



Initial Review Submissions to WCG IRB

CHLA
March 9, 2021

WCG IRB Announcement



In October 2020, WCG announced the formal unification of their five industry-leading IRBs – Western IRB (WIRB), Copernicus Group IRB (CGIRB), Midlands IRB (MLIRB), New England IRB (NEIRB), and Aspire IRB – into the single WCG IRB.

WCG IRB clients experience a singular, unified process and fee schedule. WCG IRB continues to deliver gold standard service with the highest regard to ethics and integrity.

What We Will Cover In Today's Session

- System Walkthrough
- Submission Process
- Navigating Workspaces
- Existing Legacy MyConnexus Users: System Transition “Need to Know” Information
- Resources and Support





System Access & Signing In



System Access

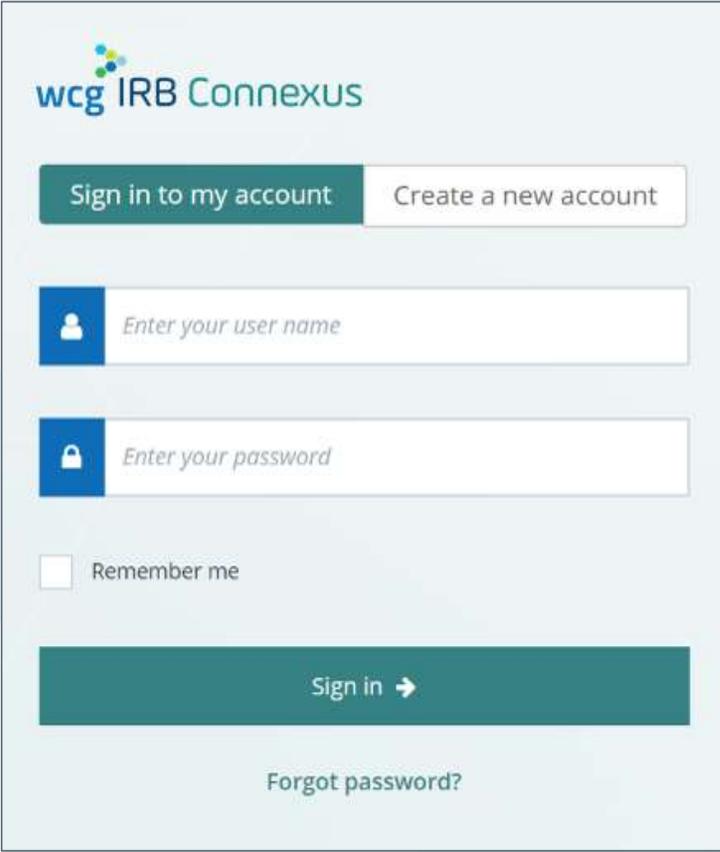


- **WCG IRB Website:** <http://www.wcgirb.com>
 - Login to WCG IRB Connexus link
- **Direct Link:** <https://connexus.wcgirb.com>



Signing In

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



The screenshot shows the login interface for wcg IRB Connexus. At the top left is the logo. Below it 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 for the user name with a person icon and the placeholder text 'Enter your user name'; the second is for the password with 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 labeled 'Sign in →' and a link for 'Forgot password?'.

