



# Managing studies approved by WCG IRB

CHLA  
March 18, 2021

## WCG IRB Announcement



In October 2020, WCG announced the formal unification of their five industry-leading IRBs – Western IRB (WIRB), Copernicus Group IRB (CGIRB), Midlands IRB (MLIRB), New England IRB (NEIRB), and Aspire IRB – into the single WCG IRB.

WCG IRB clients experience a singular, unified process and fee schedule. WCG IRB continues to deliver gold standard service with the highest regard to ethics and integrity.

## What We Will Cover In Today's Session

- System Walkthrough
- Submission Types and Process for approved sites
- Navigating Workspaces
- Existing Legacy MyConnexus Users: System Transition “Need to Know” Information
- Resources and Support





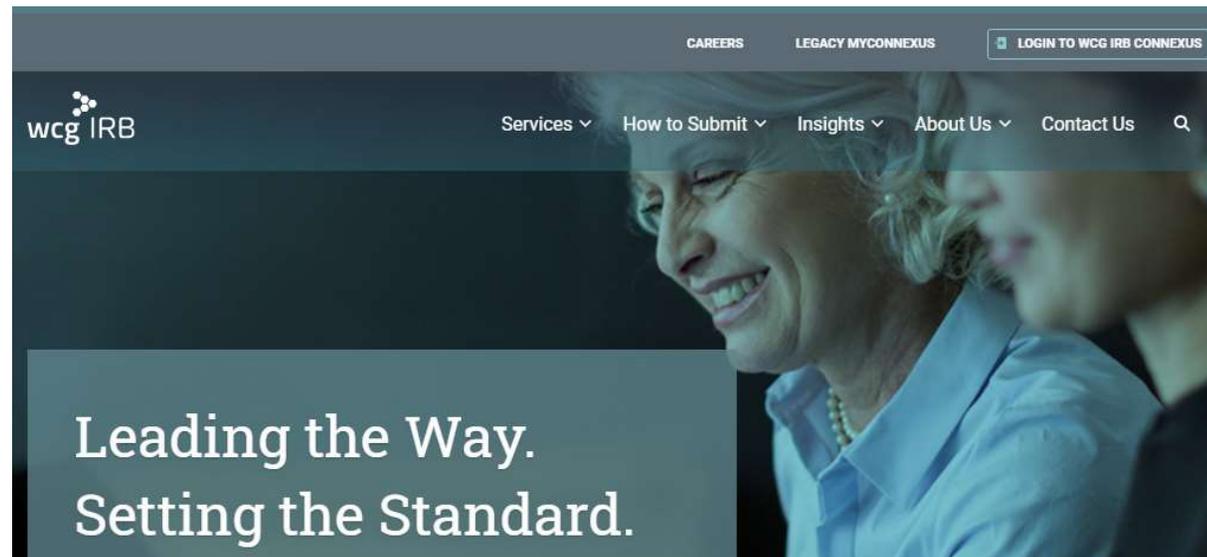
# System Access & Signing In



## System Access

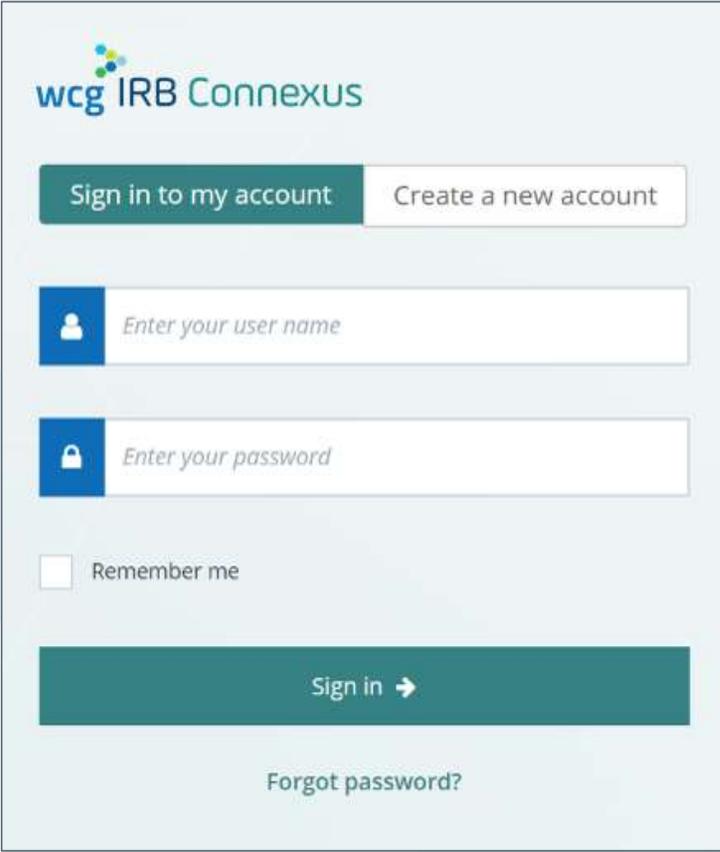


- **WCG IRB Website:** <http://www.wcgirb.com>
  - Login to WCG IRB Connexus link
- **Direct Link:** <https://connexus.wcgirb.com>



## Signing In

- Legacy MyConnexus users need to reset password and accept the Terms & Conditions upon initial sign in, click on Forgot Password
- Use the same registered email address as you have in Legacy MyConnexus
- Your username is your email address
- New users can register using **Create a new account**



The screenshot shows the login interface for wcg IRB Connexus. At the top left is the logo. Below it are two buttons: 'Sign in to my account' (highlighted in dark teal) and 'Create a new account'. There are two input fields: the first is for the user name with a person icon and the placeholder text 'Enter your user name'; the second is for the password with a lock icon and the placeholder text 'Enter your password'. Below the password field is a checkbox labeled 'Remember me'. At the bottom is a large dark teal button labeled 'Sign in →' and a link for 'Forgot password?'.

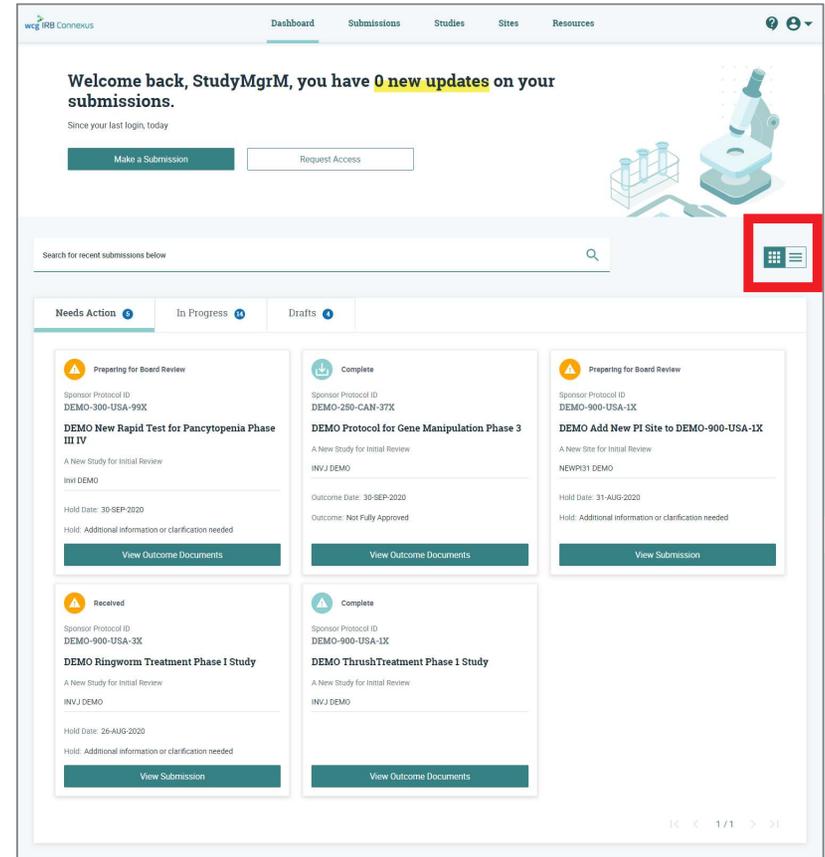


# The Dashboard



# WCG IRB Connexus Dashboard

- Central hub for most WCG IRB Connexus activity
- Contains:
  - Notification area
  - Make a Submission button
  - Request Access button
  - Track Submissions area
    - Search
    - Tabs – Needs Action, In Progress, Drafts
    - Two different views per your preference



