

RELIANCE AGREEMENTS AND EXTERNAL IRBS: A PRACTICAL GUIDE TO COLLABORATIVE RESEARCH



EMORY
UNIVERSITY

Institutional Review Board
Research Administration



Children'sSM
Healthcare of Atlanta

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JULY 12, 2019

OBJECTIVES

- KEY TERMS
- WHEN A RELIANCE AGREEMENT IS APPROPRIATE
- SINGLE IRB REQUIREMENTS FOR FEDERAL STUDIES
- WHAT HAPPENS WHEN EMORY AND CHILDREN'S IS SERVING AS THE REVIEWING IRB FOR ANOTHER INSTITUTION?
- WHAT HAPPENS WHEN EMORY AND CHILDREN'S IS RELYING ON ANOTHER INSTITUTION?
- QUESTIONS

KEY TERMS

- REVIEWING IRB (ALSO CALLED THE “IRB OF RECORD”)
- RELYING IRB OR INSTITUTION
- CENTRAL IRB (FORMERLY “COMMERCIAL IRB”)
- RELIANCE AGREEMENT (ALSO CALLED AN “INSTITUTIONAL AUTHORIZATION AGREEMENT” OR IAA)
- MASTER AGREEMENT OR UMBRELLA AGREEMENT
- MEMORANDUM OF UNDERSTANDING (MOU)
- LOCAL CONTEXT

The Four Parties...



ENGAGEMENT IN HUMAN SUBJECTS RESEARCH

THE SITES MUST BE ENGAGED IN HUMAN SUBJECTS RESEARCH.

SITES THAT ARE NOT ENGAGED IN HUMAN SUBJECTS RESEARCH DON'T REQUIRE IRB REVIEW AND THUS WOULD NOT REQUIRE A RELIANCE AGREEMENT TO RELY ON ANOTHER INSTITUTION FOR IRB REVIEW.

OHRP GUIDANCE: [HTTPS://WWW.HHS.GOV/OHRP/REGULATIONS-AND-POLICY/GUIDANCE/GUIDANCE-ON-ENGAGEMENT-OF-INSTITUTIONS/INDEX.HTML](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html)

[ENGAGEMENT DETERMINATION CHECKLIST ON COLLABORATIVE RESEARCH WEBPAGE UNDER THE "WHAT IS COLLABORATIVE/MULTI-SITE RESEARCH?" TAB](#)

- RESEARCHERS MUST BE EMPLOYEES OR AGENTS OF THE INSTITUTION.
- RESEARCHERS MUST BE DOING AT LEAST ONE OF THE FOLLOWING ACTIVITIES:
 - *ENROLLING/CONSENTING SUBJECTS*
 - *ADMINISTERING A STUDY INTERVENTION*
 - *INTERACTING WITH HUMAN SUBJECTS*
 - *ACCESSING IDENTIFIABLE INFORMATION*
 - *RECEIVING THE DIRECT FUNDS THROUGH A GRANT/AWARD*

WHAT DO THE REGS SAY?

OHRP:

“Cooperative research projects are those projects...which involve more than one institution. ...[An] institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.”

45 CFR 46.114

FDA:

“...institutions involved in multi-institutional studies may use joint review, reliance upon the review of another qualified IRB, or similar arrangements aimed at avoidance of duplication of effort.”

21 CFR 56.114

THE CURRENT REGULATORY LANDSCAPE

NIH SINGLE IRB MANDATE:

As of January 2018, all **multi-site NIH grant proposals** required the submission of a Single IRB Plan naming which institution would serve as the IRB for all participating sites. Some exceptions apply.

SINGLE IRB COMMON RULE REQUIREMENT:

As of January 21, 2019, the New Common Rule is in place. All **federally-funded multi-site studies** which 1) receive IRB approval after that date or 2) transition to the New Common Rule are required to use a single IRB by January 2020.

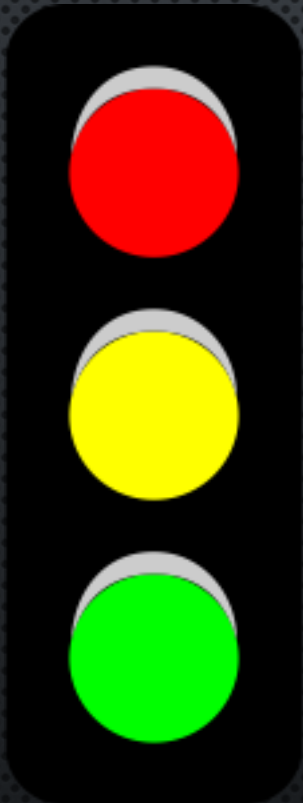
If you are submitting a federal or NIH grant application....

You should follow the process (on Emory's website or email the Children's IRB) for identifying a single IRB. Visit our Collaborative Research webpage under the "NIH and Federal Single IRB Requirements" tab.



