
NCI CIRB OVERVIEW

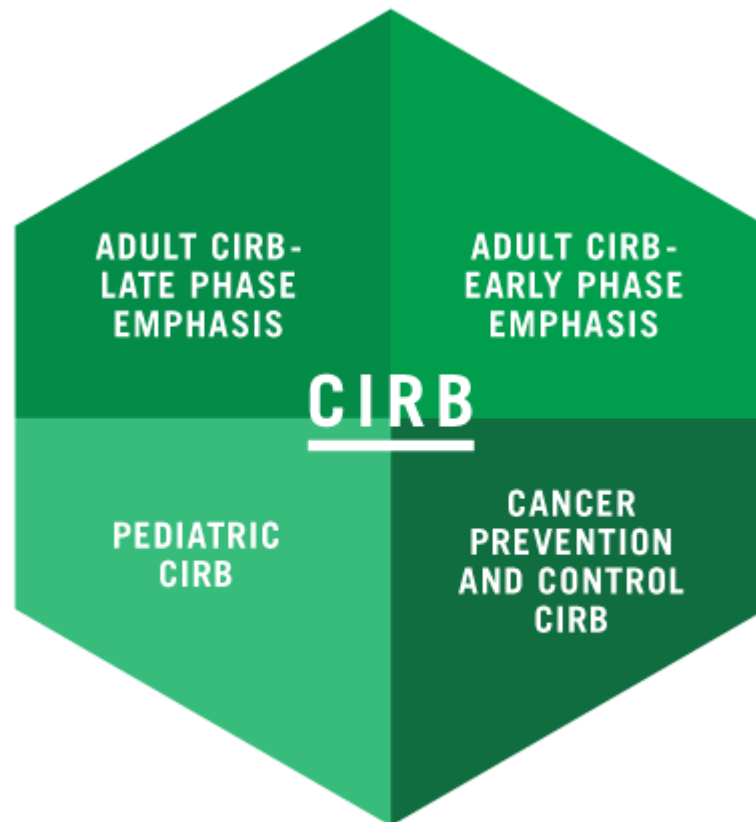
APRIL 25, 2019

SWOG SPRING MEETING -
SAN FRANCISCO

AMANDA P. SLY

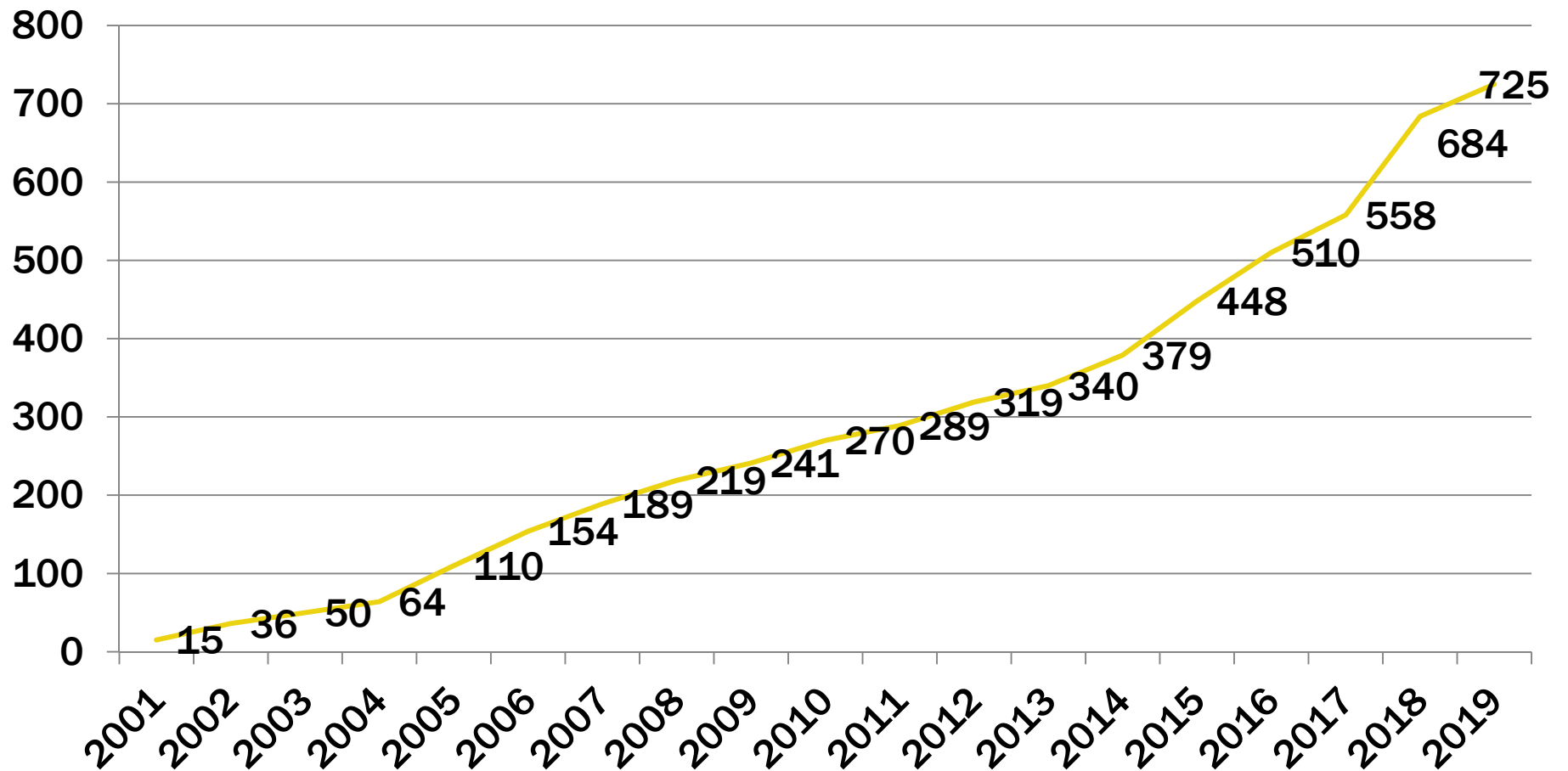
CIRB Overview

NCI CIRB SCOPE

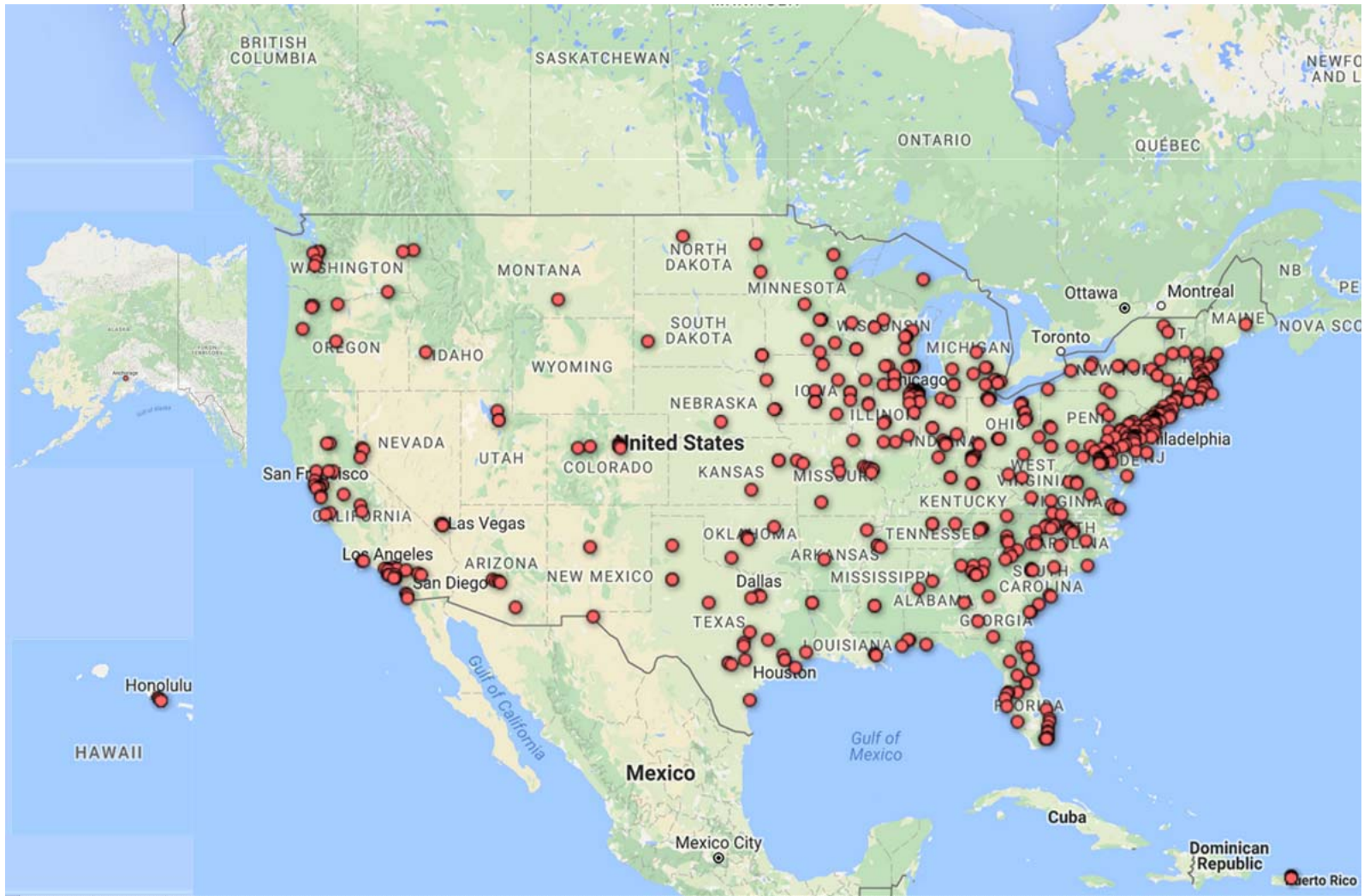


NUMBER OF STUDIES REVIEWED AND APPROVED BY THE CIRB

Number of Studies Reviewed and Approved (cumulative)



MAP OF ENROLLED SIGNATORY INSTITUTIONS (AS OF OCTOBER 1, 2017)



TOTAL NUMBER OF INSTITUTIONS ENROLLED IN THE NCTN

	ALLIANCE	COG	ECOG-ACRIN	NRG	SWOG
Total Unique Institutions	1359	234	1445	2031	1300
Institutions Not in CIRB	49	0	108	108	60
Enrolled in the CIRB	1347	234	1922	1922	1237
Enrolling in the CIRB	17	0	1	1	3
Percent Enrolled/Enrolling	96%	100%	94%	95%	95%

As of April 2, 2018

CIRB WEBSITE

- CIRB website

