Managing studies approved by WCG IRB

CHLA
March 18, 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.

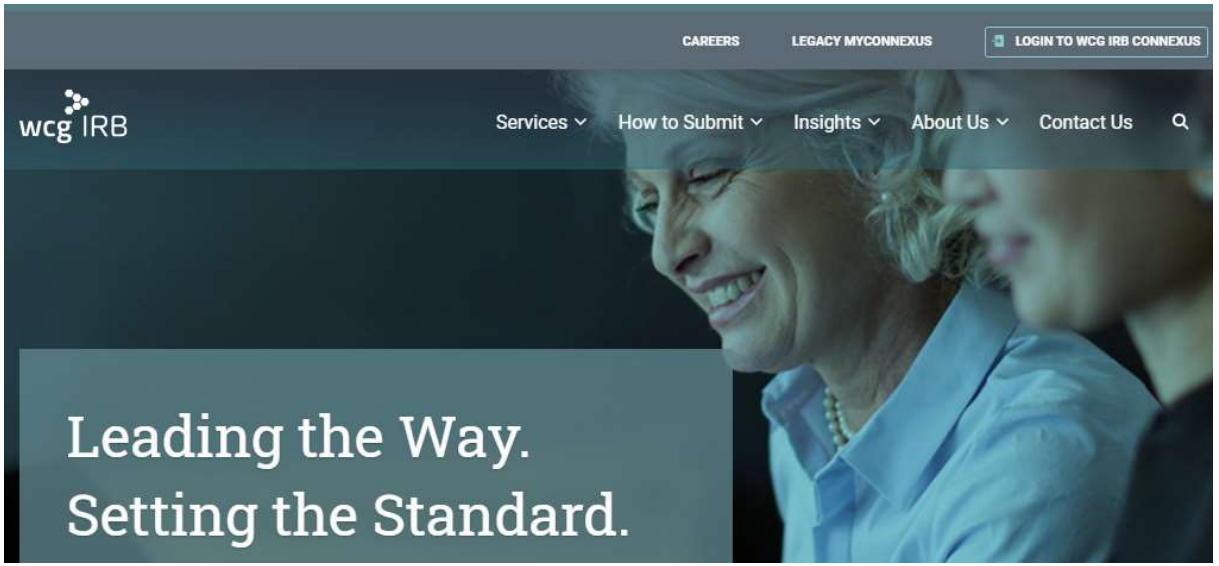
What We Will Cover In Today's Session

- System Walkthrough
- Submission Types and Process for approved sites
- Navigating Workspaces
- Existing Legacy MyConnexus Users: System Transition "Need to Know" Information
- Resources and Support

System Access & Signing In

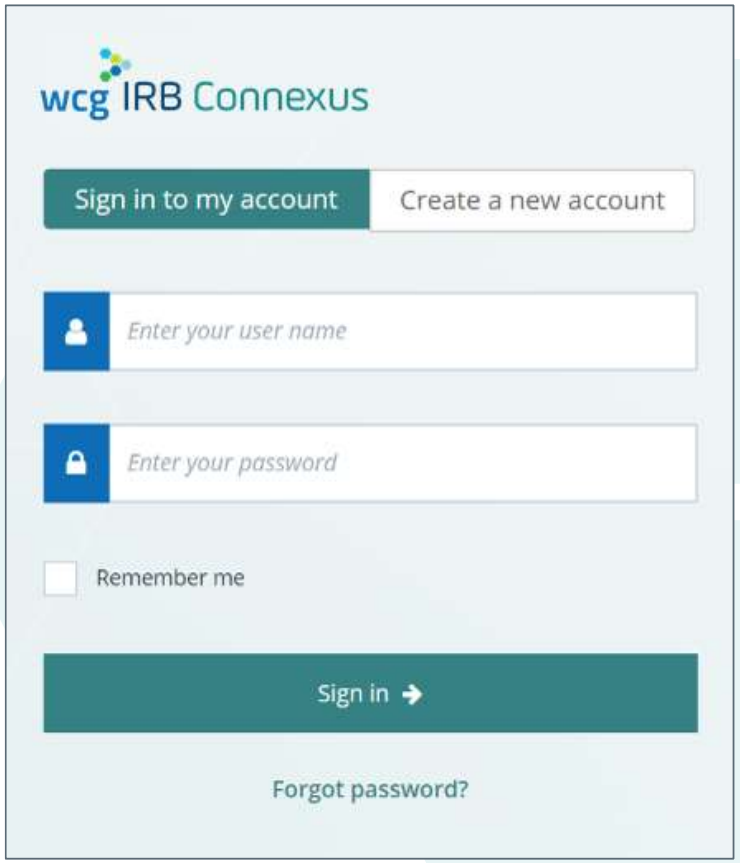
System Access

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



Signing In

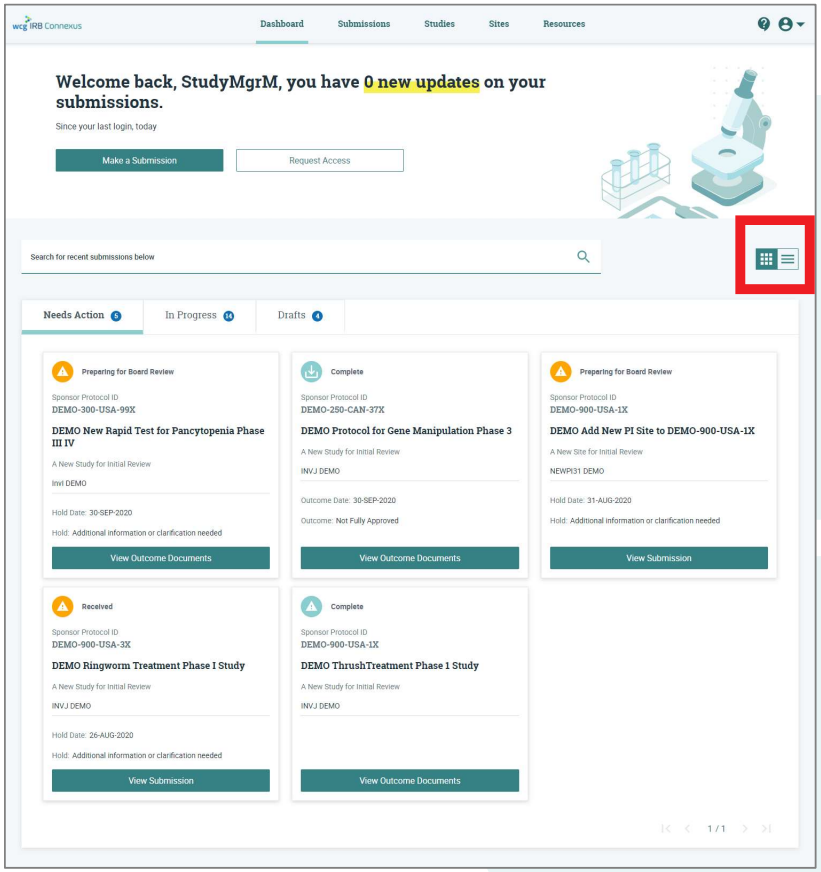
- Legacy MyConnexus users need to reset password and accept the Terms & Conditions upon initial sign in, click on Forgot Password
- Use the same registered email address as you have in Legacy MyConnexus
- Your username is your email address
- New users can register using **Create a new account**



The Dashboard

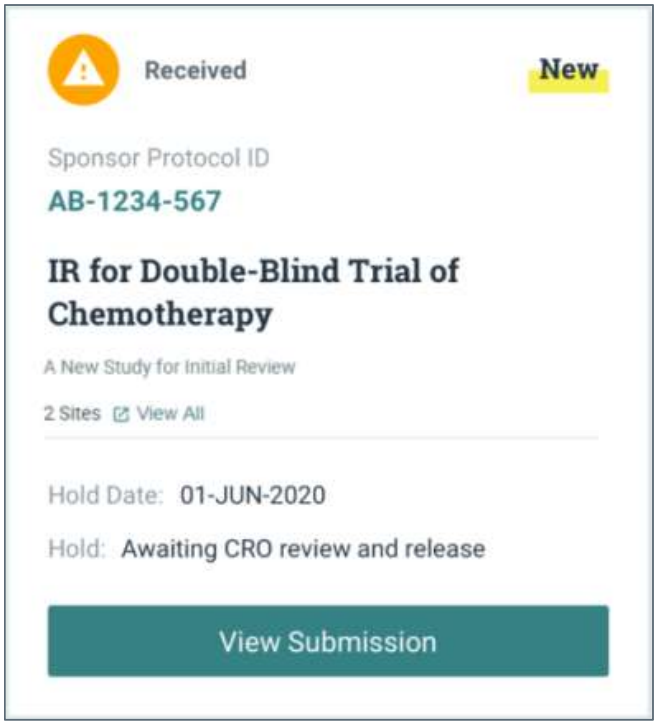
WCG IRB Connexus Dashboard

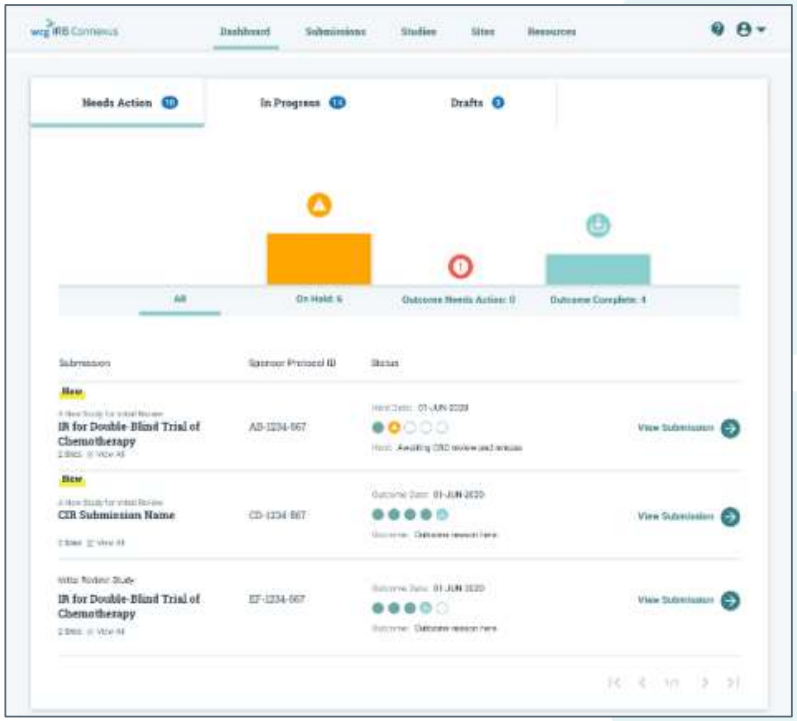
- Central hub for most WCG IRB Connexus activity
- Contains:
  - Notification area
  - Make a Submission button
  - Request Access button
  - Track Submissions area
    - Search
    - Tabs – Needs Action, In Progress, Drafts
    - Two different views per your preference



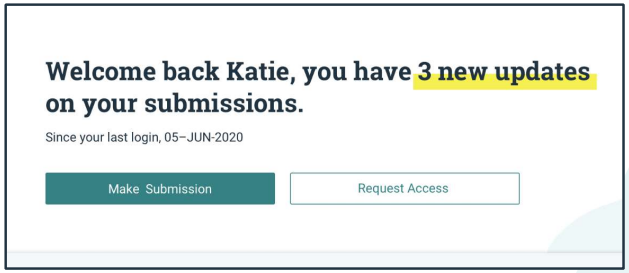
Dashboard – Card and Table Views

- Two different options for easily viewing submission/study details





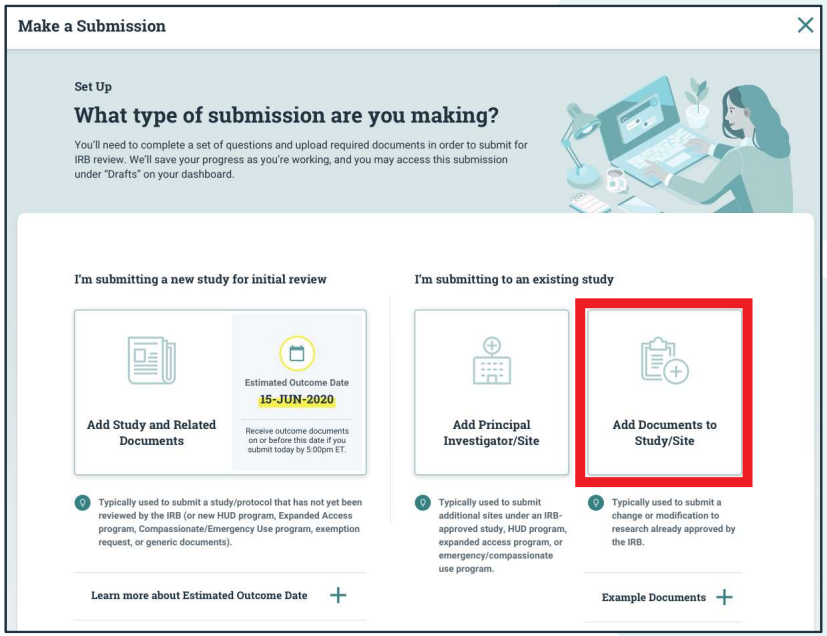
Make a Submission



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

Select one of the following options:

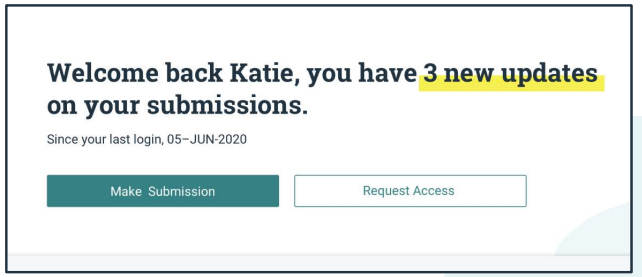
- Initial Review of New Protocol (not yet reviewed by WCG)
- For existing studies:
  - Add Principal Investigator/Site (to submit a new PI for initial review)
  - Add Documents to Study/Site (for an ongoing/existing approved study)

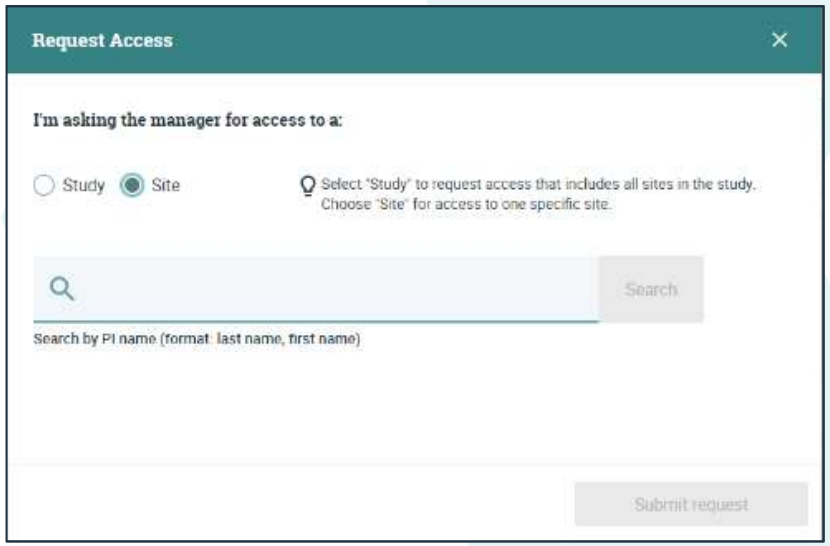


Request Access

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





Roles Overview

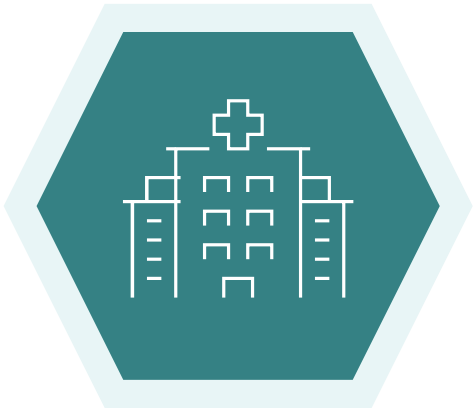
There are different levels of access, each with specific permissions. Your permission level depends on how your manager adds you to a study or a site.

