***[ ]* APPLICATION FOR CONTINUED APPROVAL**

***[ ]* FINAL REPORT**

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

**TITLE OF STUDY:**

**DATE OF APPLICATION:**

**DMHAS STUDY NUMBER:**

**CURRENT EXPIRATION DATE:**

**PRINCIPAL INVESTIGATOR:**

 **Name and Title:**

 **Institutional Affiliation:**

 **Phone**:

 **E-mail:**

**ALTERNATE CONTACT IF APPLICABLE:**

 **Name and Title:**

 **Institutional Affiliation:**

 **Phone:**

 **E-mail:**

**CURRENT IRB APPROVALS FROM OTHER INSTITUTIONS:**

 **Approval date:**       **Institution:**

 **Approval date:**       **Institution:**

**NOTE: Submit copy of most recent approvals**

**CERTIFICATE OF CONFIDENTIALITY:**

**If, at time of initial approval, the plan was to obtain a Confidentiality Certificate, please note date of issuance:**

     **[ ]  N/A**

**WAIVER OR ALTERATION OF CONSENT REQUIREMENTS:**

**Was a waiver or alteration of consent requirements approved?** **[ ] Yes** **[ ] No**

**ANTICIPATED OR ACTUAL END DATE OF STUDY:**

**CURRENT RECRUITMENT SITES:**

**Identify any site where recruitment has ended since last review:**

**CURRENT STUDY SITES:**

**Location of any ongoing study interaction/intervention(s):**

**Identify any site where research activity has ended since last review:**

**CURRENT RESEARCH ACTIVITIES:**

**Is the study permanently closed to enrollment of new participants? [ ] Yes [ ] No**

**Is the remaining research activity limited to data analysis only? [ ] Yes [ ] No**

**If yes, have all identifiers or links to identifiers been removed from the data being analyzed?**

**[ ] Yes [ ] No.**

**NOTE: If all data has been de-identified with no way to link the data to participants, a Final Report should be submitted at this time.**

**STUDY PROGRESS:**

**Brief summary of the course of the study so far including the experience of the participants:**

**FINDINGS TO DATE:**

**Brief summary of findings to date:**

**APPLICATION FOR STUDY REVISION:**

**At this time, do you want IRB review any revisions in the protocol, informed consent form, recruitment material, instruments, investigators, or other aspect of or material related to the study?** **[ ]  Yes** **[ ]  No**

**Proposed revision(s):**

**Reason for revision(s):**

**NOTE: Submit a ‘tracked changes’ copy of each revised document showing the changes made and a clean copy of each document to be stamped following approval.**

**Attachments:**

**[ ]  Revised IRB application/protocol is attached**

 **[ ]  Revision does not affect IRB application/protocol**

**[ ]  Revised consent form or other study forms is attached**

 **[ ]  Revision does not affect any study forms**

**ONGOING CONSENT**

**Please describe the manner in ongoing consent is being obtained from participants:**

**SAFETY MONITORING:**

**Does recent literature or findings obtained thus far suggest a change in the level of risk or additional information that might impact a subject's decision to participate or to continue participation in the study? [ ] Yes [ ] No**

**If yes, please summarize and indicate if the appropriate information has been shared with participants?**

**PROTOCOL DEVIATIONS:**

**Total number of protocol deviations since beginning of study:**

**Number and summary of each protocol deviation since last review:**

**ADVERSE EVENTS:**

**Total number of adverse events since beginning of study:**

**Total number and summary of any adverse events that have occurred since last review:**

**PARTICIPANT COMPLAINTS:**

**Total number of complaints received since beginning of study:**

**Number and summary of any complaints received since last review regarding the study:**

**ONGOING CONFIDENTIALITY PROTECTIONS:**

**Please describe the manner in which computer and non-computer research data is being stored to ensure security and confidentiality:**

**PARTICIPANT ENROLLMENT:**

**Total number of DMHAS participants targeted for enrollment in the study:**

 **Total number of participants targeted for enrollment in study:**

**Total number of DMHAS participants enrolled since initial approval:**

 **Total number of participants enrolled since initial approval:**

 **Total number of participants enrolled since last review:**

**Number of participants enrolled from DMHAS sites since last review:**

 **Number of participants still active in the study:**

**If the number of participants enrolled differs significantly from stated plan, explain discrepancy:**

**PARTICIPANT WITHDRAWALS:**

**Total number of people who began consent process but declined to participate since beginning of study:**

**Number of people who began consent process but declined to participate since last review**      **; and their reasons:**

**Total number of participants who have withdrawn since beginning of study:**

**Number of participants who have withdrawn from the study since last review**      **; and their reasons:**

**Total number of participants who have been withdrawn from the study by the investigator since beginning of study:**

**Number of participants who have been withdrawn from the study by the investigator since last review;**      **; and the reasons:**

**DISPOSAL OF MATERIAL**

**Based on DMHAS IRB and OHRP policy of three-year retention of records, state the date and method in which study documentation will be destroyed:**

**By printing my name below, I certify the following:**

* ***No changes in IRB approved staff, procedures, methods, informed consent forms, other study documents, or materials signed, seen or heard by participants, including instruments, will be made without prior IRB approval.***
* ***I will promptly report to the DMHAS IRB any protocol deviations, adverse events, participant complaints, or unanticipated problems involving risks to subjects or others participating in the approved research.***
* ***I will comply with the requirements of the DMHAS Commissioner's IRB Policy Chapter 8.1 and HHS regulations at 45 CFR 46 Protection of Human Subjects.***

**Principal Investigator Name Date Time**