COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF MENTAL HEALTH
INSTITUTIONAL REVIEW BOARD

GUIDELINES FOR THE REPORTING OF ADVERSE INCIDENTS RELATING TO RESEARCH

The Department of Mental Health's (DMH's) Institutional Review Board must implement the following guidelines for the reporting of Adverse Events to research and ensure that they are also implemented by the Principal Investigator of any research protocol approved by it. The Guidelines define "Adverse Event" and establishes when a Principal Investigator must report such events to the DMH Institutional Review Board and when the Board must further report an event to designated Department officials. **To help ensure compliance, the Board must provide a copy of the Guidelines to each Principal Investigator of an approved research protocol.**

I. DEFINITIONS:

Adverse event* means any unfavorable and unintended diagnosis, symptom, sign (including an abnormal laboratory finding), syndrome or disease that either occurs during the research study, having been absent at baseline, or if present at baseline, now appears to be worse. It also means any event that is otherwise reportable to a sponsor or co-sponsor of the research as an "Adverse Event."

Serious Adverse Event* means any untoward medical occurrence that:
(1) results in death,
(2) is life threatening,
(3) requires or prolongs hospitalization,
(4) causes persistent or significant disability/incapacity; or
(5) in the judgment of the investigator represents a significant hazard. A life-threatening Adverse Event is an event that places a participant at immediate risk of death from the event as it occurred; a life threatening event does not include an event that, had it occurred in a more severe form, might have caused death, but as it actually occurred, did not create an immediate risk of death.

*The DMH Institutional Review Board will ask every Principal Investigator to define "Adverse Event" for the purposes of his or her proposed study and to provide a plan for identifying, grading, and reporting such events to the Board. The Board might modify the above definitions for a particular study to ensure the protection of human participants; providing, however, that the Board shall only add (not delete) events to the definition of "Serious Adverse Event."

II. PRINCIPAL INVESTIGATOR'S RESPONSIBILITIES

A. **Duty to Report.** The Principal Investigator must report all Adverse Events to the Chair of the DMH Institutional Review Board or to the Chair that is designated by the Board to receive such reports. An Adverse Event must be reported within the time frames and in the format designated below.

B. Time Frames for Reporting. Unless otherwise specified in the applicable research protocol as approved by the Department's Institutional Review Board, the Principal Investigator must report Adverse Events as follows:

1. Serious Adverse Event. A Serious Adverse Event must be reported verbally as soon as it is reasonably possible and in writing by the next business day following the Event. The attached report form, or a similar form approved by DMH's Institutional Review Board, shall be used for this purpose. Serious Adverse Events, both related and unrelated to the research, must be reported.

2. Adverse Event that is Not a Serious Adverse Event. A summation of all Adverse Events that do not qualify as Serious Adverse Events must be provided to the Chair of the Board by the Principal Investigator at the time of the Periodic Review, or as otherwise determined appropriate by the DMH Institutional Review Board. The summation shall be in the format designated by the DMH Institutional Review Board. At a minimum the following information shall be provided for each Adverse Event: date, degree of seriousness, relationship to the research, if expected or not, and the actions taken.

C. Filing a Summation for Each Continuing Review. Whenever the Principal Investigator is required to submit a DMH Periodic Review Form, or when otherwise requested by the DMH Institutional Review Board, the Principal Investigator shall submit a summation of all Adverse Events (serious and non-serious) that have occurred to date. The summation shall be in the format designated by DMH's Institutional Review Board.

D. Addressing Impact on Participants. When reporting a Serious Adverse Event to the DMH's Institutional Review Board, the Principal Investigator must address the need and method to communicate pertinent information to research participants; the need to redesign or amend the research protocol, and whether or not a change in the description of risk is warranted in the protocol and the consent form.

E. Critical Incident Reporting. If the research protocol is being conducted at a DMH Facility or a DMH operated or contracted program, the DMH's Critical Incident Reporting Protocol and guidelines must be complied with <u>in addition to</u> the requirements set forth in these guidelines. These guidelines do not in any way amend or replace those required by the DMH's Critical Incident Reporting Protocol and guidelines.