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



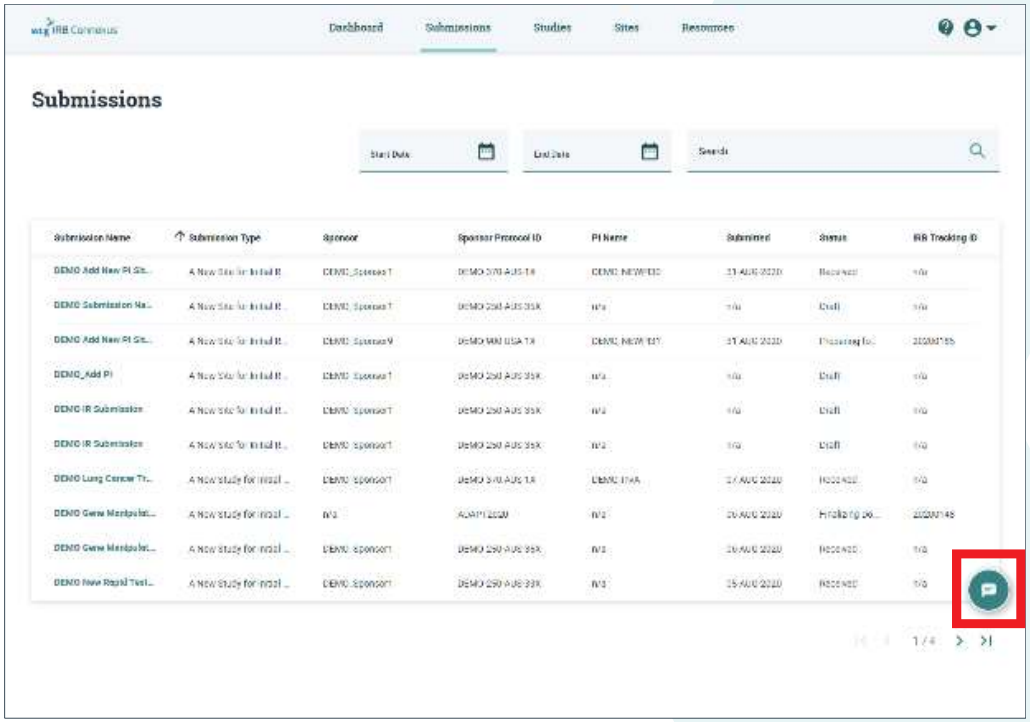
Site tasks each role may perform based on permission levels:

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

Navigating Workspaces

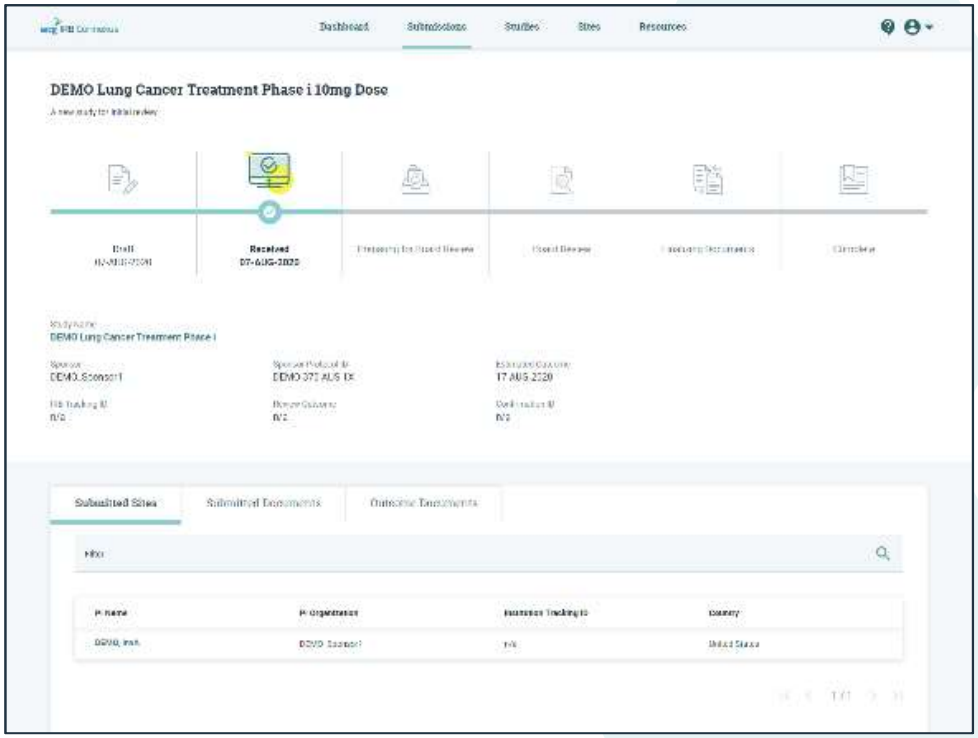
WCG IRB Connexus Submissions Landing Page

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



Submission Details

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



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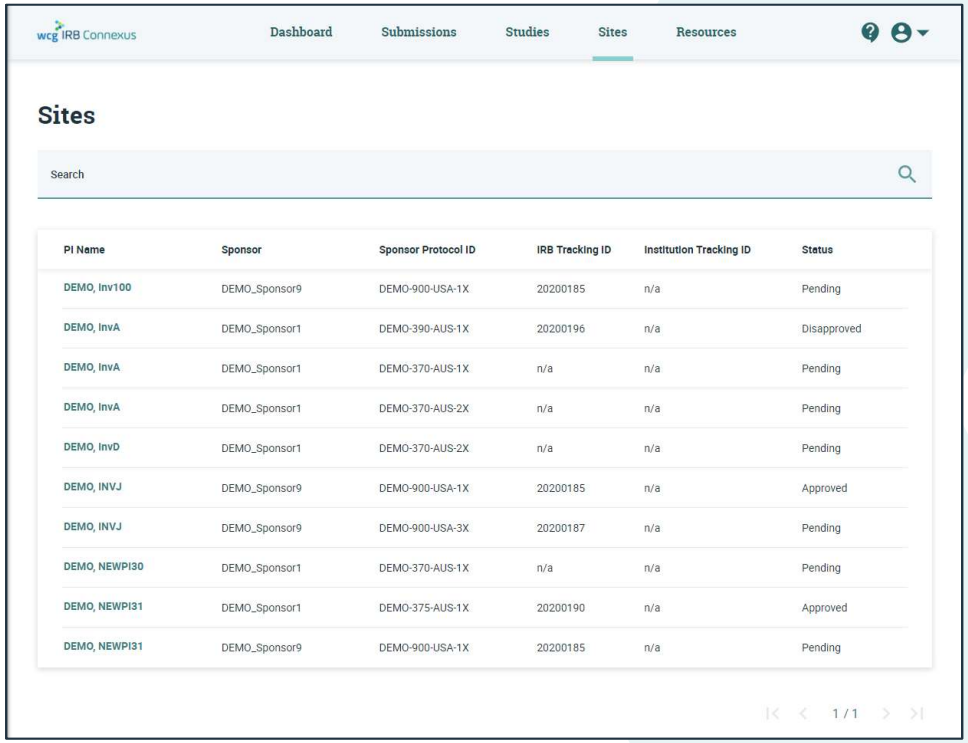
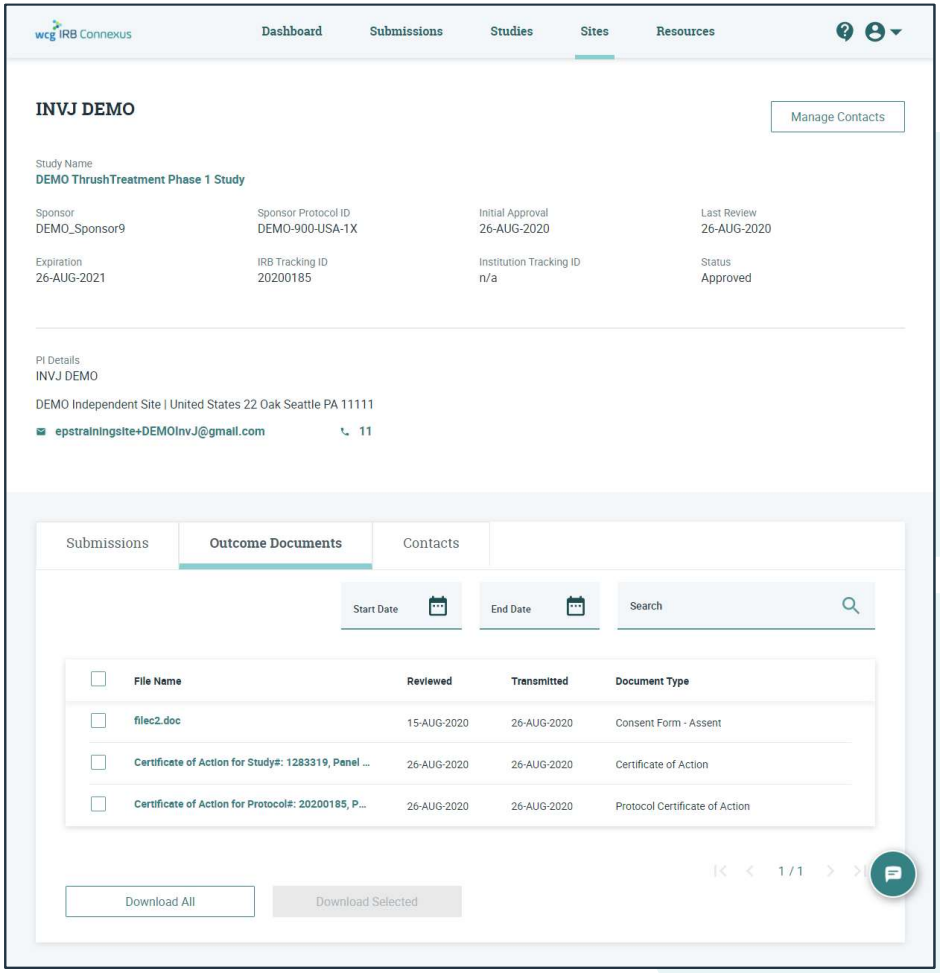
WCG IRB Connexus Sites (PIs) Landing Page

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



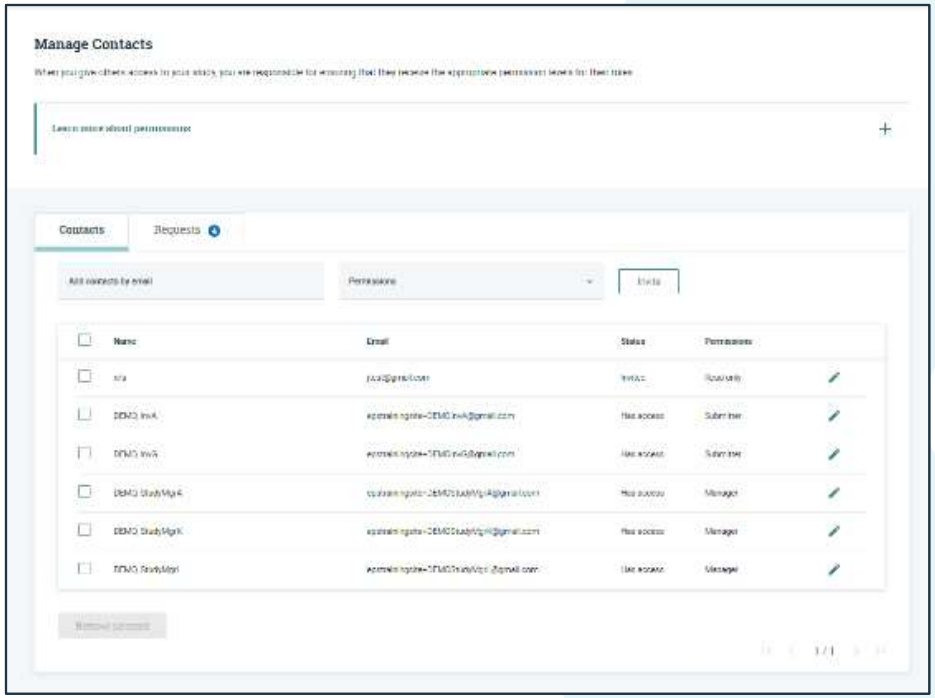
Site (PI) Details

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



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



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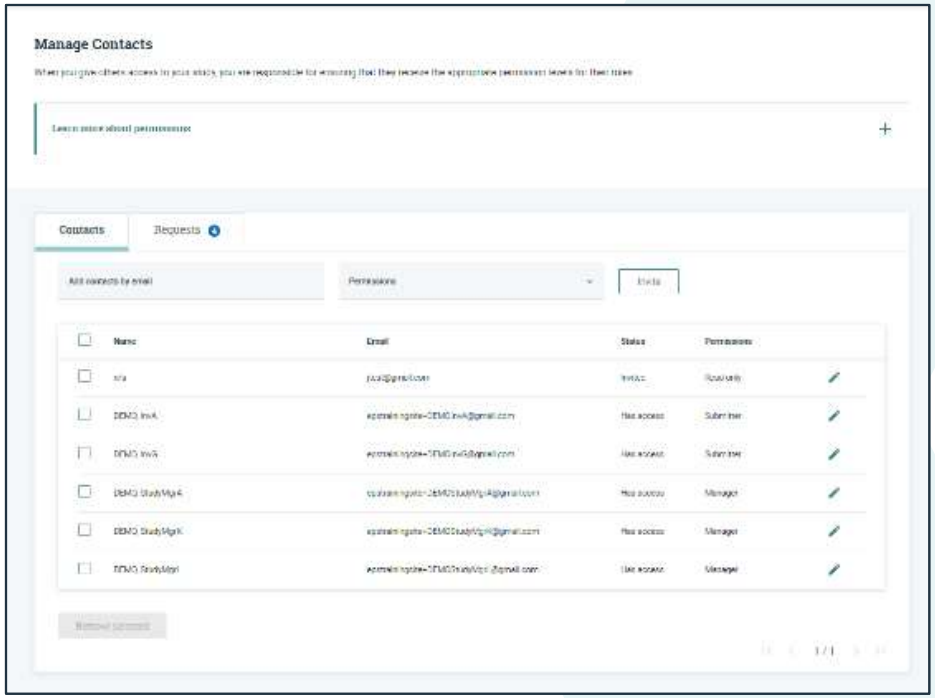
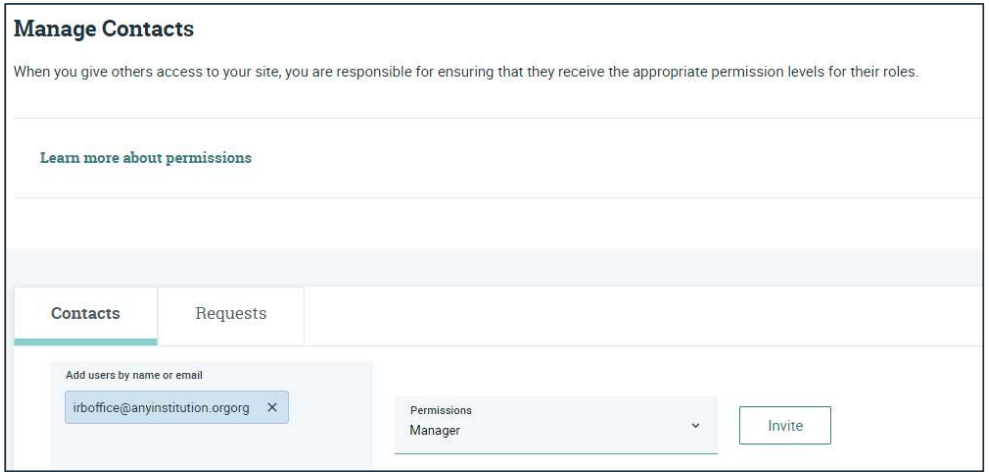


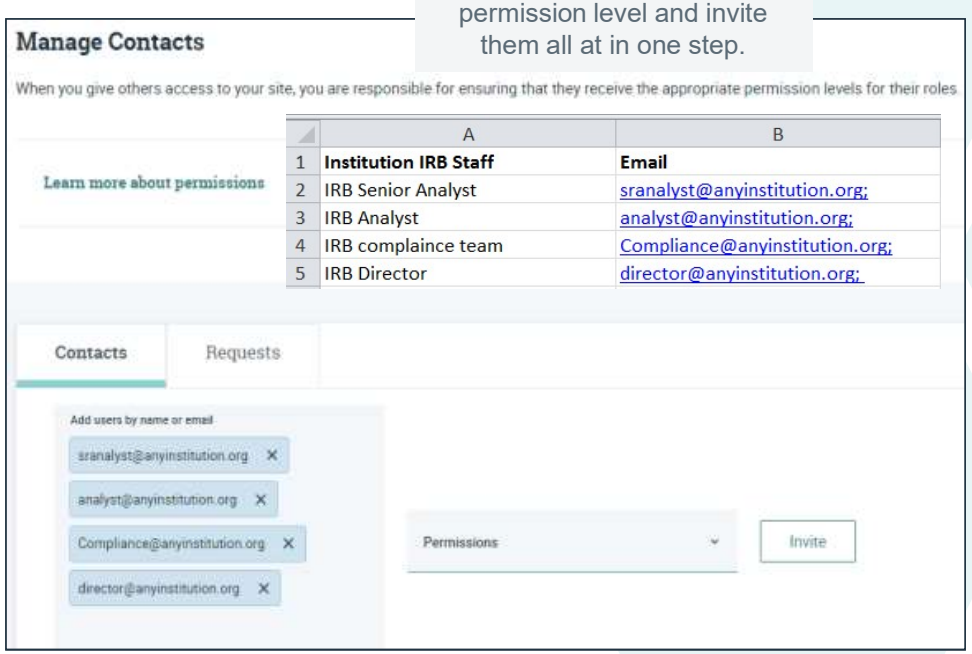
Manage Contacts

- 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.

