COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF MENTAL HEALTH

PRINCIPAL INVESTIGATOR'S PACKAGE

December 1, 2011

DIVISION OF CLINICAL AND PROFESSIONAL SERVICES
CENTRAL OFFICE RESEARCH REVIEW COMMITTEE
25 STANIFORD STREET
BOSTON, MA 02114

INDEX

ADDITIONAL MATERIALS
Attached or Available as Indicated

1. BELMONT REPORT
   Based on the Nuremberg Trials, these principles set universal standards for research. All Assurance Statements and Agreements provide for adherence to the Belmont Report. Available at http://ohsr.od.nih.gov/guidelines/guidelines.html.

2. FEDERALWIDE ASSURANCE
   The CORRC is a federally registered Institutional Review Board (IRB) and has an approved Federal wide Assurance (FWA00000324). A national registry of approved IRBs may be found at http://www.hhs.gov/ohrp.

3. RESEARCH REGULATIONS
   All research must be carried out in accordance with federal and state research regulations. DMH regulations are consistent with federal regulations, but, in many cases, DMH research regulations are more restrictive than the federal regulations. Regulations are available on line at:
   Federal Regulations 45 CFR 46: http://ohsr.od.nih.gov/guidelines/guidelines.html
   State Regulations 104 CMR 31.00: www.mass.gov/dmh

4. DEPARTMENT RESEARCH GUIDELINES (by request)
   - PLACEBO CONTROLS
   - ADVERSE EVENT REPORTING
   - RESEARCH INVOLVING CHILDREN, FORENSIC PATIENTS AND/OR PREGNANT WOMEN AS SUBJECTS.

5. UNAFFILIATED INVESTIGATOR AGREEMENT (attached)

6. DEPARTMENT OF MENTAL HEALTH PERIODIC REVIEW FORM (attached)

7. ROSTER OF CORRC MEMBERS (by request)

8. HIPAA COMPLIANCE ADDENDUM FOR CONSENT FORMS (attached)

9. ADVERSE EVENT REPORTING FORM (attached)

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PART A. BASIC INFORMATION ABOUT THE DMH CENTRAL OFFICE RESEARCH REVIEW COMMITTEE

I. CENTRAL OFFICE RESEARCH REVIEW COMMITTEE (CORRC)

The CORRC is the federally registered Institutional Review Board (Registration No. IORG0000186) of the Department of Mental Health (DMH). It has an approved Federalwide Assurance (FWA00000324). The CORRC operates pursuant to M.G.L. c. 12, §1 and 104 CMR 31.03. The DMH Commissioner appoints the CORRC members. The Chair of the CORRC reports to the Deputy Commissioner of Clinical and Professional Services.

Standards and procedures applicable to and applied by CORRC include the following:

(a) The Commonwealth of Massachusetts Department of Mental Health Federalwide Assurance for Institutions within the United States; (See Attachments)
(b) Title 45 of the Code of Federal Regulations (CFR), Part 46 (45 CFR 46);
(c) The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research report entitled: *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (the "Belmont Report");
(d) DMH regulations 104 CMR 1.00, et. seq. (See Attachments);
(e) DMH policies;
(f) DMH research guidelines issued by the Commissioner or the Deputy Commissioner of Clinical and Professional Services (See Attachments); and
(g) The Operating Procedures for the Central Office Research Review Committee.

II. RESEARCH SUBJECT TO REVIEW BY THE CORRC

All research, regardless of funding source, must be reviewed by the CORRC if:

(a) A DMH employee, as an employee, participates as a research investigator or a subject;
(b) A DMH client is a subject of the research, unless the research in no way is related to DMH, or a facility or program operated or contracted for by DMH;
(c) The research involves disclosure of data by DMH; or
(d) The terms of an agreement or other regulations require CORRC review.

104 CMR 31.01 Authority and Scope.

Inquiries as to whether a project falls within the parameters of 104 CMR 31.01 should be made to the Chair of the CORRC.

If 104 CMR 31.01 is applicable, the research cannot be conducted unless reviewed and approved by the CORRC. Additionally, no such research may be conducted unless the DMH Commissioner, or designee, determines that the research will promote the mission of DMH.

III. PURPOSE

The purpose of the research review is to protect human subjects from research risks. All potential risks must be identified and procedures to reduce those risks must be specified. Evaluation of the scientific merit of the study (e.g., peer review) is not the primary charge of the CORRC, and it is assumed that the Principal Investigator has undertaken such a scientific review before the protocol is submitted to the CORRC. However, the CORRC may disapprove a proposal if it determines that it is not scientifically sound.

IV. PRINCIPLES OF REVIEW

The following principles guide the review process.

(a) The proposed research design is sound and involves no unnecessary research risks.
(b) Any risks are reasonable and in relation to the benefits.
(c) Risks to subjects are identified and minimized.
(d) Subject selection is equitable.
(e) Informed consent is obtained.
(f) Additional safeguards exist for vulnerable subjects.
(g) Privacy and confidentiality are maximized.

V. MEETINGS

The CORRC meets regularly, generally the first Thursday of every month, at noon, at the DMH Central Office, 25 Staniford Street, Boston, MA. Investigators are invited to attend meetings to discuss their research. CORRC meetings are open to the public, but votes taken by the CORRC are taken in executive session.

VI. PROPOSAL SUBMISSION

Researchers must submit a written proposal to the CORRC to review. The proposal must conform to the Research Proposal section of this Principal Investigator's Package (Part E). Sixteen (16) copies of a proposal (all materials with the exception of the detailed technical supplemental materials, such as external protocols, for which five (5) copies are sufficient) must be submitted for review. However, email submission of documents is encouraged, and materials submitted as email attachments do not need to be submitted as hard copies.

The Principal Investigator should first submit a single set of materials to the Chair of the CORRC, as soon as the materials are ready. The materials will be reviewed and the Principal Investigator will be contacted to discuss whether the proposal is ready for submission to the full committee. Do not submit 16 copies without this prior review.

It takes approximately five to six weeks from submission of a proposal for preliminary review to the final CORRC action. The CORRC usually votes on research proposals on the day they are presented, provided that sufficient materials are submitted and further consultation is not necessary. Written confirmation of the CORRC's decision is made promptly.

