STATE OF THE IRB

FY 2018- 2019

Nathalia Henry, Executive Director, IRB Office

May 15, 2019
IRB OFFICE ELEVATOR PITCH:

Protects the rights and welfare of participants in human research.

∞

Administratively supports the IRB which is responsible for approving research protocols, informed consent documents and other study related materials before a study can begin.

∞

Provides guidance, education and relevant compliance tools, and equips the University’s research community to conduct ethical human research that minimizes risk to participants and maximizes benefit.
IRB OFFICE ORG CHART

Ann Adams
AVP, Office for Research

Administrative Assistant IV

Executive Director

SBS Manager

Lead IRB Analyst

Senior IRB Analyst

IRB Analyst

Biomedical Manager

Lead IRB Analyst

5 Senior IRB Analysts

3 IRB Analysts

Assoc. IRB Analyst

Total: 22
ED:1
Managers: 3
Analysts: 16
Reliance/Training Lead: 1
Admin Asst. IV: 1
IRB OFFICE KEY RESPONSIBILITIES

- Operationalize HRPP
- Formulate & maintain policies and procedures
- Maintain Federal Wide Assurance
- Maintain AAHRPP accreditation
- Serve as IRB of Record for Northwestern and Affiliates, [and other institutions with which we have established agreements]

- Oversees IRB Operations of 6 panels and designated reviews
- Communicate IRB actions to researchers
- IRB Member recruitment, training and payment
- eIRB+ maintenance w/ORIT
- Billing for Industry sponsored studies
IRB OFFICE KEY RESPONSIBILITIES (continued)

Reliance:
- IRB Authorization Agreements (to rely on an external IRB, or to serve as IRB of Record)
- Consultations for sIRB
- Letters of Support

Education & Training:
- Human Subjects Training (online and in person)
- Annual IRB Member retreat
- IRB Office staff CIP certification/re-certification

Compliance:
- Post Approval Monitoring (In-person visit, Self assessment, Consent process observation)
- Directed Review Audits
- External & University Reporting
- Participant Complaints
- Other Investigations
- Internal QA-QI activities
METRICS

Active & Exempt Studies by FY

Fiscal Year

2016
2017
2018

Number of Active Studies

2268
3089
4110

Active Studies
Exempt Studies
TOTALS

FY2018:
4904
METRICS (continued)

Active & Exempt Studies by FY

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Active Studies</th>
<th>Exempt Studies</th>
<th>TOTALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td></td>
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</tr>
<tr>
<td>2017</td>
<td></td>
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<tr>
<td>2018</td>
<td>794</td>
<td>4110</td>
<td>4904</td>
</tr>
</tbody>
</table>

FY2018

* Federally funded: 26%
* Industry 17%
* Other external sources: 20%
* Internally funded: 37%
METRICS (continued)

Active & Exempt Studies by FY

Number of Active Studies

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Active Studies</th>
<th>Exempt Studies</th>
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<tbody>
<tr>
<td>2016</td>
<td>2268</td>
<td>60%</td>
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<tr>
<td>2017</td>
<td>31%</td>
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<tr>
<td>2018</td>
<td>31%</td>
<td>9%</td>
</tr>
</tbody>
</table>
METRICS (continued)

Number of Submissions FY2018

Total Submissions: 14936
Average per Month: 1245
### METRICS (continued)

Median # days to obtain approval by review type and submission type

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<tbody>
<tr>
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<td>58</td>
<td>31</td>
<td>42</td>
<td>30</td>
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<td>31</td>
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<tbody>
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<td>Committee</td>
<td>20</td>
<td>11</td>
<td>14</td>
<td>27</td>
<td>15</td>
<td>29</td>
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<tr>
<td>Exempt</td>
<td>15</td>
<td>29</td>
<td>15</td>
<td>29</td>
<td>15</td>
<td>29</td>
<td>15</td>
<td>15</td>
<td>29</td>
</tr>
</tbody>
</table>
METRICS (continued)

