CTN WEB SEMINAR SERIES: A FORUM TO EXCHANGE RESEARCH KNOWLEDGE

Considerations for Utilizing Single IRBs within the National Drug Abuse Treatment Clinical Trials Network

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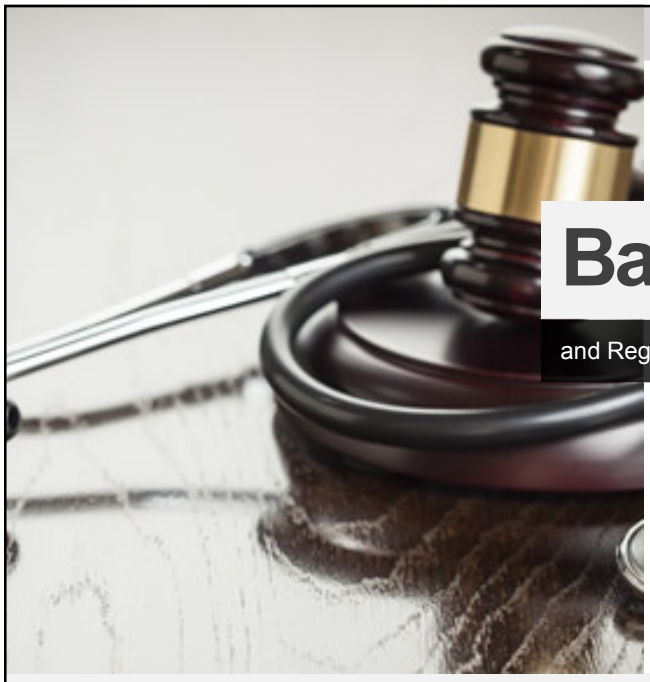
Outline

- Background and current regulatory landscape
- Identifying a Single IRB
  - When to begin the Single IRB process
  - Overview of commercial and academic options
  - Vetting a potential Single IRB
- Considerations for working with a Single IRB
  - Local site considerations
  - IRB Authorization Agreements
  - Submission procedures
  - Budget considerations
- Resources
- Questions

IRB – Institutional Review Board



Background

and Regulatory Landscape

NIH Single IRB (sIRB) Policy

- Published on June 21, 2016
- Sets the expectation that multi-site studies conducting the same protocol use a single IRB.
- Became effective January 25, 2018
- NIDA CTN is in alignment with the policy (see CTN Policies & Procedures V7 for network guidance)

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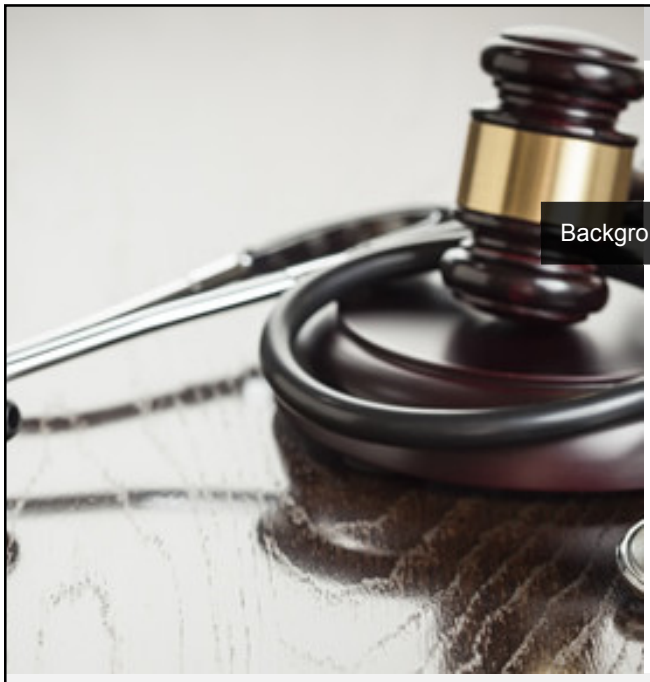

Background and Regulatory Landscape *(continued)*

Common Rule Update (45 CFR 46, Subpart A)

- Federal Policy for the Protection of Human Subjects ("The Common Rule")
- Revised to incorporate sIRB requirement for all federally-funded studies (January 21, 2019)
- IRB oversight for federally-funded, U.S. based cooperative research projects required to use a single IRB starting January 20, 2020

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Single IRB ≠ Central IRB

Central IRB

- "The IRB of record that provides the ethical review for all sites participating in more than one multi-site study. The sites are usually in a network, consortium, or particular program."

Single IRB

- "The IRB of record, selected on a study-by-study basis, which provides the ethical review for all sites participating in a multi-site study."

