

16. SUB-STUDIES, OUTSIDE ADDITIONS TO THE CORE PROTOCOL, AND ADJUNCT STUDIES

As the National Children’s Study proceeds, it will serve as a platform on which to build additional scientific research. Aspects of the NCS will yield ideas for sub-studies within the core protocol planning process and opportunities for adjunct studies, as well.

16.1 Sub-Studies Within the Core Protocol

The core protocol was developed through the NCS Program Office protocol planning process and paid for with NCS funds. This core protocol is to be performed on the entire cohort. Additionally, there will be some “sub-studies” of the core protocol planned by the NCS protocol planning team but performed on just a portion of the cohort. Sub-studies are generally funded by NCS and planned and approved through the same process as the core protocol. The Study Centers will carry out a sub-study as an integral portion of the core protocol.

16.2 Outside Initiated and Funded Studies That Pertain to the Entire Cohort

Outside initiated and funded proposals for the entire cohort will be considered as proposed modifications of the core protocol, ultimately decided upon and incorporated into the protocol by the same process that is used for the core protocol planning. The review process for such proposals will be a combination of the adjunct study review process and the core protocol planning process, as appropriate for the specific proposal.

16.3 Adjunct Studies

An adjunct study is performed on a portion of the cohort at one or more Study Centers, on all or a portion of their Center participants and/or their biospecimens or environmental samples. Adjunct studies are derived from or initiated and planned outside the NCS Program Office protocol planning process (e.g., can be initiated by a Study Center, government agency, independent investigator, industry, etc.), and are funded by such mechanisms as government grants applied for by the initiator, public-private partnerships, etc. Adjunct studies are reviewed and approved through a defined process and are implemented with the concurrence of the specific involved Study Centers. Individual Centers have the option of not participating in any particular (“outside initiated”) adjunct study. Adjunct studies, therefore, are considered optional for the Study Centers.

While adjunct studies are generally neither planned by the NCS protocol planning team nor funded by NCS, in very specific circumstances the NCS may require or authorize and fund specific adjunct studies (for a portion of the cohort) to be planned “outside” the regular protocol planning process yet paid for with NCS funds (e.g. specific studies at specific Study Centers). These are referred to as “Internal Adjunct Studies,” to reflect their internal (NCS) direction and funding despite “external” (i.e., other than NCS protocol planning team) scientific development.

16.4 Review Process

Adjunct studies and other additions to the protocol will undergo a formal review to assure maintenance of the quality and integrity of the Study and to address scientific merit; scientific “fit” with the NCS; burden to the participant and the Study; risk and other human subjects’ issues; etc. A brief preliminary application has been developed as well as an in-depth full application to assure attention to the quality of the proposal and also to facilitate the submission, review, and approval of such proposals. Both are electronic and allow for relevant sections of government grant applications to be “cut and pasted” into the form.