

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; 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 Children's Study Advisory Committee.

The meeting 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.

Name of Committee: National Children's Study Advisory Committee; Ethics Subcommittee.

Date: July 29, 2008.

Time: 10 a.m. to 12 p.m.

Agenda: The agenda items will include the NCS informed consent with specific reference to genetics. For questions or to register call Circle Solutions at (703) 902-1339 or via e-mail ncsinfo@mail.nih.gov. Public observers must attend in person at 6100 Executive Blvd, Room 5A01.

Place: National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Jessica Sapienza, Adjunct Study Program Analyst, National Children's Study, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5C01, Bethesda, MD 20892, (703) 902-1339, ncsinfo@mail.nih.gov.

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their 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.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: July 1, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Toxicology Program (NTP); Request for Information (RFI): High Throughput Screening (HTS) Approaches for Toxicology

AGENCY: National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

ACTION: Request for Information (RFI) and notice of public meeting.

SUMMARY: This notice is for planning purposes only. It does not constitute a solicitation or Request for Proposal (RFP), nor does it restrict the Government as to the ultimate acquisition approach. The Government does not intend to award a contract on the basis of this RFI or to otherwise pay for the information solicited. Any contract that might be awarded based on information received or derived from this RFI will be the outcome of the competitive process. Any purchases that might result from information received or derived from this RFI will be at the discretion of the Government.

Purpose: To ensure development of a rigorous and comprehensive battery of HTS assays, the NTP seeks information and comments on the identification and selection of critical cellular toxicity pathways for interrogation in cell-based high throughput screens. The NTP is also interested in receiving recommendations on particular molecular targets within these critical cellular toxicity pathways that are most informative for profiling the pathways, both in cell-based and biochemical assay formats. In addition to information on cellular pathways and targets, the NTP seeks information on technologies and assay systems that might be used in the development of a comprehensive approach to high throughput toxicity screening.

Responses to RFI: The Government requests a brief (no more than 1 page) description of the proposed presentation addressing one or more of the points listed below or other directly related topics. In considering responses to this RFI, please keep in mind the assay protocol requirements for assays run at the NIH Chemical Genomics Center

(NCGC) (http://www.ncgc.nih.gov/guidance/HTS_Assay_Guidance_Criteria.html).

- Recommendations on the identification and selection of critical cellular pathways involved in toxicity and associated with a phenotypic manifestation of toxicity in vivo (disease outcome).

- Information on assays that can be used to measure the activity of a compound on a target within a critical pathway.

- Information on the selection of the best targets within pathways and networks in order to accurately and fully characterize the activity of a compound within a specific pathway or the ability of a compound to trigger a stress-responsive pathway resulting in a defined toxicity or disease.

- Information on assays, technologies, or methods that will aid in identifying compounds which are active only after metabolic activation.

- New technologies or technologies under development that can be exploited in HTS programs, such as those underway at the NCGC or as secondary, targeted, follow-up testing to expand and more carefully characterize the findings from initial screens.

All responses should include the following information: Company name, company address, name of presenter, telephone number, and e-mail address. Responses should be submitted by August 11, 2008, either electronically via the meeting Web site or by fax, e-mail, or mail to: Jennifer Smith, Contract Specialist, NIEHS, P.O. Box 12874, Mail Drop EC-02, 79 T.W. Alexander Drive, Building 4401, Room 134, Research Triangle Park, NC 27709; fax: 919-541-2712; e-mail: smithj3@niehs.nih.gov. Responses will be reviewed to ensure that the Government, by extending an invitation to a party to participate in the RFI meeting, will receive information directly relevant to its HTS program for toxicity assessment and that the party fully understands the nature of the meeting and the type of information sought. Acknowledgement of receipt of responses will not be made nor will respondents be notified of the Government's assessment of the information received. No basis for claims against the Government shall arise as a result of a response to this request for information or in the Government's use of such information as either part of its evaluation process or to develop specifications for any subsequent announcement. Responses will not be returned. The summarized responses (without identifiers) may appear in internal reports or be made