# Dashboard – Card and Table Views

- Two different options for easily viewing submission/study details

 **Received** **New**

Sponsor Protocol ID  
**AB-1234-567**

**IR for Double-Blind Trial of  
Chemotherapy**

A New Study for Initial Review

2 Sites [View All](#)

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Hold Date: 01-JUN-2020

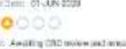
Hold: Awaiting CRO review and release

[View Submission](#)

wcg IRB Connects Dashboard Submissions Studies Sites Resources

**Needs Action 10** **In Progress 15** **Drafts 3**

**All** **On Hold 6** **Outcome Needs Action 0** **Outcome Complete 1**

Submissions	Sponsor Protocol ID	Status	
<b>New</b> A New Study for Initial Review <b>IR for Double-Blind Trial of Chemotherapy</b> 2 Sites <a href="#">View All</a>	AB-1234-567	NEW DATE: 01-JUN-2020  Hold: Awaiting CRO review and release	<a href="#">View Submission</a>
<b>New</b> A New Study for Initial Review <b>CR Submission Name</b> 2 Sites <a href="#">View All</a>	CD-1234-567	Outcome Date: 01-JUN-2020  Outcome: Outcome review here	<a href="#">View Submission</a>
<b>Withhold Study</b> <b>IR for Double-Blind Trial of Chemotherapy</b> 2 Sites <a href="#">View All</a>	EF-1234-567	Outcome Date: 01-JUN-2020  Outcome: Outcome review here	<a href="#">View Submission</a>

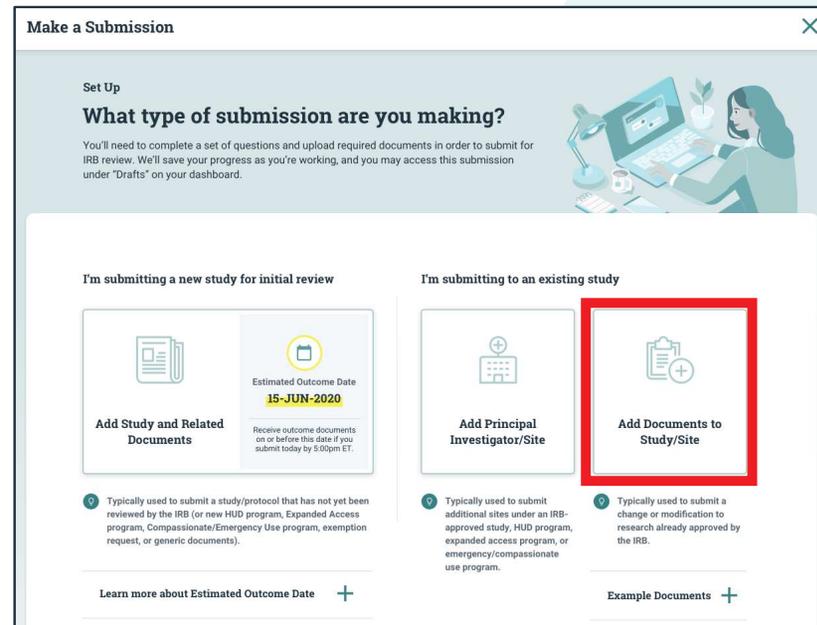
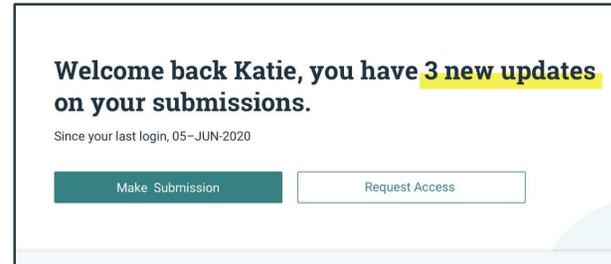
10 15 3 1

# Make a Submission

The **Make Submission** button on the Dashboard allows you to start any type of submission

Select one of the following options:

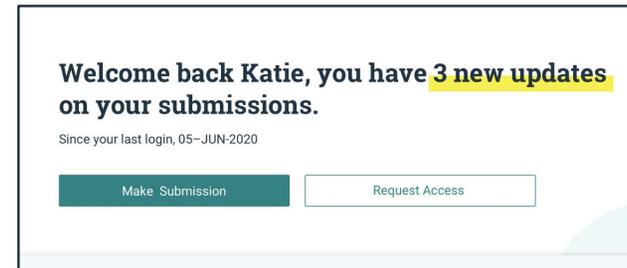
- Initial Review of New Protocol (not yet reviewed by WCG)
- For existing studies:
  - Add Principal Investigator/Site (to submit a new PI for initial review)
  - Add Documents to Study/Site (for an ongoing/existing approved study)



# Request Access

You should request access to Sites.

- All managers of the target study or site will receive a notification and may accept or reject it
- You will receive an email notification when it has been accepted or rejected
- Managers are responsible for ensuring users receive the appropriate permission level for their role
- Managers may also invite users to join Sites
- **Study access is not needed to submit a new PI and is primarily reserved for Sponsor/CRO contacts**



**Request Access** [Close]

I'm asking the manager for access to a:

Study  Site 💡 Select "Study" to request access that includes all sites in the study. Choose "Site" for access to one specific site.

Search

Search by PI name (format: last name, first name)

Submit request

## Roles Overview

There are different levels of access, each with specific permissions. Your permission level depends on how your manager adds you to a study or a site.

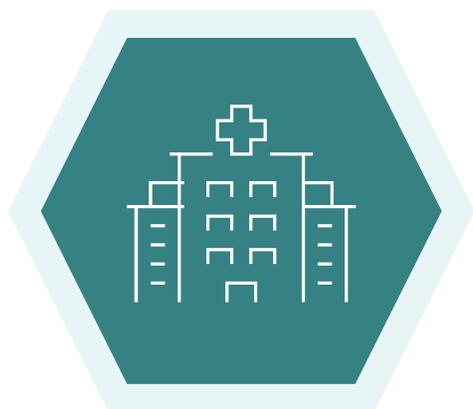
Legacy MyConnexus users will automatically have access to their same studies, sites, and submissions in WCG IRB Connexus.

The permissions levels are as follows:

- Manager
- Submitter
- Read Only



## Site Roles



Site tasks each role may perform based on permission levels:

	Manager	Submitter	Read Only
Manage user access (add/edit/remove)	✓		
Make submissions	✓	✓	
View and download submission documents	✓	✓	✓
View and download outcome documents	✓	✓	✓



# Navigating Workspaces



# WCG IRB Connexus Submissions Landing Page

- Displays all submissions
- Click **Submission Name** to view details
- Contains:
  - Search / Quick Filters
  - Table displaying all submission entries

Submission Name	Submission Type	Sponsor	Sponsor Protocol ID	PI Name	Submitted	Status	IRB Tracking ID
DEMO Add New PI G...	A New Study for Initial IR...	DEMO_Sponsor T	DEMO 250 A-US-18	DEMO_NEWPI02	23 AUG 2020	RECEIVED	000
DEMO Submission Na...	A New Study for Initial IR...	DEMO_Sponsor T	DEMO 250 A-US-18X	W2	000	ENROLL	000
DEMO Add New PI G...	A New Study for Initial IR...	DEMO_Sponsor V	DEMO 500 USA 18	DEMO_NEWPI07	21 AUG 2020	PENDING FOR...	20200705
DEMO_Add PI	A New Study for Initial IR...	DEMO_Sponsor T	DEMO 250 A-US-18X	W2	000	ENROLL	000
DEMO IR Submission	A New Study for Initial IR...	DEMO_Sponsor T	DEMO 250 A-US-18X	W2	000	ENROLL	000
DEMO IR Submission	A New Study for Initial IR...	DEMO_Sponsor T	DEMO 250 A-US-18X	W2	000	ENROLL	000
DEMO Lung Cancer Tr...	A New Study for Initial IR...	DEMO_Sponsor T	DEMO 510 A-US-18	DEMO_17AA	27 AUG 2020	RECEIVED	000
DEMO Demo Manipulat...	A New Study for Initial IR...	W2	AUSP112000	W2	26 AUG 2020	PENDING FOR...	20200748
DEMO Demo Manipulat...	A New Study for Initial IR...	DEMO_Sponsor T	DEMO 250 A-US-18X	W2	26 AUG 2020	RECEIVED	000
DEMO New Rapid Test...	A New Study for Initial IR...	DEMO_Sponsor T	DEMO 250 A-US-18X	W2	25 AUG 2020	RECEIVED	000

