Guidance for Human Subjects Research Protection

Human Subjects Research (HSR) Protection Requirements for the State and Local Implementation Grant Program (SLIGP) 2.0

All SLIGP 2.0 grant recipients must comply with Department of Commerce regulations relating to the protection of human subjects for all research conducted or supported with grant funds. The Department's policies related to the protection of human subjects are found in 15 C.F.R. Part 27.[1]

Based on the data that we collected during the original SLIGP grants, we believe it is unlikely that any SLIGP 2.0 recipient-conducted data collection activities would involve human subjects. Nevertheless, because the requirements in 15 C.F.R. Part 27 apply to SLIGP 2.0 grants, SLIGP 2.0 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 definitions 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:
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> - 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 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 vulnerable classes from being subject to research without their informed consent and that subject should not incur increased risk of harm from their research involvement, beyond the normal risks inherent in everyday

[1] 15 C.F.R. Part 27, *available at* https://www.gpo.gov/fdsys/pkg/CFR-2018-title15-vol1/pdf/CFR-2018-title15-vol1-part27.pdf.

life. To that end, NTIA requires grant recipients to take special precautions if HSR involves vulnerable classes. Vulnerable classes include pregnant women, children, fetuses, and prisoners as set forth in the regulations adopted by the National Institute of Health at Part 46, Subparts B, C, D of Title 45 of the Code of Federal Regulations.[2] These policies ensure that human subject responses are protected when participating in research studies conducted as part of Federal grant programs.

SLIGP 2.0 Program Office Expectations

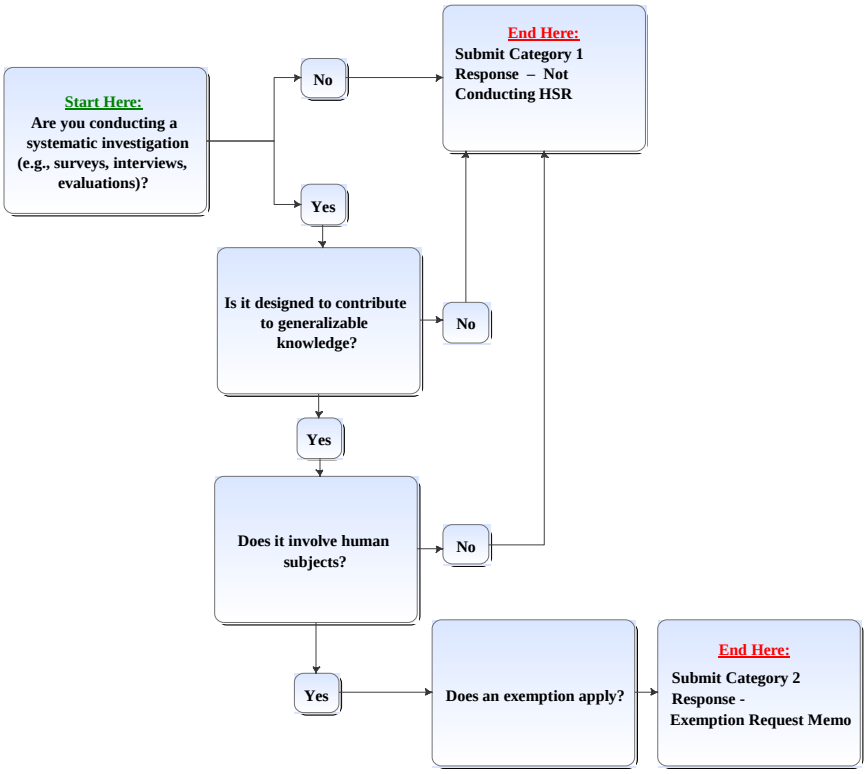
Some SLIGP 2.0 recipients may conduct surveys of individuals as part of their SLIGP 2.0 activities. Although it is unlikely these activities will qualify as HSR, NTIA must ensure that all SLIGP 2.0 recipients understand and comply with the appropriate HSR protection classifications, policies, and requirements by obtaining written assurances from and certifying that any SLIGP 2.0 recipient research activities comply with the requirements set forth in the Department's policy.

Recipients should review the *SLIGP 2.0 HSR Classification – Determination Chart* below and consider the SLIGP 2.0 planned activities to determine which HSR category applies to their grants.

[2] 45 C.F.R. Part 46, Subparts B, C, and D, *available at* https://www.gpo.gov/fdsys/pkg/CFR-2017-title45-vol1/pdf/CFR-2017-title45-vol1-part46.pdf.

SLIGP 2.0 HSR Classification – Determination Chart

The determination chart included below can be used by SLIGP 2.0 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. Please note that because of SLIGP 2.0'S programmatic focus and allowable grant activities and expenditures, SLIGP 2.0 recipients will not be likely engaging in research that would require review and approval by an Institutional Review Board (IRB). Therefore, information on the IRB review approval process is not included in the determination chart.



SLIGP 2.0 HSR Classification Categories and Determination Criteria

After completing the determination chart, all SLIGP 2.0 recipients should know their HSR classification categories (defined below). SLIGP 2.0 recipients should contact their FPO if they have questions about the categories.

HSR Classification Category	Determination Criteria[3]
Category 1: Not Conducting Human Subjects Research	• The activity does not qualify as research, as defined in 15 C.F.R. § 27.102(d), 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(f).
Category 2: Exemption Request	• 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. § 27.101(b)(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. § 27.101(b)(2). • 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. *See* 15 C.F.R. § 27.101(b)(4).

Required Grant Recipient Action

Recipients must provide an HSR memo to their SLIGP 2.0 FPO prior to conducting any research or administration of any surveys funded with SLIGP 2.0 funds. To satisfy the SLIGP 2.0 HSR requirements,

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

recipients must state which HSR classification category is applicable and the examples of planned SLIGP 2.0 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 NTIA has approved the recipient's request substantiating an HSR exemption. If a recipient conducts research before receiving NTIA approval of an exemption, 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 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 SLIGP project grant number **[INCLUDE GRANT NUMBER HERE]** do not include human subjects research as defined in 15 C.F.R. § 27.102.
>
> 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. § 27.101(b); or (2) **approved** by an outside Institutional Review Board in accordance with 15 C.F.R. § 27.103.

For Category 2 Grant Recipients:

Recipients requesting an Exemption from Human Subjects Research Policy, please submit a request in letter format that resembles in form and substance the sample language set forth below. Please note, only the Department of Commerce can confer a Research Exemption.

[Federal Program Officer]
State and Local Implementation Grant Program 2.0
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 SLIGP project grant number [INCLUDE GRANT NUMBER HERE].

As described in 15 C.F.R. § 27.101(b), 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. § 27.101(b)(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. § 27.101(b)(2).
>
> 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. § 27.101(b)(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?
>
> There must be sufficient information to determine how the research will be conducted.]

I believe the exemption is warranted because:

[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. § 27.101(b)(2).

Example 2: The research relies on sources that are publically available and can be found at [list locations where the data is publically available]. Exemption Available: 15 C.F.R. § 27.101(b)(4).

Example 3: The research relies on existing data, documents, and records that are not publically 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. § 27.101(b)(4).

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

[Please note that if your research cannot qualify for an exemption or includes vulnerable classes 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 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. 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. § 27.101(b); or (2) approved by an outside Institutional Review Board in accordance with 15 C.F.R. § 27.103.

[SIGNATURE]

Name
Title