

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.

- SECTION A: SIGNATORY INSTITUTION INFORMATION 2
- SECTION B: COMPONENT INSTITUTIONS AS DEFINED BY THE CIRB 3
- SECTION C: SIGNATORY INSTITUTION PRINCIPAL INVESTIGATOR INFORMATION 5
- SECTION D: AFFILIATE INSTITUTIONS AS DEFINED BY THE CIRB 111

OMB#: 0925 – xxxx

Expiry Date: xx/xx/xxxx

Collection of this information is authorized by The Public Health Service Act, Section 411 (42 USC 285a). Rights of your participation in the NCI CIRB is protected by The Privacy Act of 1974. Participation is voluntary, and there are no penalties for not participating or withdrawing from the NCI CIRB at any time. Refusal to participate will not affect your benefits in any way. The information collected will be kept private to the extent provided by law. Names and other identifiers will not appear in any report of the NCI CIRB. Information provided will be combined for all participants and reported as summaries. You are being requested to complete this instrument so that we can conduct activities involved with the operations of NCI CIRB Initiative.

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 (0925-0046-16). Do not return the completed form to this address.

Section A: Signatory Institution Information

| 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) | |
|--------------------------------------|--|

Section B: Component Institutions as Defined by the CIRB

Section B: Component Institutions as Defined by the CIRB

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

NOTE: Information about Affiliate Institutions is captured in Section D.

Component Institution Information

| | | |
|-------------------|-------|----------------|
| Institution Name | | CTEP Site Code |
| Street Address | | |
| Street Address #2 | | |
| City | State | Zip |

Component Institution Information

| | | |
|-------------------|-------|----------------|
| Institution Name | | CTEP Site Code |
| Street Address | | |
| Street Address #2 | | |
| City | State | Zip |

Component Institution Information

| | | |
|-------------------|-------|----------------|
| Institution Name | | CTEP Site Code |
| Street Address | | |
| Street Address #2 | | |
| City | State | Zip |

Component Institution Information

| | | |
|-------------------|-------|----------------|
| Institution Name | | CTEP Site Code |
| Street Address | | |
| Street Address #2 | | |
| City | State | Zip |

Component Institution Information

| | | |
|-------------------|-------|----------------|
| Institution Name | | CTEP Site Code |
| Street Address | | |
| Street Address #2 | | |
| City | State | Zip |

Component Institution Information

| | | |
|-------------------|-------|----------------|
| Institution Name | | CTEP Site Code |
| Street Address | | |
| Street Address #2 | | |
| City | State | Zip |

Section B: Component Institutions as Defined by the CIRB

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|--|----------------|-----|
| Component Institution Information | | |
| Institution Name | CTEP Site Code | |
| Street Address | | |
| Street Address #2 | | |
| City | State | Zip |
| Component Institution Information | | |
| Institution Name | CTEP Site Code | |
| Street Address | | |
| Street Address #2 | | |
| City | State | Zip |
| Component Institution Information | | |
| Institution Name | CTEP Site Code | |
| Street Address | | |
| Street Address #2 | | |
| City | State | Zip |
| Component Institution Information | | |
| Institution Name | CTEP Site Code | |
| Street Address | | |
| Street Address #2 | | |
| City | State | Zip |
| Component Institution Information | | |
| Institution Name | CTEP Site Code | |
| Street Address | | |
| Street Address #2 | | |
| City | State | Zip |
| Component Institution Information | | |
| Institution Name | CTEP Site Code | |
| Street Address | | |
| Street Address #2 | | |
| City | State | Zip |
| Component Institution Information | | |
| Institution Name | CTEP Site Code | |
| Street Address | | |
| Street Address #2 | | |
| City | State | Zip |
| Component Institution Information | | |
| Institution Name | CTEP Site Code | |
| Street Address | | |
| Street Address #2 | | |
| City | State | Zip |
| Component Institution Information | | |
| Institution Name | CTEP Site Code | |
| Street Address | | |
| Street Address #2 | | |
| City | State | Zip |

Section C: Staff Requiring Access to IRBManager

Section C: Staff Requiring Access to IRBManager

Provide contact information for investigators and research staff who require access to IRBManager.

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.
- 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 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.

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

Person Information

| | | |
|------------|---|----------------|
| First Name | Last Name | CTEP Person ID |
| Role | <input type="checkbox"/> Signatory Primary Contact Person <input type="checkbox"/> Principal Investigator <input type="checkbox"/> Research Staff | |

Person Information

| | | |
|------------|---|----------------|
| First Name | Last Name | CTEP Person ID |
| Role | <input type="checkbox"/> Signatory Primary Contact Person <input type="checkbox"/> Principal Investigator <input type="checkbox"/> Research Staff | |

Person Information

| | | |
|------------|---|----------------|
| First Name | Last Name | CTEP Person ID |
| Role | <input type="checkbox"/> Signatory Primary Contact Person <input type="checkbox"/> Principal Investigator <input type="checkbox"/> Research Staff | |

Person Information

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| First Name | Last Name | CTEP Person ID |
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Person Information

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| First Name | Last Name | CTEP Person ID |
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Person Information

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| First Name | Last Name | CTEP Person ID |
| Role | <input type="checkbox"/> Signatory Primary Contact Person <input type="checkbox"/> Principal Investigator <input type="checkbox"/> Research Staff | |

Person Information

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| First Name | Last Name | CTEP Person ID |
| Role | <input type="checkbox"/> Signatory Primary Contact Person <input type="checkbox"/> Principal Investigator <input type="checkbox"/> Research Staff | |

