



WCG IRB Submissions Training - UCLA

Andy Parkhurst
Institutions Partnership Manager

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What You Will Learn Today



- Connexus Access and Dashboard
- Submission Workflow
- System Navigation
- Resources and Support
- Q & A





System Access & Signing In

2 Ways to Access the System

- **Logins & Support Webpage:**
 - <https://wgcclinical.com>
 - Click Client Logins & Support
 - LOGIN to WCG IRB Connexus
- **Direct Link:**
 - <https://connexus.wgirb.com>



Signing In



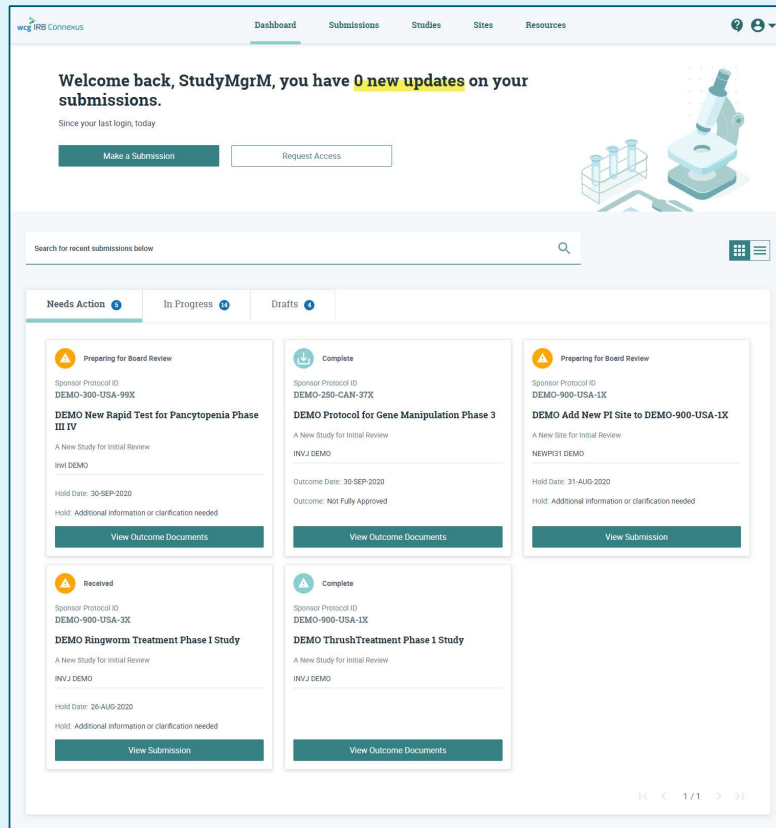
- Your username is your email address
- New Users can register using the **Create a new account** button

A screenshot of the WCG Connexus login interface. At the top left is the WCG logo and the text 'Connexus'. Below this are two buttons: 'Sign in to my account' (highlighted in dark teal) and 'Create a new account'. There are two input fields: the first is labeled 'Enter your user name' with a person icon, and the second is labeled 'Enter your password' with a lock icon. Below the password field is a checkbox labeled 'Remember me'. At the bottom of the form is a large dark teal button labeled 'Sign in' with a right-pointing arrow. Below the button is a link labeled '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** 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 vs Chart View



 **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](#)

wcg IRB Connects Dashboard Submissions Studies Sites Resources

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



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

Submission	Sponsor Protocol ID	Status	Action
New A New Study for Initial Review IR for Double-Blind Trial of Chemotherapy 2 Sites View All	AD-1234-567	Hold Date: 01-JUN-2020 Hold: Awaiting CRO review and release	View Submission
New A New Study for Initial Review CIR Submission Name 2 Sites View All	CD-1234-567	Outcome Date: 01-JUN-2020 Outcome: Outcome review here	View Submission
New A New Study for Initial Review IR for Double-Blind Trial of Chemotherapy 2 Sites View All	ED-1234-567	Outcome Date: 01-JUN-2020 Outcome: Outcome review here	View Submission

