Matters to be Discussed: The meeting will convene to address matters related to the conduct of Study section business and for the study section to consider safety and occupational health-related grant applications. Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Price Connor, PhD, NIOSH Health Scientist, 1600 Clifton Road, NE., Mailstop E–20, Atlanta, Georgia 30333, Telephone (404) 498–2511, Fax (404) 498–2571.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: September 3, 2009.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E9–21991 Filed 9–11–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Public Forums

Notice is hereby given of two forums of the working groups of the NIH Scientific Management Review Board: Deliberating Organizational Changes and Effectiveness Working Group and Substance Use, Abuse and Addition Working Group. The forums will serve as the first among a series of sessions for gathering information on the agency's organizational structure and recommendations for enhancing the NIH mission through greater agency flexibility and responsiveness.

The forums will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The input from these meetings will be summarized in a report that will be presented to the Scientific Management Review Board in open session at an upcoming meeting.

Name of Committee: Substance Use, Abuse, and Addiction Working Group of the Scientific Management Review Board.

Date: September 23, 2009.

Open: 8 a.m. to 3 p.m.

Agenda: Presentation and discussion will include an overview of the science of substance use, abuse, and addiction and the public health needs in this area of research.

Place: National Institutes of Health, Building 60, Chapel and Lecture Hall, 9000 Rockville Pike, Bethesda, MD 20892.

Name of Committee: Deliberating Organizational Change and Effectiveness Working Group of the Scientific Management Review Board.

Date: September 24, 2009.

Open: 8 a.m. to 3 p.m.

Agenda: Presentations and discussion will include an overview of NIH mission and function from scientific and stakeholder perspectives, including elaboration upon the principles and attributes fundamental to its success.

Place: National Institutes of Health, Building 60, Chapel and Lecture Hall, 9000 Rockville Pike, Bethesda, MD 20892.

Contact Person: Dr. Lyric Jorgenson, PhD, NIH–AAAS Science and Technology Policy Fellow, Office of Science Policy, Office of the Director, NIH, National Institutes of Health, Building 1, Room 218, MSC 0166, 9000 Rockville Pike, Bethesda, MD 20892, *smrb@mail.nih.gov*, (301) 496–6837.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person. The meeting will also be webcast. The draft meeting agenda and other information about the SMRB, including information about access to the webcast, will be available at *http://smrb.od.nih.gov.*

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxis, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Dated: August 28, 2009.

Lynn Hudson,

Acting Director, Office of Biotechnology Activities.

[FR Doc. E9–22000 Filed 9–11–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Advisory Child Health and Human Development Council, September 21, 2009, 8 a.m. to September 21, 2009, 5 p.m., National Institutes of Health, Building 31, 31 Center Drive, Bethesda, MD 20892 which was published in the **Federal Register** on September 1, 2009, 74 FR 54224.

This notice is being amended to provide additional attendee viewing and Videocast access instructions for open session of Council. In order to facilitate public attendance at the open session of Council, reserve seating will be made available to the first five individuals reserving seats in the main meeting room, Conference Room 6. Please Contact Ms. Lisa Kaeser, Program and Public Liaison Office, NICHD, at 301–496–0536 to make your reservation. Additional seating will be available in the meeting overflow rooms, Conference Rooms 7 and 8. Individuals will also be able to view the meeting via NIH Videocast. Please go to the following link for Videocast access instructions at: *http://www.nichd.nih.gov/about/overview/advisory/nachhd/virtual-meeting-200910.cfm.* The meeting is partially closed to the public.

Dated: September 3, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–21998 Filed 9–11–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0667]
[FDA 225–09–0010]

Memorandum of Understanding With 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 the Food and Drug Administration and Duke University. The purpose of this MOU is to establish a framework for collaboration between the Parties and for pursuing specific collaborative projects. This collaboration between the Parties shall be known as the Cardiac Safety Research Consortium.

DATES: The agreement became effective August 4, 2009.

FOR FURTHER INFORMATION CONTACT: Wendy R. Sanhai, Office of the Commissioner (HZ–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7867, FAX: 301–827–5891.