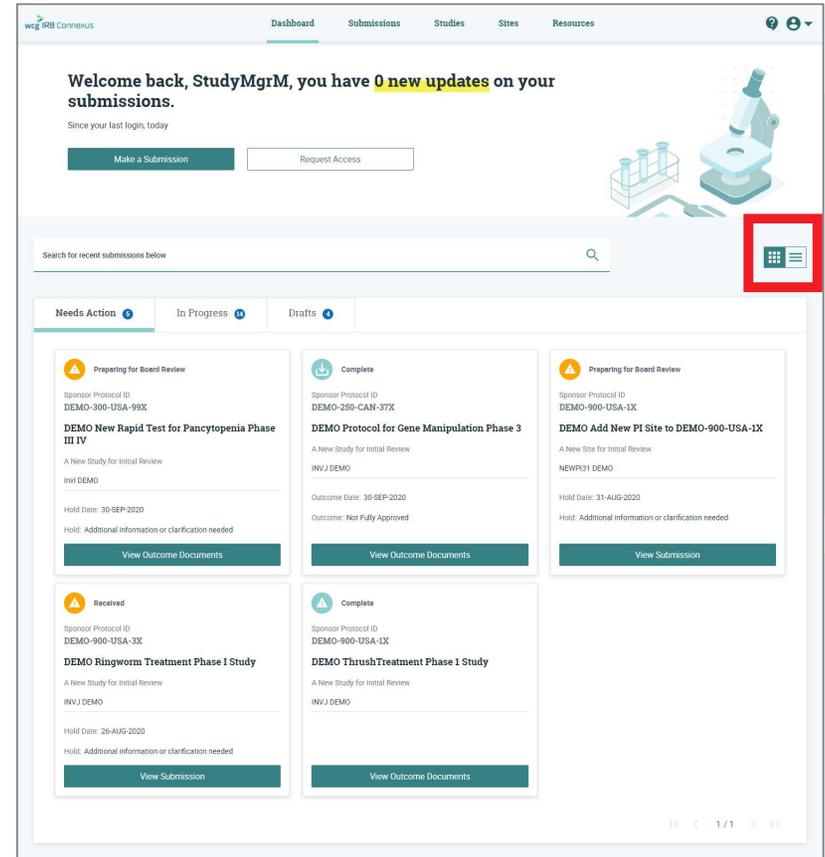


The Dashboard



WCG IRB Connexus Dashboard

- 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 and Table Views

- Two different options for easily viewing submission/study details

 **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 CONTINUUS Dashboard Submissions Studies Sites Resources

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

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

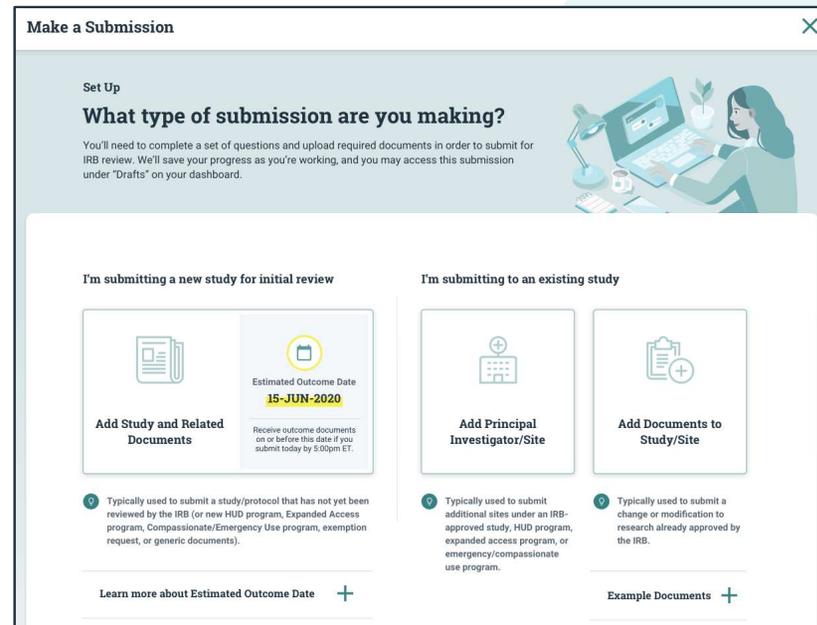
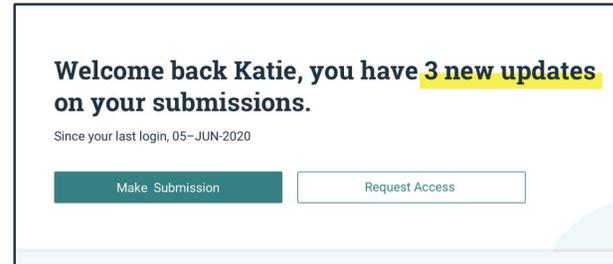
Submissions	Sponsor Protocol ID	Status	
New A New Study for Initial Review IR for Double-Blind Trial of Chemotherapy 2 Sites View All	AB-1234-567	    New Date: 01-JUN-2020 Hold: Awaiting CRO review and release	View Submission
New A New Study for Initial Review CR Submission Name 2 Sites View All	CD-1234-567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

Make a Submission

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

Select one of the following options:

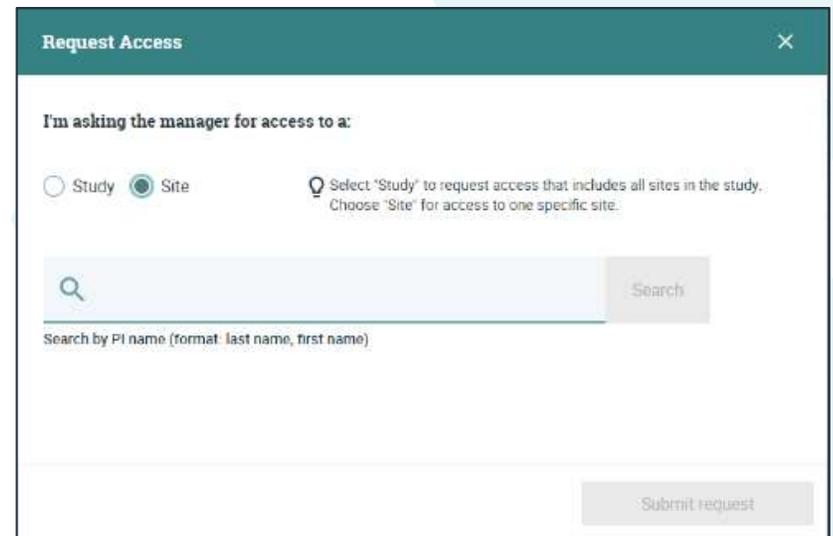
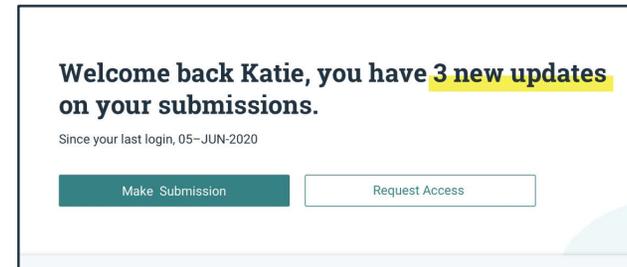
- Initial Review of New Protocol (not yet reviewed by WCG)
- For existing studies:
 - Add Principal Investigator/Site (to submit a new PI for initial review)
 - Add Documents to Study/Site (for an ongoing/existing approved study)



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 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
- **Study access is not needed to submit a new PI and is primarily reserved for Sponsor/CRO contacts**



Roles Overview

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.

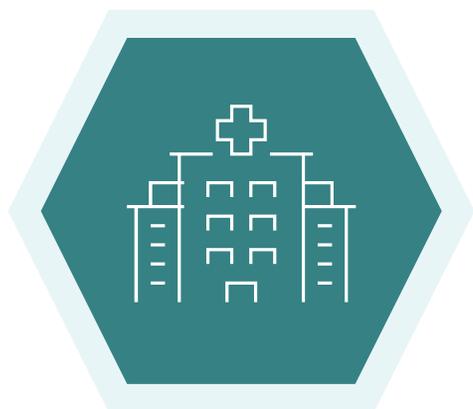
The permissions levels are as follows:

