



**Office of Clinical Research
Lunch & Learn**



**Introduction to the updated
WCG IRB Connexus Portal:
General Training and Q&A
Thursday, July 15th, 2021**

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.

 **Health.**

03-20 IRB #2020-0249

 **Health.**
Lindner Center of HOPE



 **Health**™



**Office of Clinical Research
First Friday**

Friday, August 6th, 2021

High Enroll Recruitment services

Ginger Conway MSN, CNP

COO High Enroll, LLC

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**

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**Introduction to
WCG IRB Connexus™
for University of Cincinnati**

July 15, 2021



What We Will Cover In Today's Session

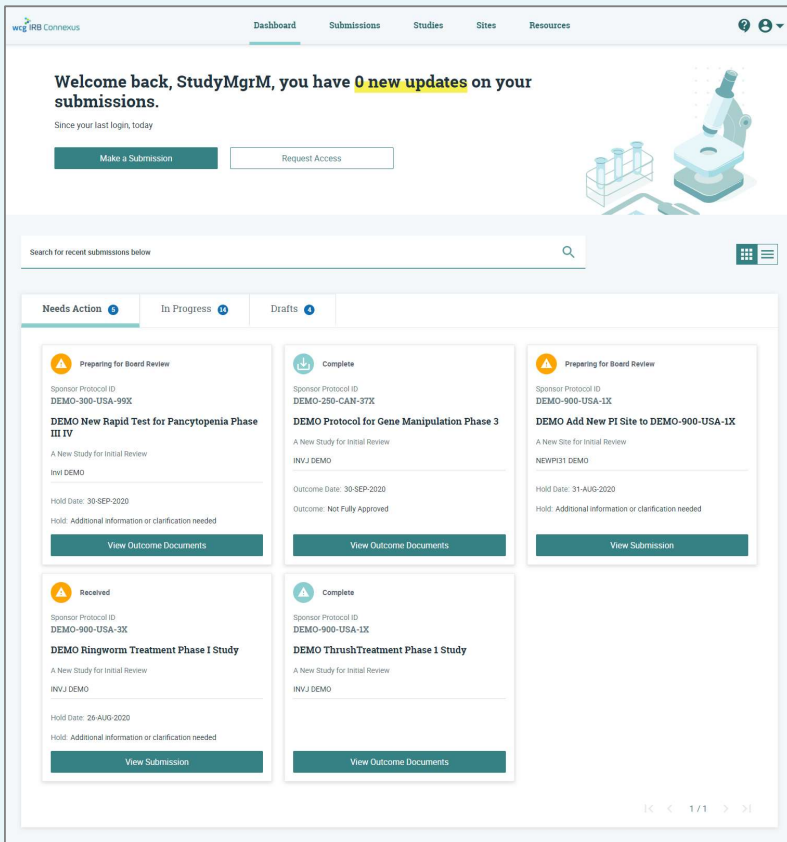
- Introduction to the New **WCG IRB Connexus**
- Highlighting What's New
- System Walkthrough
- New Submission Workflow
- System Transition "Need to Know" Information
- Resources and Support