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: August 31, 2009.

David Horowitz,

Assitant Commissioner for Policy.

BILLING CODE 4160–01–S

MEMORANDUM OF UNDERSTANDING

BETWEEN THE

FOOD AND DRUG ADMINISTRATION

AND

DUKE UNIVERSITY

FOR THE

CARDIAC SAFETY RESEARCH CONSORTIUM

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 clinically qualified to predict and assess therapeutic response in clinical trials and have the potential to be adopted for use in patient management, medical product[2] development and for regulatory decision making by the Food And Drug Administration (FDA);

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 working with stakeholders, under its public health mission to improve patient care and stimulate innovation in medical product development , and in the context of biomarker development for use in assessing the safety and efficacy of products under its regulatory jurisdiction.

Whereas FDA, under the terms and conditions of a Cooperative Research and Development Agreement (CRADA), is collaborating with Mortara Instrument, Inc, a CRADA partner, to design and build an ECG Warehouse to hold digital electrocardiograms (ECGs) obtained in clinical studies to assess proarrhythmic risk;

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

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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

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 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 development 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 stakeholders, 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 research teams. 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

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

1. Goals of CSRC. The Parties will form steering committees, technical working groups, and an Executive Committee (EC) to develop concepts for implementation as CSRC projects. 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 research teams 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 utilize the Cardiac Risk ECG Library to qualify new ECG biomarkers of cardiac risk and create a set of ECG reference standards;
c. To solicit feedback from the scientific community, generate consensus, and publish consensus statements regarding critical cross-cutting public health issues related to cardiac safety of medical products;
d. To develop additional predictive and evaluative tools to facilitate regulatory and 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. **Scientific Oversight Committee and Research Teams.** The Scientific Oversight Committee (SOC)and research teams shall 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 SOC and research teams shall 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 SOC and research teams will aim to increase the scientific knowledge base for cardiovascular disease and public health and enhance the cardiovascular safety of medical products. The steering committees and research teams will include representatives from each Party as well as public and private partners and will meet or teleconference monthly. The SOC and research team chairs will report to the EC, which will make the final decisions on projects that will be implemented. A meeting (face-to face or teleconference) of the steering committees and working groups will be held al least quarterly 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 SOC and research teams 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, and 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 shall 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, 6A-08, HF-18 Rockville, MD. 20857 Phone: (301) 827-7867, Fax (301) 827-5891
Copy to:	Benjamin C. Eloff, Ph.D. Senior Scientific Program Manager Office of the Commissioner, FDA 5600 Fishers Lane, 6A-08, HF-18 Rockville, MD. 20857 Phone: (301) 827-0156, Fax (301) 827-5891
For DCRI:	Mitchell Krucoff, M.D. Professor of Medicine Division of Cardiology Department of Medicine Duke University School of Medicine DUMC Box 3968 Durham, NC 27710 Phone:919-286-6860; Fax 919-286-6861
For Duke:	Office of Research Administration Duke University Medical Center 2200 W. Main Street, Suite 820 Durham, NC 27705 Attn: Director 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 shall 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 (Effective date) 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.

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 8/4/09

Jesse L. Goodman, M.D., MPH
Chief Scientist and Deputy Commissioner (Acting) for
Scientific and Medical Programs
US Food and Drug Administration

DUKE UNIVERSITY

Date

H. Gilbert Smith, Ph.D.
Director, Office of Corporate
Research Collaborations

[FR Doc. E9–22001 Filed 9–11–09; 8:45 am]
BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0407]

Pediatric Clinical Trials Workshop: Unmet Needs, Trial Designs and Clinically Meaningful Safety and Effectiveness Outcomes

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Pediatric Clinical Trials Workshop: Unmet Needs, Trial Designs and Clinically Meaningful Safety and Effectiveness Outcomes.'' The purpose of the public workshop is to solicit information from primary and secondary health care providers, academia, industry, and professional societies on various aspects of device clinical trials involving pediatric diseases and patients. Information from this public workshop will help stimulate interest in pediatric device clinical trial research methods, and develop topics for further discussion regarding the safety of pediatric device clinical trials. The information gathered in this and future workshops will help to develop future guidance for developing safe clinical trials for devices intended for pediatric patients. We encourage participation and comments from workshop attendees on the topics and questions discussed. Please see instructions for registration and for providing comments in the sections of this document entitled ''*Registration*'' and ''*Comments*.''

