Introduction to the updated WCG IRB Connexus Portal: General Training and Q&A

Thursday, July 15th, 2021

UC Health

Office of Clinical Research

New CDA and CTA Submission Process

All new clinical trial contracts are being processed by the Sponsored Research Services (SRS) Contract Management team at the University of Cincinnati.

Important: An executed CDA between UC and the study sponsor MUST be executed before a CTA can be negotiated by UC.
A new online submission process has been developed to support the new contracting process:
https://redcap.research.cchmc.org/surveys/?s=CLDDCECC84

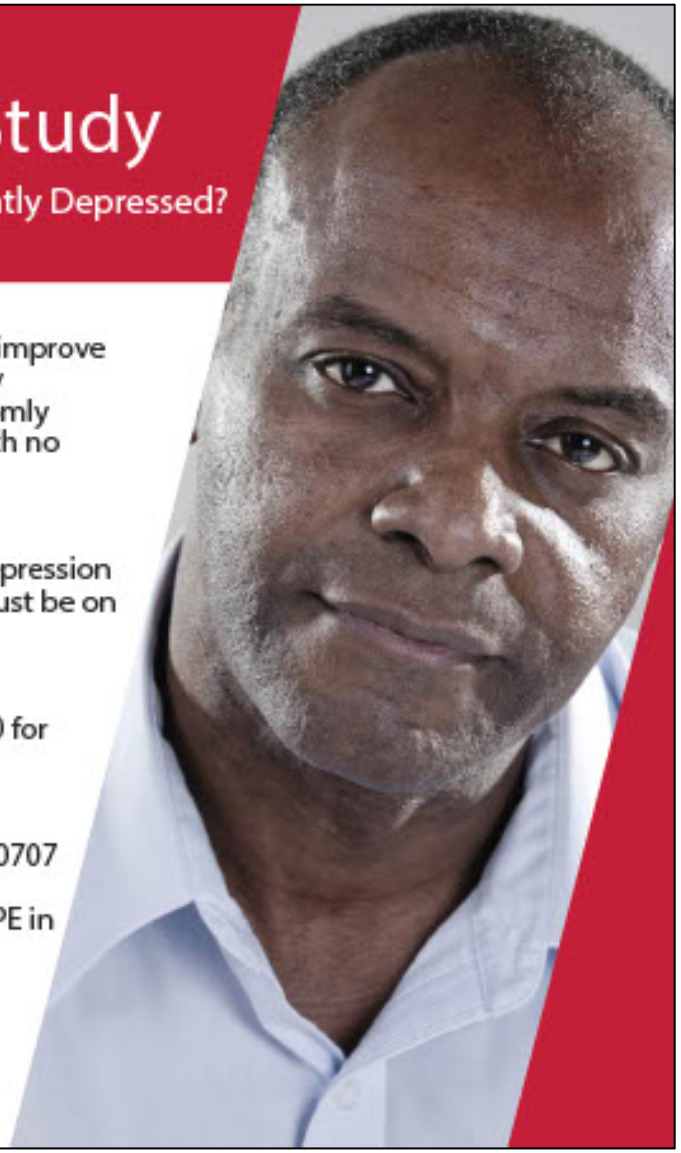
Existing agreements executed through UC Health will continue to be managed at UC Health until their conclusion.

As always, feel free to reach out to the Office of Clinical Research for any questions

July 2021 Study of the Month

Bipolar Depression Study

Do You Have Bipolar Disorder and Are Currently Depressed?



What
The purpose of this research is to see if Mydayis will improve mood in patients with bipolar disorder and currently suffering from depression. Participants will be randomly assigned to take Mydayis or a placebo (a fake pill with no active ingredient).

Who
Adults, age 18-55 who are currently experiencing depression and diagnosed with bipolar disorder. Participants must be on a mood stabilizer prescribed by their doctor.

Pay
Eligible participants will be compensated up to $390 for their time, effort and travel.

Details
For more information, please contact us at 513-536-0707 or visit www.LCOH.info and fill out a pre-screen questionnaire. Located at the Lindner Center of HOPE in Mason, Ohio.

UC Health | UC Health Lindner Center of HOPE

03-20 IRB #2020-0249

UC Health

Friday, August 6th, 2021

High Enroll Recruitment services

Ginger Conway MSN, CNP

COO High Enroll, LLC

UC Health

Today's Presentation:

Introduction to the updated WCG IRB Connexus Portal: General Training and Q&A

This training and overview of the new Connexus IRB portal will cover new portal features and workflow, all updated all with the user in mind. The target audience for this presentation is CRPs who use WCG IRB as their IRB of record and use Connexus to manage regulatory for their studies.

Christopher Gennai,

CIP | Senior Institutions Partnership Manager

WCG IRB

cgennai@wirb.com | www.wcgirb.com

UC Health

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Introduction to WCG IRB Connexus™ for University of Cincinnati

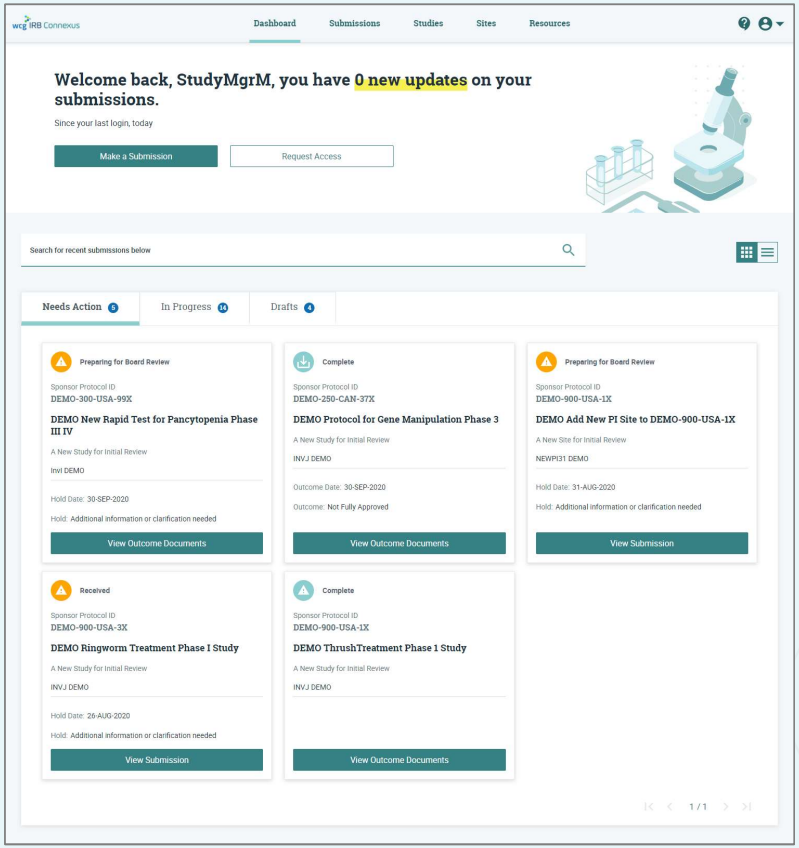
July 15, 2021

What We Will Cover In Today's Session

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

WCG IRB Connexus Overview

WCG IRB Connexus Overview



- 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 – Understanding the Key Differences

Legacy MyConnexus	WCG IRB Connexus
Sites would require access to study workspaces to submit a new PI	Users can submit a new PI without being granted access to the study
Administrators / Client Services would enter contacts	Users add contacts when they create submissions
Users required to search for forms outside of the system 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)
Workflow to make new submissions started from a study or site workspace	Make a Submission from the Dashboard and then select Submission Type

wcg IRB

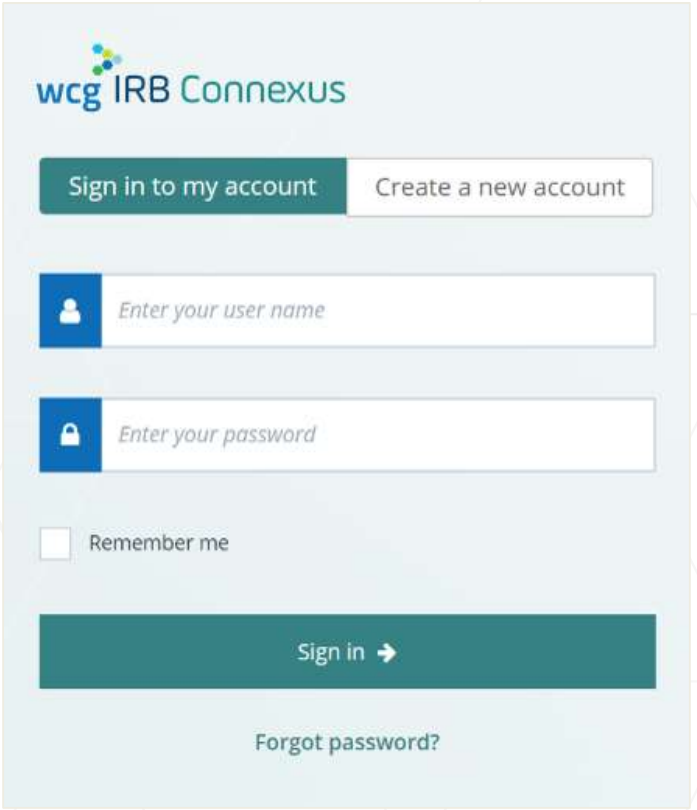
System Access & Signing In

3 Ways to Access the System

1. **Direct Link:** https://connexus.wcgirb.com
2. **Via the WCG IRB Website:** http://www.wcgirb.com
   - Click “Login to WCG IRB Connexus” link in the top navigation
3. **Download Forms:** How to Submit>Download IRB Forms

