1843) (BHC Act) and Regulation Y (12 CFR Part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act. Additional information on all bank holding companies may be obtained from the National Information Center website at *www.ffiec.gov/nic/*.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than November 17, 2008.

A. Federal Reserve Bank of New York (Ivan Hurwitz, Bank Applications Officer) 33 Liberty Street, New York, New York 10045–0001:

1. Banco Santander S.A., Boadilla, Spain, to acquire 75.1 percent of the voting shares of Sovereign Bancorp, Inc., Philadelphia, Pennsylvania, and thereby indirectly acquire Sovereign Bank, Wyomissing, Pennsylvania, and thereby engage in operating a savings and loan associationm pursuant to section 225.28(b)(4)(ii) of Regulation Y.

Board of Governors of the Federal Reserve System, October 20, 2008.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E8–25296 Filed 10–22–08; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Toxicology Program (NTP); NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); Availability of the Biennial Progress Report of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM): NIH Publication No. 08–6529

AGENCY: National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

ACTION: Availability of the ICCVAM Biennial Progress Report.

SUMMARY: NICEATM announces the availability of the ''Biennial Progress Report: Interagency Coordinating Committee on the Validation of Alternative Methods: 2006–2007.'' In accordance with requirements of the ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*–3), this report describes progress and activities during 2006–2007 by ICCVAM and NICEATM. The report is available on the NICEATM–ICCVAM Web site at *http://iccvam.niehs.nih.gov/about/ICCVAMrpts.htm.* Copies can also be requested from NICEATM at the address given below.

ADDRESSES: Requests for copies of the report should be sent by mail, fax, or email to Dr. William S. Stokes, NICEATM Director, NIEHS, P.O. Box 12233, MD EC–17, Research Triangle Park, NC 27709, (phone) 919–541–2384, (fax) 919–541–0947, (e-mail) *niceatm@niehs.nih.gov.* Courier address: NICEATM, 79 T.W. Alexander Drive, Building 4401, Room 3128, Research Triangle Park, NC 27709.

FOR FURTHER INFORMATION CONTACT: Dr. William S. Stokes, NICEATM Director (919–541–2384 or *niceatm@niehs.nih.gov*).

SUPPLEMENTARY INFORMATION:

Background Information on ICCVAM, NICEATM, and SACATM

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that use, generate, or disseminate toxicological information. ICCVAM conducts technical evaluations of new, revised, and alternative methods with regulatory applicability. ICCVAM also promotes scientific validation, regulatory acceptance, and national and international harmonization of toxicological test methods that more accurately assess safety and hazards of chemicals and products and that refine, reduce, and replace animal use. The ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*–3, available at *http://iccvam.niehs.nih.gov/docs/about_docs/PL106545.pdf*) established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM. NICEATM administers ICCVAM and provides scientific and operational support for ICCVAM-related activities. NICEATM and ICCVAM collaborate in evaluating new and improved test methods applicable to the needs of Federal agencies. Additional information about ICCVAM and NICEATM can be found at the NICEATM–ICCVAM Web site (*http://iccvam.niehs.nih.gov*).

ICCVAM, NICEATM, and the Director of the NIEHS receive advice regarding statutorily mandated duties of ICCVAM and activities of NICEATM from the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM), a Federally chartered advisory committee. Additional information about SACATM, including the charter, roster, and records of past meetings, can be found at *http://ntp.niehs.nih.gov/go/167.*

Dated: October 8, 2008.

Samuel H. Wilson,

Acting Director, National Institute of Environmental Health Sciences and National Toxicology Program.

[FR Doc. E8–25223 Filed 10–22–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Final Guidance on Engagement of Institutions in Human Subjects Research

AGENCY: Office for Human Research Protections, Office of Public Health and Science, Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: The Office for Human Research Protections (OHRP), Office of Public Health and Science, is announcing the availability of a guidance document entitled, ''OHRP Guidance on Engagement of Institutions in Human Subjects Research.'' The guidance document describes: (1) Scenarios that, in general, would result in an institution being considered engaged in a human subjects research project; (2) scenarios that would result in an institution being considered not engaged in a human subjects research project; and (3) IRB review considerations for cooperative research in which multiple institutions are engaged in the same non-exempt human subjects research project. The guidance document is intended primarily for institutional review boards (IRBs), research administrators and other relevant institutional officials, investigators, and funding agencies that may be responsible for the conduct, review and oversight of human subject research that is conducted or supported by the Department of Health and Human Services (HHS).

