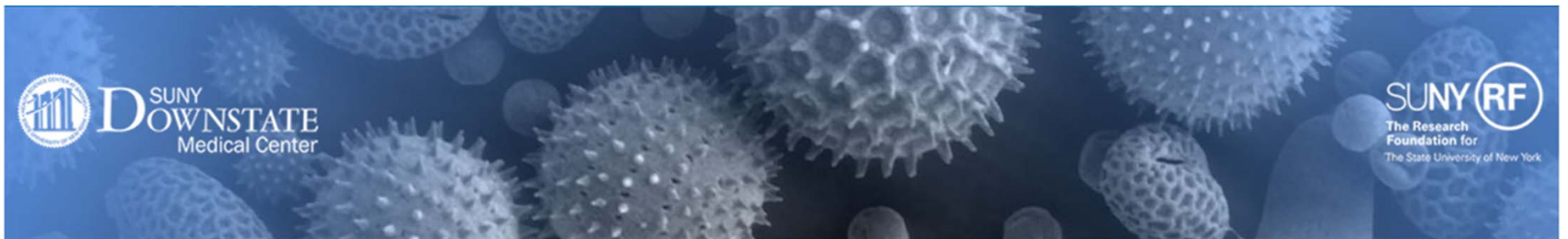


HIGHLIGHTS OF NEW POLICY IRB-01

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Executive Director, Human Research Protections and Quality Assurance



Objectives

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- 1) Understand highlights of IRB-01 policy
- 2) Know where to find additional information
- 3) Understand who to contact for help



IRB-01 Approval and Effective Dates

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- IRB-01 Policy was approved March 2017 by the Executive Performance Improvement Council and the Medical Executive Committee
- Effective date is June 30, 2017

Note: For quick reference, the IRB-01 page numbers are included in these slides.

Activities Requiring IRB Review (10-11)

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- **Clinical Trials** involving drugs, biologics, devices; including use of specimens to validate 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), including exempt research

Initial Expedited Reviews

(17)



- A study may not be expedited at the time of initial review if the research includes any of the following:
 - ▣ Biomedical interventions with children, pregnant women, neonates, prisoners, or cognitively impaired adults
 - ▣ Certificate of Confidentiality

Initial Expedited Reviews

(17)



- IRB may defer the initial review to the convened (full) board for any reason (e.g., sensitive issues, study design concerns, etc.)
- ▣ Study may continue to be reviewed by expedited review procedures for any follow-up, or at the time of continuing review, unless the IRB determines otherwise

External IRB Oversight (20-23)


- Submit IRB Application (or Amendment to add local PI) to the External IRB
 - ▣ IRB Reliance (Authorization) Agreement may be required
 - ▣ Follow procedures, policies, directives, determinations and practices of the external IRB, Downstate IRB, and any applicable agreements
- Submit Downstate “IRB Application for External IRB Oversight”

External IRB Oversight (20-23)



- Downstate IRB must acknowledge External IRB approval before research can begin at Downstate
 - ▣ All local research requirements must be met
- Any IRB notices from External IRB must be submitted to Downstate IRB within 30 days for acknowledgement
- Limited continuing review/progress report required at Downstate IRB

Who can be a Principal Investigator? (24-25)



- Seasoned investigator with a field-specific terminal degree who is a Faculty Member at SUNY Downstate
- 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? (24-25)

- Qualify to be a PI at an external site, when the research makes Downstate engaged:
 - ▣ Federal funding or support is provided to Downstate, or
 - ▣ Co-investigators or key personnel are:
 - Employee of SUNY Downstate
 - 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.

Multiple Principal Investigators (25)

- Multiple PIs are permitted:
 - ▣ Each PI outlines responsibilities in IRB application (e.g., scientific and technical direction)



Delegation of Clinical Trial Tasks (29)

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- PI may delegate tasks to hospital staff or residents for ***clinical trials with an IND or IDE**
 - ▣ Must be qualified for tasks
 - ▣ May be provider of ancillary or intermittent care
 - ▣ May not make direct or significant contributions to the research
 - PI must supervise the activities
 - Delegations should be documented in research record
 - PI determines if delegated staff will be listed as investigators on an IRB application
- * Delegation of research tasks CANNOT be made in other types of research*

Non-Research Staff (30)

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- May perform routine clinical or administrative services to support the research (e.g., lab services, transcription, specimen collections, EKG, radiology, physical or occupational therapy)
- Conditions:
 - ▣ The services performed do not merit professional recognition or publication privileges;
 - ▣ The services performed are typically performed for non-research purposes; and
 - ▣ The individual does not administer any study intervention being tested or evaluated under the protocol

