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Beaumont

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Document Contact	Michele Sedlak: Lab Quality Coord
Area	Laboratory-Quality
Applicability	All Beaumont Hospitals

Laboratory RL Solutions Event Reporting System

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

The purpose of the quality reporting system is to improve patient safety and to reduce the risk of error. It is not meant as a punitive action against the responsible employee. A quality reporting system follows the Just Culture process. It is important to measure and assess process variance as a means of improving patient safety and minimizing opportunities for process error. It is the responsibility of every laboratory employee to work toward improving laboratory processes. Refer to Safety Event Reporting - RL Solutions.

II. DEFINITIONS:

A. **Safety Event (Occurrence):** "Any process/incident inconsistent with the routine operation of the hospital or the routine care of patients in any setting. This includes errors that result in actual or potential harm to a patient or visitor, including near misses or unsafe conditions."

B. **Serious Safety Event**: "An unexpected occurrence involving unanticipated death, serious physical or psychological injury, or risk thereof not related to the natural course of the patient's illness or underlying condition." Refer to Serious Safety Events for additional information.

C. **Safety Category Owner**: "A designated individual responsible for each occurrence Safety Event Category. Category Owners are responsible for follow-up, referring for Organization or Dept. Review, performance improvement recommendations, tracking, trending."

D. **File Manager:** A department leader or designee responsible for each occurrence in their department. File managers are responsible for follow-up and sign-off on all ERS files in their department once satisfied that all needed review and follow-up is completed.

E. **Confidentiality**: All Event Report Summaries (ERS) are **confidential** documents. Copies of

these reports must **not** be given to patients/visitors or be placed in the medical record.

F. **"Minor Errors":** Minor errors are those process variances which generally do not result in serious or potential harm to a patient, but which may impact process efficiency.

III. PROCEDURE

A. To report Lab/Specimen ERS process variances and patient safety concerns, report via RL solutions.
    1. From the Corewell Health intranet home page, click **"Report a Safety Concern."**
    2. Under **"Patient safety concerns,"** click **"Submit an EAST concern."** Refer to the procedure RL Solutions Quality/Safety Report Instructions.

B. To report a team member safety concern, report via SafetyPause. Refer to SafetyPause Team Member Event Reporting System.
    1. From the Corewell Health intranet home page, click **"Report a Safety Concern."**
    2. Under **"Team member safety concerns"** click **"Submit a SafetyPause."**

C. To report "non-ERS" process variance (i.e. "Minor errors"), use the department specific process for reporting issues. **Note**: Complete the internal variance process as defined by your department.

D. **For Category Owners:**
    1. Review the ERS and task to the appropriate manager/designee for review/follow up.
    2. Analyze, track and trend, propose process improvement recommendations on an ongoing basis.
    3. Follow ups, department reviews, and first responder interviews will be conducted as needed.
    4. At times, managers may not respond to ERS Reports which have been forwarded to them for follow-up. For these **non-responses:**
        a. Resend these reports up to an additional two times; then if still no response,
        b. On the 3rd send, also copy the ERS Report to the Operations Director (of the "send to" recipient).

E. **File Manager Review Process for ERSs:**
    1. The manager who receives the ERS should *first* review the procedure and process to validate it is complete in content, clearly written, and does not provide opportunity for user-error.
    2. Meet with the employee to discuss the incident, identify the root cause(s), and identify the Action Plan(s) to use in avoiding future such occurrences of this type.
    3. Document investigation and follow up in the ERS in a timely manner.
        a. In the ERS file, click on the **"Add Follow Up"** in the upper left corner and select **"Work done on file"**. Document the follow up and click **"Add"**. There is an alternate way to document follow up under the "File Manager Sign off

Section."

IV. SPECIAL NOTES:

A. **Duplicate Reports:** As multiple users identify process variance, there may, on occasion, be multiple ERS Reports generated for the same variance incident. It is the responsibility of the Category Owner to filter these duplicates from the RL solutions system.

B. **Multiple Patients:** At times, a process variance may have effect upon multiple patients. (e.g. missed pick-up, or mislabeled specimens). For each patient who is affected, generate a separate ERS report. Exceptions may be made for cases where very large numbers of patients are affected. Refer these cases to the Category Owner.

C. **Anonymous Reporting Using RL Solutions:** Under certain conditions, employees may feel more comfortable/safer submitting a report anonymously. This can be done at the point of Log-in to RL Solutions. Instead of clicking the "Log-in" button, click the "Submit Anonymously" button.

