

**Northwestern University  
Institutional Review Board  
(IRB)**

**State of the IRB**

**May 18, 2018**

Northwestern | RESEARCH

**Nathalia Henry,  
Executive Director, IRB Office**

**IRB Office Highlights and  
Updates**

# **IRB OFFICE ELEVATOR PITCH:**

**Protects the rights and welfare of participants in human research.**

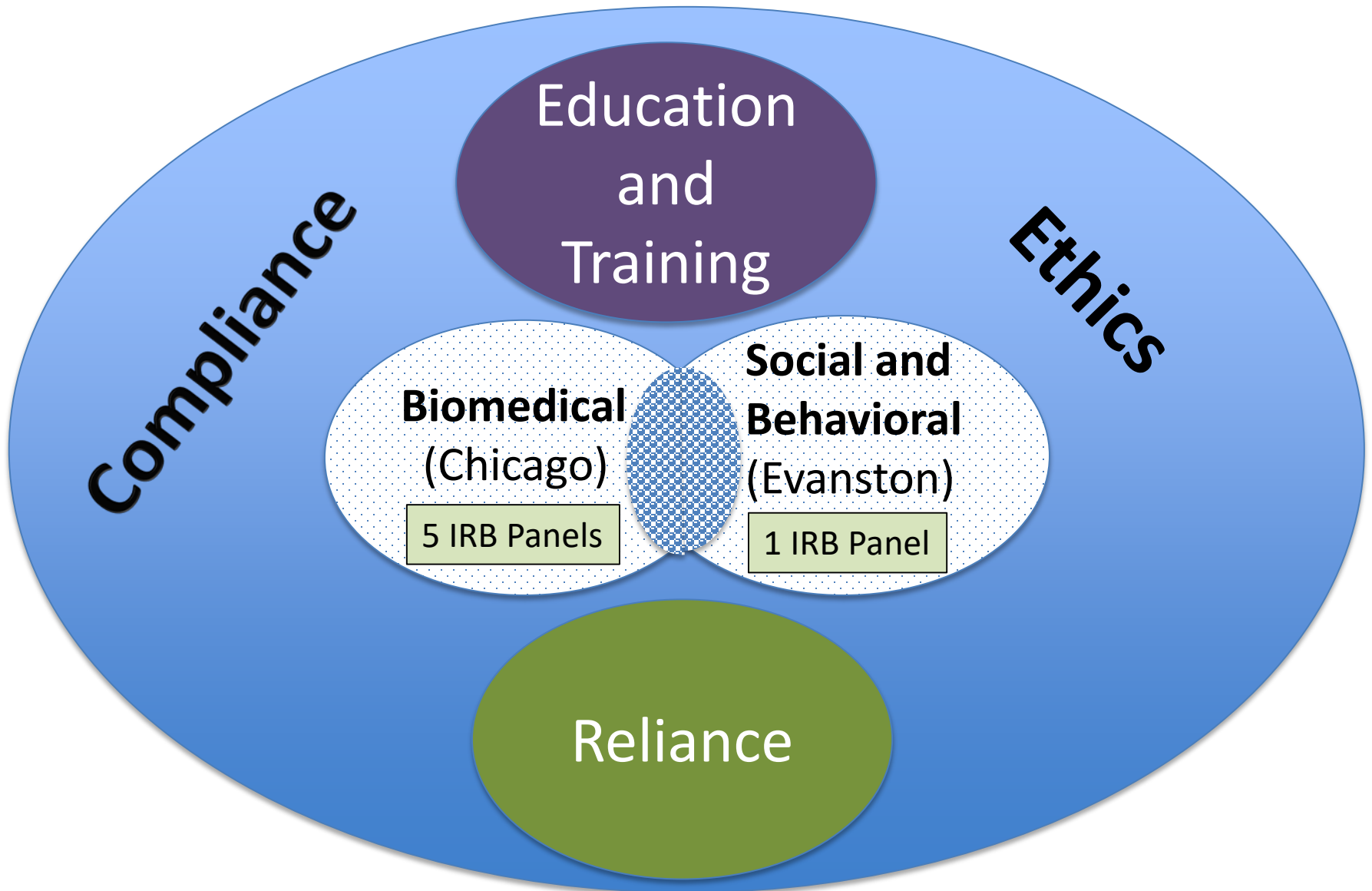


**Administratively supports the IRB which is responsible for approving research protocols, informed consent documents and other study related materials before a study can begin.**



