**Seleda Perryman,**

*Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.*

[FR Doc. 2010–23767 Filed 9–22–10; 8:45 am]

**BILLING CODE 4150–05–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Draft Revision of the Federalwide Assurance

**AGENCY:** Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health, Office for Human Research Protections.

**ACTION:** Notice.

**SUMMARY:** The Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health, is announcing the availability of the draft revised Federalwide Assurance (FWA) form and Terms of Assurance, and is seeking comment on these draft documents. OHRP is proposing several changes to simplify and shorten the FWA form and Terms of Assurance. Institutions engaged in non-exempt human subjects research conducted or supported by the Department of Health and Human Services (HHS) must hold an OHRP-approved FWA. The draft revised FWA form and Terms of Assurance, when finalized, will supersede the current FWA documents available on the OHRP Web site at *http://www.hhs.gov/ohrp/assurances/assurances_index.html.* OHRP will consider comments received before implementing any revisions to the FWA documents.

**DATES:** Submit written comments by October 25, 2010.

**ADDRESSES:** Submit written requests for single copies of the draft revised FWA form and Terms of Assurance 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 301–402–2071. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft revised FWA documents.

You may submit comments, identified by docket ID number HHS–OPHS–2010–0023, by one of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Enter the above docket ID number in the "Enter Keyword or ID" field and click on "Search." On the next web page, click on the "Submit a Comment" action and follow the instructions.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Irene Stith-Coleman, PhD, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

Comments received, including any personal information, will be posted without change to *http://www.regulations.gov.*

**FOR FURTHER INFORMATION CONTACT:** Irene Stith-Coleman, PhD, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, 240–453–6900; e-mail *Irene.StithColeman@hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

#### I. Background

OHRP is announcing the availability of the draft revised FWA form and Terms of Assurance, and is seeking comment on these draft documents. Institutions engaged in non-exempt human subjects research conducted or supported by HHS must hold an OHRP-approved FWA. The draft revised FWA form and Terms of Assurance, when finalized, will supersede the current FWA documents available on the OHRP Web site at *http://www.hhs.gov/ohrp/assurances/assurances_index.html.* The current FWA form has been approved by the Office of Management and Budget for use through May 31, 2011.

The draft revised FWA form and Terms of Assurance have the following key changes in comparison to the current FWA documents:

(1) The current separate FWA forms for U.S. and non-U.S. institutions have been combined into a single form that will still collect the same basic information previously requested in the current separate forms, except as noted in items (3) and (4) below.

(2) The Terms of Assurance document has been shortened and simplified. In the current version, some portions of the text appear twice; those duplications have been eliminated by re-organizing portions of the document. In addition, there are several items covered in the current version that are either not required by the regulations to be part of an assurance, or which are addressed in the FWA form itself. These items have been eliminated from the Terms of Assurance document.

(3) The revised FWA form would replace the current requirement that all IRBs (both internal and external IRBs) relied upon by the institution be specifically designated with the requirement that only internal IRBs be specifically designated or that, if an institution does not have an internal IRB, only one external IRB be specifically designated. This change to the FWA form is being proposed in response to the recommendation from the Secretary's Advisory Committee on Human Research Protections (SACHRP) that the FWA be modified to remove the current requirement to designate specific IRBs within the assurance document itself, replacing this with a commitment by the institution to rely only on registered IRBs (see SACHRP's July 15, 2009 letter to the Secretary on the OHRP Web site at *http://www.hhs.gov/ohrp/sachrp/documents/20090715LettertoHHSSecretary.pdf*).

(4) The revised FWA form would no longer request submission of the HHS Institution Profile code or the Federal Entity Identification number.

(5) The revised FWA form would allow the FWA to be signed by the institution's signatory official electronically and eliminate the need for submission of a hard-copy signature page by mail or facsimile. Upon implementation of this change, OHRP intends to require that institutions submit all FWAs (including new submissions, updates, and renewals) using the electronic submission system available through the OHRP Web site at *http://ohrp.cit.nih.gov/efile/,* unless an institution lacks the ability to do so electronically. Such electronic submission currently is required for IRB registration. If an institution believed it lacked the ability to submit its FWA electronically, it would be required to contact OHRP by telephone or email and explain why it was unable to submit its FWA electronically.

(6) The standard period of approval for an FWA would be increased from the current 3-year period to a 5-year period.

#### II. Electronic Access

The draft revised FWA form and Terms of Assurance are available on OHRP's Web site at *http://www.hhs.gov/ohrp/requests/.*

#### III. Request for Comments

OHRP requests comments on the draft revised FWA form and Terms of Assurance. OHRP will consider all comments before implementing any revisions to the FWA documents.

Dated: September 16, 2010.

**Jerry Menikoff,**

*Director, Office for Human Research Protections.*

[FR Doc. 2010–23759 Filed 9–22–10; 8:45 am]

**BILLING CODE 4150–36–P**