The MD Anderson IRB requires that the investigators submit EAEs only if modifications to the protocol-related documents are required. The Sponsor in this situation is responsible for determining if safety related changes are required.

<table>
<thead>
<tr>
<th>Is adverse event serious</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is adverse event unexpected</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Is adverse event related</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Department: __________
Unit #: __________
Phone: __________
Name of person filing this form __________

Did subject die? Yes | No

(Please provide date and attribution, if yes) Date _____
And Attribution/Relation __________

Name of Agent(s) or Device __________
Sponsor/Manufacturer Report # __________

SAE/Reaction (Use terms from NCI CTC Terminology)

<table>
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<tr>
<th>Grade</th>
<th>Attribution:</th>
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</tbody>
</table>

MD Anderson Protocol Number
MD Anderson Protocol Status (see choices below)
Did Sponsor request changes to Protocol/ICD
MD Anderson PI Name
MD Anderson PI Signature
Date

Abbreviations:
Status: A= Active; PA= Pending Activation; CNPE ON = Closed to new patient entry but Pts on treatment; CNPE OFF = Closed to new patient entry but Pts off treatment; T = Terminated.

Are these events in the risk section of the ICD? No | Yes
Does the MD Anderson ICD need revision? No | Yes
Should current/previous enrolled subjects be notified of these SAEs? No | Yes
Comments: __________

Attach the sponsor’s Adverse Event Form (Med Watch or Sponsor Safety Report)

OHSP STAFF: __________ Date returned __________ for: □ Incomplete form □ Incorrect information □ Other

If returned to PI for incomplete or incorrect AE form, the corrected forms should be returned to OHSP, Unit 1437 within 2 weeks.

Note: With this new form no need to attach the risk section of the ICD