

limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 14, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Bryan Emery or Pearl Muckelvene at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 24, 2012.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2012-1888 Filed 1-27-12; 8:45 am]

**BILLING CODE 4160-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2012-N-0001]

**Annual Computational Science Symposium; Public Conference**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public conference.

**SUMMARY:** The Food and Drug Administration (FDA), in cosponsorship with the Pharmaceutical Users Software Exchange (PhUSE), is announcing a public conference entitled "The FDA/PhUSE Annual Computational Science Symposium." The purpose of the conference is to help the broader community align and share experiences to advance computational science. At the conference, which will bring together FDA, industry, and academia, FDA will update participants on current initiatives, and collaborative working

groups will address specific challenges in accessing and reviewing data to support product development. These working groups will focus on solutions and practical ways to implement them.

**DATES:** *Date and Time:* The public conference will be held on March 19 and 20, 2012, from 9 a.m. to 4:30 p.m.

*Location:* The public conference will be held at the Silver Spring Civic Building at Veterans Plaza, One Veterans Pl., Silver Spring, MD 20910, 1-(240)-777-5300.

*Contact:* Chris Decker, U.S. Regional Director, Pharmaceutical Users Software Exchange (PhUSE), 64 High St., BROADSTAIRS CT10 1JT, United Kingdom, (202) 386-6722, e-mail: [office@phuse.eu](mailto:office@phuse.eu).

**SUPPLEMENTARY INFORMATION:**

**I. Working Groups and Their Areas of Focus**

Six working groups will address particular challenges related to the access and review of data to support product development:

- Working Group 1: Data Validation and Quality Assessment,
- Working Group 2: Reducing Risk Within the Inspection Site Selection Process,
- Working Group 3: Challenges of Integrating and Converting Data Across Studies,
- Working Group 4: Standards Implementation Issues With the Clinical Data Interchange Standards Consortium Data Models,
- Working Group 5: Development of Standard Scripts for Analysis and Programming, and
- Working Group 6: "Non-Clinical Road-Map" and Impacts on Implementation.

A description of the planned activities of the working groups can be found at <http://www.phuse.eu/Working-Groups.aspx>. (FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

**II. Registration and Accommodations**

*A. Registration*

To register, please submit the registration form online at <https://www.phuse.eu/PhUSE-Conference-2012-Registration.aspx>. Registration fees cover the cost of facilities, materials, and food functions. Seats are limited, and conference space will be filled in the order in which registrations are received. Onsite registration will be available to the extent that space is available on the day of the conference.

The costs of registration for different categories of attendee are as follows:

**COST OF REGISTRATION**

Category	Cost
Industry representatives registering by January 15, 2012 .....	\$750
Industry representatives registering after January 15, 2012 .....	950
Those with Government affiliation ...	300
Representatives of nonprofit organizations .....	600
Those attending for a single day .....	650

Government and nonprofit attendees and exhibitors will need an invitation code to register at the discounted rate. An invitation code can be obtained by sending an email to: [office@phuse.eu](mailto:office@phuse.eu). All registrants will pay a fee with the exception of a limited number of speakers/organizers who will have a complimentary registration.

*B. Accommodations*

Attendees are responsible for their own accommodations. Attendees making reservations at the Courtyard by Marriott Silver Spring Downtown Hotel are eligible for a reduced conference rate of \$199, not including applicable taxes. Those making reservations online should use the group code "SPRSPRB" to receive the special rate. If you need special accommodations because of disability, please contact Chris Decker (see *Contact*) at least 7 days before the meeting.

**III. Posters and Exhibits Information**

Posters will be presented and may include demonstrations to provide an interactive experience. Although PhUSE welcomes demonstrations to support and explore the posters that are presented, neither PhUSE nor FDA endorse any commercial software or vendor. The creator of what is judged the best poster will be recognized and offered the opportunity to present the poster at the closing session.

Poster topics include:

- Data submission standards development, implementation, and best practices;
- User experience and evaluation of current processes and tools and their effects on organizational performance;
- Needs and specifications for proposed new tools and processes;
- Business processes driving the development of information systems; and
- The effect of processes and tools on problem solving quality, efficiency, and cost.

Those interested in more information should refer to the PhUSE Web site at <http://www.phuse.eu/ssc4p.aspxweb>.

The conference will make available an exhibition hall. The exhibitor price for this conference is \$3,500.

Dated: January 24, 2012.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Revision to Proposed Collection; Comment Request; National Institute of Child Health and Human Development; the National Children's Study, Vanguard (Pilot) Study

**SUMMARY:** In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Child Health and Human Development (NICHD), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

#### Proposed Collection

*Title:* The National Children's Study, Vanguard (Pilot) Study.