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



System Access & Signing In

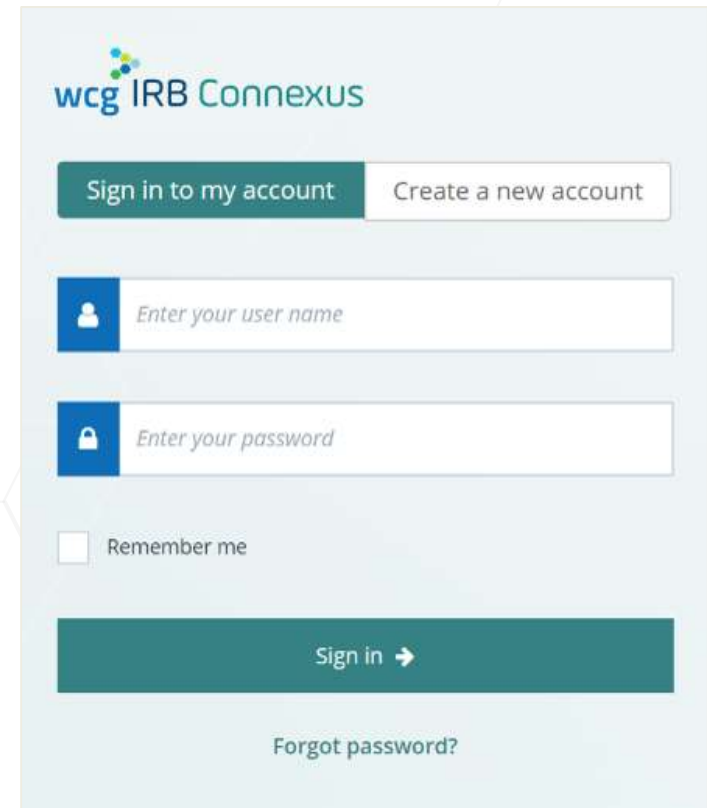
3 Ways to Access the System



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

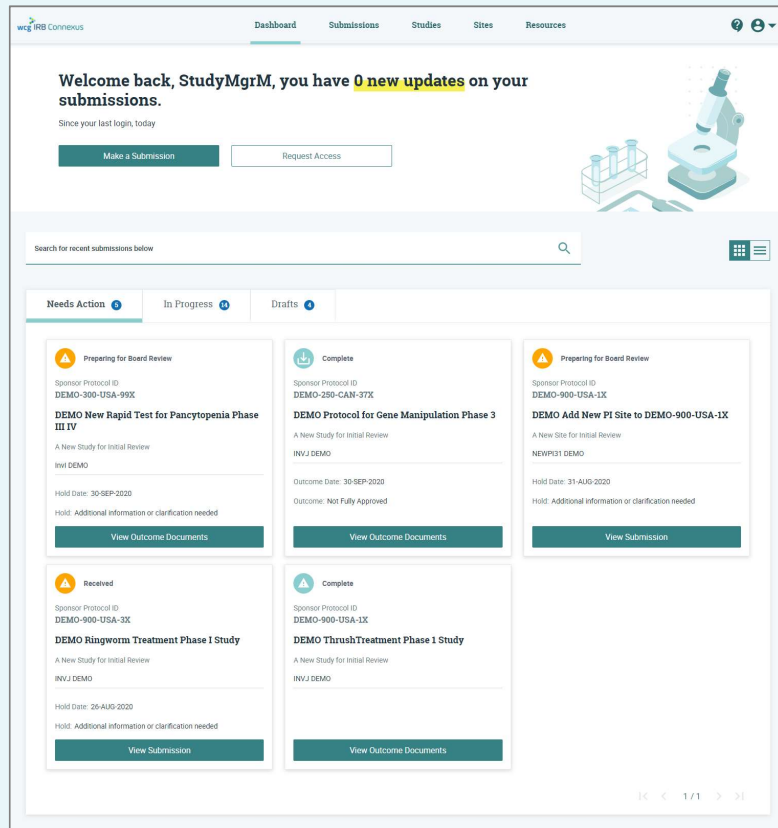


The screenshot shows the login page for wcg IRB Connexus. At the top left is the wcg IRB logo. Below it, the text "wgc IRB Connexus" is displayed. There are two buttons: "Sign in to my account" (highlighted in dark teal) and "Create a new account" (white with a dark teal border). Below these are two input fields: the first has a user icon and the placeholder text "Enter your user name"; the second has 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 with the text "Sign in" and a right-pointing arrow. Below that is a link for "Forgot password?".



Dashboard and Access Roles Overview

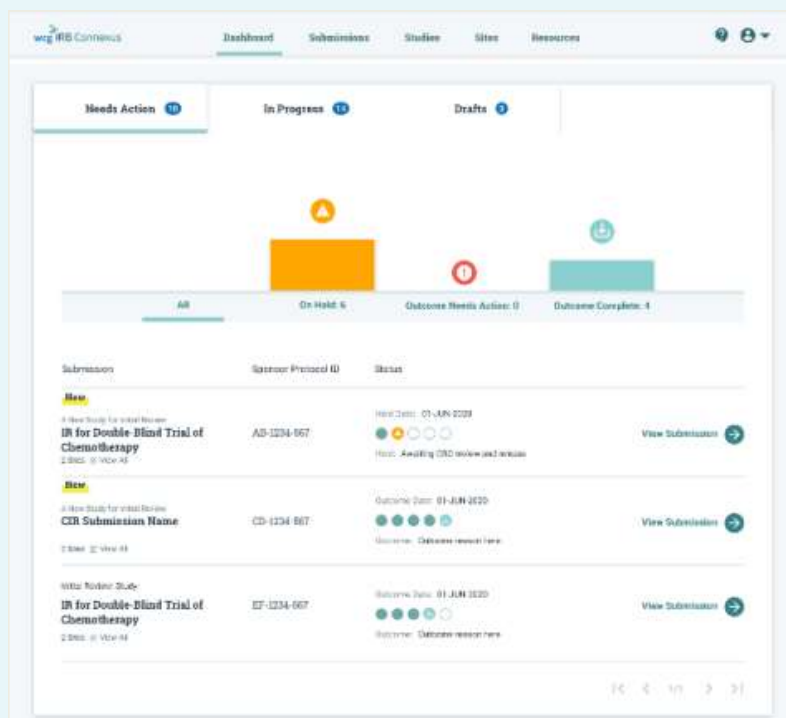
WCG IRB Connexus Dashboard



- 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

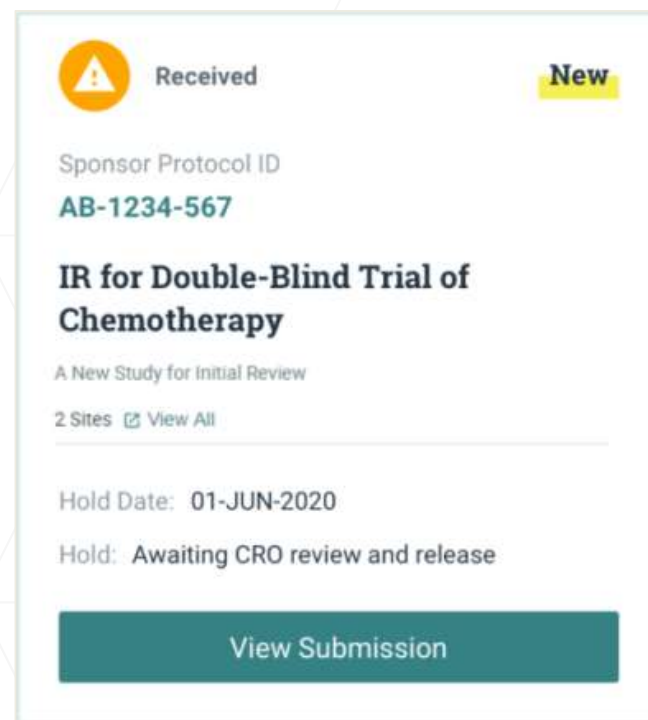
Dashboard – Card and Table Views

Two different options for easily viewing submission/study details:



The screenshot shows the WCG IRB Connect dashboard with a table view of submissions. The dashboard includes navigation tabs for Dashboard, Submissions, Studies, Sites, and Resources. A summary bar at the top shows 'Needs Action' (11), 'In Progress' (10), and 'Drafts' (9). Below this, a bar chart displays submission counts for 'All', 'On Hold: 6', 'Outcome Needs Action: 0', and 'Outcome Complete: 1'. The main table lists three submissions with columns for Submission, Sponsor Protocol ID, and Status.

Submission	Sponsor Protocol ID	Status
New A New Study for Initial Review IR for Double-Blind Trial of Chemotherapy 2 Sites View All	AB-1234-567	Hold Date: 01-JUN-2020 Hold: Awaiting CRO review and release View Submission →
New A New Study for Initial Review CR Submission Name 2 Sites View All	CD-1234-567	Outcome Date: 01-JUN-2020 Outcome: Outcome result here View Submission →
With Review Due IR for Double-Blind Trial of Chemotherapy 2 Sites View All	EF-1234-567	Outcome Date: 01-JUN-2020 Outcome: Outcome result here View Submission →



The screenshot shows a detailed card view for a submission. It features a 'Received' status with a warning icon and a 'New' badge. The card displays the Sponsor Protocol ID 'AB-1234-567', the title 'IR for Double-Blind Trial of Chemotherapy', and a subtitle 'A New Study for Initial Review'. It also shows '2 Sites' with a 'View All' link, a 'Hold Date: 01-JUN-2020', and a 'Hold: Awaiting CRO review and release' message. A prominent 'View Submission' button is located at the bottom.