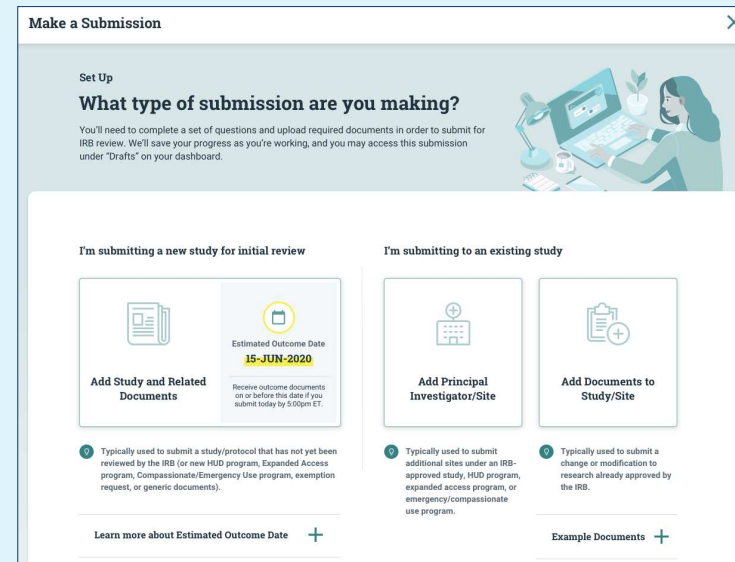
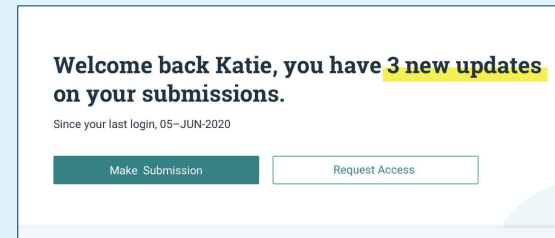
10 6 0 1

Make a Submission Options

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

Select one of the following options:

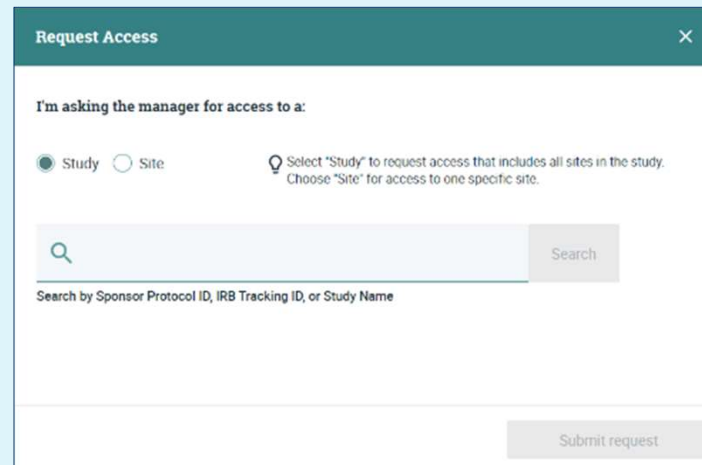
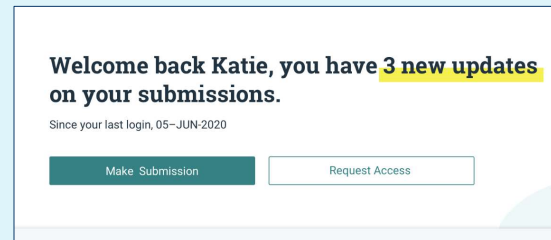
- Initial Review of a New Protocol (~2 weeks barring any holds):
- For existing studies (~1 week barring any holds):
 - Add Principal Investigator/Site (to submit a new PI for Initial Review)
 - Add Documents to Study/Site (to submit amendments to current approvals)



Request Access

When you request access to a Study and Site:

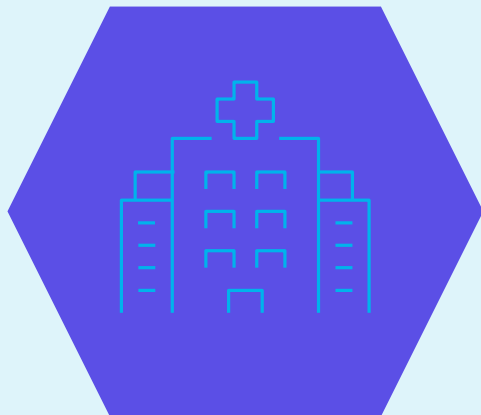
- A notice is sent to all Managers regarding the request
- You will receive an email notification when it has been accepted or rejected
- Managers are responsible for ensuring users receive the appropriate permission level for their role
- Managers may also invite users to join Studies or Sites



Site Roles Overview



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




Estimated Outcome Date
15-JUN-2020

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


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

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

I'm submitting to an existing study



Add Principal Investigator/Site



Add Documents to Study/Site

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.

