Reportable New Information

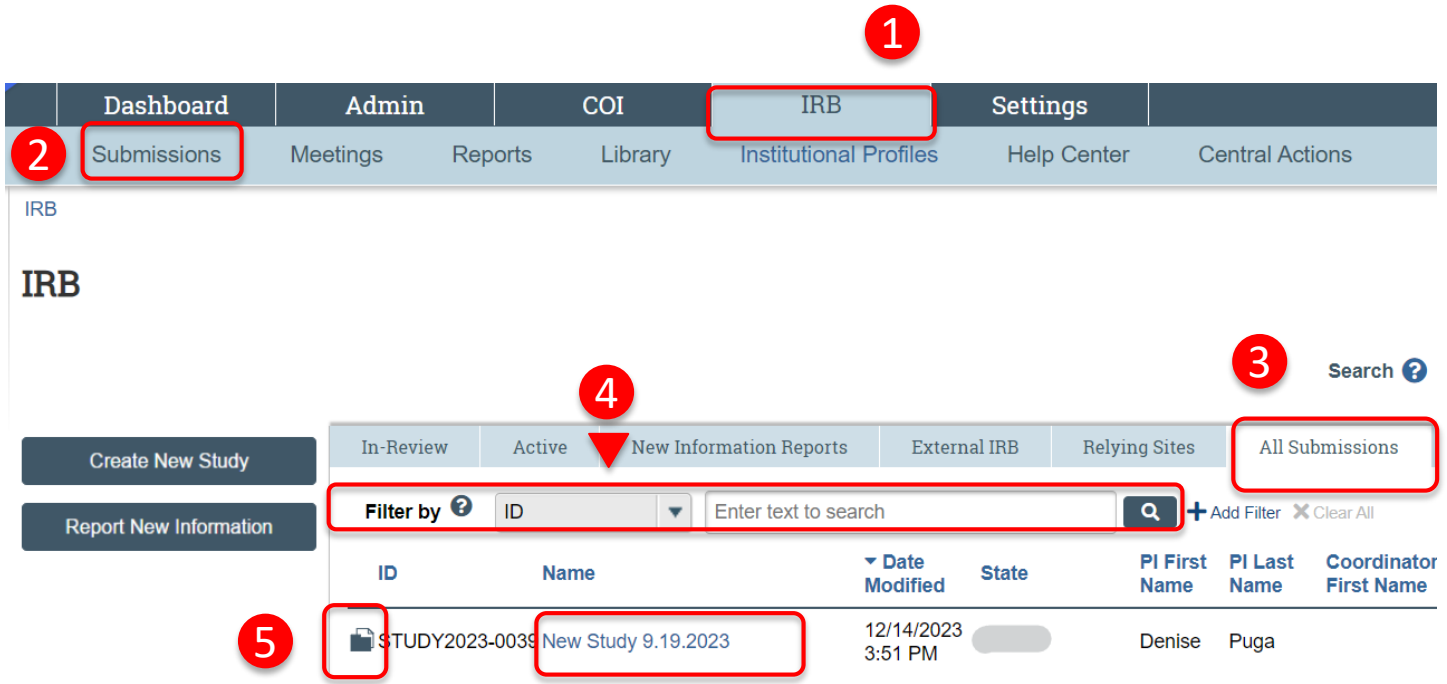
Human Research Protection Program

(Last Updated: 12/14/2023)

This PowerPoint will guide you through how to submit Reportable New Information form in Huron.