- Manager
- Submitter
- Read Only



Site Roles

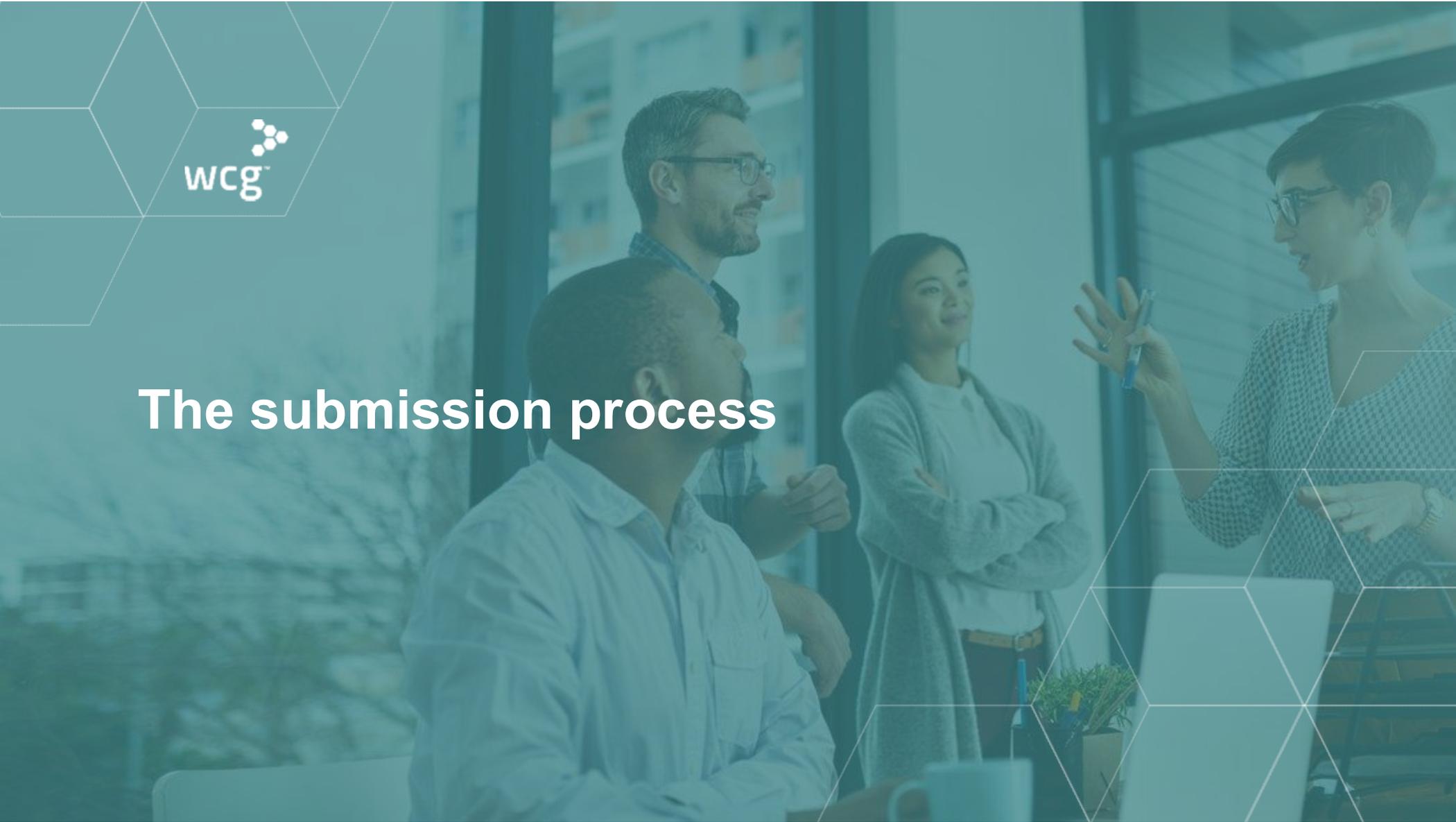
Site tasks each role may perform based on permission levels:



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



The submission process



Reliance Request to use WCG IRB



- **Before submitting to WCG IRB:**
 - Confirm we are the central IRB
 - Submit a **complete** ceded review application in iStar – do not leave sections blank
 - Complete all department/division and ancillary reviews – Clearance will not be issued until these are complete
 - Once clearance is issued, you can submit to WCG IRB!
- **Your ceded review application to CHLA must include:**
 - Approved protocol (obtain from the sponsor/CRO)
 - Key Information Summary
 - Communicate with the sponsor/CRO! Ask if the approved consent template includes a key information summary
 - If no key information summary is in the approved consent template, you must create one. Check the HSPP website for a template
 - CHLA COIRC Conflict Management Plan and Financial COI Consent Statement
 - CHLA specific recruitment or subject materials

Make a Submission: Initial Review of New PI

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

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

Ensure you have the WCG Protocol # for making the new PI submission (study workspace access is not needed):

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

Make a Submission: Initial Review of New PI

Ensure you have the WCG Protocol # for making the new PI submission (study workspace access is not needed):

Setup

Specify the study's IRB Tracking ID

Find a Study
20201230 

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

Sponsor DEMO_Sponsor10	Sponsor Protocol ID DEMO-118-USA-1X
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Make a Submission: Initial Review of New PI

Give your submission a meaningful name

Setup

Tell us the name of your submission

Sponsor

DEMO_Sponsor10

Sponsor Protocol Id

DEMO-118-USA-1X

Submission Name *

 The submission name should be a short summary of the submission that is easy for your reference.

Make a Submission: Initial Review of New PI

- Most submission documentation has now been incorporated into an interactive online form
- The system will guide you to fill out and submit any additional documentation that is required
- Complete a few more set-up questions: Translations, Recruitment Bonuses, Financial Interest Disclosure

Setup

Tell us a bit more about your submission, and we'll tell you what you need for board review.

Providing this information now will allow us to tell you what forms and documents are required in your submission as accurately as possible.

Translations

Documents for subject must be in language understandable by the subject or the subject's representative. Translated documents must be IRB approved before use.

Will you need translated documents or approval of translated documents? *

Yes

No

Recruitment Bonuses

Recruitment bonuses are extra payments tied to the rate or timing of recruitment or enrollment.

Will the Principal Investigator (PI) or research team be offered recruitment bonuses? *

Yes

No

Financial Interest Disclosure

Does the Principal Investigator (PI), the PI's immediate family, or any other research personnel or their immediate families, have any of the following financial interests in any entity that is sponsoring the research, or an entity that is manufacturing the product or service being tested, not reported to this IRB in previous submissions for this protocol?

- Any **remuneration** from the entity in the previous twelve months that exceeds \$5,000, when aggregated for the individual and their immediate family
- Any **equity interest** in the entity
- Any **intellectual property rights and interests**
- Any **governance or executive relationship** with the entity

Yes

No

*

Make a Submission: Initial Review of New PI

Translations

- All subject facing materials must have IRB approval before presenting them to the subject, including translated documents
- Check with your sponsor/CRO about translations before submitting: Who will translate the documents? Sponsor, CRO, WCG IRB
- To avoid additional translation costs and delays, translation requests should be submitted after IRB approval as they include CHLA specific documents
- For approval of sponsor/CRO translated documents:
 - Submit a translated Word version of the IRB approved document(s)
 - Certificate of translation – signed, protocol sponsor and protocol number, list the name of the translated document(s), attestation of the translator’s fluency and accuracy of the translation

The screenshot shows a web form titled "Translated Documents". It includes a section for "Languages Requested" with a question "Is this the first time you are requesting translation for this protocol?" and radio buttons for "Yes" and "No". Below this is a dropdown menu to "Indicate the language requested" and a "+ Add another language" link. The "Type of Submission" section has two checkboxes: "I have already translated document(s)" and "I want the IRB to facilitate translation(s) through their translation vendor". There is a table with columns for "File Name" and "Document Title", and a "+ Add another document" link. At the bottom, there is a "Special Instructions" section with a prompt: "Provide any special instructions or additional relevant information for this submission."

