B. COLLECTION OF INFORMATION EMPLOYINGSTATISTICAL METHODS

B.1. Respondent Universe and Sampling Methods

All participants in an OHRP Training activity will be asked to complete an evaluation form. Sampling is not appropriate in these circumstances, due to the immediacy of the data collection activity. All Institutional Review Board (IRB) chairs identified by the OHRP will be sent a letter inviting participation in the organizational assessment. IRB chairs will select IRB members to participate within their organization.

B.2. Procedures for the Collection of Information

The protocol for administration of the *Initial Assessment Survey* questionnaire is as follows:

Immediately following the completion of each educational activity sponsored by OHRP, questionnaires will be distributed to all participants. All participants will be asked to complete the survey, and return it to a designated place that is convenient to the room exit.

Approximately three to six months subsequent to the educational event, a list of attendees will be provided to the survey coordinator. A letter will be emailed to each attendee inviting attendees to participate in the *Follow-up Assessment Survey*; the respondent will have the option to complete an online survey immediately via an embedded link to the web site containing the survey form, or by going later to the designated web site.

All IRB chairs in the OHRP database will be mailed a request for completion of the S*urvey of Organization Representatives* regarding training needs, and will be asked to solicit participation by others in their IRB. Completion of the survey will be web-based.

B.3. Methods to Maximize Response Rates and Deal with Nonresponse

An individual dedicated to survey distribution and retrieval will be present at each conference**.** An embedded link to the web survey will be included in each emailed request for participation.

B.4. Test of Procedures or Methods to be Undertaken

Respondents were recruited using a recent attendee list from an OHRP National Conference and Regional Community Forum and the OHRP IRB Registration List. Participants were interviewed by telephone. Each respondent completed one of three forms*: Initial Assessment Survey* (3 respondents); *Follow-up Assessment Survey* (3 respondents); or *Survey of Organization Representatives* (5 respondents). The instruments were pre-tested for content, wording and time needed for administration. This pre-test was considered adequate for the purposes of this study.

B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The statistical aspects of this study design were developed by James Bell Associates, 1001 19th Street North, Arlington VA 22209, 703-528-3230, in consultation with OHRP. The organization responsible for data collection activities and analysis during the first two years of the evaluation process is James Bell Associates. In subsequent years the assessment activities will be transitioned to the OHRP.

Attachment

Legislative Authority

From the U.S. Code Online via GPO Access
[wais.access.gpo.gov]
[Laws in effect as of January 7, 2003]
[Document not affected by Public Laws enacted between
January 7, 2003 and February 12, 2003]
[**CITE**: **42USC289**]

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 6A--PUBLIC HEALTH SERVICE

SUBCHAPTER III--NATIONAL RESEARCH INSTITUTES

Part H--General Provisions

Sec. 289. Institutional review boards; ethics guidance program

(a) The Secretary shall by regulation require that each entity which applies for a grant, contract, or cooperative agreement under this chapter for any project or program which involves the conduct of
biomedical or behavioral research involving human subjects submit in or with its application for such grant, contract, or cooperative agreement assurances satisfactory to the Secretary that it has established (in accordance with regulations which the Secretary shall prescribe) a board (to be known as an ``Institutional Review Board'') to review biomedical and behavioral research involving human subjects conducted at or supported by such entity in order to protect the rights of the human subjects of such research.

(b)(1) The Secretary shall establish a program within the Department of Health and Human Services under which requests for clarification and guidance with respect to ethical issues raised in connection with biomedical or behavioral research involving human subjects are responded to promptly and appropriately.

(2) The Secretary shall establish a process for the prompt and appropriate response to information provided to the Director of NIH respecting incidences of violations of the rights of human subjects of research for which funds have been made available under this chapter. The process shall include procedures for the receiving of reports of such information from recipients of funds under this chapter and taking appropriate action with respect to such violations.

(July 1, 1944, ch. 373, title IV, Sec. 491, as added Pub. L. 99-158,

Sec. 2, Nov. 20, 1985, 99 Stat. 873.)

Section Referred to in Other Sections`

This section is referred to in sections 280e, 283f, 287c, 289a-1 of this title.