METHODIST HEALTHCARE
INSTITUTIONAL REVIEW BOARD

Adverse Event Report Form

All serious adverse events (SAE's) occurring in subjects enrolled in research studies under the MHIRB auspices must be reported to the MHIRB within 5 days of discovery using this form. Life-threatening events that may be due to the test article, and all deaths, regardless of the relationship to the test article, must be reported to the MHIRB with 72 hours of discovery. Any follow-up reports should be sent to the MHIRB as soon as possible. ALL INFORMATION MUST BE TYPED. Please call MHIRB Administration at 516-2323 for the electronic version of this form.

MHIRB # Date of Report:
Project Name
PI Name
Address

Subject ID/Initials Date/Time of Incident

Name of event
Description of the event in detail; attach supporting lab/diagnostic/OR reports, etc.

Relationship to test article (in your opinion):
☐Related ☐Probably related ☐Possibly related ☐Unrelated

Subject outcome (check all that apply)?
☐Death ☐Recovery
☐Resulted in or prolonged hospitalization ☐Resulted in permanent disability

Was this event expected?	☐Yes	☐No
Was medical treatment provided for this event?	☐Yes	☐No
Does the subject require further medical treatment?	☐Yes	☐No
Will the subject remain in the study?	☐Yes	☐No
Is this event listed in the informed consent?	☐Yes	☐No
Are consent form changes required?	☐Yes	☐No
Will it be necessary to notify other subjects of this event?	☐Yes	☐No

The above information is accurate and complete to the best of my knowledge.

_____ _____
Principal Investigator Signature Date

For MHIRB Administration Use Only:
The Methodist Healthcare Institutional Review Board has received and noted the above listed safety reports.

Accepted: _____ Date:_____
MHIRB
Follow Up required: _____

_____
Revised Informed Consent

Approved:_____ Date:_____
MHIRB