## Submission Details

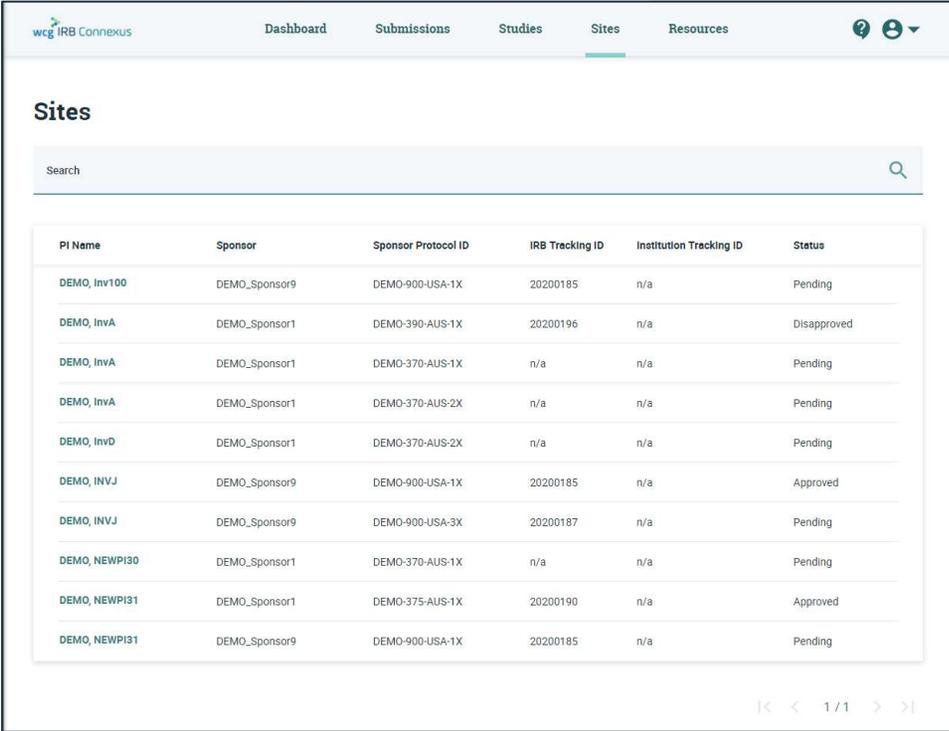
- Displays submission status and other submission details
- Also displays (if applicable):
  - Submitted Sites
  - Submitted Documents
  - Outcome Documents

The screenshot shows the 'Submission Details' page for a study titled 'DEMO Lung Cancer Treatment Phase I 10mg Dose'. The page features a progress bar with six stages: Draft (07-01-2020), **Received** (07-09-2020), 'Temporary for Use of Review', 'Final Review', 'Final Approval Documents', and 'Complete'. Below the progress bar, there is a 'Study Info' section with three columns: Sponsor (DEMO Sponsor), Sponsor Protocol ID (DEMO 071 AUS 1X), and Study Start Date (17 AUG 2020). At the bottom, there is a 'Submitted Sites' section with a search bar and a table listing sites.

Site Name	Organization	Insurance Linking ID	Country
DEMO, INC	DEMO Sponsor	123	United States

# WCG IRB Connexus Sites (PIs) Landing Page

- Display all **Sites** you have access to
- Click the PI Name for more details
- Contains:
  - Search
  - Table displaying all site information



The screenshot shows the 'Sites' landing page in the WCG IRB Connexus system. The page features a navigation bar with the following items: 'wgc IRB Connexus' logo, 'Dashboard', 'Submissions', 'Studies', 'Sites' (highlighted), and 'Resources'. There are also utility icons for help, user profile, and a dropdown menu. Below the navigation bar, the 'Sites' section is titled, followed by a search bar. The main content is a table with the following columns: 'PI Name', 'Sponsor', 'Sponsor Protocol ID', 'IRB Tracking ID', 'Institution Tracking ID', and 'Status'. The table contains 10 rows of data. At the bottom right of the table, there are pagination controls showing '|< < 1 / 1 > >|'.

PI Name	Sponsor	Sponsor Protocol ID	IRB Tracking ID	Institution Tracking ID	Status
DEMO, Inv100	DEMO_Sponsor9	DEMO-900-USA-1X	20200185	n/a	Pending
DEMO, InvA	DEMO_Sponsor1	DEMO-390-AUS-1X	20200196	n/a	Disapproved
DEMO, InvA	DEMO_Sponsor1	DEMO-370-AUS-1X	n/a	n/a	Pending
DEMO, InvA	DEMO_Sponsor1	DEMO-370-AUS-2X	n/a	n/a	Pending
DEMO, InvD	DEMO_Sponsor1	DEMO-370-AUS-2X	n/a	n/a	Pending
DEMO, INVJ	DEMO_Sponsor9	DEMO-900-USA-1X	20200185	n/a	Approved
DEMO, INVJ	DEMO_Sponsor9	DEMO-900-USA-3X	20200187	n/a	Pending
DEMO, NEWPI30	DEMO_Sponsor1	DEMO-370-AUS-1X	n/a	n/a	Pending
DEMO, NEWPI31	DEMO_Sponsor1	DEMO-375-AUS-1X	20200190	n/a	Approved
DEMO, NEWPI31	DEMO_Sponsor9	DEMO-900-USA-1X	20200185	n/a	Pending

## Site (PI) Details

- Displays in-depth site information
- Also displays (if applicable):
  - Site Submissions
  - Outcome Documents
  - Site contacts
  - Manage Contacts

The screenshot shows the 'wgc IRB Connexus' interface. The top navigation bar includes 'Dashboard', 'Submissions', 'Studies', 'Sites', and 'Resources'. The main content area is titled 'INVJ DEMO' and includes a 'Manage Contacts' button. Below this, the 'Study Name' is 'DEMO ThrusTreatment Phase 1 Study'. A table provides key details:

Sponsor	Sponsor Protocol ID	Initial Approval	Last Review
DEMO_Sponsor9	DEMO-900-USA-1X	26-AUG-2020	26-AUG-2020
Expiration	IRB Tracking ID	Institution Tracking ID	Status
26-AUG-2021	20200185	n/a	Approved

Below the table, 'PI Details' for 'INVJ DEMO' are shown: 'DEMO Independent Site | United States 22 Oak Seattle PA 11111' and an email address 'epstrainingsite+DEMOInvJ@gmail.com'.

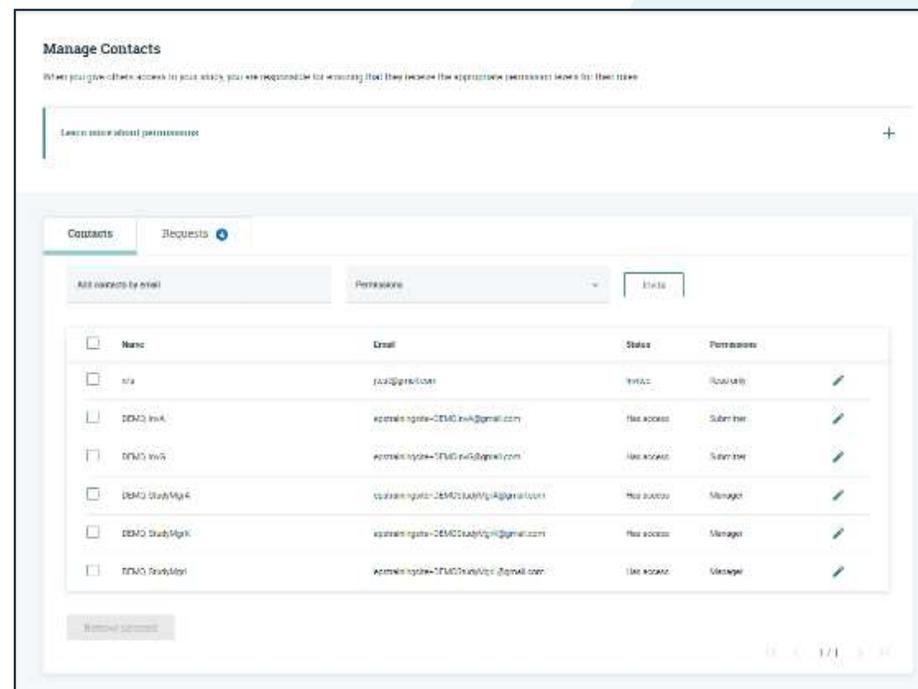
The lower section features a tabbed interface with 'Outcome Documents' selected. It includes filters for 'Start Date' and 'End Date', and a search bar. A table lists documents:

<input type="checkbox"/>	File Name	Reviewed	Transmitted	Document Type
<input type="checkbox"/>	filec2.doc	15-AUG-2020	26-AUG-2020	Consent Form - Assent
<input type="checkbox"/>	Certificate of Action for Study#: 1283319, Panel ...	26-AUG-2020	26-AUG-2020	Certificate of Action
<input type="checkbox"/>	Certificate of Action for Protocol#: 20200185, P...	26-AUG-2020	26-AUG-2020	Protocol Certificate of Action

At the bottom, there are 'Download All' and 'Download Selected' buttons, and a pagination indicator showing '1 / 1'.