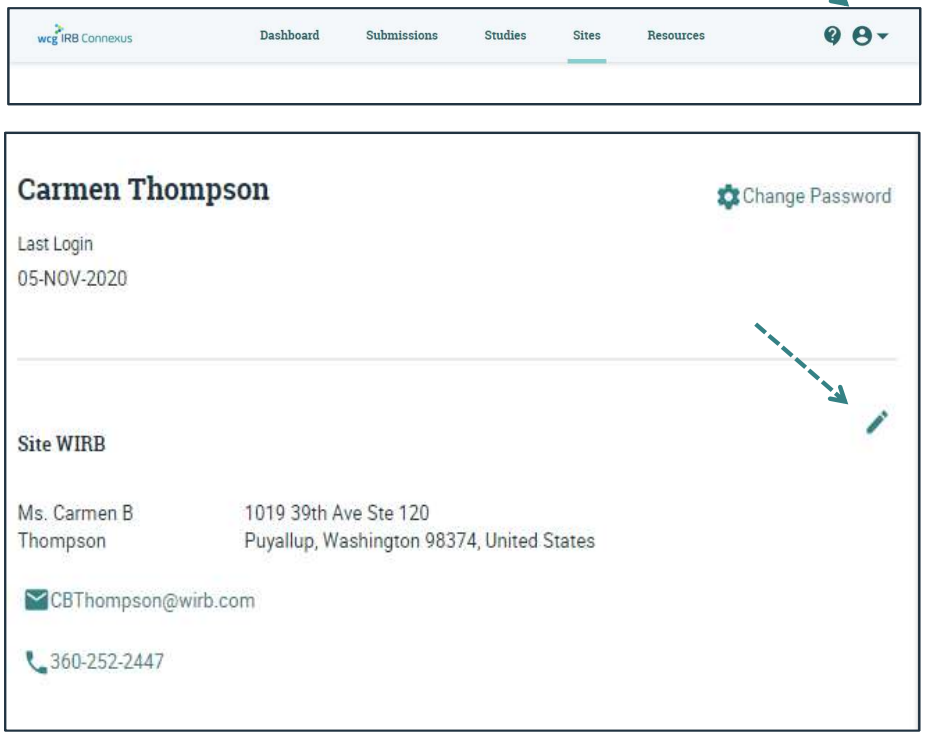


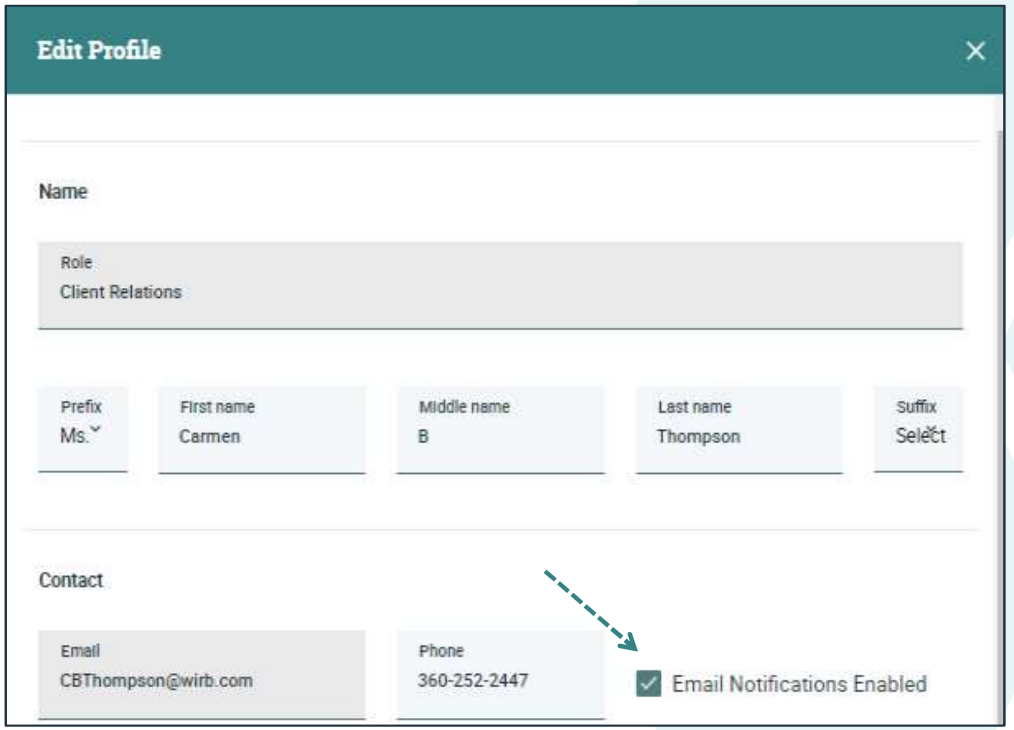


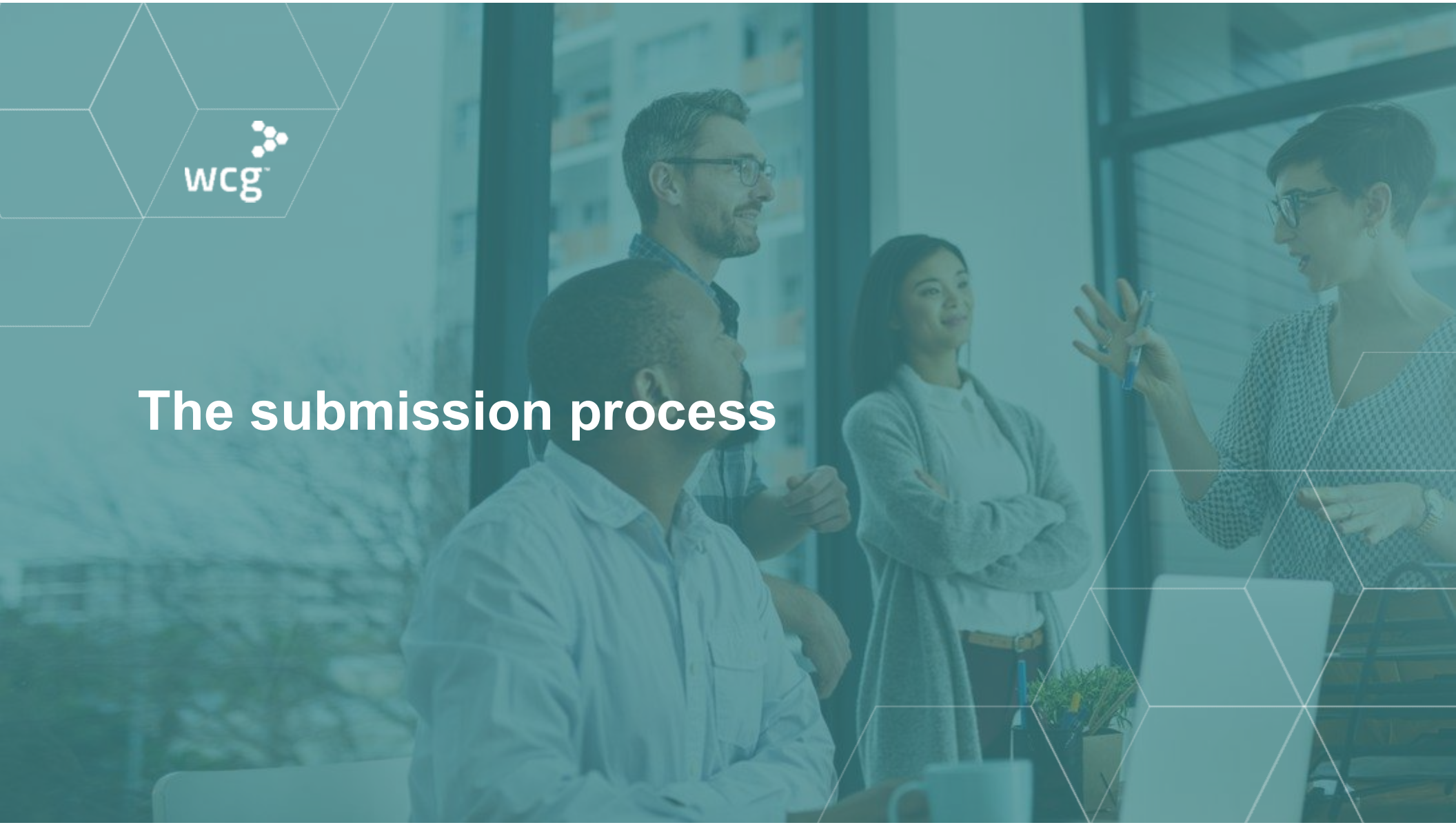
	A	B
1	**Institution IRB Staff**	**Email**
2	IRB Senior Analyst	sranalyst@anyinstitution.org;
3	IRB Analyst	analyst@anyinstitution.org;
4	IRB complaince team	Compliance@anyinstitution.org;
5	IRB Director	director@anyinstitution.org;

User Profile

To disable access request notifications:



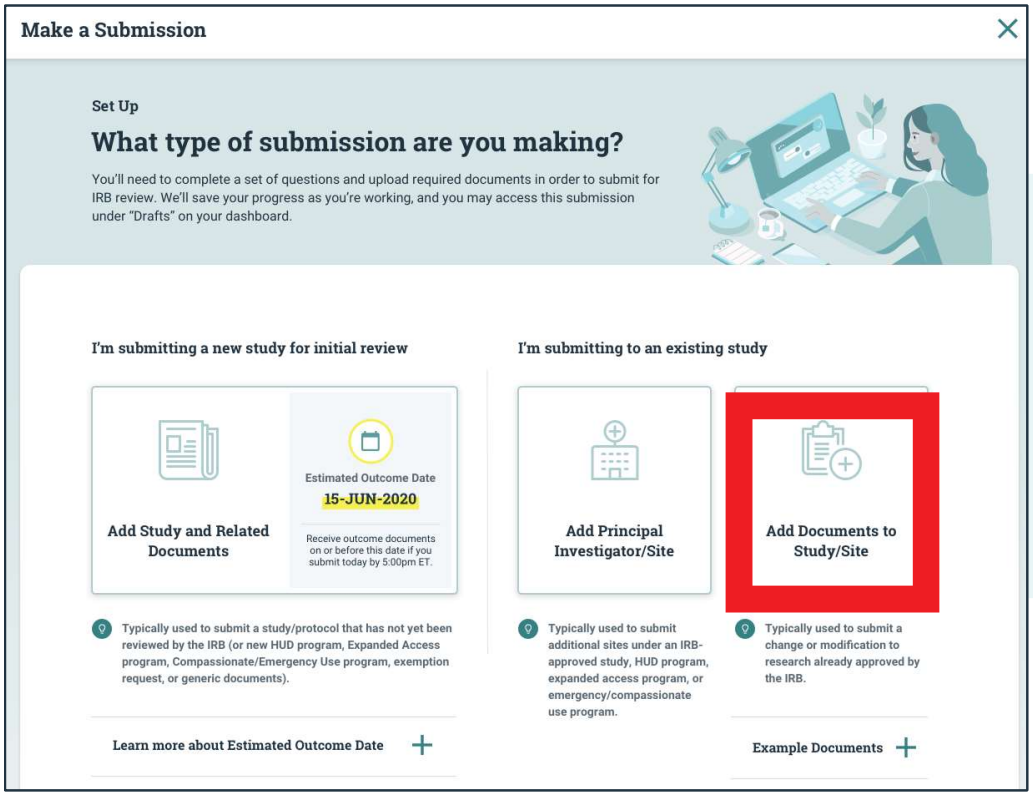




The submission process

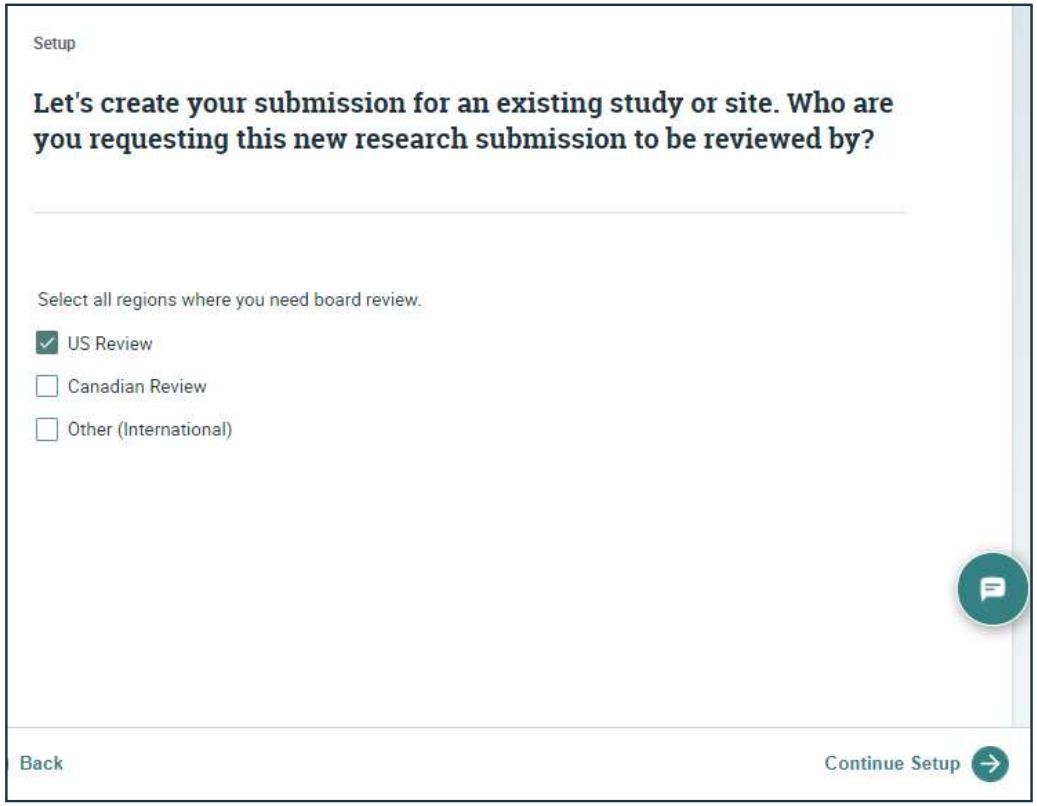
Make a Submission: Adding Documents to a Site

