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

Unanticipated Problem and/or Serious or Continuing Noncompliance Submission Application -- UP and/or SCN Submission Application

OMB #0925-0753 Expiration Date: 03/31/2026

The purpose of the information collection is to conduct reviews of clinical trial studies. NCI guidelines mandate the participation of institutions in the CIRB for Network group studies. You are being requested to complete this instrument so that we can conduct activities involved with the operations of the NCI CIRB Initiative. Although your participation in Network group research and completion of the forms is voluntary, if you wish to participate in the CIRB, you must complete all questions on the form. The information you provide will be combined for all participants and reported as summaries. It will be kept private to the extent provided by law.

NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0753). Do not return the completed form to this address.

This application has been designed to meet the regulatory requirements for review, so answer each question as completely as possible.

- All answers must be in lay language.
- If an answer to any question cannot be provided, provide an explanation for the missing answer.
- If you have any questions regarding the completion of this application, contact the CIRB Helpdesk at support@ncicirbcontact.zendesk.com or 888-657-3711.

Study ID

Study Title

Event

Study Chair

Checklist of CIRB-Requested Supporting Documents

Please confirm that the appropriate documents have been attached to the worksheet.

☐ Word version of Consent form with the same Protocol Version Date as the protocol without change memo (REQUIRED)

☐ Change Memo (REQUIRED)

☐ Participant-directed letter or memo

☐ Consent form addendum to be signed by participants

☐ Information to be provided to PIs to facilitate verbal notification of participants.

☐ New/Updated recruitment material and distribution plan

☐ New/Updated forms intended to be completed by study participants and distribution plan

☐ New/Updated study-specific educational materials and distribution plan

☐ Updated Investigator's Brochure(s)

Attach appropriate supporting documents:

Protocol Version Date

What is the eligible population for this study? (Required)

☐ Adult only

☐ Pediatric only

☐ Adult and Adolescents and Young Adults (AYA)

☐ Pediatric and Adolescents and Young Adults (AYA)

☐ Adult and Pediatric

☐ Adult, Pediatric, and Adolescents and Young Adults (AYA)

Description of the Event being Reported

1. Enter the date the event occurred. (Required)

2. Provide a summary of the event. (Required)

Add any supporting documents to provide additional details regarding the event:

3. Describe any corrective action and preventative plan that has been implemented, is being implemented, or planned to be implemented, to address the event. (Required)

Add applicable attachment(s), including audit reports and CAPA reports.

4. Have the study participants been notified of this event? (Required)

☐ Yes

☐ No

Provide copies of the communication.

5. Enter the number of Study Participant(s) enrolled on this protocol at time of submission. (Required)

Number of Participants On-Treatment (Required)

Number of Participants Off-Treatment (Required)

Number of Participants in Follow-up (Required)

Number of participants affected by the event (Required)