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)

- **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)
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) 613-8355
- Executive Director, Kevin Nellis at (718) 613-8461
- IRB Staff at (718) 613-8480

For additional guidance on human subjects research, see: [http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html](http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html)

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.

There are 6 types of IRB Review, as outlined in the table below:

<table>
<thead>
<tr>
<th>TYPE OF REVIEW</th>
<th>REQUIRED FORM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Determination Letter (indicates IRB review is NOT required)</td>
<td>Use this form to document and request such a determination.</td>
</tr>
<tr>
<td>Exempt Review</td>
<td>Follow the instructions on the “Application for Exempt Review”</td>
</tr>
<tr>
<td>Expedited Review</td>
<td>Follow the instructions on the “Application for Expedited or Full Review”</td>
</tr>
<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>
</tr>
<tr>
<td>External IRB Review (some multi-site research)</td>
<td>Follow the instructions on the “Application for External IRB Oversight”</td>
</tr>
</tbody>
</table>

**Three Key Definitions:**

**Research** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

**Research participant** means a living individual about whom an investigator (whether professional or student) conducting research obtains
1. data through intervention or interaction with the individual, or
2. identifiable private information.
Is IRB Review Required for Human Research? (Under the Common Rule)

1) Is it research?
   • YES
   • If “NO” to either question, consult “IRB Decision Aid” or call IRB @ extension 8480

2) Does it Involve Research Participants (Human Subjects)?
   • YES
   • Submit an IRB Application
Is it Research?
(Under the Common Rule)

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge
Does it Involve Research Participants (Human Subjects)? (Under the Common Rule)

- **Living*** individuals about whom an investigator conducting research, obtains either...
  - Data through **intervention or interaction** with the individual, or
  - **Individually identifiable private information****

* HIPAA Exception: Includes PHI from deceased patients or employees
** Includes identifiable specimens

* Living
** Individually identifiable
How is IRB approval obtained?

Follow instructions on IRB Electronic Submissions website:
http://research.downstate.edu/irb/irb-electronic-submissions.html
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>Name</th>
<th>Phone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phyllis G. Supino, EdD, IRB Chair</td>
<td>(718) 613-8355</td>
</tr>
<tr>
<td>Daniel Cukor, PhD, Vice Chair, Board A</td>
<td>(718) 270-2077</td>
</tr>
<tr>
<td>Stanley Friedman, MD, Vice Chair, Board B</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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</tbody>
</table>
Summary

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