VII. DRAFT PROPOSALS

While researchers are invited to discuss research issues with the CORRC Chair, the CORRC does not formally review draft proposals and will only approve or disapprove a formal research proposal. All materials must be in a final form before review by the full committee.

Students must obtain the approval of their advisors prior to submitting a proposal to the CORRC. A signed written approval from the student's advisor must be submitted with the proposal.

VIII. CORRC APPROVAL

Following review and approval of the submitted materials, CORRC will provide the Principal Investigator with a letter of approval. The consent form and any flyers or public documents will be given a date-stamp approval.

Research activities must not begin prior to full approval. Only approved documents may be used. Any subsequent changes to the procedures of the study cannot be implemented until the documentation is updated and re-approved by the CORRC.

IX. MONITORING

Subsequent to approval by the CORRC, the CORRC will monitor the progress of the research. A monitoring schedule will be set forth in the approval letter. At a minimum, a project will be monitored once a year, or if the project is less than one year, once during the duration of the research**.**

The CORRC works in conjunction with an Area Research Monitoring Committee, established in each DMH Area, and provides information about research studies to that Committee. That Committee may contact the Principal Investigator and request additional information**.** *From time to time, the* ***CORRC will send to the Principal Investigator a CORRC Periodic Review Form that the Principal Investigator must complete and return to the CORRC by the time and date specified. Failure to do so may result in suspension or termination of the research.*** A copy of the Department Periodic Review Form is attached (Attachment 6).

The CORRC may require additional progress reports and/or may conduct additional audits of the research to ensure that it is being conducted in compliance with the approved protocol.

NO CHANGES TO THE PROTOCOL, THE INFORMED CONSENT FORM, OR MATERIALS ASSOCIATED WITH THE PROJECT, MAY BE MADE WITHOUT THE PRIOR APPROVAL OF THE CORRC.

Any serious adverse events involving human subjects must be reported promptly to the CORRC (Attachment 9).

X. REVIEWS BY OTHER INSITUTIONAL REVIEW BOARDS

The Department may enter into Cooperative Research with other Federally registered Institutional Review Boards with approved Federal wide Assurances. However, proposals will always be subject to CORRC review, because DMH regulations impose requirements in addition to those imposed by federal law.

PART B. CORRC CONTACT INFORMATION.

The CORRC meets on a regular basis on the first Thursday of each month. Meetings are held in the West Conference Room of the Erich Lindemann Mental Health Center from noon to 2:00 PM. Meetings are open to the public, and investigators are urged to attend the meeting in order to respond to questions and discuss issues with the Committee during the review.

Investigators should send an email to the CORRC Chair to discuss procedures for scheduling a review. Any protocol needs to be pre-reviewed by the Chair before it is brought to the full committee. The Chair is available for technical assistance at any point during the preparation of a research protocol.

MAILING ADDRESS:

Chair
Central Office Research Review Committee (CORRC)
Department of Mental Health
Clinical & Professional Services
25 Staniford Street
Boston, MA 02114

TELEPHONE NUMBER: **(617) 626-8115**

FAX NUMBER: **(617) 626-8330**

E-MAIL ADDRESS: CORRC@massmail.state.ma.us

PART C. CHECKLIST FOR CENTRAL OFFICE RESEARCH REVIEW COMMITTEE SUBMISSION

All research must support the mission of the Department of Mental Health. The following Documents are required for all research proposals.

I. RESEARCH PROPOSAL SUMMARY (See Page 8)

This is a brief, one-to-two page summary of the important points of the proposed research written in lay language.

It also must include a statement as to how this research will promote the mission of DMH. The mission of DMH is to improve the quality of life for adults with serious and persistent mental illness and children with serious mental illness or severe emotional disturbance. This is accomplished by ensuring access to an integrated network of effective and efficient and culturally competent mental health services that promotes consumer rights, responsibilities, rehabilitation, and recovery. DMH is also charged with conducting research into the causes of mental illness.

II. RESEARCH PROPOSAL (See Page 9)

This is a specific and detailed description of the proposed research, addressing the questions contained in this package. Research protocols supplied by external parties, such as sponsoring corporations, are not adequate as they do not address issues of specific site implementation and all issues of concern to human subjects. External protocols may be included as an attachment; generally only five copies are required. The CORRC approves only specific and well-defined proposals; it does not give blanket authorization for preliminary or undefined topic areas.

III. INFORMED CONSENT FORM (See Page 16)

The specific consent form(s) to be used in the project must be supplied to the CORRC. Consent forms in languages other than English, if applicable, should be included. The form(s) should follow the guidelines set forth in Guidelines for the Informed Consent Form in this package (Part F). The CORRC is available to provide technical assistance and consultation before, during, and after the initiation of a project.

IV. COPIES OF ALL TESTS, QUESTIONNAIRES, OR OTHER NON-STANDARD INSTRUMENTS TO BE USED

If an instruments is standardized and well-known (e.g., SCID, CGI), a copy is not required.

V. COPIES OF ALL LETTERS, SCRIPTS, POSTERS, NOTICES, FLYERS, WRITTEN MATERIALS AND ADVERTISEMENTS TO BE USED FOR SUBJECT RECRUITMENT.

VI. BRIEF RESUMES OF THE PRINCIPAL INVESTIGATOR AND CO-PRINCIPAL INVESTIGATORS.

VII. PROOF OF EACH INVESTIGATOR'S COMPLETION OF TRAINING IN THE PROTECTION OF HUMAN SUBJECTS. An on-line training system is available at http://ohsr.od.nih.gov/, or investigators may complete a local facility training that meets the NIH standards.

VIII. DULY EXECUTED UNAFFILIATED INVESTIGATOR AGREEMENT FOR EACH INVESTIGATOR WHO IS NOT AN EMPLOYEE OF DMH. See the attachments for a copy of the form.

IX. HIPAA ADDENDUM TO THE INFORMED CONSENT FORM. HIPAA regulations impose strict requirements around the use of Personal Health Information. If these requirements are included in an addendum, rather than included in the consent form, then the HIPAA addendum must be attached.