- For WCG IRB translations:
 - Submit completed Translation request submission

Make a Submission: Initial Review of New PI

- 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

The screenshot displays the 'Make a Submission' interface. At the top, the title 'Make a Submission' is followed by 'test PI submission' and a long URL. An 'AUTOSAVED' indicator with a close button is in the top right. A left sidebar contains a 'Submission Checklist' with a back arrow, and a list of steps: 'Setup' (checked), 'Principal Investigator' (partially filled), 'Contacts' (empty), 'Initial Review Questionnaire' (empty), 'Financial Interest Disclosure' (empty), and 'Submission Documents' (empty). Below the checklist is a 'Review & Submit' button and a 'Need some help?' section with contact information. The main content area is titled 'Principal Investigator' and 'Add Principal Investigator information', featuring input fields for Prefix, First Name, Middle Name, Last Name, and Suffix. A 'Contacts' button with a right arrow is in the bottom right corner. A 'Setup' button with a left arrow is in the bottom left corner.

Make a Submission: New PI Form Overview

- Be sure to add all contacts who need to be listed who need to received IRB correspondence
- You can add study coordinators, or sponsor/CRO contacts
- Not all Study Staff need to be listed to receive all communication about your submission, but rather can be added via the Manage Contacts tools for that Investigator

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 IRB Determination Letter

Contacts

Contact Type

Prefix

First Name

Make a Submission: New PI Form Overview

- 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 Overview

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

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 Overview

- Always mark “yes” to Institutional Services question
- Include the name of your organization and your Institution #
- **CHLA**
- **#130163**

Institutional Services

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

Yes
 No

Name of organization relying on WIRB (if known)

WIRB Institution # of organization relying on WIRB (if known)

Make a Submission: New PI Form Overview

- Be sure to select the appropriate indication of how you plan to submit your consent form
- **Yes – CHLA has pre-approved language**
- **Always select: Option 1**

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: New PI Form Overview

- Reference document our staff uses to add CHLA specific language
 - Purple text must be submitted by the site per study (Key Information Summary, COI)
 - Black text is required for all consents
 - Grey shaded will be added verbatim unless the CHLA HSPP authorizes the deviation
 - WCG IRB will contact the CHLA HSPP if sponsor/site is requesting deviated language

Do not include HIPAA language in the body of any consent form (including pregnant partners). This institution has a stand-alone HIPAA form. If HIPAA is embedded in the WCG Template consent form, remove it and include a Confidentiality section. Use WCG "conf" if there is no confidentiality language in the consent form. Remove all references to "protected health information" and replace with "research information" or "research data".

**CHILDREN'S HOSPITAL LOS ANGELES
INFORMED CONSENT/PARENTAL PERMISSION/ASSENT TO PARTICIPATE IN A
RESEARCH STUDY**

Always add "Children's Hospital Los Angeles" above the title of the consent form(s), assent(s) form, or addenda. See above for an example.

This institution requires a key information section immediately following the standard headings. If the sponsor template has a key information section, this institution will use this. If it does not, the site will submit a document in the Connexus application with the key information language as appropriate to the study. If there is no language in the sponsor template or a site document is not submitted place the study on hold and ask the site for the information.

Include a conflict of interest section in all consent forms:

Conflict of Interest

There are no investigator or institutional conflicts of interest to disclose to subjects.

OR

If there is a COI, the site will provide their institution's COI Management Plan in the Connexus application and the required language about the conflict for the consent form. Insert the COI management plan ICF language into the created consent form.

Questions:

Use the WCGIRB standard template language – plus following WCGIRB 'rights' language. This language does not have to be verbatim, as long as the CHLA HSPP office is listed after WCGIRB.

You may also call Children's Hospital Los Angeles, Human Subjects Protection Program office at (323) 361-2265.

Confidentiality:

Remove all references to "protected health information" and replace with "research information" or "research data".

Add "CHLA Institutional Review Board (IRB)" and "CHLA Authorized Individuals" as bullets in the list of individuals who may review research records.

Make a Submission: Upload Required Documents

- The end of the form will show a Document Checklist for what you have to submit
- Be sure to include your CHLA specific documents
 - ✓ **CHLA HSPP Clearance Letter**
 - ✓ **Key Information Summary** (if not included in the current approved template)
 - ✓ **CHLA COIRC Conflict Management Plan and COI Consent statement** (if applicable)
 - ✓ **CHLA specific recruitment/subject materials**
 - ✓ **PI Medical License/CV** (if not on file or current)

The screenshot shows a web interface for uploading documents. At the top, it says "Submission Documents" and "Upload the files that you'll be submitting for this study." Below this, there is a note: "To avoid processing delays, remove security/password protection from all submission documents." The main area is titled "Documents" and contains a large dashed box for file uploads with the text "Drop Files here or click to upload" and "Files may be up to 1 GB". To the right of this box is a link "What can I upload?". Below the upload area is a "Document Checklist" section with the heading "Submit the following documentation:" and two bullet points: "Advertisements and recruitment scripts specific to your site" and "Curriculum vitae for the PI, if not on file with the IRB". At the bottom, there is a section titled "Available on the WCG IRB Website:" with the text "The following documents can be downloaded on the IRB Website and must be uploaded with your submission." and the website URL "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 “Submit for IRB Review” in the bottom right-hand corner of the screen to submit for IRB Review

Review & Submit

Almost done! Make sure you've reviewed all submission materials before submitting to the IRB.

You may return to any section of this submission and make edits before submitting.

My Submission

Initial Review of a New PI/Site

Draft

test

Secukinumab Trial Analyzing the potential of Intravenous administration To Upgrade the Response in psoriasis (STATURE)

Download Draft PDF

Need some help?

Contact WCG: 800-562-4789
Hours: 8:00AM to 8:00PM Eastern Time, Monday to Friday

[Email Us](#)

Submit for IRB Review

Make a Submission: Confirm and Share access

- A confirmation message will appear that your PI has been submitted
- Your confirmation ID should appear within a few minutes and is accessible via your Submissions landing page
- You can also manage access directly after submission by clicking Invite Contacts

Your new Principal Investigator has been submitted! Next, share access to your submission with others.

Share access to your submission by inviting contacts. These contacts will have the ability to view this new submission and its outcome documents and will receive notifications of updates to this submission.

[Invite Contacts](#)

Draft 05-MAR-2021	Received 05-MAR-2021	Preparing for Board Review	Board Review	Finalizing Documents	Complete

Initial Review of a New PI/Site

Received

Sponsor Protocol ID
WEIS-000-aa

IR test

A New Site for Initial Review

Study Name: A Phase I trial of infant peanut challenge

Sponsor: WEIS, Inc.

