ECHO
Environmental influences on Child Health Outcomes
A program supported by the NIH

IDeA States Pediatric Clinical Trials Network

Junior Pilot Studies Orientation: Study Start Up and ICFs

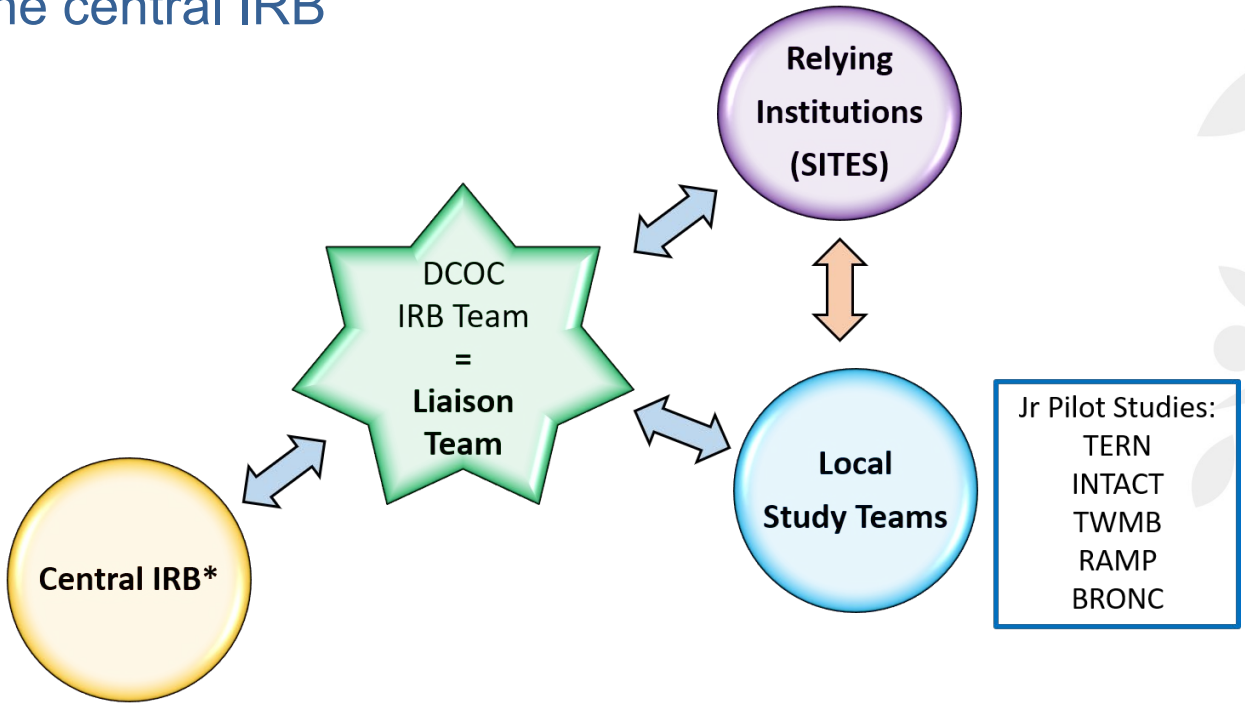
09-September-2022

Objectives:

- DCOC IRB Team. Who are we?
- How we help you with study start up
- How we help you with study-specify ICF and HIPAA forms.
  - ✓ Template
  - ✓ Site-specific language or “local context”
  - ✓ Potential pitfalls for ICFs