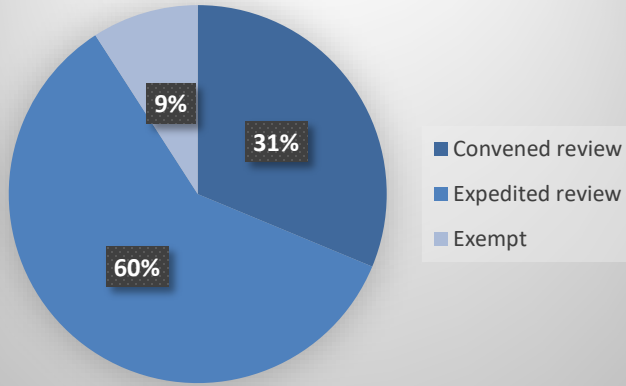
**Provides guidance, education and relevant compliance tools, and equips the University's research community to conduct ethical human research that minimizes risk to participants and maximizes benefit.**

# FUNCTIONAL FRAMEWORK

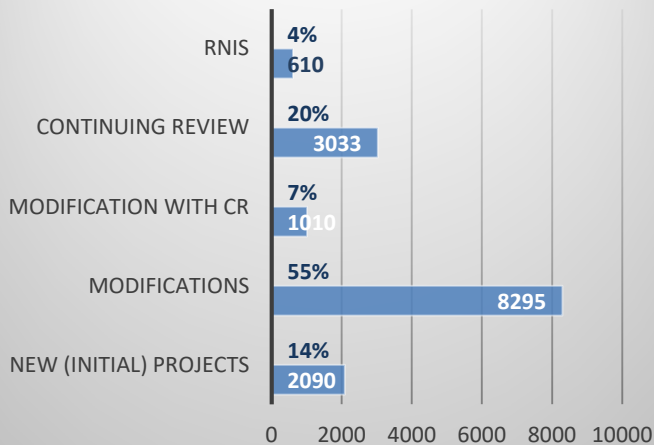


# PORTFOLIO HIGHLIGHTS

## Active Projects

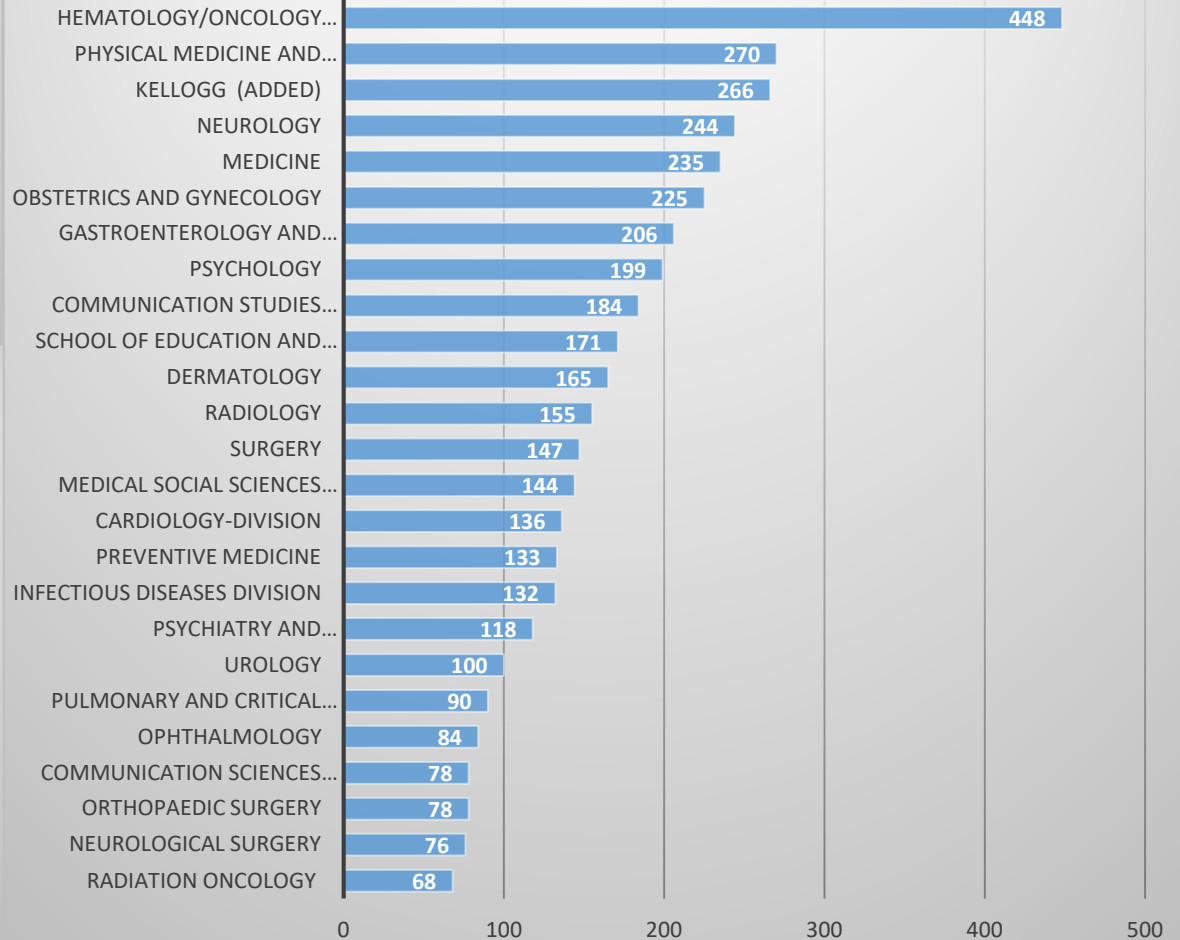


## Submissions



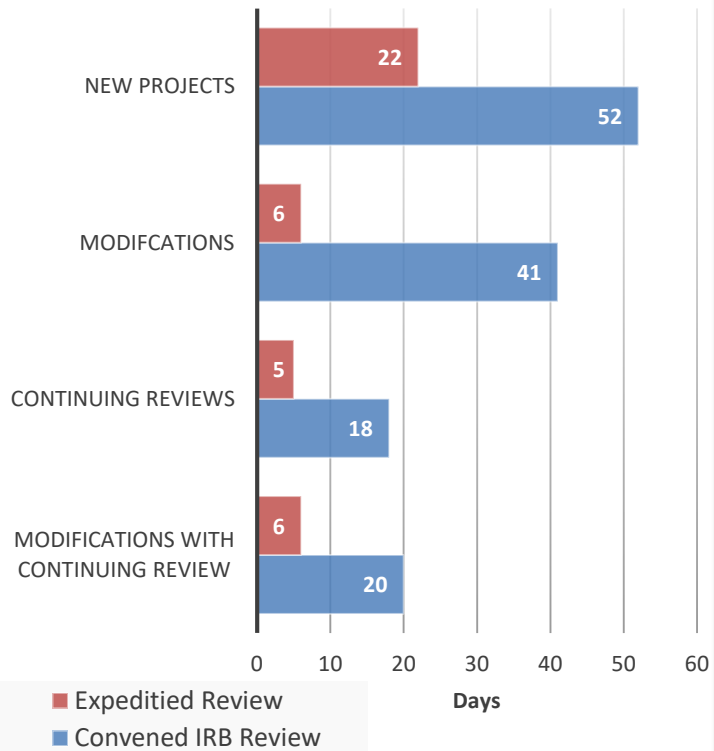
## Research Producers - Top 25 Departments

