Introduction to WCG IRB Connexus™

CHLA –November 5, 2020

Presented by:
Carmen Thompson, CIP

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.

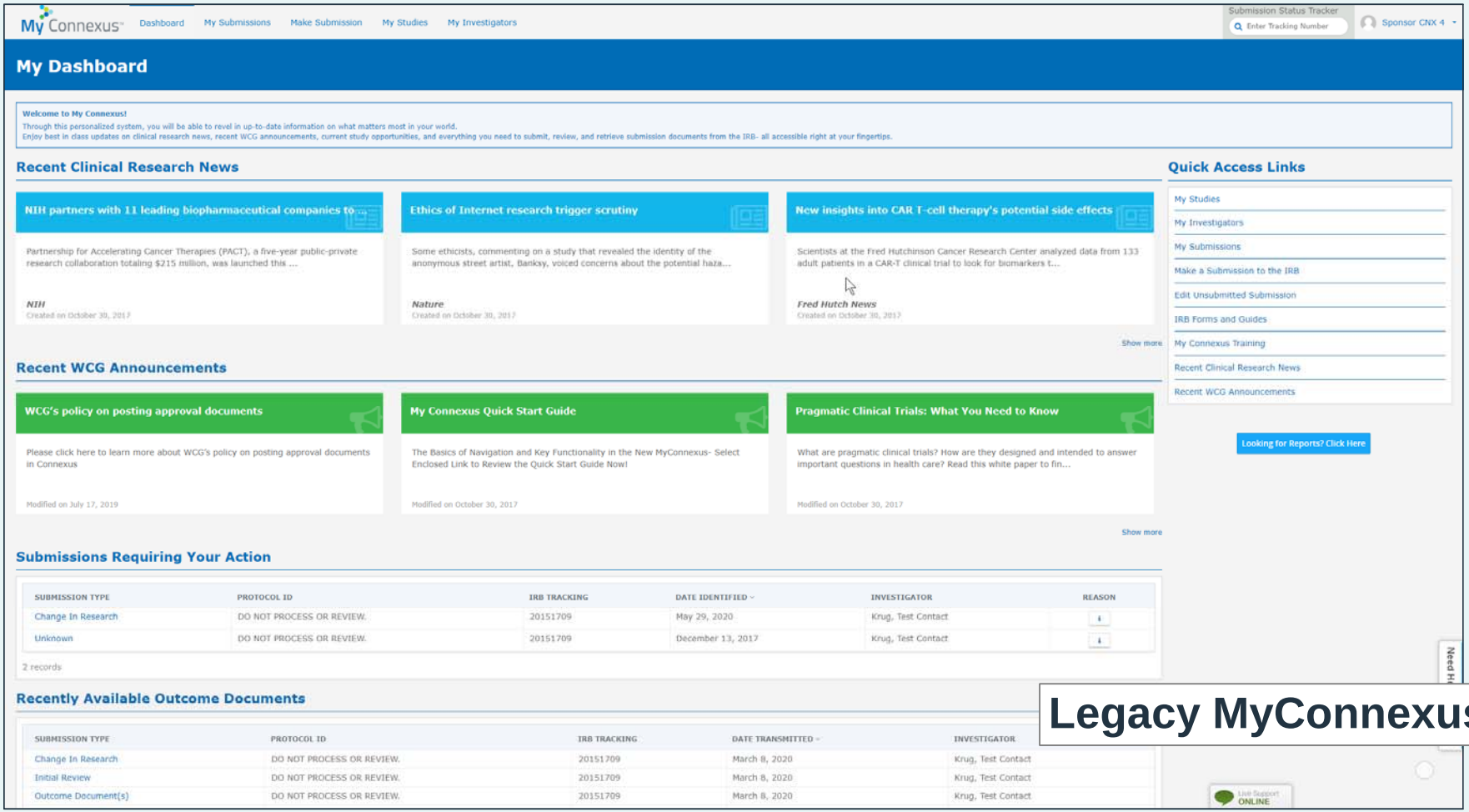
WCG IRB clients experience a singular, unified process and fee schedule. WCG IRB continues to deliver gold standard service with the highest regard to ethics and integrity.

What We Will Cover In Today's Session

- Introduction to the new **WCG IRB Connexus**
- What's New?
- System Walkthrough
- New Submission Workflow
- Navigating Workspaces
- System Transition "Need to Know" Information
- Resources and Support

wcg IRB

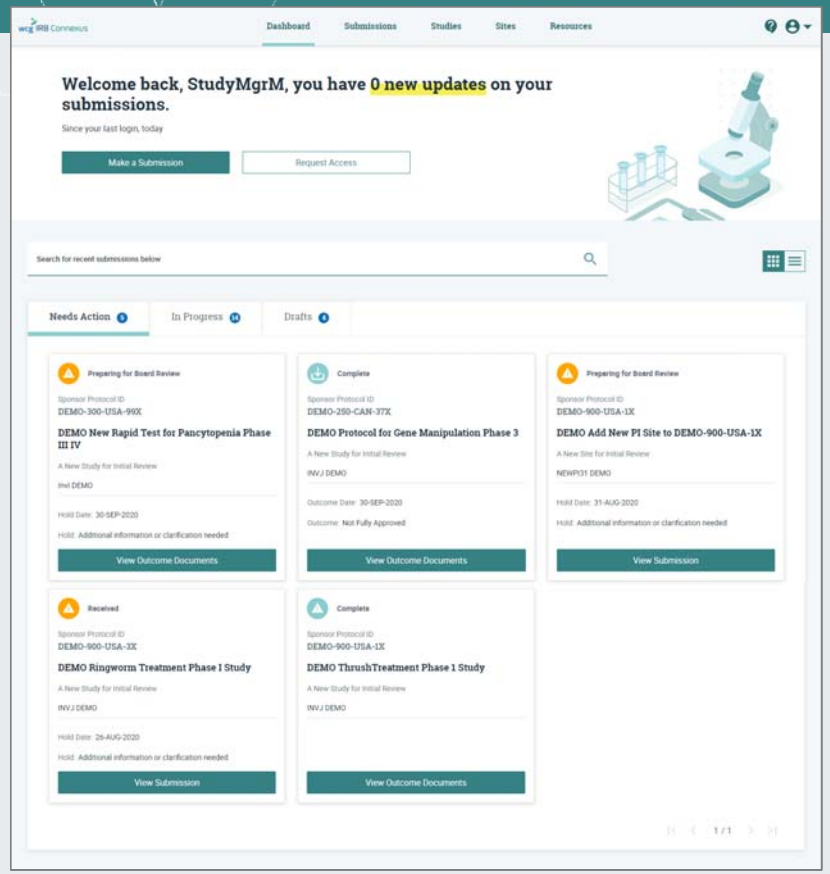
WCG IRB Connexus Overview



Legacy MyConnexus™

wcg IRB

WCG IRB Connexus



- Simplified study submission and tracking process
- Track your review progress through a transparent process
- Incorporates most submission forms into a single interactive, online submission process

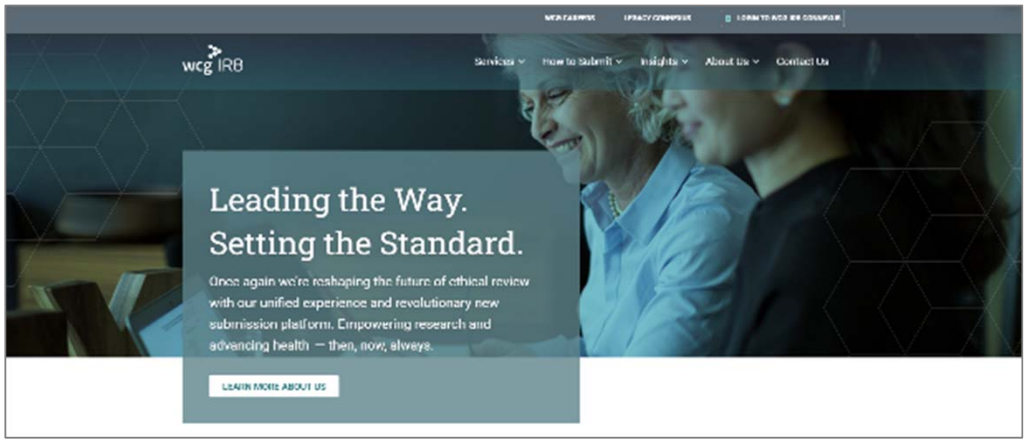
Legacy MyConnexus vs. WCG IRB Connexus – Key Differences

Legacy MyConnexus	WCG IRB Connexus
Administrators / Client Services would enter contacts	Users add contacts when they create submissions
Administrators / Client Services manage access to Studies and Sites	Users manage access to Studies and Sites
Users required to search for forms in several locations and formats	Commonly required forms integrated into submission process; directed to many other forms located in a central location (http://www.wcgirb.com)
Primary communication with IRB via email making it difficult to track submissions	Primary communication with IRB via system, which allows for easier tracking