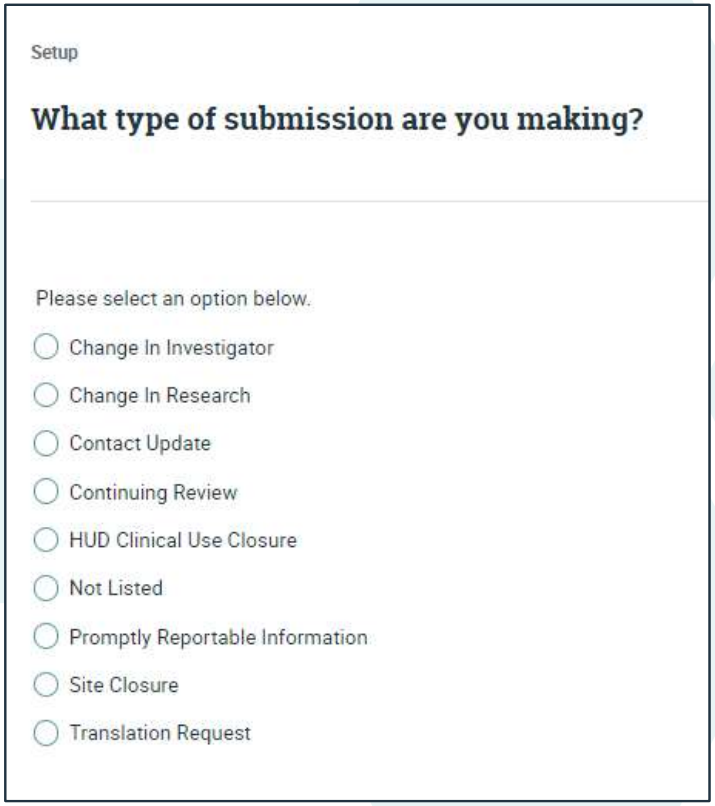
For making any change in research/modification to an already approved site, select below option:



Make a Submission: Adding Documents to a Site

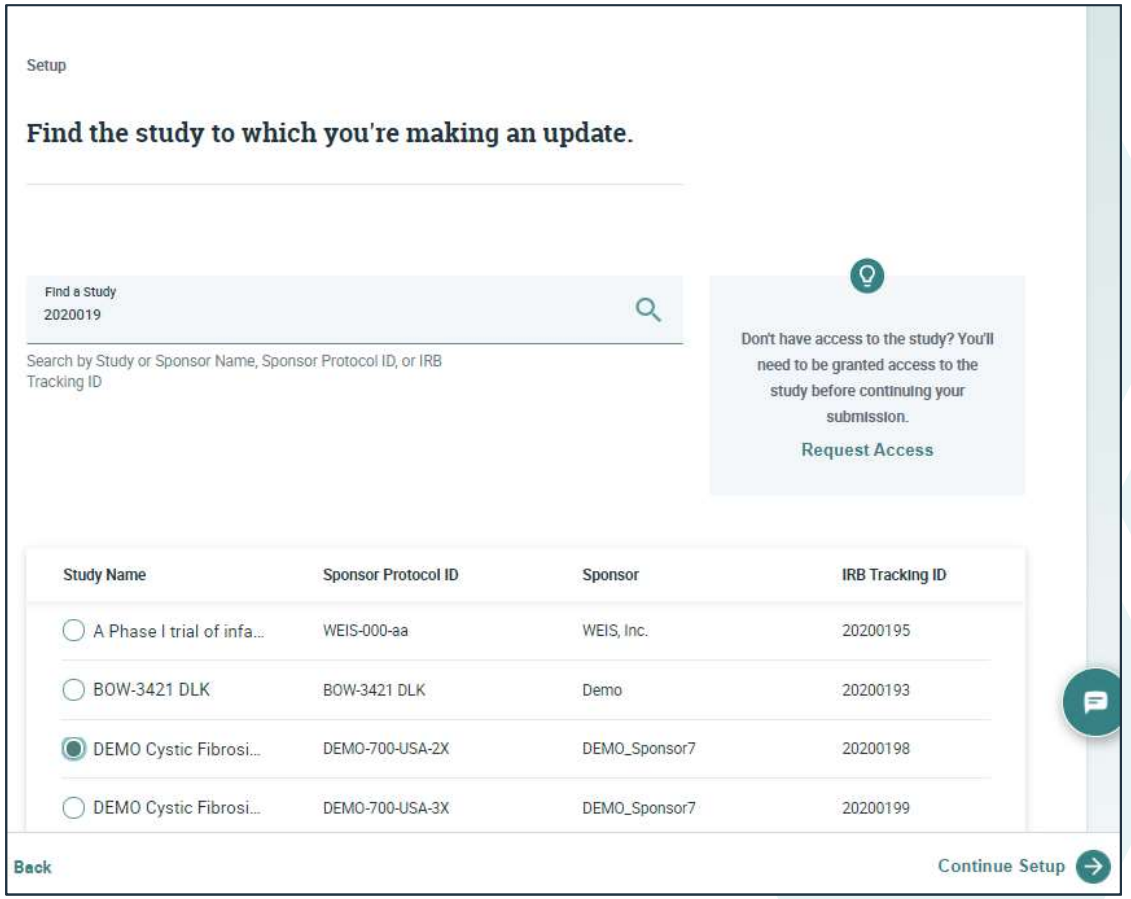
Begin the submission Setup and select the type of submission you are making:





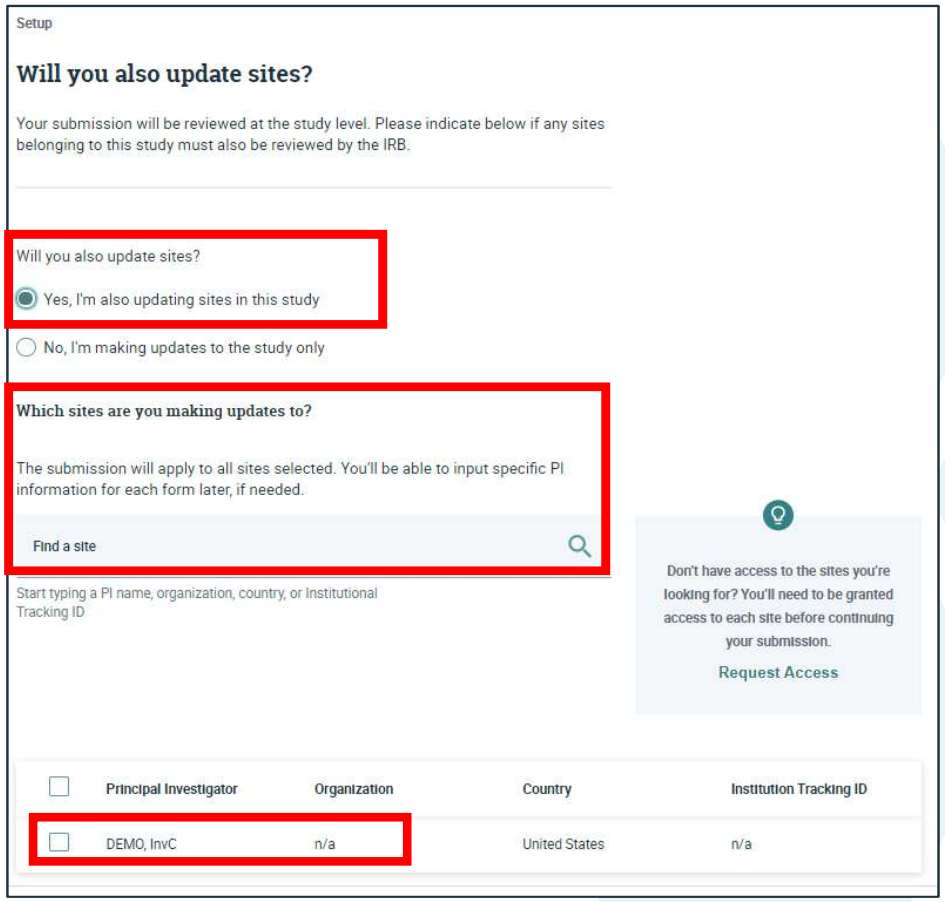
Make a Submission: Adding Documents to a Site

- All types of submissions will require you to enter the corresponding WCG IRB Tracking ID
- Study information will populate
- Select the appropriate study



Make a Submission: Adding Documents to a Site

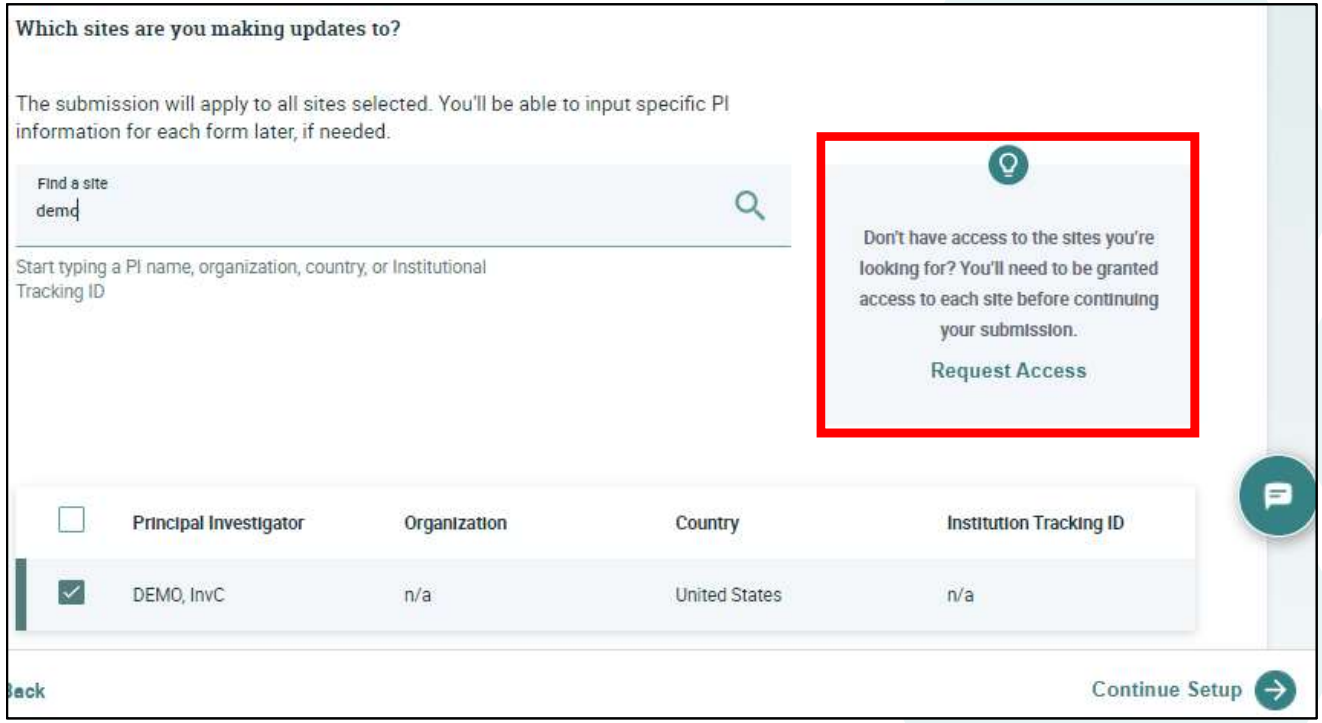
- Will you also update sites?
  - Yes, I'm also updating sites in this study
- Which sites are you making updates to?
  - Select the PI name



Make a Submission: Adding Documents to a Site

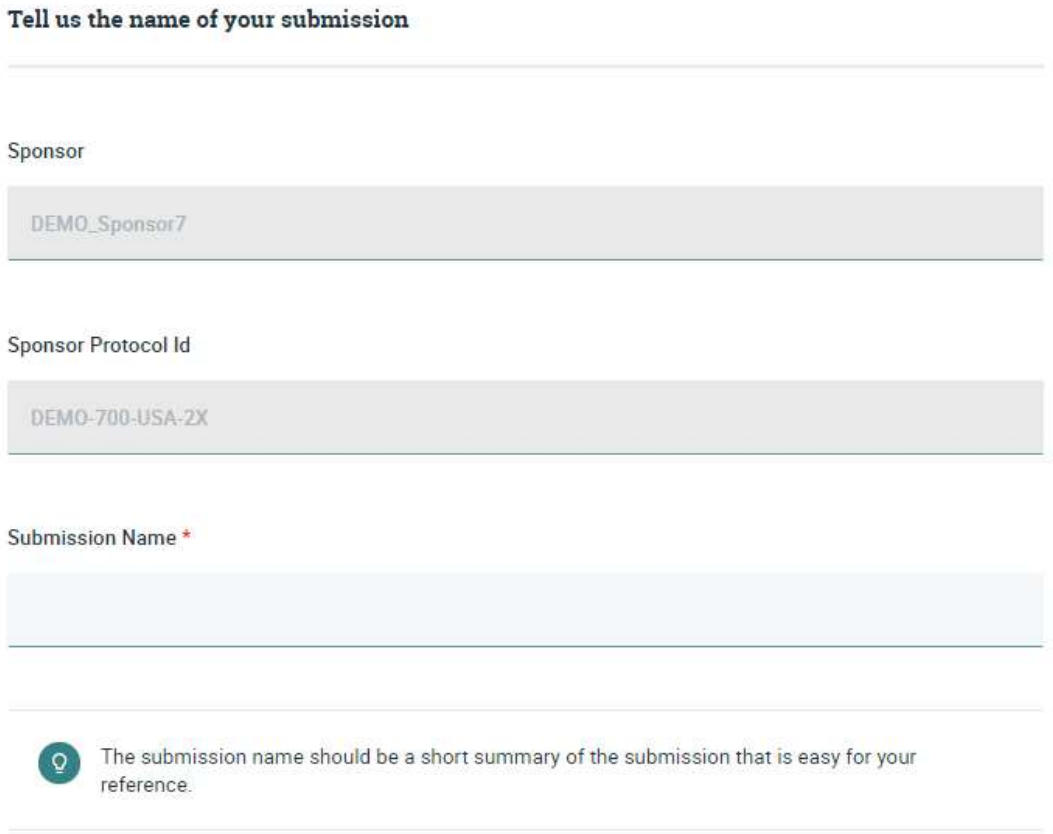
What if your PI is not listed for that IRB Tracking ID?

