DEPARTMENT OF HEALTH SERVICES
COUNTY OF LOS ANGELES

SUBJECT: USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

POLICY NO: 361.27

PURPOSE:

To establish a policy and procedure for use and disclosure of Protected Health Information (PHI) for research purposes.

POLICY:

It is the policy of the Department of Health Services (DHS) to permit use and disclosure of the Protected Health Information (PHI) it maintains for research, regardless of the source of funding of the research, only as provided in the policy. Specifically, the DHS facility will only permit the use and disclosure of PHI for research purposes as follows:

- If the individual who is the subject of the PHI provides prior authorization; or
- Without the individual's prior authorization if:
  - An Institutional Review Board (IRB) or Privacy Board has approved a waiver or alteration of the authorization requirement;
  - Representations are obtained from the researcher that the use or disclosure of PHI is solely for preparation for research, e.g., to prepare a research protocol; or
  - Representations are obtained from the researcher that the use or disclosure of PHI is solely for research on the PHI of decedents; or
- Without prior authorization, if the PHI is de-identified in compliance with HIPAA's de-identification requirements or partially de-identified as a limited data set in compliance with HIPAA's limited data set.

DEFINITIONS:

Authorization means the signed authorization language used by the health care facility 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 operations activities and other purposes that do not require the individual's permission.

Institutional Review Board or IRB means the board established in accordance with applicable federal regulations to review research protocols to protect the rights of research participants and to minimize their risks related to the research.

Informed Consent Form means the form that must be provided to participants in clinical research studies that contains, among other things, language informing the participants of the risks associated with the study.

Privacy Board means a board that (a) is comprised of members with varying backgrounds and appropriate professional competency to review the effect of a research protocol on the participants' privacy rights; (b) includes at least one member who is not affiliated with the DHS facility, is not affiliated with any entity conducting or sponsoring the research, and is not related to any person who is affiliated with such entities; and (c) does not permit its members with a conflict of interest to review a research project.

PROCEDURE:

I. Define the Purpose of the Research:

A. If the DHS facility determines that the PHI will be reviewed only in preparation for research, proceed to Section V, below.

B. If the DHS facility determines that the request is for research on the PHI of decedents, proceed to Section VI, below.

C. In other cases, the DHS facility will initially review all requests for access to PHI that the DHS facility collects or maintains. The DHS facility will define the purpose of the research and make a determination as to whether it is feasible to de-identify the PHI, either fully or as a limited data set (i.e., if the purpose of the research can be accomplished with fully or partially de-identified data).

To determine whether it will be feasible to de-identify the PHI, either fully or as a limited data set, the DHS facility must review DHS Policy No. 361.19, "De-Identification and Re-Identification of Protected Health Information/Limited Data Sets." If the DHS facility determines that it is feasible to de-identify PHI for the research, it must follow the procedures set forth in DHS Policy 361.19 to ensure the PHI is properly de-identified.

D. If the DHS facility determines that it is not feasible to de-identify the PHI, either fully or as a limited data set, it will determine if it is feasible to obtain the authorization of individuals who are the subjects of the PHI.

   Note: In the case of research related to treatment (i.e., clinical trials), an authorization is mandated.

E. If the DHS facility determines that it is feasible to obtain prior authorization from the individuals, proceed to Section II, below.

F. If the DHS facility determines that, for research unrelated to treatment, it is not feasible to obtain prior authorization from the individuals, or if an alteration of prior authorization is needed, proceed to Section III, below.

II. Uses and Disclosures of PHI for Research with Authorization

A. If the DHS facility determines that it is feasible (or mandated, in the case of clinical research trials) to obtain the individuals' authorization, it will ensure that the Authorization form discloses how the individuals' PHI will be used or disclosed and otherwise contains information required to be set forth in the Authorization Form. The language in the Authorization Form may be combined with the Informed Consent Form for the research so that the individuals do not have to sign two forms.

B. If the Authorization Form is to be signed by someone other than the individual, the DHS facility will ensure that the person signing has appropriate authority as the individual's Personal Representative as set forth in DHS Policy No. 361.17, "Use and Disclosure of Protected Health Information (PHI) of Deceased Individuals and Minors and for Making Disclosures to Personal Representatives."