Adequacy of Research Site (31)

14

- IRB may require assessment of the site's adequacy.
 - ▣ Adequacy of the facility's staff
 - ▣ Medical equipment
 - ▣ Emergency or specialized care, if the need arises

PI Responsibilities with IDE & IND Trials (41-45)

15

- Policy outlines requirements for trials with an IDE or IND
- Consult FDA website to understand regulatory responsibilities
 - [PI responsibilities for IDEs](#)
 - [PI Responsibilities for INDs](#)
 - [PI Responsibilities for Investigator-Initiated IND Applications](#)

Requirements for Certain Research (45-48)

16



Endogenous compounds (e.g., bradykinin, histamine, angiotensin)



Live organisms (e.g., virus, bacteria, or fungi)



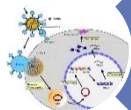
Cosmetics



Dietary supplements, food, food-derived products, spices, or herbs



Electronic cigarettes



Gene transfer



Marijuana

Enrollment List (49)

- Upon request, an enrollment list must be made available to the IRB, DMC Leadership, auditors, or government inspectors
- At a minimum, this list should include the research participant's name and also their medical record number, if they are a patient
- **TIP:** *If the IRB waives documentation of informed consent, the investigator's signature and a witness' signature may be included on the enrollment list, when there is IRB approval to enroll cognitively impaired adults or those with limited English proficiency.*

Medical Record Research Note (49)

18

- For research participants who are also patients enrolled into a **clinical trial involving an IND or IDE** at Downstate
- Research note must be placed in the medical record, unless
 - ▣ the IRB determines that it is not in the best interest of the patient or
 - ▣ when a Certificate of Confidentiality is appropriate

Medical Record Research Note (49)

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- Include the following information, when required:
 - IRB study number
 - Study name
 - Sponsor
 - Principal Investigator
 - Main contact information for the study
 - Date the patient was enrolled
 - Known contraindications
 - Anticipated length of study period (years)

Informed Consent and Research Authorization (50-53)

20

- Refer to IRB templates to ensure all required components are included in the informed consent form
- Modify sponsor's model template to address [local research context](#), when applicable:
 - HIV information
 - Genetics testing
 - Specimen storage
 - Video or audio recordings
 - HIPAA authorization language
 - Signature lines

Distribution of Signed Copies of Informed Consent Materials (57)

21

- Signed Original: Research record
- Copies to:
 - ▣ Person authorizing the research
 - ▣ Medical Record, for clinical trials
 - Unless the IRB determines that it is not in the best interest of the patient or when a Certificate of Confidentiality is obtained

Verification That No Material Changes Have Occurred (66-67)

22

- The IRB must obtain independent verification, utilizing sources other than the investigators that no material changes occurred during the IRB-designated approval period
- Following monitoring, findings are submitted to IRB

Consent Monitoring (67-68)

23

- The IRB may require special monitoring of the consent process by an impartial observer (consent monitor)
- Reduces the possibility of coercion and undue influence
- Ensures process for obtaining legally effective informed consent
- More likely for
 - ▣ High risk studies
 - ▣ When corrective actions are required
 - ▣ When parental permission is waived

Stamping Requirements (68-69)

24

- Long Forms (informed consent documents, HIPAA research authorizations, information sheets, assent Documents), including addendums
- Short Forms
- Summaries of what will be said to a potential research participant
- Oral consent or recruitment scripts
- Recruitment posters, advertisements, or flyers (if feasible)

Post IRB Approval (74)

- Review the IRB approval letter for accuracy and determinations and contact the IRB if there are any discrepancies, errors, or questions
- Ensure [Applicable Clinical Trial Requirements](#) are followed
- Ensure that laboratory reports from research laboratories are not used for diagnosis, treatment and prevention of disease, unless the research laboratory is properly certified or accredited
- For NYC H+H, Kings County studies, obtain [STAR approval](#)

Reportable Events (74-79)

- There are **23 different types** of events that must be reported to the IRB
- All reportable events **MUST** be reported to the IRB within the specified deadlines
- Additional information is provided in the IRB Guidance on “Reportable Events”
- Events are defined in the IRB Guidance on “Acronyms and Definitions”
- For additional information see:
<http://research.downstate.edu/irb/irb-policies.html>

Reporting Privacy or Information Security Violation or Breach (75)

IMMEDIATELY Report to the IRB
(and also to the Privacy Officer
and/or Data Security Officer)



What is an Adverse Event (AE)? (IRB Guidance)

