

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 (which includes lapses in approval).

eResearch Home Workspace



1. Click **Approved** to display approved studies.
2. Click the **Name** of the study to view the approved study workspace.

eResearch Study Workspace



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

Adverse Event Form

1. Report of Adverse Event (AE) or Other Reportable Information or Occurrence (ORIO)

1.1 * AE/ORIO Title: Leave the HUM Number in the title, then revise the title to indicate the type of report you are completing (AE or ORIO), and your referent for the report. Examples: HUM00003155_Adverse Event - UM 3/15/06, HUM00003155_ORIO_Subject Incarceration 3-30-06

HUM00014348_Adverse Event - Wed Jul 25 10:21:18 EDT 2007

This report is being submitted for the following study:

Study Title: Sample Study III PE: Ingrid Investigator
eResearch ID: HUM00014348 GRC ID:
Expiration Date: 7/23/2008 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

1.2 * Type of Report--choose one

Select one:

Adverse Events Report

Other Reportable Information or Occurrence (ORIO)

Clear

* Required

Save | Print... Continue >>

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 workspace.

5. Select **Adverse Events Report** or **Other Reportable Information and Occurrence (ORIO)**.

6. Click

Adverse Event Form

1-1. Report of Adverse Event (AE)

1-1.1 * Adverse Event Types:

Type	Description
<input type="radio"/> UM Serious Adverse Events Report	Initial and/or follow-up reports of serious adverse events involving subjects included in this UM study. <ul style="list-style-type: none"> Subjects of one of the performance sites listed in section 3-1 Subjects are under the oversight of the UM investigator(s) and/or UM IRB <p>Definition of serious: An adverse experience that resulted in any of the following outcomes:</p> <ul style="list-style-type: none"> Death A life-threatening experience 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 or surgical intervention to prevent one of the outcomes listed in this definition.
<input type="radio"/> UM Non-Serious Adverse Events Report	Initial and/or follow-up reports non-serious adverse events involving subjects included in this UM study. <ul style="list-style-type: none"> Subjects of one of the performance sites listed in section 3-1 Subjects are under the oversight of the UM investigator(s) and/or UM IRB
<input type="radio"/> External Adverse Events Report	Initial and/or follow-up reports serious and non-serious adverse events that are external to this UM study in that: <ul style="list-style-type: none"> Subjects are enrolled at “sister-sites” in a multi-site study where the same research study is being conducted. AND/ Subjects are involved in a research study other than the one approved for the UM study (UM or non-UM). OR Events occurred as part of patient care outside of any research study. Protocols/procedures are the same as followed on this UM study A non-UM IRB has direct oversight of the investigators and subjects Subjects are not subjects at one of the performance sites listed in section 3-1
<input type="radio"/> UM Coordinating Center Aggregate Adverse Events Report	Adverse events reported to UM where UM is the coordinating center for multiple sites. <ul style="list-style-type: none"> UM is the lead site supervising the study OR UM is coordinating adverse event oversight

1-1.2 * Does this report include follow-up to previously reported events?

Yes No Clear

Save | Print... Continue >>

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

8. Indicate whether this report includes follow-up to previous reported events

9. Click

Previous Adverse Events

1-3. Previous Adverse Events

1-3.1 * Indicate all previously approved reports being updated:

No Adverse Events are available for revision.

The following Adverse Events are under revision: if you need to modify any of the following, click on the Associated AE/ORIO Submission name. You can use the "Post Correspondence" activity to request edit rights if the submission is under review.

Associated AE/ORIO Submission	Unique Identifier	Keywords/AE Type	Event Assessment
HUM00014348_Adverse Event - Tue Nov 14 16:29:33 EST 2006	123456	UM Serious Adverse Events Report	Serious, Unexpected, Unrelated

* Required

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.

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 2.2. 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:
HUM00014348_Adverse Event - Mon Jul 30 12:36:15 EDT 2007

This report is being submitted for the following study:

Study Title: Sample Study III **PI:** Ingrid Investigator
eResearch ID: HUM00014348 **GCRC ID:**
Expiration Date: 7/23/2008 **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
informed consent	0.01

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 IRB REVIEWERS: 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.

