

Date: Friday, August 07, 2009 2:32:31 PM

Print

**01 Adverse Event/ORIO**

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**1.1\* Type of Report--choose one**

Other Reportable Information or Occurrence (ORIO)

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**01-2 Other Reportable Information or Occurrence (ORIO)**

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**ORIO Title:**

HUM00007024\_ORIO -Report to or from an Oversight Entity

**This report is being submitted for the following Study:**

**Study Title:** Sample Application  
**PI:** [pi June Insko](#)  
**eResearch ID:** HUM00007024  
**MCRU ID:**  
**Expiration Date ID:** 9/26/2007  
**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
<a href="#">1_Adult_Consent_2-14-06.doc</a> 	0.01
<a href="#">2_Arabic_Short_Form_9-21-06.doc</a> 	0.01
<a href="#">3_Spanish_Short-Form_9-27-06.doc</a> 	0.01

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**1-2.1\* Other Reportable Information or Occurrences (ORIO) types:**Report(s) to or from oversight entity

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**1-2.2\* Does this report include follow-up to previously reported information or occurrences?** Yes  No

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**10. Report(s) from or to an Oversight Entity**

**10.1\*** Indicate whether report(s) are to or from the following oversight entities. Select all that apply:

To	From	Oversight Entity
		Sponsor or monitoring report, advisory, or update
		Internal UM office (University Internal Audits, IRB, ORCR, OVPR)
		DSMB/DSC
		FDA Form 483, EIR, Warning Letter, NIDPO, study specific communications, clinical hold letters, etc.
		Other government oversight agency (OHRP, OBA, NRC, ORI, ORC, OIG etc)
		Granting agency (NIH, NSF, NCI, etc.) communication impacting the conduct of this human subjects study
		Other (specify in 10.3 Description of Report)

**----General Information----**

**10.2.1\*** Provide up to six keyword descriptor for this report:

**10.2.2\*** Date study team submitted or received report:

**10.2.3\*** Specify the oversight entity involved in the communication:

**10.3\*** Description of Report:

**----Investigators' Assessment----**

**10.4.1\*** Does the event(s) or information being submitted suggest that the research places subjects or others at a greater risk of physical or psychological harm than was previously known or recognized?

Yes  No

**10.4.2\*** Has the integrity or validity of the data been compromised?

Yes  No

**10.5\*** Investigators' Response:

**10.6** Additional Information:

**10.7** Supporting Documentation:

Name

Version

There are no items to display

**15. Supporting Documents--IRBMED**

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15.1 If the study sponsor requires that the IRBMED approval letter contain a list of supporting documents, list the names of the documents in the box below as they should appear on the IRBMED approval letter:

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## 16. End of Adverse Event/ORIO

### Available Activities

**The Submit activity must be executed to send this application to any required committees for review.**

[Error Check](#)

[Submit Adverse Event](#)

[Move to Ready to Submit Inbox](#)