



## Policy and Procedures for the Involvement of HCHS/SOL in Research Consortia

**HCHS/SOL defines a consortium as** an organized group of scientific investigators who have agreed to participate in cooperative research efforts towards a shared goal. This cooperation usually involves multiple institutions or organizations over an extended period of time and also has its own governance structure, such as steering and publications committees. Consortia are able to address scientific questions that cannot be addressed via individual studies due to scope, resources, population characteristics or size, and/or expertise.

### Procedures for investigators who would like to include HCHS/SOL in their consortium:

1. Investigators outside of the HCH/SOL network must first identify a HCHS/SOL parent study PI (or Co-PI) who will support, review, and sponsor Ancillary Studies or Publications proposals associated with the Consortium.
2. To request the involvement of HCHS/SOL, a Consortium must submit a proposal to either the Publications Committee (PC) or the Ancillary Studies Committee (ASC) and a Consortium form with general information. A HCHS/SOL website account is required to submit these proposals.
  - Consortia that will **only request existing data from HCHS/SOL without seeking funding**, to develop single or multiple publications, must submit an initial manuscript proposal to the HCHS/SOL Publications Committee, following policies and procedures described in HCHS/SOL Publications Policy. All subsequent manuscript proposals must be submitted to the PC.
  - Consortia that will **generate new data, involve HCHS/SOL participant contact, and/or seek external funding** (beyond simple Coordinating Center support) will submit an Ancillary Study proposal to the HCHS/SOL Ancillary Studies Committee, following policies and procedures described in HCHS/SOL Ancillary Studies Policy.
3. After initial approval of a consortium, a HCHS/SOL liaison will be appointed who is usually the person who brings the proposal to the HCHS/SOL for approval or is the sponsoring PI/Co-PI, or a person named by the sponsoring PI. Each approved consortium will receive a distinct tracking number used to monitor further activities.

### Responsibilities of the HCHS/SOL Consortium Liaison:

- To ensure adherence of the consortium to HCHS/SOL general policies and procedures.
- To facilitate the process and communication of Data Use Agreement (DUA) and transfer of data to the consortium for approved manuscript proposals, and/or for data harmonization where appropriate.
- To determine whether a fee for service or subcontract arrangement is needed to facilitate HCH/SOL's role in providing data and supporting the consortium effort, and to work with the Coordinating Center to determine costs as needed.
- To serve as the primary reviewer for consortium proposals and manuscripts submitted to the PC, although in some cases there may be other reviewers as well.
- To ensure there is appropriate representation of HCHS/SOL investigators on manuscripts and obtain HCHS/SOL co-author nominations to conform with the agreed-upon number of slots.
- To inform the HCHS/SOL of manuscripts or other activities arising from the Consortium that use HCHS/SOL data, through yearly reports, produced in collaboration with HCHS/SOL parent study PI.

## Tracking of Revisions to Policy and Procedures for the Involvement of HCHS/SOL in Research Consortia

Version, Date	Revision Summary
<b>1 – Nov. 2023</b>	ORIGINAL. HCHS/SOL Steering Committee must approve first HCHS/SOL joining the Consortium, and afterwards investigators can submit proposals (Ancillary Study proposals or manuscript proposals).
<b>2 – Feb. 2026</b>	Simplified process from two steps to one step. There is no longer needed to first receive “Approval in Concept” by the HCHS/SOL Steering Committee. Instead, the Consortia request goes directly to either the Ancillary Studies Committee or the Publications Committee.