DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting. The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.


Date: March 12, 2013.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5B01, 6100 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Peter Zelazowski, Ph.D., Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892, 301-435-6902, peter.zelazowski@nih.gov.

(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)


Michelle Trout,
Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Information: Main Study Design for the National Children’s Study

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The Eunice Kennedy Shriver National Institute for Child Health and Human Development (NICHD), National Institutes of Health (NIH), is issuing a Request for Information (RFI) as part of the National Children’s Study’s (NCS) effort to engage communities and receive public input on specific design questions for incorporation into the Main Study Design of the NCS. The information obtained from RFI responses will be used to guide the construction of decision points or parameters for the Main Study design over the next 12–18 months. This RFI was preceded by a workshop with the National Academy of Sciences which posed similar questions. For background information on this workshop, please visit: http://www.nationalchildrensstudy.gov/research/workshops/Pages/nationalacademyofsciencesworkshop.aspx.

DATES: RFI Release Date is February 11, 2013. Response Close Date is February 25, 2013.

ADDRESSES: To respond by February 25, 2013, please submit comments via email to NCS_RFI@mail.nih.gov. Please include citations for any references or reports that can be used as source material.

FOR FURTHER INFORMATION CONTACT: Questions about this request for information may be directed to Kate Winseck, MSW, The National Children’s Study, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6100 Executive Blvd., Rm. 5C01, Bethesda, MD 20891, NCS_RFI@mail.nih.gov, 301-594-9147.

SUPPLEMENTARY INFORMATION: The National Children’s Study is a congressionally mandated longitudinal birth cohort study intended to examine the effects of environmental exposures on the growth, development, and well-being of children. The NCS was mandated by the Children’s Health Act of 2000 (Pub. L. 106–310). The Study consists of several components, including: a pilot or Vanguard Study, a Main Study focused on exposure–response relationships, substudies embedded in the Vanguard Study or the Main Study, and formative research projects. Data collection for the Vanguard Study began in January 2009. The design was changed in 2010 from a door-to-door household recruitment model to include an Alternate Recruitment Study (ARS). The ARS tested three different recruitment strategies that differed as to initial point of contact with potential participants—direct outreach, household-based through an NCS contractor, and provider-based through a licensed health care practitioner. Currently the NCS is testing, through Provider-Based Sampling Substudy, a further refinement of the provider-based sampling and recruitment using hospitals and birthing centers in addition to clinics and health care provider offices that are sampled.

Between the summer of 2011 and the fall of 2012, the NCS held a series of meetings with federal and non-federal statistical sampling experts and others to discuss the most effective sampling approach and design for the Main Study. The NCS had multiple separate discussions and consultations with additional individuals and organizations. Based on these extensive discussions and consultations, the NCS is proposing the use of a multi-stage probability sample for the Main Study. The NCS plans to enroll women through multiple entry points into the Main Study, such as perinatally at hospitals and birthing centers, and prenatally through prenatal care providers. Additionally, women whose children are already enrolled will be followed as a preconception sample of subsequent births. Lastly, about 10% of the total number of participants to be recruited would be set aside for recruitment of a convenience sample for populations with characteristics or exposures of particular scientific interest that would likely be underrepresented in the other strata.

The questions solicited in this RFI focus on how much the NCS should emphasize prenatal data collection, and what the NCS could anticipate gaining through the prospective data collection compared to retrospective data acquisition and the use of extant sources such as medical records, other databases and modeling. The issue is not whether to have a prenatal stratum, but what proportion of NCS resources should be devoted to the effort.

Responses to this RFI will be used to inform the Main Study design.

Proposed Main Study Design

1. Goals and Outcomes

The primary objective of the NCS is to examine relationships among exposures and outcomes that affect children’s health and development. These factors include environmental exposures (with a broad definition of environment) and biological/genetic context. The NCS is not a study in a conventional sense. It will primarily function as a high quality data collection platform for researchers to explore hypotheses, access biospecimens and environmental samples, and analyze data. The Study’s objectives stated in the Children’s Health Act of 2000 are presented, along with the respective design considerations, in Table 1.