

### Notify IRB

The Notify IRB functionality is used when a member of the research team needs to notify the IRB of a specific research activity or event.

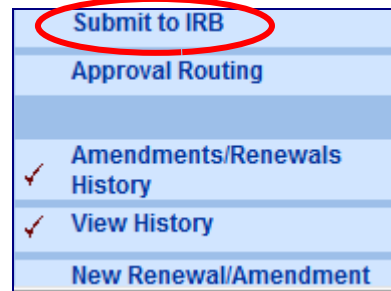
Use this functionality to report the following types of activities and events when they occur during the research. Be sure to upload the appropriate form located on <http://www.yale.edu/hrpp/forms-templates/index.html>

- Adverse Events (Internal and External)
- Protocol Deviation / Unanticipated Problems
- Lost/ Stolen Laptops
- DSMB or progress reports not submitted when requesting renewal of approval
- External IRB Notices and Approvals
- FDA Notifications/Progress Reports
- Grant Certifications
- Investigator Brochures that do not include amendments
- Quality Assurance Monitoring Visit reports,
- Publications
- QUACS Correspondence
- Responses to IRB QA/ Audit Findings
- Sponsor Close Out Visit
- Subject Complaint

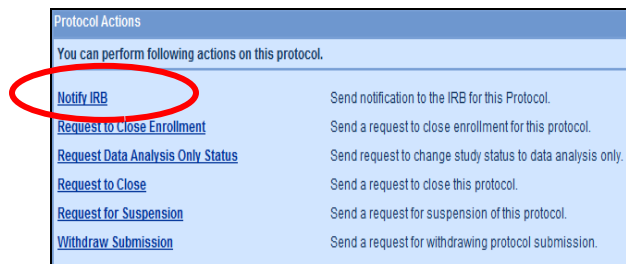
1. Bring up the protocol that you wish to submit a report on by searching for it in **All Protocols**. Click on the link to open it.

<a href="#">0901004566R001</a>	<a href="#">Research Participant Perception of Care Project Part 1</a>
<a href="#">0901004566</a>	<a href="#">Research Participant Perception of Care Project Part 1</a>
<a href="#">0901004565A001</a>	<a href="#">Research Participant Perception of Care Project 1</a>
<a href="#">0901004565</a>	<a href="#">Research Participant Perception of Care Project 1</a>
<a href="#">0901004564A002</a>	<a href="#">Research Participant Perception of Care Project 1</a>

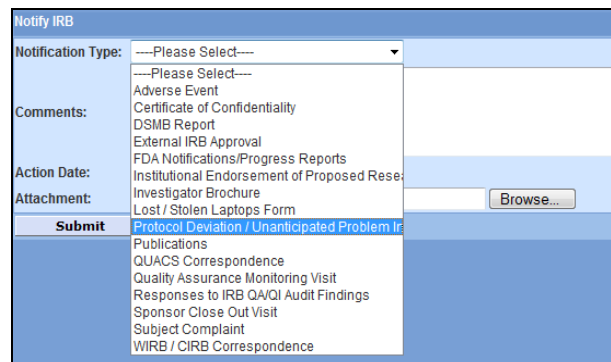
2. The selected protocol displays. Choose **Submit to IRB** from the left hand menu



3. This brings up the list of **Protocol Actions** that can be performed on the protocol. Select **Notify IRB**.



4. The **Notify IRB** screen displays. Click on the drop down menu next to **Notification Type** and choose the appropriate selection.



5. Provide detailed description of what is being reported in the **Comments**. Include any preliminary findings.

- The **Action Date** will default to today's date.
- Complete the Yale IRB appropriate form(s) when reporting a serious and unexpected adverse event, protocol deviation or unanticipated problem or lost laptop. You must include the type of form or document that you are including and the date of the upload in the file name given to the document. This will help aid in document recognition and version control. (See <http://www.yale.edu/hrpp/forms-templates/biomedical.html> or upload actual monitoring reports, DSMB reports or others as appropriate from your computer files.

- Use the Add Attachment functionality to upload the document(s). In the Description field line, provide a description of the event-specific document being uploaded and the date. In the Attachment field line, note the name of the document that you are uploading. Be sure to include the date Using **Browse**, upload the attachment(s) you wish to send to the IRB from your computer files.

Description	Last Updated	Updated By
IRB Report Form for Protocol Deviation re Subject Enrollment: 01112011	02/14/2011 12:56 PM	Uscinski, Kathleen

- Click **Save Submission Details**.
- To send the Notification to the IRB for review, click on the Complete Submissions button from the left hand menu .

- Click the **OK** button to complete the submission.



Coeus Quick Guides

**How to Notify the IRB of Unanticipated Problems, Adverse Events,  
Data Safety Monitoring Reports & Other Notifications**