Institutional Review Board Orientation & IRB Submission Process

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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.
- Serves as a Privacy Board to ensure HIPAA compliance.

Key Historical Events

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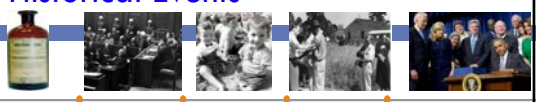

1937	1946-47	1960's	1972-91	2010's-2020's
Sulfanilamide Elixir Incident	**Nuremberg Trials**	**Thalidomide Tragedy**	**Tuskegee Syphilis Study Exposé**	**Government Aims to Accelerate, Discover, & Develop Biomedical Products; Reduce Regulatory Burden**
Food, Drug, and Cosmetic Act ('38)	*Nuremburg Code ('47)*	*Drug Amendments added to FD&C Act ('62)*	*National Research Act ('74)*	*21st Century Cure's Act ('16)*
		FDA Informed consent regulations ('63)	*The Belmont Report ('79)*	*Revised Common Rule (Effective '19)*
			Common Rule ('81)	*Single IRB oversight of multi-site studies. (Effective '19 & '20)*
			Revised CR ('91)	

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)

-AND-

  - Designed to develop or contribute to **generalizable knowledge**.

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

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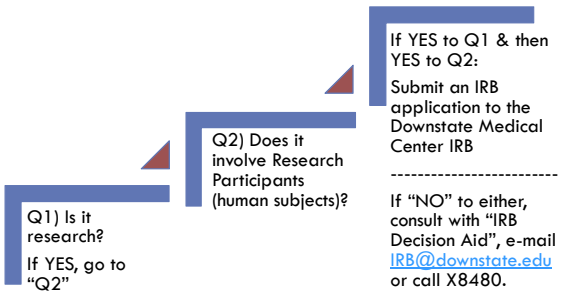
- In order for research to be considered human research (and thus requiring IRB approval before the study begins), the research must involve **living individuals** about whom an investigator (whether professional or student) conducting research either
  - obtains **information or biospecimens** through **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**.

What is Human Research?



Is IRB Approval Required for Performance Improvement Activities?

- It depends! Does it meet the definition of human research?
- Performance improvement activities do not need IRB approval if:
  - Intent is to improve internal operations, &
  - 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 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)
- Some journals require informed consent/HIPAA Authorization

Types of IRB Applications

- Most Common:
  - Exempt
  - Expedited or Full Board
  - External IRB Oversight
  - IRB Decision Aid
- Other Types:
  - Clinical Use of a Humanitarian Use Device (HUD)
  - Expanded Access (Investigational Drug/Biologic for Treatment Use)
  - Honest Broker Agreement (used with other applications)

Exemption Categories

(Revision effective January 2019)

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

Examples of Expedited Review

(May be revised in near future by HHS)

- Clinical studies of drugs and medical devices only under specific conditions (no IND or IDE)
- Chart reviews (Consider Exemption #4, if PHI involved)
- Survey research (Consider Exemption #2)
- 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 (Consider Exemption #4)
- Collection of data from voice, video, etc. (Consider Exemption #2 and/or #3)
- Research employing surveys, focus groups, etc. (Consider Exemption #2)

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 #1 or #2:
  - 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 and for research approved by a Tribal IRB
- Requires IRB Reliance Agreement (IRA) with the External IRB
  - IRA on file: BRANY IRB, NCI CIRB, & those in the SMART IRB Network (over 667 participating sites)
  - Other IRAs determined on a case by case basis with approval of Downstate Institutional Official (IO)
- Downstate IRB must acknowledge external IRB approval and confirm all local research requirements are met
- Cannot be used for the following:
  - Downstate as a single site, unless a Tribal IRB is required
  - Research previously disapproved by the Downstate IRB
- When completing a "Request for External IRB Oversight" application, include only Downstate Workforce to confirm local context

*General External IRB Process (Not easier but different)

- Reliance Request
  - Reliance Agreement initiated
  - Local research context clarified to external IRB
- Pre-Activation (Pre-Review of materials by Downstate IRB)
  - Model templates
  - Local research context
- Obtain approval from External IRB
- Activation by Downstate after confirming it meets:
  - Downstate institutional requirements
  - Local research context

**Actual steps may be different for each External IRB*

IRB Decision Aid – Application for a Determination that IRB Approval is Not required

- Use FORM A when there is no intention of developing or creating generalizable knowledge, and the proposed activity is limited to one of the following:
  - Health care operations activity (e.g., performance improvement),
  - Case report or case series (up to three individuals)
  - Operational activity,
  - Pilot activity, feasibility activity, or evidence-based practice activity,
  - Training or educational activity, or
- Use FORM A when Downstate is not engaged in human research.
- Use FORMB B for any request

Downstate IRB has Oversight of the Downstate Workforce

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- Faculty members, employees, and staff paid by Downstate
- Employees, staff, or contractors paid by the Research Foundation for SUNY, working on behalf of Downstate
- Individuals with a Downstate Voluntary Faculty appointment with medical privileges (credentialed by University Hospital SUNY Downstate)
- Retired Downstate faculty member with emeritus status (approved by IO & Dean/Department Chair)
- Residents, Fellows, or Medical Students who are sponsored by Downstate
- Students in a Downstate academic program
- Temporary Employees or SUNY contractors working on behalf of Downstate
- Downstate Volunteers (officially approved by the Downstate Volunteer Office)

External Investigators' Reliance with Downstate Serving as the IRB of Record

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- External Investigators include:
  - External consultants (paid by sponsors or other entities outside of Downstate)
  - External employees
  - Individuals with Voluntary Faculty appointments without medical privileges
- Request IRB Reliance Agreement (IRA), except for NYC H+H, Kings County (KC) investigators (IRA already in place)
- Request Individual Investigator Agreement (IIA) for:
  - Independent investigators not affiliated with an institution, who therefore are not under an IRA, or
  - External investigator from an institution without a Public Health Services regulated COI policy and adjudication process

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 members of the Downstate workforce

Notes: An external PI cannot be acknowledged by the Downstate IRB on an IRB application for External IRB Oversight.