- You may not have access to the site workspace
- Use the Request Access button on the right
- Submit the Request
- Make the submission after you receive access granted email



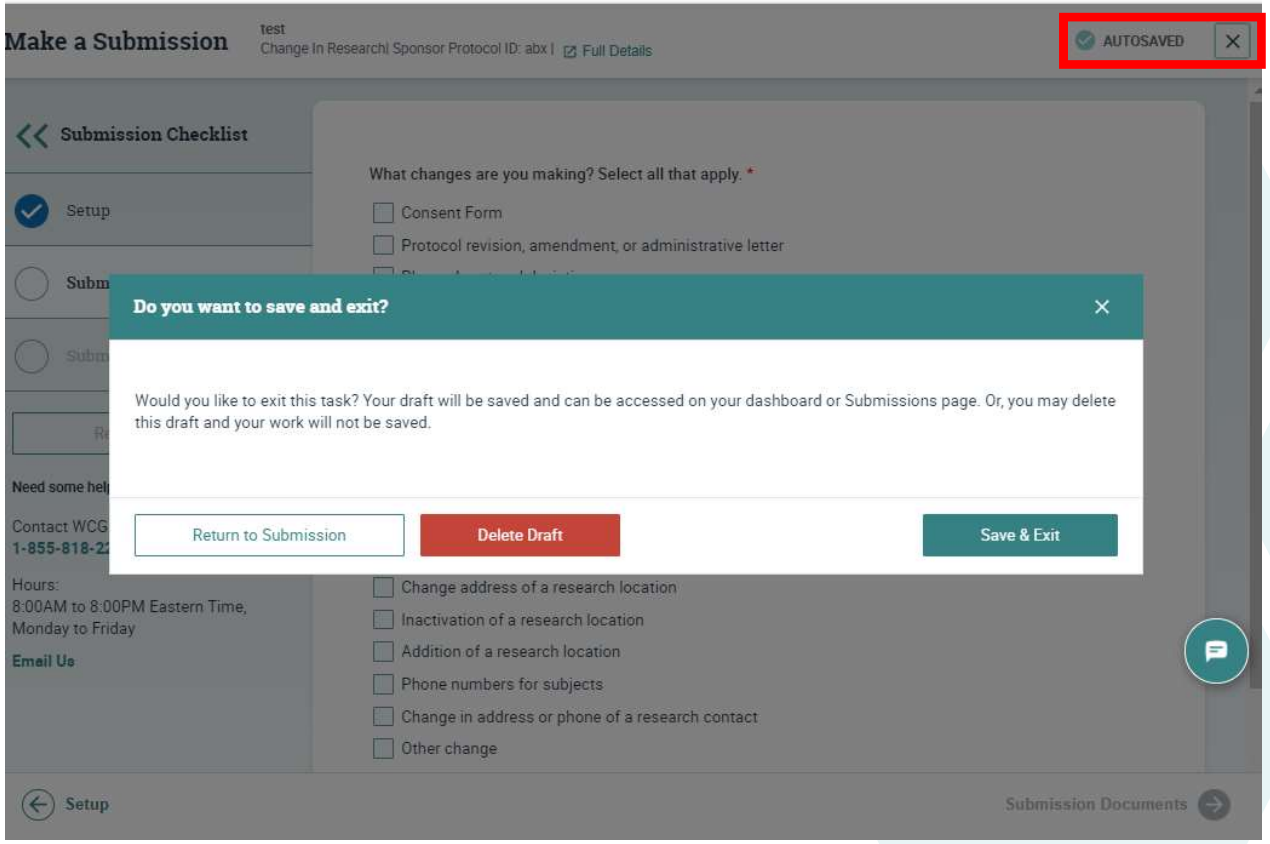
Make a Submission: Adding Documents to a Site

Give your submission a meaningful name



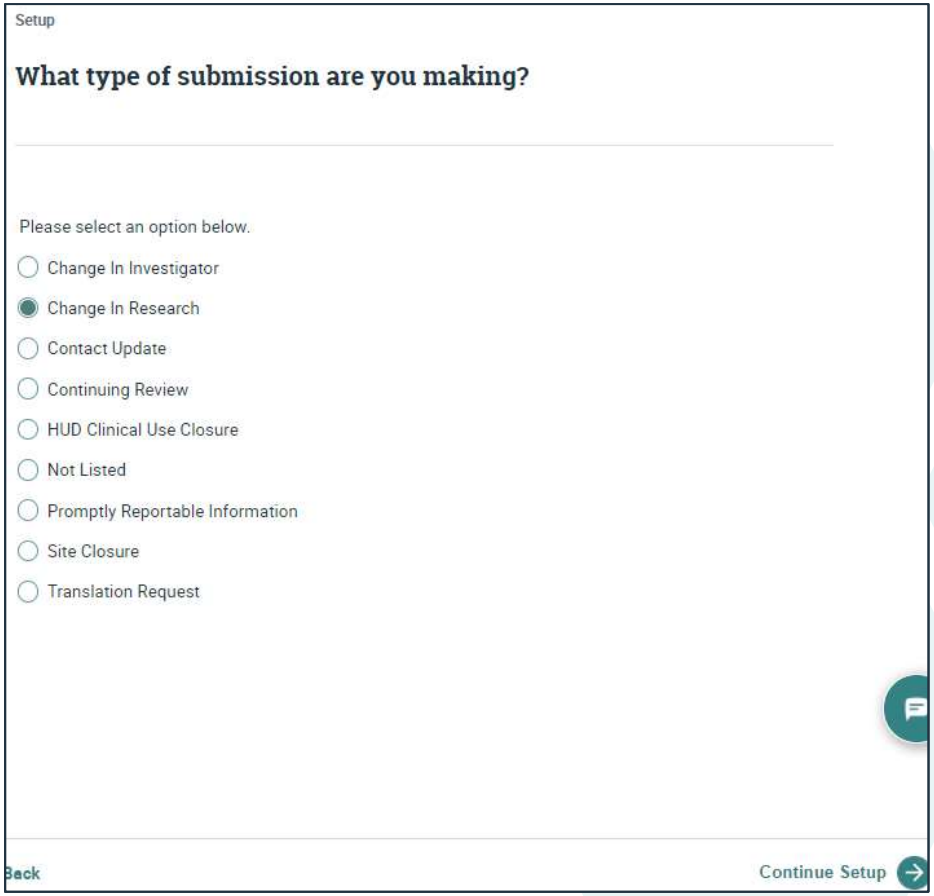
Make a Submission: Adding Documents to a Site

- Once you've set up your submission, it will be autosaved
- To exit the submission, click on the X on the top right
- Select the option carefully, drafts that are deleted cannot be retrieved
  - Return to submission
  - Delete draft
  - Save and exit to save a draft



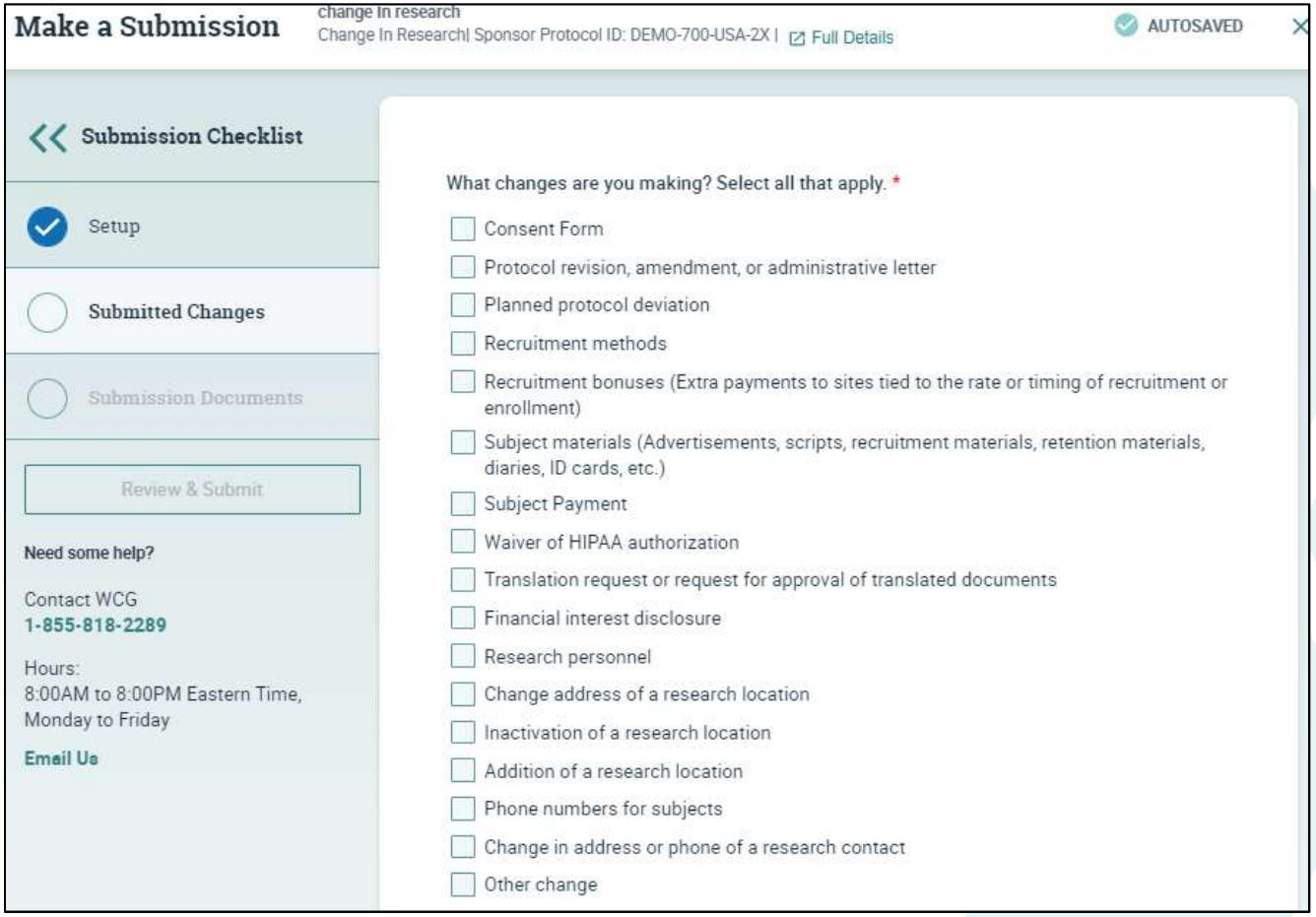
Make a Submission: Change in Research

Select the appropriate option and set up the submission



Make a Submission: Change in Research

- Select all changes you are submitting
- Additional questions will populate based on the type of submission being made



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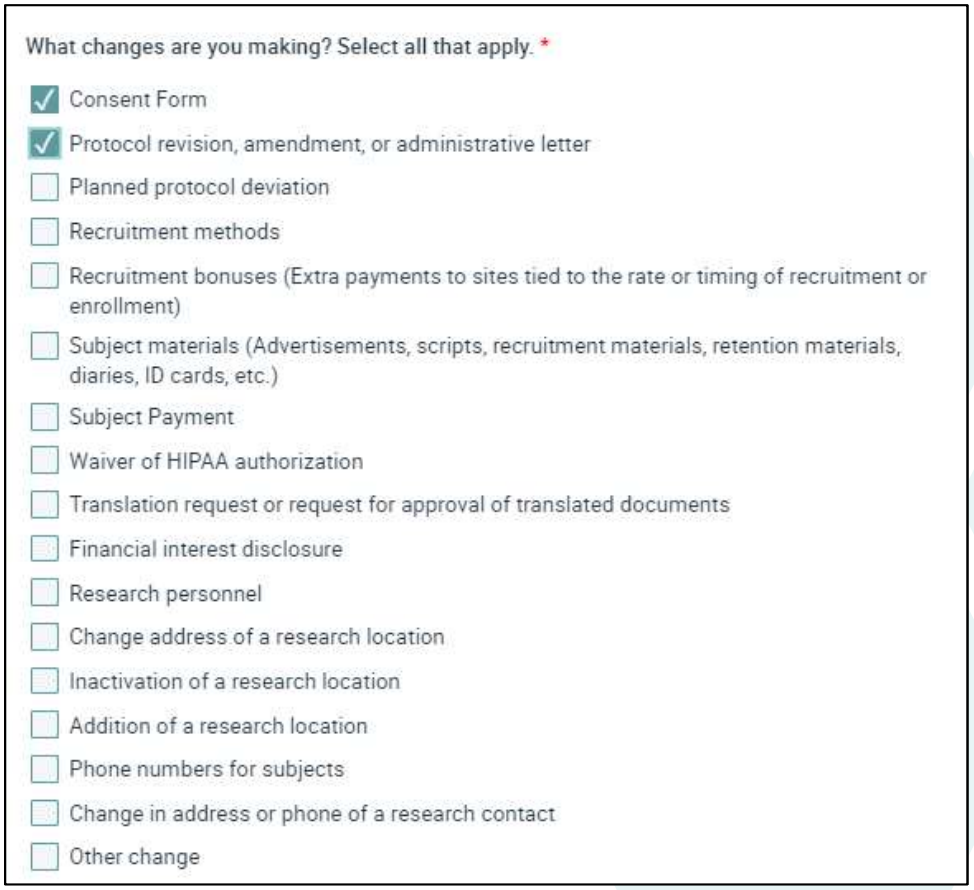
Make a Submission: Change in Research

Consent Form Modifications

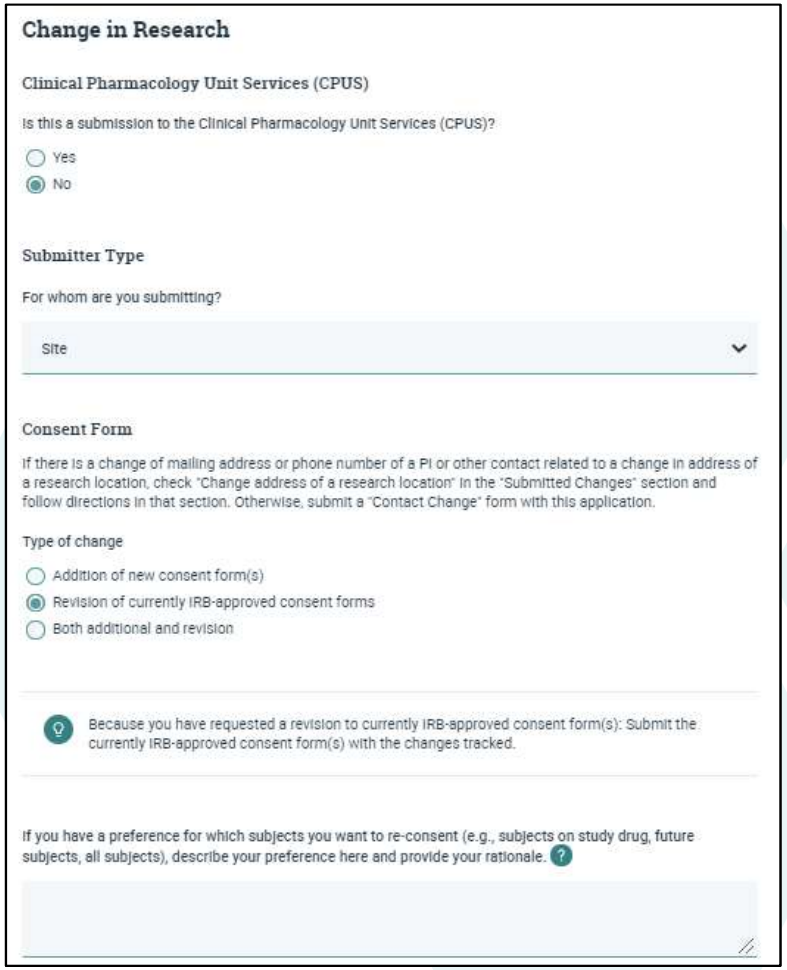
- CHLA initiated consent form modifications must have CHLA HSPP clearance before submitting to WCG IRB
- Submission for CHLA initiated consent form updates must include:
  - Updated language using tracked (redline) changes on the most current IRB approved version
- Changes initiated by the sponsor do not require CHLA clearance