Number of Submissions



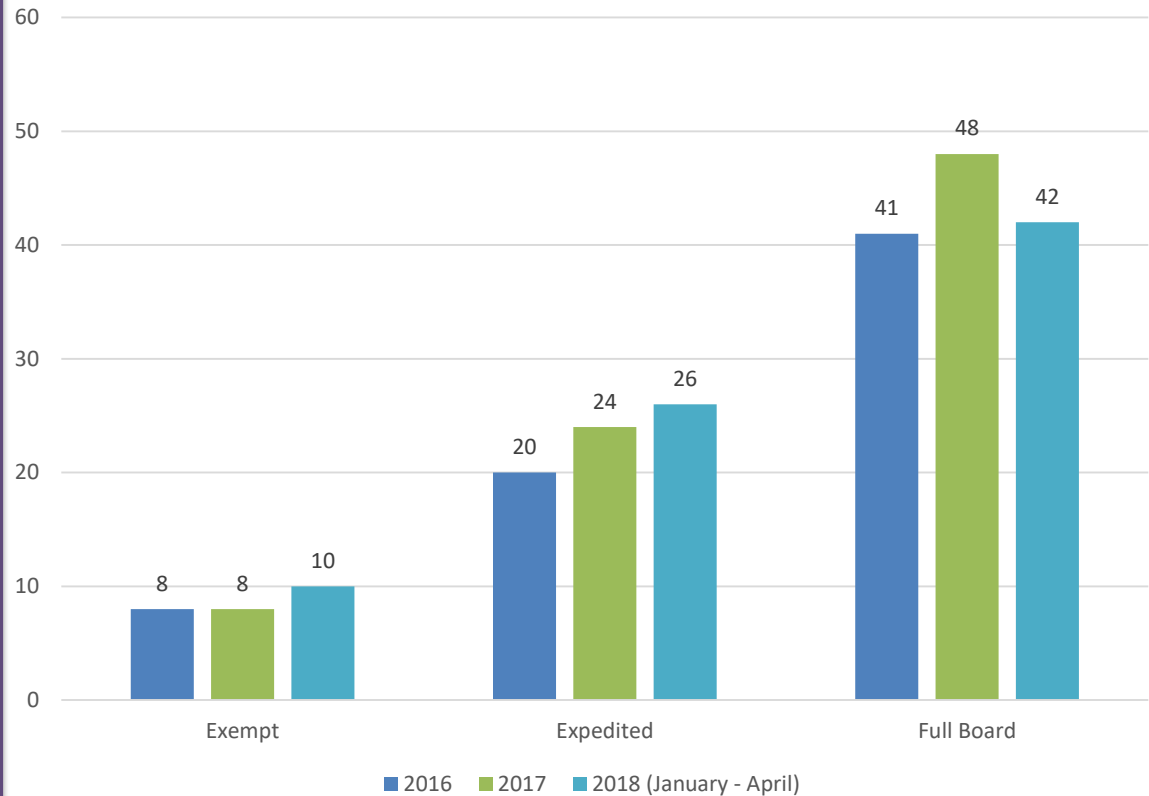
# PERFORMANCE HIGHLIGHTS

## Turnaround Times (from submission to approval)



Data from June-December 2017

## Median # of Days to Obtain Approval - Overall Office



# CUSTOMERS, PARTNERS, STAKEHOLDERS



- IRB Members
- IRB Office Staff
- Researchers
- Research Affiliates
- Consultants

