Objectives

1) Understand when activities require IRB approval
2) Know how to start the IRB application process.
Institutional Review Board (IRB)

- Protects the rights and welfare of research participants.
- Empowered to approve, require modifications, or disapprove Human Research.
- Ensures Human Research is scientifically/scholastically valid, ethical, and in compliance with all requirements.
- Ensures compliance through oversight functions.
Activities Requiring IRB Review

- **Clinical Trials** involving drugs, biologics, devices; including use of specimens to validate a medical device, diagnostic instrument, or laboratory test (FDA).
- **Expanded Access** to investigational drug or biologic for treatment use (FDA).
- **Humanitarian Use Device (HUD)** for clinical purposes (FDA).
- **Research involving Protected Health Information (PHI)** from living or deceased patients or employees (HIPAA).
- **Human (Subjects) Research** as defined by “Common Rule” (45 CFR Part 46).
- **Research requiring IRB Approval based on other laws** (NYS Article 24A, American Indian Law, Alaskan Native Law)
IRB Decision Aid

Whenever you are not sure how to answer a question, contact the IRB for help. Questions may be directed initially to:
- IRB Chair, Phyllis G. Supino, EdD at (718) 613-9365
- Executive Director, Kevin Nelligan at (718) 613-9361
- IRB Staff at (718) 613-8480

For additional guidance on human research, see HHS/OHRP Decision Charts.

Privacy and HIPAA related questions may be directed to the Downstate Privacy Officer, Shoshana Milstein, at (718) 270-7470.

Information Security related questions may be directed to the Downstate Information Security Officer, David Loewy at (718) 270-2431.

For animal research, refer to the Institutional Animal Care and Use Committee (IACUC).

This guidance incorporates HHS regulatory definitions as well as HIPAA, FDA, and other Federal and NY state regulations.

<table>
<thead>
<tr>
<th>TYPES OF IRB REVIEW</th>
<th>REQUIRED FORM</th>
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<tbody>
<tr>
<td>Determination Letter (indicates IRB review is NOT required)</td>
<td>Use this form to document and request such a determination.</td>
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<tr>
<td>Exempt Review</td>
<td>Follow the instructions on the “Application for Exempt Review”</td>
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<tr>
<td>Expedited Review</td>
<td>Follow the instructions on the “Application for Expedited or Full Review”</td>
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<tr>
<td>Convened (Full) IRB Review</td>
<td>Follow the instructions on the “Application for Expedited or Full Review”</td>
</tr>
<tr>
<td>Use of a Humanitarian Use Device (HUD) for clinical purposes</td>
<td>Follow the instructions on the “Application for HUD for Clinical Purposes”</td>
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<tr>
<td>External IRB Review (some multi-site research)</td>
<td>Follow the instructions on the “Application for External IRB Oversight”</td>
</tr>
<tr>
<td>Expended Access to Investigational Drug/Biologic For Treatment Use (Including external IRB review of a multi-site activity)</td>
<td>Follow the instructions on the “Application for Expanded Access to Investigational Drug/Biologic For Treatment Use”</td>
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<tr>
<td>Cooperative research review (“Single IRB” review of federally supported or conducted study)</td>
<td>As applicable, either follow the instructions on the “Application for External IRB Oversight” or contact the Downstate IRB if it has been designated to be the single IRB of record.</td>
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When is IRB Review & Approval Required for an Activity?

Q1) Is it research?  
If YES, go to “Q2”

Q2) Does it involve Research Participants (human subjects)?

If YES to Q1 & then YES to Q2 then submit an IRB application to the Downstate Medical Center IRB

If “NO” to either, consult with “IRB Decision Aid”, e-mail IRB@downstate.edu or call X8480.
Q1: Is it Research? (Under the Common Rule)

- A Research Activity is BOTH:
  - A **systematic investigation** (including research development, testing, and evaluation)
  - AND
  - Designed to develop or contribute to **generalizable knowledge**.
Q2: Does it Involve Research Participants (Human Subjects)? (Under the Common Rule)

- In order 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**.
Is IRB Approval Required for Performance Improvement Activities?

