IRB Submission Process

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2:30 PM

Webinar Functions

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- Presentation is being recorded.
- Say hi to others with Chat balloon.
- ASK questions with Q&A balloon.
- Raise hand to be invited to speak.
- Questions answered at the end.

Downstate Institutional Review Board (IRB) & Privacy Board

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- Protects the rights & welfare of Research Participants .
- May approve, require modifications, or disapprove Research.
- Ensures Human Research complies with all requirements.
- May conduct or request audits.
- Serves as a Privacy Board to ensure HIPAA compliance.

Q1: Is it Research? (Under the Common Rule)

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- A Research Activity is BOTH:
  - A **systematic investigation**, including research development, testing, and evaluation
    - activity that is planned, orderly, methodical, and uses data collection to answer a question

-AND-

  - Designed to develop or contribute to **generalizable knowledge**
    - knowledge gained from a study may be applied to populations outside of the specific study population

Q2: Is it Human Research?

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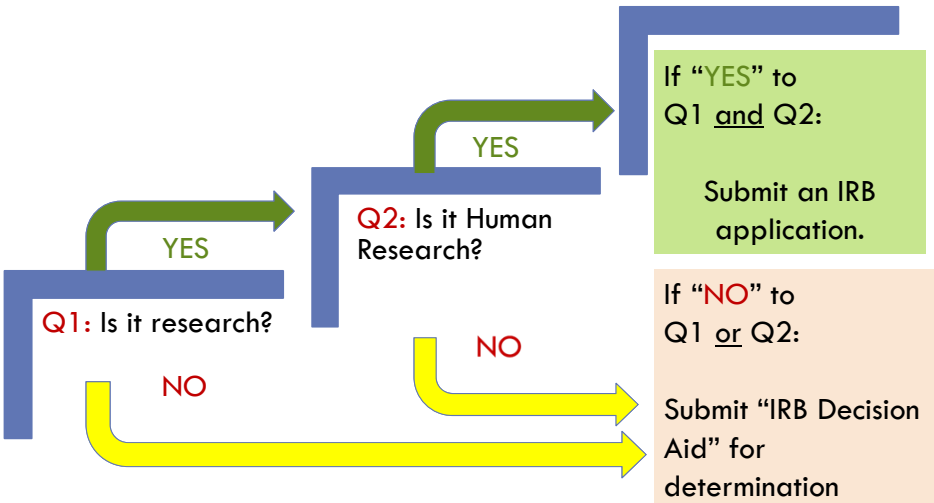
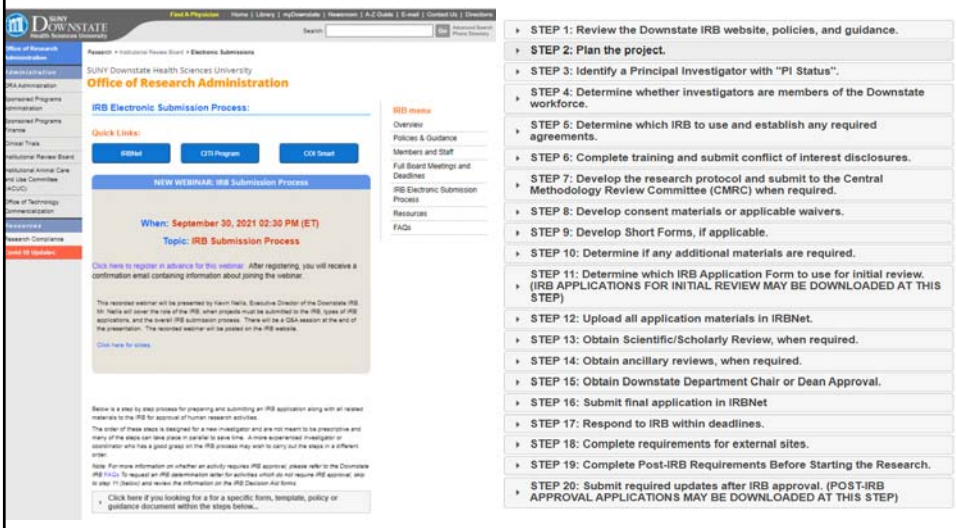
- To be considered human research, the research must involve **living individuals** about whom an investigator conducting research either:
  - obtains **information or biospecimens** through **intervention or interaction** with the individual, and uses, studies, or analyzes the information or biospecimens; or
  - obtains, uses, studies, analyzes, or generates **identifiable private information or identifiable biospecimens**.

Is IRB Approval Required?

