



**Introduction to
WCG IRB Connexus™
for University of North
Carolina Chapel Hill**

July 21st, 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

The screenshot displays the WCG IRB Connexus dashboard. At the top, there is a navigation bar with links for Dashboard, Submissions, Studies, Sites, and Resources. A welcome message reads: "Welcome back, StudyMgrM, you have 0 new updates on your submissions." Below this, there are buttons for "Make a Submission" and "Request Access". A search bar is located below the navigation. The main content area is divided into three tabs: "Needs Action", "In Progress", and "Drafts". The "Needs Action" tab is active, showing a grid of submission cards. Each card includes a status icon (e.g., a yellow triangle for "Preparing for Board Review", a green checkmark for "Complete", and a yellow triangle for "Received"), the Sponsor Protocol ID, the study title, and the hold date. Buttons for "View Outcome Documents" and "View Submission" are provided for each card. The bottom of the dashboard features a pagination control showing "1 / 1".

- 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

2 Ways to Access the System



Direct Link: <https://connexus.wcgirb.com>

Via the WCG IRB Website: <http://www.wcgirb.com>

Click "Login to WCG IRB Connexus" link in the top navigation

To 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

A screenshot of the WCG IRB Connexus login interface. At the top left is the "wcg IRB Connexus" logo. Below it are two buttons: "Sign in to my account" (dark teal) and "Create a new account" (white with teal border). There are two input fields: the first has a blue user icon and the placeholder text "Enter your user name"; the second has a blue lock icon and the placeholder text "Enter your password". Below the password field is a "Remember me" checkbox. At the bottom is a large dark teal "Sign in →" button and a "Forgot password?" link.

wcg IRB Connexus

Sign in to my account Create a new account

Enter your user name

Enter your password

Remember me

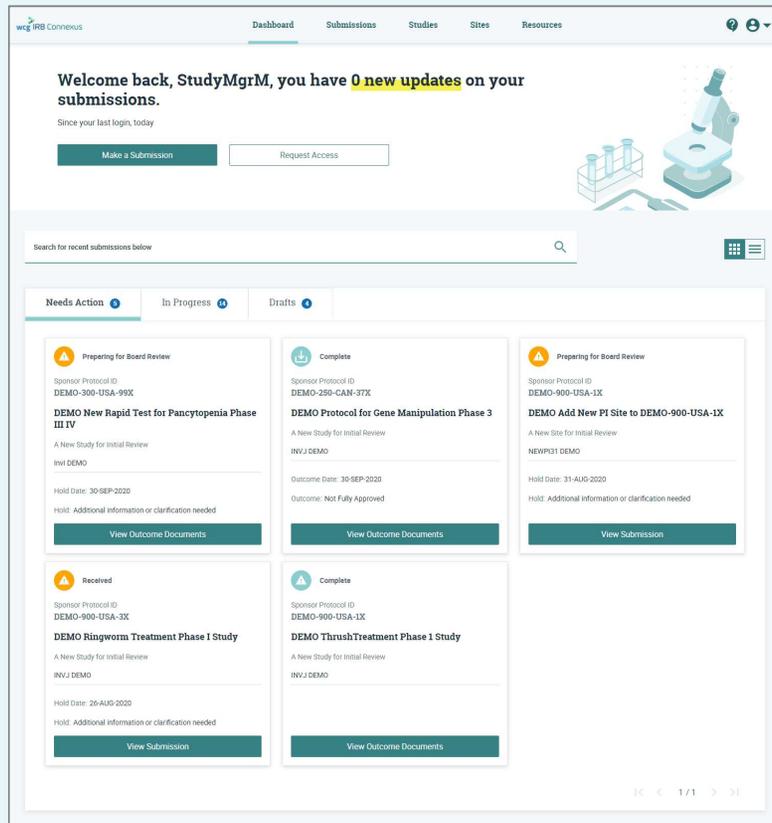
Sign in →

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. At the top, there are navigation tabs: Dashboard, Submissions, Studies, Sites, and Resources. Below the navigation, there are three status filters: Needs Action (11), In Progress (12), and Drafts (3). A bar chart below the filters shows the distribution of submissions: All (orange bar with 11), On Hold (6, red bar), Outcome Needs Action (0, teal bar), and Outcome Complete (1, teal bar). Below the bar chart is a table with columns for Submission, Sponsor Protocol ID, and Status. The table lists three submissions for the study 'IR for Double-Blind Trial of Chemotherapy'.