Dates and Times: The public workshop will be held on October 29, 2009, from 8 a.m. to 5:30 p.m. and October 30, 2009, from 8 a.m. to 12 noon.

Location: The public workshop will be held at the Holiday Inn College Park located off I–95 at 10000 Baltimore Ave., College Park, MD 20740. The hotel front desk number is 1–301–345–6700. For directions, please refer to the meeting Web page: *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm170938.htm*

Contact Person: Barbara Buch, Center For Devices and Radiological Health, Food and Drug Administration, Bldg. 66, rm. 1406, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–5650, FAX: 301–847–8117, e-mail: *barbara.buch@fda.hhs.gov*. If you need special accommodations due to a disability, (such as wheelchair access or a sign language interpreter), please notify Barbara Buch by September 30, 2009.

Registration: Registration and seating will be on a first-come, first-served basis and discussion preference will be afforded to clinical research investigators involved in pediatric clinical device trials, health care givers, and patient advocates. Please provide your name, title, organization affiliation, address, and e-mail contact information. There is no registration fee to attend the workshop. There will be no onsite registration. Please register electronically at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* by September 30, 2009. Due to limited space, and to maximize participation, attendees are asked to delegate one or two representatives from their organizations to participate in the general sessions. A report of The Workshop and The Information presented will be available following the meeting via a link on the meeting Web page. If you wish to make an oral comment during or to attend the public workshop, please note this in your registration information. The online registration form will instruct you as to the information you should provide prior to the meeting. In general, a summary of the presentation and an electronic copy of the presentation should be submitted by October 1, 2009. We will try to accommodate all persons who wish to make oral comments during the general sessions. However, we strongly recommend that you provide written comments as instructed in this document to ensure that your opinion, comments, and suggestions are captured. Please refer to the section, ''*Comments*'' for instructions on how to submit written comments.

Comments: The deadline for submitting comments regarding this public workshop is November 30, 2009.

Regardless of attendance at the public workshop, interested persons may submit written or electronic comments. Written comments should be submitted to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Electronic comments should be submitted to *http://www.regulations.gov*. Comments should be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION:

I. Why Are We Holding This Public Workshop?

The purpose of the public workshop is to solicit expert input on topics related to pediatric device clinical trials. The agency seeks discussion between FDA and other interested parties regarding the conduct of clinical trials to investigate device use in pediatric populations. Other purposes of the public workshop are, to identify any gaps in such research, and to provide information about evaluating the short- and long-term safety and effectiveness of pediatric medical devices using valid and sound scientific methods. Since the 2007 Food and Drug Administration Amendments Act was signed into law, there has been increased interest in conducting scientifically sound clinical research related to pediatric populations. It is hoped that this meeting will provide a forum for open discussion and information exchange among interested parties, FDA, and other stakeholders to lay a framework for further research into the use of devices to treat disorders and diseases that affect pediatric patients.

II. What Will Be the Format for the Meeting?

The format for the meeting will include a general session in the morning on the first day. Invited expert speakers will present information regarding current needs and concerns about clinical trials that involve pediatric patients. These presentations will provide the topics for the small breakout groups, which will begin in the afternoon session of day one and continue through the morning of day two of the public workshop. Each of the smaller breakout group discussion sessions will be led and moderated by a panel of experts in each of the specialty focus areas listed in section III of this document. Each small group session will begin with an invited presentation to describe the issues of concern in the specific specialty. This will be followed by a moderated question and comment session including both prespecified questions posed to the assembled group and any that arise during the workshop's discussions. Those in attendance will have the opportunity in these small group discussions to participate in the discussion, ask questions, and provide comments for consideration. Small group discussions will be concluded in the morning of day two. Small group participation will be limited by space and will be available on a first-come, first-served basis. When registering for