



State and Local Implementation Grant Program (SLIGP)

Guidance for Human Subjects Research Protection

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

All State and Local Implementation Grant Program (SLIGP) award recipients must comply with Department of Commerce (Department) regulations relating to the protection of human subjects for all research conducted or supported with grant funds.¹ The term “human subject” means 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.² The term “research” means a **systematic investigation**, including research development, testing and evaluation, **designed to develop or contribute to generalizable knowledge**.³ Factors that may be used to evaluate whether research **would** develop or contribute to generalizable 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.

The fundamental principle of the protection of human subjects is that people should not be involved in research without their informed consent, and that subjects should not incur increased risk of harm from their research involvement, beyond the normal risks inherent in everyday life. To that end, the Department must certify that the research elements of SLIGP grant recipient projects adequately protect human subjects.⁴ The Department’s policies relating to the protection of human subjects are found in 15 C.F.R. § 27.⁵ In addition, it is NTIA’s policy that recipients of grant funding also protect vulnerable classes in conducting human subjects research. To that end, NTIA requires grant recipient to take special precautions if human subjects research involves pregnant women, children, fetuses,

¹ 15 C.F.R. § 27.101 *et seq.* (2013).

² 15 C.F.R. 27.102 (f).

³ 15 C.F.R. 27.102 (d). Examples of systematic investigations include surveys, interviews, observations, research development of testing and evaluations that are designed to develop or contribute to the generalizable knowledge.

⁴ *See* 15 C.F.R. § 27.103.

⁵ 15 C.F.R. Part 27 available at <http://www.gpo.gov/fdsys/pkg/CFR-2010-title15-vol1/pdf/CFR-2010-title15-vol1-part27.pdf>.



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and prisoners as set forth in the regulations adopted by the National Institute of Health at Part 46, Subparts B, C, and D of Title 45 of the Code of Federal regulations.⁶ These policies ensure that human subject responses are protected when participating in research studies conducted as part of Federal grant programs.

SLIGP Program Office HSR Expectations

Some SLIGP recipients indicated in their applications plans to conduct surveys of individuals as part of their SLIGP activities. Recipients noted that these surveys would collect information on the proposed nationwide public safety broadband network (PSBN) including users' needs, thoughts related to the PSBN, or other topics relevant to SLIGP activities. Although it is unlikely these activities will qualify as human subject research, NTIA must ensure that all SLIGP recipients understand and comply with the appropriate human subjects research protection classifications, policies, and requirements by obtaining written assurances from and certifying that any SLIGP recipient research activities comply with the requirements set forth in the Department's policy.

HSR Classification Types and HSR Memo Requirement

Depending on planned activities, a SLIGP recipient may be required to submit specific documentation to their respective Federal Program Officer (FPO) to identify with a specific HSR Classification type. To assist in this process, SLIGP recipients should utilize *SLIGP HSR Classification – Determination Chart* that can be found on page 3 of this guidance. By responding to the questions in the chart, SLIGP recipients will be able to determine, based on individual SLIGP project plans, the appropriate classification and the type of HSR Memo to submit to their respective FPO.

