(2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension.

Title of Information Collection: Reference Request for Applicants to the U.S. Public Health Service Commissioned Corps.

Form/OMB No.: OS–0937–0025.

Use: These forms will be used by individuals to apply for appointment in the U.S. Public Health Service Commissioned Corps and to obtain references as part of the application process. Information supplied on the forms will be used by appropriate Department officials to evaluate candidates for appointments.

Frequency: On Occasion.

Affected Public: Individuals or Households.

Annual Number of Respondents: 5,000.

Total Annual Responses: 5,000.

Average Burden Per Response: 24 min.

Total Annual Hours: 2,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov,* or call the Reports Clearance Office on (202) 690–6162. Written comments and recommendations for the proposed information collections must be received within 30 days of this notice directly to the Desk Officer at the address below:

OMB Desk Officer: John Kraemer, OMB Human Resources and Housing Branch, *Attention:* (OMB #0937–0025), New Executive Office Building, Room 10235, Washington, DC 20503.

Date: November 30, 2006.

Alice Bettencourt,

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

[FR Doc. E6–20915 Filed 12–7–06; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: OS–0990–0000]

30-Day Notice; Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: New Collection.

Title of Information Collection: Evaluation of Office on Women's Health Publications.

Form/OMB No.: OS–0990–New.

Use: To improve future publications and to demonstrate accountability of efforts, the office of Women's Health (OWH) will evaluate four health communications materials. Discussion groups and web-based or paper-based surveys will be used from randomly selected participants and returned response cards.

Frequency: 1 time.

Affected Public: Individuals or Households.

Annual Number of Respondents: 1648.

Total Annual Responses: 1648.

Average Burden per Response: 17.2 min.

Total Annual Hours: 472.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov,* or call the Reports Clearance Office on (202) 690–6162. Written comments and recommendations for the proposed information collections must be received within 30 days of this notice directly to the Desk Officer at the address below:

OMB Desk Officer: John Kraemer, OMB Human Resources and Housing Branch, *Attention:* (OMB #0990–New), New Executive Office Building, Room 10235, Washington, DC 20503.

Date: November 30, 2006.

Alice Bettencourt,

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

[FR Doc. E6–20916 Filed 12–7–06; 8:45 am]

BILLING CODE 4150–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Draft 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 draft guidance document entitled, ''OHRP Guidance on Engagement of Institutions in Human Subjects Research.'' The draft guidance document would revise and replace 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.'' To facilitate public review of the draft guidance document, OHRP has developed a table presenting a side-by-side comparison of OHRP's draft revised guidance document and the current guidance documents on the engagement of institution in human subjects research, which is available on the OHRP Web site at *http://www.hhs.gov/ohrp/requests/.*

OHRP's current engagement guidance documents and the proposed draft guidance document provide examples of when institutions generally would be considered to be engaged or not engaged in human subjects research. The draft document is intended primarily for institutional review boards (IRB), 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 HHS. OHRP will consider comments received before issuing the final guidance document.

DATES: Submit written comments by February 6, 2007.

ADDRESSES: Submit written requests for single copies of the draft 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, The Tower Building, 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 guidance. Submit written comments to ENGAGEMENT GUIDANCE COMMENTS, Office for Human Research Protections, The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Comments also may be sent via e-mail to *engagementohrp@hhs.gov.* or via facsimile at 301-402–2071.

FOR FURTHER INFORMATION CONTACT: Mr. Glen Drew, Office for Human Research Protections, Department of Health and Human Services, The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852; 301–496–7005; e-mail *glen.drew@hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Health and Human Services (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) require that each institution ''engaged'' in human subjects research that is conducted or supported by HHS provide OHRP with a satisfactory assurance that the institution will comply with the regulations, 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.

OHRP is proposing to replace these two documents with a single document, ''OHRP Guidance on Engagement of Institutions in Human Subjects Research,'' draft dated October 27, 2006. This guidance is only applicable to 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 submit an FWA to OHRP. Like OHRP's existing guidance documents on engagement, this draft document provides: (1) Examples of activities that, in general, would result in an institution being considered engaged in a human subjects research project; and (2) examples of activities that, in general, would result in an institution being considered *not* engaged in a human subjects research project. The draft guidance document proposes modifications to the set of examples of when an institution generally would be considered engaged or not engaged in human subjects research. The proposed modifications include combining, clarifying, and changing existing examples, as well as adding further examples and explanation.

To facilitate public review and comments, OHRP has created a comparison table presenting a side-by-side display of the text from OHRP's draft guidance document matched with the comparable text from the 1999 guidance documents. This table is available on the OHRP Web site at *http://www.hhs.gov/ohrp/requests/.* The table is not part of the draft guidance document.

II. Electronic Access

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

III. Request for Comments

OHRP is making its draft guidance document available for public comment. OHRP's revised guidance document on the engagement of institutions in human subjects research will be finalized and issued after the public comments have been considered.