The screenshot shows the CIRB website homepage. At the top left is the logo "CIRB FOR THE NATIONAL CANCER INSTITUTE". At the top right are links for "IRBManager" and "CTSU". A navigation menu includes "HOME", "ABOUT", "FOR INSTITUTIONS", "FOR NETWORKS", "FOR BOARD MEMBERS", "STUDIES", and "CONTACT US". A search icon is located below the navigation menu. The main content area features a large green banner with the text "WELCOME TO THE CIRB" and "The Central Institutional Review Board for the National Cancer Institute". Below the banner are three columns of content: 1) A person icon with the text "Our priority is to protect the participants in adult and pediatric clinical trials." 2) A building icon with the text "We serve institutions across the nation in conducting NCI sponsored research." 3) A star icon with the text "Our national team of experts ensures that the studies are reviewed to meet the highest ethical and quality standards." To the right of these columns is a grey box titled "ANNOUNCEMENTS" containing the text "No new announcements." and a link to "Announcements Archive".

CIRB WEBSITE



IRBManager CTSU

HOME

ABOUT

FOR INSTITUTIONS

FOR NETWORKS

FOR BOARD MEMBERS

STUDIES

CONTACT US



› Institutions Home

Becoming a Signatory Institution

Quickguides

INSTITUTIONS

This section is for people at [Signatory Institutions](#) and people at organizations that want to become Signatory Institutions. It includes information on becoming a Signatory Institution, as well as Quickguides on all tasks associated with being a Signatory Institution.

Institutions that are part of the NCI Division of Cancer Prevention (DCP) Phase 0/III Cancer Prevention Clinical Trials Program (Consortia) have different processes for gaining access to IRBManager and obtaining CIRB-approved documents. For more information, go to [Navigating the CIRB as a Consortia Site](#).