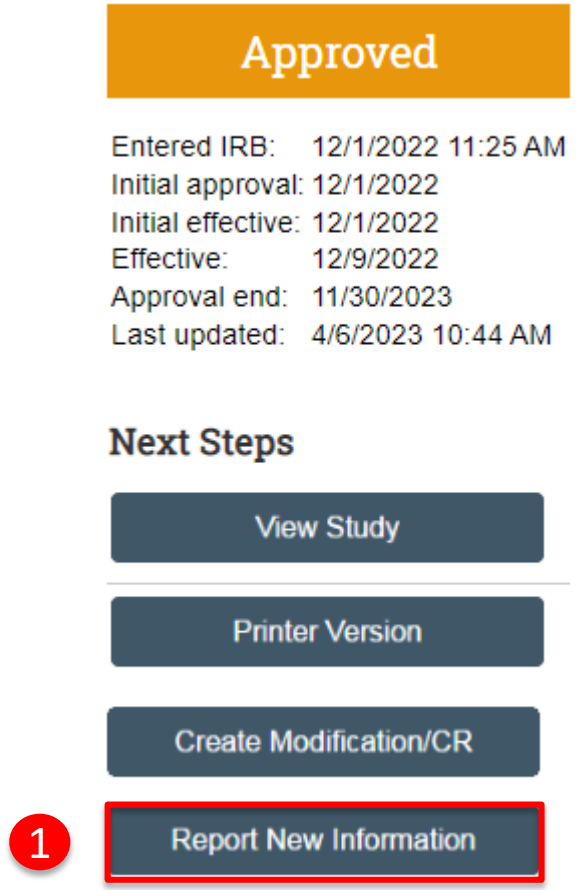
Getting started

1. Navigate to the **IRB workspace**
2. Select **Submissions** tab
3. Select **All Submissions** tab
4. Note: **Filter by** allows you to sort through your studies by name, PI first and last name, and submission type.
5. Open your study by selecting the **folder symbol** or the **name** of the study.



Reportable New Information

1. Select **Reportable New Information**

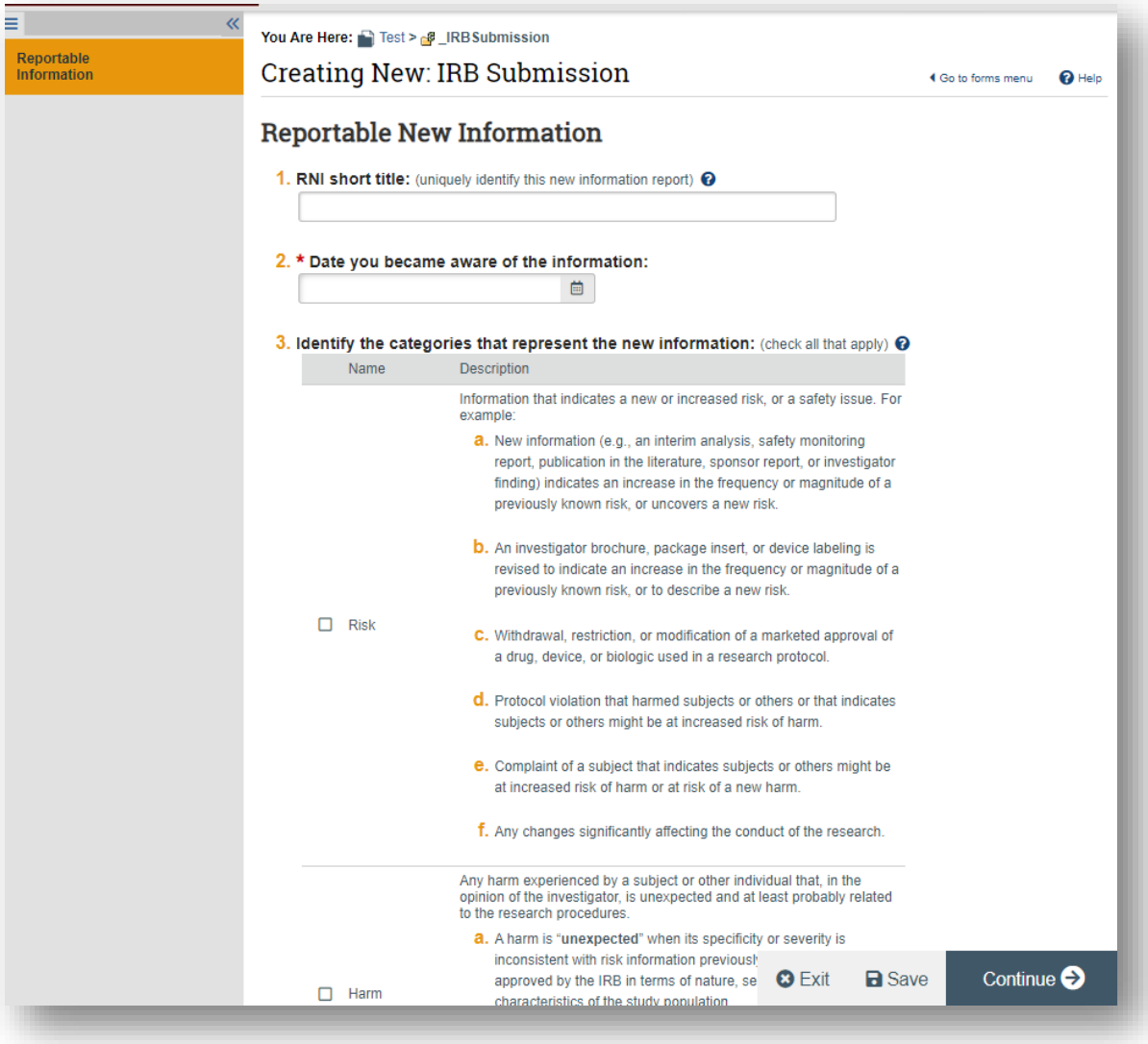


Reportable New Information

- When completing the **Reportable New Information** page**:**
  - All questions marked with a red asterisk (*) require a response.

