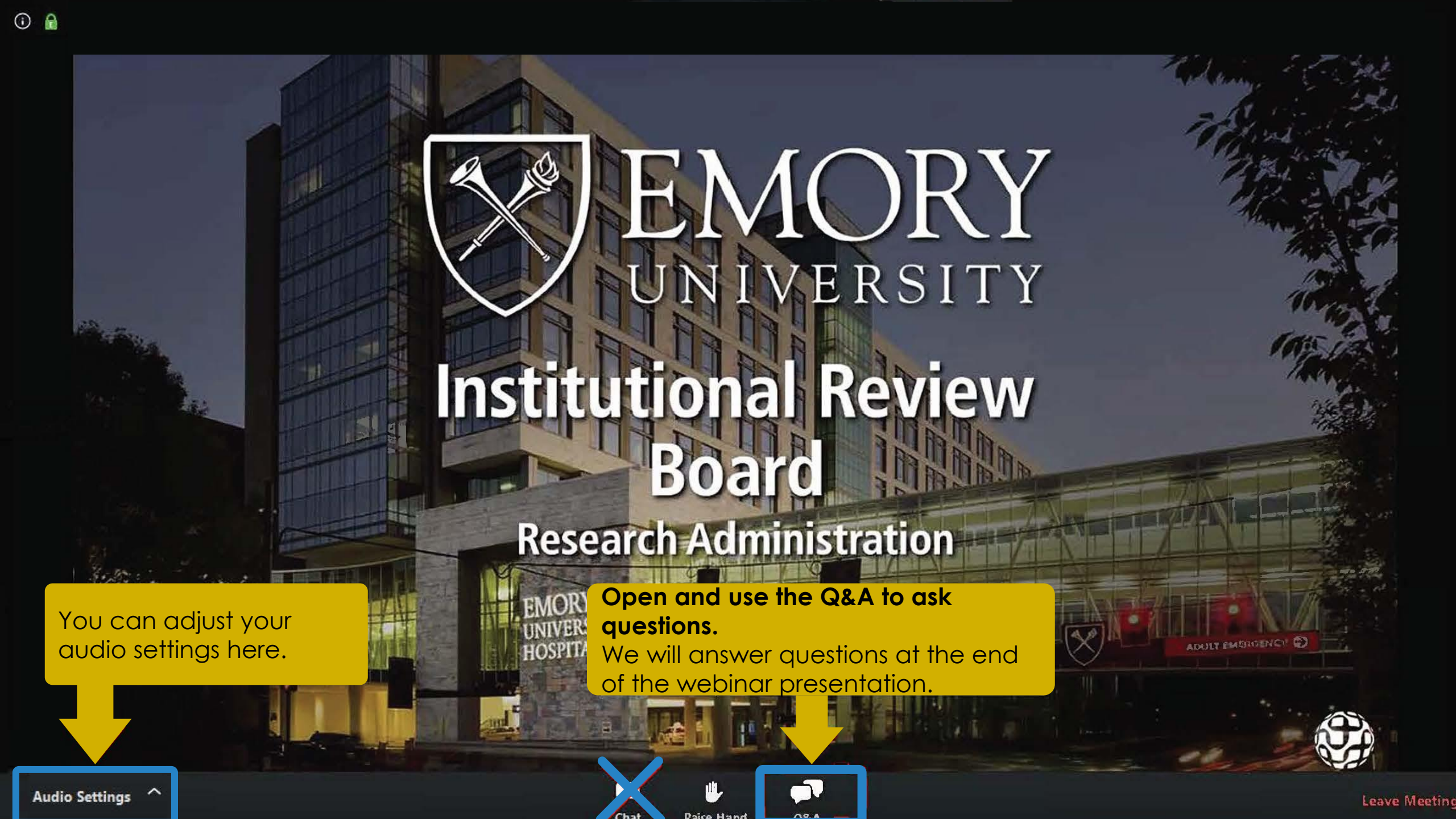
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SETTING THE STAGE

What is special about federal grants?

Why does the IRB care so much?

When Emory gets a federal grant, Emory has to **certify** to the federal agency that there is adequate IRB approval to cover the human subjects research activities.

Federal grants have special requirements and compliance risks for the University, like…

… Single IRB review requirements for all multisite research

… Audit potential

… Certificates of Confidentiality that automatically cover **just** the grant-funded work

Again, why does the IRB care so much?

The IRB needs to review not just the procedures, not just the study population, but also the **specific aims** of the research

Why? The purpose of the study helps determine the **risk/benefit ratio**, which is central to the IRB's scope

Each grant, each new aims, can introduce new review requirements

We need to review the *research overall*...

Our experience has shown that IRB submissions become muddy when used for multiple different grants, PI's, and sets of aims over time.

