University of Texas M. D. Anderson Cancer Center
Potential Unanticipated Problems Notification Form

MDACC Protocol No.: Principal Investigator Name:

Protocol Title:

Dates that problem occurred:

Location/Site of occurrence: List sites here.

(Please note: In order for this to be an unanticipated problem, the answer to each of these questions must be ‘yes’.)

Was this problem unexpected given the research procedures described in the IRB approved protocol and the characteristics of the subject population being studied?

☐ Yes
☐ No

Was this problem related, or possibly related to participation in the research?

☐ Yes
☐ No

Does this problem potentially place subjects or others at a greater risk of harm that was previously known or recognized? (e.g., includes physical, psychological, economic or social harm)

☐ Yes
☐ No

Provide a detailed description of the problem that occurred:
Describe steps taken to resolve the problem and procedures implemented or planned to avoid problems in the future. ____

Name(s) of individual(s) involved, if applicable: ____

Does this unanticipated problem warrant any changes to the protocol or the informed consent document?

☐ Yes
☐ No

If Yes, please describe the changes: ____

Have these changes been submitted for IRB approval?

☐ Yes
☐ No

Has this problem been reported to the Sponsor or other responsible Organization?

☐ Yes
☐ No

Name of Sponsor or Organization: ____

Date Reported: ____

Actions, if any, requested by Organization or Sponsor: ____

____
Signature of Investigator          Date