

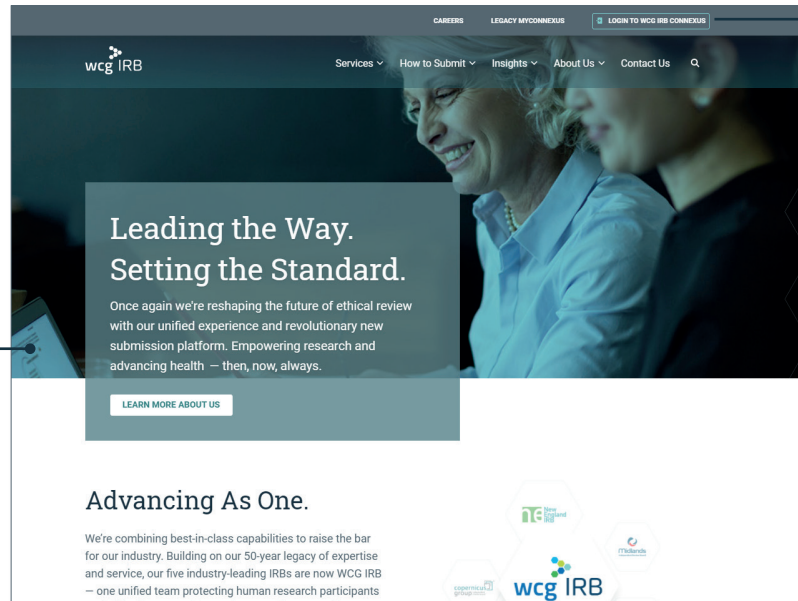
## System Access

### How do I access the WCG IRB Connexus Portal?

The two most common ways to access the WCG IRB Connexus portal are:

#### 1 Access via WCGIRB webpage:

Navigate to [www.wcgirb.com](http://www.wcgirb.com) and click on the **LOGIN TO WCG IRB CONNEXUS** link.



### What if I don't have an account?

If you are new to Connexus (you have never used Connexus in the past), then you will need to create an account.

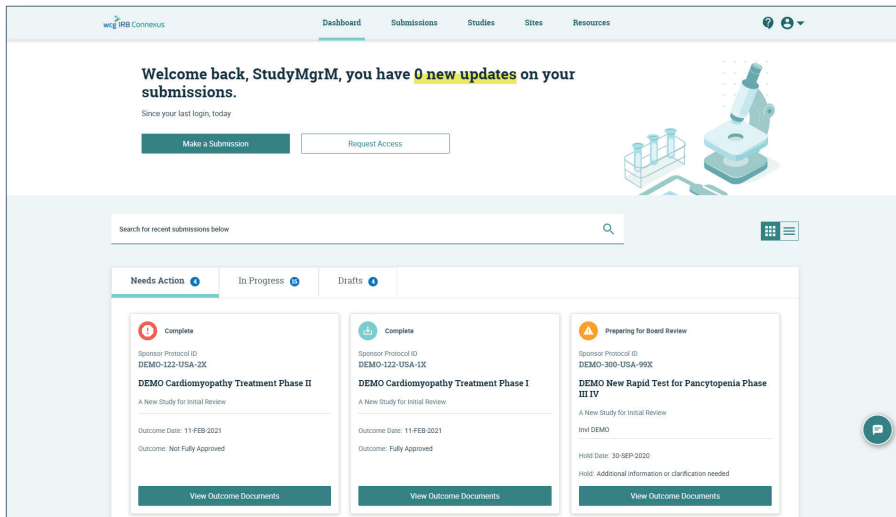
**Method 1:** Click the **Create a new account** button found on the login page to get started. Once you log in, you will need to **request access** to your study-sites.

#### 2 Access directly via the login page:

To bypass the main webpage and go straight to the Connexus login page, navigate to [connexus.wcgirb.com](http://connexus.wcgirb.com).

**Method 2:** A Site Manager invites you to a study-site from within Connexus. This method will generate a notification with a link you can use to start the registration process. Once you log in, you will automatically have **access to that site**.

## Navigation



### Need Help?



Search the Resources page to learn more about working with Connexus. The Resources page can be accessed from the top navigation menu, and contains a user guide, instructional videos, and task-oriented quick reference guides.



If you need help, you can click the “Need Help” icon to access WGC IRB Client Services Contact Information.