In addition to the information for CIRB institutions, additional resources include:

- › [CIRB Standard Operating Procedures](#)
- › [List of Institutions](#)

CIRB WEBSITE



IRBManager CTSU

- HOME
- ABOUT
- FOR INSTITUTIONS**
- FOR NETWORKS
- FOR BOARD MEMBERS
- STUDIES
- CONTACT US
- Q

Institutions Home

Becoming a Signatory Institution

Quickguides ▾

Overview of the Study Review Process

Navigating the CIRB as a Consortia Site

Managing a Site

Managing a Study

Special Considerations

IRBManager Basics

QUICKGUIDES

This section contains Quickguides for all activities associated with being a Signatory Institution.

Quickguides can be printed or shared on any page using the icon in the upper right hand corner of the page.

NCI CIRB STRUCTURE

CIRB

Initial, continuing, and amendment review

Local context for enrolled institutions

Trial-wide potential unanticipated problems and serious or continuing noncompliance (UP/SCN)

Locally-occurring potential UP/SCN

Review of studies that have an enrolled participant that become incarcerated while on study

INSTITUTION

Oversight of the research at the enrolled institutions

Adequate staff and resources are available to the PI

Identification and reporting of locally-occurring UP/SCN

HIPAA

LOCAL CONTEXT

Local context considers:

- › Local population for any unique requirements and protections for the institution's vulnerable populations
- › Investigator resources
- › Confirmation that boilerplate language for the consent form complies with the federal regulations

Established through:

- › Signatory Institution Worksheet
- › Principal Investigator Worksheet when the PI is ready to open a study, the PI must submit a Study-Specific Worksheet to confirm the status of local context

CIRB REVIEW PROCESS

CIRB REVIEW

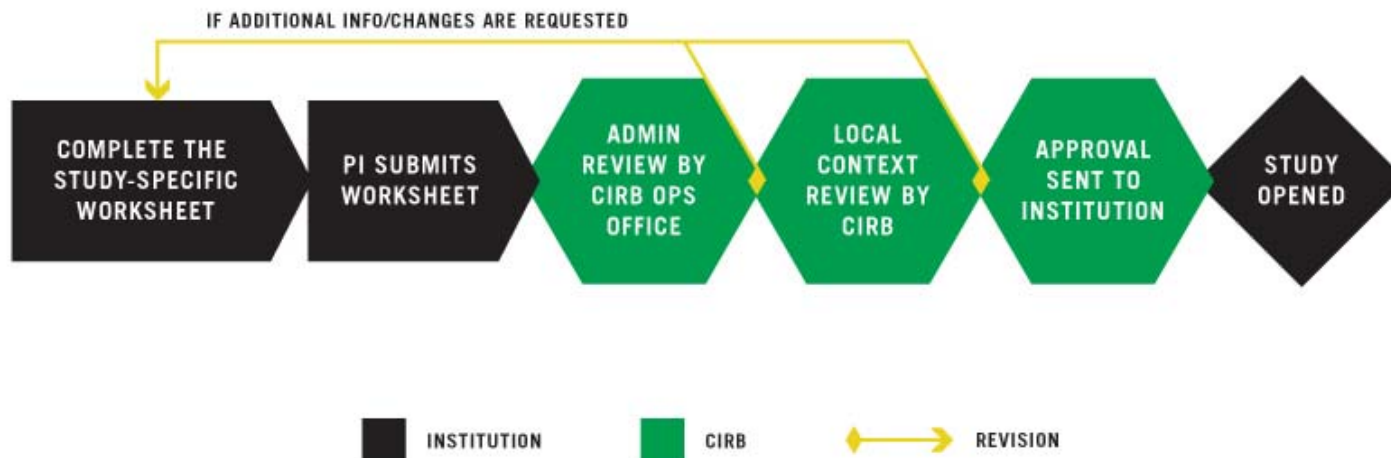


LOCAL CONTEXT REVIEW



OPENING A STUDY

- Identify a study that is CIRB-approved
 - Access the CIRB-approved documents from the CIRB tab on the CTSU website
- Opening a Study



CIRB Process and Policy

ENROLLMENT IN THE CIRB

HOW DO I ENROLL MY INSTITUTION IN THE CIRB?