Key information: A MOD to add a grant is *not necessarily faster* than submitting a new IRB

THE SIMPLEST MODEL WOULD BE THAT ONE GRANT CORRESPONDS TO ONE IRB SUBMISSION.

BUT WE REALIZE LIFE ISN'T QUITE THAT SIMPLE...

EXAMPLES

Dr. Jean's Study

There is a longitudinal study of people with a certain genetic disorder, led by an Emory faculty PI, Dr. Jean, who manages all aspects of that program. The protocol's overarching aim is to study various phenotypes and genotypes of this disorder, along with outcomes over time, to inform potential treatment possibilities (any clinical trials would be in separate IRB submissions). The project is now a rich trove of data on this genetic condition.

Dr. Jean wants to add a training grant awarded to someone on her team, that will allow them to collect some additional survey data from their cohort along with a new subanalysis

- **Most likely, this could be added via a modification**

Dr. Jean is asked to Modify her IRB to add a new grant awarded to her colleague in the same department, Dr. Lean.

- Dr. Lean's work needs some of the same data Dr. Jean has collected on her cohort. The specific aims of Dr. Lean's grant do not fully overlap with Dr. Jean's protocol.
- The colleagues would like to avoid burdening the cohort with an additional consent process, so ask to Modify Dr. Jean's IRB.
- Dr. Lean's grant also includes a collaborator from the University of Poukeepsie.

Dr. Lean's Project, continued

- This would make Dr. Jean responsible for the human subjects research on Dr. Lean's grant.
- It would also require the external collaborator to be brought under Dr. Jean's IRB protocol, due to the single IRB review requirement.
- Dr. Lean should have talked to our Reliance Team before grant submission. The project needs a separate IRB submission.
- If Dr. Jean's consent form allowed for storage and sharing for future research, and it would be impracticable to consent the cohort for Dr. Lean's study, the IRB may be able to waive additional consent for Dr. Lean's use of the samples.

An ongoing clinical trial under Dr. Clink has accumulated leftover samples that were collected as part of the trial. The trial's consent form allowed for sharing samples and data with other researchers. The trial was funded by an R01.

Dr. Clink receives an NIH supplement to do some additional analyses.

- Most likely, this can be added as a modification

The trial is a very long one, so Dr. Clink needed to apply for a non-completing renewal that described progress so far and the rest of the plans for the trial

- This can also be added as a modification. Any changes to the research plan must be reflected in a revised protocol document.

A colleague, Dr. Plink, asks Dr. Clink if they can share samples and some data from the trial for Dr. Plink's grant-funded project. The colleague does not need any direct identifiers for this work, just some of the clinical data that accompanies the samples.

- If the Clinical Trial and the new project share personnel, then a new IRB submission is needed

- If the new project does not involve any of the Clinical Trial personnel (even as co-authors), the new project may be "not human subjects" research, and not require IRB review. (The data must not include any HIPAA identifiers.)
  - **Ideally the PI's would consult with IRB at grant submission time, to make sure "Human Subjects" checkbox is accurate**

A faculty member in the Rollins School of Public Health, Dr. Particles, obtained a large data set from CMS that includes health data along with geographical identifiers.

The aim of Dr. Particles' project is to correlate certain types of particulate pollution with health issues across the country.

A trainee in Dr. Particles' lab gets a grant to add analyses related to a new, but similar particulate, and the project aligns with the overall aims of the existing project

- **This is likely acceptable as a modification**

Another PI at Rollins receives a grant to address different aims but leveraging the same dataset.

- This should be a separate IRB submission
- If helpful, Dr. Particles could create an IRB submission specifically for the large dataset, to serve as a **repository** for future research use. Dr. Particles would then oversee requests to use the data, but would not be responsible for overseeing the various projects. She could employ an honest broker model to provide completely deidentified data when possible, so recipients would not need IRB review. (Detailed geographical data would have to be removed.)
- BUT, Dr. Particles and Emory would need to be aware of any data use terms agreed to with CMS before sharing the data with other Emory researchers.

Do's

- Review our guidance at Just In Time stage, **before** starting a submission
- Try to keep clean, separate submissions as much as possible – better for everyone in the long term
- Talk with the IRB if unsure
- Talk with the IRB Reliance Team **before** submitting the grant if there will be external collaborators
- If taking the MOD route, prepare for time for IRB scrutiny
- Create a separate data/specimen repository, if that is what is needed

Don't's

- Don't rely on past precedent or what colleagues say you can do – use current IRB guidance
- Don't panic at JIT stage (normally) – it's OK for the IRB review to take some time
- Don't try to add specific aims/grants to repository protocols
- Don't hesitate to talk to us

QUESTIONS? COMMENTS?

Please let us know what you think of this webinar!

IRB Webinar Feedback Survey