

WCG Submission in IRBNet – GUIDANCE

WCG utilizes IRBNet as an IRB management system; therefore, IRBNet is taking the place of Connexus for WCG submissions made at Prisma Health. Initial site and site update approval requests to WCG are submitted directly to WCG via the IRBNet system. A separate submission in the WCG Connexus system is not required.

⇒ **For WCG Submissions (not made on your behalf by the sponsor), including new WCG submission - you'll submit directly to WCG IRB via IRBNet (New Studies, Continuing Reviews, Reportable Events, etc):**

- Please follow WCG guidelines for their submission requirements to build their packages.
- There is a WCG IRB library available via Forms and Templates that has a Researcher Guide and Handbook available for reference as needed.
- WCG should apply the site's previously approved unique language to the study level (template) consent form.
- Once you are ready to submit a package to WCG IRB, click "Submit this Package" button and deselect "Only show My Default Boards."
- In the Search for an Organization bar, type "WCG" – and select "WCG IRB (formerly WIRB), Payallup, WA."
- Click "continue" and follow the prompts to submit directly to WCG IRB.

Please select a Board:

The screenshot shows a search interface with a text input field containing "WCG", a "Search" button, and a "Clear" button. Below the input field is a checkbox labeled "Only show My Default Boards" which is unchecked. A red circle highlights the checkbox, and the word "Uncheck" is written in red above it. Below the checkbox is a dropdown menu with one visible option: "WCG IRB (formerly WIRB), Puyallup, WA". To the left of the dropdown is the text "Select a Board *". At the bottom of the interface are "Continue" and "Cancel" buttons. A legend at the bottom left indicates that "*" denotes required fields.

Once WCG has made a determination on the submission, it should then be submitted to Prisma Health IRB for local acknowledgement.

- Navigate to the package that needs acknowledgment within IRBNet and from the left side menu select "submit this package".
- This time, choose the applicable Prisma Health IRB committee to submit the **same** package to. The WCG determination will be viewable by IRB staff from the "Reviews" section of the left side menu. IRB staff will be able to see WCG's Certificate of Action, the documents submitted for review, and the WCG determination and subsequently issue our own acknowledgement letter. This step should only add a few additional clicks and should not involve building an entirely new package to submit for local acknowledgment for WCG IRB submissions.
- Once Prisma Health IRB has acknowledged the submission, and acknowledgment letter will be available under Board Documents.

⇒ **For submissions made via the sponsor on behalf of the study team (typically study-wide amendments, etc):**

- The sponsor/CRO will submit to WCG for review via the Connexus portal.
- If a submission involves consent revisions, WCG will apply the site's previously approved unique language to the new study level (template) consent form.
- The approval letters of submissions initiated in Connexus will be transmitted and viewable within IRBNet as a package*. Approval letters and patient facing documents will be accessible in IRBNet. *All other non-patient facing materials (protocol, IB, etc.) are provided to you by the sponsor.*
*If you find that a particular CoA has not transmitted from Connexus to IRBNet, please reach out to an IRB coordinator as this is a WCG error that will need to be resolved.
- The study team will be responsible for ensuring the sponsor has provided them with all other newly approved study documents listed on the approval letters (protocol, IBs, etc.) that were submitted on their behalf to WCG IRB.

Once WCG has made a determination, and you have received the Certificate of Action and/or consent forms from WCG within their IRBNet package and all relevant documentation from the sponsor,

- Please Create a New Package in IRBNet and submit the CoA and all approved attachments for local acknowledgement (just like you would with any other reviewing IRB).
- Please include the "WCG Reviewed Sponsor Generated Amendment Cover Sheet" with your submission so that package numbers can be connected.
- This will ensure the IRBNet record stays up to date with all currently approved materials and can act as a "regulatory record" for each study team.
- Once Prisma Health IRB has acknowledged the submission, and acknowledgment letter will be available under Board Documents.

⇒ **For local submissions not requiring WCG IRB review (local staff change amendments or study status updates already acknowledged by WCG):**

- Submit them via the normal IRBNet external submission process to Prisma Health IRB for acknowledgement.
- For submissions requiring local acknowledgment only, there is a cover sheet available in the Forms and Templates library titled "FORM_External Submission Cover Sheet" that should be included in the package submission. The cover sheet should be utilized for study staff change amendments and study status changes.
- Once Prisma Health IRB has acknowledged the submission, and acknowledgment letter will be available under Board Documents.

WCG IRB has a library within IRBNet that houses their researcher guidance and all their required forms for their submissions. To locate WCG IRB's library within IRBNet:

- Click Forms and Templates
- Select WCG IRB Documents for Researchers from the drop down menu

Welcome to IRBNet
Tory Holt

- Submission Manager
- Agendas and Minutes
- My Projects
- Create New Project
- My Reminders (1)
- Other Tools**
- Track Training (1)
- Forms and Templates**
- Library Manager

Forms and Templates

These libraries have been made available to you by your Boards so that you can easily download blank forms, document templates and reference materials to assist you in your work.

Select a Library: **WCG IRB (formerly WIRB), Puyallup, WA - Documents for Researchers** ▼

Documents in this Library:

Document Description	Last Updated	
Additional WCG IRB forms and templates available here	06/12/2023 10:55 AM	
FORM - Change in Research Submission Form (HRP-201)	06/13/2023 01:24 PM	
FORM - Clinical Use of a Humanitarian Use Device (HUD) HRP-284	06/21/2023 01:05 PM	
FORM - Financial Interest Disclosure Form (HRP-216)	06/21/2023 01:05 PM	
FORM - HUD Clinical Use Closure (HRP-253)	06/21/2023 01:07 PM	
FORM - Initial Review Submission Form (HRP-212)	06/13/2023 01:25 PM	
FORM - Initial Review Submission Form Addendum for Department of Defense Funded Research (HRP-215)	06/12/2023 11:26 AM	
FORM - Promptly Reportable Information (HRP-204)	06/13/2023 01:24 PM	
FORM - Recruitment Bonus Disclosure Form (HRP-217)	06/21/2023 01:05 PM	
FORM - Request for a Partial Waiver of Authorization for Recruitment (HIPAA Partial Waiver)	06/12/2023 12:33 PM	
FORM - Request for Full Waiver of Authorization under HIPAA	06/12/2023 12:33 PM	
FORM - Single Patient Expanded Access Submission Forms (HRP-280, HRP-281, HRP-282, HRP-283)	06/12/2023 12:01 PM	
FORM - Study Closure Report Form (HRP-252)	06/13/2023 01:25 PM	