Becoming a Signatory Institution

Part 1: Applying for Membership

To begin enrollment, an institution must apply for CIRB membership. This part of the process includes:

- Submitting an Enrollment Form
- Submitting an Authorization Agreement
- Establishing the institution's main contact, plus any additional contacts, who will be interacting with the CIRB

Part 2: Documenting Local Context

- After completing Part 1, the institution will then be granted access to CIRB Worksheets to establish the institution's local context.

AFTER ENROLLMENT IN THE CIRB

HOW DO I UPDATE MY INFORMATION ONCE ENROLLED?

- All updates are made by your institution's RUMS Update Person
- Instructions for Making Changes
 - Component or Affiliate Institution changes visit the CIRB Quickguide entitled **UPDATING YOUR CIRB INSTITUTION ROSTER USING RUMS**
<https://ncicirb.org/institutions/institution-quickguides/managing-site/updating-your-cirb-institution-roster-using-rums>
 - Personnel changes visit the CIRB Quickguide entitled **UPDATING YOUR CIRB PERSON ROSTER USING RUMS**
<https://ncicirb.org/institutions/institution-quickguides/managing-site/updating-your-cirb-person-roster-using-rums>

BOILER PLATE AND CONSENT FORM CHANGES

WHAT IS BOILERPLATE LANGUAGE?

It's the institution's standard template language that is inserted (added not replace) into a CIRB-approved model consent form. Boilerplate language is not the same thing as your institution's template consent form.

Some examples of boilerplate language are:

- Local contact information.
- State and local laws pertaining to informed consent.
- Institutional policy related to research on NCI-funded studies as allowed in the CIRB Quickguide.
- Reference CIRB Quickguide **BOILERPLATE LANGUAGE Q & A**
<https://ncicirb.org/content/boilerplate-language-q>

BOILER PLATE AND CONSENT FORM CHANGES

NEW BOILER PLATE POLICY

- New policy regarding boilerplate language was issued November 27, 2018 by Dr. Jeff Abrams
- Greatly limit changes to the model consent form via boilerplate
- Deletions permitted: ONLY pregnancy language for faith based institutions
- Additions permitted: Additions are outlined in the CIRB Quick guide entitled **GUIDELINES FOR PERMITTED BOILERPLATE LANGUAGE ADDITIONS** and is found on the CIRB website. This guide outlines section by section which additions are permissible and which are not.

<https://ncicirb.org/content/guidelines-permitted-boilerplate-language-additions>

BOILER PLATE AND CONSENT FORM CHANGES

WHAT SHOULD NOT BE SUBMITTED AS BOILERPLATE LANGUAGE?

- Changes to the NCI Consent Form Template.
- Changes to the section titles.
- Language stating the sponsor will pay for an injury.
- Deletion of required template language.
- Changes inconsistent with the requirements of the Networks.
- Wordsmithing changes.
- Changes to the standard risk tables for study drugs.
- HIPAA language must not be embedded in the informed consent document and must be a standalone document.

BOILER PLATE AND CONSENT FORM CHANGES

WHAT SHOULD NOT BE SUBMITTED AS BOILERPLATE LANGUAGE?

- GINA language is not research specific and should not be included in the informed consent document.
- Financial conflict of interest (COI) for an institution or investigator. COI should be included in a Study Specific Worksheet if needed and added as its own section at the of the document.
- Dosimetry information related to research images or research radiation. This may be included in a Study Specific Worksheet if the scans or radiation are all for research and not for standard of care.

SHORT FORMS

DOES THE CIRB ALLOW SHORT FORMS?

- Short Forms will assist local institutions by streamlining the enrollment of study participants who do not speak English.
- Short forms were developed in collaboration with CTSU and available on their website.

- Short Forms are available on the CTSU website in 11 languages.

Arabic	Korean	Vietnamese
Creole (Haitian)	Portuguese – Brazil	Tagalog
French	Russian	Italian
German	Spanish	

- Reference CIRB Quickguide **SHORT FORM Q & A**

<https://ncicirb.org/institutions/institution-quickguides/managing-study/short-form-q>

SHORT FORMS

WHEN CAN A SHORT FORM BE USED?

