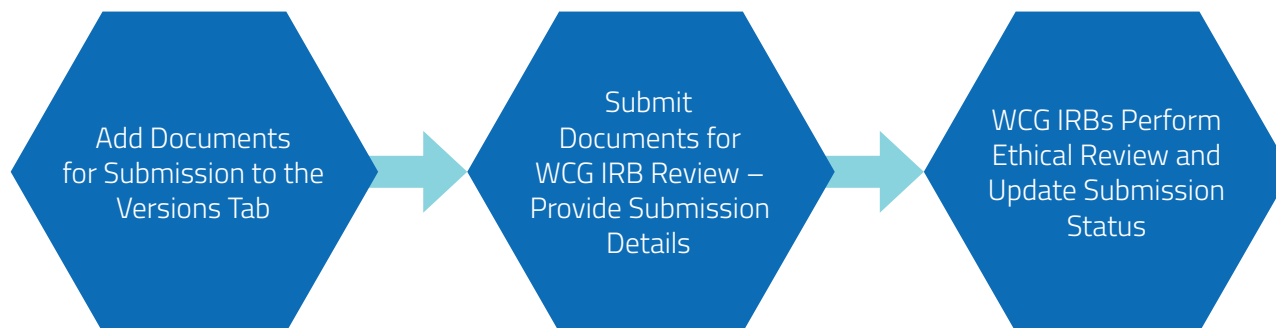## WCG IRB Review Functionality Overview

WCG IRB Tab

The WCG IRB tab is a feature available for both Velos eResearch and Velos eResearch eXpress that enables study teams to directly submit study documentation to the WCG IRB for approval. This functionality can be accessed from any study management page.

Prerequisites

Before using the WCG IRB functionality, the following items must be in place:

- Define a Principal Investigator for the study on the Study Details tab
- Enter the Sponsor Protocol Number in the Sponsor Protocol Number field of the Study Details tab
- Add all documents that need to be submitted for IRB review to the Versions tab and place them in the Freeze status
- "IRB" permission must be granted at the Study Team level

WCG IRB Submission Process Overview

Add Documents for Submission to the Versions Tab → Submit Documents for WCG IRB Review – Provide Submission Details → WCG IRBs Perform Ethical Review and Update Submission Status

Add Documents for Submission to Study Documents Tab

Add a new Study Document

From the **Versions** tab, located within a study, select **ADD NEW VERSION/ DOCUMENT**.

Change Attachment Status to "Freeze"

Before an added document can be added to a submission for WCG IRB review, it needs to be placed in the "Freeze" status. Click the edit icon to edit a document's status.

Change the status to Freeze using the Status dropdown menu, select an effective date for the status, and enter your e-signature. Click the **Submit** button to save the changes.

Submit Documents for WCG IRB Review – Provide Submission Details

Click the **WCG IRB** tab to open the WCG IRB page.
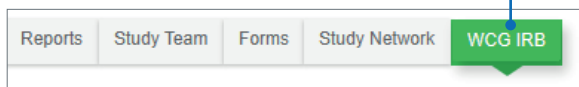
| Reports | Study Team | Forms | Study Network | **WCG IRB** |

Click the **Create New Submission** button to start a submission.

Search submissions 🔍 | **Create New Submission**

Enter Submission Details

Within the Create New Submission window, enter a submission name, the submission group type, and the submission type into the available fields. The Notes field is optional.

The Principal Investigator field is read only and is taken from the PI assigned to the study in the Study Details tab.

Create New Submission ✕

Protocol number: P709845

1 Provide Submission Details ————— 2 Select Documents to Include

SUBMISSION DETAILS

Name*
Enter a Submission Name

Submission Group Type*
Select an option ⌄

Submission Type*
Select an option ⌄

Principal Investigator
Velos Admin

Notes
Enter notes, up to 1024 characters

Save as Draft | Step 2: Select Document

Click **Step 2: Select Document** to save your changes and continue with the submission process, *or* click **Save as Draft** to save your current progress and continue the submission at another time.

Submit Documents for WCG IRB Review – Select Documents to Include

Determine which documents you would like to be included in this submission by clicking the checkbox next to the appropriate documents. Note that only documents added to the **Versions** tab in the "Freeze" status will display here.
Then click **Submit to WCG IRB.**

Create New Submission

1 Provide Submission Details   2 Select Documents to Include

ATTACHED DOCUMENTS TO CHOOSE
Only documents in the "freeze" state will be included for selection.

