EPIC Onsite Research Monitoring Guidance Document

Updated April 09, 2024

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 Amanda Kohn, akohn@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 Sarah Ford-Trowell at strowell@mfa.gwu.edu, Sr Manager of Regulatory and Compliance

6.) Sarah Ford-Trowell will review the form for accuracy and completeness. Then, a 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 Sarah Ford-Trowell

8.) Sarah Ford-Trowell 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 Zoe Foster at zfoster@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 Sarah Ford-Trowell

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 Zoe Foster at zfoster@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 Zoe Foster at zfoster@mfa.gwu.edu

Attachments:

EPIC Release to Inspector - Batch Release Tip Sheet

EPIC Monitoring Request Form

The GW Medical Faculty Associates

EPIC Access for Study Monitors Request Form

Staff Name Requesting Access:	Click or tap here to enter text.
Staff Department Requesting Access:	Click or tap here to enter text.
Study Protocol ID Being Monitored:	Click or tap here to enter text.
Name of Monitor Needing Access:	Click or tap here to enter text.
Company/Agency of Monitor:	Click or tap here to enter text.
Timeframe for EPIC Monitoring Access:	**From (Date/Time):** Click or tap here to enter text. **To (Date/Time):** Click or tap here to enter text.
What type of Monitoring Visit is this:	☐ **Routine Monitoring Visit** ☐ **Sponsor Audit** ☐ **Federal Agency Audit** ☐ **Other (Please Explain):** Click or tap here to enter text.
Inspector Key Generated:	Click or tap here to enter text.

Below is for OCR Office Use Only

The above information was reviewed and approved by:

____________________ ____________________ _______________

Printed Name Signature Date

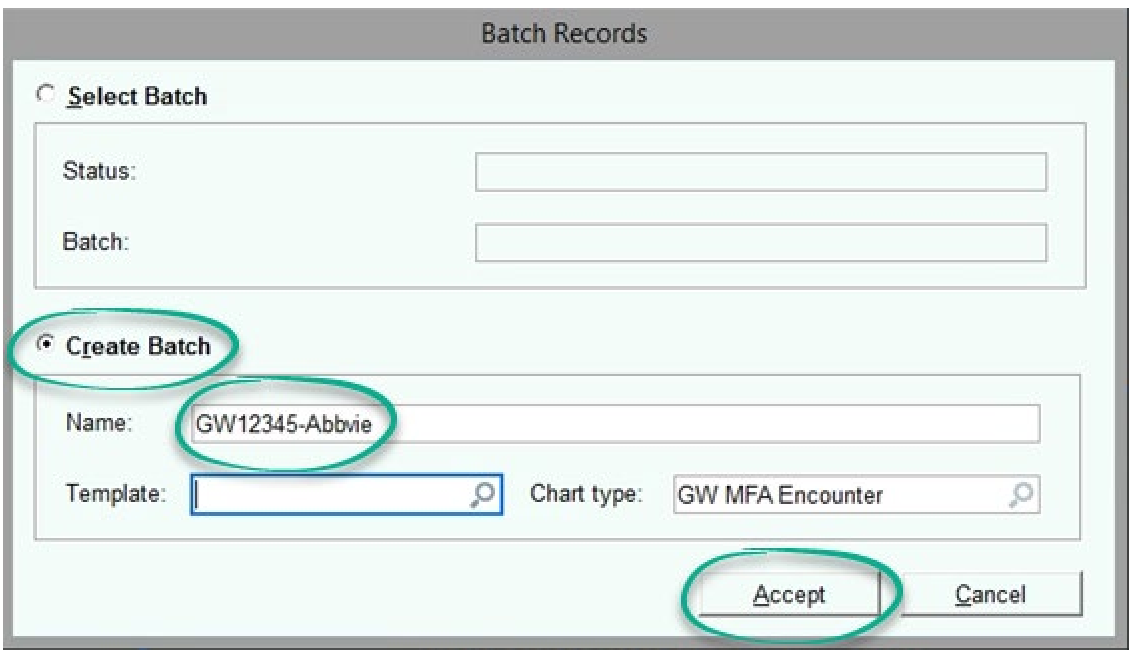
Assigned Generic User ID: ____________________

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.