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](#)

Hold Date: 01-JUN-2020

Hold: Awaiting CRO review and release

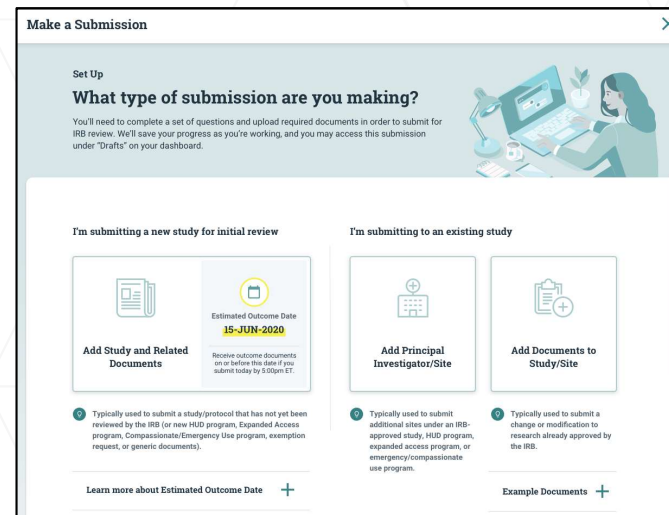
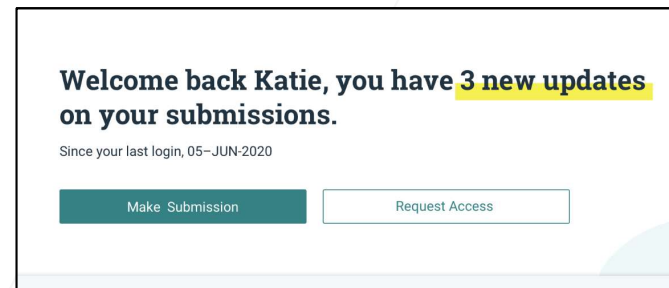
[View Submission](#)

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)

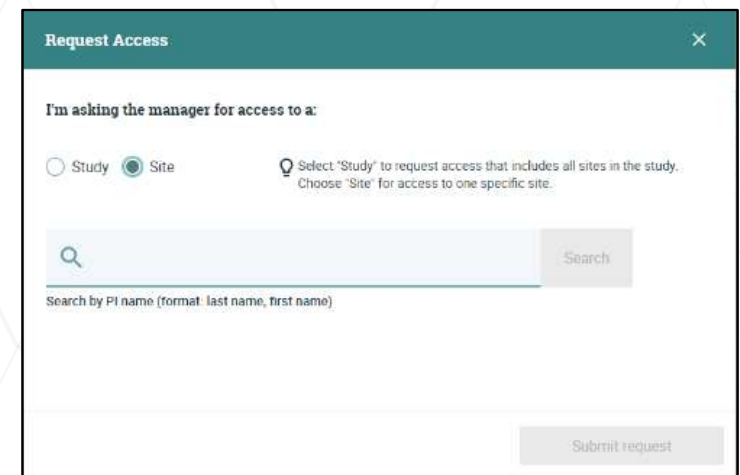
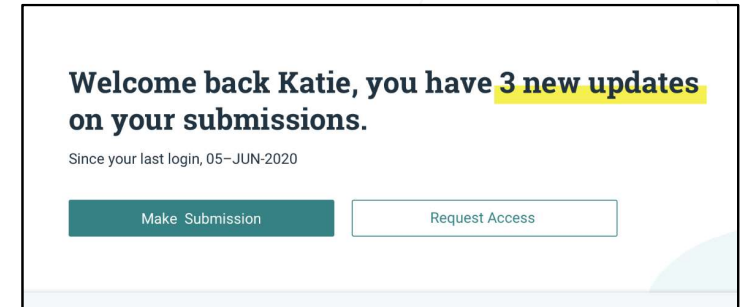


Request Access



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



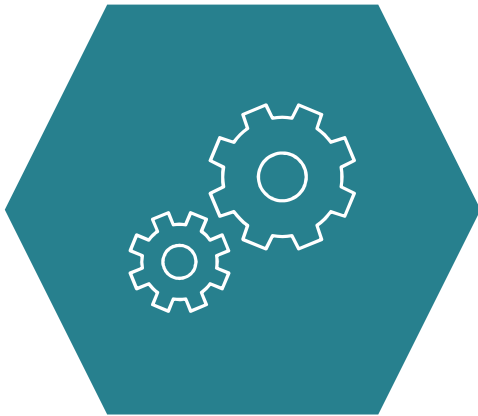
Site Roles (applicable to being a participating site on an existing protocol)



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:

