**REPORT OF ADVERSE EVENT**

**Submit this report when an adverse event is (1) unanticipated AND (2) related or possibly related, and (3) either serious or not serious. Email this form and all study documents in Microsoft® Word format to** [**mhadmhasirb@ct.gov**](mailto:mhadmhasirb@ct.gov)

**TITLE OF STUDY:**

**DATE OF REPORT:**

**DMHAS ID NUMBER:**

**PRINCIPAL INVESTIGATOR:**

**Name and Title:**

**Phone:**

**E-mail:**

**DATE OF ADVERSE EVENT:**

**DATE PI DISCOVERED EVENT:**

**SITE WHERE EVENT OCCURRED:**

**NUMBER OF PARTICIPANTS INVOLVED/AFFECTED:**

**TYPE OF ADVERSE EVENT:**

**UNANTICIPATED:** The type or magnitude of the AE is NOT consistent with the risks outlined in the current protocol or consent document

**RELATED OR POSSIBLY RELATED TO STUDY INTERVENTION:**  There is a reasonable possibility the AE may have been caused by the study intervention OR it is possible that the AE may have been caused by the study intervention but there is insufficient information to determine the likelihood of this possibility

**SERIOUS:** Resulted in death or disability; is life threatening; resulted in hospitalization or other significant and unanticipated treatment; or other consequences deemed serious by the investigator.

**NOT SERIOUS**

**DESCRIPTION OF ADVERSE EVENT:**

**EXPLANATION OF RELATIONSHIP OF ADVERSE EVENT TO STUDY:**

**ACTION TAKEN TO AMELIORATE ANY DISCOMFORT OR NEGATIVE CONSEQUENCE RELATED TO THE ADVERSE EVENT(S):**

**ACTION TAKEN TO REDUCE/ELIMINATE LIKELIHOOD OF RECURRENCE:**

**DOES THE ADVERSE EVENT SUGGEST/REQUIRE A CHANGE IN STUDY PROTOCOL AND/OR CONSENT FORM?**

**Yes No**

**DOES THE ADVERSE EVENT REQUIRE THAT PARTICIPANTS ALREADY ENROLLED BE PROVIDED WITH ANY ADDITIONAL INFORMATION? Yes No**

**If yes, please describe plan:**

**DESCRIPTION OF ANY ACTION PLANNED OR TAKEN AS A RESULT OF THE EVENT:**

A

**NOTE: IF THE PLANNED ACTION REQUIRES IRB APPROVAL, SUBMIT AN APPLICATION FOR APPROVAL OF REVISION.**

**By printing my name below, I certify that the above information is true and accurate.**

**Principal Investigator Name Date Time**