- Complete the **Reportable New Information Page**
  - Note: If the original study is a multi-site study, the question, “Participating Sites” will appear for the user to choose any, if applicable, sites that the RNI pertains to.

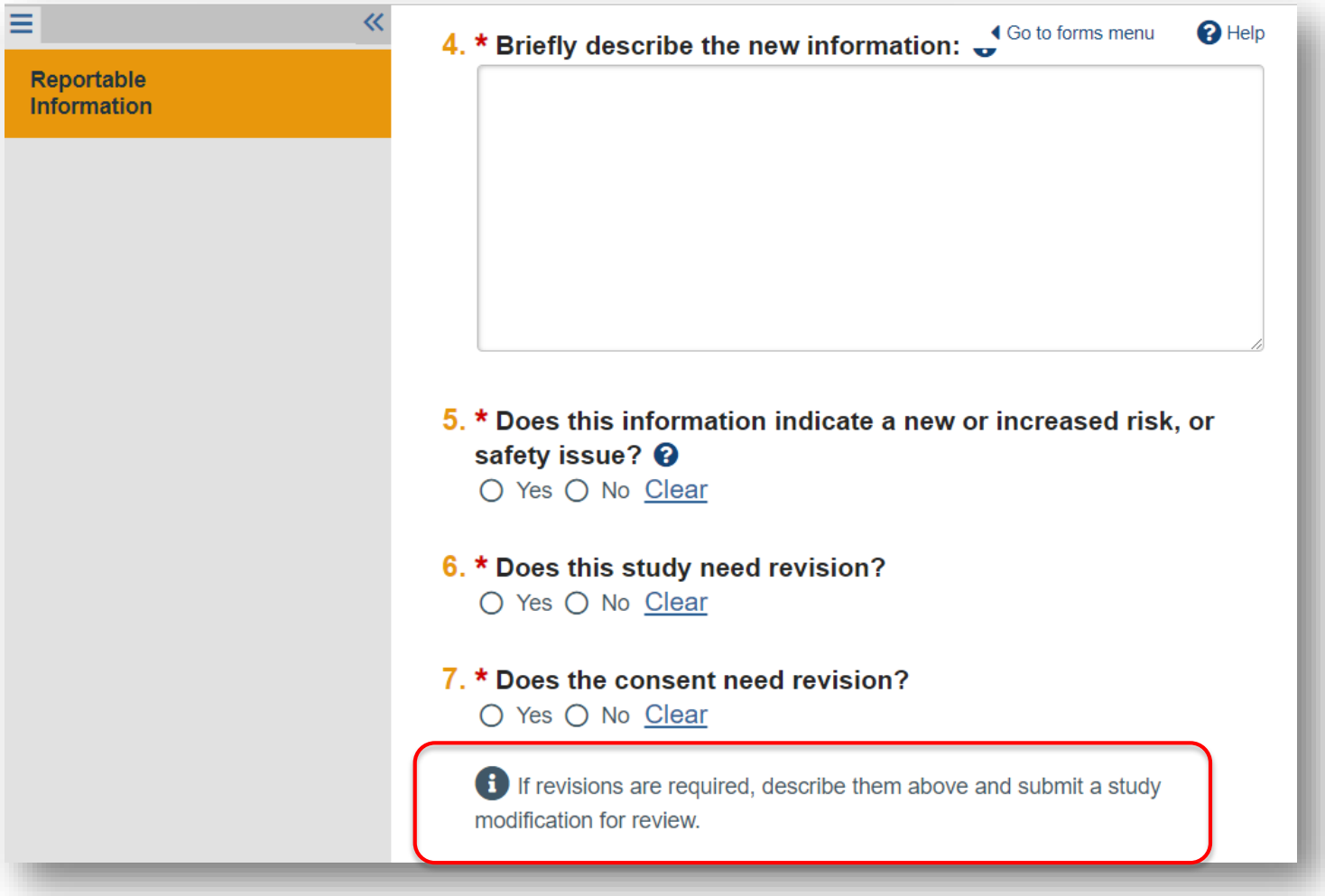
Important additional guidance on how to complete the Reportable New Information form can be found on the next few slides.



If revisions are required

If the study or consent requires revision, a separate modification request must be created and submitted for review. For example, if participant over-enrollment took place, a modification must be submitted to increase maximum participant enrollment.

