

Supplemental Methodological Studies

Revised November 3, 2011

Overview

Supplemental Methodological Studies (SMS) pertain to focused studies that take place during the Vanguard (pilot) phase of the National Children's Study. They are geared to inform the Main Study as to the feasibility, acceptability, and/or cost of items pertaining to recruitment, operational and logistic issues, and Study visit assessments. Supplemental Methodological Studies are initiated from outside of the Program Office and are developed outside the Study protocol planning process. They are funded externally; that is, not with the National Children's Study appropriation. The Principal Investigator will be identified by the applicant. Each SMS will have a Study Co-Investigator. SMS that will be conducted at more than one location will also have a Study Facilitator for each additional location (see [Responsibilities section](#)).

Supplemental Methodological Studies are integrated with the Vanguard phase. That is, they involve National Children's Study participants and/or laboratory samples. Requests for just data are not SMS. In contrast, substudies are a type of formative research involving participants and/or laboratory samples, but initiated and funded by the National Children's Study.

Supplemental Methodological Studies will generally be short-term efforts to support the Vanguard pilot goals. For these studies to inform the design of the Main Study, a prompt turn-around time is pertinent.

Please send general inquiries to NCSSupMethStudies@mail.nih.gov

Review Process for Supplemental Methodological Studies Proposals

The National Children's Study Research Partnerships Program Director leads the formal process of review and approval of Supplemental Methodological Studies (SMS). Review of SMS applications will be conducted by Program Office scientists and, as needed, additional subject matter experts.

The review will assure the quality of integrity of the proposed SMS and assess: 1) its support of Vanguard Study goals (feasibility, acceptability, and cost of methodological aspects of the Study) and of current needs to inform the Main Study; and 2) its impact on the Vanguard Study infrastructure and participants.

Specific areas of review include but are not limited to: scientific value; relevance and "fit" with the Vanguard Study; burden to participants and to the Study infrastructure; appropriate use of the limited biospecimens and environmental samples; etc.

The initial review may result in a "Deferred Decision" pending response to specific questions or revisions as indicated by reviewer feedback. Alternatively, an application may be given "Provisional Approval" pending receipt and approval of additional required documentation. Applications that are not approved may, in some circumstances, be offered opportunity to revise and resubmit.

Selection of Site

If the applicant does not know which Centers or locations are appropriate for the specific Supplemental Methodological Study (SMS), the SMS Team will assist with establishing an appropriate connection. Identifying and obtaining concurrence of a specific Study Center(s) is not absolutely required prior to application submission. It is, however, to the applicant's advantage to contact specific Study Centers early in the process of developing the proposal as the Study Center's agreeing to implement an SMS is voluntary. The Study Center(s)/location(s) must be selected prior to final approval of an SMS.

Selection of National Children’s Study Co-Investigator (and Facilitators, If Applicable)

It is required that each Supplemental Methodological Study (SMS) have a designated National Children’s Study Co-Investigator. The National Children’s Study Co-Investigator is identified by the applicant and is distinct from the co-investigator(s) on the team proposing the SMS, but may be a Study Center Principal Investigator, or other named Study Center senior investigator (named in the Study Center/location contract), or may be a member of the Program Office. The person selected must be in a position to be able to objectively oversee the implementation of the SMS.

If more than one Study Center or location is involved with a given SMS, the SMS applicant must designate a National Children’s Study Facilitator from each additional location to work with the Study Co-Investigator in carrying out the assigned functions at their respective location(s).

The Co-investigator and Facilitators for SMS cannot charge their time for this effort to the National Children’s Study contract. These costs must be covered by the SMS funding source.

It is to the SMS applicant’s advantage to communicate early with a National Children’s Study Co-Investigator/Facilitator(s). However, if the National Children’s Study Co-Investigator is not known at the time of application, the Program Office SMS Team can assist in identifying a National Children’s Study Co-Investigator or Facilitator(s) as indicated.

Inclusion of the National Children’s Study Co-Investigator and/or Facilitator(s) in the authorship of any publications pertaining to the SMS is a matter of negotiation between the parties.

Responsibilities of the National Children’s Study Co-Investigator (and Facilitators, If Applicable)

Liaison: Provides support to the Supplemental Methodological Study (SMS) Principal Investigator by serving as liaison between the Supplemental Methodological Studies Investigator(s) and the National Children’s Study Program Office staff.

- Facilitates communication between the SMS Principal Investigator/applicant and the National Children’s Study during both the application process and implementation
- Facilitates communication with the Program Office, including but not limited to data access, publication, and specimen and sample access.

Advocate: Assumes accountability as an advocate for the National Children’s Study.