Signing In

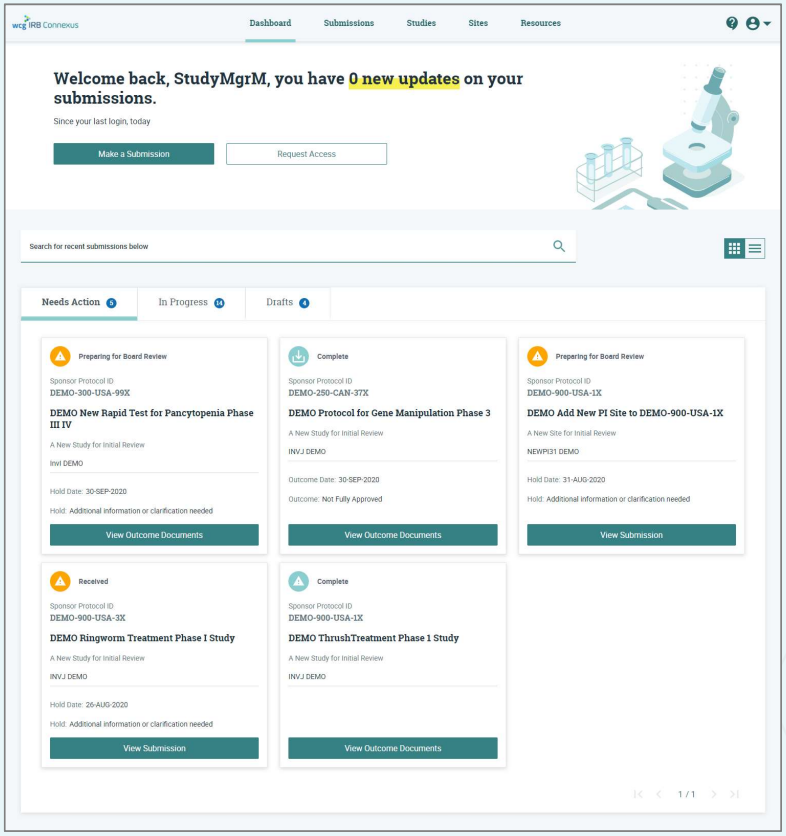
- Legacy MyConnexus users need to reset password and accept the Terms & Conditions upon initial sign in
- Use the same registered email address as you have in Legacy MyConnexus
- Your username is your email address
- New users can register using the **Create a new account** button



wcg IRB

Dashboard and Access Roles Overview

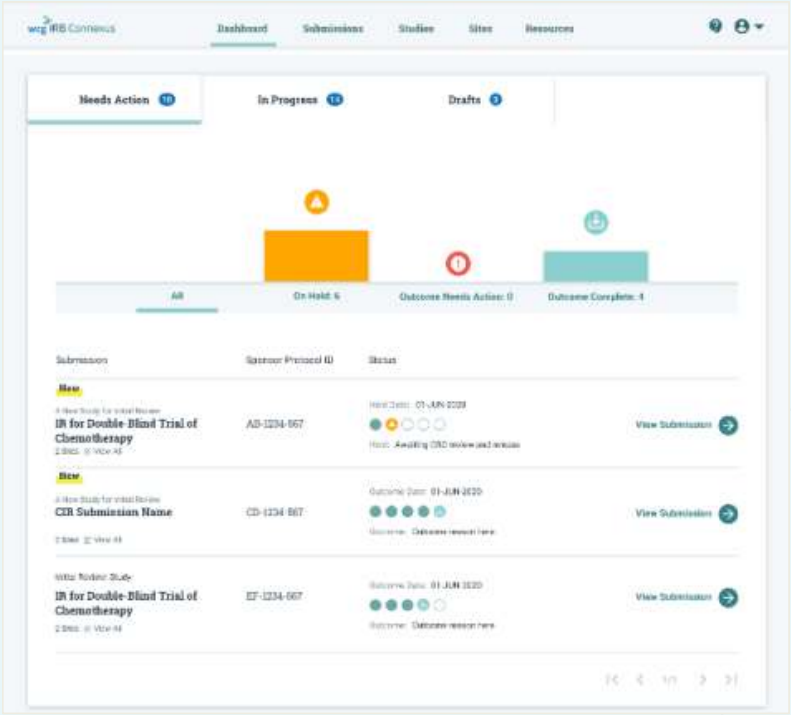
WCG IRB Connexus Dashboard

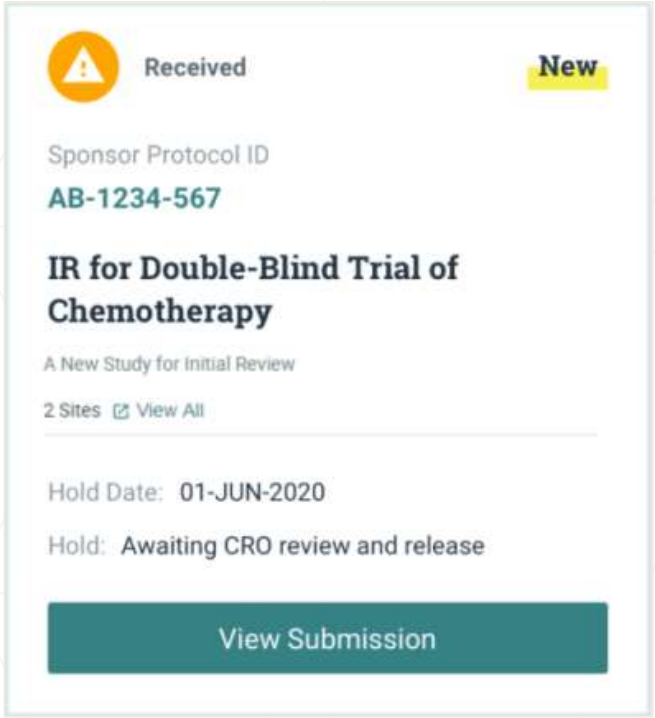


- This is your landing page and central hub for most WCG IRB Connexus activity
- Contains:
  - **Notification** section
  - **Make a Submission** button
  - **Request Access** button
  - **Track Submissions** area
    - Search
    - Tabs for callouts: Needs Action, In Progress, Drafts
    - Two different views, per your preference

Dashboard – Card and Table Views

Two different options for easily viewing submission/study details:



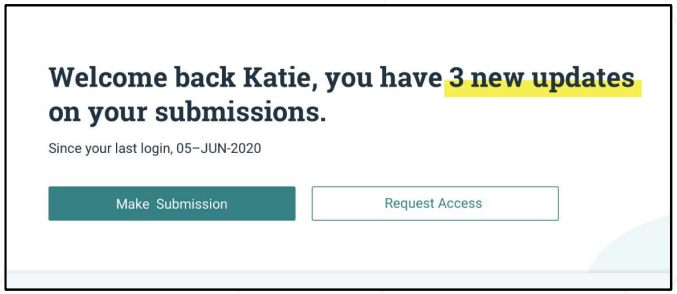


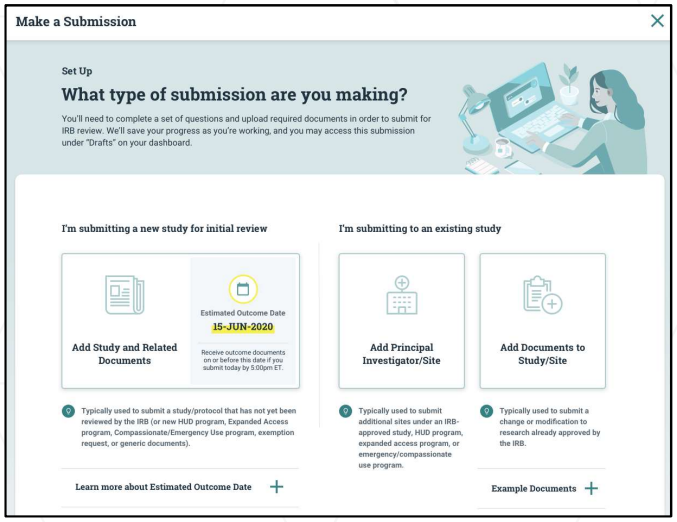
Make a Submission

The **Make a 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 IRB)
- 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)

