EDW Exception Workflow Viewable in Study Tracker

The required method for reviewing NMHC electronic health record data for research purposes is through an EDW report. Where data are not available in the EDW through a report, FSM policy allows direct electronic medical records access through an exception process. The Research Use of EDW Data policy further outlines how research data can obtained in compliance with NU and NMHC agreements. Please review the Permissible Use FAQ for more information about how this policy may apply to your research and how to access electronic health record data in a compliant manner.

EDW Study Exception

When a study exception is submitted via REDCap through the “Research Use of NMHC Data” form, a submission status for the exception will appear in Study Tracker. This will occur after the application and Study Tracker have synced, generally within the next business day. You can view this exception status on your studies dashboard upon logging into Study Tracker.

Upon opening a specific study in Study Tracker, further information regarding the EDW Exception application can be found at the bottom of the Compliance page. Application status updates (i.e. Submitted, Awaiting EDW Review, Awaiting PI Attestation, Approved, Denied) will be updated and included in this section to track the progress of the EDW exception approval.
Once a study receives approval, a history button will display next to the “Approved” status allowing you to see the different status’ and timepoints associated with the EDW Exception application for this study.

Questions about the EDW Exception process can be sent directly to the EDW Support Team at nmedw@northwestern.edu.
How to Add a Study Team Member to the EDW Exception Application

In the previous workflow, study team members were added on the REDCap form. This is no longer the case. Once the study’s EDW Exception Status displays as ‘Approved’ in Study Tracker, you can then add the Study Team Member(s) who should have EDW Exception access in Study Tracker directly.

Locate the ‘Epic Section’ under the ‘Settings’ tab. The section labeled “Study Team Members With Access to Epic” will then display the option to add the reason to access Epic of “Research Use of Electronic Medical Record data (EDW Exception).” Update each of the Study Team Member’s Epic access as applicable. The option to add a Study Team Member for “EDW Exception” will only display AFTER the study’s EDW Exception application has been approved and only those on the authorized personnel list may be added.

For further questions on Study Tracker usage please contact the Study Tracker Support Team at studytracker@northwestern.edu. Additional resources and information regarding the FSM Policy and Study Tracker usage can be found on the Study Tracker FAQ NUCATS page.
Summary of Changes Effective 3/21/2022

- Attestations are submitted via updated REDCap intake form, “Research Use of NMHC Data”.
- A PI will sign off on the attestation in REDCap after the exception is approved (this is the same).
- Those who are added in Study Tracker to the approved exception will receive an attestation to sign the first time they have an approved exception (via REDCap), not each time.
- Use Study Tracker to see the exception status for a study.
  - For those studies approved prior to March 21st, only the last status in REDCap will be displayed in Study Tracker.
  - For those studies approved after March 21st, study tracker will show the full history of the exception approval process.
- Use Study Tracker to see and update the study team members listed on an approved exception.
  - Exceptions by person can be found under the user profile in the upper right-hand corner of study tracker.
  - Exceptions by study can be found on the Compliance tab in each study record.
  - Exceptions by department/organization can be found in the Org reports tab, under “EDW Exceptions”.
- Attestations will be required of the entire research team for actively approved studies on a yearly basis.
- Exceptions approved for systems other than Epic (Syngo, Visage, etc.) will not automatically carry forward. If a study was approved for an exception for one of these systems prior to March 21st, the exception request to add that system must be re-submitted.
- To submit your exception request, please click on this NEW REDCap intake form: https://redcap.nubic.northwestern.edu/redcap/surveys/?s=JJFE7RDJNC.