INSTRUCTIONS:

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) includes very specific requirements that research participants must provide a written authorization for the use of their Protected Health Information (PHI). All research participants 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 Institutional Review Board 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 participants recruited after April 14, 2003, if:

You do not already have an approved HIPAA 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, Department of Mental Health
Institutional Review Board (IRB)
Margaret.guyer-deason@mass.gov

Thank you.

COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF MENTAL HEALTH
INSTITUTIONAL REVIEW BOARD

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

Protocol Title:_____
Principal Investigator:_____
DMH IRB#: _____
Research Participant'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 Institutional Review Board oversight.

- *Department of Mental Health Institutional Review Board, 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:

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

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 inform the Principal Investigator by speaking to any member of the research team or providing a written letter. If you do take back this authorization, 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 information 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 participant or personal representative **Date**

Printed name of personal representative: _____

Relationship to research participant: _____

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

_____