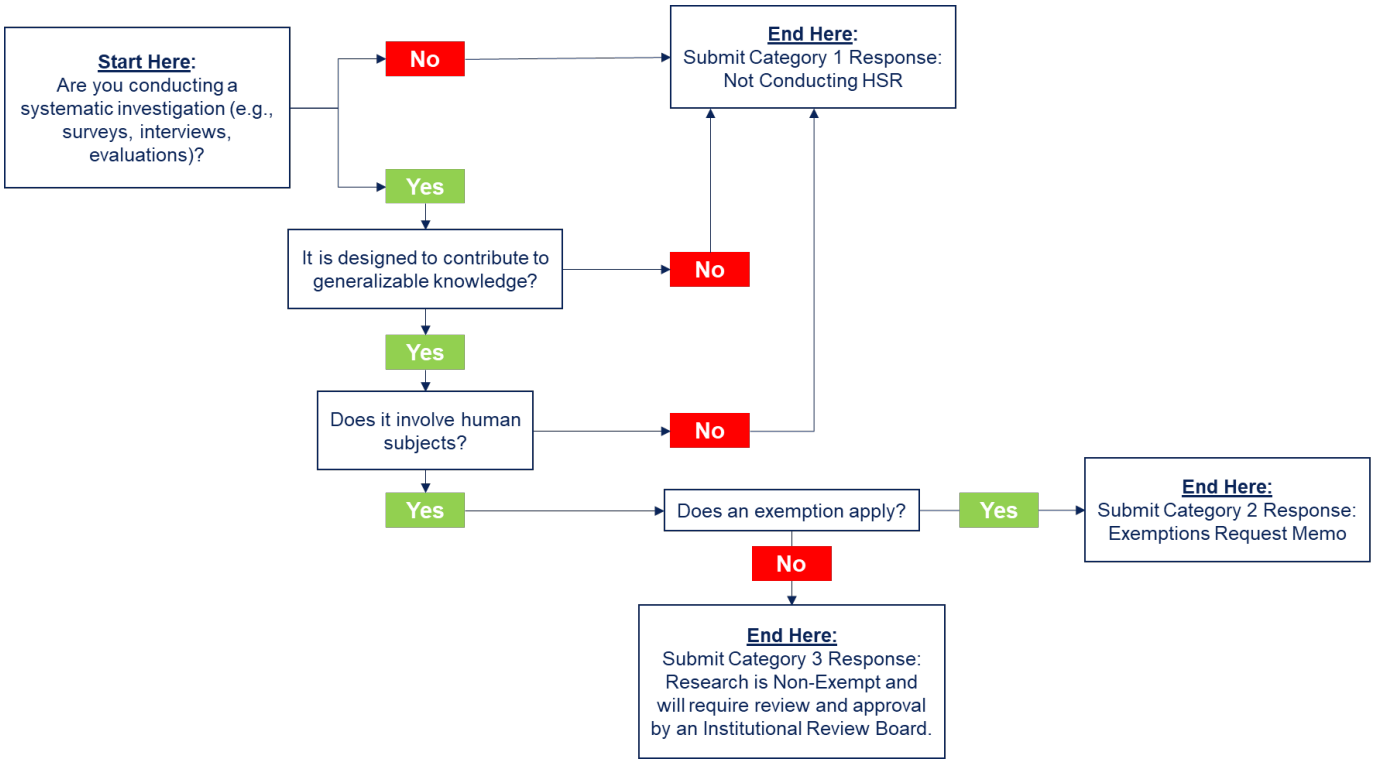
v. Documentation of any reportable events, such as serious adverse events, unanticipated problems resulting in risk to subjects or others, and instances of noncompliance.

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 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.

DE recipients should review the *DE HSR Classification – Decision Tree* below and consider the DE planned activities to determine which HSR category applies to their grants.

State Digital Equity Planning Grant Program HSR Classification – Decision Tree

The decision tree included below can be used by DE 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 regulations on the protection of human subjects. For DE 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.



State Digital Equity Planning Grant Program HSR Classification Categories and Determination Criteria

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

HSR Classification Category	Determination Criteria[4]
Category 1: Not Conducting Human Subjects Research	• The activity does not qualify as research, as defined in 15 C.F.R. § 27.102(l), because it does not follow a systematic investigation designed to develop or contribute to generalizable knowledge. • The activity does not involve human subjects as defined in 15 C.F.R. § 27.102 (e)(1).
Category 2: Exemption Request[5]	• 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). • 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. If research involves survey or interview procedures, it does not involve children under the age of 18 as subjects. If research involves observation of public behavior and children under the age of 18 as subjects, the investigator(s) will not participate in the activities being observed. *See* 15 C.F.R. § 27.104(b)(3), (d)(2). • The research will involve benign behavioral interventions in conjunction with the collection of

[4] Determinations only remain valid so long as the activities on which the determination is based remain unchanged.
[5] The listed exemptions are those most likely to be relevant to DEgrant recipient activities. For the full list of exempt research categories, grant recipients should review 15 C.F.R. § 27.104(d).

