**CIRB Instructions**

**Submission of Study Chair Response (SCR) to the CIRB**

This document provides instructions on how to respond to the CIRB after the CIRB Approves Pending Modification (APM) or Tables a review.

**Checklist for Documents Required in Response to CIRB’s Stipulations:**

Attach the following documents to your response email to the CIRB:

**For All Studies:**

[ ]  Updated Change Memo addressed to the CIRB listing point by point responses to each CIRB stipulation.

[ ]  Updated CIRB Application with new Protocol Version Date

[ ]  Clean Protocol without Change Memo

[ ]  Clean Consent Form(s) in Microsoft Word format without Change Memo

[ ]  Supporting documents required by the CIRB (e.g. Wallet Cards, Pill Diaries, PRO’s, etc.)

**For CTEP studies**:

[ ]  Protocol with Change Memo for FDA submissions (clean and tracked changes)

[ ]  Consent Form(s) with Change Memo for FDA submissions (clean and tracked changes)

**For DCP studies**:

[ ]  Protocol with tracked changes

[ ]  Consent Form(s) with tracked changes

**General Formatting Requirements:**

1. **Cover Memo/Updated Change Memo**
	1. Memos must include point-by-point responses to each CIRB stipulation and must list the changes made to the document.
	2. For multiple CIRB reviews, the responses to the CIRB stipulations must be cumulative and saved within the same document with the most recent responses listed first.
2. **Protocol, Consent Form and Other Study Documents:**

***Both Initial Reviews and Amendments***

1. If changes are made to *either* consent form *or* protocol, both documents must have an updated and matching version date. If the only change to a document is the version date, this must be noted in the change memo.
2. New changes related to the CIRB stipulations should be placed at the top of the document to ensure the changes are chronological with the most current changes listed first. Include a header or introductory statement to make it clear that these are the changes made in response to CIRB stipulations.
3. All changes requested by the CIRB must be included in the protocol and consent form and tracked.

***Initial Reviews ONLY***

1. The list of changes made prior to the CIRB’s initial review during either CTEP or DCP’s review must be removed.

***Amendment Reviews ONLY***

1. The list of changes must include all changes made to the documents since the last CIRB-approved version inclusive of any CTEP or DCP requested changes. Change made prior to CIRB review must be incorporated in a cumulative change memo.
2. **No password protection**
3. **Microsoft Word Documents are required**
4. **Tracked changes are required**

**Submission Deadline:**

The deadline is 14 calendar days from the date of the CIRB Outcome Letter. If an extension is required, contact the CIRB Operations Office.

**Questions or Requests for Clarification Regarding CIRB Stipulations:**

Contact your CIRB Coordinator if you have questions or requests for clarification. The CIRB Coordinator can generally provide clarifications, however, for more complex issues, a conference call with representatives of the CIRB and the Study Team may be needed. You may request a conference call by contacting the CIRB Operations Office.

**Additional Changes not Requested by the CIRB:**

For CTEP studies: Any changes made to any study-related documents (including the protocol, consent form, participant documents) that were not requested by the CIRB must be reviewed by CTEP again prior to review by the CIRB, thus resulting in a delay of CIRB review In general, non-CIRB requested changes are discouraged and the response should address only changes required by the CIRB unless you are otherwise instructed by NCI or the CIRB Operations Office.

For DCP studies: Additional changes to study-related documents not requested by the CIRB are not permitted.

**Updated CIRB Applications:**

Each submission to the CIRB must be accompanied by a CIRB Application Form. Therefore, the original CIRB Application Form must be updated and submitted with the response to the CIRB. The revised CIRB Application should reflect a new Protocol Version Date, if applicable, and any changes requested by the CIRB in the stipulations that impact the application’s content. Please review to confirm that the revised information in the CIRB application matches the revised protocol and associated documents submitted for CIRB review.

**How to Contact the CIRB Operations Office:**

The outcome letter from the CIRB includes contact information for the CIRB Coordinators. Each CIRB has a designated email address:

Adult CIRB – Early Phase Emphasis EarlyPhaseCIRB@emmes.com

Adult CIRB – Late Phase Emphasis AdultCIRB@emmes.com

Cancer Prevention and Control CIRB CPCCIRB@emmes.com

Pediatric CIRB PediatricCIRB@emmes.com

You may also reach the CIRB Coordinators via the CIRB Helpdesk at NCICIRBContact@emmes.com or at 1-888-357-3711. The Helpdesk is staffed from 8am to 4pm (Eastern) Monday through Friday excluding holidays.