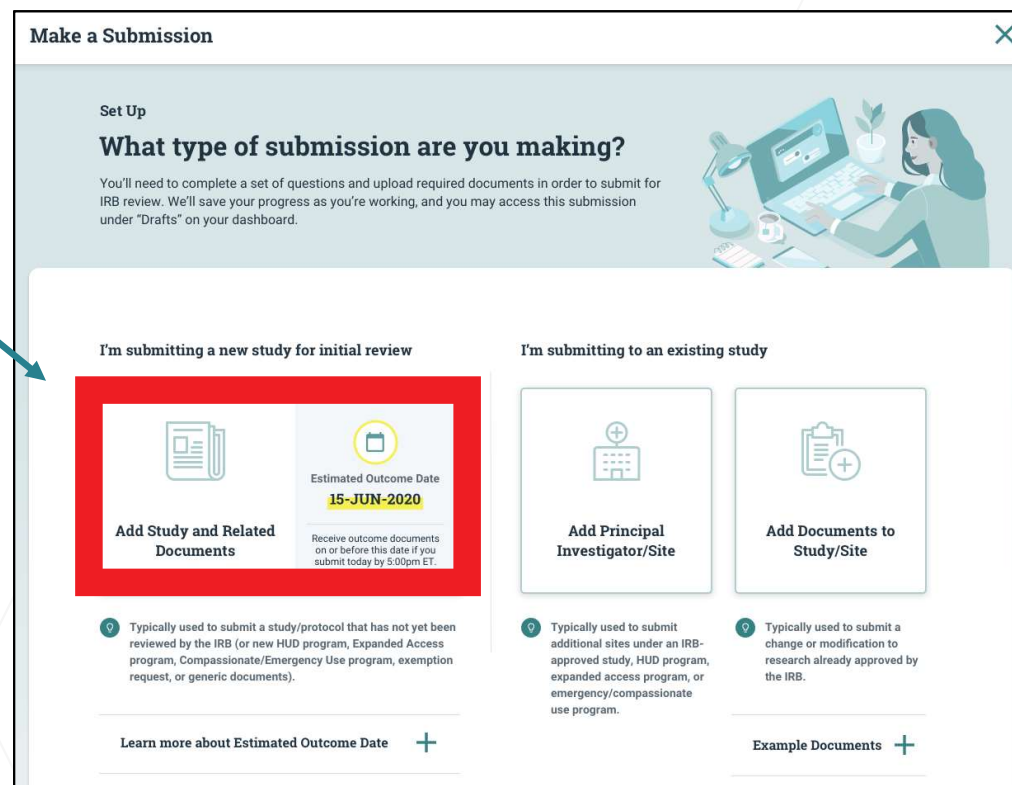
	Manager	Submitter	Read Only
View list of investigators and sites	✓	✓	✓
View investigator and site details	✓	✓	✓
Manage user access (add/edit/remove)	✓		
Make submissions	✓	✓	
View submissions	✓	✓	✓
View and download submission documents	✓	✓	✓
View and download outcome documents	✓	✓	✓
Same access level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



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

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.

I'm submitting to an existing study



Add Principal Investigator/Site



Add Documents to Study/Site

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).

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

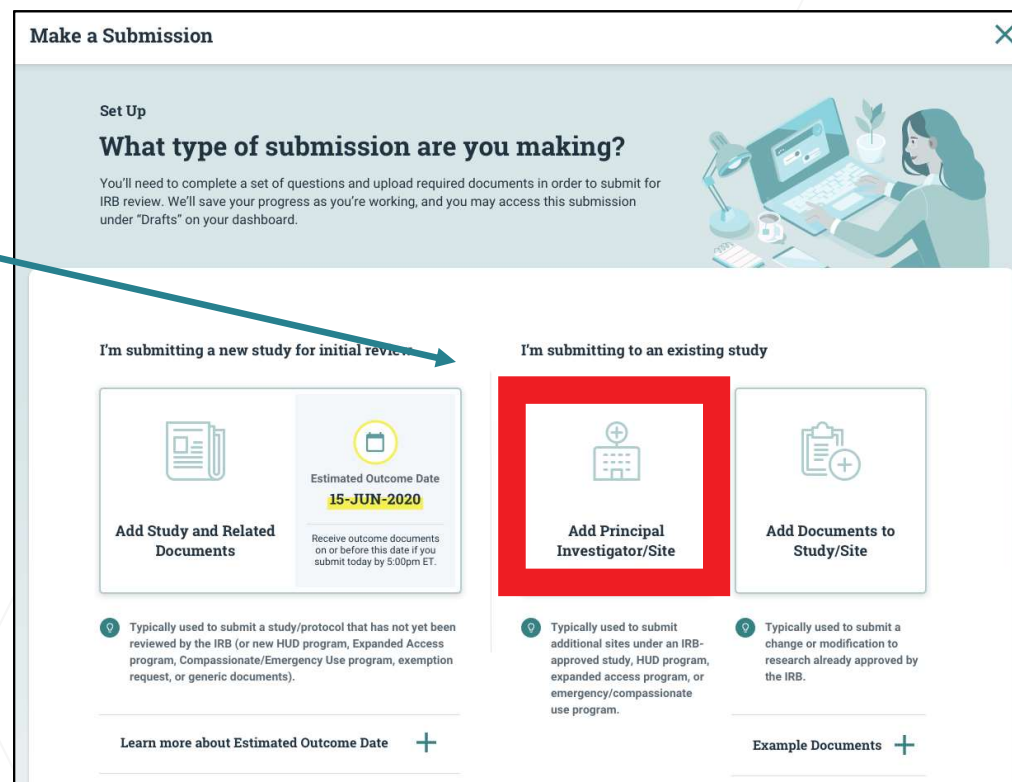
Typically used to submit a change or modification to research already approved by the IRB.

[Learn more about Estimated Outcome Date](#) +

[Example Documents](#) +

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**):



The screenshot shows a web interface for finding a study. At the top, it says "Setup" and "Find the study to which you're adding a new site or PI." Below this is a search bar with the placeholder text "Find a Study" and a magnifying glass icon. Underneath the search bar, it says "Search by Study or Sponsor Name, Sponsor Protocol ID, or IRB Tracking ID". A red callout box highlights a help icon (a question mark in a circle) and the text: "Don't have access to the study? You may still submit by specifying the study's IRB tracking ID. Enter IRB Tracking ID". A blue arrow points from the text above to the help icon in the callout box.

