**DREXEL UNIVERSITY**
**GUIDELINES FOR WIRB SUBMISSIONS**

Drexel University (DU) has had an agreement in place authorizing the Western Institutional Review Board (WIRB) to review and approve industry sponsored multi-center clinical trials on behalf of DU investigators.

All **NEW** submissions to WIRB for review must be made to Human Research Protection (HRP), the submission to be provided in an "electronic" format. This change in application format coincides with and enhances the pending implementation of the Coeus electronic application program.

## The Process for Submission

The following requirements must be met before submitting the forms electronically to the HRP. See instructions below for completing the forms. All forms must be typed according to WIRB requirements. Incomplete forms or submissions will be returned to the investigator.

## Training Requirements

1. All investigators and key personnel conducting research procedures must complete the Human Subjects Research Basic Training certification (CITI Training) program.
2. If protocol is a clinical trial or involves use of drug/device; CITI GCP training is required.
3. If protocol involves access to or collection of PHI; CITI HIPS and HIPAA I & II DU Core Modules training is required.
    - CITI and Drexel Core Training Modules may be found at: http://www.drexel.edu/research/compliance/training/
4. If the study involves handling biological specimens, individuals who are handling such specimens must document that they have completed the "Bloodborne Pathogen Training". This training is provided by the Office of Safety and Health, annual recertification is required. Web-based training can be obtained by logging on to **http://www.drexel.edu/facilities/healthSafety/**.
5. This training can be completed in parallel when WIRB/IRB is reviewing your research project.

## Required Materials for Submission

All WIRB required forms and links are posted on the ORRC Website at **http://www.research.drexel.edu/compliance/IRB/wirb.aspx**.

Please note that WIRB requires investigator and all co-investigator's CV and professional license, if any, and are to be included with the application.

The forms available from the HRP website are to be completed:

1. Project Submission Transmittal Form
2. Internal Authorization Form

3. Review Checklist Form
4. Initial Review Submission Form
5. Consent Form Template
6. Conflict of Interest Form

AND AS NECESSARY

7. Application for the use of Radioactive Materials or Use of Radiation

**Electronic Submission Process**

New submissions to WIRB shall be provided to the HRP in an electronic format as follow.

1. IRB/WIRB application documents that require signatures will be scanned and saved to your PC/MAC, while word docs or PDFs, such as consent forms, written protocols or investigator brochures, etc. can be saved directly without need for scanning.
2. Each individual document type is scanned or saved and individually labeled; ex: (ICF word doc. Investigator 12345; written protocol PDF, Investigator 12345; I.B. PDF, Investigator 12345; WIRB Initial Review form word doc, Investigator 12345…).
3. 20 MBs is the maximum size in total of all attachments that an email is capable of sending or receiving. Each document is attached to the email as an individual word doc/PDF document and titled appropriately.
4. If the MB size of all documents in total exceeds 20 MBs you have the following options:
    - a. compress the attachments into a Zip file and attach to the email,
    - b. save the application to a CD/DVD and drop off in the ORRC, or
    - c. send the application in multiple separate emails, however you must label each email in the "subject" box as 1 of 2; 1 of 3, etc.
5. New applications as well other forms of action with the IRB, such as Continuing Reviews, on-site A/Es, Amendments, etc.; may be emailed to ORRC@drexel.edu ***and*** Cc'd to the primary WIRB coordinator Lois Carpenter; lac87@drexel.edu . The "subject" line of the email to include protocol number and PI name.

HRP will forward the **NEW** submission packets to WIRB within 24 hours.

Communications to WIRB in regards to continuing reviews, amendments and on-site adverse events shall be made directly to WIRB with an exact copy of those documents submitted as email attachment to the ORRC for placement in the PI's Coeus record.

If you need assistance to complete WIRB forms or if you wish to meet with an IRB coordinator to receive assistance to submit a WIRB application, please contact the ORRC at 215-255-7857 or email to Lois Carpenter; lac87@drexel.edu