D-H Site Supplement Template Crosswalk

The Site Supplement template should be used for studies where a sponsored research protocol exists or a multi-site study where D-H is not the lead site. This document should be completed and submitted, along with either the sponsored protocol or the lead site protocol. It is important to note that several sections that were included in CPHS documents are not in the research protocol templates. This information that was previously found in submission worksheets are duplicate information to Worksheets and Checklists available in the HRPP Toolkit.

The following tool is designed to provide you with a map of where information is located in the new D-HH Site Supplement Template.

New D-HH Site Supplement	CPHS Application or Appendix
1.0 Study Summary	- *Not a previous section in Protocol PLUS* - Clinical Protocol: Study Summary
2.0 Study Interventions/Investigational Agent	- *Not a previous section in Protocol PLUS* - Clinical Protocol: 1.2 Investigational Agent - Clinical Protocol: 5.1 Study Drug Description - Clinical Protocol: 5.7 Drug Packaging - Clinical Protocol: 5.9.1 Receipt of Drug Supplies - Clinical Protocol: 5.9.2 Storage
3.0 Procedures	- Protocol PLUS: 2. Placebo Use or Inconsistency with Standard Care - Protocol PLUS: 3. Genetics
4.0 Data and Specimen Banking	- CPHS Supporting Document: Data, Specimens, and Registries Research Plan (Section outlined creation of registry, database, or bank)
5.0 Sharing of Results with Subjects	*New Section* *(Information gathered previously in the Consent Form)*
6.0 Inclusion and Exclusion Criteria	- CPHS Supporting Document: Data, Specimens, and Registries Research Plan (Section outlined creation of registry, database, or bank)
7.0 Vulnerable Populations • *HRP-413 - CHECKLIST - Non-Viable Neonates* • *HRP-414 - CHECKLIST - Neonates of Uncertain Viability*	- Protocol PLUS: 4. Equitable Participant Selection (b. Vulnerable populations) - CPHS Supporting Document: Research involving Neonates - CPHS Supporting Document: Research Involving Pregnant Women and Fetuses

• *HRP-412 - CHECKLIST - Pregnant Women* • *HRP-416 - CHECKLIST – Children*	- CPHS Supporting Document: Research Involving Children
8.0 Local Number of Subjects	- Protocol PLUS 4. Equitable Participant Selection (a. Estimated number of participants at Dartmouth CPHS reviewed sites)
9.0 Local Recruitment Methods	- Protocol PLUS: 6. Recruitment - Protocol PLUS: 8. Compensation or Gifts
10.0 Withdrawal of Subjects	- *No associated section in Protocol PLUS* - Clinical Protocol: 4.4.1 When and How to Withdraw Subjects
11.0 Risk to Subjects	- Protocol PLUS: 1. Risk & Benefits (a & b) - Protocol PLUS: 2. Placebo Use or Inconsistency with Standard Care
12.0 Data Management and Confidentiality	- Protocol PLUS: 10. Confidentiality of Data
13.0 Provisions to Monitor the Data to Ensure the Safety of Subjects	- Protocol PLUS: 1. Risk & Benefits (d)
14.0 Provisions to Protect the Privacy Interests of Subjects	- Protocol PLUS: 9. Privacy of Participants
15.0 Compensation for Research-Related Injury	- Protocol PLUS: 5. Financial impact on participants (b) For an injury or illness related to research….
16.0 Economic Burden to Subjects	- Protocol PLUS: 5. Financial impact on participants (a) List the tests, visits, and procedures performed for only research purposes and specify who will pay
17.0 Consent Process • *HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process*	- Protocol PLUS: 7. Informed Consent, Assent, and Authorization - CPHS Supporting Document: Waivers & Alterations Request Form
18.0 Process to Document Consent in Writing • *HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent*	- Protocol Plus: 7. Informed Consent, Assent, and Authorization - CPHS Supporting Document: Waivers & Alterations Request Form
19.0 Setting	*New Section*
20.0 Resources Available	*New Section*