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 Submissions →
New A New Study for Initial Review CDR Submission Name 2 Sites View All	CD-1234-567	Outcome Date: 01-JUN-2020 Outcome: Outcome result here View Submissions →
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 Submissions →

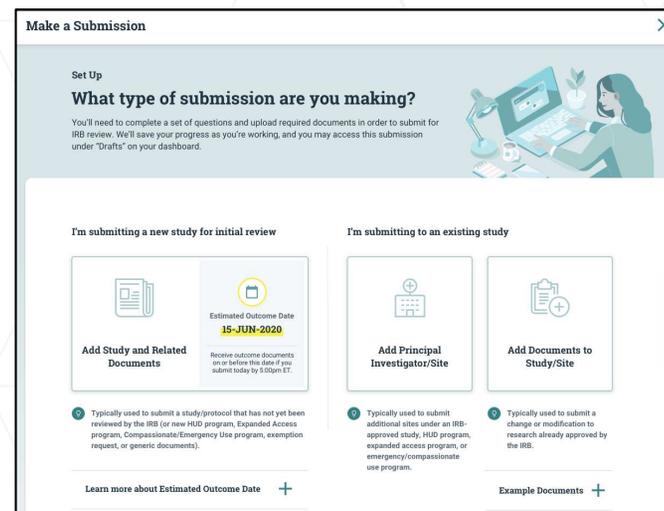
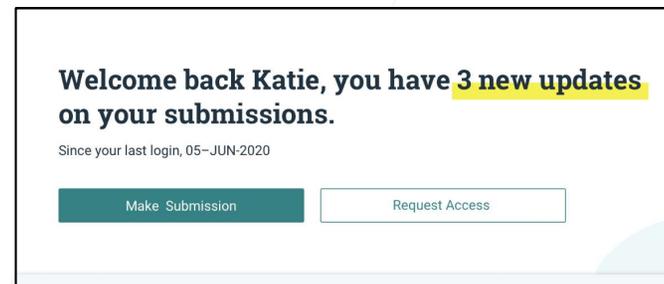
The screenshot shows a detailed card view for a submission. At the top left is an orange warning icon and the text 'Received'. At the top right is a yellow 'New' badge. Below this is the 'Sponsor Protocol ID' 'AB-1234-567'. The main title is 'IR for Double-Blind Trial of Chemotherapy', followed by the subtitle 'A New Study for Initial Review'. Below that, it says '2 Sites' and 'View All'. Further down, it lists 'Hold Date: 01-JUN-2020' and 'Hold: Awaiting CRO review and release'. At the bottom is a large teal button labeled '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)

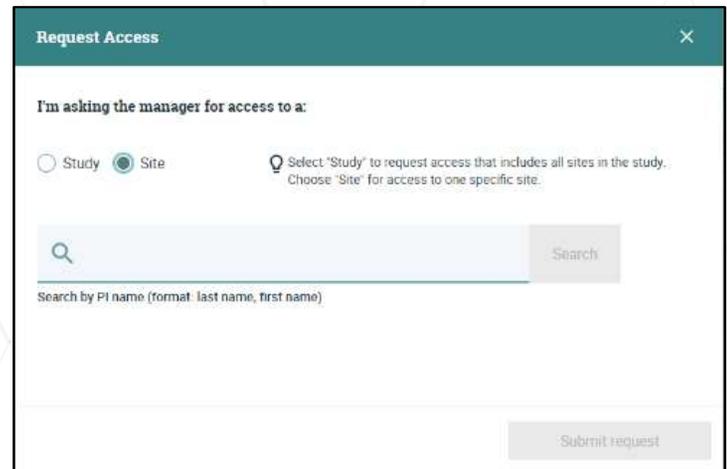
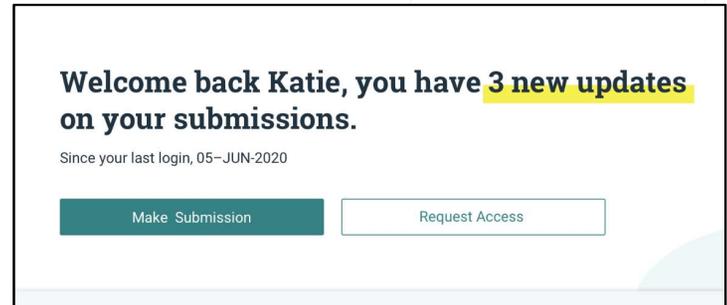


Request Access



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.

