IRB Mission and IRB Office Role

Protects the rights and welfare of participants in human research.

Infinity

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

Infinity

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.
Regulatory/Functional Framework

- Education and Training
  - Biomedical (Chicago): 5 IRB Panels
  - Social and Behavioral (Evanston): 1 IRB Panel

Compliance

Ethics

Reliance
Human Research Protection Program (HRPP)

Protecting research participants is a shared responsibility.

- IRB Members
- IRB Office Staff
- Researchers
- Research Affiliates (NMHC, SRALab, LCH)

- Schools/Colleges (Deans & Dept. Heads)
- Provosts Office
- Office for Research depts: OSR; ORI; COI, ORIT ..etc
- NU- Qatar

- Legal (OGC)
- Sponsors & Funding Agencies
- Research Participants
- Regulators and Accrediting bodies
# IRB OFFICE KEY RESPONSIBILITIES

<table>
<thead>
<tr>
<th>Operationalize HRPP</th>
<th>Oversees IRB Operations of 6 panels and designated reviews</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formulate &amp; maintain policies and procedures</td>
<td>Communicate IRB actions to researchers</td>
</tr>
<tr>
<td>Maintain Federal Wide Assurance</td>
<td>IRB Member recruitment, training and payment</td>
</tr>
<tr>
<td>Maintain AAHRPP accreditation</td>
<td>eIRB+ maintenance w/ ORIT</td>
</tr>
<tr>
<td>Serve as IRB of Record for Northwestern and Affiliates, [and other institutions with which we have established agreements]</td>
<td>Billing for Single IRB and Industry sponsored studies</td>
</tr>
</tbody>
</table>
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
IRB OFFICE STRATEGIC INITIATIVES

• Infrastructure, Staff Knowledge & Expertise
• Technology and Process Improvement
• Communication, Customer Service and Education
• Compliance Oversight and Support
• Collaborative Relationships with Peer Institutions and Regulatory Bodies
Office for Research Values

In the Office for Research, we:

**UNDERSTAND EMPATHY**
We treat each other with compassion, dignity, and respect through listening to learn, not to confirm our views.

**MODEL ACCOUNTABILITY**
We keep our commitments, actively participate, and take ownership of our successes and failures.

**ENSURE FAIRNESS**
We build transparent and equitable processes, and embrace high ethical standards.

**EMBRACE COMMUNITY**
We build and nurture relationships between people and enable connections to grow, learn, and excel.

**VALUE CREATIVITY**
We take responsible risks and encourage autonomy to find innovative solutions and continuous improvement.
FY2021 IRB Office Key Metrics

**Total Submissions:** 14,061

**Active Studies:** 7578

<table>
<thead>
<tr>
<th>TYPE</th>
<th>PANEL</th>
<th>EXP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>NEW</td>
<td>73</td>
<td>35</td>
</tr>
<tr>
<td>CR</td>
<td>20</td>
<td>5</td>
</tr>
<tr>
<td>MOD/CR</td>
<td>21</td>
<td>13</td>
</tr>
<tr>
<td>MOD</td>
<td>41</td>
<td>12</td>
</tr>
</tbody>
</table>

**Funding Sources:**
- *Federal: 23%
- *Industry: 10%
- *Other External: 22%
- *Internal: 45%

**Convened IRB Meetings:** 110

**Principal Investigators:** 1407

**Research Staff:** 7994
COVID-19 Metrics

443 PROJECTS

- Social Behavioral: 54%
- Biomedical: 46%

294 Principal Investigators

91 Departments
Active & Exempt Studies by Fiscal Year

Fiscal Year | Active Studies | Exempt Studies | TOTALS
---|---|---|---
2016 | 2268 | 551 | 2819
2017 | 3089 | 743 | 3832
2018 | 4110 | 794 | 4904
2019 | 5178 | 487 | 5665
2020 | 6180 | 767 | 6947
2021 | 6747 | 831 | 7578
IRB Submission Types FY2021

Number of Submissions by Submission Types:

- **STUDY**: 1739
- **MOD**: 10227
- **MODCR**: 186
- **CR**: 1449
- **RNI**: 460

Number of Submissions:

- 2021
# Turnaround Times by IRB Submission

<table>
<thead>
<tr>
<th>Year</th>
<th>STUDY</th>
<th>MOD</th>
<th>CR</th>
<th>MODCR</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017</td>
<td>13</td>
<td>9</td>
<td>11</td>
<td>12</td>
</tr>
<tr>
<td>2018</td>
<td>33</td>
<td>10</td>
<td>28</td>
<td>15</td>
</tr>
<tr>
<td>2019</td>
<td>30</td>
<td>13</td>
<td>14</td>
<td>17</td>
</tr>
<tr>
<td>2020</td>
<td>15</td>
<td>42</td>
<td>29</td>
<td>22</td>
</tr>
<tr>
<td>2021</td>
<td>31</td>
<td>43</td>
<td>28</td>
<td>13</td>
</tr>
</tbody>
</table>