System Access & Signing In

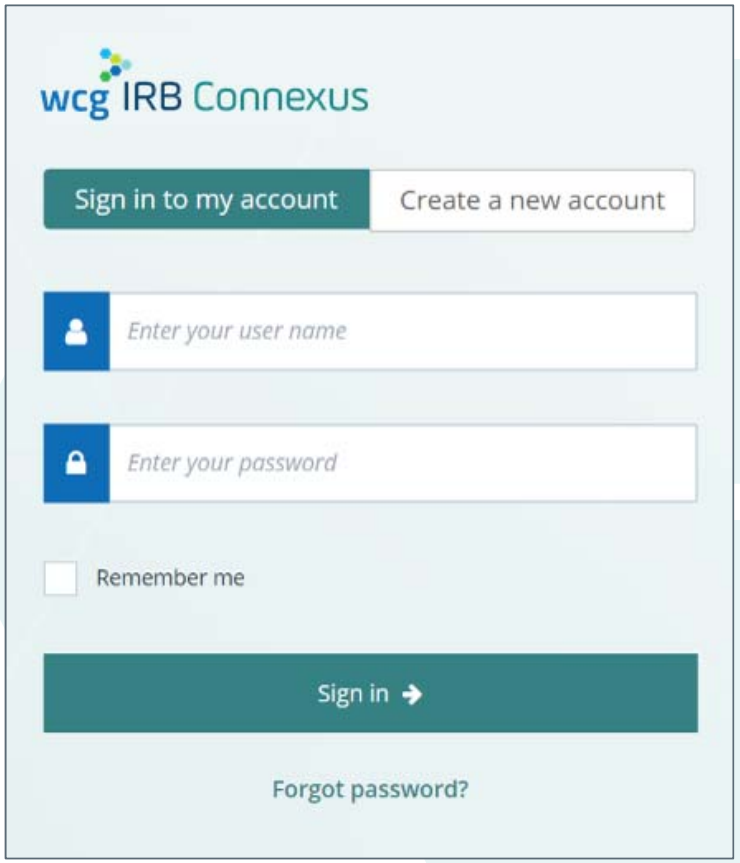
System Access

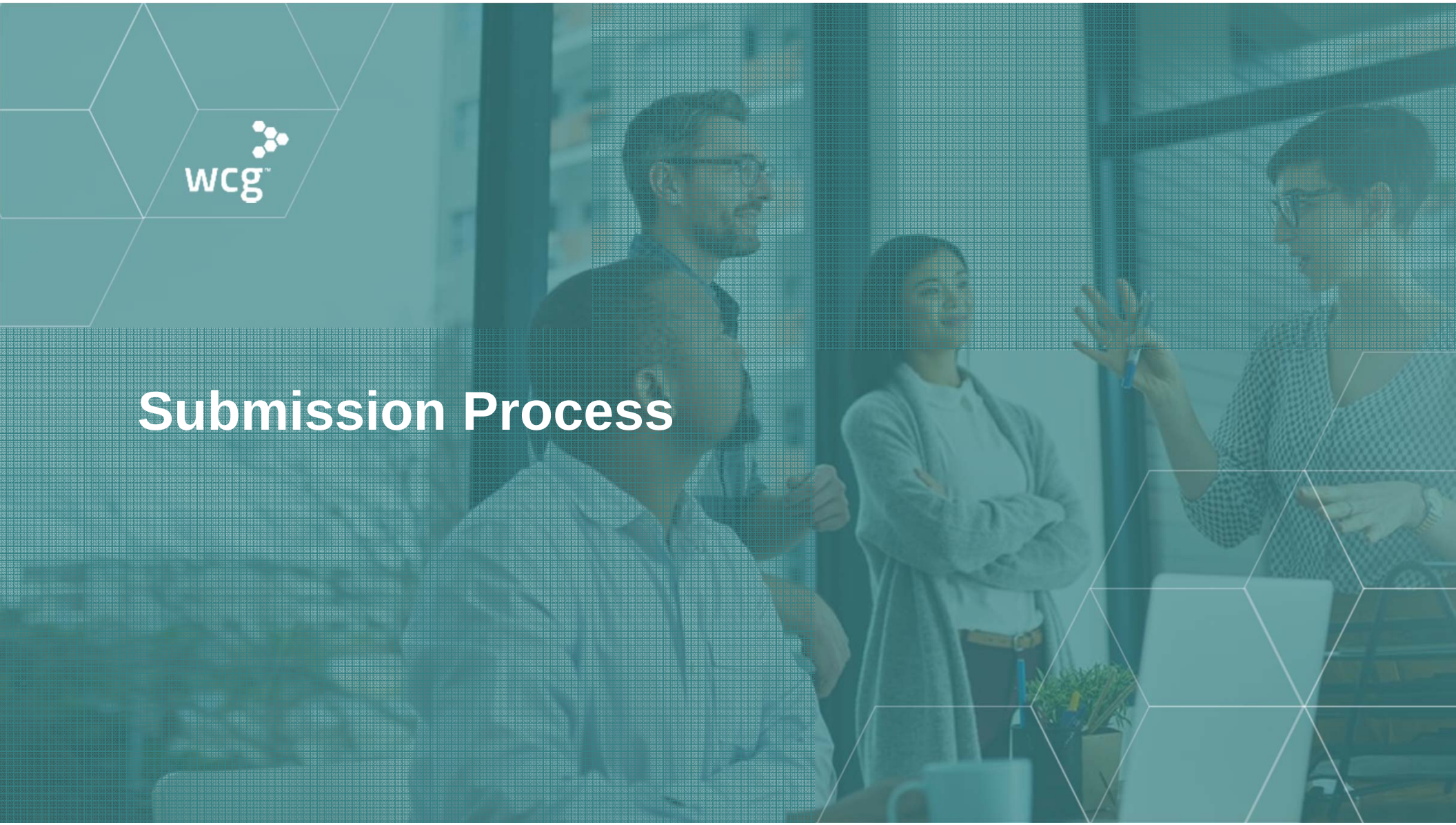
- **WCG IRB Website:** http://www.wcgirb.com
  - **Login to WCG IRB Connexus** link
- **Direct Link:** https://connexus.wcgirb.com



Signing In

- Legacy MyConnexus users need to reset password and accept the Terms & Conditions upon initial sign in
- New users can register using **Create a new account**