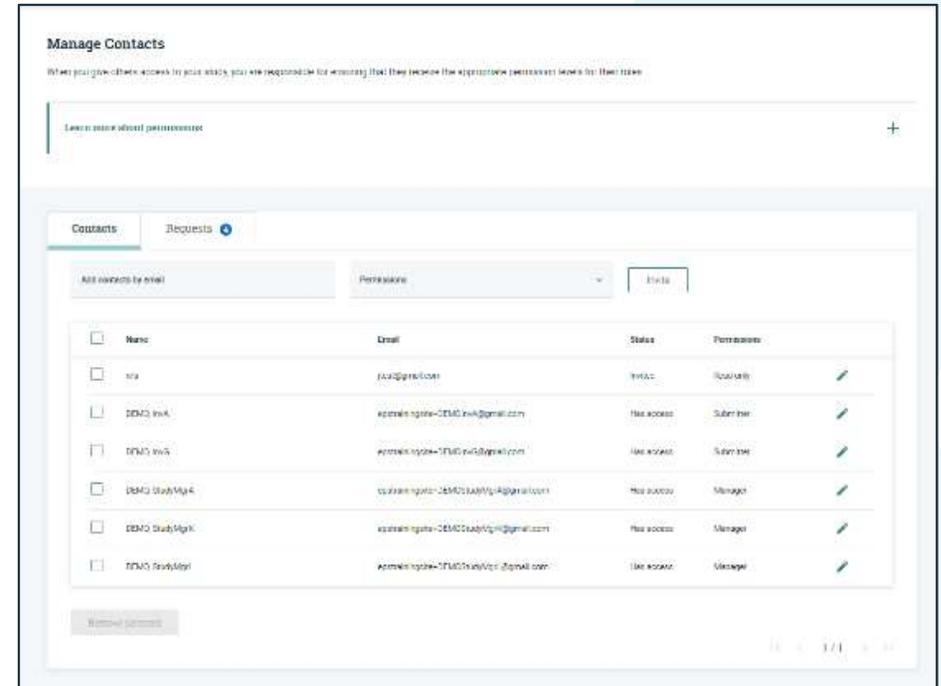
# Manage Contacts

- Only accessible from Study or Site Details page for sites in which you have the **Manager** permission role
- View and manage current site contacts
- Invite contacts to join a site
- Approve or deny pending site access requests



# Manage Contacts

- Only accessible from Study or Site Details page for sites in which you have the **Manager** permission role
- View and manage current site contacts
- Invite contacts to join a site
- Approve or deny pending site access requests



# Manage Contacts

- For all CHLA affiliated research:
  - Always add CHLA HSPP [irbreliance@chla.usc.edu](mailto:irbreliance@chla.usc.edu) as a contact type Manager
  - Do not remove CHLA HSPP [irbreliance@chla.usc.edu](mailto:irbreliance@chla.usc.edu)

## Multiple contacts

If you work with a team and your team needs access to your site workspace, keep a document with their emails separated by a comma or semicolon. Copy, paste, select permission level and invite them all at in one step.

**Manage Contacts**

When you give others access to your site, you are responsible for ensuring that they receive the appropriate permission levels for their roles.

[Learn more about permissions](#)

**Contacts** | Requests

Add users by name or email

X

Permissions: Manager

Invite

**Manage Contacts**

When you give others access to your site, you are responsible for ensuring that they receive the appropriate permission levels for their roles.

[Learn more about permissions](#)

	A	B
1	<b>Institution IRB Staff</b>	<b>Email</b>
2	IRB Senior Analyst	<a href="mailto:sranalyst@anyinstitution.org">sranalyst@anyinstitution.org</a> ;
3	IRB Analyst	<a href="mailto:analyst@anyinstitution.org">analyst@anyinstitution.org</a> ;
4	IRB compliance team	<a href="mailto:Compliance@anyinstitution.org">Compliance@anyinstitution.org</a> ;
5	IRB Director	<a href="mailto:director@anyinstitution.org">director@anyinstitution.org</a> ;

**Contacts** | Requests

Add users by name or email

X

X

X

X

Permissions: [Dropdown]

Invite

# User Profile

To disable access request notifications:



**Carmen Thompson** Change Password

Last Login  
05-NOV-2020

---

**Site WIRB**

Ms. Carmen B Thompson  
1019 39th Ave Ste 120  
Puyallup, Washington 98374, United States

CBThompson@wirb.com

360-252-2447

A dashed green arrow points from the text above to a pencil icon in the top right corner of the profile card.

### Edit Profile

**Name**

Role  
Client Relations

Prefix Ms. ▾	First name Carmen	Middle name B	Last name Thompson	Suffix Select
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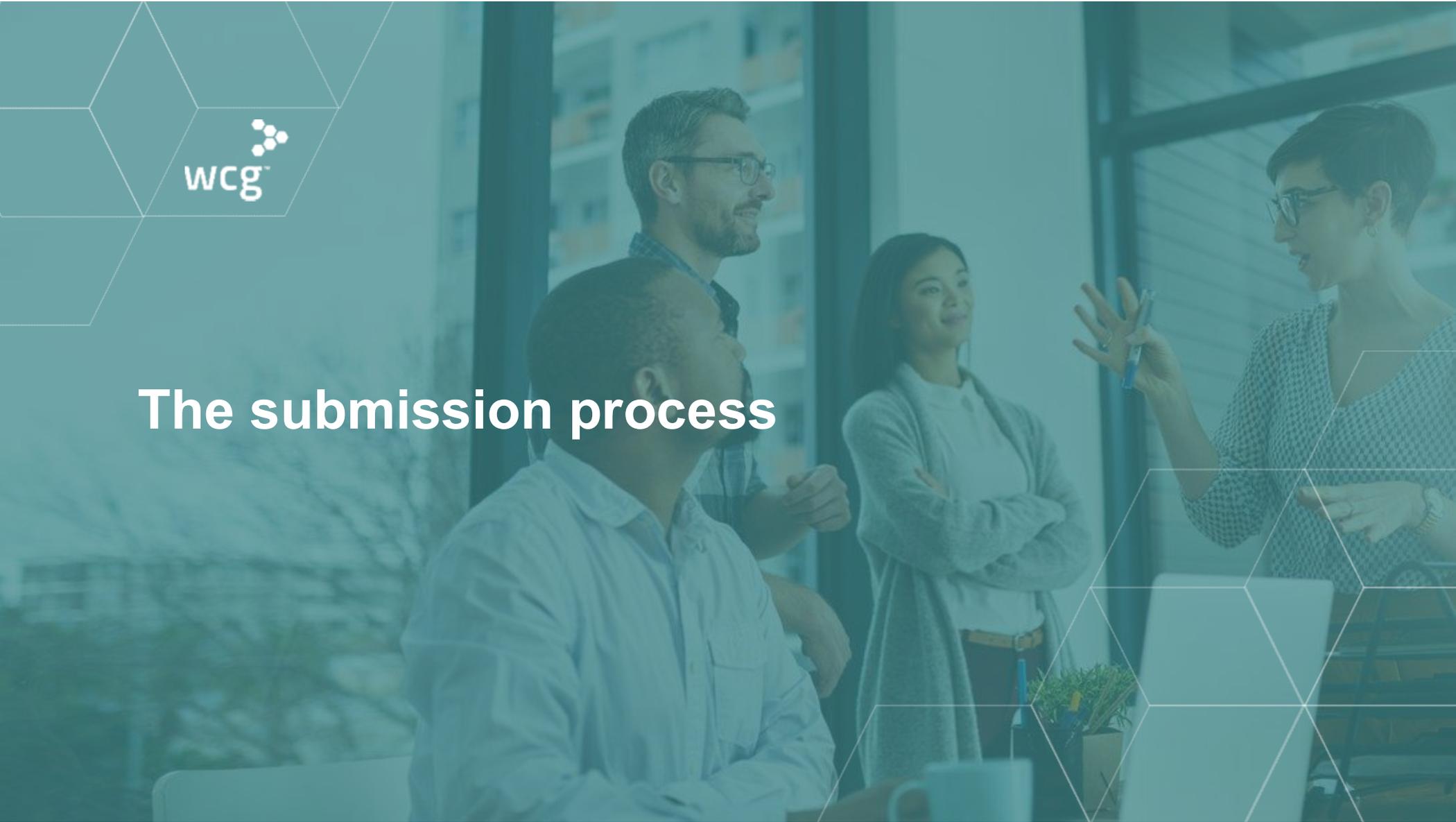
**Contact**

Email CBThompson@wirb.com	Phone 360-252-2447	<input checked="" type="checkbox"/> Email Notifications Enabled
------------------------------	-----------------------	---

A dashed green arrow points from the text above to the 'Email Notifications Enabled' checkbox.