V. REFERENCES:

A. SWARM Alerts: Missing or Lost Specimens

B. Notification of Corrected Laboratory Results

C. Reporting Laboratory Device-Related Adverse Patient Events

D. SafetyPause Team Member Event Reporting System

E. ERS File Manager Training, February 2024.

Attachments

Attachment A - Entering a ERS in RL Solutions.pdf

Attachment B- File Manager Review in RL Solutions.pdf

Approval Signatures

Step Description	Approver	Date
CLIA Site Licensed Medical Directors	Muhammad Arshad: Chief, Pathology	9/27/2024
CLIA Site Licensed Medical Directors	Jeremy Powers: Chief, Pathology	9/26/2024

CLIA Site Licensed Medical Directors	Ann Marie Blenc: System Med Dir, Hematopath	9/26/2024
CLIA Site Licensed Medical Directors	Hassan Kanaan: OUWB Clinical Faculty	9/23/2024
CLIA Site Licensed Medical Directors	Ryan Johnson: OUWB Clinical Faculty	9/16/2024
CLIA Site Licensed Medical Directors	Subhashree Mallika Krishnan: Staff Physician	9/16/2024
CLIA Site Licensed Medical Directors	Masood Siddiqui: Staff Pathologist	9/16/2024
CLIA Site Licensed Medical Directors	John Pui: Chief, Pathology	9/16/2024
CLIA Site Licensed Medical Directors	Kurt Bernacki: System Med Dir, Surgical Path	9/16/2024
Policy and Forms Steering Committee Approval (if needed)	Michele Sedlak: Lab Quality Coord	9/16/2024
	Sarah Britton: VP, Laboratory Svcs	9/9/2024
Operations Directors	Joan Wehby: Dir, Lab Services	9/3/2024
Operations Directors	Brittnie Berger: Dir Sr, Lab Operations	8/14/2024
Operations Directors	Amy Knaus: Dir, Pathology Service Line	8/9/2024
Operations Directors	Christopher Ferguson: Dir, Lab Services	8/9/2024
Operations Directors	Elzbieta Wystepek: Dir, Lab Services	8/8/2024
	Michele Sedlak: Lab Quality Coord	8/8/2024

Applicability

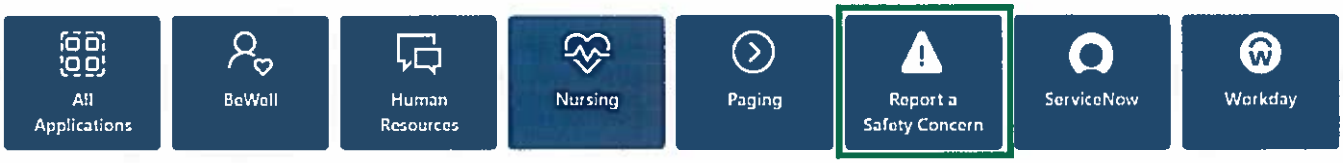
Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Taylor, Trenton, Troy, Wayne

Corewell Health

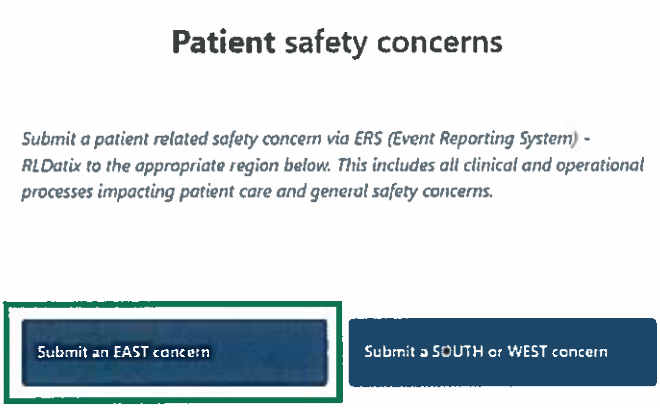
Corewell Health East
Dearborn • Farmington Hills • Grosse Pointe • Royal Oak • Taylor • Trenton • Troy • Wayne

Entering an ERS report in RL Solutions

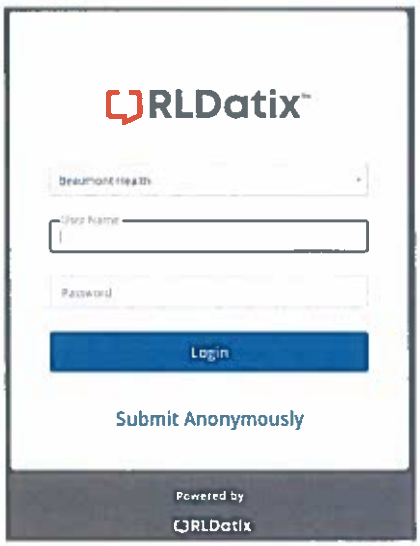
1. From the Corewell Health intranet home page, click "Report a Safety Concern."