Make a Submission: Change in Research

Consent Form Modifications

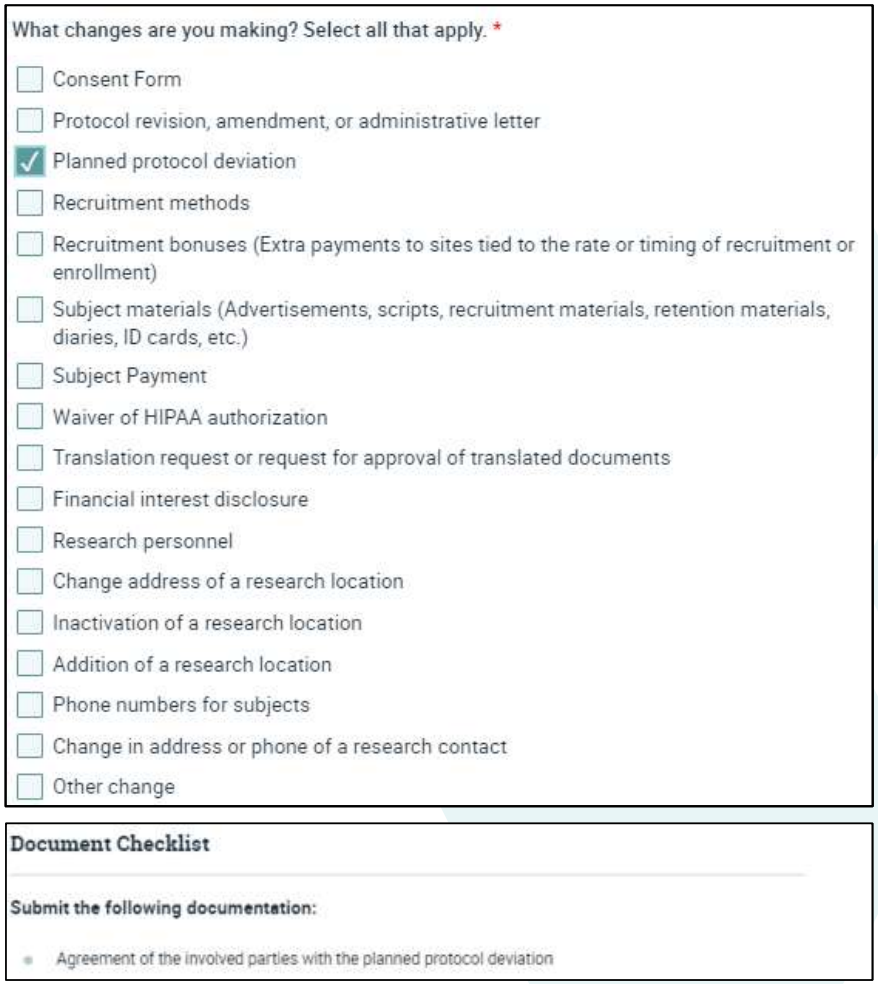
- Additional questions will populate based on the type of submission being made, complete as appropriate
- CPUS – always mark No
- Submitter Type – always select Site
- Complete the questionnaire
- Upload documents



Make a Submission: Change in Research

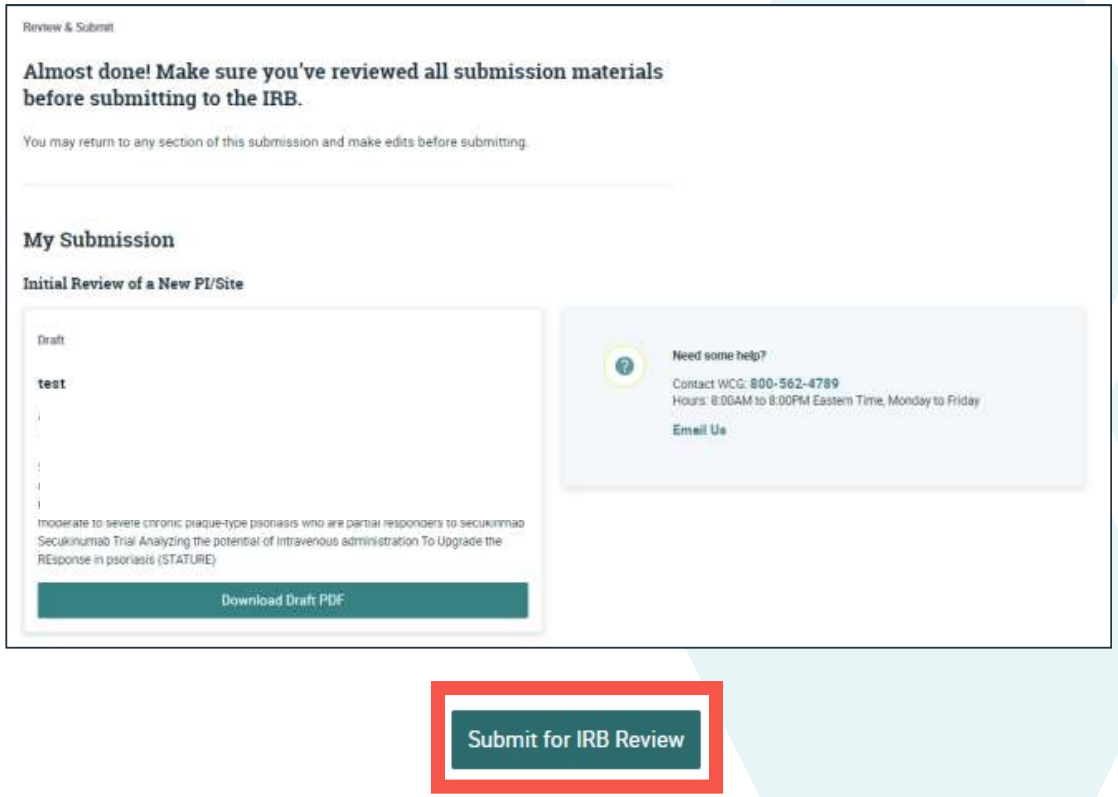
Planned Protocol Deviations

- Submitted as a change in research
- **Planned** protocol deviations must have IRB approval
- Allow 2-3 business days to process
- All parties must be in agreement, submit correspondence from PI and sponsor/CRO/monitor
- Complete the form and provide: Date of planned deviation, Description, How it deviates from the protocol, Reason for deviating from the protocol
- Upload documents



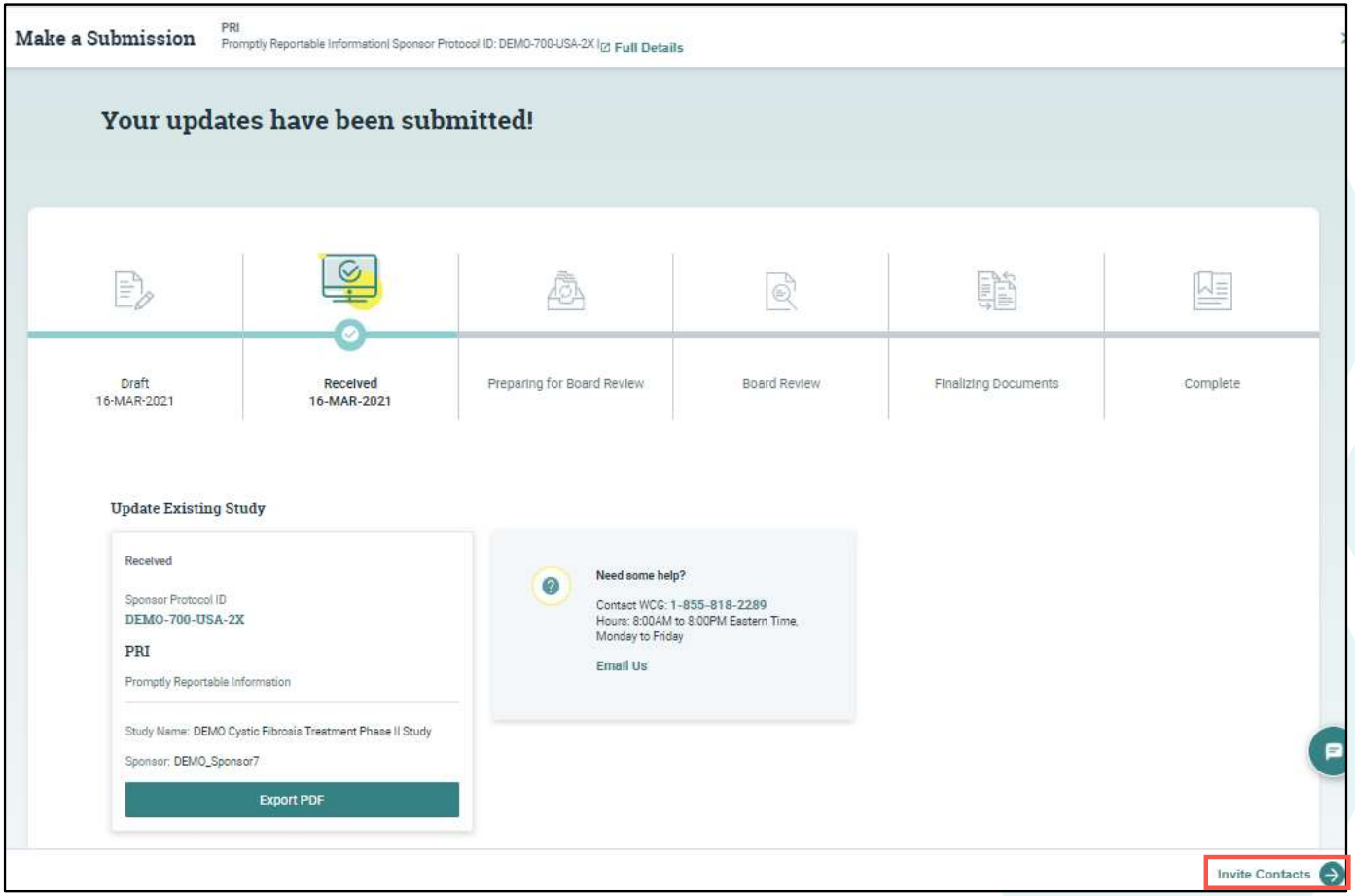
Make a Submission: Review & Submit

- The last step before you submit will allow you to download a PDF of your completed online form
- Check that all sections have been completed, if not, your submission could be put on hold for additional information or clarification
- Click “Submit for IRB Review” in the bottom right-hand corner of the screen to submit for IRB Review



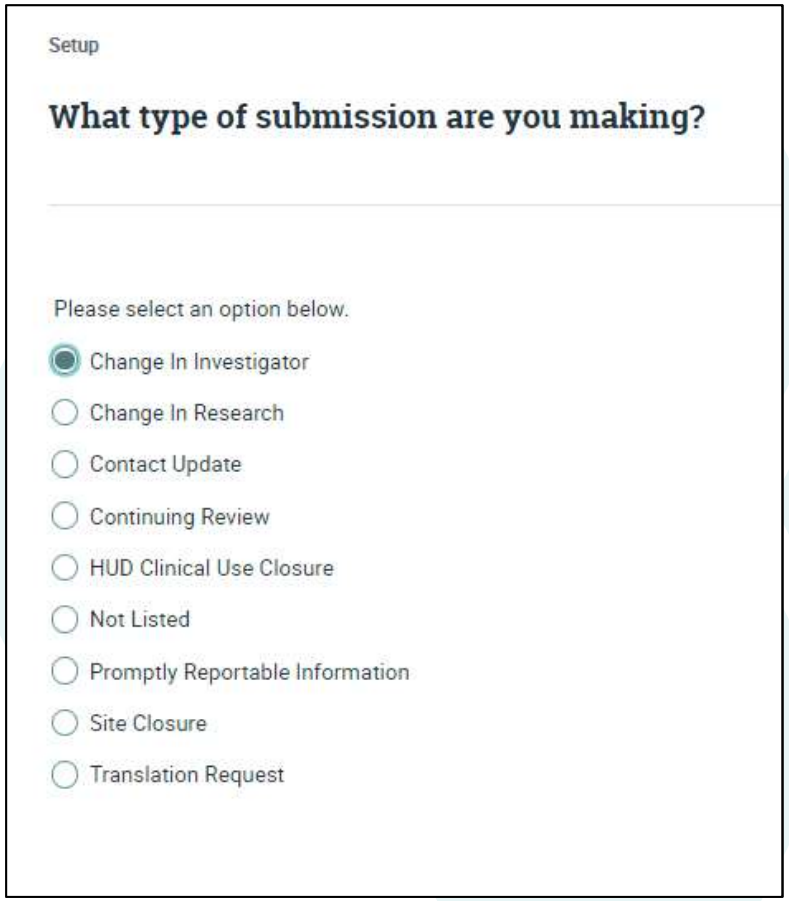
Make a Submission: Confirm and Share access

- A confirmation message will appear that your updates have 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



Make a Submission: Change in PI

- Select Change in Investigator
- Enter the IRB tracking ID
- Select the PI name
- Change in PI requires an initial review questionnaire for the new PI
- Follow the initial review submission process for CHLA to obtain CHLA HSPP clearance
- No consent form needs to be submitted unless there are changes to the IRB approved consent form other than PI contact information
- Sponsor confirmation of change in PI required
- Upload documents, review and submit



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Make a Submission: Translations

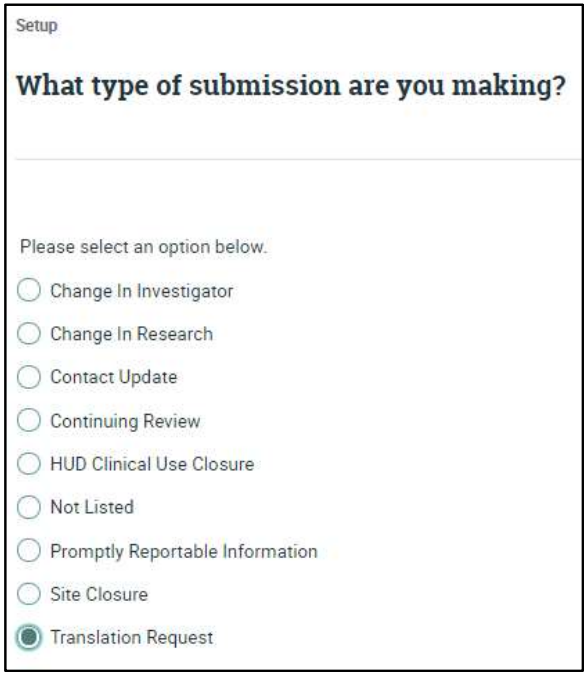
Translations

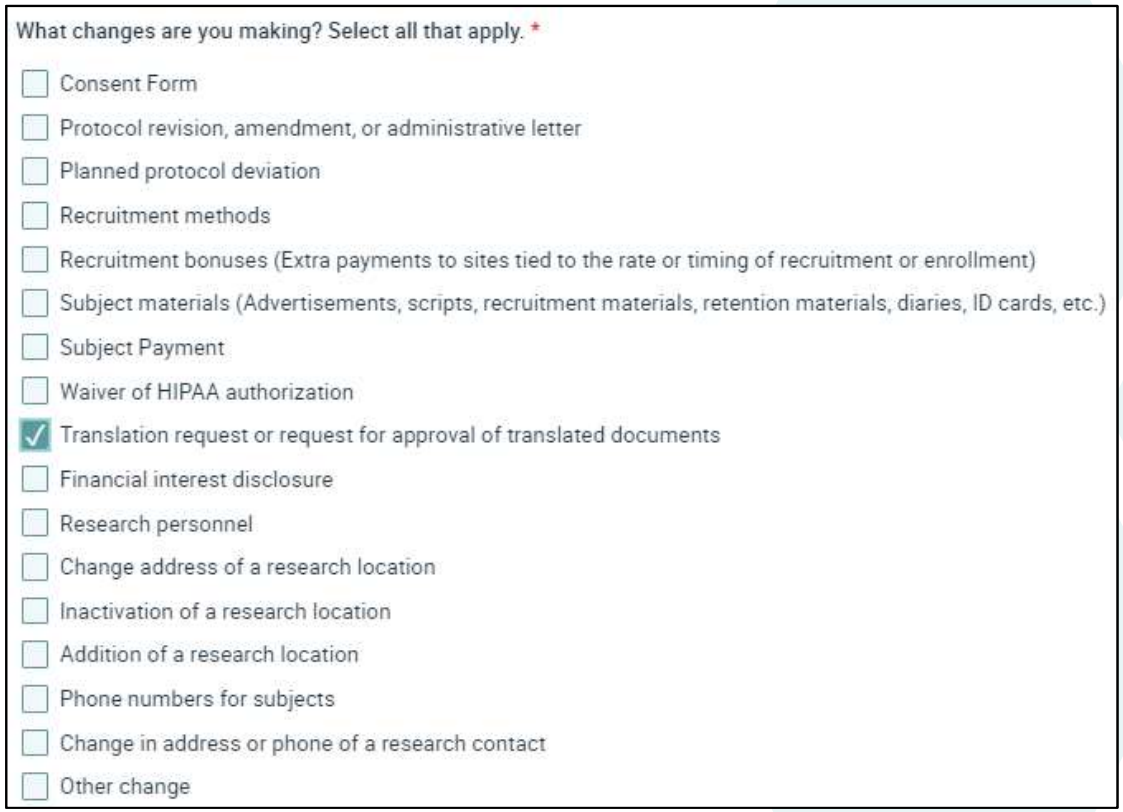
- All subject facing materials must have IRB approval before presenting them to the subject, including translated documents
- If you submit a document for review and translation, it will be approved first. After approval, the translation team will process the translation request.
- Check with your sponsor/CRO 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
- For WCG IRB translations:
  - Submit completed Translation request submission