- Any untoward physical or psychological occurrence
- Can be any unfavorable and unintended event, such as:
 - ▣ Abnormal laboratory finding
 - ▣ Symptom
 - ▣ Disease
- May be associated with the research or the use of a medical investigational test article
- Does not necessarily have to have a causal relationship with the research

When is an AE “Serious” or “Alarming”? (IRB Guidance)

- “Serious”:
 - ▣ Death
 - ▣ Life-threatening experience
 - ▣ Initial hospitalization
 - ▣ Prolongation of hospitalization
 - ▣ Persistent or significant disability or incapacity
 - ▣ Congenital anomaly or birth defect
 - ▣ The need for medical, surgical, behavioral, social, or other intervention to prevent outcomes such as the above
- “Alarming”:
 - ▣ Not defined by the FDA; determined by PI or Sponsor

Reporting Internal SAEs to IRB (76)

- Report an internal SAE that occurs in a Clinical Trial **within 24 hours** if the AE meets all of the following criteria:
 - Serious (or alarming)
 - Unanticipated (or unexpected)
 - Would have implications for the conduct of the study
 - (e.g., requiring a significant, and usually safety-related, change in the protocol such as revising inclusion/exclusion criteria or including a new monitoring requirement, informed consent, or investigator's brochure)

Note: Reporting requirements to sponsor/FDA for are stricter.

Reporting Internal Unanticipated Problems Involving Risks to Participants or Others (77)

- Report an internal local Unanticipated Problems Involving Risks to Participants or Others (UPIRPO) within **5 days** if serious; otherwise within **30 days**.
- An *unanticipated problem involving risks to participants or others* (UPIRPO) in general is to include any incident, experience, or outcome that meets **ALL** of the following criteria:
 - ▣ **unexpected** (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the research population being studied;

(continued next slide)

Reporting Internal Unanticipated Problems Involving Risks to Participants or Others (77)

(continued from previous slide)

- ▣ **related or possibly related** to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- ▣ suggests that the research places the **research participants or others at a greater risk of harm** (including physical, psychological, economic, or social harm) than was previously known or recognized.

Amendments (79-81)

33

- **ANY** proposed changes to non-exempt human research must be submitted to the IRB
 - ▣ IRB must approve all changes before implementation
- **EXCEPTION:** change that is necessary to eliminate apparent immediate hazards or to protect the life or physical well-being of the research participant
 - ▣ Must be reported to the IRB within **5 business days**

Changes in Exempt Research (79-81)

34

- **ONLY** required to submit an amendments involving:
 - ▣ New or changed Significant Financial Interest (SFI) or conflict of interest disclosure Management Plan
 - ▣ Change in investigative staff
 - ▣ Change that places the research under a different exempt category, or requires a higher level of review (e.g., expedited or full board review)

Non-Compliance (85-86)

35

- Investigators must report suspected or real noncompliance
- May come to the attention of the IRB through other sources
- May be reported anonymously to 877-349-SUNY or

[Compliance Line Website](#)

- **No one may retaliate against anyone making a report**

Non-Compliance (85-86)

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- May be due to faulty communication or systematic error rather than the negligent actions of a single individual
- Identification and investigation of noncompliance provides an opportunity for improvement
- Reporting non-compliance honors the respect of those who participate in human research

IRB Review of Non-Compliance (87-88)

37

- IRB Chair or Vice-Chair may take interim actions and make some determinations
- All serious non-compliance or continuing non-compliance determinations must be made by the convened (full) IRB
- Focus is on corrective actions, prevention, mitigation of adverse effects, and quality improvement, rather than being a punitive process

IRB Review of Non-Compliance (87-88)

38

- Department Chair and Dean notified, if serious or continuing
- Investigation committee may be formed
- PI must make required corrective actions
- Federal and State authorities and Sponsors notified, when applicable

Appealing IRB Decisions (89)

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- A PI may appeal any IRB decision, except for a suspension or termination of IRB approval
- The PI must submit a written appeal via IRBNet within 60 days
- The PI or the IRB may involve the Institutional Official for a resolution
- Final decision must be made by the IRB (full board)

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

IRB menu

[Home](#)[Electronic Submissions](#)[Training & Conflict of Interest](#)[Members and Staff](#)[Meeting Schedule](#)[Policies & Guidance](#)[Resources](#)[FAQs](#)

IRB Net & CITI Program links

[IRB Net](#)[CITI Investigator Education Certification](#)

IRB Contacts



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Summary

- This presentation covered key highlights of the new IRB-01 policy
- Refer to IRB Policy and Guidance for additional information
- Contact the IRB for help (x8480)