2. Under "Patient safety concerns," click "Submit an EAST concern."



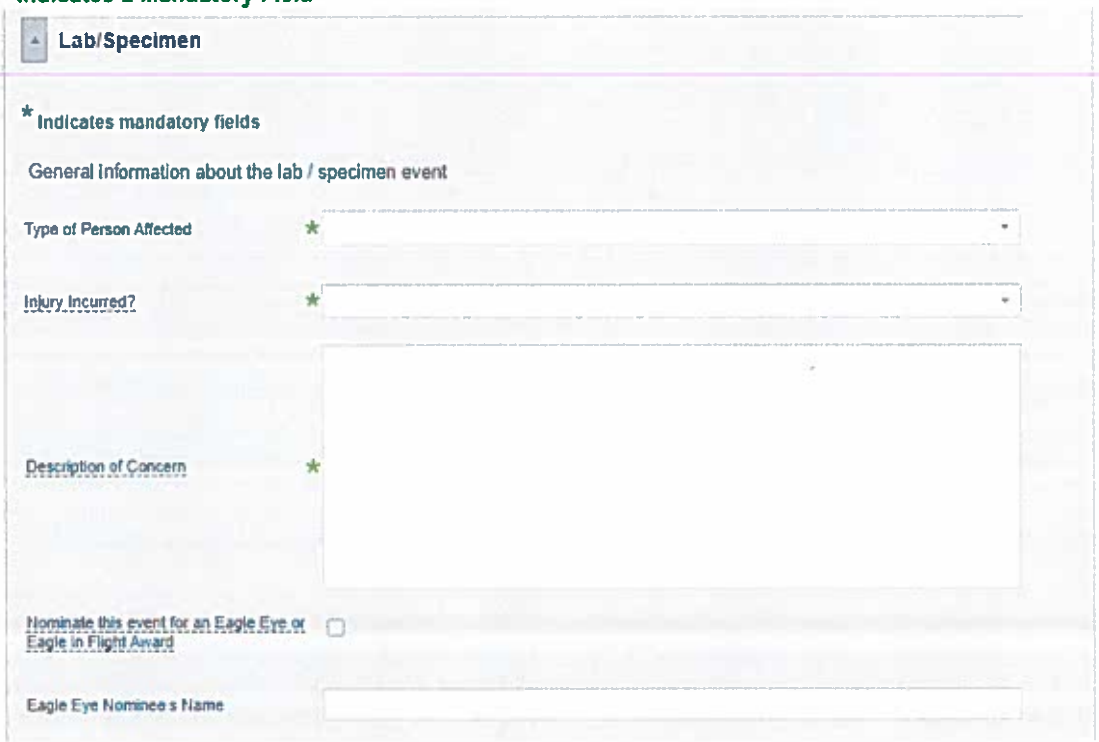
3. Login using your credentials or submit anonymously.



Entering an ERS report in RL Solutions

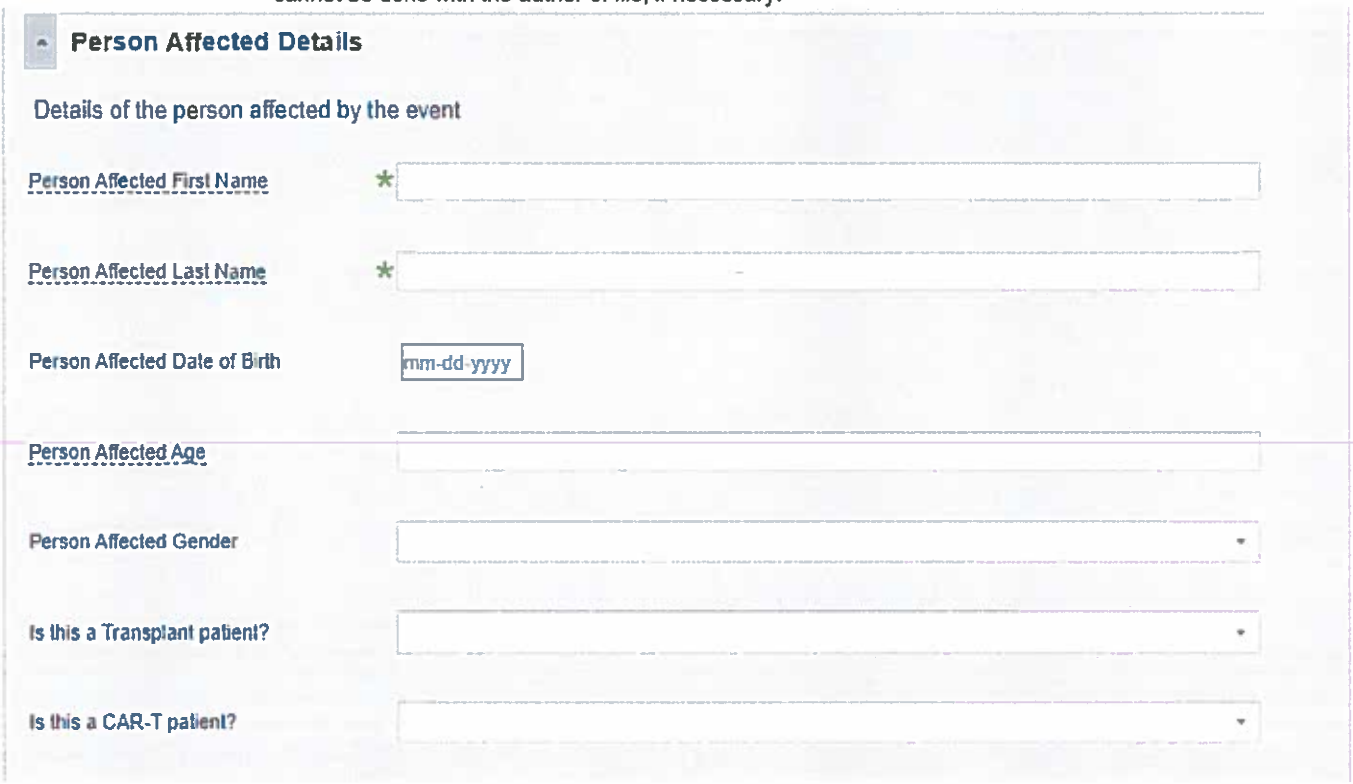
4. There are many categories to select from. For laboratory issues, select "Lab/ Specimen" or "Blood Product" (Blood Bank use).

