

# **Preparing New Researchers**

From an Institutional Review Board  
Administrators Point-of-View



# Researcher...and Beyond



## Who is Dr. Myra?

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# What is IRB?



The most common question I hear from new researchers is “what is IRB?”

This is a loaded question, because often embedded in the question is a whole bunch of baggage associated with IRB’s that include, “we keep them from their research,” “we are a road block,” “researchers have to jump through hoops,” “IRB’s are too slow,” and “IRB’s make the work harder.” I know when a researcher calls IRB, I may face these preconceptions about my role and department.

REACHING THE RESEARCHER— Yes, we need new researches to understand IRB formatting and submission (the “what” of IRB), but we also need them to understand the “why” behind IRB.

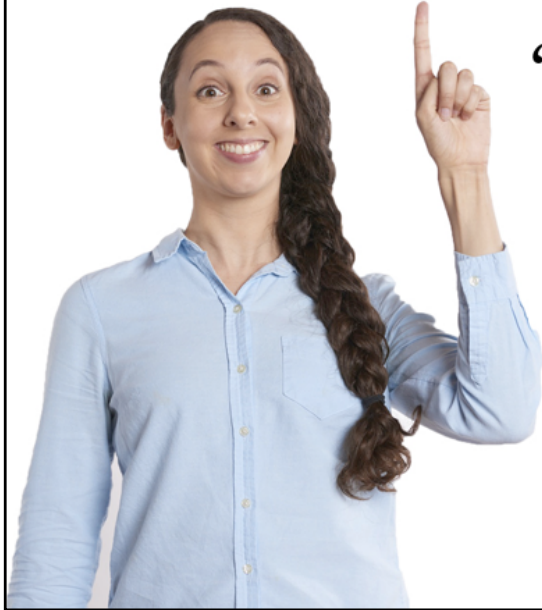
## **Generally IRB is about:**

- (1) Regulation (we help new researchers understand this)
- (2) Administrative (we help researchers process paperwork, and technological upkeep)
- (3) Ethics (*the mission of the IRB and the messages we communicate is that we are here to help protect human subjects—IRB matters because researchers could potentially hurt people, and we do not want that, as such our job is to protect human subjects involved in research.*)

But how do we get to the point of talking about IRB, when new researchers are often

confused about our role (or apprehensive) in the first place? We need to work on reframing the message.....IRB is not here obstruct, we are here to engage in an intellectual exchange about ethical conduct.

## Reframing the Message



“Every day may  
not be good...  
but there’s  
something  
good in  
every day”

— Alice Morse Earle

To begin, when I reframe the message of what IRB is, and why we are important for institutions---I pull up a handy quotable quote.

# Returning to What is IRB?



After reframing the message and sharing a personal experience about what IRB is, and why it is important. We can then, engage in the mission of IRB.

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# **IRB**

The purpose of the Institutional Review Board is to ensure that all research involving human subjects is conducted in accordance with federal, institutional, and ethical guidelines. The IRB review process is designed to protect the rights and welfare of the research participants.

Once you help researchers move beyond feeling like IRB is out to destroy their research you can begin describing the history of IRB and why we serve an important role in human subject research. I like establish this historical framework for new researchers so they feel they are operating on a legacy of previous work and understand that it's our duty as researchers to uphold high levels of ethics so as not to make the mistakes of the past.

# History of IRB

The modern history of human subjects protections began with the discovery after World War II of numerous atrocities committed by Nazi doctors in war-related research experiments. The Nuremberg Military Tribunal developed 10 principles, known as The Nuremberg Code, to judge the Nazi doctors.....

...The National Research Act of 1974 established the modern IRB system for regulating research involving human subjects. In 1991, 16 federal agencies formally adopted the core of these regulations in a common Federal Policy for the Protection of Human Subjects (also known as the "Common Rule").

What is it important to talk about the history of IRB with new researchers?

It's important to include historical context for new researchers because some really bad things happened and that's why we have the regulations.

When new researchers find importance and relevance in IRB they will more likely understand that the "hoops" they have to jump through are there for a valid reason.



# Basic Ethical Principles

- The *Belmont Report* specifies three guiding ethical principles that inform the work of IRB administrators—respect for persons, beneficence, and justice.
- RESPECT FOR PERSONS:
  - People are autonomous decision-makers. For persons incapable of such self-determination additional protections should apply.
- BENEFICENCE:
  - Maximize possible benefits and minimize possible harms.
- JUSTICE:
  - Who ought to receive the benefits of research and bear its burdens?  
To each person: (1) an equal share, (2) according to individual need, (3) according to individual effort, (4) according to societal contribution, and (5) according to merit.

Training researchers on how to “see” these ethical principals in their own work is also important and I think is only possible when the IRB administrator describes how these principals and codes of conduct fit within the researchers own work.

As such, when I meet with new researchers, I ask them to give me an “elevator pitch” of their work. When they speak, I’m listening to their descriptions of their work and trying to identify how to weave in ethical principals that pertain to their own research.