Source: NIH Office of Science Policy Frequently Asked Questions. (2018). Retrieved from Frequently Asked Questions https://osp.od.nih.gov/ufaqs/what-is-the-difference-between-a-central-irb-and-a-single-irb/

When should the single IRB process begin?

After concept approval; early protocol dev't

- Start preliminary research on available single IRB options.
- If preferred, approach Lead Investigator's institution to serve as the sIRB of Record.
- If preferred or if necessary, explore additional sIRB options (commercial, academic).

Mid-to-late protocol dev't

- Vet potential sIRBs and rank potential sIRBs in order of preference.
- Select single IRB.
- Develop a Single IRB Plan – required for initial submission to CTN DSMB.

During site selection

- Examine whether the IRBs affiliated with all potential sites will agree to rely on the sIRB.

Following NIDA's official approval

- Finalize contract with sIRB.
- Complete initial protocol-level submission within 30 days.

Single IRB Plan

Template

CTN-00XX
Single Institutional Review Board Plan

1. Policy adherence statement:

   The following study sites and corresponding IRBs have agreed to adhere to all policies outlined by The National Drug Abuse Treatment Clinical Trials Network (UG1) as indicated in RFA DA 15 008.

   [List all study sites using the following format]:

   - *Name of Institution (e.g. Institution B)*
     Department/Division
     Street Address
     City, State ZIP

2. The name and OHRP registration number of the IRB that will serve as the single IRB of record:

   Name of IRB
   Street Address
   City, State ZIP
   Office Phone Number(s)
   Fax Number
   Email Address
   Website (if applicable)
   OHRP IRB Registration Number

3. Single IRB Use Statement for all participating sites:

   The ***[enter # of sites]*** participating sites and corresponding IRBs have all agreed to rely on the single IRB listed above (#2), through written reliance agreements (sample attached).

What are my options?

Academic sIRB

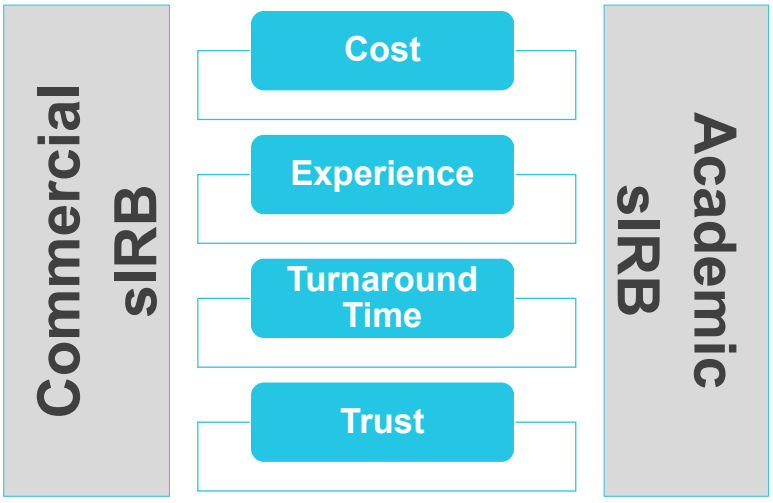
- Lead Investigator's local IRB
- Other options

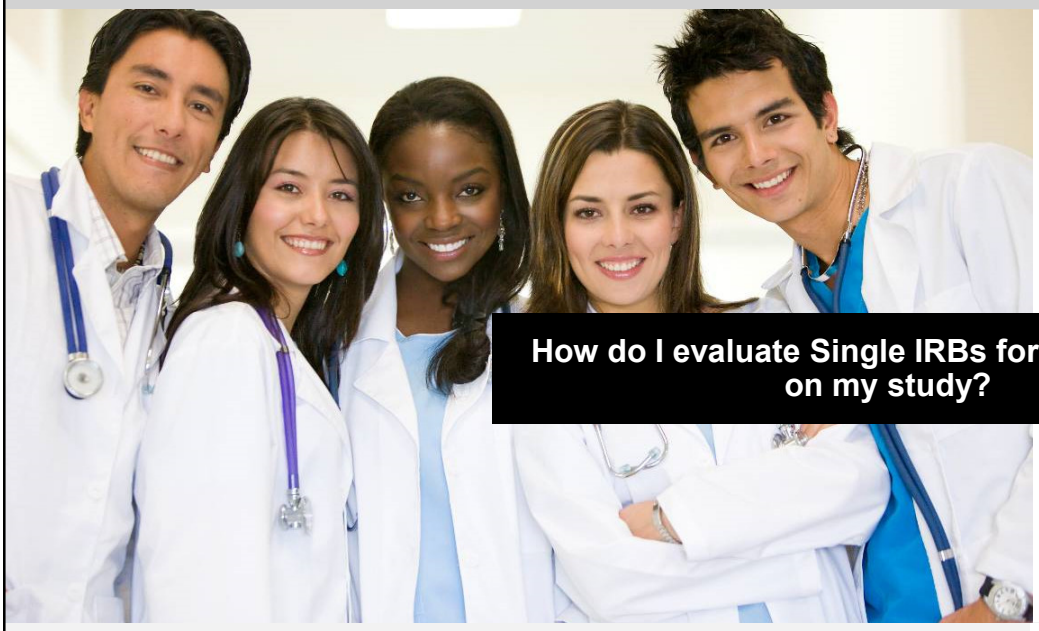
What are my options?

