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

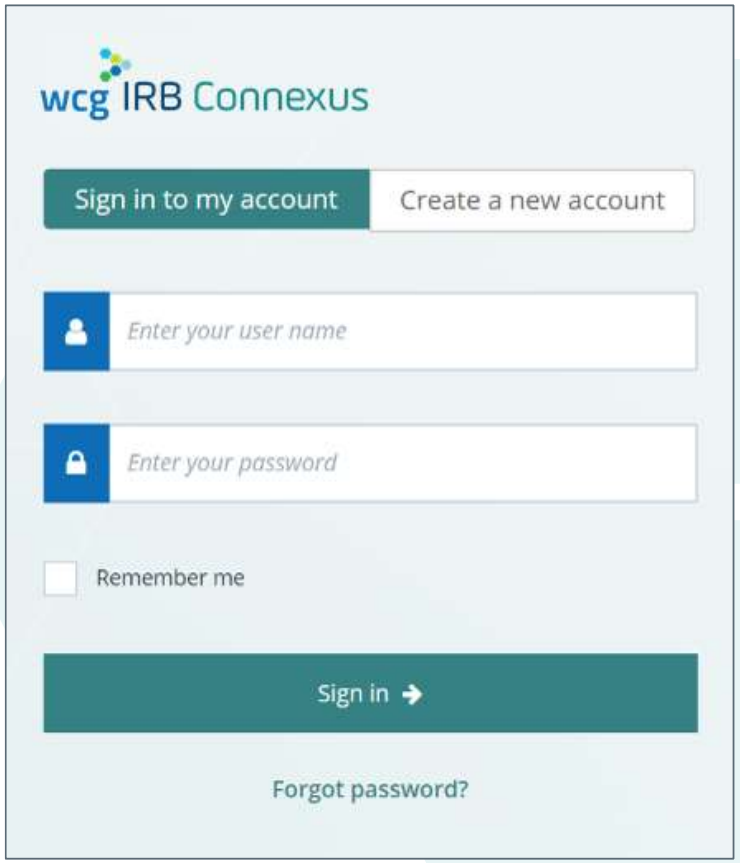
System Access & Signing In

System Access

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

Signing In

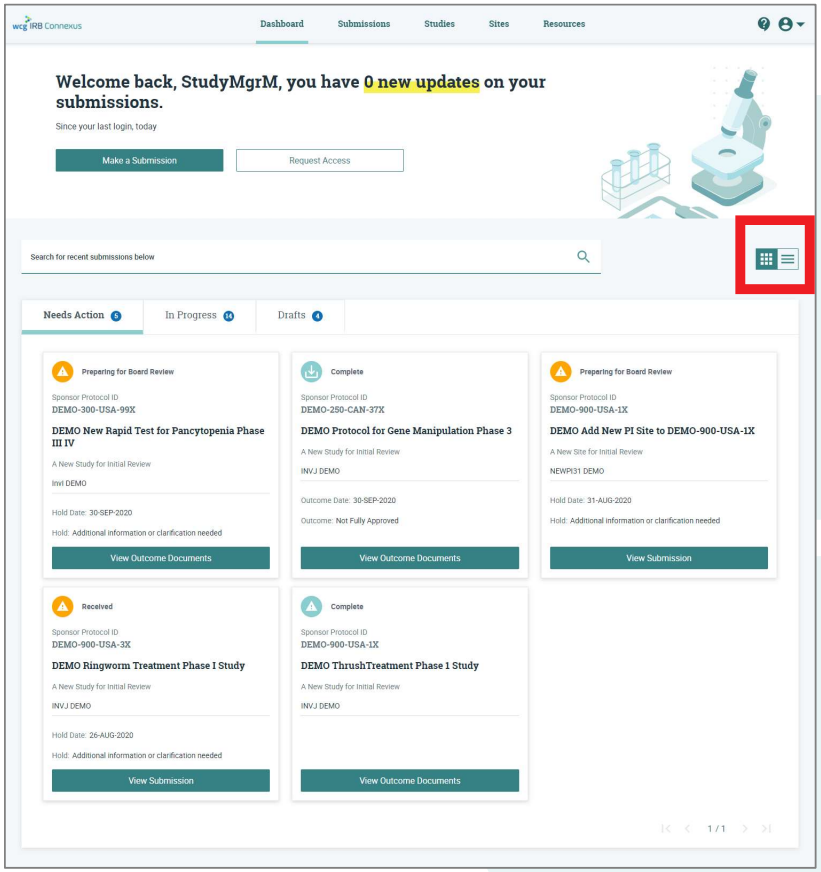
- Legacy MyConnexus users need to reset password and accept the Terms & Conditions upon initial sign in, click on Forgot Password
- Use the same registered email address as you have in Legacy MyConnexus
- Your username is your email address
- New users can register using **Create a new account**



The Dashboard

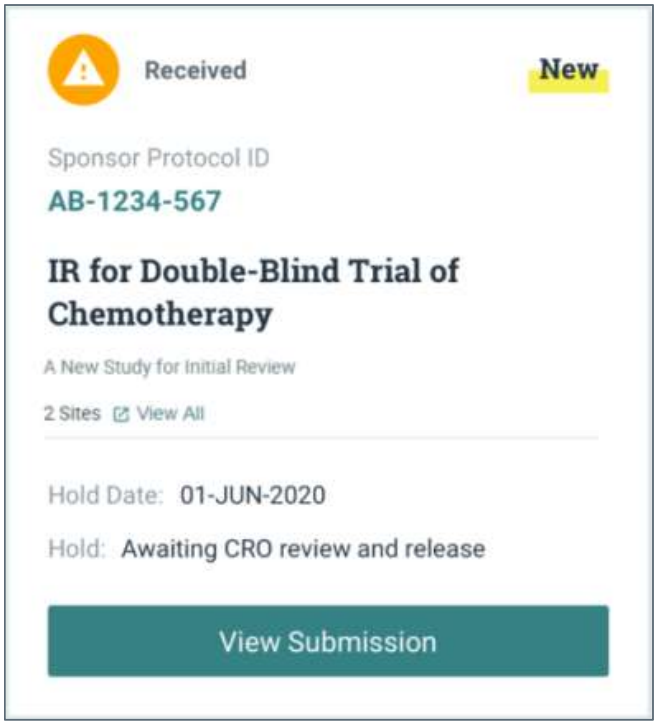
WCG IRB Connexus Dashboard

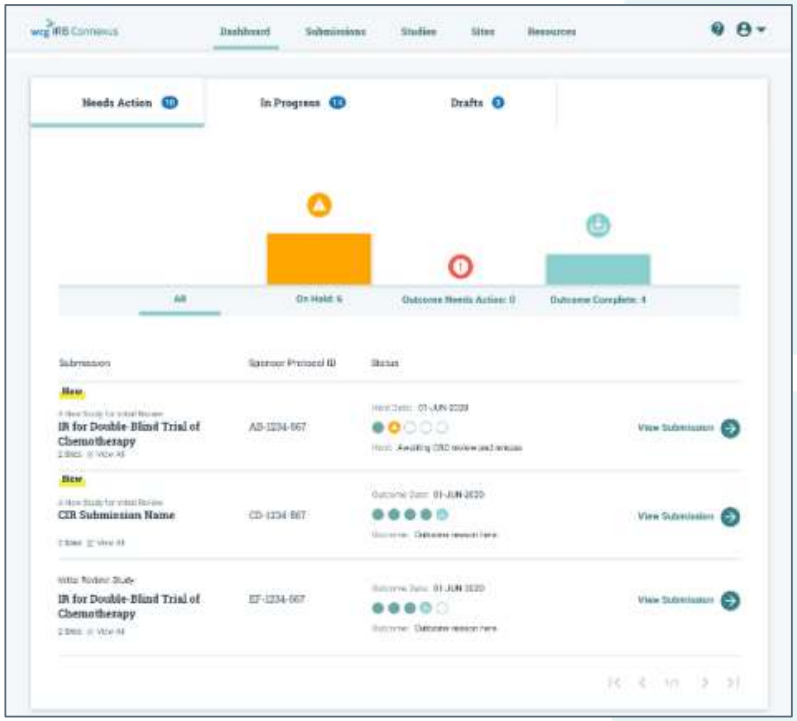
- Central hub for most WCG IRB Connexus activity
- Contains:
  - Notification area
  - Make a Submission button
  - Request Access button
  - Track Submissions area
    - Search
    - Tabs – Needs Action, In Progress, Drafts
    - Two different views per your preference



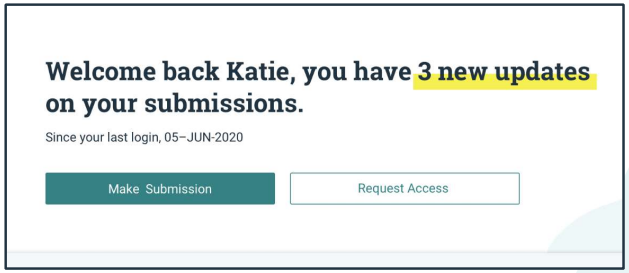
Dashboard – Card and Table Views

- Two different options for easily viewing submission/study details





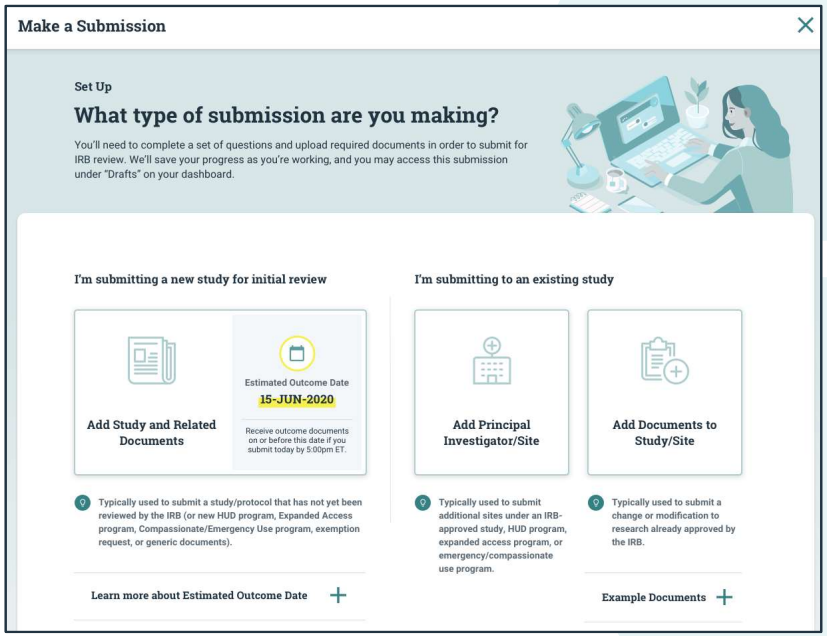
Make a Submission



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

Select one of the following options:

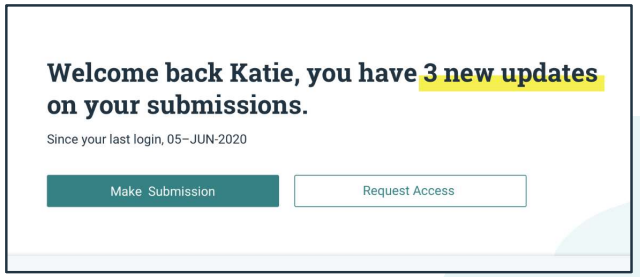
- Initial Review of New Protocol (not yet reviewed by WCG)
- For existing studies:
  - Add Principal Investigator/Site (to submit a new PI for initial review)
  - Add Documents to Study/Site (for an ongoing/existing approved study)

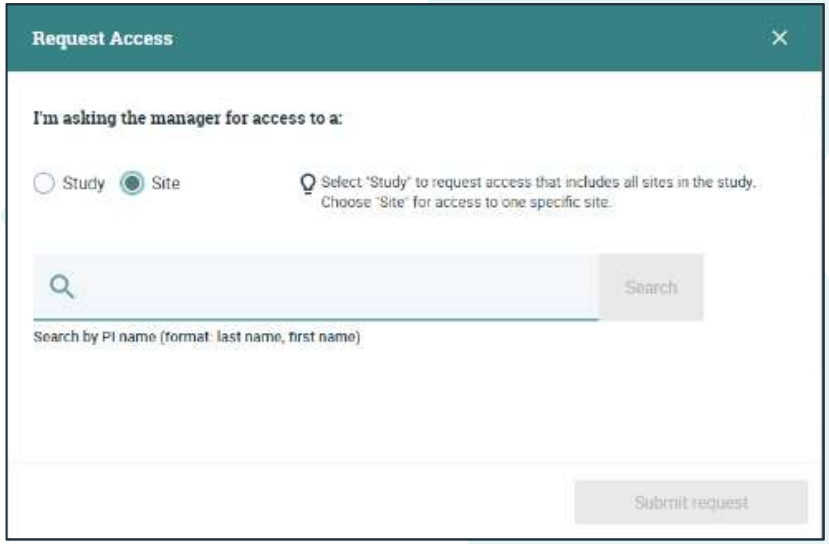


Request Access

You 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

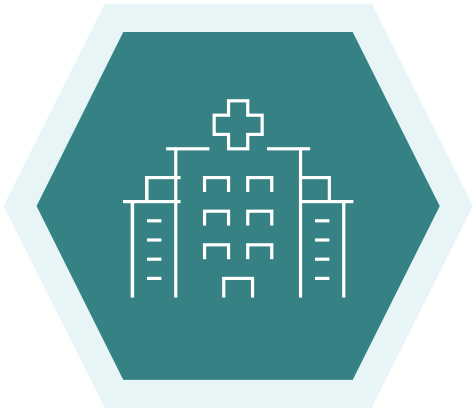
There are different levels of access, each with specific permissions. Your permission level depends on how your manager adds you to a study or a site.

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

The permissions levels are as follows:

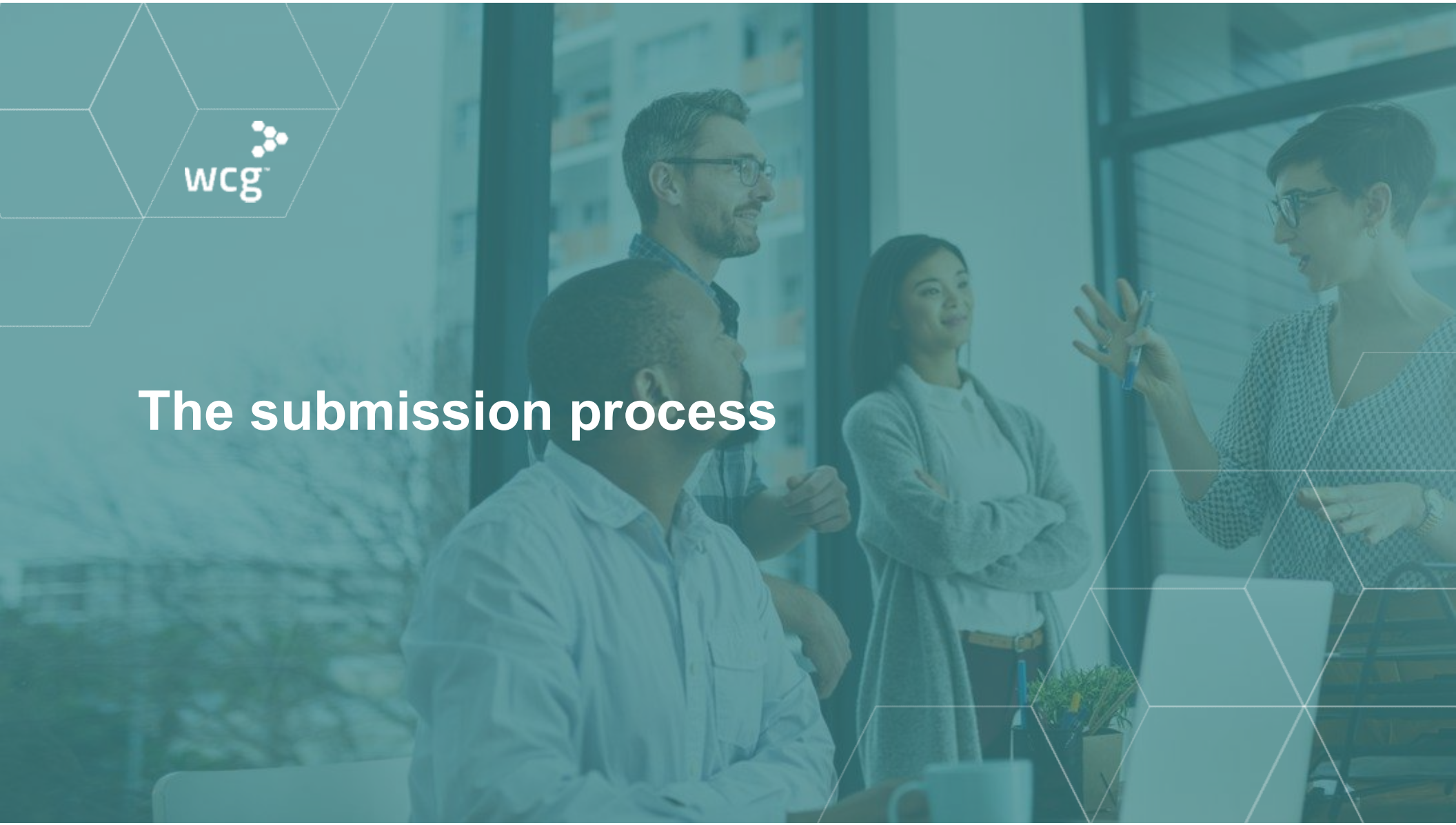
- Manager
- Submitter
- Read Only

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

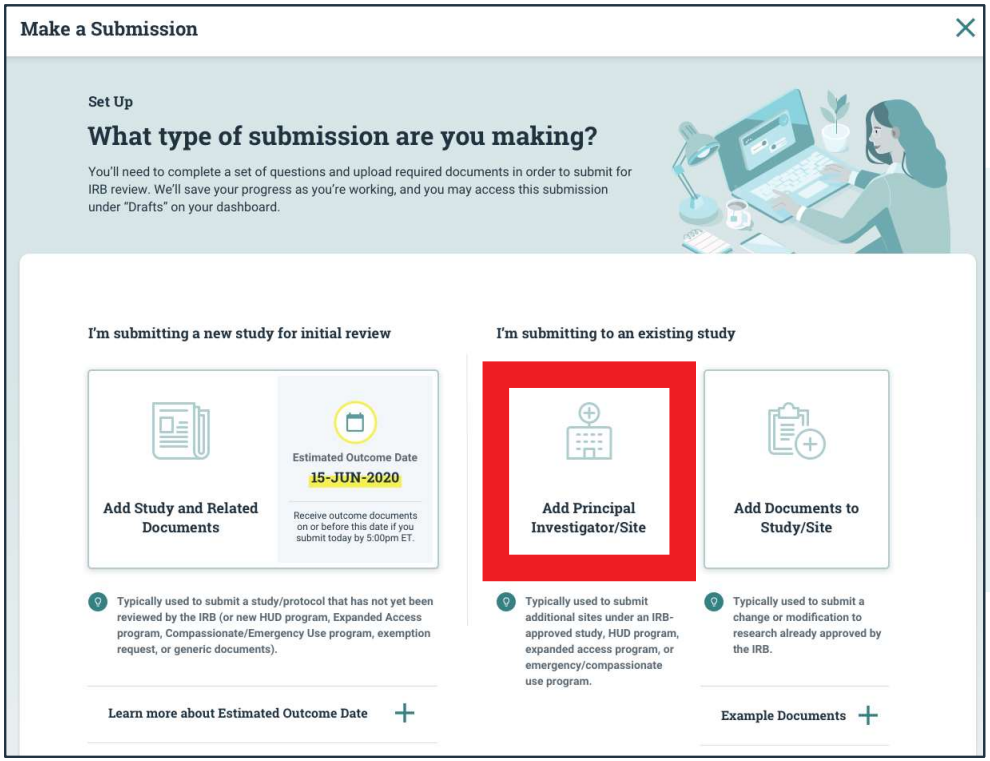
Reliance Request to use WCG IRB

- **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

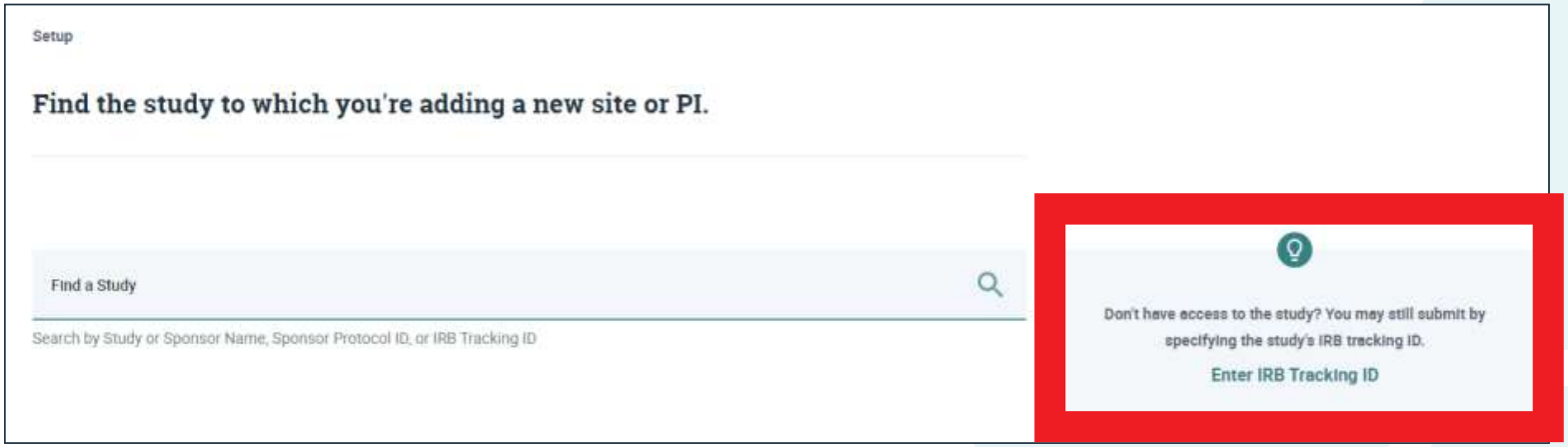
Make a Submission: Initial Review of New PI

