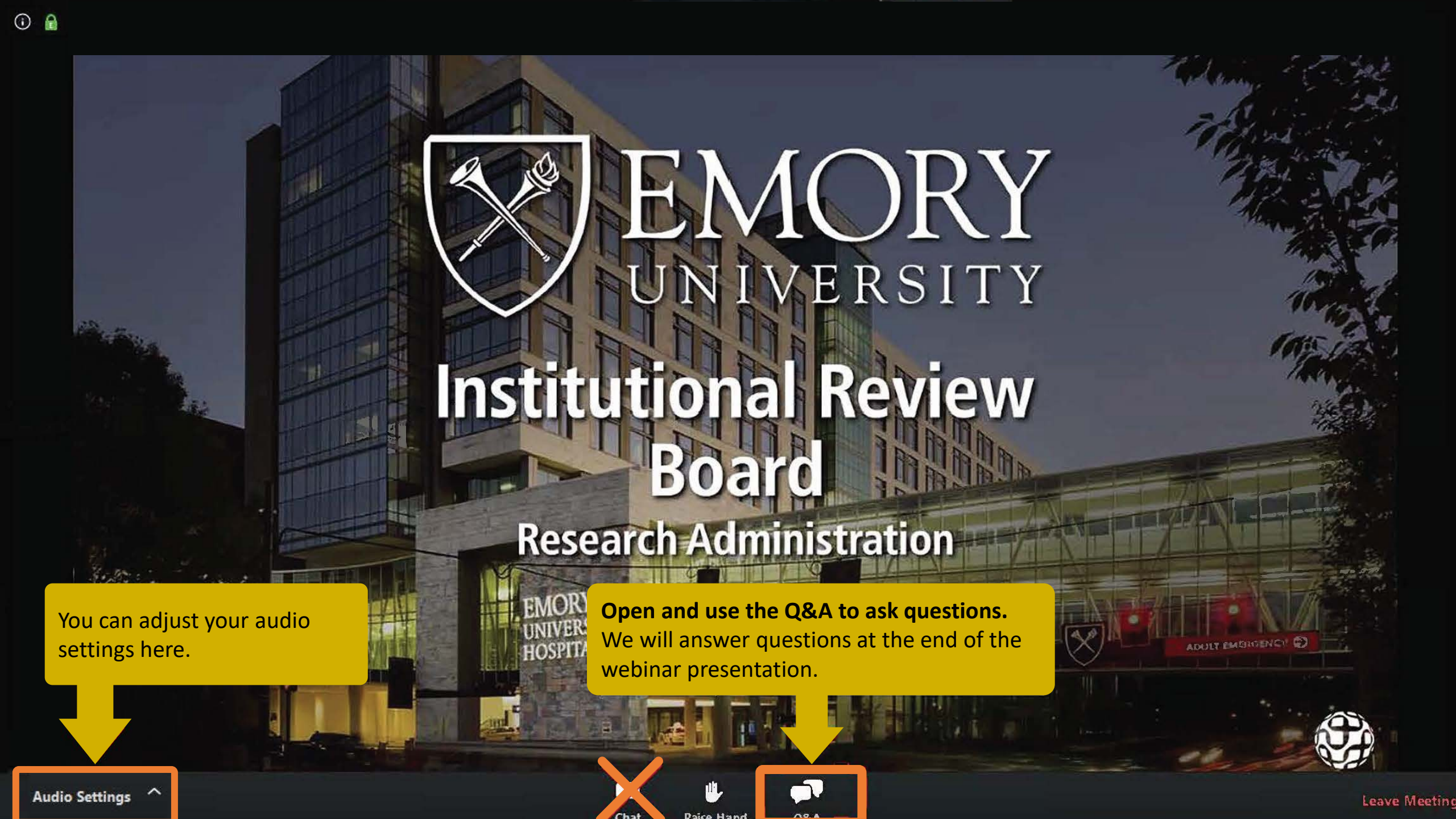
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We will answer questions at the end of the webinar presentation.
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INTERNATIONAL RESEARCH CONSIDERATIONS

EMORY UNIVERSITY IRB WEBINAR

FEBRUARY 13, 2025

TOPICS TO BE COVERED

Initial submission process

Local IRB review vs. Letter of Cultural Context

Local site permission

Translation of study documents

Active enrollment vs. secondary analysis

Collaborative research

Federal Funding

IRB REQUIREMENTS

The Emory IRB, in reviewing Research protocols that will be conducted at a non-Emory site, must have obtained sufficient knowledge about the local research context to ensure that adequate protections are in place for the conduct of the Research in that geographic location.