Commercial sIRB

- Many available options
- CTN studies have previously worked with:
  - Western IRB (WIRB)
  - Quorum IRB
  - Advarra IRB (previously Chesapeake IRB)
  - Brany IRB

Considerations for using an Academic or Commercial sIRB





How do I evaluate Single IRBs for potential use on my study?

General questions to ask when evaluating sIRBs

- What is your experience with multi-site, randomized clinical trials involving an FDA-approved study medication?
- Is there a specific application/review track for multi-center, randomized trials involving study medications? How would you approach continuing review of this study?
- Describe your application process.
- How will support for the study be staffed/managed at the IRB?
- Are you able to perform pre-review services to review protocol and provide guidance? Is there a cost associated?
- What is your schedule of fees?
- What is your process for tracking approval status and requests for follow-up?
- What is your meeting schedule and typical turn-around time?
- What is your standard review and approval time for multi-center randomized clinical trials?
- **Do you have any accreditations?**
- How long does it typically take to set up a contract with your organization?

FDA – U.S. Food and Drug Administration; AAHRPP – Association for the Accreditation of Human Research Protection Programs

Examples of CTN network-specific questions for sIRBs

sIRB-related questions

- The sites will be spread out across the U.S. Describe your availability for support.
- Are you able to function as a single IRB of record and work with local IRBs? How much input do you allow the site IRB based on local knowledge?
- How do you communicate with sites?

Study population questions

- What is your experience with research with substance abuse populations?
- Have you overseen trials involving participants with opioid use disorder, and medications indicated for opioid use disorder?
- Have you had experience applying for Prisoner Certification from the OHRP? If yes, please describe your experience/process.

OHRP – Office of Human Research Protections

Other considerations for evaluating sIRBs

Local Site

- Local context review
- Periodic submissions of AEs, PDs, RNIs
- Scientific reviews
- Ancillary reviews (e.g., genetics, radiation)
- Institutional capacity to perform the trial
- Financial implications

AEs – Adverse Events; PDs – Protocol Departures/Deviations; RNIs – Reportable New Information;
AAHRPP – Association for the Accreditation of Human Research Protection Programs

Version Date: 03/31/2011

Sample text for an Institution with a Federalwide Assurance (FWA) to rely on the IRB/IEC of another institution (institutions may use this sample as a guide to develop their own agreement).

Institutional Review Board (IRB) Authorization Agreement

roviding IRB Review (Institution/Organization A): _____

Federalwide Assurance (FWA) #, if any: _____

signated IRB (Institution B): _____

_____ may rely on the designated IRB for
uman subjects research described below: (*check one*)

n subjects research covered by Institution B's FWA.

