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Welcome!

- The session will begin shortly; if you are joining via Zoom, please take a moment to make sure your microphone is muted.
- The presentation portion of this session will be recorded.
- This presentation will solicit active participation from audience members.
- Not registered? Please register now using the QR code.

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FAQs, Facts, & Fiction

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Jessica Kisenwether, Ph.D., CIP, CCC-SLP

9+ years of experience in human research protections, serves as a regulatory expert for multiple institutions.

Licensed speech-language pathologist in PA and NY.

18 years of research experience in the area of speech science, specifically subjective and objective measures of voice, swallowing, dysfluency, and speech.

Published in numerous journals and presented at state, national, and international conferences

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Joined WCM in 2022

Objectives

1. Review the scope of the IRB, when IRB review is needed, levels of IRB review, needs of the IRB
2. Dispel myths and common misunderstandings about the IRB and its processes
3. Provide an opportunity for the community to share their understanding of current IRB processes and ask questions

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Purpose of the IRB

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- To give me grief!
- To protect the institution from liability
- To protect the researcher from liability
- To eliminate risk to participants
- … ?

Purpose of the IRB

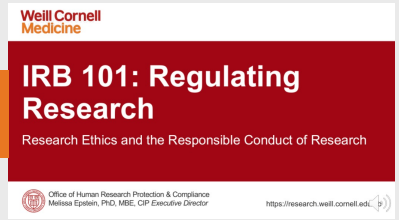
What does the IRB do?

- **Ensure the ethical treatment of human participants in research.**

How?

- **Belmont Principles**
  - **Beneficence, Justice, Respect for Persons**
- **Federal, State, and Local Regulations**

For a discussion on the history of the IRB, please watch our METS from September 2023



Food and Drug Administration

- Clinical investigations using a test article
- Currently does not harmonize with 45CFR46
- 21 CFR 312 Drugs
- 21 CFR 812 Devices

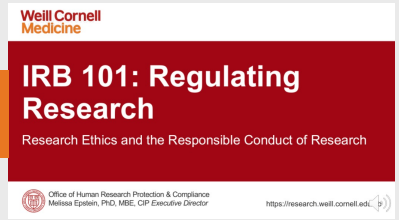
Department of Health and Human Services

- Subpart A - the “Common Rule”
- Subpart B - pregnant woman, neonates, fetuses
- Subpart C - prisoners
- Subpart D - children

Other Regulations…

Organization	Regulation
OHRP	**Common Rule** (45 CFR §46)
FDA	Device, Drug and IRB regulations (21 CFR §812; §312, §50, and §56)
DoD	Instruction 3216.02
Office of Civil Rights	**HIPAA** (45 CFR §160 and §164)
ICH	International Conference on Harmonisation (ICH) Good Clinical Practice
EUGDPR	European Union General Data Protection Regulation
NIH	Imposes requirements on funded research
State, **Local**, and **Institutional** Regulations	

For a discussion on which regulations apply when, please watch our METS from September 2023



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Purpose of the IRB

- To give me grief!
- To protect the institution from liability
- To protect the research participants
- To eliminate risk to participants
- … ?

To ensure the ethical treatment of human research participants

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When Do I Need IRB Review and/or Approval?

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- For any projects involving humans as participants
- For greater than minimal risk studies
- … ?

When do I need IRB review and/or approval?

When do I need IRB review and/or approval?

1. When the proposed activity is Federally funded

AND

2. When you are conducting ‘human subjects research’ as defined by the Federal regulations

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1

When the proposed activity is Federally funded

Regulatory Requirement
vs
State, Local, or Institutional Requirement

AND

2

When you are conducting ‘human subjects research’ as defined by the Federal regulations

45CFR46
vs
21CFR50,56

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Revised Common Rule

FIRST we must satisfy the definition of research:

45CFR46.102(e):

Research means a **systematic investigation** including research development, testing and evaluation, **designed** to develop or contribute to **generalizable knowledge**.

- **A proposed activity must be both a systematic investigation AND designed to develop or contribute to generalizable knowledge.**
- **If one aspect or both are not satisfied, the activity is not research per the Common Rule and IRB review is not required.**

Considerations

The IRB must only consider the *current* proposed topic when approaching the regulatory definitions. Meaning, future or subsequent goals that may result from the proposed activity do not contribute to the decision.

Helpful Questions

1. **What do you intend to do in the proposed activity (i.e. what is the true purpose at this stage?)**
2. **What do you intend to do with the results (will you simply improve upon a tool/program/etc.? OR will you attempt to validate a tool/program/etc. that has already been developed?)**

Revised Common Rule

If and only if the research definition has been satisfied, then we approach the definition of human subjects:

A living individual about whom an investigator obtains:

- information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens **OR**
- uses, studies, analyzes, or generates identifiable private information/biospecimens

Considerations

- **Identifiability is specific to the context of accessing data**
- **Anonymous interactions/interventions are still human research**

Helpful Questions

1. **Are data being collected about a “what” or a “whom”?**
2. **Can an individual be linked with his/her/their data points?**

Food and Drug Administration

In regard to the 'research' definition:

21CFR56.102(c) and (l)

- **Clinical investigation** means any experiment that involves a test article and one or more human subjects, and that either requires prior submission to the FDA or when the results will be used to support an application for a research or marketing permit.
- **Test article** means any drug (including a biological product), medical device, food additive, color additive, electronic product, or any other article subject to FDA oversight.

Food and Drug Administration

In regard to the 'human subject' definition:

21CFR56.102(e)

Human subject means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control.

- A subject may be a healthy human or a patient with a disease.

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When do I need IRB review and/or approval?

- For any projects involving humans
- For greater than minimal risk studies
- … ?

For projects that are federally funded and meet the regulatory definitions of human subjects research.