PART D. THE RESEARCH PROPOSAL SUMMARY

A Research Proposal Summary must be included in the materials submitted to the CORRC. THE CORRC will furnish a copy of the Research Proposal Summary to the Commissioner and/or the Deputy Commissioner of Clinical and Professional Services during the pre-approval stage and to all applicable DMH Area Director(s) and Area Medical Directors after the study is approved.

The Research Proposal Summary is a one-to-two page summary that provides the following information using bullet points and a minimum of text:

1. Submission date

2. Project title

3. Source of funding, including institutional or corporate sponsor and protocol references

4. Principal Investigator(s), degree(s) and affiliation(s), telephone number, address, and email address

5. Brief description of the project including:

   (a) Overview and purposes;
   (b) Methods and procedures;
   (c) Subjects – numbers, description, and inclusion criteria;
   (d) Data to be recorded; and
   (e) Start date and duration of study.

6. DMH Area(s), facilities and program site(s) that will be involved in the research.

7. Potential risks to subjects

8. Potential benefits to subjects

9. A statement of how the research will promote the mission of the Department of Mental Health

10. Other IRBs involved.

PART E. THE RESEARCH PROPOSAL

The Research Proposal provides a complete overview of the site-specific project in a format that directly answers questions relevant to the CORRC. Protocols provided by a sponsoring corporation should be provided to the CORRC, but do not replace the Research Proposal required by this Part E. *The Research Proposal must provide specific information about how the protocol will be implemented at each site. The Committee is especially interested in the methods of subject identification, contact, recruitment and monitoring.*

Each page of the Research Proposal must be consecutively numbered and include the submission or revision date. The narrative should be brief and succinct, but the essential points must be clearly indicated.

The Research Proposal must contain the following information.

1. Submission Date / Version Date

2. Project Title.

3. Funding/Sponsor

Identify the source of funding or sponsor for the study, including protocol number.

4. Principal Investigator(s)

Identify the investigator(s) conducting the research, their organizational affiliations, contact information and credentials. Briefly summarize prior research by the principal investigator in this field.

5. Location(s)

Identify the DMH Area, facility and program location(s) where the project will be conducted. Include the program name(s), and also the name(s), telephone number(s) and address(es) of the person(s) in charge of the program at the stated location(s). If the PI has had contact with these entities prior to CORRC approval, explain in detail.

6. Subjects

Describe the subjects to which access is sought. Include relevant information on expected gender, ethnicity, and age groups of subjects. Address the subjects' expected state of mental and physical health. Summarize exclusion and inclusion criteria.

Identify how many subjects will be recruited. If this is a multi-site study, identify the total number of subjects to be recruited and the number at this site.

Describe <u>in</u> <u>detail</u> the process of identifying and contacting potential subjects, recruiting them into the study, obtaining consent, determining competency to give consent, and monitoring their well-being during and after the study. How will potential subjects be identified? How and by whom initial contact with potential subjects will be made? Describe the consent process and monitoring procedures to ensure that subjects' well-being is adequately addressed. *This is one of the critical steps that the CORRC will review intensively.*

Attach any written materials that will be used, such as posters or advertisements, or letters to DMH staff. If contact will be made by telephone or interview, attach a script or outline of the intended communication.

7. Research Methods and Procedures

This section should provide the reviewers with a clear overview of the proposed research. Comprehensive project descriptions may also be attached, e.g., protocols developed by (or for) sponsoring organizations or developed for academic purposes. However, the CORRC needs a specific description of procedures that will be followed at the research site. Literature should be attached only to the extent that it conveys to the CORRC potential scientific merit and/or contribution to the field.

A suggested format for this section includes:

Specific Aims and Purposes*:* State the specific aims and objectives of the research, including hypotheses. Describe how the proposed research relates to the mission of the Department of Mental Health.

Methods and Procedures: Describe in detail the steps that will be taken to conduct the research. Often a chart showing meetings and action steps such as evaluations is helpful. It is important to understand the research project from the perspective of the subject.

Data to be Recorded: List and describe all data, including laboratory tests, evaluations, questionnaires, and forms. If data will be recorded from existing records, specify the data elements and what records will be accessed. If laboratory tests will be performed, list the tests.

Be specific about the source of the data, when the data will be recorded, the forms that will be used and the conditions under which data will be recorded. Explain which members of the research team will record, have access to and/or process the data.

Start Date and Duration of the Study*:* State the duration of the research, including how long a subject will be involved in the project, and the overall duration of the entire study.

8. Assessment of Risk to Subjects

From the subject's perspective, identify all foreseeable risks, including physical, psychological, social, economic, legal or other, and their likelihood and potential severity. Loss of confidentiality or privacy is considered to be a serious research risk in any study. Describe all steps that will be taken to minimize all identified risks and discomforts.

Describe steps taken to minimize the loss of confidentiality or privacy. Describe procedures to ensure that subject participation in the study and responses to study procedures are kept confidential. Describe where data will be kept, whether it is locked, and who has access to the data, and how long the data will be kept.

9. Procedures for Monitoring Subjects' Well-Being

Describe procedures for monitoring the well being of subjects and procedures to be followed if there is any adverse effect to a subject during or upon termination of the research. If this is a drug study, describe how the clinical status of the subject will be monitored, including the clinical staff. Describe procedures to ensure that the well-being of individual subjects takes precedence over the requirements of the study design.

10. Care and Treatment Statement

Describe how the care and treatment of subjects may be affected during and after the research.

11. Informed Consent (See Part F)

Describe the intended informed consent procedures and attach the Informed Consent Form(s) that will be used. Describe how the clinical determinations that each subject has the capacity to give informed consent will be done in compliance with 104 CMR 31.05(c).

12. Benefits

Describe the expected benefits of the research to the subjects and the potential benefits to others. Note – it is expected that most research projects do not provide a likelihood of personal benefit to individual subjects. Also note that compensation for participation is *not* a benefit.

13. Remuneration, Costs and Reimbursements

State how subjects will be compensated for their participation. Describe any foreseeable financial costs to subjects and what reimbursement, if any, subjects will receive to offset such costs.

14. Explain why the research requires the participation of persons with mental illness.

15. Safeguards for Confidentiality

Describe safeguards for maintaining confidentiality of the data collected, including the manner of data disposal at the termination of the research. Special procedures may be needed for forms of data that cannot easily be made anonymous, such as photographs, videotapes or audiotapes.