- Assures that the SMS burden to National Children’s Study participants and Study infrastructure does not exceed that which was proposed and approved.
- Assures the process throughout the SMS implementation is as was approved.
- Assures that the actual use of biospecimens and environmental samples is as was approved in the review process.
- Assures continued compliance with the relevant National Children’s Study policies and agreements, such as those pertaining to data use, publications, specimen/sample/repository use, and other agreements.
- Oversees, facilitates, and assures the timely development and implementation of the approved SMS, informing the Program Office Supplemental Methodological Studies Team of any inability to initiate the SMS within the anticipated and approved timeframe.
- Notifies the Program Office Supplemental Methodological Studies Team if the project is not progressing according to plan or is discontinued for any reason.

- Assures that the Supplemental Methodological Studies Team receives a periodic progress report from the SMS Principal Investigator regarding the status of the initiated SMS. Such reports are required at completion of the SMS, annually if the SMS extends over a year, and as requested by the SMS Team.
- Assures that appropriate documentation regarding continued IRB approval is provided to the Program Office IRB Team.

A signed [National Children's Study Co-Investigator/Facilitator Agreement Form](#) (PDF 35 KB) must be submitted prior to final approval of an SMS.

Timing of Submission and Duration of Approval

Supplemental Methodological Studies (SMS) pertain to the Vanguard pilot phase. The SMS proposal needs to reflect that the project can be completed in a timely manner to inform the planning of the Main Study. If all required documentation is not provided in a timely manner (generally 6 to 12 months, depending upon the needs) after National Children's Study approval, a reassessment of the proposal will be undertaken. This will be an iterative process; however, it is possible that Study approval could be rescinded if the prospects for implementing and completing the SMS in a timely manner are not acceptable.

Informatics

Interface with the National Children's Study informatics platform will be necessary for **data regarding** Supplemental Methodological Studies (SMS) which, by definition, "integrate" with the National Children's Study (that is, which involve National Children's Study participants and/or laboratory samples).

Data Access and Confidentiality

Supplemental Methodological Study (SMS) Investigators who require access to National Children's Study data files for the purpose of planning, implementing, and evaluating their methodological study must request and receive approval for a National Children's Study Data Use Agreement prior to accessing or collecting National Children's Study data. This Agreement includes a Data Sharing Plan. The terms of the [Data Use Agreement](#) are described in detail in the National Children's Study Data Access and Confidentiality Manual and briefly described on the National Children's Study Web site.

For a copy of the Manual or the Data Use Agreement forms, or for questions about data access procedures, please request via e-mail to NCSDDataAccess@nih.gov. Federal regulations regarding data access, confidentiality, and use will be enforced. Failure to comply could result in revocation of data privileges, termination of data agreements, fines, legal action, and contractual repercussions as appropriate. If National Children's Study data are needed to develop the SMS proposal, then a request for data should be submitted separate from and prior to submitting the proposal. However, if National Children's Study data are not required for the purpose of developing the proposal, then the Data Use Agreement can be submitted after provisional SMS approval. The Data Sharing Plan should be submitted for review and approval after provisional approval of the SMS proposal.

Material Transfer Agreement for Use of National Children's Study Biospecimens and Environmental Samples

Use of National Children's Study laboratory materials (biospecimens and environmental samples) for Supplemental Methodological Studies (SMS) requires execution of a Material Transfer Agreement between the institution requesting the material and NICHD. Refer to [An Overview of Material Transfer Agreements in NICHD Clinical Research](#) (PDF 285 KB).

Separate Material Transfer Agreement templates are required to request use of [biological specimens](#) (PDF 79 KB) and to request use of [environmental samples](#) (PDF 110 KB).

Send Material Transfer Agreements to NCSRepository@mail.nih.gov with a copy to SuppMethApp@mail.nih.gov.

Institutional Review Board (IRB) Guidance

Institutional Review Board (IRB) review will be required for Supplemental Methodological Studies (SMS) that interface directly with National Children's Study participants and/or use participants' identifiable data, biospecimens, and/or environmental samples. The IRB will determine whether or not the samples are identifiable. SMS will require local (and perhaps NICHD) IRB review and approval or alternatively a determination by the relevant IRB that the study is not considered to be human subjects research.

NICHD IRB: The National Children's Study Program Office staff (Human Subject Protections/IRB Team) will determine whether a given application requires NICHD IRB review. If so, the IRB Team will initiate the process at NICHD. If NICHD IRB approval is required, this approval should, whenever possible, precede local IRB approval and must be obtained prior to implementation.

Local IRBs: Applicants are responsible for assuring that SMS receive the required local IRB review(s). Applicants must submit documentation of all applicable local IRB determinations (approvals, waivers, etc.) and the IRB-approved protocol with a cover letter highlighting any interim changes from what was reviewed and provisionally approved to NCS_IRBs@mail.nih.gov with a copy to the project's National Children's Study Co-Investigator and a copy to SuppMethApp@mail.nih.gov. Initial documentation of IRB determinations should be submitted either with the application or as soon as possible thereafter. Final approval to implement the project will be provided only after documentation of local IRB approval(s) or a waiver has been received and reviewed by the Program Office. Documentation of continuing local IRB approval must be submitted two weeks prior to the Supplemental Methodological Study protocol's approval expiration date (as determined by the local IRB).