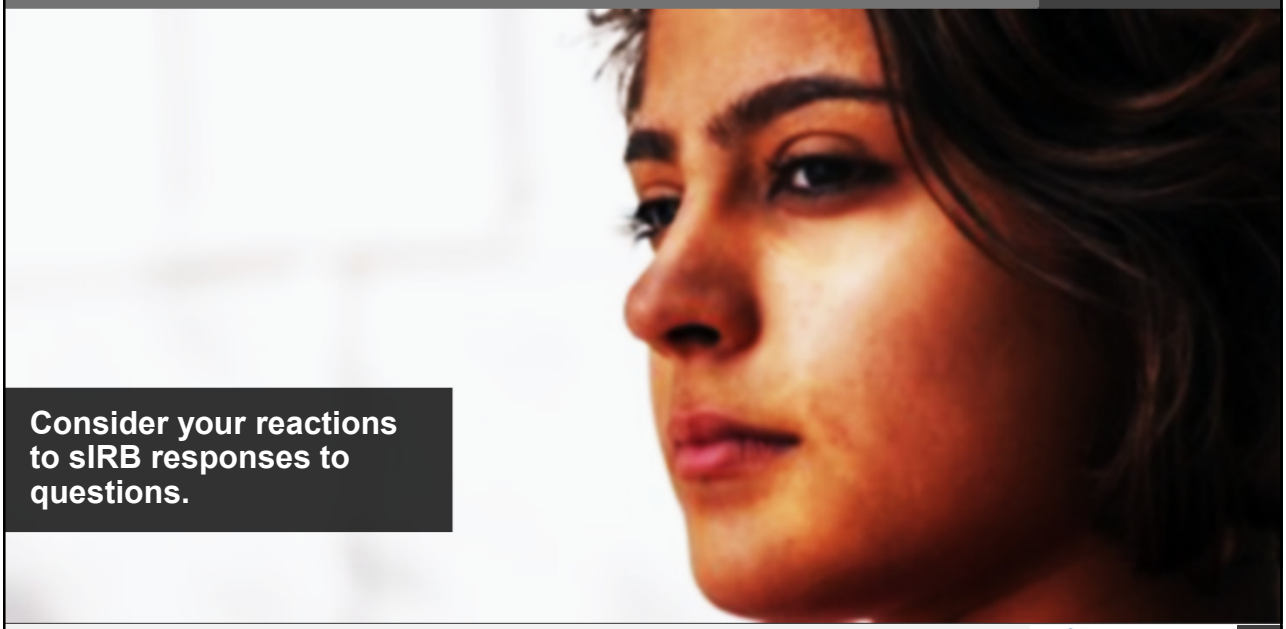
Other considerations for evaluating sIRBs *(continued)*

Local Site

- Local context review
- Periodic submissions of AEs, PDs, RNIs
- Scientific reviews
- Ancillary reviews (e.g., genetics, radiation)
- Institutional capacity to perform the trial
- Financial implications

Budget

- How and when to fund sIRB costs?
- How much are sIRB costs? Obtain detailed estimate of costs, including:
  - Initial submissions (study-level; site-level)
  - Informed consent reviews (initial; amendments)
  - Protocol amendments
  - PI changes/administrative changes
  - Review of unanticipated problems/PDs/AEs
  - Continuing review costs
  - Recruitment materials and other participant-facing documents (initial costs and cost to review any modifications).



Consider your reactions to sIRB responses to questions.

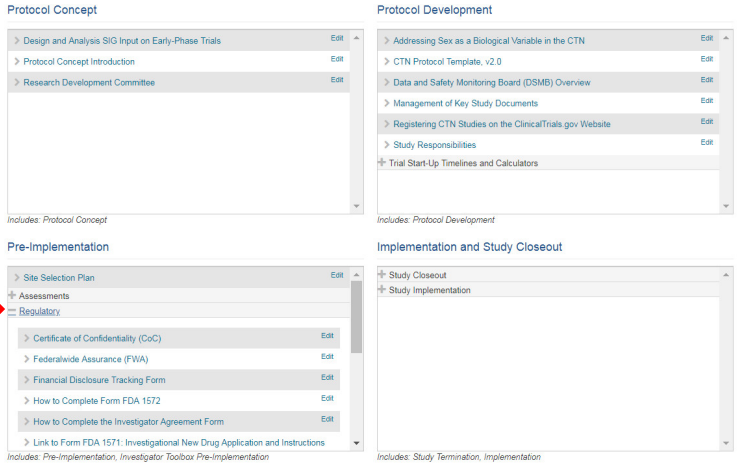
How do submissions to the sIRB typically work?

Initial study-level submission	• Performed by Lead Node; includes all study-level information and study-wide documents
Initial site-level submissions	• Performed by site; includes site-specific documents and information
Maintenance submissions	• Site-level: AEs, PDs, RNIs, UAPs, CRs; personnel changes • Protocol-level: protocol/consent changes; study-wide CRs; study-wide recruitment materials, etc.
Site-level closeout submission	• Submitted by site when site is closing out
Study-level closeout submission	• Submitted by Lead Node when entire protocol is closing

AEs – Adverse Events; PDs – Protocol Departures/Deviations; RNIs – Reportable New Information; UAPs – Unanticipated Problems; CRs – Continuing Reviews

CTN Investigator Toolbox

https://ctndsc2.com/content/investigator-toolbox



Other resources

- NIH Single IRB Policy - https://grants.nih.gov/grants/guide/notice-files/not-od-16-094.html (see Frequently Asked Questions on the NIH sIRB Policy)
- Single IRB Plan - https://ctndsc2.com/system/files/DSMB_overview.pdf (included within the “Data and Safety Monitoring Board” document under the “Protocol Development” section of the Investigator’s Toolbox on the CTN Website)
- Sample IRB Authorization Agreement - https://www.hhs.gov/ohrp/sites/default/files/ohrp/assurances/forms/irbauthorizpdf.pdf (provided by DHHS)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Thank You
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