YOU SHOULD NOT send a grant application in without consulting with Emory or Children's IRB about your Single IRB Plan and without getting a single IRB quote to include in your budget.

WHAT IF I NEED A RELIANCE AGREEMENT FOR A BRAND NEW STUDY?



For NIH/federally-funded studies, **STOP**. Your project should have already gone through the IRB's process for NIH and federal grant proposals. If it didn't, contact the IRB Reliance Listserv for Emory investigators or email the Children's IRB for Children's Investigators.

For other brand new multi-site studies, we generally do not agree to serve as Reviewing IRB or rely on another Reviewing IRB unless it is required by the sponsor.

For brand new collaborative studies, we are more open to serving as the Reviewing IRB or relying on another Reviewing IRB.

If you want a reliance agreement for a brand new study, submit a [Reliance Request Form](#) to the Emory IRB Reliance Listserv as instructed on the Collaborative Research webpage under the "[How Do I Request a Reliance Agreement for a Brand New Study?](#)" tab. For Children's, enter the study into eIRB.

DO I NEED THE EMORY IRB, CHILDREN'S IRB OR BOTH TO BE INVOLVED?

FOR STUDIES WHERE EMORY AND CHILDREN'S ARE BOTH ENGAGED, FOLLOW THE FLOWCHART ON THE EMORY WEBSITE HERE: [HTTP://WWW.IRB.EMORY.EDU/FORMS/EXTERNAL-IRBS/INDEX.HTML](http://www.irb.emory.edu/forms/external-irbs/index.html) UNDER THE "CHOA INVOLVEMENT" TAB.

FOR FEDERALLY-FUNDED STUDIES WHERE WE ARE REQUIRED TO RELY ON AN OUTSIDE SINGLE IRB, SEND A RELIANCE REQUEST TO EMORY IRB ONLY.

- EMORY IRB WILL EXECUTE ONE RELIANCE AGREEMENT WITH THE OUTSIDE SINGLE IRB ON BEHALF OF EMORY AND CHILDREN'S.
- EMORY IRB WILL INCLUDE CHILDREN'S IRB IN ANY COMMUNICATIONS TO THE OUTSIDE SINGLE IRB.
- DEPENDING ON THE DETAILS OF THE STUDY, YOU MAY HAVE TO COMPLETE A LOCAL EXTERNAL IRB SUBMISSION AND RECEIVE INSTITUTIONAL SIGNOFF FROM EMORY, CHILDREN'S, OR BOTH.

WHAT IF I NEED A RELIANCE AGREEMENT FOR AN ONGOING STUDY?

Criteria:

1. Emory or Children's IRB has already approved a study.
2. Now you're adding non-Emory/Children's collaborators or sites to that study.
3. You'd like Emory or Children's IRB to serve as the Reviewing IRB for the other collaborators or sites.

For Emory: Submit an Ongoing Emory-Approved Reliance Request Form to the study's assigned analyst via email. That form is on the Collaborative Research webpage under the "What If My Ongoing Study Now Needs an External Site or Non-Emory Study Team Members or Sites Added?" tab.

For Children's: Make the modification to the study in eIRB. If an external team member is added, indicate their place of employment.

With your Reliance Request Form, your analyst will have to determine...

- Whether the non-Emory collaborators are acting as "agents" of another institution or organization
- Whether the collaborators' activities "engage" them in human subjects research under the regulations
- Whether reliance is appropriate based on the details of the study

WHAT IF A NETWORK OR CONSORTIUM REQUIRES ME TO USE A SINGLE IRB FOR ALL OF THEIR STUDIES?

In order for Emory to act as a participating site in a particular network or consortium, Emory must rely on the single IRB chosen for the network or consortium.

Submit a [Network/Consortium Request Form](#) to the IRB Reliance Listserv as instructed on the Collaborative Research webpage under the [“What If a Network or Consortium Requires the Use of a Single IRB?”](#) tab.

It's possible we've already agreed to rely on another IRB for the network/consortium. We have a table of our umbrella agreements on the Collaborative Research webpage under the [Umbrella Agreements/MOUs](#) tab.

You may be asked to have us sign a Letter of Support stating we'll rely on the chosen single IRB as part of your application to become a participating site. If this is the case, send your Network/Consortium Request Form as instructed along with the Letter of Support template so that we can provide that for you.

THE RELIANCE PROCESS AT
EMORY...

Step 1

Study Team Sends Reliance Request Form to IRB Reliance Listserv



Step 2

eIRB Submission for Emory only



Reliance Agreement Negotiation and Execution

Step 3



EMORY REVIEWING.....