16. Final Product(s)

Describe the intended final product, its intended use and manner of dissemination or publication. Describe publication agreements and ownership of the data. Will the data be available for subsequent research? Does the PI intend to contact subjects in the future for follow up studies? *Note that re-use of data or research subjects for future projects is not permitted unless sought in advance and separately requested. Intended re-contact should be documented in the procedures and consent form.*

Indicate any intentions to establish copyright, patents, or similar rights and identify all interested parties in such rights.

17. Financial Summary

Provide a financial summary of the project's financing, including the funding source and amount of funding for the research. Explain the mechanism for receipt of funding and how investigators are compensated (e.g., being paid based on the number of subjects recruited). Explain any relations between the investigators and the sponsor. These relationships may include compensation for teaching, travel, stock ownership, ownership of any entity contracting to perform or monitor the research, or the relationship of any member of the investigator's immediate family.

18. Compensation for Injuries

Describe any medical treatment and/or financial compensation available to the subject in case of injury. Indicate if any investigator will serve a dual role with any subject (e.g., treating physician, therapist, social worker).

19. Insurance

Describe any insurance (type, amount, and purpose) that the principal investigator, or other, intends to purchase for the project. Describe any of the subject's insurance or entitlements that may be invoked.

20. Use of DMH Resources

Describe the manner in which any DMH resources will be used in conducting the research and any expected compensation to DMH or its employees.

21. Other IRBs Involved

List any other agencies or committees that have reviewed or will be requested to review this study. Attach any approval letters obtained from other IRBs. Has the proposed research been rejected by an agency for reasons other than funding availability?

22. Adverse Events

Define "Adverse Event" for purposes of the study and describe the plan for identifying, grading and reporting such events to the CORRC or other entities. (See, the attached DMH Guidelines for Adverse Event Reporting.)

23. Required Attachments

(a) Resume of the Principal Investigator(s)
(b) For each investigator proof of completion of the Federal Office for Human Research Protections' training for researchers. Currently on-line at: http://ohsr.od.nih.gov/.
(c) For each investigator who is not an employee or an agent of DMH, a duly signed Unaffiliated Investigator Agreement (See, attached).

24. Attachments that are appropriate, when applicable:

(a) Approval Form(s) from other IRBs that have reviewed this project.
(b) Copies of non-standardized questionnaires, instruments, tests, etc.
(c) Copies of posters, flyers, letters, etc.
(d) Scripts of intended communications by telephone or interview.
(e) External research protocols (usually, only five (5) copies are required of the technical drug research protocols - check with the CORRC before submitting materials).

ADDITIONAL INSTRUCTIONS FOR SPECIFIC TYPES OF RESEARCH PROJECTS

A. Projects involving drugs

1. Describe fully the drugs (or other substances) to be used, side effects and interactions.
   (a) Fully describe the drug and results of relevant safety and effectiveness research.
   (b) Indicate the dosage to be used and the established dosage parameters and the procedures for establishing individual clinically effective dosages.
   (c) Indicate whether a federal IND is required.

2. Describe fully the procedures to be used in ensuring subjects' well-being during critical phases of the project.
   (a) Describe the wash-out period for existing drugs and the phase-in period for the new drugs. Procedures for monitoring subjects during these critical times must include face-to-face monitoring by a qualified person on a daily basis. Will this be done by research staff or primary treaters?
   (b) Describe procedures for ensuring the security of the storage of the drug and dispensing the drug.
   (c) The investigational drug may turn out to be less effective than the drug that was discontinued. This is a potential risk that must be indicated to the subject.
   (d) Indicate if the new drug will be made available to the subject at the termination of the study.
   (e) At the termination of the study, if the new drug is discontinued and another drug, typically the old drug, is started, item (a) above is applicable again.

B. Projects involving placebos. DMH Guidelines for Studies that Involve Placebo Controls are available upon request.

1. It must be demonstrated that the study is appropriate for placebo controls.
2. The benefits must outweigh the risks to subjects;
3. The selection criteria set forth in the guidelines must be met.
4. The protocol must demonstrate that the required study procedures set forth in the guidelines have been incorporated in full.

C. Projects involving children or individuals under guardianship. DMH Guidelines for Studies that Involve Children, Forensic Patients or Pregnant Women as Subjects are available upon request.

1. Specifically describe the need to use children as research subjects, and why "normal" children or adolescents cannot be used.
2. Describe the procedures for obtaining assent from research subjects when parents or guardians have legal authority in the matter. If a waiver is requested, explain why.

3. Describe the Principal Investigator's prior experience with this population.
4. Specify which categories of risks listed in the Guidelines are applicable to the study.

D. Projects involving forensic patients. DMH Guidelines for Studies that Involve Children, Forensic Patients or Pregnant Women as Subjects are available upon request.

1. Specify which of the four types of permissible research apply to the protocol.
2. Explain how the risks involved in the research are commensurate with the risks that would be accepted by other participants who are not forensic patients.
3. Explain how the selection process, informational materials, and the plans for follow-up care, meet the requirements of the guidelines.

E. Project involving pregnant women. DMH Guidelines for Studies that Involve Children, Forensic Patients or Pregnant Women as Subjects are available upon request.

1. Specify how the research falls into one or more of the categories of "allowed research" as specified in the guidelines.
2. Describe the procedures for obtaining consent from both the mother and father, if applicable. Explain if special monitoring of the consent process has been planned, if not, why is it not considered necessary?

F. Projects involving special equipment, devices, or special procedures.

1. Describe the equipment, the environment, and from a subject's perspective, what will happen on a step-by-step basis.
2. Indicate whether the procedures will be available to the subjects after the project is concluded.

G. Projects involving access to medical or other records

1. Indicate the physical location where the records will be kept.
2. List the specific data elements that will be recorded. Attach all recording forms.
3. Indicate who will review the records and who will have access to the data.
4. Describe the steps that will be taken to protect confidentiality of the data (e.g., recording code numbers instead of names).
5. The Informed Consent Form must clearly describe to the subject that permission is being requested to review specific records for the purpose of recording specific data elements.

H. Federally sponsored research.

1. Provide a copy of all applicable federal regulations and guidelines.
2. Specify all required federal signatories and the status of obtaining such signatures.

