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IRB OVERVIEW AND UPDATES

- About me – Diann Johnson, MPH
- IRB overview
- Governing concepts
- Submission process
- What's new and exciting?

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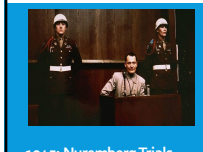
IRB DEVELOPMENT: WHAT HAVE WE LEARNED FROM HISTORY?

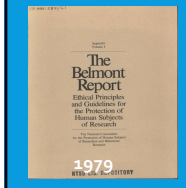


1945: Nuremberg Trials

1953: National Institutes of Health

1964: Declaration of Helsinki

1972: Tuskegee Syphilis Study (began in 1932)



Title 45
Code of Federal Regulations
Part 46

IRBs today

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BELMONT PRINCIPLES

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WHAT IS ETHICAL RESEARCH?

- Personal integrity of researcher, fair, honest
- Right of privacy of participants; data protection
- Disclosure of study methods
- Reason for research
- Informed willingness for study participation
- Respect for integrity of individual
- Acknowledge financial support, conflict of interest

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WHY DOES THE IRB EXIST?

- Formally designated under FDA regulations
- Charged with reviewing human subjects research
- authority to approve, require modifications in (to secure approval), or disapprove research modifications in (to secure approval), or disapprove research
- Suspend or stop any human subjects research project

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IRB AIMS AND ACTIVITIES

- All participants in human research are protected from any unnecessary risk
- Potential participants are able to make an informed decision to participate
- When possible, the participant and/or society at large benefits from the knowledge gained.

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THE DOWNSTATE IRB: WHO WE ARE, WHO IS INVOLVED IN REVIEW

Your project: slated for Administrator review or Full Board?

Who we are

- IRB voting members
- Varied expertise
- Community representation
- Administrative staff

Tips for submission/review:

- Reach out to our office or your reviewer directly!
- If Full Board review is needed, be prepared to come to answer questions
- Know your study

Administrator (solo) reviewer:

- For non-research determinations
- For studies determined to be Exempt
- For multisite studies (external IRB studies; Downstate is not IRB of record)
- Administrative pre-review (staff) and a single IRB member for Expedited level review (minimal risk studies)

Full Board:

- For greater than minimal risk studies, other circumstances (e.g. some noncompliance, adverse events)
- Meets once monthly (may meet more often for time-sensitive COVID-related studies)

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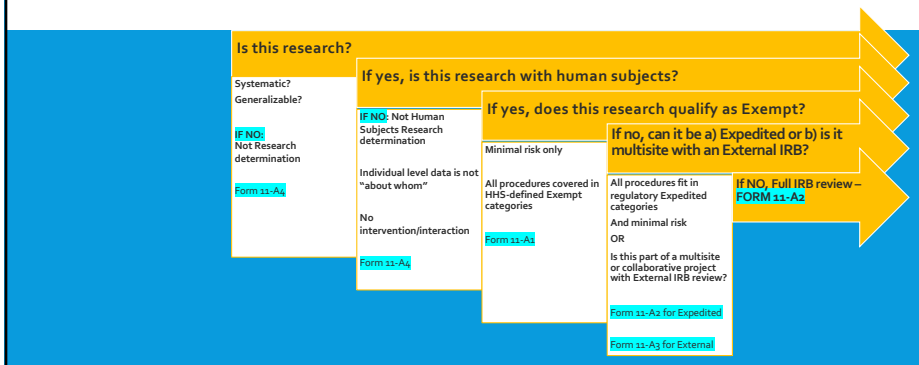
LEVELS OF REVIEW AND THE IRB "THINKING HIERARCHY"



***Tip*: Contact us before you pick your application! IRB staff are here for consultation on which path is advised.**
START EARLY!

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WHAT IS EXEMPT?

The following DHHS categories of human subjects research are exempt from this policy:

(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices
(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording)
(3) (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses
(4) Secondary research for which consent is not required:
(5) Research and demonstration projects that are conducted or supported by a Federal department or agency,
(6) Taste and food quality evaluation and consumer acceptance studies:
(7) Storage or maintenance for secondary research for which broad consent is required:
(8) Secondary research for which broad consent is required:

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WHAT IS EXPEDITED?

The following DHHS categories of human subjects research are expedited:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture
3. Prospective collection of biological specimens for research purposes by noninvasive means.
4. Collection of data through noninvasive procedures
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior
8. Continuing review of research previously approved by the convened IRB as follows:
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

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WHAT IS FULL BOARD REVIEW?

- Greater than minimal risk studies
- Reviewed by the Full IRB Committee
- Quorum must be present

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IRB DETERMINATION

- IRB review is NOT required

Examples:

• A Healthcare Operations Activity (HOA) (e.g., Performance Improvement, Resident Training) NOT designed to develop NOR contribute to generalizable knowledge.

