

Adjunct Studies Overview

Overview

As the National Children's Study proceeds, scientific knowledge will evolve and the Study will serve as an appropriate platform upon which to build additional scientific studies. Investigators from various sectors (such as academia, government, and industry) are encouraged to propose (and obtain approval to conduct) adjunct studies. Such studies will enhance the breadth, depth, and value of the Study and will assure continued interest of a diverse group of investigators, which is critical to the overall success of the Study. To protect the quality and integrity of the Study, adjunct studies will be reviewed and approved by a defined, rigorous process. Adjunct studies will generally require outside (non-Study) funding.

Definitions

Adjunct Studies: An adjunct study involves a portion of the National Children's Study cohort, utilizing new or existing Study data and Study participants and/or their bio-specimens and/or environmental samples. Adjunct studies can take place at one or more Study Centers, on all or a portion of their Center participants. Generally, adjunct studies will be initiated and planned outside of the Study protocol planning process and funded with non-Study funding; that is, by such mechanisms as government grants (for example, R-O1) applied for by the initiator, by intramural federal resources, through public private partnerships, or from other sources.

Additions to the Core Protocol: Outside initiated proposals for studies that pertain to the entire cohort are considered modifications of or additions to the core protocol. These additions or changes, once approved, will be incorporated into the core protocol through the core protocol planning process. If such proposals add cost to the Study, they will likely require outside funding, as with adjunct studies.

Internal Adjunct Studies: In specific circumstances, the National Children's Study may require, authorize, and fund specific adjunct studies (for a portion of the cohort) to be planned outside the core protocol planning process, yet funded with Study funds. These are referred to as "Internal Adjunct Studies" to reflect internal (Study) direction, initiation, and funding despite external development.

Categories of Adjunct Studies – Human Subjects Considerations

As appropriate, any given adjunct study may or may not require separate informed consent from National Children's Study participants. The adjunct study proposal must reflect the applicant's assessment as to whether or not specific informed consent is required for that project. The review process will assess this as well. When informed consent is required, the adjunct study informed consent document will clearly identify this adjunct study as additional to the core Study and will clearly inform participants of the voluntary nature of participation in this portion of the Study.

Categories of adjunct studies:

- a. Without direct interaction with human subjects
 - analysis of biologic specimens
 - analysis of environmental samples
- b. With direct interaction with human subjects
 - "minimal risk" research (Federal Guidelines 45CFR46.404–406), e.g., observational studies and questionnaires
 - "more than minimal risk" research with no prospect of direct benefit
 - intervention research (with prospect of direct benefit) as an embedded case-control study
 - other

Requests to analyze just existing data are reviewed by a separate process and are not submitted to the Adjunct Study Team for consideration.

Review of Adjunct Study Proposals

The National Children's Study Program Office/Research Partnerships Program Director coordinates a formal process for review and approval of all adjunct studies. This is a two-tier process with evaluation first of an initial brief Preliminary Application which, if it appears to be an appropriate adjunct study proposal, is then followed by a more in-depth Full Application. There are several tiers of review, some of which will occur simultaneously in order to facilitate timeliness of review. (Requests for just de-identified data do not fall within the Adjunct Studies purview.)

To assure the quality and integrity of the proposed study and to assess its impact on the core Study, specific areas of review include but are not limited to: scientific merit, scientific relevance and "fit" with the Study, burden to participants and to the Study, risk, and other human subjects issues. Highest priority shall be given to studies that (1) relate to and enhance the core Study objectives; (2) have strong scientific and public health merit; (3) have potential for positive impact on healthcare practice or policy; (4) produce minimal burden on Study participants and do not unduly complicate or compromise the core Study; and (5) require the unique characteristics of the Study cohort such that there is mutual benefit.

Upon National Children's Study approval of the Full Application, documentation of that approval will be provided to assist proposers in seeking funding. Final approval to initiate the adjunct study will be contingent upon assurance of funding and completion of required "outside" reviews (for example, IRBs, OMB) as indicated.

The areas of review on the National Children's Study Adjunct Study Application form largely mirror the major areas in NIH Research Grant applications. The adjunct study application allows for "cutting and pasting" relevant portions of those grant applications in order to minimize work. Funding details will be requested only after the proposal application is approved.

The National Children's Study (Program Office) Adjunct Studies Team shall work with investigators proposing adjunct studies to enhance opportunity for success of proposals. The Adjunct Studies Team shall monitor the status of adjunct study applications, completion of appropriate reviews and documentation, receipt of funding, and initiation of the project. Progress reports will be required periodically from each adjunct study Principal Investigator (PI).

The current timeline calls for the first year of the Vanguard Centers' participation from summer 2008 until summer 2009 to serve as the pilot for all National Children's Study protocols. Adjunct studies should be planned to begin no earlier than the completion of the pilot year for each respective age of the cohort.

Participation of National Children's Study Investigators as "Co-Investigators"

Every adjunct study requires the participation of a National Children's Study investigator whose essential role is to ensure accountability to the Study for the use of Study participants, data, bio-specimens, and/or environmental samples. Study investigators include Study Center PIs (or designated senior member of their team) and Program Office or Interagency Coordinating Committee (ICC) members. The Study investigator must be designated as a co-investigator of the adjunct study. When an adjunct study is based at a particular Study Center or Centers, the Center PI (or designee) will generally serve as the Study co-investigator for that adjunct study.

At the time of application submission, some applicants may not know which Study Center(s) or Study co-investigators (Study Center, Program Office, or ICC) are most appropriate as collaborators for that proposal. Identifying or contacting a specific Study Center(s) and/or a potential Study co-investigator are not required prior to application submission. However, if proposers have a specific Study Center(s) and/or Study co-investigator in mind, they are encouraged to contact that Center or individual about the proposal early in the process of developing the proposal. This would be highly advantageous in facilitating the review process. As part of the review and approval process, a Center(s) and Study co-investigator will be mutually agreed upon.

Data Access and Publications

As part of the full application, the proposer must agree to comply with National Children's Study policies and procedures regarding data access and use as well as publication procedures. Access to Study participant data, bio-specimens, and/or environmental samples will be limited to that which is specifically pertinent to and authorized for the approved adjunct study.