NCI CIRB OVERVIEW

OCTOBER 12, 2017

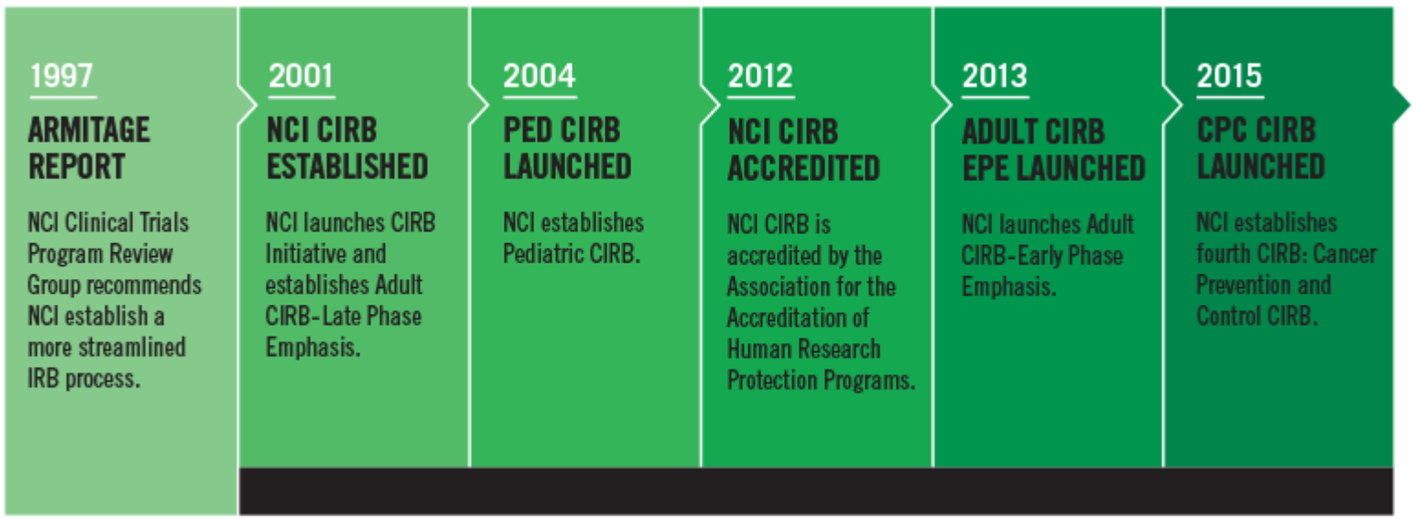
SWOG FALL MEETING – CHICAGO, ILLINOIS

LAURA COVINGTON

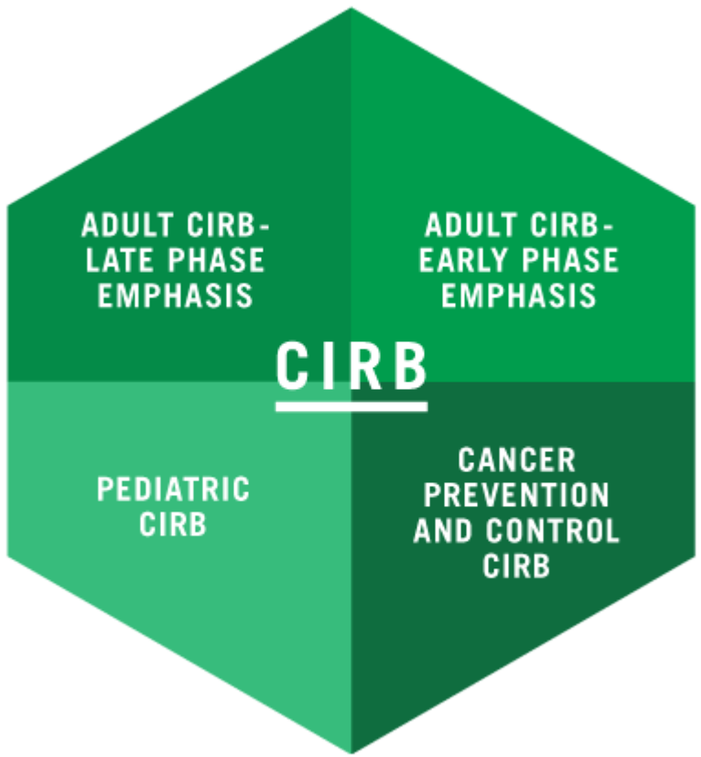
C›I›R›B

FOR THE NATIONAL CANCER INSTITUTE

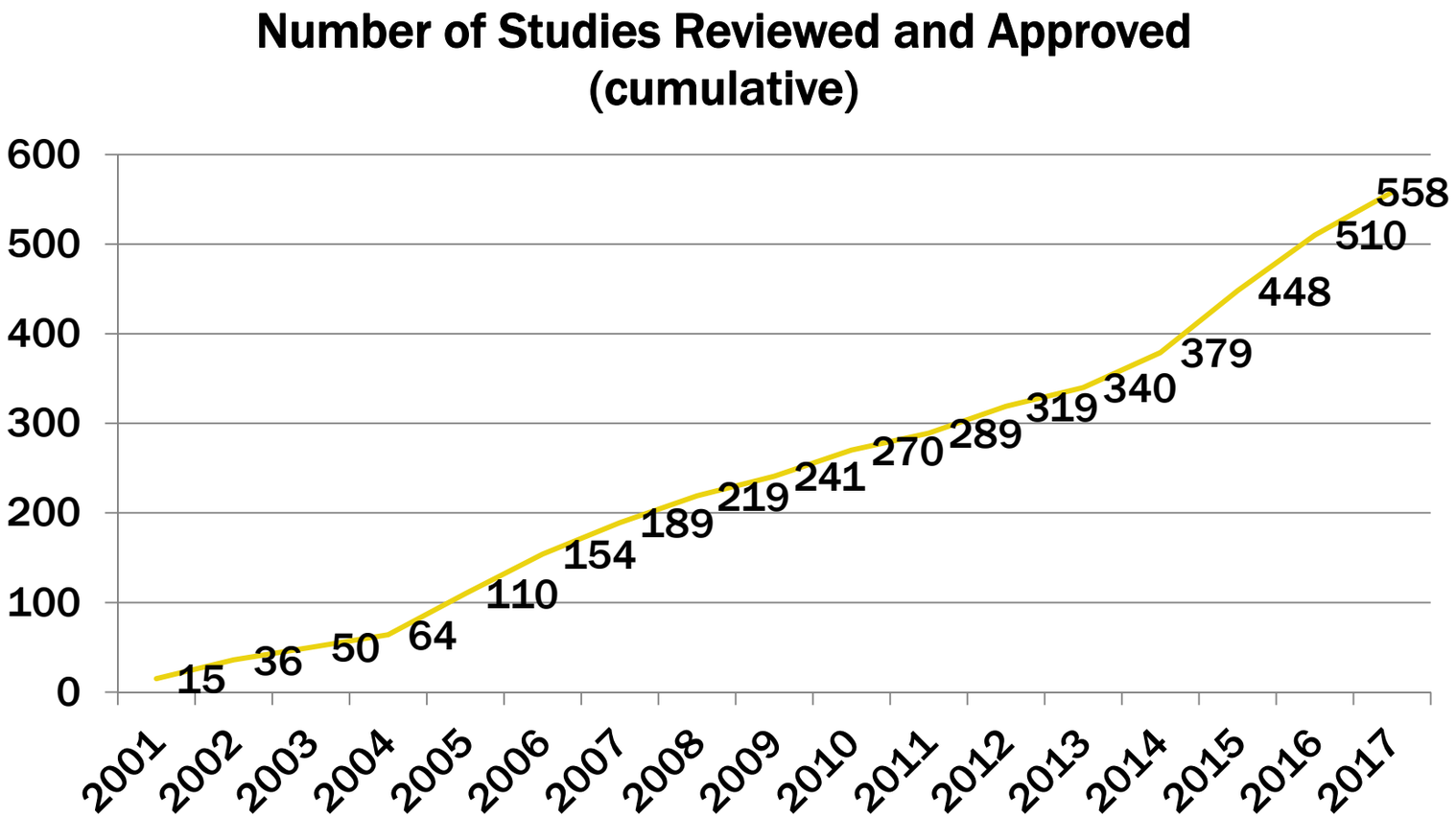
BACKGROUND


1997
ARMITAGE REPORT
NCI Clinical Trials Program Review Group recommends NCI establish a more streamlined IRB process.
2001
NCI CIRB ESTABLISHED
NCI launches CIRB Initiative and establishes Adult CIRB-Late Phase Emphasis.
2004
PED CIRB LAUNCHED
NCI establishes Pediatric CIRB.
2012
NCI CIRB ACCREDITED
NCI CIRB is accredited by the Association for the Accreditation of Human Research Protection Programs.
2013
ADULT CIRB EPE LAUNCHED
NCI launches Adult CIRB-Early Phase Emphasis.
2015
CPC CIRB LAUNCHED
NCI establishes fourth CIRB: Cancer Prevention and Control CIRB.