Top 25 Department Submitters
FY 2018

0 200 400 600 800 1000 1200

ROBERT H. LURIE COMPREHENSIVE CANCER CENTER
PHYSICAL MEDICINE AND REHABILITATION
NEUROLOGY
MEDICAL SOCIAL SCIENCES (MSS)
OBSTETRICS AND GYNECOLOGY
PSYCHOLOGY
GASTROENTEROLOGY AND HEPATOLOGY DIVISION
HEMATOLOGY/ONCOLOGY DIVISION
CARDIOLOGY-DIVISION
PREVENTIVE MEDICINE
PSYCHIATRY AND BEHAVIORAL SCIENCES
DERMATOLOGY
RADIOLOGY
SURGERY
MEDICINE
GENERAL INTERNAL MEDICINE DIVISION
COMMUNICATION SCIENCES AND DISORDERS
FEINBERG SCHOOL OF MEDICINE (FSM)
UROLOGY
INFECTIOUS DISEASES DIVISION
PULMONARY AND CRITICAL CARE DIVISION
SCHOOL OF EDUCATION AND SOCIAL POLICY
COMMUNICATION STUDIES
NU CLINICAL AND TRANSLATIONAL SCIENCES INSTITUTE (NUCATS)
SHIRLEY RYAN ABILITYLAB (SRA)
110: IRB Meetings convened in FY2018

<table>
<thead>
<tr>
<th>Biomedical</th>
<th>SBS</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>3</td>
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<tr>
<td>1.5-3</td>
<td>1-2</td>
</tr>
</tbody>
</table>

- Average # Agenda Items
- Meeting Length (in hours)
METRICS (continued)

Reliance Agreements

EXTERNAL IRBs
TOTAL = 450

- Biomedical: 81%
- Social-Behavioral: 19%

NU: IRB OF RECORD
TOTAL = 125

- Biomedical: 58%
- Social-Behavioral: 42%
METRICS (continued)

NIH Single IRB Activity

PRE-CONSULTATION REQUESTS
Total = 75

- Social-Behavioral: 55%
- Biomedical: 45%

43 Total Letters of Support
- 28 Northwestern as sIRB
- 15 Cede to External IRB
### METRICS (continued)

**Post Approval Compliance Activities**

<table>
<thead>
<tr>
<th>Number</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>116</td>
<td>• PI Assessments Completed</td>
</tr>
<tr>
<td>48</td>
<td>• Directed Audits and Post Approval Monitoring Visits</td>
</tr>
<tr>
<td>93</td>
<td>• External Reports Sent</td>
</tr>
<tr>
<td>37</td>
<td>• Compliance Reviews and other Investigations</td>
</tr>
</tbody>
</table>
**“VOICE OF THE CUSTOMER” & OPPORTUNITIES**

1. Timeliness of Approvals
2. Consistency of Reviews
3. eIRB+ system

<table>
<thead>
<tr>
<th>Opportunities</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Organizational Structure and Staff Composition</td>
</tr>
<tr>
<td>- Operations and Workflow</td>
</tr>
<tr>
<td>- Customer Service and Outreach</td>
</tr>
<tr>
<td>- Relationships with Other Units, Affiliates and Peer Institutions</td>
</tr>
<tr>
<td>- Tools and Technology</td>
</tr>
</tbody>
</table>
CHALLENGES

- Turnaround times
- Appropriate staffing levels
- IRB Member recruitment and incentives
- Panel meeting structure and workflow
- Shifting regulations
- Manage maintenance and upgrades to the electronic platform
- Research Community engagement/partnership, and educational/consultative support on the front end, rather than being viewed as a punitive unit that issues corrective action plans
ACCOMPLISHMENTS

