

**COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF MENTAL HEALTH
CENTRAL OFFICE RESEARCH REVIEW COMMITTEE
PERIODIC REVIEW FORM**

CORRC Tracking Number: _____

Principal Investigator(s): _____

Address: _____

Telephone Number: _____

Title of Project: _____

I. PROJECT STATUS (check one)

- The project did not start and is not in operation. *(Skip all questions below, sign and date the form.)*
- The project did not start but is expected to start during the next year. *(Complete the form, sign and date it and include a clean copy of the planned Consent Form.)*
- The project is ongoing and open to enrollment. *(Complete the form, sign and date it and include a clean copy of the Consent Form currently being used.)*
- The project is ongoing but is closed to enrollment. *(Complete the form, sign and date it.)*
- The project concluded on _____ *(inset date)*, which was after the date of the last Periodic Review by CORRC. *(Complete the form, sign and date it and attach a summary of the results.)*

II. RESEARCH PROJECT SPECIFIC:

1. Since approval or the last Periodic Review, whichever was later, *(insert a number)* human subjects were studied.
 - 1A. How many human subjects are currently participating in the study?
 - 1B. How many human subjects have participated since the study began?
2. How much longer is the study likely to continue? Years Months
3. In an attached narrative provide a progress report. Summarize all-important aspects of progress or results to date and if the study is to continue the reasons for the continuance. An abstract or other report may be included. **Check if attached** . ***If not checked, explain below.***
4. Did any "adverse event" occur during the course of this study, at any site since approval or the last Periodic Review, whichever was later? Unless specifically modified by CORRC for your

proposal an “adverse event” is 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.” No Yes ***(If yes, include in an attached narrative a summation of the adverse events, the actions taken as a result, etc.)***

5. Were there any unanticipated problems involving risk to subjects or others? No Yes ***(If yes, explain in an attached narrative)***
6. Have there been any new significant findings (favorable or unfavorable) that might affect CORRC’s human subject risks/benefits analysis or which may otherwise influence subjects’ willingness to continue as subjects? No Yes ***(If yes, explain in an attached narrative.)***
7. Has the protocol been changed since its approval, or if later, since the last Periodic Review? This includes, but is not limited to, changes to the subject population, recruitment and selection criteria, research site, recruitment methods or documents, the informed consent process, the informed consent documentation, and the methods for ensuring confidentiality. No Yes ***(If yes, provide the current version number and date of the protocol. Make sure that a copy has been filed with the CORRC. Also explain the changes in an attached narrative.)***
8. Attach clean copies of each informed consent document that is currently being used. These will be returned with the appropriate approvals added. **Check if attached** . ***If not checked explain.***
9. Have there been any changes in any subject’s capacity to give informed consent? No Yes ***(In all instances attached a narrative that explains how capacity to give informed consent is monitored and if Yes is checked, provide details as to the changes that were noted.)***
10. Have current informed consent forms been obtained from all subjects? No Yes. ***(If No, explain in an attached narrative.)***
- 10A. Does each informed consent form include documentation that a clinical determination was made of the subject’s capacity to give informed consent? No Yes. ***(If No, explain in an attached narrative.)***
- 10B. Attached narrative that explains how and where the informed consent forms are retained.
11. Attach an explanation as to how participation in the study impacts overall clinical care. This explanation should address how and by whom decisions about a subject’s care are made and how communication is maintained between research and clinical staff involved in the subject’s treatment.
12. Attach a summary (not to exceed 3 pages) of any additional information about the project that you want CORRC to consider in its Periodic Review.

III. AVAILABLE PRESENT KNOWLEDGE

1. Since approval or the last Periodic Review, whichever was later, have there been any material changes in the knowledge base that relate to the continued relevance of the study?
 No Yes *(If Yes, explain in an attached narrative the changes and why the study is still relevant. An updated bibliography may be attached if useful in responding to this question.)*
2. Since approval or the last Periodic Review, whichever was later, have there been any material changes in the knowledge base relevant to any of the interventions that are used in your study?
 No Yes *(If Yes, explain in an attached narrative the changes and how they impact the risk/benefit of your study. Also include a summary of all adverse events that you are aware of in other similar studies.)*

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:

Jeffrey Burke, Co-Chair
Central Office Research Review Committee (CORRC)
Clinical & Professional Services
Department of Mental Health
Westborough State Hospital
167 Lyman Street
Westborough, MA 01581