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:

Setup

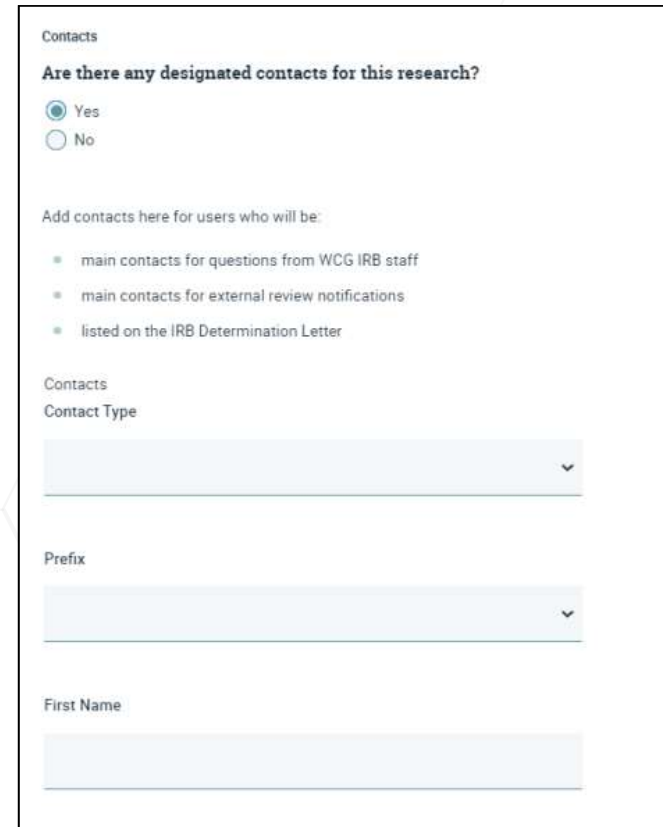
Specify the study's IRB Tracking ID

Find a Study  Search

The IRB Tracking ID must be an 8 or 9 digit number.

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



The screenshot shows a form titled "Contacts" with the following sections:

- Are there any designated contacts for this research?**
 - Yes
 - No
- Add contacts here for users who will be:**
 - main contacts for questions from WCG IRB staff
 - main contacts for external review notifications
 - listed on the IRB Determination Letter
- Contacts**
 - Contact Type**: A dropdown menu.
 - Prefix**: A dropdown menu.
 - First Name**: A text input field.

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

Research Location

Physical address where subjects will be seen or research will take place:

Locations

Location

Company/Institution/Organization

Country

Address Line 1

Address Line 2

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)
 - SOCR 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**

Institutional Services

Will you conduct this research through an organization that has a contract or Master Services Agreement (MSA) to use WCG IRB (formerly, Western IRB) for IRB Services?

- Yes
 No

Name of organization relying on WCG IRB (if known)

WCG IRB Institution # of organization relying on WCG IRB (if known)

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

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


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)

Submission Documents

Upload the files that you'll be submitting for this study.

To avoid processing delays, remove security/password protection from all submission documents

Documents What can I upload? 

Drop Files here or [click to upload](#)
Files may be up to 1 GB

Document Checklist

Submit the following documentation:

- Advertisements and recruitment scripts specific to your site
- Curriculum vitae for the PI, if not on file with the IRB

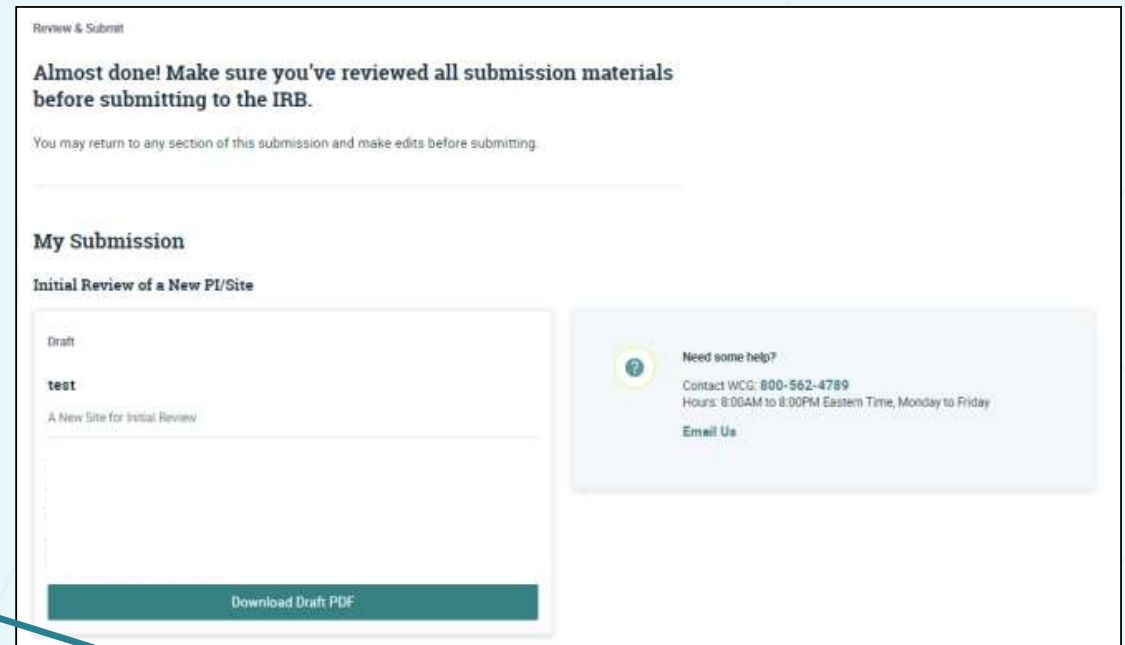
Available on the WCG IRB Website:

The following documents can be downloaded on the IRB Website and must be uploaded with your submission.

