Survey (FACES), the National Head Start Impact Study, Head Start's Performance-Based Outcome System, and the ongoing evaluation of the Early Head Start program.

DATES: October 27, 2006, 8:30 a.m.–5 p.m.

Place: The Westin Embassy Row Hotel, 2100 Massachusetts Avenue, NW., Washington, DC 20008.

Agenda: The Committee will continue the discussions begun at previous Committee meetings.

SUPPLEMENTARY INFORMATION: This, the fourth meeting of the Committee, is open to the public. Persons wishing to bring written statements or papers focused on relevant, existing research with Head Start populations or on measures appropriate for low-income four- and five-year old children are welcome to do so. Individuals may e-mail such documents to *Secretaryadvisory-hs@esi-dc.com* or mail to: ESI, ATTN: Townley Knudson, Head Start Secretary's Advisory Committee, 1150 Connecticut Avenue, NW., Suite 1100, Washington, DC 20036.

Documents received shall be presented to the Committee. The Committee meeting records shall be kept at the Aerospace Center located at 901 D Street, SW., Washington, DC 20447. The Committee's charter, past meeting agendas, meeting proceedings and materials related to this meeting can be found at: *http://www.acf.hhs.gov/programs/hsb/budget/AdvCmteSep05/index.htm.*

An interpreter for the deaf and hard-of-hearing, will be available upon advance request by contacting *Secretaryadvisory-hs@esi-dc.com.*

Due to a clerical error at the Administration for Children and Families, this meeting notice may be published less than 15 days prior to the meeting.

Dated: October 10, 2006.

Robert A. Sargis,

Reports Clearance Officer.

[FR Doc. 06–8671 Filed 10–13–06; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–06–8404]

Memorandum of Understanding Between the Food and Drug Administration, and Duke University for the Cardiac Safety Research Consortium

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, on behalf of its Duke Clinical Research Institute (DCRI). FDA and Duke University agree to collaborate under the terms and conditions of this MOU, through steering committees and technical working groups, to develop strategic plans, set priorities, and leverage resources and expertise from multiple sources, including the private sector, toward the goals of identifying indicators of cardiovascular risk, predicting adverse cardiovascular events associated with therapeutic interventions, improving the clinical utility of biomarker technologies as diagnostic and assessment tolls that facilitate the development of safer and more effective cardiovascular therapies, diagnostic, and assessment tools. This collaboration between the Parties shall be known as the Cardiac Safety Research Consortium.

DATES: The agreement became effective August 15, 2006.

FOR FURTHER INFORMATION CONTACT:

For FDA: Wendy R. Sanhai, Office of the Commissioner (HF–18), Food and Drug Administration, 5600 Fishers Lane, 14B–45, Rockville, MD 20857, 301–827–7867, FAX: 301–443–9718, *wendy.sanhai@fda.hhs.gov*.

For Duke Clinical Research Institute: Christopher H. Cabell, Department of Medicine, Duke University School of Medicine, DUMC Box 2705, Durham, NC 27705, 919–668–8611, FAX: 919–668–7066, *chris.cabell@duke.edu*.

For Duke: Office of Research Administration, Duke University Medical Center, 2424 Erwin Rd., suite 1103, Durham, NC 27705, 919–684–5175, FAX: 919–684–6278.

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: October 6, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S

Reference # 225-06-8404

MEMORANDUM OF UNDERSTANDING

BETWEEN THE

FOOD AND DRUG ADMINISTRATION

AND

DUKE UNIVERSITY

FOR THE

CARDIAC SAFETY RESEARCH CONSORTIUM

Reference # 225-06-8404

Whereas extensive cross-sector and multi-disciplinary efforts are needed to develop and to understand the clinical utility of a new generation of biomarkers[1] and other technologies, which can be used for detection, early diagnosis, prognosis and clinical assessment tools in cardiovascular research and clinical decision-making;

Whereas such new cardiovascular assessment tools, including biomarkers, if proven effective in predicting and assessing therapeutic response in clinical trials and thereby "qualified" have the potential to be adopted as assessment tools for use in medical product[2] development and Food And Drug Administration (FDA) regulatory evaluation and guidance;

Whereas Duke University, a nonprofit, research, education, and healthcare institution is an organization (Duke) for and on behalf of its Duke Clinical Research Institute, (DCRI) whose mission it is to develop and share knowledge that improves the care of patients around the world through innovative clinical research;