III. INSTITUTIONAL REVIEW BOARD'S RESPONSIBILITIES

A. Duty of the Chair to Notify Other Department Officials. Upon receipt of a Serious Adverse Event report, the Chair of the DMH Institutional Review Board shall notify the Deputy Commissioner of Clinical and Professional Services and the Area Medical Director of the Area in which the Event occurred.

The Chair shall also forward copies of the Adverse Events summary submitted that is part of the periodic review process to the Deputy Commissioner of Clinical and Professional Services and the applicable Area Medical Director(s) within such time frames as the Deputy Commissioner shall designate.

B. Duty of the Chair to Notify the Full Board. The Chair shall report all Serious Adverse Events to the full Board within the time frame he or she deems appropriate; provided, however such reports shall not be made later than the next scheduled meeting. The Chair shall consider calling a special meeting of the Board to address a Serious Adverse Event.

C. Evaluation and Board Action. It is the duty of the Board to evaluate all Serious Adverse Event reports and all Adverse Event summations that it receives. Such assessments shall be done promptly.

In evaluating a Serious Adverse Event report, and/or a summation of Adverse Events that are not Serious Adverse Events, and/or a summation of all Adverse Events, DMH's Institutional Review Board shall consider the following:
(a) the seriousness of the Event(s),
(b) the relationship of the Event(s) to the research,
(c) whether the Event(s) was expected or not,
(d) appropriateness of the action(s) taken or proposed by the Principal Investigator, and
(e) need to inform current or future participants either by change in the protocol and informed consent documents or by other written or verbal communication.

In its response to the report of any Adverse Event, DMH's Institutional Review Board is authorized to take such action as it deems necessary to safeguard research participants. This includes, but is not limited to, modifying the protocol, changing the informed consent procedure or form(s); suspending participant enrollment; or terminating the protocol.

Commonwealth of Massachusetts
Department of Mental Health
Institutional Review Board

SERIOUS ADVERSE EVENT REPORT FORM

1. PRINCIPAL INVESTIGATOR INFORMATION:

Protocol Number: _____
Protocol Title: _____
Principal Investigator: _____
Telephone Number: _____
Email Address: _____
Mailing Address: _____
_____

2. PARTICIPANT INFORMATION:

Gender: [ ] M [ ] F [ ]Trans Female [ ] Trans Male [ ] Non-binary
DMH Client: [ ] Y [ ] N
Participant ID: _____
Current Status of the Participant:

_____
_____
_____
_____
_____
_____
_____

3. EVENT INFORMATION

Date Event Started: _____ **Date Event Ended:** _____
Site of Event: _____
Event Summary Description. Give a brief description of the circumstances leading to the Adverse Event, describe its course (include diagnosis/syndrome, component signs and symptoms); and indicate any unscheduled diagnostic procedures or treatment measures and corresponding dates.

_____
_____
_____
_____
_____
_____
_____

Death [ ]Yes [ ] No **Hospitalization** [ ] Yes [ ] No **Life Threatening** [ ] Yes [ ]No
Disability [ ]Yes [ ] No

4. RELATIONSHIP OF SERIOUS ADVERSE EVENT TO RESEARCH

[ ] Unrelated (Clearly not related to the research)

[ ] Unlikely (Doubtfully related to the research)

[ ] Possible (May be related to the research)

[ ] Probable (Likely related to the research)

[ ] Definite (Clearly related to the research)

Have similar adverse events occurred in this protocol? [ ] Yes [ ] No
If "Yes," how many?_____ Please describe: _____

5. CORRECTIVE ACTION:

What steps do you plan to take as a result of the adverse event reported above? Provide documentation to the Institutional Review Board for review and approval of any of the steps checked below:

[ ] no action required
[ ] amend the consent procedures
[ ] amend the protocol
[ ] suspend the protocol
[ ] terminate the protocol
[ ] inform current participants
[ ] other (describe below)

Investigator Signature_____ Date _____