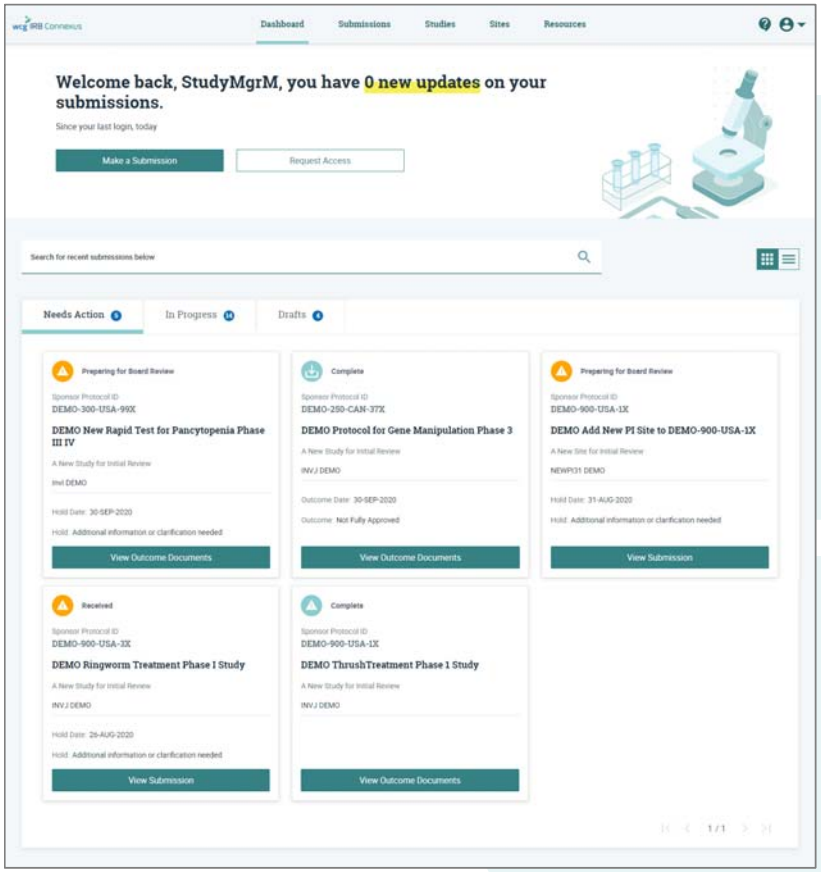




Submission Process

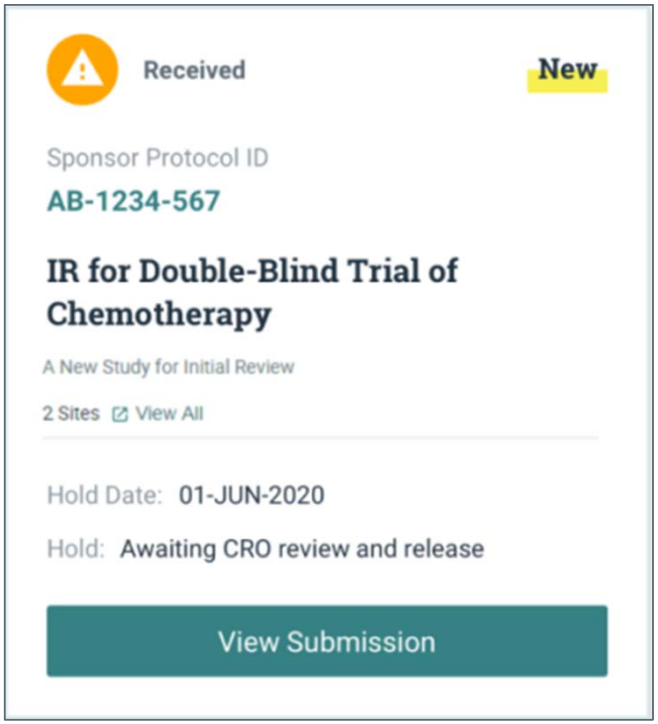
WCG IRB Connexus Dashboard

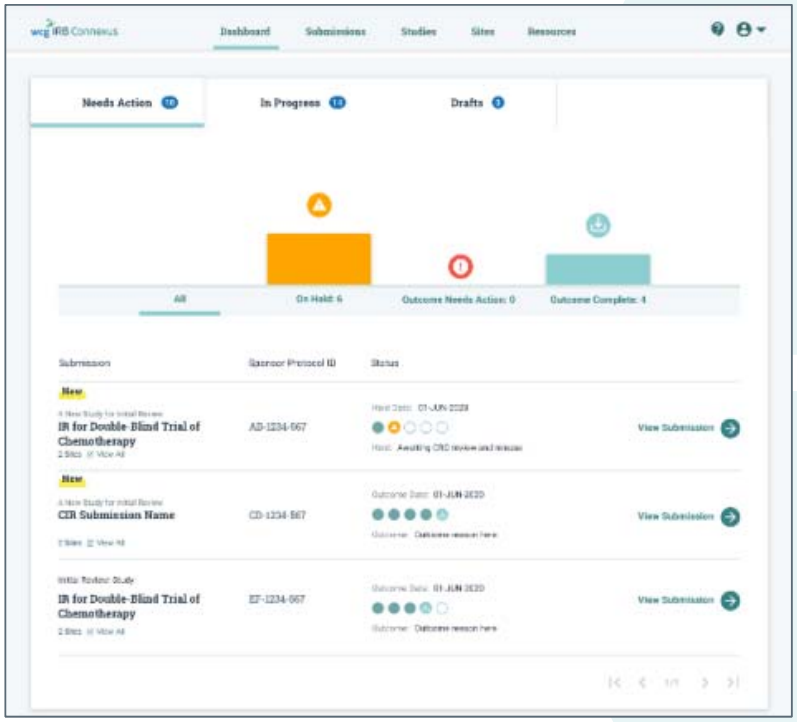
- Central hub for most WCG IRB Connexus activity
- Page contains:
  - Navigation Bar
  - Notification area
  - Make a Submission button
  - Request Access button
  - Track Submissions area
    - Search
    - Tabs – Needs Action, In Progress, Drafts
    - Two different views per your preference



Dashboard – Card and Table Views

- Two different options for easily viewing submission/study details



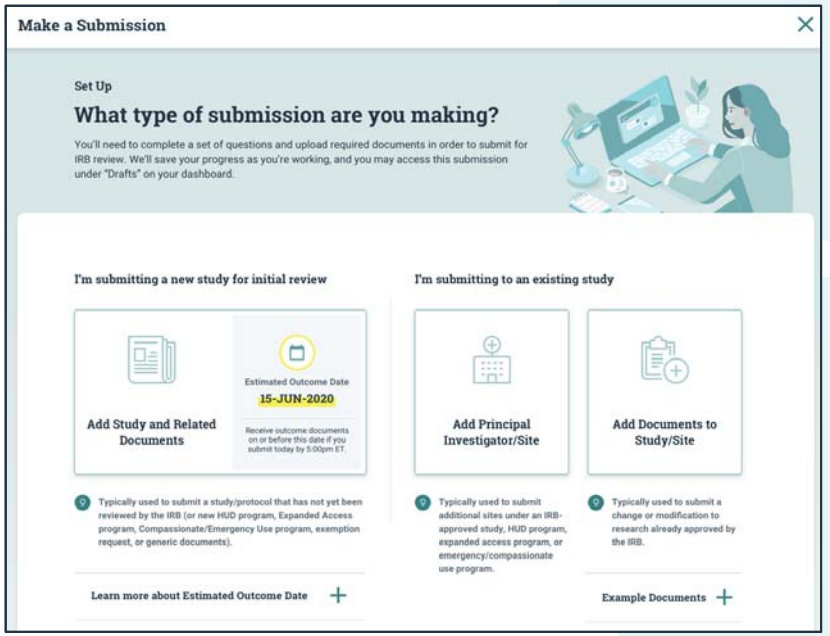


Make a Submission

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

Select one of the following options:

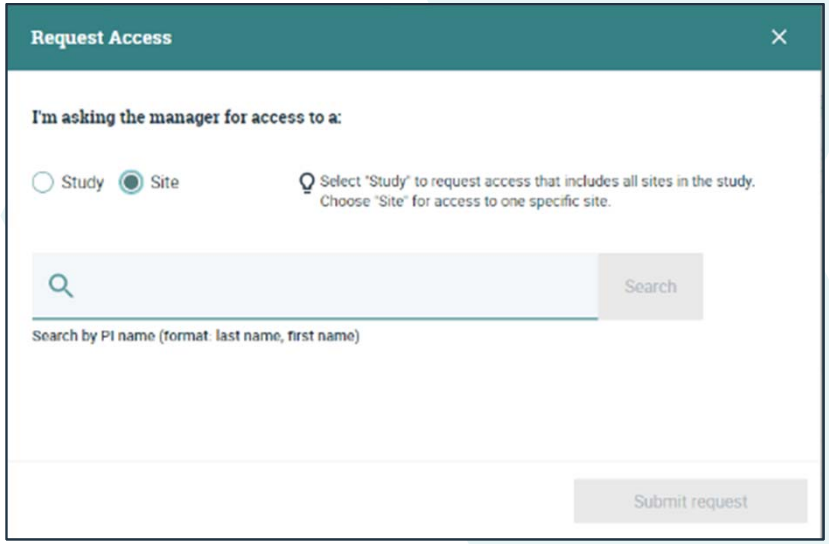
- Initial Review of New Protocol (not yet reviewed by WCG)
- For existing studies:
  - Add Principal Investigator/Site (to submit a new PI for initial review)
  - Add Documents to Study/Site (for an ongoing/existing approved study)



Request Access

You may request access to Studies and 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 Studies or Sites



Roles Overview

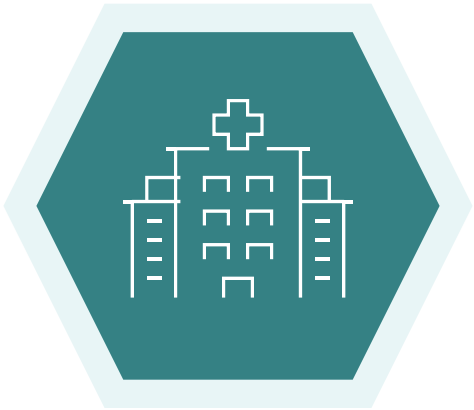
There are different levels of access, each with specific permissions. Your permission level depends on how your manager adds you to a study or a site.

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

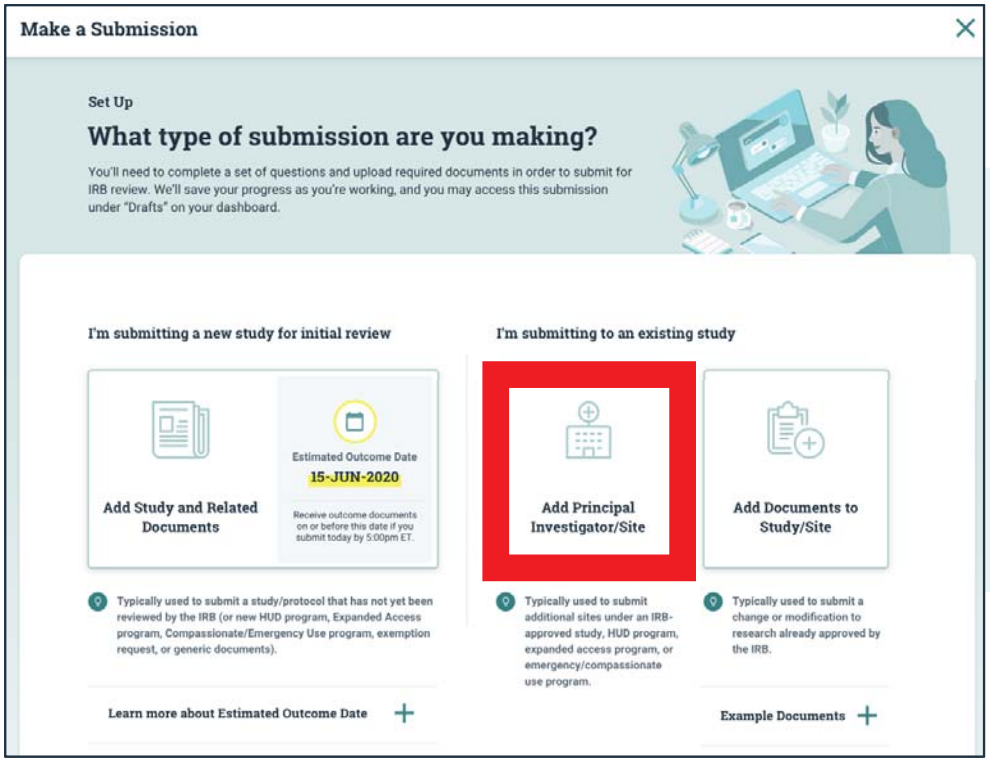


Site tasks each role may perform based on permission levels:

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

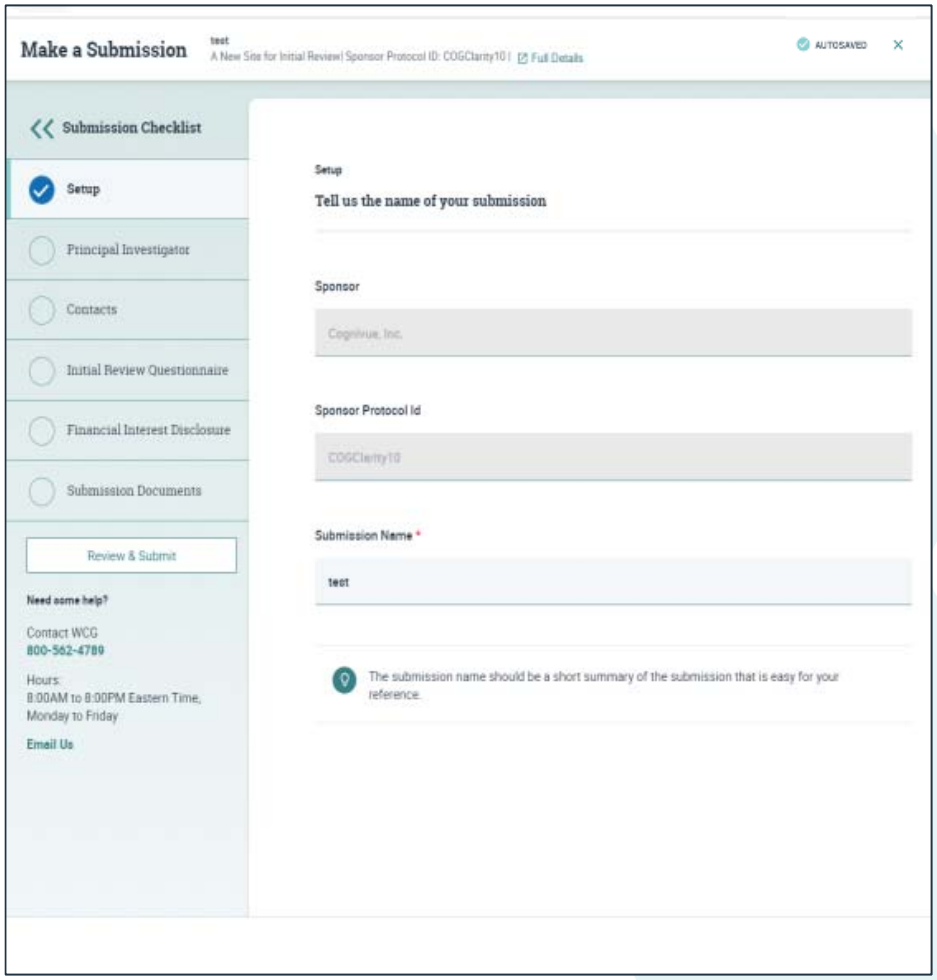
Make a Submission: Initial Review of New PI

For adding a new PI to a multi-site study already on file with WCG, select below option:



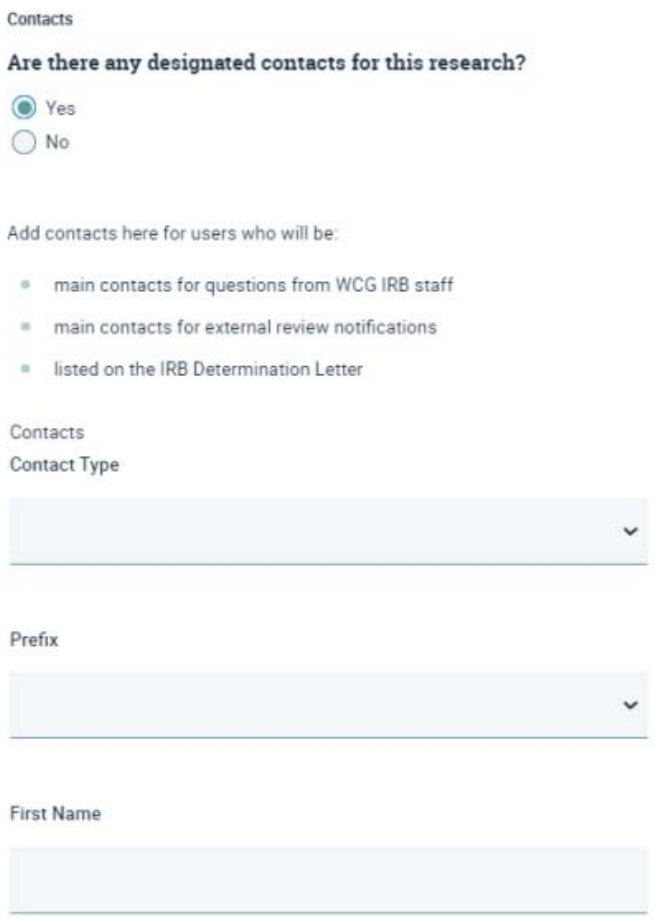
Make a Submission: Initial Review of New PI

- Most submission documentation has now been incorporated into an interactive online form
- The system will guide you to fill out and submit any additional documentation that is required
- Progress through each step of the submission process is defined by:
  - Checkmark: Step complete
  - Partially-filled circle: Started, but incomplete step
  - Empty circle: Not yet started
- A draft can be saved and resumed at any time



Make a Submission: New PI Form Overview

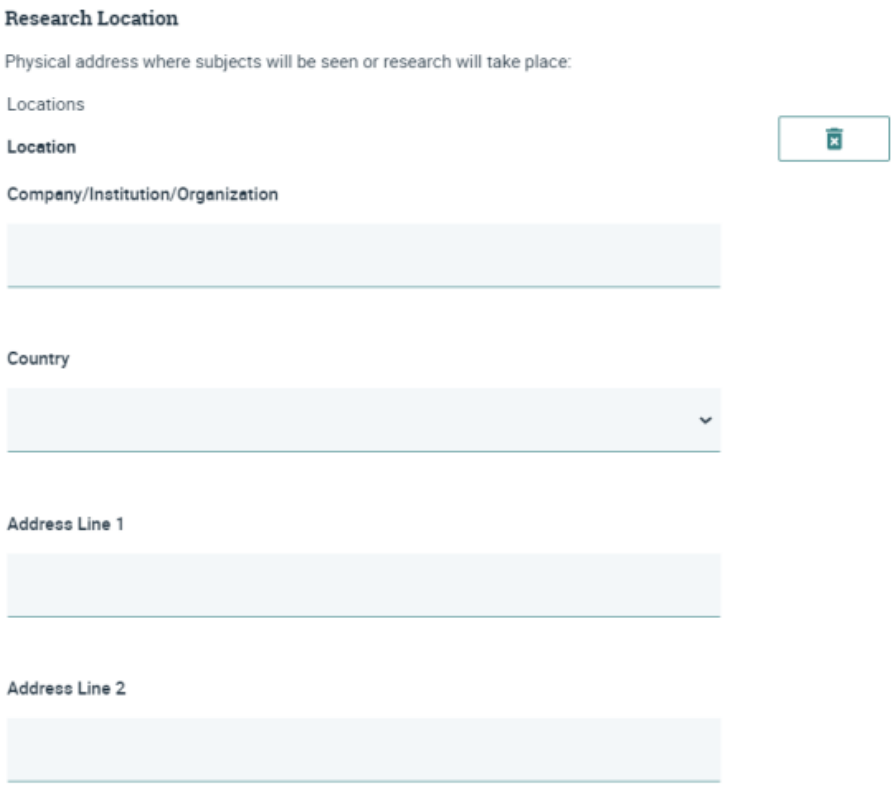
- Be sure to add all contacts who need to receive the day-to-day correspondence from the IRB
- You can add study coordinators, or sponsor/CRO contacts
- Not all Study Staff need to be listed to receive all notifications, but rather can be added to view Outcome Documents via the Manage Contacts tools for that Investigator



Make a Submission: New PI Form Overview

- Add all locations that are engaged in the research
- Be sure to double-check the information for accuracy, as approved locations appear on the Certificate of Action

- Only CHLA affiliated locations should be listed



Make a Submission: New PI Form Overview

- Certificates of training are not required to be submitted to WCG
- Only the CV and Medical License (if applicable) of the PI is needed, if not already on file with WCG

