IRB Process and Procedures
General Discussion

Office of Research
Human Research Protection
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IRB Coordinator III
Topics of Discussion

- Developing and Designing A Research Study
- Preparing Your Submission For The IRB
- Submitting To The IRB
- What Happens After IRB Approval Is Granted
- Making Changes To An IRB Approved Protocol
- Extending Your IRB Approved Protocol
- Closing Your IRB Approved Protocol
What Is Research?

- *Research* is defined as a *systematic investigation*, including *research development*, *testing and evaluation*, designed to *develop or contribute to generalizable knowledge*. *

- Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes.

- For example, surveys, questionnaires, interviews, and focus groups maybe considered research activities.

*HHS regulations define research at 45 CFR 46.102(d)*
Preparing a Research Study

- Things to consider
  - Design and its Impact on IRB Review and Compliance
  - Available Resources
  - Adequate Staffing
  - Consulting with Qualified Personnel
Developing A Research Study Which Allows Innovation In Accordance With Regulations
Design, IRB Review and Compliance

- Consulting with your academic advisor/Principal Investigator
- Choosing your hypothesis
- Choosing your desired population
- Choosing inclusion/exclusion criteria
- Determine if and how you will interact with subjects
- Determine how you will advertise
- Will you consent subjects, waiver or alteration of the consent process or request a waiver of written documentation of consent process?
Resources

- Do you have ample access to the desired population?
- Is the assistance of an outside agency required?
- Have all staff members completed the required CITI and Drexel core trainings?
- Have any department required trainings been completed?
**Staff**

- Do you have enough staff to safely and effectively carrying out the research study?
- Do you have qualified researchers on the study?
- Is a specialist or expert required?
Consultation

- It is important that all students/residents reach out to their academic advisor/Principal Investigator with any research design related questions
- It is important that all faculty/staff members consult with departmental research liaisons with any research design related questions
- The Human Research Protection/IRB office is available to answer questions which cannot be resolved at the departmental level
Preparing For IRB Submission
Determining The Risks Involved

- The level of review is determined by the level of risk to subjects
  - "Minimal Risk" requires that the likelihood and degree of harm or discomfort expected in the proposed research are not greater in and of themselves from those normally encountered in daily life or during the performance of routine physical or psychological examinations or tests.
  - "Minimal Risk" does not include the administration of medication or the use of any device placed inside the body.
IRB Levels of Review

- Study may fall within the guidelines of one of the following levels of review:
  - Letter of Reliance (Authorization Agreement)
  - Letter of Determination
  - Case study or case report
  - Standard Application
    - Exempt from IRB review (essentially no risk)
    - Expedited review (minimal risk)
    - Full review (more than minimal risk) requiring rigorous review of risks and benefits by convened IRB
Specialized Applications

- Request for Letter of Determination, Letter of Reliance, Case Studies, and Case Reports each have their own applications which are located on the research website.
  - These applications provide specific instructions and requests additional documents exclusive to that particular application.
What Should Be Included In A Standard Application

- **At a minimum**, all applications will provide the IRB the following: (Exempt, Expedited and Full applications use the same application format)
  - Proposal Transmittal Form (unless the form has already been uploaded into COEUS).
  - HRP 201 Contact Information (for each person listed on the study).
  - Financial Conflict of Interest Forms (The link for conflict of interest form found within HRP-201 Contact Form, all personnel must complete a COI disclosure form 1 and disclosure form 2 if required).
  - HRP 211 Application for Initial Review
  - HRP 503 Template Protocol.
  - Written proposal/Grant/thesis.
What Should Be Included In A Standard Application (cont’d)

- **As Applicable** documents to submit:
  
  - HRP 502 Template Consent form
  - Assent Form
  - Surveys/questionnaires/data collection tools
  - Advertisements/flyers/recruitment script/what will be said to introduce the study
  - Letters of permission to access privately held data, specimens or populations of subjects
  - Phone scripts
Pre-submission Review

- Review all documents included in the submission prior to submission to the IRB
  - Ensure all of the required documents are included in the submission
  - All permission letters from external and internal sites are preferred to be on letterhead and signed, however PDF copies of email are also accepted
  - Completeness of all forms, including all required signatures (which may also be PDF)
  - Department Chairs cannot sign as Department Chairs and be an investigator on the study. Please have someone else in authority sign in their place
  - All advertisements submitted must be included and according to template (Drexel University logo and standard statement included)
Consultation

- It is important that all students/residents initially reach out to their academic advisor/Principal Investigator with any research application related questions
- It is important that all faculty/staff members initially consult with departmental research liaisons with any research application related questions
- The Human Research Protection/IRB office is available to answer questions which cannot be resolved at the departmental level
IRB Submission and Review Process
Preparing For Electronic Submission To IRB

- IRB application documents that require signatures can be saved as a PDF document and signed using a PDF signature. If no PDF signature is available, document can be printed, signed, then scanned and saved.
- Microsoft word documents or PDFs, such as consent forms, written protocols or investigator brochures, that do not require a signature may be saved directly to your computer.
- Each application document must be attached individually. All inclusive PDF submissions will be returned.
- All submissions must be sent to HRPP@drexel.edu with a Cc to the appropriate IRB Coordinator.
IRB Meeting Deadlines

- Meeting dates and deadlines for submission to the full board meetings are posted on Human Research Protection Website [http://www.drexel.edu/research/compliance/humanSubjects/irb/calendars/](http://www.drexel.edu/research/compliance/humanSubjects/irb/calendars/)

- There are NO deadlines for New Exempt and Expedited review applications.

