

Date: Tuesday, August 18, 2009 11:45:01 AM

Print

01 Adverse Event/ORIO

1.1* Type of Report--choose one

Other Reportable Information or Occurrence (ORIO)

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

HUM00007024_ORIO - Breach of Confidentialty

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
1_Adult_Consent_2-14-06.doc 	0.01
2_Arabic_Short_Form_9-21-06.doc 	0.01
3_Spanish_Short-Form_9-27-06.doc 	0.01

1-2.1* Other Reportable Information or Occurrences (ORIO) types:

Protocol deviation/violation

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

06. Protocol Deviation/Violation Report**6.1* Protocol Deviation/Violation involving:**

Select all that apply:

Breach of confidentiality

----General Information----**6.2.1* Date Deviation/Violation occurred:****6.2.2* Date the Deviation/Violation came to the attention of the study team:****6.2.3* From what source did the study team receive the information?****6.2.4 Date subject was consented :****6.2.5 Subject identifier :****6.3* Description of Event or Information****----Investigators' Assessment----****6.4.1* 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**6.4.2* Has the integrity or validity of the data been compromised?** Yes No**6.5* Investigators Response:****6.6 Additional Information:****6.7 Supporting Documentation:**

Name

Version

There are no items to display

15. Supporting Documents--IRBMED

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:

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](#)