

Quickguide to Facilitated Review



1. Principal Investigator (PI) receives a new study from the Cooperative Group and wants to open the study.



2. The research staff checks CIRB website (www.ncicirb.org) to confirm study is on CIRB menu.

Local IRBs select the option they prefer:

| Option 1 | | Option 2 |
|---|----|---|
| <p>Research staff downloads and prints out all current review materials (CIRB Application, protocol, informed consent, correspondence, any SAE reports, amendments, primary review and minutes from Participant's Area of CIRB website).</p> <p>Research staff submits materials to Local IRB.</p> | OR | <p>Research staff downloads and prints out most of the current review materials (CIRB Application, protocol, informed consent, correspondence, any SAE reports and amendments) from Participant's Area of the CIRB website.</p> <p>Research staff submits materials to Local IRB.</p> <p>Local IRB Coordinator downloads remaining review materials (primary reviews and minutes).</p> |



3.

| | | |
|--|----|--|
| | OR | |
|--|----|--|



4. The IRB Coordinator provides the review materials to Local IRB Chair/subcommittee for Facilitated Review.

5. Facilitated Review: Per local policy, Local IRB Chair/subcommittee reviews all materials for local context, revises consent per local template, if necessary, and accepts CIRB review.



6. The Local IRB Coordinator completes the electronic Facilitated Review Acceptance Form on the CIRB website for each Facilitated Review accepted. A confirmation email is sent from the CIRB to the Local IRB Coordinator confirming receipt.



7. The CIRB is now the IRB of record for this study and is responsible for continuing review, review of amendments and other study-specific documents as well as adverse events distributed by the Group.

Further questions? Toll free (888) 657-3711 or ncicirbcontact@emmes.com