Research Team Training

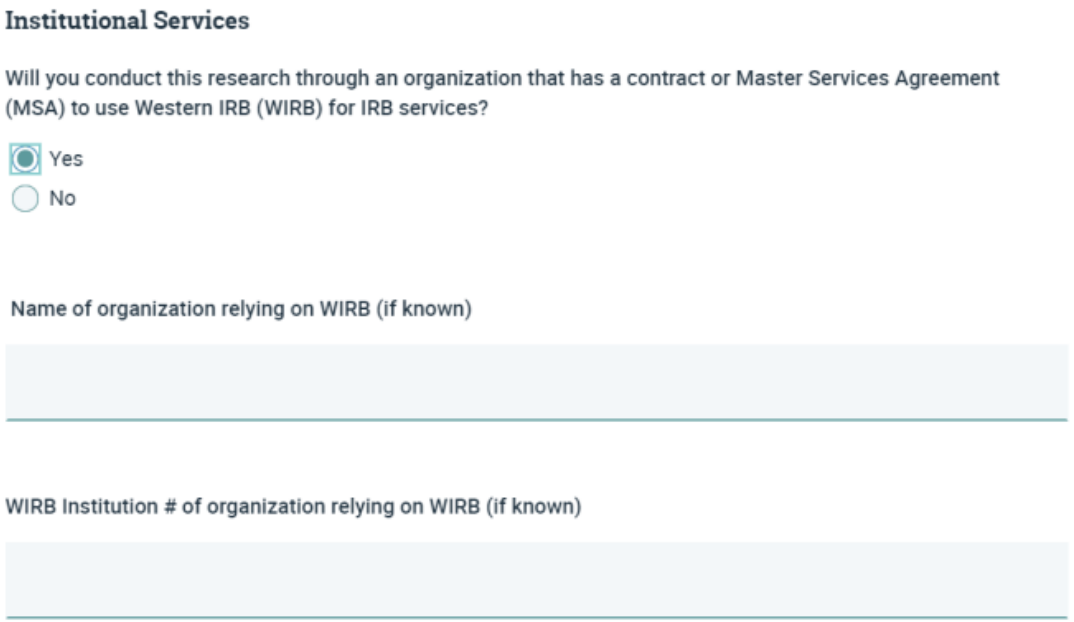
The Principal Investigator (PI) must ensure that all investigators and research staff undergo training on the ethics and regulations of human subject protections before being involved in the conduct of this research. For clinical research, the Principal Investigator (PI) must ensure that all investigators and research staff undergo training on Good Clinical Practice (GCP).

- Have all investigators and research staff involved with the conduct of this research taken one or more of the following programs and all applicable training programs noted as required?
  - ACRP Certified Clinical Investigator Training
  - CenterWatch: Protecting Study Volunteers in Research
  - Collaborative IRB Training Initiative (CITI)
  - DIA Certified Investigator (CCI)
  - SOCRA Clinical Research Professional (CRP)
  - Tri-Council Policy Statement online training (TCPS)
  - WCG Academy

(•) Yes
( ) No

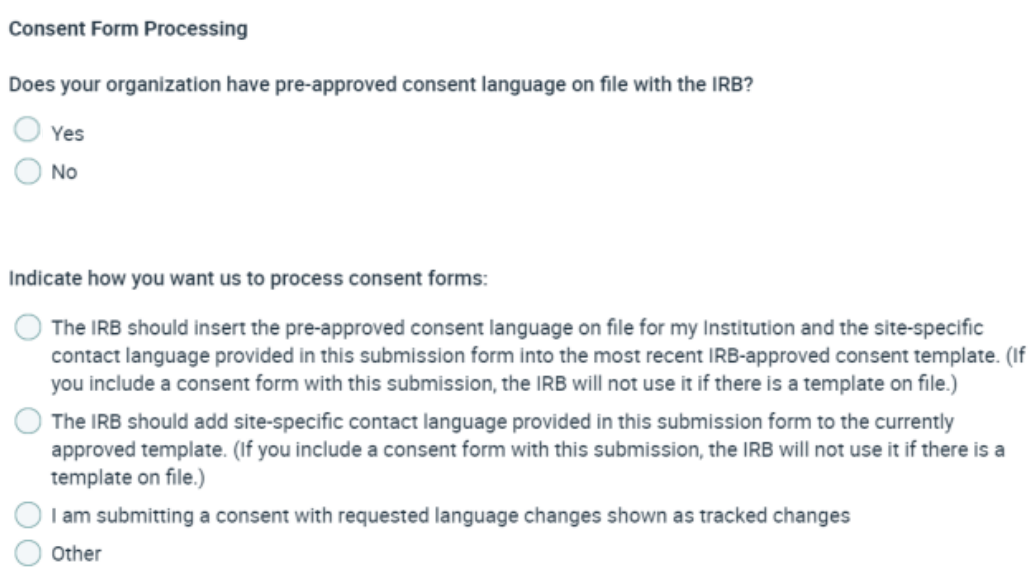
Make a Submission: New PI Form Overview

- Always mark “yes” to Institutional Services question
- Include the name of your organization and your Institution # CHLA
- INSTITUTION #: 130163



Make a Submission: New PI Form Overview

- Indicate if your institution has required consent language on file with WCG
- Be sure to select the appropriate indication of how you plan to submit your consent form, or if you want WCG to insert your site-specific info on your behalf



Consent Form Processing

Does your organization have pre-approved consent language on file with the IRB?

- ○ Yes
- ○ No

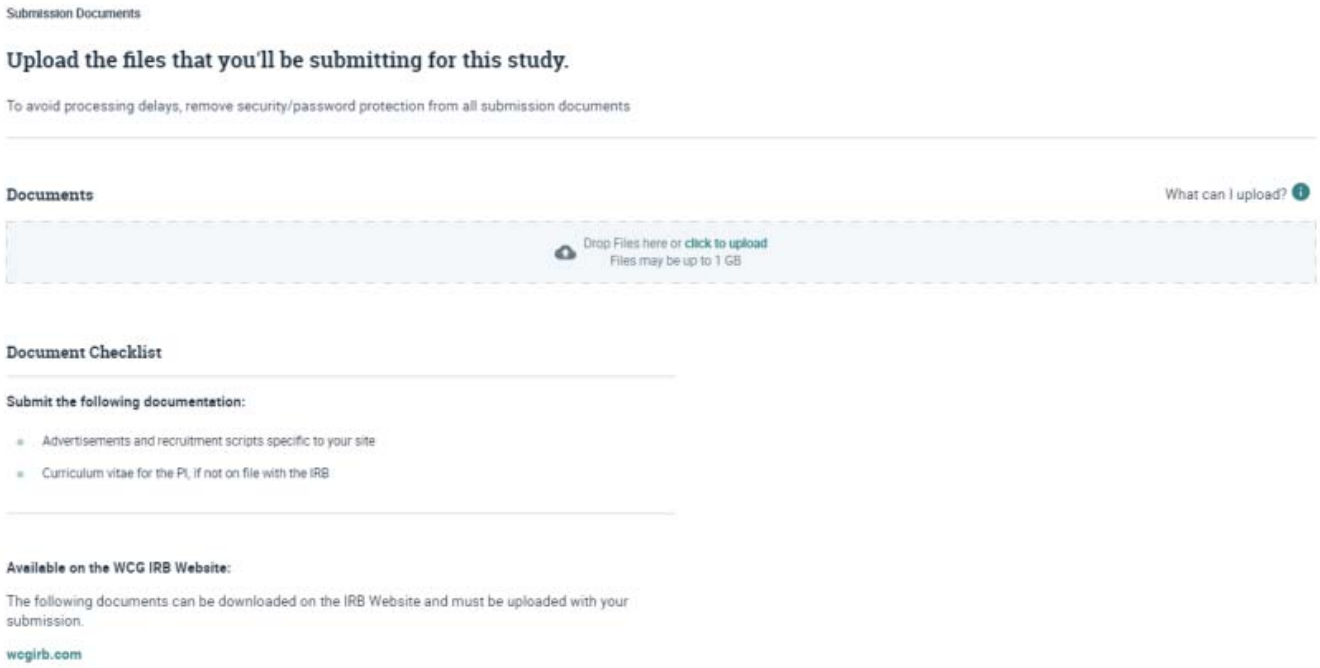
Indicate how you want us to process consent forms:

- ○ The IRB should insert the pre-approved consent language on file for my Institution and the site-specific contact language provided in this submission form into the most recent IRB-approved consent template. (If you include a consent form with this submission, the IRB will not use it if there is a template on file.)
- ○ The IRB should add site-specific contact language provided in this submission form to the currently approved template. (If you include a consent form with this submission, the IRB will not use it if there is a template on file.)
- ○ I am submitting a consent with requested language changes shown as tracked changes
- ○ Other

- Yes - CHLA has pre-approved consent language
- Other: WCG IRB should use the Consent Form checklist and send to site contacts for pre-review.