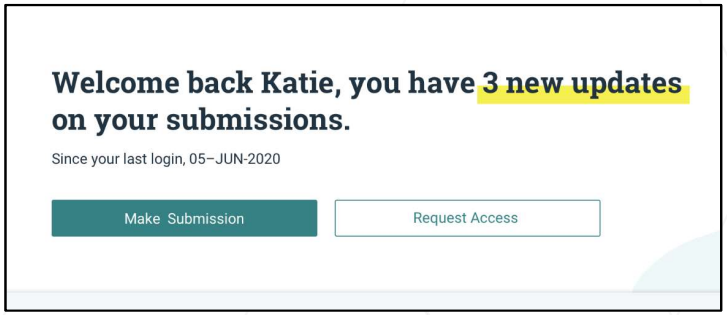


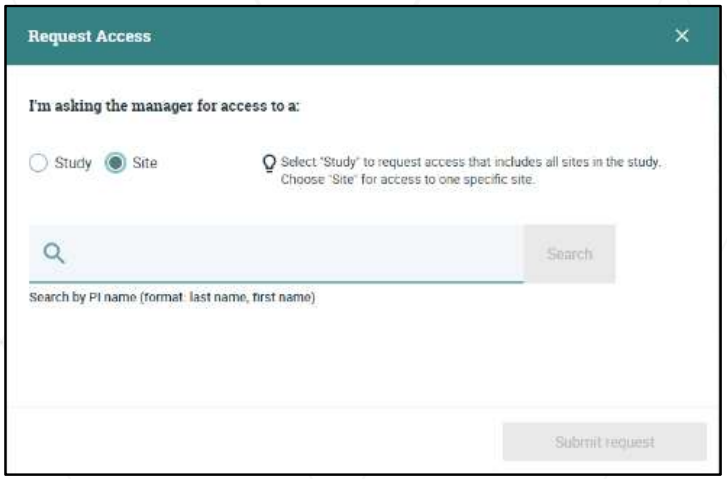


Request Access

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 your request has been accepted or rejected by a manager
- Managers are responsible for ensuring users receive the appropriate permission level for their role
- Managers may also invite users to join Studies or Sites
- **NOTE: Study workspace access is NOT NEEDED to submit a new PI for a multi-site industry-sponsored study**





Roles Review

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 (applicable to being a participating site on an existing protocol)

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	✓	✓	✓

Site Roles (applicable to being a participating site on an existing protocol)

Study-level tasks each role may perform based on permission levels:

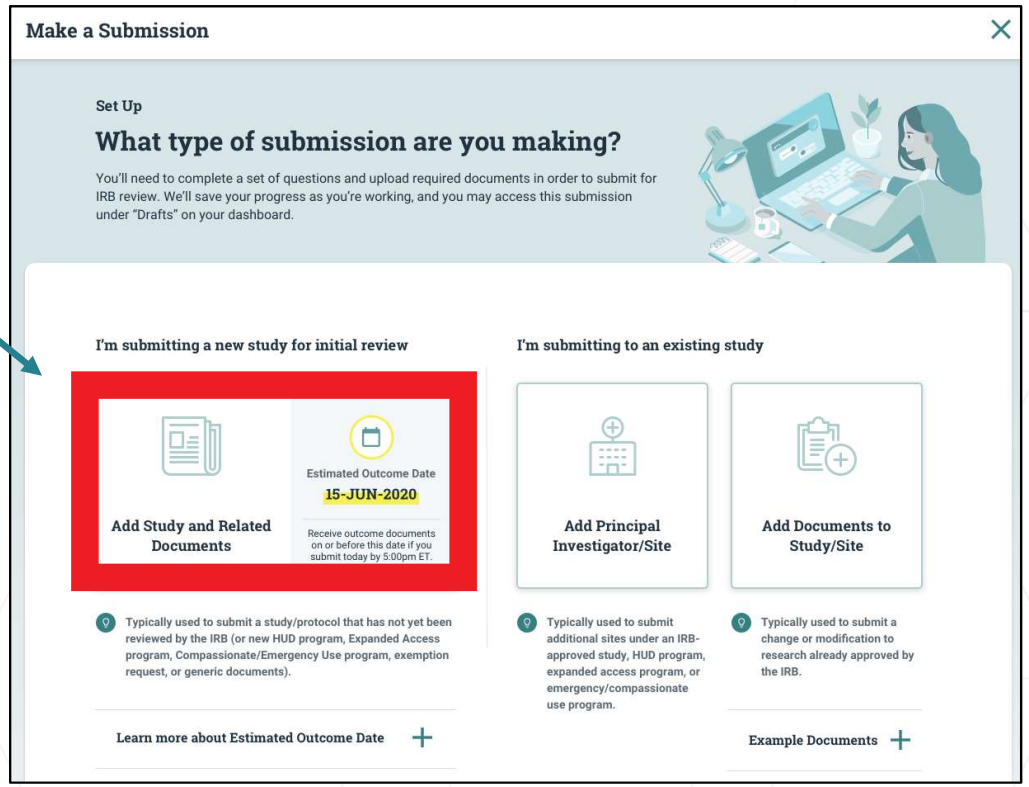
	Manager	Submitter	Read Only
View list of investigators and sites	✓	✓	✓
View investigator and site details	✓	✓	✓
Manage user access (add/edit/remove)	✓		
Make submissions	✓	✓	
View submissions	✓	✓	✓
View and download submission documents	✓	✓	✓
View and download outcome documents	✓	✓	✓
Same access level to each investigator/site	✓	✓	✓

wcg IRB

Submission Process

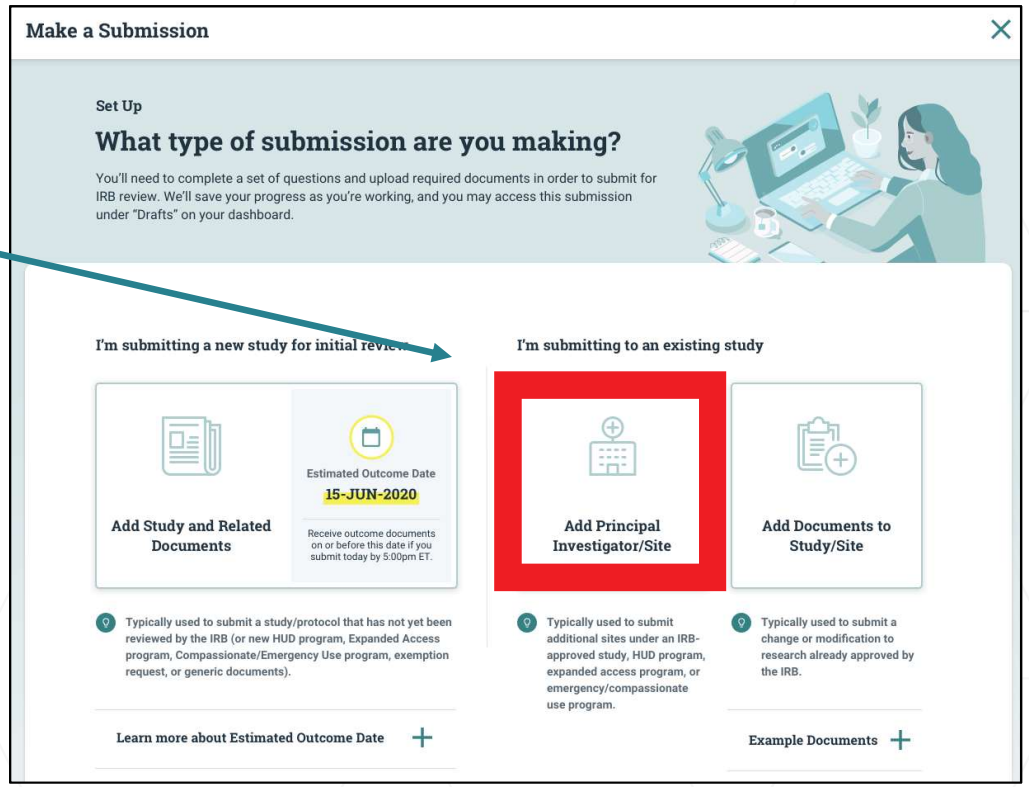
Make a Submission: Initial Review of New Study

For submitting a new protocol to WCG IRB, select the option shown:



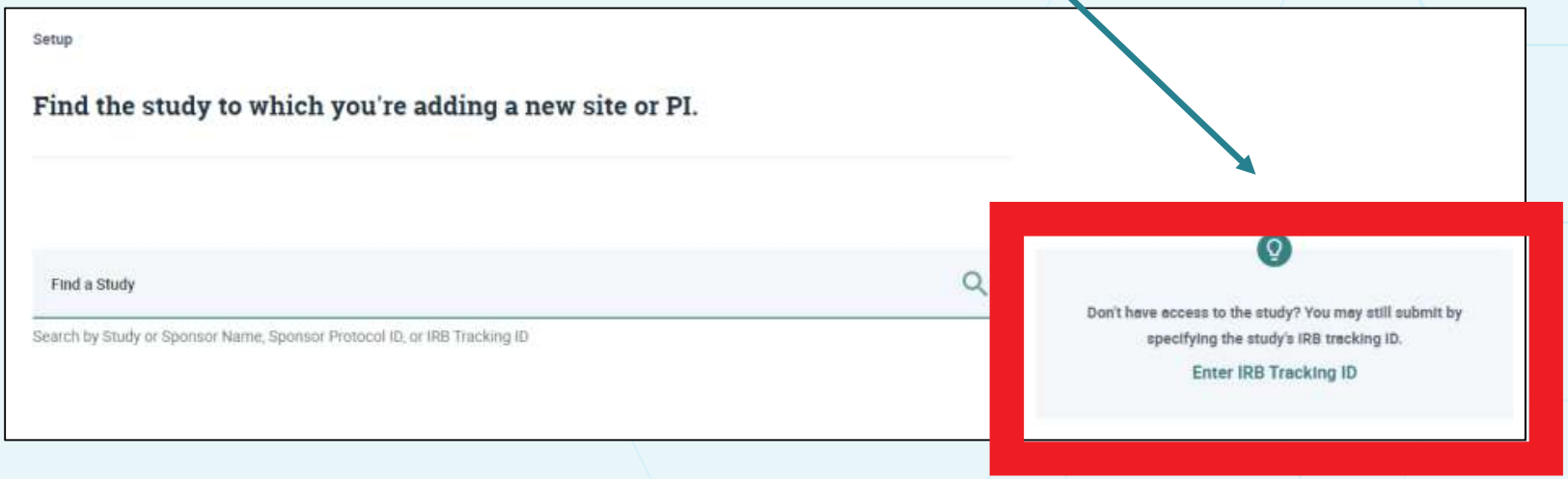
Make a Submission: Initial Review of New PI

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



Make a Submission: Initial Review of New PI

If you are adding a new site onto an existing multi-site study, ensure the submitter has the WCG IRB Protocol # to make the new PI submission (**study workspace access is not needed**):

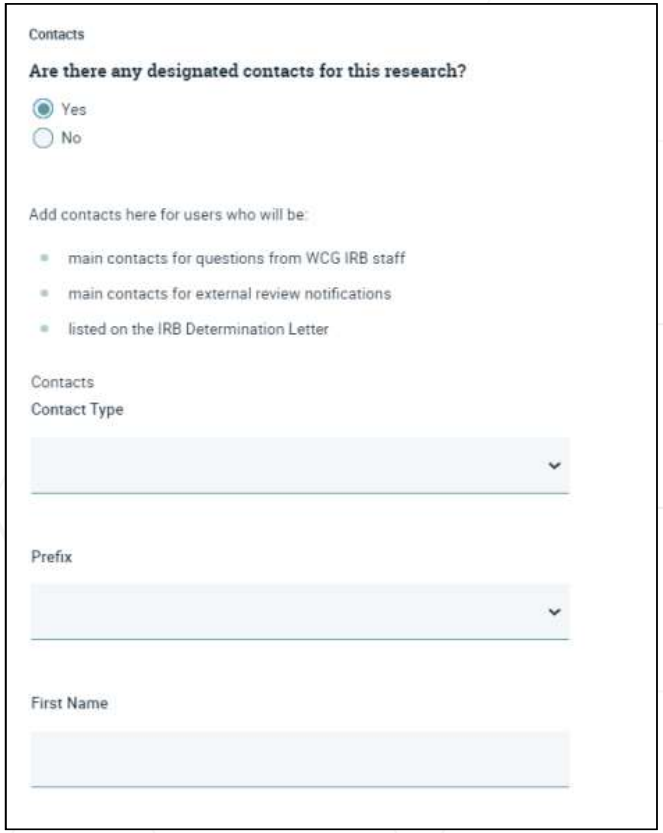


Make a Submission: Initial Review of New PI

Study teams should enter the protocol ID for which they are submitting an initial new site/PI review, and click continue to proceed with the submission:

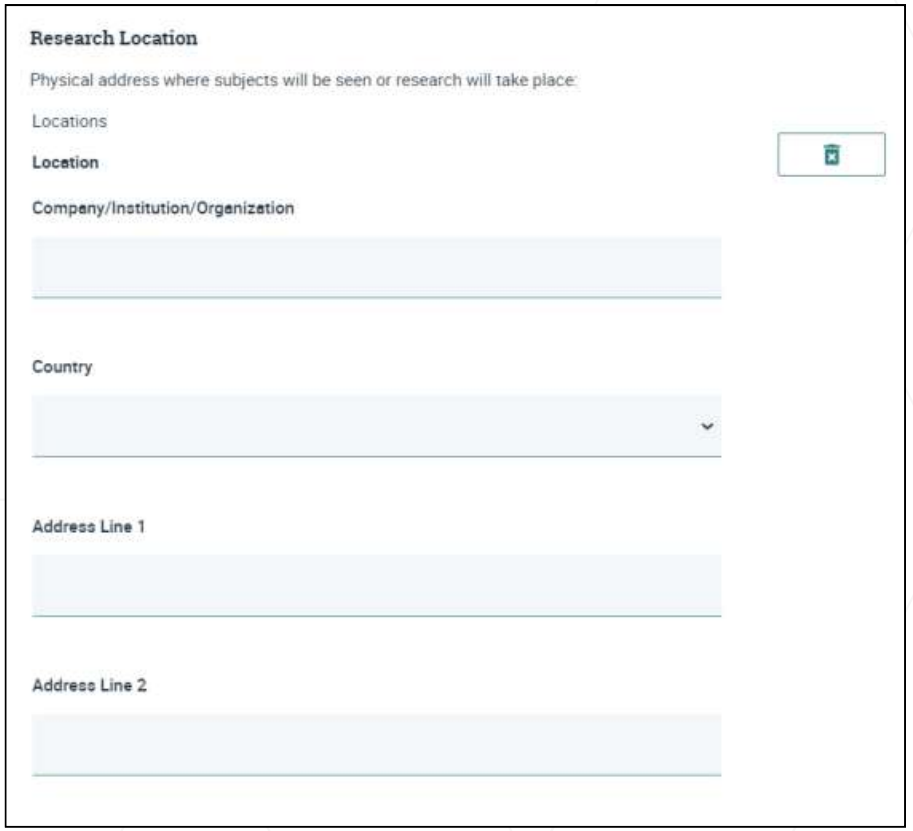
Make a Submission: Initial Review of New PI Form

- Be sure to add **all** contacts who need to receive the day-to-day correspondence from WCG IRB
- You can add study coordinators or sponsor/CRO contacts
- **Note:** if you do not want all of your study staff receive notifications, but you do want them to have access to Outcome Documents, you can add them separately using the **Manage Contacts** tool



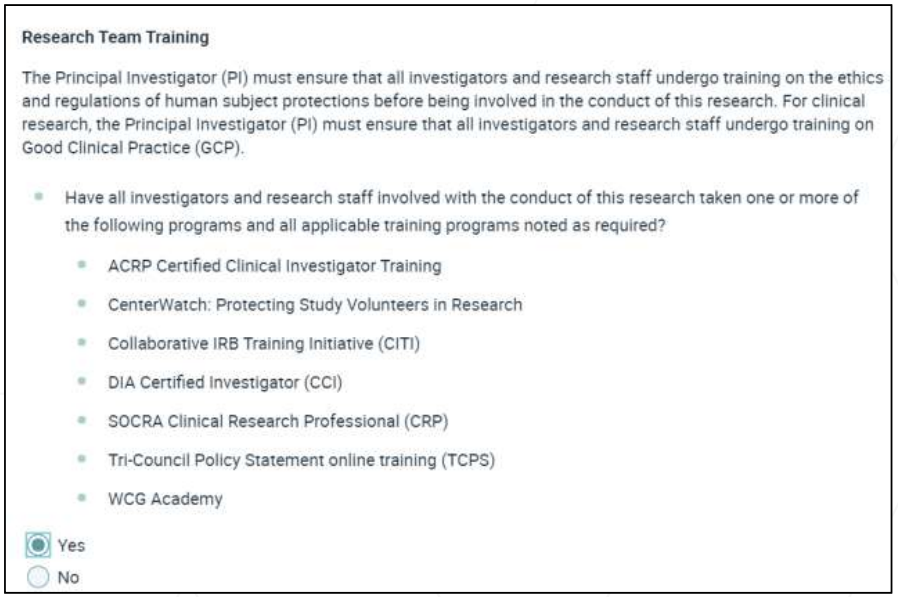
Make a Submission: Initial Review of New PI Form