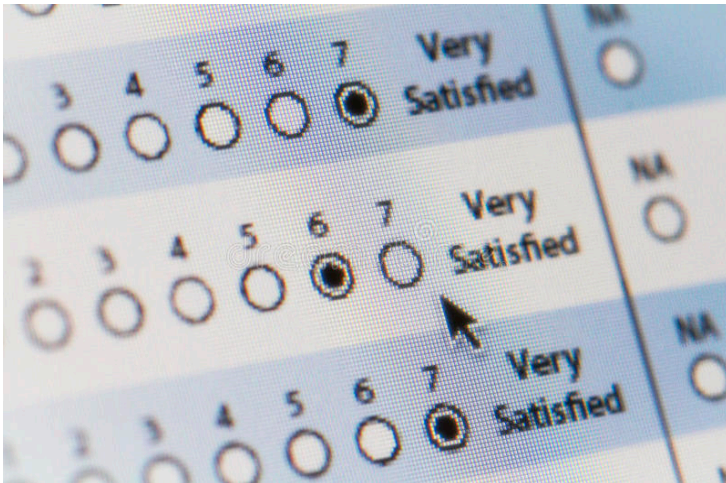
- Schools/Colleges (Deans & Dept. Heads)
- Provosts Office
- Office for Research depts: OSR; ORI; COI, ORIS ..etc

- OGC
- Sponsors & Funding Agencies
- Research Participants
- Regulators and Accrediting bodies

# “VOICE OF THE CUSTOMER” & OPPORTUNITIES

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

- Organizational Structure and Staff Composition
- Operations and Workflow
- Customer Service and Outreach\*
- Relationships with Other Units, Affiliates and Peer Institutions
- Tools and Technology\*





# ACCOMPLISHMENTS & GOALS

2017-2018

- **Staffing** (New Executive Director + 2 Analysts)
- **AAHRPP Annual Report**
- **Program Review**
- **eIRB+ 8.1 Upgrade**
- **IRB Member Recruitment & Training** (2 Vice Chairs)
- **sIRB Readiness** (1st phase: pre-consultation & resources)
- **New Protocol and Consent Templates**
- **Regulatory changes**

2018-2019

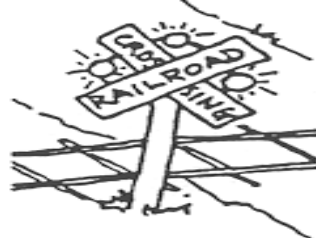
- **sIRB readiness** (2nd phase: multisite eIRB workflow & fee schedule)
- **AAHRPP reaccreditation**
- **IRB Member recruitment** (by department)
- **COI system integration**
- **Education and training campaign**
- **Compliance e-solutions**
- **Regulatory changes**

# REGULATORY CHANGES

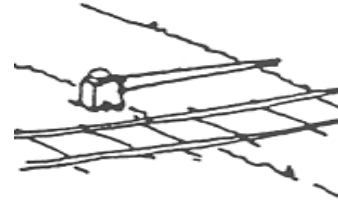
- 21<sup>st</sup> Century Cures Act
- NIH Single IRB Mandate
- NIH Certificates of Confidentiality
- NIH Clinical Trial definition
- Revised Common Rule
- EU General Data Protection Regulation (GDPR)



PASSIVE



ASSERTIVE



AGGRESSIVE



ABSOLUTE

# 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**



# HRPP COMMUNITY

- **HRPP includes research staff**
- **IRB Advisory Board**
- **Workgroup Members (e.g. sIRB, Education & Outreach)**
- **IRB Member Service and Recruitment**
- **Constructive Feedback**
- **Fresh, Innovative Ideas: Wouldn't it be nice if.....**



# **Lisa Linn, Biomedical IRB Manager**

## **Biomedical IRB Highlights and Updates**

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# Biomedical Informed Consent Template

## Key Information:

The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

- Purpose of the study
- Duration of Participation
- Participation is Voluntary
- Anticipated Benefits
- Most Important/Relevant Risks
  - Strike a balance, not too many but not too few.
  - If this was clinical care, what would a physician tell a patient

# Additional Consent Template Language

## Certificate of Confidentiality

- NIH automatically issues CoCs as part of the awards terms and conditions for any research on or after December 13, 2016.