Show all Category ▾   all Type ▾   all Version ▾   Search documents 🔍

	Category ▲	Type	File Name	Version	Date
☐	Miscellaneous	-	IB_Addendum.pdf	1	04-13-2020

Showing 1 to 1 of 1 entries

DOCUMENTS TO INCLUDE IN SUBMISSION

Use checkboxes in grid at left to select documents for submission

← Back

Save as Draft   Submit to WCG IRB

After selecting a document to be included in the submission, a document information card will appear on the right side of the screen. If you need to remove a document from the submission simply uncheck the checkbox next to the document or click the X button in the upper right corner of the document information card.

ATTACHED DOCUMENTS TO CHOOSE
Only documents in the "freeze" state will be included for selection.

Show all Category ▾   all Type ▾   all Version ▾   Search documents 🔍

	Category ▲	Type	File Name	Version	Date
☑	Miscellaneous	-	IB_Addendum.pdf	1	04-13-2020

DOCUMENTS TO INCLUDE IN SUBMISSION
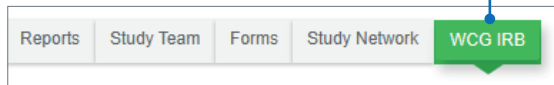
📄 **IB_Addendum.pdf**   x
Miscellaneous   -   Version 1

📄 **IB_Addendum.pdf**   x
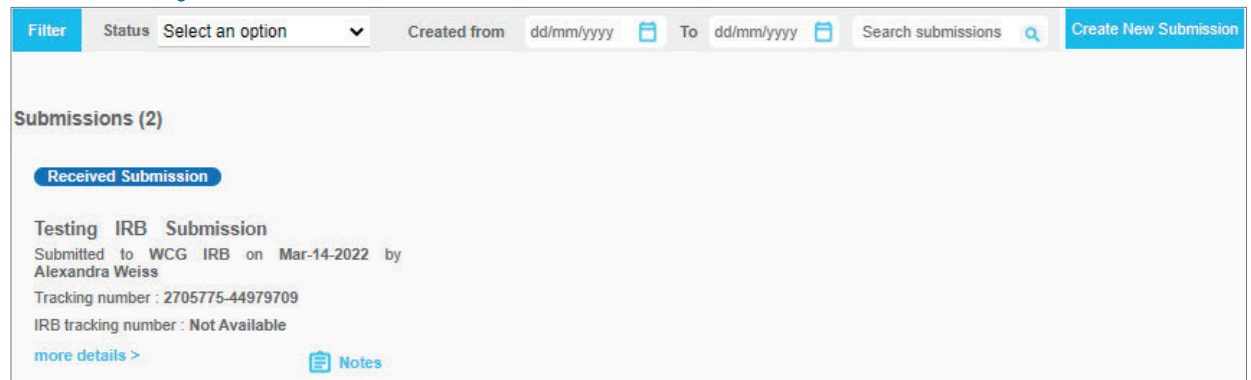Miscellaneous   -   Version 1

Submission Outcomes – Review Submission Status

NOTE: In order to refresh the status information in the WCG IRB tab, you must exit and reopen the WCG IRB tab for any changes in IRB review status to be pulled into Velos eResearch.

Click the **WCG IRB** tab to open the WCG IRB page.

Locate the submission for review by scrolling through the list of submission information cards on the left of the WCG IRB page, or use the Filter and Search fields at the top of page to locate a specific submission.

| Reports | Study Team | Forms | Study Network | WCG IRB |

Filter Status Select an option ⌄   Created from dd/mm/yyyy   To dd/mm/yyyy   Search submissions 🔍   Create New Submission

Submissions (2)

Received Submission

Testing IRB Submission
Submitted to WCG IRB on Mar-14-2022 by **Alexandra Weiss**
Tracking number : 2705775-44979709
IRB tracking number : Not Available
more details >   📋 Notes

Submissions (2)

① **Received Submission**

② **Testing IRB Submission**
③ Submitted to WCG IRB on Mar-14-2022 by **Alexandra Weiss**
Tracking number : 2705775-44979709
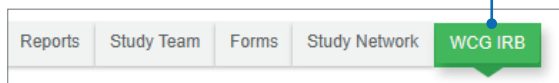IRB tracking number : Not Available
④ more details >   ⑤ 📋 Notes

