UCLA/Advarra Lunch and Learn Presentation and Discussion

Initial **Site** Review Process

ADVARRA IRB

Initial Study Submission in CIRBI

- **Minimum** Submission Requirements:
  - CIRBI Study Application
  - PI CV
  - Tracked ICF in Word (if required)
  - External Review Accepted Letter

Administrative Review

- Confirmation of a complete/accurate submission by Client Services Coordinator (CSC)
- Clarifications Sent in CIRBI (if required)
- CIRBI will send automatic reminders for needed Clarifications

Scheduling and Board Review

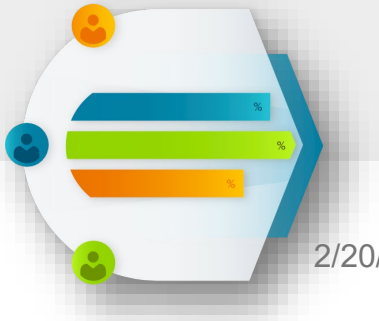
- Submission sent to IRB Reviewer(s)
- Any Pre-meeting Clarifications sent in CIRBI *prior* to IRB Meeting
- Board Review takes place

Informed Consent Form (ICF) Negotiations

- IRB's ICF redlines sent via CIRBI for site review
- Opportunity to Accept redlines as-is OR submit additional edits
- Post-meeting Clarifications relayed (if required)
- Any Additional edits or Post-Meeting Clarifications will require follow-up IRB Review

IRB Determination Documents Issued

- IRB-approval notice and ICF(s) finalized and undergo Advarra Quality check
- Email notification sent when documents are issued in CIRBI
- Modifications able to be submitted



Initial Submission Timelines

ADVARRA IRB

Initial **Investigator/Site** Submission

Receipt & Initial Processing of CIRBI Submission	Administrative pre-review & follow-up with Site (as applicable) Includes Review and Sign-off from Sponsor/CRO	IRB Member Review	**If Needed:** Site ICF Negotiations (in instances of Local IRB Sign-off Requirements or Additional IRB Edits)	Approval Documents & ICF(s) Generated, QC'd, & Posted in CIRBI
1 Business Day	Dependent on Response Times	**1-2 Business Days**	Dependent on Response Times	**1-2 Business Day**

- Advarra
- Site

Site Submission Best Practices

ADVARRA IRB

Common Needs for Site Clarification – Items That Can Add Time

- **Budget/Patient Compensation:**
  - Should be in place prior to CIRBI submission – cannot proceed with IRB review w/o information.
  - Compensation/stipend issues are major reason for IRB approval delay
- **Sites with ICF Edits:**
  - Minimize incorporating unique language into the study ICF template
  - Applies to sites with unique information (other than PI info on page 1, HIPAA/privacy, Injury, and Compensation Information)
  - Sponsor/CRO to provide site with WORD document of **most current** IRB Approved ICF Template for edits (only if needed)
  - If IRB makes additional ICF edits during review, redlines will be sent to Site for review ***prior*** to release
- **Follow-up Questions from Board Reviewer:**
  - IRB may Defer site application pending follow-up information
  - Will be communicated via Clarification process in CIRBI

Status Requests and Escalations

To Request Status Updates on Your Submission:

First Action:

Contact your Advarra **Coordinator** listed in CIRBI using *"Contact IRB"* activity on the submission page

Second Action:

Contact your Advarra **Coordinator** listed in CIRBI at the phone number listed in CIRBI

If Needed:

Contact **Client Success** Partner via e-mail or phone for additional support