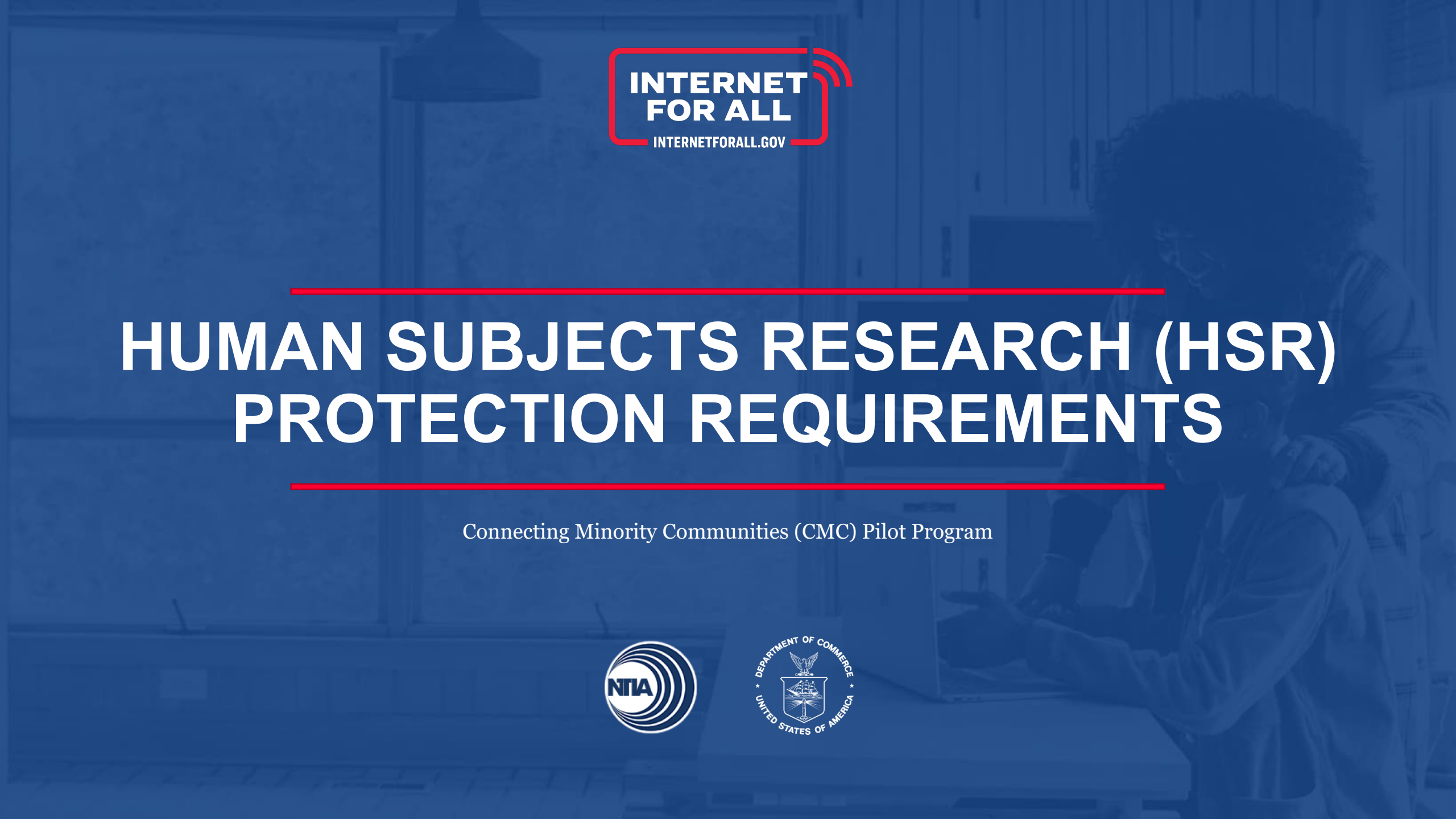

HUMAN SUBJECTS RESEARCH (HSR) PROTECTION REQUIREMENTS

Connecting Minority Communities (CMC) Pilot Program

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OVERVIEW OF HSR

Human Subjects Research Overview

- All Connecting Minority Communities Pilot Program (CMC) grant recipients must comply with Department of Commerce (DOC) regulations relating to the protection of human subjects for all research conducted or supported pursuant to a National Telecommunications and Information Administration (NTIA) grant award.
- The DOC must certify that research elements of projects adequately protect human subjects.
- **No research involving human subjects may be undertaken, conducted, or costs incurred and/or charged for HSR unless expressly authorized by specific award condition, or otherwise approved in writing by the Grants Officer.**
- Some CMC recipients may conduct surveys of individuals as part of their CMC-funded activities. Although it is unlikely these activities will qualify as HSR, NTIA must ensure that all CMC recipients understand and comply with the appropriate HSR protection classifications, policies, and requirements.

