

Dated: March 17, 2009.

Jennifer Spaeth,

*Director, Office of Federal Advisory
Committee Policy.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

[Docket No. NIH-2009-0002]

Public Meeting on Expansion of the Clinical Trial Registry and Results Data Bank

AGENCY: National Institutes of Health,
HHS.

ACTION: Notice of public meeting;
request for comments.

SUMMARY: With this notice, the National Institutes of Health (NIH) of the U.S. Department of Health and Human Services (HHS) announces a public meeting and requests input from interested parties on issues that the agency will consider as it develops regulations to expand the clinical trial registry and results data bank commonly known as ClinicalTrials.gov in accordance with section 801 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) [Pub. L. 110-85]. FDAAA requires a public meeting to be held to provide an opportunity for input from interested parties with regard to regulations that are to be issued within three years of enactment of the law. The NIH seeks input from all interested parties about issues to be considered in the proposed rulemaking. Comments on these issues will inform the development of draft regulations, which will be made available for public comment via a separate Notice of Proposed Rulemaking (NPRM) that will be issued in the **Federal Register** at a later date. Section III of this document lists specific topics and questions on which input is sought.

Public Meeting Date and Time: The public meeting will be held on Monday, April 20, 2009, from 9 a.m. to 5 p.m.

Location: The public meeting will be held in Masur Auditorium, which is located on the NIH Campus, Building 10, South Side, First Floor, 10 Center Drive, Bethesda, Maryland 20892. The NIH, like all Federal Government facilities, has instituted security measures to ensure the safety of its patients, employees, visitors, and facilities. All visitors must enter the NIH campus through the Gateway Center, which is located adjacent to the Medical Center Metro Station (Red Line) at the

South Drive entrance to the campus from Rockville Pike/Wisconsin Avenue (Route 355). Security personnel will ask you to submit to vehicle and personal inspection. Visitors over 15 years of age must provide a form of government-issued ID, such as a driver's license or passport. Visitors under 16 years of age must be accompanied by an adult. Additional information is available online at <http://www.nih.gov/about/visitor/>.

Registration and participation: The NIH desires broad participation in the public meeting. To ensure sufficient seating for all participants, we request that you register by 5 p.m. on Monday, April 13, 2009. Registration may be accomplished online at <http://prsinfo.clinicaltrials.gov/public-meeting-april09.html> or by submitting the following information to the Contact Person indicated below: Name; Title; Business affiliation (if any); Address; Telephone and fax numbers; and e-mail address. When registering, please indicate whether you need any special accommodations (such as wheelchair access). Sign-language interpretation will be provided at the meeting. Registration is on a first-come, first-served basis. Walk-in registrations will be accepted at the site on a space-available basis. Interested parties may also view the meeting remotely via live videocast, which will be accessible on the Internet at <http://videocast.nih.gov>.

Oral Statements at the Meeting

Participants wishing to make an oral statement during the public meeting should make their request when they register and should submit a written statement summarizing their remarks. Written statements should be submitted to the meeting docket at <http://www.regulations.gov> or to the Contact Person indicated below by 5 p.m. on Monday, April 13, 2009. Written statements should identify by number each discussion question addressed, and written statements that exceed 10 pages should include a one-page executive summary. Registered individuals will be notified of the approximate scheduled time of their remarks prior to the meeting. The NIH will try to accommodate all persons who wish to make a public comment at the meeting, including those who register at the site, but it may need to limit the number of presentations and/or the time allotted for each presentation. Nevertheless, the full text of all written statements will be included in the docket, which will remain open for submissions after the conclusion of the meeting. In order that they may be considered by the agency during the development of the proposed

rule, written comments should be submitted to the docket by Monday, June 22, 2009. Instructions for submitting written comments are described in Section IV of this notice.

