

Reviewer Guide

1. **Accessing the Review Checklist** - When you are assigned as a reviewer, you will receive an email notification alerting you to the submission. You can access the reviewer checklist from the email or from your OneAegis home screen.

Email – The link within the email will take you directly to the checklist. Once you complete your review, you can always access it again by clicking on the checklist link. The analyst checklist is available within the link. There is a space for notes within the checklist too.

2026-016 Notice of Review Assignment



no-reply@corewellhealth.oneaegis.com

To Wood, Shannon

Retention Policy 18_Month_Email_Retention_Policy (1 year, 5 months)

Expires 8/7/2027

 This sender no-reply@corewellhealth.oneaegis.com is from outside your organization.



This Message Is From an External Sender

This message came from outside your organization.

Hello,

This is a notification to alert you that you have been assigned to review and sign off on the following submission:

IRB: 2026-016

Study Title: Testing Human Subjects Determination

Principal Investigator: Shannon PI Test

Submission Type: IRB Request for Determination Submission xForm

Submitting User: Shannon PI Test

IRB Assigned Analyst: Shannon Wood, MPH, CIP

Please use the following link to access the form [IRB Request for Determination Checklist](#)

Reviewer Checklist Link

Thank you,

Office of the IRB

THIS IS AN AUTOMATED EMAIL. DO NOT REPLY.

Home Screen – You can see all of your reviews that need to be completed, by clicking on “My Reviews.”

Corewell Health | Home | Meetings | Create Study | Reports | Contacts | Administration

Find Study

Study

Committee

Site

Status *All

Sponsor/CRO

Sponsor Id

PI

Any Contact

Keyword(s)

Find Clear

All assigned reviews will be located here.

Open Items | **My Reviews** | xForms Assigned To Me | All Open Reviews

Open Items This Week

Access Reviewer Checklist Here

On the “My Reviews” tab, you can access the checklist directly on the left-hand side of the screen. You can access the xForm (submission form from the study team) by click on the xForm link in the middle of the screen and you can also access the event (submission as a whole) by clicking on the link underneath the xForm link.

Assigned IRB Analyst if you have questions

Open Items | **My Reviews** | xForms Assigned To Me | All Open Reviews

Type	Review Item	Assigned By	Due
IRB Reviewer Checklist	IRB Continuing Review xForm IRB Continuing Review 2025-12345-CHW	10/15/2025 Shannon W	
IRB Reviewer Checklist	IRB Continuing Review xForm IRB Continuing Review 2025-12345-CHW	10/15/2025 Shannon W	
IRB Reportable New Information Checklist	IRB Reportable New Information (RNI) xForm IRB Reportable New Information (RNI) 2025-12345-CHW	11/21/2025 Amanda M	
IRB Reviewer Checklist	IRB Continuing Review xForm IRB Continuing Review 2025-12345-CHW	01/12/2026 Shannon W	
IRB Reviewer Checklist	IRB Modification to Approved Research xForm IRB Modification to Approved Research 1800-000-TST	01/21/2026 Shannon W	
IRB Reviewer Checklist	IRB Continuing Review xForm IRB Continuing Review 1900-000-TST	09/19/2025 Nikkie F	10/10/2025

Event Screen – On the event screen, you will be able to access the Reviewer Checklist by clicking on the checklist underneath “Type”, see submission attachments, and review the original IRB submission.

Do **NOT** click on the hand next to the Reviewer Checklist. This will not take you to the reviewer checklist.

Attachments and Email Correspondence

Reviewer Checklist Link

Assigned IRB Analyst

Original Submission Form

Original Submission Application Link

2. **Reviewer Checklist** – The reviewer checklist will open in its own tab.