# The submission process



# Make a Submission: Adding Documents to a Site

For making any change in research/modification to an already approved site, select below option:

### Make a Submission

Set Up

## What type of submission are you making?

You'll need to complete a set of questions and upload required documents in order to submit for IRB review. We'll save your progress as you're working, and you may access this submission under "Drafts" on your dashboard.



#### I'm submitting a new study for initial review



### Add Study and Related Documents

Estimated Outcome Date  
**15-JUN-2020**

Receive outcome documents on or before this date if you submit today by 5:00pm ET.

Typically used to submit a study/protocol that has not yet been reviewed by the IRB (or new HUD program, Expanded Access program, Compassionate/Emergency Use program, exemption request, or generic documents).

Learn more about Estimated Outcome Date +

#### I'm submitting to an existing study



### Add Principal Investigator/Site

Typically used to submit additional sites under an IRB-approved study, HUD program, expanded access program, or emergency/compassionate use program.

Example Documents +



### Add Documents to Study/Site

Typically used to submit a change or modification to research already approved by the IRB.

Example Documents +

## Make a Submission: Adding Documents to a Site

Begin the submission Setup and select the type of submission you are making:

Setup

**Let's create your submission for an existing study or site. Who are you requesting this new research submission to be reviewed by?**

---

Select all regions where you need board review.

- US Review
- Canadian Review
- Other (International)

Back Continue Setup →

Setup

**What type of submission are you making?**

---

Please select an option below.

- Change In Investigator
- Change In Research
- Contact Update
- Continuing Review
- HUD Clinical Use Closure
- Not Listed
- Promptly Reportable Information
- Site Closure
- Translation Request

## Make a Submission: Adding Documents to a Site

- All types of submissions will require you to enter the corresponding WCG IRB Tracking ID
- Study information will populate
- Select the appropriate study

Setup

**Find the study to which you're making an update.**

Find a Study  
2020019

Search by Study or Sponsor Name, Sponsor Protocol ID, or IRB Tracking ID

Don't have access to the study? You'll need to be granted access to the study before continuing your submission.  
[Request Access](#)

Study Name	Sponsor Protocol ID	Sponsor	IRB Tracking ID
<input type="radio"/> A Phase I trial of infa...	WEIS-000-aa	WEIS, Inc.	20200195
<input type="radio"/> BOW-3421 DLK	BOW-3421 DLK	Demo	20200193
<input checked="" type="radio"/> DEMO Cystic Fibrosi...	DEMO-700-USA-2X	DEMO_Sponsor7	20200198
<input type="radio"/> DEMO Cystic Fibrosi...	DEMO-700-USA-3X	DEMO_Sponsor7	20200199

Back Continue Setup →

## Make a Submission: Adding Documents to a Site

- Will you also update sites?
  - Yes, I'm also updating sites in this study
- Which sites are you making updates to?
  - Select the PI name

Setup

### Will you also update sites?

Your submission will be reviewed at the study level. Please indicate below if any sites belonging to this study must also be reviewed by the IRB.

Will you also update sites?

Yes, I'm also updating sites in this study

No, I'm making updates to the study only

### Which sites are you making updates to?

The submission will apply to all sites selected. You'll be able to input specific PI information for each form later, if needed.

Find a site 

Start typing a PI name, organization, country, or Institutional Tracking ID

Don't have access to the sites you're looking for? You'll need to be granted access to each site before continuing your submission.

[Request Access](#)

<input type="checkbox"/>	Principal Investigator	Organization	Country	Institution Tracking ID
<input checked="" type="checkbox"/>	DEMO, InvC	n/a	United States	n/a

## Make a Submission: Adding Documents to a Site

### What if your PI is not listed for that IRB Tracking ID?

- You may not have access to the site workspace
- Use the Request Access button on the right
- Submit the Request
- Make the submission after you receive access granted email

Which sites are you making updates to?

The submission will apply to all sites selected. You'll be able to input specific PI information for each form later, if needed.

Find a site  
demo

Start typing a PI name, organization, country, or Institutional Tracking ID

Don't have access to the sites you're looking for? You'll need to be granted access to each site before continuing your submission.

[Request Access](#)

<input type="checkbox"/>	Principal Investigator	Organization	Country	Institution Tracking ID
<input checked="" type="checkbox"/>	DEMO, InvC	n/a	United States	n/a

Back Continue Setup →

# Make a Submission: Adding Documents to a Site

Give your submission a meaningful name

Tell us the name of your submission

Sponsor

DEMO\_Sponsor7

Sponsor Protocol Id

DEMO-700-USA-2X

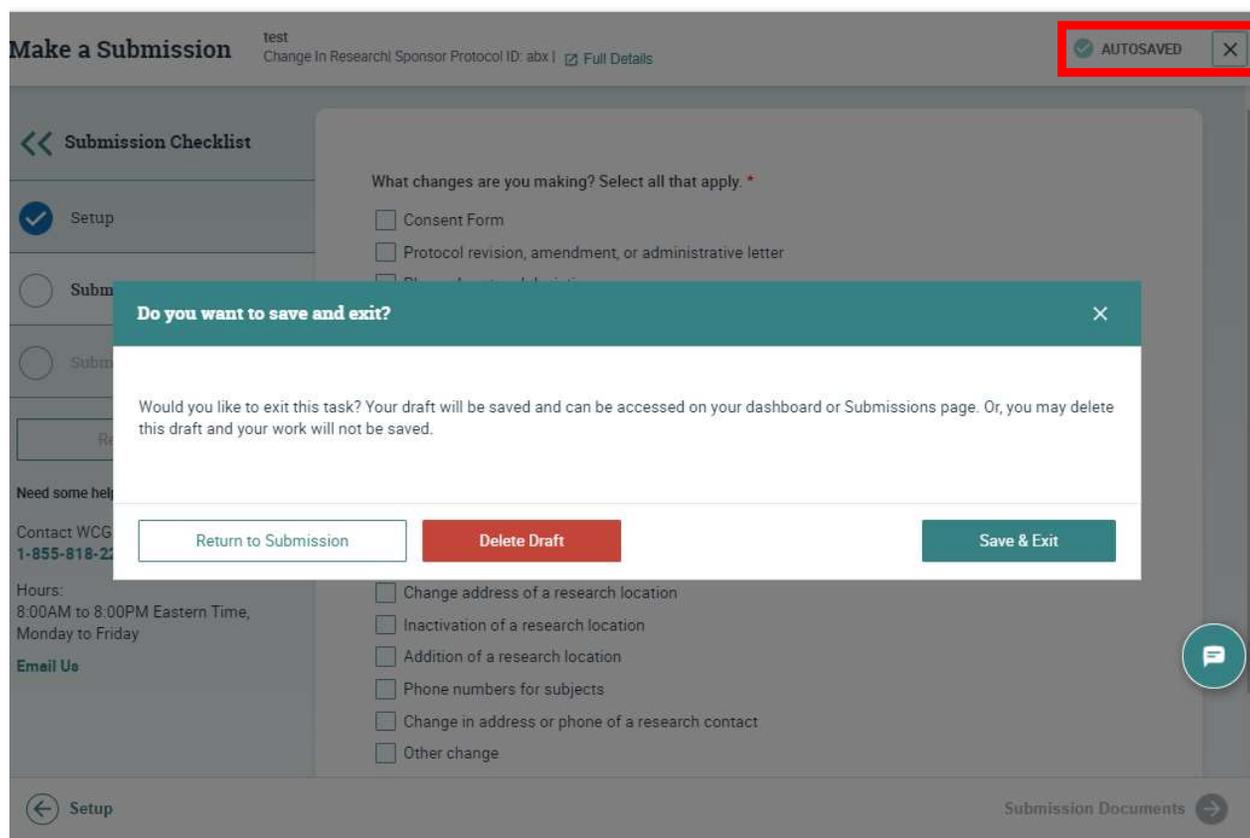
Submission Name \*



The submission name should be a short summary of the submission that is easy for your reference.

## Make a Submission: Adding Documents to a Site

- Once you've set up your submission, it will be autosaved
- To exit the submission, click on the X on the top right
- Select the option carefully, drafts that are deleted cannot be retrieved
  - Return to submission
  - Delete draft
  - Save and exit to save a draft



## Make a Submission: Change in Research

Select the appropriate option and set up the submission

Setup

**What type of submission are you making?**

---

Please select an option below.