You can live chat with a member of client services in real time by clicking on the chat icon on the bottom right side of the page. This tool can be used during Client Services hours of operation.

### How do I use the Dashboard?

As the default landing page, the Dashboard is where you will likely spend a lot of your time in Connexus. The following can be achieved using the Dashboard:



#### Track “In Progress” Submissions:

The Dashboard spotlights your “In Progress” submissions, including any that require immediate attention. Use the submission information displayed within the **Needs Action** and **In Progress** tabs to:

- Monitor the progress submissions under review
- Learn more about additional actions that may need to be taken on any submissions tagged as “Needs Action”
- Download outcome documents from recently approved submissions (displayed under Needs Action for 10 days after approval).



#### Make a Submission:

Use the **Make a Submission** button to create a new submission for review. However, it is important to make sure the study-site does not already exist first. See **Add a New Site to a Study** before using **Make a Submission** to add your site to Connexus.



#### Request Access to a Site:

Used to request access to your specific study site. In most cases you will be requesting access to a site, and not the study. See **Proper Method for Requesting Access** to learn more.

Make a Submission

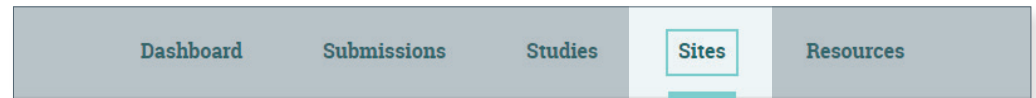
Request Access

## Where is my Study-Site Information?

In Connexus, a study-site is the entry on the **Sites** page that displays your site information as it pertains to a specific study. Therefore, your site may be displayed multiple times on the sites page as each instance represents your site as it is associated with a specific study. Each site details page displays study-site information such as associated submissions, outcome documents, PI Name, and contacts.

### 1 Locate the specific Study-Site:

Use the available search bar to locate the specific study-site you need to access, then click on the **PI Name** for that site to access the **Site Details** page..



Sites			
Search			
PI Name	Sponsor	Sponsor Protocol ID	IRB Tracking ID
DEMO_Inv100	DEMO_Sponsor9	DEMO-900-USA-1X	20200185

### 2 Locate Study-Site Information and Documentation:

The **Site Details** page displays information about that study-site as well as providing links to any study-site specific submissions, and an interface to view or download outcome documents

Study Name  
**DEMO Anti-Depressant Therapy Phase I**

Sponsor DEMO_Sponsor10	Sponsor Protocol ID DEMO-118-USA-1X	Initial Approval 05-JAN-2021	Last Review 05-JAN-2021
Expiration 05-JAN-2022	IRB Tracking ID 20201230	Institution Tracking ID n/a	Status Approved

PI Details  
InvK DEMO  
Independent Practice | United States 11 West San Diego CA 88888  
epstrainingite+DEMOInvK@gmail.com 11

Submissions Outcome Documents Contacts

Start Date End Date Search

## Requesting Access to an Existing Study-Site

To request access, click the **Request Access** button on the Dashboard.

Request Access

### 1 Select the option "Site":

This will allow you to request access for a study-site. Do **not** select "Study".

### 2 Search by the site's PI name:

Search for the study-site by entering the site's PI name in the form "Last Name, First Name", and then click **Search**.

### 3 Enter the IRB Tracking ID (if necessary):

This step is only necessary if the PI you searched for is associated with more than one site in the Connexus system. You can obtain the **IRB tracking ID** from the study team.

### 4 Submit your request for access:

After locating the correct study-site using the search tools above, you can click the **Submit Request** button. This will send an email notification to the study-site manager, who will be responsible for granting you access. You will receive a confirmation email notifying you if your request has been granted or denied, and if granted, what permission level you have been assigned for this study-site.

**i** You may submit to a site that does not already exist for the study by **Adding a Site to an Existing Study** using the IRB Tracking ID.

**i** A Study Manager may grant you Site Participant access or you may request access to a study following similar steps below. Site Participants have limited access to Submission Details and Study Details.

**Request Access** ×

**I'm asking the manager for access to a:**

Study
  Site
 💡 Select "Study" to request access that includes all sites in the study. Choose "Site" for access to one specific site.