## Data/Specimens Sharing language

- Optional but strongly consider for future use of data or specimens.
- NIH database of Genotypes and Phenotypes (dbGaP)

# Short Form Review Process

## **Using translated short form from the IRB website:**

Can report as an RNI after use.

Must use the IRB approved English consent form as the summary orally presented to the subject.

## **Not Using translated short form from the IRB Website:**

Must submit as a modification prior to use.

Include translated short form and certificate of translation.

**Can use the Short Form Process up to two times before translating the full informed consent document.**



# **Kile King, IRB Lead Analyst**

## **Social Behavioral IRB Highlights and Updates**

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# Mobile Apps/Mobile Medical Apps Guidance

The purpose for the guidance on the use of mobile apps and mobile medical apps is to provide researchers, IRB staff, and IRB committee members with a common understanding of the following:

1. Definition of mobile apps and mobile medical apps
2. Regulatory requirements pertaining to mobile apps and mobile medical apps
3. Points to consider when utilizing mobile apps or mobile medical apps in research

# Mobile Apps/Mobile Medical Apps Worksheet

<b>N</b>	<b>WORKSHEET: Mobile Apps and Mobile Medical Apps</b>			
	NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
	HRP-3XX	Executive Director, IRB Office Northwestern University	???	Page 1 of 2

<b>IRB Number</b>	
<p>The purpose of this worksheet is to provide support for IRB Office staff pre-reviewing research involving mobile apps and mobile medical apps. This worksheet is to be used for guidance and does not need to be completed or retained.</p>	
<b>1 Is the app a Mobile App?</b>	
<p><b>Mobile App</b><sup>1</sup>: software applications downloaded to a mobile device, such as a cell phone or tablet, which provide the mobile device user with software that can be utilized on their mobile device in many different ways. For example, web browsing, social media connections, ridesharing applications, and many more. Many of these mobile apps also collect information about the user via the user's device.</p> <p><input type="checkbox"/> Yes. If yes, proceed to #2.</p> <p><input type="checkbox"/> No. If no, do not proceed with the Worksheet. The Worksheet is intended to be used with studies involving mobile apps.</p>	
<b>2 Is the app a Mobile Medical App?</b>	
<p><b>Mobile Medical App</b><sup>2</sup>: as defined by the FDA, mobile medical apps are medical devices that are mobile apps that also meet the definition of a medical device<sup>2</sup>, and are an accessory to a regulated medical device or transform a mobile platform into a regulated medical device. For example, mobile apps that alter the function or settings of an infusion pump, such as turning the pump on or off; mobile apps that use a microphone or speaker within a mobile platform to serve as a audiometer to allow healthcare providers to determine hearing loss at different frequencies; mobile apps that use an attachment to the mobile platform to measure blood glucose levels; etc.</p> <p><input type="checkbox"/> Yes. If yes, proceed to #3.</p> <p><input type="checkbox"/> No. If no, proceed to #4.</p>	
<b>3 Applicable regulatory requirements<sup>3</sup> related to the Mobile Medical App.</b>	
<input type="checkbox"/>	The mobile medical app is considered high risk to patient safety or is listed as a mobile medical app that the FDA considers a medical device. (If true, the mobile app is considered a medical device and it needs to follow the standard regulatory review process for medical devices. Review and complete other applicable Worksheets and Checklists and complete #4 below.
<input type="checkbox"/>	The mobile medical app is considered low risk to patient safety AND the mobile medical app falls is considered a type of mobile medical apps that the FDA will utilize enforcement discretion <sup>4</sup> . (If true, the mobile app may be considered for expedited review). Complete #4 below.
<input type="checkbox"/>	The FDA does not consider the mobile medical app to be a medical device <sup>5</sup> . Complete #4 below.
<b>4 Mobile App/Mobile Medical App Requirements (All must be checked)</b>	
<input type="checkbox"/>	The app appropriate for the study population. (e.g. age appropriate, content, font size/color)
<input type="checkbox"/>	The protocol includes a plan to address functionality of the app. (e.g. app not working, only available on certain types

