**OHR10**

**02/2018**

**Serious Adverse Event (SAE) Reporting Form**

**.**

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

Principal Investigator: Department:

IRB Control #: Sponsor(s):

Title of Project:

Subject Initials: Subject ID #: Gender:

Event Date - Onset: Terminated: Ongoing? Date PI/TJU Aware:

Study Drug(s)/Device:

Date of Last Study Drug/Device/Treatment: Description of adverse reaction:

Severity of adverse reaction: Further AE Description:

Action Taken:

[ ] Resulted in or prolonged inpatient hospitalization [ ] Resulted in permanent disability

[ ] Subject died Autopsy performed (date):

Cause of adverse reaction (if not related to research): [ ] Underlying disease [ ] Concomitant medication (List):

If other explain:

Is this: A new report? A Follow-Up Report? Date of First Report:

In your opinion, was the SAE caused by the therapy /procedures associated with this protocol?

Is the risk of this adverse reaction described in the consent form?

If **Not Currently in consent form,** should this risk be described in the consent form?

If **No,** please provide justification for not including this reaction as a risk in the consent form:

Has this adverse reaction been reported to the sponsor? To the FDA?

Should presently enrolled subjects be informed of event?

If **Yes,** have they been informed?

Signature of Individual Preparing Report Date

PI Certification: I certify that I have reviewed this AE and that it [ ] should [ ] should not be included in the consent form.

Signature of Principal Investigator Date

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