Review Assignment

Review Type: IRB Reviewer Checklist
 Reviewer: Wood, Shannon, MPH, CIP
 Review Item: **IRB Modification to Approved Research xForm**
 Event: IRB Modification to Approved Research

Assigned: 01/21/2026 by Wood, Shannon, MPH, CIP
 Due:
 Study-Site: 1800-000-TST
 Event Start Date: **01/12/2026**

Submission Event Link

Review xForm

Collaborators Reviewer Checklist Page 1 of 1 Next

IRB Designated Reviewer Checklist -- Reviewer Checklist

Event	IRB Modification to Approved Research defined 01/13/2026
Study	1800-000
PI	Iest, Shannon PI
Title	A Phase 1, Open-Label, Dose-Escalation Study to Evaluate the Safety and Efficacy of HMI-103 Administered Intravenously in Adult Participants With Classical PKU Due to PAH Deficiency
Assigned IRB Analyst	Wood, Shannon, MPH, CIP

Assigned IRB Analyst if you have questions

Study Home Screen
 You can see past events and general study information

Analyst Pre-Review Checklist and Additional Checklists for you to complete (if applicable)

Analyst Prepared HRP Checklist Packet [Add Note](#) [View Audit](#)

Download the attached HRP checklist packet. Review the analyst pre-review and the submission. You can access the Submission xForm and the attachments by (insert instructions)

Once you have reviewed the submission, complete any blank checklists the analyst has included for you. To complete the packet, (insert instructions about filling and signing in Adobe)

Now that you have completed the HRP checklists, please upload your packet in the next section below.

Name	Type	Date
checklists 2021-171.pdf	Checklist	01/21/2026

Upload your checklists here, if applicable. [Add Note](#) [View Audit](#)

Add Attachment

Please select your determination: (Required) [Add Note](#) [View Audit](#)

Do you have any remaining comments or notes for this submission? [Add Note](#) [View Audit](#)

This question does not require a response and may be skipped.

Designated Reviewer Signature (Required) [Add Note](#) [View Audit](#)

Sign...

Click "Next" below and "Submit" on the following screen to complete your review.

Next Save for Later More ▾

Click "Sign" to sign off on the Review

Non-CH employees will need to enter their passwords

To complete the review, you must click "Next" and "Submit" on the following screen to send the submission back to the Analyst

Reviewer Determinations

For most studies, you will have these determinations available to you.

- If the submission was assigned to you via expedited review and you believe it needs Full Board review, select “Full Board Review Required” to send this submission back to the Analyst Pre-Review stage so they can assign it to a meeting.
- If the submission was assigned to you via expedited review and you have multiple questions that will take the study team time to respond to, then you can always “Return to Analyst for More Information” and this will return the form back to the Analyst Pre-Review stage. The analyst can also update their checklist if needed at that point.

Please select your determination: (Required)

▼

[Option]

Approved

Approved with Modifications Required

Deferred

Disapproved

Full Board Review Required

Return to Analyst for More Information

Tabled

If you select any of these categories, you will be given the opportunity to enter in comments to go along with your determination.

RNI Determinations – The RNI determinations are differently. You will need to determine if you can acknowledge the event first. Afterwards, an additional question will appear asking you if the event is non-compliance, a UAP, etc. If you select “Defer,” then a box will appear asking you to enter in your comments for the deferral.

Please select your determination: (Required) [Add Note](#) [View Audit](#)

Acknowledge

What apply: (Required) [Add Note](#) [View Audit](#)

Follow the research regulations, CH Policy or the requirements or determinations of the