The guidance document announced in this notice finalizes the draft guidance with the same title that was made available for public comment in the **Federal Register** on December 8,

2006 (71 FR 71169). OHRP received twenty-four comments on the draft guidance document, and those comments were considered as the guidance was finalized. The final guidance document replaces two existing OHRP guidance documents on the engagement of institutions in human subjects research: (1) The January 26, 1999, document on ''Engagement of Institutions in Research,'' and (2) the December 23, 1999, document on ''Engagement of Pharmaceutical Companies in HHS Supported Research.''

DATES: Comments on OHRP guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled, ''OHRP Guidance on Engagement of Institutions in Human Subjects Research,'' to the Division of Policy and Assurances, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–453–6909. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance document. Submit written comments to ENGAGEMENT GUIDANCE COMMENTS, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Comments also may be sent via e-mail to *ohrp@hhs.gov* or via facsimile at 240–453–6909.

FOR FURTHER INFORMATION CONTACT: Ms. Julie Kaneshiro, Office for Human Research Protections, Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852; 240–453–6900; e-mail *julie.kaneshiro@hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

OHRP, Office of Public Health and Science, is announcing the availability of a guidance document entitled, ''OHRP Guidance on Engagement of Institutions in Human Subjects Research.'' HHS, through OHRP, regulates research involving human subjects conducted or supported by HHS in regulations codified at 45 CFR part 46. The HHS human subject protection regulations stipulate substantive and procedural requirements for the conduct of HHS-conducted or -supported research, including requirements for review and approval by an IRB before research involving human subjects may begin, criteria for IRB approval of research, and requirements for informed consent or the waiver of informed consent.

The HHS protection of human subjects regulations at 45 CFR 46.103(a) and (b) require that each institution ''engaged'' in human subjects research that is conducted or supported by HHS (1) provide OHRP with a satisfactory assurance that the institution will comply with the regulations, and (2) certify to the HHS agency conducting or supporting the research that the research has been reviewed and approved by an IRB designated in the assurance and will be subject to continuing review by an IRB, unless all the research meets one or more of the categories for exemption from the regulatory requirements under 45 CFR 46.101(b). The Federalwide Assurance (FWA) is the only type of assurance currently accepted by OHRP. The FWA generally identifies required policies and procedures for the institution and describes the activities to which the regulations apply.

On January 26, 1999, the Office for Protection from Research Risks (OPRR), OHRP's predecessor office, issued guidance on ''Engagement of Institutions in Research.'' OPRR later issued guidance on ''Engagement of Pharmaceutical Companies in HHS Supported Research,'' dated December 23, 1999.

In the **Federal Register** of December 8, 2006 (71 FR 71169), OHRP announced the availability of a draft guidance document entitled, ''OHRP Guidance on Engagement of Institutions in Human Subjects Research,'' dated October 27, 2006, which OHRP proposed would replace the two guidance documents that had been issued in 1999. OHRP received twenty-four comments on the draft guidance and those comments were considered as the guidance was finalized. See section II. Discussion of Public Comments for a summary of the main comments received and OHRP's responses.

This guidance is only applicable to HHS-conducted or -supported research projects that have been determined to involve human subjects and that are not exempt under the HHS regulations at 45 CFR 46.101(b). Once an activity is determined to involve non-exempt human subjects research, this guidance can be used to determine whether an institution involved in some aspect of the research would be considered ''engaged'' in human subjects research, and would thus need to (1) hold or obtain an applicable OHRP-approved FWA, and (2) certify to the HHS agency conducting or supporting the research that the research has been reviewed and approved by an IRB designated in the assurance and will be subject to continuing review by an IRB.

II. Discussion of Public Comments

Most of the comments expressed general support for OHRP's draft guidance document. Some comments suggested clarifying changes and others recommended more substantive changes to the scenarios described in the draft guidance. All of the comments received were considered as the guidance was finalized. A discussion of the main comments follows.

Institutions Engaged in Human Subjects Research

Awardee Institutions

OHRP's draft guidance document proposed that institutions that receive an award through a grant, contract, or cooperative agreement directly from HHS for non-exempt human subjects research (i.e., awardee institutions) would generally be considered engaged in human subjects research, even where all activities involving human subjects are carried out by agents of another institution. A few of the commenters urged OHRP to reconsider its view that such awardee institutions should generally be considered engaged in human subjects research when all activities involving human subjects are carried out by agents of another institution. The commenters noted that considering such awardee institutions to be engaged in human subjects research often results in duplicative review by IRBs and administrative burden for awardee institutions that choose to modify their FWAs to rely on another institution's IRB to satisfy the regulatory requirements under 45 CFR part 46. These commenters questioned whether human subjects were offered greater protections by considering such awardee institutions to be engaged in human subjects research.

