COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF MENTAL HEALTH
INSTITUTIONAL REVIEW BOARD

PERIODIC REVIEW FORM

DMH IRB#: _____ Principal Investigator(s): _____

Title of Project: _____

Required Attachments:
1. Current protocol
2. Current Informed Consent Form
3. List of all adverse events including date of event, brief description, and outcome
4. List of all investigators and research staff

I. PROJECT STATUS (check one)

☐ The project did not start and is not in operation.
Provide a brief explanation here, skip all questions below, sign and date the form.

For all 'project statuses' below, complete <u>all</u> parts of the form, sign and date it.

☐ The project did not start but is expected to start during the next year.
Provide a brief explanation here:

☐ The project is ongoing and open to enrollment.

☐ The project is ongoing but is closed to enrollment (participants are enrolled and engaged)***.***

☐ The project is complete and data analysis continues with PHI.

☐ The project concluded on _____*(insert date)*.

<u>Attach</u>: a statement certifying that you have destroyed all PHI or deidentified the data according to HIPAA standards; provide a summary of the results.)

II. RESEARCH PROJECT SPECIFIC:

1. HUMAN SUBJECTS

A. Since initial approval <u>or</u> the last Periodic Review, *<u>whichever was more recent</u>*,

a. How many human subjects were **<u>screened</u>** to participate in the study? ☐

b. How many human subjects were **<u>consented</u>** to participate in the study? ☐

c. How many human subjects have **<u>withdrawn</u>** from the study? ☐

B. **How many human subjects are currently participating** in the study?

C. What is the **total number of human subjects who have been consented** into the study **since the beginning**?

D. If this is a records review study, what is the **total number of individual records** that have been reviewed **since the beginning of the study**?

2. PROGRESS TO DATE (Since initial approval or the last Periodic Review, whichever was more recent).

A. Summarize all-important aspects of progress or results to date. Describe briefly current stage of research, how much longer this stage is planned to continue, and what stage/activities will follow.

a. How much longer is the study likely to continue? (Indicate years/months)

B. Did any "adverse event" occur during the course of this study, at any site, since the initial approval or the last Periodic Review, whichever was more recent?

☐ No ☐ Yes

If YES:

a. How many '**adverse events**' occurred:

b. How many '**serious adverse events**' occurred:

Provide a narrative summary of all adverse events and the actions taken as result. Indicate if there have been any changes to the risks/benefits of the study and how this has been handled.

C. Indicate whether current informed consent forms been obtained from all subjects and if not, why not.

☐ Yes ☐ No, Waiver of documentation ☐ No, waiver of consent ☐ No (explain below)

Describe how and where the informed consent forms are stored. Include a summary of any incidents that have occurred in relation to the informed consent process and how they have impacted the informed consent process.

D. Have there been any unanticipated problems during this study that have involved risk to subjects or others?

☐ No ☐ Yes

If yes, provide a summary and indicate how this has been handled.

E. Have there been any significant study findings (favorable or unfavorable) that might affect DMH IRB's human subject risks/benefits analysis, or which may otherwise influence subjects' willingness to continue as subjects?

☐ No ☐ Yes

If yes, provide a summary and indicate how this has been handled.

F. Summarize all amendments to the research protocol since the initial approval or the last Periodic Review, whichever was more recent.

G. Provide any additional information about the research study that you would like the DMH IRB to consider in its Periodic Review.

III. AVAILABLE PRESENT KNOWLEDGE

Since initial approval or the last Periodic Review, *whichever was more recent*, have there been any material changes in the scientific knowledge base (e.g. changes in evidence regarding interventions used in the study or known serious adverse events in related studies) that may relate to the continued relevance of the study?

☐ **No** ☐ **Yes**

If Yes, briefly explain the changes, why the study is still relevant, and how this may or may not affect risk/benefit analysis. An updated bibliography may be attached if useful in responding to this question.

IV. SIGNATURE

By signing this form, I confirm that the information contained herein and all attachments are true to the best of my knowledge and belief.

_____ _____

Principal Investigator (SIGNATURE) Date

SEND COMPLETED FORMS TO:

Margaret Guyer, PhD
Chair, Department of Mental Health
Institutional Review Board (DMH IRB)
25 Staniford Street
Boston, MA 02114
margaret.guyer-deason@mass.gov