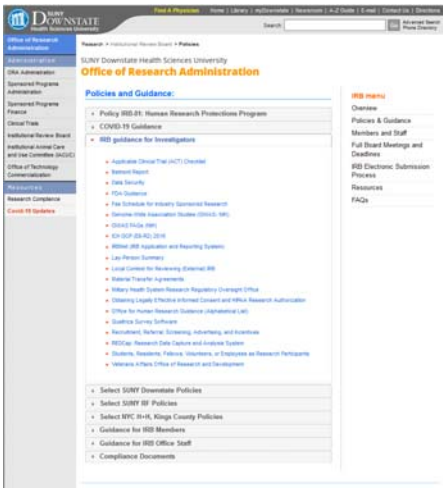


IRB Submission Webpage



https://research.downstate.edu/irb/electronic-submission.html

IRB Policies and Guidance



https://research.downstate.edu/irb/policies.html

Downstate IRB Oversight with Collaborating Sites

- Exempt study: External investigators use sites' IRB [KC may use Downstate IRB]
- Downstate IRB can review external sites for intramurally supported research:
  - Individual Investigator Agreement (IIA)
  - IRB Reliance Agreement (IRA) [in place with Kings County]

External IRB Oversight

- Existing IRB Reliance Agreements in place
  - NCI Central IRB (NCI CIRB) for NCI sponsored research.
  - WIRB Copernicus Group (WCG) IRB:
    - Industry sponsored clinical investigations
    - Federally funded non-exempt human research which requires a Single IRB (sIRB) when Downstate is the primary awardee for a multi-site study
  - BRANY IRB [KC agreement in place]
  - IRBs within the SMART IRB Network (910 IRBs including Advarra IRB)
- Others require IRB Reliance Agreements
  - Use other IRB as directed by Sponsor
  - Use other qualifying IRB, with IRB Reliance Agreement

Central Methodology Review Committee (CMRC)

- Excluding studies with external IRB oversight, prior to IRB submission, submit the protocol to the CMRC when it meets one or more of the following criterion:
  - Involves an interaction or an intervention with a drug, biologic, or medical device.
  - Includes prospective specimen collection.
  - Non-exempt human research with inclusion criteria for the prospective enrollment of one or more of the following populations: pregnant women, human fetuses, neonates, prisoners, children, individuals with physical disabilities, individuals with mental disabilities or cognitive impairments, economically disadvantaged, socially disadvantaged, terminally ill or very sick, under-represented populations, under-served communities, people of diverse backgrounds, or institutionalized persons (persons in correctional facilities, nursing homes or mental health facilities).

Central Methodology Review Committee (CMRC) -continued

- Involves deception research (full research purpose is not disclosed to participant).
- Any study not otherwise described above which requires Full Board review by the Downstate IRB. Consult with the IRB for guidance, if needed.
- If CMRC review is required by the Downstate IRB (include a copy of the IRB communication).

NOTE: MAKE SURE ALL IRB DOCUMENTS ARE CONGRUENT WITH CMRC CERTIFIED PROTOCOL

Types of Downstate IRB Applications

- Most Common Applications::
  - Exempt (11-A1)
  - Expedited or Full Board (11-A2)
  - External IRB Oversight (A3)
  - IRB Decision Aid (A4A & A4B)
- Other Applications:
  - Exempt for DOJ/DIJ funded research (A1B)
  - Expanded Access (Investigational Drug/Biologic for Treatment Use) (A5)
  - Clinical Use of a Humanitarian Use Device (HUD) (A6)
  - Honest Broker Agreement (used with other applications) (A7)

Exemption Categories

1) Normal educational practices in established educational settings

2) Educational tests, surveys, interviews, or observation of public behavior

3) Benign behavioral interventions with adults with prospective agreement

4) Secondary research for which consent is not required (includes retrospective chart reviews with HIPAA waiver)

5) Federal research and demonstration projects

6) Taste and food quality evaluation and consumer acceptance studies

Expedited Review of Some Studies That Are No Greater Than Minimal Risk

- Clinical investigations of drugs and medical devices only under specific conditions (no IND or IDE)
- Collection of blood samples
- Biological specimens obtained by non-invasive means
- Collection of data through non-invasive means

NOTE: Some of the other federal expedited review categories (1998) now qualify for exempt research under the revised Common Rule (2018).

Examples of Full Board Review

- Studies involving greater than minimal risk.
- Clinical Trials involving IND, IDE, or HUD.
- Humanitarian Use Device (HUD) for clinical purpose.
- Expanded Access (Drug/Biologic for Treatment Use).
- Initial review of research that meets the criteria for "expedited review" category that involves a drug, device or blood collection, if the study includes a biomedical intervention with children, pregnant women, neonates, prisoners, or cognitively impaired adults.
- IRB Member refer any study to full board.