# IRB Protocol Submission

- **Systematic**
- **Comprehensive**
- **All possible**  
(with some negotiations and compromises)
- **An intellectual exchange**



So, how do I communicate the importance of highly ethical research? How do I take regulations and ethical codes of conduct and embed them within a new researchers own work? I follow this process:

An IRB Protocol Submission is – **Systematic** (there is an order to things, follow that order of operation and protocols move faster); **Comprehensive** (explain to reviewers your consenting and recruitment process, we want to know how you're protecting participants); **All Possible** (your research hopes and dreams are possible, you just have to meet the required regulations to do so); **An Intellectual Exchange** (treat us like an ally, we want to see good work out there, we will do our best to make it happen by asking tough questions and keeping your protocol compliant with local, state, and federal regulations).

# Narrative and IRB



And I bring humor to what I do and I laugh, a lot...which often surprises new researchers “What?! IRB administrators laugh?” Um, yea, we are humans too...

*For example, I bet you thought the photos of the woman on these slides was me!? Well, that’s not true, these are all stock photos. But it’s funny to think that I’d create this presentation AND pose in all of these photos. Hah, ha! =)*

Ultimately, my approach to engaging new researchers is to tell stories of previous work (unidentified, of course) and give examples of researchers who have done similar work, and the paths they took to ensure their subjects were protected. I usually include some kind of joke or opportunity to laugh, as people feel much more comfortable talking about research when they feel there is a safe and friendly environment.

# Mentor IRB

Mentor IRB an online system used to house all important documents and communication related to research with human subjects.

- Tracking Protocols
- Common Format for Protocol Submissions
- Accessible Remotely and Conveniently
- Streamlined Communication Among All Users (researchers, administrators, and IRB board)



Okay, so how do I do all this magic within my department?

Well, we use Mentor. Which houses all of our protocols and allows me as an administrator the opportunity to communicate on multiple platforms with different people all in one place. It's like a communicators digital playground. It also stores each protocol and serves as the platform for the lifespan of a protocol (from initial submission to research termination).

You can access Mentor by logging on to MyTC/Research Tab/Mentor IRB. Once in Mentor you can find templates in "Documentation." Then, when you're ready you can submit a new protocol under My Protocols/Create New"

# Writing and IRB

## Overall

- Justification for selection of subjects
- Detail probability of risk
- Create adequate provisions to handle adverse events
- Do not overstate protection of confidentiality
- Clarify data storage
- Explain eventual disposition of audio/videotapes
- Address potential for coercion due to PI's Position of Authority

*Support English Language Learners (ELL), General Clarity of Writing, and Suggest PI's Proofread Often*

## Participant Materials:

- Age appropriate language
- Contextually appropriate
- Culturally appropriate
- Avoid biased writing
- Clear and understandable
- Avoiding scientific jargon
- Do not overstate benefits
- Detail full time involvement



Moving on to another IRB administrator's hurdle...

So, the new researcher on board. They understand the purpose of IRB (what is IRB) and why it's important (historical context), but now they need to prepare their materials for submitting a new protocol.

And here comes the elephant in the room....**WRITING**....[cue horror music and screams]

One of the challenges I face is training new researchers on how to WRITE an IRB application. Which is not something many of them have done before.

So, it's important to address the: "How do I write an IRB application?" question early on.

To begin, I guide researchers on how to write a protocol by describing the two modes of writing they will face: (1) Writing for IRB Reviewers and (2) Writing for Participants

Of course, IRB administrators do not write the protocol for them, but we do coach researchers on how to write with clarity and understandability.

One of the best ways IRB administrators help researchers with writing is to provide

them with templates. You can also provide them sample protocols from their department.

## Role of the Faculty Sponsor

- Review research methods prior to IRB.
- Guide student ethical research and ways to ensure the rights and welfare of the human subjects involved are protected.
- Offer suggestions to address research challenges and concerns.

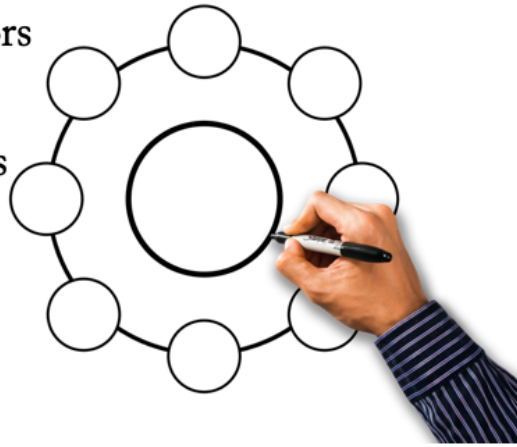


I ALWAYS Make friends with faculty sponsors.

Creating a unique template for each department within my institution would be exhausting. That's why I lean on Faculty Sponsors. I meet with faculty members within each department and asked them to describe the kind of work they do with student researchers. This gives me the foundation to create templates that align with each department (e.g., the music department usually conducts low risk exempt studies where as the Biobehavioral Studies conducts more risky studies and is usually full board).