**DAYS**

**Committee**

- 2017: 65
- 2018: 58
- 2019: 51
- 2020: 68
- 2021: 73

**Exempt**

- 2017: 30
- 2018: 30
- 2019: 30
- 2020: 31
- 2021: 35

**Expedited**

- 2017: 13
- 2018: 14
- 2019: 15
- 2020: 18
- 2021: 19

**Turnaround Times by IRB Submission**

<table>
<thead>
<tr>
<th>Year</th>
<th>STUDY</th>
<th>MOD</th>
<th>CR</th>
<th>MODCR</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017</td>
<td>13</td>
<td>9</td>
<td>11</td>
<td>12</td>
</tr>
<tr>
<td>2018</td>
<td>33</td>
<td>10</td>
<td>28</td>
<td>15</td>
</tr>
<tr>
<td>2019</td>
<td>30</td>
<td>13</td>
<td>14</td>
<td>17</td>
</tr>
<tr>
<td>2020</td>
<td>15</td>
<td>42</td>
<td>29</td>
<td>22</td>
</tr>
<tr>
<td>2021</td>
<td>31</td>
<td>43</td>
<td>28</td>
<td>13</td>
</tr>
</tbody>
</table>

**DAYS**

**Committee**

- 2017: 65
- 2018: 58
- 2019: 51
- 2020: 68
- 2021: 73

**Exempt**

- 2017: 30
- 2018: 30
- 2019: 30
- 2020: 31
- 2021: 35

**Expedited**

- 2017: 13
- 2018: 14
- 2019: 15
- 2020: 18
- 2021: 19

**Turnaround Times by IRB Submission**

<table>
<thead>
<tr>
<th>Year</th>
<th>STUDY</th>
<th>MOD</th>
<th>CR</th>
<th>MODCR</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017</td>
<td>13</td>
<td>9</td>
<td>11</td>
<td>12</td>
</tr>
<tr>
<td>2018</td>
<td>33</td>
<td>10</td>
<td>28</td>
<td>15</td>
</tr>
<tr>
<td>2019</td>
<td>30</td>
<td>13</td>
<td>14</td>
<td>17</td>
</tr>
<tr>
<td>2020</td>
<td>15</td>
<td>42</td>
<td>29</td>
<td>22</td>
</tr>
<tr>
<td>2021</td>
<td>31</td>
<td>43</td>
<td>28</td>
<td>13</td>
</tr>
</tbody>
</table>
Top 10 Departments for IRB Submission Volume FY2021

1. Hematology/Oncology Division
2. Medicine
3. Physical Medicine and Rehabilitation
4. Neurology
5. Radiology
6. Medical Social Sciences (MSS)
7. Cardiology-Division
8. Obstetrics and Gynecology
9. Gastroenterology and Hepatology Division
10. Physical Medicine and Rehabilitation
## Post Approval Compliance Activities

<table>
<thead>
<tr>
<th></th>
<th>Activities</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>199</td>
<td>PI Assessments/Post Approval Monitoring</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Directed Audits</td>
<td></td>
</tr>
<tr>
<td>52</td>
<td>External Reports Sent</td>
<td></td>
</tr>
<tr>
<td>33</td>
<td>Compliance Reviews and other Investigations</td>
<td></td>
</tr>
</tbody>
</table>
Reliance and Single IRB

EXTERNAL IRBs
TOTAL = 959

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

NU: IRB OF RECORD
TOTAL = 151

- Biomedical: 54%
- Social-Behavioral: 46%

Total Letters of Support
71
Northwestern as sIRB

136
Single IRB Growth

- Number of Single IRB Pre-Consultation Requests
- Letters in Support of the Northwestern IRB serving as the IRB of record
- Number of quotes for IRB Fees provided

Number of Requests:
- FY2018: 65
- FY2019: 83
- FY2020: 135
- FY2021: 136
- FY2018: 22
- FY2019: 18
- FY2020: 70
- FY2021: 71
- FY2018: 0
- FY2019: 2
- FY2020: 63
- FY2021: 67
FY21 IRB Office Education Activities

IRB Education Activities

- FY18: 1274 (Live Presentations), 3890 (CITI Training)
- FY19: 1106 (Live Presentations), 3974 (CITI Training)
- FY20: 1391 (Live Presentations), 4247 (CITI Training)
- FY21: 1207 (Live Presentations), 4269 (CITI Training)
FY 2020-2021 Accomplishments