Human Subjects Research Regulations

- HSR requirements are incorporated into CMC Pilot Program awards through:
  - Specific Award Condition (SAC)
  - Section F.05.i of the DOC Financial Assistance Standard Terms and Conditions

- The following regulations take precedence over this webinar:
  - 15 CFR Part 27 – DOC HSR regulations
  - 45 CFR Part 46, Subparts B-D – National Institutes of Health regulations

What is Research?

- **Research:** The systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge. Examples include:
  - Surveys
  - Interviews
  - Observations
  - Research development of testing
  - Evaluations 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

Refer to the HSR Guidance Document for additional information.

What are Human Subjects?

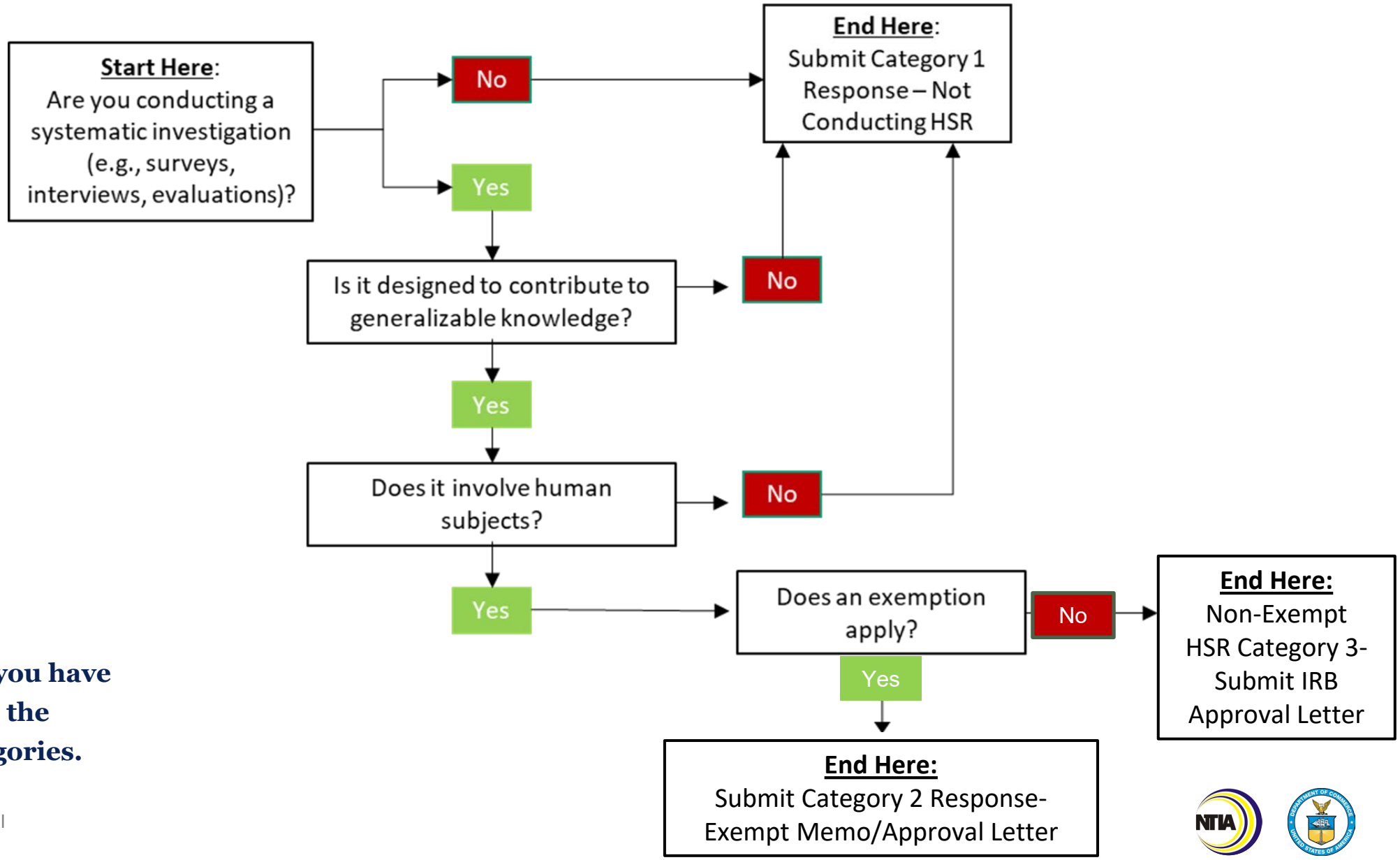
- **Human Subject:** A living individual about whom an investigator (whether professional or student) conducting research obtains:
  (1) Data through intervention or interaction with the individual; or
  (2) Identifiable private information.
- NTIA requires grant recipients to take special precautions if HSR involves certain populations as set forth in 45 CFR Part 46, Subparts B-D. These populations include:
  - Pregnant women
  - Children
  - Fetuses
  - Prisoners