Emory study team receipt of Local Context Worksheet and Site-Specific Consent/HIPAA form(s) from Relying Site Study Team

Step 6

Emory study team supply of site/amendment approval letter and approved site-specific documents to Relying Site Study Team

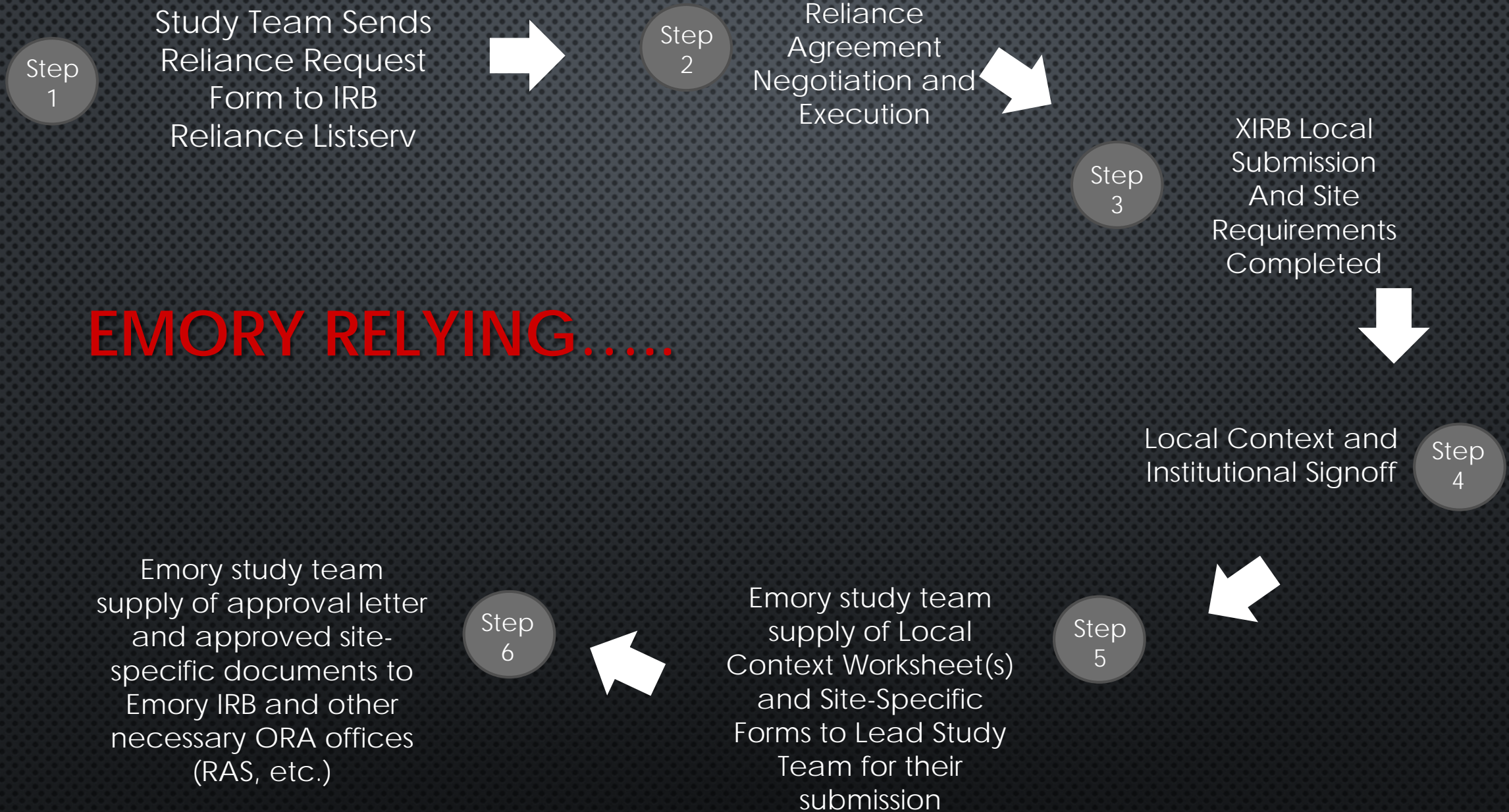


Step 5