wcgirb.com

Make a Submission: Review & Submit

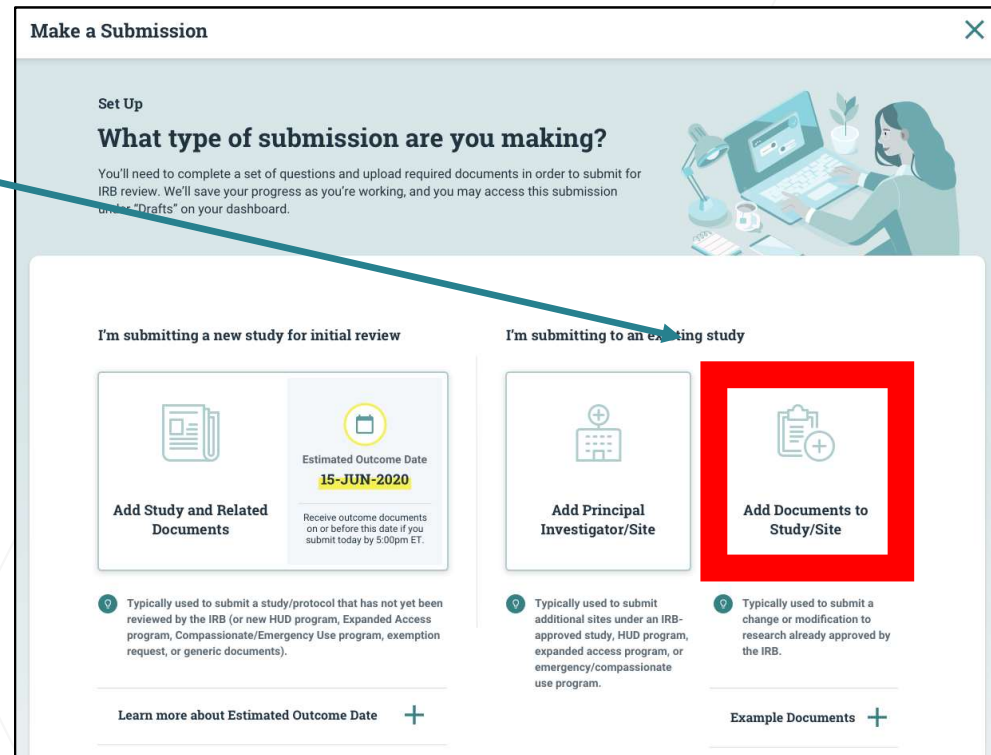
- The last step before you submit will allow you to download a PDF of your completed online form
- Click the **Submit for IRB Review** button in the bottom right-hand corner of the screen to submit for IRB Review
- A confirmation ID will appear within a few minutes and is accessible via your Submissions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



Submit for IRB Review

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

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.

I'm submitting to an existing study

- Add Documents to Study/Site**

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).

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

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

[Learn more about Estimated Outcome Date](#) +

[Example Documents](#) +

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

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



Navigating Workspaces

WCG IRB Connexus Submissions Landing Page

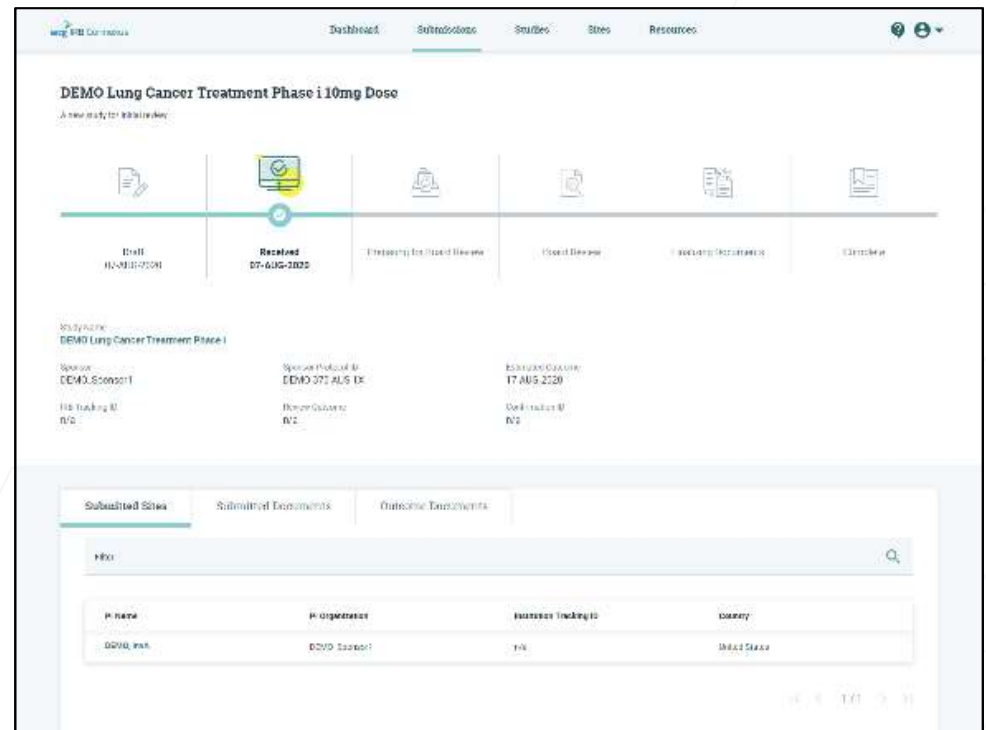


- Displays all submissions
- Click **Submission Name** to view details
- Contains:
 - Search / Quick Filters
 - Table displaying all submission entries

Submission Name	Submission Type	Sponsor	Sponsor Protocol ID	PI Name	Submitted	Status	IRB Tracking ID
DDMO Add New PI Site...	A New Site for Initial E...	DDMO_SponsorT	DDMO-070-AUG-18	DDMO_NEWPIED	31 AUG 2020	Reserved	n/a
DDMO Submission Ma...	A New Site for Initial E...	DDMO_SponsorT	DDMO-250-AUG-20K	n/a	n/a	Decl	n/a
DDMO Add New PI Site...	A New Site for Initial E...	DDMO_SponsorV	DDMO-VAM-USA-18	DDMO_NEWPIED	31 AUG 2020	Processing for...	20200755
DDMO_Add PI	A New Site for Initial E...	DDMO_SponsorT	DDMO-250-AUG-20K	n/a	n/a	Decl	n/a
DDMO IR Submission	A New Site for Initial E...	DDMO_SponsorT	DDMO-250-AUG-20K	n/a	n/a	Decl	n/a
DDMO IR Submission	A New Site for Initial E...	DDMO_SponsorT	DDMO-250-AUG-20K	n/a	n/a	Decl	n/a
DDMO Lung Cancer Tr...	A New Study for Initial ...	DDMO_SponsorT	DDMO-340-AUG-18	DDMO-ITPA	27 AUG 2020	RECEIVED	n/a
DDMO Gwaw Menopau...	A New Study for Initial ...	n/a	AAWH12020	n/a	26 AUG 2020	Processing for...	20200748
DDMO Gwaw Menopau...	A New Study for Initial ...	DDMO_SponsorT	DDMO-250-AUG-20K	n/a	26 AUG 2020	RECEIVED	n/a
DDMO New Regal Test...	A New Study for Initial ...	DDMO_SponsorT	DDMO-250-AUG-20K	n/a	25 AUG 2020	RECEIVED	n/a

