Office of Research

Drexel University Protocol Submission Checklist

This checklist specifies the various requirements to submit an IRB application. Investigators submitting for Exempt, Expedited or Full applications to the IRB will find this checklist useful. Students applying for IRB review are strongly encouraged to adhere to these guidelines.

Initial Submissions

Study Personnel Requirements

- ☐ Only faculty and staff members may serve as PI. Students, medical research residents, and fellows should be co-investigators.

- ☐ CITI Training (www.citiprogram.org)
  Minimum courses required:
  - ☐ Human Subjects Research
  - ☐ Conflict of Interest
  - ☐ Health Information Privacy and Security*
    *Only if you plan to collect or access PHI
  - ☐ Good Clinical Practice**
    **Only if sponsor required, funded by NIH, or protocol adheres to GCP

- ☐ COEUS Training
  Only the study personnel submitting via COEUS need access to the platform. Individuals who do not need access to the platform are not required to complete COEUS training.
  - ☐ Receive approval from your department chair to obtain COEUS access. This may be in the form of an email or letter. You will need this document when completing the COEUS eIRB Authorization Form
  - ☐ Complete the COEUS eIRB Authorization Form
  - ☐ Receive COEUS eIRB training. You can access online training via:
    - Blackboard – request access here
    - Career Pathway, or
    - Contact HRPP@drexel.edu or (215) 762-3944

COEUS Submission

- ☐ Students creating a protocol in COEUS should indicate "Student Project" as the Type under the "General Info" tab

- ☐ All other applications for Exempt, Expedited, or Full reviews should indicate "Standard" as the Type under the "General Info" tab

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

- ☐ Financial Conflict of Interest (FCOI) Form 1 MUST be submitted for every individual on the protocol. If a conflict is identified (if answered "yes" to any question), the individual must also complete and submit FCOI Form 2.

- ☐ HRP-503 Protocol
  All sections included in the HRP-503 template should be addressed. If a section does not apply, indicate "not applicable." The following guidance documents are to be referenced if applicable:
  - HRP-410 Waiver/Alteration of the Consent Process
  - HRP-411 Waiver of Documentation of Consent
  - HRP-441 Waiver of HIPAA Authorization

- ☐ Additional forms and/or materials are to be provided for IRB review **as applicable**. Any information that will seen/heard by subjects must be reviewed by the IRB. Supplemental documents may include:
  - ☐ HRP-502 Consent Form
  - ☐ Assent (for children ≥ 7 years of age)
  - ☐ Advertisements/flyers/recruitment scripts
  - ☐ Questionnaires/surveys
  - ☐ Interview scripts/focus group scripts
  - ☐ Any written material that will be seen/heard by research subjects
  - ☐ Letter of Permission for use of privately controlled data or facilities
  - ☐ Individual Investigator Agreement (IIA) for any investigators who are not affiliated with an institution or are 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 Agreement (DUA): any researcher who is not affiliated with Drexel and/or American Academic Health Systems (AAHS) should contact the Drexel University Privacy Board for guidance on DUA requirements

- ☐ If you cannot look up and add an individual directly into COEUS, the individual should complete:
  - ☐ HRP-201 Contact Information Form
  - ☐ Financial Conflict of Interest Form 1
  - ☐ Financial Conflict of Interest Form 2 (if answered "yes" to any questions on Form

  Upload these documents to the attachment section of the submission

- ☐ When Good Clinical Practice is a requirement of the sponsor or protocol, or if funded by NIH, the study personnel should complete the HRP-432 Good Clinical Practice Form

Ancillary Reviews

Additional ancillary reviews may be required, depending on the setting and protocol procedures:

- ☐ Facility Research Committee review may be needed if the study is conducted at Hahnemann University Hospital or St. Christopher's Hospital for Children
- ☐ Financial Conflict of Interest review may be needed if a conflict of interest is indicated
- ☐ Local law review: If the research is planned to occur outside of Pennsylvania, legal review is required to assess whether external state laws need to be considered during IRB review
- ☐ 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

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Modifications

- ☐ HRP-213 Modification Form: The Word document version of this form is no longer required. Please complete the electronic COEUS Modification application.

- ☐ Attach any modified documents to the COEUS amendment

Continuing Review Progress Report/Final Report

- ☐ HRP-212 Continuing Review Form: The Word document version of this form is no longer required. Please complete the electronic COEUS continuing review/final report application

- ☐ Attach any relevant documentation to the COEUS renewal, e.g.,
  - Clean and tracked versions of the HRP-503 Protocol
  - Clean and tracked versions of the HRP-502 Consent Form