[Export PDF](#)

Need some help?

Contact WCG: 1-855-818-2289
Hours: 8:00AM to 8:00PM Eastern Time, Monday to Friday

[Email Us](#)

After You Submit: What to Expect

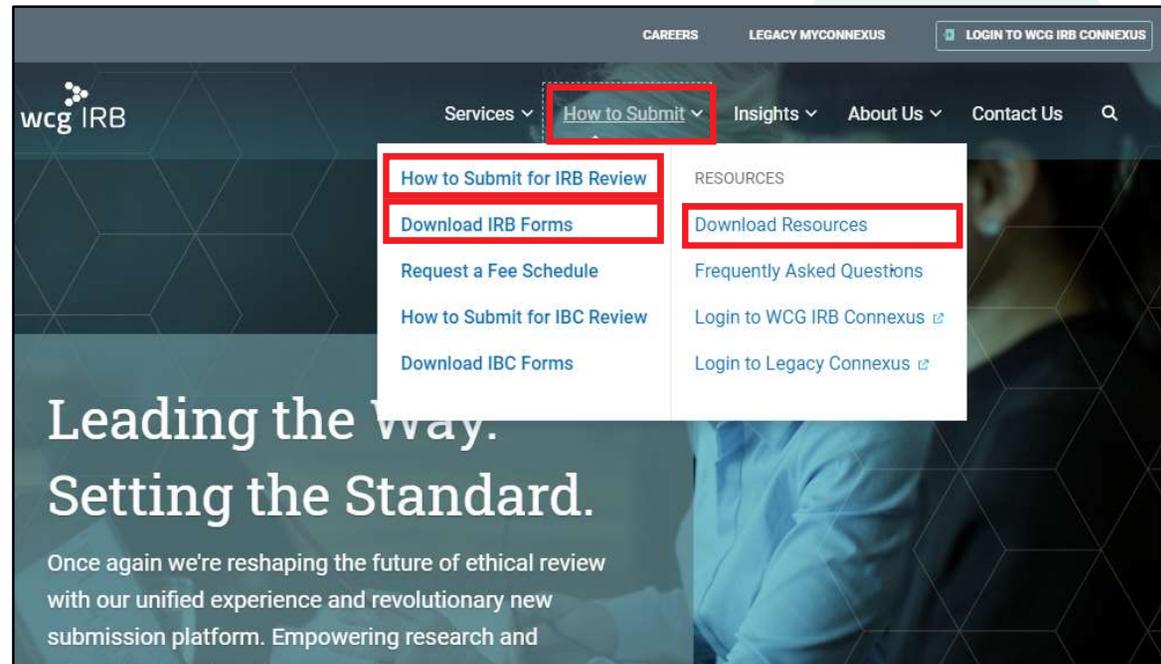
- IRB staff may reach out if there are any clarifications or missing items. They will begin to reference a work order number.
 - Your work order is advanced to our pre-board team to prepare your consent form. They will reach out if there are any questions with the processing of your consent form.
 - The work order is then sent for scheduling to a WCG Board Panel or Expedited Reviewer
 - Once reviewed, the work order is sent to our post-Board team. They will prepare and add any Board language and finalize your approval documents within 1-2 days.
 - All users with access will receive an email when outcome documents have been posted to Connexus in the Outcome documents tab
- You will receive a Certificate of Action (COA):
 - Board Action Date (Review Date)
 - Expiration Date (if approved)
 - Approved Research Location(s) and PI
 - The documents that were reviewed
 - **Review your COA!**
 - WCG IRB communicates Board actions via a COA. Your COA will state the action taken: Approved, Conditionally Approved, Deferred
 - Conditional Approvals/Deferrals will require further action, follow the instructions on the COA.

After You Submit: What to Expect

IRB Resources

CHLA Study Teams are responsible for ensuring the all WCG IRB requirements are met

- Certificate of Action lists PI/site responsibilities
- Download IRB Forms
wcgirb.com -> How to Submit -> Download IRB Forms
 - Guide for Researchers
 - Submission Form, Misc Forms
- Download Resources
wcgirb.com -> How to Submit -> Download Resources
 - Investigator Guidance – Investigator Obligations and other SOP documents





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 G...	A New Study for Initial IR...	DEMO_Sponsor T	DEMO 250 A-US-18	DEMO_NEWPI02	23 AUG 2020	RECEIVED	000
DEMO Submission Na...	A New Study for Initial IR...	DEMO_Sponsor T	DEMO 250 A-US-18X	000	000	DECL	000
DEMO Add New PI G...	A New Study for Initial IR...	DEMO_Sponsor V	DEMO 000 USA 18	DEMO_NEWPI01	21 AUG 2020	PENDING FOR...	20200105
DEMO_Add PI	A New Study for Initial IR...	DEMO_Sponsor T	DEMO 250 A-US-18X	000	000	DECL	000
DEMO IR Submission	A New Study for Initial IR...	DEMO_Sponsor T	DEMO 250 A-US-18X	000	000	DECL	000
DEMO IR Submission	A New Study for Initial IR...	DEMO_Sponsor T	DEMO 250 A-US-18X	000	000	DECL	000
DEMO Lung Cancer Tr...	A New Study for Initial IR...	DEMO_Sponsor T	DEMO 510 A-US-18	DEMO_01AA	27 AUG 2020	RECEIVED	000
DEMO Demo Manipulat...	A New Study for Initial IR...	000	AUSP112020	000	26 AUG 2020	PENDING FOR...	20200148
DEMO Demo Manipulat...	A New Study for Initial IR...	DEMO_Sponsor T	DEMO 250 A-US-18X	000	26 AUG 2020	RECEIVED	000
DEMO New Rapid Test...	A New Study for Initial IR...	DEMO_Sponsor T	DEMO 250 A-US-18X	000	25 AUG 2020	RECEIVED	000