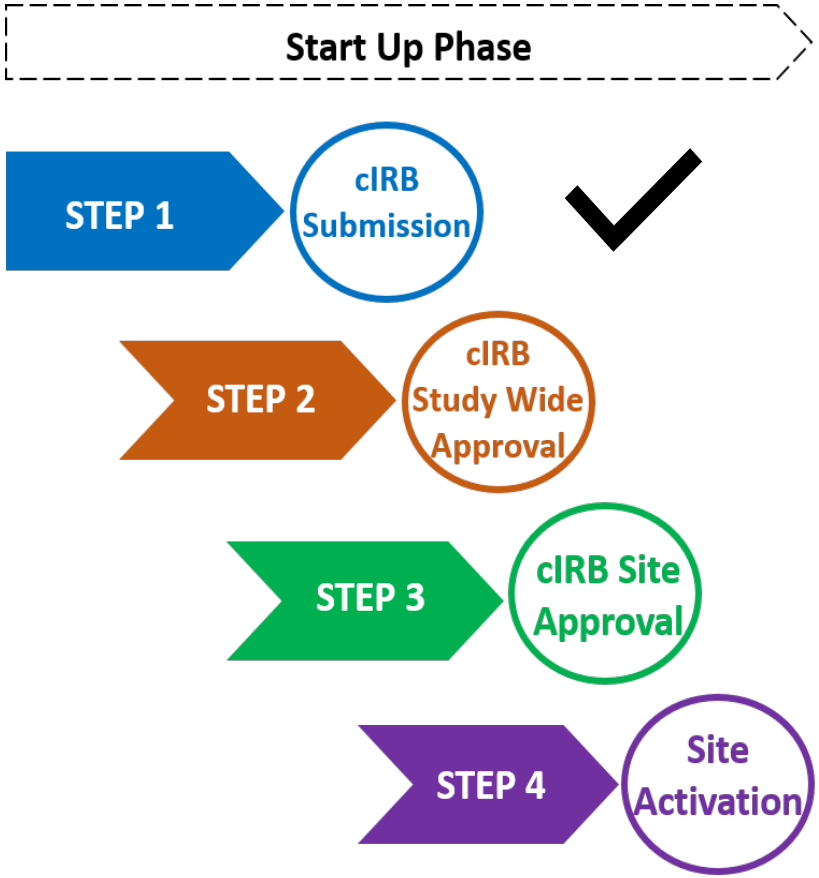
DCOC IRB Team

We manage the communication between the sites (institutions), local study team and the central IRB



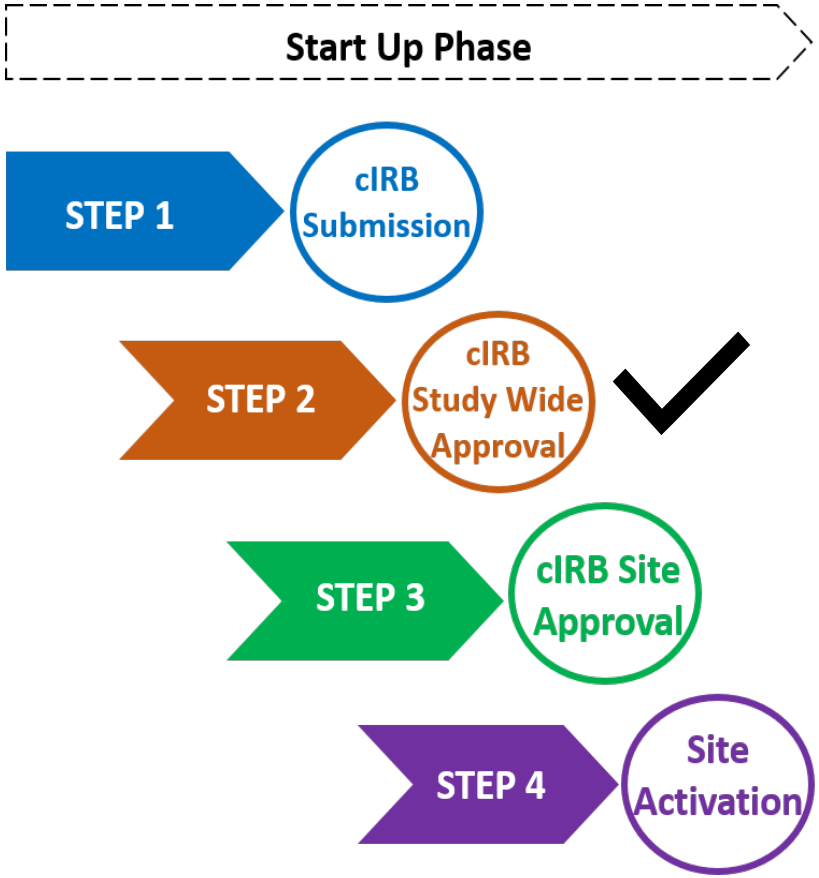
*central IRB (cIRB) is the reviewing IRB or IRB of record.

For all ISPCTN studies, the cIRB is the University of Arkansas for Medical Sciences. Exception: Alaska or other Native American sites. Native American sites do not use the cIRB.