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



Make a Submission: Initial Review of New PI

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

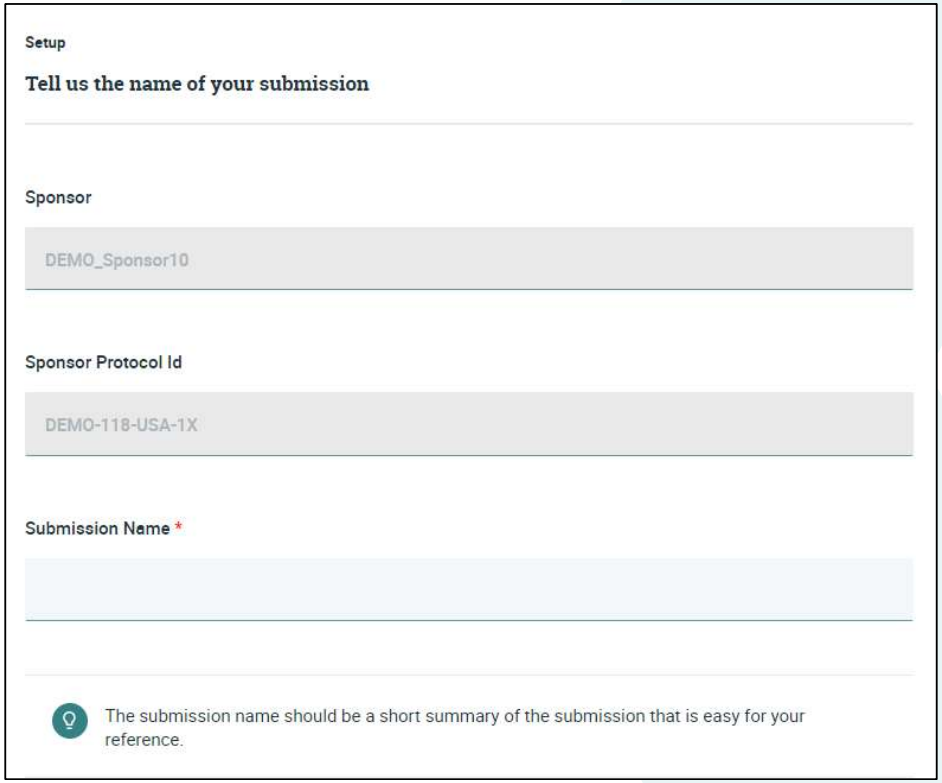


Make a Submission: Initial Review of New PI

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

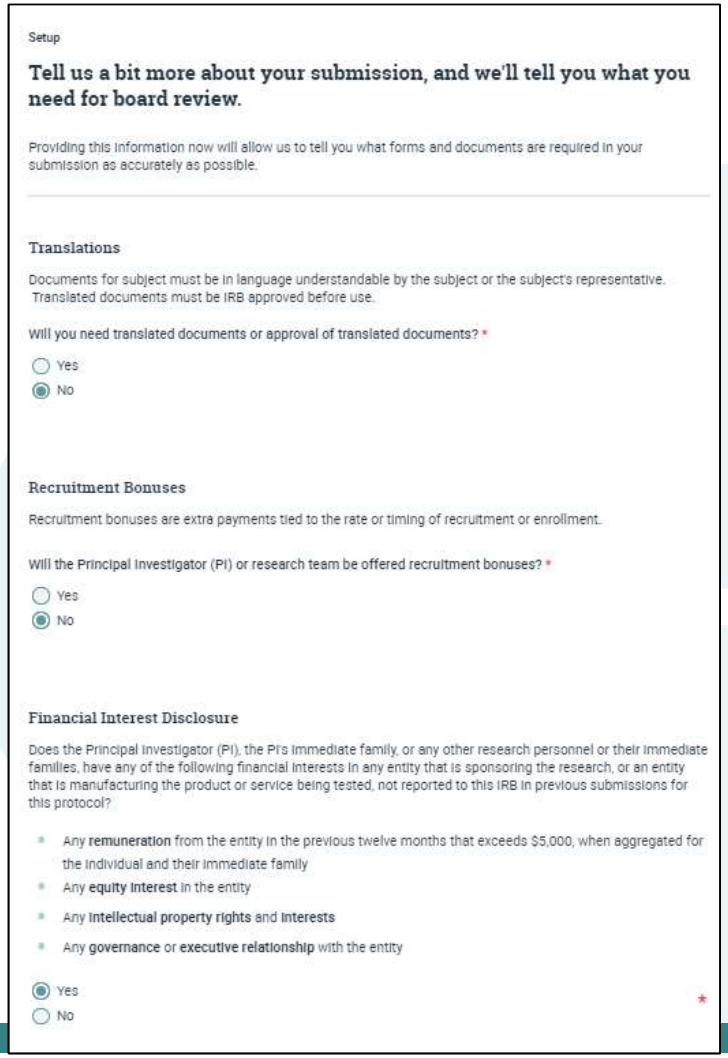
Make a Submission: Initial Review of New PI

Give your submission a meaningful name



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?

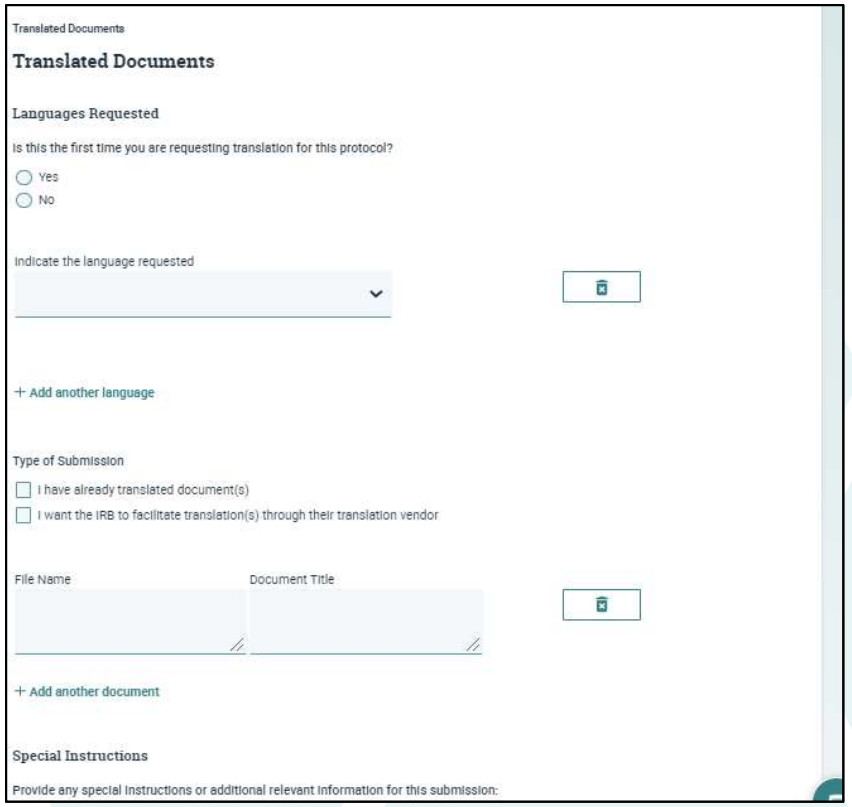
- Any **remuneration** from the entity in the previous twelve months that exceeds $5,000, when aggregated for the individual and their immediate family
- Any **equity interest** in the entity
- Any **intellectual property rights** and **interests**
- Any **governance** or **executive relationship** with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

- ◉ Yes *
- ○ No

Make a Submission: Initial Review of New PI

Translations

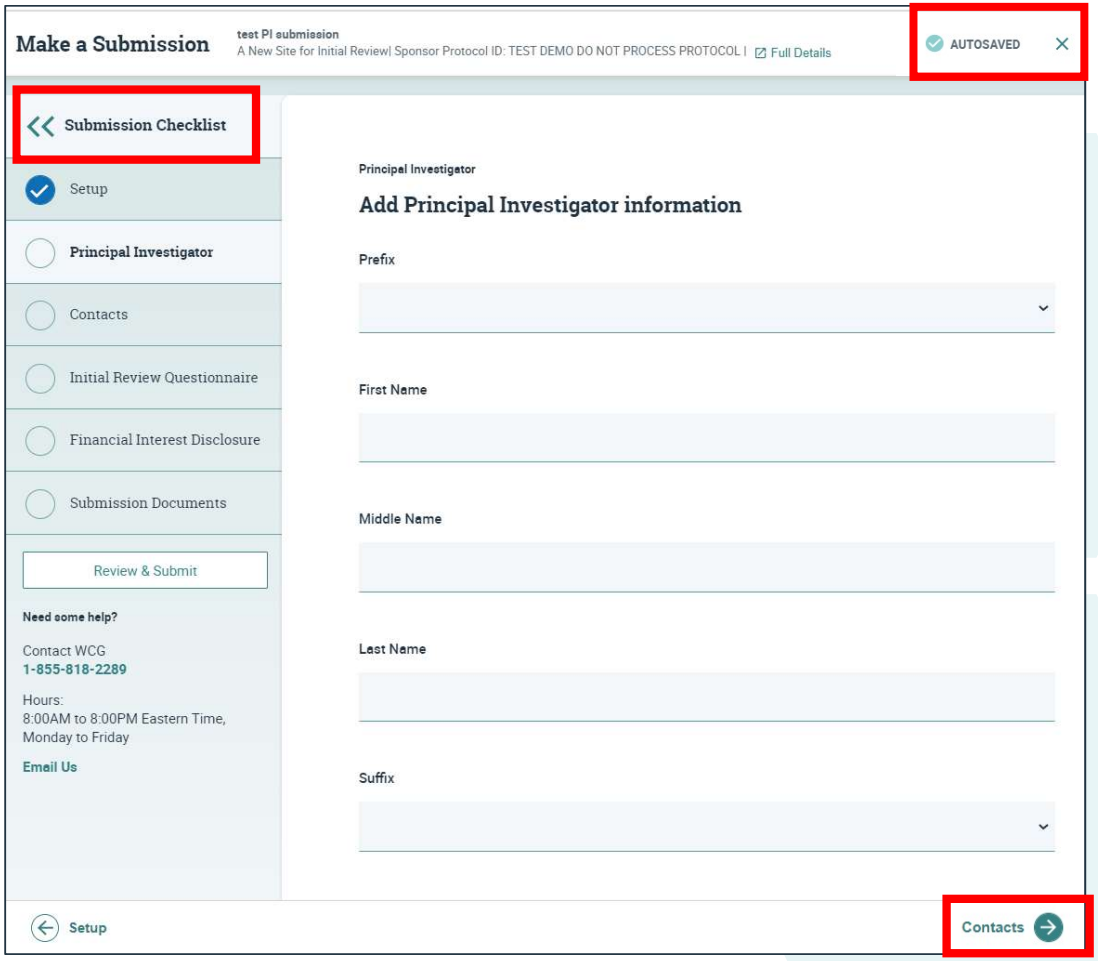
- All subject facing materials must have IRB approval before presenting them to the subject, including translated documents
- Check with your sponsor/CRO about translations before submitting: Who will translate the documents? Sponsor, CRO, WCG IRB
- To avoid additional translation costs and delays, translation 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