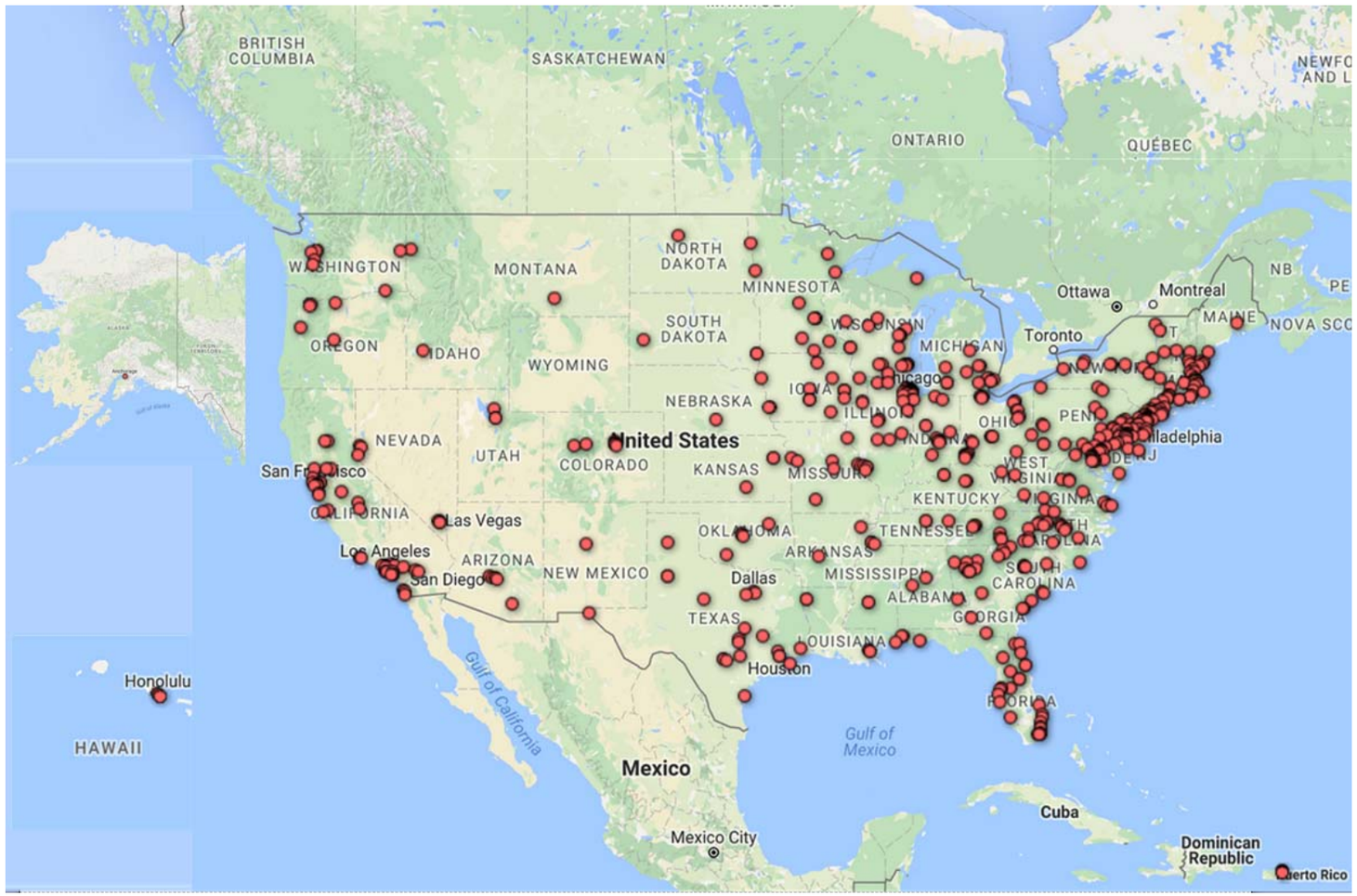
NCI CIRB SCOPE



NUMBER OF STUDIES REVIEWED AND APPROVED BY THE CIRB



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	1355	235	1424	2029	**1271**
Institutions Not in CIRB	111	3	124	194	**105**
Enrolled in the CIRB	1228	228	1284	1818	**1156**
Enrolling in the CIRB	16	4	16	17	**10**
Percent Enrolled/Enrolling	92%	99%	91%	90%	**92%**

As of September 1, 2017

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

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

Review of studies enrolling prisoners at the institution

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

KEY CIRB ROLES

CIRB's Term	Common Meaning
Study Chair	The individual responsible for the overall conduct of the study across all participating institutions. Submits studies for initial review, continuing review, amendments, etc.
Signatory Institution	An institution that enrolls in the CIRB and may include component and affiliate institutions.
Signatory Institution Primary Contact	The main contact at the Signatory who helps establish the Signatory Institution with the CIRB and is copied on all correspondence with the CIRB.
Principal Investigator (PI)	The individual(s) at a Signatory Institution responsible for the conduct of the study at their specific institution. The PI may open studies with the CIRB.
Research Staff	Individuals that support the PI and may assist in the completing submissions to the CIRB.

CIRB ROSTER

- Who should be on the CIRB roster?
  - People who complete or view IRBManager Worksheets
  - People who access CIRB documents via the CTSU website
- How do you add people to the CIRB roster
  - Prerequisites: CTEP Person ID and CTEP IAM account
- What are the CIRB roles? (Quickguide: Individual Roles within CIRB)
    - Signatory Institution Primary Contact: point of contact for the CIRB; copies on all correspondence from the CIRB to the institution and PI
    - Principal Investigator (PI): person who will be opening studies with the CIRB and is responsible for that study
    - Research Staff: person who supports the PI
    - RUMS Update Person: person who can update the CIRB roster in RUMS

ENROLLMENT IN THE CIRB

- Initial Signatory Institution enrollment 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