Emory study team submission of Amendment to Onboard Participating Site

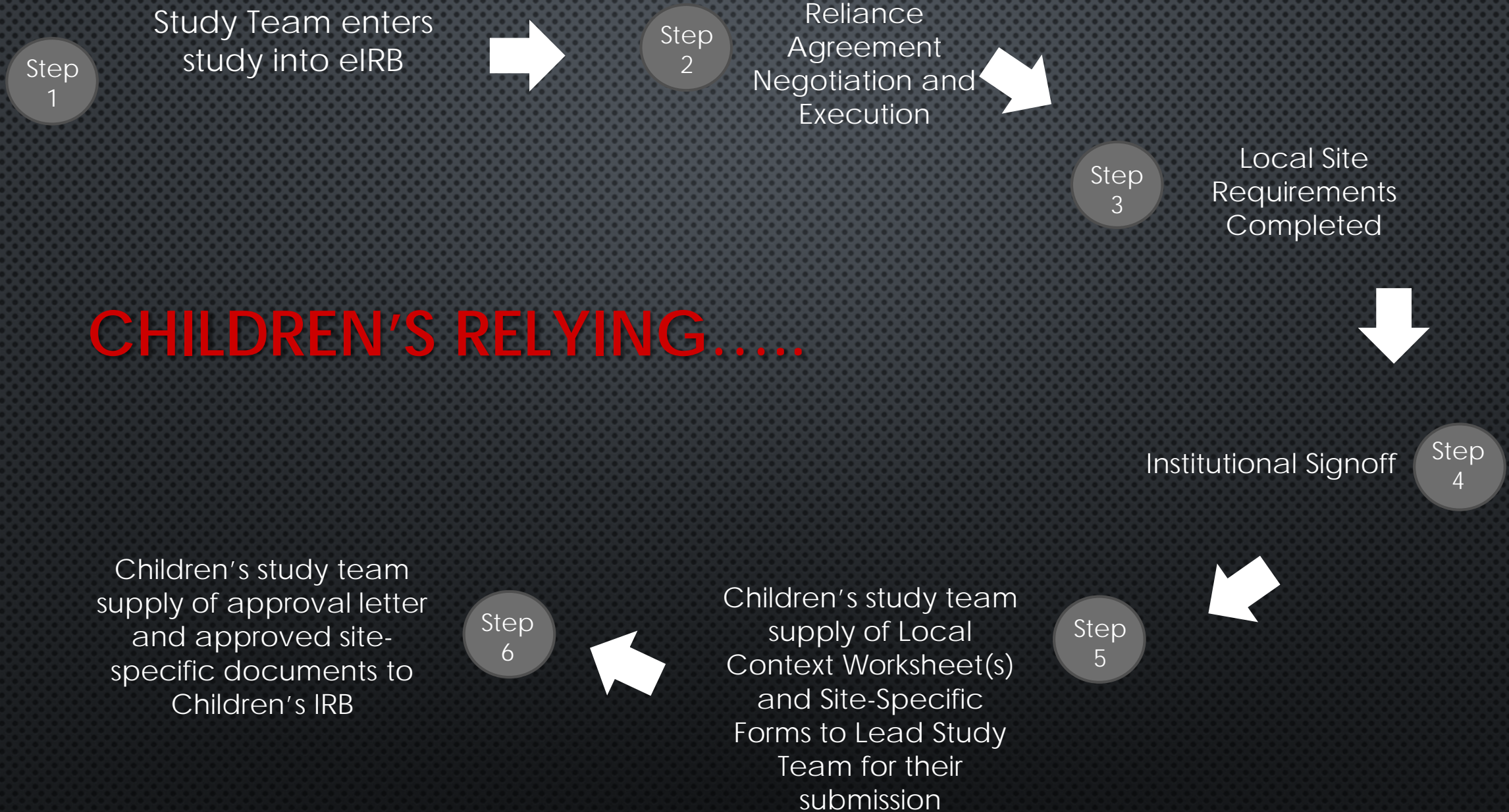


Step 4



CHILDREN'S REVIEWING.....

Use Central IRB



INFORMED CONSENT

- REVIEWING STUDY TEAM CREATES:

- MODEL/MASTER CONSENT TEMPLATE
- REVIEWING/LEAD TEAM'S LOCAL VERSION BASED ON MODEL/MASTER CONSENT TEMPLATE

- RELYING STUDY TEAM CREATES:

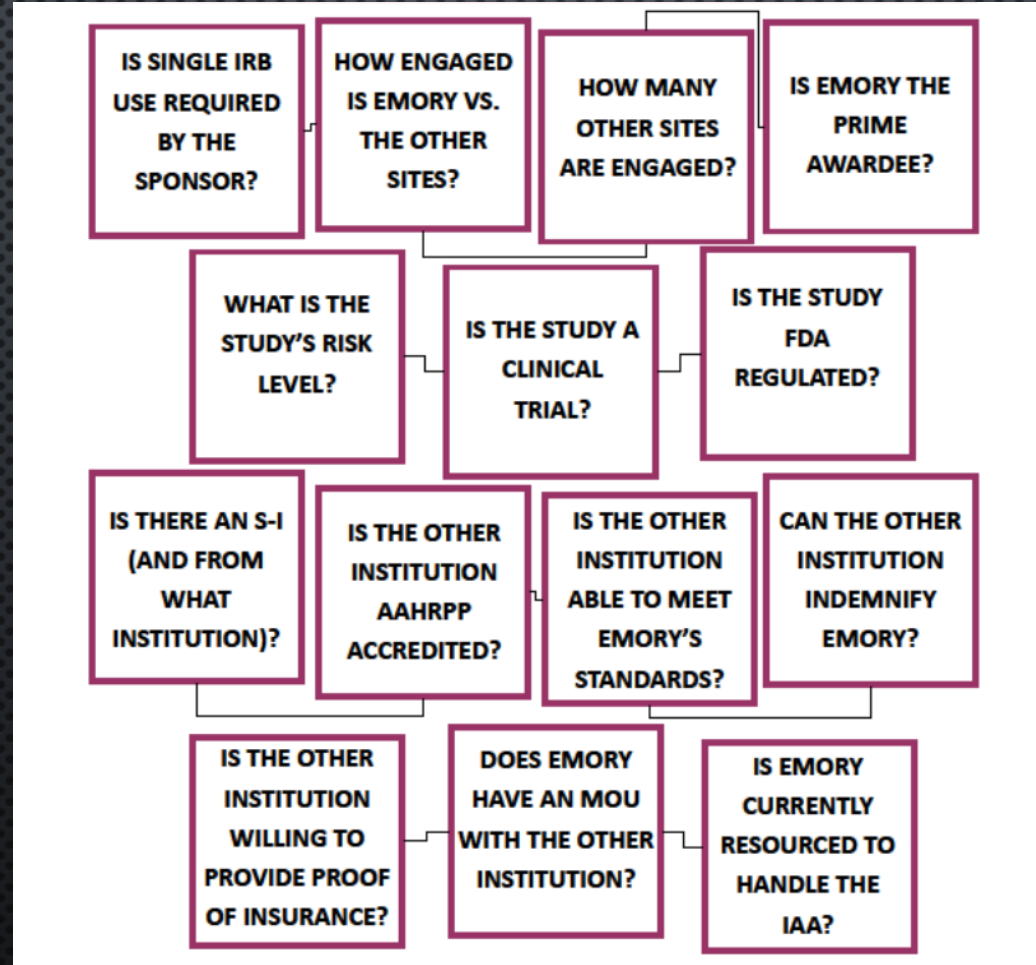
- RELYING TEAM'S LOCAL VERSION BASED ON MODEL/MASTER CONSENT TEMPLATE, PLUGGING IN EMORY SITE-SPECIFIC PROVISIONS IN CERTAIN PLACES

*WHERE EMORY IS RELYING, WE HAVE AN XIRB CONSENT CHECKLIST TOOL ON THE WEBSITE TO HELP YOU FIGURE OUT WHICH SITE-SPECIFIC PROVISIONS MUST BE ADDED BASED ON YOUR STUDY DETAILS

*WHERE CHILDREN'S IS RELYING, THE IRB WILL ADD LANGUAGE WHERE APPROPRIATE BASED ON THE SUBMISSION IN eIRB

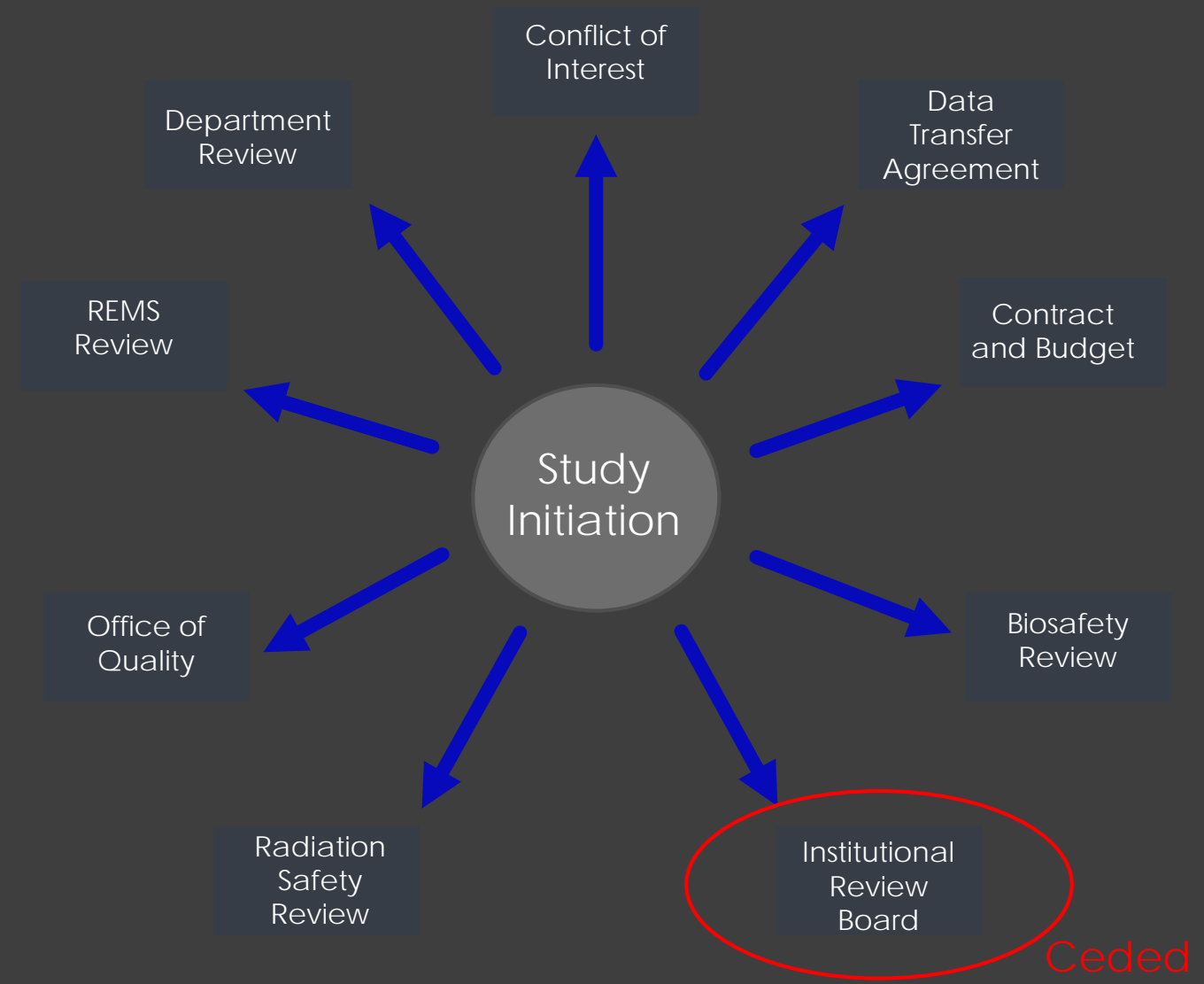
FAQS...