- Performance improvement activities do not need IRB approval if:
  - Intent is to improve internal operations, and there is
  - There is no intent to contribute to generalizable knowledge

**Example:**

- A clinic surveys their patients to improve the quality of service
- **Without changing intent,** clinic staff could
  - Share the results at a conference
  - Publish the results
Is IRB Approval Required for Pilot or Feasibility Studies?

- It depends! Does it meet the definition of human research?
- Is the activity **systematic**?
  - Is it planned, orderly, methodical?
  - Will the data be analyzed?
- Is the activity **generalizable**?
  - Does it develop future research?
  - Will the knowledge apply to other populations?
- Is the activity **human research**?
  - Are “actors” used?
  - Can the investigators link the data to individuals?
Activities That **DO NOT** Require IRB Approval

- Case Reports/Series of up to three (3) individuals
- Scholarly and journalistic activities
- Public health surveillance activities
- Off-label use of FDA approved drug/biologic for clinical care
- Two activities that only require reporting to IRB within 5 days:
  - Emergency use of investigational drug, biologic, or device
  - Changes necessary to eliminate apparent immediate hazard or to protect the life or physical well-being of a research participant in an IRB approved research study
HOW is IRB approval obtained?

Follow instructions on IRB Electronic Submissions website:
http://research.downstate.edu/irb/irb-electronic-submissions.html
Institutional Review Board (IRB)

Electronic Submissions and Management of Downstate IRB Activities:

The Downstate Medical Center IRB uses an electronic IRB submission and reporting system (IRBNet) for the electronic submissions and management of human research activities and required reporting. Please refer to the guidance for the IRBNet (IRB Application and Reporting System) for more details on how to use the system. Application forms and template materials are provided below. Guidance and policy can be viewed by clicking on tab within the IRB Menu for Policies & Guidance. Information on required training and conflict of interest disclosures can be viewed by clicking on the tab within the IRB Menu for Training & Conflict of Interest.

Anyone associated with Downstate may create an IRBNet user name and password by following the instructions below:

Note: Each user agrees to comply with the Individual User Terms of Use policy which may be found at https://www.irbnet.org/release/public/terms.jsp

Step 1: Create an IRBNet user account

- Go to www.irbnet.org and click the "New User Registration" link. Follow the online instructions. Complete all items with red asterisk (*). When asked to identify your "organization" type SUNY in the text box and then select "SUNY Downstate Medical Center, Brooklyn, NY".
- Remember to click on the "Register" button in order to finalize your "New User Registration."
- Press the "Continue" button on the "Registration is Complete" page and follow "Step 2" to activate your IRBNet user account.

Step 2: Activate your IRBNet user account
<table>
<thead>
<tr>
<th>IRB Contacts</th>
<th>(718) 270-1729</th>
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<tbody>
<tr>
<td>Clinton Brown, MD, IRB Chair</td>
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</tr>
<tr>
<td>Daniel Cukor, PhD, Vice Chair</td>
<td>(718) 270-2077</td>
</tr>
<tr>
<td>Stanley Friedman, MD, Vice Chair</td>
<td>(718) 270-1335</td>
</tr>
<tr>
<td>Kevin L. Nellis, MS, CIP, Executive Director, Human Research Protection &amp; Quality Assurance</td>
<td>(718) 613-8461</td>
</tr>
<tr>
<td>Diann Johnson, MPH, Associate IRB Administrator</td>
<td>(718) 270-4341</td>
</tr>
<tr>
<td>Danielle Lewis, MD, MPH, IRB Management Analyst</td>
<td>(718) 270-4454</td>
</tr>
<tr>
<td>Nikol Celestine, BA, CIP, IRB Management Analyst</td>
<td>(718) 270-4411</td>
</tr>
<tr>
<td>Nakih Gonzales, IRB Assistant</td>
<td>(718) 270-4372</td>
</tr>
<tr>
<td>IRB Office (BSB 3-26)</td>
<td><a href="mailto:IRB@downstate.edu">IRB@downstate.edu</a></td>
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<td>(718) 613-8480</td>
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Summary

- Know when IRB approval is required
- Submit online application
- Follow instructions and guidance
- Call the IRB for help