



EPIC Onsite Research Monitoring Guidance Document

Updated April 21, 2025

The purpose of this Guidance Document is to describe the standard procedures to be followed by research team members when requesting research study monitor EPIC access.

RESPONSIBILITY:

This Guidance Document sets forth responsibilities for research team members when requesting EPIC access for research monitors. This applies to external research monitors, sponsor auditors, or federal agency monitors for on-site monitor access to the George Washington University EPIC system.

PROCEDURE:

If a monitoring visit occurs where the monitor(s) need to access Protected Health Information (PHI) in EPIC, the following criteria must be met and the CRA must adhere to the requirements outlined in this document.

Requirements for Onsite Monitoring Visits Requiring EPIC Access

For a monitoring visit conducted onsite, please follow the steps below:

- 1.) Email clinicalresearch@mfa.gwu.edu to request a laptop for the monitor to use while they are onsite. NOTE: The monitor will have to sign the laptop in and out every day they are onsite.
- 2.) Once a monitoring visit is scheduled with the study monitor, fill out the EPIC Monitoring Request Form on the OCR website (<https://clinicalresearch.gwu.edu/researchers/forms-tools-templates> under EPIC) no later than two weeks before the scheduled visit.
- 3.) Create a batch release of the pre-determined subjects in EPIC. Follow the EPIC Tip Sheet (Linked Here) **NOTE: Monitors will ONLY be granted access to the subjects that they have outlined in their monitoring visit plan, NO additional subjects can be added to the list by the monitor to be review after the inspector ID has been generated and the form has been submitted to the OCR.**
- 4.) Document the Inspector Key generated from the bath release on the EPIC Monitoring Request Form
- 5.) Email the completed EPIC Monitoring Request Form with Inspector ID to the Senior Manager of Regulatory and Compliance
- 6.) The Senior Manager will review the form for accuracy and completeness. Then, an IS&T ticket will be submitted on the research team's behalf to the EPIC IT team
- 7.) The EPIC IT team will send the generic username and password back to the Senior Manager.
- 8.) The Senior Manager will complete the EPIC Monitoring Request form by entering the generic username and password provided by EPIC IT and send it back to the research team



- 9.) The study coordinator will release the patient chart(s) and information to the provided account assignment username. See EPIC Tip Sheet (linked)
- 10.) The monitor will be able to only access the designated research folder that contains subject PHI in EPIC
- 11.) Once the pre-approved time for monitor access has been reached, the system will automatically kick them out
- 12.) In case of an urgent need for access to EPIC (i.e. in the event of a For cause audit), contact the Epic Analyst via solutioncenter@mfa.gwu.edu.

For Regulatory Department

- 1.) Ensure that the request is sent to solutioncenter@mfa.gwu.edu as a ticket so that it can be tracked and referenced if there are any issues with the monitor's access
- 2.) Upload into SharePoint the Monitor's name, what department they are monitoring, how long they will be here, the Protocol ID, and primary study contact

For Research Monitors

- 1.) A laptop will have to be signed out the day of the monitoring visit and signed in once it has been returned to the OCR.
- 2.) Monitors will use the provided account assignment username and password to login to the network as well as into EPIC
- 3.) Please be aware that monitors will only have 10 login attempts, i.e., when you login to EPIC that counts as 1 attempt and if you log out for lunch and come back, that is 2 attempts, and so on and so forth.
- 4.) Please be aware that monitors will only be able to view pre-determined subject records; subjects **CANNOT** be added to the list the day of to be reviewed- a separate monitoring visit will have to be scheduled in order to do so.

For Research Staff

- 1.) Please ensure that you have requested EPIC access once you have scheduled a monitoring visit and no later than two weeks before the scheduled visit.
- 2.) If you have not been granted monitoring access within 2 weeks of submitting the form, please reach out to the Senior Manager.
- 3.) Monitors will only have access to a pre-determined list of subjects, subjects cannot be added to be reviewed the day of the monitoring visit
- 4.) Please be aware the monitor will only have 10 login attempts
- 5.) EPIC will automatically kick out the monitor at the conclusion of the time allotted. If more time is needed, please reach out to the Epic Analyst at solutioncenter@mfa.gwu.edu and reference the ticket number
- 6.) Review the EPIC Monitoring Request Tip Sheet (Link) for information on how to batch release research subjects in EPIC



7.) In case of an urgent emergency, contact the Epic Analyst at solutioncenter@mfa.gwu.edu.