Agenda and other meeting materials: An agenda for the public meeting will be posted on the meeting Web site <http://prsinfo.clinicaltrials.gov/public-meeting-april09.html> and submitted to the public docket by Wednesday, April 15, 2009. The NIH may make other background material available on the meeting Web site in advance of the meeting and will submit all such information to the public docket.

Contact Person: Christine Ireland, Committee Management Officer, National Library of Medicine, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20892-7968; telephone: 301-594-4929; fax: 301-402-2952; e-mail: irelanc@mail.nih.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The NIH, through its National Library of Medicine (NLM), has maintained a clinical trial registry data bank, commonly known as ClinicalTrials.gov, since 2000. The registry was established, in part, in response to the Food and Drug Administration Modernization Act of 1997 [Pub.L. 105-115], and as of March 2009 it contained information on more than 69,000 clinical trials conducted in more than 160 countries.

The Food and Drug Administration Amendments Act of 2007 (FDAAA) [Pub.L. 110-85], enacted in September of 2007, increases the amount and type of clinical trial information that is to be made publicly available through the data bank. Section 801 of the FDAAA requires the Director of NIH to expand the data bank and requires "responsible parties" (generally, trial sponsors or designated principal investigators) to submit specified registration and results information describing "applicable clinical trials" (as defined in FDAAA) of certain drugs, biological products, and devices. The FDAAA specifies a set of registration data elements to be submitted to the data bank and authorizes the Secretary to modify the registration data elements by regulation if such modification "improves and does not reduce" the clinical trial information submitted to ClinicalTrials.gov. The FDAAA also specifies the deadline by which responsible parties are to submit registration information (in general, within 21 days of enrolling the first patient) and establishes a requirement

for updating information if there are changes to report.

The FDAAA also requires the NIH to expand ClinicalTrials.gov to include information describing the results of certain applicable clinical trials. The law requires responsible parties to submit “basic results” information for applicable clinical trials for which the drugs, biological products, and devices under study are approved under section 505, 515, or 520(m) of the Federal Food, Drug, and Cosmetic (FDC) Act, licensed under section 351 of the Public Health Service (PHS) Act, or cleared under section 510(k) of the FDC Act. As specified in the law, the information to be submitted consists of certain administrative information and two categories of numerical data related to the clinical trial: (1) A table of demographic and baseline characteristics of the patient population, overall and for each arm of the clinical trial, including the number of patients who dropped out of the clinical trial or were excluded from the analysis; and (2) a table of values for each of the primary and secondary outcome measures, for each arm of the trial, including the results of scientifically appropriate tests of the statistical significance of such outcome measures. Narrative summaries of the trial results are not permitted. The required basic results information has been implemented in ClinicalTrials.gov as four modules of tabular data that describe the participant flow, baseline characteristics of the patient population, outcome measures and statistical analysis, and adverse events. The FDAAA specifies that, in general, results must be submitted not later than 12 months after the trial completion date, which is defined as the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome; however, the law provides several options for delayed submission of results information (*e.g.*, when seeking initial approval of a drug or device or seeking approval of a new use for the drug or device). The FDAAA includes provisions to ensure that information submitted to the data bank is complete and accurate and not false, misleading, or promotional. The NIH and the Food and Drug Administration (FDA) are instructed to conduct a pilot quality control project to determine the “optimal method” of verifying that submitted results information is nonpromotional and not false or misleading in any particular way.

The FDAAA required the NIH Director to modify ClinicalTrials.gov to include the required registration information by December 26, 2007, and

to accommodate the submission of required “basic results information” by September 27, 2008. The NIH met these deadlines, and, since those dates, registration information has been submitted for more than 20,000 clinical trials, and basic results information has been submitted for more than 430 clinical trials. In addition, data providers may submit adverse event reporting information on a voluntary basis; reporting of adverse event information will become mandatory at a later date.