Whereas Duke started and maintains one of the nation's first cardiovascular computerized clinical databases, said cardiovascular database being sustained for over 30 years as one of the world's largest repositories of follow-up on patients with carefully documented coronary heart disease;

Whereas Duke's DCRI has evolved into an organization with major efforts in clinical trials, outcomes research, and health policy;

Whereas FDA, with its unique perspective on research and development activities and in-depth understanding of clinical trial design, regulatory policy, and scientific know-how in reviewing medical products, is interested in exploring biomarker technologies as assessment tools for use in FDA guidance to facilitate medical product development;

Whereas FDA, under the terms and conditions of a Cooperative Research and Development Agreement (CRADA), has collaborated with Mortara Instrument, Inc, a CRADA partner, to design and implement an ECG Warehouse to hold ECGs obtained in drug trials to assess proarrhythmic risk;

Whereas said ECG Warehouse is now operational and capable of supporting multiple research and regulatory functions;

Whereas FDA and Duke (the Parties) have agreed to each leverage their existing resources and expertise, working with multiple public and private partners to further research and the

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[1] Biological marker (biomarker) is a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention. Clin Pharmacol Ther 2001;69:89-95.

[2] *Medical Products* includes drug and biological products and medical devices

development of pre-competitive diagnostic and assessment tools in cardiovascular disease to advance public health;

Whereas the private sector, including industry, academia, non-profit organizations and others have expressed interest in working with the Parties to further scientific exploration of cardiovascular biomarkers and associated technologies to enhance diagnostics and therapeutic development of medical products;

Now, therefore, the Parties agree to collaborate under the terms and conditions of this Memorandum of Understanding (MOU), through steering committees and technical working groups, to develop strategic plans, set priorities, and leverage resources and expertise from multiple sources, including the private sector, toward the goals of identifying indicators of cardiovascular risk, predicting adverse cardiovascular events associated with therapeutic interventions, improving the clinical utility of biomarker technologies as diagnostic and assessment tools that facilitate the development of safer and more effective cardiovascular therapies, diagnostic, and assessment tools. This MOU sets forth the framework for collaboration between the Parties and for pursuing specific collaborative projects that may involve additional partners and will be implemented through separate agreements, as needed. This collaboration between the Parties shall be known as the Cardiac Safety Research Consortium (CSRC). The Parties anticipate that ideas and concepts, from multiple sources, will be developed by the steering committees and technical working groups. Such concepts and ideas may lead to partnerships that will be approved by an Executive Committee (EC) and implemented through separate agreements.

The Parties agree as follows:

RESPONSIBILITIES OF THE PARTIES

To pursue the goals described above, the Parties agree to work through the process described below.

1. **Goals of CSRC**. The Parties will form public-private steering committees, technical working groups, and an Executive Committee (EC) to develop concepts for potential pursuit as a CSRC activity. Under the framework of this MOU, these collaborative efforts will be developed under separate agreements that specify policies, terms, and responsibilities of each party. The EC, steering committees, and technical working groups shall consider approaches for the development and application of diagnostic and/or clinical assessment tools or biomarker technologies that enhance diagnostic or therapeutic strategies for various forms of cardiovascular disease. Specific areas of scientific activities will include, but will not be limited to, the following:

    a. To create an ECG library from clinical trials that could be used for identifying early predictors of cardiac risk (Cardiac Risk ECG Library)
    b. To use the Cardiac Risk ECG Library to qualify new ECG biomarkers of cardiac risk;

c. To use the Cardiac Risk ECG Library to create a set of ECG reference standards;
d. To develop additional research and regulatory evaluation tools to facilitate clinical decision-making and future medical product development in the interest of public health; and
e. To develop standards, nomenclature, and tools to facilitate and accelerate the development of standards, and the evidence base for, new diagnostics and assessment tools, and develop educational tools to make this information more widely available to researchers, clinicians, and patients.

2. **Steering Committees and Technical Working Groups**. Each steering committee and technical working group will be responsible for developing and prioritizing concepts, developing feasibility plans for specific projects, preparing white papers on scientific rationale, evaluating existing knowledge gaps and availably technologies, addressing general concepts in experimental design, preparing protocols to evaluate biomarkers in clinical trials, developing milestones and outlining approaches for assessing progress. Moreover, the steering committees and technical working groups will consider development of standards, nomenclature, and tools to facilitate and accelerate the development of, and evidence base for, new diagnostics, assessment tools, and medical products. As a result of this process, the steering committees and technical working groups will aim to increase the scientific knowledge base for cardiovascular disease and public health. The steering committees and technical working groups will include representatives from each Party as well as public and private partners and will meet or teleconference monthly. The steering committees and technical working group chairs will report to the EC, which will make the final decisions on projects that will be implemented. A quarterly meeting (face-to face or teleconference) of the steering committees and working groups will be held to discuss progress, develop consensus on working group activities, and foster communications and directions for facilitating the project(s).