PART F.THE INFORMED CONSENT FORM 104 CMR 31.05 (5)

The consent process is intended to educate potential subjects about the research project and request their voluntary participation. A verbal explanation of the project, with discussion and questions, is important in augmenting the written consent form. The Informed Consent Form is a guide to this process and is the written record that the subject entered the study voluntarily and with full understanding of the research project.

Since each research project is different, there is no generic Informed Consent Form. However, this document provides a description of required sections and the specific required information that is required in each section. *Suggested language*, that the researcher may modify as needed, is indicated in *italicized text.*

In developing a consent form for a specific research project, please note the following points:

- It must provide full and complete information about the project, organized carefully so that the specific sections, described below, are covered thoroughly.
- It must be written in language that is understandable without using jargon or technical language.
- The language should be written in the second person, so as to avoid any undue sense of coercion for potential subjects. The final Statement(s) of Consent, however, should be written in the first person.
- The degree of detail, and the length of the consent form, should reflect the level of risk that the project entails for the subject.

Informed Consent and HIPAA

HIPAA requires that research subjects sign an Authorization Form, which is a permission document that permits the covered entity to use/disclose Protected Health Information (PHI) for anything other than treatment, payment or health care operations.

Authorization for PHI Uses and Disclosures

A valid Privacy Rule Authorization is an individual's signed permission that allows a covered entity to use or disclose the individual's PHI for the purpose(s) and to the recipient(s) stated in the Authorization. When an Authorization is obtained for research purposes, the Privacy Rule requires that it pertain only to a specific research study, not to future, unspecified projects. If an Authorization for research is obtained, a covered entity's uses and disclosures must be consistent with what is stated in the Authorization.

An Authorization differs from an informed consent in that an Authorization is an individual's permission for a covered entity to use or disclose his or her PHI for a certain purpose, such as a research study. An informed consent, on the other hand, is the

individual's permission to participate in the research. An informed consent provides research subjects with a description of the study and of its anticipated risks and/or benefits, and a description of how the confidentiality of records will be protected, among other things. An Authorization can be combined with an informed consent document or other permission to participate in research. Whether combined with an informed consent or separate, an Authorization must contain the specific core elements and required statements stipulated in the Privacy Rule.

Authorization Core Elements

- A description of the PHI to be used or disclosed, identifying the information in a specific and meaningful manner.
- The names or other specific identification of the person or persons (or class of persons) authorized to make the requested use or disclosure.
- The names or other specific identification of the person or persons (or class of persons) to whom the covered entity may make the requested use or disclosure.
- A description of each purpose of the requested use or disclosure.
- Authorization expiration date or expiration event that relates to the individual or to the purpose of the use or disclosure ("end of the research study" or "none" are permissible for research, including for the creation and maintenance of a research database or repository).
- Signature of the individual and date. If the individual's legally authorized representative signs the Authorization, a description of the representative's authority to act for the individual must also be provided.

Authorization Required Statements

- A statement of the individual's right to revoke his/her Authorization and how to do so, and, if applicable, the exceptions to the right to revoke his/her Authorization or reference to the corresponding section of the covered entity's notice of privacy practices.
- Whether treatment, payment, enrollment, or eligibility of benefits can be conditioned on Authorization, including research-related treatment and consequences of refusing to sign the Authorization, if applicable.
- A statement of the potential risk that PHI will be re-disclosed by the recipient and no longer protected by the Privacy Rule. This may be a general statement that the Privacy Rule may no longer protect health information disclosed to the recipient.

The web site listed below may be used to reference this text as well as a general overview of Clinical Research and the HIPAA Privacy Rule.
http://privacyruleandresearch.nih.gov/clin_research.asp

Investigators have a choice between developing a HIPAA-compliant consent form in which the required language is contained within the consent form, or using a HIPAA addendum which is a separate document that subjects must read and sign. Investigators should check with their local institution of affiliation for guidance.

INFORMED CONSENT FORM

1. HEADING

Study Title
Title of the Study
Corporate Sponsor of the Study
Principal Investigator
Principal Investigator, with telephone and email address
Associated Investigators, with telephone and email addresses
Institution of Affiliation

2. PURPOSE

The study must be described in clear user-friendly language. It must be stated that this is a research project, and the purposes and objectives of the study should be explained. If the subject is being recruited because of specific clinical characteristics, this must be stated.

The source of funding for the project should be identified. If a corporate sponsor or a grant funds the study, the subject must be informed of this.

3. PROCEDURES

The specific steps that will be followed must be spelled out in sufficient detail that the subject is aware of all aspects of his/her involvement with the project. Procedures that are experimental, i.e., non-routine, must be identified.

The total number of research subjects, in total and at this site, and the number of sites, must be stated.

Potential subjects must be informed of the nature of the data that will be recorded about them. A description of the data to be recorded, the sources of the data, how the data will be stored and steps taken to preserve confidentiality, the parties that will have access to the data, and how long the data will be kept must be described. The degree of detail should be based on the degree of risk, the extent to which the procedures are not routine, and the degree of sensitive or personal issues involved. HIPAA definitions of Protected Health Information that should be considered include:

- Laboratory tests,
- Results from standardized instruments or rating scales,
- Results from locally-developed instruments or rating scales,
- Data from the subject's chart or medical record,
- Clinician's or Case Manager's assessments
- Demographic characteristics.

The duration of each step of the project should be given, as well as the duration of the overall project.

If the study involves treatment, alternative procedures or courses of treatment that could be used instead of the experimental procedures should be described.

Where relevant:

"You will be receiving treatment as a part of this research study. You or your insurance company will [not] be charged or held responsible for the costs of that care."

"All study-related costs associated with your being in this research project will be paid for by [sponsor name].

4. RISKS AND DISCOMFORTS

Any foreseeable risks and/or discomforts must be described in detail.

Risks may include loss of confidentiality, statutory duty to disclose information (mandated reporting), disruption of ongoing treatment, potential ineffectiveness of experimental treatment, side effects of experimental medications, etc.

Discomforts may include fatigue, recall of unpleasant experiences, travel to the study site, etc.

Procedures for minimizing risk or managing bad outcomes should be described, as well as proposed medical treatment and/or financial compensation in case of injury.