To provide more complete results information and to enhance patient access to and understanding of the results of clinical trials, the FDAAA (as codified in 42 U.S.C. 242(j)(3)(D)) requires the Secretary to further expand the registry and results data bank by regulation. The regulations are to be promulgated within three years of the law’s enactment. The FDAAA specifies topics to be considered in developing the regulations and requires the Secretary to convene a public meeting to solicit input from interested parties with regard to the regulations. Specific elements that are to be considered or included in the rulemaking are those identified for discussion at the public meeting in Section III.

III. Purpose and Scope of the Public Meeting

This public meeting is intended to provide an opportunity for interested parties to share their perspectives on the issues to be considered in the rulemaking for the expanded registry and results data bank that is required by the FDAAA. The NIH anticipates that the event will be of interest to a broad range of stakeholders, including patients and human subjects; patient advocacy groups; manufacturers of drugs, biological products, and devices whose products are subject to registration and results reporting under FDAAA; academic medical centers; researchers, and other organizations that engage in clinical research; members of Institutional Review Boards; journal editors who publish the result of clinical trials; and experts in evidence-based medicine who make use of the results of clinical trials. The NIH encourages broad participation in the public meeting. To provide an additional opportunity for interested parties to provide input on the issues to be considered in the rulemaking, the docket will remain open for submission of written comments after the meeting. In order for the agency to consider the comments during development of the proposed rule, the comments should be submitted by Monday, June 22, 2009.

III. Issues for Discussion

In keeping with the topics to be considered in the rulemaking for the expanded registry and results data bank, the NIH invites comments from interested parties on any and all of the following topics and questions:

1. Whether to require submission of results information for applicable clinical trials of drugs, biological products, and devices that are not approved under sections 505, 515, or 520(m) of the FDC Act, licensed under section 351 of the PHS Act, or cleared under section 510(k) of the FDC Act (whether or not clearance, approval or licensure was sought). Please comment on issues such as the potential advantages and disadvantages to the public and public health of disclosing results information for trials involving drugs, biological products, and devices that are not approved, licensed, or cleared; the effects (if any) on the development of drugs, biological products, and devices; the reporting burden on data submitters; and the appropriate timing of submission and public disclosure of information, taking into account the certification process established by the FDAAA when approval, licensure, or clearance is sought for a product under study in an applicable clinical trial. In particular, consider scenarios involving trials of different types of unapproved products: (a) Applicable clinical trials of products for which marketing applications or premarket notification submissions are never submitted to the FDA; (b) applicable clinical trials of products for which marketing applications or premarket notification submissions are submitted, but a decision is pending; and (c) applicable clinical trials of products for which marketing applications or premarket notification submissions are submitted and the FDA decides not to approve, license, or clear the product for marketing.

2. Whether narrative summaries of the clinical trial and its results can be included in the data bank without being misleading or promotional. Comment on issues such as the potential advantages and disadvantages to patients, research subjects, and the public of requiring responsible parties to submit narrative summaries that are written in nontechnical, understandable language for patients; the utility to the scientific community of requiring responsible parties to submit narrative summaries written in technical language; the content and structure of any such narratives; and procedures that could be established to help ensure the content is not misleading or promotional.

3. What additional information, if any, that is written in nontechnical, understandable language for patients should be required to be submitted to the data bank or should be provided in the data bank to assist patients in understanding and interpreting the information available in the data bank. Please consider the types of information that would best assist patients and other members of the public in understanding and interpreting results information in the data bank, including information on adverse events. Comment on issues such as the types of information that might assist patients and the public in understanding the results of individual clinical trials and of clinical trials in general. Identify existing sources of explanatory information that are oriented toward patients and the public and could be included in or linked to the data bank.

4. Whether to require submission of the full clinical trial protocol or only such information on the protocol as may be necessary to help evaluate the results of the trial. Comment on the value of the full clinical trial protocol versus partial information from the protocol in evaluating the results of a trial and the completeness of results data submission.