- Change In Investigator
- Change In Research
- Contact Update
- Continuing Review
- HUD Clinical Use Closure
- Not Listed
- Promptly Reportable Information
- Site Closure
- Translation Request

Back Continue Setup →

## Make a Submission: Change in Research

- Select all changes you are submitting
- Additional questions will populate based on the type of submission being made

change in research  
Change In Research | Sponsor Protocol ID: DEMO-700-USA-2X | [Full Details](#) AUTOSAVED

### Make a Submission

← Submission Checklist

- Setup
- Submitted Changes
- Submission Documents

[Review & Submit](#)

**Need some help?**  
Contact WCG  
**1-855-818-2289**  
Hours:  
8:00AM to 8:00PM Eastern Time,  
Monday to Friday  
[Email Us](#)

What changes are you making? Select all that apply. \*

- Consent Form
- Protocol revision, amendment, or administrative letter
- Planned protocol deviation
- Recruitment methods
- Recruitment bonuses (Extra payments to sites tied to the rate or timing of recruitment or enrollment)
- Subject materials (Advertisements, scripts, recruitment materials, retention materials, diaries, ID cards, etc.)
- Subject Payment
- Waiver of HIPAA authorization
- Translation request or request for approval of translated documents
- Financial interest disclosure
- Research personnel
- Change address of a research location
- Inactivation of a research location
- Addition of a research location
- Phone numbers for subjects
- Change in address or phone of a research contact
- Other change

# Make a Submission: Change in Research

## Consent Form Modifications

- CHLA initiated consent form modifications must have CHLA HSPP clearance before submitting to WCG IRB
- Submission for CHLA initiated consent form updates must include:
  - Updated language using tracked (**redline**) changes on the most current IRB approved version
- Changes initiated by the sponsor do not require CHLA clearance

What changes are you making? Select all that apply. \*

- Consent Form
- Protocol revision, amendment, or administrative letter
- Planned protocol deviation
- Recruitment methods
- Recruitment bonuses (Extra payments to sites tied to the rate or timing of recruitment or enrollment)
- Subject materials (Advertisements, scripts, recruitment materials, retention materials, diaries, ID cards, etc.)
- Subject Payment
- Waiver of HIPAA authorization
- Translation request or request for approval of translated documents
- Financial interest disclosure
- Research personnel
- Change address of a research location
- Inactivation of a research location
- Addition of a research location
- Phone numbers for subjects
- Change in address or phone of a research contact
- Other change

# Make a Submission: Change in Research

## Consent Form Modifications

- Additional questions will populate based on the type of submission being made, complete as appropriate
- CPUS – always mark No
- Submitter Type – always select Site
- Complete the questionnaire
- Upload documents

### Change in Research

Clinical Pharmacology Unit Services (CPUS)

Is this a submission to the Clinical Pharmacology Unit Services (CPUS)?

Yes  
 No

**Submitter Type**

For whom are you submitting?

Site ▼

**Consent Form**

If there is a change of mailing address or phone number of a PI or other contact related to a change in address of a research location, check "Change address of a research location" in the "Submitted Changes" section and follow directions in that section. Otherwise, submit a "Contact Change" form with this application.

**Type of change**

Addition of new consent form(s)  
 Revision of currently IRB-approved consent forms  
 Both additional and revision

 Because you have requested a revision to currently IRB-approved consent form(s): Submit the currently IRB-approved consent form(s) with the changes tracked.

If you have a preference for which subjects you want to re-consent (e.g., subjects on study drug, future subjects, all subjects), describe your preference here and provide your rationale. 

# Make a Submission: Change in Research

## Planned Protocol Deviations

- Submitted as a change in research
- **Planned** protocol deviations must have IRB approval
- Allow 2-3 business days to process
- All parties must be in agreement, submit correspondence from PI and sponsor/CRO/monitor
- Complete the form and provide: Date of planned deviation, Description, How it deviates from the protocol, Reason for deviating from the protocol
- Upload documents

What changes are you making? Select all that apply. \*

- Consent Form
- Protocol revision, amendment, or administrative letter
- Planned protocol deviation
- Recruitment methods
- Recruitment bonuses (Extra payments to sites tied to the rate or timing of recruitment or enrollment)
- Subject materials (Advertisements, scripts, recruitment materials, retention materials, diaries, ID cards, etc.)
- Subject Payment
- Waiver of HIPAA authorization
- Translation request or request for approval of translated documents
- Financial interest disclosure
- Research personnel
- Change address of a research location
- Inactivation of a research location
- Addition of a research location
- Phone numbers for subjects
- Change in address or phone of a research contact
- Other change

**Document Checklist**

---

Submit the following documentation:

- Agreement of the involved parties with the planned protocol deviation

# Make a Submission: Review & Submit

- The last step before you submit will allow you to download a PDF of your completed online form
- Check that all sections have been completed, if not, your submission could be put on hold for additional information or clarification
- Click “Submit for IRB Review” in the bottom right-hand corner of the screen to submit for IRB Review

### Submission Checklist

- Setup
- Promptly Reportable Information
- Submission Documents

Some sections of your submission are incomplete. You may still submit, but submitting without completing all questions may delay review of your submission.

### Review & Submit

**Almost done! Make sure you've reviewed all submission materials before submitting to the IRB.**

You may return to any section of this submission and make edits before submitting.

---

### My Submission

#### Initial Review of a New PI/Site

Draft

test

...

...

...

moderate to severe chronic plaque-type psoriasis who are partial responders to secukinumab  
Secukinumab Trial Analyzing the potential of Intravenous administration To Upgrade the  
REsponse in psoriasis (STATURE)

Download Draft PDF

**Need some help?**

Contact WCG: 800-562-4789  
Hours: 8:00AM to 8:00PM Eastern Time, Monday to Friday

[Email Us](#)

**Submit for IRB Review**

## Make a Submission: Confirm and Share access

- A confirmation message will appear that your updates have been submitted
- Your confirmation ID should appear within a few minutes and is accessible via your Submissions landing page
- You can also manage access directly after submission by clicking Invite Contacts

The screenshot displays the 'Make a Submission' interface for a Promptly Reportable Information (PRI) submission. The header shows the submission title 'Make a Submission' and the protocol ID 'DEMO-700-USA-2X'. A progress bar indicates the submission status: Draft (16-MAR-2021), Received (16-MAR-2021), Preparing for Board Review, Board Review, Finalizing Documents, and Complete. The 'Received' stage is highlighted with a green checkmark. Below the progress bar, there is a section titled 'Update Existing Study' with a 'Received' status. It lists the Sponsor Protocol ID as 'DEMO-700-USA-2X' and the Study Name as 'DEMO Cystic Fibrosis Treatment Phase II Study'. An 'Export PDF' button is visible. To the right, a 'Need some help?' section provides contact information for WCG: 1-855-818-2289, with hours from 8:00AM to 8:00PM Eastern Time, Monday to Friday, and an 'Email Us' link. At the bottom right, there is an 'Invite Contacts' button with a right-pointing arrow.

## Make a Submission: Change in PI

- Select Change in Investigator
- Enter the IRB tracking ID
- Select the PI name
- Change in PI requires an initial review questionnaire for the new PI
- Follow the initial review submission process for CHLA to obtain CHLA HSPP clearance
- No consent form needs to be submitted unless there are changes to the IRB approved consent form other than PI contact information
- Sponsor confirmation of change in PI required
- Upload documents, review and submit

Setup

**What type of submission are you making?**

---

Please select an option below.

- Change In Investigator
- Change In Research
- Contact Update
- Continuing Review
- HUD Clinical Use Closure
- Not Listed
- Promptly Reportable Information
- Site Closure
- Translation Request

# Make a Submission: Translations

## Translations

- All subject facing materials must have IRB approval before presenting them to the subject, including translated documents
  - If you submit a document for review and translation, it will be approved first. After approval, the translation team will process the translation request.
  - Check with your sponsor/CRO about translations before submitting: Who will translate the documents? Sponsor, CRO, WCG IRB
  - To avoid additional translation costs and delays, translation requests should be submitted after IRB approval as they include CHLA specific documents
- For approval of sponsor/CRO translated documents:
    - Submit a translated Word version of the IRB approved document(s)
    - Certificate of translation – signed, protocol sponsor and protocol number, list the name of the translated document(s), attestation of the translator’s fluency and accuracy of the translation
  - For WCG IRB translations:
    - Submit completed Translation request submission

## Make a Submission: Translations

Submit as a stand-alone translation request or as a change in research with additional changes.

Setup

**What type of submission are you making?**

---

Please select an option below.

- Change In Investigator
- Change In Research
- Contact Update
- Continuing Review
- HUD Clinical Use Closure
- Not Listed
- Promptly Reportable Information
- Site Closure
- Translation Request

What changes are you making? Select all that apply. \*

- Consent Form
- Protocol revision, amendment, or administrative letter
- Planned protocol deviation
- Recruitment methods
- Recruitment bonuses (Extra payments to sites tied to the rate or timing of recruitment or enrollment)
- Subject materials (Advertisements, scripts, recruitment materials, retention materials, diaries, ID cards, etc.)
- Subject Payment
- Waiver of HIPAA authorization
- Translation request or request for approval of translated documents
- Financial interest disclosure
- Research personnel
- Change address of a research location
- Inactivation of a research location
- Addition of a research location
- Phone numbers for subjects
- Change in address or phone of a research contact
- Other change

# Make a Submission: Translations

**Translated Documents**

**Languages Requested**

Is this the first time you are requesting translation for this protocol?

