General description of report: This information collection is mandatory (12 U.S.C. 1844(c)). Confidential treatment is not routinely given to the data in these reports. However, confidential treatment for the reporting information, in whole or in part, can be requested in accordance with the instructions to the form, pursuant to sections (b)(4), (b)(6), and (b)(8) of the Freedom of Information Act (5 U.S.C. 522(b)(4)).

Abstract: The FR Y–11S is an abbreviated reporting form that collects four data items: Net income, total assets, equity capital, and total off-balance-sheet data items. The FR Y–11S is filed annually, as of December 31, by top-tier BHCs for each individual nonbank subsidiary (that does not meet the criteria for filing the detailed report) with total assets of at least $50 million, but less than $250 million, or with total assets greater than 1 percent of the total consolidated assets of the top-tier organization.


   Agency form number: FR Y–7NS, FR Y–7Q.
   OMB control number: 7100–0125.
   Frequency: Annually and quarterly.
   Reporters: Foreign banking organizations.
   General description of report: This information collection is mandatory (12 U.S.C. 1844(c), 3106(c), and 3106). Confidential treatment is not routinely given to the data in these reports. However, confidential treatment for information, in whole or in part, on any of the reporting forms can be requested in accordance with the instructions to the form, pursuant to sections (b)(4) and (b)(6) of the Freedom of Information Act (5 U.S.C. 522(b)(4) and (b)(6)).

Abstract: The FR Y–7NS collect financial information for non-functionally regulated U.S. nonbank subsidiaries held by FBOs other than through a U.S. BHC, U.S. FHC, or U.S. bank. The FR Y–7NS is filed annually, as of December 31, by top-tier FBOs for each individual nonbank subsidiary (that does not meet the filing criteria for filing the detailed report) with total assets of at least $50 million, but less than $250 million. The FR Y–7Q collects consolidated regulatory capital information from all FBOs either quarterly or annually. FBOs that have effectively elected to become FHCS file the FR Y–7Q quarterly. All other FBOs (those that have not elected to become FHCS) file the FR Y–7Q annually.


DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Comments on Human Subjects Protections in Scientific Studies

AGENCY: The Presidential Commission for the Study of Bioethical Issues, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Presidential Commission for the Study of Bioethical Issues is requesting public comment on the Federal and international standards for protecting the health and well-being of participants in scientific studies supported by the Federal Government.

DATES: To assure consideration, comments must be received by May 2, 2011.

ADDRESSES: Individuals, groups, and organizations interested in commenting on this topic may submit comments by e-mail to info@bioethics.gov or by mail to the following address: Public Commentary, The Presidential Commission for the Study of Bioethical Issues, 1425 New York Ave. NW., Suite C–100, Washington, DC 20005.


SUPPLEMENTARY INFORMATION: On November 24, 2009, the President established the Presidential Commission for the Study of Bioethical Issues (Commission) to advise him on bioethical issues generated by novel and emerging research in biomedicine and related areas of science and technology. The Commission is charged to identify and promote policies and practices that assure ethically responsible conduct of scientific research, healthcare delivery,
and technological innovation. In undertaking these duties, the Commission seeks to identify and examine specific bioethical, legal, and social issues related to potential scientific and technological advances; examine diverse perspectives and possibilities for international collaboration on these issues; and recommend legal, regulatory, or policy actions as appropriate.

The Commission has begun a review of the current rules and standards for protecting human subjects in scientific studies supported by the Federal Government. The President requested this study on November 24, 2010, following revelations that the U.S. Public Health Service supported research on sexually transmitted diseases in Guatemala from 1946 to 1948 involving the intentional infection of vulnerable populations. President Obama asked the Commission Chair “to convene a panel to conduct * * * a thorough review of human subjects protection to determine if Federal regulations and international standards adequately guard the health and well-being of participants in scientific studies supported by the Federal Government.”

The President charged the Commission to seek the insights and perspective of international experts and consult with counterparts in the global community. The Commission will provide the President with a report of its findings and recommendations later this year.

To implement this mission, the Commission wishes to develop a thorough understanding of the current U.S. and international standards for protecting the health and well-being of participants in scientific studies supported by the Federal Government. To this end, the Commission is inviting interested parties to provide input and advice through written comments. Among other issues, the Commission is interested in receiving comments on the existing standards for protecting human subjects, both domestically and internationally; how the current system of global research works in practice; and the ethical and social justice issues that emerge from the current research system. Comments concerning the benefits of medical research; differences across global norms and standards; standards for ancillary care and post-trial access to treatment; trial design; duties to participants; challenges, if any, faced by U.S.-funded researchers working internationally, or international research involving U.S.-funded research; and other specific information are all especially welcome.

The Commission is under a very tight deadline and would appreciate comments within 60 days. Please address comments by e-mail to info@bioethics.gov, or by mail to the following address: Public Commentary, The Presidential Commission for the Study of Bioethical Issues, 1425 New York Ave. NW., Suite C–100, Washington, DC 20005. Comments will be publicly available, including any personally identifiable or confidential business information that they contain. Trade secrets should not be submitted.

Dated: February 17, 2011.
Valerie H. Bonham,
Executive Director, The Presidential Commission for the Study of Bioethical Issues.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Subcommittee on Procedures Review, Advisory Board on Radiation and Worker Health (ABRWH), National Institute for Occupational Safety and Health (NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–96, 43), the Centers for Disease Control and Prevention (CDC) announces the following meeting for the aforementioned subcommittee:

Time and Date: 9 a.m.–5 p.m., March 22, 2011.
Place: Cincinnati Airport Marriott, 2395 Progress Drive, Hebron, KY 41018. Telephone (859) 334–4611, Fax (859) 334–4619.
Status: Open to the public, but without a public comment period. To access by conference call dial the following information: (866) 659–0537, Participant Pass Code 9932701.

Background: The ABRWH was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the compensation program. Key functions of the ABRWH include providing advice on the development of probability of causation guidelines that have been promulgated by the Department of Health and Human Services (HHS) as a final rule; advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule; advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program; and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC).

In December 2000, the President delegated responsibility for funding, staffing, and operating the ABRWH to HHS, which subsequently delegated this authority to CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, and will expire on August 3, 2011.

Purpose: The ABRWH is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advising the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is a reasonable likelihood that such radiation doses may have endangered the health of members of this class. The Subcommittee on Procedures Review was established to aid the ABRWH in carrying out its duty to advise the Secretary, HHS, on dose reconstructions. The Subcommittee on Procedures Review is responsible for overseeing, tracking, and participating in the reviews of all procedures used in the dose reconstruction process by the NIOSH Division of Compensation Analysis and Support (DCAS) and its dose reconstruction contractor.