

Appendix I. Protection of Human Subjects Research and Evaluation

Most evaluations of TOP projects involve human subjects (e.g., project staff, end users, beneficiaries, partners). Federal policy defines a human subject as an individual about whom an investigator conducting research obtains:

- data through intervention or interaction with an individual (e.g., videotaping people, observing children using new software, surveying personnel regarding a new delivery of service to a client); or
- information through patient records, a company's customer data, web use logs, etc.

For a more detailed overview on human subject research, the Department of Health and Human Services Office of Human Research Protection provides a helpful guidebook on their website at http://ohrp.osophs.dhhs.gov/irb/irb_guidebook.htm.

If your project is designated for an award and your evaluation involves human subjects, you will need to document how you plan to protect human subjects in your evaluation. You will be required to request that the Department of Commerce either:

- accept an approval of your evaluation plan by an Institutional Review Board (IRB) that has been approved by the U.S. Department of Health and Human Services¹, OR
- approve an exemption for your evaluation plan. All eligible exemptions for research and evaluations involving human subjects are listed in Part 27 of Title 15 of the Code of Federal Regulations, the Common Rule for Protection of Human Subjects.

On TOP's website at http://www.ntia.doc.gov/top/granteeresources/handbooks/hsr_checklist.htm you will find a checklist that can be used to determine if human subjects are involved in your research project, or if an exemption applies. The Department of Commerce regulations are available online at <http://www.doc.gov/oebam/gforms.htm>.

TOP recognizes that most applicants will not have the full details of their evaluation available for submission to an IRB or request an exemption prior to the April 27, 2004 application deadline. Therefore, TOP will allow applicants additional time after the grant is awarded to fulfill this requirement.

¹ The U.S. Department of Health and Human Services maintains a listing of approved IRBs at <http://ohrp.cit.nih.gov/search/asearch.asp#ASUR>.

Appendix II. Sample Budget Narrative

Appendix III. Application Forms

This section contains blank copies of the following application forms needed to complete a TOP application:

- C Standard Form 424, *Application for Federal Assistance*
- C Standard Form 424A, *Budget Information–Non-Construction Programs*

As indicated in the *Announcement*, your application will be not be considered in the current grant round and will be returned if it lacks any of the following required elements: (1) a Standard Form 424, *Application for Federal Assistance*, with an original signature; (2) a Project Narrative; and (3) a Budget Narrative.

TOP has online tools available on its website, <http://www.ntia.doc.gov/top>, that can generate the Standard Form 424 and Standard Form 424A. The online forms have self-correcting features and automatically totals each item to ensure accuracy. In addition, TOP maintains links to copies of blank forms in PDF format on its website that can be printed and used in your application. If you need additional copies of forms or materials, you may also contact the TOP office (202) 482-2048.

If you create the forms online, you must print them, sign in the appropriate locations, and include them with your application. **TOP will not accept the electronic submission of any forms or other information.**