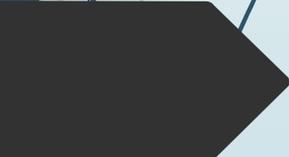




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discover new facts  
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# Does my study need IRB Review?

Non Human Subjects Research  
Determinations- *With Examples*



Emory University IRB  
May 12, 2016  
Jessica Baker

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# Objectives

- ▶ Review the definition of research with human subjects
- ▶ Go over what qualifies as de-identified data
- ▶ Determine when a case study needs IRB review
- ▶ Determine when a quality improvement project needs IRB review
- ▶ Go over the difference between public health practice and public health research
- ▶ Review when classroom activities are considered research and when they are not
- ▶ Go over how to submit a project for an IRB Determination



# Back to Basics...

- ▶ The IRB exists to protect human research participants, but there are many projects for which the regulations do not require IRB review
- ▶ We try to limit our scope to what is required by the regulations
- ▶ Projects that meet the definition of research with human subjects must be reviewed by the IRB (though if “exempt” per the regulations, no further IRB oversight is required after initial review)

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# “Exempt” or Not Human Subjects Research?

- ▶ “Exempt” is a term defined in the federal regulations
- ▶ “Exempt” refers to research with human subjects that is so low-risk that the regulators exempt it from IRB oversight
- ▶ “Exempt” is often used more broadly by those not familiar with the regulations, to describe any project that does not require IRB review
- ▶ Note: “Exempt” research requires a full initial IRB submission and cannot be reviewed via email or our website tool

# Human Subjects Research

- ▶ Research is “a **systematic investigation** designed to contribute to **generalizable knowledge**.”

(paraphrased from [45 CFR 46.102](#))





# Human Subjects Research

- ▶ ***Systematic Investigation?***
  - ▶ NOT by itself a hallmark of research! Many good non-research projects involve systematic investigation
    - ▶ Methodical exploration of a question or theory (includes sociobehavioral methods)
    - ▶ Typically includes data collection and analysis
    - ▶ Includes development, design, and testing phases
  - ▶ Can Include:
    - ▶ Interviews, surveys, chart reviews, epidemiological studies, observational studies
  - ▶ Generally does NOT include:
    - ▶ Training people how to use research methods

# Human Subjects Research



- ***Designed to be Generalizable?***
  - Difficult to define, but typically designed to be generalizable if:
    - Aims to draw conclusions about people or practices beyond a specific individual or internal program
  - The ***design and intent*** to generalize makes it research
  - Publication or presentation alone does not imply something is research

# Human Subjects Research

## *DHHS Definition:*

- ▶ A Human Subject is a living individual about whom an investigator obtains:
  1. Data through intervention or interaction; or
  2. Identifiable private information
- ▶ Identifiable if identity can be ascertained (e.g. 18 HIPAA identifiers if HIPAA applies)
- ▶ Private means a reasonable expectation that no recording is taking place, and information is used for intended purposes

[45 CFR 46.102](#)



# Human Subjects Research

## *FDA Definition:*

- ▶ A Human Subject is an individual who is or becomes a participant in research, either as a recipient of the test article or as a control.
  - ▶ May be either a healthy volunteer or a patient
  - ▶ Also **human specimens** in clinical investigations, e.g. assays or *in vitro* diagnostic devices [21 CFR 50.3\(g\)](#)



# Human Subjects Research

- ▶ Typically does **NOT** include human subjects:
  - ▶ Analysis of fully deidentified, delinked dataset
  - ▶ Research with deidentified samples
    - ▶ Exception for FDA definition, when in a clinical investigation involving human specimens
  - ▶ Deceased individuals





# Deidentified Datasets: When Not Human Subjects?

- ▶ Analyzing data collected previously, stripped of all possible identifiers
  - ▶ No one on study team stripped the identifiers themselves for current study, nor could they access a key linking codes to identifiers
  - ▶ Others may still be able to link codes to identifiers, but have agreement not to release key to study team
  - ▶ Yes, it's research, but Not human subjects because there is no interaction or intervention and no identifiable information
- 

# Note on “Deidentified”

- ▶ To the IRB, deidentified means:
  - ▶ No one on study team has access to identifiers *at any time*
  - ▶ For research where HIPAA applies, all 18 HIPAA identifiers are removed
  - ▶ Where HIPAA does not apply, it means that there is no feasible way to identify someone from the data (directly or via code)