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

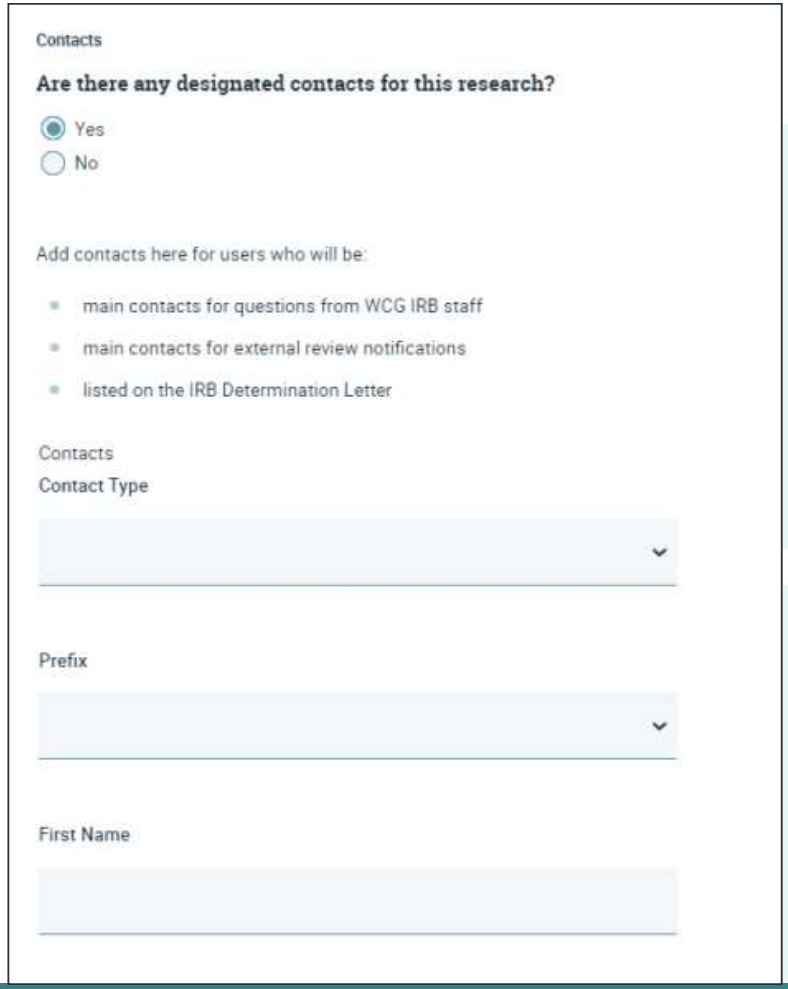
Make a Submission: Initial Review of New PI

- 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



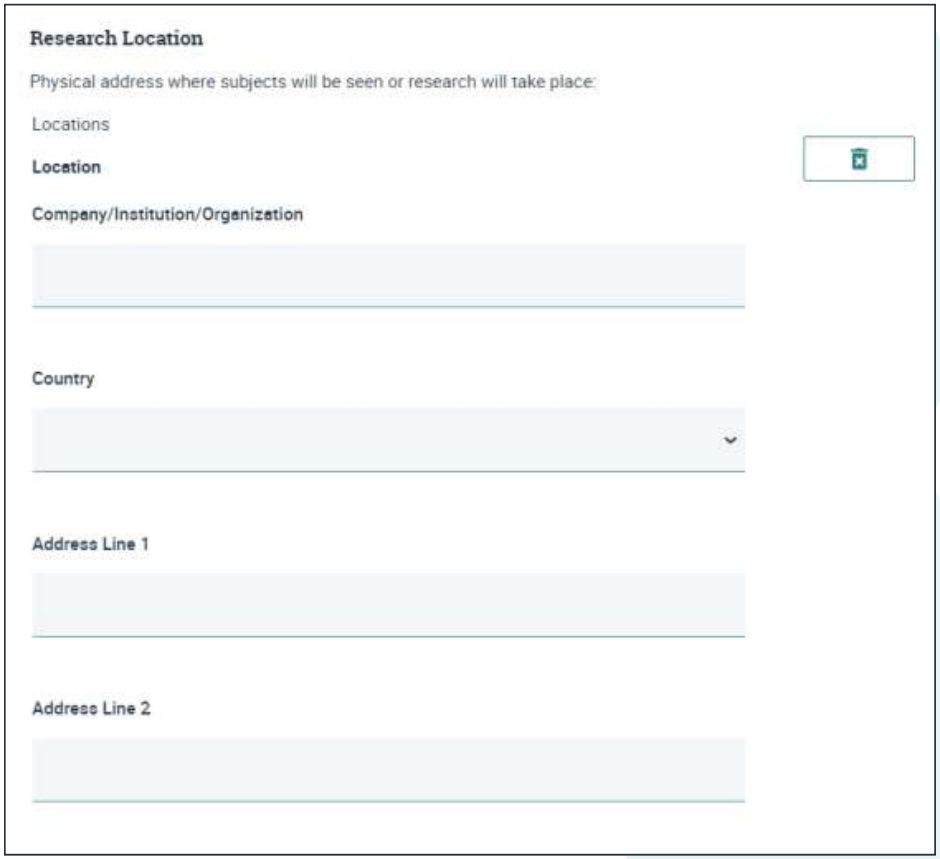
Make a Submission: New PI Form Overview

- 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



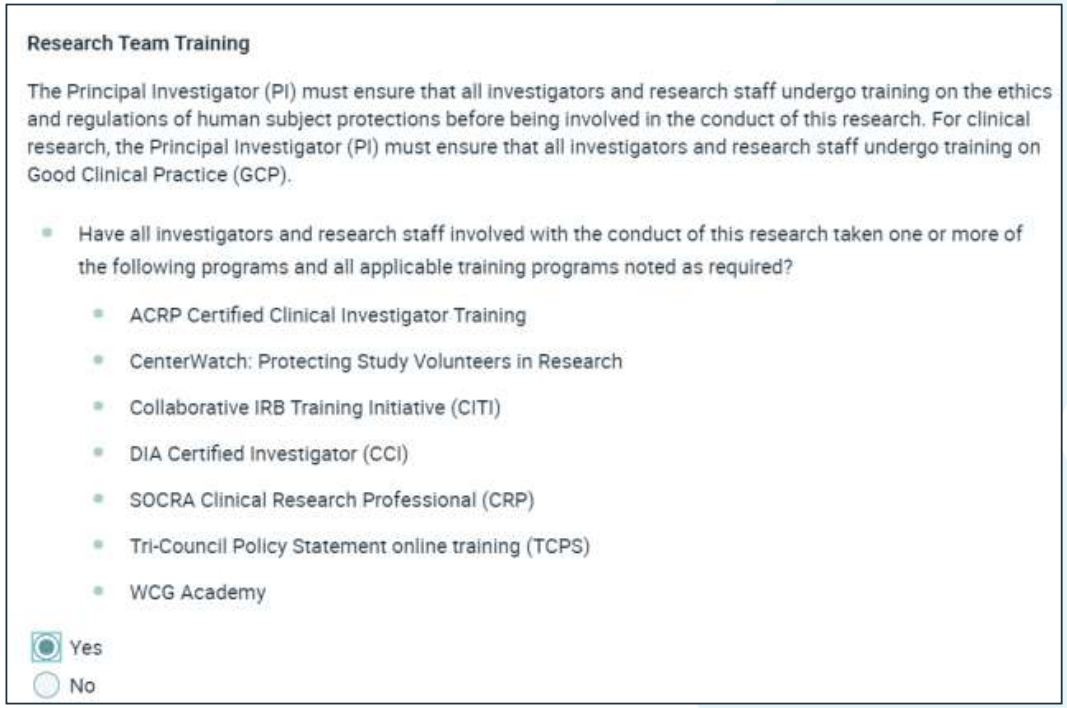
Make a Submission: New PI Form Overview

- 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



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)
  - SOCRA Clinical Research Professional (CRP)
  - Tri-Council Policy Statement online training (TCPS)
  - WCG Academy

