Session 1: IRB

1st Annual SUNY Downstate Clinical Trials Symposium
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1:00 PM Breakout Session

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Agenda

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Applicable Clinical Trials and PRS reporting (CT.gov)
What’s new with the IRB
Using an External (Reviewing) IRB

Determine which IRB to Use:

• Refer to Step 5 on the IRB Submission website
• An external (reviewing) IRB is required for:
  • Multi-site research that requires sIRB review
  • Research which is funded by an Industry Sponsor
  • Multi-site research overseen by an external (reviewing) IRB
• Use the WCG IRB, when Downstate is the primary awardee; otherwise, the Main Study PI or Sponsor determines which Qualifying IRB to use

Using an External (Reviewing) IRB

Determine which agreements are required:

• Downstate has Master IRB Reliance Agreements (IRA) in place to use WCG IRB, BRANY IRB, NCI CIRB, IRBs (including Advarra) within the SMART IRB Online Reliance System.
  • Establish an IRB Reliance Agreement, if an IRA is not in place
• Establish any other necessary agreements, such as:
  • Business Associate Agreement (BAA)
  • Clinical Trial Agreement (CTA)
  • Confidentiality Agreement (CA)
  • Data Agreements (DA)
  • Data Use Agreement (DUA)
  • Facility Use Agreement (FUA)
  • Material Transfer Agreement (MTA)

NOTE: Individual Investigator Agreements (IIAs) are not applicable, when using External IRB.
Using an External (Reviewing) IRB

Determine which IRB fees to budget:

• Refer to **IRB Fee Schedule**
• Include applicable IRB fees in the research budget:
  • Most external IRBs will bill sponsor directly.
  • Include the one-time Downstate local IRB review fee ($1,000), if Downstate is funded by an Industry sponsor.

Submit the materials to the Downstate IRB for local review:

• Submit **Form 11-A3: Application for External IRB Oversight** to Downstate IRB for administrative confirmation of local requirements.
• May request optional pre-review before submitting to External IRB.
• Include only members of the Downstate Workforce on the IRB applications.

*Note: Investigators from other sites follow their own institution’s IRB policy.*
Applicable Clinical Trials and PRS reporting (CT.gov)

- Trials that require CT.gov registration:
  - All NIH funded Clinical Trials
  - Any ACT as defined by ACT Checklist
  - CT as required by VA, CMS, WHO, PCORI, or ICMJE journals

- List Responsible Party in contract & IRB application:
  - Sponsor
  - Holder of IND or IDE
  - Funder of a procurement agreement
  - Provider of a study drug

- If Downstate is the Responsible Party, the PI must take on this role and contact Diann Johnson in the IRB Office to set up a Protocol Registration and Results System (PRS) account.

- Register within 21 days after enrolling first research participant OR prior to enrolling first participant if there are plans to publish in an ICMJE journal

- The Responsible Party must provide regular and timely updates on the https://www.clinicaltrials.gov website.

- Administrative and scientific information
- Adverse events
- Research results

- Non-compliance:
  - Subject to CT suspension and reporting to the Sponsor, FDA, OHRP, and NIH.
  - Subject to FDA fines of > $10,000 per day to the PI’s Department or College, when Downstate is Responsible Party
Applicable Clinical Trials and PRS reporting (CT.gov)

- Downstate IRB application process:
  - Provide NCT# and Responsible Party on the Downstate IRB application
  - Add the required language to informed consent form:
    
    A description of this clinical trial will be available on [http://www.ClinicalTrials.gov](http://www.ClinicalTrials.gov), as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What’s New with the IRB?

Announcements and updates are posted on the [SUNY Downstate IRB Website](http://www.ClinicalTrials.gov)
Thank you!

Ask any IRB related question...

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