Informed Consent

Applicants are responsible for developing all informed consent forms and materials required for the conduct of their Supplemental Methodological Study (SMS). Applicants should review the National Children's Study general consent form in collaboration with the local IRB(s), and determine whether the research proposed in the SMS is covered by the National Children's Study general consent or whether it requires additional consent forms and materials or waivers of informed consent or documentation of informed consent. The general consent form can be obtained upon request from the National Children's Study Program Office at: NCS_IRBs@mail.nih.gov.

Office of Management and Budget Guidance

The National Children's Study Program Office staff will determine whether referral to the Office of Management and Budget (OMB) is required for a given Supplemental Methodological Study proposal. If OMB referral is necessary, Program Office staff will inform the applicant and the applicant will provide the information necessary for OMB to consider approval. This includes, but is not limited to, a description of the study design, protocol, evaluation plan, and respondent burden hours. The Program Office will initiate the OMB referral, and will inform the applicant of the outcome. In general, OMB action, if indicated, is preferred to begin prior to IRB assessment. If OMB approval is indicated, it is required before information collection begins.

Funding and Contracted Services

Funding details will be required only after the Application is provisionally approved. Funding shall include any necessary coverage for specific Coordinating Center, repository, and other National Children's Study contracted services and materials necessary to carry out the project.

Examples of functions that may be carried out by National Children's Study contracted services to assist with Supplemental Methodological Study (SMS) planning and implementation may include, but are not limited to:

- Identification and tracking of participants
- Conducting impact analyses, such as potential additional burden on Study infrastructure and participants
- Developing “pick-lists” for obtaining laboratory samples
- Aliquotting, handling, and shipping laboratory materials.

Guidance will be provided by the Program Office regarding logistics and costs, if indicated, for any services required of the National Children’s Study or its contractors to support the SMS.

Publications

All publications pertaining to Supplemental Methodological Studies (SMS) (whether core data centrally collected or local data) will comply with the National Children’s Study publication policies and procedures, including containing applicable acknowledgements and disclaimers, similar to those below, as appropriate.

- “This analysis was conducted as part of the National Children’s Study, supported by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, and funded, through its appropriation, by the Office of the Director of the National Institutes of Health.”
- Any support that an author or his or her organization received in connection with the work being published must be acknowledged. For example:
 - “Supported in part by NICHD Contracts No(s) _____.” (Insert contract numbers as appropriate for Study Center[s], Repository, specific laboratories, or other contracts.)
 - “Supported in part by NIH Grant No. _____.” (Insert grant number or other grant identification if the activity reported upon was supported by any grant funding.) All sources of funding related to that particular analysis must be cited in each manuscript.

The above are simply examples of the types of acknowledgments and disclaimers that *may* be appropriate for a given publication. The language can be modified, but the intent should be included as indicated above.

If any restricted-use data are intended for publication (such as a manuscript or abstract) or presentation, the document must be provided to the National Children’s Study Confidentiality Officer for disclosure review prior to submission for view by persons not party to an National Children’s Study Data Use License, including the general public. Please contact the National Children’s Study Confidentiality Officer at NCSDDataAccess@nih.gov.

Additionally, the National Children’s Study Program Office will be notified of all peer reviewed accepted publications, presentations, and published abstracts regarding Supplemental Methodological Studies: title of publication, name(s) of authors, name of journal or other venue, date, volume, and number of pages. The National Children’s Study Program Office will be provided a reprint in electronic format at SuppMethApp@mail.nih.gov. The publication will be reflected in the National Children’s Study Bibliography.

Application for Supplemental Methodological Studies for the National Children’s Study

This HTML version of the application is read only. This version should only be used if Microsoft Word is unavailable. To prepare an application for submission, you must copy and paste the content into a word processing program.

The preferred format for submission is the Microsoft Word application with expanding text fields provided on the National Children’s Study Web site (under Research/Supplemental Methodological Studies).

Applications for Supplemental Methodological Studies should be *a maximum of 5 pages in black 12 point Arial or Georgia font*, on 8.5” X 11” pages with 1-inch margins. Figures, graphs, charts, etc. must fit within the page and margin requirements. Include *a 1-page abstract with your application*. The abstract does not count toward the 5-page maximum.

Requests for just data are NOT Supplemental Methodological Studies (SMS) and do not utilize this application. SMS involve interaction with participants or requests for biospecimens or environmental samples.