Yes  
 No

Select one of the following:

I will facilitate all translations  
 The IRB should facilitate all translations  
 I will facilitate subject materials and advertisements, but the IRB will facilitate translation of consent forms  
 I will facilitate translation of consent forms, but the IRB will facilitate subject materials and advertisements

Indicate the language requested

[+ Add another language](#)

Type of Submission

I have already translated document(s)

[Submission Documents](#)

Complete the questionnaire, upload documents, review and submit

Type of Submission

I have already translated document(s)  
 I want the IRB to facilitate translation(s) through their translation vendor

**Approval of Documents Translated by an External Vendor**

For each document submitted, provide the following information:

- Document File Name
- Title of the Document from the IRB Certificate of Action

File Name	Document Title
<input type="text"/>	<input type="text"/>

[+ Add another document](#)

## After You Submit: What to Expect

- Processed by change in research, translations IRB staff. They may reach out if there are any clarifications or missing items after a few days of submission. They will begin to reference a work order number.
  - The work order is then sent to Expedited Reviewer or to scheduling for Full Board review
  - Once reviewed, the work order is sent to our post-Board team. They will prepare add any Board language and finalize your approval documents within 1-2 days.
  - All users with access will receive an email when outcome documents have been posted to Connexus in the Outcome documents tab
- You will receive a Certificate of Action (COA):
    - Board Action Date (Review Date)
    - Expiration Date (if approved)
    - The documents that were reviewed
    - If a consent form update is approved, re-consenting instructions will be provided
  - **Review your COA!**
  - WCG IRB communicates Board actions via a COA. Your COA will state the action taken: Approved, Conditionally Approved, Deferred
  - Conditional Approvals/Deferrals will require further action, follow the instructions on the COA.

## CHLA Requirement for Amendments

- **After receiving WCG IRB approval for an amendment:**
  - Determine if the WCG IRB approval contains updated consent/assent form(s) or updated CHLA specific documents
  - If yes: file an amendment in iStar when you receive a new approval letter and updated study documents
  - Upload: WCG IRB certificate of action, approved consent/assent form, site specific documents
  - If no: obtain the sponsor documents and update your regulatory binder. No need to create an amendment in iStar.

- **NOTE:** WCG does **not** transmit or publish proprietary sponsor documents (protocol documents, protocol support documents, IBs, DMSB reports, etc.)
- **IMPORTANT:** Develop a communication plan with the sponsor/CRO to ensure
  - How your team will obtain protocol documents
  - If submissions will be made by them for your site

## Make a Submission: Continuing Review

- Select continuing review
- Enter the IRB tracking ID
- Select the PI name
- Upload the completed continuing review report form (CRRF)
- Review and submit

Setup

**What type of submission are you making?**

---

Please select an option below.

- Change In Investigator
- Change In Research
- Contact Update
- Continuing Review
- HUD Clinical Use Closure
- Not Listed
- Promptly Reportable Information
- Site Closure
- Translation Request

## Continuing Review: What to Expect

- All Site expiration dates are aligned to the protocol expiration date
  - Sites approved less than 90 days prior to the protocol expiration date will be advanced to the new continuing review period automatically
  - Continuing review reports are emailed to all study contacts about 80 days before the expiration date
  - Processed by ongoing review IRB staff. They may reach out if there are any clarifications on the CRRF. They will begin to reference a work order number.
  - The work order is sent for review once all sites and the protocol progress report are received, within 30 days of the expiration date
  - Once reviewed, the work order is sent to our post-Board team. They will prepare add any Board language and finalize your approval documents within 1-2 days.
- All users with access will receive an email when outcome documents have been posted to Connexus in the Outcome documents tab
  - You will receive a Certificate of Action (COA):
    - Board Action Date (Review Date)
    - Expiration Date (if approved)
  - **Review your COA!**
  - WCG IRB communicates Board actions via a COA. If there are additional Board requirements (ie. a report was not received), there will be instructions on the COA.

### CHLA Requirement

- Create an amendment in iStar and upload your continuing review certificate of action

## Make a Submission: Promptly Reportable Information

- Select Promptly Reportable Information
- Enter the IRB tracking ID
- Select the PI name
- Begin to complete the form: Type (Site), VA (No), select the problem being reported

Setup

**What type of submission are you making?**

---

Please select an option below.

Change In Investigator

Change In Research

Contact Update

Continuing Review

HUD Clinical Use Closure

Not Listed

Promptly Reportable Information

Site Closure

Translation Request

**Promptly Reportable Information**

**Submitter Type**

For whom are you submitting?

Site

---

**VA Research**

Is this report related to Veterans Affairs (VA) research? 

Yes

No

## Make a Submission: Promptly Reportable Information

- Select the problem being reported
- One option per form/submission

### Problem Type - Items that must be reported within 5 days

If you do not see your problem type listed below, it does not require reporting to the IRB. Need to keep this information for your records? You may print this form without submitting.

What category best describes this problem? ?

- Adverse event or IND safety report that requires a change to the protocol or consent
- Allegation of noncompliance or finding of noncompliance
- Audit, inspection or inquiry by a federal agency
- Breach of confidentiality
- Change in financial interest disclosure
- Incarceration of a subject in a research study not approved to involve prisoners
- New or increased risk
- Protocol deviation made without prior IRB approval to eliminate an immediate hazard to a subject
- Protocol deviation that harmed a subject or placed subject at risk of harm
- State medical board action or hospital medical staff action
- Subject complaint that cannot be resolved by the research team
- Suspension or premature termination by the sponsor, investigator, or institution
- Unanticipated adverse device effect (Any serious adverse effect on health or safety or any lifethreatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.)
- Written report from a federal agency (e.g., FDA Form 483)
- Information NOT listed above where the sponsor/CRO/monitor has directed a report to the IRB

# Make a Submission: Promptly Reportable Information

- Complete the form:
  - Date of discovery
  - Date of occurrence
  - Full description of the problem
  - Actions taken place to prevent recurrence
  - Planned actions to prevent recurrence
- Upload documents, review and submit

<p><b>Subject Information</b></p> <p>Does this report involve one or more specific subjects?</p> <p><input type="radio"/> Yes</p> <p><input type="radio"/> No</p> <p><b>Problem Description</b></p> <p>What is the date you learned of this problem?</p> <p>Month</p> <p>Mon</p> <p>Day</p> <p>DD</p> <p>Year</p> <p>YYYY</p> <p>What is the date of occurrence? (if known)</p> <p>Month</p> <p>Mon</p> <p>Day</p> <p>DD</p> <p>Year</p> <p>YYYY</p>	<p>Describe the problem: ?</p> <p>Describe actions already taken to mitigate harm, correct the problem, prevent a recurrence: (if none, justify.)</p> <p>Describe planned actions to mitigate harm, correct the problem, prevent a recurrence: (if none, justify.)</p> <p>Were one or more subjects harmed or placed at risk because of this problem?</p> <p><input type="radio"/> Yes</p> <p><input type="radio"/> No</p> <p>Will the protocol or consent form be changed because of this report?</p> <p><input type="radio"/> Yes</p> <p><input type="radio"/> No</p>
--	---

# Make a Submission: Promptly Reportable Information

## What if the problem is not listed?

- If the sponsor/CRO/monitor is requiring submission to the IRB, select the last option
- It does not our prompt reporting requirement, information can be noted, filed. May be submitted at continuing review if it pertains to questions on the continuing review report form

### Problem Type - Items that must be reported within 5 days

If you do not see your problem type listed below, it does not require reporting to the IRB. Need to keep this information for your records? You may print this form without submitting.

What category best describes this problem? ?