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 includes a progress bar with stages: Draft (10-01-2020), Received (07-03-2021), [Pending for final Review], [Final Review], [Approval Documents], and [Complete]. Below the progress bar, there is a table with study information:

Study Name	Sponsor	Sponsor Protocol #	Estimate/Start Date
DEMO Lung Cancer Treatment Phase I	DEMO Sponsor1	DEMO 377 ALS 1X	Estimate/Start Date: 17 AUG 2020
IRB Tracking #:	IRB	Review Category:	IRB
IRB Tracking #:	IRB	IRB Tracking #:	IRB

Below the table, there are three tabs: 'Submitted Sites', 'Submitted Documents', and 'Outcome Documents'. The 'Submitted Sites' tab is active, showing a search bar and a table with columns: 'IRB Name', 'IRB Organization', 'IRB Tracking ID', and 'Country'. The table contains one entry:

IRB Name	IRB Organization	IRB Tracking ID	Country
DEMO, INC	DEMO Sponsor1	IRB	United States

WCG IRB Connexus Sites (PIs) Landing Page

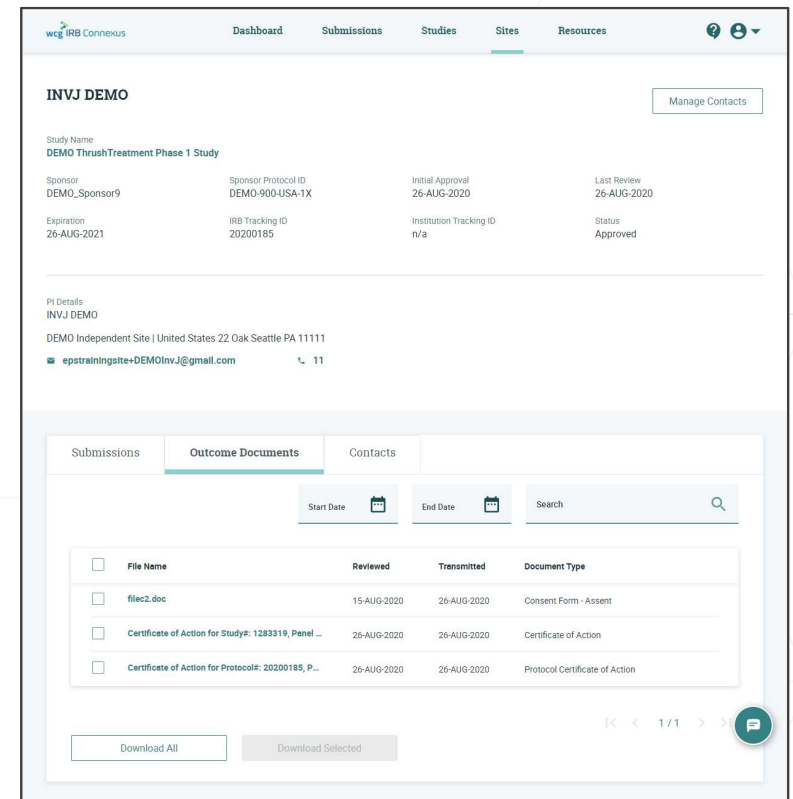


- Displays all **Sites** you have access to
- Click the PI Name for more details
- Contains:
 - Search function
 - Table displaying all site information, including the status of where particular documents are in IRB review

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 'wcg 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 ThruTreatment 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, including the address 'DEMO Independent Site | United States 22 Oak Seattle PA 11111' and email 'epstrainingste+DEMOInv.J@gmail.com'. A secondary navigation bar has 'Submissions', 'Outcome Documents', and 'Contacts'. The 'Outcome Documents' section is active, showing a table with columns for 'File Name', 'Reviewed', 'Transmitted', and 'Document Type'. The table contains three entries:

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, a pagination indicator '1 / 1', and a chat icon.

WCG IRB Connexus Studies Landing Page

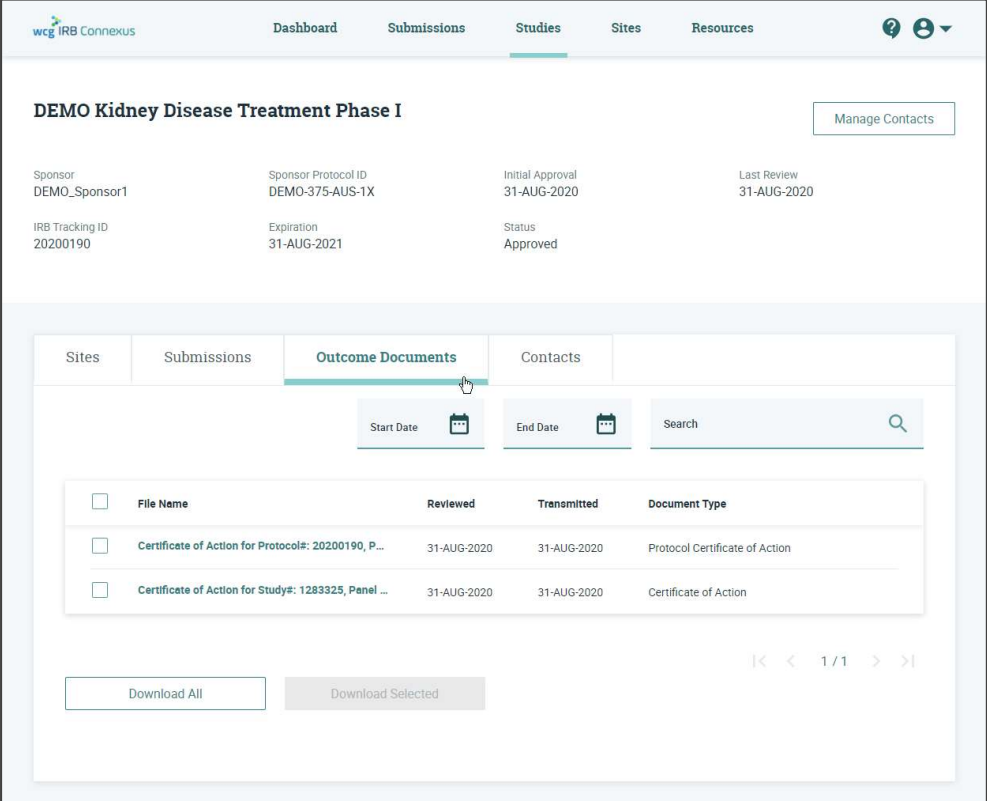


- Displays all **Studies** you have access to
- Click the Study Name for more details
- Contains:
 - Search function
 - Date filters
 - Table displaying study information, including the status of where particular documents are in IRB review