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What if my project is ‘not human subjects research’?

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- I will lose my funding
- I cannot start my project
- It’s not research
- There is no oversight of the project
- I cannot publish the results
- There is no risk
- …?

What if my project is ‘not human subjects research’?

NHSR Determination

- **This simply means the proposed activity does not meet the definition of research and/nor human subject per 45CFR46/21CFR56**
  - As a results, IRB review/approval is not needed
  - The project does not fall under IRB purview
- **The proposed activity may still involve:**
  - human subjects (including PHI, sensitive information, etc.)
  - other regulatory institutional mandates (i.e. HIPAA, DUA)
  - risk

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- I will lose my funding
- I cannot start my project
- It's not research
- There is no oversight of the project
- I cannot publish the results
- There is no risk
- …?

The project is not under the purview of the IRB

What if my project is 'not human subjects research'?

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What if my project *is* human subjects research?

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- If it's exempt I don't need to submit to the IRB
- It's if minimal risk I don't need to submit to the IRB
- If it's minimal risk it will be fast tracked
- …?

What if my project *is* human subjects research?

Levels of Review

Exempt

Expedited

Full Board

Exempt

Expedited

Full Board

Minimal Risk

"the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests"

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Exempt

Expedited

Full Board

Anything that is not minimal risk and/nor does not meet the exempt/expedited categories.

Levels of Review

Exempt

Expedited

Full Board

Exempt

Expedited

Full Board

Must meet all of the requirements outlined in the Federal regulations.

Can be reviewed by the IRB chair or designated IRB member(s)

Must be reviewed by the convened IRB (quorum)

Exempt

Expedited

Full Board

Does not need to meet some of requirements outlined in the Federal regulations (e.g. the approval criteria, informed consent).

Exempt Research

IF:

1. Meets definition of human subjects research per the Federal regulations
2. Is minimal risk
3. Falls within one or more of the exempt categories of research

THEN:

1. Is "exempt" from some the outlined regulatory requirements
2. Does not require continuing review (WCM requires post-approval monitoring [PAM-AR])
3. Does not require the review of an IRB member

Expedited Research

IF:

1. Meets definition of human subjects research per the Federal regulations
2. Is minimal risk
3. Falls within one or more of the expedited categories of research

THEN:

- Must meet the applicable regulatory requirements
- Can require either continuing review or PAM-AR
- Requires the review of one or more IRB members

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- If it's exempt I don't need to submit to the IRB
- It's if minimal risk I don't need to submit to the IRB
- If it's minimal risk it will be fast tracked
- …?

- The IRB must determine level of review
- Exempt only means exempt from some of the regulatory requirements
- There is no difference between expedited and full board review in regard to regulatory requirements

What if my project *is* human subjects research?

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So…when do I have to submit to the WCM IRB?

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- When I’m using WCM facilities
- When I’m studying WCM patients
- When WCM is the funder
- …?

So…when do I have to submit to the WCM IRB?

WCM is engaged when:

WCM employees or agents are conducting non-exempt human subjects research

and/or

WCM is the primary awardee

When WCM employees or agents for the purposes of the research obtain:

1. Data about the participants through intervention or interaction;
2. Identifiable private information about the participants; or
3. The informed consent of the participants

Some examples where WCM is not engaged in non-exempt human research

- When WCM is receiving de-identified data from another institution for analysis
- When a researcher from an outside institution wishes to study a WCM employee's patient population
- When WCM employees or agents provide clinical trial-related medical services that are dictated by the protocol and would typically be performed as part of routine clinical monitoring and/or follow-up of participants enrolled at a study site by clinical trial investigators, excluding administering the study intervention

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- When I’m using WCM facilities
- When I’m studying WCM patients
- When WCM is the funder
- …?

When WCM is engaged.

So…when do I have to submit to the WCM IRB?

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What does the IRB need to know?

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- Depends on whether I submitted something similar in the past
- Same info as PRMC
- Same info as the protocol template
- Same info as my grant application
- That I have eliminated risk
- How I will protect the data
- …?

What does the IRB need to know?

Approval Criteria (45 CFR 46.111 / 21 CFR 56.111)

In order to approve research involving human subjects, the IRB must determine the following requirements are satisfied:

- ❑ Risks to subjects are minimized by:
  1) Using procedures consistent with sound research design, using procedures already done on the subjects for other purposes, and;
  2) Without exposing subjects to unnecessary risk.
- ❑ Risk to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be reasonably expected as a result
- ❑ Selection of subjects is equitable
- ❑ Additional safeguards have been included in the study to protect the rights and welfare of subjects who are vulnerable to coercion or undue influence
- ❑ Informed consent will be appropriately documented or appropriately waived in accordance with §46.117(c)
- ❑ The research plan has adequate provision for monitoring the data collected to ensure subject safety
- ❑ There are adequate provisions to protect the privacy of subjects
- ❑ There are adequate provisions to maintain the confidentiality of data
- ❑ The informed consent process is adequate
- ❑ The documentation of informed consent is adequate

IRB Review Application (IRA)

Biomedical

For studies that will use a device/drug or implement a clinical trial

Biorepository

For the establishment of a repository for potential future use

SBER and Records

For social, behavioral, or educational research

Medical Education

For studies that qualify under exempt category 1 only

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- Depends on whether I submitted something similar in the past
- Same info as PRMC
- Same info as the protocol template
- Same info as my grant application
- That I have eliminated risk
- How I will protect the data
- …?

Enough information to satisfy the approval criteria (.111).

What does the IRB need to know?

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What have *you* heard and how can we help?

Contact Us

Scan the QR code to request a consult during our on-site
Tuesday, 1/9 through Thursday 1/11

Contact Us

IRB Member Portal

Forms, Templates & Guidelines

Request a Consultation

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