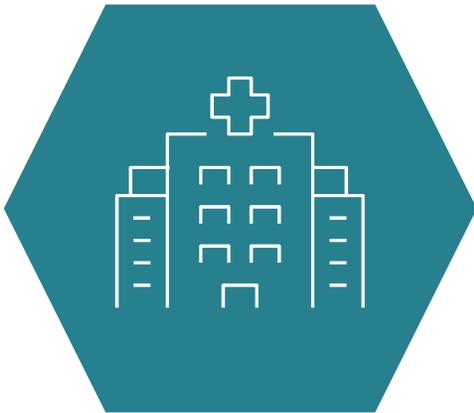
Legacy MyConnexus users will automatically have access to their same studies, sites, and submissions in WCG IRB Connexus.

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:

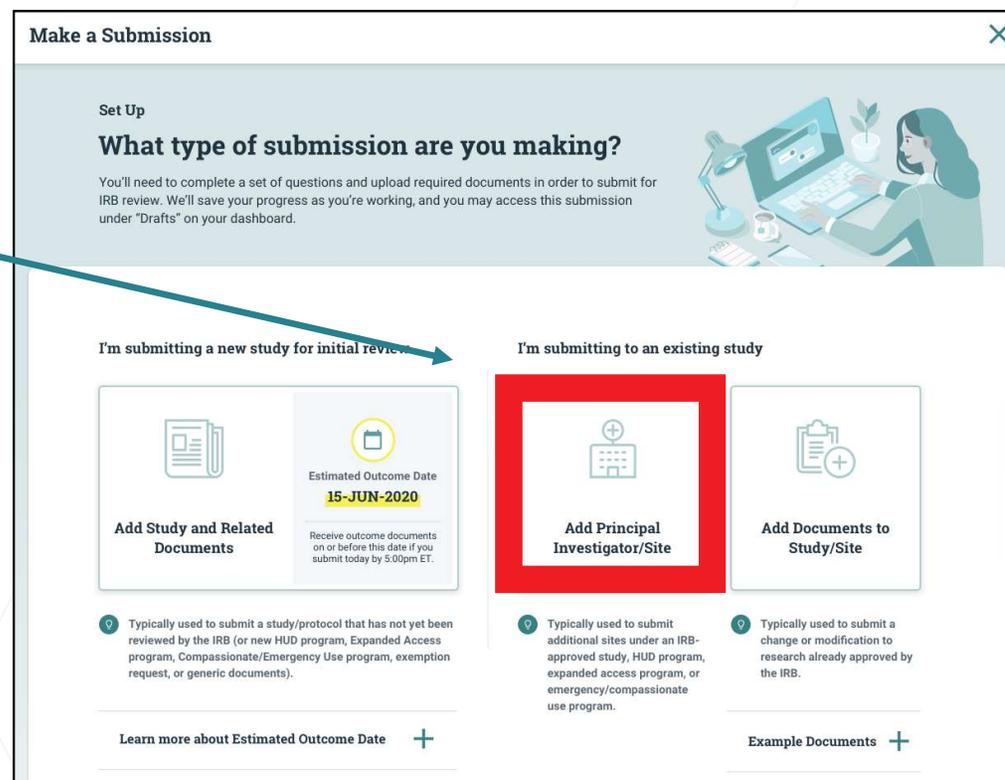
	Manager	Submitter	Read Only
Manage user access (add/edit/remove)	✓		
Make submissions	✓	✓	
View and download submission documents	✓	✓	✓
View and download outcome documents	✓	✓	✓



Submission Process

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

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**
- Add Principal Investigator/Site**

I'm submitting to an existing study

- Add Documents to Study/Site**
- Add Principal Investigator/Site**

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).

