Objectives

1) **WHY** is IRB approval required?

2) **WHEN** do activities require IRB approval?

3) **WHO** can be a Principal Investigator?

4) **HOW** is IRB approval obtained?

5) **WHAT** are some tips for success?

6) **WHERE** is the IRB Office located?
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.
**WHY** is IRB approval required?

Key historical events that led up to the development of federal regulations
Nuremberg Trials (1946-47)

- Post-WWII trials of 23 Nazi Doctors for war crimes and crimes against humanity
- 16 Doctors found guilty
- 7 Doctors received death penalty
- Lead to Nuremberg Code:
  - Principle #1: Voluntary consent is absolutely essential
Thalidomide Tragedy (1960’s)

- Thalidomide approved in Europe as sleeping pill (1950s)
- U.S. doctors received “free samples” to do “research”
- Frances Kelsey, MD (FDA) did not approve the drug in USA, due to lack of clinical evidence against side effects (1960)
- Link to newborn disabilities was made in 60’s
- >10,000 babies affected, worldwide
- 1962: Drug Amendments added to F,D&C Act
- 1963: Informed consent regulations established
Tuskegee Syphilis Study Exposé (1972)

- Eunice Rivers, RN hired to recruit participants into a six (6) week study
- Offered “free medical care” for “bad blood”
- Not offered penicillin (1943)
- Research continued for forty (40) years
Tuskegee Syphilis Study Exposé (1972)

- 1967-8: Peter Buxton, social worker, reports concerns to PHS, but is ignored for several years
- 1972: Blows whistle to the Associate Press
- 1973: Research stops and Congress investigates
National Research Act (1974)

- Created National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
- 1979: Commission published many research guidance documents including The Belmont Report
- 1981: DHHS & FDA Published regulations Based on The Belmont Report
WHEN do activities require IRB approval?

It depends...
# IRB Decision Aid

**When 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) 613-6355
- **Executive Director**, Kevin Neilis at (718) 613-8461
- **IRB Staff** at (718) 613-8480

For additional guidance on human research, see [HHS/IRB Decision Charts](#).

Privacy and HIPAA related questions may be directed to the Downstate Privacy Officer, Shoshana Milestein, 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.

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<thead>
<tr>
<th>TYPES OF IRB REVIEW:</th>
<th>REQUIRED FORM:</th>
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<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</td>
<td>Follow the instructions on the “Application for HUD for Clinical Purposes”</td>
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<tr>
<td>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>Expanded Access to Investigational Drug/Biologic For</td>
<td>Follow the instructions on the “Application for Expanded Access to</td>
</tr>
<tr>
<td>Treatment Use (Including external IRB review of a multi-site</td>
<td>Investigational Drug/Biologic For Treatment Use”</td>
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<tr>
<td>activity)</td>
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<tr>
<td>Cooperative research review (“Single IRB” review of</td>
<td>As applicable, either follow the instructions on the “Application for External</td>
</tr>
<tr>
<td>federally supported or conducted study)</td>
<td>IRB Oversight” or contact the Downstate IRB if it has been designated to be</td>
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<tr>
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<td>the single IRB of record.</td>
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</table>
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)
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 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 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 participant in IRB approved research
**WHO can be a Principal Investigator?**

**IRB Policy-01: PI Status**
Who can be a Principal Investigator?

- Seasoned investigator with a field-specific terminal degree who is a Faculty Member at SUNY Downstate
- Meet the criteria for PI status by the NYC H + H, Kings County (e.g., Clinician with clinical privileges at NYC H + H, Kings County).
- Faculty member under recruitment to SUNY Downstate with written approval by a Dean
- Be approved to be a PI by written memo or e-mail from the Downstate Institutional Official
Who can be a Principal Investigator?

- Qualify to be a PI at an external site, when the research makes SUNY Downstate engaged:
  - Federal funding or support is provided to Downstate, or
  - Co-investigators or key personnel who are:
    - Employee of SUNY Downstate Medical Center
    - Employee of Research Foundation for SUNY-DMC
    - Resident or Fellow trained under a GME program affiliated with Downstate
    - Student in a Downstate Academic Program

Note: A PI who is an external employee to DMC and listed on a DMC IRB application agrees to abide by DMC policies for the duration of the study.
HOW is IRB approval obtained?

