



# DEPARTMENT OF MENTAL HEALTH POLICY/PROCEDURE

SUBJECT: <b>USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH</b>	POLICY NO. <b>500.9</b>	EFFECTIVE DATE <b>04/14/03</b>	PAGE <b>1 of 5</b>
APPROVED BY:  Director	SUPERSEDES	ORIGINAL ISSUE DATE	DISTRIBUTION LEVEL(S) <b>1</b>

## PURPOSE

- 1.1 To protect the privacy of Protected Health Information (PHI) of individuals who are participants or subjects in research within the Department of Mental Health (DMH).
- 1.2 To assure all applicable standards and regulations of the Health Insurance Portability and Accountability Act (HIPAA) are enforced as necessary for research within DMH.

**NOTE: This policy and procedure applies to all DMH workforce members who use and disclose PHI in connection with research.**

## POLICY

- 2.1 It is the policy of DMH to permit use and disclosure of PHI for research purposes, regardless of the source of the funding for the research, only as provided in this policy. DMH will permit uses and disclosures for research purposes as follows:
  - 2.1.1 If the individual who is the subject of the PHI provides prior authorization.
  - 2.1.2 Without the individual's prior authorization if:
    - 2.1.2.1 An Institutional Review Board (IRB) has approved a waiver of the authorization requirement.
  - 2.1.3 Without the individual's prior authorization under any of the following circumstances:
    - 2.1.3.1 Representations are obtained from the researcher that the use or disclosure of the PHI is solely for the preparation of the research.
    - 2.1.3.2 Representations are obtained from the researcher that the use or disclosure of the PHI is solely for research on the PHI of decedents.
    - 2.1.3.3 The PHI is de-identified in compliance with HIPAA's de-identification requirements or a limited data set is used (DMH Policy 500.8 "De-Identification of Protected Health Information and Use of Limited Data Sets").



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### DEFINITIONS

- 2.1 **“Authorization”** means the signed authorization language used by DMH to obtain an individual’s permission prior to using or disclosing that individual’s PHI for purposes that do not fall within the definitions of treatment, payment or health care operation activities or other purposes that do not require the individual’s signature.
- 2.2 **“Institutional Review Board (IRB)”** means a board established in accordance with applicable federal regulations to review research protocols to protect the rights of research participants to minimize their risks related to the research. The Human Subjects Research Committee (HSRC) is designated to review all research proposals involving DMH clients, including those projects already approved by outside IRBs, and to assure that all research is carried out within standards and policies of DMH.
- 2.3 **“Human Subjects Research Committee” (HSRC)** means a DMH committee which is responsible for the review of all research protocols which include DMH clients as research subjects, including those research protocols already approved by an IRB to assure that all research is conducted in accordance with the standards and policies of DMH. The HSRC is not an IRB. The HSRC provides an extra level human subjects protection with respect to DMH clients.
- 2.4 **“Workforce”** means employees, volunteers trainees and other persons whose conduct in the performance of work for a covered entity is under the direct control of such entity, whether or not they are paid by the covered entity.

### PROCEDURE

- 3.1 Use and Disclosure of PHI for Research with Authorization
- 3.1.1 When the researcher determines it is feasible (or mandated, in the case of clinical trials) to obtain the individual’s authorization, the researcher will undertake to ensure the Authorization Form (Attachment I) discloses how the individual’s PHI will be used or disclosed and otherwise contains the information required to be set forth in the HSRC approved Authorization Form.
- 3.1.2 At this time, all subjects must have the capacity to give informed consent. Proxy/surrogate consent may not be used for research conducted within DMH or its contract agencies, that require authorization by the individual research. Capacity to consent will be determined by a psychiatrist, clinical psychologist or other qualified professional not otherwise involved in the research. Research protocols may not include cognitively impaired individuals lacking capacity to give informed consent in the subject population.



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- 3.1.3 For studies including Minors in the subject population the researcher must ensure that the person signing the Authorization on behalf of the Minor has appropriate authority as the Minor's Personal Representative. Minors who are in the custody of the court (i.e. dependent child or ward status) may have the Authorization signed by the court.
- 3.1.4 Certain research protocols may require that the research subject not know the exact nature of the therapeutic intervention. Therefore, it is not required that an individual be provided with access to their PHI while they are participating in a clinical trial. In such cases, the research subject must be informed of this on the individual research Authorization Form and/or on the informed consent form to participate in the research.
- 3.1.5 If the research subject refuses to sign the research Authorization, he/she may not participate in the clinical trial. The Authorization form must contain a statement to that effect.
- 3.1.6 When the individual's authorization is obtained, his/her PHI can be used or disclosed in a manner in accordance with the terms of the authorization language. When the researcher wishes to use or disclose PHI for a purpose not set forth in the Authorization Form, the researcher may request another authorization form and present it to HSRC for approval, unless an exception pursuant to this policy applies.
- 3.2 Use and Disclosure without Authorization
- 3.2.1 There may be instances where it is not possible or practicable to obtain an Authorization to conduct research, such as in the case of records research. The Department will permit use or disclosure of PHI without authorization when an approval of the waiver of the authorization is provided by HSC.
- 3.2.2 The HSRC will review the research protocols and the request for a waiver and will issue only such waiver if it determines the following criteria are met:
- 3.2.2.1 The research cannot practicably be conducted without the waiver.
- 3.2.2.2 The research cannot practicably be conducted without access to and use of the PHI.
- 3.2.2.3 Use or disclosure of PHI involve no more than minimal risk to the privacy of the individual, based on at least one of the following requirements:
- There is an adequate plan to protect the identifiers from improper uses and disclosures;
  - There is an adequate plan to destroy the identifiers at the earliest opportunity, unless there is a health or research justification for retention, or unless required by law; or