If new information becomes available that may change the risks, or might change your decision to be in this research project, you will be notified in a timely fashion.

5. BENEFITS AND SIGNIFICANCE

Direct, personal benefits to the subject as a consequence of participation should be described. Remuneration is not considered to be a benefit and is described in Section 7. Many research studies do not have the potential for direct personal benefit for participants.

Possible benefits for others that may result as a consequence of the study may be described.

6. CONFIDENTIALITY

The means by which confidentiality of data and the anonymity of the subject will be protected during and after the study must be described in detail. Specific details must include:

- what data elements will be recorded and the sources of those data elements,
- how and where the data will be stored (e.g., in a locked file in the researcher's office),
- what personal identifying data will be recorded,
- whether the research data are entered into the subject's permanent medical record,
- how and when data will be destroyed,
- how reports will be written (e.g., "***no individuals will be identified***").

Researchers cannot promise absolute confidentiality, since research records are subject to court subpoenas or inspection by research monitoring authorities. In addition, the investigator may be a mandated reporter for suspected instances of abuse. Suggested language: *Confidentiality will be protected to the extent allowed by the law. For example, if we determine from information that you provide that any other person is at risk or may have been abused, we may be required to notify the appropriate authorities. If this were to happen, we would discuss this with you.*

Other parties that may have access to the research records and the purpose of their access must be stated: *Research records that identify you and the consent form signed by you may be looked at for regulatory purposes by:*

- *The sponsor,*
- *The U.S. Food and Drug Administration (if appropriate),*
- *Agencies of the U.S. Department of Health and Human Services, and*
- *The Central Office Research Review Committee (CORRC), DMH Area Monitoring Committees, or their designees. The CORRC is a group of people appointed by the Commissioner of the Department of Mental Health to perform independent reviews of research. Area Monitoring Committees are established in each DMH Area under the Area Medical Director to work with the CORRC in monitoring ongoing approved research projects.*

If the data to be recorded falls under HIPAA regulations as Protected Health Information, the subject has the right to review any data that is collected about him/hers: *"You have the right to review any data that is recorded about you."* Specific exceptions to this requirement, such as blinded drug trials, should be described.

The retention period for the research records must be specified: *"The study results will be retained in your research record [for six years or until after the study is completed, whichever is longer]. At that time either the research information not already in your medical record will be destroyed or information identifying you will be permanently removed from the study results. Any research information in your medical record will be kept indefinitely."*

If the data sought are particularly sensitive or if procedures make it possible that sensitive information might be revealed to the researcher, more specific language is required. For example, if there is a risk that a subject may disclose information about abuse, appropriate language would be: *"We are required to report abuse or threats to harm others to appropriate authorities. If that were to happen, we would discuss this with you."*

7. REMUNERATION

The amount of money that will be paid to the subject must be stated. Other forms of compensation, such as coupons, should be described. If the subject will not be compensated for their participation, that must be stated.

8. SERVICES AND RELATIONSHIPS TO THE DEPARTMENT

It must be clearly stated that*: Your participation is voluntary and independent of care and treatment. Any services received now or in the future will not be affected by your decision to participate or not to participate. You may withdraw from the study at any time without any impact on services you receive now or in the future.*

The potential subject should be told clearly that if an adverse event occurs, the researcher is required to make a report to the sponsor and to the CORRC. In addition, the subject's medical record may need to be reviewed, depending on the event: *"If an adverse event occurs, we may need to review your entire medical record. All data that have been already collected for study purposes, and any new information about an adverse event related to the study, may be sent to the study sponsor."*

In an inpatient study, practical limitations on immediate withdrawal and discharge should be described. For example, *"If you are an inpatient when you decide to withdraw, the study doctor will evaluate your clinical condition and decide whether you require continued hospitalization or transfer to other services."*

9. VOLUNTARY PARTICIPATION/WITHDRAWAL

Your participation in this study is completely voluntary. You may decide not to participate in this study. If you do participate, you may freely withdraw from the study at any time. The Department of Mental Health does not urge or encourage anyone associated with DMH to take part in a research project. Your decision not to participate or to withdraw from the study will have no effect whatsoever on any services or benefits you receive.

Your participation in this study may be stopped at any time by the study staff, without your consent, if they feel that it is in your best interest, or if you do not comply with the study procedures.

10. INQUIRIES

If you have questions or want to discuss the research study, you may contact: the name and local telephone number of the investigator should be given.

If you have questions or want to discuss your rights as a research subject, you may contact: the name and local telephone number of the local or on-site Human Rights Officer or Consumer Advocate should be given.

11. CONSENT STATEMENT AND SIGNATURES

This section should begin with a statement to the potential subject: *Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all your questions.*

This section should include a consent statement that the subject fully understands all aspects of the study, has had the opportunity to ask questions, and consents voluntarily to participate. The subject must be given a copy of the signed Informed Consent Form.

A sample Consent Statement is: *"I have read this consent form and the purpose of this study, including procedures to be followed and the risks and benefits, which have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have additional questions.*

I voluntarily consent to be in this study with the understanding that I may withdraw at any time.

I have been told that I will be given a signed copy of this consent form.

By signing this consent form, I have not waived any of the legal rights which I otherwise would have as a subject in a research study."

Subject's Signature and date. If the project includes multiple procedures, such as review of medical records or contact with family members, it is advisable to have the subject sign separately for each procedure or release of information.

If the subject is a minor, the parents or legal guardian may consent in place of the subject. If the subject is an adult and not competent, a legal guardian may give consent if legally authorized. In these cases, the study must not proceed without the subject's assent and cooperation.

Investigator's Signature and date. The investigator or representative who presented the consent process must sign a statement that s/he has explained the study and provided opportunity for questions. Additionally, a member of the research staff must document that s/he made a clinical determination that the subject had the capacity to give informed consent.

Witness's signature and date. The CORRC or the Principal Investigator may determine that an independent witness is necessary because of special risks. The witness should sign a statement that the consent process was reasonable and voluntary.

12. DETERMINATION OF COMPETENCE AND UNDERSTANDING

The burden is on the Principal Investigator to document that the subject is competent, i.e., has the capacity to understand the research project, that the subject understands what is involved by participating, and that the subject agreed to participate voluntarily, i.e., without coercion.