Reviewing IRB (External IRB Oversight)

STEP 1: IRB Reliance Agreement (IRA):

- Master agreements: WCG IRB, BRANY, NCI CIRB, & SMART IRB Network
- Establish IRA with other IRBs with approval of Downstate IRB & IO
- Downstate IRB clarifies local research requirements for the external IRB

STEP 2 (optional): Pre-Activation/Pre-Review of materials by Downstate IRB:

- Considered optional, unless required by Sponsor or Reviewing IRB.
- Downstate IRB clarifies local research requirements for the external IRB

STEP 3: Obtain External IRB approval (Downstate workforce only)

STEP 4: Activation by Downstate IRB:

- Downstate confirms all local research requirements are met
- Acknowledges Reviewing IRB (External IRB) approval
- Downstate reserves the right to request amendments or make recommendations

IRB Decision Aid – Application for a Determination that IRB Approval is Not required

- FORM A4A
  - Downstate is not engaged in human research
  - Health care operations activity with no intention of developing or creating generalizable knowledge
- FORM A4B
  - Data or specimens from deceased individuals
  - Specimens or commercial cell lines that cannot be linked to an individual by the investigator,
  - De-identified or coded materials
  - Limited data set

Is IRB Approval Required for Performance Improvement Activities?

- Does the activity meet the definition of research, including the intent to develop or contribute to generalizable knowledge*?
  - If YES, IRB approval** is required, if there is an intervention/interaction or it involves identifiable private information or identifiable biospecimens.
  - If NO, IRB approval is NOT required***

*Intent to publish is an insufficient criterion for determining whether a quality improvement activity involves research. Planning to publish an account of a quality improvement project does not necessarily mean that the project fits the definition of research; people seek to publish descriptions of non research activities for a variety of reasons, if they believe others may be interested in learning about those activities. Conversely, a quality improvement project may involve research even if there is no intent to publish the results

**Most likely will qualify for Exempt or Expedited review

***Recommend requesting IRB Decision Aid

Is IRB Approval Required for Performance Improvement Activities?

Example:

- The Emergency Department monitors their process for treating COVID-19 patients with the intent of improving the quality of their service and patient outcomes at Downstate.
- Identifiable patient information is collected
- Without changing intent, clinic staff could
  - Share the de-identified data or results at a conference
  - Publish the de-identified data or results
- Recommend obtaining an IRB determination letter stating IRB approval is not required (IRB Form A4A)

Is IRB Approval Required for Case Reports or Case Series?

- Case Reports/Series of up to three (3) individuals do not need IRB approval
  - Such limited activities are generally not considered to be both systematic and generalizable
- Examples:
  - Review records of 3 patients
  - Review records of one patient and ask questions of 2 family members
- May request an IRB Determination letter (may be required by journal or conference) (IRB Form A4A)
- Some journals require informed consent/HIPAA Authorization

Ancillary Reviews (if applicable)

- Downstate Research Pharmacy
- UHB Pathology
- Institutional Biosafety Committee (IBC)
- NIH NExTRAC
- System to Track Approved Research (STAR) @ Kings County

Reminder: Submit Timely Post-IRB Approval Applications (Step 20)

- Acknowledgement (IRB Form B1)
- Reportable Events (IRB Form B3)
- Amendment (IRB Form 20-B2A)
- Amendment- Staff Changes Only (IRB Form 20-B2A)
- Continuing Review/ Check-In Report/ Study Closure (Form 20-B4)

Summary

- Submit IRB applications online
  - Initial IRB approvals
  - Required updates
- Follow instructions, policies, and guidance on IRB website
- Contact the IRB Office for help

IRB Contacts

Clinton Brown, MD, IRB Chair	(718) 270-1729
Stanley Friedman, MD, Vice Chair	(718) 270-1335
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Laura Henderson, MA, CIP, Associate IRB Administrator	(718) 270-4454
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Additional Contacts

Office of Compliance and Audit Services (Privacy Officer, HIPAA, Compliance Training, Audits, Internal Controls, Clinical Reimbursements, Financial Conflict of Interest Committee)	(718) 270-4033
Igor Gorelik, Information Security Officer	(718) 613-8593 (929) 359-0401
Sponsored Programs Administration (Contracts, Grant Review, Submission, and Management)	(718) 270-2680
Finance and Administration (Financial Analysis, HR, Payroll, Purchasing)	(718) 270-3027
NEW Technology Transfer Integration (Matthew Mroz, SUNY RF Central) Matthew.Mroz@rfsuny.org	(518) 434-7175
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Thank you

for helping protect our study participants!