3. Click **Accept**.

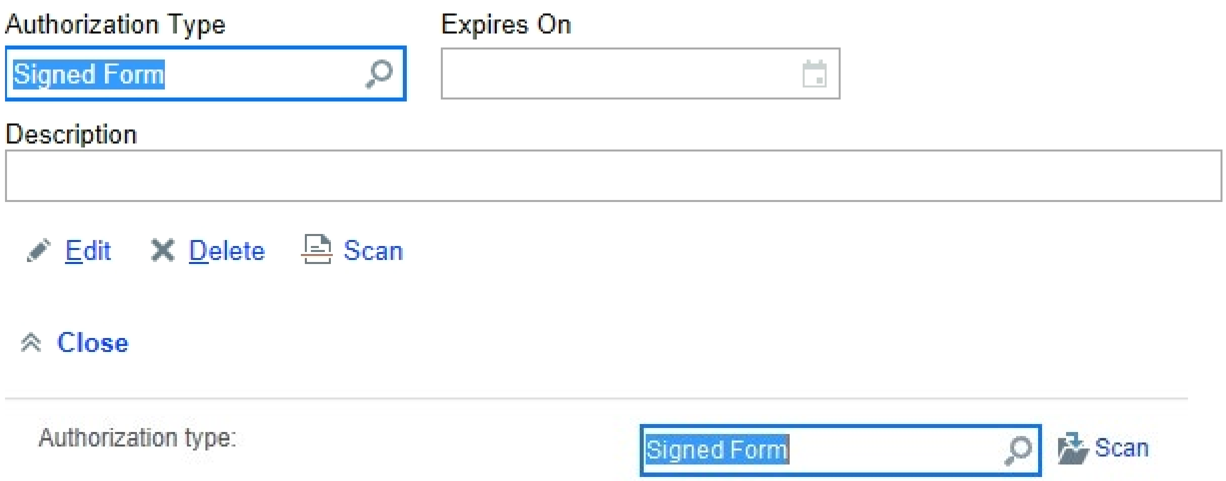


3. In the requestor field search "Research Monitor"

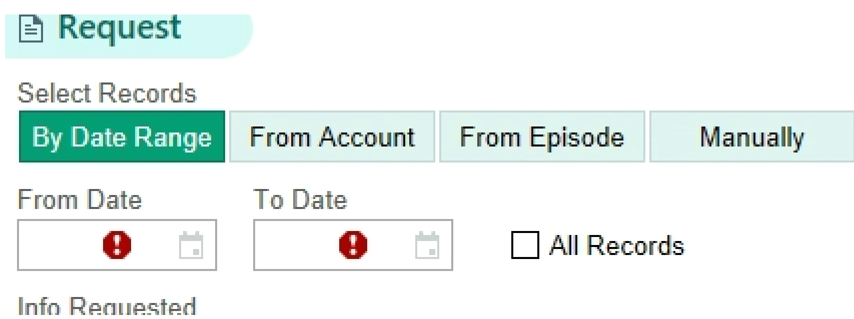
4. Select a **Release type**; the standard will be **Audit**.