10 **Add**

Event Identifier	Date Event Began	Keywords	Relatedness	Expected?	Primary Supporting Document	Primary Supporting Report
There are no items to display						

2.3 * UM Investigator's overview assessment of new and/or updated information in this submission.
 An "overview assessment" should address the following if they apply:

- Explain how AEs included in this report impact the study
- List any AEs that the UM investigator believes the IRB should give special attention and explain why
- List any AEs recorded as "unrelated" in 2.2 that the UM investigator believes were caused by participating in the study even if not caused by the drug, device, or other intervention under direct study
- List any AEs on which the UM PI and an oversight body disagree (e.g the sponsor's opinion of seriousness, relatedness, or expectedness differs from the UM PI's). Provide the event numbers and explain the disagreement.
- Explain voluntary holds or urgent changes that will be initiated on any part of the study because of the AEs included in this report. Provide a description of the changes and rationale.

NOTE: Solely referring to uploaded document(s) or other sections without providing an overview is not acceptable.

2.4 * Are subjects still being recruited at any of these sites?

Location	Country	"Engaged" in the research?
University of Michigan	USA	yes

Yes No

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

Adverse Event Detail Form

Edit HUM_AE Detail

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.

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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:

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11. Fill out the required fields in the **Adverse Event Detail** form.

12. Click **OK**.

Note: To report multiple adverse events of the same type within one form, click **OK and Add Another**.

Adverse Event Form

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

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.

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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.

* Required

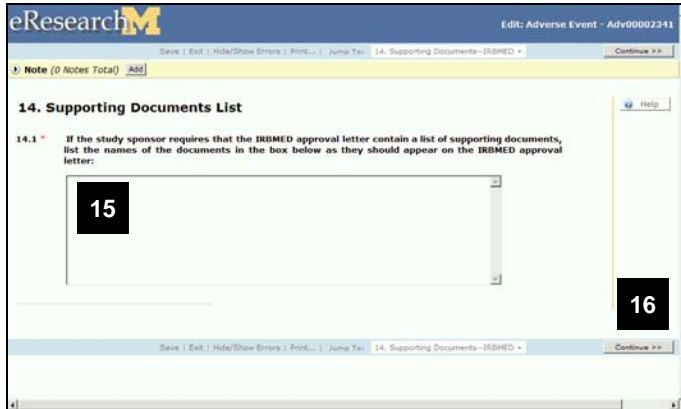
14

Save | Exit | Hide/Show Errors | Print... | Jump To: 02. UM Serious AE Reporting Form | Continue >>

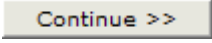
13. Fill out the remaining fields in the Adverse Event Form.

14. Click **Continue >>**.


Adverse Event Form



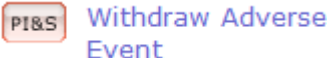
15. Optional, enter the names of the documents in the box below as they should appear on the IRBMED approval, if the study sponsor requires that the IRBMED approval letter contain a list of supporting documents.

16. Click .

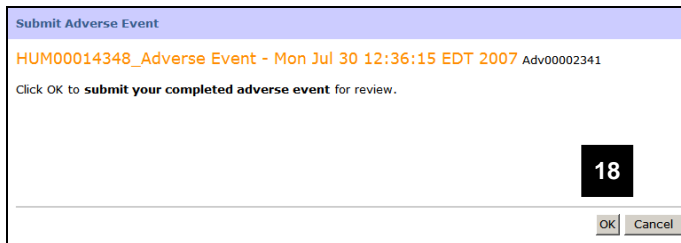


17. Click  from the end of the submission or workspace.

Note: If you are not ready to submit the Adverse Event, you can still go back and edit it.

You can withdraw the Adverse Event after it has been submitted by clicking  from the Study Workspace.

Submit Adverse Event



18. Click .