(•) Yes
( ) No

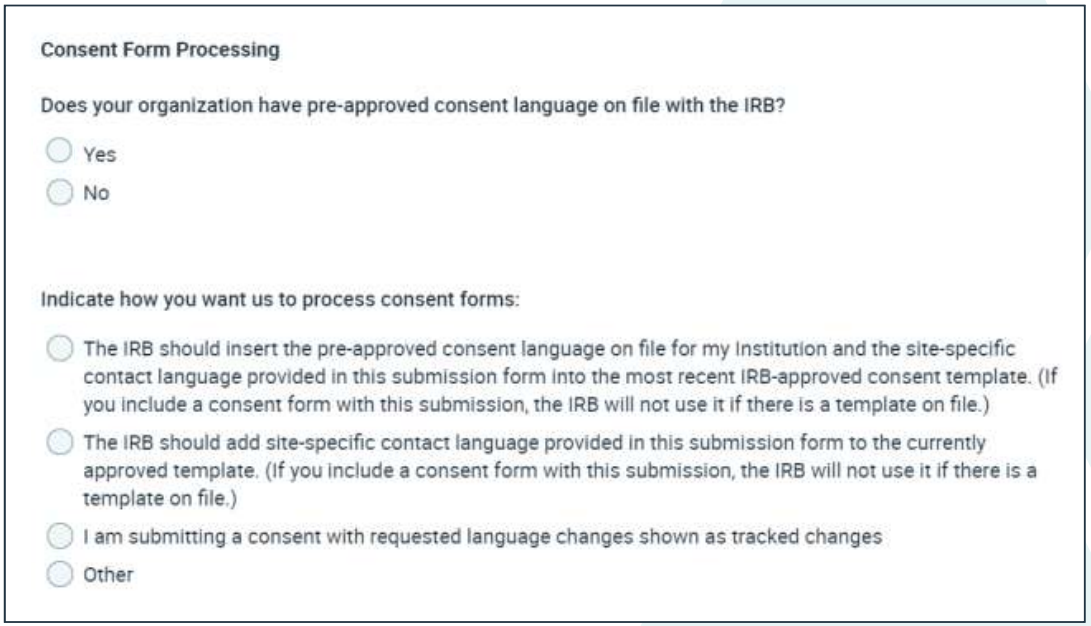
Make a Submission: New PI Form Overview

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

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**



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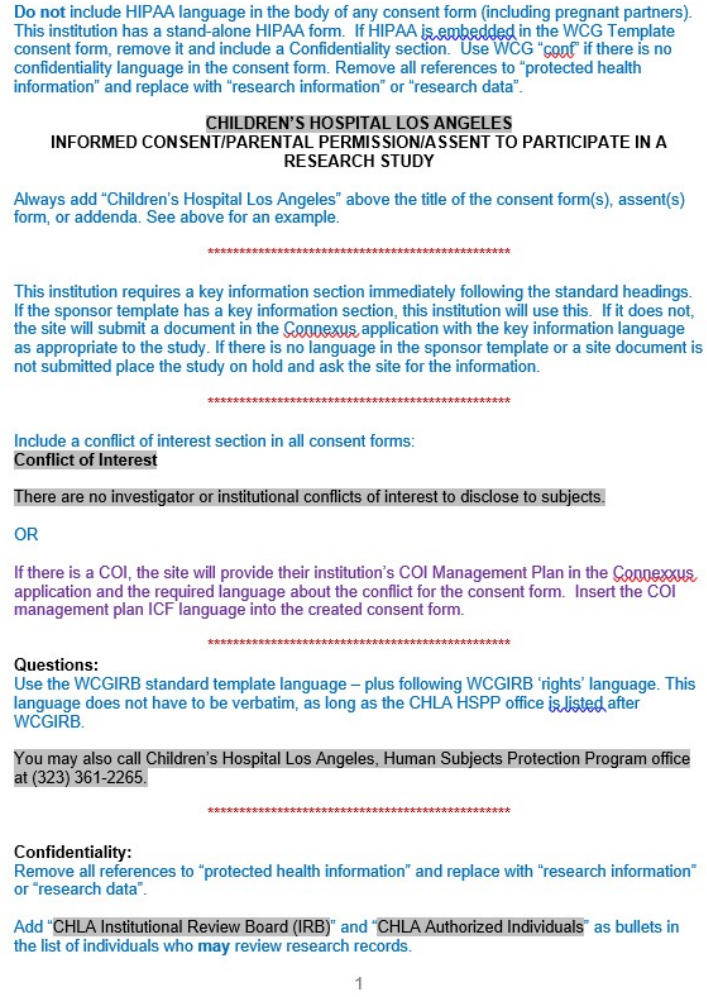
Make a Submission: New PI Form Overview

- 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.

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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 Connexxus 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.

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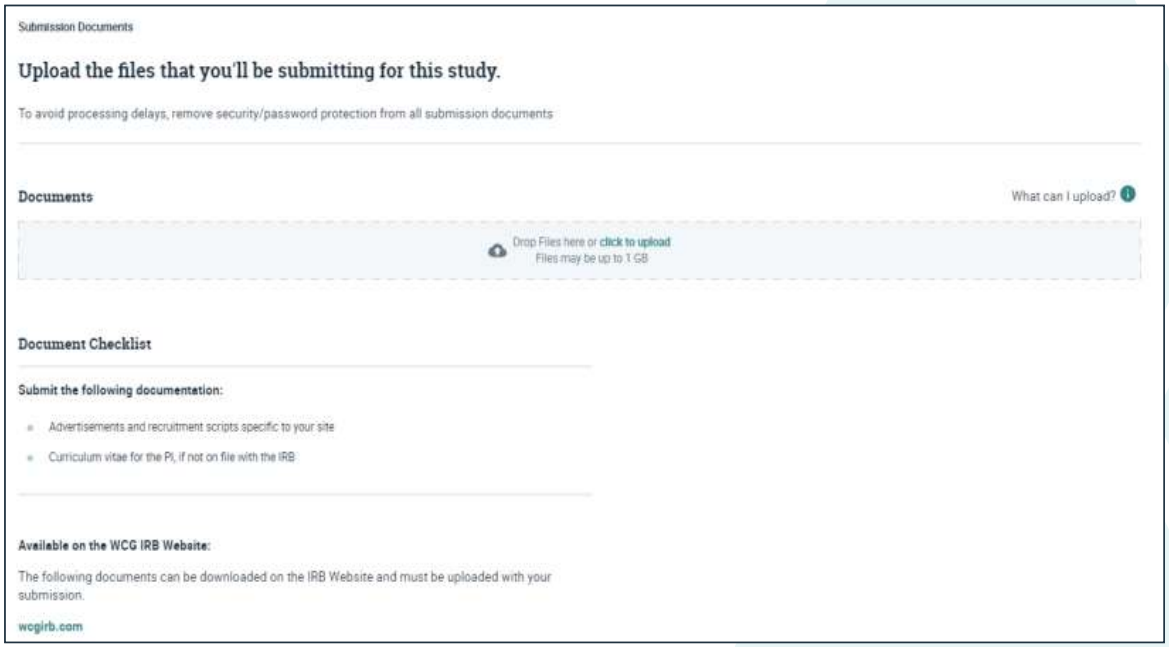
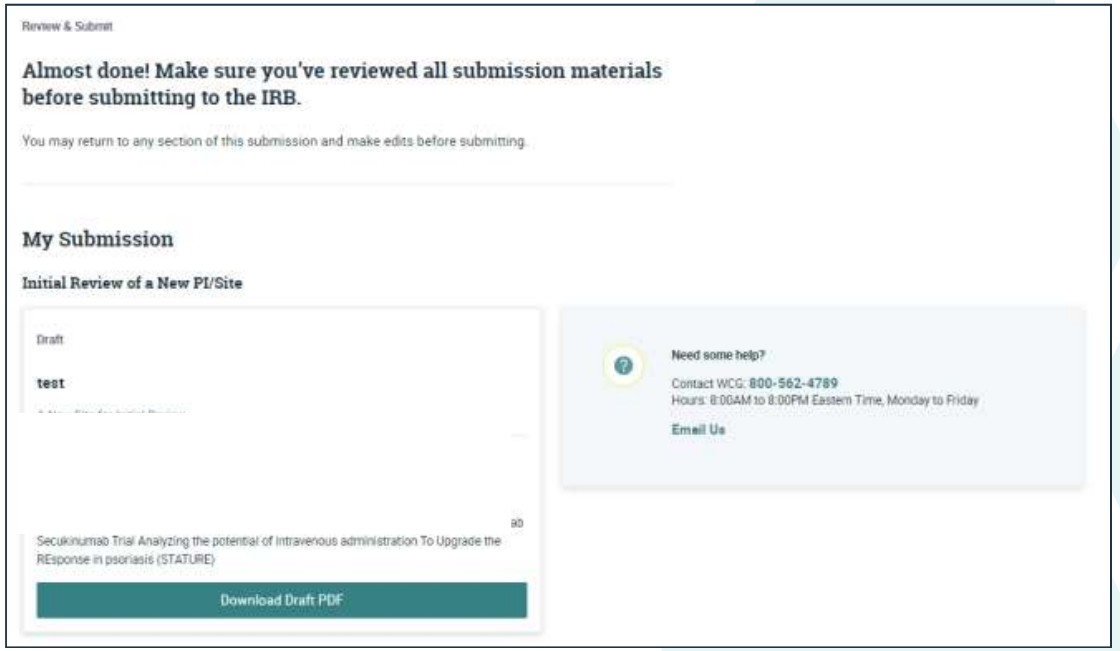
Make a Submission: Upload Required Documents

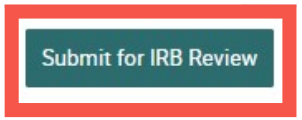
- The end of the form will show a Document Checklist for what you have to submit
- Be sure to include your CHLA specific documents
  - ✓ **CHLA HSPP Clearance Letter**
  - ✓ **Key Information Summary** (if not included in the current approved template)
  - ✓ **CHLA COIRC Conflict Management Plan and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



Make a Submission: Review & Submit

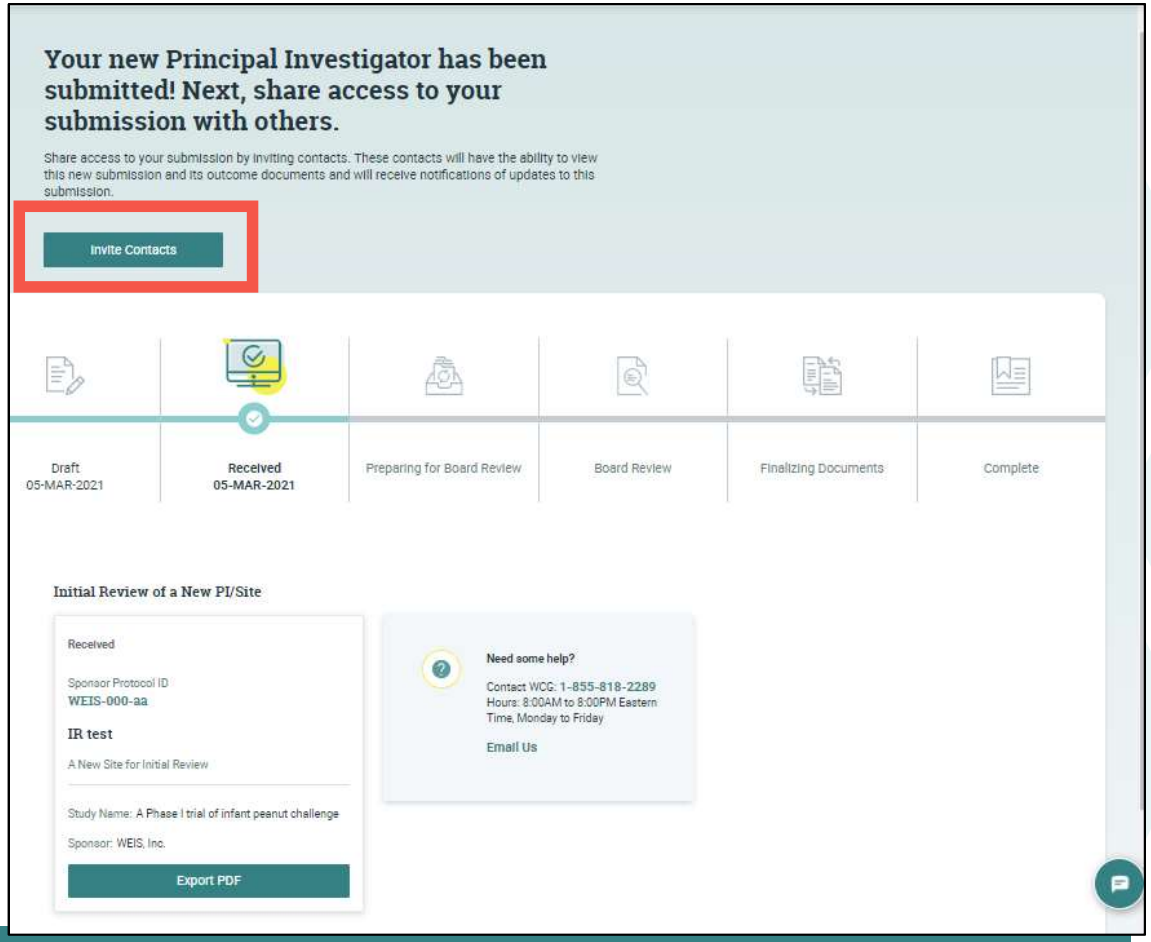
- The last step before you submit will allow you to download a PDF of your completed online form
- Click “Submit for IRB Review” in the bottom right-hand corner of the screen to submit for IRB Review