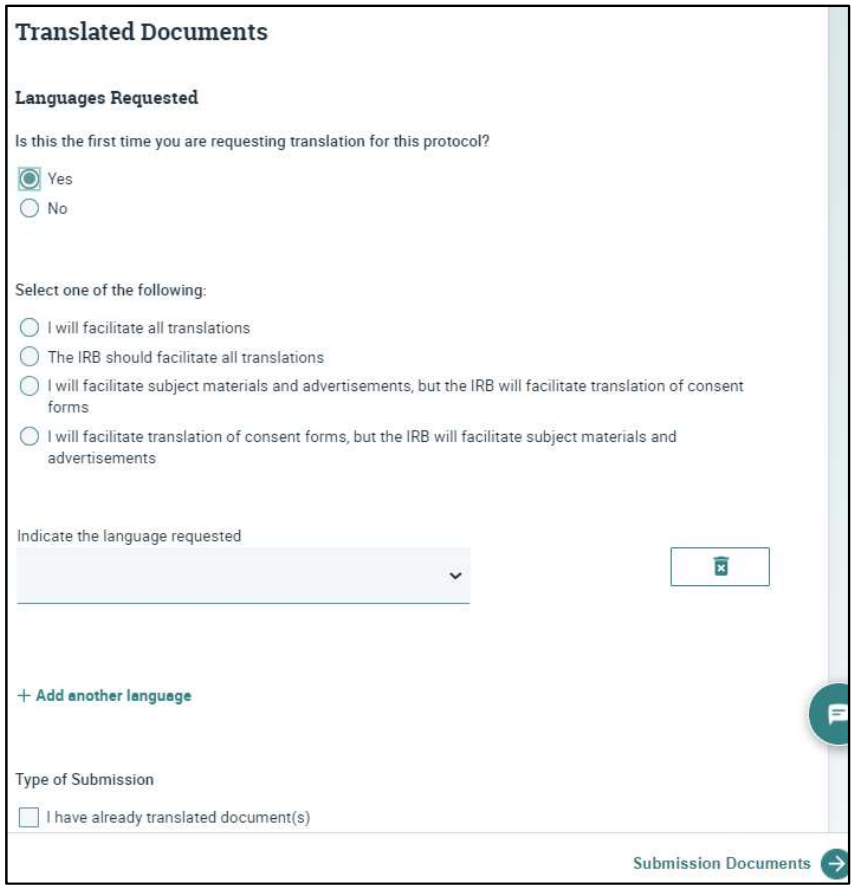
Make a Submission: Translations

Submit as a stand-alone translation request or as a change in research with additional changes.

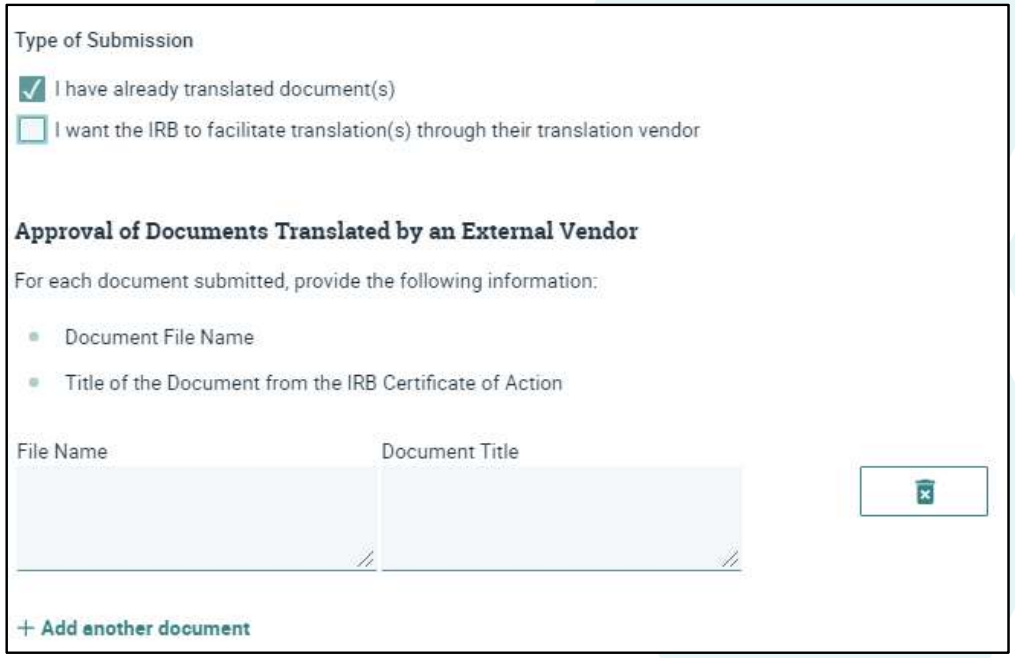




Make a Submission: Translations



Complete the questionnaire, upload documents, review and submit



After You Submit: What to Expect

- Processed by change in research, translations IRB staff. They may reach out if there are any clarifications or missing items after a few days of submission. They will begin to reference a work order number.
- The work order is then sent to Expedited Reviewer or to scheduling for Full Board review
- Once reviewed, the work order is sent to our post-Board team. They will prepare 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)
  - The documents that were reviewed
  - If a consent form update is approved, re-consenting instructions will be provided
- **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.

CHLA Requirement for Amendments

- **After receiving WCG IRB approval for an amendment:**
  - Determine if the WCG IRB approval contains updated consent/assent form(s) or updated CHLA specific documents
  - If yes: file an amendment in iStar when you receive a new approval letter and updated study documents
  - Upload: WCG IRB certificate of action, approved consent/assent form, site specific documents
  - If no: obtain the sponsor documents and update your regulatory binder. No need to create an amendment in iStar.

- **NOTE:** WCG does **not** transmit or publish proprietary sponsor documents (protocol documents, protocol support documents, IBs, DMSB reports, etc.)
- **IMPORTANT:** Develop a communication plan with the sponsor/CRO to ensure
  - How your team will obtain protocol documents
  - If submissions will be made by them for your site

Make a Submission: Continuing Review

- Select continuing review
- Enter the IRB tracking ID
- Select the PI name
- Upload the completed continuing review report form (CRRF)
- Review and submit

Continuing Review: What to Expect

- All Site expiration dates are aligned to the protocol expiration date
- Sites approved less than 90 days prior to the protocol expiration date will be advanced to the new continuing review period automatically
- Continuing review reports are emailed to all study contacts about 80 days before the expiration date
- Processed by ongoing review IRB staff. They may reach out if there are any clarifications on the CRRF. They will begin to reference a work order number.
- The work order is sent for review once all sites and the protocol progress report are received, within 30 days of the expiration date
- Once reviewed, the work order is sent to our post-Board team. They will prepare add any Board language and finalize your approval documents within 1-2 days.

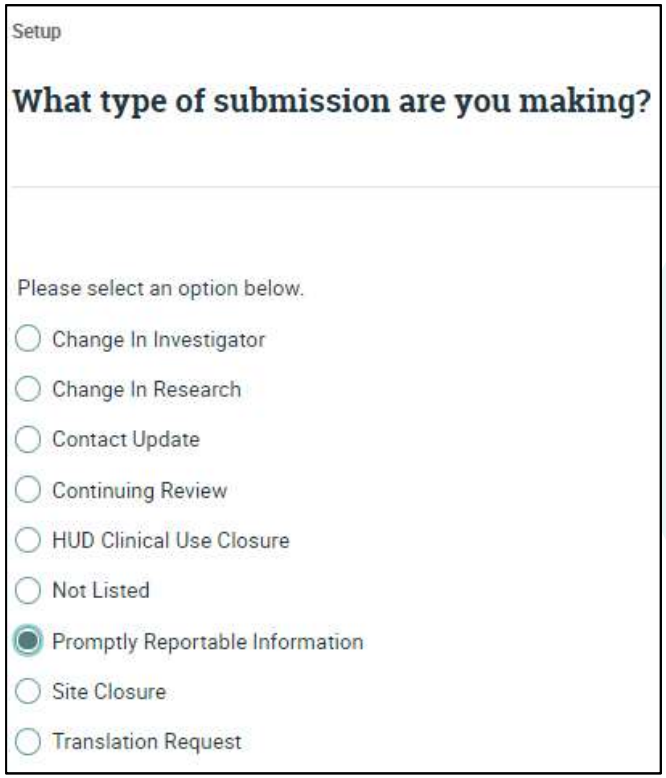
- All users with access will receive an email when outcome documents have been posted to Connexus in the Outcome documents tab
- You will receive a Certificate of Action (COA):
  - Board Action Date (Review Date)
  - Expiration Date (if approved)
- **Review your COA!**
- WCG IRB communicates Board actions via a COA. If there are additional Board requirements (ie. a report was not received), there will be instructions on the COA.

CHLA Requirement

- Create an amendment in iStar and upload your continuing review certificate of action

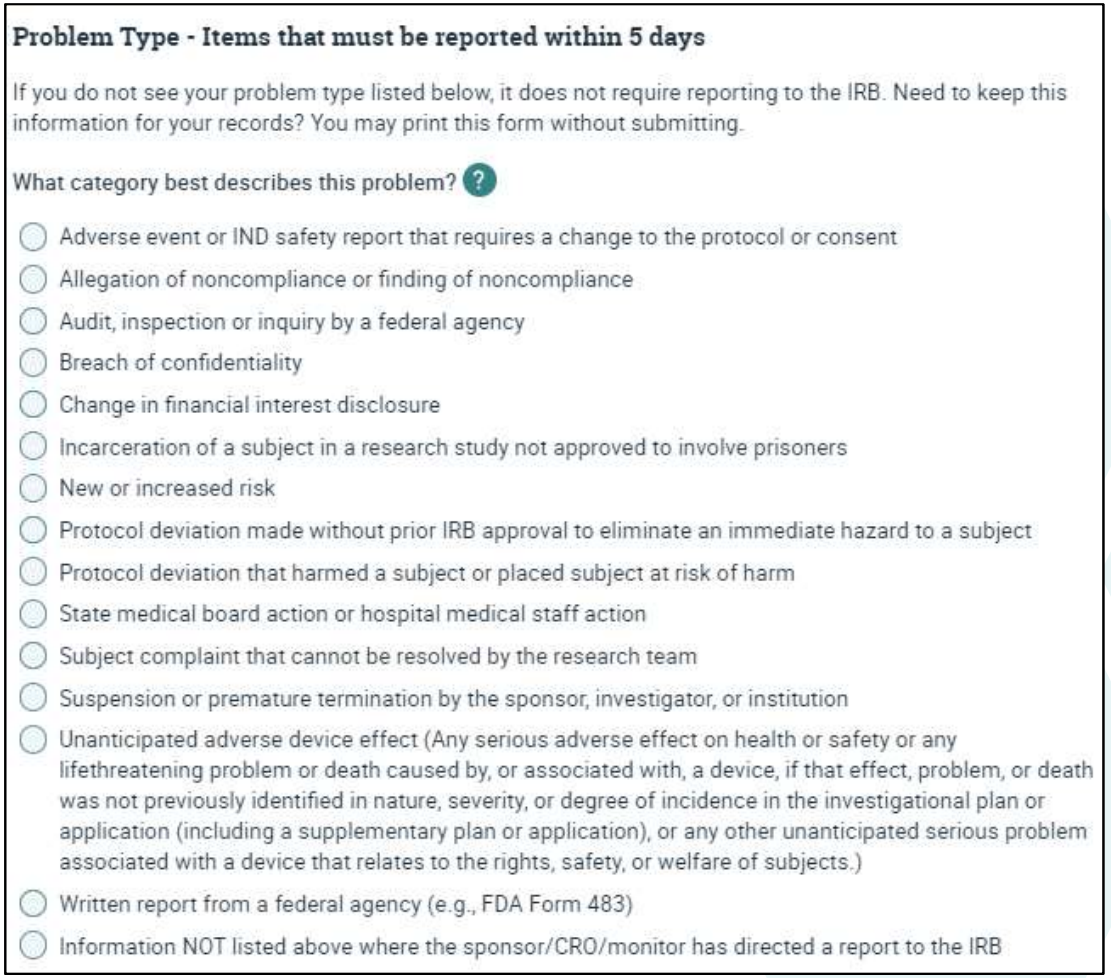
Make a Submission: Promptly Reportable Information

- Select Promptly Reportable Information
- Enter the IRB tracking ID
- Select the PI name
- Begin to complete the form: Type (Site), VA (No), select the problem being reported



Make a Submission: Promptly Reportable Information

- Select the problem being reported
- One option per form/submission



Problem Type - Items that must be reported within 5 days

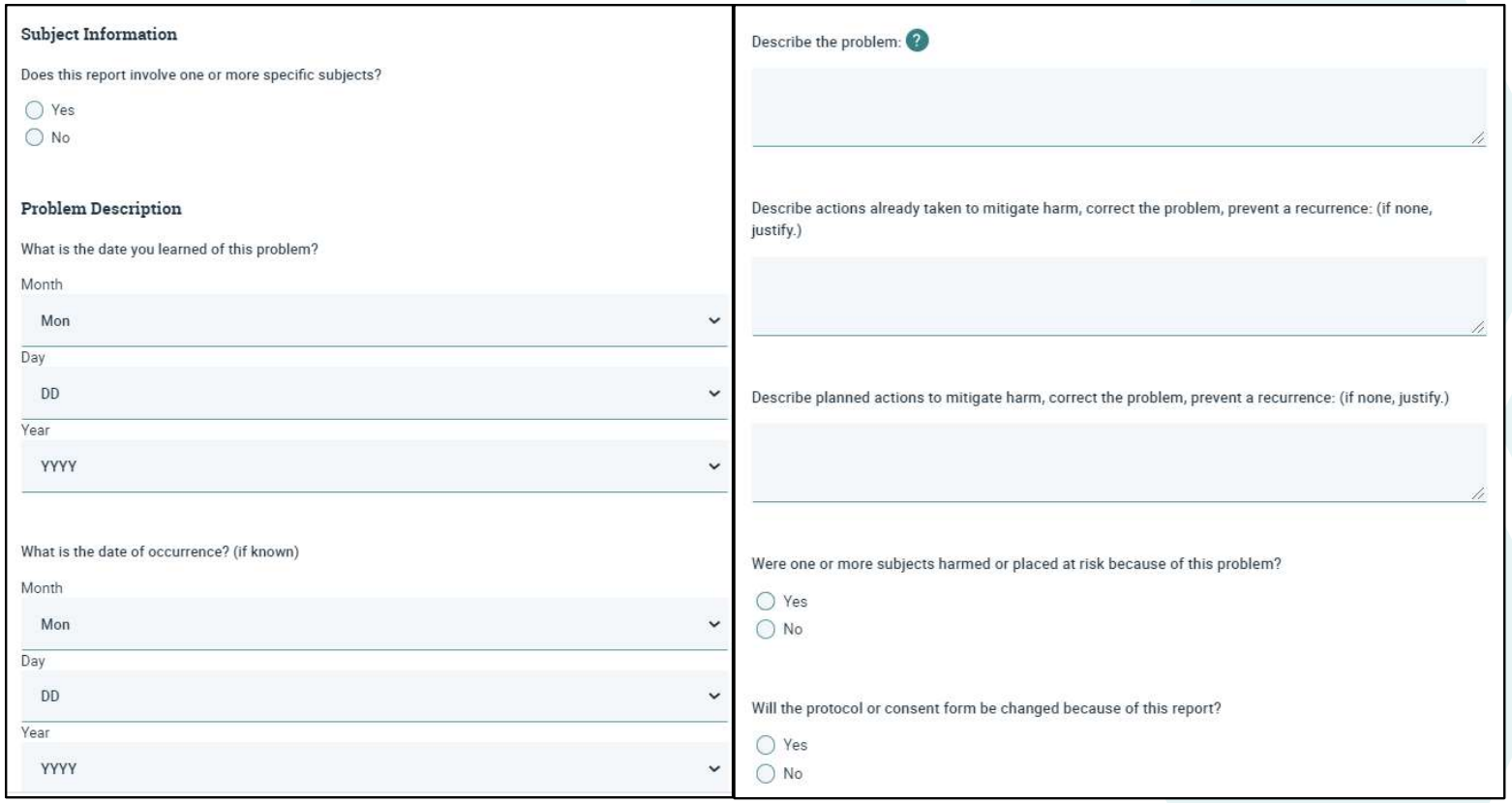
If you do not see your problem type listed below, it does not require reporting to the IRB. Need to keep this information for your records? You may print this form without submitting.