Follow instructions on IRB Electronic Submissions website:

http://research.downstate.edu/irb/irb-electronic-submissions.html
Electronic Submissions

Institutional Review Board (IRB)

Electronic Submissions and Management of Downstate IRB Activities:

The Downstate Medical Center (IRB uses IRBNet for the electronic submission and management of human research activities and required reporting. Please refer to the guidelines for the IRBNets (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

- After successful completion of “Step 1,” the user will receive an activation e-mail to the registered e-mail address.
- Sign-in to the e-mail account that you entered into the system and click on the link within that e-mail to activate your IRBNet account.
- You may begin using IRBNet as soon as activation is complete.

If you forget your password, navigate to https://www.irbnet.org/release/public/login/hint.jsp and follow the instructions on the website.
Types of IRB Applications

- Exempt
- Expedited or Full Board (one form for both types)
- External IRB Oversight (for multi-site research)
- Clinical Use of an Humanitarian Use Device (HUD)
- Expanded Access to Investigational Drug/Biologic for Treatment Use
- Determination Letter (indicates IRB review is NOT required)
Exemption Categories*

1) Normal educational practices in established educational settings
2) Educational tests, surveys**, interviews**, or observation of public behavior – unless identified & sensitive
3) Research on elected or appointed officials or candidates for public office
4) Research on existing data, if publically available or recorded without identifiers
5) Evaluation of public service programs
6) Taste and food quality evaluation and consumer acceptance studies

* Does not apply to research with prisoners.
** Does not apply to research with children.
New Exemption Categories

- New categories are scheduled to go into effect as soon as July 19, 2018 under an Interim Final Rule; however, rule could be delayed until January 21, 2019.
- In general the new rule broadens the scope of research that will be exempt.
- OHRP is in the process of developing new guidance for the revised Common Rule, in parallel with efforts to establish whether another delay is necessary.
- For information, see: https://www.hhs.gov/ohrp/ifr-delays-revisions-common-rule-published-fr.html-1
Examples of Expedited Review

- Clinical studies of drugs and medical devices only under specific conditions
- Chart reviews
- Survey research which is sensitive and includes identifiable information
- Collection of blood samples
- Biological specimens obtained by non-invasive means
- Collection of data through non-invasive means
- Materials collected solely for non-research purposes
- Collection of data from voice, video, etc.
- Research employing surveys, focus groups, etc.
- Continuing review under specific conditions

Examples of Full Board Review

- Studies involving greater than minimal risk
- Clinical Trials involving IND, IDE, HUD, or NSR device
- Humanitarian Use Device (HUD) for clinical purpose
- Initial review of research that meets the criteria for “expedited review”:
  - If it involves biomedical interventions with children, pregnant women, neonates, prisoners, or cognitively impaired adults
  - If referred by the expedited reviewer
**External IRB Oversight**

- Can request the use of an external IRB for multi-site studies

- Cannot be used for the following:
  - Downstate as a single site
  - Research reviewed by DMC IRB and determined to require revisions or has not been approved by DMC IRB
Conflict of Interest Disclosures and Training Requirements

- Conflict of Interest Disclosures required for “Investigators for the purposes of COI,” as determined by PI.
  - Investigators who are considered to be essential to work performance or responsible for design, conduct, or reporting of research.
  - The PI does not need to include transient staff and trainees, such as medical students, residents and fellows who merely implement a protocol developed by an Investigator or enter data into an electronic data capturing system.

- All CITI and other training requirements must be completed

- See IRB Guidance: [http://research.downstate.edu/irb/irb-training.html](http://research.downstate.edu/irb/irb-training.html)
Electronic Signature Requirements

- PI
- Scientific Review Committee (and SRC form)
- Department Chair
- Pathology Services, when applicable
- Pharmacy, when drug or biologic is involved
- Paper Signatures (when applicable):
  - IBC Approval Letter
WHAT are some tips for success?