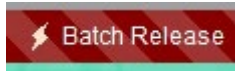
Attachments:

EPIC Release to Inspector - Batch Release Tip Sheet

EPIC Monitoring Request Form

Research Coordinator: Release to Inspector (Batch Release of Info to Study Monitors)

1. Click **Batch Release** from the top toolbar.



2. Click on **Create Batch**, and give it a name. The recommended Naming Convention is the Study Code (alphanumeric) followed by the person or entity to whom it will be released.

Name:

3. Click **Accept**.

A screenshot of the "Batch Records" dialog box. It has two tabs: "Select Batch" and "Create Batch". The "Create Batch" tab is selected and highlighted with a green circle. Inside this tab, there are fields for "Name" (containing "GW12345-Abbie"), "Template" (with a search icon), and "Chart type" (containing "GW MFA Encounter" with a search icon). At the bottom right, there are "Accept" and "Cancel" buttons, with "Accept" circled in green.


3. In the requestor field search "Research Monitor"

Include uncommon requesters



4. Select a **Release type**; the standard will be **Audit**.

Release type:


5. For Purpose, select **External Audit**.


Purpose:  

6. Select an Authorization type of **Signed Form**.

Authorization Type:  Expires On: 


Description:

 [Edit](#)  [Delete](#)  [Scan](#)





 [Close](#)

Authorization type:  [Scan](#)

7. Select the date range you'd like to release the records or select All Records.


 **Request**

Select Records

From Date:   To Date:   All Records

Info Requested

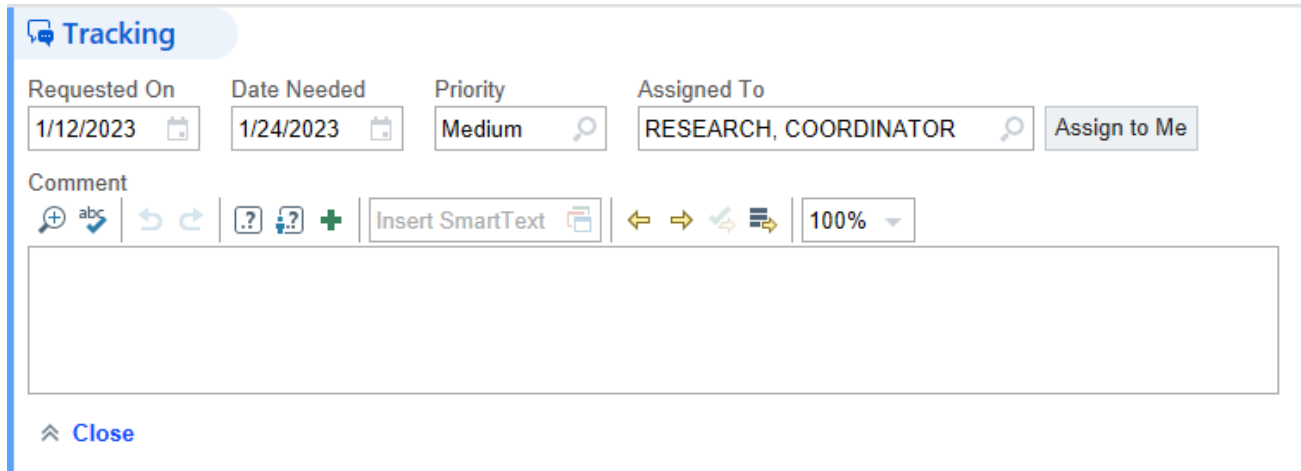
8. Click the check box next to Info requested for **All**.

Info requested:  All

9. At Output Format, select **Inspector**.



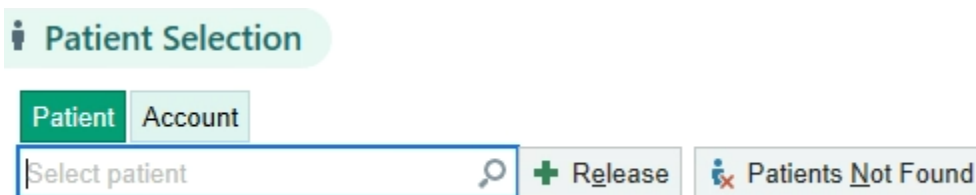
10. Tracking section assign to yourself and complete all the sections, be sure to press "Assign to me". (Best practice to perform the batch release 1 week prior to the visit)



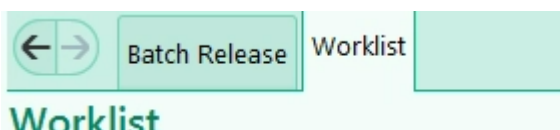
11. In the next section, indicate what patient the release is for. You can add one, or multiple.