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

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

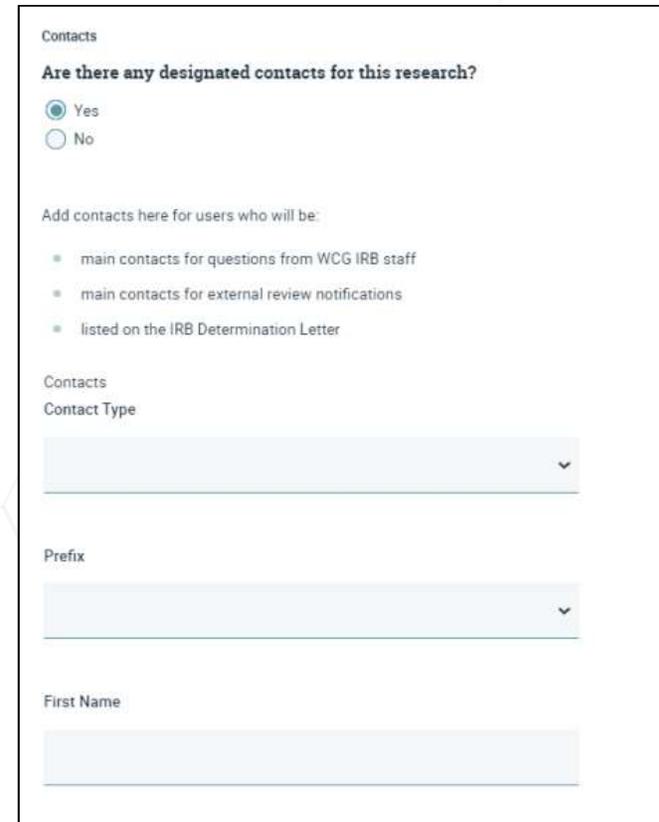
Specify the study's IRB Tracking ID

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 web form titled "Contacts". It begins with the question "Are there any designated contacts for this research?" and two radio button options: "Yes" (selected) and "No". Below this is a section titled "Add contacts here for users who will be:" followed by three bullet points: "main contacts for questions from WCG IRB staff", "main contacts for external review notifications", and "listed on the IRB Determination Letter". The form then has a sub-section titled "Contacts" with a "Contact Type" dropdown menu, a "Prefix" dropdown menu, and a "First Name" 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)
 - 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 #
- **UNC Institution #: 76615**

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

- UNC *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:** UNC submitters will be sending in a Cover Page with required language elements and a tracked ICF (4th Option of “Other”)

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 institutional sign-off

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

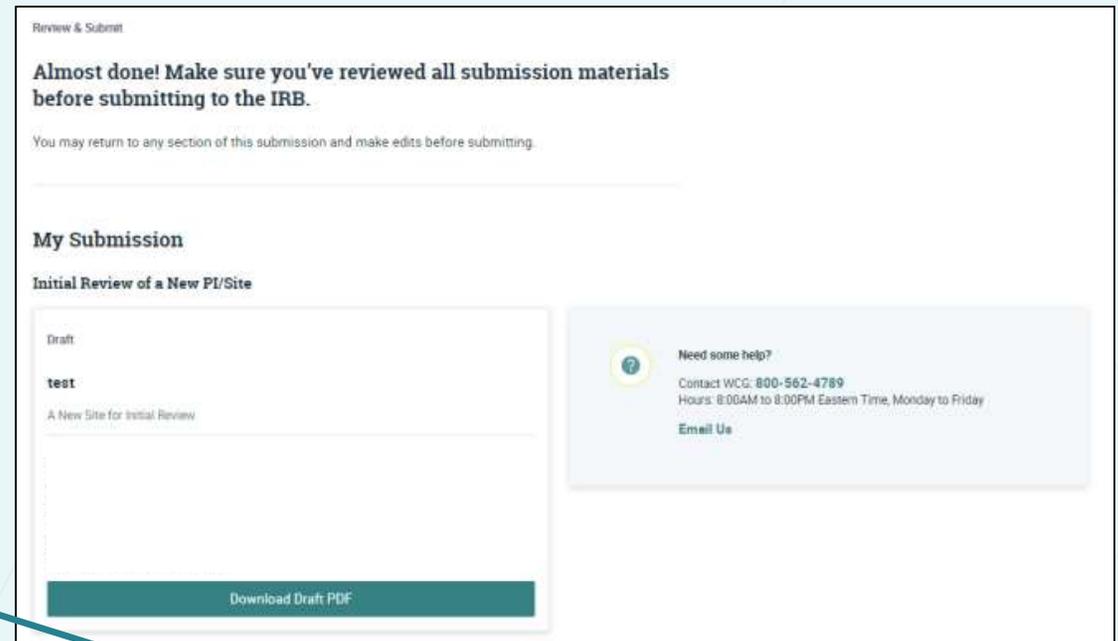
Available on the WCG IRB Website:

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

wcgirb.com

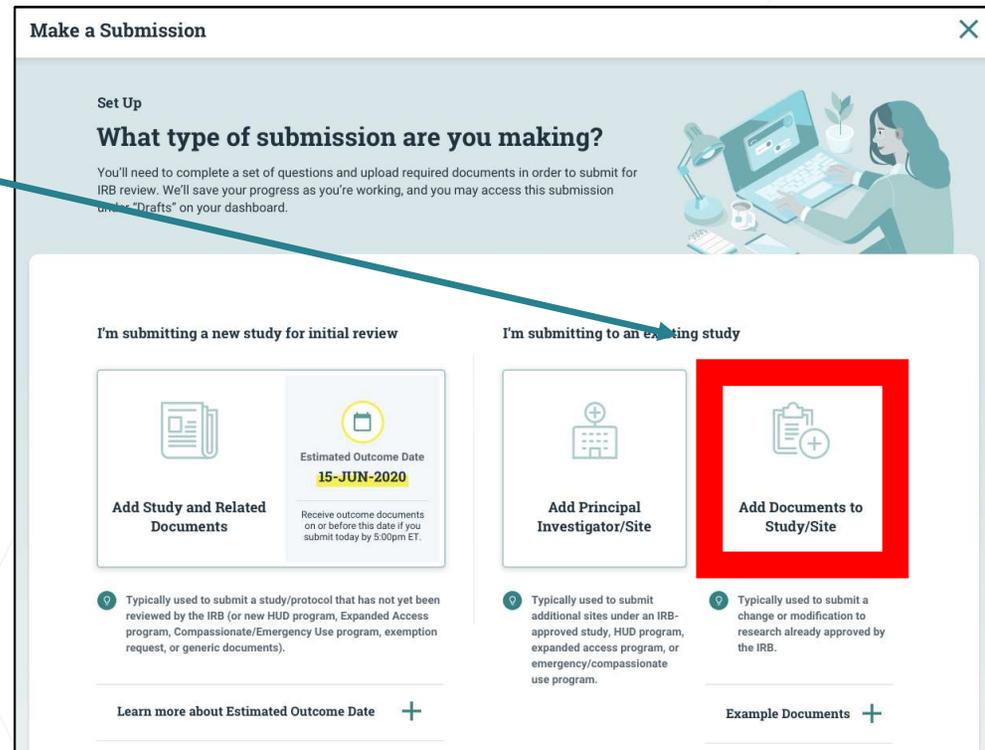
Make a Submission: Review & Submit

- 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



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

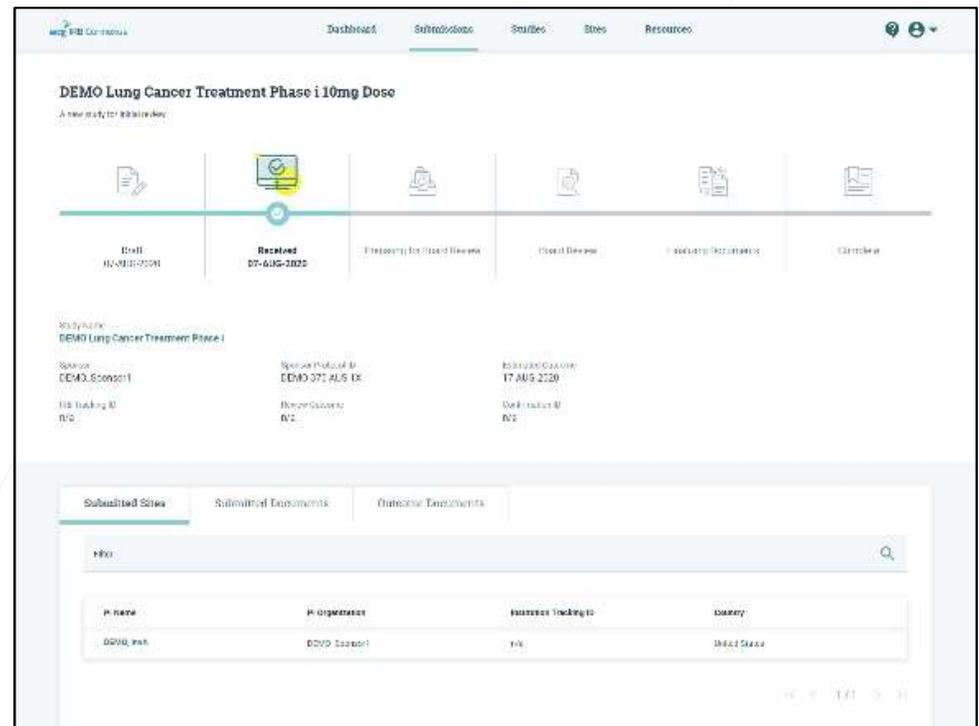


- Displays all submissions
- Click **Submission Name** to view details
- Contains:
 - Search / Quick Filters
 - Table displaying all submission entries

Submission Name	Submission Type	Sponsor	Sponsor Protocol ID	PI Name	Submitted	Status	IRB Tracking ID
DEMO Add New PI Site...	A New Site for Initial E...	DEMO_SponsorT	DEMO-070-AUG-18	DEMO_NEWPIED	31 AUG 2020	Reserved	n/a
DEMO Submission Na...	A New Site for Initial E...	DEMO_SponsorT	DEMO-250-AUG-20K	n/a	n/a	Decl	n/a
DEMO Add New PI Site...	A New Site for Initial E...	DEMO_SponsorV	DEMO-VAM-USA-18	DEMO_NEWPIED	31 AUG 2020	Processing for...	20200795
DEMO_Add PI	A New Site for Initial E...	DEMO_SponsorT	DEMO-250-AUG-20K	n/a	n/a	Decl	n/a
DEMO IR Submission	A New Site for Initial E...	DEMO_SponsorT	DEMO-250-AUG-20K	n/a	n/a	Decl	n/a
DEMO IR Submission	A New Site for Initial E...	DEMO_SponsorT	DEMO-250-AUG-20K	n/a	n/a	Decl	n/a
DEMO Lung Cancer Tr...	A New Study for Initial ...	DEMO_SponsorT	DEMO-340-AUG-18	DEMO-ITAA	27 AUG 2020	RECEIVED	n/a