Make a Submission: Upload Required Documents

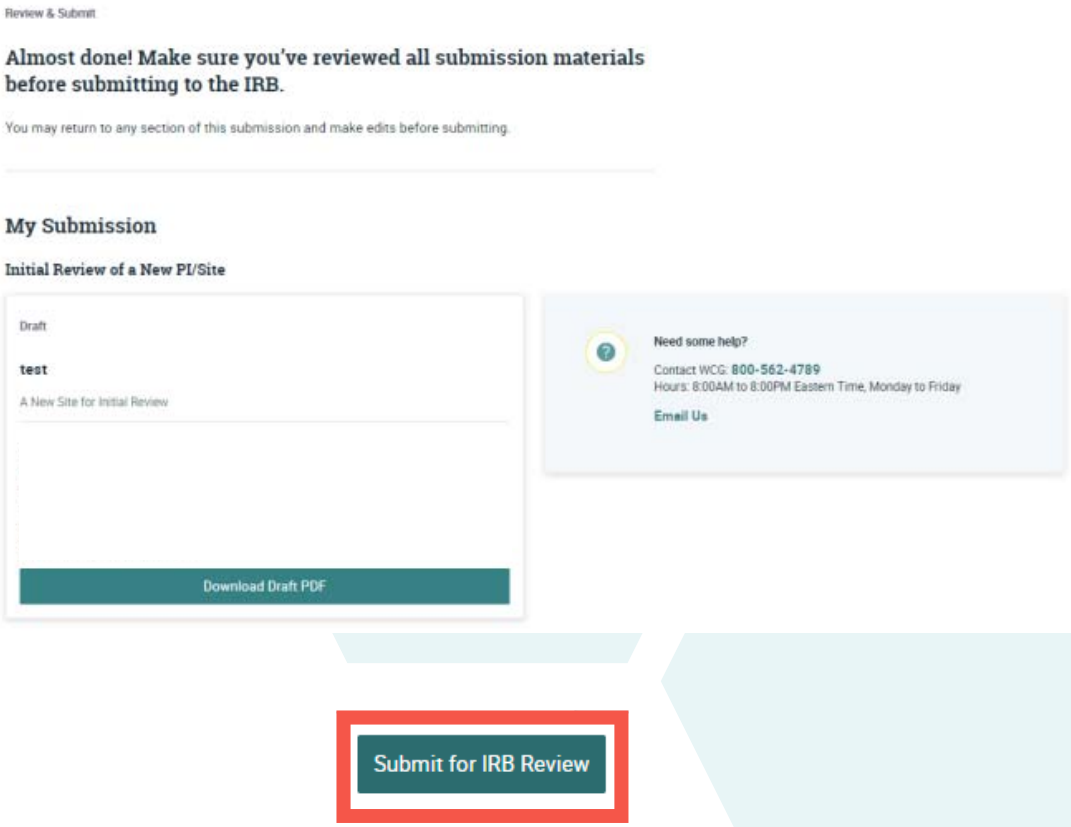
- CHLA Notice of Ceded Review Clearance Letter
- CHLA Consent Checklist
- CHLA completed assent forms for studies enrolling children under 13 and not using the sponsor's assent template
- Site specific documents



- The end of the form will show a Document Checklist for what you have to submit
- Be sure to include any required documents (like sign-off) per Institutional Requirements

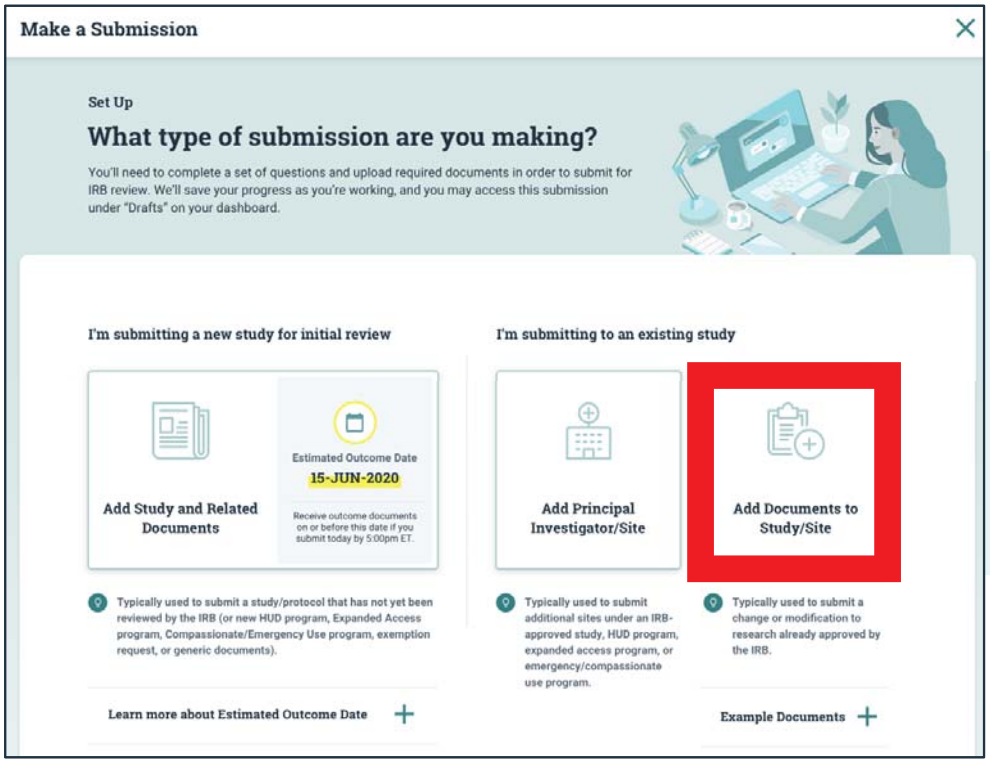
Make a Submission: Review & Submit

- The last step before you submit will allow you to download a PDF of your completed online form
- Click “Submit for IRB Review” in the bottom right-hand corner of the screen to submit for IRB Review
- A confirmation ID should appear within a few minutes and is accessible via your Submissions landing page



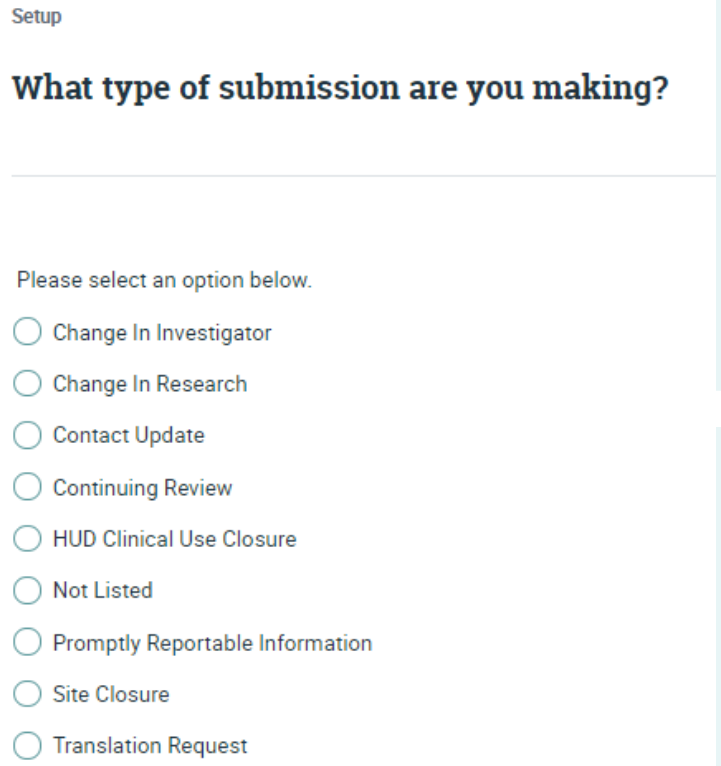
Make a Submission: Subsequent Submissions (Amendments, Promptly Reportable Info)

For adding documents to an existing approved PI with WCG, select below option:



Make a Submission: Subsequent Submissions (Amendments, Promptly Reportable Info)

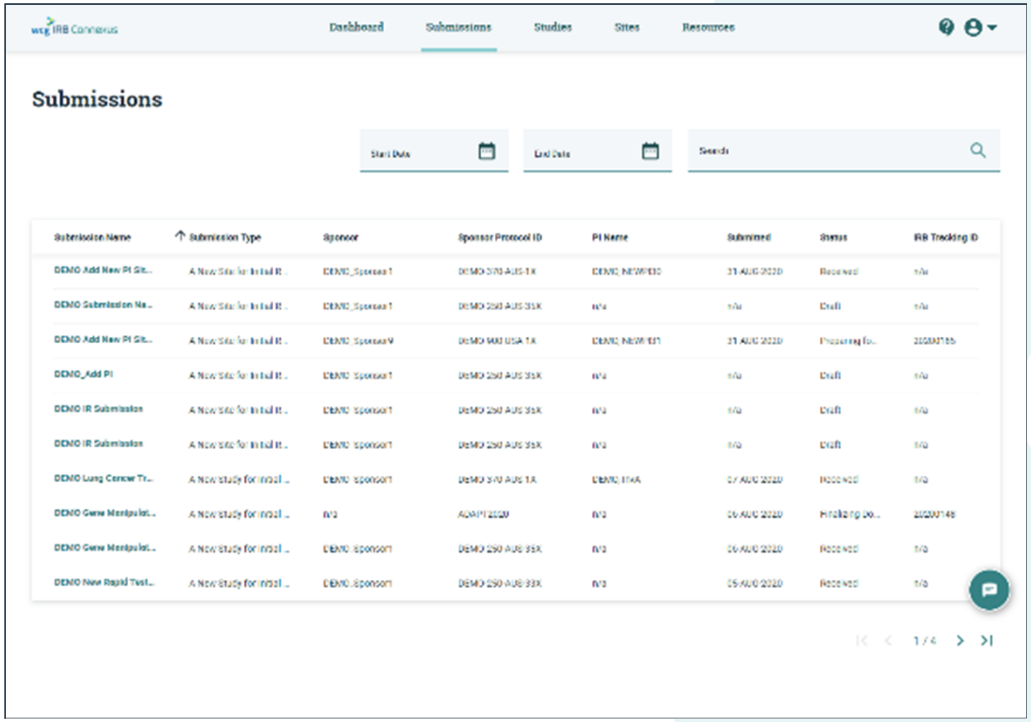
- Select the type of submission you will be making
- Follow the on-screen instructions/questions
- Upload documents and submit



