

**MEMO**

**To: Members, National Children's Study Federal Advisory Committee**

**From: Alan R. Fleischman, M.D., Chair**

**Re: Research Plan Discussion Questions**

**Date: June 13, 2007**

The Research Plan is a very large and comprehensive document. It is not my intention for the Advisory Committee to provide a complete peer review of the Research Plan as if the Committee were a Study Section. Rather, it is my hope that we can provide some observations and recommendations to the Study in order to enhance the Plan and provide some constructive thoughts about the development of the Research Plan over time.

Members of the Advisory Committee have very different areas of expertise and interest. Each member should focus on the parts of the Plan and the relevant questions below that are most consistent with their interests and come prepared to share observations accordingly.

We will organize discussion of the Research Plan into three sessions in order to provide sufficient time to briefly comment on several areas of importance.

**Session I:**

1-In light of finite resources provided for the Study and reasonable limitations on participant burden, does the Research Plan respond to the directive of the Children's Health Act of 2000, Congress and the President's Task Force?

2-Are the "Priority Outcomes" of sufficient public health importance and scientific interest to be the major focus of the Study?

3-Are the plans for genetic and genomic analyses appropriate to study the affect of genetics and gene-environment interaction on health growth and development of children?

4-Does the plan for data and sample repositories create an effective platform for future study and analyses of questions not yet posed or currently recognized?

## **Session II:**

1-Are the Specific Aims of the Study clear and able to be addressed by the Research Plan?

The specific aims of the Study are:

- To determine the presence or absence of effects, both harmful and helpful, related to the timing, frequency, magnitude, and duration of specific chemical, physical, biological, and psychosocial exposures in children's environments from preconception to adulthood.
- To determine possible environmental contributions to, or causes of specific diseases and conditions of children, including, but not limited to, prematurity and other outcomes of pregnancy, neurological and developmental disorders, psychiatric and behavioral disorders, altered physical development and sexual maturation, obesity and insulin resistance, asthma, and injuries.
- To determine how genetic variation and mechanisms, and the interaction of genes with environmental factors, influence disease risk and developmental trajectories in children.
- To serve as a national resource for future studies of child health and development by providing a rich database and repository of environmental and biological samples and information that can be used to address future questions and hypotheses.

2-Is the balance of measures across the key exposure domains and the early outcomes appropriate and reasonable?

## **Session III:**

1-Are the plans for analysis adequate and able to fulfill the goals of answering the hypotheses and additional important questions that may arise in the future?

2-Are the Human Subjects concerns adequately addressed for a document of this type?

3-Is the level of burden placed on participants reasonable for a study of this scale and scope?

4-Does the general plan for an Information Management System appear to be clear and reasonable and able to meet the needs of the Study?