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



Make a Submission: New PI Form

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



Research Team Training

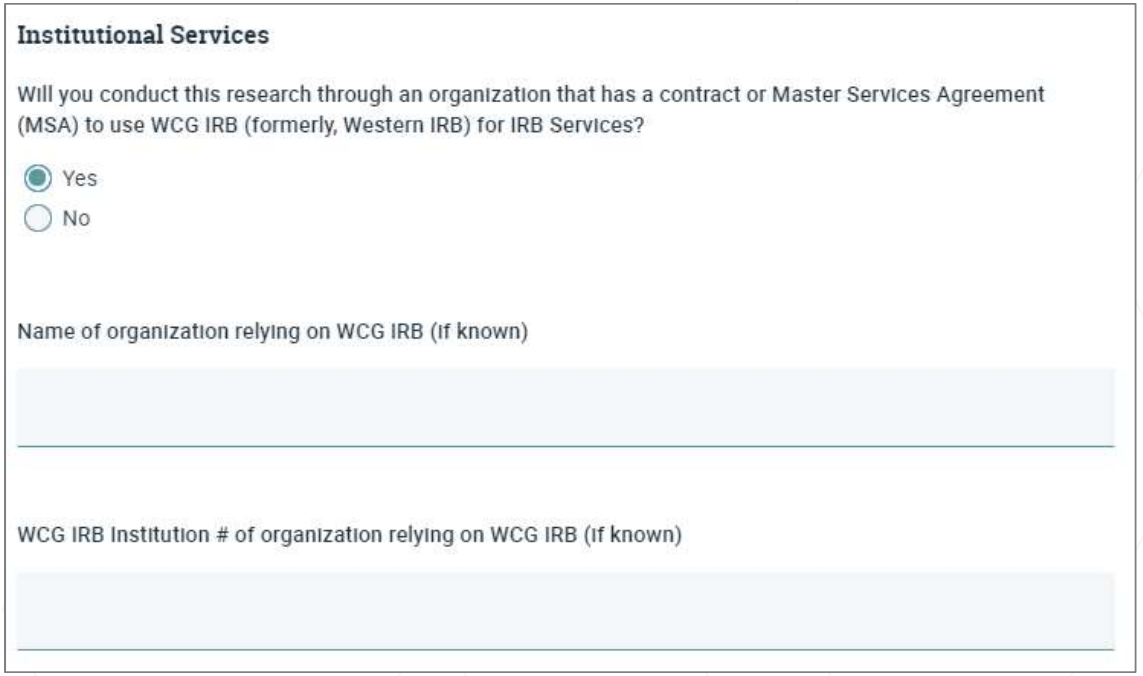
The Principal Investigator (PI) must ensure that all investigators and research staff undergo training on the ethics and regulations of human subject protections before being involved in the conduct of this research. For clinical research, the Principal Investigator (PI) must ensure that all investigators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

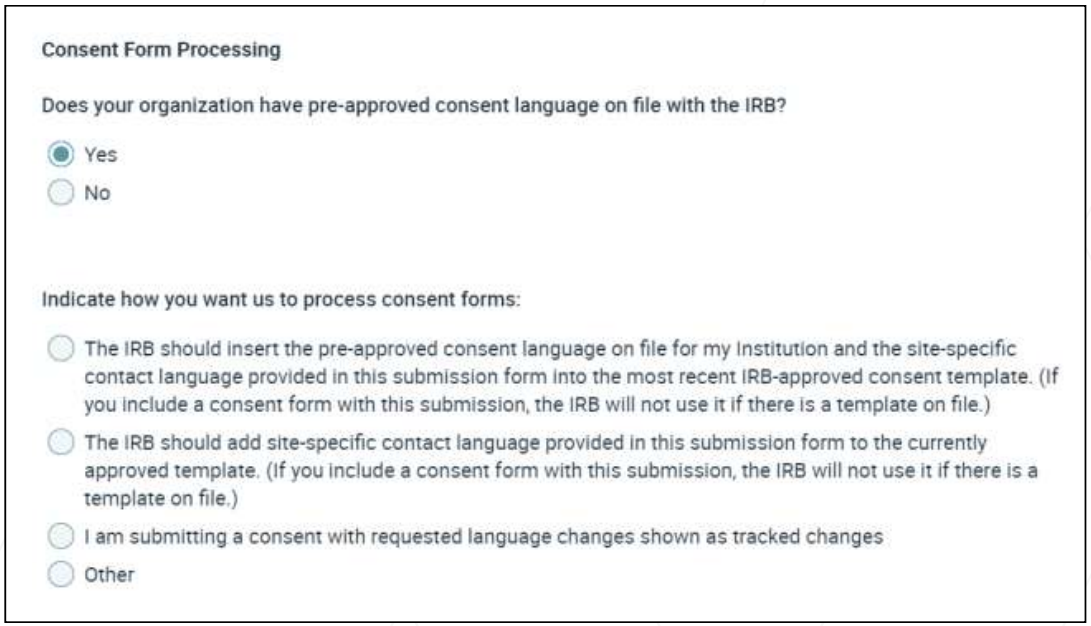
Make a Submission: New PI Form

- Always mark “yes” to Institutional Services question
- Include the name of your organization and your Institution #
- **University of Cincinnati**
- **Institution #: 63908**



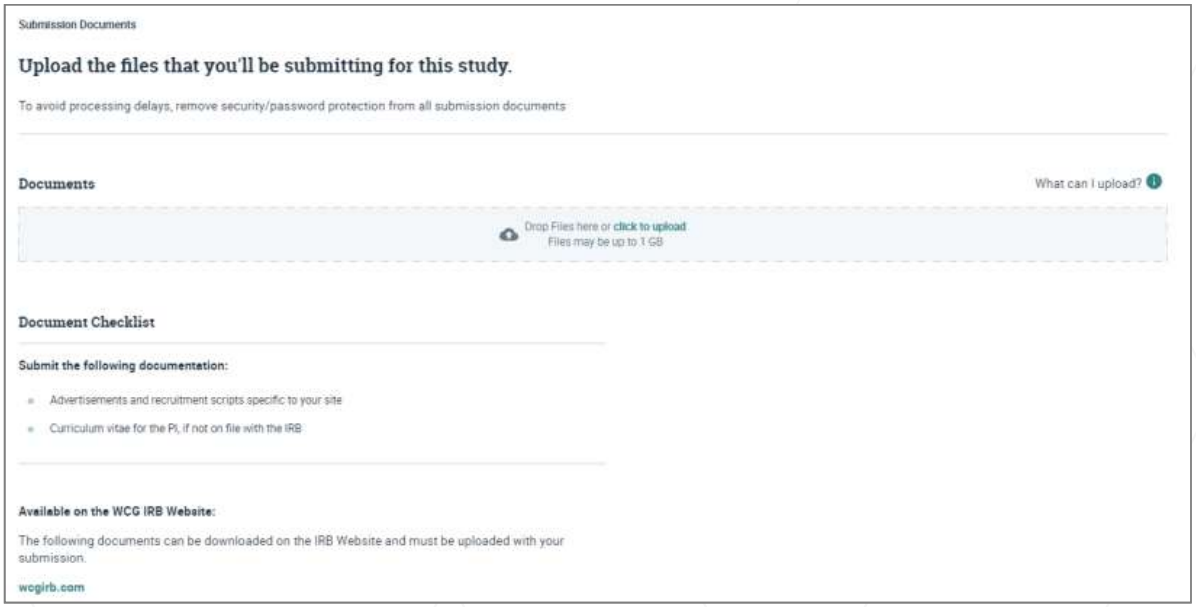
Make a Submission: New PI Form

- UC does have required consent language on file with WCG IRB; indicate Yes to first question
- Be sure to select the appropriate indication of how you plan to submit your consent form
- **For new site submissions:** Typically UC submitters will be sending in a submitted consent with requested language as tracked changes (3rd option)
- **For new protocol submissions:** Select "Other" and indicate that you will be submitting a new consent form