5. Procedures the agency might consider for quality control, with respect to completeness and content of clinical trial information, to help ensure that data elements are not false or misleading and are nonpromotional. Consider the effect of different approaches on the workload of both data submitters and the agency and on the quality of data available to the public, as well as suitable means for the agency to communicate information about its quality assurance processes to data submitters and the public.

6. Whether the 1-year period for submission of basic results information should be increased to a period not to exceed 18 months. Comment on the advantages and disadvantages of increasing the period for submission of clinical trial information from 1-year after the completion date to a period not to exceed 18 months. Consider the implications for all stakeholders, including governmental bodies, data submitters, and users of ClinicalTrials.gov; the extent to which such a change would affect public health or the utility of the data bank; the possible effect on the number of requests that responsible parties would submit to the NIH requesting an extension of the results reporting deadline; and the possible improvements to the quality and or completeness of initial submissions of

results data to the NIH. Consider the implications of delay periods of different lengths between 12 and 18 months.

7. Whether the clinical trial information required by the regulation should be required to be submitted for applicable clinical trials for which "basic results" information is submitted before the effective date of the regulation. Consider the advantages and disadvantages to data submitters and users of the data bank, including patients, prospective human subjects, care providers, and researchers.

8. The appropriate timing and requirements for updates of clinical trial information and procedures for tracking such updates. Please comment on the advantages and disadvantages of requiring more frequent updating of information submitted to the clinical trial registry and results data bank, which elements (if any) would benefit from more frequent updating, and what would be the optimal frequency of such updates.

9. The standard format for the submission of clinical trial information required by the regulation, including adverse event information, and additions or modifications to the manner of reporting of the data elements established under the basic results reporting provisions of the FDAAA.

10. A statement to accompany the entry for an applicable clinical trial when the primary and secondary outcome measures for such clinical trial are submitted as a "voluntary submission" after the date specified in the FDAAA for submission of such information.

11. Other issues associated with Section 801 of the FDAAA that will inform rulemaking.

IV. Request for Comments

As described previously in this Notice, participants wishing to make an oral statement at the Public Meeting are requested to notify the NIH and to submit to the meeting docket or the Contact Person a written version of their remarks on the topics identified in Section IV by 5 p.m. on Monday, April 13, 2009. The docket will remain open after the meeting, and, regardless of attendance at the public meeting, interested persons may submit written or electronic comments to the docket so that they may be considered by the agency during the subsequent rulemaking. To ensure consideration, written comments should be submitted to the docket by Monday, June 22, 2009. Submit electronic comments to Docket No. NIH-2009-0002 at <http://www.regulations.gov>. The site contains instructions for submitting comments.

V. Transcripts

A transcript of the public meeting will be submitted to the docket and posted to <http://prsinfo.clinicaltrials.gov/public-meeting-april09.html> approximately 15 working days after the public meeting.

Dated: March 16, 2009.

Raynard S. Kington,

Acting Director, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Advisory Allergy and Infectious Diseases Council.

The meeting will be open to the public. Individuals who wish to listen to the meeting should register with Jemma Long at the phone number of the contact person listed below at least two days in advance of the meeting.

Name of Committee: National Advisory Allergy and Infectious Diseases Council; Allergy, Immunology and Transplantation Subcommittee.

Date: March 31, 2009.

Time: 1 p.m. to 1:30 p.m.

Agenda: The subcommittee will be discussing a concept clearance for the Human Immunology Profiling Centers of Excellence (U01/U19).

Place: National Institutes of Health, 6610 Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Daniel Rotrosen, PhD, Director, Division of Allergy, Immunology & Transplantation, National Institutes of Health/NIAID, 6610 Rockledge Drive, MSC 6601, Bethesda, MD 20892-6601, 301-496-1886, drotrosen@niaid.nih.gov.

This notice is being published less than 15 days prior to the meeting date due to timing limitations created by the Economic Recovery Act.

Information is also available on the Institute's/Center's home page: <http://www.niaid.nih.gov/facts/facts.htm>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)