The IRB is your BFF!

Qualities of a BFF

- They are emotionally supportive
- They listen to you and respond thoughtfully
- They go out of their way to help you
- They don't expect perfection
- They are therapeutic
- They help you navigate
- They have your back
- They tell you what you need to hear, even if it's not what you want to hear

What is the IRB?

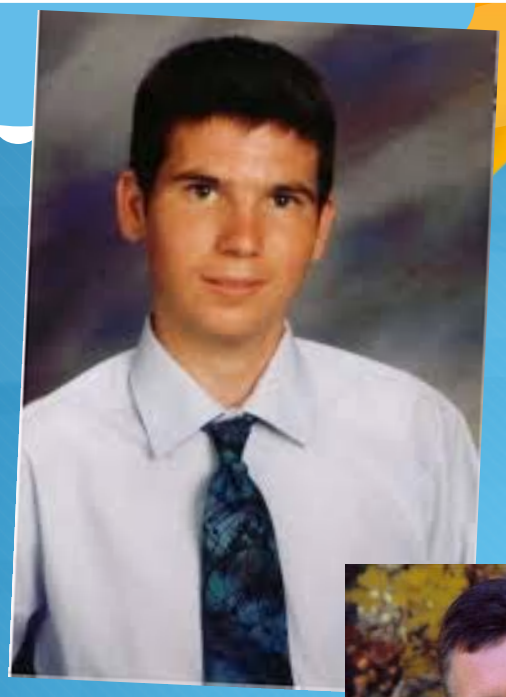
- A committee charged with the review of human subjects research to assure that the rights and welfare of human participants are adequately protected.
- IRBs are required to have a diverse mix of scientific, non-scientific, and community members.

Who is the IRB?

- Staff
- Compliance
- Board Members

Why do we have IRBs?

- Tuskegee Syphilis Study (1932-1972)
- Nazi War Crimes (1935-1945)
- Cold War Human Radiation Experiments (1944-1974)
- Milgram Studies of Obedience to Authority (1960s)
- Thalidomide Experiment (1962)
- San Antonio Contraceptive Study (1970s)



Why do we still have IRBs?


Spike In Retractions Highlights Problems In Research
Hoax papers: The shoddy, absurd and unethical side of academia
'Guinea pigs': experimental implants done despite no approval for human use
Women scarred by 'study,' branding
State to review physicians' roles in bizarre practices
Research Violations Stay in Dark Over Retaliation Fears
Medicine and ethics: Will we learn to take research scandals seriously?
5 Times People Didn't Know Their Bodies Were Science Experiments
These researchers didn't give AF about 'informed consent'.
Universities accused of unethical 'pick and mix' reporting of drug trial results
THE SHOCKING LACK OF SCIENCE BEHIND LETHAL INJECTIONS
Uber's Behavioral Experiment On Drivers May Raise Ethical Questions, But It Is Hardly Unique
Doctors tortured patients at Ontario mental-health centre, judge rules
ER Patients Were Injected With Ketamine As Part Of A Clinical Study Without Their Consent

What guides IRBs?

- Food and Drug Act Established (1938)
- Nuremburg Code (1947)
- Declaration of Helsinki (1964)
- FDA Establishment of Regulations (1960s -1980s)
- National Research Act (1974)
- Belmont Report (1979)

Prep Work

- Training/Accounts
- Know which IRB to use
- Know the basics
- Know your forms

Training

- Children's Requirements
  - CITI/GCP
  - COI
- Emory Requirements
  - Request an eIRB Account
  - CITI/GCP
  - EHSO
  - COI
  - Emory Research Management System (ERMS)
  - Key Concepts/Clinical Research Training

Which IRB is your BFF?

- Emory
- CHOA
- Georgia Tech
- Georgia State
- Morehouse

The Basics

- Do I need to submit to the IRB?
- What type of review?
- Do I need to get consent?

Do I need to submit?

- Is it Research?
  - Systematic Investigation and Generalizable?
  - Using a drug or a device?
- Are Human Subjects involved?
  - Living Individual?
  - Obtaining data through intervention, interaction or obtaining PHI?