OHRP believes that institutions that receive an award directly from HHS for non-exempt human subjects research should generally be considered engaged in human subjects research. However, the office understands these commenters' concerns and agrees that in some circumstances, institutions that receive an award for non-exempt human subjects research, but that do not carry out any of the activities involving human subjects, should not be considered engaged in the human subjects research. OHRP will continue to consider this issue in consultation with the HHS funding agencies.

Institutions Not Engaged in Human Subjects Research

Release of Identifiable Private Information or Biological Specimens

In the **Federal Register** of December 8, 2006 (71 FR 71169), OHRP noted that the office was particularly interested in the public's comments on the proposal that institutions whose employees or agents release to investigators at another institution identifiable private information or identifiable biological specimens pertaining to the subjects of the research, not be considered engaged in human subjects research.

The public comments supported this proposed scenario. OHRP retained this scenario in the final guidance document, with only minor clarifying changes (see scenario B.(6) in the final guidance).

Administration of Clinical Trial-Related Medical Services

In the **Federal Register** of December 8, 2006 (71 FR 71169), OHRP also noted that the office was particularly interested in the public's comments on the proposal that institutions (including private practices) not selected as research sites whose employees or agents administer clinical trial-related medical services, not be considered engaged in human subjects research provided that specified conditions were met. One of the proposed conditions was that the institution's employees or agents do not administer the primary study interventions being tested under the protocol.

The public comments on this proposed scenario were generally supportive, but several commenters sought clarifications on some of the proposed conditions. In addition, a few of the commenters recommended that OHRP expand the scenario to permit the employees or agents of an institution not selected as a research site to administer the study intervention being tested or evaluated under the protocol, and still not consider such an institution to be engaged in human subjects research.

In the final guidance, OHRP retained the proposed scenario, with minor changes in response to the public comments (see scenario B.(2) in the final guidance). However, OHRP also has included another scenario in the final guidance that would allow employees or agents of an institution not initially selected as a research site to administer the study interventions being tested or evaluated under the protocol, provided that this occurs on a one-time or short-term basis, and specified conditions are met (see scenario B.(3) in the final guidance). OHRP believes this is responsive to the concern raised in a public comment that research subjects are sometimes unexpectedly hospitalized or otherwise unexpectedly unable to receive a study intervention being tested or evaluated in a protocol from an institution that had previously been designated as a research site.

III. Comments

Interested persons may submit comments regarding this guidance document to OHRP at any time. Please see the **ADDRESSES** section for information on where to submit written comments.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance document on OHRP's Web site at *http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.htm.*

Dated: October 16, 2008.

Ivor A. Pritchard,

Acting Director, Office for Human Research Protections.

[FR Doc. E8–25177 Filed 10–22–08; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Community-Based Abstinence Education Performance Progress Report.

OMB No.: 0970–0272.

Description: The discretionary funding Community-Based Abstinence Education Program (CBAE) is authorized by Title XI, Section 1110, of the Social Security Act (using the definitions contained in Title V, Section 510(b)(2) of the Social Security Act).

Performance Progress Report/Program Narrative

The CBAE Performance Progress Report/Program Narrative is a semiannual report form through which grantees report performance information used by the Administration for Children and Families (ACF) to evaluate each grantee's compliance with Federal law and progress toward achieving its goals. Performance information includes:

Description of major activities and accomplishments during the reporting period;

Description of deviations or departures from the original project;

Description of significant findings and events;

Description of dissemination activities;

Description of other activities; and

Description of activities planned for the next reporting period, including goals and objectives.

Program-Specific Performance Measure

The CBAE program is developing a program-specific performance measure in response to the PART review (a process by which the Office of Management and Budget analyzes and rates a Federal program's procedures and strategies for evaluating its effectiveness), for which the program received a rating of Adequate. In an effort to gather program-specific data on rates of abstinence pre- and post-program participation, ACF and the Office of Management and Budget determined that a program-specific performance measure should be developed to assess key outcomes among program participants. The CBAE office convened a panel of abstinence education experts to gather input on the measure, and, based on the input provided, the CBAE office is developing the measure. CBAE grantees will be required to ask ten to fifteen questions of the youth served in a pre- and post-survey, as well as a representative sample of the youth served in a post-post-survey.

The questions are being carefully constructed by an experienced evaluator to measure initiation and discontinuation of sexual intercourse as well as two key predictors of initiation: Sexual values and behavioral intentions.

The program office will collect and compile data to establish baselines and ambitious targets for the program-specific performance measure. The data will be aggregated and results will be shared with the public as they become available.

Respondents: Performance Progress Report/Program Narrative—Non-profit community-based organizations, faith-based organizations, schools/school districts, universities/colleges, hospitals, public health agencies, local governments, Tribal councils, small businesses/for-profit entities, housing authorities, etc. Program-Specific Performance Measure—Youth Participants.