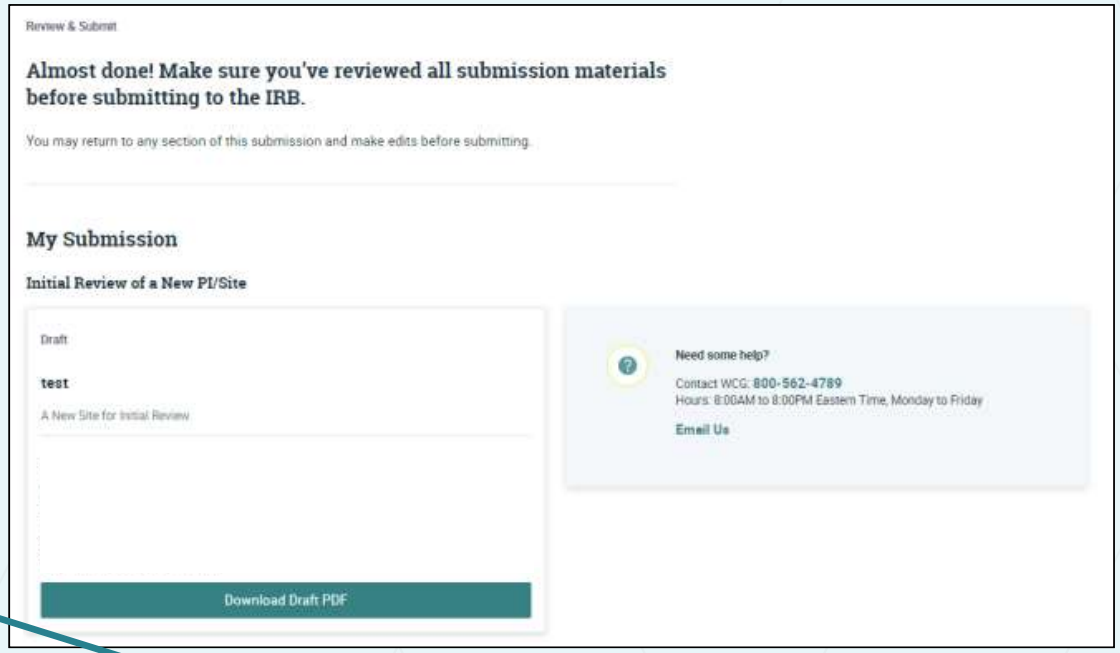
Make a Submission: Upload Required Documents

- The end of the form will show a Document Checklist for what you need to submit in order to make your submission to WCG IRB complete
- Be sure to include your appropriate institution sign-off and indemnification email (if available at submission)



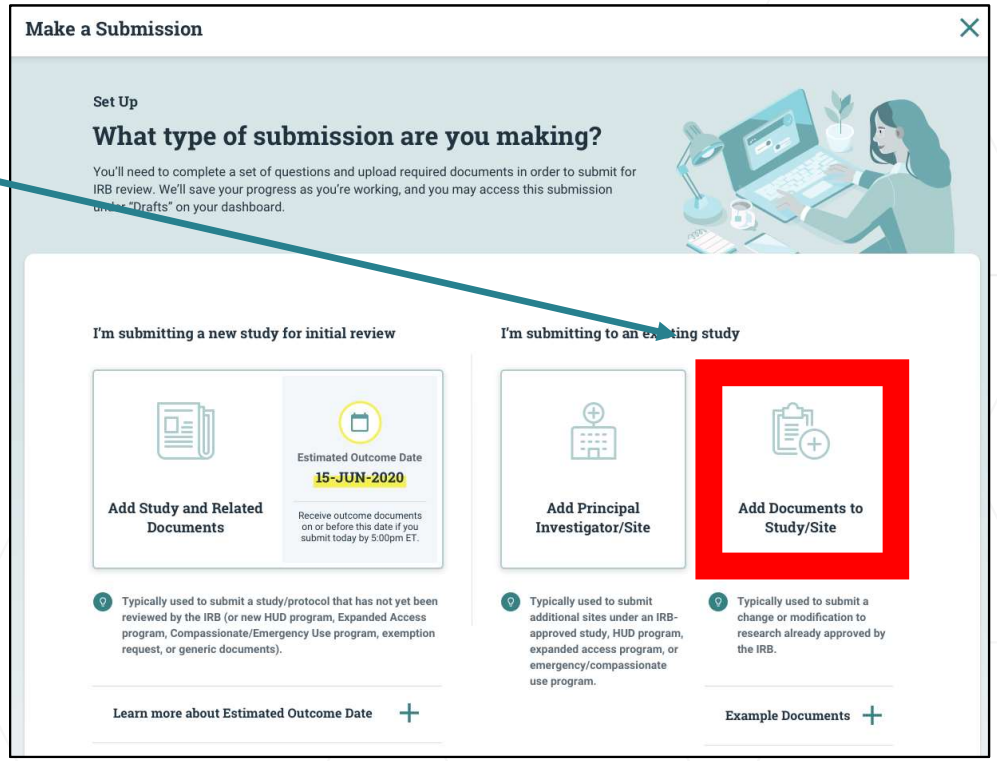
Make a Submission: Review & Submit

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



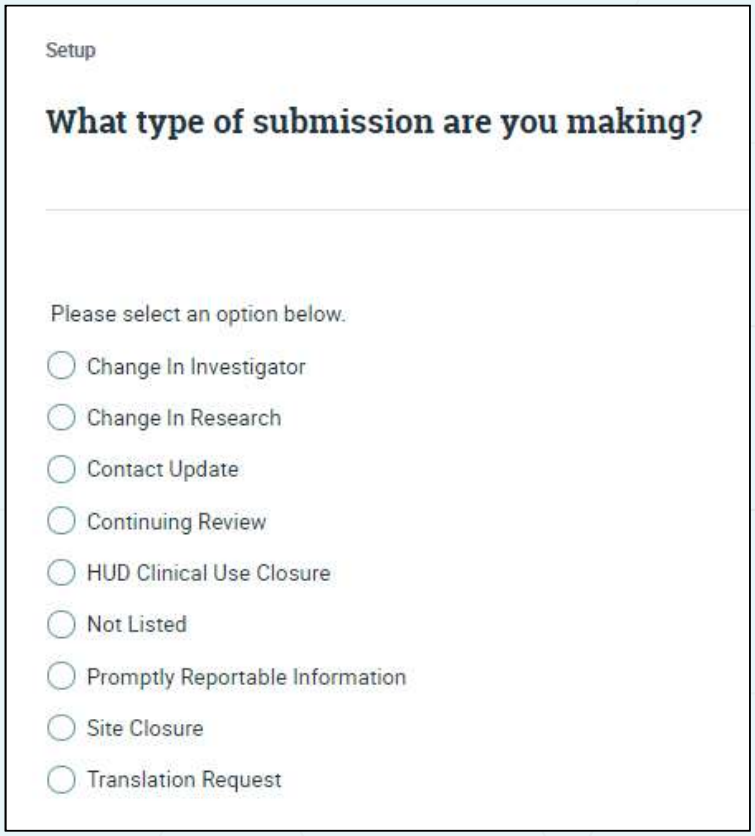
Make a Submission: Subsequent Submissions (Amendments, Promptly Reportable Info)

For adding documents to/submitting for an existing approved PI or study with WCG IRB, select the option below:



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



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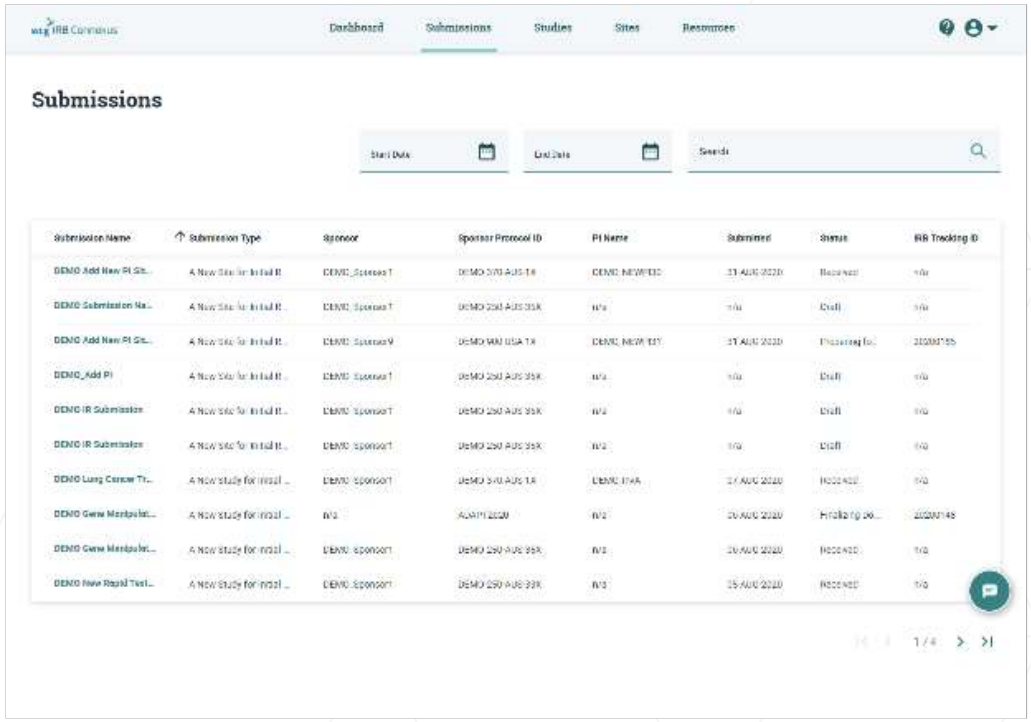
Navigating Workspaces