- Full Association for the Accreditation of Human Research Protection Programs (AAHRPP) re-accreditation.
- Implemented formal education and training curriculum for IRB Office Staff (ISTOP)
- Collaborated with Research Finance to implement cost-based fee structure for the IRB review of sIRB studies when Northwestern serves as the IRB of record.
- Cancer Center NOTIS-eIRB+ feed to support Scientific Review Committee workflow compliance
- Established FAIR (Fostering Accessibility and Inclusivity in Research) Committee
FY 2020-2021 Accomplishments

- Swiftly and successfully transitioned to remote work and virtual IRB meetings due to COVID-19 pandemic. Provided guidance to HRPP to successfully navigate pandemic planning and operations.
- Clinical Affiliate Expansion support
- Compliance e-solution project kick off
- Established HRPP Compliance Committee
- New Hires, Promotions, Panel Members
- Office for Research (OR) Values
Collaborative Committees

- **IRB Advisory Committee (Bi-monthly)**
  - Foster a better understanding of the needs and responsibilities of IRB members, IRB Office staff, and the research community.
  - Use their knowledge of the regulatory basis on which human subjects research must be reviewed and conducted and identify methods and opportunities for continuous quality improvement of protocol review and IRB communication.
  - Recommendations to the IRB Office Leadership and IRB Chairs for ways to improve the current review and approval process and enhance human research protections.
    - Contact: Pranjal Patankar (Lead IRB Analyst)

- **HRPP Compliance Committee (Quarterly)**
  - Engage the research community in sharing compliance best practices, review case studies, formulate corrective and preventive action plans, and better collaborate to achieve a high standard of compliance in human participant research at Northwestern.
    - Contact: Angela Baumgartner (Sr. Compliance Analyst)
COVID-19 IRB Guidance for Research

- **3/12/20**: Memo to research community
  - Allow changes to study prior to IRB approval to remove any apparent immediate hazards to current research participants

- **06/19/20**: Guidelines for safe return to campus research
  - General requirements
  - COVID-19 participant pre-screener

- **7/9/20**: FAQ on submitting changes to study conduct due to COVID-19
  - When to submit an Reportable New Information (RNI) versus a Modification in eIRB+

[https://www.irb.northwestern.edu/covid-19-resources/](https://www.irb.northwestern.edu/covid-19-resources/)
COVID-19 IRB Guidance for Research

- **6/21/21: Return to Campus Guidelines for Phase 5**
  - Resumption of on-campus and in-person research activities, incl.:
    - study monitoring
    - enrollment of new participants in alignment with IRB approved protocol.
    - Hybrid options may be implemented.
    - Reportable New Information submissions and/or protocol modifications are not required for researchers to resume activities on IRB-approved protocols.
  - Easing of social distancing and density restrictions for research spaces (note: [Indoor masking reinstated 08/05/2021](#))
  - Continue pre-screening research participants and safety precautions
  - Participants must maintain voluntary consent
COVID-19 Impact on Human Research

• COVID is not a risk of the research itself; does not change IRB risk levels; should not be listed as a risk in the consent form.

• Enrollment, Study Visits and Data Collection
  • Virtual Enrollment/Electronic Consent Process
  • Virtual Visits and Remote Data Collection: Zoom, Qualtrics, REDCap

• Safety Precautions
  • (Pre-screening participants, Masking, Hygiene, Density and Social Distancing, PPE, Cleaning/Sanitization Protocols)

• COVID-19 rapid antigen testing resource
  [link](https://www.northwestern.edu/coronavirus-covid-19-updates/health/testing/visitor.html)
  – Jacobs Center (2001 Sheridan Road) in Evanston
  – 345 E. Superior Street in Chicago
## Updated Industry Sponsored Fee Schedule

### Industry Sponsored Fees (Effective September 1, 2021)

<table>
<thead>
<tr>
<th>Service</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Study Application</td>
<td>$3,000</td>
</tr>
<tr>
<td>Modifications (Inclusive, priced at 3 per year, and billed annually)</td>
<td>$2,250 annually ($750 per modification)</td>
</tr>
<tr>
<td>Continuing Review</td>
<td>$1,500</td>
</tr>
<tr>
<td>Study Closure</td>
<td>$325</td>
</tr>
<tr>
<td>Reportable Events</td>
<td>$0</td>
</tr>
<tr>
<td>Compliance Maintenance (Billed annually)</td>
<td>$250</td>
</tr>
</tbody>
</table>
Mission: Nurture inclusive and equitable practices across the Northwestern University human research landscape in alignment with the Belmont Principle of Justice.

JUSTICE

- Fair treatment
- Fair Distribution of risks and benefits
- Equitable selection of research participants
Partner with groups across the University's HRPP to create and share resources in order to implement these practices.