[Example Documents](#) +

Make a Submission: Initial Review of New PI

To add a new site onto an existing multi-site study, ensure the submitter has the WCG IRB Tracking ID # to make the new PI submission

(study workspace access is not needed):

- Select “Enter IRB Tracking ID” on the right to submit under the study

Setup

Find the study to which you're adding a new site or PI.

Find a Study

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

Don't have access to the study? You may still submit by specifying the study's IRB tracking ID.
Enter IRB Tracking ID

Setup

Specify the study's IRB Tracking ID

Find a Study Search

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

Online Submission Form



Make a Submission DEMO Hypertension Treatment Phase IV
A New Study for Initial Review Sponsor Protocol ID: DEMO-USA-999-5X1 | Full Details AUTOSAVED X

Submission Checklist

- Setup
- Contacts
- Initial Review Questionnaire
- Recruitment Bonus Disclosure
- Submission Documents

Review & Submit

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

Contacts

In this Contacts section of the initial review submission, you will add contacts for the IRB to enter into its internal system. These contacts will be study team staff who can answer questions the IRB staff may have about the submission. These contacts will also receive notifications from this internal system, including the Continuing Review Report Forms that the system generates each year.

Submitter as contact

Should the submitter be added as a contact for this research?

Yes
 No

Sponsor contacts for this research

Sponsor contact information is not known

Sponsor Contact Information

Is this contact for all Principal Investigators under this research?

Yes
 No

Prefix

First Name

Last Name

Suffix

Initial Review Questionnaire

- Most submission documentation is 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

Site Contacts

- Be sure to add **all** contacts who need to receive day-to-day correspondence from WCG IRB (we do not need a full list of all site staff)
- You can add study coordinators and/or Sponsor/CRO contacts
- **Note:** Adding individuals to this section **does not** grant them Connexus access to the workspace. They will still need to either request access or be provided access manually by a Manager afterwards.

Contacts


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 Certificate of Action

Contacts

Contact Type 

Prefix

First Name

Research Locations

- 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

Company/Institution/Organization Line 1 ✕

Company/Institution/Organization Line 2

Country

Address Line 1

Address Line 2

Research Team Training

- Certificates of training are not required to be submitted to WCG IRB
- Only the CV and Medical License (if applicable) of the PI are needed, if not already on file with WCG IRB
 - An Updated CV will be requested if the one on file is 5 years out of date

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
 - WCG InvestigatorSpace® Training

- Yes
 No

Institutional Services

- Always mark “**Yes**” to the Institutional Services question, since your institution has an MSA with WCG IRB
- Include the name of your organization and your WCG IRB Institution #
 - **UCLA #61626**

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)

Consent Form Processing

- Your institution **does** have required consent language on file with WCG IRB; indicate **Yes** to the first question
 - Select the 3rd option below when submitting a redlined consent for review.

