

Adverse Event Summary Report

Important Information

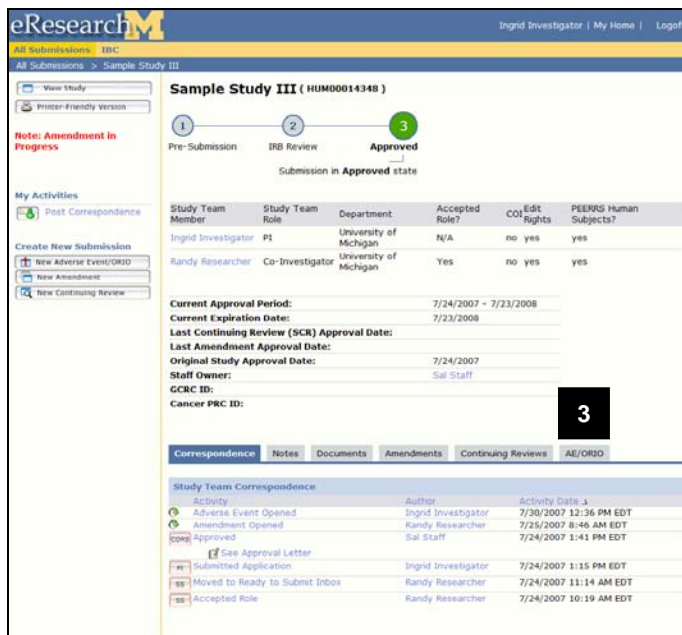
- Anyone with access to a study can run an Adverse Event Summary Report on it to see how many and what types of Adverse Events have occurred.

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



1. Click **AE/ORIO**.

eResearch Study Workspace

Sample Study III (HUM00014348)

1 Pre-Submission 2 IRB Review 3 **Approved**

Submission in **Approved** state

Study Team Member	Study Team Role	Department	Accepted Role?	Edit CO Rights	PEERS Human Subjects?
Ingrid Investigator	PI	University of Michigan	N/A	no	yes
Randy Researcher	Co-Investigator	University of Michigan	Yes	no	yes

Current Approval Period: 7/24/2007 - 7/23/2008
Current Expiration Date: 7/23/2008
Last Continuing Review (SCR) Approval Date:
Last Amendment Approval Date:
Original Study Approval Date: 7/24/2007
Staff Owner: Sal Staff
GCRC ID:
Cancer PRC ID:

Correspondence | Notes | Documents | Amendments | Continuing Reviews | **AE/ORIO**

4 **AE Summary Report**

Summary: AE Summary Report

ID	Name	Date Modified	Owner	State	Last State Change
Adv00002341	HUM00014348_Adverse Event - Mon Jul 30 12:36:15 EDT 2007	7/30/2007 1:31 PM	Investigator, Ingrid	Core Committee Staff Review	7/30/2007 1:31 PM

- Click on the **Summary: AE Summary Report** link.

Adverse Event Workspace

eResearchM
File Application - H4M0000241

5 Adverse Event Summary Report

Date: Wed Nov 8 13:23:27 EST 2006

Study Title: Implicit Egrotion and Interpersonal Attraction
PI: Angela Miller
eResearch ID: H4M0000241
Expiration Date: 5/1/2007
Current IRB Risk Level: No more than minimal risk
OCRC ID:

Adverse Events are also reported to: The approved application does not specify any additional monitoring.
AE reporting time table for this study:

List of Approved (watermarked) Documents:
 Mail Recruitment Message
 IRB consent.doc
 eResearch-ICT.doc

Click on the Submission ID # to view the submission and all documents contained therein.