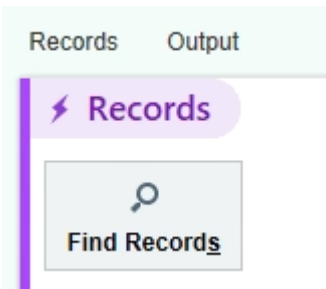
12. Search by name and add them to the list.



13. On the right, click "Worklist" to review the patient's information and select which records you would like to release.



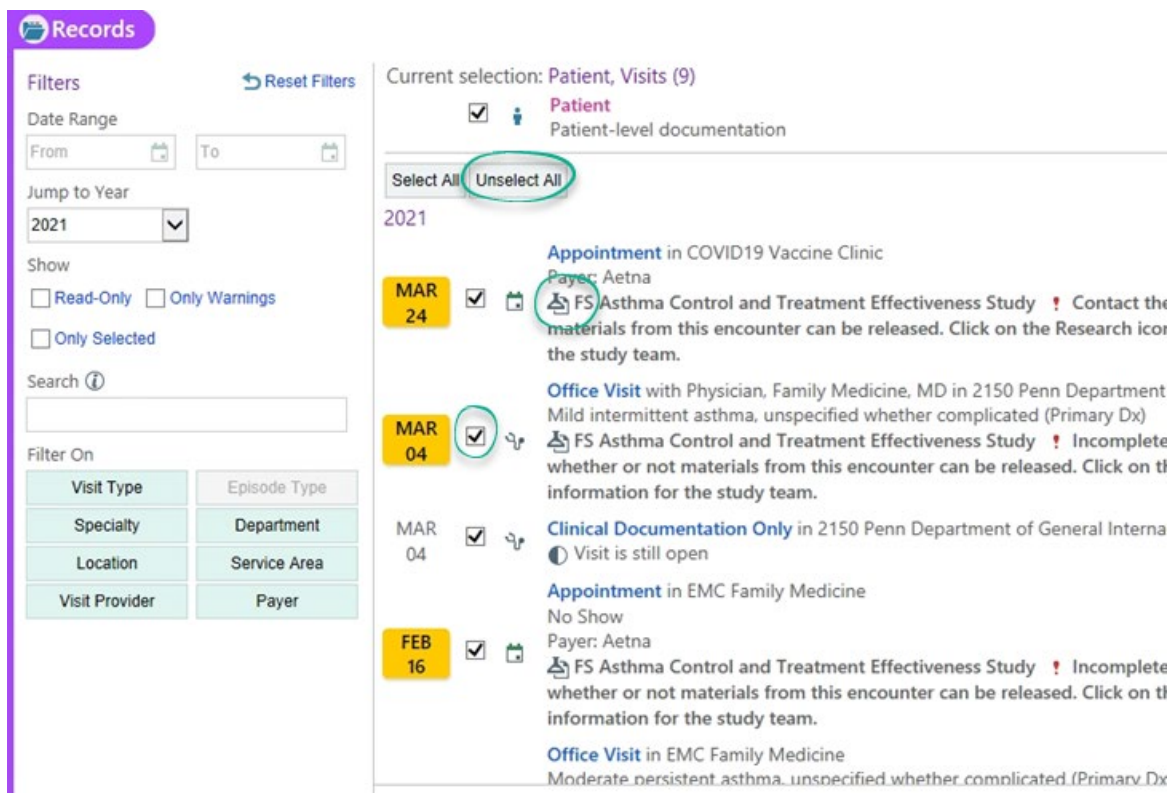
14. Click on each link, one by one. The patient's workspace will open. Click the large button **Find Records**.



15. When the records load, click **Edit Selection**.



16. All records are pre-selected by default. You will need to **Unselect All**, then **check off** the records you would like to release. The **Beaker** icon next to the record item indicates a link to Research.



17. You can also filter by: Date Range, Keyword Search, or a speed button like Department

18. Make sure to leave **Generate files on accept** checked. Once you have selected the records, click **Accept and generate files**.

19. Once generated, you will navigate back to the batch release tab and click the deliver button to reveal the inspector key.



20. The key should resemble the image below, press send and document the key.

Release to Inspector ✕

Key

P69-6AJ-446-3KR

Uses Left	Available From	Available To
<input type="text" value="10"/>	<input type="text" value="9/21/2023"/>	<input type="text" value="10/5/2023"/>

Comments

21. **Accept and you will see your key generated.**