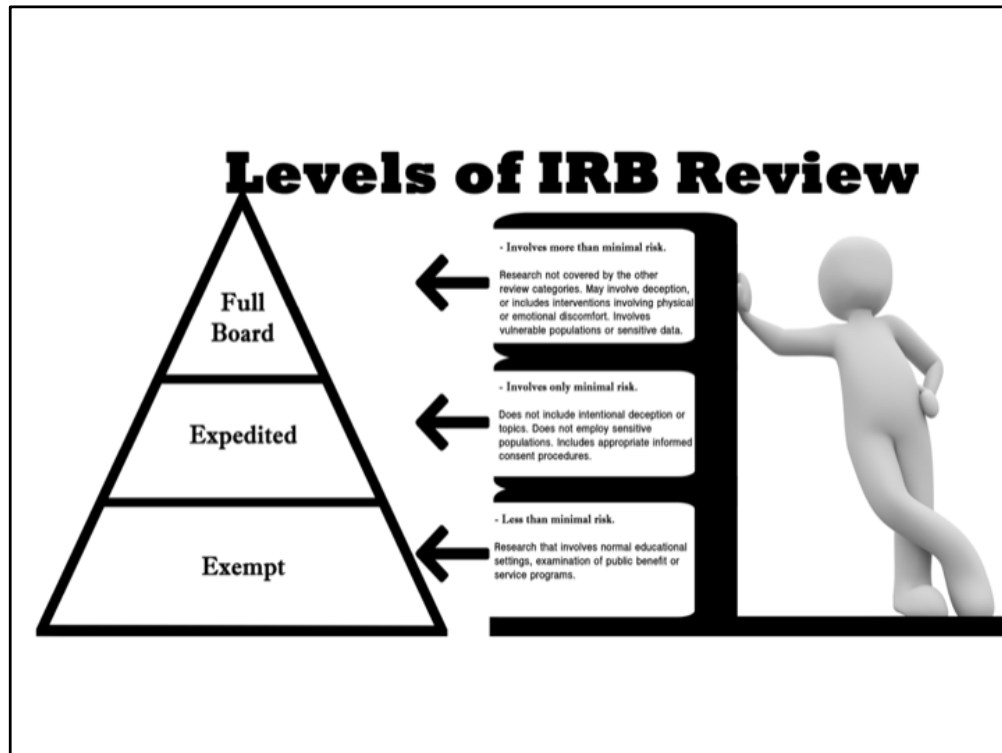
# Many Research Roles

- In addition to faculty sponsors...
- Primary Investigators
- Research Coordinators
- Research Assistants
- Research Participants



Each researcher has their own concerns. We have resources to help guide all researcher within all of their roles.





Here is a run-down of what all researcher should know:

- a) Exempt (doesn't mean exempt from the process of IRB)
- b) Expedited (doesn't mean it is a faster process)
- c) Full (rarely used in behavioral/social research)

# Recruitment



Questions researchers should be able to answer:

- a) Do you have access to a participant group?
- b) Is there a clear process for recruiting participants?
- c) Have you created materials to contact people and introduce them to this study?

# External Sites



Questions researchers should be able to answer:

- a) Have you obtained site permission?
- b) Does that site have an IRB?
- c) While you can submit a study for review prior to receiving permissions, you cannot get final approval until all submissions have been submitted.

# Consent Process



Consenting is a PROCESS, not just a form (note: online consenting is unique).

Questions researchers should be able to answer:

- (a) Do you have your consent form? Parental Permission Form? Assent Form?
- (b) Have you thought about the entire procedure from recruitment to consent to study procedures?

# Risks and Benefits



Questions researchers should be able to answer:

- (a) What are the risks of your study?
- (b) Be consistent with the risks throughout the application and consent form. No Foreseeable Risks  $\neq$  Minimal Risks.
- (c) Many studies include a possible risk of loss of confidentiality. If that applies to your study, be sure to list it. Benefits: Are there any direct benefits to the participant?
- (d) It is often the case that there are no direct benefits to the participant, and the only benefit is towards future knowledge in the content areas. If that is the case, this information should be clear in both the application and Informed Consent Document.
- (e) Payment and/or extra credit are not considered benefits.
- (f) Is there any conflict of interest? If so, explain.
- (g) Are you deceiving participants? Is it scientifically justified? Are you debriefing participants at the end of the study?

# Privacy & Confidentiality



Questions researchers should be able to answer:

- (a) Do you know the difference between de-identified (key to an identifier) vs. anonymous
- (b) Do you understand what confidentiality means (e.g., don't identify the participants)?
- (c) Are you working with your own students? Did you fill out a separate "working with your own students" form?

# Transferring Data



Questions researchers should be able to answer:

- (a) Are you moving your data from one location to another?
- (b) How are you safely transporting this data? – Encrypted data (and secure data).
- (c) Did you fill out a data-sharing-agreement form?

## **Summary of The IRB Process**

- Do your homework ahead of time.
- Be informed, review IRB examples, and use templates.
- Be diligent in protecting your participants.
- Follow local, state, and federal IRB regulations.
- Remain ethical at all times.
- IRB is systematic, comprehensive, all possible, and an intellectual exchange

Happy researching!