- There is no protocol eligibility restriction based on language that prohibits enrollment of the participant.
- The Signatory Institution's policies permit the use of short form consents.
- These policies have been reported to the CIRB on either the Annual Signatory Institution Worksheet or the Annual PI Worksheet.
- A CIRB-approved short form exists in a language understandable to the potential participant.
- **Institutional Policy on Short Forms:**
 - For Signatory Institutions that do not already have a policy in place for the use of short form consents, we recommend that one be developed.
 - What should be in this policy is outlined detail in the **SHORT FORM Q & A** quickguide
- You may submit your own translated short forms for approval on either the Annual Signatory Institution Worksheet or the Study-Specific Worksheet.

TRANSLATIONS

DOES THE CIRB PROVIDE TRANSLATIONS?

Trial-wide translations approved by the CIRB require:

- › An approved English version (can be submitted with translation)
- › A translated version of the English document
- › Certificate of accuracy that the translation reflects the English version

Trial-wide Spanish Consent Forms

- › Translated by CTSU
- › Approved by the CIRB
- › Posted on the CIRB tab

Local Translations

- › Submitted via Worksheet
- › Requirements are the same as for trial-wide translations
- › Approval letter provided

2018 COMMON RULE CHANGES

DID THE CONTINUING REVIEW POLICY CHANGE?

- 2018 Common Rule allows for Continuing Review (CR) may be conducted on a more limited basis in certain circumstances
- CIRB's policy has remained unchanged. CR is required once per year and continue until all identifiable data has been analyzed.

IS THE CIRB CONDUCTING LIMITED IRB REVIEW?

- Categories for Exempt IRB review were updated and Limited IRB Review was added.
- CIRB will conduct all limited reviewed as full expedited reviews.

IS THE CIRB ALLOWING FOR BROAD CONSENT?

- Broad consent was added to the 2018 Common Rule.
- The CIRB will not allow for Broad Consent.

SINGLE IRB POLICY AND COMMON RULE

SINGLE IRB POLICY

- NIH single IRB (sIRB) Policy
 - Effective January 25, 2018
 - New NIH policy requiring a single IRB for multi-site research
- 2018 Common Rule
 - Single IRB regulation change effective January 19, 2020
 - Scope of changes are limited to internal CIRB processes should not impact sites
 - New NCI Consent Form Template effective December 17, 2017
 - CIRB SOP's have been updated

PRISONERS

DOES THE CIRB REVIEW FOR PRISONERS?

The CIRB is in the process of updating SOPs and procedures to allow for the review of participants who become incarcerated while on study. The CIRB will not review for research which targets prisoners.

The CIRB is constituted to review if a study participant becomes incarcerated during the course of a study and the investigator determines it in the best interest of the study participant to remain on study while incarcerated.

- › Investigator submits a requests for enrolled participant to continue on a CIRB-approved study while incarcerated.
- › CIRB will Review investigator requests for enrolled participants to continue on a CIRB-approved study while incarcerated and provide a determination letter.
- › Conduct a convened review for enrolled participants on a study to fulfill the regulatory requirements of subpart C

STUDY CLOSURE AND TRANSFER PROCESS CHANGE

WHAT HAS CHANGED TO THE STUDY CLOSURE AND TRANSFER PROCESS?

- As of 04/10/19, the Study Closure and Transfer of Review Responsibilities worksheet was updated
- Changed to allow multiple studies as part of a single submission.
- Reduce the need for individual worksheet submissions for each affected study, thus reducing the administrative burden on local site staff.
- Reference CIRB Quickguide **COMPLETING THE STUDY CLOSURE OR TRANSFER OF STUDY REVIEW RESPONSIBILITY WORKSHEET**
<https://ncicirb.org/institutions/institution-quickguides/managing-study/short-form-q>

CHANGE OF PI PROCESS CHANGE

WHAT HAS CHANGED TO THE CHANGE OF PI PROCESS?

- As of 10/01/18, a new worksheet called the Change of PI Worksheet was been implemented
- This allows multiple studies to be changed to a new PI as part of a single submission.
- Reduce the need for individual Worksheet submissions for each affected study, thus reducing the administrative burden on local site staff as well as the CIRB's review process.
- The removal of study specificity will require staff to submit a separate revised Annual Principal Investigator Worksheet or revised Study-Specific worksheet for any affected study that has a change in the local context considerations.
- Reference CIRB Quickguide **CHANGING THE PI ON A STUDY**
<https://ncicirb.org/content/changing-pi-study>

CIRB HELPDESK CONTACT

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[HTTPS://NCICIRB.ORG](https://ncicirb.org)