Study Name	Sponsor	Sponsor Protocol ID	IRB Tracking ID	Last Review	Expiration	Status
DEMO Gene Manipul...	DEMO_Sponsor1	DEMO-250-AUS-35X	n/a	n/a	n/a	Pending
DEMO Kidney Diseas...	DEMO_Sponsor1	DEMO-375-AUS-1X	20200190	31-AUG-2020	31-AUG-2021	Approved
DEMO Lung Cancer T...	DEMO_Sponsor1	DEMO-370-AUS-1X	n/a	n/a	n/a	Pending
DEMO Lung Cancer T...	DEMO_Sponsor1	DEMO-370-AUS-2X	n/a	n/a	n/a	Pending
DEMO New Rapid Te...	DEMO_Sponsor1	DEMO-250-AUS-33X	n/a	n/a	n/a	Pending
DEMO Protocol for R...	DEMO_Sponsor1	DEMO-369-AUS-13X	n/a	n/a	n/a	Pending
DEMO Psoriatic Arth...	DEMO_Sponsor1	DEMO-390-AUS-1X	20200196	n/a	n/a	Pending
DEMO Ringworm Tre...	DEMO_Sponsor9	DEMO-900-USA-3X	20200187	n/a	n/a	Pending
DEMO Thrush Treatm...	DEMO_Sponsor9	DEMO-900-USA-1X	20200185	26-AUG-2020	26-AUG-2021	Approved
Phase II trial of chem...	n/a	ADAPT2020	20200148	01-JAN-0001	06-AUG-2021	Approved

Study Details

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



The screenshot displays the 'wgc IRB Connexus' interface. The top navigation bar includes 'Dashboard', 'Submissions', 'Studies' (selected), 'Sites', and 'Resources'. The main content area is titled 'DEMO Kidney Disease Treatment Phase I' and includes a 'Manage Contacts' button. Below the title, key study information is presented in a grid:

Sponsor DEMO_Sponsor1	Sponsor Protocol ID DEMO-375-AUS-1X	Initial Approval 31-AUG-2020	Last Review 31-AUG-2020
IRB Tracking ID 20200190	Expiration 31-AUG-2021	Status Approved	

Below this information, there are tabs for 'Sites', 'Submissions', 'Outcome Documents' (selected), and 'Contacts'. The 'Outcome Documents' tab shows a table with columns for 'File Name', 'Reviewed', 'Transmitted', and 'Document Type'. The table contains two entries:

<input type="checkbox"/>	File Name	Reviewed	Transmitted	Document Type
<input type="checkbox"/>	Certificate of Action for Protocol#: 20200190, P...	31-AUG-2020	31-AUG-2020	Protocol Certificate of Action
<input type="checkbox"/>	Certificate of Action for Study#: 1283325, Panel ...	31-AUG-2020	31-AUG-2020	Certificate of Action

At the bottom of the 'Outcome Documents' section, 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

When you give others access to your study, you are responsible for ensuring that they receive the appropriate permissions based on their role.

[Learn more about permissions](#)

Contacts Requests

All contacts by email Permissions Filter

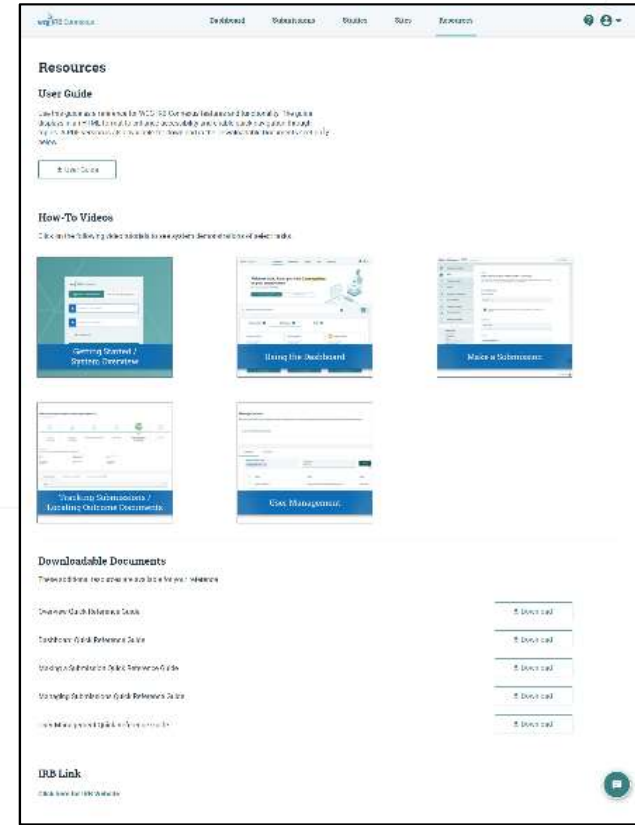
<input type="checkbox"/>	Name	Email	Status	Permissions	
<input type="checkbox"/>	ira	ira@gnk.com	Invited	Submitter	
<input type="checkbox"/>	DEMO InvA	admin@gnk-DEMO InvA@gmail.com	Has access	Submitter	
<input type="checkbox"/>	DEMO InvB	admin@gnk-DEMO InvB@gmail.com	Has access	Submitter	
<input type="checkbox"/>	DEMO StudyMgA	admin@gnk-DEMO StudyMgA@gmail.com	Has access	Manager	
<input type="checkbox"/>	DEMO StudyMgB	admin@gnk-DEMO StudyMgB@gmail.com	Has access	Manager	
<input type="checkbox"/>	DEMO StudyMgC	admin@gnk-DEMO StudyMgC@gmail.com	Has access	Manager	

0 items selected

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

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

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