One option is to provide a brief statement that attests to these three criteria, with the signature and date of the person making the attestation.

Another option is to include a brief, True-False quiz about the study to the subject with the requirement that all questions must be answered correctly and all other criteria satisfied before the consent form can be signed.

PART G. RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR

The Principal Investigator is responsible for obtaining approval for the proposed project before any work is initiated. Failure to do this, or the performing of recruitment or research without obtaining CORRC approval, is a serious offense under both federal and state regulations.

In addition to obtaining CORRC approval for the proposed project, the Principal Investigator also has the following ongoing obligations to the CORRC:

I. TRAINING

The Principal Investigator will complete any training required by DMH or the CORRC.

II. PERIODIC REVIEW

Federal and state regulations require that an approved project must be monitored on an ongoing basis, at least once each year, or if shorter, once during the protocol's duration. If the CORRC approves a research protocol, it will establish a monitoring schedule for that protocol.

The CORRC works in conjunction with an Area Monitoring Committee established in each DMH Area and shares information about research studies with that Committee. In turn, the Area Monitoring Committee may contact the Principal Investigator and request additional information.

As part of any monitoring, the CORRC will mail to the Principal Investigator a Periodic Review Form (a copy of this form is attached) for completion by the Principal Investigator by the date specified by the CORRC. Additionally, the Informed Consent Form must also be re-approved and date-stamped as part of any monitoring scheduled by the CORRC.

III. NOTIFICATION OF SERIOUS ADVERSE EVENTS

The Principal Investigator must report to the designated Chair of the CORRC within twenty-four hours all "Serious Adverse Events" as that term is defined in the DMH Guidelines for Reporting Adverse Events or by the CORRC for purposes of the protocol. Additionally, the Principal Investigator must report to the designated Chair of the CORRC all other "Adverse Events" as that term is defined in the DMH Guidelines for Reporting Adverse Events, or by the CORRC for purposes of the protocol, at such times as is designated in the Guidelines, or if different as the CORRC designates.

IV. ONGOING CHANGES IN THE APPROVED PROTOCOL OR FORMS

Periodically, changes in an approved protocol or forms may be necessary. Before implementing these changes, they must be approved by the CORRC or by the Chair if they determine that the changes are not substantive and do not require a review by the full CORRC.

The CORRC must be notified of changes in a protocol, consent form, or documentation in writing, and clean copies of the new forms must be provided. The CORRC will then issue an updated approval letter for the study as well as any other required documentation (e.g., re-stamped consent form).

V. NOTIFICATION OF TERMINATION OF THE PROJECT

The CORRC and DMH Area Monitoring Committee need to know when a project is formally ended. The Periodic Review Form may be used for this purpose. Copies of publications resulting from the project are not required, but a bibliography of such materials is important.

VI. RESEARCH STANDARDS

The Principal Investigator is responsible for reviewing the following standards and for ensuring that his or her research protocol is in compliance with such standards at all times**.** *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*; the U.S. Department of Health and Human Services (DHHS) regulations for the protection of human subjects at 45 CFR 46; the DMH Federalwide Assurance, and the relevant DMH regulations, policies, guidelines and procedures for the protection of human subjects; including but not limited to, 104 CMR 31.00. In addition, the Principal Investigator is responsible for complying with all other national, state, or local laws or regulations that may provide additional protection for human subjects. The Principal Investigator's primary responsibility is to safeguard the rights and welfare of each research subject, and the subject's rights and welfare must take precedence over the goals and requirements of the research.

VII. DETERMINATIONS OF THE CORRC AND APPROPRIATE DMH OFFICIALS

The Principal Investigator must abide by all determinations of the CORRC and must accept the final authority and decisions of the CORRC, including but not limited to directives to terminate participation in designated research activities. Similarly, the Principal Investigators must abide by the determinations of certain DMH officials as specified in the DMH research regulations, 104 CMR 31.00, et. Seq. and procedures. The Principal Investigator must provide all information requested by DMH or the CORRC in a timely fashion and must cooperate in any audit conducted by either and complete such self-assessments as may be requested.

VIII. INFORMED CONSENT

The Principal Investigator will seek, document, and maintain records of informed consent from each subject or the subject's legally authorized representative as required under DHHS and DMH regulations and as stipulated by the CORRC. The Principal Investigator will not enroll subjects in the research prior to the proposal's approval by the CORRC. All consent forms and procedures must be compliant with HIPAA policies and regulations.

IX. FDA-REGULATED PRODUCTS

In conducting research involving FDA-regulated products, the Principal Investigator will comply with all applicable FDA regulations and fulfill all Principal Investigator responsibilities (or Investigator-sponsor responsibilities, where appropriate), including those described at 21 CFR 312 and 812.

ATTACHMENT 1

UNAFFILIATED INVESTIGATOR AGREEMENT

Commonwealth of Massachusetts
Department of Mental Health
Unaffiliated Research Investigator Agreement

Name of Institution Providing IRB Oversight:
OHRP Federal wide Assurance Number:
Name of Unaffiliated Investigator:
Department Research Review Committee File No.:

(1) The above-named Unaffiliated Investigator has reviewed *the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects Research*; the U.S. Department of Health and Human Services (DHHS) regulations for the protection of human subjects at 45 CFR 46, and relevant Commonwealth of Massachusetts Department of Mental Health (Department) regulations, policies, guidelines and procedures for the protection of human subjects; including but not limited to, 104 CMR 31.00.

(2) The Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Agreement.

(3) The Investigator will comply with all other National, State, or local laws or regulations that may provide additional protection for human subjects.

(4) The Investigator will abide by all determinations of the Department's Research Review Committee designated under the above Assurance and will accept the final authority and decisions of the Department's Research Review Committee, including but not limited to directives to terminate participation in designated research activities.

(5) The Investigator will complete any training required by the Department or the Department's Research Review Committee prior to initiating research covered under this Agreement.

(6) The Investigator will report promptly to the Chair of the Department's Research Review Committee proposed changes in the research conducted under this Agreement. The investigator will not initiate changes in the research without prior Research Review Committee review and approval, except when necessary to eliminate immediate hazards to subjects.