OHRP is particularly interested in the public's comments on two examples of activities which *would not* result in the institution being considered engaged in a human subjects research project under OHRP's current draft guidance document:

1 *Example B(1):* Institutions whose employees or agents release to the investigators at another institution identifiable private information or identifiable biological specimens pertaining to the subjects of the research; and,

2 *Example B(7):* Institutions (including private practices) not selected as research sites whose employees or agents administer clinical trial-related medical services if all of the following conditions are met:

(a) The institution's employees or agents do not enroll subjects, or obtain the informed consent of any subject for research participation;

(b) The institution's employees or agents do not administer the primary study interventions being tested under the protocol;

(c) The institution's employees or agents provide only services that either are clinically indicated, or are dictated by the protocol but not clinically indicated, and would typically be performed as part of routine clinical monitoring and/or follow-up of subjects enrolled at a study site by clinical trial investigators, such as a blood test, chest X-ray, CT scan, medical history and physical examination, or an assessment and reporting of an adverse event;

(d) The investigator(s) from an institution engaged in the research retain responsibility for oversight of all protocol-related activities and assure that appropriate arrangements are made for any safety monitoring and adverse event reporting required under the IRB-approved protocol;

(e) When appropriate, the informed consent document states that follow-up data are to be provided to the investigators by the institution's employees or agents; and,

(f) When providing follow-up data to the investigators, the institution's employees or agents provide such data to the investigators in accord with the procedures described in the informed consent.

Proposed example (B)(1) would represent a modification in OHRP

policy. OHRP's current guidance document issued in 1999 states that an institution whose employees or agents release individually identifiable private information about subjects, for research purposes, without the subjects' explicit written permission is considered to be engaged in human subjects research. The proposed modification in guidance is based on the definition of human subject at 45 CFR 46.102(f), which states in part, ''human subject means a living individual about whom an investigator * * * conducting research obtains * * * identifiable private information.'' (emphasis added). OHRP has concluded that releasing identifiable private information for research purposes is not equivalent to obtaining identifiable private information; thus, an institution releasing such identifiable private information is not involved in an activity including a ''human subject'' as defined by the HHS protection of human subjects regulations. Therefore, the revised example would clarify that an institution, whose employees or agents release to the investigators at another institution identifiable private information about living individuals or identifiable biological specimens that came from living individuals, is not considered engaged in human subjects research.

Proposed example (B)(7) would represent another modification in OHRP policy. OHRP's current guidance document states that an institution (or private practitioner) whose clinical staff provide protocol-related care and/or follow-up to subjects enrolled at distant sites by clinical trial investigators in OHRP-recognized Cooperative Protocol Research Programs (CPRPs) (e.g., the oncology group clinical trials sponsored by the National Cancer Institute) is not considered to be engaged in human subjects research provided certain specified conditions are met. OHRP is proposing two key modifications to this current example: (1) That the example not be limited to scenarios involving human subjects research at OHRP-recognized CPRPs; and (2) that the example exclude an institution whose employees or agents administer the primary study intervention being tested in the research. OHRP is proposing to broaden the example beyond OHRP-recognized CPRPs because OHRP does not believe that the conditions specified in example (B)(7) of the current draft guidance document are unique to clinical trials conducted under CPRPs. In addition, to better protect human subjects involved in research, OHRP believes that an institution whose employees or agents administer the primary study intervention being tested in the study should be required: (1) To obtain an OHRP-approved FWA, and (2) to certify to the HHS agency conducting or supporting the research that the application of proposal for research has been reviewed and approved by an IRB designated in the FWA, and will be subject to continuing review by an IRB. Therefore, through example (B)(7) in the current draft engagement guidance document, OHRP is proposing to clarify that institutions whose employees or agents administer the primary study intervention being tested in the study would be engaged in human subjects research. OHRP does not believe the requirement for an FWA will be unduly burdensome for such institutions since OHRP has simplified the assurance process with the implementation of the FWA, and now permits an institution holding an OHRP-approved FWA to extend the applicability of its FWA to cover collaborating independent investigators and collaborating institutional investigators through an Individual Investigator Agreement (IIA) (see *http://www.hhs.gov/ohrp/humansubjects/assurance/guidanceonalternativetofwa.htm*).

In addition, OHRP wants to highlight three other proposed changes in the current draft guidance document:

1. The draft guidance document does not include examples regarding when ''statistical centers,'' ''operations centers,'' or ''coordinating centers'' for multi-site research would be engaged in human subjects research. The existing January 26, 1999 guidance document includes examples of when such entities would be engaged in human subjects research (see the January 26, 1999 document on ''Engagement of Institutions in Research, examples (A)(6) and (A)(7)). OHRP is proposing to delete these examples in the new engagement guidance document since OHRP believes that these entities' activities are subsumed under example (A)(5) in the draft engagement guidance document, which states that an institution would be engaged in human subjects research if the institution's employees or agents ''* * * obtain for research purposes identifiable private information or identifiable biological specimens from any source * * *.'' In addition, the January 26, 1999 document provided guidance on what component(s) of the study would require review by the IRB for the statistical, operations, or coordinating centers. Because this issue of IRB review could apply to any institution engaged in a component of a cooperative research project, OHRP's draft guidance document addressed this general issue separately at the end of the section III. A.