# “Deidentified” Datasets From External Databases



- ▶ Typically national-level databases may appear “deidentified” but administrators state that re-identification is technically possible
- ▶ May require separate data use agreement
- ▶ The IRB will often review these if data source believes reidentification possible

# Case Studies



- Case studies involve the collection and presentation of detailed information about a particular participant or small group to highlight an interesting condition, treatment, presentation or outcome.
- To determine whether a case study or case series requires IRB review, recall that human subjects research is designed to contribute to generalizable knowledge.
  - A case study highlights a few particular cases for purposes of demonstration rather than for purposes of drawing generalized conclusions.
  - HIPAA regulations should still be considered, if applicable

# Case Study

- Below are some criteria that tend to be representative of either case studies or research

Case Study	Research
Reports on 5 or fewer subjects	Reports on more than 5 subjects
Not meant to be a representative sample	Draws conclusions about a broader population based on the reported cases
Specific to subjects' conditions or treatments	Not as specific to individuals, instead focused more on conditions or treatments
Reported/published information specifically notes case reports	Reported/published in a way that suggests broad findings or recommendations

# Case Study Example- No IRB Review Required

- ▶ A profile of three people with the same rare disease
  - ▶ Procedures include: obtaining historical health information, in-depth interviews, comparing different treatments, collecting outcome data
  - ▶ Intent is to highlight differences and similarities in the cases
  - ▶ **Not meant to be generalizable!**



# Case Study Example- IRB Review Required

- ▶ A profile of ten people with the same disease
  - ▶ Procedures include: obtaining historical health information, in-depth interviews, comparing different treatments, collecting outcome data
  - ▶ Intent is to determine the best treatment
  - ▶ **Meant to be generalizable!**





# Quality Improvement

- ▶ QA/QI projects often include activities such as conducting surveys, reviewing identifiable data, and implementing methods for improvement.
- ▶ The key is determining whether this type of project is **designed to be generalizable**
- ▶ QA/QI projects focus on improving the performance of an institutional practice in comparison with an **established** standard or goal. The results of the project are not intended to apply to anyone beyond the scope of the project, and conclusions are drawn only in relation to the particular practice at the institution.
- ▶ QI projects mainly implement proven or tested procedures; they are not designed to evaluate the safety or efficacy of a new procedure, only to see how well it works at the institution

# Quality Improvement

QA/QI	Research
Focus is local and specific, meant to improve institutional practice	Explores a hypothesis or theory to draw general conclusions beyond the scope of institution
Participants are not meant to be representative of a broader population	Results or data may be generalized as being representative of population at large
Conclusions directly applicable to institution, no claim that they are generalizable	Conclusions meant to be generalizable and apply to institutions beyond site where project took place
Publications focus on improvement at institution, allows external institutions to draw own conclusions about applicability	Publications meant to be generalizable, suggests applicability to other institutions

# Quality Improvement-No IRB review required

- ▶ A study of a state prison health system is undertaken to improve patient satisfaction
  - ▶ Procedures include: chart review, interviews with prisoners, satisfaction surveys, implementation of new intervention and collection of data before and after the new intervention
  - ▶ Results will be provided to the prison health authority with recommendations for the system
  - ▶ **Not intended to be generalizable outside of the prison system studied**



# Quality Improvement- IRB Review Required



- ▶ A study of a state prison health system is undertaken to improve patient satisfaction
  - ▶ Procedures include: chart review, implementation of new intervention and collection of data before and after the new intervention
  - ▶ Results will make recommendations for other prison health systems
  - ▶ **Intended to be generalizable**

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# Public Health Practice vs. Public Health Research

- ▶ Scientific methods are used in both public health **practice** activities and public health **research** projects.
- ▶ Knowledge gained may be **generalizable** in both cases.
- ▶ The purpose of public health **research** is to generate or contribute to generalizable knowledge.
- ▶ The primary intent of public health **practice** is practical:
  - ▶ to prevent or control disease or injury and improve health, to improve a public health program or service, or to evaluate a program.