Person Information

| | | |
|------------|---|----------------|
| First Name | Last Name | CTEP Person ID |
| Role | <input type="checkbox"/> Signatory Primary Contact Person <input type="checkbox"/> Principal Investigator <input type="checkbox"/> Research Staff | |

Section C: Staff Requiring Access to IRBManager

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|--|-----------|----------------|
| Person Information | | |
| First Name | Last Name | CTEP Person ID |
| Role <input type="checkbox"/> Signatory Primary Contact Person <input type="checkbox"/> Principal Investigator <input type="checkbox"/> Research Staff | | |
| Person Information | | |
| First Name | Last Name | CTEP Person ID |
| Role <input type="checkbox"/> Signatory Primary Contact Person <input type="checkbox"/> Principal Investigator <input type="checkbox"/> Research Staff | | |
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Section C: Staff Requiring Access to IRBManager

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| Person Information | | |
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Section C: Staff Requiring Access to IRBManager

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| Person Information | | |
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| Role <input type="checkbox"/> Signatory Primary Contact Person <input type="checkbox"/> Principal Investigator <input type="checkbox"/> Research Staff | | |
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Section C: Staff Requiring Access to IRBManager

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|--|-----------|----------------|
| Person Information | | |
| First Name | Last Name | CTEP Person ID |
| Role <input type="checkbox"/> Signatory Primary Contact Person <input type="checkbox"/> Principal Investigator <input type="checkbox"/> Research Staff | | |
| Person Information | | |
| First Name | Last Name | CTEP Person ID |
| Role <input type="checkbox"/> Signatory Primary Contact Person <input type="checkbox"/> Principal Investigator <input type="checkbox"/> Research Staff | | |
| Person Information | | |
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Section C: Staff Requiring Access to IRBManager

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|---|---|---|
| Person Information | | |
| First Name | Last Name | CTEP Person ID |
| Role | <input type="checkbox"/> Signatory Primary Contact Person | <input type="checkbox"/> Principal Investigator <input type="checkbox"/> Research Staff |
| Person Information | | |
| First Name | Last Name | CTEP Person ID |
| Role | <input type="checkbox"/> Signatory Primary Contact Person | <input type="checkbox"/> Principal Investigator <input type="checkbox"/> Research Staff |
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| Person Information | | |
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| Person Information | | |
| First Name | Last Name | CTEP Person ID |
| Role | <input type="checkbox"/> Signatory Primary Contact Person | <input type="checkbox"/> Principal Investigator <input type="checkbox"/> Research Staff |
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| First Name | Last Name | CTEP Person ID |
| Role | <input type="checkbox"/> Signatory Primary Contact Person | <input type="checkbox"/> Principal Investigator <input type="checkbox"/> Research Staff |
| Person Information | | |
| First Name | Last Name | CTEP Person ID |
| Role | <input type="checkbox"/> Signatory Primary Contact Person | <input type="checkbox"/> Principal Investigator <input type="checkbox"/> Research Staff |
| Person Information | | |
| First Name | Last Name | CTEP Person ID |
| Role | <input type="checkbox"/> Signatory Primary Contact Person | <input type="checkbox"/> Principal Investigator <input type="checkbox"/> Research Staff |
| <p>If you need to add more staff who require access to IRBManager to assist with completing the required worksheets, access the form located at the following URL https://www.ncicirb.org/Personnel_SignatoryInstitution.doc. Complete the form, save it as a Word document, and email it with your completed Enrollment Form to the CIRB Operations Office at ncicirbcontact@emmes.com.</p> | | |
| <p>Click here to move to the next section.</p> | | |

Section D: Affiliate Institutions as Defined by the CIRB

Section D: Affiliate Institutions as Defined by the CIRB

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

| | |
|--|----------------|
| Affiliate Institution Information | |
| Institution Name | CTEP Site Code |
| FWA Number | |
| Affiliate Institution Information | |
| Institution Name | CTEP Site Code |
| FWA Number | |
| Affiliate Institution Information | |
| Institution Name | CTEP Site Code |
| FWA Number | |
| Affiliate Institution Information | |
| Institution Name | CTEP Site Code |
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| Institution Name | CTEP Site Code |
| FWA Number | |
| Affiliate Institution Information | |
| Institution Name | CTEP Site Code |
| FWA Number | |
| Affiliate Institution Information | |
| Institution Name | CTEP Site Code |
| FWA Number | |

Section D: Affiliate Institutions as Defined by the CIRB (continued)

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|--|----------------|
| Affiliate Institution Information | |
| Institution Name | CTEP Site Code |
| FWA Number | |
| Affiliate Institution Information | |
| Institution Name | CTEP Site Code |
| FWA Number | |
| Affiliate Institution Information | |
| Institution Name | CTEP Site Code |
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| Affiliate Institution Information | |
| Institution Name | CTEP Site Code |
| FWA Number | |
| Affiliate Institution Information | |
| Institution Name | CTEP Site Code |
| FWA Number | |
| <p>If you need to add more Affiliate Institutions, access the form located at the following URL https://www.ncicirb.org/Institution_Affiliate.doc. Complete the form, save it as a Word document, and email it with your completed Enrollment Form to the CIRB Operations Office at ncicirbcontact@emmes.com.</p> | |
| <p>If there are no other Affiliate Institutions, you have completed this form. Please review and return the completed worksheet to the CIRB Operations Office via email to ncicirbcontact@emmes.com. Thank you.</p> | |