**OHR20**

**Unanticipated Problem (UAP) Reporting Form**

**08/2014**

**DO NOT INCLUDE ANY OF THE SUBJECT’S PERSONAL IDENTIFIERS**

Principal Investigator:

Department/Division:

IRB Control #: JeffTrial Protocol #:

Sponsor(s):

Title:

Subject ID: Subject Initials: Date of Problem: Date PI/TJU Notified:

Description of Problem:

The Unanticipated Problem is a Protocol Deviation/Violation: [ ] Yes [ ] No

Did the Unanticipated Problem pose risk to subjects or others? [ ] Yes [ ] No

If NO, have PI or Co-I sign and date and retain form for your records, but IRB will not review, if YES, describe risk: Describe the Corrective Action Plan:

Has Problem Been Resolved? [ ] Yes [ ] No

Is this a Follow-up report: Initial Report Date: Initial Report ID:

Does the consent or protocol require modification? [ ] Yes [ ] No If YES, submit OHR 12.

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Signature of person preparing report Date

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 telephone # e-mail address

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Signature of Principal or Co-Investigator Date

**For IRB reviewer only:**

Does this event also represent possible non-compliance? [ ] Yes [ ] No

Non-compliance is defined as a violation of any federal, state or local regulation, or any university or IRB policy that governs human research.

If YES, notify the Director or Associate Director, OHR

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