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

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

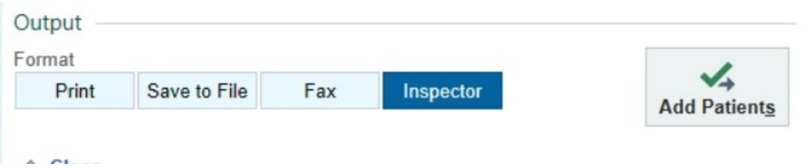


7. Select the date range you'd like to release the records or select All Records.

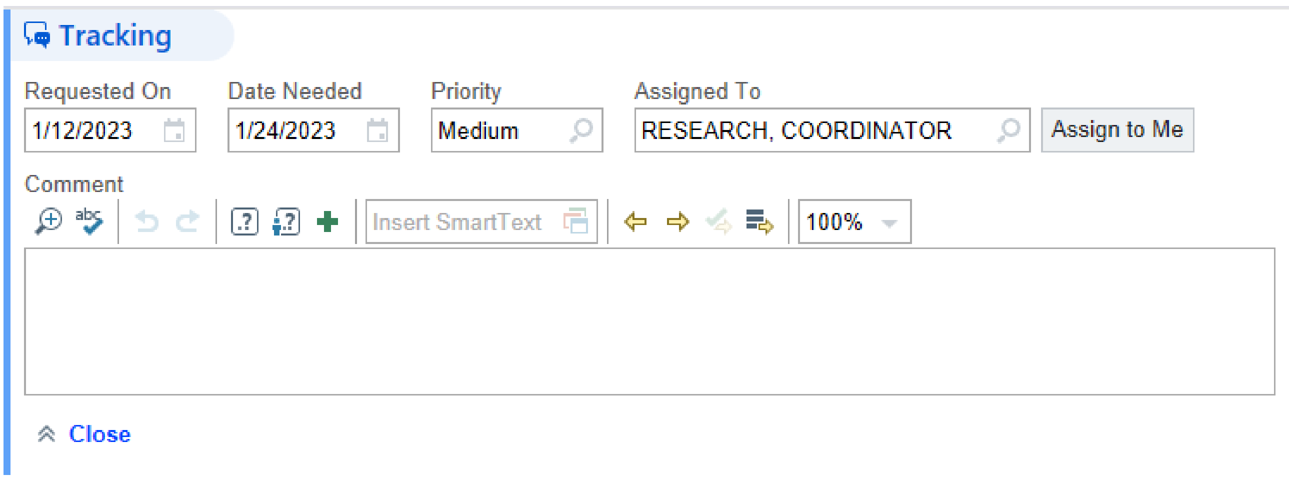


8. Click the check box next to Info requested for **All**.

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

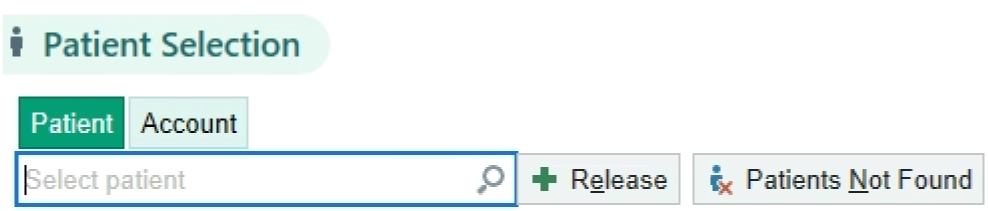


10. Tracking section assign to yourself and complete all the sections, be sure to press “Assign to me”. (Best practice to perform the batch release 1 week prior to the visit)

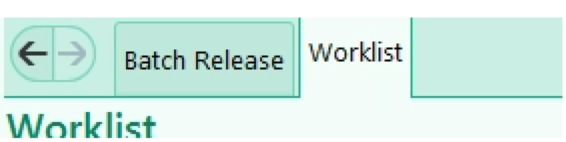


11. In the next section, indicate what patient the release is for. You can add one, or multiple.

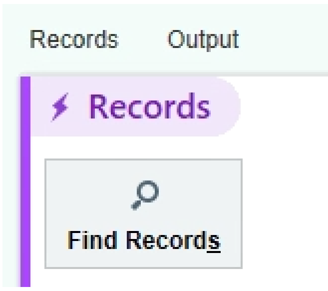
12. Search by name and add them to the list.



