BROADBANDUSA
CONNECTING AMERICA'S COMMUNITIES

FREQUENTLY ASKED QUESTIONS (FAQ)
Broadband Technology Opportunities Program
Protection of Human Subjects in Research

1. How do I get additional information about protection of human subjects in research?

   Please contact your Federal Program Officer (FPO) for additional information related to the treatment of human subjects in research for your project. Francine Jefferson also is available for general questions related to the topic, and her email address is fjefferson@ntia.doc.gov.

2. How do we determine whether our data collection activities constitute "research" under the regulations?

   The definition of "research" in the regulations hinges on whether your information collection activities are "a systematic investigation, including research development, testing and evaluation, designed to *develop or contribute to generalizable knowledge*." The U.S. Department of Justice's Office of Justice Programs (OJP) provides more guidance for determining whether an activity constitutes research involving human subjects.

   For example, program evaluations, program assessments, or other activities related to internal improvements in service or quality assurance purposes (e.g., customer satisfaction surveys) would not contribute to generalizable knowledge. However, program evaluations, program assessments, demonstration projects, or other related activities would contribute to generalizable knowledge if they were:

   - Conducted to examine whether the program had the desired effect on program participants, and that evaluation can inform other programs;
   - Conducted with the intent to replicate the program;
   - Designed to draw general conclusions; and/or
   - Designed to inform policymakers.

   A decision tree which may help determine if your activities meet the definition of "research" can be found at http://www.ojp.gov/funding/pdfs/decision_tree.pdf. Please refer to this guidance as you evaluate the information collection activities proposed for your BTOP project.

3. What do we do if we think our activities are not "research"?

   Please send a response to your FPO by June 22, 2011 (if in email) or postmarked by June 22 (if by USPS) stating that your activities do not fall under the definition of "research," and provide a brief description of the activities to support your statement. A template of the letter can be found in Attachment D of the Guidance for Protection of Human Subjects, which is posted online at http://www2.ntia.doc.gov/files/btop_hsr_guidance.pdf.

4. We plan to apply for approval of our research approach from the Institutional Review Board (IRB), but we do not expect to have a determination by the deadline of June 22. How should we respond to the request?

   Please send a response to NTIA before the deadline stating that you have applied, or intend to apply, for IRB approval. NTIA will follow up with your organization to obtain the determination when you receive it, and we will proceed with our review at that time.