Relying on WIRB: Process Review

March 14, 2019

Objectives of this Presentation

- WIRB Relationship with Emory IRB
- WIRB Process
- Common Questions
- Resources
- Your Questions

WIRB Relationship with Emory IRB

- [WIRB](#) is the biggest commercial IRB in the world.
- Emory started its relationship with WIRB in 2007.
- We updated the submission process in 2016 and the informed consent process in 2018
- All new drug and device clinical trials that are industry-designed, -initiated, and -sponsored are sent to WIRB for review (with select exceptions). See http://www.irb.emory.edu/forms/external-irbs/WIRB.html.
- We also use WIRB as our IRB when we're asked to serve as the single IRB of record for multisite studies, per NIH mandate. Note that this needs to be included in the study budget. See the main [Collaborative Research page](#), under "NIH Single IRB Policy."
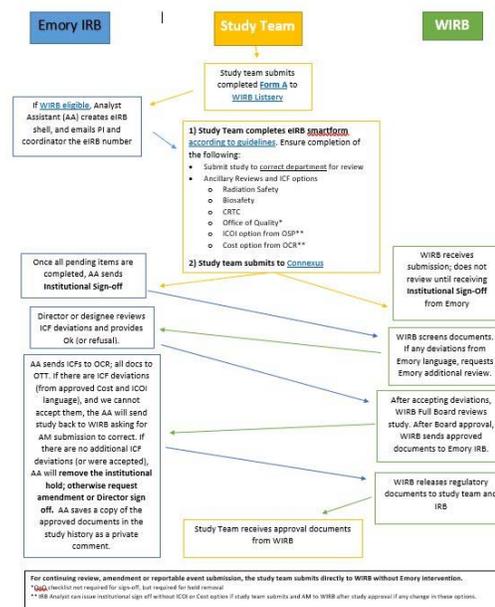
WIRB Process: Overview

Chart on our website under: http://www.irb.emory.edu/forms/external-irbs/WIRB-Flow-Chart.pdf

WIRB Process: Eligibility Verification

Form A Process

- Study Team fills out Form A, and emails it to our WIRB-listserv at wirb-l@listserv.cc.emory.edu
- If WIRB-eligible, the IRB Analyst Assistant (AA) will create an eIRB shell and email the link and instructions to the study PI and coordinator (as listed in the form)
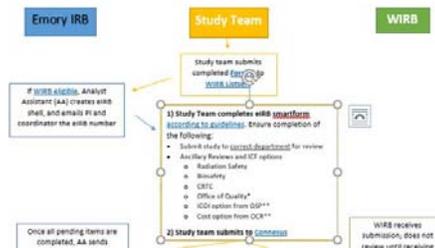
WIRB Process: Emory eIRB

Completion of eIRB smartform

- Study team completes and submits the abbreviated eIRB form according to our guidelines.
- **Review the instructions carefully to prevent delays.**
- Ensure completion of the following:
  - ✓ Submit study to the **correct department** for dept. review
  - ✓ Choose ONLY the correct ancillary review triggers (Radiation Safety, Biosafety, CTRC, Office of Quality)
  - ✓ Route study through EPEX to ensure Emory IRB will receive consent language options from OTT and OCR

Completion of eIRB smartform

WIRB Process: Emory eIRB

- The eIRB shell defaults to "IRB" as department approver: Must Edit This
- Select the appropriate department from spreadsheet on Emory IRB website

WIRB Submission in Connexus

WIRB Process: Submission to WIRB

Study team submits to WIRB via Connexus

- Should be **done in parallel** with eIRB submission (after eligibility verification)
- Will need to request an account first time at https://connexus.wcgclinical.com/Default.aspx

WIRB Process: Emory Institutional Sign-Off

Institutional Sign Off process

- WIRB will not review until they have Emory IRB "institutional sign-off" that Emory's specific requirements have been met
- Must be an email with certain language from specified members of IRB staff
- Indicates that all ancillary approvals are complete and provides consent form language options
- Office of Quality not required for this step
- You can request sign-off prior to consent form option confirmation, but AMENDMENT MAY BE NEEDED if incorrect (costs $$ so advise sponsor)

WIRB Process: WIRB Review

WIRB Review and Consent Language Deviations

- WIRB screens submission and corresponds with Study Team and Sponsor as they review, just like any other IRB
- If Sponsor requests edits to Emory consent form language, WIRB alerts Study Team and Emory IRB (via CC) saying that Emory IRB review and sign-off is required for deviations
- **Emory IRB Staff review deviations only when asked by WIRB, after WIRB has screened the consent forms**
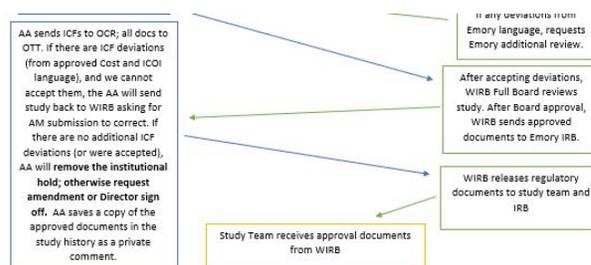
WIRB Process: Post WIRB Approval