3. **Priority Projects**. Priority projects that emerge from the steering committees and technical working groups will be publicized as areas of interest of the CSRC with the intention of involving participation and input from public and private sector partners. Through this process, the CSRC will seek to engage the private sector in the implementation of the research. Numerous implementation strategies are anticipated and available. These strategies may include the following:

- The FDA may perform certain research projects directly with DCRI or through other collaborations through separate agreements.
- The private sector may perform projects directly, or may fund the research that may be administered, managed, and facilitated through DCRI and governed by separate agreements. To the extent that federal agencies are involved in the implementation of

any project, each agency is bound by all applicable federal statutes, regulations, and policies and required to act within its statutory authority.[3]

4. **Special Projects**. To the extent that implementation of specific projects involves working with the non-federal sector, the Parties will, consistent with all applicable statutes, regulations, policies, and their legal authorities facilitate dialogue with the appropriate potential collaborators or other partners of interest. Such interactions, facilitated and governed by separate agreements, may include a range of stakeholders, such as private non-profit organizations, industry, industry trade organizations, academic institutions, professional organizations, and patient advocacy groups.

GENERAL PROVISIONS

Proprietary and/or nonpublic information will not be disclosed under this MOU, unless such disclosure is governed by appropriate confidentiality disclosure agreements, or to the extent such disclosure is permitted by law.

Any notice or other communication required or permitted under this MOU will be in writing and will be deemed given as of the date it is received and accepted by the receiving party.

[3] To the extent that federal employees are involved in the implementation of specific projects, federal employee participation will be governed by all applicable statutes, regulations, and policies on interactions with outside organizations and reviewed for permissibility by the appropriate authority within the employee's agency on a case-by-case basis.

CONTACTS

Notices or formal communications pursuant to this MOU should be sent to:

For FDA: Wendy R. Sanhai, Ph.D.
Senior Scientific Advisor
Office of the Commissioner, FDA
5600 Fishers Lane, 14B-45, HZ-1
Rockville, MD. 20857
Phone: (301) 827-7867, Fax (301) 443-9718
wendy.sanhai@fda.hhs.gov

For DCRI: Christopher H. Cabell, M.D.
Assistant Professor of Medicine
Division of Cardiology
Department of Medicine
Duke University School of Medicine
DUMC Box 2705
Durham, NC 27705
Phone: 919-668-8611, Fax: 919-668-7066
chris.cabell@duke.edu

For Duke: Office of Research Administration
Duke University Medical Center
2424 Erwin Road, Suite 1103
Durham, North Carolina 27705
Phone: 919-684-5175, Fax: 919-684-6278

TERM, TERMINATION AND MODIFICATIONS

1. This MOU constitutes the entire agreement between the Parties pertaining to the CSRC.
2. There are no representations, warranties, agreements, or understandings, express or implied, written or oral, between the Parties hereto relating to the subject matter of this MOU that are not fully expressed herein.
3. No supplements, amendments, or modifications to this MOU will be binding unless executed in writing by the Parties; such modifications are to take the form of amendments.
4. This MOU, when accepted by the Parties, will have an effective date from date of the last to sign and will remain in effect for three (3) calendar years from the effective date, unless modified or terminated. Either Party may terminate this MOU upon sixty (60) days written notice.

Reference # 225-06-8404

SIGNATURES OF RESPONSIBLE PARTIES

We, the undersigned, agree to abide by the terms and conditions of this MOU.

APPROVED AND ACCEPTED FOR:

FOOD AND DRUG ADMINISTRATION

Date 8/7/06

Janet Woodcock, MD
Deputy Commissioner for Operations
U.S. Food and Drug Administration

DUKE UNIVERSITY

Date 8/15/06

R. Sanders Williams, MD
Dean, School of Medicine
Duke University

OCRC 8/14/06

[FR Doc. 06–8708 Filed 10–13–06; 8:45 am]
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