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- There are adequate written assurances from researchers that the PHI will not be further used or disclosed except as required by law, for authorized research oversight, or for other research which would be permitted by HIPAA.

3.2.3 When the HSRC approves the waiver, it will maintain the following documents:

- 3.2.3.1 Written statement identifying the HSC and the date it approved the waiver.
- 3.2.3.2 Description of the PHI needed.
- 3.2.3.3 Statement that the HSRC reviewed the waiver under normal or expedited procedures.
- 3.2.3.4 Signature of the HSRC chair or designee, or
- 3.2.3.5 Written statement that the criteria for a waiver of the Authorization requirement, as those criteria are described in Section 3.2.2 are met.

3.2.4 Uses and disclosures of PHI authorized by the HSRC may be relied upon as satisfying the minimum necessary requirement, if reasonable.

### 3.3 Review of Protected Health Information in Preparation for Research

- 3.3.1 If PHI is needed solely for research, such as to prepare a protocol, DMH may permit researchers to access PHI without individuals' prior authorization and without HSRC approval of a waiver of authorization, if the requirements of this Section 3.3 are met.
- 3.3.2 DMH must ensure the researchers review and sign a "Representation of Researcher for Review of Protected Health Information held by Los Angeles County Department of Mental Health in Preparation for Research" form (Attachment II), indicating that the researcher will provide the following representations the HSRC and to DMH.
  - 3.3.2.1 Review of PHI will be limited as necessary to prepare for research.
  - 3.3.2.2 The researcher will not remove the PHI and will record it only in de-identified form.
  - 3.3.2.3 Review of the PHI is necessary for the research.
- 3.3.3 The HSRC must approve the request to review PHI in preparation for research.



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3.3.4 The Department is responsible for ensuring that only those researchers who have signed such a form with the information from Section 3.3.2 will have access to PHI for research preparation.

### 3.4 Research on Protected Health Information of Decedents

3.4.1 In the event that access to PHI is needed solely to conduct research of the PHI of decedents, DMH may permit researchers to access PHI without authorization and without HSRC approval of a waiver of authorization if the following requirements are met.

3.4.1.1 DMH must ensure that the researchers review and sign a "Representation of Researcher for Research Involving Protected Health Information of Decedents held by Los Angeles County Department of Mental Health" form (Attachment III) the researcher makes the following representations to the HSRC and to DMH.

3.4.1.1.1 Only the PHI of decedents will be reviewed for the research.

3.4.1.1.2 Review of the PHI is necessary for the research.

3.4.1.1.3 At the Department's request, the researcher will provide documentation of death of the individuals whose PHI will be reviewed.

### DOCUMENT RETENTION

3.5 Documentation required or completed under this policy shall be retained for at least six (6) years after completion of the research.

### AUTHORITY

HIPAA, 45 CFR Section 164.508 and 164.512(i)

### ATTACHMENTS

- Attachment I Authorization for Request or Use/Disclosure of Protected Health Information (PHI)
- Attachment II Representation of Researcher to Review Protected Health Information held by Los Angeles County Department of Mental Health to Prepare Research
- Attachment III Representation of Researcher to Review Protected Health Information of Decedents held by Los Angeles County Department of Mental Health

**AUTHORIZATION FOR REQUEST OR USE/DISCLOSURE  
OF PROTECTED HEALTH INFORMATION (PHI)**

**COUNTY OF LOS ANGELES DEPARTMENT OF MENTAL HEALTH (“LACDMH”)**

**CLIENT:**

\_\_\_\_\_  
Name of Client/Previous Names

\_\_\_\_\_  
Birth Date

\_\_\_\_\_  
MIS Number

\_\_\_\_\_  
Street Address

\_\_\_\_\_  
City, State, Zip

**AUTHORIZES:**

**DISCLOSURE OF PROTECTED HEALTH  
INFORMATION TO:**

\_\_\_\_\_  
Name of Agency

\_\_\_\_\_  
Name of Health Care Provider/Plan/Other

\_\_\_\_\_  
Street Address

\_\_\_\_\_  
Street Address

\_\_\_\_\_  
City, State, Zip Code

\_\_\_\_\_  
City, State, Zip Code

**INFORMATION TO BE RELEASED:**

Assessment/Evaluation

Results of Psychological Tests

Diagnosis

Laboratory Results

Medication History/

Treatment

Entire Record (Justify)