• Activities that do not involve systematic investigations.

• Case series or case study of up to three (3) cases

• Activities limited to using data from individuals who have been deceased for more than 50 years

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THE IRB REVIEW PROCESS

- We must review all documents especially those that the subject will see
  - Examples – consent and assent forms, cover letter, survey instrument
- Study must be reviewed and approved before study recruitment or any data is collected
- IRB approval period
- The IRB looks at the potential research risks and the ways to minimize or reduce these risks

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WHAT TYPE(S) OF RESEARCH WE REVIEW?

- Biomedical
- Socio-behavioral
- Surveys
- Interviews
- Focus groups
- Medical Chart and Registry reviews
- Research on educational practices
- Case studies
- Deploy an intervention/treatment
- Database analysis
- Specimen collection

WHAT ARE SOME AREAS OF RESEARCH INTERESTS?

- Mental health
- Autism
- Oncology
- Diabetes
- Immigrant Health
- COVID-19
- Monkeypox
- Health Disparities

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WHAT'S NEW?

- Central Scientific Review Committee (CMRC)
- Quality Assessment Program (QAP)
- New or Updated Guidance Documents
- New and updated IRB forms/materials
- IRB's Website
- FDA Proposed Rules

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CENTRAL SCIENTIFIC REVIEW COMMITTEE (CMRC)

- Evaluates Downstate human research protocols
- Pilot Phase 3
- Specific criteria and instructions for CMRC review
- CMRC review should be done before IRB submission
- CMRC Review Request Form
- Scientific Review Committee (SRC)

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QUALITY ASSESSMENT PROGRAM (QAP)

- Review, inspect and verify the ethical conduct of human research, integrity of data, adherence to the IRB approved protocol, and applicable institutional, state, and federal regulations, policy, and guidance
- Non-punitive in nature
- Designed to be a productive process for investigators while striving for continuous improvement in every area of the research enterprise.

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NEW OR UPDATED GUIDANCE DOCUMENTS

- Determining which IRB to Use, which Agreements are required and which IRB fees to budget (12/1/22)
- COI Requirements (7/1/22)
- Quality Assessment Program (6/1/22)
- Quality Assessment Program -Template Letters to PI (6/1/22)
- Fee Schedule (5/17/22)

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NEW OR UPDATED GUIDANCE DOCUMENTS

- Training Requirements (5/10/22)
- Injury Language (5/4/22)
- Lay-Person Summary (5/4/22)
- Recruitment, Referral, Screening, Advertising, and Incentives (5/1/22)
- Enrolling or Excluding Pregnant People, Contraception, Pregnancy Testing, and Partners of Participants Who Become Pregnant (2/2/22)

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NEW OR UPDATED FORMS:

- CMRC Review Request Form (Phase 3) (8/11/22)
- Form 11-A5: Application for Expanded Access to Investigational Drug/Biologic for Treatment Use (6/30/22)
- Form 21-1: Quality Assessment Form (6/1/22))
- Form 21-2: Corrective & Preventative Action Plan (CAPA) Form (6/1/22)

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NEW OR UPDATED FORMS:

- Form 11-A4: Application for Determination Letter (IRB Decision Aid) (replaced 2 former application forms) (3/2/22)
- Form 11-A2: Application for Expedited or Full Review (2/2/22)
- Form 11-8: Exclusion of Pregnant People and/or Plans to Study Outcomes of Unexpected Pregnancies (2/2/22)
- Form 11-9: Research involving Pregnant People and/or Fetuses (2/2/22)

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IRB'S WEBSITE

Institutional Review Board
SUNY Downstate Health Sciences University

https://www.downstate.edu/research/research-services/institutional-review-board/electronic-application-process.html

- IRB's "Vision, Mission and Values"
- Notice of new and updated materials

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FDA PROPOSED RULES

- Two notices of proposed rule-making (NPRMs) published in the Federal Register
- Simplify and harmonize the FDA's regulations with the revised HHS Federal Policy for the Protection of Human Subjects (the revised Common Rule), in accordance with the 21st Century Cures Act (Cures Act).
- Most significant changes: aligning informed consent requirements and IRB requirements, and **eliminating the continuing review requirement for studies that have progressed to the point that they involve only data analysis.**

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KEY TIPS ON NAVIGATING THE IRB PROCESS AT DOWNSTATE

Common causes of delays

- "Sticking point" review areas: recruitment, consent process, data sharing, collaborations outside of Downstate
- Wrong review path selected
- Administrative details: incomplete submission packages; training and attestations for study personnel; missing e-signatures; template language removal in documents; outdated forms and templates; inconsistencies
- Not obtaining CMRC review early; Ancillary review requirements; agreements for multi-institution research) - usually for greater than minimal risk studies

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We are here to help – get in touch with our office!

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QUESTIONS?

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