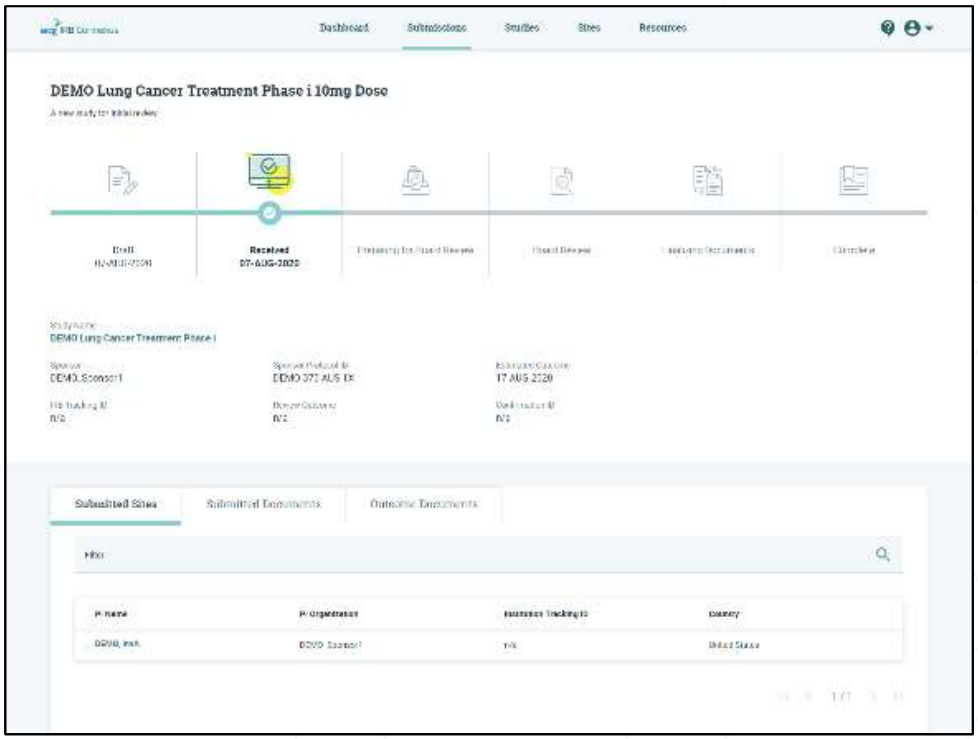
WCG IRB Connexus Submissions Landing Page

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



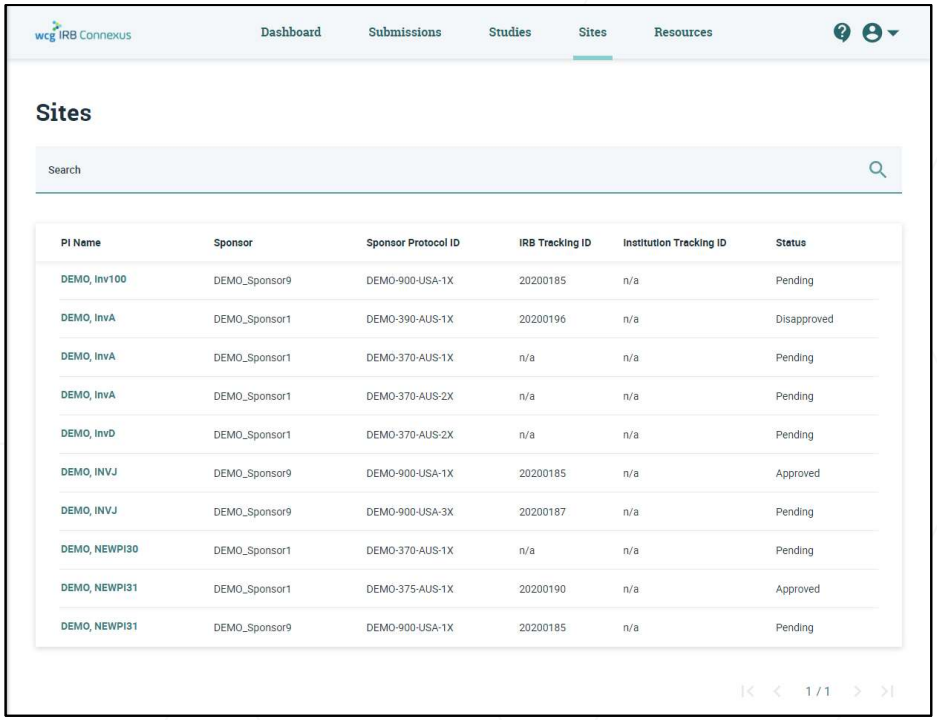
Submission Details

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



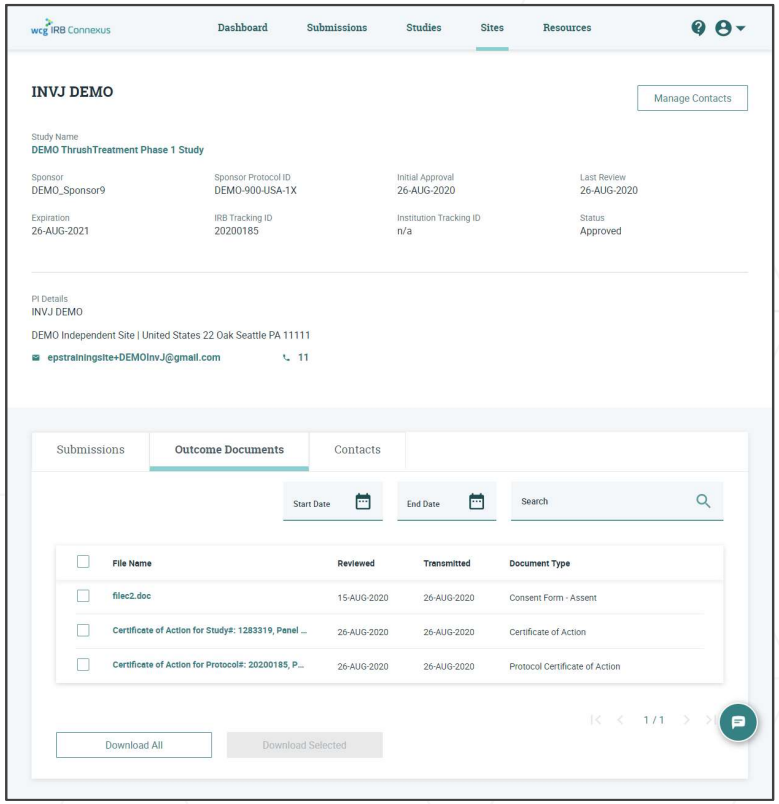
WCG IRB Connexus Sites (PIs) Landing Page

- Displays all **Sites** you have access to
- Click the PI Name for more details
- Contains:
  - Search function
  - Table displaying all site information, including the status of where particular documents are in IRB review



