Additional Information:

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *infocollection@acf.hhs.gov.*

OMB Comment:

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–6974, *Attn:* Desk Officer for the Administration for Children and Families.

Dated: November 14, 2007.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 07–5787 Filed 11–21–07; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Child Care and Development Fund Tribal Annual Report (ACF–700 Report).

OMB No.: 0980–0241.

Description: The Child Care and Development Fund (CCDF) report requests annual Tribal aggregate information on services provided through the CCDF, which is required by the CCDF Final Rule (45 FR parts 98 and 99). Tribal Lead Agencies (TLAs) are required to submit annual aggregate data appropriate to Tribal programs on children and families receiving CCDF-funded child care services. The CCDF statute and regulations also require TLAs to submit a supplemental narrative as part of the ACF–700 report. This narrative describes general child care activities and actions in the TLA's service area and is not restricted to CCDF-funded child care activities. Instead, this description is intended to address all child care available in the TLA's service area. The ACF–700 and supplemental narrative report will be included in the Secretary's report to Congress, as appropriate, and will be shared with all TLA's to inform them of CCDF-funded activities in other Tribal programs.

Respondents: Tribal Governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–700 Report	260	1	38	9,880
Estimated Total Annual Burden Hours:				9,880.

Additional Information:

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *infocollection@acf.hhs.gov.*

OMB Comment:

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register.** Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–6974, *Attn:* Desk Officer for the Administration for Children and Families.

Dated: November 15, 2007.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 07–5788 Filed 11–21–07; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–07–8005]

Memorandum of Understanding Between the Food and Drug Administration and Duke University

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA and Duke University. The purpose of this MOU is to establish the terms of collaboration between FDA and Duke, beginning with an initiative to strengthen Human Subjects Protection by reexamining and modernizing the conduct of clinical trials to ensure that design, execution, and analysis are of optimal quality. To this end, Duke will be the convener of a Public Private Partnership, to which FDA will be a founding partner, to systematically modernize the clinical trial process.

DATES: The agreement became effective September, 22, 2007.

FOR FURTHER INFORMATION CONTACT: Melissa Robb, Office of Critical Path Programs, Office of Scientific and Medical Programs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1516.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: November 16, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–P

Control No. 225-07-8005

MEMORANDUM OF UNDERSTANDING
Between
THE UNITED STATES FOOD AND DRUG ADMINISTRATION
Office of Critical Path Programs
And
DUKE UNIVERISTY
DURHAM, NC

This Memorandum of Understanding (MOU) between the U.S. Food and Drug Administration (FDA) and Duke University (Duke) formalizes an agreement to develop collaborative activities in the areas of research, education, and outreach.

I. Purpose

The purpose of this MOU is to establish terms of collaboration between FDA and Duke, beginning with an initiative to reexamine the clinical trials process. To this end, Duke will be the convener of a Public Private Partnership (PPP), to which FDA will be a founding partner, to systematically modernize the clinical trial process. This initiative will add a unique aspect to the training being provided to the next generation of health care professionals at Duke, and provide FDA with a mechanism to promote one aspect of their Critical Path agenda, the modernization of clinical trials. Participants will have the opportunity to participate in a program that will focus on clinical trial quality. FDA and Duke will explore the possibilities of other collaborative activities including: sabbaticals, pre-doctoral and post-doctoral fellowships and student internships as this partnership develops.

II. Background

FDA and Duke have a shared interest in strengthening Human Subject Protection (HSP) by modernizing the conduct of clinical trials to ensure that design, execution, and analysis are of optimal quality. Duke's mission includes a commitment to help those who suffer, cure disease and promote health through sophisticated medical research and thoughtful patient care. This mission is consistent with a fundamental part of FDA's mission to protect and promote public health. Both FDA and Duke endorse scientific training for government employees, academicians, and students to establish a solid foundation in interdisciplinary science and medicine.

III. Substance of MOU

For this initiative, participants may include Duke students, residents, fellows, and faculty or FDA staff.

A. General

Through the PPP described above, this national effort will focus on developing generalizable standards to ensure that clinical trials are as efficient as possible, without compromising the reliability of the inferences drawn. The primary focus will be on clinical trial conduct in the United States, but global implications will be considered.