How we help you get to STEP 1

1. Submit study-specific documents
    - Protocol
    - ICF & HIPAA template
    - Participant-facing materials
    - Other study-specific documents
2. Complete the electronic submission form. Answer questions about many things, e.g.,
    - Enrollment goals
    - Study population
    - HIPAA-related issues
    - Recruitment methods



How we help you get to STEP 2

Work with study team to reply to cIRB contingencies

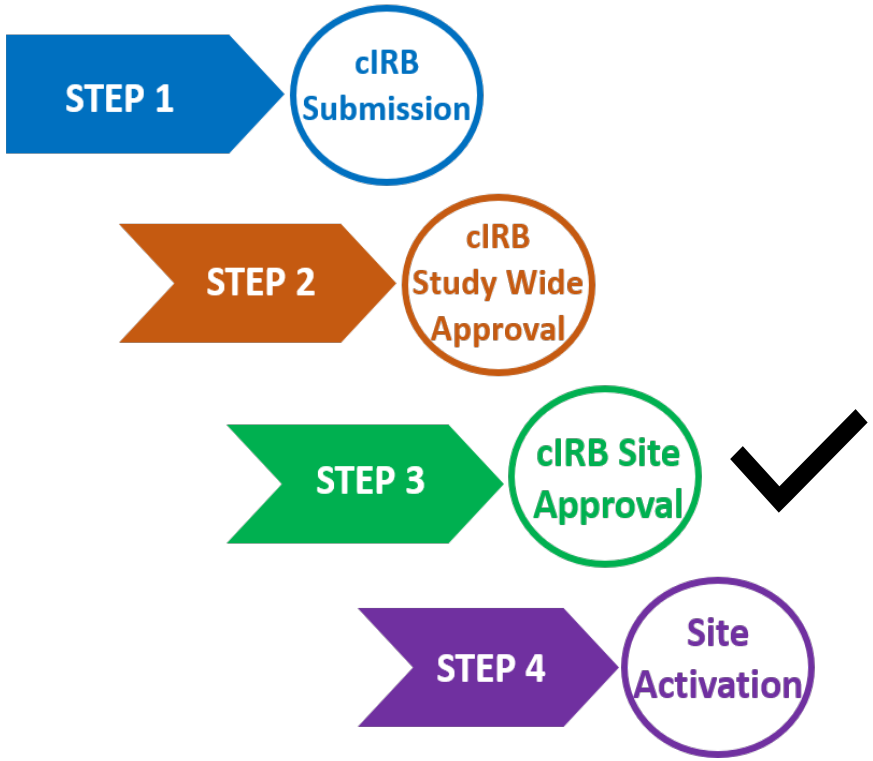
⇩

<u>Initial cIRB approval</u> of the study

Approval letter includes:

- Risk determination
- Waivers granted (if any)

Start Up Phase



How we help you get to STEP 3

Reliance agreement ⇨ Ceding determination

Collect from sites:

Site-specific language

ICF & HIPAA

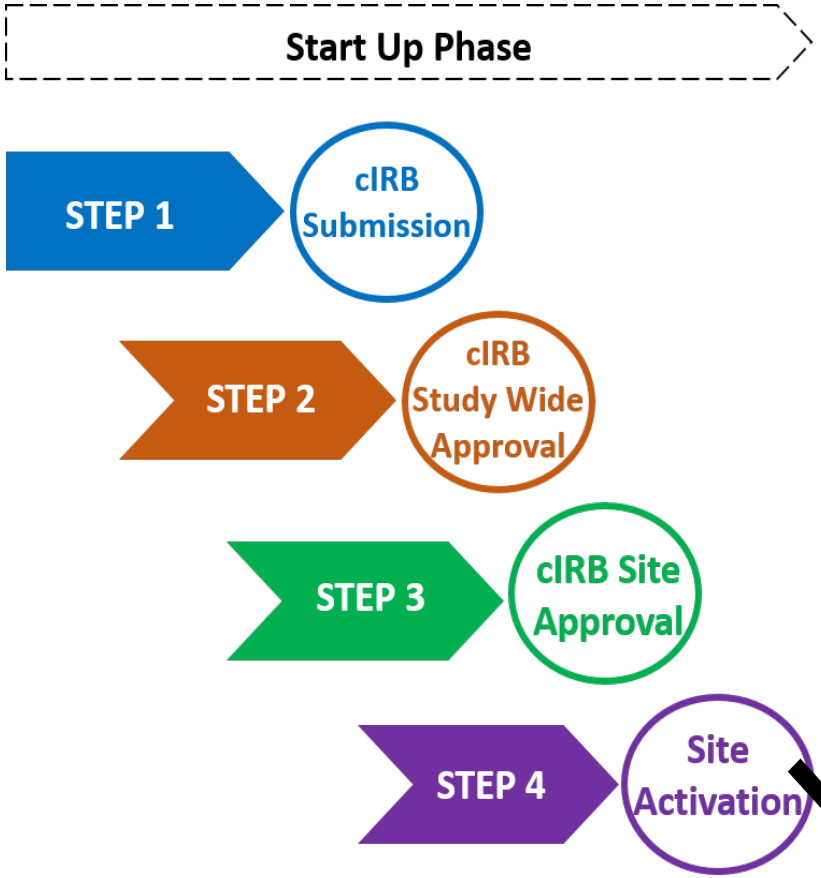
Site Investigator information

Attestation

CV signed & dated

⇩

Site Addition Submission to cIRB & cIRB site approval



How we help you get to STEP 4

Review documents collected from sites:

- Delegation of Authority Log
- Signature Log
- Human Subject Research & Good Clinical Practice training records
- CV and professional licensures
- Laboratory certification and normal values (if applicable)

How we help you get to **STEP 1**

1. Submit study-specific documents
   - Protocol
   - ICF & HIPAA template
   - Participant-facing materials
   - Other study-specific documents
2. Complete the electronic submission form. Answer questions about many things, e.g.,
   - Enrollment goals
   - Study population
   - HIPAA-related issues
   - Recruitment methods

How we help you get to **STEP 3**

Reliance agreement ⇨ Ceding determination

Collect from sites:

Site-specific language
ICF & HIPAA

Site Investigator information
Attestation
CV signed & dated

⇩

Site Addition Submission to cIRB & cIRB site approval

Study-specific ICF and HIPAA Template

Documents in plain language

<Insert local institution name>

Informed Consent Form

- **We are asking you/your baby to be in a clinical trial (research study). You/your baby do not have to join the study.**
- **You/your baby will still get medical care from [insert local context here] even if you/your baby are not in the study.**
- **Please take as much time as you need to read this form and decide what is right for you/your baby.**

In this consent form, the terms "I" refers to both you and your baby.

Why am I being asked to be in this clinical trial (research study)?

- We want to learn more about how to help babies born with Neonatal Opioid Withdrawal Syndrome (NOWS). Babies who, while growing inside their mothers, have been exposed to opioids can have NOWS. There are many names for opioids. Some of the brand names, generic names, and street names are listed on the last page of this form. The signs of NOWS are different in different babies. Signs can include tremors, seizures, fussiness, vomiting, poor feeding, as well as many other symptoms.
- This study may help us learn more about which method(s) might work better than others for treating NOWS. Specifically, the research team is testing whether it may be better to wean babies fast or slow from the methadone or morphine that is being used to treat

What if I say no, I do not want to be in this study?

- Nothing bad will happen.
- You/your baby can still get treatment with either morphine or methadone. Your baby's medical team will decide when the dose is changed at [*insert local context here*].

What happens if I say yes, but change my mind later?

- You can stop being in the study at any time.
- Nothing bad will happen.
- You/your baby can still get medical care at [insert local context here].
- If you decide to stop being in the study, call (*insert head researcher name*) at (*insert phone #*).

Will it cost me anything to be in the study?

The study will not cost you anything. You or your insurance company will be responsible for your regular medical care, as usual, including the costs of the medicines and treatments used to care for your baby's NOWS symptoms.

Will I be paid for being in the study?

Yes. We will give you $50 for each of the following contact times: 1 month post-discharge and when the baby is 6, 12, and 18 month old. You will be paid $100 for the 24-month visit. If you/your baby remain in the study for the entire 2 years, the payment total will be $300. These payments will be provided at the contact time or shortly thereafter. This is to thank you for your time. We will *(LOCAL CONTEXT - [illegible] method of payment)*. If you change your mind and decide not to be in the study, you will only be paid for the parts you completed.

If you receive more than $600 in one year (January-December) from *(insert local context/institution)* we may send you a tax form if required by law.

Site-Specific Language

DCOC IRB Team collects and reviews site-specific language.

- Institution name, Site-investigator and research team **information**
- Local entities that will have access to participants' records
- **State laws** and **institutional policies:**
  - ✓ Mandatory reporting
  - ✓ Payment in case of injury
  - ✓ Method(s) for reimbursing participants

Requirements writing ICF and HIPAA:

- As per UAMS IRB (cIRB) Policy 15.1:
  "present information in sufficient detail relating to the research, and must be **organized and presented in a way that facilitates the prospective subject's or LAR's understanding of the reasons why one might or might not want to participate**, rather than merely a list of isolated facts". [45 CRF 46.116(5((ii)]
  https://irb.uams.edu/irb-policies/current-irb-policies/consent/

  The consent document should be written in language that is at or below an eighth grade reading level. No complex scientific or technical language should be used without an explanation in lay or common terms.