# Public Health Practice vs. Public Health Research

Public Health Practice	Research
Direct performance or oversight by governmental health authority	Conducted by academic centers with experience in conducting research
Primary intent is to prevent or control a disease or injury	Aims to draw conclusions about a hypothesis to contribute to the field at large
Focused on improving health of a specific population or group	Generates knowledge that can be applied broadly
Benefits and risks primarily designed to accrue to participating community	Benefits apply beyond participating community that bears risks
May involve people who did not specifically volunteer to participate (no informed consent)	Involves research subjects who voluntarily consent to participate (though consent may be waived by the IRB)

# Public Health Practice- No IRB Review Required

- ▶ Emory faculty help an NGO implement a new prevention outreach program
  - ▶ Procedures include: collection of data prior to and after implementation of the new program and surveys to gauge participant response
  - ▶ Reports will be generated to inform NGO administrators and Ministry of Health
  - ▶ **Not meant to inform the literature, or impact practices outside the target community**
  - ▶ Can still disseminate experience at conferences as a case report



# Quality Improvement Example- IRB Review Required



- ▶ Emory faculty working on clean water work with international organization to distribute and evaluate new products and educational tools to improve access to clean water
  - ▶ Procedures include: collection of data and survey responses prior to and after implementation of the new procedure in two pilot areas
  - ▶ Reported results will make recommendations for rolling out the interventions to other areas along with identifying barriers to clean water in similar areas
  - ▶ **Intent is to be generalizable- IRB review is required!**

# Classroom Activities



- Some research methods and research design classes include hands-on projects that may seem like research.
  - Classroom activities are often meant to satisfy a course requirement or to teach a particular lesson, not to spread beyond the classroom in a way that would suggest generalizable research.
- Some instructors undertake projects to improve student performance. No IRB review is required when the intention is solely to improve the teacher's or a department's teaching methods.
  - **However**, if an instructor has an academic interest in pedagogy, and is using the classroom to test innovations in pedagogy, IRB submission would likely be required

# Classroom activities- No IRB Review Required



- ▶ Improving test scores in a math class by utilizing technology
  - ▶ Procedures include: surveys with students, review of test scores before and after implementation
  - ▶ Intent is to improve one department's students' test scores
  - ▶ **Not meant to be generalizable**

# Classroom activities- IRB Review Required (May Be Exempt)

- ▶ Testing a new technology in several math classes with aim of obtaining representative sample
  - ▶ Procedures include: anonymous surveys with students, review of test scores before and after implementation
  - ▶ Intent is to show that technology use improves test scores
  - ▶ **If designed to be generalizable - needs IRB review (may be exempt)**





# Another Litmus Test...

- ▶ Whether classroom innovation, quality improvement, or public health:
  - ▶ if you are adding additional data collection or procedures to your project in order to make the results more robust for publication or utility in generalizing - *beyond* what you would do solely for your own/institution's needs - then you are likely doing some "research"



# Not Totally Clear? We Agree!

- ▶ The regulations leave plenty of ambiguity and whether a particular project needs IRB oversight is not obvious
  - ▶ Depends on particularities, often there are exceptions
- ▶ TAKEAWAY:
  - ▶ [Submit your project to the IRB for an official determination](#)
  - ▶ Determination request form on the IRB website is quick and convenient, not nearly as involved as an eIRB submission.
  - ▶ Request a Determination tool located on the Emory IRB website under “Forms & Guidance” tab

**Request Determination of  
IRB Review**

# Submitting a project to the IRB for a Determination

- ▶ You will be asked to answer some questions and attach a protocol, proposal, or project summary.
- ▶ Once submitted, your project is sent to the IRB listserv, which is monitored by an IRB analyst on a rotating basis each day.
- ▶ You should immediately receive a receipt notifying you that your submission was received.
- ▶ You should get some initial response within three business days.



# Submitting a project to the IRB for a Determination



- ▶ Be sure to respond to any questions your reviewing analyst may have by replying to your analyst directly.
- ▶ Make sure you address the criteria covered in this webinar.
- ▶ Your analyst will provide you with an email determination once all questions have been answered.
- ▶ If you require a formal determination letter, just let your analyst know!

# Questions?

IRB Contacts on the QA and Education team:

► **Maria Davila**

(404)712-0724 or [maria.davila@emory.edu](mailto:maria.davila@emory.edu)

► **Shara Karlebach**

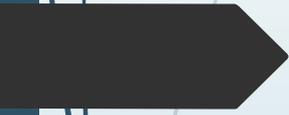
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# Thank You!

*Please consider taking a moment to complete our survey, link located on the webinars page of the website.*