HSR REQUIREMENTS

Basic Requirements for CMC Pilot Program Recipients

- **The Common Rule** (15 CFR Part 27) requires that non-Federal entities maintain ethical policies and procedures for the protection of human subjects.
- If it becomes evident that human subjects may be involved in this project, the recipient must submit appropriate documentation to the Federal Program Officer (FPO) for approval.
- If applicable, this documentation must include:
    - Documentation establishing approval of an activity in the project by an Institutional Review Board (IRB) under a Federal-wide Assurance issued by the Department of Health and Human Services or other Federal agency guidelines (see also 15 CFR § 27.103);
    - Documentation to support an exemption for an activity in the project under 15 CFR § 27.104(d);
    - Documentation of IRB approval of any modification to a prior approved protocol or to an informed consent form;
    - Documentation of an IRB approval of continuing review approved prior to the expiration date of the previous IRB determination; and
    - Documentation of any reportable events, such as serious adverse events, unanticipated problems resulting in risk to subjects or others, and instances of noncompliance.

HSR Classification Decision Tree



Contact your FPO if you have questions about the classification categories.

HSR Classifications

- **Category 1: Not Conducting Human Subjects Research**
  - The activity does not qualify as research (per 15 CFR § 27.102(l)) because it does not follow a systematic investigation designed to develop or contribute to generalizable knowledge
  - If your study meets a Category 1 criteria, you must provide justification
    - Provide a brief statement explaining why your project meets Category 1 criteria and attach any relevant supporting documentation (project narrative, program evaluation, etc.), if applicable
- **Category 2: Exemption Request**
  - If your study meets a Category 2 exempt category, state which category from the full list of exempt research categories listed under 15 CFR § 27.104(d)
  - Research is conducted in established or commonly accepted educational settings involving normal education practices (15 CFR § 27.104(d)(1))
  - Research involves the use of educational tests, survey procedures, interview procedures, or observation of public behavior and the information obtained cannot identify the subjects (15 CFR § 27.104(b)(3), (d)(2))
  - Research involves benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses or audiovisual recording and the information obtained cannot identify the subjects (15 CFR § 27.104(d)(3))
  - Secondary research for which consent is not required (15 CFR § 27.104(d)(4))
- **Category 3: Non-Exempt; IRB Approval Required**
  - If your research does not qualify for an exemption or includes certain populations, you will need to subject your research protocol to IRB review and approval as described in 15 CFR § 27.109 and 45 CFR § 46.109.
  - Research that involves more risk to subjects needs review by an IRB
  - Your in-house IRB should review the study
  - If you don't have an in-house IRB, you will need to establish a relationship with an IRB to review your study

Exempt Vs. Not Exempt

WHAT TO DO IF EXEMPT

If you believe your HSR is exempt (Category 2), send your FPO a request in letter format that resembles in form and substance the sample language set forth in your HSR Guidance within 45 days of award start date.

Please note, only the Department of Commerce (DOC) can confer a Research Exemption.

For more info on exemptions, please refer to 15 CFR § 27.104. If your research involves children under 18, also refer to 45 CFR § 46.401(b).

WHAT TO DO IF NOT EXEMPT

If your project includes HSR that is not exempt, your research procedures must be approved by an IRB that is approved by the U.S. Department of Health and Human Services.

If you do not have an IRB, see https://ohrp.cit.nih.gov/search/irbsearch.aspx?styp=bsc for registered IRBs.

