### 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.

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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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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
5. 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

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