Submission Details

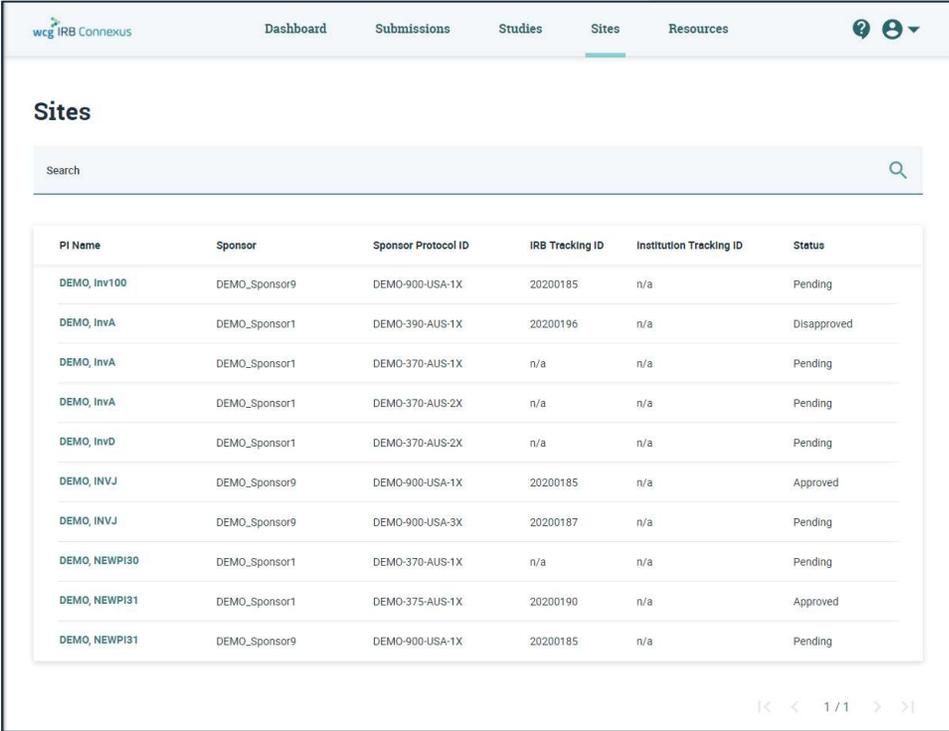
- Displays submission status and other submission details
- Also displays (if applicable):
 - Submitted Sites
 - Submitted Documents
 - Outcome Documents

The screenshot shows the 'Submission Details' page for a study titled 'DEMO Lung Cancer Treatment Phase I 10mg Dose'. The page features a progress bar with six stages: Draft (12-AUG-2020), **Received** (07-09G-2022), 'Preparing for IRB review', 'IRB Review', 'Awaiting Documents', and 'Complete'. Below the progress bar, the study name is repeated. Key information includes: Sponsor: DEMO, Sponsor ID: DEMO-SC00001, IRB Tracking ID: N/A, Sponsor Protocol ID: DEMO-071-AUS-18, Review Outcome: N/A, and Submission Date: 17-AUG-2020. At the bottom, there are three tabs: 'Submitted Sites', 'Submitted Documents', and 'Outcome Documents'. The 'Submitted Sites' tab is active, showing a search bar with 'N/A' and a table with one entry.

PI Name	PI Organization	Institution Linking ID	Country
DEMO, INC	DEMO, SC00001	N/A	United States

WCG IRB Connexus Sites (PIs) Landing Page

- Display all **Sites** you have access to
- Click the PI Name for more details
- Contains:
 - Search
 - Table displaying all site information



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 ThrusTreatment 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

PI Details: INVJ DEMO
DEMO Independent Site | United States 22 Oak Seattle PA 11111
✉ epstrainingsite+DEMOInvJ@gmail.com 📞 11

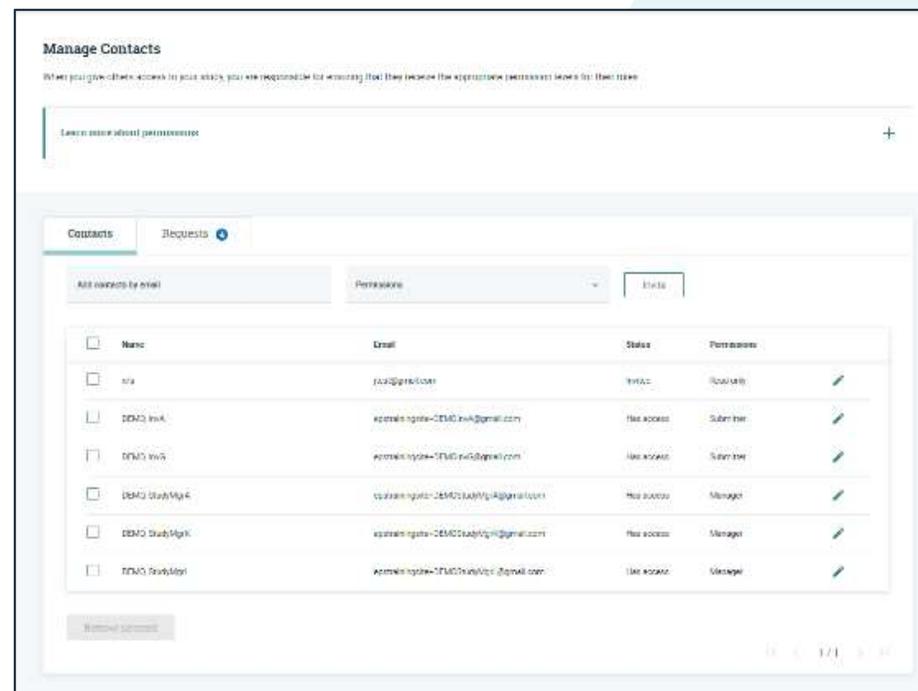
The 'Outcome Documents' tab is active, showing a table with columns: File Name, Reviewed, Transmitted, and Document Type. The table contains three rows of documents:

File Name	Reviewed	Transmitted	Document Type
filec2.doc	15-AUG-2020	26-AUG-2020	Consent Form - Assent
Certificate of Action for Study#: 1283319, Panel ...	26-AUG-2020	26-AUG-2020	Certificate of Action
Certificate of Action for Protocol#: 20200185, P...	26-AUG-2020	26-AUG-2020	Protocol Certificate of Action

At the bottom of the document list, there are 'Download All' and 'Download Selected' buttons. A pagination control shows '1 / 1' and a chat icon.

