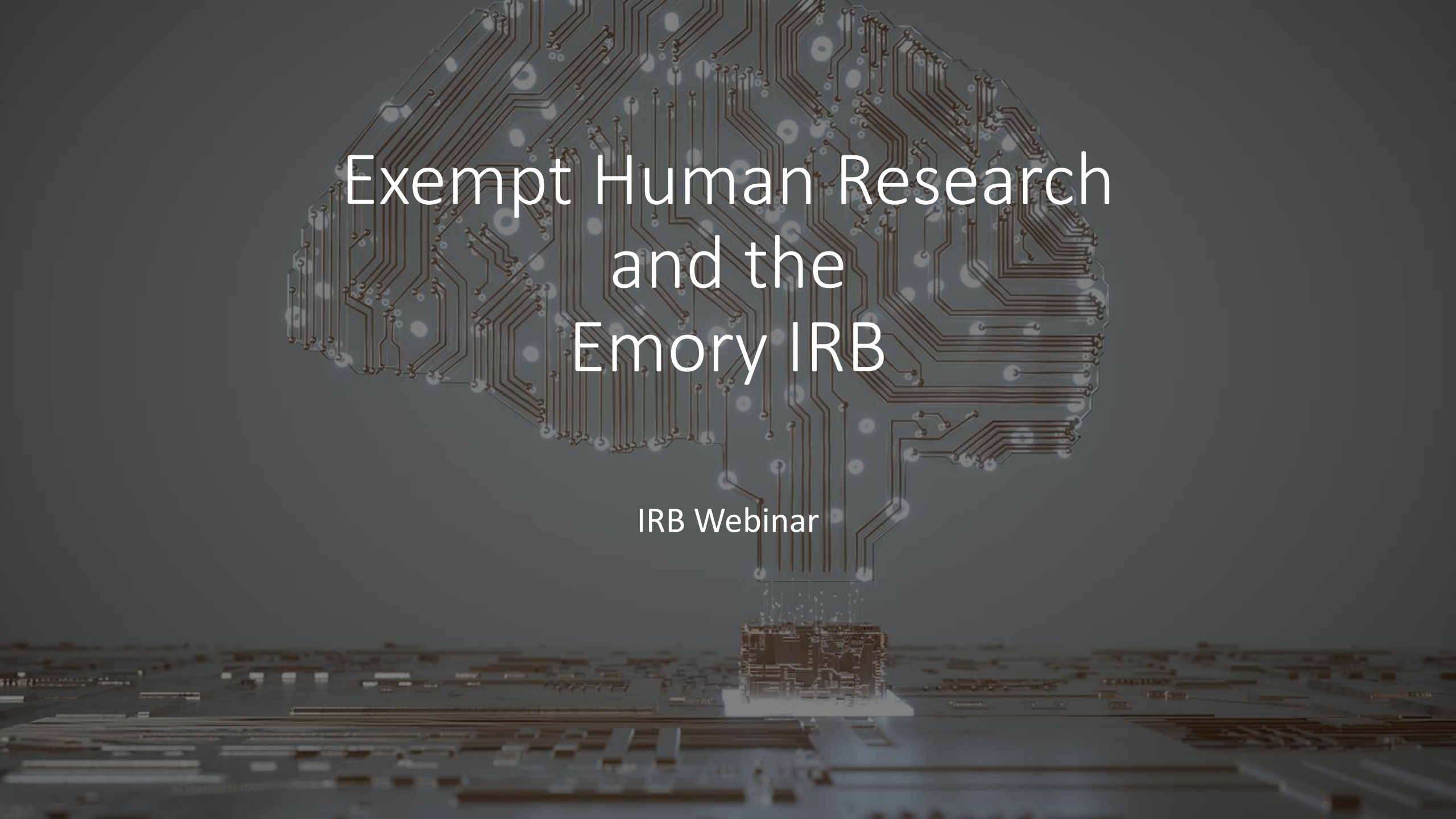


Exempt Human Research and the Emory IRB

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

“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

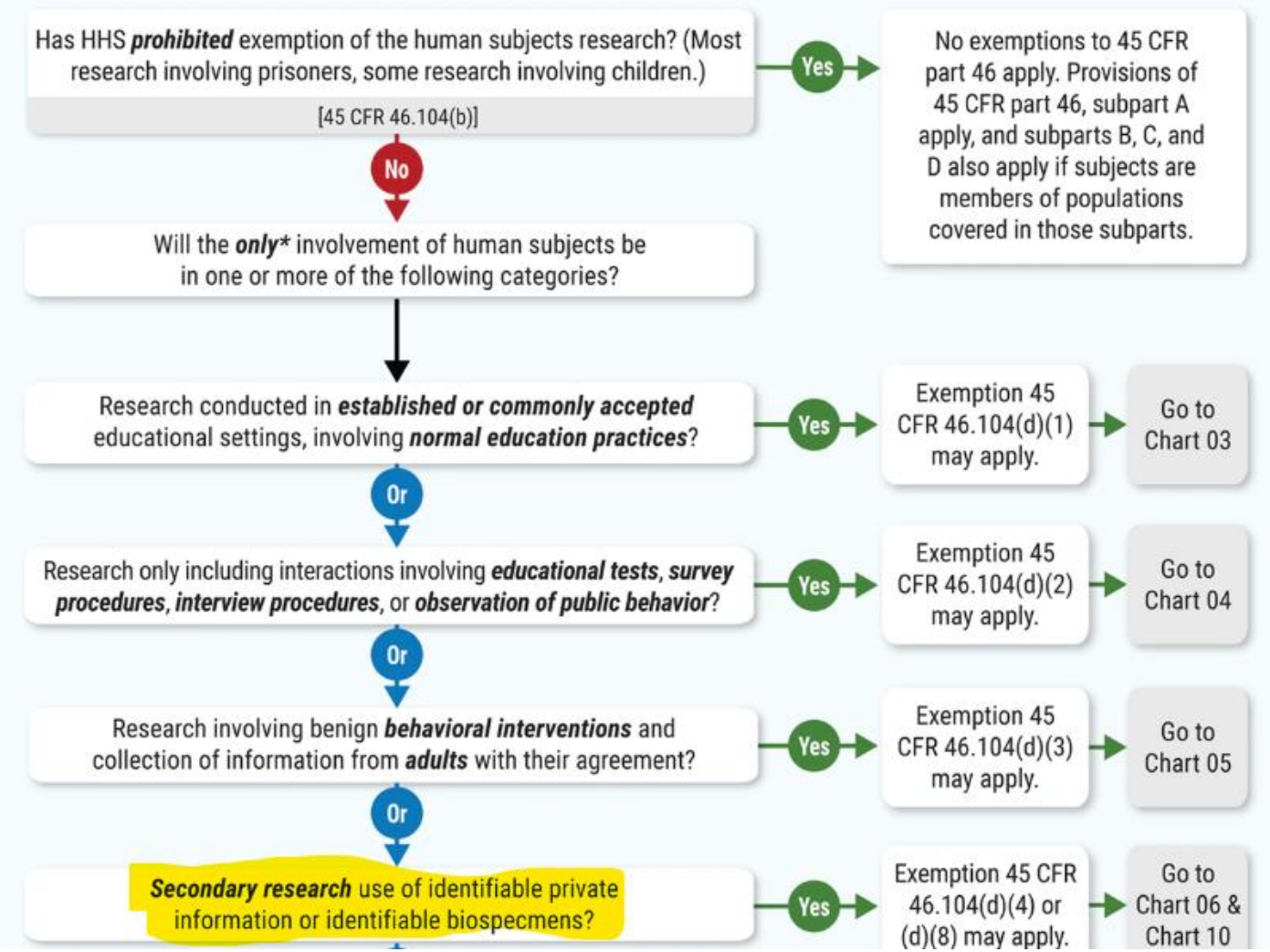
Mainly EDUCATIONAL PRACTICES and SURVEYS/INTERVIEWS

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

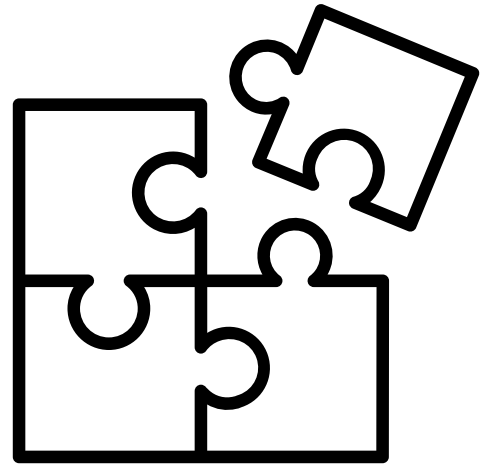
- If Emory has a Memorandum of Understanding (MOU) in place (e.g; CHOA), whichever partner would have been the IRB of record, would also do the exemption determination

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?