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



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 you 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 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

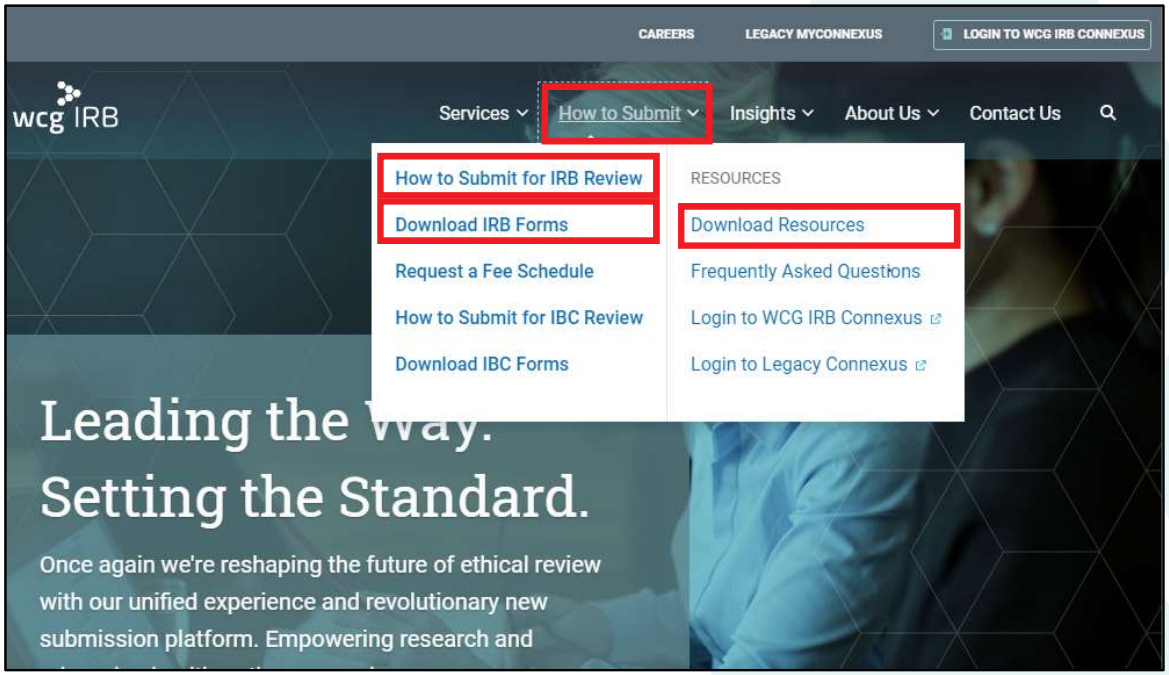
- You will receive a Certificate of Action (COA):
  - Board Action Date (Review Date)
  - Expiration Date (if approved)
  - Approved Research Location(s) and PI
  - The documents that were reviewed
- **Review your COA!**
- WCG IRB communicates Board actions via a COA. Your COA will state the action taken: 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

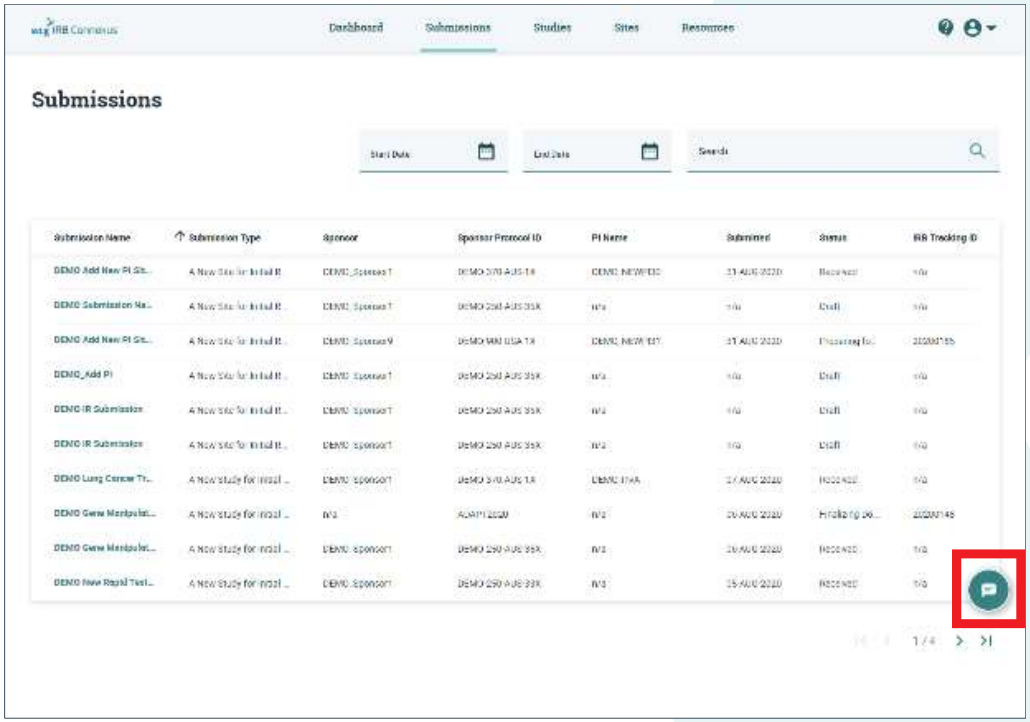
- Certificate of Action lists PI/site responsibilities
- Download IRB Forms
  wcgirb.com -> How to Submit -> Download IRB Forms
  - Guide for Researchers
  - Submission Form, Misc Forms
- Download Resources
  wcgirb.com -> How to Submit -> Download Resources
  - Investigator Guidance – Investigator Obligations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



Navigating Workspaces

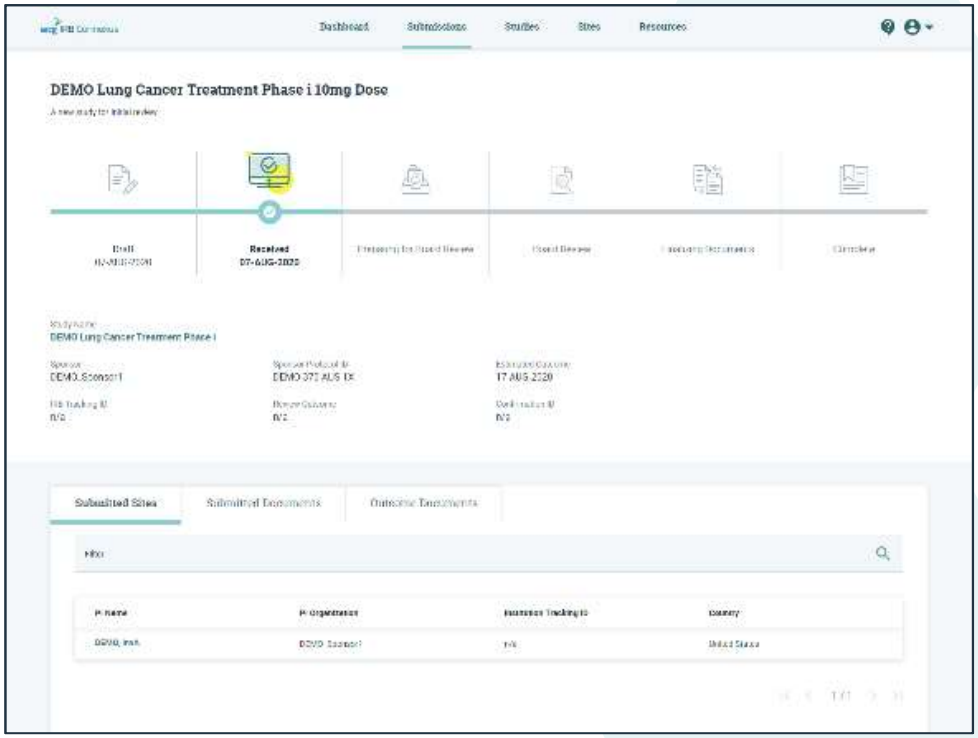
WCG IRB Connexus Submissions Landing Page

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



Submission Details

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



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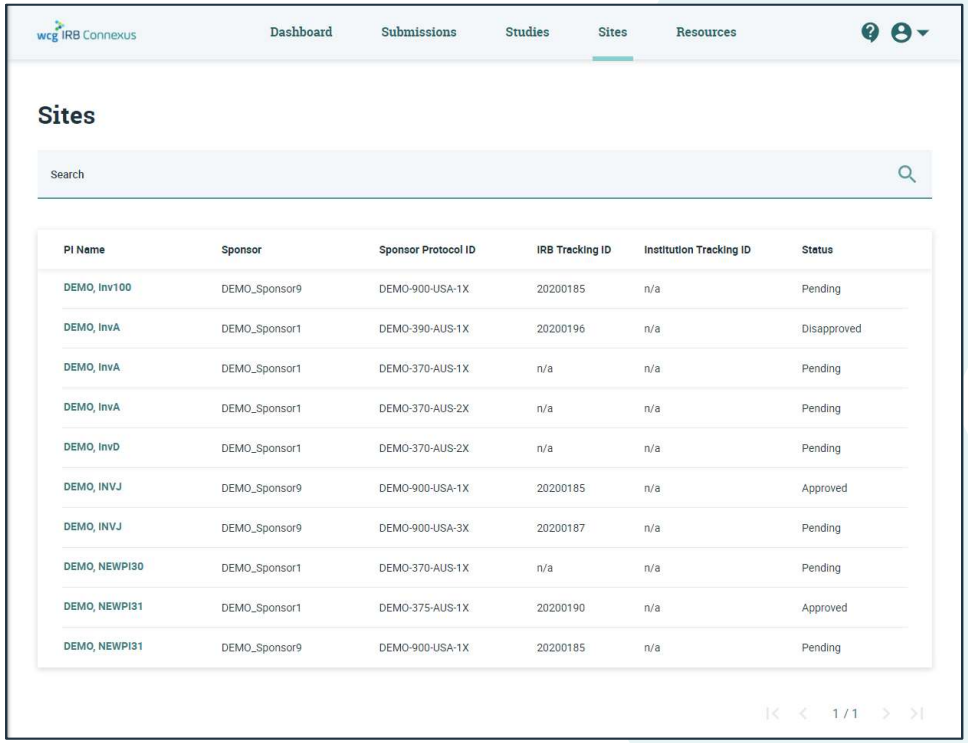
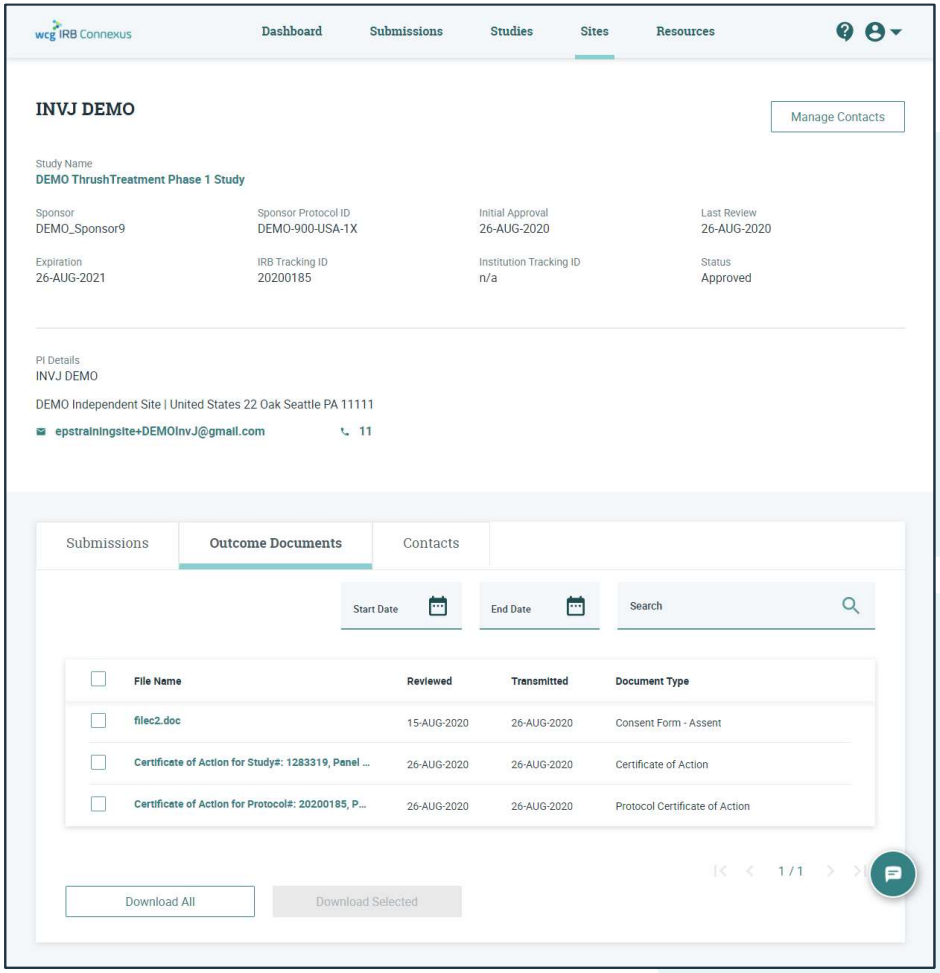
WCG IRB Connexus Sites (PIs) Landing Page

