Drexel UNIVERSITY
Office of Research

St. Christopher's Hospital for Children Protocol Submission Checklist

Initial Submissions

- ☐ **HRP-211 Initial Application:** Application signed by Principal Investigator (PI) and Department's Section Chief. The Section Chief signature takes the place of the Department Chair signature.
  - **Note:** Only faculty and staff members may serve as PI. Students, medical research residents/fellows are co-investigators.

- ☐ **Signed HRP-211 by the St. Christopher's Office of Research Support by Jane McGowan/Mary Moran and Maureen Meier.**
  - **Note:** Case reports must also be signed by the above individuals.

- ☐ **Hardcopy documentation required for study personnel who cannot be located in COEUS:**
  - Financial Conflict of Interest Form 1
  - Financial Conflict of Interest Form 2 (if answered "yes" to any questions on Form 1)
  - Add these documents to the submission

- ☐ **HRP-503 Protocol**
  - All sections included in the HRP-503 template should be addressed. The following guidance documents are to be referenced if applicable:
    - Waiver/Alteration of the Consent Process (HRP-410)
    - Waiver of Documentation of Consent (HRP-411)
    - Waiver of HIPAA Authorization (HRP-441)

- ☐ **Written Proposal/narrative. Note: Some studies may not have a proposal. Please include the proposal in the submission if you have one.**

- ☐ **Completed CITI Training: Medical CITI Learner Group**
  - **Minimum courses required for Medical include:**
    - Human Subjects Research
    - Health Information Privacy & Security (HIPS)-only required for Learner Group 2 if PHI will be collected or accessed as part of the research.

- Conflict of Interest
- Good Clinical Practice (GCP)-If funded by NIH or if protocol adheres to GCP.
    - When Good Clinical Practice is a requirement of the sponsor or protocol, the study personnel should complete the HRP-432 Good Clinical Practice Form.

If Applicable, the following would also need to be submitted:

- HRP-502 Informed Consent
- Assent (for children ≥ 7 years of age)
- Advertisements/flyers/recruitment/phone script/what will be said to introduce the study, in addition to any written material that will be seen/heard by research subjects.
- Letters of permission to access privately held data, specimens, or populations of subjects.
- Any documents that subject/parent needs to complete such as a diary.
- Individual Investigator Agreement (IIA) for any researcher who is not affiliated with an institution or is affiliated with an institution which does not have an FWA.
- Business Associate Agreement (BAA) is required from any individual providing services related to the research, and will have access to PHI.
- Data Use Agreements (DUA): any researcher who is not affiliated with Drexel and/or American Health Systems (AAHS) should contact the Drexel University Privacy Board for guidance on DUA requirements.

Modifications/Amendments

- **HRP-213 Modification Form (hardcopy):** These submissions do not require Office of Research Support review/signature but do require signature by the PI.

Continuing Review Progress Report/Final Report:

- **HRP-212 Continuing Review Form (hardcopy):** These submissions do not require Office of Research Support review/signature but do require signature by the PI and Section Chief.

Additional ancillary reviews (for Initial Submissions and Modifications)

- **Financial Conflict of Interest:** Compliance reviews financial conflict of interest for any researcher that completes a FCOI 2 form declaring financial conflict of interest.
- **Local Law Review:** Research that includes sites/facilities outside of Pennsylvania are reviewed for any laws for consideration when conducting research.

- **Facility Research Committee Review:** May be needed for research using St. Christopher's Hospital facilities.
- **Biosafety Committee Review:** May be required if the protocol involves any procedures that pose biological hazards.
- **Radiation Safety Committee Review:** May be required if the protocol will involve radiation and human subjects.