Navigating Workspaces

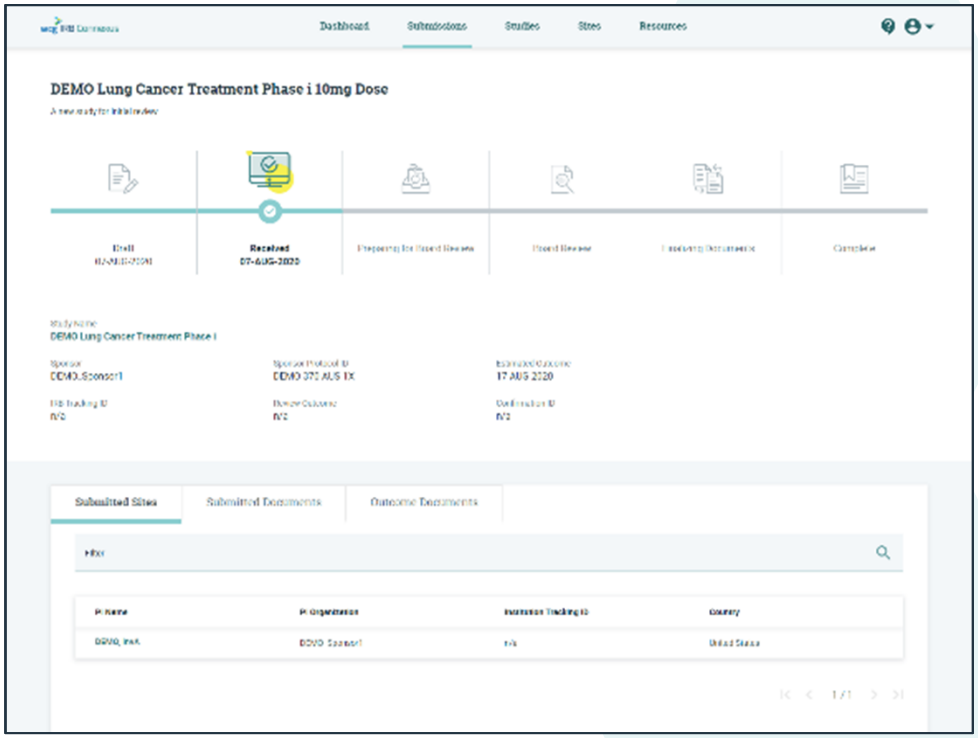
WCG IRB Connexus Submissions Landing Page

- Display all submissions by selecting Submissions from the Navigation Bar
- Page contains:
  - Search / Quick Filters
  - Table displaying all submission entries
- Click **Submission Name** to view details



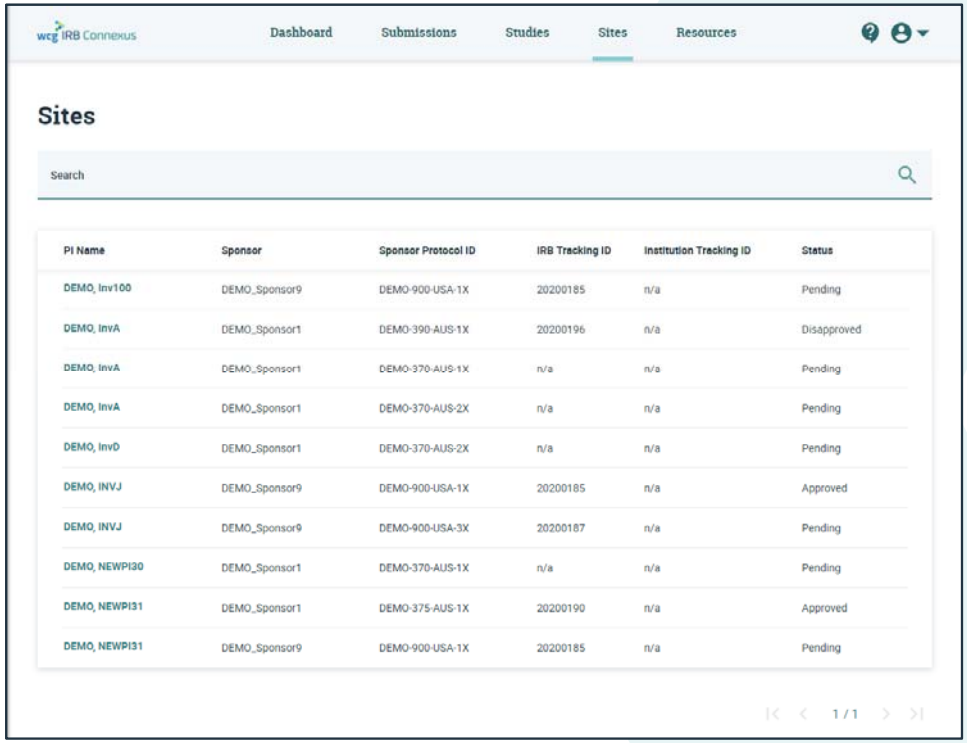
Submission Details

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



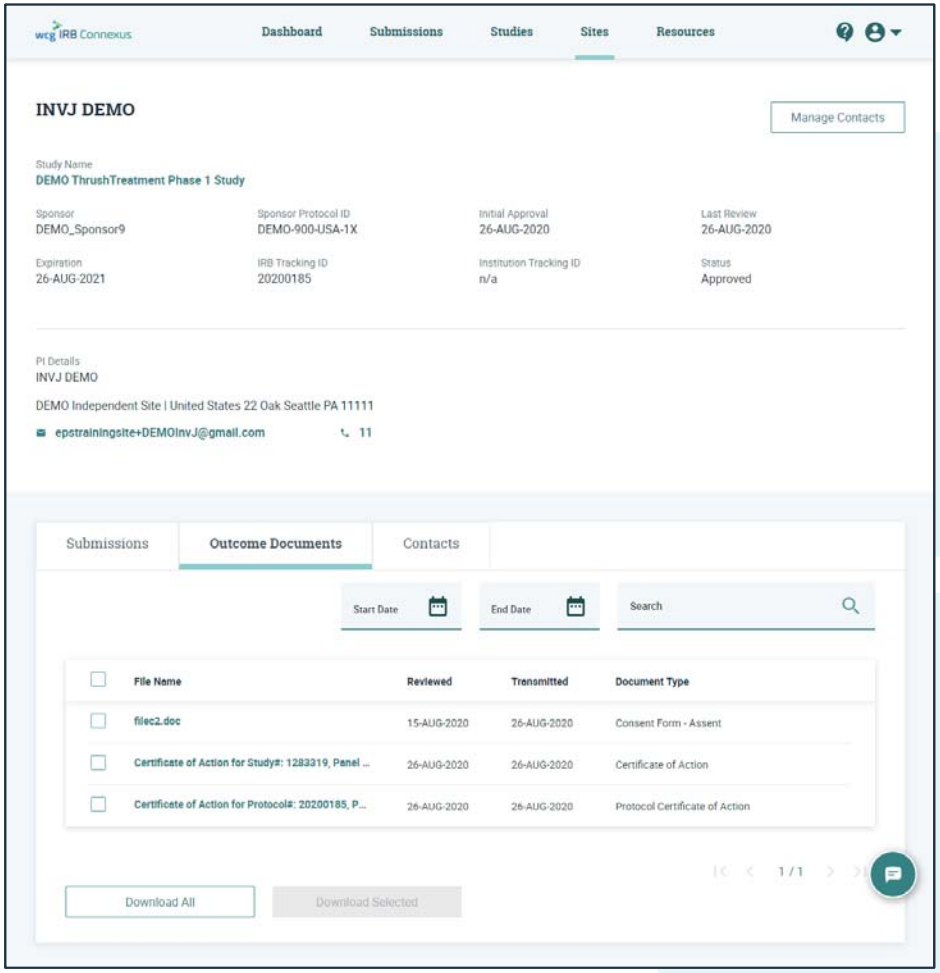
WCG IRB Connexus Sites Landing Page

- From the Navigation Bar, select **Sites** to display all the sites you have access to
- Click the PI Name for more details
- Page contains:
  - Search
  - Table displaying all site information