Consent Form Processing

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

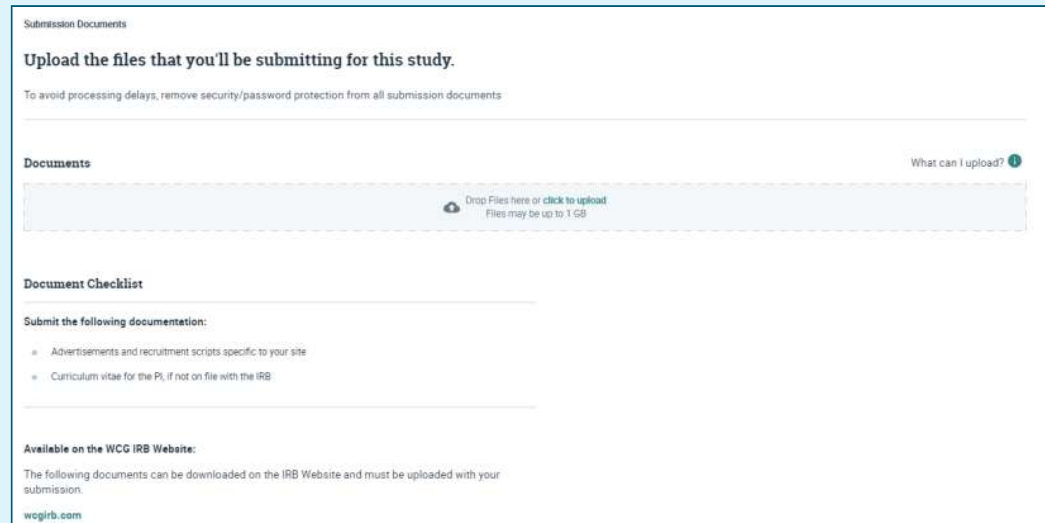
- Yes
 No

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

Uploading Additional Documents

- The end of the form will show a Document Checklist
- To upload a document, click on the link or drag and drop files into the designated area
- Avoid security or passwords on documents, as that may result in delays for your submission
- Additional smart forms that may be required can be located by navigating to the www.wcgclinical.com website and clicking the **IRB & IRC Resource Center** tab
- **NOTE:** UCLA OHRPP Sign-off cover letter is required for UCLA Initial Review Submissions to WCG IRB



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

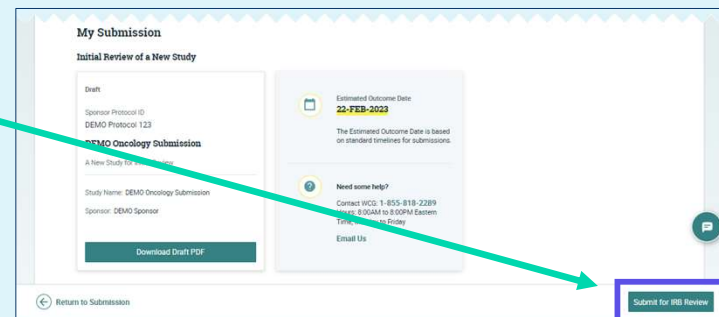
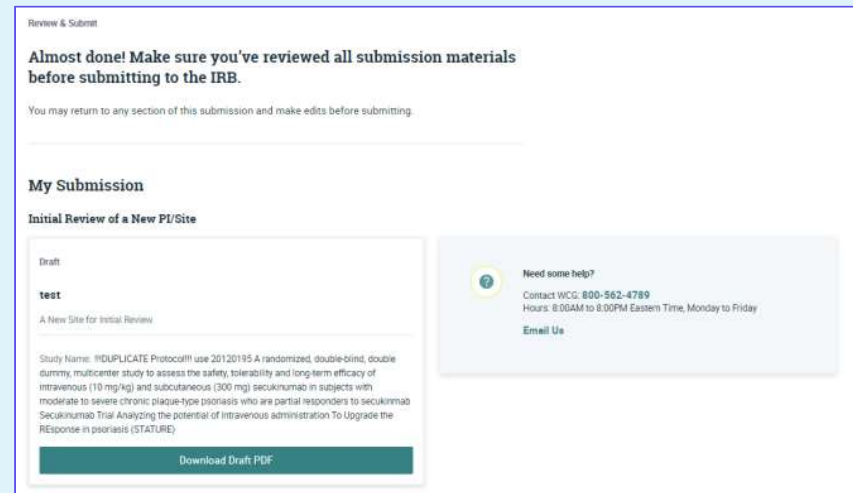
Available on the WCG IRB Website:

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

wcfgirb.com

Submit for IRB Review

- 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: Change in Research




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




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

I'm submitting to an existing study



Add Principal Investigator/Site



Add Documents to Study/Site

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.

[Example Documents](#) +

Make a Submission: Change in Research

- 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.

