Exempt Human Research and the Emory IRB

IRB Webinar
About the IRB

• Emory IRB serves the whole University: Healthcare/Woodruff Health Sciences Center as well as Emory College of Arts and Science, Laney Graduate School, Rollins School of Public Health, Goizueta, Law School...

• Sociobehavioral Committee (SHB): primarily expedited (non-Committee) reviews
  • Faculty from various Schools/departments
  • Includes those with international research expertise

• Biomedical Committee:
  • Meets each week
  • Chairs also do expedited reviews
  • Certain panels specialize more (pediatrics, cancer)
**Not “research”**

Not a "systematic investigation designed to contribute to generalizable knowledge" and Not a "clinical investigation" per FDA

**Not “human subjects”**

Not obtaining, using, studying, analyzing, or generating identifiable private information or identifiable biospecimens, and No interaction or intervention to gather data or specimens about/from the participants

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**“Exempt”**

Yes: Is “human subjects research”

But

• So low risk, no need for ongoing IRB oversight
• Fits in one of the Exempt categories of the Common Rule
• Not FDA-regulated
Not Human research

• Can use our online determination tool instead:

Does My Project Need IRB Review? | Emory University | Atlanta GA
Types of research that are exempt

Mainly EDUCATIONAL PRACTICES and SURVEYS/INTERVIEWS

NEW since 2018: “Benign behavioral interventions” that are brief, meaning limited to one day

See our website: [IRB Review Types | Emory University | Atlanta GA]
OHRP Decision Chart

*Emory excludes most research records from HIPAA, so cannot use the highlighted exemption
What cannot be Exempt?

- Research involving minors, except in traditional education research
- Research involving prisoners
- FDA-regulated studies (e.g. evaluating a mobile app for a behavioral intervention, or use of deidentified specimens to test a new assay)

Note: VA has slightly different rules
TO BEGIN AN EXEMPT STUDY...

- **Must be submitted** to the IRB (via eIRB)
- Same application as all other studies (because researchers may not know how the study will be classified)
- Must use our protocol templates (ensures we have what we need for a quick determination)
- Qualified IRB staff make the final determination
  - Avoids faculty burden
  - Use a minimized review checklist
Minimal requirements for Exemption

- Use of protocol template
- Informed consent has appropriate elements
- CITI training for personnel
- Departmental approval
- Cultural context letter for international studies

Multisite research:
- No reliance agreements for Exempt research – each site does their own
- BUT if lead site already did exemption, we have option to accept their review
Why Do We Need So Much Information?

• Many things can affect how a study is categorized...
  
  • Sensitivity of the information collected  
  • Identifiability of the data  
  • Age range  
  • Duration of behavioral intervention  
  • Deception about the purpose of the study  
  • The purpose of the project  
    • Does it meet the definition of “research?”  
    • May actually be QI, oral history, program evaluation - and need no IRB review at all
Research Involving Non-Emory Institutions

• If Emory has a Memorandum of Understanding (MOU) in place (e.g.; CHOA), whichever partner would have been the IRB of record, would also do the exemption determination.
Possible other requirements

• International research considerations
  • GDPR, China’s PIPL – may impact consent language, data handling

• OIT Security Review
  • if sensitive, identifiable information on a novel web/mobile platform

• COI Review
Tricky areas

• Research with HIPAA-covered PHI
  • As noted in the prior OHRP decision chart, one of the categories allows this to be exempt...
  • **BUT**: Emory *excludes* most research records from HIPAA, so cannot use that new exemption
  • Burden on researcher is about the same regardless

• International research
  • Still need cultural context letter, since the exempt categories are specific to US regulations
Grants and Exemption

Options for grants:

- Not human subjects
- Human subjects but Exempt (with category)
- Non-Exempt human subjects

Use NIH decision trees to help decide

If IRB determination doesn’t match at JIT, not a roadblock
Modifications to Exempt Studies

Modifications are only required for exempt studies when *substantive changes* are being made that could alter the original review determination.

- Examples of substantive changes are changes to:
  - subject populations (like adding a vulnerable population category, such as minors or prisoners),
  - data collection methods, or
  - identifiability of data (where data were previously de-identified).
  - addition of Federal funding
No Modification Needed...

The following changes are unlikely to impact the Exempt determination:

- altering study instruments or recruitment materials
- changing the target enrollment number
- adding fully trained staff (unless a new staff member needs access to the study record in eIRB)
- removing staff
Other helpful tips

• Familiarize yourself with the IRB target turnaround times.

• Faculty Advisor Review:
  • Please list your faculty advisor as PI and the analyst will request Department Approval. For RSPH, the student can be PI, with the advisor as "Co-Investigator" in the Local Study Team Members section of the smartform. RSPH advisors will be asked to log a comment issuing their approval.
  • For other undergraduate and graduate projects, the faculty advisor needs to be listed as PI, and the study will go through department review. SOM requires a faculty member to be the PI, and studies to go through department review.
Questions?