The parties agree to the following in support of this effort:

- The creation of PPP, consisting of the following components:
  - Executive Committee to be composed of members from involved parties;
  - Steering Committee to provide direction and guidance in support of this effort; and
  - Core functional groups to implement strategies to achieve the outlined deliverables.

- To collaborate in order to achieve short-term deliverables, such as:
  - Standards for monitoring and auditing;
  - Standards for data quality and quantity;
  - Standards for case report forms; and
  - Identification of pragmatic research topics (research on research).
- To collaborate in order to achieve long-term deliverables that reexamine the clinical trial enterprise, such as:
  - Developing a functional definition of clinical trial types with descriptions of optimal quality parameters;
  - Developing a model for the "ideal" clinical trial site;
  - Developing metrics for evaluating site functionality;
  - Developing metrics for evaluating site quality (cleanliness of data, inclusiveness of enrollment, HSP, etc.);
  - Developing best practices for key processes (Clinical Trial Management Systems);
  - Developing best practices for interface of the site with key components of research enterprise;
  - Exploring the concept of a clinical trial site accreditation program (including training);
  - Exploring the concept of Individual investigator and support personnel credentialing program; and
  - Assess customer (i.e., public, industry, and regulators) satisfaction.

B. FDA

FDA Office of Critical Path Programs (OCPP) will provide the following:

- Scientific and regulatory expertise related to the objectives of the partnership;
- Project management to achieve the short-term and long-term deliverables;
- Opportunities to participate in certain training courses and seminars at FDA or web-based training provided through FDA or Center Staff College's, as resources permit;
- Communication with OCPP staff via face-to-face meetings, conference calls or teleconference; and
- Communication of this collaborative effort through web pages, press releases, teleconferences, information conversations with colleagues, faculty and students, joint conferences and symposia.

C. Duke

Duke will provide the following:

- Function as a host of the PPP;
- Proactive efforts in establishing collaborative research efforts;
- Continuing and frequent communication with Duke faculty and staff, to include face-to-face communication and teleconferences;
- Welcome to FDA staff wishing to visit relevant Duke programs and laboratories;
- Communication of this collaborative effort through web pages, press releases, informal conversations with colleagues, faculty and students, joint conferences and symposia;
- Encouragement of graduate students/residents to elect short-term opportunities at FDA; and
- Opportunities to attend graduate courses.

Coverances

Duke and FDA may decide to enter into a Cooperative Research and Development Agreement (CRADA) at a future time to conduct collaborative research and projects of mutual interest. The terms of such a CRADA will address Intellectual Property rights.

Finances and Resources

Duke and FDA agree that this MOU does not commit either to make specific levels of financial or personnel support or to provide specific office or laboratory space for the programs and that the provision of such support will be based on available resources and provided in accordance with the laws, regulations and policies under which each entity operates.

Citizenship and Security Clearance

Duke participants in the collaboration envisioned in this MOU will be United States citizens or permanent residents. Information may be obtained from participants by the Agency for security clearance or access to FDA facilities and offices. The information obtained may be re-disclosed to the other Federal agencies in fulfillment of official responsibilities to the extent that such disclosure is permitted by law.

Protection of Non-Public Information

As a condition of their participation, Duke participants whose involvement will require access to any information that is not customarily releasable by FDA to the public will be required to sign an appropriate commitment to protect non-public information, to be provided by FDA.

IV. Liaison Contact

The individual to whom all inquiries to FDA should be addressed is:

Melissa Robb
Senior Regulatory Program Manager
Office of Critical Path Programs
Office of Scientific and Medical Programs
Office of the Commissioner
Food and Drug Administration

The individual to whom all inquiries to Duke should be addressed is:

Deborah A. Roth
Associate Dean for Clinical Research Administration
Duke University
Chief Operating Officer
Duke Translational Medicine Institute

AGREED TO:

UNITED STATES FOOD AND DRUG ADMINISTRATION

BY: _____ Date 9/22/07
Signature of authorized Representative

Janet Woodcock, MD — Deputy Commissioner and Chief Medical Officer

DUKE UNIVERSITY

BY: _____ Date 09/20/07
Signature of authorized Representative

DCR LVLD SEPT. 20 07

R. Sanders Williams, MD — Dean, School of Medicine

[FR Doc. 07–5793 Filed 11–21–07; 8:45 am]
BILLING CODE 4160–01–P