



## **NEW IRB SUBMISSIONS**

Tips for getting your submissions processed more efficiently

*IRB Webinar- February 12, 2015*

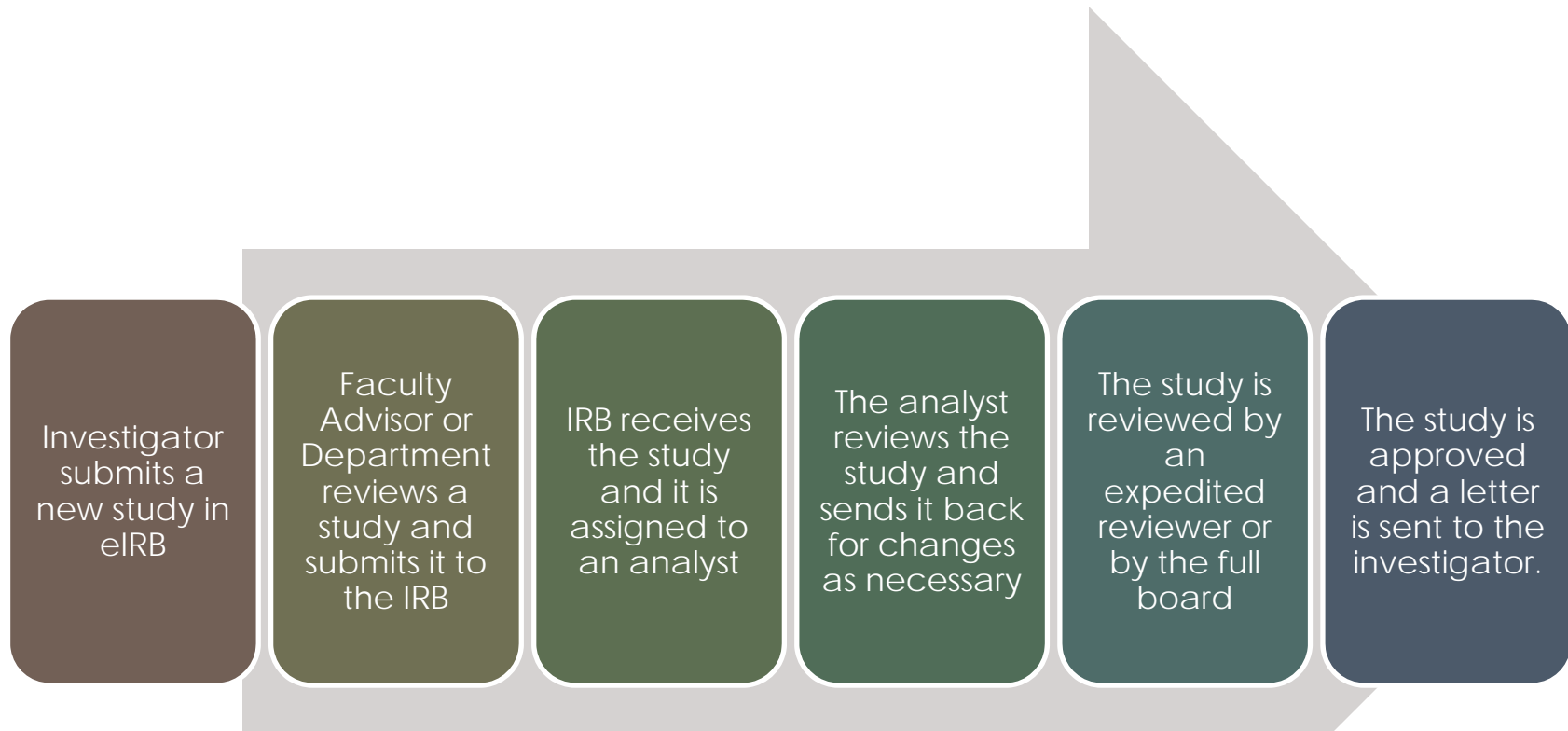
## DISCLOSURE!

The goal of this webinar is to give you additional information you may need during your submission process. For a detailed guide of how to navigate eIRB please refer to our instructional videos at:

<http://www.irb.emory.edu/training/videos.html>



# OVERVIEW OF THE PROCESS



## TIPS TO GET FROM SUBMISSION TO APPROVAL

- In addition to the documents provided, you should be aware of other Emory requirements.
- When working with the Atlanta VA, Children's Hospital of Atlanta (CHOA) , St. Joseph's or Grady, please consider that they may have extra requirements that must be completed before you may start your study, even if approved by the Emory IRB.
- If working on an international CT, you may need to look for other information prior to submission.

Let's look at different scenarios....



## MAYBE YOU DO NOT NEED IRB REVIEW!

- We had a previous webinar about this process. You can access it at this link:  
<http://emory.adobeconnect.com/p2qloyczz48/>
- BUT! We just want to give you a link to our tool that helps you determine if you need IRB review or not.
- You can find the tool here:  
<http://www.irb.emory.edu/forms/NHSRform.php>



## COLLABORATIVE INSTITUTIONS

- For situations where one of the sites is from an Emory collaborative institution, such as the VA, CHOA, St. Joseph's, or Grady please note the following...



