### 9C20844B-9BFB-4AB9-A757-14007340F01B@local

### ICH GCP Adverse Event Report

[ ]  AE’s existing at the time of initial IRB submission.

[ ]  AE’s post IRB-approval that meet the criteria of serious and unexpected.

- Report must be submitted no later than **30** working days beyond any member of the study

 team being informed of the event.

Do notattach individual IND Safety Reports or MedWatch forms.

**Please Note:** If in reporting events below, you answer “No” to #4 and “Yes” to #5, the event may meet the definition of “Unanticipated Problem.” For additional information, please see IRB policy, “IRB Reporting and Review of Unanticipated Problems.” Attach a copy of the “Risks Section” only of the most recent, approved consent form.

**SP Code:**       **Date:**

**Title:**

**Initial IRB Approval Date:**

**Principal Investigator:**

(You may attach as many copies of page 3 as needed.)

[ ]

1. Brief description of adverse event:
2. Indicate the date the Marshfield study team became aware of this event:
3. Event Identifier/Report#:
4. Is this risk identified in the informed consent document?

**[ ]** Yes

 [ ] No

1. In response to this event, are you aware of the sponsor’s intention to modify the investigator’s brochure, protocol or informed consent document:

[ ] Yes (If ‘Yes,’ please briefly summarize the modification and submit a Change or Update to Original Submission form):

[ ] No

**SIGNATURE**

I have reviewed this completed form. I understand that it is my responsibility to ensure that all information contained within the report is accurate to the best of my knowledge.

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Signature of Principal Investigator Date

 Printed Name of Principal Investigator Routing Location

Name of person completing report Routing Location

#### Submit completed paperwork to: Office of Research Integrity & Protections – 1R4

Revised: 8/28/2015

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[ ] Yes (If ‘Yes,’ please briefly summarize the modification and submit a Change or Update to Original Submission form):

[ ] No

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