DEMO Gwaw Menzoube...	A New Study for Initial ...	n/a	AWM112550	n/a	26 AUG 2020	Processing for...	20200748
DEMO Gwaw Menzoube...	A New Study for Initial ...	DEMO_SponsorT	DEMO-250-AUG-20K	n/a	26 AUG 2020	RECEIVED	n/a
DEMO New Regal Test...	A New Study for Initial ...	DEMO_SponsorT	DEMO-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 WCG IRB submission details page for a study titled "DEMO Lung Cancer Treatment Phase I 10mg Dose". The page includes a navigation bar with "Dashboard", "Submissions", "Studies", "Sites", and "Resources". A progress bar indicates the submission status: Draft (10-01-2020), Received (07-03-2021), [Pending for final Review], [Final Review], [Approval Documents], and [Complete]. Below the progress bar, key information is displayed: Study Name (DEMO Lung Cancer Treatment Phase I), Sponsor (DEMO Sponsor1), Sponsor Protocol ID (DEMO 377 ALS 1X), Estimated Start Date (17 AUG 2020), IRB Tracking ID (N/A), Review Category (N/A), and Submission ID (N/A). At the bottom, there are tabs for "Submitted Sites", "Submitted Documents", and "Outcome Documents". The "Submitted Sites" tab is active, showing a table with columns for Site Name, Organization, Institution Tracking ID, and Country. One site is listed: DEMO, INC, DEMO Sponsor1, N/A, United States.