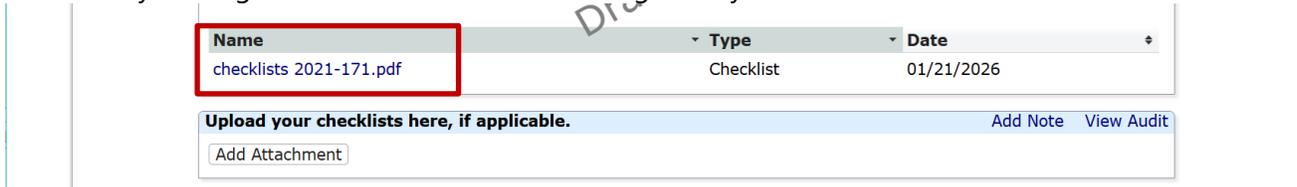
<i>Continuing Non-Compliance</i>	<i>A pattern of non-compliance (serious or non-serious) that suggests a potential for future non-compliance without intervention; a repeated unwillingness to comply with applicable research standards, regulations or determinations of the IRB; or a persistent lack of knowledge of how to comply on the part of the investigator or a willful lack of commitment by the investigator and study team to protect human participants.</i>
<i>Serious Non-Compliance</i>	<i>Non-Compliance that has, or could, reasonably be anticipated to have the potential to increase a physical, psychological, safety, or privacy risk to, or impair the rights of, local subjects.</i>
<i>Unanticipated Problem (UAP) Involving Risks to Subjects or Others</i>	<i>Any information or event that is (1) unanticipated or unexpected in nature, severity or frequency; (2) indicates that subjects or others are at increased risk of harm than was previously known or recognized; and (3) related to the research. Harm can be physical, emotional/psychological, social, or economic, and can include privacy harms.</i>

Continuing Non-Compliance
 Non-Compliance that is neither Serious nor Continuing
 Serious Non-Compliance
 Suspend IRB Approval
 Terminate IRB Approval
 Unanticipated Problem
 N/A - Acknowledge Only

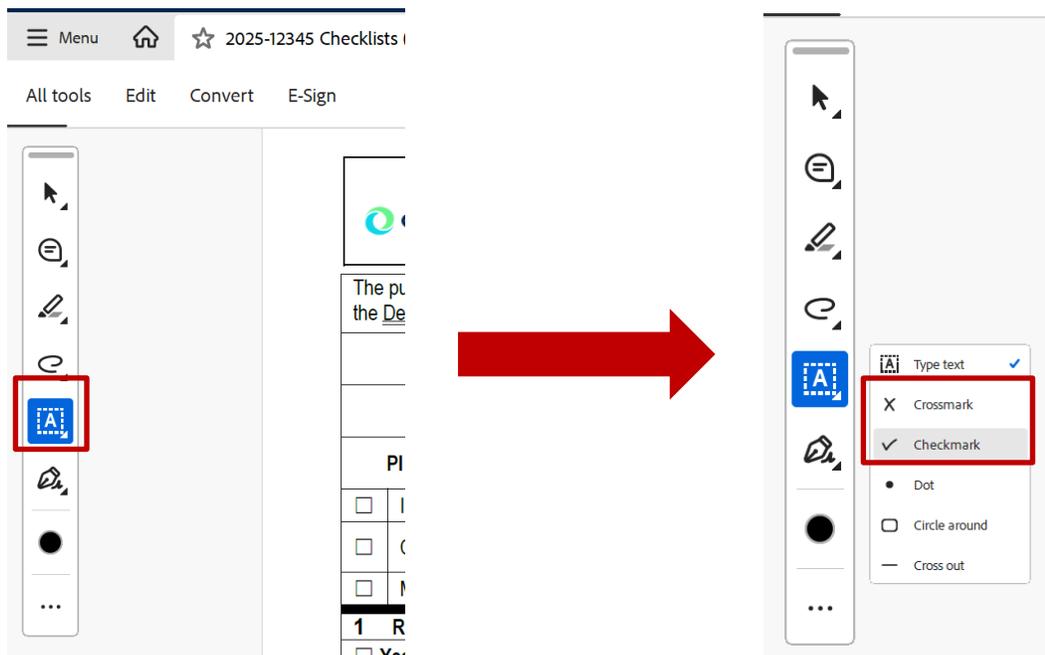
3. Completing the analyst checklist, if applicable.

The analyst will prepare a pdf checklist packet that includes the analyst pre-review and any checklists the reviewer may need to complete. If you identify additional checklists are needed, feel free to reach out to the assigned analyst for that checklist or you can access them on our external website (coming soon!).

If you need to complete any checklist in the pdf format, download the checklist from the Reviewer Checklist by clicking on the document. This file will go into your downloads folder.



Open the document and locate the side bar on the left-hand side of the pdf. Locate the text box with an 'A' in the center. A side menu will appear and you can select a "Crossmark" or "checkmark" to complete the PDF.