Suggested Timeline (Start Early!)

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- Review Downstate IRB website for instructions and details:
  - https://research.downstate.edu//irb/irb.html
- Complete training and submit COI disclosures
  - http://research.downstate.edu/irb/irb-training.html
- Plan your project
- Identify Investigator with PI Status
- Develop Protocol (Templates on IRB website)
  - Hypothesis, Aims, & Objectives
  - Methods, Procedures, Data Collection
  - Consult Biostatistician for power analysis and statistical tests

Suggested Timeline (Continued)

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- Complete IRBNet Registration form in IRBNet
- Upload all applicable materials in IRBNet
  - Application
  - Consent form(s), including short forms
  - IND/IDE documentation
  - Data Collection tools
  - Waivers
  - Recruitment materials
  - Other materials as outlined on IRB website
- Request IRB Office Pre-Review (OPTIONAL –share in IRBNet)
- Obtain e-signatures (PI, Chair/Dean, Ancillary Reviewers)
- Submit to IRB in IRBNet

Downstate IRB Approval/Disapproval

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- When reviewed by Downstate IRB:
  - Approve
  - Approve with conditions
    - Response reviewed by expedited review
  - Modifications required to secure approval
    - Response reviewed by Full Board, if initial review was required by Full Board
  - Disapprove/ Not Approved / Deferred / Tabled
- When reviewed by an External IRB:
  - (Pre-Review) Acknowledgement Pending External IRB Approval
  - (Final) Acknowledgement (of external IRB approval)/Activation

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

Post IRB Approval Requirements

- Check IRB approved materials for accuracy
- For NYC H+H, Kings County studies, obtain STAR approval
- Obtain Sponsored Programs approval, when applicable
- Obtain Institutional Biosafety Committee Approval, when required, before starting study
- Obtain legally effective informed consent, using IRB approved "stamped" document(s) (when applicable)

Post IRB Approval Applications

- Acknowledgement
- Reportable Events
- Amendment (2 TYPES)
  - Staff Changes Only
  - All other changes
- Continuing Review (3 OPTIONS)
  - Abbreviated forms for External IRB or HUD for Clinical Use
- Check-In Report (for studies with 3 year approval periods)
- Final Report (Study Closure)

Reportable Events

- Government Inspections (or audit)
- Privacy or Information (Data) Security Violation (Breach)
- Incarceration of a research participant
- Any FDA Action or Changes to HUD
- Unanticipated Serious Adverse Event
- Research related Injury involving provision of healthcare
- Apparent non-compliance (including serious or continuing non-compliance)
- New information that indicates a change to the risks or potential benefits of the project
- Significant new finding
- Changes to eliminate an apparent immediate hazard
- Termination or suspension
- Administrative or enrollment hold
- Local unanticipated problem involving risks to participants or others
- Unexpected Adverse Event
- Audit or Monitor activities
- Unanticipated adverse device effect
- Interim Analysis report or DSMB report
- Adverse Event, external event, or other sponsored required reporting

Contact IRB for HELP

- Call: (718) 613-8480
- E-mail: IRB@downstate.edu
- IRB Office: Basic Science Building Room 3-26
  - Appointments recommended
  - Walk-ins welcome (9AM – 5 PM)

Downstate 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	(718) 613-8480

Additional Downstate Contacts

- Privacy Officer: (718) 270-4033
- Information Security: (718) 270-4621
- Sponsored Programs Administration: (718) 270-2680
- Office of Technology Commercialization: (718) 613-8515
- Office of Compliance and Audit Services: (718)270-4033
- Compliance Training Program: (718) 270-4033

NYC H+H, Kings County

- All research conducted at NYC H+H, Kings County must also be in compliance with H+H policy and approved in System to Track and Approve Research (STAR). IRB Approval is required before information can be entered in STAR. For more information refer to the NYC H+H, Kings County policies at: https://research.downstate.edu//irb/irb-policies.html
- For any questions about NYC H+H, Kings County policy, please contact:
  - Michele Follen, MD, PhD, MBA; Director of Research and Chair, Facility Research Review Committee, NYC Health + Hospitals/Kings County (718) 613-8401 or follenm@nychhc.org
  - Bryce Petty, CCRC, Facility Research Coordinator: (718) 613-8185 or Bryce.Petty@nychhc.org (Bryce Petty is the best contact for STAR)

Note: The Site Principal Investigator for a study conducted at NYC H+H, Kings County must be a full-time, part-time or voluntary physician who is a member of the Medical Staff at Kings County and who has appropriate clinical privileges as defined in the Facility's Medical Staff Bylaws. This individual must also be approved by the reviewing IRB as personnel on the study.

Summary

- Submit online applications to obtain IRB approvals
- Follow instructions and guidance
- Call or visit the IRB Office for help