COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF MENTAL HEALTH
GUDELINES FOR THE REPORTING OF ADVERSE INCIDENTS RELATING TO RESEARCH

The Department Research Review Committee 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 Department Research Review Committee and when the Committee must further report an event to designated Department officials. **To help ensure compliance, the Committee 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 judgement of the investigator represents a significant hazard. A life-threatening Adverse Event is an event that places a subject 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 Department Research Review Committee 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 Committee. The Committee might modify the above definitions for a particular study to ensure the protection of human subjects; providing, however, that the Committee 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 Department Research Committee or to the Co-Chair that is designated by the Committee 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 Research Review Committee, 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 the Department Research Review Committee, 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 Committee by the Principal Investigator every four (4) months, or as otherwise determined appropriate by the Department Research Review Committee. The summation shall be in the format designated by the Department Research Review Committee. 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 Department Periodic Review Form, or when otherwise requested by the Department Research Review Committee, 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 the Department Research Review Committee.

D. Addressing Impact on Subjects. When reporting a Serious Adverse Event to the Department Research Review Committee, the Principal Investigator must address the need and method to communicate pertinent information to research subjects; 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 Department Facility or a Department operated or contracted program, the Department'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 Department's Critical Incident Reporting Protocol and guidelines.

III. RESEARCH REVIEW COMMITTEE'S RESPONSIBLITLIES

A. Duty of the Chair to Notify Other Department Officials. Upon receipt of a Serious Adverse Event report, the Chair of the Department Research Review

Committee 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 summation of Adverse Events that are not Serious and of all Serious Adverse Events 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 Committee. The chair shall report all Serious Adverse Events to the full Committee 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 Committee to address a Serious Adverse Event.

C. Evaluation and Committee Action. It is the duty of the Committee 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, the Department Research Review Committee 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 subjects 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 the Department Research Review Committee is authorized to take such action as it deems necessary to safeguard research subjects. This includes, but s not limited to, modifying the protocol, changing the informed consent procedure or form(s); suspending subject enrollment; or terminating the protocol.