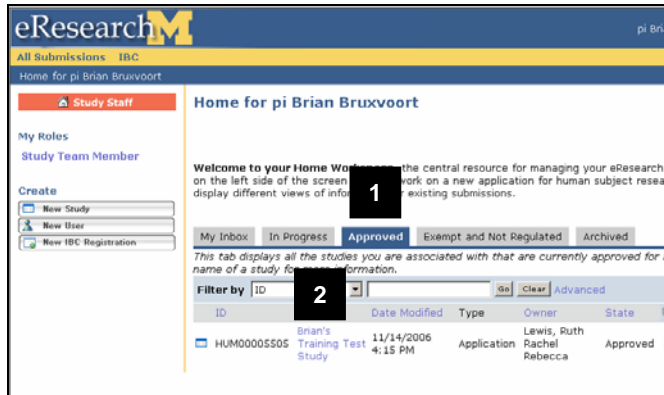


Creating an Adverse Event / ORIO

Important Information

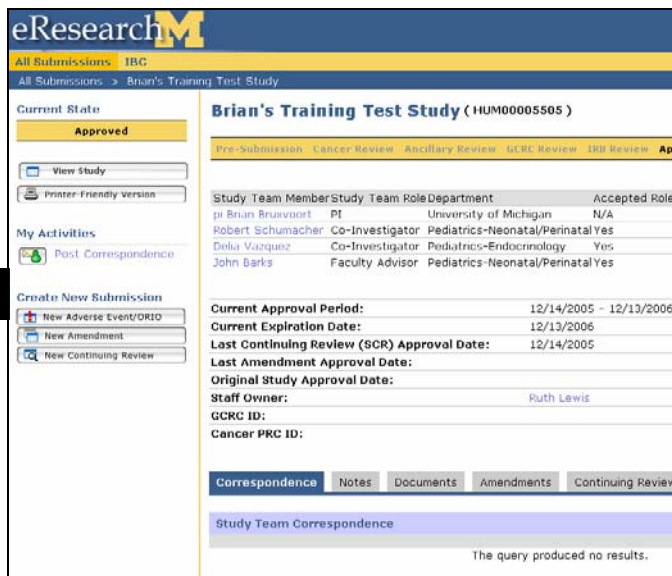
- Study teams are required to submit Adverse Events (AEs) and Other Reportable Information and Occurrences (ORIOs) via the eResearch system. ORIOs include audits, other reports, protocol deviations, protocol violations, facility/data accidents, and complaints.

eResearch Home Workspace



1. Click **Approved Studies** to display a list of approved studies
2. Click the **Name** of the study to view more detail.

eResearch Study Workspace



3. On the Study Workspace, click the **New Adverse Event/ORIO** button.

Adverse Event Form

4 Enter a title for your Adverse Event / ORIO

Note: To make tracking the adverse event easier, include the HUM # of the original study in the title. Once approved, the adverse event is accessed through the approved study work-space.

5 Select whether you are reporting an **Adverse Event (AE)** or **Other Reportable Information and Occurrence (ORIO)** and continue to the next screen.

Adverse Event Form

6 Select the **Type of Adverse Event or ORIO** which you are reporting.

Note: New to the eResearch 1.5 release, you can report multiple adverse events of the same type within the same submission.

7 Indicate whether this report includes follow-up to previous reported events and continue to the next screen.

Note: If you select **Yes** to this question (1-1.2), you will be required to indicate the previous reported events which this report follows.

Associated AE/ORIO Submission	Unique Identifier	Keywords/AE Type	Event Assessment
HUM0000241_Adverse Event - Tue Nov 14 16:29:33 EST 2006	123456	UM Serious Adverse Events Report	Serious, Unexpected, Unrelated

Adverse Event Form

2. UM Serious AE Reporting Form

General Instructions: read and follow all instructions.

- To add a new event click the **Add** button in section 2.1. A 'detail page' will open. Answer the questions on the detail page and click **OK** or **OK and Add Another**. The table will auto-fill with the information provided in the detail page.
- To update a previously reported event click the particular "Event Identifier" in the table. A 'detail page' will open. Update the questions on the detail page and click **OK**. The table will auto-update with the information provided in the detail page.
- Complete the remaining sections.
- Click **Finish** when done.

