### PROTOCOL DEVIATION TRACKING FORM

**MDACC Protocol Number:** __________________________

**Principal Investigator (PI):** __________________________

**Date of IRB Notification:** _____________

**Sponsor:** __________________________

**Home IRB:** __________________________

**Date of IRB Notification:** _____________

**DEVIATION CATEGORY:**
- I=Informed Consent
- E=Eligibility Criteria
- D=Disease Outcome/Response
- TP=Treatment/Procedures
- AE=Adverse Events
- EV=Evaluations
- O=Other

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<tr>
<th>DATE</th>
<th>MDAH NO.</th>
<th>ACC #</th>
<th>SUBJECT INITIALS</th>
<th>DEVIATION CATEGORY</th>
<th>DESCRIPTION OF DEVIATION</th>
<th>CORRECTIVE ACTION PLAN</th>
<th>SPONSOR COMMENTS</th>
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**Person Completing Form:** __________________________

**Date:** _____________

**Principal Investigator’s Signature:** __________________________

**Date:** _____________

**Comments:** __________________________

**IRB Reviewer’s Signature:** __________________________

**Date:** _____________

**IRB Reviewer’s Comments:** __________________________

**Date of IRB Notifications:** _____________

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If not submitting via PDOL, please submit completed original form to the IRB, Unit 1637.

Please keep a copy in PI’s Regulatory Binder.

PLEASE NOTE: Deviation log must be submitted at Continuing Review for IRB review.