

Children's Wisconsin Transition: Frequently Asked Questions

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1. What studies will be transitioned from the CW IRB to the MCW IRB?

Projects that currently are approved by the CW IRB will need to be transferred to MCW IRB oversight. The transfer of these projects will begin on July 1, 2022, for studies expiring in November 2022, coordinated with the expiration date of the research project.

CW IRB projects that will not be transferred to MCW IRB oversight at this time and will continue to be processed by the CW HRPP Office include:

- Exemptions
- Case Reports
- Quality Improvement
- Not Human Subjects Research
- Reliance on another IRB

2. How do I transfer my project from the CW IRB to the MCW IRB?

IRBNet projects will receive a notification from eBridge beginning 120 days prior to protocol expiration. The process of transferring currently approved research projects will begin by submitting a 'Transfer Project' application in eBridge no later than 90 days prior to the research project's expiration date. This submission will consist of completing the new research project submission, PRO SmartForm and the Continuing Progress Report (CPR) SmartForm.

3. How do I know if my project is ready to be transferred?

The Principal Investigator (PI) and Primary Contact (PC) of IRBNet projects will receive a notification from eBridge beginning 120 days prior to protocol expiration. Research projects are being transferred into eBridge in batches based on expiration date.

Batch 1: Projects with an expiration date between November 2022 through April 2023

Batch 2: Projects with an expiration date of May 2023 through October 2023

Batch 3: Research projects not in Batch 1 or 2 and projects in data analysis/manuscript preparation that involves the use of identified and/or coded data.

If you are a PI or PC on an existing IRBNet project and you did not receive a notification from eBridge, but your project expiration falls into batch 1 as described above, please contact the CW HRPP office at chwirb@chw.org.

4. When should I submit my transfer CPR?

The CW and MCW HRPP Offices recommend starting the transfer process 120 days prior to the research project's expiration date and submitting for MCW IRB review no later than 90 days prior to expiration.

5. How do I change the contact person on my transfer CPR?

1. Navigate to the PRO workspace
2. Select the activity "Update My Project" located on the left side of the screen under "Activities" (This activity is available to the PI and any project team member with edit access to the PRO)
3. In the popup, select "Update" in 2.1 next to the current Contact Person and uncheck the box in B denoting that this person is the Primary Contact before selecting "OK".
4. Either select "Update" next to a person in the table you want to be the new Contact Person or select "Add" to add a person to be the new Contact Person.
4. If adding a new person, enter the requested information in the popup, check the box in B, and select "OK" (Note: If you cannot find the project team member in the list to select, then this person does not have an eBridge account. Ask this person to complete an eBridge Registration form.)
5. Any new or updated project team member information should appear in the table in 2.1. Select "OK" once all new project team members have been added or updated.
6. The requested changes will either be automatically applied or routed to the IRB Office for review

6. How do I add new study staff to my transfer CPR?

1. Navigate to the PRO workspace
2. Select the activity "Update My Project" located on the left side of the screen under "Activities" (This activity is available to the PI and any project team member with edit access to the PRO)
3. In the popup, select "Add" in 2.1.
4. Enter the requested information in the popup and select "OK" (Note: If you cannot find the project team member in the list to select, then this person does not have an eBridge account. Ask this person to complete an eBridge Registration form.)
5. The new project team member should appear in the table in 2.1. Select "OK" once all new project team members have been added.
6. The requested changes will either be automatically applied or routed to the IRB Office for review

7. Do all my project team members need an eBridge account?

In order to be listed as a project team member in eBridge, the individual will need an active eBridge account.

To register for an eBridge account, go to [eBridge](#), select 'Registration' in the top right, and complete the web form. The registration will be sent to the eBridge help desk to create an account. Once an account is created, the individual can be added to the project using the "Update My Project" activity in the PRO workspace.

8. What consent, parental permission and assent form templates should I use?

The MCW templates should be used. Templates can be found on the MCW [HRPP website, under "Assent Templates"](#). These templates have been updated to include CW institution specific information.