5. **Lab/ Specimen Reporting Tutorial**
   a. *** Indicates a Mandatory Field**



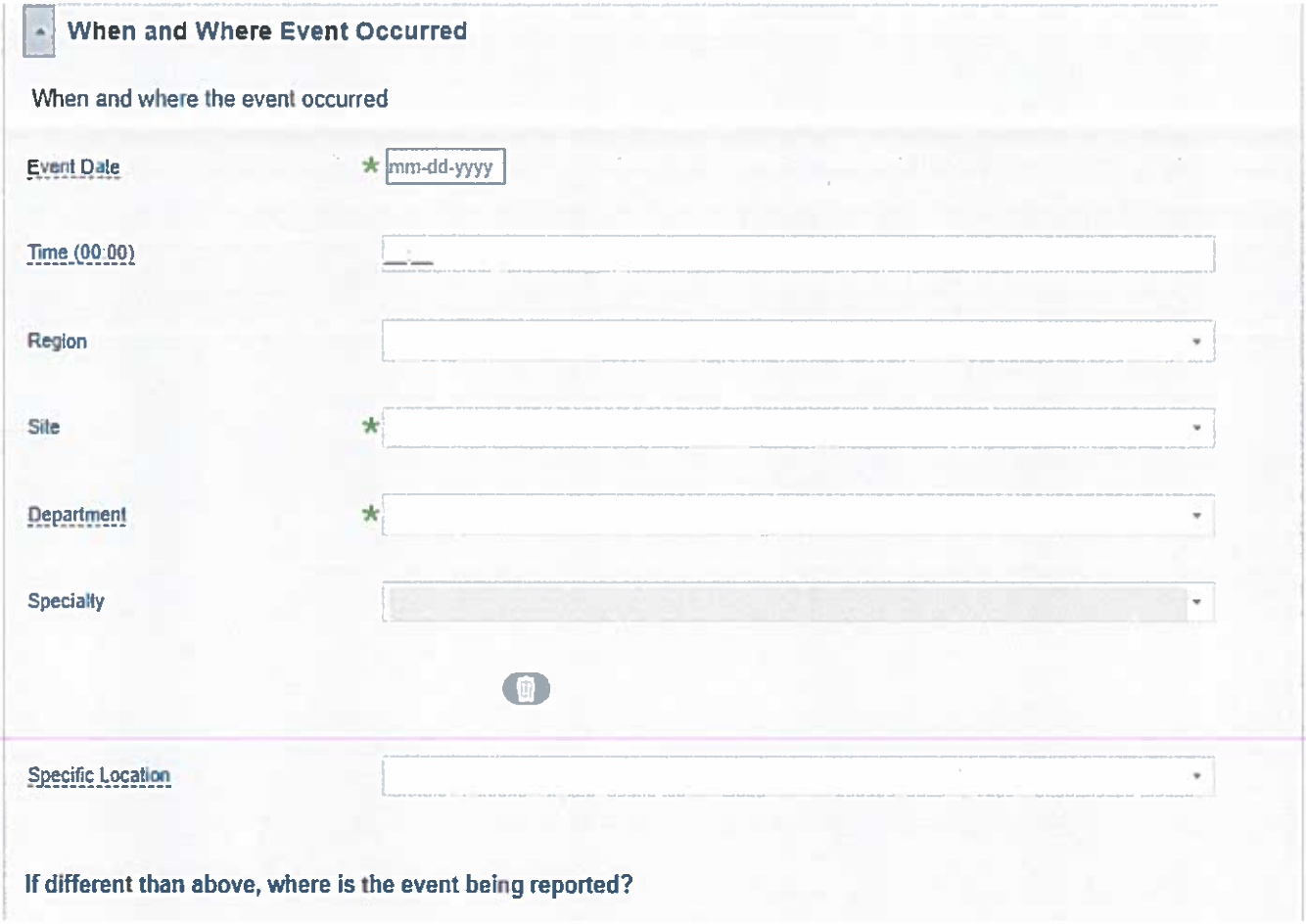
Entering an ERS report in RL Solutions

b. Type of Person Affected
    i. Inpatient, Outpatient, Emergency, etc.
c. Injury Incurred?
    i. Yes, No, Unknown
d. Brief Factual Description
    i. Describe the incident.
    ii. Include as much detail as possible to help investigate the issue/ concern.
    iii. If you spoke to staff on the unit, it is ideal to include their names so follow up can be done accordingly.
    iv. If you choose to enter an anonymous RL, it is important to fully describe the event factually as follow up cannot be done with the author of file, if necessary.



e. Person Affected First Name
    i. In most cases, the person affected is the patient. Enter the patient's First Name.