EMORY IRB POLICIES AND PROCEDURES; CHAPTER 16 LOCAL RESEARCH CONTEXT; RESEARCH CONDUCTED AT NON-EMORY SITES

COMMON ETHICAL AND/OR REGULATORY CODES OF CONDUCT

For international sites receiving federal funding, US regulations allow for adherence to equivalent research codes. They must include at least the requirements of the Common Rule.

US Codes and Regulations:

- Belmont Report
- 45 CFR 46 (the “Common Rule”)
- FDA’s 21 CFR 50 (Protection of Human Subjects)
- 21 CFR 56 (Institutional Review Boards)

International Codes:

- Declaration of Helsinki
- International Conference on Harmonization (ICH/GCP E6)
- Council for International Organizations of Medical Sciences (CIOMS): International Ethical Guidelines for Biomedical Research Involving Human Subjects

https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html

What is the IRB submission and review process at Emory for an international study?

The submission process is the same as it would be for a US-based study. There are, however, additional considerations that you must address in your study documents.

Commonly submitted items for international studies:

- Protocol
- Consents/assents
- Recruitment materials
- Instruments (e.g., surveys)
- Local IRB approval letter or letter of cultural context
- Site permission documentation

Do I need in-country IRB/ethics committee approval?

- If you will conduct your study in collaboration with an in-country institution that has access to an IRB, that IRB must approve the study before you can commence in-country study activities.
- If you will conduct a study that includes any greater-than-minimal risk activities, an in-country IRB or equivalent should approve the study before you can commence in-country study activities.
- If you will conduct a clinical trial of a drug, device, or biologic, an in-country IRB must approve the study before you can commence in-country study activities. You may also be required to submit to the local competent authority in that country to obtain approval to test the drug or device.
- If you have no in-country collaborators that will conduct the research and IRB/ethics committee is not required for you to conduct the research at that location, you only need to submit a letter of cultural context to the Emory IRB.

What are the requirements of a letter of cultural context?

The author should be:

- Unengaged in the proposed study activities,
- Knowledgeable of the cultural landscape of the areas/populations being explored,
- Experienced in conducting human subjects research in the proposed area, and
- An academic, health care provider, humanitarian organization administrator, educational administrator, or governmental official, but it should be someone with an intuitive connection to the population and concepts at hand.

The letter should be:

- On institutional letterhead if applicable, and
- An attestation to the cultural appropriateness of the study protocol, proposed activities, instruments, consent forms, and consent process; this is what we will use as our basis for our review of in-country study activities.

I will conduct an analysis using data, including identifiers, from a non-US source. Does this require in-country IRB review or cultural context letter?

- No. You do not need cultural context or in-country IRB review to conduct a secondary analysis of identifiable data collected outside the US.

I will conduct an analysis using data, including identifiers, from a non-US source. Does this require in-country IRB review or cultural context letter?

- IRB review may take longer due to complex international privacy laws, and legal consult may be needed.
- Data transfer agreements may be needed; consult with Emory's Office of Technology Transfer (OTT).
- Regardless of the data's origins, the IRB will want to ensure that the research use of the data complies with ethical principles, e.g., informed consent, if applicable. HIPAA, however, will not apply.

Will I need to provide documentation of permission to conduct the study from any local sites (i.e., site permission)?

In most cases, yes. If you will enroll or conduct study activities at places like the ones listed below, we usually need to know that you have that place or organization's permission to conduct the study on their premises and/or enroll "their" patients, employees, and/or students:

- Hospitals/clinics
- Schools
- Universities
- Community organizations
- Businesses

If written in a non-English language, you must also provide a translated copy for our review.