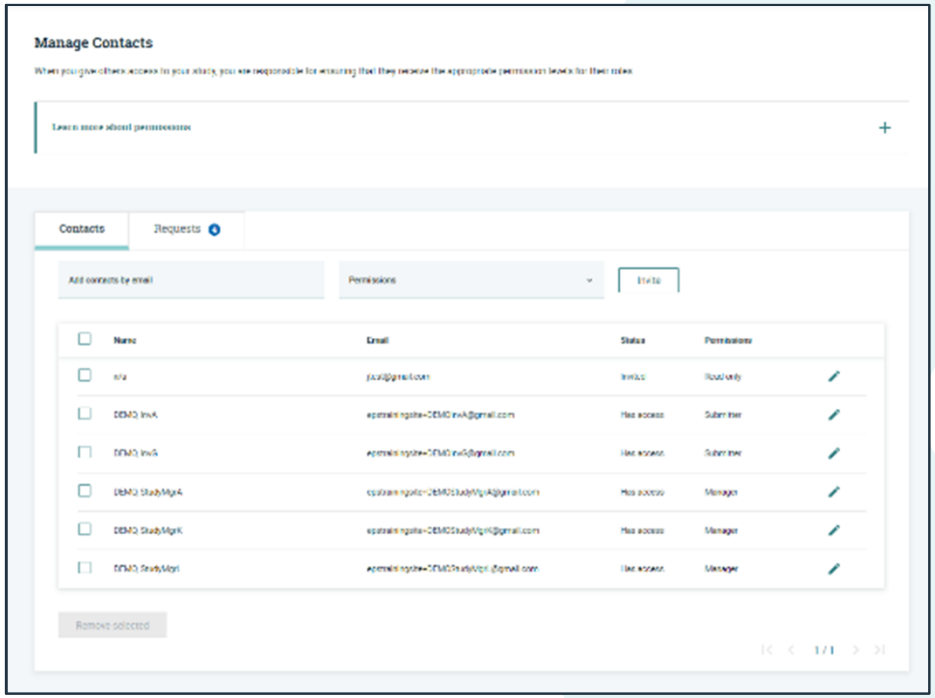
Site Details

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



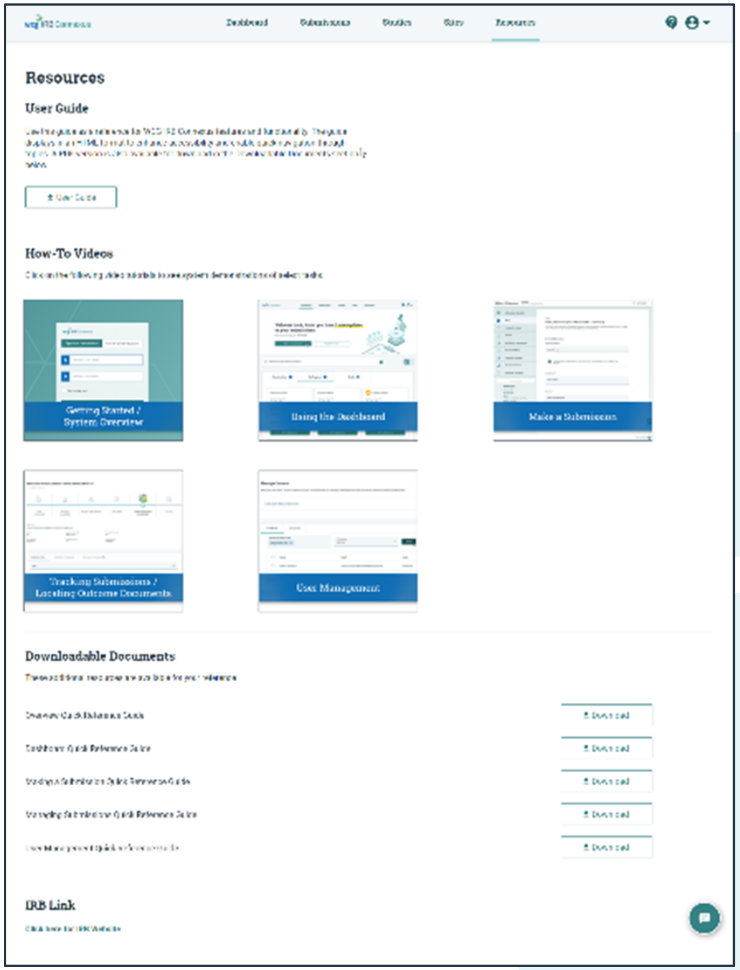
Manage Contacts

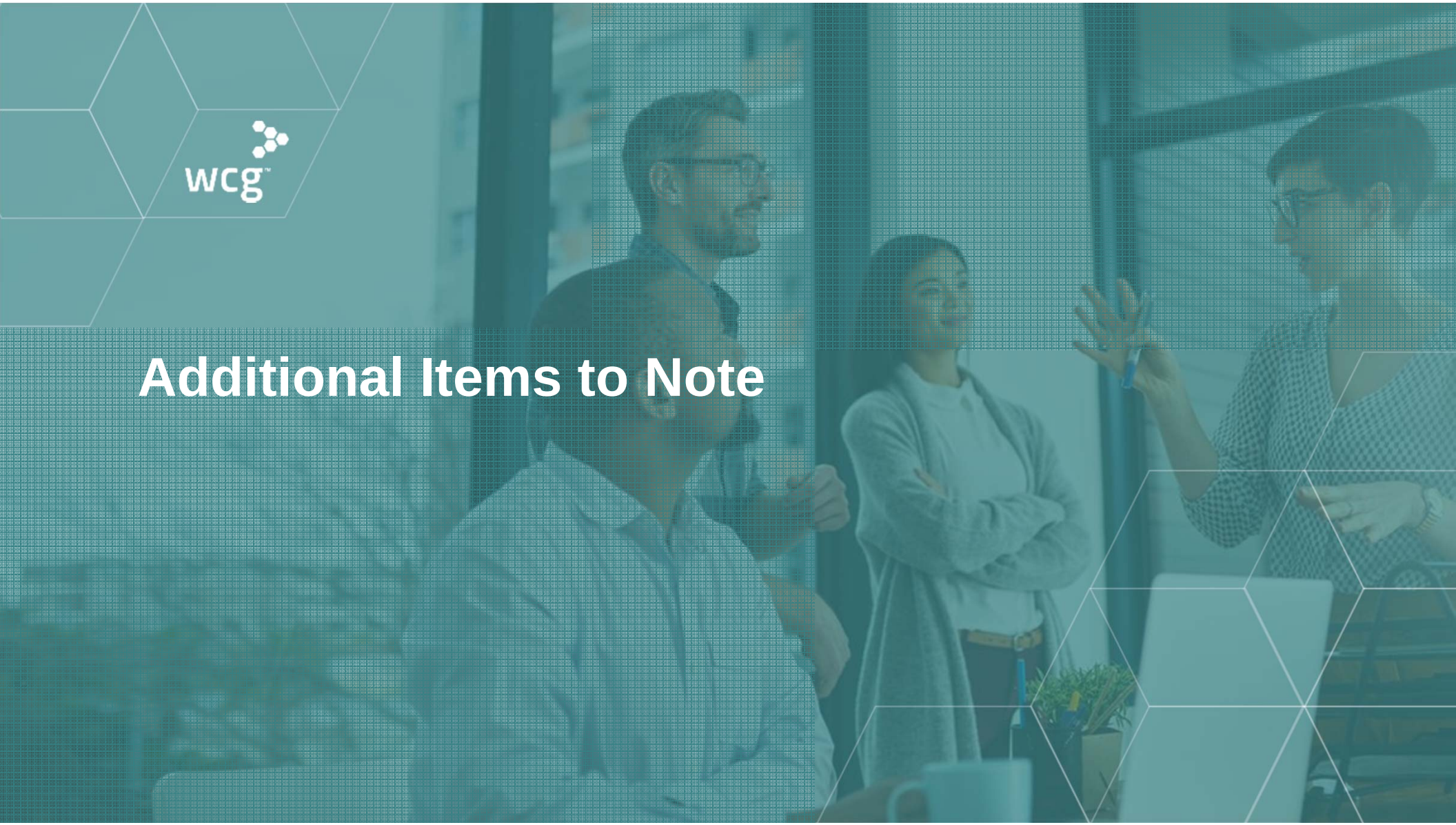
- Only accessible from Study or Site Details page for sites in which you have the **Manager** permission role
- View and manage current site contacts
- Invite contacts to join a site
- Approve or deny pending site access requests



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 with proper transition. Only closed study data 3 years old or less will be migrated.

Additional Information

- All new users being transitioned 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

Reminder Regarding Registration

- **You will receive an invitation with instructions on how to log into your new WCG IRB Connexus account. Please wait for your invitation before logging into the new WCG IRB Connexus portal.**

- You may continue to use Legacy MyConnexus until you receive your invitation to transition to WCG IRB Connexus.

We are here to partner with you – contact us!

For general questions and inquiries:

1-855-818-2289 | clientservices@wcgirb.com

Live Chat via Connexus

For CHLA specific, escalated or urgent issues:

Carmen Thompson

360-252-2447 | cbthompson@wirb.com

wcg IRB

Thank You