Non-Human Subjects Determination Form

Scenario 1

- A Pediatric Institute investigator is conducting a retrospective chart review looking at Children's records?

  -What if it's a CHOA investigator?

- Is it research? Yes
- Which IRB? A chart review limited to the review of Children's medical records should come to the CHOA IRB, regardless of PI affiliation.

Scenario 2

An Emory fellow is conducting a prospective chart review with patients at Children's?

-What if it's a Pediatric Institute investigator?

- Is it research? Yes
- Which IRB? A chart review limited to the review of Children's medical records should come to the CHOA IRB, regardless of PI affiliation.

Scenario 3

A CHOA investigator is receiving de-identified data set from IS&T to conduct a study to determine if kids with asthma were more likely to have severe flu symptoms?

-What if it's an Emory investigator?

- Is it research? Yes, but not research with human subjects (i.e., no identifiable data and no interaction with subjects)
- Which IRB? For NHSR determinations, you can submit to either IRB, neither IRB or both IRBs. We suggest submitting to at least one IRB for an official determination.

Scenario 4

A CHOA investigator is doing a case report on 6 patients?

-What if it is a case report on 2 patients?

- Is it research with 6 subjects? At Emory yes. For CHOA, it depends…
- Is it research with 2 subjects? At Emory no. For CHOA, it depends but it is highly unlikely that we would call a 2 patient case study research.

Scenario 5

A Pediatric Institute investigator is conducting a federally funded clinical trial at Children's?

-What if the study is industry sponsored?

- Is it research? Yes
- Which IRB? Emory if it's federally funded, Children's if it's industry sponsored.

Scenario 6

An Emory physician needs to treat a CHOA patient with an Emergency Use drug?

- Is it research? No, but it still requires submission to the IRB.
- Which IRB? Emergency Use cases should go to the IRB at the facility where the patient is receiving the investigational drug or device.

Other Levels of Review

- Exempt
- Expedited
- Full Board

Do I need to get consent?

- Your study may be eligible for a waiver if:
  - No greater than minimal risk
  - Will not adversely affect rights and welfare
  - Could not practicably be carried out without the waiver

How long does it take?

Type of Review	Turnaround Time (Days)
NHSR Determination	2
Exempt	4
Expedited	4
Full Board	29

The Forms

- Initial Submission Form (current) eIRB Submission (Jan 2019)
- Protocol Template
- Consent Template/HIPAA Authorization Form
- Assent Template

- IRB Authorization Acknowledgement Form

Other Forms

- Continuing Renewal
- Amendment
- Event Reporting
- Non-Compliance

Closing a Study

- Closed to enrollment ;
- Subjects have completed intervention/data collection; AND
- All data collection and analysis of identifiable information has been completed.

Helpful Hints

- Contact the IRB early in the process
- Contact the IRB with questions in the application
- Ask all potential study staff to confirm training is up to date
- Make sure consent and protocol are consistent
- Respond to IRB requests quickly, but not too quickly
- Let us know if you have a deadline
- Don’t save IRB forms to your desktop for repeated use
- Only list one PI

Takeaways

- Make the IRB your BFF
- Have a basic understanding of what doesn't need to be submitted to the IRB
- Know which IRB to submit to
- Know when to close your study

Helpful Links - CHOA

- IRB Forms
  - Initial Submission Form
  - Protocol Template
  - Consent/HIPAA Template
  - Assent Template
  - IAA Acknowledgement Form (If you received approval from an IRB other than CHOA)
- HIPAA FAQs
- HIPAA Identifiers

Contact Information - CHOA

- irb@choa.org
- https://www.choa.org/research/institutional-review-board
- Meredith.capasse@choa.org
- 404-785-7477; 770-880-7917 (cell)

Helpful Links - Emory

- eIRB
- Does My Project Need IRB Review?
- New Submission Guidance
- Consent Toolkit
- Emory Contact Information

Contact Information - Emory

- irb@emory.edu
- http://irb.emory.edu/
- Call your Study Analyst for Study Specific Questions or any Staff for General Questions

Protocol Template

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Questions