BROADBANDUSA
CONNECTING AMERICA'S COMMUNITIES

Human Subjects Research (HSR)

Broadband Technology Opportunities Program (BTOP)

Laura Breeden

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Agenda

- Overview and Disclaimer
- What is Human Subjects Research?
- Common Exemptions
- What to Do
- Q&A

Overview and Disclaimer

- The Department of Commerce (DOC) must certify that the research elements of projects adequately protect human subjects.
- Section M.06 of the DOC Financial Assistance Standard Terms and Conditions incorporates HSR requirements.
- The 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 that provide additional protection for prisoners, pregnant women, fetuses, and children.

What is Research?

- "Research" is a systematic investigation designed to develop or contribute to ***generalizable knowledge*:**
  - Project may include research even if BTOP is not considered "research" for other purposes.
  - DOC defines "research" broadly to encompass the study, testing, or evaluation of human behavior, reactions, and thought processes as well as tangible study of the human body.

What is a Human Subject?

- A "human subject" is a living individual *about whom* an investigator conducting research obtains either:
  - Data through intervention or interaction with the individual, or
  - Identifiable private information.

Basic Requirement

- By **June 22, 2011,** each PCC and SBA grantee must provide the information necessary for NTIA to certify one of the following:
  - The grantee is not conducting HSR;
  - The grantee is conducting HSR, but it is exempt from the regulations; OR
  - The research procedures have previously been approved by an Institutional Review Board (IRB).

HSR Activities

- The regulations state that no federal funds can be expended for HSR unless the research procedures have previously been approved by an IRB or the HSR is exempt.
- Therefore, you must not conduct any HSR until documentation substantiating an exemption or IRB approval is approved by the Grants Office.
- You MAY perform protocol or instrument development related to HSR.

Exemptions - Overview

Common Exemptions:

27.101(b)(1): Educational research

27.101(b)(2): Educational tests, surveys, interviews, and observations of public behavior

27.101(b)(4): Use of previously existing data

Educational Research

- There is an EXEMPTION for research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
  - (i) research on instructional strategies, or
  - (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

- *Examples: Observation of student-teacher interactions, videos of instruction.*

Educational Tests

- Educational tests (cognitive, diagnostic, aptitude, achievement) are EXEMPT if either:
  - Information is NOT recorded so that human subjects can be identified, directly or through identifiers, OR
  - Disclosure of subjects' responses could NOT reasonably place subjects at risk of liability or damage their financial standing, employability, or reputation.

- *Example: Pre- and post-tests for a computer skills workshop, if they don't include the participants' names, email addresses, or other identifying information.*

Surveys and Interviews

- Survey or interview procedures are EXEMPT if:
  - The human subjects are of legal age (generally, 18) to consent to procedures involved in the research, AND
  - EITHER
    - Information is NOT recorded so that human subjects can be identified, directly or through identifiers, OR
    - Disclosure of subjects' responses could NOT reasonably place subjects at risk of liability or damage their financial standing, employability, or reputation.

Surveys and Interviews - Examples

Examples of exempt survey and interview procedures:

Phone surveys of adults to determine barriers to broadband adoption, where results are not associated with individual respondents (or would not expose them to harm).

Interviews of adults to assess interest in subscribing to broadband service, where responses are not reasonably likely to expose the participants to risks or harm.

Observation of Public Behavior

- Observation of public behavior is EXEMPT if either:
  - Information is NOT recorded so that human subjects can be identified, directly or through identifiers, OR
  - Disclosure of subjects' responses could NOT reasonably place subjects at risk of liability or damage their financial standing, employability, or reputation.
- BUT, if subjects are under 18, the exemption applies only if the investigators do not participate in the activities being observed.

- *Example: Counts of people, including children, walking into PCC.*

Existing Data

- Collection or study of existing data, documents, or records is EXEMPT, if:
  - Data sources are publicly available, OR
  - Information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers.
- To qualify, the data must be in existence *before* the project begins.

What To Do If Not Conducting HSR

- If you are **not** conducting HSR, send your FPO a letter by **June 22, 2011**, explaining why your data collection and analysis activities do not qualify as HSR.

- *Example: Data collection activities are not research if they are not intended to develop or contribute to generalizable knowledge.*

Exempt Versus Not Exempt

What To Do If Exempt

- If you believe your HSR is exempt, send your FPO a letter using the template in Attachment B of the HSR Guidance, by **June 22, 2011**.
- NTIA will review the letter and provide a recommendation to the Grants Office.
- For more info on exemptions, please refer to 15 CFR § 27.101(b). 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 http://ohrp.cit.nih.gov/search/irbsearch.aspx?styp=bsc for registered IRBs.

Institutional Review Board Review Basics

- 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.

IRBs and Vulnerable Populations

- Research subject to IRB review must include safeguards to protect the rights and welfare of vulnerable populations.
- Under the HSR regulations, vulnerable populations include:
  - Children,
  - Prisoners,
  - Pregnant women,
  - Mentally disabled persons, and
  - Economically or educationally disadvantaged persons.

Q&A

BTOP Compliance Contact for Human Subjects Research:

Katherine Scott
kscott@ntia.doc.gov
(202) 482-2205