*Type of Information Collection*

*Request:* Revision.

*Need and Use of Information*

*Collection:* The purpose of the proposed methodological study is to continue the Vanguard phase of the National Children's Study with updated instruments and additional biospecimen collections and physical measures and to evaluate the feasibility, acceptability, and cost of a different sampling strategy for enrollment of pregnant women. This study is one component of a larger group of studies being conducted during the Vanguard Phase of the National Children's Study (NCS), a prospective, national longitudinal study of child health and development. In combination, these studies will be used to inform the design of the Main Study of the National Children's Study.

#### Background

The National Children's Study is a prospective, national longitudinal study of the interaction between environment, genetics on child health and development. The Study defines "environment" broadly, taking a

number of natural and man-made environmental, biological, genetic, and psychosocial factors into account. Findings from the Study will be made available as the research progresses, making potential benefits known to the public as soon as possible.

The National Children's Study (NCS) has several components, including a pilot or Vanguard Study, and a Main Study to collect exposure and outcome data. The sample frame for the NCS Vanguard and Main Study was initially based on a national probability sample using geography as the basis and selecting about 100 of the about 3000 counties in the United States as the basis for Primary Sampling Units. Within the Primary Sampling Units, smaller geographic segments were selected as Secondary Sampling Units in an attempt to normalize live birth rates per area sampled. Women who resided at the time of enrollment within a designated Secondary Sampling Unit and were either pregnant or between 18 and 49 were eligible for enrollment. The initial recruitment technique within the selected geographic areas was household contact by field workers going door to door.

The Vanguard Study was launched in January 2009, and by summer 2009, field experience suggested that the household contact recruitment strategy was not feasible with available resources. Thus, in 2010 new recruitment strategies were launched to evaluate options. By late 2011, the NCS had sufficient data to evaluate operational aspects of various recruitment strategies. Preliminary analyses suggested that a provider based recruitment strategy was the most efficient, but due to constrictions of the geographic sampling frame, the potential of the strategy was limited. Specifically, many women had to be screened at a particular provider to locate the relatively few who resided in a designated segment. Anticipating this limitation, the NCS Program Office developed and discussed with the NCS Advisory Committee a different sampling frame, using provider location. This new sampling strategy is termed Provider Based Sampling (PBS). Information from this data collection is critical to determine the plausibility of a provider based sampling frame as an option for some parts of the NCS Main Study.

#### Research Questions

Two research goals will be accomplished by this information collection. The first goal is to systematically pilot additional study visit measures and collections whose

scientific robustness, burden to participants and study infrastructure, and cost for use in the Vanguard (Pilot) Study and to inform the Main Study. The second goal is to test the feasibility, acceptability, and cost of Provider Based Sampling using three locations.

#### Methods

We will continue with the current data collection schedule which include pre-pregnancy, pregnancy, and birth periods, as well as postnatal data collection points at 3, 6, 9, 12, 18, and 24 months of age. We propose to add or modify the selected measures below to address analytic goals of assessing feasibility, acceptability and cost of specific study visit measures.

#### *Supplemental Information and Biospecimen Collections*

*Core Questionnaire:* We propose to pilot use of a core questionnaire containing key variables and designed to collect core data at every study visit contact from the time that the enrolled child is 6 months of age to the time the child is 5 years of age.

*30-Month Data Collection Module:* We propose piloting the approach of use of a core instrument plus an age specific module with the 30 month visit.

*Validation Questions for 18, 24 and 30 month:* We propose addition of brief, telephone-based questions that would be fielded to a random sample of each interviewer's cases after completion of the 18-Month, 24-Month, and 30-Month interviews to monitor interviewer performance and identify occurrences of data falsification.

Nonrespondent Questionnaire will collect information on why a participant chose to not enroll or withdraw from the NCS. This information may be used to revise our approaches to recruitment and will help the Study frame other systematic analyses of nonresponse bias.

*Physical Measures:* The addition of 6 month and 12 month infant measures of child anthropometry and blood pressure may provide critical pieces of information for future research on the causes of obesity, diabetes, premature puberty and a host of other health outcomes.

*Revised Father Questionnaire:* The NCS seeks to incorporate behavioral, emotional, educational and contextual consequences to enable a complete assessment of psychosocial influences on children's well-being. The Revised Father Questionnaire now includes measures addressing key social/personal resources and fathers' capacity, desire and attitudes towards engaging with mothers and children.