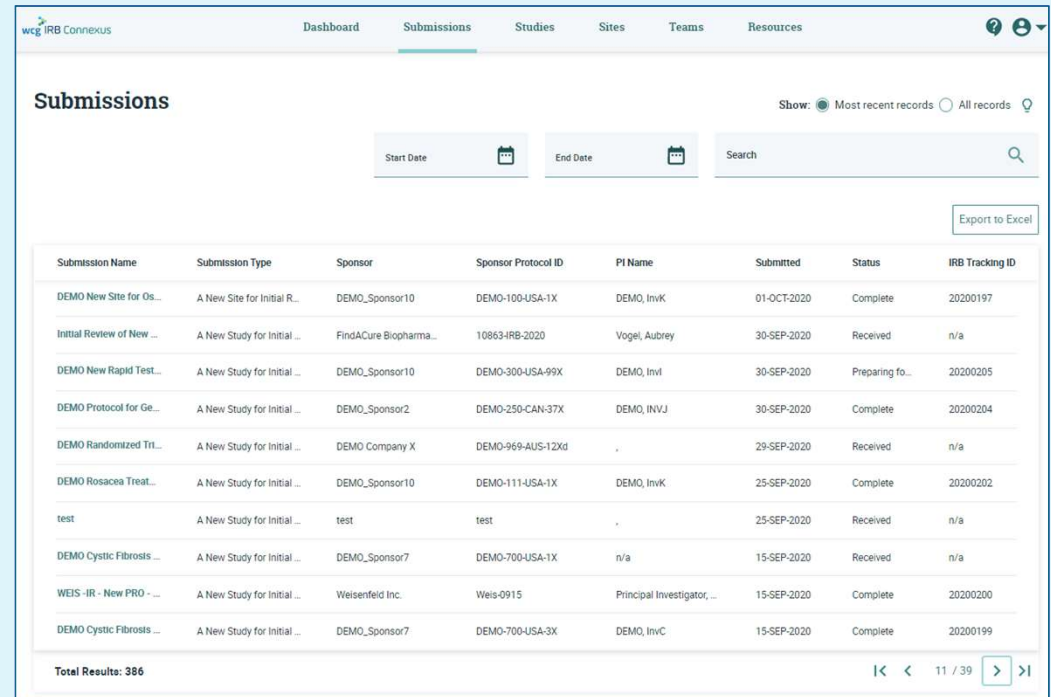
- Change In Investigator
- Change In Research
- Contact Update
- Continuing Review
- HUD Clinical Use Closure
- Promptly Reportable Information
- Site Closure
- Translation Request



Navigating Workspaces

Submissions Tab

- Displays all submissions
- Click a **Submission Name** to view details
- Contains:
 - Search / Quick Filters
 - Table displaying submission entries
 - Defaults to Most recent or select All Records



The screenshot shows the 'Submissions' tab in the IRB Connexus system. At the top, there is a navigation bar with 'Dashboard', 'Submissions', 'Studies', 'Sites', 'Teams', and 'Resources'. Below the navigation bar, the 'Submissions' section includes a 'Show:' dropdown set to 'Most recent records', a search bar, and an 'Export to Excel' button. The main content is a table with the following columns: Submission Name, Submission Type, Sponsor, Sponsor Protocol ID, PI Name, Submitted, Status, and IRB Tracking ID. The table contains 10 rows of submission data.

Submission Name	Submission Type	Sponsor	Sponsor Protocol ID	PI Name	Submitted	Status	IRB Tracking ID
DEMO New Site for Os...	A New Site for Initial R...	DEMO_Sponsor10	DEMO-100-USA-1X	DEMO, InvK	01-OCT-2020	Complete	20200197
Initial Review of New ...	A New Study for Initial ...	FindACure Biopharma...	10863-IRB-2020	Vogel, Aubrey	30-SEP-2020	Received	n/a
DEMO New Rapid Test...	A New Study for Initial ...	DEMO_Sponsor10	DEMO-300-USA-99X	DEMO, InvI	30-SEP-2020	Preparing fo...	20200205
DEMO Protocol for Ge...	A New Study for Initial ...	DEMO_Sponsor2	DEMO-250-CAN-37X	DEMO, INVJ	30-SEP-2020	Complete	20200204
DEMO Randomized Tri...	A New Study for Initial ...	DEMO Company X	DEMO-969-AUS-12Xd	,	29-SEP-2020	Received	n/a
DEMO Rosacea Treat...	A New Study for Initial ...	DEMO_Sponsor10	DEMO-111-USA-1X	DEMO, InvK	25-SEP-2020	Complete	20200202
test	A New Study for Initial ...	test	test	,	25-SEP-2020	Received	n/a
DEMO Cystic Fibrosi...	A New Study for Initial ...	DEMO_Sponsor7	DEMO-700-USA-1X	n/a	15-SEP-2020	Received	n/a
WEIS -IR - New PRO - ...	A New Study for Initial ...	Weisenfeld Inc.	Weis-0915	Principal Investigator, ...	15-SEP-2020	Complete	20200200
DEMO Cystic Fibrosi...	A New Study for Initial ...	DEMO_Sponsor7	DEMO-700-USA-3X	DEMO, InvC	15-SEP-2020	Complete	20200199