WHAT FACTORS DOES EMORY OR CHILDREN'S IRB USE TO DETERMINE WHETHER WE WILL ENTER INTO A RELIANCE AGREEMENT?



WHY DO I NEED A LOCAL SUBMISSION?

- WHEN EMORY OR CHILDREN'S CEDES REVIEW, THE ONLY COMPONENT THAT MOVES TO THE OTHER INSTITUTION IS IRB REVIEW.
- EVERYTHING ELSE REMAINS AT EMORY OR CHILDREN'S.
- EVEN THOUGH IRB REVIEW IS CEDED, THE IRB IS STILL RESPONSIBLE FOR SOME ASPECTS OF REVIEW (E.G. INVESTIGATOR TRAINING, LOCAL CONTEXT, SOMETIMES HIPAA PRIVACY REVIEW).
- WE ALSO NEED A RECORD OF THE STUDY TO MAINTAIN INSTITUTIONAL ACCREDITATION.



ACCESS TO EMORY OR CHILDREN'S PATIENTS, DEPARTMENTS, OR RECORDS

In order for Emory or Children's to be "engaged", Emory or Children's personnel have to be involved in one of the following activities:

- Enrolling/consenting subjects
- Doing data analysis with identifiable information
- Having some other access to identifiable information
- Administering study interventions/handling study interactions
- Emory or Children's receiving the direct award

If Emory or Children's is not engaged in the research but an external site wants to gain access to Emory or Children's patients, departments, or records for their human subjects research:

- They should NOT go through the Emory or Children's IRB or seek a reliance agreement. Instead, they should pursue IRB review at their own institution.
- They should request "site permission" by contacting the Emory or Children's department directly.

WHAT IF THERE IS A CHANGE TO THE STUDY?

WHETHER A CHANGE TO THE OVERALL STUDY OR TO JUST ONE OF THE SITES....



THE LEAD/REVIEWING INSTITUTION STUDY TEAM IS RESPONSIBLE FOR SUBMITTING AMENDMENTS FOR 1) THE OVERALL STUDY, 2) LEAD STUDY TEAM-SPECIFIC CHANGES 3) ANY PARTICIPATING SITE CHANGES.

THE RELYING SITE STUDY TEAM IS RESPONSIBLE FOR PROVIDING ANY NECESSARY INFORMATION OR DOCUMENTATION TO THE LEAD/REVIEWING INSTITUTION STUDY TEAM FOR THE SUBMISSION.

NOTE: IF EMORY OR CHILDREN'S IS RELYING ON AN EXTERNAL IRB, NO AMENDMENTS NEED TO BE SUBMITTED HERE.

IF THE AMENDMENT TRIGGERS NEW ANCILLARY REVIEWS, THE REVIEWING IRB MAY REQUIRE YOU TO CONTACT US FOR A NEW LOCAL CONTEXT REVIEW AND ACKNOWLEDGMENT BEFORE APPROVING THE AMENDMENT.

ANY AMENDMENT APPROVAL LETTERS OR NEW APPROVED DOCUMENTS FROM THE EXTERNAL IRB SHOULD BE UPLOADED INTO A LOGGED COMMENT IN YOUR EMORY XIRB LOCAL SUBMISSION OR INTO THE STUDY RECORD IN CHILDREN'S eIRB.

HOW DO I HANDLE CONTINUING REVIEW?

THE LEAD STUDY TEAM IS RESPONSIBLE FOR SUBMITTING AMENDMENTS FOR 1) THE OVERALL STUDY, 2) LEAD STUDY TEAM-SPECIFIC CHANGES 3) ANY PARTICIPATING SITE CHANGES.