Collaborators

- Office for Research (OR) units
- Center for Community Health (CCH)
  - Darius Tandon, PhD
- Alliance for Research in Chicagoland Communities (ARCC)
- Center for Health Equity Transformation (CHET)
- Feinberg Office for Diversity and Inclusion
- OR Director of Diversity, Equity, and Inclusion- Aisha Ghori Ozaki
- Northwestern University Chief Diversity Officer- Robin Means Coleman
- Social Justice Report Advisory Groups
<table>
<thead>
<tr>
<th>FAIR: Researcher’s Role</th>
<th>“Your recruitment plan should incorporate methods that specifically address, and detail how potential participants from particular racial and ethnic groups/under-represented populations (with respect to the study) will be recruited. This is to ensure that the recruitment plan is inclusive and representative of the eligible population within the location at which the research is being conducted, and considers the impact of the research on all such populations.”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revised protocol language prompts investigators to address diversity, equity and inclusion</td>
<td></td>
</tr>
</tbody>
</table>


Community Based Participatory Research

- The IRB Office collaborates with FSM's Center for Community Health to facilitate community engagement and community-based participatory research, to positively impact equity, inclusion, justice, and the research participant experience.

- **Community Engagement:** Collaboration between institutions of higher education and their larger communities (local, regional/state, national, globe) for the mutually beneficial exchange of knowledge and resources in a context of partnership and reciprocity.

  --Carnegie Foundation for the Advancement of Teaching (2015)
IRB Membership: We need YOU!

- §46.107

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
Monthly Time Commitment

Monthly IRB Meeting

Assigned Reviews

4-6 hours/month

Attendance requirements: **70-80%** of scheduled meetings
Minimum of ~9 meetings/year
## Biomedical IRB Panels

<table>
<thead>
<tr>
<th>Panel</th>
<th>Recurrence</th>
<th>Time</th>
<th>Specialty/Focus</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Monthly, 1&lt;sup&gt;st&lt;/sup&gt; Fridays</td>
<td>2:00-5:00pm</td>
<td>Biomedical</td>
<td>Chicago Campus (meeting virtually)</td>
</tr>
<tr>
<td>C</td>
<td>Monthly, 2&lt;sup&gt;nd&lt;/sup&gt; Fridays</td>
<td>2:00-5:00pm</td>
<td>Biomedical</td>
<td>Chicago Campus (meeting virtually)</td>
</tr>
<tr>
<td>D</td>
<td>Monthly, 3&lt;sup&gt;rd&lt;/sup&gt; Thursdays</td>
<td>2:30-5:30pm</td>
<td>Biomedical</td>
<td>Chicago Campus (meeting virtually)</td>
</tr>
<tr>
<td>B</td>
<td>Monthly, 4&lt;sup&gt;th&lt;/sup&gt; Thursdays</td>
<td>2:00-5:00pm</td>
<td>Biomedical</td>
<td>Chicago Campus (meeting virtually)</td>
</tr>
<tr>
<td>E</td>
<td>Monthly, 4&lt;sup&gt;th&lt;/sup&gt; Fridays</td>
<td>2:00-5:00pm</td>
<td>Social &amp; Behavioral</td>
<td>Evanston Campus (meeting virtually)</td>
</tr>
<tr>
<td>Q</td>
<td>Weekly, Mondays</td>
<td>11:30am-1:00pm</td>
<td>Biomedical &amp; Continuing Review</td>
<td>Chicago Campus (meeting virtually)</td>
</tr>
</tbody>
</table>
IRB Panel Member Onboarding Process

Submit Brief Application via email*
Guest Observer Attendance
New Member Training session
Select Preferred Panel

* [https://www.irb.northwestern.edu/become-an-irb-member/](https://www.irb.northwestern.edu/become-an-irb-member/)
Lisa Linn, Biomedical IRB Manager: l-linn@northwestern.edu, and Cheryl Paulus, IRB Analyst: cheryl.Paulus@northwestern.edu
FY 2022 Goals and Priorities

- Faculty Use of IRB Services
- sIRB Billing and Industry Sponsored Fee Schedule
- Diversity, Equity and Inclusion: Research participants and IRB Panel Membership
- Community Based Participatory Research
- Program for Onboarding and Education of Members (I-POEM)
- IRB Office Website overhaul
- Online Investigator Manual
- Data Analytics and Metrics
- Compliance e-solution
Contact Us

Chicago
Biomedical Research IRB Office
Arthur Rubloff Building, 7th Floor
750 N. Lake Shore Dr.
Chicago, IL 60611
Phone: (312) 503-9338
irb@northwestern.edu

Evanston
Social and Behavioral Research IRB Office
Chambers Hall, 2nd Floor
600 Foster St.
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