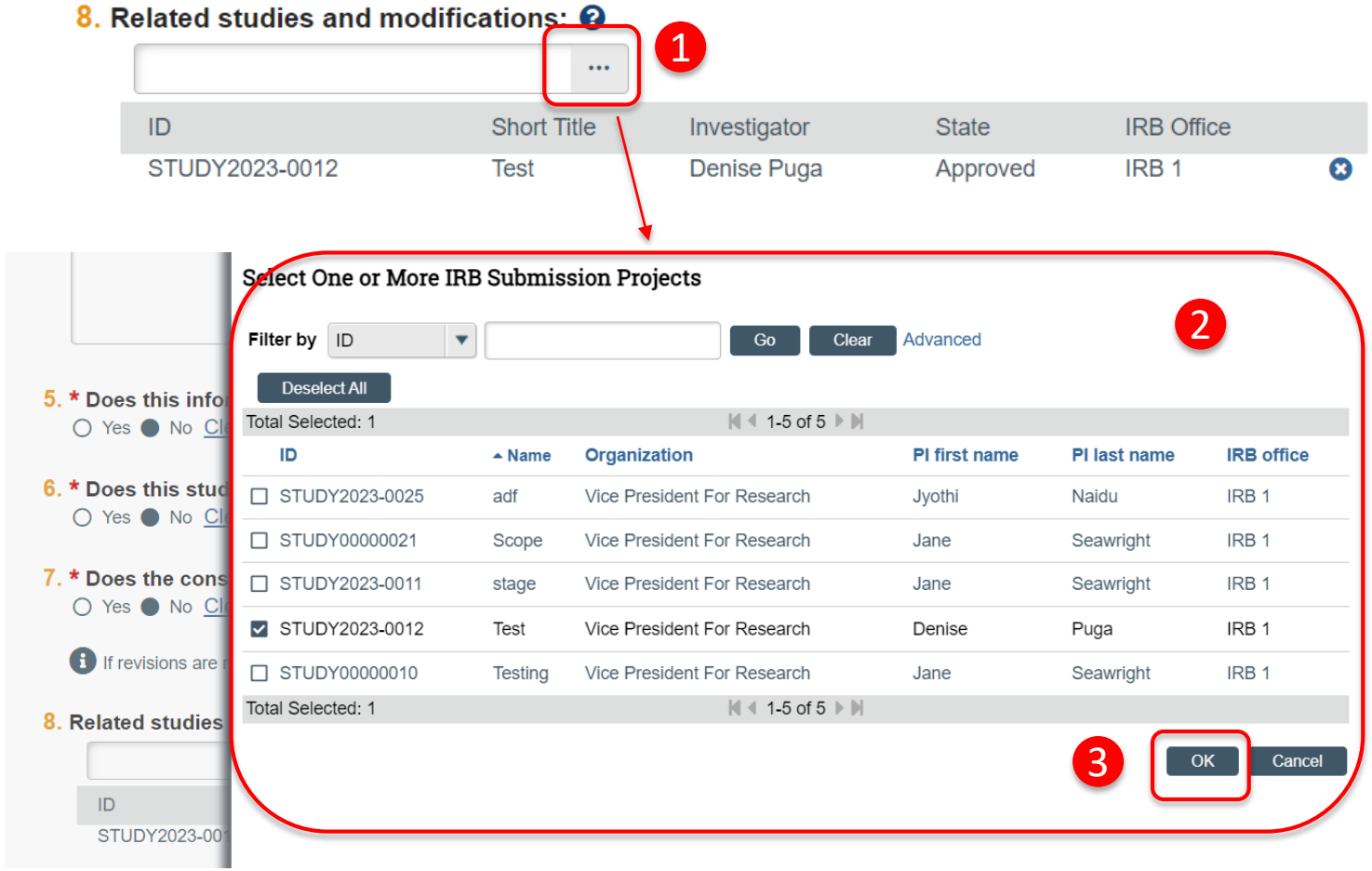
Note: Instructions on how to submit a modification can be found **here**.



Link Related Studies

If the new information affects multiple studies, you may link other protocols to the Reportable New Information form. To do so:

1. Click the ellipsis […], this will generate a list of all studies you are currently listed on.
2. Select the studies that are affected by the new information.
3. Select **OK**



Corrective and Preventive Action Plan

When a deviation from the IRB-approved protocol or an unanticipated problem has occurred in a study, it is the responsibility of the principal investigator to report the event to the IRB. In addition, steps must be taken to protect the welfare and safety of subjects, and ensure that the event does not reoccur in the future. When an unanticipated problem or noncompliance has occurred, it is important to develop a corrective and preventive action plan (CAPA) to protect study participants.

