**REPORT OF ADVERSE EVENT**

**Email this form and all study documents in Microsoft® Word format to** **mhadmhasirb@ct.gov**

**TITLE OF STUDY:**

**DATE OF REPORT:**

**DMHAS ID NUMBER:**

**PRINCIPAL INVESTIGATOR**

 **Name and Title:**

 **Phone:**

 **E-mail:**

**DESCRIPTION OF ADVERSE EVENT**

**Date of adverse event:**

**Date PI discovered event:**

**Description of adverse event:**

**Relationship of adverse event to study:**

**Study site where event occurred:**

**Number of participants involved/affected:**

**Action(s) taken to ameliorate any discomfort or negative consequence related to the adverse event(s):**

**Action(s) taken to reduce/eliminate likelihood of recurrence:**

**Does the adverse event necessitate 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 event such as internal procedural change; intervention with research staff; consent form change; protocol change; etc.:**

**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**

**Is a revision of procedures planned in response to the adverse event? [ ] Yes [ ] No**

**If yes, 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**