Before, during, and after IRB approval...
## Apply the Belmont Principles

<table>
<thead>
<tr>
<th>Principle</th>
<th>Application</th>
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</table>
| **Respect for Persons**       | - Informed Consent, Parent/Legal Guardian Permission, or Legally Authorized Representative  
|                               | - Disclose all information  
|                               | - Ensure comprehension  
|                               | - Ensure voluntariness  
|                               | - Protects autonomy  
|                               | - Protect those with diminished autonomy  |
| **Beneficence**               | - Risk/benefit ratio must be justified  
|                               | - Do no harm  
|                               | - Maximize benefits  
|                               | - Minimize risks  |
| **Justice**                   | - Equitable selection  
|                               | - Recruit those with limited English proficiency when there is a therapeutic benefit  
|                               | - Equal distribution of benefits and risk  |
Apply IRB Policy and Guidance

- Follow IRB-01 policy
- Understand criteria for IRB approval
- Follow IRB guidance on how to use IRBNet
- Follow IRB guidance which is applicable to the study
- Notify investigators to complete training and COI disclosures in advance
- Comply with all regulatory requirements
Seek Help From Mentors & Biostatistician

- Consult with your mentors
- Ensure valid research methodology is used
- Include a statistical plan
- Contact a Biostatistician in your Department for help or:
  - Jeremy Weedon, PhD
  - Dimitre G. Stefanov, PhD
Include All Required Materials

- Registration Form (IRBNet Wizard Form)
- Protocol
- IRB Application
- Informed Consent Document, if applicable
- Waivers, if applicable
- All other applicable materials described on IRB Website
Request IRB Office Pre-Review (Optional)

- Click “Share this Project” and send to IRB Staff to request Pre-Review
- IRB Staff will review against policy and regulations and provide feedback and suggested revisions
Most Important Tip

- Don’t forget to click the “Submit this Package” button.
- The IRB cannot see any materials until they are officially submitted in IRBNet.
Types of IRB Approval/Disapproval

- Approve
- Approve with conditions
  - Response reviewed by expedited review
- Require modifications to secure approval
  - Response reviewed by Full Board, if initial review was required by Full Board
- Disapprove
Respond to the IRB in a Timely Manner

- **“Unlocked”** package in IRBNet by IRB:
  - Revise as requested
  - Lock package and mark revisions complete

- **“Modifications Letter”** published by IRB:
  - Submit follow-up package in IRBNet
  - Include point by point response cover letter

- **CAUTION:** Withdrawn by IRB if response is not timely
Understanding Post IRB Approval Requirements

- Check IRB approved materials for accuracy
- For NYC H+H, Kings County studies, obtain STAR approval
- Obtain Pre-Awards approval, when applicable
- Obtain legally effective informed consent, using IRB approved “stamped” document(s)
Understand Post IRB Approval Requirements

- Submit follow-up applications within required deadlines
  - Continuing Review
  - Amendments
  - Reportable Events
  - Final Report
- Be prepared to participate in audits
Start Using SUNY PACS
After it is Implemented

- SUNY PACS will be implemented for the IRB, IACUC, Pre-Awards, Agreements, IBC, and COI (Target: 7/1/18)
- Post IRB approval follow-up events
- New studies
WHERE is the IRB Office located?

Call or visit us for help...

Follow the “10 minute” rule...
IRB Office

- 9 am to 5 pm
- Appointments are recommended; however, walk-ins accepted anytime
- Basic Science Building: Room 3-26
  - Near elevator that goes to cafeteria
## IRB Contacts

<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>
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<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) <a href="mailto:IRB@downstate.edu">IRB@downstate.edu</a></td>
<td>(718) 613-8480</td>
</tr>
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</table>
Summary

- Know when IRB approval is required
- Submit online application
- Follow instructions and guidance
- Call the IRB for help
Kevin L. Nellis, MS, CIP
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