#### INSIGHT HUMANS MODULE (IRB) Q&A

OCTOBER 9, 2025



#### LATEST INSIGHT UPDATES

- All new studies should now be submitted in Insight!
- ► Almost all studies have been migrated to Insight and can receive Amendments, Continuing Reviews, etc.
  - Around 96 studies failed the migration process, and IT is working to get them migrated.
- ▶ All Attachments are not yet loaded. That will take another 1-2 weeks.
  - ► WARNING: DO NOT RELY ON "ATTACHMENTS" IN INSIGHT YET, FOR MIGRATED STUDIES. eIRB has the current IRB-approved documents for those studies. Download from there as needed until further notice. Use eIRB versions as basis for Amendments in Insight.
- Expiration dates may still appear incorrectly, Insight team is working on a solution, and an update will be provided when it is received
- eIRB is now closed to all new activity. You can still view your studies, however, and download documents if needed, until sometime in February. After that, un-migrated records will be available in an archive.
  - ► There are a small number of RNIs in eIRB that will be finalized in eIRB and not migrated into Insight.

# DIFFERENCES BETWEEN EIRB AND INSIGHT

- PI sign-off required for ALL submissions and resubmissions
- ► All attachments now in one place
- Requested changes are in comment bubbles on the forms themselves and require responses to each before submitting back
- CITI is validated automatically including which type of course (biomedical vs sociobehavioral)
- Withdraw = Discard permanently
- ▶ Different submission types for Emory review protocols vs. external (ceded) IRB, cannot change between them
- Staff updates are accepted as soon as PI signs off (no IRB review process)
- Studies that don't require "Continuing Review" do require "Expedited Check-In" and studies are automatically closed if you don't respond



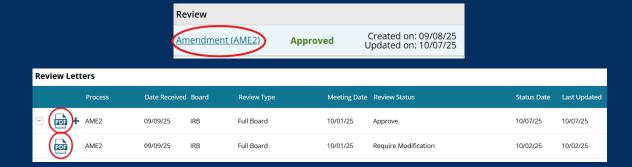
# DIFFERENCES BETWEEN EIRB AND INSIGHT

- Study ID not assigned until submitted
- ► There will no longer be a specific IRB analyst for a specific study; when transactions are submitted, they will be assigned to the next available analyst in a rotation
- ► The ability to define who receives notifications from the system ("Contact" checkbox) and who can transact and edit submissions ("Manage" in permission) vs view only ("View" in permission)
- Conflict of Interest disclosures are in the PI sign-off activity completed in the Investigator Disclosure, part II form
- Consent forms have a separate Version Date field in the Insight system that must be added after they are uploaded
- Not all submissions need protocol attachments
  - Chart reviews, Exemptions, secondary data analysis
  - ► REMINDER: Chart reviews cannot be determined exempt at Emory – Do not select D4 in Study Overview for these studies
- Automatic reminders are sent to the owner of outstanding tasks (e.g. Pl sign off, ancillary review) every 7 days until the action is complete
- ▶ Do not add external users to the list of study staff in the staff form, instead use the external team member spreadsheet on our <u>website</u> and include in the attachments section (same as eIRB)



# ACCESSING APPROVED CONSENT FORMS AND LETTERS

- To access approval letters, select the transaction on the right side of the workspace (IR letters are accessible in main study workspace)



- Stamp-approved consent forms are accessible on the main study page for a study



#### RESOURCES

- Insight System Help Most up-to-date information regarding Insight Humans Module, this page also includes instructions on how to update migrated studies in Insight
- Insight SharePoint website Access training videos and job aids for Humans and other modules
- ► To find the latest templates required for submissions:
  - Protocol Templates
  - Consent Toolkit

#### SHARE YOUR THOUGHTS ON INSIGHT FORMS!