HSR MEMO REQUIREMENTS

Required Recipient Action – HSR Memo Submission

1. **At the start of their award, Recipients should work with their Institutional Review Board Office (IRB) to identify their HSR Classification Category and develop their HSR Memo.**
2. **Within 45 calendar days of award, Recipients must submit their HSR memo to UGAM@NIST.gov and copy their CMC FPO**. To satisfy the CMC Pilot Program HSR requirements, recipients must state which HSR classification category is applicable and the examples of planned CMC Pilot Program project activities that justify inclusion in that category.
   - Examples are on the following slides.
3. **The FPO will notify the Recipient once their HSR Memo has been approved.**
   - 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, among other potential consequences.

Category 1 Recipients – Sample HSR Memo

- **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 CMC project grant number ***[INCLUDE AWARD NUMBER HERE]*** *do not include human subjects research as defined in 15 CFR § 27.102(e) because* ***[INCLUDE REASONS FOR CATEGORY 1 DETERMINATION]***

  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.*

Category 2 Recipients – Sample HSR Memo

- **Provide a letter to FPO certifying the following (recommended text):**

  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 CMC project grant number ***[INCLUDE AWARD NUMBER HERE]****.*

  As described in 15 CFR § 27.104(d), we believe that the following exemption(s) listed below apply to our proposed evaluation: ***[List the exemption(s) that apply to your research]***

  Our research will involve: ***[Summarize research plan]***

  We believe the exemption is warranted because: ***[Explain reasoning]***

- Include any attachments that support your request for an exemption (including your evaluation plan, evaluation contracts, evaluator strategies, evaluator qualifications, sample questions to be used in surveys or focus groups, etc.)
- The IRB can support the drafting of this letter to be sent to the FPO
- Refer to the HSR Guidance Document for a full sample memo

Category 3 Recipients – IRB Approval Letter

- If your research does not qualify for an exemption or includes certain populations, your research protocol will need IRB review and approval as described in 15 CFR § 27.109 and 45 CFR § 46.109
- Your in-house IRB should review the study and document their approval. Their approval letter should be sent to the FPO.
- If you do not have an in-house IRB, you will need to establish a relationship with an IRB to review your study.

INSTITUTIONAL REVIEW BOARD (IRB)

Institutional Review Board (IRB) Review

All HSR categories should coordinate with an IRB office to complete the HSR Memorandum

- If your institution **has an IRB office**:
  - The IRB office should review your project and provide the HSR Memorandum for all categories

- If your institution **does <u>not</u> have an IRB office**:
  - You and any team members responsible for overseeing and implementing the CMC grant may draft and submit the HSR Memorandum for categories 1 and 2
  - You must find an IRB to review your project if it fits in category 3
- IRB review ensures that research subjects' rights and welfare are protected by ensuring:
  - Risks are minimized and reasonable in relation to anticipated benefits
  - Selection of subjects is equitable
  - Informed consent is obtained and appropriately documented
  - Subject's privacy is protected and data are kept confidential
  - When some subjects may be at risk for coercion or undue influence, there are additional protections in place

Documents to include in your submitted HSR package

IRB Documents

Submissions should have *one* of these documents depending on whether the awardee has an in-house IRB Office or IRB:

- For Category 1 or Category 2:
  - Approval letter or other correspondence regarding approval of the study from in-house IRB Office, *or*
  - Justification letter if no in-house IRB Office
- For Category 3:
  - Approval letter from in-house IRB, *or*
  - Approval letter from external IRB

Study Documents

As applicable, attach all documents related to the HSR aspects of this award:

- Protocol or proposal
- Surveys
- Consent forms
- Other relevant forms or documents

Award Documents

Attach the proposal narrative – we do not need the funding information

COMMON EXEMPTIONS

Common HSR Exemptions

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 cannot be identified, directly or through identifiers linked to the subjects;

(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; or

(3) the information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, and a limited IRB review is conducted.

More Common HSR Exemptions

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. If the information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, a limited IRB review is conducted.

See 15 C.F.R. § 27.104(d)(3).

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.

More Common HSR Exemptions Cont.

SECONDARY RESEARCH, NO CONSENT, 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 . . . . *See* 15 C.F.R. § 27.104(d)(4) for full list of criteria.

HSR Resources

Resources for ensuring compliance with HSR requirements include:

1 ASSIGNED FPO

Contact your FPO if you have questions about ensuring HSR compliance.

2 HSR GUIDANCE DOCUMENT

Refer to the HSR Guidance Document for in-depth information about ensuring compliance and sample HSR memos.

Reminder: HSR Memos to UGAM@NIST.gov and copy their CMC FPO within 45 days of award start date.

Q&A

INTERNET FOR ALL

INTERNETFORALL.GOV

THANK YOU

NTIA

DEPARTMENT OF COMMERCE

UNITED STATES OF AMERICA