IRB Submission Process

Kevin Nellis, MS
Executive Director, Human Research Protections and Quality Assurance
(March 10, 2021)

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Downstate Institutional Review Board (IRB) & Privacy Board

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- Protects the rights and welfare of Research Participants (Human Subjects).
- Empowered to approve, require modifications, or disapprove Human Research.
- Ensures Human (Subjects) Research is scientifically/scholastically valid, ethical, and in compliance with all requirements.
- Ensures compliance through oversight functions.
- May conduct or request audits.
- Serves as a Privacy Board to ensure HIPAA compliance.

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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

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Q2: Does it Involve Research Participants (Human Subjects)? (Under the Common Rule)

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- For research to be considered human research (and thus requiring IRB approval before the study begins), the research must involve **living individuals** about whom an investigator (whether professional or student) 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**.

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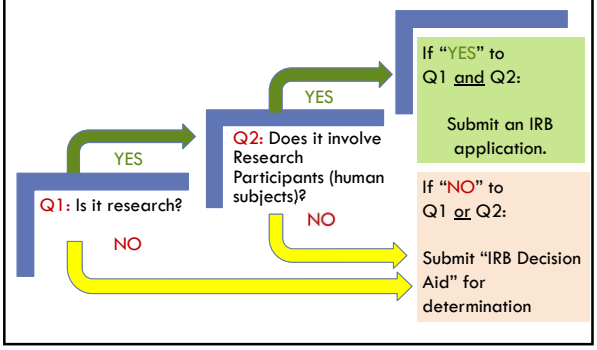
Is IRB Approval Required?



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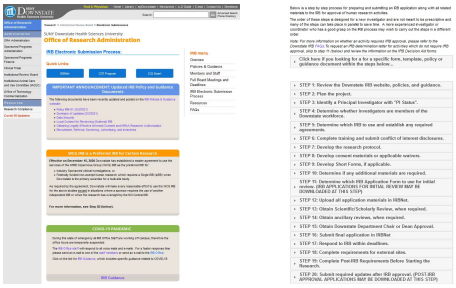
IRB Submission Webpage



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

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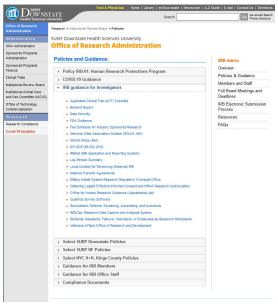
IRB Policies and Guidance



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

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Research During COVID-19 Public Health Emergency

- New applications must include:
  - Compelling reason to initiate new research,
  - Explanation on how the benefits of the research outweigh the risks of COVID-19 exposure for research participants and others (e.g., investigators, staff, family members)
  - Description of procedures to mitigate the risk of COVID-19 (see IRB guidance): https://research.downstate.edu/irb/policies.html
- Submit Ramp-Up Plan to SVPR Office:
  - https://www.downstate.edu/health-alerts/back-to-work/research-activities.html

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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]
- 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
- Other qualifying IRB

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Types of Downstate IRB Applications

- Most Common Applications:
  - Exempt (A1A)
  - Expedited or Full Board (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)

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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

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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).

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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.

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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

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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

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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.*

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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)

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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

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Ancillary Reviews

- NEW Central Methodology Review Committee (CMRC) has been appointed by IO on behalf of President Riley
  - CMRC review will start soon for review of certain protocols before they are submitted to the Downstate IRB
  - Downstate Protocol Template
  - Plan to streamline IRB application forms
  - Department/College SRC will no longer be required by the Downstate IRB
  - CMRC certifies the protocol is ready for IRB review
- Downstate Research Pharmacy
- UHB Pathology
- Institutional Biosafety Committee (IBC)
- NIH NExTRAC
- System to Track Approved Research (STAR) @ Kings County

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Reminder: Submit Timely Post-IRB Approval Applications

- Acknowledgement
- Reportable Events
- Amendment (2 TYPES)
  - Staff changes
  - All other changes
- Continuing Review (3 TYPES)
  - Abbreviated forms for External IRB or HUD for Clinical Use
- Check-In Report (for studies with 3-year approval periods)
- Final Report/Study Closure (2 TYPES)
  - New: HUD for Clinical Use or Investigational Drug/Biologic for Treatment Use

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Summary

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

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IRB Contacts

Clinton Brown, MD, IRB Chair	(718) 270-1729
Stanley Friedman, MD, Vice Chair	(718) 270-1335
Jeannette Jakus, MD, Vice Chair	(718) 270-1229
Kevin L. Nellis, MS, CIP, Executive Director, Human Research Protection & Quality Assurance	(718) 613-8461
Diann Johnson, MPH, Associate IRB Administrator	(718) 270-4341
Nikol Celestine, BA, CIP, IRB Management Analyst	(718) 270-4411
Nakih Gonzales, IRB Assistant	(718) 270-4372
IRB Office (BSB 3-26) IRB@downstate.edu Appointments recommended; walk-ins welcome	(718) 613-8480

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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
Technology Commercialization (Commercialization and IP)	(718) 613-8514
Michele Follen, MD, PhD, MBA, Director of Research and Chair, Facility Research Review Committee (KC)	(718) 613-8401
Bryce Petty, CCRC, Facility Research Coordinator (KC)/STAR contact	(718) 613-8185

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Thank you

for helping protect our study participants!

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