DOWNSTATE
HEALTH SCIENCES UNIVERSITY

IRB Member Orientation Session I

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Applicability of Regulations

General Information

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Criteria and considerations for IRB approval

IRB Actions

IRB Member Roles & Review Goals

IRB Member Roles

- Scientist/Nonscientist
- Affiliation
- Community member
- Prisoner representative

IRB Member Goals

- Terms: (1 year; renewable to 3 years)
- Maintain confidentiality
- Training and education
- Inform IRB Office of extended absences
- Review goals
  - For full board studies, enter comments no later than **COB on Friday** before scheduled meeting
  - Other submissions, **enter review ASAP, but no later than**
    - **3 days** for IRB determinations
    - **5 days** for urgent requests
    - **10 days** all others
- Disclose conflicts or interest
- Attendance goals -important to meet quorum and voting requirements
  - Attend all meetings if possible
  - Attend at least 5 of estimated 6 meetings per year.
- Performance evaluations

Applicability of Regulations

Regulations:

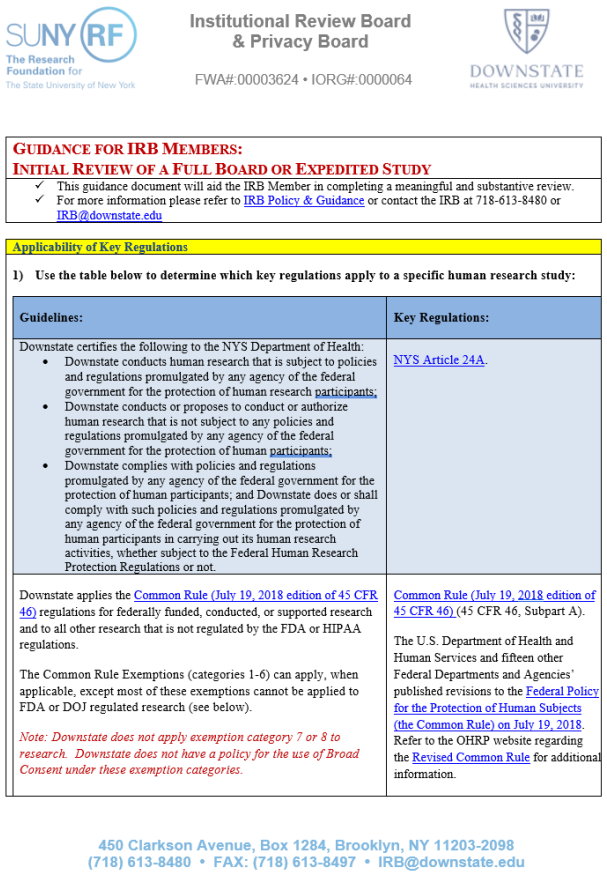
- 2018 Common Rule (45 CFR 46)
  - Federally funded or supported research
  - Research not regulated by FDA or HIPAA regulations
  - Applies to multisite research from institutions that voluntarily comply with the Common Rule
  - Subparts B, C, D, and E apply when applicable, as indicated within the regulations.
  - Expedited review categories
- HIPAA Privacy Rule (45 CFR Parts 160, 162, and 164)
  - Research involving Protected Health Information (PHI)
- FDA (21 CFR 11, 50, 56, 312, 320, 812, 814, etc.)
  - Investigational studies involving research participants (including specimens) and FDA regulated articles (e.g., drugs including biologics, food or color additives, and medical devices), including bioavailability and bioequivalence studies.
- Applicable Clinical Trial (ACT) –As defined by the FDA/NIH
- International Council for Harmonisation (ICH) Harmonized Guideline: Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2).
  - Generally, applies to Clinical Trials, especially international trials
- Single IRB (sIRB) Requirements (Federally funded/supported)
- NIH Certificate of Confidentiality Requirements (NIH funded)
- Federal Department or Agency requirements, for example:
  - VA – VHA Handbook 1200.05
  - Department of Defense
  - Department of Justice (PRE-2018 Common Rule (45 CFR 46)
- Family Educational Rights and Privacy Act (FERPA)
  - Gives parents certain rights regarding children's education records
- Protection of Pupil Rights Amendment (PPRA)
  - Gives parents certain rights regarding surveys with children when funded by ED
- Children's Online Privacy Protection Act (COPPA)
  - Gives parents certain rights regarding online surveys with children
- NYC DoE IRB – Must review certain research taking place at NYC Public schools
- NY Privacy Shield – Applies to private data of NY residents
- Foreign regulations, including EU General Data Protection Regulation (GDPR)

General Information

IRB Review Guidance

Available on IRB Website (Guidance for IRB Members)

[Institutional Review Board Policies | SUNY Downstate Health Sciences University]



SUNY RF The Research Foundation for The State University of New York

Institutional Review Board & Privacy Board

FWA#:00003624 • IORG#:0000064

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GUIDANCE FOR IRB MEMBERS:
INITIAL REVIEW OF A FULL BOARD OR EXPEDITED STUDY

- ✓ This guidance document will aid the IRB Member in completing a meaningful and substantive review.
- ✓ For more information please refer to IRB Policy & Guidance or contact the IRB at 718-613-8480 or IRB@downstate.edu

Applicability of Key Regulations

1) Use the table below to determine which key regulations apply to a specific human research study:

Guidelines:	Key Regulations:
Downstate certifies the following to the NYS Department of Health: • Downstate conducts human research that is subject to policies and regulations promulgated by any agency of the federal government for the protection of human research participants; • Downstate conducts or proposes to conduct or authorize human research that is not subject to any policies and regulations promulgated by any agency of the federal government for the protection of human participants; • Downstate complies with policies and regulations promulgated by any agency of the federal government for the protection of human participants; and Downstate does or shall comply with such policies and regulations promulgated by any agency of the federal government for the protection of human participants in carrying out its human research activities, whether subject to the Federal Human Research Protection Regulations or not.	NYS Article 24A.
Downstate applies the Common Rule (July 19, 2018 edition of 45 CFR 46) regulations for federally funded, conducted, or supported research and to all other research that is not regulated by the FDA or HIPAA regulations. The Common Rule Exemptions (categories 1-6) can apply, when applicable, except most of these exemptions cannot be applied to FDA or DOJ regulated research (see below). *Note: Downstate does not apply exemption category 7 or 8 to research. Downstate does not have a policy for the use of Broad Consent under these exemption categories.*	Common Rule (July 19, 2018 edition of 45 CFR 46) (45 CFR 46, Subpart A). The U.S. Department of Health and Human Services and fifteen other Federal Departments and Agencies' published revisions to the Federal Policy for the Protection of Human Subjects (the Common Rule) on July 19, 2018. Refer to the OHRP website regarding the Revised Common Rule for additional information.

450 Clarkson Avenue, Box 1284, Brooklyn, NY 11203-2098
(718) 613-8480 • FAX: (718) 613-8497 • IRB@downstate.edu

Downstate IRB Guidance

Institutional Review Board Policies | SUNY Downstate Health Sciences University

Consolidated IRB guidance related to COVID-19

Applicable Clinical Trial (ACT) Checklist

Belmont Report

Data Security

FDA Guidance

Enrolling or Excluding Pregnant People, Contraception, Pregnancy Testing, and Partners of Participants Who Become Pregnant

Fee Schedule for Industry Sponsored Research

Genome-Wide Association Studies (GWAS- NIH)

GWAS FAQs (NIH)

ICH GCP (E6-R2) 2016

IRBNet (IRB Application and Reporting System)

Lay-Person Summary

Local Context for Reviewing (External) IRB

Material Transfer Agreements

Military Health System Research Regulatory Oversight Office

Obtaining Legally Effective Informed Consent and HIPAA Research Authorization

Office for Human Research Guidance (Alphabetical List)

Qualtrics Survey Software

Recruitment, Referral, Screening, Advertising, and Incentives

REDCap: Research Data Capture and Analysis System

Students, Residents, Fellows, Volunteers, or Employees as Research Participants

Veterans Affairs Office of Research and Development

Belmont Principals

The Belmont Report | HHS.gov

Principal	Application
Respect for Persons -Protects autonomy -Protect those with diminished autonomy	-Informed Consent, Parent/Legal Guardian Permission, or Legally Authorized Representative - Disclose all information - Ensure comprehension - Ensure voluntariness
Beneficence -Do no harm -Maximize benefits -Minimize risks	-Risk/benefit ratio must be justified
Justice -Equal distribution of benefits and risk	-Equitable selection -Consider recruitment of those with limited English proficiency when there is a therapeutic benefit

Types of IRB Applications

IRB Applications for Initial Review

STEP 11 @ IRB Submissions website:

Most frequently used forms:

Form 11-A1: Application for Exempt Review

Form 11-A2: Application for Expedited or Full Review

Form 11-A3: Application for External IRB Oversight

Form A4A: Application for a Determination Letter (IRB Decision Aid)

Less commonly used forms:

Form A1B: Application for Exempt Review - DOJ/DIJ Funded Research Only

Form A5: Application for IRB Approval of Expanded Access to Investigational Drug/Biologic for Treatment Use

Form A6: Application for HUD for Clinical Purposes

Form A7: Application for Independent Honest Broker Assurance Agreement

Forms related to Enrolling or Excluding Pregnant People, Contraception, Pregnancy Testing, and Partners of Participants Who Become Pregnant:

- Form 11-8: Exclusion of Pregnant People and/or Plans to Study Outcomes of Unexpected Pregnancies
- Form 11-9: Research involving Pregnant People and/or Fetuses

Post-IRB Approval Applications

STEP 20 @ IRB Submissions website:

Submit the applicable application forms to the IRB after the IRB has granted initial approval:

Form 20-B1: Application for Acknowledgment

Form 20-B2A: Application for Amendment

Form 20-B2B: Application for Amendment - STAFF CHANGES ONLY

Form 20-B3: Application Form for Reportable Event

Form 20-B4: Application for Continuing Review/Check-In/Study Closure/Re-Activation

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 that involves a drug, device or blood collection, if the study includes a biomedical intervention with children, pregnant women, neonates, prisoners, or cognitively impaired adults.

IRB Member refer any study to full board.

Expedited Review

Some Studies That Are No Greater Than Minimal Risk

Clinical investigations of drugs and medical devices only under specific conditions (no IND or IDE)

Collection of blood samples

Biological specimens obtained by non-invasive means

Collection of data through non-invasive means

NOTE: Some of the other federal expedited review categories (1998) now qualify for exempt research under the revised Common Rule (2018).

Exemption Categories

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

REMINDER

Please attend Session II & III

Contact the IRB Office with any questions or write to IRB@downstate.edu

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Thank You!