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

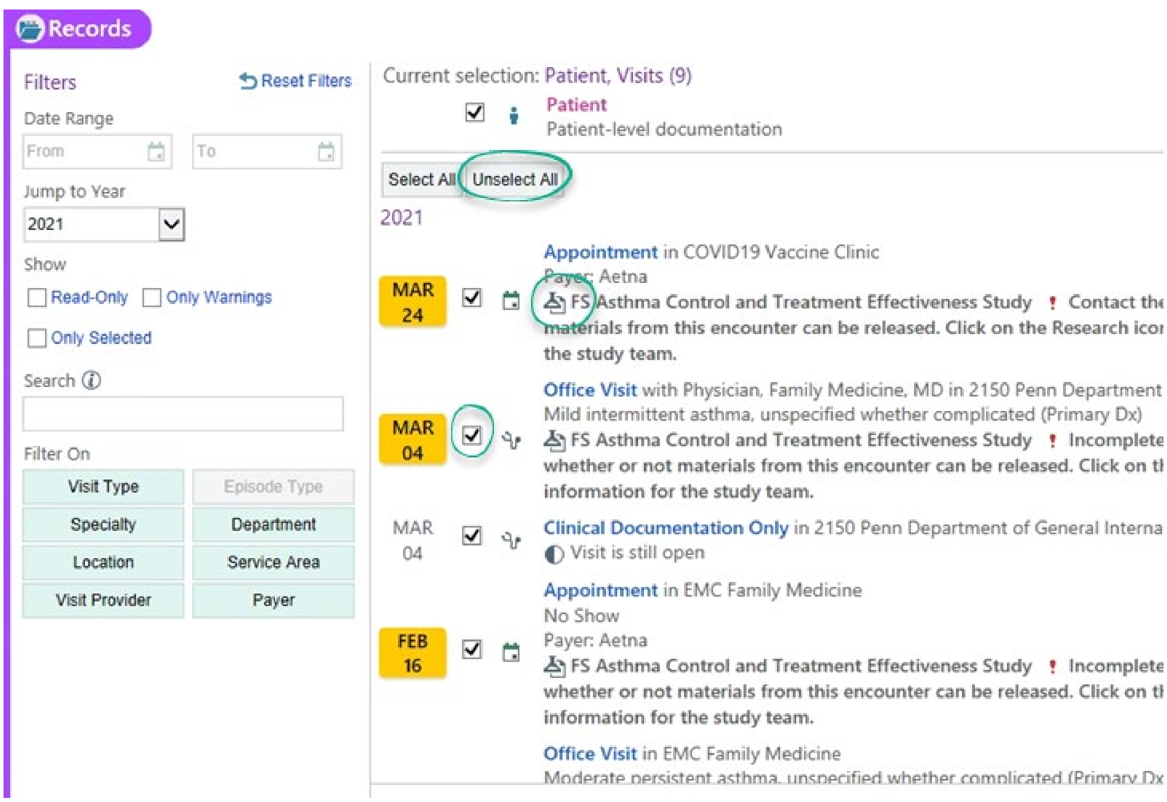


14. Click on each link, one by one. The patient's workspace will open. Click the large button **Find Records**.



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.

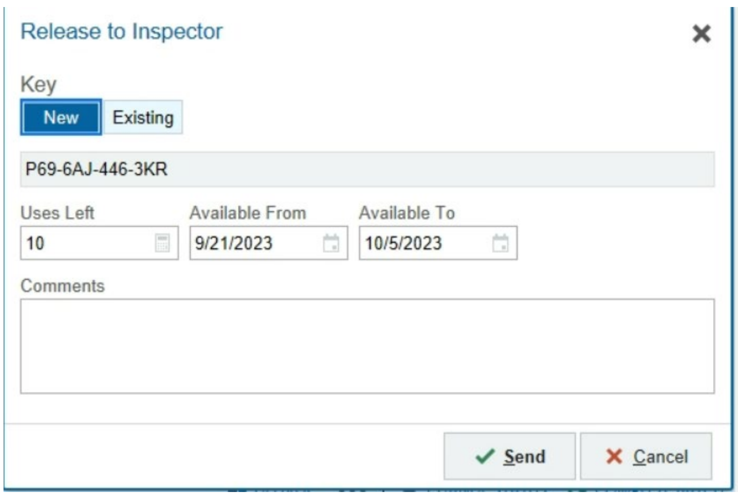


17. You can also filter by: Date Range, Keyword Search, or a speed button like Department

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.



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