	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. *See* 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. *See* 15 C.F.R. § 27.104(d)(4).
Category 3: Human Subjects Research Non-Exempt	• The activities qualify as research as defined in 15 C.F.R. § 27.102(l) • The activities do involve human subjects as defined in 15 C.F.R. § 27.102 (e)(1) • The activities do not qualify for an exemption request • The activities will require review and approval by an Institutional Review Board

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, conducted, or costs incurred and/or charged for human subjects research, until the appropriate documentation is approved in writing by the Grants Officer.

Recipients must provide an HSR memo to their DE FPO and Grants Office prior to conducting any research or administration of any surveys funded with DE funds. To satisfy the DE HSR requirements, recipients must state which HSR classification category is applicable and the examples of planned DE project activities that justify inclusion in that category.

If research activities require an exemption request, a recipient may not conduct any research involving human subjects until expressly approved in writing by the Grants Officer, approving the recipient's request substantiating an HSR exemption. If research activities require a review and approval of an Institutional Review Board (IRB), a recipient may not conduct any research involving human subjects until the Grants Office has been notified of the recipients review and approval from an Institutional Review Board (IRB). If a recipient conducts research before receiving Grants Office approval of an exemption or before receiving IRB approval for non-exempt research, 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 Grant Recipients:

Provide an email or letter to the Grants Office and DE FPO 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 DE project grant number [INCLUDE GRANT NUMBER HERE] do not include human subjects research as defined in 15 C.F.R. § 27.102(e).
>
> 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 or any charges for activities involving human subjects being incurred and/or charged to the project. 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.

For Category 2 Grant Recipients:

Recipients requesting an Exemption from the Human Subjects Research Policy, please submit a request in letter format 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. Please note, only the Department of Commerce can confer a Research Exemption):

[Federal Program Officer]
State Digital Equity Planning Grant Program
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 an exemption for the proposed research for our DE project grant number [INCLUDE GRANT NUMBER HERE].

As described in 15 C.F.R. § 27.104(d), we believe that 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 involving normal educational 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. 15 C.F.R. § 27.104(d)(1).

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. If research involves survey or interview procedures, it does not involve children under the age of 18 as subjects. If research involves observation of public behavior and children under the age of 18 as subjects, the investigator(s) will not participate in the activities being observed. 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).

The research will involve the collection or study of existing data, documents, or records. The information collected is publicly available, or the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. 15 C.F.R. § 27.104(d)(4).

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 you will 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.]

[Example 1: The investigator will not record the names of survey participants, and the information that will be collected could not reasonably place the participants at risk of criminal or civil liability, or be damaging to their financial standing, employability, or reputation. Moreover, there will be no participants under the age of 18. Exemption Available: 15 C.F.R. § 27.104(d)(2).

Example 2: The research relies on sources that are publicly available and can be found at [list locations where the data is publicly available]. Exemption Available: 15 C.F.R. § 27.104(d)(4).

Example 3: The research relies on existing data, documents, and records that are not publicly available. However, the investigator will record the information in such a manner that subjects cannot be identified directly or through identifiers linked to the subject. Exemption Available: 15 C.F.R. § 27.104(d)(4).

Recipient should clearly specify that procedures you will employ to ensure that certain populations (e.g., *prisoners*) will be excluded from your research.]

[Please note that if your research cannot qualify for an exemption or includes certain populations you will need to subject your research protocol to Institutional Review Board (IRB) review and approval as described in 15 C.F.R. § 27.109 and 45 C.F.R. § 46.109.]

[In addition, you should include as attachments any items (including your evaluation plan, evaluation contracts, evaluator strategies, evaluator qualifications, sample questions to be used in surveys or focus groups, etc.) that will support your request for an exemption.]

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 or any charges for activities involving human subjects being incurred and/or charged to the project. 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 Grant Recipients:

Provide an email or letter to the DE 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 BEAD project grant number [INCLUDE GRANT NUMBER HERE] do include human subjects research as defined in 15 C.F.R. § 27.102(e) and do not qualify for an exemption.

We understand that the protection of human subjects is a priority and our research activities will be approved by an outside Institutional Review Board in accordance with 15 C.F.R. § 27.109. We will comply with NTIA's requirements for the review and approval IRB process. Additional materials documenting the review and approval will be forthcoming and submitted to NTIA as required.