# Social and Behavioral IRB Updates

## Updated Protocol and Consent Templates (December 2017)

- All new studies must utilize new templates
- All existing studies that are actively enrolling must update consent forms using the new template
- Some existing studies may need to update their protocol using the new template

## Coming soon

- GDPR requirements
- Changes to the Common Rule

# **Piper Hawkins-Green, IRB Compliance Analyst**

## **Compliance Program Highlights and Updates**

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# IRB Compliance Activities

- Post Approval Monitoring
  - In-person visit
  - Self assessment
  - Consent process observation
  - Recruitment
- Directed Review
- External Reporting
- Research Complaints
- Other Investigations
- Internal QA-QI activities

# Self Assessments

- Post approval monitoring provisions are outlined in [§ 46.109](#) & [§ 46.110](#)
- Routine compliance review of research activities
- 3 – 5% of all active research studies
- Randomly selected
- Revised checklist decreased turnaround time
- Gauge trends throughout the institution
- Compliance through education

# Research Complaints

- Complaints about research activities
- Questions about research participants' rights
- Concerns about research procedures
- Investigations performed with input from research team and complainant
- May require additional actions



# IRB Compliance Program

## Questions and Concerns

If you have questions or concerns about a research project, please contact the IRB Compliance Program using any of the following mechanisms:

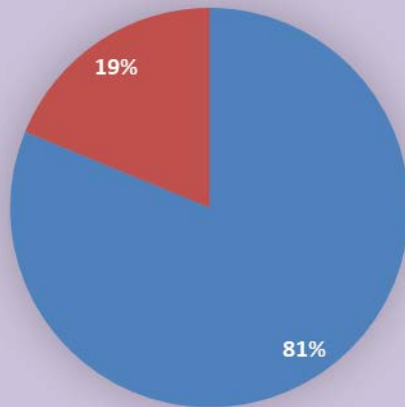
- Contact an IRB Compliance Analyst
- Email the compliance program at [irbcompliance@northwestern.edu](mailto:irbcompliance@northwestern.edu)
- Call the IRB Office at (312) 503-9338.
- File an anonymous complaint of noncompliance using the [EthicsPoint website](#).
  - EthicsPoint is a secure service for the research and academic community that allows the reporter to remain anonymous while reporting possible noncompliance to relevant institutional officials, and receive feedback from those same officials.

**Marcella Oliver,  
IRB Reliance and Education  
Lead**

**Reliance Process Highlights  
and Updates**

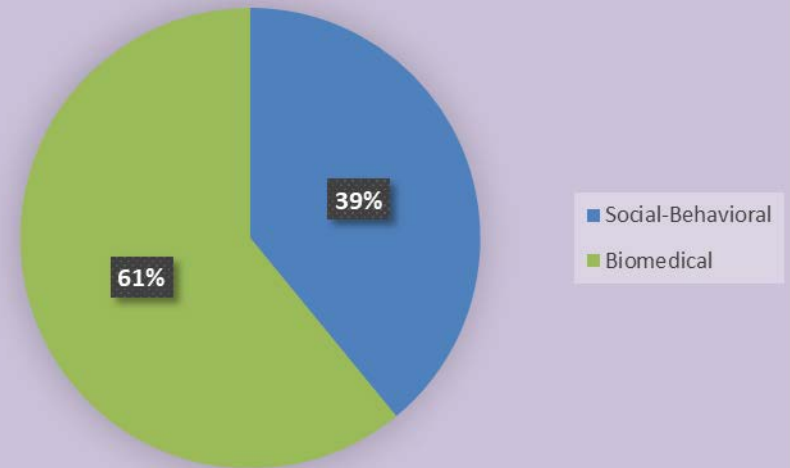
# Reliance Agreements

External IRB's (Research Type)  
Total = 407



■ Biomedical ■ Social-Behavioral

NU IRB\_IRB of Record  
Total = 128 Confirmed



■ Social-Behavioral  
■ Biomedical

# Reliance Agreements, cont.

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- NEW STUDIES**
- RELIANCE AGREEMENTS AND SINGLE IRB** 
- MODIFICATIONS
- CONTINUING REVIEW / CLOSURE
- REPORTABLE NEW INFORMATION
- COMPLIANCE AND AUDITS