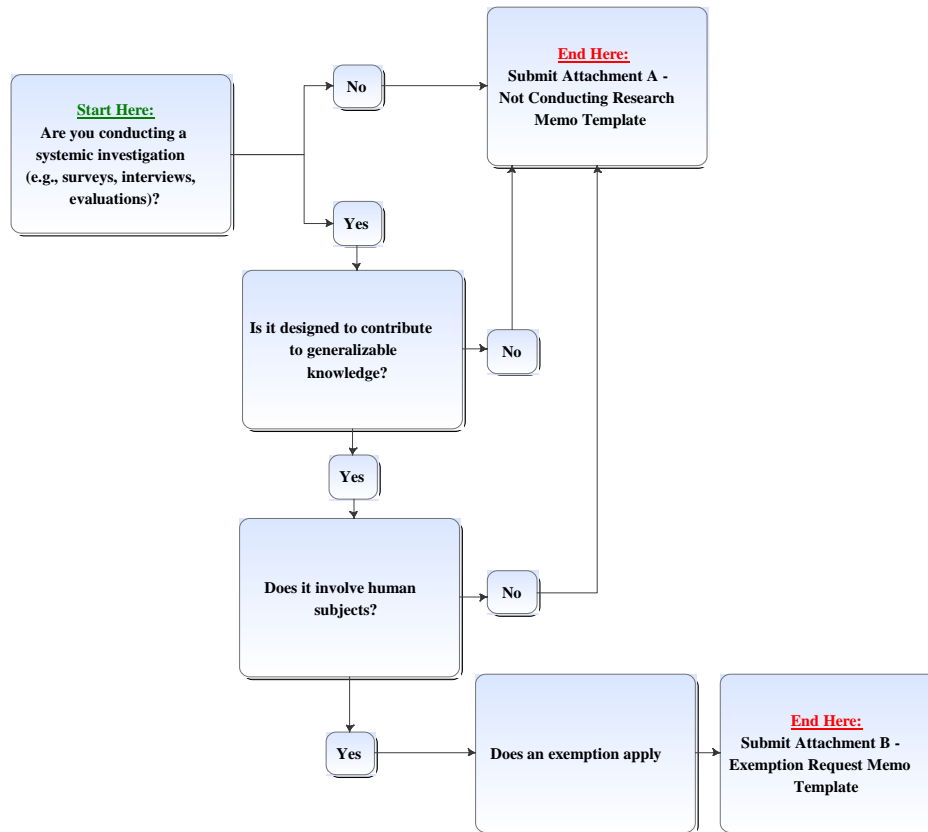
⁶ 45 C.F.R. Part 46, Subparts B, C, and D, available at <http://www.gpo.gov/fdsys/pkg/CFR-2010-title45-vol1/pdf/CFR-2010-title45-vol1-part46.pdf>.



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SLIGP HSR Classification – Determination Chart

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



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After completing the determination chart from the previous page, all SLIGP recipients should know their HSR classification category (defined further in the chart below). If recipients have any questions about their category, they should contact their respective FPO for further clarification.

HSR Classification Category	Determination Criteria ⁷
<p>Category 1: Not Conducting Human Subjects Research</p>	<ul style="list-style-type: none"> • 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).
<p>Category 2: Exemption Request</p>	<ul style="list-style-type: none"> • 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. 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.⁸ 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).

⁷ Determinations only remain valid so long as the activities on which the determination is based remain unchanged.



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SLIGP and HSR Memo Classification Types and HSR Satisfaction Processing

SLIGP recipients must submit a HSR memo (templates for recipients provided in the appendices) to their respective FPO stating which HSR classification category is applicable to their grant. Specifically, to satisfy the SLIGP HSR requirements, recipients will include (1) the applicable category (summarized below) and (2) examples of planned SLIGP project activities that justify inclusion in that category.

- Category 1: Attachment A – Not Conducting Human Subjects Research
- Category 2: Attachment B – Exemption Request

If research activities require an exemption request and the recipient is applying for an HSR exemption, a recipient may **not** conduct any research or administer any surveys involving human subjects until documentation substantiating an exemption has been approved by NTIA. If research is conducted before receiving 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 figure below summarizes the steps that all SLIGP recipients will follow to satisfy HSR expectations:

HSR Processing Steps



The templates provided in the Appendix are samples that may help recipients complete their respective memos. Recipients may refer to the recommended templates when completing their letters. The highlighted information denotes information that is intended to be state-specific and reflect project plan information. The sections not highlighted in yellow are standard text not intended for any modification.



Appendix

ATTACHMENT A

Sample Correspondence from Recipient that is Not Conducting Human Subjects Research

If recipient is not conducting human subjects research, please submit a response in writing that resembles in form and substance the sample language set forth below. Please send the response to your Federal Program Officer and copy the SLIGP account.

State and Local Implementation Grant Program
U.S. Department of Commerce
National Telecommunications and Information Administration
1401 Constitution Avenue, NW
Room 7324
Washington, DC 20230

[NAME OF SLIGP FEDERAL PROGRAM OFFICER]:

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.

[PROGRAM OFFICIAL NAME]

[TITLE]

[CONTACT INFORMATION]



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Appendix

ATTACHMENT B Sample Exemption Request

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

Staten and Local Implementation Grant Program
U.S. Department of Commerce
National Telecommunications and Information Administration
1401 Constitution Avenue, NW
Room 7324
Washington, DC 20230

[NAME OF SLIGP 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;



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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



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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 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]