- WIRB deadlines: Contact WIRB directly at [www.WIRB.com](http://www.WIRB.com)
Who Are Your Reviewers?

- Letter of Determinations, Case Reports, Case Studies and Exempt reviews are reviewed by the IRB Coordinators in the Human Research Protection Office.
- Expedited Reviews are reviewed by members of the IRB. The applications are reviewed outside of the Committee meeting by an experienced member.
- Full Committee Reviews are Conducted by the Convened IRB at the scheduled monthly meeting.
- There are also independent Committee reviews that may be required, they include Tenet, IACUC, Biosafety, Radiation Safety and Privacy Board.
Who To Contact

- **Adult Medical IRB #1: Exempt and Expedited Applications** = Barbara Ferrigno, bf34@drexel.edu
- **Adult Medical IRB #1: Full Submission Applications** = Melissa Casey, mac542@drexel.edu
- **Social and Behavioral IRB #3: All Applications** = Teresa Hinton, tch47@drexel.edu
- **Pediatric Medical IRB #4: All Applications** = Linda Tate, lmt43@drexel.edu
- **Western IRB (WIRB) All Applications** = Lois Carpenter, lac87@drexel.edu
- **Letters of Determination and Reliance Requests** = Cheryl Storino, cls69@drexel.edu
What Happens Next?
Getting Started

- Begin Recruiting
  - Researchers may begin recruiting for a research study once IRB approval has been received.
  - For Media Advertising, please contact Brad Levinson, Director, Marketing, University Communications at 215-895-0379 or brad.d.levinson@drexel.edu
  - Only IRB approved advertisements are to be used to recruit participants. This means only advertisements including the Drexel University IRB approval stamp.
Consent and Enrollment

- Enrollment of Subjects
  - If a phone screen or script is used, researchers must develop a system to document its use and retain this documentation as part of the regulatory file as required.
  - All consenting of subjects into the research must follow the guidance provided on forms HRP-090 (Informed Consent Process for Research) and HRP-091 (Written Documentation of Consent).
  - Only IRB approved consent forms are to be used to enroll participants. This means using only consent forms that include the Drexel University IRB approval stamp.
  - Signed consent forms must be also be retained as part of the regulatory file according to University policy.
Data Collection, Storage and Retention

- All data must be collected, stored and retained according to University policy. This will be described by the researchers in the IRB application.
- All data collected including Personal Health Information (PHI) must be stored in a locked secured location and encrypted as required by the IRB and Privacy Board.
- All data collected on behalf of Drexel University must be retained in accordance with your department’s policy.
- Student researchers may retain copies of the collected data but the originals must be retained by the Principal Investigator.
Record Retention

- All records must be managed according to Drexel University retention schedules.
- Retention schedules define records by content and establish the length of time records need to be kept.
- Scheduled records must be retained for the appropriate length of time and disposed of according to the schedule.
- [http://www.drexel.edu/generalcounsel/drexelpolicies/OGC-6](http://www.drexel.edu/generalcounsel/drexelpolicies/OGC-6)
Record Retention

- The PI shall maintain the records on every approved protocol, which shall be accessible for possible inspection and copying by the IRB and authorized representatives of DHHS and the FDA at a reasonable time and in a reasonable manner.
- All records relating to a specific Research Protocol
  - Three (3) years following completion of the research; or,
  - In the case of research involving minors, seven (7) years after the minor reaches the age of eighteen (18); or
  - At least seven (7) years after any child born to the research subject during the research reaches the age of 18.
- Research data that contains HIPAA protected information must retained on an encrypted device and retained for seven (7) years after the completion of the study.
Amendments and Renewals
When Modifications are Required

- A modification is required whenever a change is needed to an IRB approved protocol.
- Modification/Amendments are made using the HRP-213 Amendment form found on the Human Research Protection website.
- All documents affected by the change must be submitted as tracked and clean copies. A memo of the requested changes must also be included in the amendment request.
- None of the proposed research is to commence until final approval for the revision has been received from the IRB.
Renewals/Continuing Reviews

- When a research protocol is approved by the IRB under Expedited or Full Review, it is generally approved for one year. If researchers wish to continue the research past the original 12 months, a continuing review form is needed.
- Continuing review notices are sent by Human Research Protection 60, 30, and 7 days prior to the expiration of the research study.
- There is an expiration notice sent once the protocol has expired.
- Researchers failing to renew a protocol by submitting a Continuing Review Form HRP-212, will result in the Principal Investigator being placed on the Restricted List and no new applications or modifications will be accepted until the outstanding issues have been resolved.
Study Closure

- Once an IRB approved study has been completed, researchers are required to submit a final report to the IRB to close the research study.
- This closure notice is required for Exempt, Expedited, Full Review and Letter of Reliance levels of review.
- Researchers failing to submit a Continuing Review Form HRP-212 to close the IRB approved research, will result in the Principal Investigator being placed on the Restricted List and no new applications will be accepted until the outstanding issues have been resolved.
- Once the study has been closed, all records are to be retained according to University policy.
Contact Information

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