DOWNSTATE
HEALTH SCIENCES UNIVERSITY

Session 1: IRB

1st Annual SUNY Downstate Clinical Trials Symposium

October 25, 2023

1:00 PM Breakout Session

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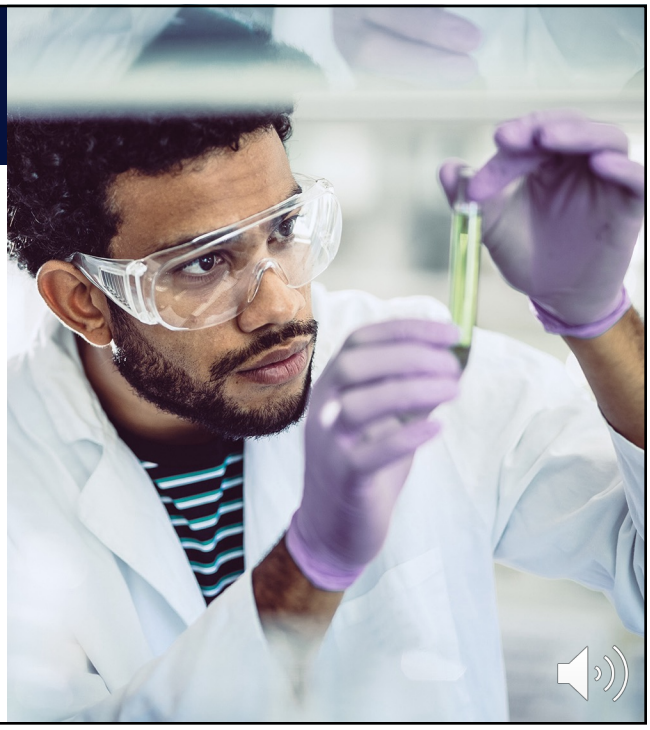
Executive Director, Human Research Protections & Quality Assurance



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Agenda

Using an External (Reviewing) IRB

Applicable Clinical Trials and PRS reporting (CT.gov)

What's new with the IRB

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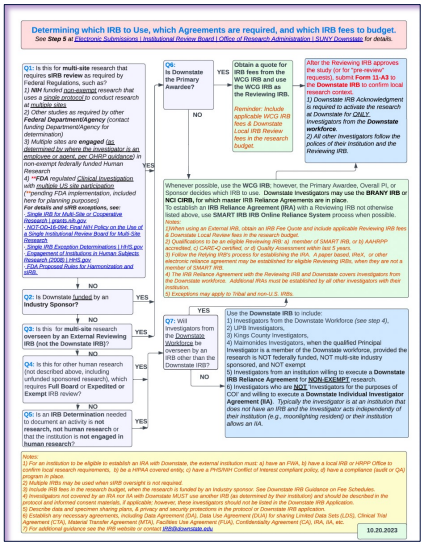
Using an External (Reviewing) IRB

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



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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.

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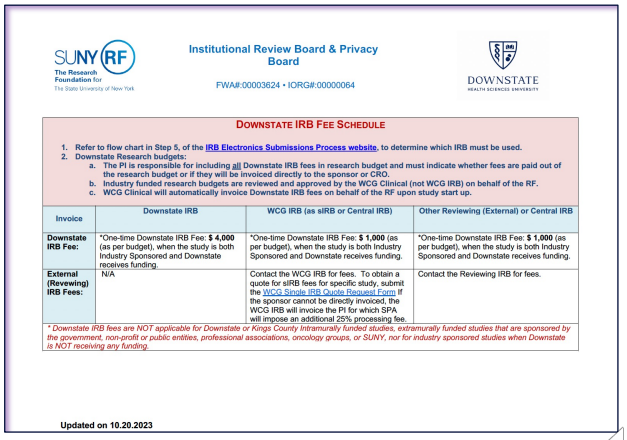
Using an External (Reviewing) IRB

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.