What category best describes this problem? ?

- ○ Adverse event or IND safety report that requires a change to the protocol or consent
- ○ Allegation of noncompliance or finding of noncompliance
- ○ Audit, inspection or inquiry by a federal agency
- ○ Breach of confidentiality
- ○ Change in financial interest disclosure
- ○ Incarceration of a subject in a research study not approved to involve prisoners
- ○ New or increased risk
- ○ Protocol deviation made without prior IRB approval to eliminate an immediate hazard to a subject
- ○ Protocol deviation that harmed a subject or placed subject at risk of harm
- ○ State medical board action or hospital medical staff action
- ○ Subject complaint that cannot be resolved by the research team
- ○ Suspension or premature termination by the sponsor, investigator, or institution
- ○ Unanticipated adverse device effect (Any serious adverse effect on health or safety or any lifethreatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.)
- ○ Written report from a federal agency (e.g., FDA Form 483)
- ○ Information NOT listed above where the sponsor/CRO/monitor has directed a report to the IRB

Make a Submission: Promptly Reportable Information

- Complete the form:
  - Date of discovery
  - Date of occurrence
  - Full description of the problem
  - Actions taken place to prevent recurrence
  - Planned actions to prevent recurrence
- Upload documents, review and submit

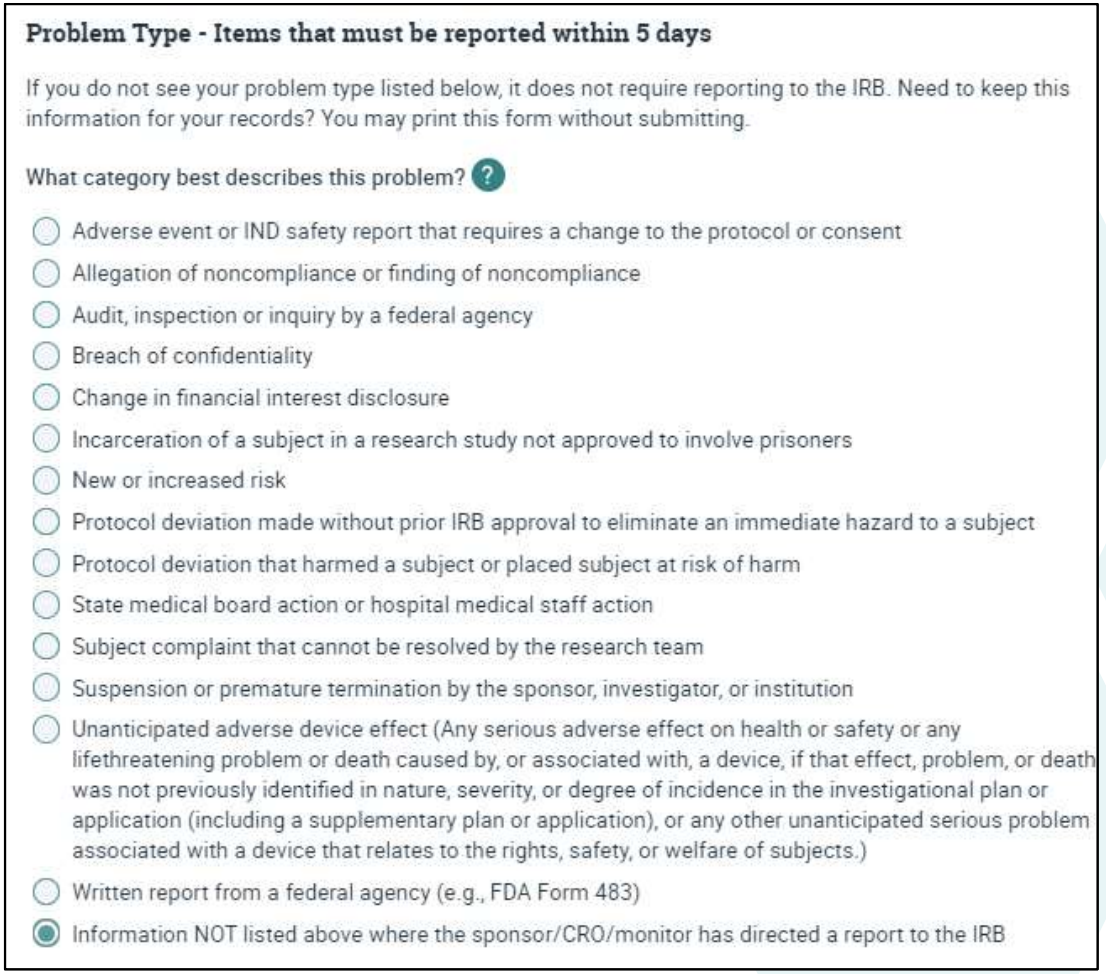


wcg IRB

Make a Submission: Promptly Reportable Information

What if the problem is not listed?

- If the sponsor/CRO/monitor is requiring submission to the IRB, select the last option
- It does not our prompt reporting requirement, information can be noted, filed. May be submitted at continuing review if it pertains to questions on the continuing review report form



Problem Type - Items that must be reported within 5 days

If you do not see your problem type listed below, it does not require reporting to the IRB. Need to keep this information for your records? You may print this form without submitting.

What category best describes this problem? ?

- ○ Adverse event or IND safety report that requires a change to the protocol or consent
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- ○ Written report from a federal agency (e.g., FDA Form 483)
- ◉ Information NOT listed above where the sponsor/CRO/monitor has directed a report to the IRB

Promptly Reportable Information Submission:

What to Expect

- WCG IRB will review the report and if significant or need more information, communicate with the appropriate parties
- If we find that the event does not constitute an increased risk to subjects and there are no remaining subject safety concerns, we will file the submission without action
- If the sponsor/CRO requires documentation that the event was reported to the IRB, you can provide them the Connexus acknowledgment of receipt
- If the sponsor/CRO needs documentation that the event was filed, contact the WCG Client Care Center

What is Expected of you

CHLA Requirements

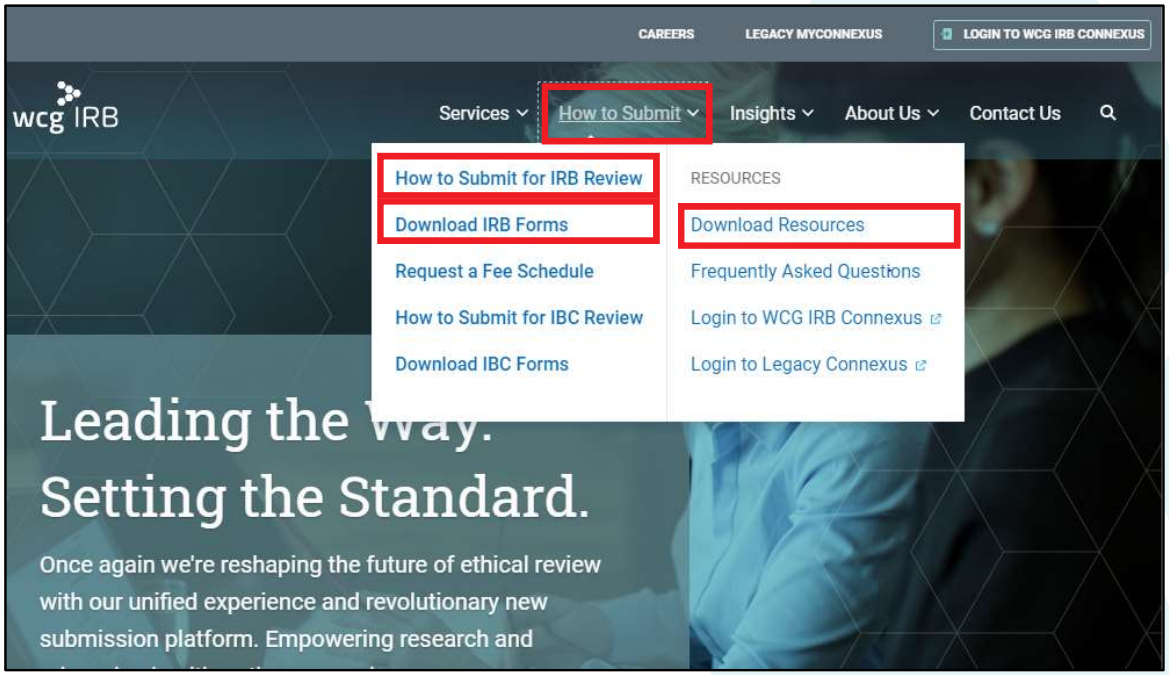
- After submitting your promptly reportable information form to WIRB, send the report by email to the CHLA HSPP office to irbreliance@chla.usc.edu
- DO NOT create and submit a reportable event submission in iStar.

After You Submit: What to Expect

IRB Resources

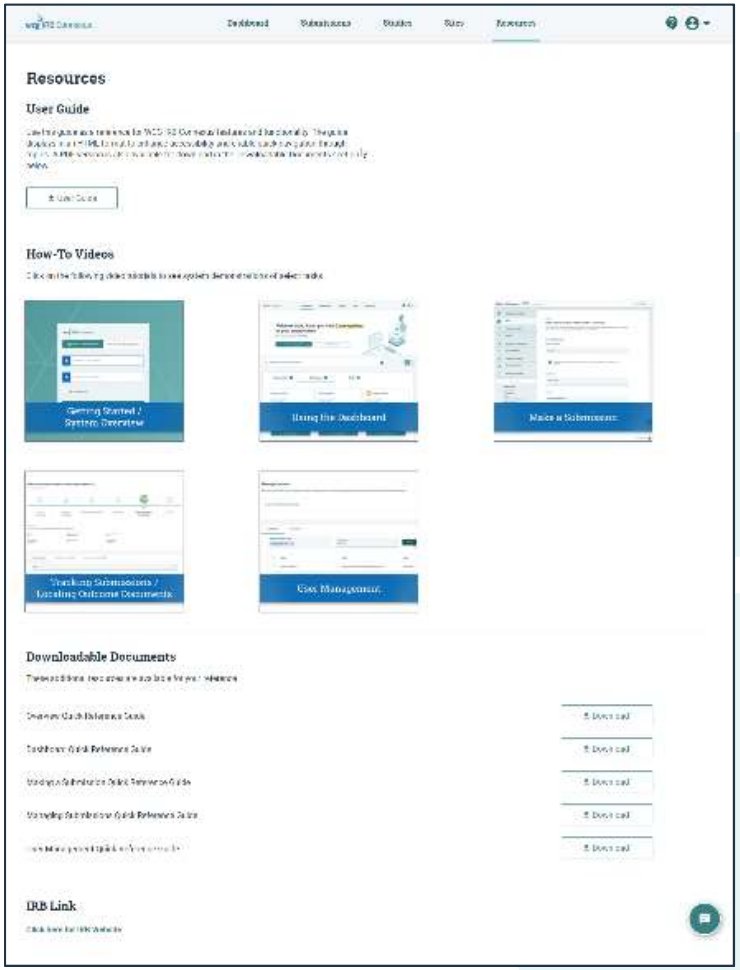
CHLA Study Teams are responsible for ensuring the all WCG IRB requirements are met

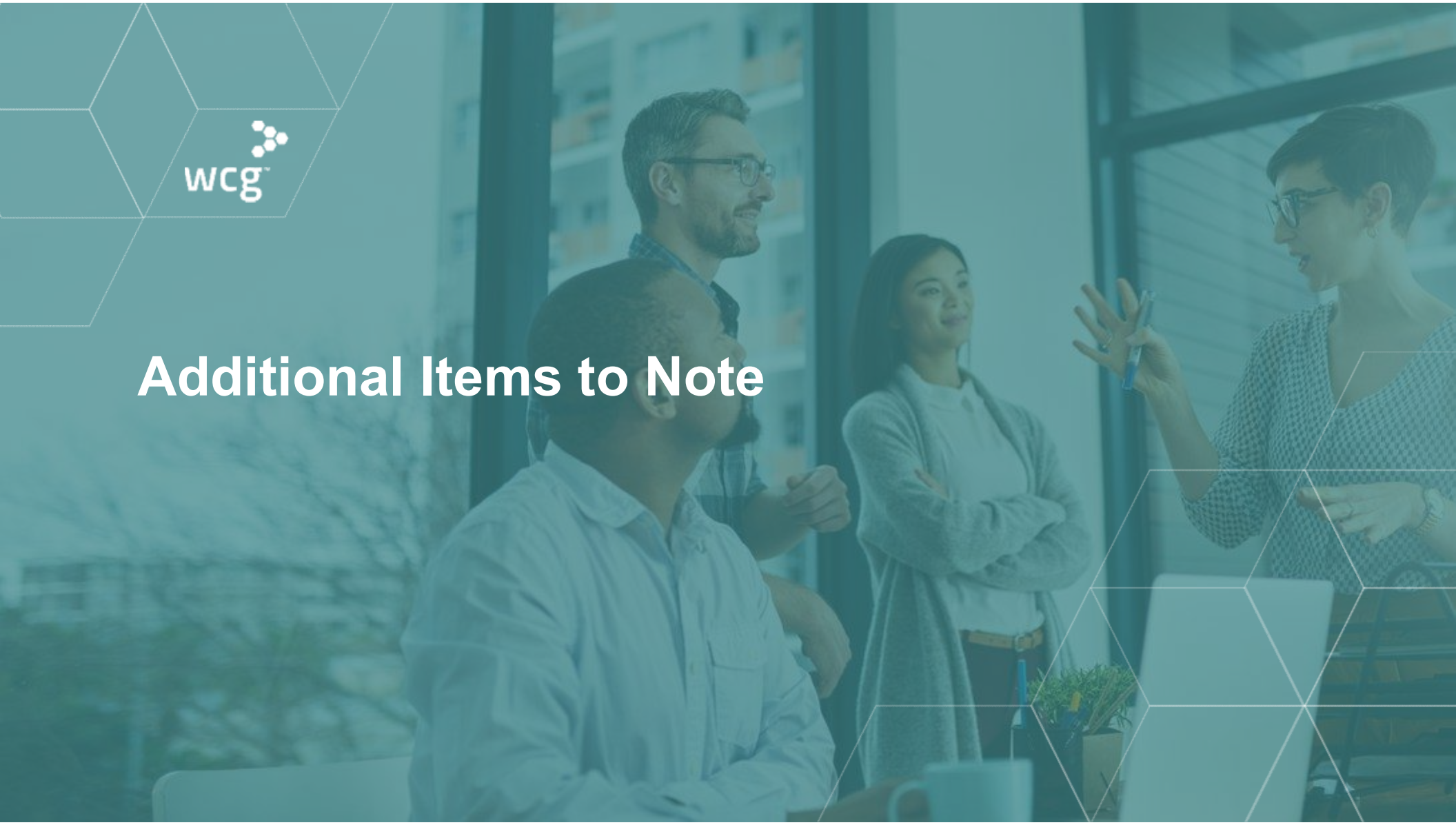
- Certificate of Action lists PI/site responsibilities
- Download IRB Forms
  wcgirb.com -> How to Submit -> Download IRB Forms
  - Guide for Researchers
  - Submission Form, Misc Forms
- Download Resources
  wcgirb.com -> How to Submit -> Download Resources
  - Investigator Guidance – Investigator Obligations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



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

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 transitioning 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:

Client Care Center

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

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Thank You