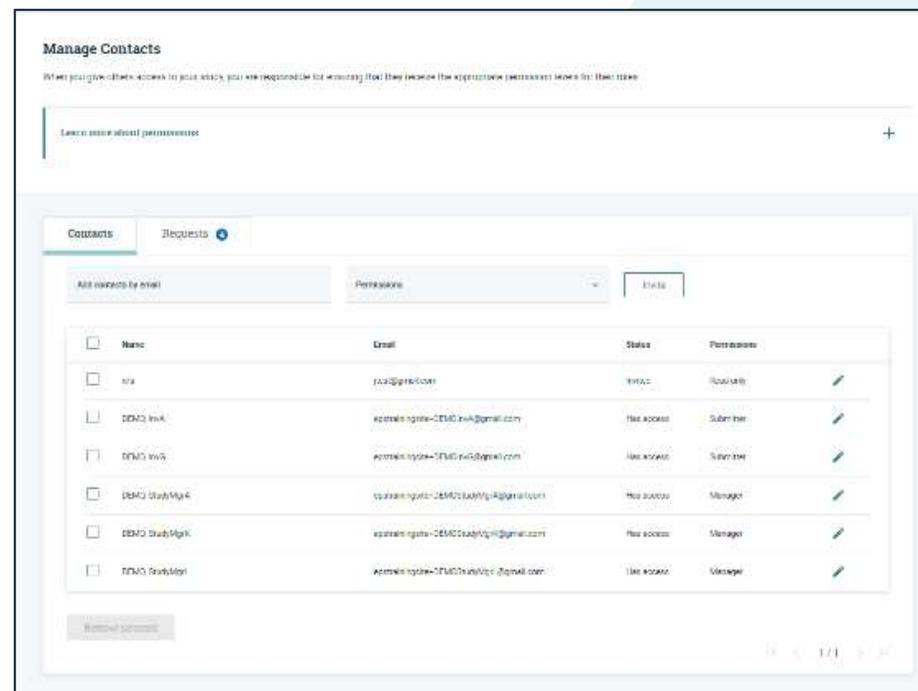
Manage Contacts

- 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

- 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

- For all CHLA affiliated research:
 - Always add CHLA HSPP irbreliance@chla.usc.edu as a contact type Manager
 - Do not remove CHLA HSPP irbreliance@chla.usc.edu

Multiple contacts

If you work with a team and your team needs access to your site workspace, keep a document with their emails separated by a comma or semicolon. Copy, paste, select permission level and invite them all at in one step.

Manage Contacts

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

[Learn more about permissions](#)

Contacts Requests

Add users by name or email

X

Permissions
Manager

Invite

Manage Contacts

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

[Learn more about permissions](#)

	A	B
1	Institution IRB Staff	Email
2	IRB Senior Analyst	sranalyst@anyinstitution.org ;
3	IRB Analyst	analyst@anyinstitution.org ;
4	IRB compliance team	Compliance@anyinstitution.org ;
5	IRB Director	director@anyinstitution.org ;

Contacts Requests

Add users by name or email

X

X

X

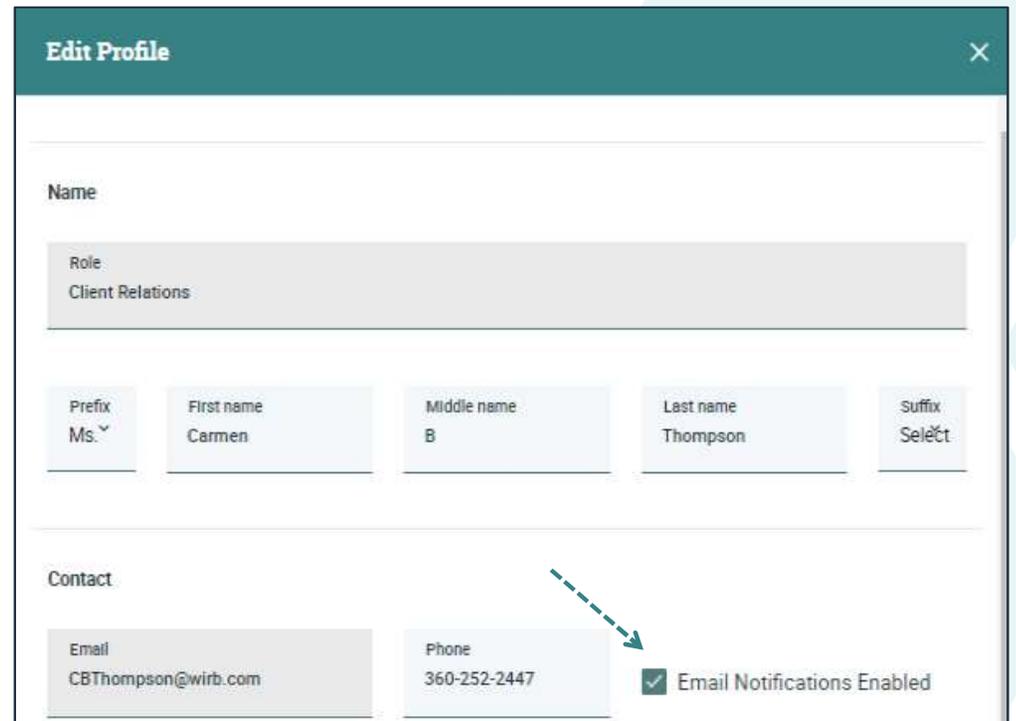
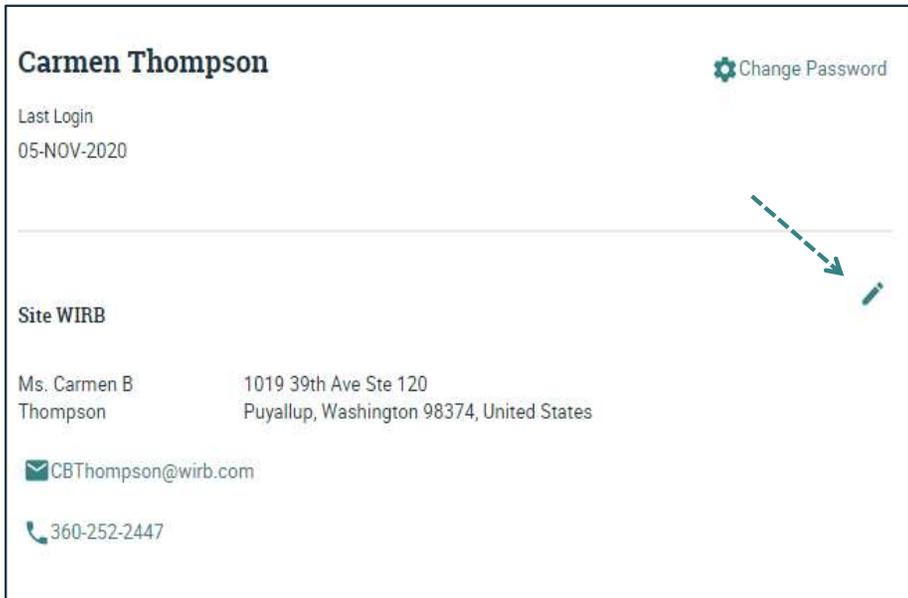
X

