NCI CIRB COVID-19 FAQs

JULY 16, 2020

NRG SUMMER MEETING
AMANDA P. SLY, MS, CIP

C›I›R›B
FOR THE NATIONAL CANCER INSTITUTE

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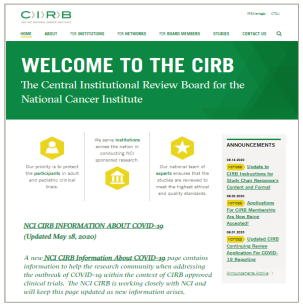
CIRB WEBSITE – COVID-19 INFORMATION

CIRB website
www.NCICIRB.org

Homepage has a link to NCI CIRB Information about COVID-19



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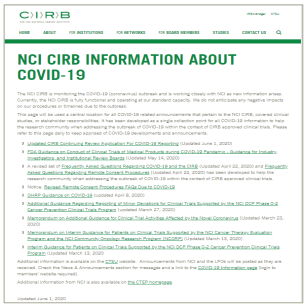
CIRB WEBSITE – COVID-19 INFORMATION

Central location for all COVID-19 related communications, including the CIRB's FAQ

A single collection location for COVID-19 information



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DEVIATIONS RELATED TO COVID-19 RESPONSE

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PROTOCOL DEVIATIONS RELATED TO COVID-19

Minor protocol deviations:

- Minor protocol deviations NOT related to COVID-19 do not need to be submitted to the CIRB.
- A compiled list of all minor protocol deviations related to COVID-19 will be reported to the CIRB by the coordinating group at the time of continuing review (CR) starting on July 15, 2020.

Major Protocol Deviations:

- Utilize standard process.
- Protocol deviations which are potential Serious and/or Continuing Noncompliance (SCNC) must be reported to the CIRB via the Unanticipated Problem and/or SCNC Worksheet.

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CONTINUING REVIEW APPLICATION UPDATE

- CIRB has updated the Continuing Review Application form to request the minor protocol deviations related to COVID-19.
  - Question 4.8 has been added requesting confirmation of any minor protocol deviations related to the COVID-19 public health emergency have been collected for the study.
  - The Summary of CIRB-Requested Supporting Documents added a selection to indicate if a minor deviation report will be attached with the submission.
- Located on CIRB Website under the Quickguides for Submitting Studies and is provided with the CIRB Continuing Review Reminder Notice.
- The revised applications are effective Wednesday, July 15, 2020 and should be used for all submissions submitted for review on or after that date.

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INFO ON STANDARD PROCESSES REGARDING SUBMISSION OF NON-COMPLIANCE?

Quickguides Available on the CIRB Website

- **REPORTING AUDIT FINDINGS** provides instructions for reporting audit findings to the CIRB as potential Serious or Continuing Non-Compliance (SCNC).
- **ALGORITHM TO ASSESS POTENTIAL NONCOMPLIANCE** provides an algorithm to assess whether or not an incident is reportable to the CIRB as potential Serious or Continuing Non-compliance (SCNC).
- **COMPLETING THE UNANTICIPATED PROBLEM AND/OR NONCOMPLIANCE REPORTING WORKSHEET** provides instructions for completing the Unanticipated Problem and/or the Noncompliance Reporting Worksheet.

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REMOTE CONSENT

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WHAT IS REMOTE CONSENT?

REMOTE CONSENT

- NCI is allowing the use of Remote Consent Procedures during the COVID-19 public emergency.
- Consent discussion is conducted by the provider via phone/video conference with the potential participant or legally authorized representative (LAR).
  - The process requires a witness.
  - The CF is signed and returned to the provider.
- Remote Consent does not require prior CIRB approval for COVID-19.
- Remote consent may utilize emails, faxes or mail to return signed consent documents. Phone scans and/or images are acceptable.

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WHAT IS REMOTE CONSENT?

VERBAL CONSENT (UNCOMMON)

- The participant/LAR doesn't sign the CF; ONLY provides consent verbally.
  - Waiver of Documentation of Consent must be made for the study.

TELEPHONE CONSENT (UNCOMMON)

- Generally interpreted as verbal consent, where confirmation of consent is obtained only via the phone.
- Scripts must be approved by the CIRB prior to utilizing telephone consent.

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WHAT IS REMOTE CONSENT?

DESIGNEE

- Designee may obtain consent per local policy.

WITNESSES

- Witnesses are required for obtaining remote consent and the sites policy must be outlined in the SIW and/or SSW.
- The CIRB does not define who may serve as a witness; this is defined by local policy.

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STUDY CHAIR RESPONSE INSTRUCTIONS

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STUDY CHAIR RESPONSE INSTRUCTIONS

Study Chair Response Instructions

- Updated June 18, 2020 to provide additional clarity regarding formatting.
- Available on the CIRB website under CIRB Quickguides for submitting Initial and Amendment reviews.
- Changes made in collaboration with the CTEP & DCP Protocol Information Office (PIO).
- To be used when preparing/submitting responses to Approval Pending Modification (APM) or Tabled.

Changes

- Clarified that Initial Review change memos may remove changes made prior to the PIO approval on hold.
- Outlines specific reqs. for formatting, where they vary between the CTEP and DCP PIOs.
- Added sample Change Memos on the CIRB website as a tool for the sites to utilize when developing a SCR.

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THANK YOU

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