HUMAN SUBJECTS RESEARCH (HSR) PROTECTION REQUIREMENTS

Tribal Broadband Connectivity Program (TBCP)

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OVERVIEW OF HSR

Human Subjects Research Overview

- All TBCP 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 NTIA grant award.
- The DOC must certify that research elements of projects adequately protect human subjects.
- **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.**
- Some TBCP recipients may conduct surveys of individuals as part of their TBCP-funded activities. Although it is unlikely these activities will qualify as HSR, NTIA must ensure that all TBCP recipients understand and comply with the appropriate HSR protection classifications, policies, and requirements.

Human Subjects Research Regulations

- HSR requirements are incorporated into TBCP 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 § 27 – DOC HSR regulations
  - 45 CFR § 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:

  (1) Obtains information through intervention or interaction with the individual and uses, studies, or analyzes the information; or

  (2) Obtains, uses, studies, analyzes, or generates identifiable private information.

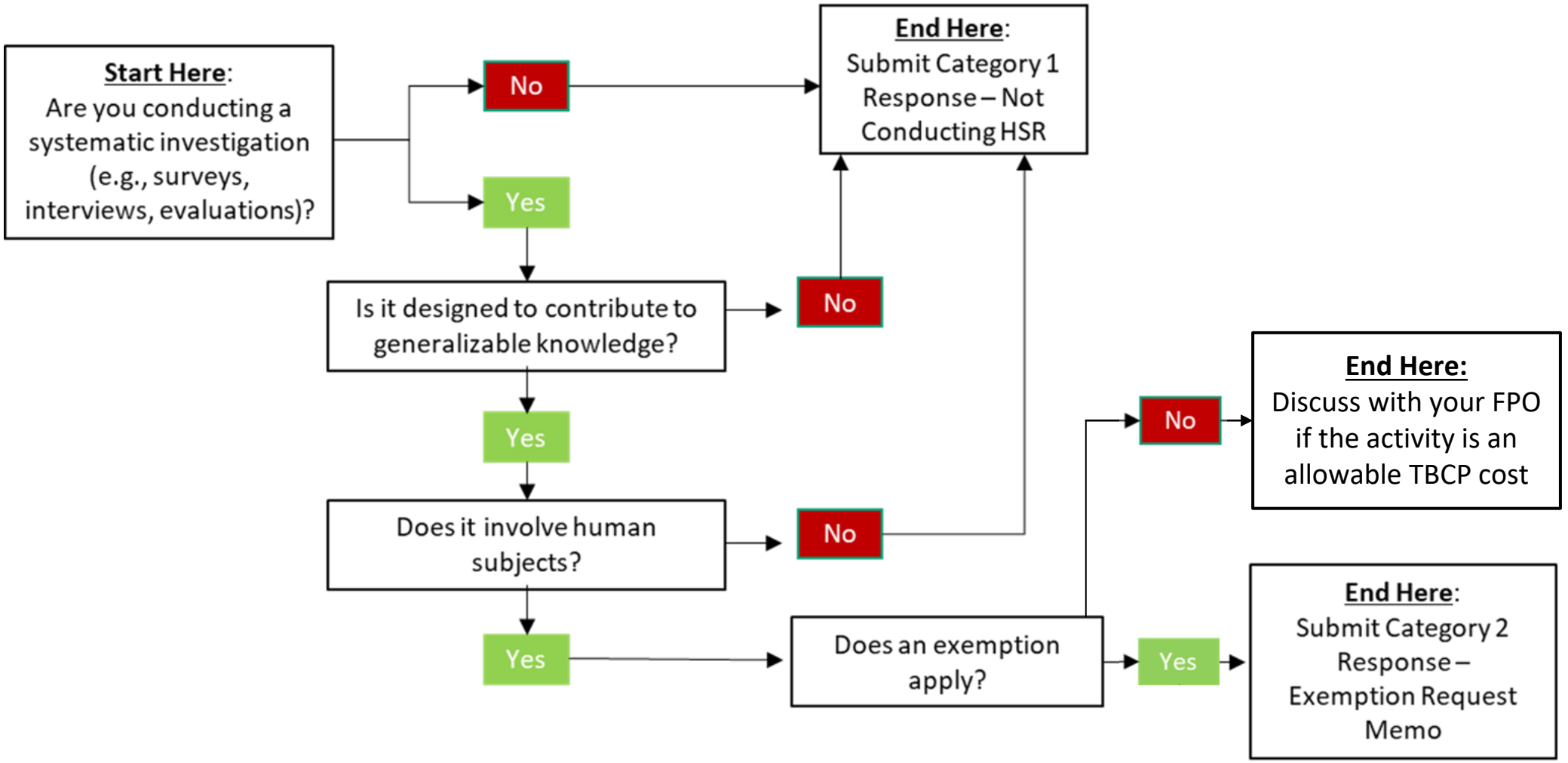
- NTIA requires grant recipients to take special precautions if HSR involves certain populations as set forth in 45 CFR § 46 Subparts B-D. These populations include:
  - Pregnant women
  - Children
  - Fetuses
  - Prisoners