Release of Institutional Hold

- After WIRB approves your study, it automatically goes to "Institutional Hold"
  - Sponsor may also request a post-approval hold to review documents
- Emory IRB receives approval documents and sends to OTT and OCR so their process not delayed
- Emory IRB verifies correct consent form language
- Also checks Office of Quality approval
- If no issues, Emory IRB staff emails WIRB (copies Study Team) to remove hold
  - Sponsor hold may still be in place

WIRB Process: Post WIRB Approval

Release of Institutional Hold - cont.

- If there are consent form issues, Director determines if acceptable
- If not, you will be required to submit an amendment to WIRB.

AA sends ICFs to OCR; all docs to OTT. If there are ICF deviations (from approved Cost and ICOI language), and we cannot accept them, the AA will send study back to WIRB asking for AM submission to correct. If there are no additional ICF deviations (or were accepted), AA will **remove the institutional hold; otherwise request amendment or Director sign off.** AA saves a copy of the approved documents in the study history as a private comment.

If any deviations from Emory language, requests Emory additional review.

After accepting deviations, WIRB Full Board reviews study. After Board approval, WIRB sends approved documents to Emory IRB.

WIRB releases regulatory documents to study team and IRB

Study Team receives approval documents from WIRB

Common Questions

What if I submitted a study to Emory IRB, instead of WIRB, by accident?

- Emory IRB will likely catch when a newly submitted study should have gone to WIRB instead and ask you via email why it did not (e.g., was there investigator conflict of interest?). If there was no reason, we'll ask that you start your WIRB submission (see steps below).

- Do not worry! Your eIRB efforts will not be wasted! We can just rename your Emory eIRB submission (preface the title with "WIRB") and do our local administrative review.

Common Questions

What forms do I need for a WIRB submission?

- Form A (WIRB Eligibility Checklist) (ver. 11-20-2018). No study may be submitted to WIRB until Emory IRB has verified WIRB-eligibility via this checklist. Save a copy in your desktop before completing.

- WIRB Emory Consent Checklist
  - This checklist will be required for every study you submit to WIRB, whether you choose to utilize WIRB's consent-merging process or merge the Emory language into the master template yourself.
  - **Note on "Costs" language:** if you choose to submit your study before the Emory IRB has verified the correct "Costs" language, please use Option#2 which is the most commonly selected (unless you have other reason to know the likely Option choice, e.g. very similar prior study with same Sponsor). **For "Injury" language:** you can ask the Sponsor what they believe the most likely Option will be or base your guess on past experience.

Common Questions

What forms do I need for a WIRB submission? cont.

- WIRB Smartform Guidance (ver. 9-27-16). This shows what parts of the Emory eIRB smartform must be completed to allow Emory IRB to provide our administrative sign-off to WIRB.

- WIRB Investigator Handbook Guide for researchers (version 4.30, released on 8/17/2017)

- WIRB Promptly Reportable Information form (version 2.0.0, released on 8/19/2016)

Common Questions

Has WIRB complied with the Revised Common Rule?

- WIRB has a new Initial Review Submission Form as of January 2019. This form replaces any previous forms. The changes to the form include new common rule requirements, ascetics, and Board ease on reviewing the information. To see the changes in the form, go here: http://www.irb.emory.edu/forms/external-irbs/wirb.html#collapse9

Common Questions

What do I need to know about consent and HIPAA authorization documents?

- Emory and WIRB are no longer using the Emory/WIRB consent template we previously posted here. For efficiency and to reduce errors, WIRB now requires Emory's language to be **inserted into the Sponsor's master template.**

- For more information about how to create the consent/HIPAA form for your study, please go here: http://www.irb.emory.edu/forms/external-irbs/wirb.html#collapse10

Common Questions

My CRO is asking me for a current list of study staff as approved with WIRB. How can I obtain that list?

- WIRB has advised emailing a list of current staff members to client services or Christopher Gennai directly (see information below), asking them to confirm its accuracy. WIRB will email you back confirming the personnel listed in your list.

Resources

- Emory WIRB Contacts
  - WIRB Listserv
  - One of the Analyst Assistants listed on the IRB Staff webpage
  - Maria Davila (Team Lead) at maria.davila@emory.edu

- WIRB Contacts
  - Christopher Gennai, CIP (Senior Account Manager, Institutions)
    - Office: (800) 562-4789
    - Fax: (360) 252-2498
    - Email: cgennai@wirb.com
  - Deena Horowitz (Account Manager, Institutions)
    - Office: (360) 252-2442
    - Email: dhorowitz@wirb.com

- Our website: http://www.irb.emory.edu/forms/external-irbs/wirb.html

Your Questions