f. Person Affected Last Name
    i. In most cases, the person affected is the patient. Enter the patient's Last Name.
g. Check spelling.

Entering an ERS report in RL Solutions

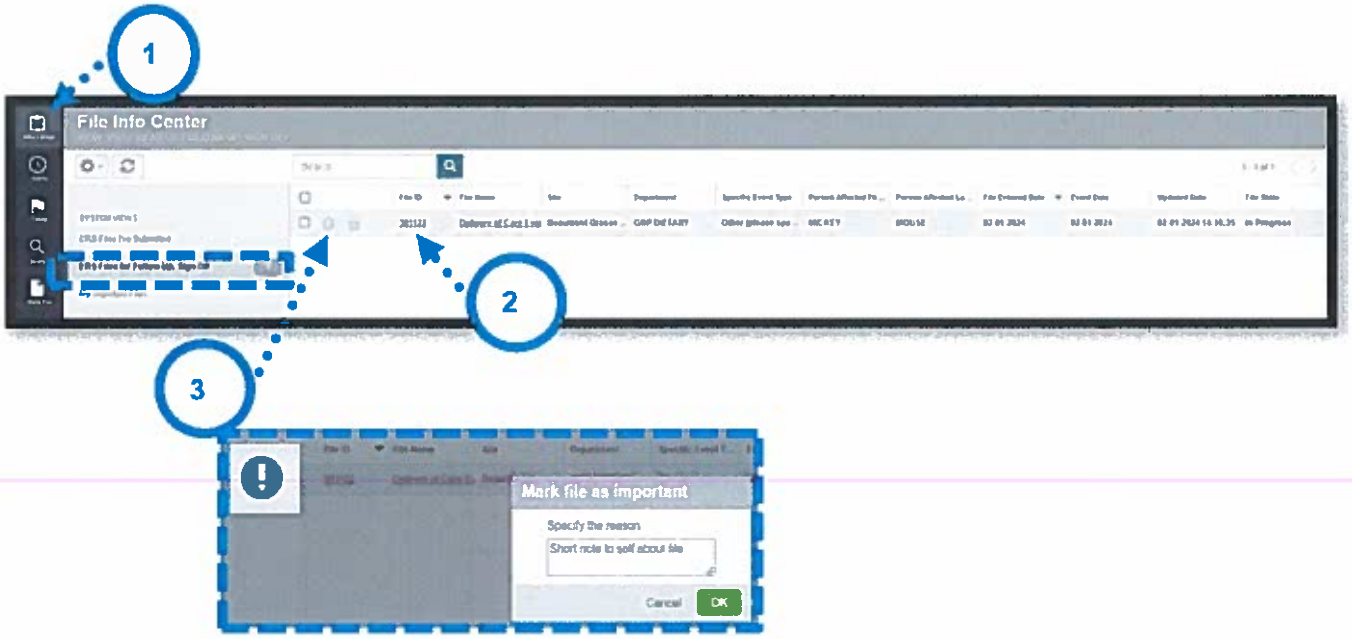


h. Event Date
    i. When did this occur?
i. Site
    i. Which campus?
j. Department
    i. **IMPORTANT FOR LAB RL** – Select the DEPARTMENT in which the employee who collected the specimen is employed.
        1) For example, if it is an unlabeled specimen from Critical Care was collected by the Critical Care staff, select Critical Care as the department. If the specimen was collected by Phlebotomy, select Phlebotomy as the department.
        2) NOTE: If the issue is related to a specimen coming from an Outreach location, select Outreach Laboratory for the department.

