

Note to File - Description of Formative and Methodological Research Projects

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

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

Planning for Future Methodological Research

The NCS supports ongoing methodological and formative research to support development of Vanguard and Main Study protocols.

Proposed methodological research may examine the feasibility, acceptability and cost of a series of Study protocols within a subset of Vanguard Study participants or external populations with similar eligibility characteristics. Examples of such 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 specific protocols and measures. At this time, the exact protocols we intend to test, and the size and specific subpopulations to be included have not been determined. As projects are developed each would be submitted for OMB/OIRA review and clearance as future 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.