D-HH Template 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 Protocol Template.

New D-HH Template Protocol	CPHS Application or Appendix
1.0 Study Summary	- Clinical Protocol: Study Summary
2.0 Objectives	- Clinical Protocol: 2 Study Objectives
3.0 Background	- Clinical Protocol: 1.1 Background
4.0 Study Endpoints	- Clinical Protocol: 3.2 Primary Study Endpoints - Clinical Protocol: 3.3 Secondary Study Endpoints - Clinical Protocol: 3.4 Primary Safety Endpoints
5.0 Study Intervention(s)/Investigational Agent(s)	- Clinical Protocol: 1.2 Investigational Agent - Clinical Protocol: 5.1 Study Drug Description - Clinical Protocol: 5.4 Preparation and Administration of Study Drug - Clinical Protocol: 5.7 Drug Packaging - Clinical Protocol: 5.9.1 Receipt of Drug Supplies - Clinical Protocol: 5.9.2 Storage
6.0 Procedures Involved	- Clinical Protocol: 5.2 Study Drug Treatment Regimen - Clinical Protocol: 5.3 Method for Assigning Subjects to Treatment Groups - Clinical Protocol: 5.5 Subject Compliance Monitoring - Clinical Protocol: 5.6 Prior and Concomitant Therapy - Clinical Protocol: 5.8 Blinding of Study Drug - Clinical Protocol: 5.9.3 Dispensing of Study Drug - Clinical Protocol: 6 Study Procedures - Protocol PLUS: 2. Placebo Use or Inconsistency with Standard Care - Protocol PLUS: 3. Genetics - CPHS Supporting Document: Genetic Research Form

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	- Clinical Protocol: 3.1 General Design
10.0 Inclusion and Exclusion Criteria	- Clinical Protocol: 4.1 Inclusion Criteria - Clinical Protocol: 4.2 Exclusion Criteria - Clinical Protocol: 4.3 Subject Recruitment and Screening (*Screening information only*)
11.0 Vulnerable Populations • *HRP-413 - CHECKLIST - Non-Viable Neonates,* • *HRP-414 - CHECKLIST - Neonates of Uncertain Viability* • *HRP-412 - CHECKLIST - Pregnant Women* • *HRP-416 - CHECKLIST - Children*	- Protocol PLUS: 4. Equitable Participant Selection (b. Vulnerable populations) - CPHS Supporting Document: Research involving Neonates - CPHS Supporting Document: Research Involving Pregnant Women and Fetuses - CPHS Supporting Document: Research Involving Children
12.0 Local Number of Subjects	- Protocol PLUS 4. Equitable Participant Selection (a) - Clinical Protocol 7.1 Statistical Plan Sample Size Determination
13.0 Recruitment Methods	- Clinical Protocol: 4.3 Subject Recruitment and Screening (Recruitment information only) - Clinical Protocol: 12.3 Subject Stipends or Payments - Protocol PLUS: 6. Recruitment - Protocol PLUS: 8. Compensation or Gifts
14.0 Withdrawal of Subjects	- Clinical Protocol: 4.4.1 When and How to Withdraw Subjects - Clinical Protocol: 4.4.2 Data Collection and Follow-up for Withdrawn Subjects
15.0 Risks to Subjects	- Protocol PLUS: 1. Risk & Benefits (a & b) - Protocol PLUS: 2. Placebo Use or Inconsistency with Standard Care
16.0 Potential Benefits to Subjects	- Clinical Protocol: 1.5 Dose Rationale and Risk/Benefits - Protocol PLUS: 1. Risk & Benefits (c)

17.0 Data Management and Confidentiality	- Clinical Protocol: 7.2 Statistical Methods - Clinical Protocol: 9.4 Records Retention - Protocol PLUS: 10. Confidentiality of Data
18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects	- Clinical Protocol: 8.4 Unblinding Procedures - Clinical Protocol: 8.5 Stopping Rules - Clinical Protocol: 8.6.1 Internal Data and Safety Monitoring Board - Clinical Protocol: 8.6.2 Independent Data and Safety Monitoring Board - Clinical Protocol: 10.1 Study Monitoring Plan - Protocol PLUS: 1. Risk & Benefits (d)
19.0 Provisions to Protect the Privacy Interests of Subjects	- Protocol PLUS: 9. Privacy of Participants
20.0 Compensation for Research-Related Injury	- 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*	- 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*	- 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*
27.0 Publication Plan	- Clinical Protocol: 13 Publication Plan
28.0 References	- Clinical Protocol: 14 References
29.0 Attachments	- Clinical Protocol: 15 Attachments