File Manager Review in RL Solutions

A. File Info Center:

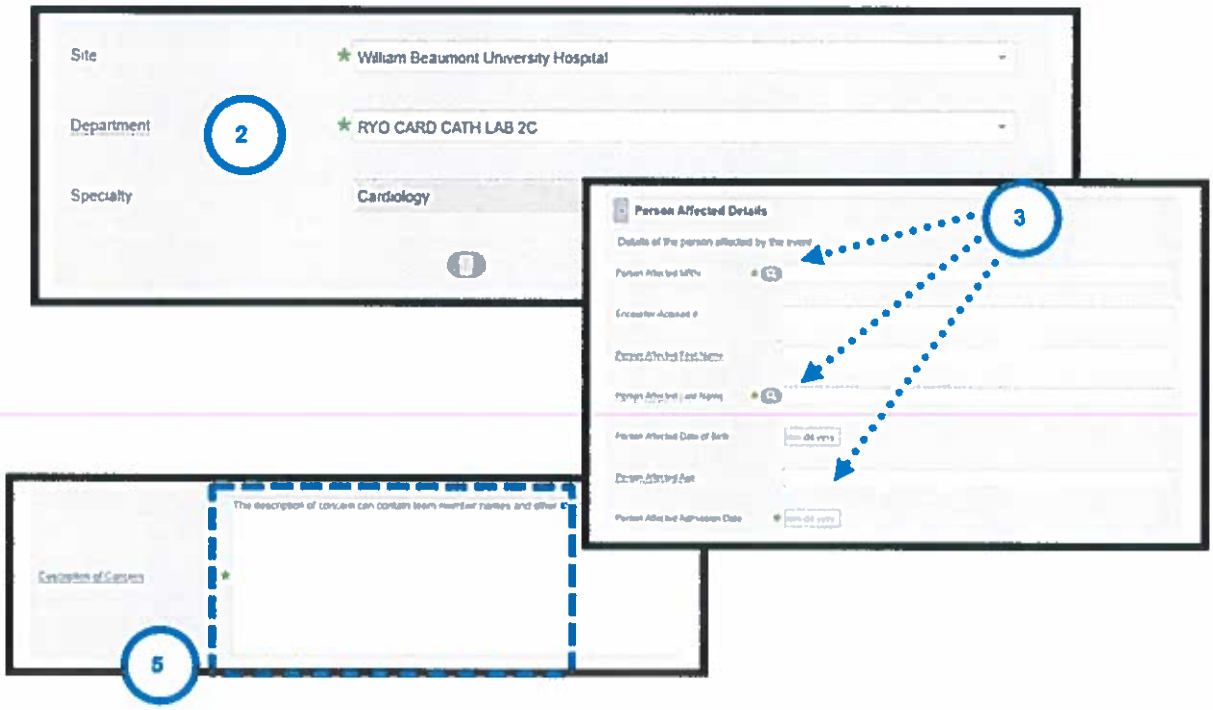
1. Click on Info Center on the left navigation pane.
   a. Under "System Views," you will see a que titled **"ERS Files for Follow-up, Sign-Off."** This is your working que. It contains all open files in your scope where you have not completed the File Manager Sign-Off.
2. Click on the File ID to open the file.
3. (Optional) Clicking the  button will mark the file as Important. You can also put a short comment explaining why you are marking it. Those files will stay in the "My Important Files" view even after they are closed.



File Manager Review in RL Solutions

B. **File Manager Review – Validate Data:**

1. Review the ERS to confirm accuracy and gain a thorough understanding of the team member's concern.
2. Determine if the event was filed with the correct site and department. If incorrect, press the garbage can to clear out the fields and select the correct department.
3. Determine if the patient information is correct (if applicable to the event).
4. If an event involves other departments, assign a task within the ERS to that department's File Manager for review and collaboration (see Step D for directions on assigning a task).
5. Remove team member names from the "Description of Concern" field.