Permissions

Invite

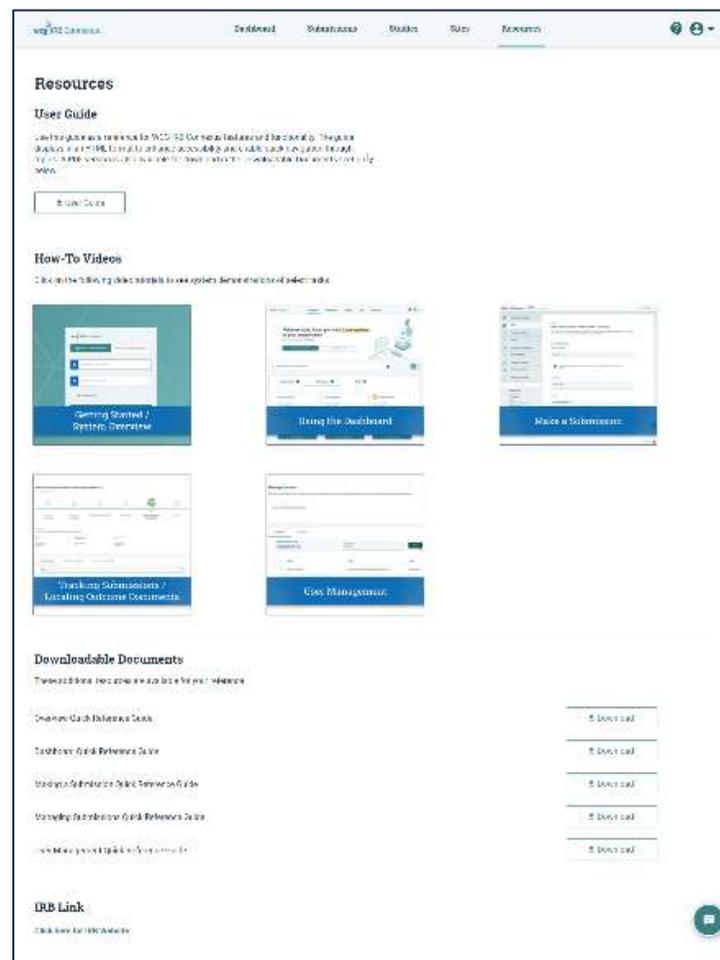
User Profile

To disable access request notifications:



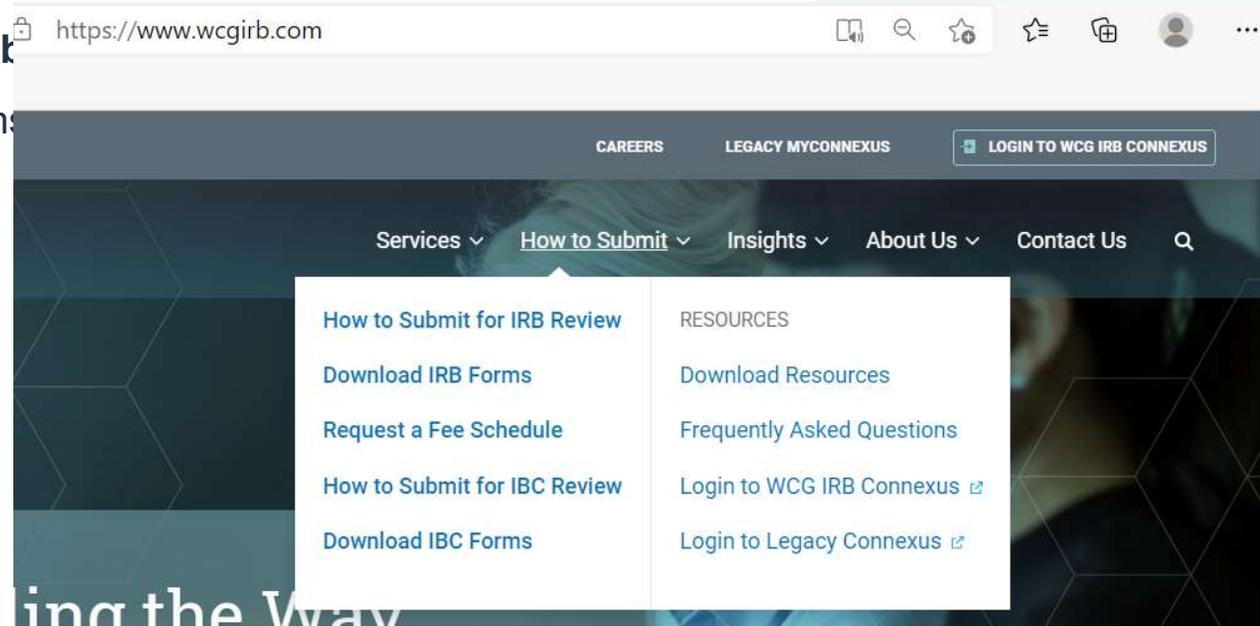
WCG IRB Connexus Resources

- PDF version of the user guide
- “How-to-Videos”
- Quick Reference Guides
- Link to WCGIRB.com



WCG IRB Resources

- Resources are available on our website
- How to Submit > Download IRB Forms
- PDF version of the user guide
- “How-to-Videos”
- Quick Reference Guides
- Link to WCGIRB.com





Additional Items to Note



Additional Information

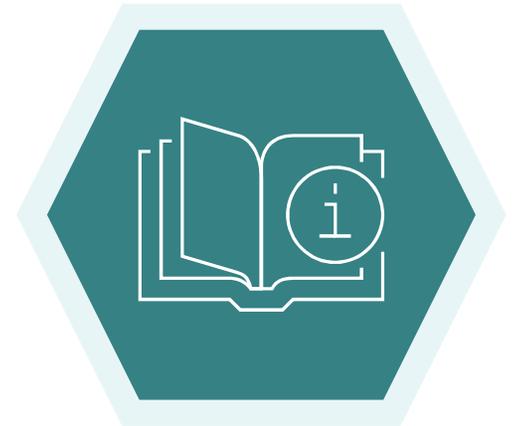
For a limited time, both legacy MyConnexus and WCG IRB Connexus will exist simultaneously

- With this in mind, there are a few considerations:
 - Draft submissions will only be available in the system where it was created
 - 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



We are here to partner with you – contact us!

For general questions and inquiries:

1-855-818-2289 | clientservices@wcgirb.com

Live Chat via Connexus

For CHLA specific, escalated or urgent issues:

Carmen Thompson

360-252-2447 | cbthompson@wirb.com





Thank You