## GRADY STUDIES

- IRB approved studies conducted at Grady need to be approved by the Research Oversight Committee (ROC) before you may start the project.
- If this is an expedited study, and you want to make the ROC meeting on time, please let us know and we might be able to review your study before the meeting takes place.
- Forms for ROC can be found here:  
<http://www.gradyhealth.org/static/office-of-research-administration>



## VA STUDIES

- Similar as in Grady studies, VA studies should be approved by the Research Development Committee (RDC) after approval by the Emory IRB.
- To conduct a study at the Atlanta VA, you will need to have in your team a PI (or Co-I) with a VA appointment.
- Physicians may obtain an appointment by being sponsored by a clinical division and privileges through the VA Medical Center Chief of Staff's Office.
- For more information, visit this link:  
<http://www.atlanta.va.gov/services/research/Investigators.asp>





## CHOA STUDIES

- CHOA has an IRB but we may review studies conducted at CHOA per our agreement.
- The CHOA IRB will review studies under a CHOA PI (no Emory appointment), even if the study also has Co-Is affiliated with Emory; or studies done with CHOA medical records.
- Prior to submitting, make sure your study needs Emory IRB review, to avoid delays.



## ST. JOSEPH'S & JOHN'S CREEK

- If doing research in these facilities, please choose them as a site in your IRB submission.
- If using a lease space (like the Emory Clinic at St. Joseph), select other.
- You need a PI or Co-I associated with this location as part of your study team.
- You are required to obtain SJHC ROC approval to verify institutional appropriateness and/ or compliance with the Catholic directives before study can begin at SJHC/John's Creek.
- We cannot approve your study until SJHC ROC approves your study.



## CLINICAL TRIALS

- If your CT is being conducted at Emory Healthcare, you need to comply with the Office of Quality standards.
- You may need to submit to the OoQ additional forms that can be found here:  
<http://irb.emory.edu/forms/clinical.html>
- The forms are required so the IRB can release your approval documents.
- We do not review these forms. For questions, please contact Laura Deane at  
[laura.deane@emoryhealthcare.org](mailto:laura.deane@emoryhealthcare.org)



## CLINICAL TRIALS

- If using a drug or device, the PI should ensure that the use is done under the currently FDA approved indication.
- If not, the drug or device may need an IND or IDE.
- An investigator holding a IND or IDE is a “sponsor” under federal regulations, and therefore need to comply with additional requirements.
- For more information, please refer to this guidance:  
<http://www.irb.emory.edu/documents/guidance-EmorySI.pdf>



## CLINICAL TRIALS

- For international clinical trials, please make sure you are following the research country laws.
- We recommend to contact Kris West, who can refer you to General Counsel. They will review the international laws you need to follow for a fee.
- In addition, you may need to hire a CRO (monitor).
- The Emory IRB may approve your study as long as it complies with all the above-explained requirements.



## CLINICAL TRIALS

- If you are conducting a new Phase IIb/ III/IV drug or analogous device studies that are industry-designed, industry-initiated, and industry-sponsored, your study will be reviewed by WIRB
- WIRB? WIRB is a commercial IRB that is not affiliated with Emory University. Learn more at [www.wirb.com](http://www.wirb.com)
- For more information about the process of submitting your study via WIRB, please follow this link:  
[http://www.irb.emory.edu/forms/external-irbs/WIRB\\_faq.html](http://www.irb.emory.edu/forms/external-irbs/WIRB_faq.html)



## SOCIO-BEHAVIORAL STUDIES

- The majority fall under the expedited, exempt or NHR categories.
- For information about these categories, please see the following:  
<http://www.irb.emory.edu/documents/Pyramid%20shb.pdf>
- If working under the School of Public Health, you are required to use an informed consent form including HIPAA language.



## INTERNATIONAL NON-CLINICAL TRIALS

- For international research (not CT), you may need to submit proof of the approval of your study from the local ethics committee or a letter of cultural context.
- For international research, HIPAA rules will not apply unless identifiable data will be brought back to the US for analysis.
- Find templates for the documents we required at this link:

<http://www.irb.emory.edu/forms/socio.html>





# CHART REVIEW

- Reviewed under the exempt or expedited review categories
  - Consider if you really need to record names, addresses, dates, etc. Exempt review may be an option if not!
  - Our reviewers will decide what category may apply for your study
- For prospective chart reviews (reviewing charts for subjects enrolled actively), you may need to obtain informed consent.



## RESEARCH WITH EMORY STUDENTS DATA

- As you may know, HIPAA applies for studies done under the covered entity.
- If a study is done solely at a student clinic (not under the covered entity), HIPAA may not apply but FERPA.
- What is FERPA? The Family Educational Rights and Privacy Act is a Federal law that protects the privacy of student education records.
- For questions, please contact our office or Kris West.



## A WORD ABOUT CONSENT FORMS!

- Make sure you use an Emory IRB template. Without our template, we will be unable to stamp your form after approval.
- If you are conducting your study at CHOA, VA, St. Josephs or Grady, you need to use the appropriate ICF template.
- You can find these documents at this link:  
[http://www.irb.emory.edu/forms/consent\\_toolkit/index.html](http://www.irb.emory.edu/forms/consent_toolkit/index.html)



## IRB CONTACT INFORMATION

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QUESTIONS?

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