2. OHRP is proposing that an institution be considered *not* engaged in human subjects research in the event the institution's employees or agents consult or collaborate on the human subjects research by obtaining coded private information or human biological specimens from an institution engaged in the research that retains a link to individually identifying information (such as name or social security number), if one of several specified conditions is met (*see* example (B)(2) in the draft engagement guidance document). OHRP believes this additional example helps to clarify the distinction and relationship between: (1) Determining when a research study involving coded private information or human biological specimens involves human subjects (*see* OHRP's August 10, 2004, Guidance on Research Involving Coded Private Information or Biological Specimens at *http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf*), and (2) determining whether an institution is engaged in human subjects research if it receives coded private information or human biological specimens for a research study that already has been determined to involve human subjects.

3. OHRP is proposing that an institution be considered *not* engaged in human subjects research if the institution's employees or agents author a paper, journal article, or presentation describing a human subjects research study (*see* example (B)(8) in the current draft engagement guidance document). This is in contrast to the January 26, 1999 guidance document, which suggests that such authorship would make an institution engaged in human subjects research (*see* example (B)(2) in the January 26, 1999 guidance document). OHRP is proposing this clarification because OHRP believes that for an institution to be engaged in human subjects research, an institution's employees or agents must obtain: (1) Data about the subjects of the research through intervention or interaction with them; or (2) identifiable private information about the subjects of the research. If the institution's employees or agents do not obtain such information, the portion of the activity conducted by the institution does not involve human subjects, as defined by 45 CFR 46.102(f). Because authorship does not always involve obtaining such data or information about the subjects of the research, OHRP does not believe that it is helpful to consider authorship as a factor in determining whether an

institution is engaged in human subjects research.

All of the modifications and clarifications proposed in OHRP's draft guidance document, including those discussed above, are reflected in the comparison table of the previous guidance documents and the new draft guidance document on OHRP's Web site at *http://www.hhs.gov/ohrp/requests/.* OHRP welcomes comments on its draft guidance.

Dated: December 1, 2006.

Melody Lin,

Deputy Director, Office for Human Research Protections.

[FR Doc. E6–20849 Filed 12–7–06; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) and the Assistant Secretary for Health have taken final action in the following case:

Nicholas McMaster, University of Chicago: Based on a College Discipline Hearing report and on additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Mr. Nicholas McMaster, undergraduate student, Biological Sciences Collegiate Division in the Departments of Psychology and Comparative Human Development at the University of Chicago (UC), engaged in research misconduct supported by National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), grant P50 ES12382 and National Institute on Aging (NIA), NIH, grant P01 AG018911.

Specifically, PHS found that Mr. McMaster fabricated data in recording the score for the lordosis reflex and in recording the cell types present in vaginal epithelium from rats in two experimental psychology protocols.

Mr. McMaster has entered into a Voluntary Exclusion Agreement in which he has voluntarily agreed, for a period of three (3) years, beginning on November 14, 2006:

(1) To exclude himself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and

(2) that any institution which submits an application for PHS support for a research project on which Mr. McMaster's participation is proposed or which uses him in any capacity on PHS supported research, or that submits a report of PHS-funded research in which he is involved, must concurrently submit a plan for supervision of his duties to the funding agency for approval. The supervisory plan must be designed to ensure the scientific integrity of his research contribution. Mr. McMaster also agrees to ensure that the institution submits a copy of the supervisory plan to ORI. He further agrees that he will not participate in any PHS-supported research until such a supervisory plan is submitted to ORI.

FOR FURTHER INFORMATION CONTACT: Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8800.

Chris B. Pascal,

Director, Office of Research Integrity.

[FR Doc. E6–20927 Filed 12–7–06; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration on Aging

Agency Information Collection Activities; Proposed Collection; Comment Request; Alzheimer's Disease Demonstration Grants to States Program Standardized Data Collection

AGENCY: Administration on Aging, HHS.

ACTION: Notice.

SUMMARY: The Administration on Aging (AoA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to Alzheimer's Disease Demonstration Grants to States Program

DATES: Submit written or electronic comments on the collection of information by February 6, 2007.

ADDRESSES: Submit electronic comments on the collection of information to: *Lori.Stalbaum@aoa.hhs.gov.* Submit written comments on the collection of information to Administration on Aging, Washington, DC 20201, ATTN: Lori Stalbaum.

FOR FURTHER INFORMATION CONTACT: Lori Stalbaum at 202–357–3452 or e-mail: *lori.stalbaum@aoa.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency request or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, AoA is publishing notice of the proposed collection of information set forth in this document. With respect to the following collection of information, AoA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of AoA's functions, including whether the information will have practical utility; (2) the accuracy of AoA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

The Alzheimer's Disease Demonstration Grants to States (ADDGS) Program is authorized through Sections 398, 399 and 399A of the Public Health Service (PHS) Act, as amended by Public Law 101–557 Home Health Care and Alzheimer's Disease Amendments of 1990. The ADDGS program funded through AoA helps states extend family support services provided by subgrantees to underserved populations, including those in rural communities.

The PHS Act requires AoA to ''provide for an evaluation of each demonstration project for which a grant is made.'' The PHS Act further states