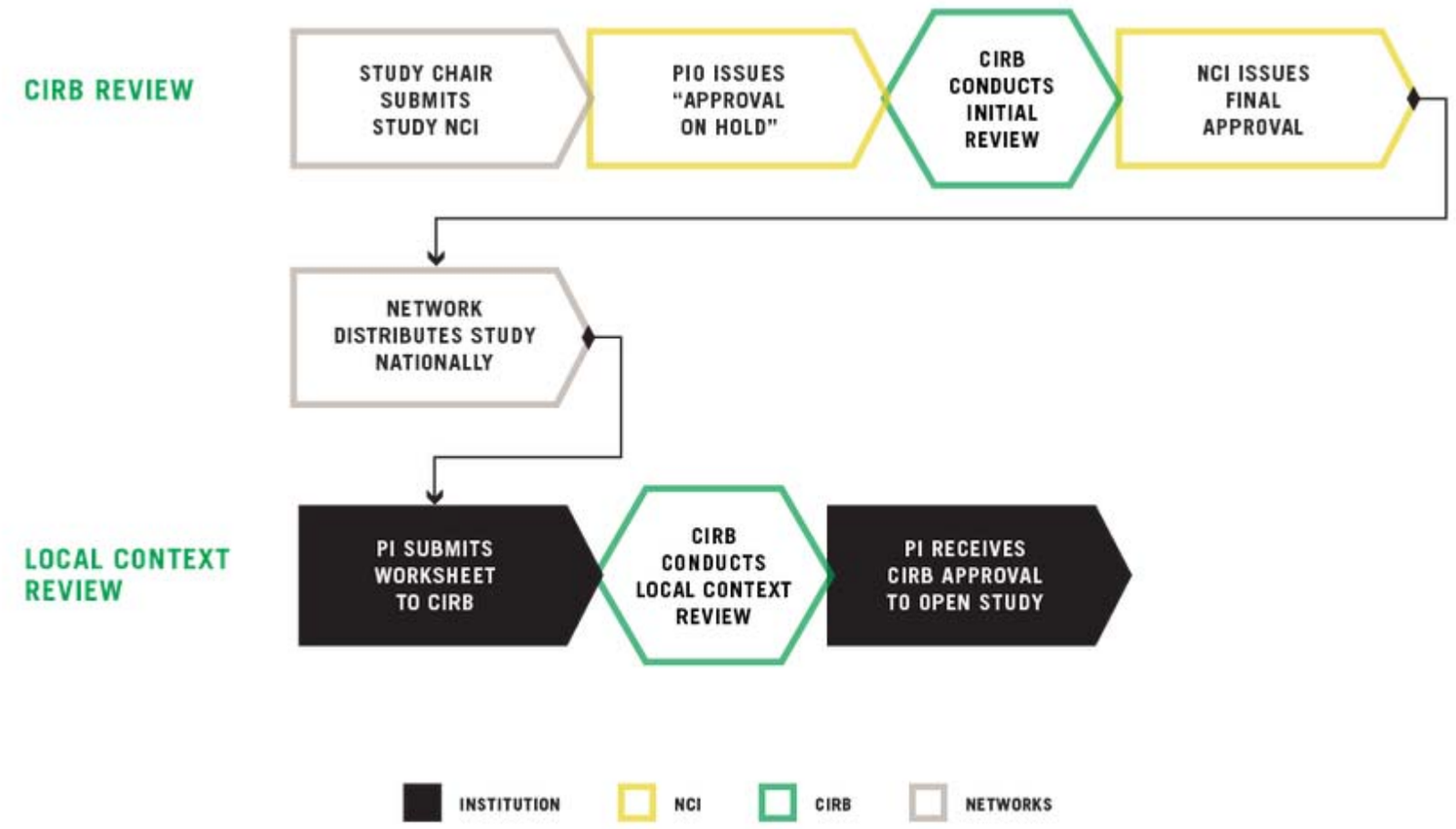
Part 2: Documenting Local Context

- 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

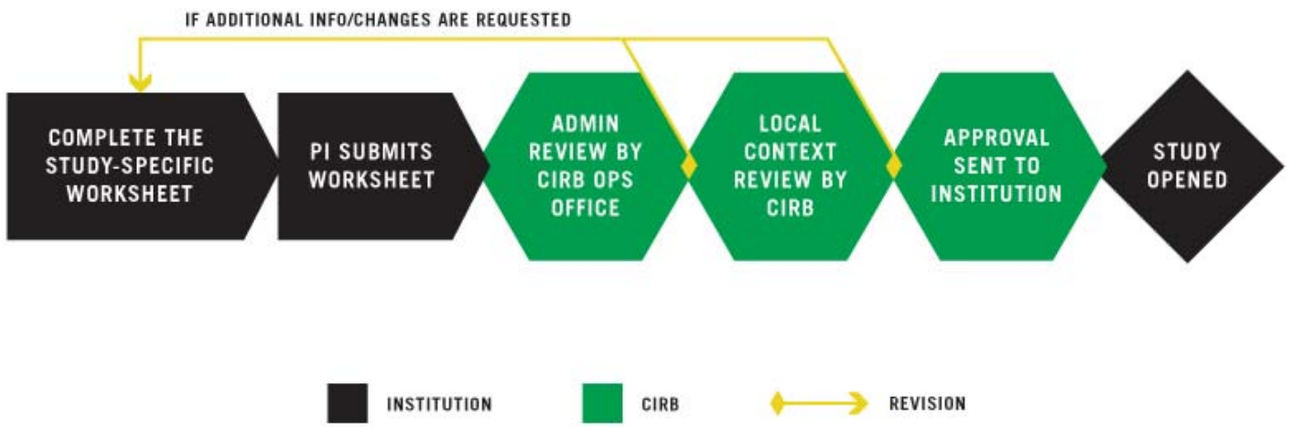
- All updates are made by your institution's RUMS Update Person Instructions for Making Changes
    - Component or Affiliate Institution changes
        - Updating Your CIRB Institution Roster Using RUMS
    - Personnel changes
        - Updating Your CIRB Person Roster Using RUMS