(7) The Investigator will report immediately to the Chair of the Department's Research Review Committee any unanticipated problems in research covered under this Agreement that involves risks to subjects or others.

(8) The Investigator will seek, document, and maintain records of informed consent from each subject or the subject's legally authorized representative as required under HHS and Department regulations and as stipulated by the Department's Research Review Committee.

(9) The Investigator acknowledges and agrees to cooperate in the Department's and the Department's Research Review Committee's responsibility for initial and continuing review, record keeping, reporting, and certification. The Investigator will provide all information requested by the Department and the Department's Research Review Committee in a timely fashion.

(10) In conducting research involving FDA-regulated products, the investigator will comply with all applicable FDA regulations and fulfill all investigator responsibilities (or investigator-sponsor responsibilities, where appropriate), including those described at 21 CFR 312 and 812.

(11) The Investigator will not enroll subjects in research under this Agreement prior to its review and approval by the Department's Research Review Committee.

(12) Emergency medical care may be delivered without the Research Review Committee's review and approval to the extent permitted under applicable Federal regulations and State law. However, such medical care may not be included as part of Federally-supported research.

(13) The Agreement does not preclude the Investigator from taking part in research not covered under the Agreement.

(14) The Investigator acknowledges that her/his primary responsibility is to safeguard the rights and welfare of each research subject, and that the subject's rights and welfare must take precedence over the goals and requirements of the research.

Signatures:

Investigator: _____ Date: _____

Department Official: _____ Date: _____

ATTACHMENT 2

DEPARTMENT OF MENTAL HEALTH PERIODIC REVIEW FORM

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 and include a clean copy of the Consent Form currently being used.)*

☐ 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, and.)*

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:

Chair
Central Office Research Review Committee (CORRC)
Department of Mental Health
Clinical & Professional Services
25 Staniford Street
Boston, MA 02114

ATTACHMENT 3

HIPAA COMPLIANCE ADDENDUM FOR CONSENT FORMS

INSTRUCTIONS:

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) includes very specific requirements that research subjects must provide a written authorization for the use of their Protected Health Information (PHI). All research subjects recruited after April 14, 2003, must have a HIPAA-compliant informed consent form and a specific HIPAA Authorization Form.

This form is intended to be used for all studies which have been determined by the Central Office Research Review Committee to entail no more than minimal risk and do not have funding from an external source.

You must use this HIPAA Authorization Form for all research subjects recruited after April 14, 2003, if:

You do not already have an approved HIPAAA addendum for the consent form, or
You do not use a consent form with the required HIPAA elements included.

If you have questions, contact
Chair
Central Office Research Review Committee (CORRC)
617-626-8115
CORRC@massmail.state.ma.us

Thank you.

RESEARCH SUBJECT'S AUTHORIZATION
FOR RELEASE OF HEALTH INFORMATION FOR RESEARCH PURPOSES

Name of Research Study:_____

CORRC Number: _____

Subject's Name: _____

We want to use your private health information in this research study. The law requires us to get your authorization (permission) before we can use your information or share it with others for research purposes. You can choose to sign or not to sign this authorization. However, if you choose not to sign this authorization, you will not be able to take part in the research study. Whatever decision you make about this research study will not affect your access to care in any way.

Section A: Using and sharing your health information

Who will be asked to give us your health information?

The informed consent form that you are asked to sign contains detailed information about who will be asked to give us your health information. You should read that section of the informed consent form carefully and if you have any questions, discuss this with the person who is presenting this form to you.

Who will be able to use your health information for research?

Only the researchers and research staff conducting this study will be able to use your health information for research purposes. This study is not supported by funding from any outside party that will have access to your information.

Who else will have access to your health information?

We may also be asked or required by law to share your health information with the following people if they request it. Once we give it to them, your information is no longer protected under the federal Privacy Rule. However, its use and further disclosures remain limited as stated in your Informed Consent Form as part of the Central Office Research Review Committee oversight.

- *Department of Mental Health Central Office Research Review Committee, including the Human Protections Administrator, and its designees*
- *Department of Mental Health*
- *Study Safety Monitors*
- *The Office of Human Research Protection and other governmental agencies that oversee research*

Section B: Description of information:

(1) What is the purpose of recording your health information?

- Find out study eligibility (screening)
- Data analysis of results (The Informed Consent Form includes a description of the purpose of this study. If you have any questions about the purpose of the study you should discuss it with the person who is presenting this form to you.)
- Study audit and oversight

(2) What specific information will be collected?

The informed Consent Form includes a detailed list of the health information that will be recorded in this study. If you have any questions about what data will be collected you should discuss it with the person presenting this form to you.

Section C: General

When does this Authorization Expire?

*This authorization expires on:*_____

Do you have the right to revoke this Authorization?

You may revoke (take back) this authorization at any time. To do this, you must ask the Principal Investigator for the names of the Privacy Officers at the institutions where we got your health information. You must then notify those Privacy Officers in writing that you want to take back your Authorization. If you do, we will still be permitted to use and share the information that we obtained before you revoked your authorization but we will only use and share your information the way the Informed Consent Form says.

1. If you revoke this authorization, we may still need to share your health information if you have a bad effect (adverse event) during the research.

Do You have access to the Information?

You have the right to see your medical records, but you will not be allowed to review medical records in your research records until after the study is completed.

.....

I have read this information, and I will receive a signed copy of this form.

_____ _____

Signature of research subject or personal representative **Date**

Printed name of personal representative: _____

Relationship to research subject: _____

Please describe the personal representative's authority to act on behalf of the subject:

_____

ATTACHMENT 4

ADVERSE EVENT REPORTING INSTRUCTIONS AND FORM

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.**

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 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 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 in addition to 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.

Commonwealth of Massachusetts
Department of Mental Health
Central Office Research Review Committee

Serious Adverse Event Report Form

1. PRINCIPAL INVESTIGATOR INFORMATION:

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

2. SUBJECT INFORMATION:

Birth Date: _____ Gender: [ ] M [ ] F
DMH Client: [ ] Y [ ] N
Current Status of the Client:
_____
_____
_____
_____
_____
_____
_____

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 on 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 Research Review Committee 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 subjects
[ ] other (describe below)

_____
_____
_____
_____
_____
_____
_____

Investigator Signature _____ Date _____