What if I will conduct consent discussions and/or research interactions in a non-English language?

- At initial review, we generally ask that study teams not yet submit translated study documents. It is likely that we will request revisions to one or more of these documents.
- Once we approve the English-language versions, we ask that translated **consent forms** (does not apply to other types of documents) be submitted with either:
  - Invoice or statement from certified translator/translation service regarding their translations, or
  - "Back-translations" into English by someone other than the person who performed the forward-translations

- The concepts of minority vs. majority, personal consent, and assent can differ across cultures. Literacy levels and existence of multiple local languages can be important considerations as well. It is the researcher's responsibility to learn the laws and customs regarding permission, consent, and assent. You should speak to these in the protocol and use them to justify any kind of consent/assent processes that differ from our usual processes. We rely on you to provide us with the supporting information.

I will conduct my study in a setting where the concepts of permission, consent, and assent differ from those in the US. What do I need to consider?

I will receive federal funding and collaborate with an in-country institution. What do I need to consider?

If the study is federally funded, and a collaborating international institution is also "engaged" in research, then an OHRP-approved Federalwide Assurance (FWA) for the site may be required *(obtaining this can take extra time)*

- To see if institution has FWA: http://ohrp.cit.nih.gov/search/
- Instructions for filing FWA: http://www.hhs.gov/ohrp/assurances/forms/fwainstructions.html

NOTE: The international site should check OHRP FWA and IRB registrations at least annually to ensure that FWA and registration continue to be in effect.

- If you will obtain data about persons in the European Economic Area (EEA), the General Data Protection Regulation (GDPR) will apply.
- There are stringent rules for the use of personal data collected in the EEA, and you should familiarize yourself with what is allowed under the regulation.
- We recommend familiarizing yourself with the law ***before*** assembling your IRB submission.

I will conduct research that includes collection and/or use of data/specimens from persons in Europe. What do I need to consider?

I will conduct research that includes enrollment of persons in the People's Republic of China. What do I need to know?

- If you will collect data from persons living in China, the Personal Information Protection Law of the People's Republic of China (PIPL) will apply.
- You must notify participants that the Chinese government may have access to study records. The IRB has modular language for this in our consent and protocol templates.
- It is best to consult with the Office of Ethics and Compliance in the early planning stages, as there are many considerations.

I will conduct research under affiliation with The Carter Center and I am not Emory faculty. What do I need to consider?

- There is only one extra step for studies where TCC personnel will act as investigators: there is a “Commitment Statement” that we have these investigators sign. These signed forms would need to be included at the time of initial submission, upon request for revisions to the initial submission, or when adding TCC personnel via modification.

- Complete the **Export Control Assessment Form** to ensure compliance when sending materials and technology outside of the US, or when sharing information with foreign nationals. See our FAQ page for a link to this form.
- Use the **International Project Review Tool** from Emory's Office of Global Strategy and Initiatives can help with other project planning and compliance-related considerations. Contact Chris Rapalje with questions.

What else should I consider concurrently when putting together my IRB submission?

- Start the submission process early! Remember that we might ask for multiple rounds of revisions.
- Confirm whether you and/or in-country partners will be “engaged in human subjects research activities” according to the regulations before creating a submission in eIRB.
- If your study involves federal funding, contact our Reliance Team at irb.reliance@emory.edu to see if they have any suggestions for your submission.
- Always use the current protocol and consent templates posted on our website.

FINAL TIPS & TAKEAWAYS

EMORY IRB WEBSITE RESOURCES

- International Research info and FAQ: https://irb.emory.edu/guidance/research-types/international-research.html
- Engagement Determination tool and Initial submission guidance: https://irb.emory.edu/guidance/getting-started/index.html
- Protocol templates: https://irb.emory.edu/forms/protocol-templates.html
- Consent templates: https://irb.emory.edu/forms/consent/index.html
- Applicable ethical codes: https://irb.emory.edu/guidance/other/index.html

Questions? Comments?

Please let us know what you think of this webinar!

THANK YOU FOR ATTENDING!