WCG IRB Connexus Sites (PIs) Landing Page

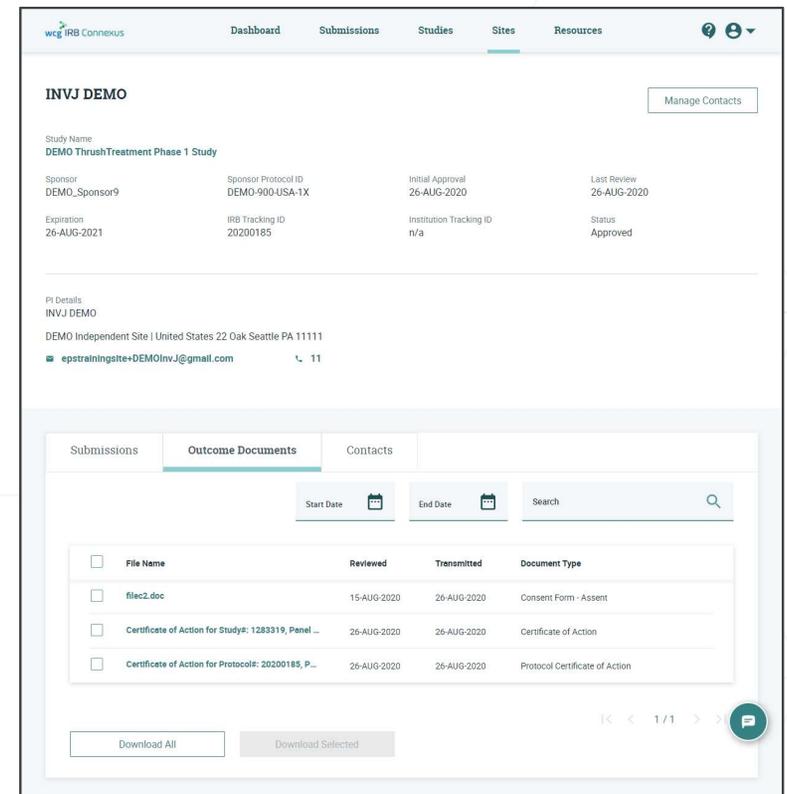


- Displays all **Sites** you have access to
- Click the PI Name for more details
- Contains:
 - Search function
 - Table displaying all site information, including the status of where particular documents are in IRB review

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



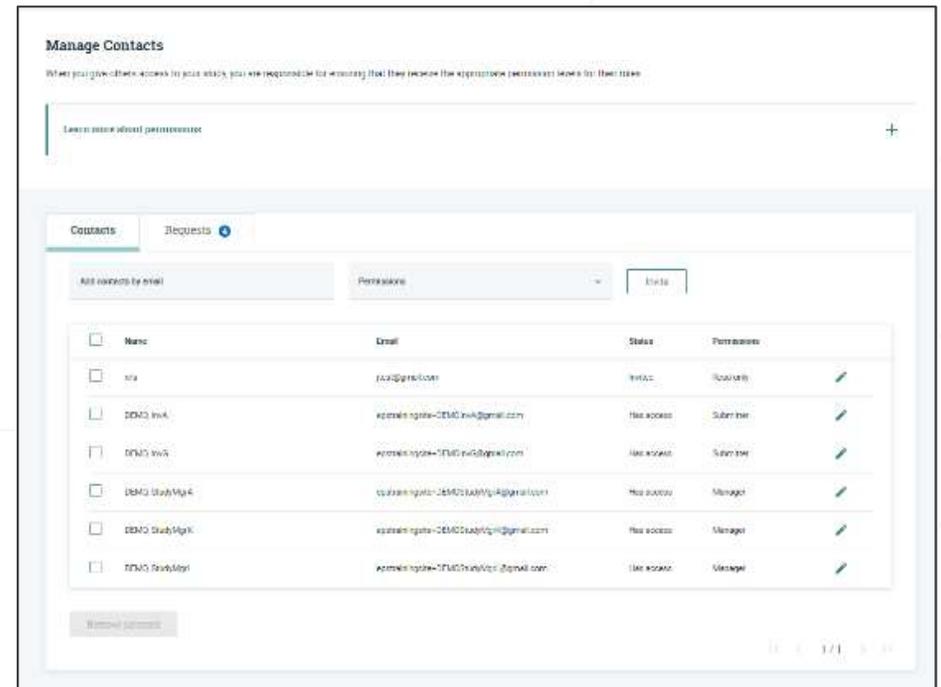
The screenshot shows the 'wgc IRB Connexus' interface. The top navigation bar includes 'Dashboard', 'Submissions', 'Studies', 'Sites', and 'Resources'. The main content area is titled 'INVJ DEMO' and includes a 'Manage Contacts' button. Below this, the 'Study Name' is 'DEMO ThruTreatment Phase 1 Study'. 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 lists three documents, all reviewed and transmitted on 26-AUG-2020. At the bottom, there are 'Download All' and 'Download Selected' buttons, a pagination indicator '1 / 1', and a chat icon.