SUNY RF The Research Foundation for The State University of New York

Institutional Review Board & Privacy Board

FWA#:00003624 • IORG#:00000064

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DOWNSTATE IRB FEE SCHEDULE

1. Refer to flow chart in Step 5, of the IRB Electronics Submissions Process website, to determine which IRB must be used.
2. Downstate Research budgets:
   a. The PI is responsible for including all Downstate IRB fees in research budget and must indicate whether fees are paid out of the research budget or if they will be invoiced directly to the sponsor or CRO.
   b. Industry funded research budgets are reviewed and approved by the WCG Clinical (not WCG IRB) on behalf of the RF.
   c. WCG Clinical will automatically invoice Downstate IRB fees on behalf of the RF upon study start up.

Invoice	Downstate IRB	WCG IRB (as sIRB or Central IRB)	Other Reviewing (External) or Central IRB
Downstate IRB Fee:	*One-time Downstate IRB Fee: **$ 4,000** (as per budget), when the study is both Industry Sponsored and Downstate receives funding.	*One-time Downstate IRB Fee: **$ 1,000** (as per budget), when the study is both Industry Sponsored and Downstate receives funding.	*One-time Downstate IRB Fee: **$ 1,000** (as per budget), when the study is both Industry Sponsored and Downstate receives funding.
External (Revewing) IRB Fees:	N/A	Contact the WCG IRB for fees. To obtain a quote for sIRB fees for specific study, submit the WCG Single IRB Quote Request Form If the sponsor cannot be directly invoiced, the WCG IRB will invoice the PI for which SPA will impose an additional 25% processing fee.	Contact the Reviewing IRB for fees.

** Downstate IRB fees are NOT applicable for Downstate or Kings County Intramurally funded studies, extramurally funded studies that are sponsored by the government, non-profit or public entities, professional associations, oncology groups, or SUNY, nor for industry sponsored studies when Downstate is NOT receiving any funding.*

Updated on 10.20.2023

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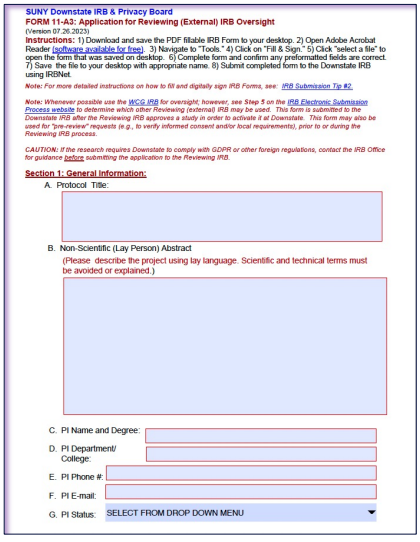
Using an External (Reviewing) IRB

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.



SUNY Downstate IRB & Privacy Board

FORM 11-A3: Application for Reviewing (External) IRB Oversight

(Version 07.26.2023)

Instructions: 1) Download and save the PDF fillable IRB Form to your desktop. 2) Open Adobe Acrobat Reader (software available for free). 3) Navigate to "Tools." 4) Click on "Fill & Sign." 5) Click "select a file" to open the form that was saved on desktop. 6) Complete form and confirm any preformatted fields are correct. 7) Save the file to your desktop with appropriate name. 8) Submit completed form to the Downstate IRB using IRBNet.

Note: For more detailed instructions on how to fill and digitally sign IRB Forms, see: IRB Submission Tip #2.

Note: Whenever possible use the WCG IRB for oversight; however, see Step 5 on the IRB Electronic Submission Process website to determine which other Reviewing (external) IRB may be used. This form is submitted to the Downstate IRB after the Reviewing IRB approves a study in order to activate it at Downstate. This form may also be used for "pre-review" requests (e.g., to verify informed consent and/or local requirements), prior to or during the Reviewing IRB process.

CAUTION: If the research requires Downstate to comply with GDPR or other foreign regulations, contact the IRB Office for guidance before submitting the application to the Reviewing IRB.

Section 1: General Information:

A. Protocol Title:

B. Non-Scientific (Lay Person) Abstract

(Please describe the project using lay language. Scientific and technical terms must be avoided or explained.)