Total Results: 386

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 New Site for Osteomyelitis Trials'. The page includes a progress bar with stages: Draft (01-OCT-2020), Received (01-OCT-2020), Preparing for Board Review, Board Review, Finalizing Documents (02-OCT-2020), and Complete (02-OCT-2020). Below the progress bar, study details are listed in a table:

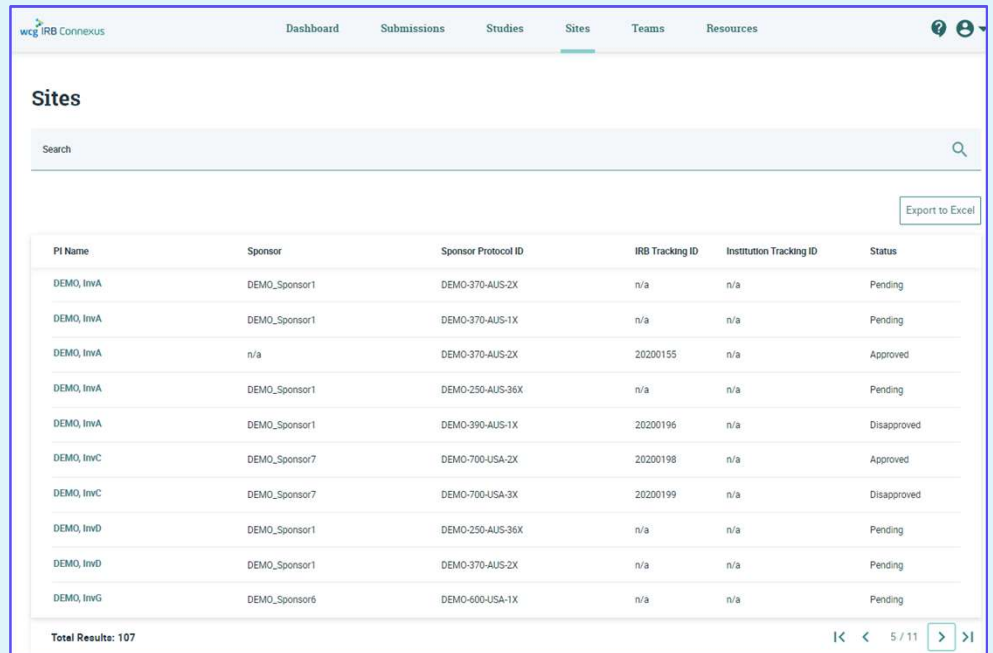
Study Name DEMO Osteomyelitis Treatment Phase 1 Study		
Sponsor DEMO_Sponsor10	Sponsor Protocol ID DEMO-100-USA-1X	Estimated Outcome n/a
IRB Tracking ID 20200197	Review Outcome Fully Approved	Confirmation ID 44494194

Below the table, there are tabs for 'Submitted Sites', 'Submitted Documents', and 'Outcome Documents'. The 'Submitted Sites' tab is active, showing a search bar and an 'Export to Excel' button. A table of submitted sites is displayed below:

PI Name	PI Organization	Institution Tracking ID	Country
DEMO_InvK	Independent Practice	n/a	United States