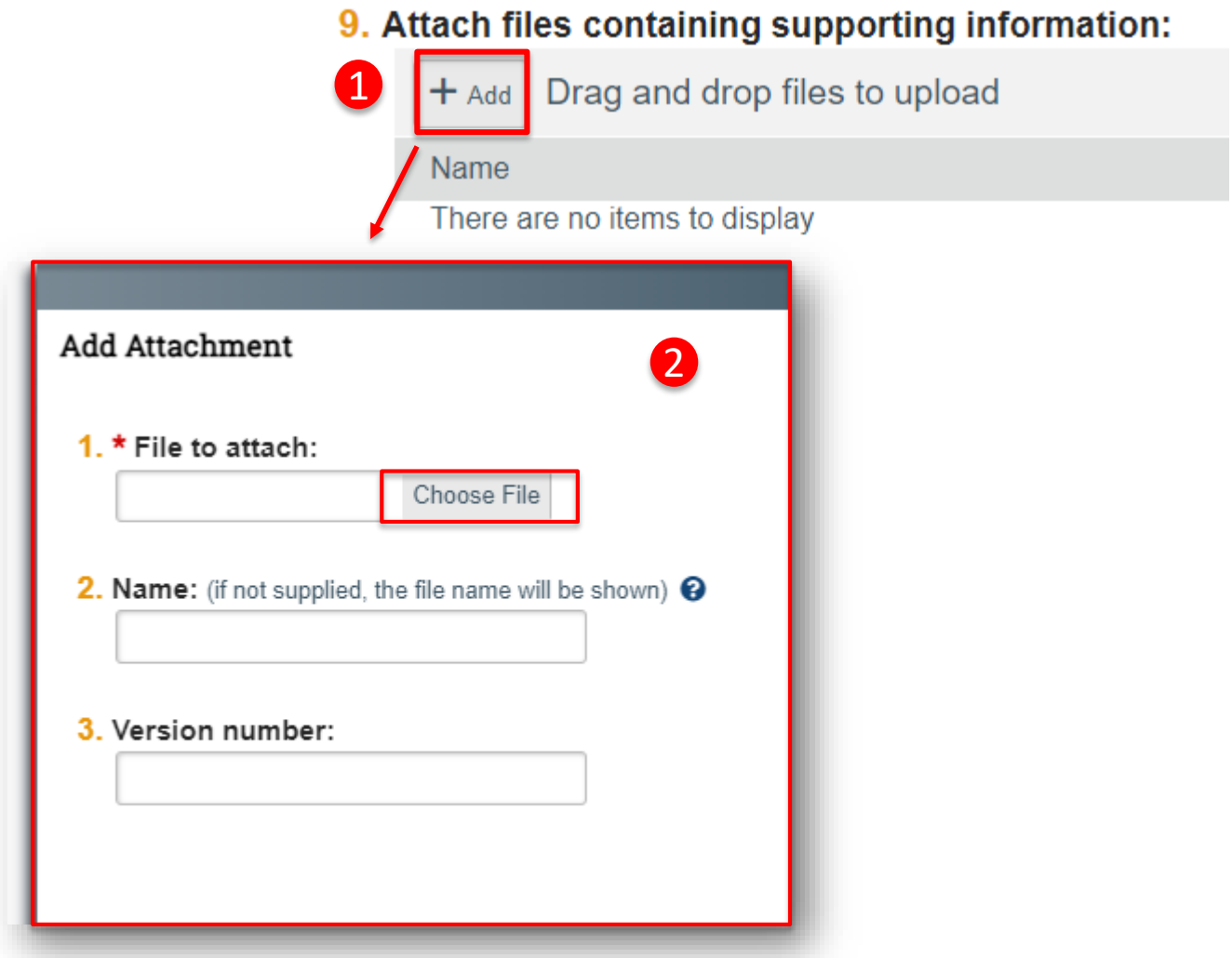
Action item:

- If you are reporting an instance of noncompliance or an unanticipated problem, please download and complete the CAPA template found **here** and attach it to your submission as a supporting document. Instructions on how to attach a supporting document in Huron can be found on the next page.

How to attach Supporting Documents

Upload a written description of the reportable new event or any other supporting document that describes the event.

1. Click **+Add** in Question 9 of the Reportable New Information page
2. Click **Choose File** to locate the desired document from your desktop
3. Click **OK**



Submitting the Reportable New Information to the IRB

1. Click **Continue** to be directed to the **Final Page**
2. From the Final Page, click **Finish**
3. From the study workspace, click **Submit RNI**
4. Click **OK**