C. PI Name and Degree:

D. PI Department/ College:

E. PI Phone #:

F. PI E-mail:

G. PI Status: SELECT FROM DROP DOWN MENU

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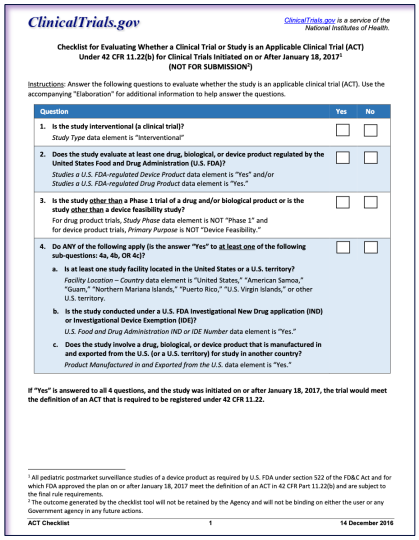
Applicable Clinical Trials and PRS reporting (CT.gov)

- 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.



ClinicalTrials.gov

ClinicalTrials.gov is a service of the National Institutes of Health.

Checklist for Evaluating Whether a Clinical Trial or Study is an Applicable Clinical Trial (ACT) Under 42 CFR 11.22(b) for Clinical Trials Initiated on or After January 18, 2017[1] (NOT FOR SUBMISSION[2])

Instructions: Answer the following questions to evaluate whether the study is an applicable clinical trial (ACT). Use the accompanying "Elaboration" for additional information to help answer the questions.

Question	Yes	No
1. **Is the study interventional (a clinical trial)?** *Study Type* data element is "Interventional"	☐	☐
2. **Does the study evaluate at least one drug, biological, or device product regulated by the United States Food and Drug Administration (U.S. FDA)?** *Studies a U.S. FDA-regulated Device Product* data element is "Yes" and/or *Studies a U.S. FDA-regulated Drug Product* data element is "Yes."	☐	☐
3. **Is the study other than a Phase 1 trial of a drug and/or biological product or is the study other than a device feasibility study?** For drug product trials, *Study Phase* data element is NOT "Phase 1" and for device product trials, *Primary Purpose* is NOT "Device Feasibility."	☐	☐
4. **Do ANY of the following apply (Is the answer "Yes" to at least one of the following sub-questions: 4a, 4b, OR 4c)?**	☐	☐
a. **Is at least one study facility located in the United States or a U.S. territory?** *Facility Location – Country* data element is "United States," "American Samoa," "Guam," "Northern Mariana Islands," "Puerto Rico," "U.S. Virgin Islands," or other U.S. territory.		
b. **Is the study conducted under a U.S. FDA Investigational New Drug application (IND) or Investigational Device Exemption (IDE)?** *U.S. Food and Drug Administration IND or IDE Number* data element is "Yes."		
c. **Does the study involve a drug, biological, or device product that is manufactured in and exported from the U.S. (or a U.S. territory) for study in another country?** *Product Manufactured in and Exported from the U.S.* data element is "Yes."		

If "Yes" is answered to all 4 questions, and the study was initiated on or after January 18, 2017, the trial would meet the definition of an ACT that is required to be registered under 42 CFR 11.22.

[1] All pediatric postmarket surveillance studies of a device product as required by U.S. FDA under section 522 of the FD&C Act and for which FDA approved the plan on or after January 18, 2017 meet the definition of an ACT in 42 CFR Part 11.22(b) and are subject to the final rule requirements.
[2] The outcome generated by the checklist tool will not be retained by the Agency and will not be binding on either the user or any Government agency in any future actions.

ACT Checklist 1 14 December 2016

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Applicable Clinical Trials and PRS reporting (CT.gov)

- 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

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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, 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.

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What's New with the IRB ?

Announcements and updates are posted on the SUNY Downstate IRB Website

Human Research Protections Clubhouse Webinars:

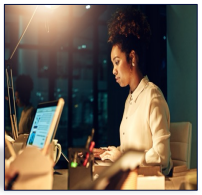
- This club is for networking and empowering professionals at all levels in the human research enterprise
- Sessions are recorded and available to those who register

New Tips, Guidance, and IRB Application to request Determinations:

- Not Research
- Not Human Research
- Institution Not Engaged

New Vice-Chair: Vivian Chin, MD

- Updated rosters are posted
- Reminder: Seeking IRB Member Nominations



Quality Assessment Program (QAP)

- Assessment types:
  - Routine (Not-For-Cause)
  - For Cause
- New Step 21 forms:
  - 21-1: Quality Assessment Form
  - 21-2: Corrective & Preventative Action Plan

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Thank you!
Ask any IRB related question…
IRB@downstate.edu

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