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



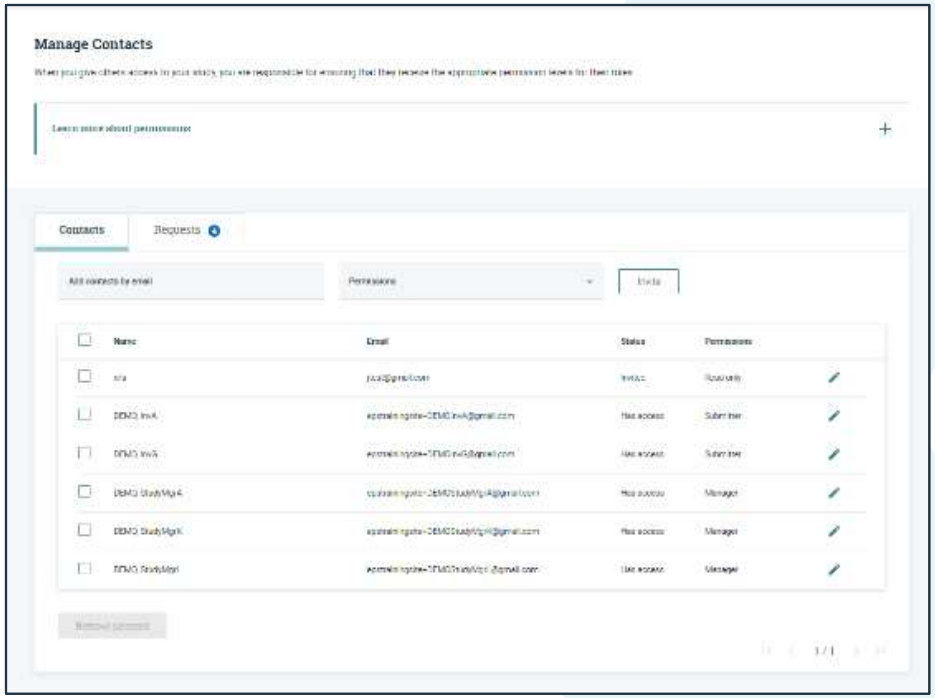
Site (PI) Details

- 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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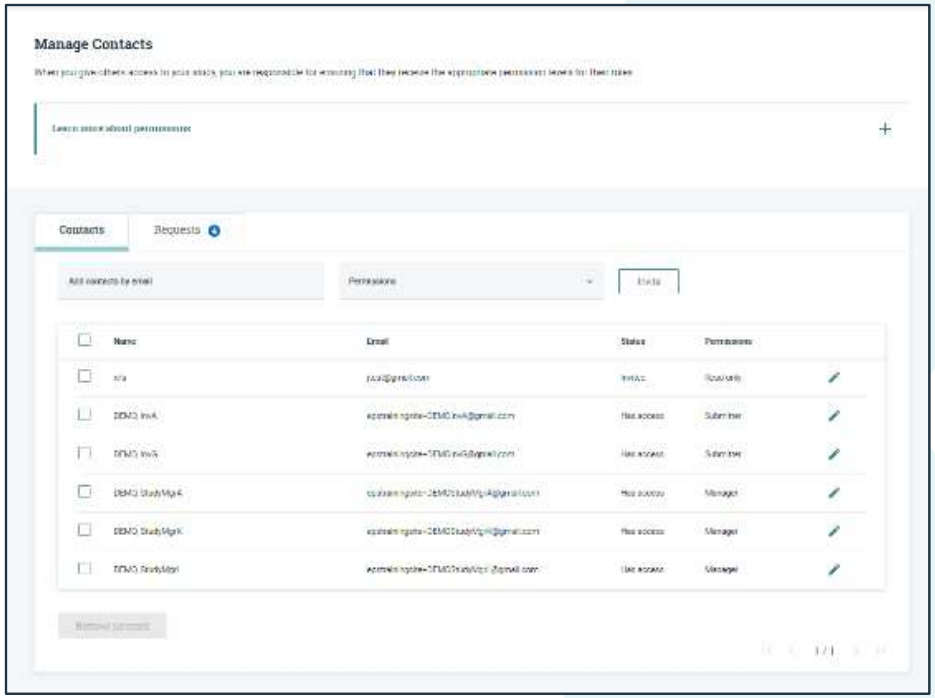
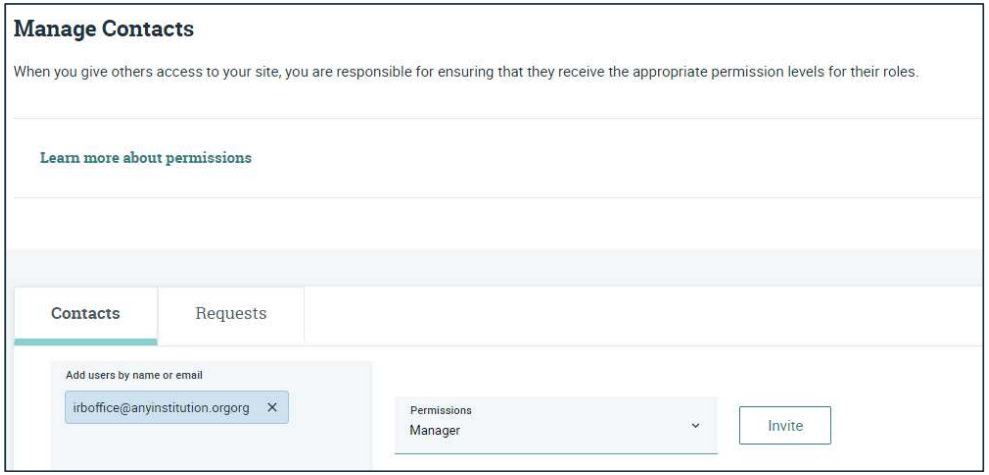


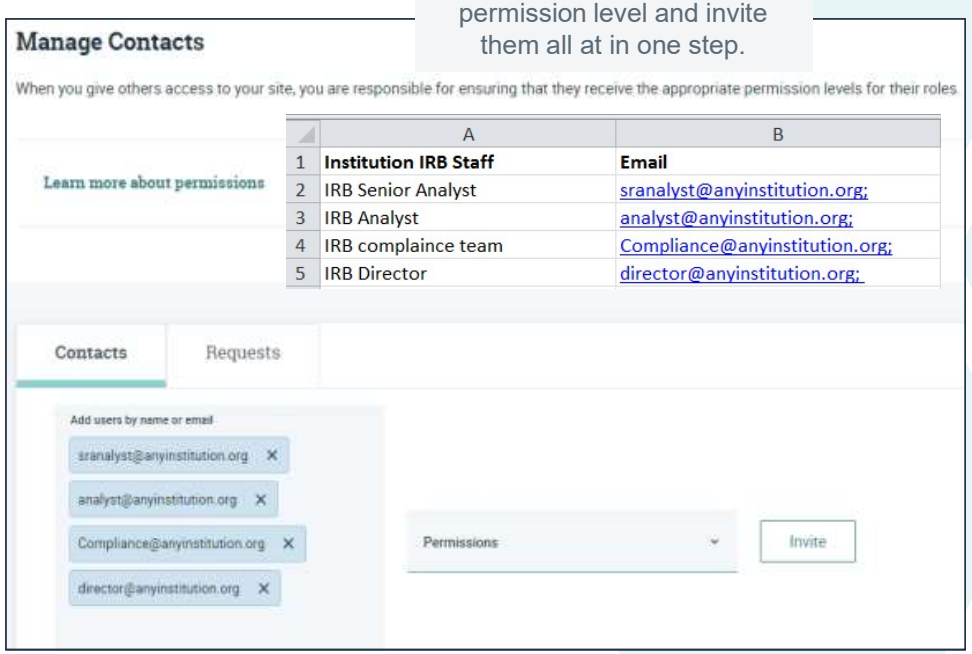
Manage Contacts

- 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.