1. **Submission Status** – Displays the current submission status.
2. **Submission Name** – Displays the name given to this submission.
3. **Submission Details** – Displays important submission details including submission date, tracking number, IRB tracking number, and any notes added to the submission.
4. **More Details Link** – Click the more details > link to display the Submission Type and Submission Group Type as defined when the submission was made.
5. **Notes** - Hover over to see any notes entered at time of submission.
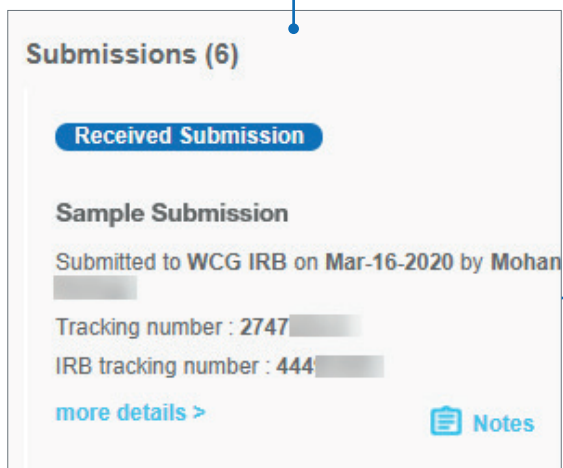
Review Submissions – Status Definitions

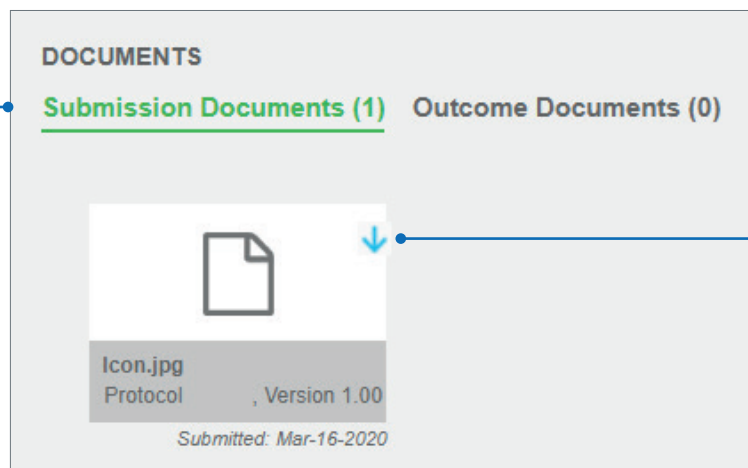| Notification	Purpose
Draft	This submission is a draft, which means it has been started, but not submitted. Clicking on a submission information card with this status allows you to continue the submission process.
Unsubmitted	The submission process in Velos eResearch was completed, but this submission is in queue, waiting to be transferred to the IRB database.
Received	The submission has been successfully received by the IRB team, and is in the process of being added to the review queue.
Received Submission	Formal confirmation of receipt by the IRB.
Processing	The submission is being processed in preparation for panel review.
Reviewing	Submission is currently being reviewed by the IRB panel.
Post-Panel Processing	The submission is currently in Post-Panel Review processing or awaiting a signature for finalization.
Transmitted	The submission results have been successfully transmitted from the WCG IRB database back to the Velos eResearch database.
Completed	IRB Review is complete. Outcome documents may be attached to this submission for your records.

Download Submission / Outcome Documents

Click the **WCG IRB** tab to open the WCG IRB page.

Reports	Study Team	Forms	Study Network	**WCG IRB**

Click directly on a submission information card.

Submissions (6)

Received Submission

Sample Submission

Submitted to WCG IRB on Mar-16-2020 by Mohan

Tracking number : 2747

IRB tracking number : 444

more details >   📋 Notes

After clicking on a submission information card, the available documents display on the right side of the page. View either submission or outcome documents by clicking on the **Submission Documents** or **Outcome Documents** link.

DOCUMENTS

Submission Documents (1)   **Outcome Documents (0)**

Icon.jpg
Protocol   , Version 1.00

Submitted: Mar-16-2020

Each available document will display as a document information card. To download a particular document, click the download arrow in the upper right corner of the information card.