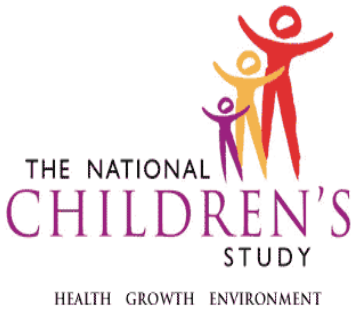

MEMO

Date: September 10, 2003

To: National Children's Study Advisory Committee Members

From: Executive Committee

Subject: Instructions for Review of Hypothesis and Formulation of Requests to Working Groups

This working meeting of the National Children's Study Advisory Committee (NCSAC) has several goals related specifically to improving communication between the NCSAC and the Working Groups (WGs). The meeting will focus primarily on a full and complete review of themes and hypotheses that are available from various sources. These include the following:***

- Hypotheses and thematic areas prepared by Lewin
- Hypotheses submitted for the September 2002 NCSAC Meeting
- Themes and hypotheses prepared by the ICC for the December 2002 NCSAC Meeting
- Hypotheses submitted for the June 2003 NCSAC Meeting
- Hypotheses submitted by other groups.

The NCSAC, during its thematic review of hypotheses, will need to identify specific instructions to the WGs about next steps in the development of the hypotheses, including:

- Exposures of concern (what are they, what media will be measured, how will the exposure be measured (Note: the word exposure is used broadly to include chemicals, physical factors, biological agents, social factors, etc.)
- Developmental periods of concern
- Outcomes that should be considered
- Developmental or life stages at which those outcomes are evaluated
- Gaps in thematic areas
- Gaps in hypotheses
- Highest priority foci for themes and hypotheses
- Collaboration needed across Working Groups for needed hypotheses synthesis

***See also the expanded description **Hypothesis Proposal Form** that is attached to *Memo to Working Groups*.

As you will have noted from the Agenda, much of the NCSAC activities will take place in breakout sessions organized according to themes. The themes are the current ones described in the ICC's document entitled: "**List of Core Hypothesis for the NCS, 11-6-02**) which is included under **Tab "P"** of this Book. Later in the meeting, the NCSAC will discuss whether it should recommend that the themes be retained or modified. In the breakout sessions, NCSAC Members will have an opportunity to discuss hypotheses submitted by their WGs that are relevant to the theme. Because of the current state of the hypotheses, some of the hypotheses are relevant to more than one theme. When this happens, the chair of the breakout group will identify the appropriate solution (e.g., retain a part of the duplicate hypothesis and send the other "part" to a different theme, or send the hypothesis in its entirety to a different theme breakout for action. Sending clear and specific instructions to the WGs is essential if they are to make revisions appropriately. This may be difficult in the case of a hypothesis that requires input from several WGs. In such a case, WG teams will be identified and a "lead WG" proposed. The NCSAC will recommend both the lead WG and the team Note takers will be available in the theme breakouts to help capture the discussion.

One of the primary goals of this meeting is to provide an opportunity for NCSAC members to understand their role as liaison to a WG, which will require:

- Communicating requests from the NCSAC to the WG
- Interacting with the WG to understand limitations and resources needed to carry out or respond to NCSAC requests
- Translating WG issues, concerns, scientific opportunities, and limitations to the NCSAC.

As previously described, this increased role for NCSAC members is necessary because of changes in NIH interpretation of the Federal Advisory Committee Act (FACA), as described on a separate transmittal. In this context, advice and recommendations on the Study flow from the NCSAC to the ICC and the NICHD Director. The NCSAC conducts its work with assistance of WGs, who operate under the guidance and direction of the NCSAC. Requests for information and materials relevant to NCSAC deliberations about the design, implementation, and conduct of the Study flow from the NCSAC to WGs. Information to assist deliberations of the NCSAC flow from WGs to the NCSAC. The NCSAC charter makes the NCSAC responsible for all activities of WGs. Therefore, NCSAC members must assume a greater degree of interaction with the WGs. Please note that the foregoing relates to NCSAC/WG interaction. The NCSAC also has interactions with the ICC, the Program Office, and the NICHD Director.

Framework for the Agenda for the September 2003 NCSAC Meeting

Sunday Evening Working Dinner: Logistics for Meeting

- Goals of meeting.
- New roles for NCSAC members.
- Design of breakout sessions for NCSAC members.
- Chairs of the breakout sessions.
- Charge for work to be done in breakout sessions.

Monday Morning

- Brief reports from ICC, NCSAC.
- Report for APA – Anderson.
- Discussion of concerns raised by the WG members and identification of solutions or pathways to solutions.
- Break out into 5 thematic sub-groups.
  - Undesirable outcomes of pregnancy
  - Altered neurobehavioral development
  - Injury
  - Asthma
  - Obesity and altered physical development

Monday Afternoon

- Continue work in thematic sub-groups.
- Convene full NCSAC from 5:00 p.m.–6:00 p.m. for brief reports.
  - Are the 5 current thematic areas sufficient for the Study?
  - Are there gaps or needed themes?
  - Progress on review of hypotheses within assigned thematic area

Tuesday Morning

- Reconvene in thematic sub-groups.

Tuesday Afternoon

- Convene full NCSAC from 12:30 p.m.–2:30 p.m. for more complete discussion. This will include reports from each theme meeting (10–15 minutes each). Following each report, the NCSAC members may wish to comment on hypotheses in themes to which they were not assigned.
- Final consideration and recommendation on thematic areas. These recommendations will go to ICC and NICHD Director.
- Final consideration and guidance for each WG. These will need to be explicit and clearly defined with an indication of how the further work performed by the WG will be utilized.

Meeting Follow-Up: Deadline Mid-October

Goals:

- NCSAC liaisons will review the outcome of the September 2003 NCSAC Meeting in conference calls with their assigned WGs.
- WGs will understand NCSAC requests and describe how long they will take to respond and resources needed to respond.
- ICC liaison will participate in the call and work with the Program Office to provide the needed resources through the science and logistics contractors.
- To have revised hypotheses for NCSAC review at December NCSAC Meeting
  The December meeting of the NCSAC will focus on complete discussion of the revised hypotheses, with the ultimate goal of offering the "final" set of recommendation.

Continued Activity of the NCSAC Liaison with Assigned WG

- Meet by conference call with WG as required to track status of WG revisions.
- Prepare report for NCSAC on WG activity for December NCSAC Meeting
- Work with ICC liaison to provide essential support for WG in conduct of activity.
  Question: Does the ICC provide support or does the Program Office? (Program Office through either Jan Leahey/Don Mattison from NCSAC members or through ICC members.)
- Bring WG questions and concerns to NCSAC Chair and Executive Secretary by mid-November.

Attachments:

List of NCSAC Assignments
Memo to Working Group Members

- Hypothesis Proposal Form