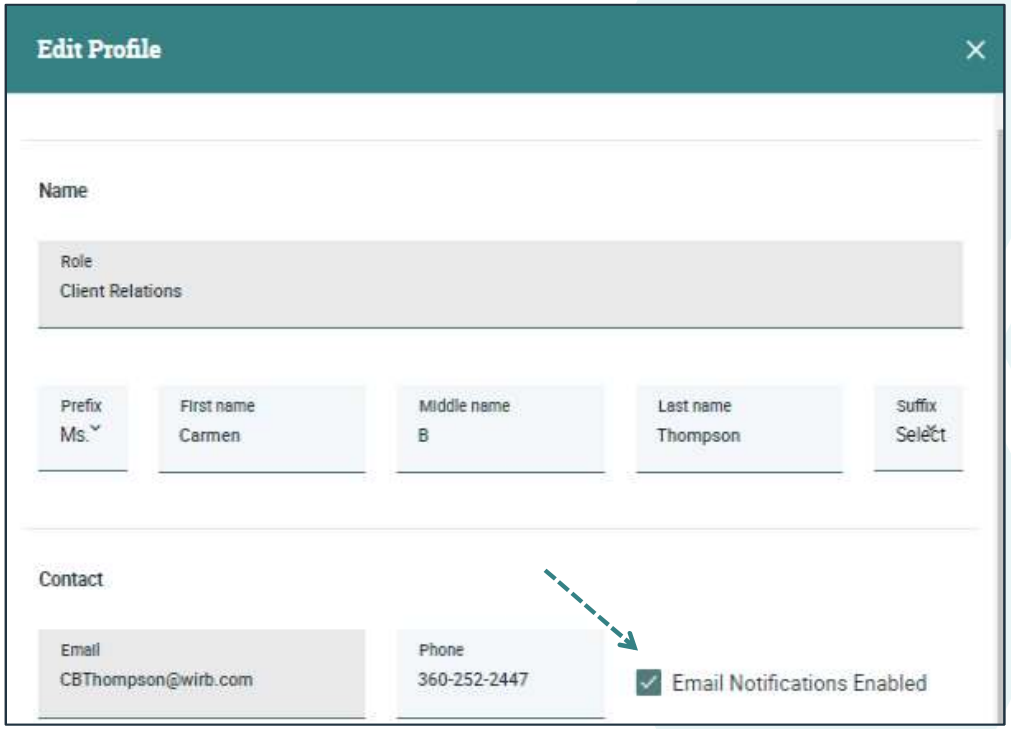




	A	B
1	**Institution IRB Staff**	**Email**
2	IRB Senior Analyst	sranalyst@anyinstitution.org;
3	IRB Analyst	analyst@anyinstitution.org;
4	IRB complaince team	Compliance@anyinstitution.org;
5	IRB Director	director@anyinstitution.org;

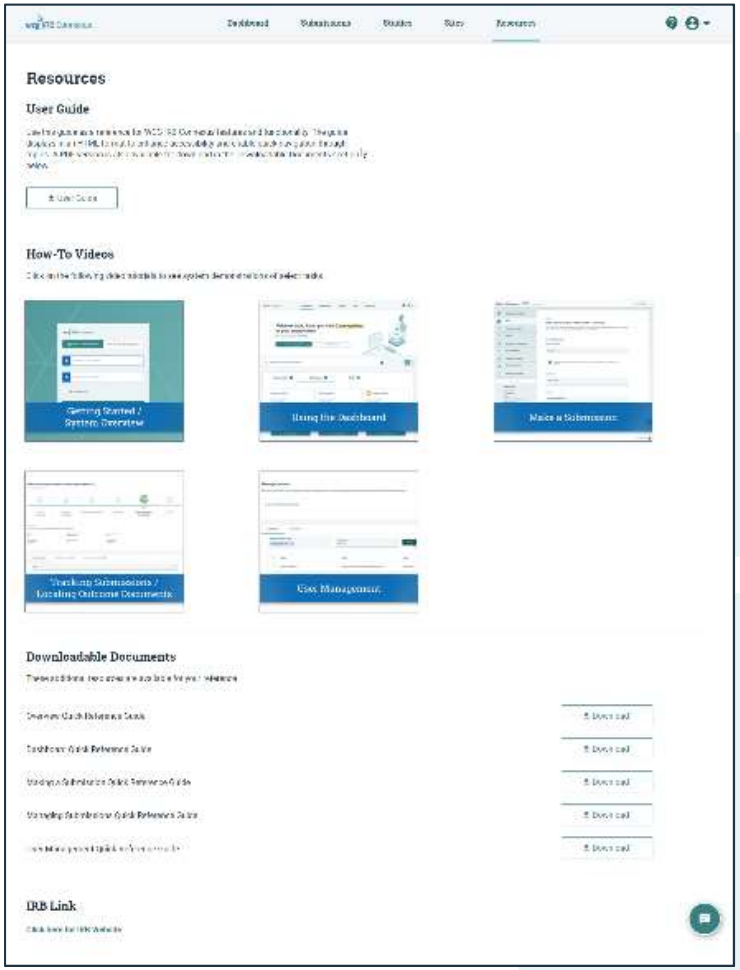
User Profile

To disable access request notifications:



WCG IRB Connexus Resources

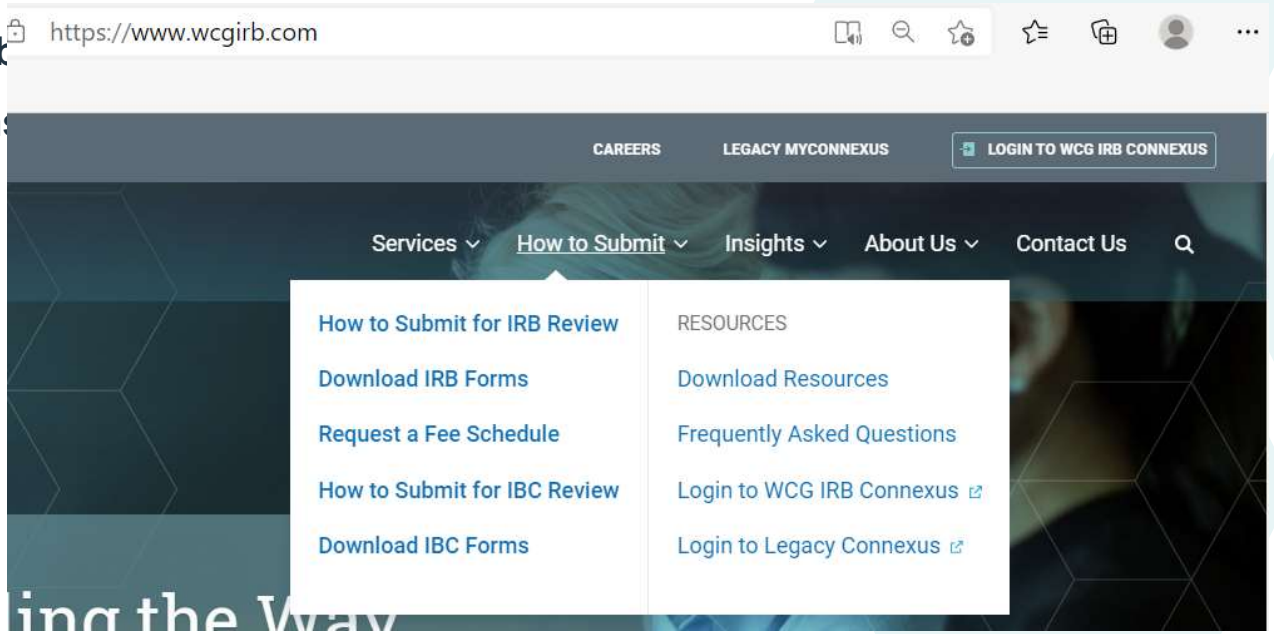
- PDF version of the user guide
- “How-to-Videos”
- Quick Reference Guides
- Link to WCGIRB.com

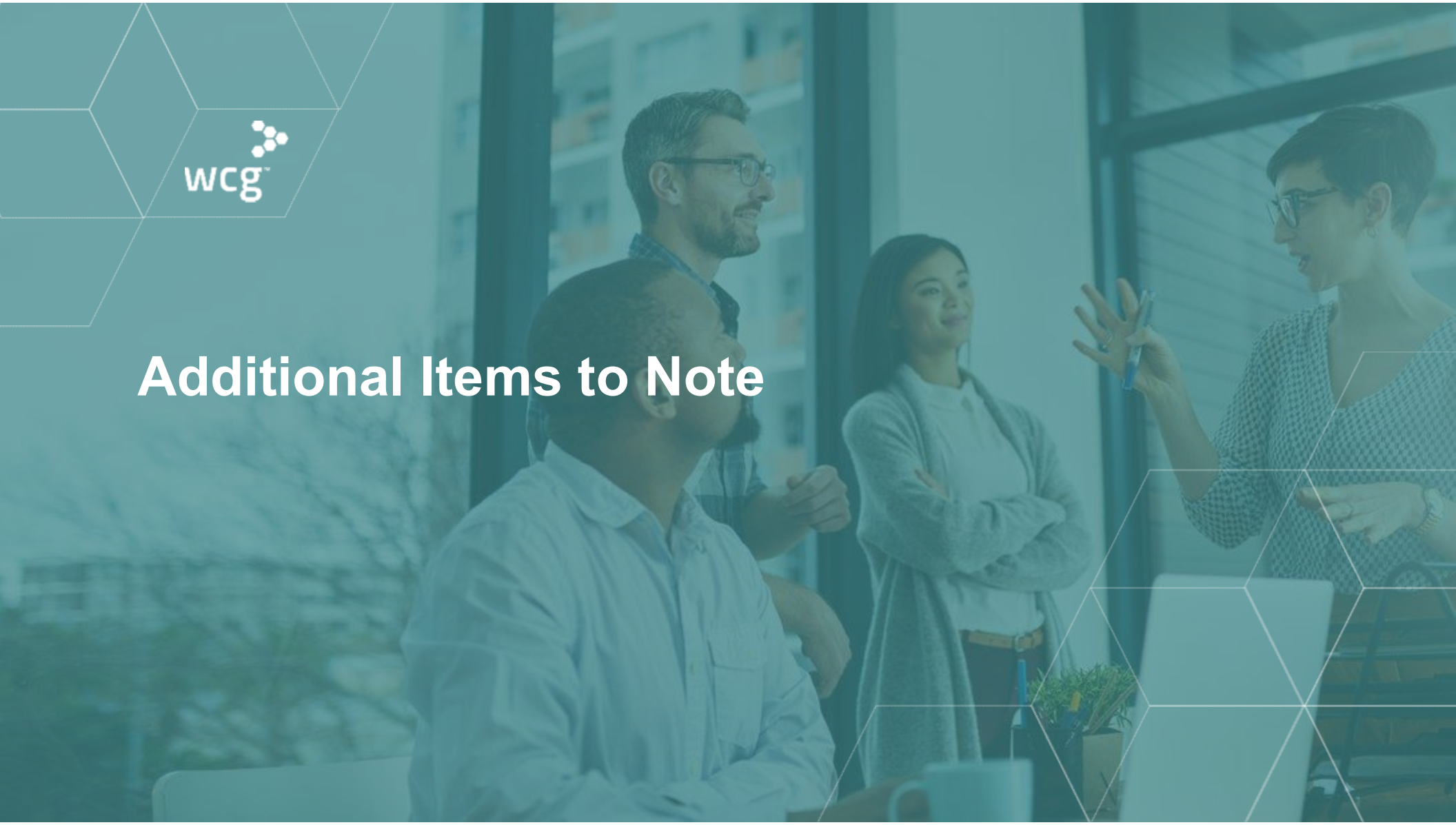


WCG IRB Resources

- **Resources are available on our web**
- 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

wcg IRB

Thank You