Current Medications

Other (Specify): \_\_\_\_\_

**PURPOSE OF DISCLOSURE:** (Check applicable categories)

Client’s Request

Other (Specify): \_\_\_\_\_

Will the agency receive any benefits for the disclosure of this information?  Yes  No

I understand that PHI used or disclosed as a result of my signing this Authorization may not be further used or disclosed by the recipient unless such use or disclosure is specifically required or permitted by law.

**EXPIRATION DATE:** This authorization is valid until the following date: \_\_\_\_/\_\_\_\_/\_\_\_\_  
Month Day Year

**AUTHORIZATION FOR REQUEST OR USE/DISCLOSURE  
OF PROTECTED HEALTH INFORMATION (PHI)**

**COUNTY OF LOS ANGELES DEPARTMENT OF MENTAL HEALTH (“LACDMH”)**

**YOUR RIGHTS WITH RESPECT TO THIS AUTHORIZATION:**

**Right to Receive a Copy of This Authorization** - I understand that if I agree to sign this authorization, which I am not required to do, I must be provided with a signed copy of the form.

**Right to Revoke This Authorization** - I understand that I have the right to revoke this Authorization at any time by telling DMH in writing. I may use the Revocation of Authorization at the bottom of this form, mail or deliver the revocation to:

\_\_\_\_\_  
Contact person

\_\_\_\_\_  
Agency Name

\_\_\_\_\_  
Street Address

\_\_\_\_\_  
City, State, Zip

I also understand that a revocation will not affect the ability of DMH or any health care provider to use or disclose the health information for reasons related to the prior reliance on this Authorization.

**Conditions.** I understand that I may refuse to sign this Authorization without affecting my ability to obtain treatment. However, DMH may condition the provision of research-related treatment on obtaining an authorization to use or disclose protected health information created for that research-related treatment. (In other words, if this authorization is related to research that includes treatment, you will not receive that treatment unless this authorization form is signed.)

I have had an opportunity to review and understand the content of this authorization form. By signing this authorization, I am confirming that it accurately reflects my wishes.

\_\_\_\_\_  
**Signature of Client / Personal Representative**

\_\_\_\_\_  
Date

If signed by other than the client, state relationship and authority to do so: \_\_\_\_\_

**REVOCATION OF AUTHORIZATION**

**SIGNATURE OF CLIENT/LEGAL REP:** \_\_\_\_\_

**If signed by other than client, state relationship and authority to do so:** \_\_\_\_\_

**DATE:** \_\_\_\_/\_\_\_\_/\_\_\_\_  
Month Day Year



# DEPARTMENT OF MENTAL HEALTH

## REPRESENTATION OF RESEARCHER TO REVIEW PROTECTED HEALTH INFORMATION HELD BY LOS ANGELES COUNTY DEPARTMENT OF MENTAL HEALTH TO PREPARE FOR RESEARCH

Name of requesting individual:	Date:
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Describe the health information that is the subject of the request to review:

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Explain the purpose supporting the need to access the health information:

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By signing this form, I hereby represent to the Human Subjects Research Committee (HSRC) and to the Department of Mental Health the following:

- a. My review of the health information will be limited as necessary for me to prepare for research.
- b. I will not remove the health information from the area allocated to me by the Department to review the health information, and will record the health information reviewed only in a manner that the subjects of the information cannot be identified.
- c. My review of the health information is necessary for the research I am conducting.

Researcher's Name (Print)	Signature	Date
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Signature of HSRC Committee Member	Date
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# DEPARTMENT OF MENTAL HEALTH

## REPRESENTATION OF RESEARCHER TO REVIEW PROTECTED HEALTH INFORMATION OF DECEDENTS HELD BY LOS ANGELES COUNTY DEPARTMENT OF MENTAL HEALTH

Name of requesting individual:	Date:
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Describe the health information that is the subject of the request to review:

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Explain the purpose supporting the need to access the health information:

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By signing this form, I hereby represent to the Human Subjects Research Committee (HSRC) and to the Department of Mental Health the following:

- a. I am reviewing the health information only for the limited purpose of research using decedents' health information.
- b. My review of the health information is necessary for the research I am conducting.
- c. If the Department so requests, I will provide documentation of death of the individuals whose health information I will review.

Researcher's Name (Print)	Signature	Date
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Signature of HSRC Committee Member	Date
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