D-HH Template Social Behavioral Sciences (SBS) Protocol Crosswalk

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. Additionally, all projects will now use the same protocol, unless your study only involves Analysis of Data/Specimens.

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

New D-HH Template Social Behavioral Science (SBS) Protocol	CPHS Application or Appendix
1.0 Study Summary	*New Section*
2.0 Objectives	- Social, Behavioral, and Non-Clinical Research: 2. Objectives and Hypothesis
3.0 Background	- Social, Behavioral, and Non-Clinical Research: 1. Introduction and Background
4.0 Study Endpoints	- Social, Behavioral, and Non-Clinical Research: 5. Study Progress Monitoring
5.0 Study Intervention	- Social, Behavioral, and Non-Clinical Research: 3. Study Design
6.0 Procedures Involved	- Social, Behavioral, and Non-Clinical Research: 3. Study Design - Social, Behavioral, and Non-Clinical Research: 8. Deception
7.0 Data and Specimen Banking	- CPHS Supporting Document: Data, Specimens, and Registries Research Plan (Section outlined creation of registry, database, or bank)
8.0 Sharing of Results with Subjects	*New Section* *(Information previously referenced in the Consent Form)*
9.0 Study Timelines	- Social, Behavioral, and Non-Clinical Research: 3. Study Design
10.0 Subject Population	- Social, Behavioral, and Non-Clinical Research: 9. Equitable Participant Selection
11.0 Vulnerable Populations • *HRP-413 - CHECKLIST - Non-Viable Neonates,* • *HRP-414 - CHECKLIST - Neonates of Uncertain Viability*	- Social, Behavioral, and Non-Clinical Research: 9. Equitable Participant Selection - Protocol PLUS: 4. Equitable Participant Selection (b. Vulnerable populations) - CPHS Supporting Document: Research involving Neonates

• *HRP-412 - CHECKLIST - Pregnant Women* • *HRP-416 - CHECKLIST - Children*	- CPHS Supporting Document: Research Involving Pregnant Women and Fetuses - CPHS Supporting Document: Research Involving Children
12.0 Local Number of Subjects	- Social, Behavioral, and Non-Clinical Research: 9. Equitable Participant Selection - Protocol PLUS 4. Equitable Participant Selection (a)
13.0 Recruitment Methods	- Social, Behavioral, and Non-Clinical Research: 10. Recruitment - Protocol PLUS: 6. Recruitment - Protocol PLUS: 8. Compensation or Gifts
14.0 Withdrawal of Subjects	*New Section*
15.0 Risks to Subjects	- Social, Behavioral, and Non-Clinical Research: 6. Risks & Benefits - Social, Behavioral, and Non-Clinical Research: 7. Unexpected Events or Incidental Findings - Protocol PLUS: 1. Risk & Benefits (a & b) - Protocol PLUS: 2. Placebo Use or Inconsistency with Standard Care
16.0 Potential Benefits to Subjects	- Social, Behavioral, and Non-Clinical Research: 6. Risks & Benefits - Protocol PLUS: 1. Risk & Benefits (c)
17.0 Data Management and Confidentiality	- Social, Behavioral, and Non-Clinical Research: 10. Confidentiality of Data - Social, Behavioral, and Non-Clinical Research: 4. Analysis - Protocol PLUS: 10. Confidentiality of Data
18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects	- Social, Behavioral, and Non-Clinical Research: 5. Study Progress Monitoring - Protocol PLUS: 1. Risk & Benefits (d)
19.0 Provisions to Protect the Privacy Interests of Subjects	- Social, Behavioral, and Non-Clinical Research: 13. Privacy of Participants - Protocol PLUS: 9. Privacy of Participants
20.0 Compensation for Research-Related Injury	- Social, Behavioral, and Non-Clinical Research: 12. Compensation or Gifts - Protocol PLUS: 5. Financial impact on participants (b) For an injury or illness related to research….

21.0 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
22.0 Consent Process • *HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process*	- Social, Behavioral, and Non-Clinical Research: 11. Informed Consent, Assent, and Authorization - Protocol PLUS: 7. Informed Consent, Assent, and Authorization - CPHS Supporting Document: Waivers & Alterations Request Form
23.0 Process to Document Consent in Writing • *HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent*	- Social, Behavioral, and Non-Clinical Research: 11. Informed Consent, Assent, and Authorization - Protocol Plus: 7. Informed Consent, Assent, and Authorization - CPHS Supporting Document: Waivers & Alterations Request Form
24.0 Setting	*New Section*
25.0 Resources Available	*New Section*
26.0 Multi-Site Research	*New Section*