CIRB REVIEW PROCESS



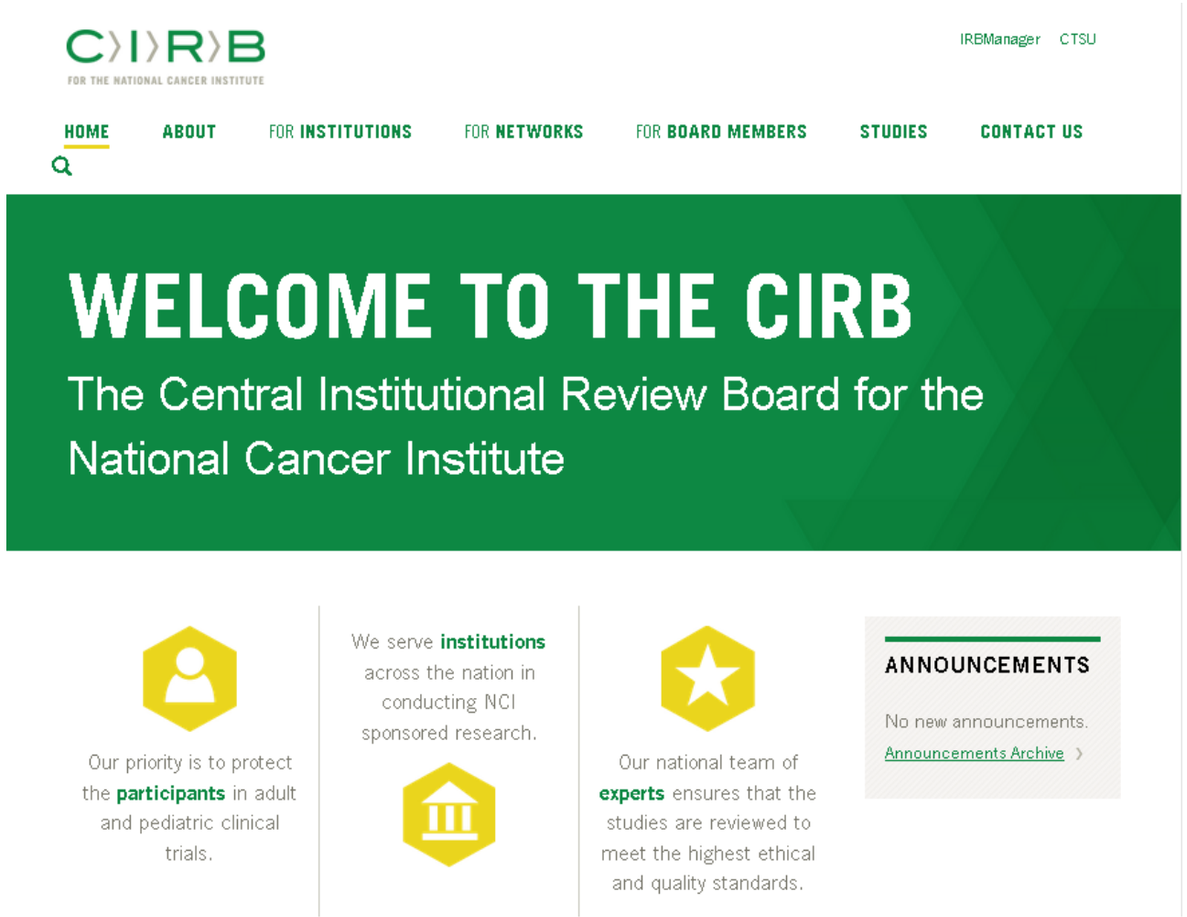
OPENING A STUDY

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

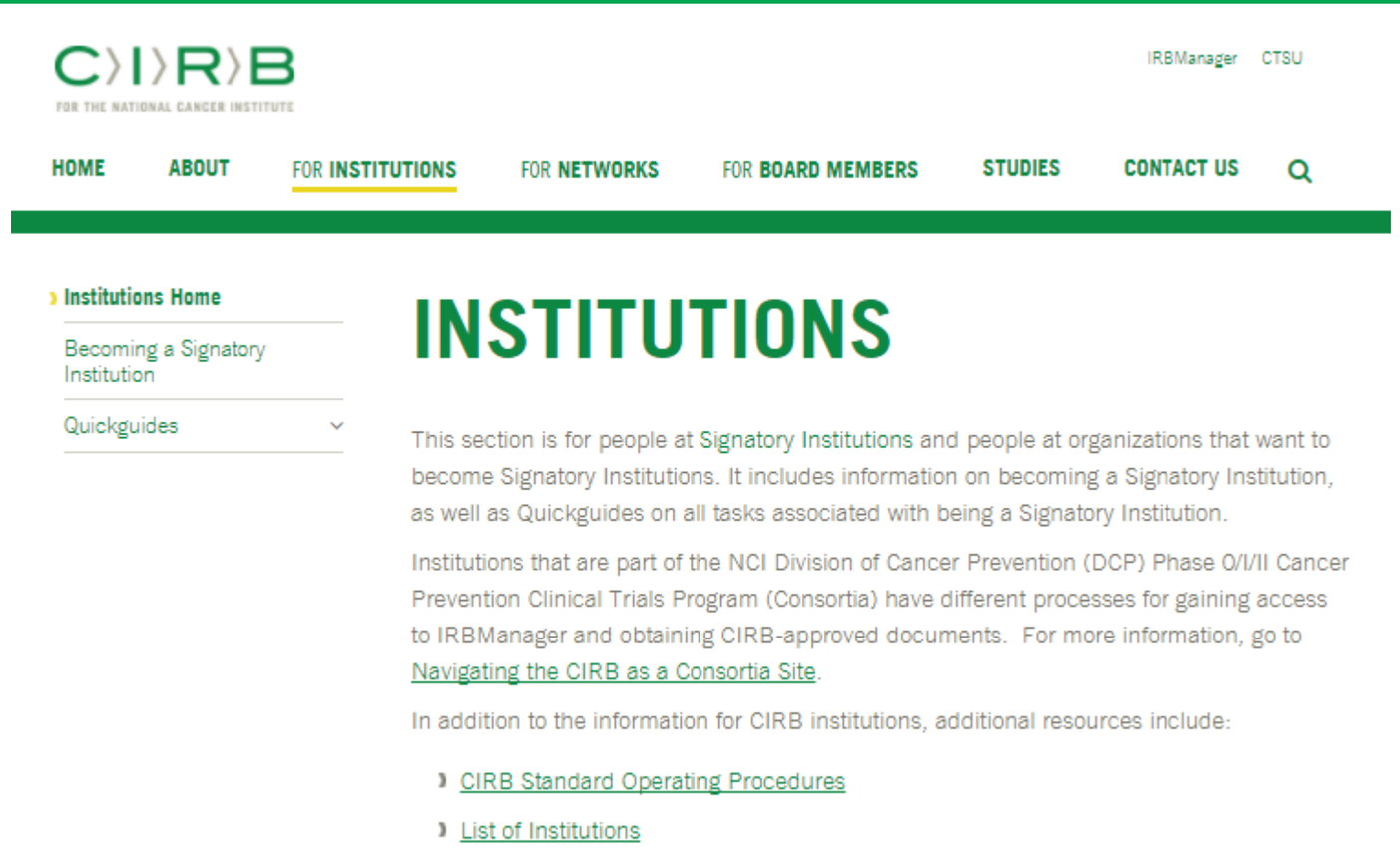


CIRB WEBSITE

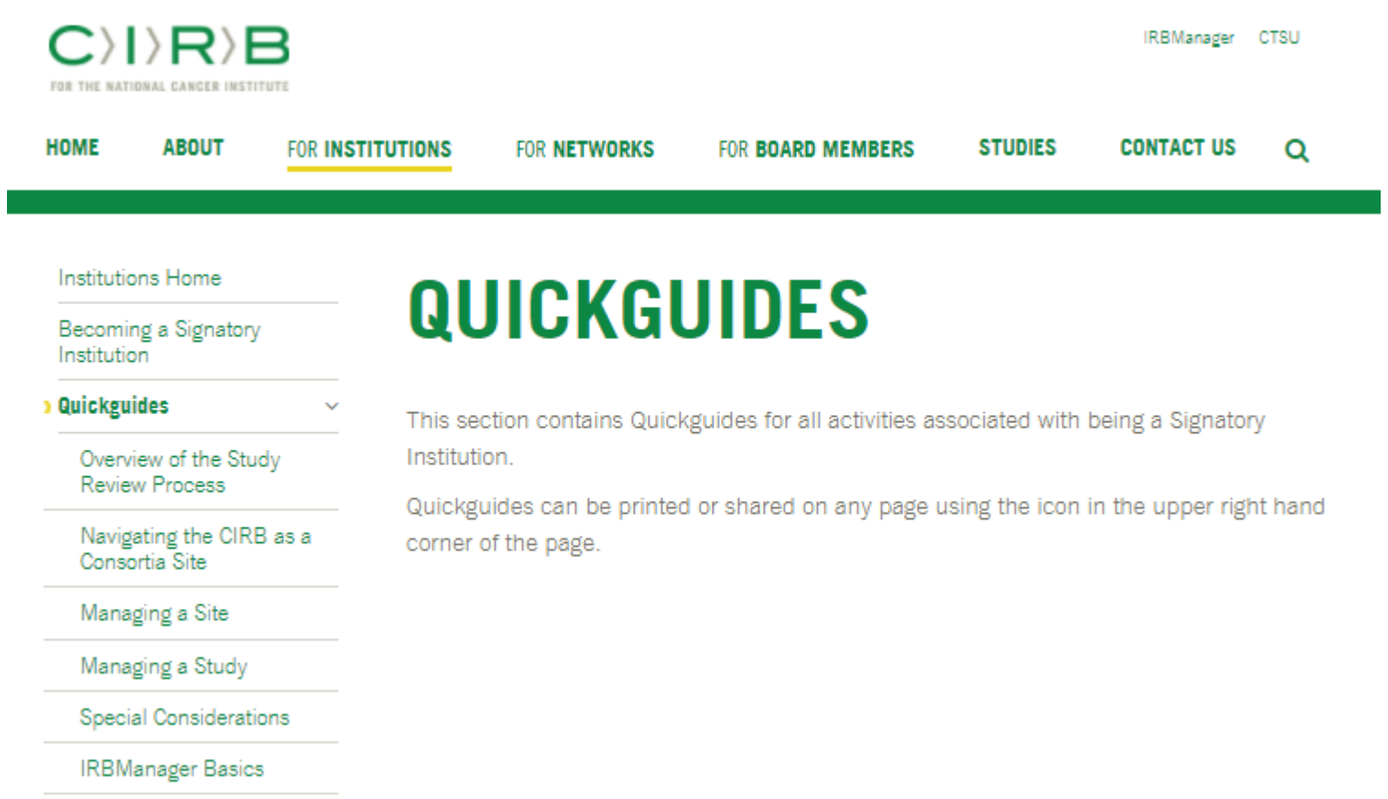
- CIRB website



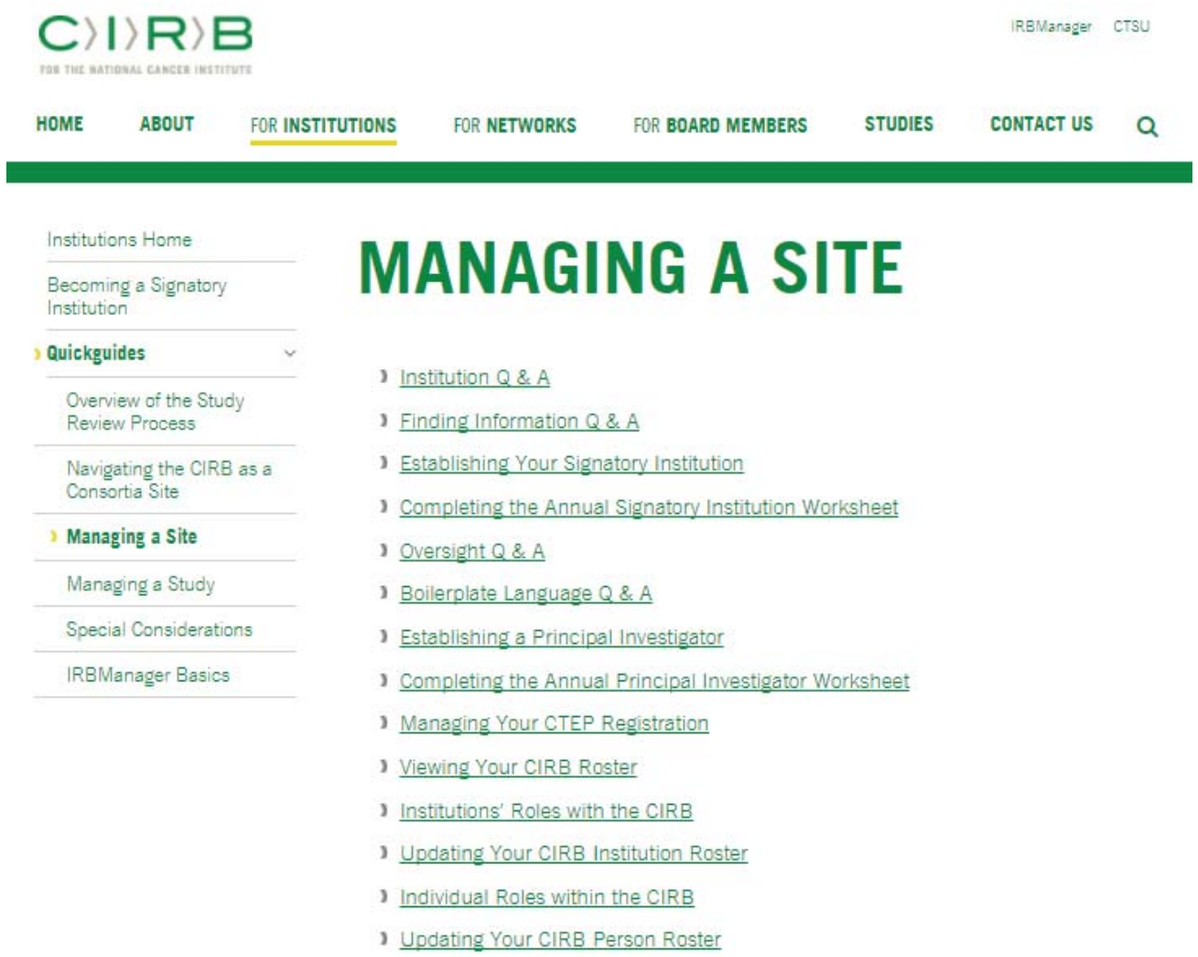
CIRB WEBSITE



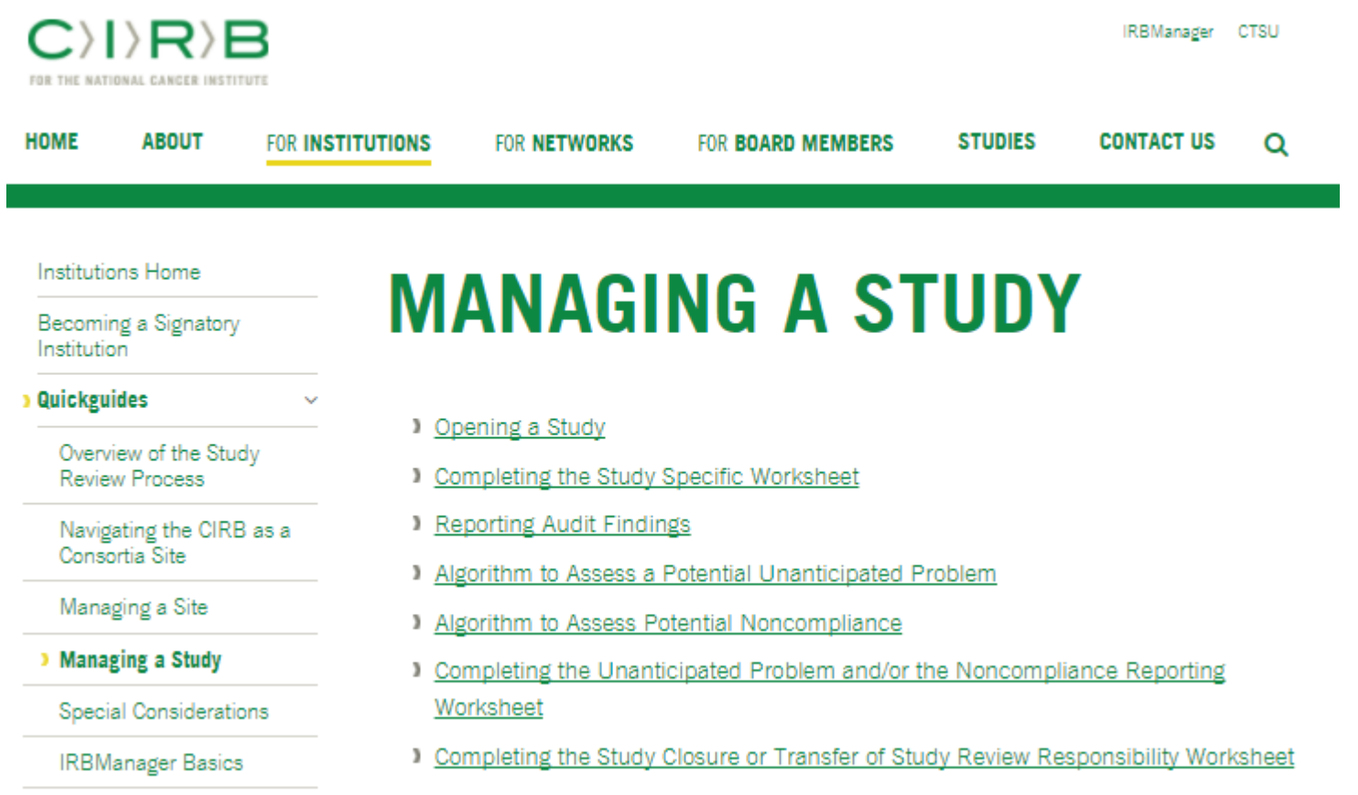
CIRB WEBSITE



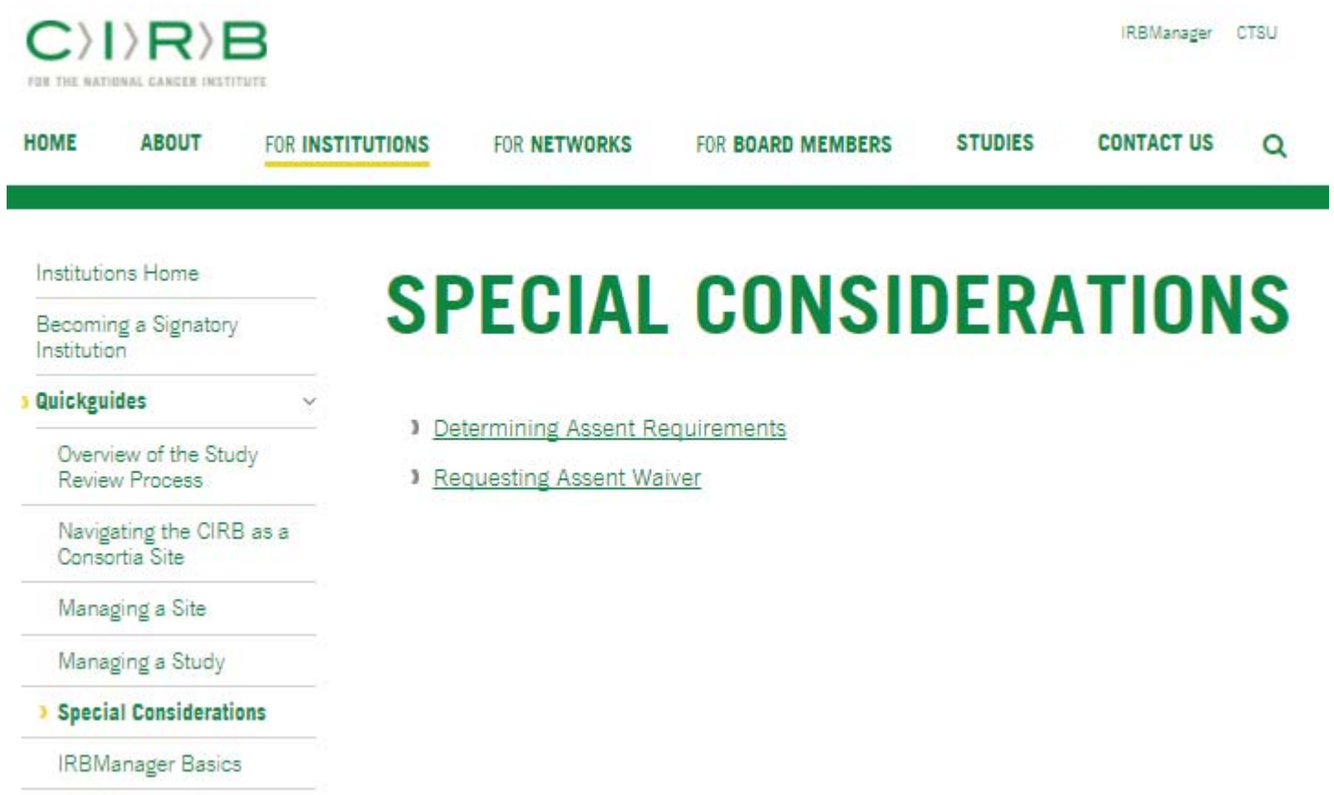
CIRB WEBSITE



CIRB WEBSITE



CIRB WEBSITE



UPCOMING POLICY CHANGES

- NIH single IRB (sIRB) Policy
    - Effective January 25, 2018
