

## Note to File - Description of Formative Research Projects

\*\*\* Future change requests will lay out protocol for each formative research project. \*\*\*

### The following description pertains to formative research projects (excerpted from Supporting Statement A):

#### NCS Recruitment Substudy: Supplemental Measures to Evaluate Selected, Coordinated Formative Research Protocols

A fourth research goal of the Recruitment Substudy is to examine the feasibility, acceptability and cost of a series of formative research protocols within a subset of Vanguard Study participants and their peers with the aim of informing the NCS Main Study.

For example, some extensive measures, including biospecimens, were previously approved for use in the initial 7 Vanguard Study locations. As described above, when first launched the additional 30 study locations in the Recruitment Substudy used streamlined data collection instruments to allow focus on improving recruitment rates. Subsequently, we would reintroduce selected measures that have been revised to improve their scientific robustness, burden, and cost. However, unlike the study visit assessments described under, "NCS Recruitment Substudy: Supplemental Measures to Evaluate Selected Study Visit Assessments," at the time of the current submission the exact protocol revisions we intend to use, and the subset of participants we would engage, have not been fully determined. Therefore, we intend to submit these particular proposals in the future as requests for non-substantive change.

Other examples of planned coordinated formative research protocols include data collection from persons not enrolled in the NCS Vanguard Study as a means of testing items for relevant populations efficiently in advance of the NCS Main Study. For example, smaller, in-depth data collection would be requested from children demographically similar to, but older than Vanguard Study children to test age-specific items, persons demographically, but not geographically, eligible to participate in the Vanguard Study to test recruitment messaging, and hospital and other service providers whose opinions could inform information collection practices for the NCS Main Study. At this time, the exact protocol revisions we intend to test, and the size and specific subpopulations to be recruited have not been fully determined. Therefore, we intend to submit these particular proposals in the future as requests for non-substantive change.

The NCS Main Study will benefit from many focused formative research projects. Therefore, we intend to use the current clearance in conjunction with generic clearance already obtained on behalf of the NCS.