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

Add contacts by email Permissions Filter

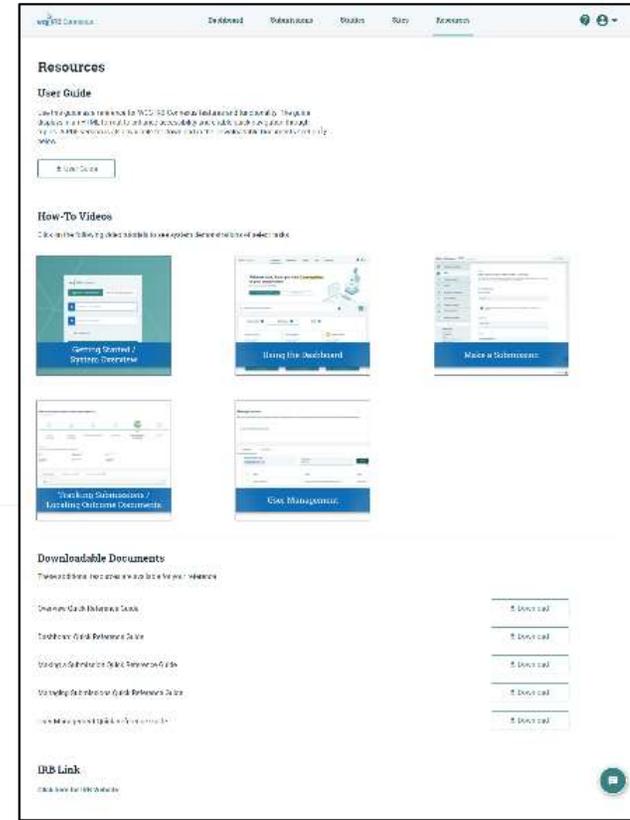
<input type="checkbox"/>	Name	Email	Status	Permissions	
<input type="checkbox"/>	ira	ira@gnk.com	Invited	Submitter	
<input type="checkbox"/>	DEMO InvA	admin@gnk-DEMO InvA@gmail.com	Has access	Submitter	
<input type="checkbox"/>	DEMO InvB	admin@gnk-DEMO InvB@gmail.com	Has access	Submitter	
<input type="checkbox"/>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

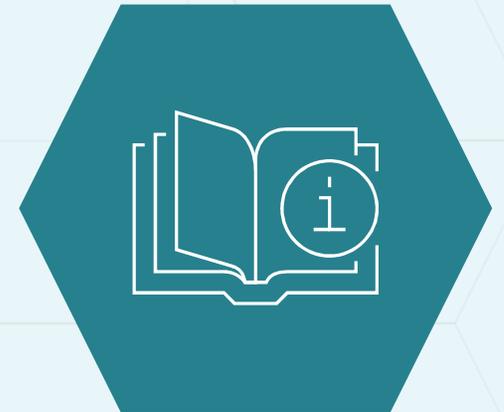




Additional Items to Note

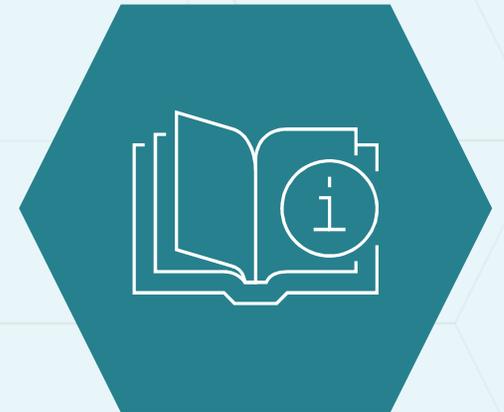
Additional Information

- 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:
 - Deena Horowitz, CIP
 - (253) 442-3137
 - dhorowitz@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