Sites Tab

- 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

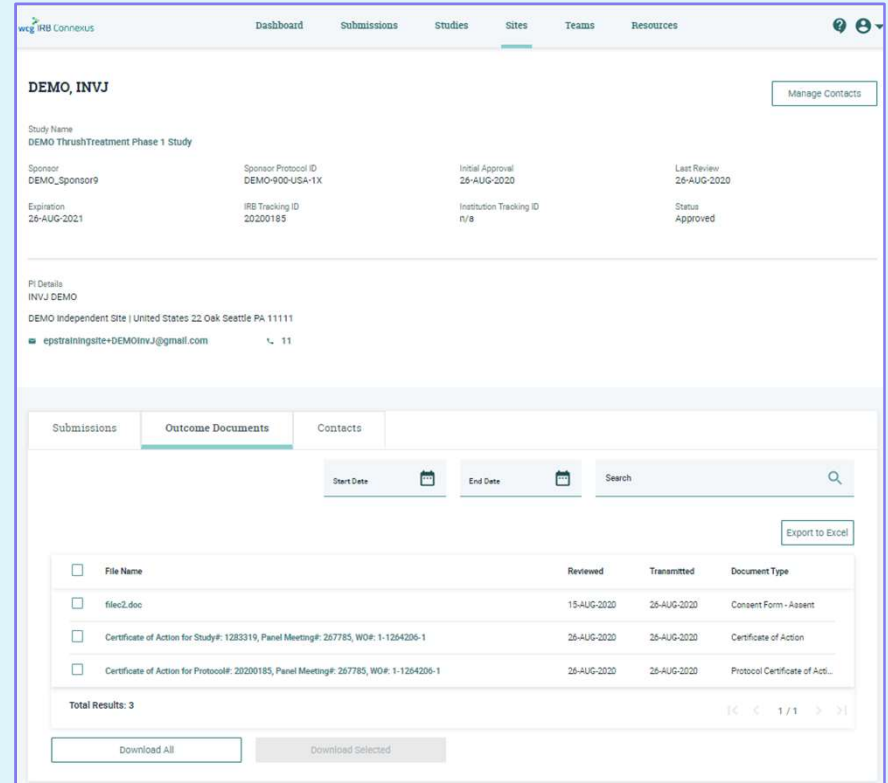


PI Name	Sponsor	Sponsor Protocol ID	IRB Tracking ID	Institution Tracking ID	Status
DEMO, InvA	DEMO_Sponsor1	DEMO-370-AUS-2X	n/a	n/a	Pending
DEMO, InvA	DEMO_Sponsor1	DEMO-370-AUS-1X	n/a	n/a	Pending
DEMO, InvA	n/a	DEMO-370-AUS-2X	20200155	n/a	Approved
DEMO, InvA	DEMO_Sponsor1	DEMO-250-AUS-36X	n/a	n/a	Pending
DEMO, InvA	DEMO_Sponsor1	DEMO-390-AUS-1X	20200196	n/a	Disapproved
DEMO, InvC	DEMO_Sponsor7	DEMO-700-USA-2X	20200198	n/a	Approved
DEMO, InvC	DEMO_Sponsor7	DEMO-700-USA-3X	20200199	n/a	Disapproved
DEMO, InvD	DEMO_Sponsor1	DEMO-250-AUS-36X	n/a	n/a	Pending
DEMO, InvD	DEMO_Sponsor1	DEMO-370-AUS-2X	n/a	n/a	Pending
DEMO, InvG	DEMO_Sponsor6	DEMO-600-USA-1X	n/a	n/a	Pending

Total Results: 107

Site (PI) Details

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



The screenshot shows the 'Site (PI) Details' page for 'DEMO, INVJ' in the WCG Connexus system. The page includes a navigation bar with 'Dashboard', 'Submissions', 'Studies', 'Sites', 'Teams', and 'Resources'. The main content area displays study information, PI details, and a table of outcome documents.

DEMO, INVJ Manage Contacts

Study Name
DEMO ThruTreatment Phase 1 Study

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

PI Details
INVJ DEMO
DEMO Independent Site | United States 22 Oak Seattle PA 11111
epstrainingite+DEMOinvj@gmail.com 11

Submissions Outcome Documents Contacts

Start Date End Date Search

Export to Excel

<input type="checkbox"/>	File Name	Reviewed	Transmitted	Document Type
<input type="checkbox"/>	file2.doc	15-AUG-2020	26-AUG-2020	Consent Form - Assent
<input type="checkbox"/>	Certificate of Action for Study#: 1283319, Panel Meeting#: 267785, WO#: 1-1264206-1	26-AUG-2020	26-AUG-2020	Certificate of Action
<input type="checkbox"/>	Certificate of Action for Protocol#: 20200185, Panel Meeting#: 267785, WO#: 1-1264206-1	26-AUG-2020	26-AUG-2020	Protocol Certificate of Act...

