COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF MENTAL HEALTH
INSTITUTIONAL REVIEW BOARD

PERIODIC REVIEW FORM

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

Title of Project: _____

Checklist of Required Attachments:

☐ Current protocol
Indicate version date here:_____

☐ Current Informed Consent Form(s)
Indicate version date(s) here:_____

☐ List of all adverse events including date of event, brief description, and outcome

☐ 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)*.
REMINDER: All parts of this form need to be completed and all attachments included as part of closing the study with DMH IRB.

Attach:

☐ a statement certifying that you have destroyed all PHI or deidentified the data according to HIPAA standards;

☐ provide a summary of the results.

☐ Bibliography of publications

II. RESEARCH PROJECT SPECIFIC:

1. HUMAN SUBJECTS

Indicate start date of study (month/year): _____

Since study began:

Study participants	Indicate # total **since study began** (e.g. entire duration of the study for 1+ years)
Screened:	
Consented:	
Withdrawn:	
Total study participants	

Since DMH IRB last reviewed study (<12 months):

Study participants	Indicate # **since last review (**e.g. within past 12 months)
Screened:	
Consented:	
Withdrawn:	
Currently participating*	

*Engaged in study interventions and/or data continues to be collected

A. Describe reasons for participants' withdrawal.

_____

_____

_____

2. RECORDS REVIEW

A. Indicate:

☐ Single moment in time

☐ longitudinal with multiple data extractions

B. Indicate **total number of individual records** that have been reviewed **since the beginning of the study:** _____

3. ADVERSE EVENTS

Since study began:

Adverse Events	Indicate # total **since study began** (e.g. entire duration of the study for 1+ years)	How many were found to be related to study participation
Serious		
Non-serious		
Total (serious/non-serious)		

Since DMH IRB last reviewed study (<12 months):

Adverse Events	Indicate # total **since last review (**e.g. within past 12 months)	How many were found to be related to study participation
Serious		
Non-serious		
Total (serious/non-serious)		

Provide a narrative summary of all serious adverse events and the actions taken as result.

_____

_____

_____

4. STUDY RISKS AND BENEFITS

Describe any changes to the risks/benefits of the study due to adverse advents, any unanticipated problems, any significant study findings (favorable or unfavorable) that might affect DMH IRB's human subject risks/benefits analysis and how this has been handled. _____

_____

_____

_____

_____

5. INFORMED CONSENT

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

☐ Yes

☐ No, Waiver of documentation.

☐ No, waiver of consent.

☐ No (explain below)

B. Summarize incidents that have occurred in relation to the informed consent process and how they have impacted the procedures for obtaining and verifying ongoing informed consent.

6. AMENDMENTS

Summarize all amendments to the research protocol since the last Periodic Review (within the past 12 months).

7. PROGRESS TO DATE

A. Describe briefly current stage of research, how much longer this stage is planned to continue, and what stage/activities will follow.

B. Summarize findings to date.

C. Summarize 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?

D. Discuss anything that may have affected participants' willingness to participate in the study.

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:

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Institutional Review Board (DMH IRB)
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If you have any questions, please contact:
Margaret Guyer, PhD
Chair, Department of Mental Health
Institutional Review Board (DMH IRB)
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