Event/Report Identifier	Keyword Description	Relationship	Expected?	Primary Supporting Document	Additional Supporting Documents	Submission ID	Report	Status
12345	test1 test2 test3 test4 test5 test6	Possibly related	no			H4M0000014	Original	IRB Review

Total # of APPROVED UM Serious Adverse Events

Number	Serious AEs
<input type="text"/>	<input type="text"/>
<input type="text"/>	Unexpected - Related
<input type="text"/>	Unexpected - Unrelated
<input type="text"/>	Expected - Related
<input type="text"/>	Expected - Unrelated

UM Non-Serious Adverse Events

Number	Non-Serious AEs
<input type="text"/>	<input type="text"/>
<input type="text"/>	Unexpected - Related
<input type="text"/>	Unexpected - Unrelated
<input type="text"/>	Expected - Related
<input type="text"/>	Expected - Unrelated

External Adverse Events for a Multi-Site Study

Total # of APPROVED External Adverse Events for a Multi-Site Study:

Number	Serious AEs
<input type="text"/>	<input type="text"/>
<input type="text"/>	Unexpected - Related
<input type="text"/>	Unexpected - Unrelated
<input type="text"/>	Expected - Related
<input type="text"/>	Expected - Unrelated

Number	Non-Serious AEs
<input type="text"/>	<input type="text"/>
<input type="text"/>	Unexpected - Related
<input type="text"/>	Unexpected - Unrelated
<input type="text"/>	Expected - Related
<input type="text"/>	Expected - Unrelated

External Adverse Events for Subjects in a Different Research Study

Total # of APPROVED External Adverse Events for Subjects in a Different Research Study:

Number	Serious AEs
<input type="text"/>	<input type="text"/>
<input type="text"/>	Unexpected - Related
<input type="text"/>	Unexpected - Unrelated
<input type="text"/>	Expected - Related
<input type="text"/>	Expected - Unrelated

Number	Non-Serious AEs
<input type="text"/>	<input type="text"/>
<input type="text"/>	Unexpected - Related
<input type="text"/>	Unexpected - Unrelated
<input type="text"/>	Expected - Related
<input type="text"/>	Expected - Unrelated

External Adverse Events for Subjects Not Enrolled in Any Research at Any Site

Total # of APPROVED External Adverse Events for Subjects Not Enrolled in Any Research at Any Site:

Number	Serious AEs
<input type="text"/>	<input type="text"/>
<input type="text"/>	Unexpected - Related
<input type="text"/>	Unexpected - Unrelated
<input type="text"/>	Expected - Related
<input type="text"/>	Expected - Unrelated

Number	Non-Serious AEs
<input type="text"/>	<input type="text"/>
<input type="text"/>	Unexpected - Related
<input type="text"/>	Unexpected - Unrelated
<input type="text"/>	Expected - Related
<input type="text"/>	Expected - Unrelated

Coordinating Center Adverse Events

Total # of APPROVED Coordinating Center Adverse Events

Number	Serious AEs
<input type="text"/>	<input type="text"/>
<input type="text"/>	Unexpected - Related
<input type="text"/>	Unexpected - Unrelated
<input type="text"/>	Expected - Related
<input type="text"/>	Expected - Unrelated

Number	Non-Serious AEs
<input type="text"/>	<input type="text"/>
<input type="text"/>	Unexpected - Related
<input type="text"/>	Unexpected - Unrelated
<input type="text"/>	Expected - Related
<input type="text"/>	Expected - Unrelated

Total # of ALL APPROVED Adverse Events

Number	Serious AEs
<input type="text"/>	<input type="text"/>
<input type="text"/>	Unexpected - Related
<input type="text"/>	Unexpected - Unrelated
<input type="text"/>	Expected - Related
<input type="text"/>	Expected - Unrelated

Number	Non-Serious AEs
<input type="text"/>	<input type="text"/>
<input type="text"/>	Unexpected - Related
<input type="text"/>	Unexpected - Unrelated
<input type="text"/>	Expected - Related
<input type="text"/>	Expected - Unrelated

3. The **Adverse Event Summary Report** opens. This report lists the number and types of all Adverse Events that have been submitted on the study.

Note: The tables with "Total #" in the title include only those AEs that have been acknowledged while the other tables show all AEs that have been submitted and their state at the time the report is generated.