9. Do I need to include a protocol with my IRB application?

Yes, a protocol is required to be included. This document should be uploaded into section 52 of the PRO SmartForm

10. Will my IRBNet info be automatically populated into eBridge?

A PRO shell will be created with basic information about the project. The PRO SmartForm will not be automatically populated with the content from IRBNet.

11. Will I have access to my completed research project(s) in IRBNet through eBridge?

Research Projects that are completed in IRBNet will not be transferred into eBridge; however, these projects will still be accessible in IRBNet.

12. For my transfer CPR, which documents should be uploaded in Section 18 of the CPR and which documents should be uploaded in Section 52 of the PRO?

CPR Section 18. Supporting Documentation should include copies of the following that has occurred since initial approval or the last CPR completed with the CW IRB (whichever is most recent) where applicable:

- Log or spreadsheet of all unanticipated problems
- Log or spreadsheet of all protocol deviations
- DSMB/DSMC report(s) or its equivalent
- External reviews or audit reports or monitoring visit reports since the last CPR
- Copies of publications resulting from this research
- Any other documents that may assist the IRB in the continuing review process
- Clean Microsoft Word version of currently effective consent , parental permission and/or assent form(s) in addition to new versions using the MCW IRB templates
- Summary report from the sponsor or the coordinating center for the project if this is a multi-site project

PRO Section 52. Supporting Documents should include the most current documents being used for the project.

The same consent forms can be uploaded to both Section 18 of the CPR and Section 52 of the PRO as long as they are the same version.

13. Can my CW funding be added to my transfer CPR?

Yes, CW funding can be added to Section 11 of the PRO.

14. If I have a project that is already approved by the MCW IRB, should I still select “Resources at Children’s Wisconsin” in 4.1?

If you are using resources at Children’s Wisconsin and are already approved by the MCW IRB, please select the checkbox “Resources at Children's Wisconsin (such as enrolling patients, imaging, pTRU, records, samples, use of facilities/buildings/clinics/services, etc.) in PRO SmartForm question 4.1.

Your submission will be routed to Ancillary Review where the Children’s Wisconsin HRPP Office has a process in place for efficiently routing your submission to the MCW IRB office for review.

The CW HRPP instructions/processes that were in place for studies that have a shadow submission in IRBNet are still in place.

15. What should I do if I want to close my CW project (IRBNet), but a transfer CPR already exists in eBridge?

Project closures that occur prior to the transfer CPR being submitted to the MCW IRB for review should be closed with the CW IRB. The CW and MCW HRPP Offices have a process in place to manually withdraw the transfer CPR in eBridge once the project is closed in IRBNet. An activity to close the transfer CPR is not available to the PI or Contact Person in eBridge.

16. Should I submit an amendment to the CW IRB if I have a transfer CPR in eBridge?

Contact the CW HRPP Office for clarification. Timing questions will be handled on a case by case basis by the CW and MCW HRPP Offices. PI and project team members should continue to submit reportable events and amendments to the CW IRB as needed to remain in compliance.

17. I already have a PRO in eBridge that relies on the CW IRB and a CW project in IRBNet with the same project work. Do I need to both transfer the CW project and maintain the existing reliance agreement?

The CW IRBNet protocol will be transferred into to eBridge for MCW IRB approval. Once the transfer CPR is approved by the MCW IRB, the MCW HRPP Office will work with you to close the existing PRO that relies on the CW IRB so that there is only one submission being maintained.

18. Existing communication recommends closing project in data analysis. Is there a timeframe for when the study needs to be closed?

A study should not close in IRBNet before data analysis is completed. At the end of 2023, we will review all IRBNet projects that are in data analysis and not yet closed. At that time, the plan then is to do a batch 3 and import those projects into eBridge.

19. I have multiple CW IRB submissions; can I transfer all the submissions at once?

The transfer of projects from the CW IRB to the MCW IRB is coordinated with the expiration date of the research project. An CW investigator with multiple projects will be notified when each project has been created in eBridge and they can begin the transfer process.

20. What do I need to do if I want to use the Pediatric Translational Research Unit (pTRU) as a part of my project?

Please reach out to the pTRU in advance of submitting to the IRB to secure approval for the use of their resources. Approval documentation must be uploaded in section 52 of the PRO SmartForm.