Search

Search by PI name (format: last name, first name)

Submit ID

There is a match for your search

Sponsor	Sponsor Protocol ID	IRB Tracking ID
<b>DEMO_Sponsor2</b>	<b>DEMO-250-CAN-37X</b>	<b>20200204</b>

Submit request

## Add a New Site to an Existing Study

### 1 Search Connexus to ensure the study-site does not already exist:

To do this, first search your **sites page**. If you do not find the site there, contact your study team to see if the site already exists in Connexus. If it does, you may **request access** to the study-site.

### 2 Add a new site to an existing study:

To add a new site to an existing study, click the **Make a Submission** button on the Dashboard.




Make a Submission

### 3 Select the option "Add Principal Investigator/Site":

This will allow you to submit the site for an existing study.




If you are the submitter for a new site, you will automatically receive Manager access to that new site.



**Add Principal Investigator/Site**

### 4 Define your submission and select the study to which you're adding a new site:

One of the first steps in the submission process is to indicate to which study the new site being submitted for approval should be associated. When submitting a new site yourself, you will likely need to enter the IRB Tracking ID to associate the study.



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

Enter IRB Tracking ID



You are not dependent on the Sponsor/CRO to grant access to the study before you can submit.

### 5 Complete your submission form and submit for IRB Review:

The Submission Checklist will guide you through the submission process by presenting you with questions based on your submission type, answers to your setup questions, and answers to some questions within the checklist itself. After you have completed the submission checklist, you can submit for IRB review by clicking the **Review & Submit** button.

← Submission Checklist

Setup

Principal Investigator

Submission Documents

Review & Submit

## Manage Study-Site Contacts

The screenshot shows the 'Sites' tab selected in the navigation menu. The main content area displays study details for 'DEMO, InvK'. A 'Manage Contacts' button is located in the top right corner of the study details section.

Sponsor	Sponsor Protocol ID	Initial Approval	Last Review
DEMO_Sponsor10	DEMO-100-USA-1X	02-OCT-2020	02-OCT-2020
Expiration	IRB Tracking ID	Institution Tracking ID	Status
02-OCT-2021	20200197	n/a	Approved

### 1 Navigate to the Manage Contacts page:

To access the Manage Contacts page, click the **Manage Contacts** button on a study-site's Site Details page. See [Where is my Study-Site Information](#) to learn how to access a site details page.

### 2 Manage existing contacts:

On the **Contacts** tab of the Manage Contacts page, you can edit permissions and remove access for existing contacts. You can also directly invite new contacts from this tab.

### 3 Manage requests for site access:

This is where all pending requests for access to this site queue until they are reviewed by a study manager. Requests can be approved or rejected. Requesting users will receive an email letting them know if their request has been approved or rejected.

The diagram shows two tabs: 'Contacts' and 'Requests'. The 'Requests' tab is highlighted with a blue circle containing the number 2, indicating it is the current focus of the instruction.

## What if I don't see the Manage Contacts Button?

Only site users with the Manager permission can access the Manage Contacts page. See [Site Roles and Notifications](#) for more information.

- Ensure that you are starting your search from the Sites (✓) page and not on the Studies (✗) page
- Verify that you are viewing the correct study-site. You may have different permissions for each site that you can access in Connexus.
- Contact the site manager to update your permissions if you believe you should have manager access

## Site Roles and Notifications

	Manager	Submitter	Read Only
Manage user access (add/edit/remove)	✓		
Add documents to existing study/site	✓	✓	
View and download submission documents	✓	✓	✓
View and download outcome documents	✓	✓	✓

### What are the site roles and permissions?

The three available roles for each site are:

**Manager:** This role is specifically tasked with managing user access to the site. **Therefore, each site should have at least 1 manager.**

**Submitter:** This role has the ability to make submissions on behalf of the site.

**Read Only:** This role can view the site details page, as well as view and download any available submission documents and outcome documents.

### What notifications can I expect to receive?

All three roles will receive notifications when submissions were made on behalf of the site, or when outcome documents have become available. Users with the manager role will additionally receive notifications whenever requests for access are submitted. Therefore, it is important for site managers to plan accordingly to receive those additional notifications.

	Notification Types		
	Access requests	Submissions made on behalf of the site	Outcome documents available for the site
Manager	✓	✓	✓
Submitter	N/A	✓	✓
Read Only	N/A	✓	✓