HSR REQUIREMENTS

Basic Requirements for TBCP Recipients

- **15 CFR § 27** requires that non-Federal entities maintain appropriate 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 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



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.
- **Category 2: Exemption Request**
  - For the full list of exempt research categories, review 15 CFR § 27.104(d).
  - 15 CFR § 27.104(d)(1): Research is conducted in established or commonly accepted educational settings involving normal education practices
  - 15 CFR § 27.104(b)(3), (d)(2): 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(d)(3): 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)(4): Secondary research for which consent is not required

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

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 as soon as possible, and before your period of performance end 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. **In this scenario, contact your FPO for further guidance before engaging in any research activities.**

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

HSR MEMO

Required Recipient Action – HSR Memo

- Recipients must provide an HSR memo to their TBCP FPO prior to conducting any research or administration of any surveys funded with TBCP funds. To satisfy the TBCP HSR requirements, recipients must state which HSR classification category is applicable and the examples of planned TBCP project activities that justify inclusion in that category.
- If research activities require an exemption request (Category 2), a recipient may not conduct any research involving human subjects until NTIA has approved the recipient's request substantiating an HSR exemption.
- Examples of an HSR Memo for Category 1 and 2 are on the following slides.
- Recipients must submit an HSR Memo to their FPO before conducting any research, and before the award's period of performance end date.

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 TBCP project grant number ***[INCLUDE AWARD NUMBER HERE]*** *do not include human subjects research as defined in 15 CFR § 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 CFR § 27.104(d); or (2)* ***approved*** *by an outside Institutional Review Board in accordance with 15 CFR § 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 TBCP 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.)
- Refer to the HSR Guidance Document for a full sample memo

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 educational practices, such as:

(1) research on regular and special education instructional strategies, or

(2) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

EDUCATIONAL TESTS, 15 CFR § 27.104(d)(2)

The research only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording). At least one of the following criteria must be met:

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

(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, or reputation; or

(3) the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 27.111(a)(7).

More Common HSR Exemptions Cont.

BENIGN BEHAVIORAL INTERVENTIONS, 15 CFR § 27.104(d)(3)

The research involves benign behavioral interventions in conjunction with the collection of information from an adult subject if the subject consents to the intervention 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;

(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; or

(3) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 27.111(a)(7).

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 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:

(1) The identifiable private information or identifiable biospecimens are publicly available;

(2) 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;

(3) the research involves only information collection and analysis involving the investigator's use of identifiable health information; or

(4) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities.

RESEARCH SUPPORTED BY A FEDERAL AGENCY, 15 CFR § 27.104(d)(5)

Research and demonstration projects that are conducted or supported by a Federal agency, and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs:

(1) Each Federal agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal agency conducts or supports under this provision.

More Common HSR Exemptions Cont.

STORAGE FOR SECONDARY RESEARCH, 15 CFR § 27.104(d)(7)

Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by § 27.111(a)(8).

SECONDARY RESEARCH FOR WHICH BROAD CONSENT IS REQUIRED, 15 CFR § 27.104(d)(8)

Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(1) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable bio-specimens was obtained in accordance with § 27.116(a)(1) through (4), (a)(6), and (d);

(2) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § 27.117;

(3) An IRB conducts a limited IRB review and makes the determination required by § 27.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and

(4) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

INSTITUTIONAL REVIEW BOARD

Institutional Review Board (IRB) Review

- If your research cannot 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. **In this scenario, contact your FPO for further guidance before proceeding.**
- IRB review requires that you:
  - Assess risks and benefits to the subjects
  - Develop informed consent procedures for all subjects
  - Protect the privacy of participant data

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 must be submitted before conducting any research or surveys, and must be received before your period of performance end date.

Q&A

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THANK YOU

NTIA

DEPARTMENT OF COMMERCE

UNITED STATES OF AMERICA