- Adverse event or IND safety report that requires a change to the protocol or consent
- Allegation of noncompliance or finding of noncompliance
- Audit, inspection or inquiry by a federal agency
- Breach of confidentiality
- Change in financial interest disclosure
- Incarceration of a subject in a research study not approved to involve prisoners
- New or increased risk
- Protocol deviation made without prior IRB approval to eliminate an immediate hazard to a subject
- Protocol deviation that harmed a subject or placed subject at risk of harm
- State medical board action or hospital medical staff action
- Subject complaint that cannot be resolved by the research team
- Suspension or premature termination by the sponsor, investigator, or institution
- Unanticipated adverse device effect (Any serious adverse effect on health or safety or any lifethreatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.)
- Written report from a federal agency (e.g., FDA Form 483)
- Information NOT listed above where the sponsor/CRO/monitor has directed a report to the IRB

# Promptly Reportable Information Submission:

## What to Expect

- WCG IRB will review the report and if significant or need more information, communicate with the appropriate parties
- If we find that the event does not constitute an increased risk to subjects and there are no remaining subject safety concerns, we will file the submission without action
- If the sponsor/CRO requires documentation that the event was reported to the IRB, you can provide them the Connexus acknowledgment of receipt
- If the sponsor/CRO needs documentation that the event was filed, contact the WCG Client Care Center

## What is Expected of you

### CHLA Requirements

- After submitting your promptly reportable information form to WIRB, send the report by email to the CHLA HSPP office to [irbreliance@chla.usc.edu](mailto:irbreliance@chla.usc.edu)
- DO NOT create and submit a reportable event submission in iStar.

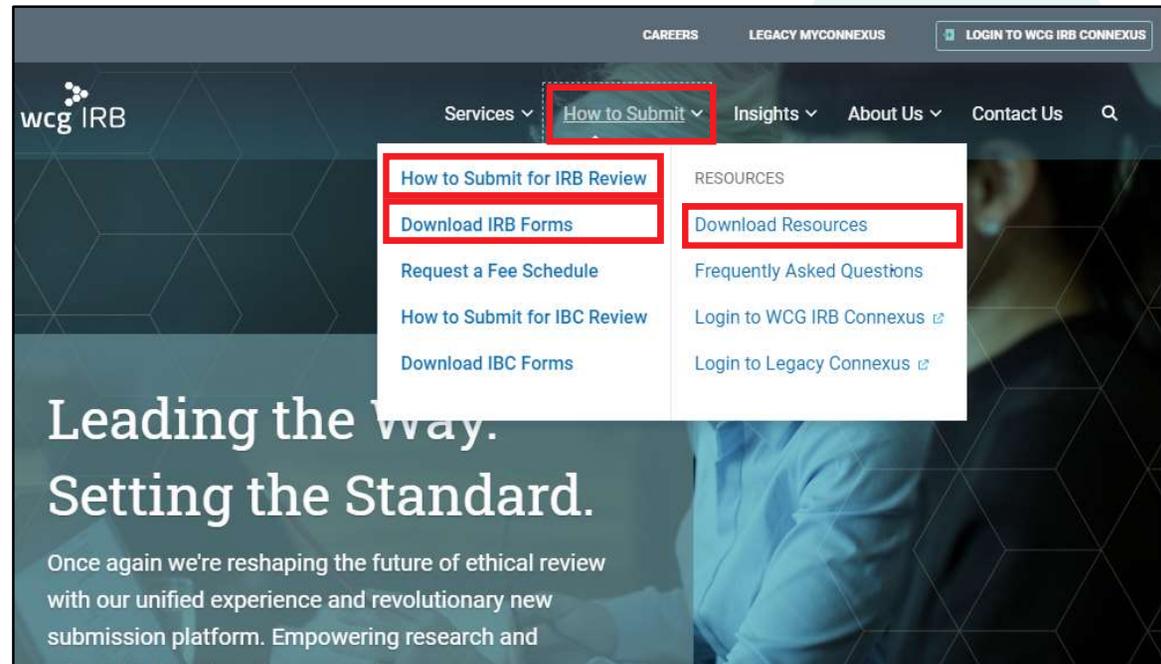


# After You Submit: What to Expect

## IRB Resources

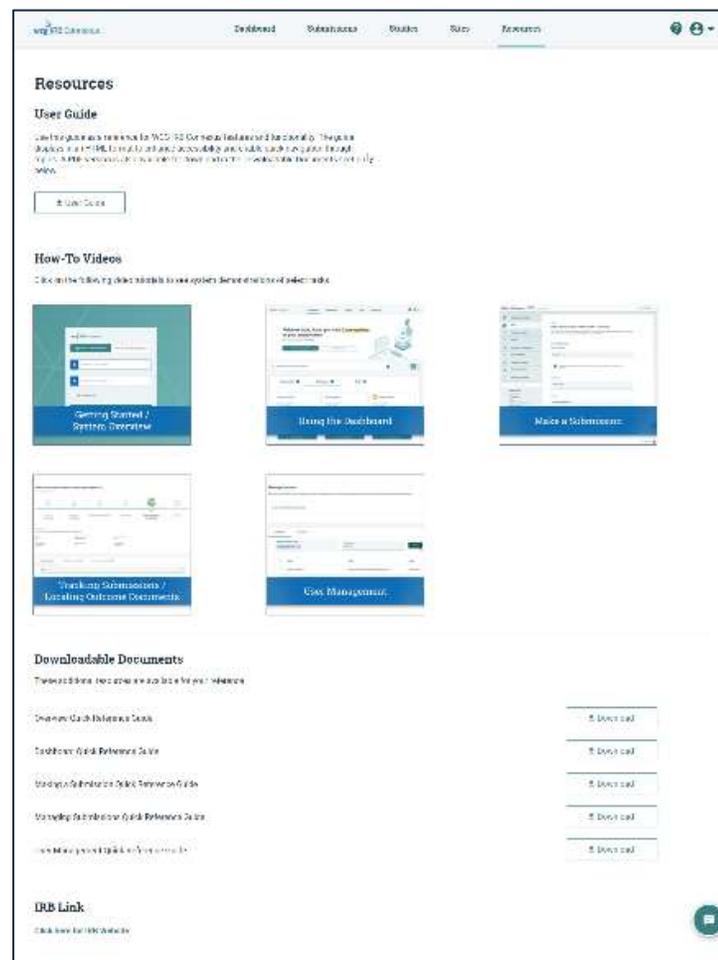
CHLA Study Teams are responsible for ensuring the all WCG IRB requirements are met

- Certificate of Action lists PI/site responsibilities
- Download IRB Forms  
wcgirb.com -> How to Submit -> Download IRB Forms
  - Guide for Researchers
  - Submission Form, Misc Forms
- Download Resources  
wcgirb.com -> How to Submit -> Download Resources
  - Investigator Guidance – Investigator Obligations and other SOP documents



# WCG IRB Connexus Resources

- PDF version of the user guide
- “How-to-Videos”
- Quick Reference Guides
- Link to WCGIRB.com





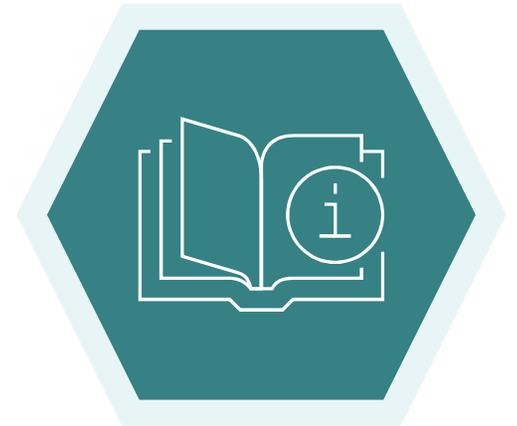
## Additional Items to Note



## Additional Information

### For a limited time, both legacy MyConnexus and WCG IRB Connexus will exist simultaneously

- With this in mind, there are a few considerations:
  - Draft submissions will only be available in the system where it was created
  - User accounts and submissions will sync between systems with a slight delay
- All active studies and sites will be migrated from legacy MyConnexus. Only closed study data 3 years old or less will be migrated.



## Additional Information

- All new users transitioning from legacy MyConnexus to WCG IRB Connexus will need to reset their passwords and use the same email address to ensure access to your Studies and Sites
- For security purposes, users must sign into WCG IRB Connexus to view any documents



## We are here to partner with you – contact us!

For general questions and inquiries:

Client Care Center

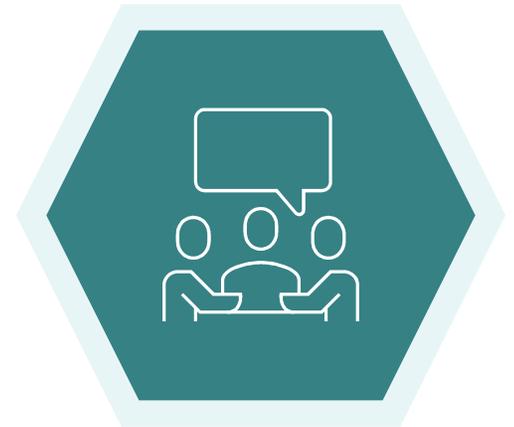
1-855-818-2289 | [clientservices@wcgirb.com](mailto:clientservices@wcgirb.com)

Live Chat via Connexus

For CHLA specific, escalated or urgent issues:

Carmen Thompson

360-252-2447 | [cbthompson@wirb.com](mailto:cbthompson@wirb.com)





**Thank You**