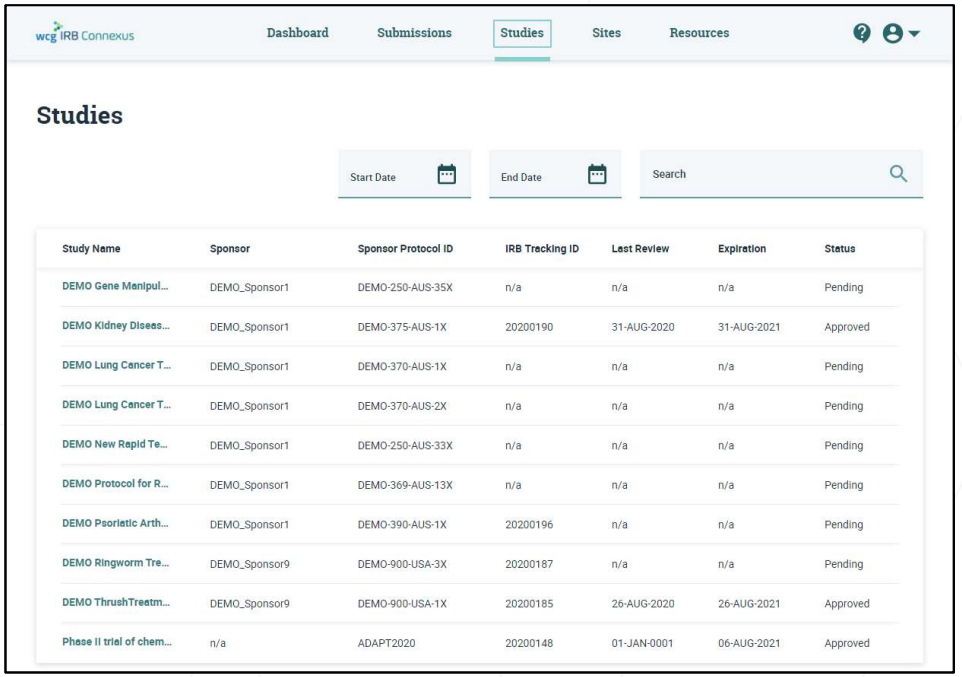
Site (PI) Details

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



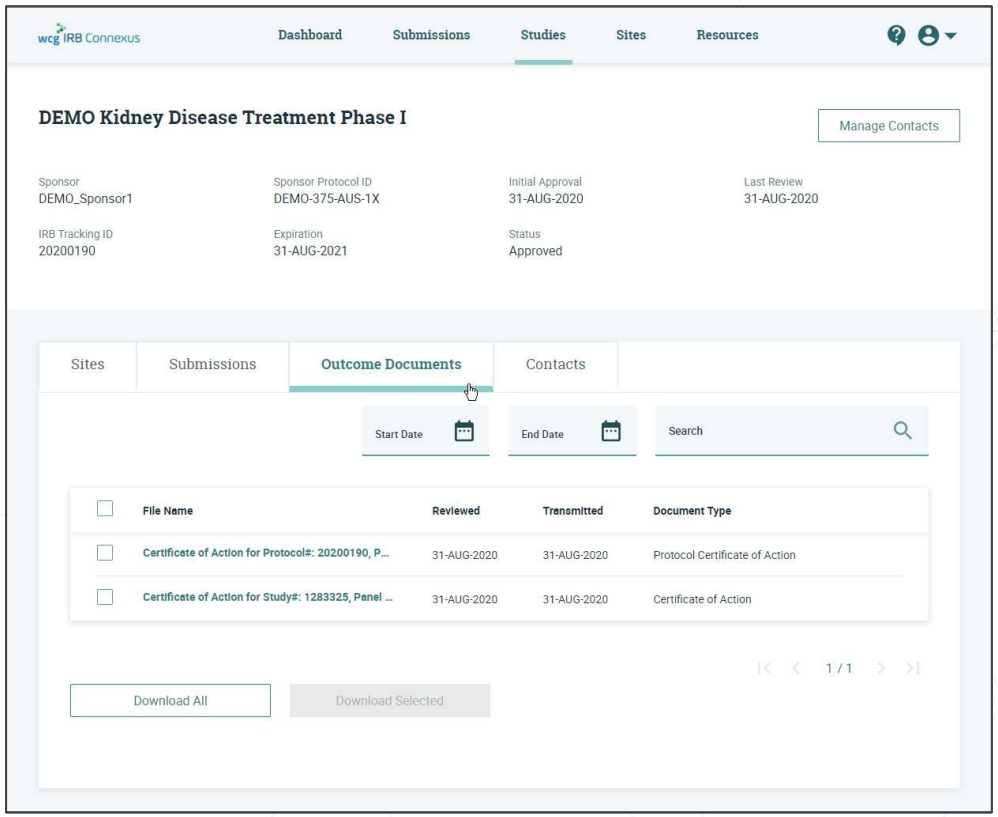
WCG IRB Connexus Studies Landing Page

- Displays all **Studies** you have access to
- Click the Study Name for more details
- Contains:
  - Search function
  - Date filters
  - Table displaying study information, including the status of where particular documents are in IRB review



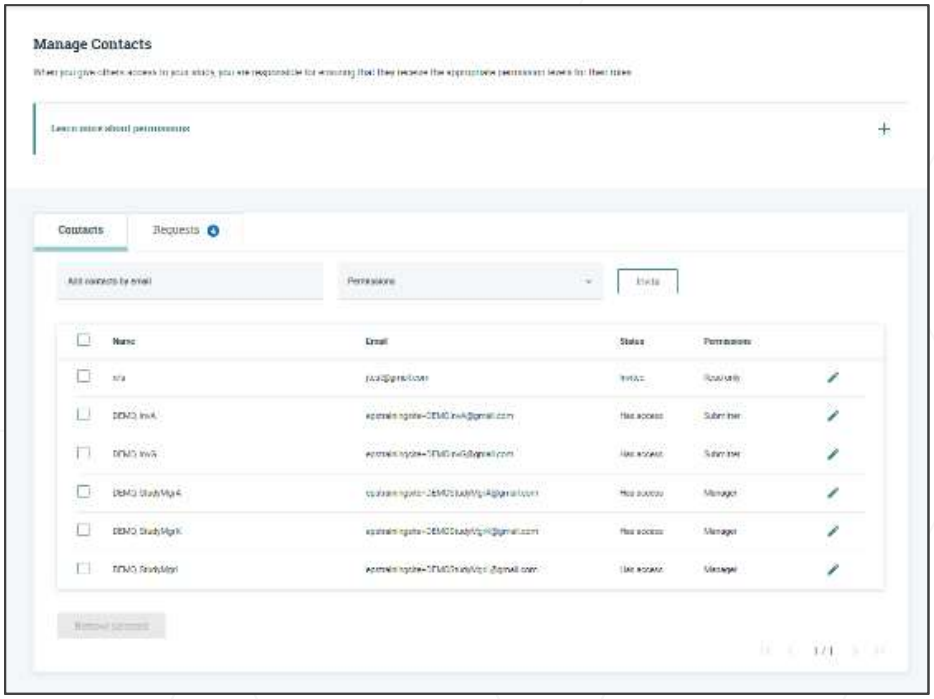
Study Details

- Displays in-depth study information
- Also displays (if applicable):
  - Associated Sites
  - Submissions for this study
  - Outcome Documents
  - Contacts
  - Manage Contacts



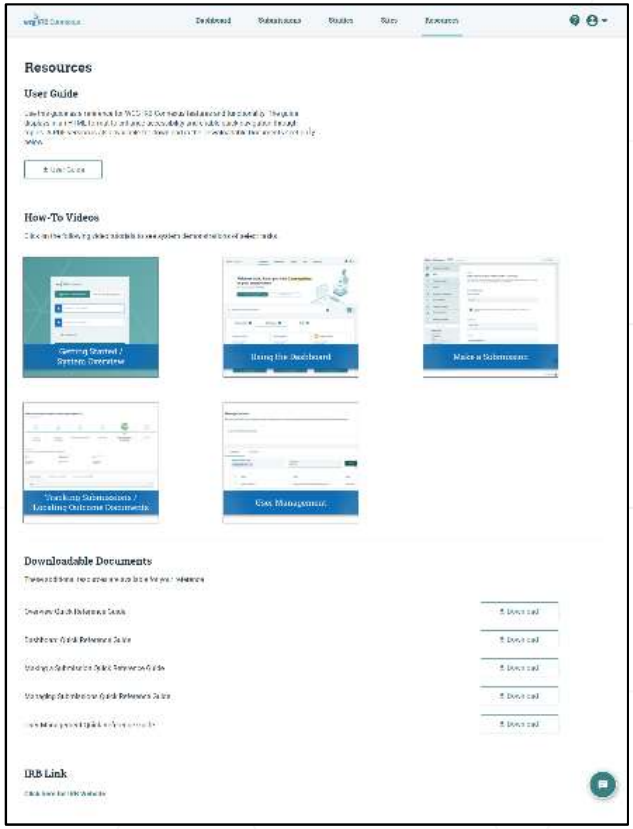
Manage Contacts

- 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



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Additional Items to Note

Additional Information

On July 12, 2021, legacy MyConnexus was disabled.

- With this in mind, there are a few considerations:
  - Legacy MyConnexus draft submissions will not be available in WCG IRB Connexus
  - 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 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

Additional Information

- **Study-level access is not needed nor should be requested for submitting as a new site on an existing, industry-sponsored protocol**
- You would only have study-level access if you are managing a new protocol and all sites
- Your approved PIs are accessible via the **Sites** option

We Are Here to Partner With You – Contact Us!

- Escalated/urgent issues:
  - **Christopher Gennai**
  - **360-252-2460**
  - **cgennai@wirb.com**

- For general questions, WCG IRB representatives may be reached at:
  - 855-818-2289
  - clientservices@wcgirb.com

Thank You

WCG IRB
info@wcgirb.com
855.818.2289

www.wcgirb.com