IF EMORY IS THE LEAD/REVIEWING INSTITUTION, WE HAVE A DOCUMENT FOR YOU TO PROVIDE THE RELYING SITE STUDY TEAMS SO THAT THEY CAN PROVIDE YOU THE INFORMATION YOU NEED FOR THE CONTINUING REVIEW PROCESS.

CONTINUE ►

THE RELYING SITE STUDY TEAM IS RESPONSIBLE FOR PROVIDING ANY NECESSARY INFORMATION OR DOCUMENTATION TO THE LEAD STUDY TEAM FOR THE SUBMISSION.

IF EMORY OR CHILDREN'S IS RELYING ON AN EXTERNAL IRB, CONTINUING REVIEW DOES NOT HAVE TO BE DONE HERE. THE LEAD STUDY TEAM IS RESPONSIBLE FOR MAKING SURE YOU OBTAIN CONTINUING REVIEW.

- *ANY CONTINUING REVIEW APPROVAL LETTERS OR NEW APPROVED DOCUMENTS FROM THE EXTERNAL IRB SHOULD BE UPLOADED INTO A LOGGED COMMENT IN YOUR EMORY XIRB LOCAL SUBMISSION OR INTO THE STUDY RECORD IN CHILDREN'S EIRB.*

ADDING STUDY TEAM MEMBERS?

If there is a change in your study team members, you must notify BOTH the Reviewing IRB and Emory or Children's IRB.

If Emory is reviewing: Add every study team member for Emory and any relying sites to the submission via Emory's normal system.

If Emory or Children's is relying: Notify the Reviewing IRB via their method for study team member changes. If you have a question about that method, contact your Lead Study Team contact or Reviewing IRB contact. You must also notify Emory or Children's IRB so that we can ensure all Emory or Children's study team members have the required training.

- Emory - For changes in investigators, simply log a comment asking the analyst to administratively change the investigators; For changes in study staff, use the study staff changes feature.
- Children's – complete a local site update in eIRB.



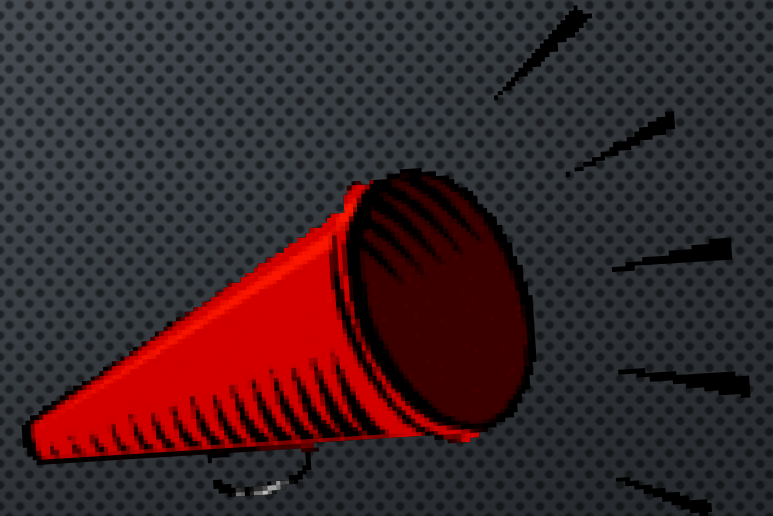
HOW DO I HANDLE REPORTABLE EVENTS?

ALL SITES MUST REPORT ALL REPORTABLE EVENTS TO THE REVIEWING IRB VIA THEIR SYSTEM. THE REVIEWING IRB IS THE IRB OF RECORD AND REVIEWS REPORTABLE EVENTS.

IF EMORY IS REVIEWING: YOUR STUDY TEAM HAS ACCESS TO THE SYSTEM AND IS RESPONSIBLE FOR REPORTING ANY REPORTABLE EVENTS FOR EMORY AND THE RELYING SITES TO EMORY IRB THROUGH THE eIRB SYSTEM.