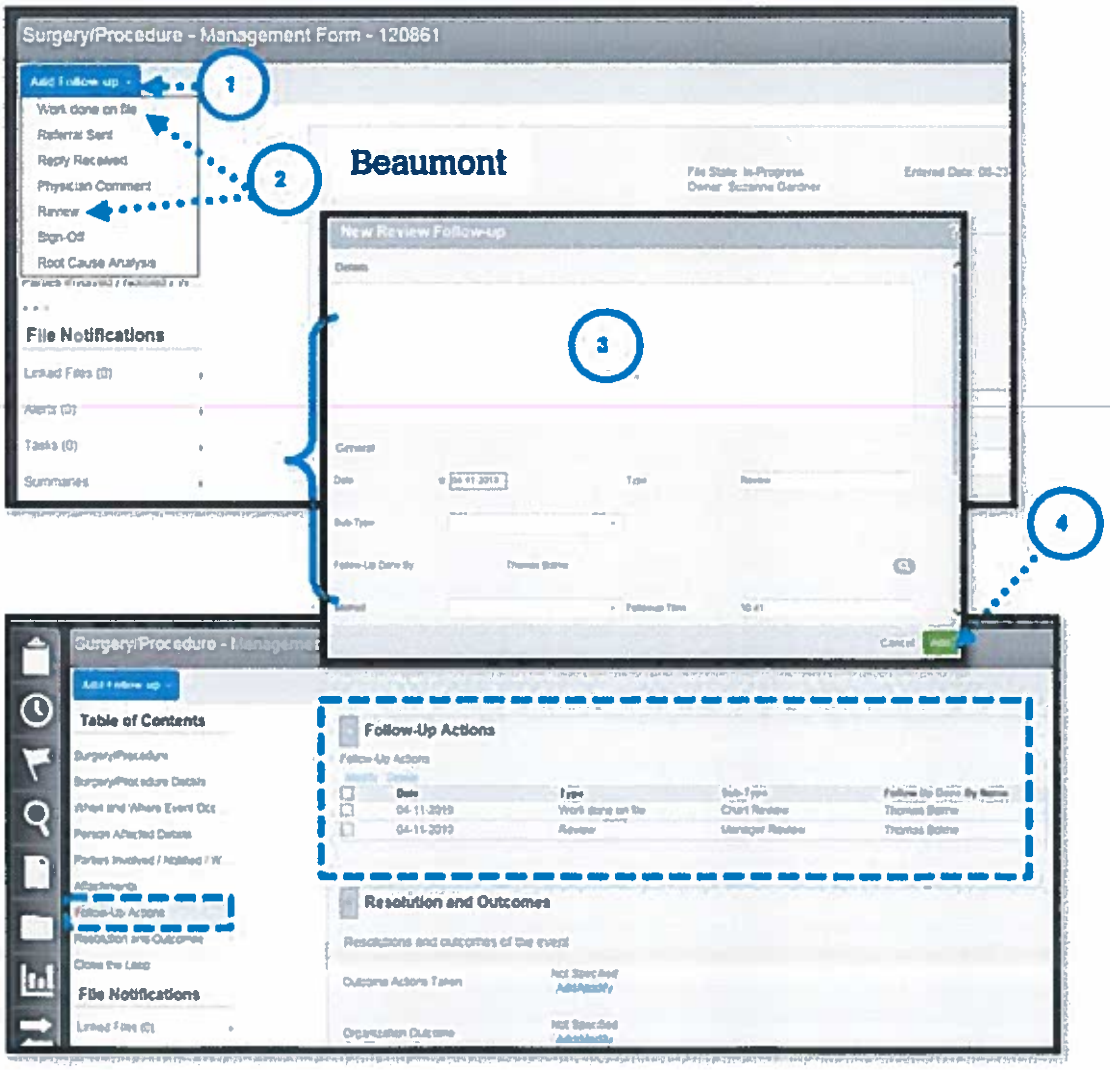


File Manager Review in RL Solutions

C. **File Manager Review – Add Follow-up:**

1. Once a file is open, click the "Add Follow-up" button.
2. Select the applicable follow-up type from the list.
3. Fill in as much detail as required. Details of your follow up should be noted in the "Details" box. Fields marked with a green asterisk are mandatory.
4. Click "Add" when complete.

