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

Atttachment_B02_Enroll_Form

OMB# 0925-0753, Expiration Date: 07/31/2021

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 15 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.

NCI CIRB SIGNATORY INSTITUTION ENROLLMENT FORM

The NCI CIRB Signatory Institution Enrollment Form is a Microsoft Word document that must be completed electronically. Once the Form is completed, save it as a Word document, and then email it to the CIRB Operations Office at ncicirbcontact@emmes.com.

July 2018

SECTION A: SIGNATORY INSTITUTION INFORMATION (INSTITUTION OF SIGNATORY OFFICIAL WHO SIGNS THE AUTHORIZATION AGREEMENT)

Signatory Institution Name		
Street Address		
Street Address #2		
City	State	Zip
OHRP Federalwide Assurance (FWA) Number		CTEP Site Code
IDENTIFY THE SIGNATORY OFFICIAL AT THE SIGNATORY INSTITUTION		
First Name	Last Name	Degree
Role	Email Address	
Telephone Number ( ) -	Extension	
RESEARCH OVERSIGHT		
Does the Signatory Institution operate an internal IRB? (Yes, No)		

Institution GUID (Internal Use Only)	CIRB-

SECTION B: DESIGNATING SIGNATORY PRIMARY CONTACT PERSON AND RUMS UPDATE PERSON

Provide contact information for at least one person who should be added to the CTSU's Roster Maintenance Update System (RUMS) as an administrative user. This person will be able manage your Signatory Institution's instance of the CIRB Roster, with the rights to add and remove new person and person role records, as well as to add new Component and Affiliate Institutions.

Role Definitions:

- Signatory Primary Contact Person – individuals who will serve as the primary point of contact for NCI CIRB related issues at the Signatory Institution.
- RUMS Update Person – individuals who be provided with administrative rights to the RUMS. The RUMS interface allows designated users associated with a Signatory Institution enrolled with the NCI CIRB to view, manage, and make changes to their own Signatory Institution instance of the CIRB Roster.

All persons listed below must have an active CTEP Person ID. To register or update information with the Cancer Therapy Evaluation Program - Identity and Access Management (CTEP-IAM) follow the directions at https://www.ctsu.org/Public/RegProced_ir-ar.aspx.

Both Section A and Section B must be completed and submitted, to the NCI CIRB Helpdesk at ncicirbcontact@emmes.com.

Once the person listed below has been added to your institution's roster, an email will be sent with directions on how to access and use RUMS to complete your Signatory Institution's Roster.

PERSON INFORMATION		
First Name	Last Name	CTEP Person ID
Role ☐ Signatory Primary Contact Person	☐ RUMS Update Person	
PERSON INFORMATION		
First Name	Last Name	CTEP Person ID
Role ☐ Signatory Primary Contact Person	☐ RUMS Update Person	
PERSON INFORMATION		
First Name	Last Name	CTEP Person ID
Role ☐ Signatory Primary Contact Person	☐ RUMS Update Person	
PERSON INFORMATION		
First Name	Last Name	CTEP Person ID
Role ☐ Signatory Primary Contact Person	☐ RUMS Update Person	
PERSON INFORMATION		
First Name	Last Name	CTEP Person ID
Role ☐ Signatory Primary Contact Person	☐ RUMS Update Person	
PERSON INFORMATION		

First Name	Last Name	CTEP Person ID
Role ☐ Signatory Primary Contact Person ☐ RUMS Update Person		
PERSON INFORMATION		
First Name	Last Name	CTEP Person ID
Role ☐ Signatory Primary Contact Person ☐ RUMS Update Person		

SECTION C: STAFF REQUIRING ACCESS TO IRBMANAGER

Use the role definition below to identify the investigators and research staff who require access to IRBManager that will be added to RUMS by your institution's RUMS Update Person.

Role Definitions:

- Signatory Primary Contact Person – individuals who will serve as the primary point of contact for NCI CIRB related issues at the Signatory Institution.
- RUMS Update Person – individuals who should be provided with administrative rights to the CTSU's Roster Maintenance Update System (RUMS). The RUMS interface allows designated users associated with a Signatory Institution enrolled with the NCI CIRB to view, manage, and make changes to their own Signatory Institution instance of the CIRB Roster.
- Signatory Institution Principal Investigators (PIs) - Investigators who have the authority to open studies under the authority of the Signatory Institution and conform to the Authorization Agreement/Division of Responsibilities with the NCI CIRB.
- Research Staff – individuals who need access to the IRBManager to complete the various required worksheets on behalf of the Signatory Institution or Signatory Institution Principal Investigators.

All persons must have an active CTEP Person ID. To register or update information with the Cancer Therapy Evaluation Program - Identity and Access Management (CTEP-IAM) follow the directions at https://www.ctsu.org/Public/RegProced_ir-ar.aspx.

Sub-Investigators and other support staff that do not require IRBManager access will still have access to the NCI CIRB website and CTSU website through their associations on the Network Group rosters.

SECTION D: COMPONENT INSTITUTIONS AS DEFINED BY THE CIRB

Use the Component Institution definition below to identify the Component Institutions covered on your Signatory Institution's Authorization Agreement that will be added to your institution's roster in RUMS by your institution's RUMS Update Person.

Component Institutions are defined by the CIRB as meeting ALL of the following criteria:

- the Component Institution operates under a different name than the Signatory Institution, but the Signatory Institution has legal authority for the Component Institution;
- the FWA number for the Component Institution is the same as the Signatory Institution;
- the local context considerations of the Component Institution are the same as the Signatory Institution. Local context considerations are reported by the Signatory Institution in the Annual Institution Worksheet About Local Context;
- the boilerplate language and institutional requirements of the Component Institution are the same as the Signatory Institution. The boilerplate language and institutional requirements are reported by the Signatory Institution in the Annual Institution Worksheet About Local Context; and
- the conduct of research at the Component Institution is monitored by the same office as the Signatory Institution.

List all Component Institutions that meet the CIRB's definition. All institutions where NCI CTEP-sponsored clinical research trials are conducted must have a CTEP Site Code. Questions or request for assignment of a CTEP Site Code should be direct to the ECU at ecuhelpdesk@mail.nih.gov.

SECTION E: AFFILIATE INSTITUTIONS AS DEFINED BY THE CIRB

Use the Affiliate Institution definition below to identify the Affiliate Institutions covered on your Signatory Institution's Authorization Agreement that will be added to your institution's roster in RUMS by your institution's RUMS Update Person.

Affiliate Institutions are defined by the CIRB as meeting ALL of the following criteria:

- The local context considerations of the Affiliate Institution are the same as the Signatory Institution. Local context considerations are reported by the Signatory Institution in the Annual Institution Worksheet About Local Context;
- The boilerplate language and institutional requirements of the Affiliate Institution are the same as the Signatory Institution. The boilerplate language and institutional requirements are reported by the Signatory Institution in the Annual Institution Worksheet About Local Context; and
- The conduct of research at the Affiliate Institution is monitored by the same office as the Signatory Institution.

List each Affiliate Institution that meets the CIRB's definition. All institutions where NCI CTEP-sponsored clinical research trials are conducted must have a CTEP Site Code. Questions or request for assignment of a CTEP Site Code should be direct to the ECU at ecuhelpdesk@mail.nih.gov

Posted: June 15, 2017