• Staffing (multiple backfills and promotions)
• AAHRPP Annual Report
• Program Review
• eIRB+ 8.1 Upgrade
• IRB Member Recruitment & Training (2 Vice Chairs and multiple new IRB members)
• sIRB (1st phase: pre-consultation & resources)
• FDA Audit (March 2018)
• Regulatory changes

OPPORTUNITIES & INITIATIVES

• sIRB (2nd phase: multisite eIRB workflow & fee schedule)
• AAHRPP reaccreditation
• IRB Member recruitment (by department)
• Burden Reducing Initiatives
• ONBASE e-solution: Document Management
• Program Review
• eIRB+ enhancements (COI integration, InfoEd matching, RSS integration, CITI feed)
• Metrics Dashboard
• Regulatory changes
REGULATORY CHANGES

- 21st Century Cures Act
- EU General Data Protection (GDPR)
- Revised Common Rule
- NIH Single IRB Policy
- NIH Certificates of Confidentiality
- NIH Clinical Trial Definition
Signed December 13, 2016 by President Obama, promotes and funds the acceleration of research into preventing and curing serious illnesses; accelerates drug and medical device development.
January 25, 2018, all sites participating in multi-site studies, for non-exempt human subjects research funded by the NIH, will use a sIRB to conduct the ethical review required for the protection of human subjects.
Effective October 1, 2017, but retroactive for studies funded on or after December 13, 2016: **CoCs are automatic for research funded by NIH, wholly or in part.** A separate document not issued- The policy & award is documentation of coverage. Compliance is a term and condition of funding.
NIH revised its definition of a clinical trial to enhance clarity: “A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.”

The expansion of the clinical trials definition means research studies not previously considered to be clinical trials human subjects research, will now be included and subject to clinicaltrials.gov, GCP training, etc.
To harmonize data privacy laws across the countries of the European Economic Area (EEA) [includes 27 EU countries plus 3 countries].

All “data subjects” who are in any EEA country for any reason.

Protects natural persons with regard to the processing of personal data and on the free movement of such data.

- Collection, use, disclose, destroy or otherwise “processing” of Personal Data, including when conducting clinical research activities;
- Rights to access, amendment and erasure
- Personal Data controllers (Sponsor) and processors (PI) to implement appropriate technical and organizational security measures

The consent process will be a two-step process:
Letter of Information + Consent.
REGULATORY CHANGES

21st Century Cures Act
- HHS & 15 other Federal Departments and Agencies
- Full implementation January 21, 2019
- Three burden reducing provisions, effective July 19, 2018:
  - Redefining “research,” to reduce the number of activities that will fall under the Common Rule
  - Eliminating the requirement that IRBs review grant applications
  - Discontinuing continuing review for some categories of research (mainly minimal risk research)
- Consent form posting on Clinicaltrials.gov
- Single IRB for Cooperative Research January 20, 2020

EU General Data Protection (GDPR)

Revised Common Rule

Northwestern | RESEARCH
IRB OFFICE STRATEGIC INITIATIVES

• Staff Knowledge and Expertise
• Technology and Process Improvement
• Communication, Customer Service and Education
• Compliance Oversight
• Collaborative Relationships with Peer Institutions and Regulatory Bodies
A DELIBERATE APPROACH

Strong
1. Mistake Proofing
2. Statistical Process Control
3. Monitoring
4. Standard Procedures
5. Checklists
6. Vigilance
7. Training
8. Communication

Weak

Process Improvement

Effectiveness

PASSIVE

ASSERTIVE

AGGRESSIVE

ABSOLUTE
Contact Information

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Evanston, IL 60208
Phone: (847) 467-1723
sbsirb@northwestern.edu

• General Questions, Concerns or Suggestions to Improve Service: irb@northwestern.edu
• Social and Behavioral Questions: sbsirb@northwestern.edu
• eIRB+ Questions: eIRB+ Contact Form
• Reliance Agreements: irbreliance@northwestern.edu
• Training and Education: irbtraining@northwestern.edu
• Compliance Issues: irbcompliance@northwestern.edu