    - New NIH policy requiring a single IRB for multi-site research
    - If you are not enrolled in the CIRB, start the enrollment process now
- Common Rule 2.0
    - Effective January 19, 2018; 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

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 (not required for validated translations)

Local Translations

- Submitted via Worksheet
- Requirements are the same as for trial-wide translations
- Cannot submit local translations for validated instruments
- Approval letter provided

TRANSLATIONS

Trial-wide Spanish Consent Forms

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

Translated Quality of Life (QOL) and Patient Reported Outcomes (PRO)

- In response to questions from sites, the CIRB will require the protocol to address eligibility and the availability of translated QOL and PRO
- If mandatory, protocol must identify available languages and instructions for accessing translated tools
- New process – expect to see in protocols later this year

SHORT FORMS

- CIRB Policy: designed for flexibility
- Trial-wide impact:
  - CIRB determines whether short forms are appropriate for a specific protocol
  - Determination noted in the protocol review outcome letter
- Local impact:
  - Annual PI Worksheet: revised questions for consenting non-English speaking participants implemented in the next month
  - No institutional short form policy? CIRB prepared an outline for creating a policy that will be available on the CIRB website when changes to the Annual PI Worksheet are implemented
- Bank of short form translations will be provided on CTSU website

CIRB HELPDESK CONTACT

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