[eIRB+ Overview and Instructions](#)

## News & Announcements

### NIH Single IRB Policy Implementation

As you were previously notified, the Northwestern University IRB Office has been diligently working to have a process in place for implementing the NIH Single IRB policy at our institution. At this time we are pleased to notify the research community that the first phase of implementation is ready for rollout. [Read More »](#)

### Important Notice: Delayed Common Rule Effective Date

The Department of Health and Human Services

## Events

**May 18** Chicago  
**State of the IRB**  
[More information](#)

**May 18** Evanston  
**State of the IRB**  
[More information](#)

## Information

[Need to Report A Concern?](#)

[eIRB+ FAQs](#)

[Research Participants](#)

[AAHRPP Accreditation](#)

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# Single IRB Policy Implementation

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## Reliance Agreements

[Reliance Agreements - Submission Process](#)

[Reliance Agreements - Agreement Types](#)

[Reliance Agreements - Resources](#)

[Reliance Agreements - FAQ](#)

[Single IRB](#)

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## Single IRB

### Single IRB

The single IRB (sIRB) mandate is a set of complementary federal policies that require certain types of federally-funded studies that involve multiple institutions to use a single IRB to accomplish IRB review and approval for all of the institutions. The basis for the Single IRB Model is to allow multiple institutions that are conducting the same protocol to use a single IRB for review. The NU IRB has allowed the use of a Single IRB for over 5 years and is well versed to assist researchers in preparing for the new phase of required use.

There are two policies that require the use of a Single IRB (NIH Single IRB Policy and Common Rule Update).

### Single IRB Policies

**The NIH Policy, effective January 25, 2018**

- Applies to: Domestic sites of NIH funded studies where each site will conduct the same protocol involving non-exempt human subjects research, whether supported by grants, cooperative agreements contracts

#### ADDITIONAL RESOURCES

- [NIH Grant Proposal Pre-Consultation](#)
- [Pre-Consultation Intake Form](#)
- [OSR Clinical Trials Webpage](#)

# Reliance Agreement Updates

- eIRB+ Upgrade changes
  - Study and Site submissions when ceding review to an External IRB
  - pSite submissions when Northwestern University serves as the IRB of Record for an External Site
- Reliance Agreement Intake Form
- NIH Single IRB Policy
  - Fee Structure
  - Will the NU IRB become a Single IRB?
  - Establishing Master Agreements

# Reliance Agreement Tips

- Utilize the Northwestern University Templates
- SmartIRB (Online Reliance System/Addendum Agreements)
- Review SOP's
- Engage the IRB as early in the process as possible
- Local/Institutional requirements are still applicable when ceding review to an External IRB

# QUESTIONS?





# Contact Information

## Chicago

Biomedical Research

Arthur Rubloff Building, 7th Floor

750 N. Lake Shore Dr.

Chicago, IL 60611

Phone: (312) 503-9338

[irb@northwestern.edu](mailto:irb@northwestern.edu)

## Evanston

Social and Behavioral Research

Chambers Hall, 2nd Floor

600 Foster St.

Evanston, IL 60208

Phone: (847) 467-1723

[sbsirb@northwestern.edu](mailto:sbsirb@northwestern.edu)

- General Questions, Concerns or Suggestions to Improve Service: [irb@northwestern.edu](mailto:irb@northwestern.edu)
- Social and Behavioral Questions: [sbsirb@northwestern.edu](mailto:sbsirb@northwestern.edu)
- eIRB+ Questions: [eIRB+ Contact Form](#)
- Reliance Agreements: [irbreliance@northwestern.edu](mailto:irbreliance@northwestern.edu)
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