

# Presentation by the NSCAC Working Group on Advising the NCS Program Office

On Behalf of the Working Group

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Chair, National Children's Study Advisory Committee

January 24, 2012

# NSCAC Working Group on Advising the NCS Program Office

- ▶ Working Group formed to develop ground rules to ensure that the NCSAC is providing needed advice and input to the Program Office.
- ▶ Members: Bruce Gelb (Chair), Jonas Ellenberg, Carol Henry, Alma Kuby, Ellen Silbergeld

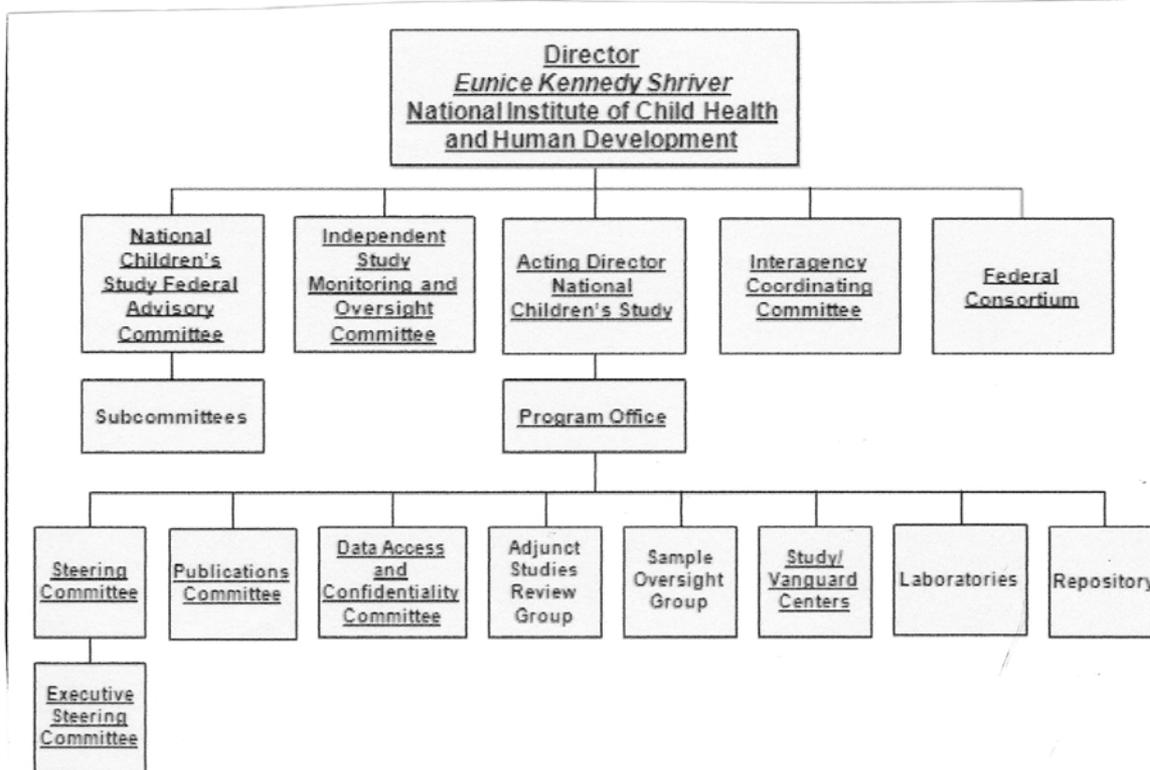
# Charter: Objectives & Scope

- ▶ The Committee will provide advice to the Director, National Institutes of Health (NIH), the Director, Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), and the Acting Director, National Children's Study (NCS), on present and future issues in the planning and implementation of the NCS.

# Charter:

- ▶ **Duties & Responsibilities**
  - The Committee makes recommendations on the planning and implementation of the NCS.
  
- ▶ **Agency or Official to Whom the Committee Reports**
  - The Committee will advise, assist, consult with, and make recommendations to the Director, NIH, the Director, NICHD, and the Acting Director, NCS.

# NCS Organization Chart



# Issues Identified by Working Group

- ▶ Advice requested seems somewhat ad hoc and not strategic in nature;
- ▶ Too little time devoted to dialogue during the NCSAC meetings; too many presentations where AC members are “observers” and learning the issue during the presentation;
- ▶ Meeting materials, especially non-Program Office information, not sent in a timely way for advanced review
- ▶ Disconnect on understanding level of advice.

# Example for Illustration

- ▶ Concern for sample size in the study discussed at the 3 meetings:
  - Recruitment strategies reviewed
  - Retention strategies reviewed
  - Power of the study for detecting disease/adverse effects reviewed
  - Increasing number of children to be recruited considered—excellent paper included in October 2011 briefing package but not discussed at meeting;
  - Trade-offs for cost and time not addressed
  - Leverage other studies suggested, but not described

# Goals for NSCAC Meetings?

- ▶ Slide decks and other briefing materials sent at least one, preferably two weeks, in advance.
- ▶ No slides used during the meeting, except for reference during discussions;
- ▶ Limited number of issues for each meeting, with the issue to be resolved 3–6 months out;
- ▶ All critical technical information presented so the issue can be understood, requests for more information are not needed, and timely, strategic advice can be rendered.

# Goals for NCSAC Meetings?

- ▶ More formal meetings;
- ▶ Issue framed by Program Office;
- ▶ Early discussion on new thinking or new issues is useful;
- ▶ Questions can be revamped during the process;
- ▶ Final review by the NCSAC
  - Lay out the question;
  - Allow the NCSAC to debate and make a formal recommendation;
- ▶ The NCS may choose to modify or ignore the recommendation.

# Suggestion for Leverage Issue:

- ▶ Briefing paper prepared for March NCSAC meeting;
- ▶ Identify/describe other candidate studies;
- ▶ Analyze/describe similarities/differences/barriers/timelines;
- ▶ Identify goal for collaboration or harmonization—information sharing or attain sufficient sample numbers for analysis?
- ▶ Proposal for how to “harmonize” with other studies.

NSCAC would review the completeness of the analysis and make recommendations on the proposal.

# Questions from NCSAC WG

- ▶ How will the Vanguard Study inform the Main Study?
- ▶ What are the barriers for implementing the “Main Study”?
- ▶ What data will the Main Study collect?
- ▶ Who or what organizations will conduct hypothesis-driven research?