Total Results: 3 [< < 1/1 > >]

Download All Download Selected

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 Study Contacts

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

[Learn more about study permissions](#)

Contacts Requests 1

Add users by name or email Permissions

<input type="checkbox"/>	Name	Team Name	Email	Status	Permissions	
<input type="checkbox"/>	DEMO, StudyMgrK	n/a	epstrainingite+DEMOStudyMgrK@...	Has access	Manager	
<input type="checkbox"/>	DEMO, StudyMgrL	n/a	epstrainingite+DEMOStudyMgrL@...	Has access	Manager	
<input type="checkbox"/>	DEMO, StudyMgrM	n/a	epstrainingite+DEMOStudyMgrM...	Has access	Manager	



Resources and Additional Support

Resources Tab



- PDF version of the user guide
- "How-to-Videos"
- Quick Reference PDF Guides

Resources

User Guide

Use this guide as a reference for WCG IRB Connexus features and functionality. The guide displays in an HTML format to enhance accessibility and enable quick navigation through topics. A PDF version is also available for download in the Downloadable Documents section below.

[User Guide](#)

How-To Videos

Click on the following video tutorials to see system demonstrations of select tasks.

Getting Started and System Overview

Using the Dashboard

User Management Overview

Make a Submission

Tracking Submissions / Locating Documents


Working with Teams

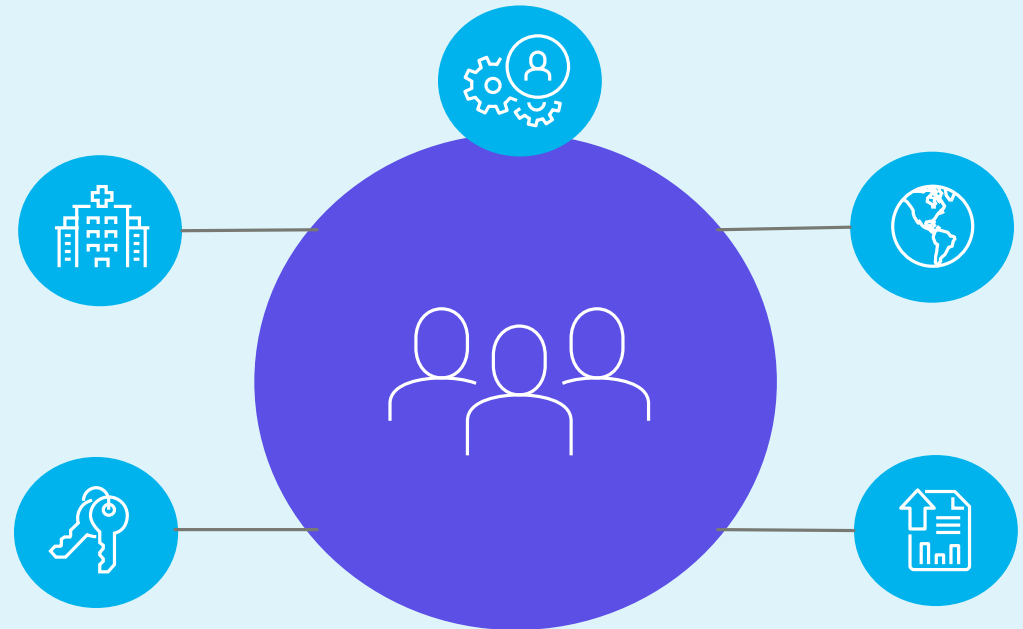
Download Outcome Documents / Export Data

Downloads	Download	Export
Download Outcome Documents / Export Data	Download	Export

- Downloadable Documents**
- These additional resources are available for your reference.
- Overview Quick Reference Guide
 - Dashboard Quick Reference Guide
 - Making a Submission Quick Reference Guide
 - Managing Submissions Quick Reference Guide
 - User Management Quick Reference Guide
 - Email Notifications
 - Site/Institution Orientation Guide
 - Working with Teams Quick Reference Guide
- IRB Link**
- [Click here for IRB Website](#)

We Are Here to Partner With You - Contact Us!

- For general questions, WCG IRB representatives may be reached at:
 - 855-818-2289
 - clientcare@wgcclinical.com
 - Via Live Chat 
- For all other inquiries:
 - Andy Parkhurst, Institutions Partnership Manager
 - 360.252.2893 (PST)
 - aparkhurst@wgcclinical.com



Questions and Answers!



Thank you!



wgcclinical.com