Hover the symbol over the box you want to mark and click once. Here is an example of what it looks like.

1 REVIEWER CF	
<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
<input type="checkbox"/> N/A	

Save the file and upload it to the reviewer checklist. I recommend keeping the file name the same so it replaces the analyst checklist in the attachment section.

Name	Type	Date
checklists 2021-171.pdf	Checklist	01/21/2026

Upload your checklists here, if applicable. [Add Note](#) [View Audit](#)

Add Attachment

4. Viewing the Meeting Agenda

Click on the "Meeting" tab at the top of OneAegis.

Corewell Health Home **Meetings** Create Study Reports Contacts Administration

Find Study

Study

Committee

Site

Status *All

Sponsor/CRO

Sponsor Id

PI

Any Contact

Keyword(s)

Locate the meeting of interest and select the "Paper" icon (agenda).

Corewell Health Home Meetings Create Study Reports Contacts Administration

Meeting Maintenance

Last 12 Months 2026 2025

Action	Date	Committee	Location
	03/03/2026	West IRB	Virtual and in person at 15 Michigan
	02/03/2026	West IRB	Virtual and In Person at 15 Michigan
	01/26/2026	East IRB 2	
	12/10/2025	Test IRB Committee	
	12/10/2025	West IRB	
	09/02/2025	Test IRB Committee	
	07/30/2025	Test IRB Committee	
	06/09/2025	Test IRB Committee	Link to meeting

On the left-hand side of the screen, under "Actions," click on "Member's View."

The screenshot shows the Corewell Health interface. At the top, there is a navigation bar with tabs: Home, Meetings, Create Study, Reports, Contacts, and Administration. Below this is a sidebar with a list of actions: Re-apply Default Sort, Member's View (highlighted with a red box), Preview Agenda, View in Word, Preview Summary, View Summary In Word, and Done. Below the actions is a 'Recent Items' section listing study IDs and names. The main content area is titled 'Agenda Display' and shows a 'Meeting' for 'Committee West IRB'. Underneath, there is an 'Agenda' section with three tabs: 'Tree view' (selected), 'Preview', and 'Summary'. A list of agenda items is shown, including 'Header', 'Re-Review: Initial Reviews', 'Initial Reviews', 'Re-Review: Modifications', 'Modifications', 'Re-Review: Continuing Reviews', and 'Continuing Reviews (1)'.

You are now viewing the entire Agenda for the meeting. Full Board items that are being reviewed are located at the top. All expedited, exempt, and study completions are located underneath the Full Board items.

- Click the IRB number to view the study home screen.
- Click on the event name to go to the event.
- Click on the down arrow next to the event name to immediately access the xforms and attachments.

This screenshot provides a detailed view of the 'Member Agenda' section. The navigation bar is the same as in the previous screenshot. The sidebar on the left includes sections for 'Actions', 'Recent Items', 'Messages', and 'Useful Links'. The main content area shows the 'Member Agenda' for 'Committee West IRB'. It lists various review categories, each with a count in parentheses: Header (0), Re-Review: Initial Reviews (0), Initial Reviews (0), Re-Review: Modifications (0), Modifications (0), Re-Review: Continuing Reviews (0), and Continuing Reviews (1). Under 'Continuing Reviews (1)', there is a 'Continuing Review' section with a table. The table has two columns: 'Study' and 'Title'. One row is highlighted, showing the study ID '1812-000-CHW' and the title 'An Open-Label, Multicenter, Extension Trial to Evaluate the Long-Term Safety and Efficacy of Apitegr...'. A red box highlights the study ID, and a red arrow points to it from the text above. Below the table, there is a 'Reportable New Information (RNI)' section with a table. The table has two columns: 'Study' and 'Title'. One row is highlighted, showing the study ID '2025-12345-CHW' and the title 'Testing a Device Through this Randomized Clinical Trial'. A red box highlights the study ID, and a red arrow points to it from the text above. Below the table, there is a dropdown menu with three options: 'xForms', 'Attachments', and 'Generated Docs'.