IRB Member Orientation
Session I

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Kevin Nellis

March 2022
Agenda (Session I)

IRB Member Roles & Goals
Applicability of Regulations
General Information
Types of IRB applications
Agenda (Session II)

Informed Consent Requirements
HIPAA Research Authorization Requirements
Waivers and Alterations
Agenda (Session III)

Risk Assessment
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

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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 FAQs & Policies](https://irb.downstate.edu) or email the IRB at 632-615-0800 or [IRB@downstate.edu](mailto:IRB@downstate.edu)

| Applicability of Key Regulations |  
|----------------------------------|---
| 1) Use the table below to determine which key regulations apply to a specific human research study | 

<table>
<thead>
<tr>
<th>Guidelines</th>
<th>Key Regulations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Downstate complies with policies and regulations established for the protection of human participants and Downstate does not employ other policies and regulations that are broader in scope or more stringent than those established by the federal government for the protection of human participants, and Downstate does not apply such policies and regulations to any agency of the federal government for the protection of human participants in conducting or in human research activities, whether subject to the Federal Human Subjects Protection Regulations or not</td>
<td>NSF Article 2.6A</td>
</tr>
<tr>
<td>Downstate applies the Common Rule (July 18, 2018 editions of 45 CFR 46) regulations for Federally-funded, conducted, as supported research and to all other research that is not regulated by the FDA or IRBAA regulations.</td>
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<tr>
<td>The Common Rule Exemptions (categories 1-6) can apply, when applicable, except that of those exemptions cannot be applied to FDA or DHHS regulated research (see below).</td>
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<tr>
<td><strong>Note:</strong> Downstate does not apply exemption category 7 or 8 to research. Downstate also will not issue a study for the use of Blood Donors under those exemption categories.</td>
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<tr>
<td>Common Rule (July 18, 2018 editions of 45 CFR 46) Exemptions A</td>
<td></td>
</tr>
<tr>
<td>The U.S. Department of Health and Human Services and other Federal Departments and Agencies may publish regulations or policies pursuant to the Federal Policy for the Protection of Human Subjects the Common Rule on July 18, 2018 that is to the effect new Common Rule, for additional information.</td>
<td></td>
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(718) 613-0486 • FAX: (718) 613-0497 • 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

<table>
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<tr>
<th>Principal</th>
<th>Application</th>
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| **Respect for Persons**    | - Informed Consent, Parent/Legal Guardian Permission, or Legally Authorized Representative  
- Disclose all information  
- Ensure comprehension  
- Ensure voluntariness |
| **Beneficence**            | - Risk/benefit ratio must be justified                                                                                                    |
| **Justice**                | - Equitable selection  
- Consider recruitment of those with limited English proficiency when there is a therapeutic benefit |

- Protects autonomy  
- Protect those with diminished autonomy  
- Do no harm  
- Maximize benefits  
- Minimize risks  
- Equal distribution of benefits and risk
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.
Expeditied 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
Thank You!