2.1 AE/ORIO Title:
 HUM00003241_Adverse Event - Tue Nov 7 10:14:57 EST 2006

This report is being submitted for the following study:
 Study Title: Implicit Egrotism and Interpersonal Attraction PI: Angela Miller
 eResearch ID: HUM00003241 GCRC ID:
 Expiration Date: 5/17/2007 Current IRB Risk Level: No more than minimal risk

AEs are also reported to:
 Organization: Reporting Mechanism: There are no items to display

AE Reporting timetable for this study: Standard AE reporting timetable

Approved (watermarked) Document(s):

name	version
0397 consent.doc	0.03
0397 recruitment message	0.02
0397research-ICT.doc	0.05

2.2 * UM Serious Adverse Events
 Initial and/or follow-up reports of serious adverse events involving subjects included in one of the performance sites listed in section 2.4 and under the oversight of the UM investigator(s) and/or a UM IRB.
 NOTE: To see recordable detail pages may include information in addition to that displayed in the table. Blank fields in the table indicate that non-required optional information was NOT provided on the detail page.

Event Identifier	Date Event began	keywordsRelatedAddressExpected	Primary Supporting Doc Date	Primary Supporting Document	Report
There are no items to display					

- Fill out the required fields in the form. For Adverse Events, you will be required to click the **Add** button and fill out the Adverse Event Detail form.

Adverse Event Detail Form

2.2 UM Serious Adverse Event Detail

This form is only for events that meet the following definition:

Definition of serious adverse event:
 An adverse experience that resulted in any of the following outcomes:

- Death
- A life-threatening experience
- Severe social, psychiatric/psychological, familial, or financial harm related to the research
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant disability/incapacity
- A congenital anomaly/birth defect
- Events that jeopardize the patient or subject and may require medical, psychiatric, dental, or surgical intervention to prevent one of the outcomes listed in this definition.

2.2.1 * Provide unique identifier for this event

2.2.2 * Initial date of event:

2.2.3 * Date event came to the attention of the study team:

2.2.4 * Location of responsible UM performance site (check all that apply):

Name
<input type="checkbox"/> University of Michigan

2.2.5 * Coded subject identifier:

2.2.6 * Provide up to six keyword descriptors for this AE:

- Fill out the required fields in the **Adverse Event Detail** form.
- Click the **OK** button to complete the Adverse Event Detail form or click the **OK and Add Another** button to report multiple adverse events of the same type within one form.

2.2.12 Other Supporting Documents:

2.2.12.1 Upload other supporting documentation here. Name the document with its title and date (Example: Sponsor-Cover-Letter-2-16-06).

name	version
There are no items to display	

Adverse Event Form

2.7.2 If applicable, indicate the revised risk assessment that will be made on an amendment application:

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Risk Level	Description
<input type="radio"/> No more than minimal risk	A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.* For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of a routine physical examination. (Note: The definition of minimal risk for research involving prisoners differs somewhat from that given for non-institutionalized adults.)
<input type="radio"/> Minor increase over minimal risk	Particularly relevant to research involving children.
<input type="radio"/> Moderate risk	
<input type="radio"/> High risk	Requires scrutiny in regards to the likelihood of direct benefits, and whether or not benefits clearly outweigh risks.

2.8 Additional Information: Provide additional pertinent information, if you require documentation of IRB submission for any information not requested/required in other fields, enter it here.

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* Required

11. Fill out the remaining fields in the Adverse Event Form.

12. Click the **Finish** button.

Note: When you click the **Finish** button, the AE is submitted automatically and you will be returned to the Study Workspace.

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Current State: HUM00005505_Adverse Event - Thu Nov 30 10:04:00 EST 2006 (Adv00000399 / IRP00005505)

Study Team Member	Study Team Role/Department	Accepted Roles	COBES	Rights	PIRMS	Human Subject?
John Schumacher	Co-Investigator, Pediatrics/Neonatal/Perinatal	Yes	Yes	Yes	Yes	Yes
John Kelle	Faculty Advisor, Pediatrics/Neonatal/Perinatal	Yes	Yes	Yes	Yes	Yes

Core Committee: IRB#02
Committee: IRB#02 B1
Submission Type: UM Serious Adverse Events
Report Type: Report

Staff Owner: Ruth Lewis

Committee Meeting:

Correspondence | Notes | Documents | Change Tracking

Study Team Correspondence

The query produced no results.

13. Click the **Submit Adverse Event** button.

Note: If you are not ready to submit the Adverse Event, you can still go back and edit it. You can also withdraw the event by clicking the **Withdraw Adverse Event** button.

Submit Adverse Event

HUM00005505_Adverse Event - Thu Nov 30 10:04:00 EST 2006 Adv00000399

Click OK to **submit your completed adverse event** for review.

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OK Cancel

14. Click the **OK** button.