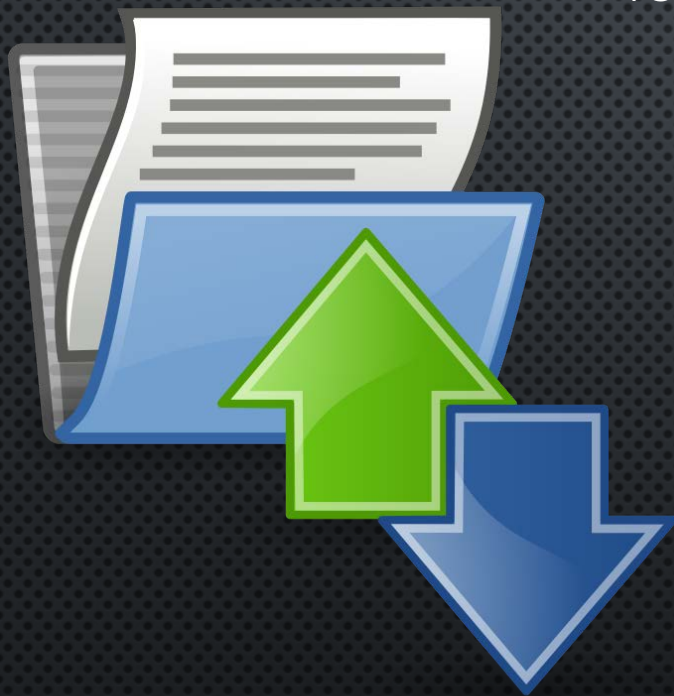
IF EMORY OR CHILDREN'S IS RELYING: YOU SHOULD REPORT DIRECTLY TO THE REVIEWING IRB OR VIA THE LEAD STUDY TEAM, BASED UPON THE POLICIES AND PROCEDURES OF THE REVIEWING IRB.

- YOU SHOULD ALSO REPORT WHAT WE CALL "EGREGIOUS REPORTABLE EVENTS" TO EMORY OR CHILDREN'S IRB IN ADDITION TO THE REVIEWING IRB. EGREGIOUS REPORTABLE EVENTS INCLUDE: WRONG SIDE SURGERY, WRONG DRUG, WRONG PATIENT, FABRICATION OR FALSIFICATION OF DATA, HIPAA PRIVACY CONCERN MATTER, ETC.
- YOU'LL REPORT IT USING THE REVIEWING IRB'S SYSTEM THEN EITHER SCREENSHOT AND SEND THE REPORT OR SEND IN THE BODY OF AN EMAIL TO THE IRB RELIANCE LISTSERV AND THE QA TEAM LEAD (MARIA DAVILA AT MARIA.DAVILA@EMORY.EDU) OR TO IRB@CHOA.ORG FOR CHILDREN'S REPORTING.



TRANSFERRING DATA

Data Transfer Agreements (DTAs) or Data Use Agreements (DUAs) are contracts that govern the legal obligations and restrictions and compliance related to the transfer of data between institutions.



Reliance Agreements and Data Transfer Agreements are two separate contracts. A study may require only one or both of these contracts in order to proceed. While the IRB handles reliance agreements, we do not process data transfer agreements.

If your study involves the transfer of data from one institution to another:

Emory - either your department, Office of Technology Transfer, or Office of Sponsored Programs will handle your DTA depending on the details of the study. Please see our FAQ webpage under the "Data Transfer Agreements" tab for more information:

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

Children's - if needed, DUAs will automatically be routed after IRB approval.

OTHER THINGS YOU SHOULD KNOW...

- CONSENT FORMS ARE GOING TO LOOK DIFFERENT.
- THERE ARE MISCONCEPTIONS THAT RELIANCE AGREEMENTS MEAN LESS WORK OR FASTER STUDY-STARTUP.
- THERE'S AN EXTRA BURDEN ON STUDY TEAMS WHEN ACTING AS A LEAD/REVIEWING INSTITUTION STUDY TEAMS.
- SMART IRB IS A TYPE OF MASTER RELIANCE AGREEMENT, NOT AN IRB.

WHERE TO FIND INFO ON THE WEBSITE - EMORY

- TO ACCESS THE WEBINARS, GO HERE:
[HTTP://WWW.IRB.EMORY.EDU/TRAINING/WEBINARS.HTML](http://www.irb.emory.edu/training/webinars.html)
- FOR QUESTIONS ABOUT RELIANCE, GO HERE:
[HTTP://WWW.IRB.EMORY.EDU/FORMS/EXTERNAL-IRBS/INDEX.HTML](http://www.irb.emory.edu/forms/external-irbs/index.html)
- FOR QUESTIONS THAT CANNOT BE ANSWERED ON THE WEBSITE, CONTACT:

HANNAH HELMSTETTER, RELIANCE SPECIALIST

HANNAH.HELMSTETTER@EMORY.EDU

404-727-8485

The screenshot shows the Emory University Institutional Review Board Research Administration website. The navigation menu includes HOME, ABOUT, POLICIES, FORMS & GUIDANCE (circled in red), EDUCATION, EIRB, MEMBERS, and PARTICIPANTS. The left sidebar contains a list of links, with 'Collaborative Research and External IRBs' highlighted in yellow. A red arrow points from this link to the main content area on the right, which displays the 'Collaborative Research and External IRBs' page. The page content includes a breadcrumb trail (Home » Forms & Guidance » Collaborative Research and External IRBs), a title, a brief description of collaborative research options, and a list of frequently asked questions with expandable sections.

WHERE TO FIND INFO – CHILDREN'S

- CALL OR EMAIL MEREDITH CAPASSE
 - 404-785-7555
 - MEREDITH.CAPASSE@CHOA.ORG

QUESTIONS?