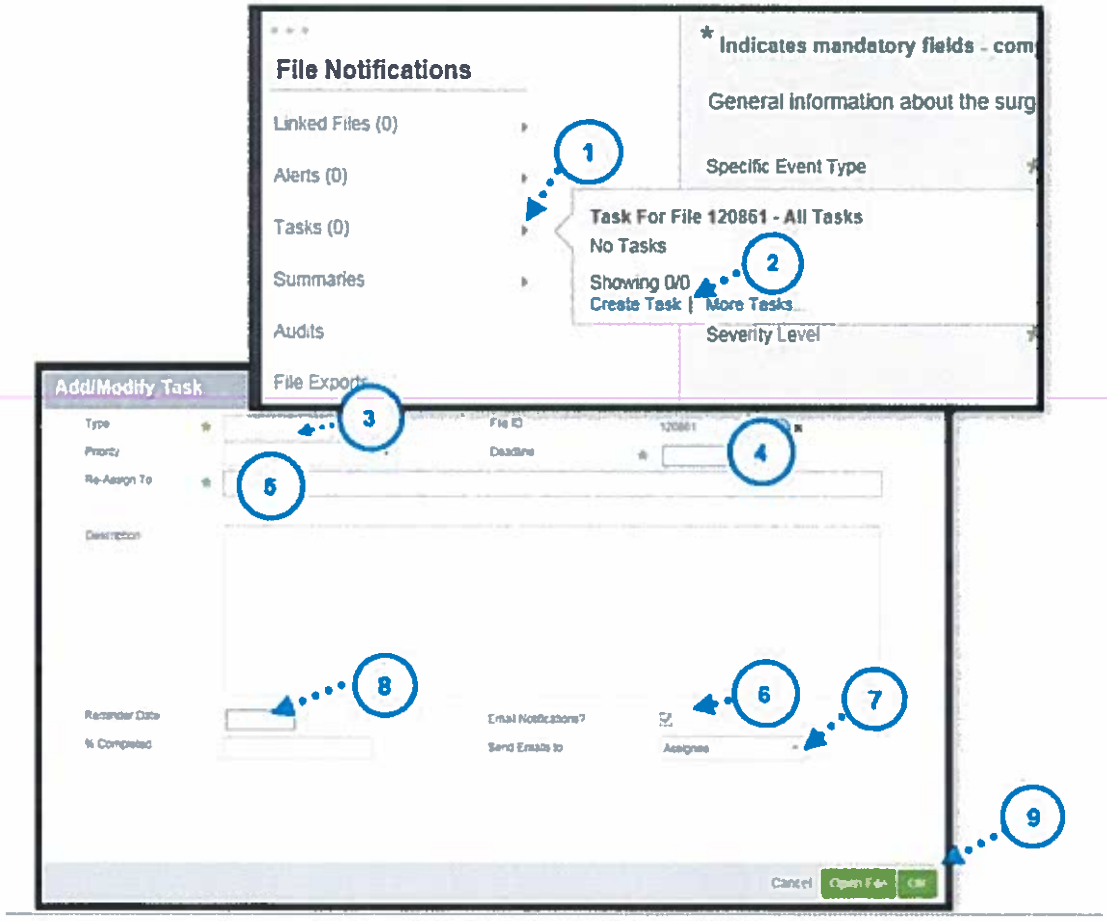
NOTE: All follow-up actions will appear on the file in the "Follow-up Actions" section.
NOTE: There is an alternate way to document follow up under the "File Manager Sign off Section."



File Manager Review in RL Solutions

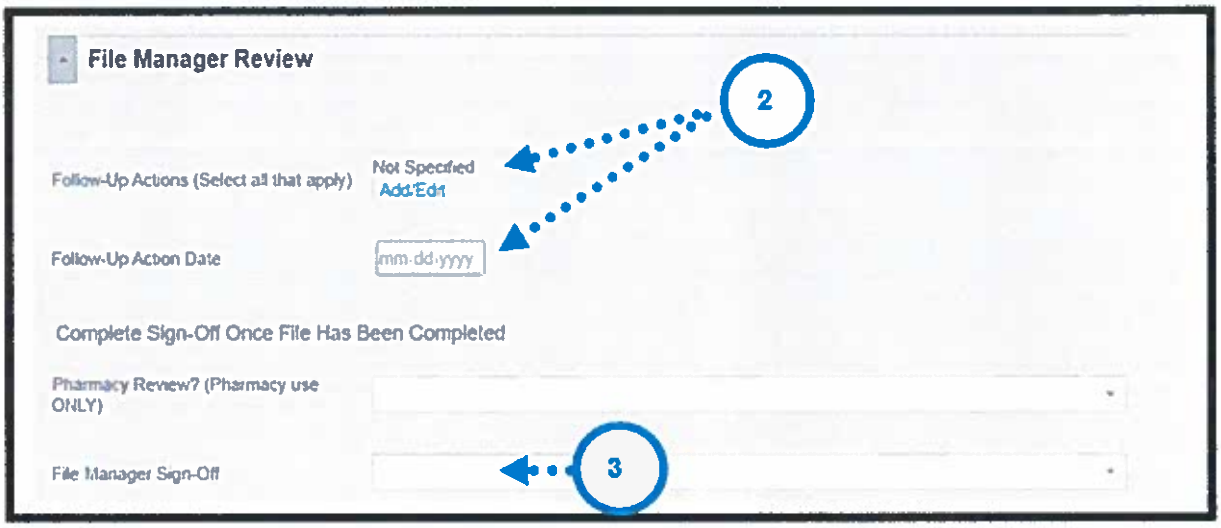
D. **File Manager Review - Assign Task:**

1. In the management form, click on "Tasks" in the "File Notifications" panel on the left.
2. Click "Create Task."
3. Enter the "Type" of task.
4. Enter the deadline for the task to be completed.
5. Type the name of the manager you would like to assign the task to.
6. (Optional) Select the "Email Notification" checkbox to send the task to recipient(s) via email.
7. Select the email recipient (i.e. yourself and assignee, or just assignee).
8. Enter the reminder date to send a reminder email to recipient (select a future date).
9. Click "OK" when done.



File Manager Review in RL Solutions

E. **File Manager Review – Sign-Off:**
1. Add the follow-up and findings from your review (see Step C for directions on adding follow-up).
2. Identify and document any action items that could prevent this event from happening again.
3. Complete the "File Manager Sign-Off" in the ERS when work on the file is complete.



F. **Reference:**
1. ERS File Manager Training, February 2024.