IRB Process and Procedures
Clinical Research

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Agenda

- Getting Started
- IRB process
- How to have a successful trial
- Identifying the “Team”
- Initiation/Site Initiating Visit (SIV)
- Sponsored study start-up
- Introduction WIRB/DU
Getting started

1. Feasibility Questionnaire
   - Used by sponsor to select site
   - Questions specific to discipline
   - Provide accurate information (answer truthfully)

2. Ensure patient population
   - Involve Principal Investigator (PI)
   - Search Allscripts/eTenet
IRB Process

All individuals involved in human clinical research at Drexel University must obtain the certification for Human Subjects Research Protection training as well as HIPAA I & II. To acquire certifications go to
https://www.citiprogram.org/

1. Register
2. Choose Drexel as your participating institution
3. Fill out required information
4. Select courses for clinicians
5. Take test (refresher course every three years)
6. Remember: 80% is passing, to print certification
Continuing

http://drexel.edu/research/compliance/humanSubjects/humansubjectstraining/

Obtain HIPAA I & II

http://www.drexelehstraining.com/Home.aspx

Depending on the type of activities conducted in your work environment specific topics will be chosen
What’s needed for a Successful Trial

1. Must have the patient population

2. Principal Investigator’s involvement

3. Laboratory work space (centrifuge, shipping supplies, annual inspections needed-check for updated sticker)

4. Equipment (ECG, weight scale, BP cuff, etc.)

5. Personnel (appropriate staff)

6. GCP standards

7. Institutions SOPs

8. Time Management (organization)
Identifying the “TEAM”

1. Principal Investigator (P.I.)
   Responsible for study.
   Can delegate duties to staff once trained.

2. Sub-Investigator
   Assist P.I. w/assigned duties

3. Coordinator
   Study - feasibility questionnaire, start-up (prepare regulatory paperwork, source documentation, locating storage for drugs/devices, receiving necessary items for study, etc.), site initiation, recruitment, implementation and closeout/termination.

4. Technicians-Imagining (echo, MRI)

5. Local laboratory
   CLIA, CAP
Site Initiating Visit (SIV)

Sponsor's representative will
1. Visit facility to validate site (check all equipment used for trial (ECG, scale, BP cuff) laboratory, offices where subject will be seen.

2. Meet w/team members to review the protocol and Good Clinical Practice

3. Meet support staff: medical records, pharmacy, laboratory, etc. (remember to notify all depts. in advance of planned visit.)
Sponsored study start-up (Part 1)

Curriculum Vitae (CV) - PI, Sub-PI

Medical Licenses – PI, Sub-PI

Conflict of Interest – all individuals in trial 1572 (if applicable)

Training (CITI)
Combining the Consent

Between Sponsor/CRO & coordinator/study staff

Combine sponsors template with DU

Mandatory sections listed below:

1. COMPENSATION FOR RESEARCH RELATED INJURY
2. CONFIDENTIALITY AND PRIVACY
3. RESPONSIBILITY FOR COST
Introduction

Western Institutional Review Board (WIRB)

- All Industry Sponsored

  1. Inquire to make sure sponsor covers “ALL” IRB fees

Drexel University (DU)

- PI initiated
- NIH grants
- Cooperative Groups (ECOG & NRG)
- Retrospective chart review
Study Submission

**Western Institutional Review Board (WIRB)**

- Review Checklist
- Project Submission Transmittal Form
- Internal Authorization Form
- Initial Review Submission Form [Drexel Institutional Review Boards | Research | Drexel University](https://research.drexel.edu/irb)
- Consent Template
- Conflict of Interest #1
- Conflict of Interest #2 (if #1 is yes)
- Application for use of Radioactive Materials (as applicable)
- Export Control Transmittal form (not listed but required) (electronically)

**Drexel University (DU)**

- Exempt, Expedited, and Full
- HRP-201 Contact Information
- HRP-211 Application for initial review
- HRP-502 Template consent (medical)
- HRP-503 Template protocol (medical)
- HRP-432 GCP (PI to complete if initial submission)
- Conflict of Interest
- Export Control Transmittal (answer questions electronically)
- Project Submission Transmittal Form
Taking a look at the forms
Preparing require forms & obtaining signatures

http://drexel.edu/research/compliance/humanSubjects/irb/
Submission Process

1. Initial submission - all documents are e-mailed to hrpp@drexel.edu (Drexel will forward the documents to WIRB). Investigators and/or study staff are not permitted to apply directly to WIRB

2. Follow-up documents can be sent directly to WIRB & cc HRPP
Study Start-up

1. Storing the drug/device
2. Creating source documents
3. Shipping specimens (need certification)
4. Send protocol, budget, and CTA through Coeus portal
   https://coeus.drexel.edu/coeus/userAuthAction.do
5. Begin informed consent (ICF) process
Consenting “TIPS”

1. Know your subjects; make sure the ICF is written so they can understand it. Involve the PI.

2. Full disclosure or risks/benefits or financial interest.

3. Provide adequate education for all parties involved in the informed consent process.

4. Make use of DU SOP’s regarding consenting and documentation of consent (HRP 090 & 091)

5. Templates for DU & WIRB can be found on the Drexel Office of Research site.
Accessing Subject’s Records

- **Tenet’s**
  - Contact Barbara Mannino (215-762-7558)
  - Prior to monitors visits, they must fill out form to gain access to specific trials

- **Allscripts**
  - Contact IT 215-762-1999
Submitting Amendments

DU amendments are e-mailed to HRPP@drexel.edu

WIRB amendments are e-mailed to clientservices@wirb.com and cc’d to HRPP@drexel.com
Study Closure

Drexel University (DU)  

HRP 212  
Continuing Review

WIRB  

WIRB Study  
Closure Report

Both forms can be obtained from the site below

http://drexel.edu/research/compliance/humanSubjects/irb/applications/