<p>I. Title of the Proposal:</p> <p>This proposal requires:</p> <p>___ Interaction with National Children’s Study participants</p> <p>___ Request for National Children’s Study biospecimens</p> <p>___ Request for National Children’s Study environmental samples</p> <p>___ Request for National Children’s Study data (in addition to the above)</p>
<p>II. Key Words (up to 5 key words, identifying the main topic(s) of the proposal):</p>
<p>III. Principal Investigator: <i>Include an NIH biosketch with application.</i></p> <p>Name:</p> <p>Field(s) of expertise:</p> <p>Position, organization, location, telephone number, e-mail address:</p> <p>___ I confirm that I have appropriate expertise and sufficient institutional support to conduct this research.</p>
<p>IV. Proposed collaborators (names, organizations, area(s) of expertise): Include NIH biosketches of key collaborators whose expertise is essential to the study.</p>
<p>V. Proposed Study Center(s) and Study location(s) at which to implement this study if known at time of application (can be submitted after provisional approval):</p> <p>Have the National Children’s Study Co-Investigator and Facilitators been selected? (Note:</p>

The National Children’s Study Co-Investigator is not simply a co-investigator of the SMS. The National Children’s Study Co-Investigator has a specific role to oversee the implementation of the SMS as a National Children’s Study advocate. National Children’s Study facilitators have the same role but at the additional locations.)

Include names of proposed National Children’s Study Co-Investigator and Facilitator(s) if known at time of application (can be submitted after provisional approval):

A signed National Children’s Study Co-Investigator/Facilitator Agreement Form must be submitted prior to final approval of an SMS.

VI. Goals of the proposed study:

VII. Explain the rationale for utilizing the National Children’s Study as a platform for this study. Reflect how this study adds value and supports the goals of the Vanguard phase (to study feasibility, acceptability, and cost of methodological aspects of the National Children’s Study; to inform the Main Study). What is the potential benefit to the National Children’s Study?

VIII. Study Design:

- A. Detailed description of study design (include the time allotment/burden for the various aspects of the SMS):**
- B. Data collection activities and any need for National Children’s Study data (see SMS Policies and Procedures, “Data Access and Confidentiality” and “Data Sharing”). Note: Request for just data are not SMS**
- C. Participant interface (numbers, ages, types of participants):**
- D. Biospecimens (purpose, types/quantities, . . .)**
- E. Environmental samples (purpose, types/quantities, . . .):**

IX. Timeline and schedule of deliverables. Include expected duration and approximate start and end dates of the study. Does the projected timeline align with that of the Vanguard phase at the specified locations? Will it be completed in time to inform the Main Study?

X. Note any potential negative impact on National Children’s Study infrastructure and participants. Are there any perceived obstacles to satisfactorily accomplishing the goals of this study?

XI. Funding:

Expected funding source:

Projected approximate cost:

<p>Funding status:</p> <p>Note any required National Children’s Study contracted services:</p> <p><i>Note: Formal funding DETAILS will be requested after provisional approval of Application. The funding source must cover any required charges that are not billable to the National Children’s Study contract.</i></p>	
XII.	Will this study require local IRB approval? ___Yes ___NO
XIII.	Proposed criteria for evaluation of the project upon completion:
XIV.	<p>Do you agree to comply with National Children’s Study policies and procedures regarding the various aspects of performing a Supplemental Methodological Study (data access, data disclosure, material transfer, IRB approvals, publications, etc.)?</p> <p>___ I agree to comply with National Children’s Study policies and procedures.</p>
XV.	<p>Submitted by (corresponding applicant name):</p> <p>E-mail address:</p> <p>Date of submission:</p>

Submission of Application and Related Documentation

Submit the Supplemental Methodological Studies application, the 1-page abstract, the PIs (and any key collaborators’ biosketches, and any specific questions about the application to the National Children’s Study Supplemental Methodological Studies submission mailbox: SuppMethApp@mail.nih.gov.

Please send a signed hard copy to the following address:

National Children’s Study
 Supplemental Methodological Studies Team
 6100 Executive Boulevard, Suite 3A01
 Bethesda, MD 20892-7510

Requests for data access and submissions of the National Children’s Study Data Use Agreement should be sent to NCSDataAccess@nih.gov with a copy to SuppMethApp@mail.nih.gov.

All applicable local IRB determinations (approvals, waivers, etc.) should be sent with the IRB-approved protocol and a cover letter describing any changes to the application that was provisionally approved to NCS_IRBs@mail.nih.gov with a copy to the selected National Children’s Study Co-Investigator and a copy to SuppMethApp@mail.nih.gov.

Material Transfer Agreements requesting use of National Children's Study biospecimens or environmental samples should be sent to NCSRepository@mail.nih.gov with a copy to SuppMethApp@mail.nih.gov.

All publications must include appropriate acknowledgments and disclaimers.

Disclosure Review: All publications including non public use data must be submitted to NCSDataAccess@nih.gov for disclosure review.