

REPORT OF ADVERSE EVENT

Please complete form electronically, print out and submit signed copy. Report may be forwarded to the IRB chair electronically but must be followed by a signed hard copy.

Date of report:

Title of study:

DMHAS Study ID Number:

Principal investigator:

Type of adverse event:

Submit report if the AE is (1) unanticipated AND (2) related or possibly related, AND (3) either serious or not serious

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 - 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

Date of adverse event:

Date investigator became aware of event:

Study site involved:

Description of adverse event:

Explanation of relationship of adverse event to study :

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

Describe 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 event such as internal procedural change; intervention with research staff; consent form change; protocol change; etc:

Is IRB approval of a revision required with relation to any proposed changes?
 yes no

Principal Investigator – Signature

Date