- We will provide you with the current ICF and HIPAA templates

How to simplify ICF and HIPAA language?

DCOC Writing Team is available to help you! E-mail them for help.

- Nader Phyllis PNader@uams.edu
- Bryce Johnson BPJohnson@uams.edu

Tips to improve understanding

Don't copy technical language from the protocol

Lay language: gestational = how far along the pregnancy is

Using pictures, videos, visuals in general

✓Example: add a picture of a device used in the research

Get a laypersons' opinion on terms used in your ICF

✓Suggested by UAMS IRB Director Edith Paal

How to check reading level (aka readability)? https://readabilityformulas.com/free-readability-formula-tests.php

Potential pitfalls for ICF and HIPAA forms

Include flexibility for study procedures.

- Your participant needs to complete multiple surveys during the study?
  - ✓If appropriate, consider a time window for completion of each survey.

- Describe the purpose of each survey without naming the exact surveys to be used.

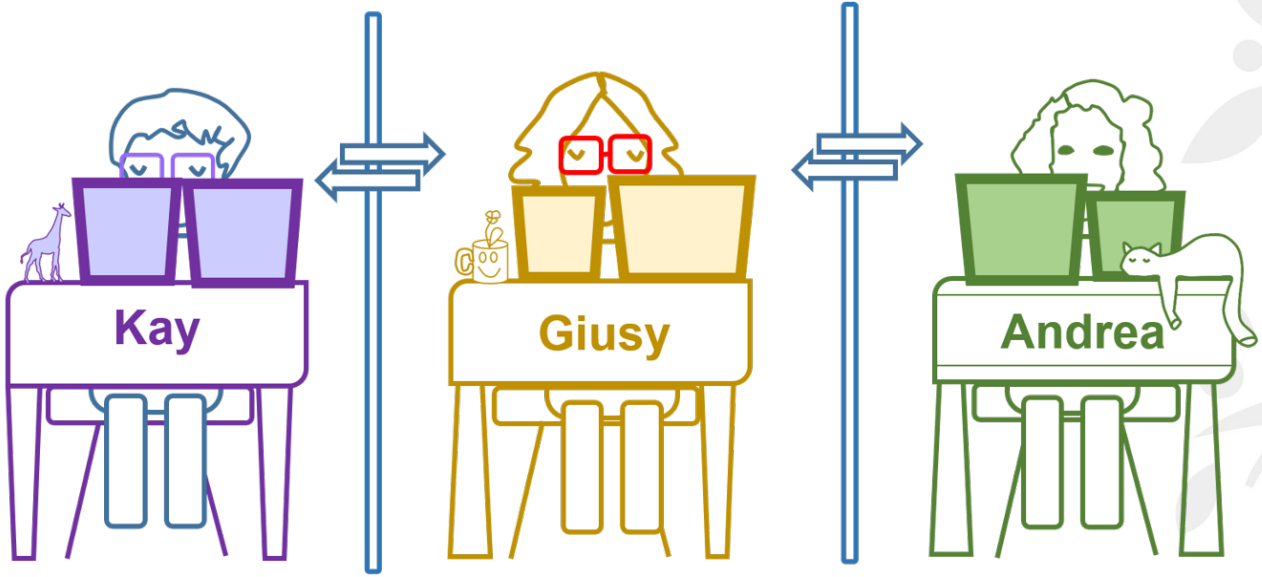
- Is your study targeting a specific population of children whose age range could change during the study?
  - ✓ Example from vaccine study:
    In case the eligible age range may change, consider not defining the specific age range, but refer to “eligible children.” This will be defined in the protocol, which is easier to modify once a study is active.

Potential pitfalls for ICF and HIPAA forms

Include flexibility for study procedures.

- Make sure there is consistency between the ICF and HIPAA forms and the procedure outlined in the protocol
- If you are using Zoom calls as video-conference system to contact participant (ex for survey), indicate in the template that you could use Zoom or equivalent system. Doing this if there is a change in the system used, you do not need to change the ICF.
- If you are planning to have the site contacting the participants be flexible on the methods of contact. Include by email, text message or other methods. This should be addressed in both Protocol and ICF.

DCOC IRB Team



Kay Shuttleworth
@
KLShuttleworth@uams.edu

Giuseppina Dusio
@
gfdusio@uams.edu

Andrea Moerman
@
MoermanAndreaM@uams.edu

NOTE_ Please include the study acronym and site name in the subject line of emails.

ECHO

Environmental influences on Child Health Outcomes

A program supported by the NIH

IDeA States Pediatric Network