C. The access provisions in DHS Policy No. 361.15, "Access of Individuals to Protected Health Information (PHI)/Designated Record Set" do not require individuals to be provided with access to the PHI while they are participating in a clinical trial, as long as the authorization informs them of this fact. The DHS facility will review the authorization language to ensure that it states that individuals will not be provided access to their PHI while the clinical trial is open.

D. The DHS facility may condition enrollment in a clinical trial on the participant's execution of an Authorization. In the event an individual refuses to sign an Authorization, the DHS

facility should consult with the Privacy Officer to determine if the individual should be denied enrollment in the trial.

1. The DHS facility shall be responsible for documenting the decision reached under Section 1.D, above. In the event that the DHS facility and the Privacy Officer determine that an individual should be denied enrollment in a study, the DHS facility is responsible for providing the individual with a written statement of such decision.

E. If the individual's Authorization is obtained, his or her PHI can be used and disclosed in any way that is consistent with the terms of the authorization language. If the DHS facility is responsible for ensuring that it obtains another authorization, unless an exception to this requirement applies (see the exceptions set forth in Sections III thru VI of this policy, as well as in DHS Policy No. 316.7, "Right of an Individual to Agree or Object to the Use and Disclosure of Protected Health Information." and DHS Policy No. 361.3, "Use and Disclosure of Protected Health Information without Authorization."

III. Uses and Disclosures without Authorization

A. 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 DHS facility will permit use or disclosure of PHI without Authorization if an approval of the waiver of the Authorization requirements or the alteration of the Authorization requirements is provided by an IRB or Privacy Board. In the event that the DHS facility makes the initial determination that is not feasible to obtain Authorization, the DHS facility will forward the request to the IRB or Privacy Board for consideration.

B. The IRB or Privacy Board will review the research protocols and the request for a waiver or alteration of Authorization and will only issue such waiver or alteration if it determines that the following criteria are met:

1. Use or disclosure of PHI involves no more than minimal risk to the privacy of individuals, based on at least one of the following elements:

a. There is an adequate plan to protect the identifiers from improper uses and disclosures;

b. 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

c. 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;

2. The research cannot practicably be conducted without the waiver or alteration; and

3. The research cannot practicably be conducted without access to and use of PHI.

C. If the IRB or Privacy Board approves the waiver or alteration of Authorization it will provide the DHS facility with the following documentation:

1. Written statement identifying the IRB or Privacy Board and the date it approved the waiver or alteration;

2. Description of the PHI needed;

3. Statement that the IRB or Privacy Board reviewed the waiver or alteration under normal or expedited procedures; and

4. Signature of board chair or designee; and

5. Written statement that the criteria for a waiver or alteration of the Authorization requirement, as those criteria are described in Section III.B have been satisfied.

D. Uses and disclosures of PHI authorized by the IRB or Privacy Board may be relied on as satisfying the minimum necessary requirement, if reasonable.

IV. Effect of Permission for Research Obtained Before April 14, 2003

A. The DHS facility may use or disclose, for a specific research study, PHI regardless of when it was created or received, as long as any of the following was obtained before April 14, 2003:

1. The individual's written permission to use or disclose his/her PHI for the research study, whether or not it complies with the requirements of the Authorization Form;

2. The individual's written informed consent to participate in the clinical study; or

3. A waiver of informed consent from the IRB, unless an informed consent is then requested from the individual after April 14, 2003.

V. Review of PHI in Preparation for Research

A. In the event that the DHS facility determines that access to PHI is needed solely in preparation for research, such as to prepare a protocol, the DHS facility may permit researchers to access PHI without individuals' prior Authorization and without IRB or Privacy Board approval of a waiver of Authorization, if the requirements of this Section are met.

B. The DHS facility must ensure that the researchers review and sign the form entitled, "Representations of Researcher to Review Protected Health Information... to Prepare for Research (Attachment A)." In signing the Form, the researchers will provide the following representations to the DHS facility:

1. Review of PHI will be limited as necessary to prepare for research;

2. The researcher will not remove the PHI and will record it only in de-identified form; and

3. Review of the PHI is necessary for the research.

C. The DHS facility is responsible for ensuring that only those researchers who have signed such a Form will have access to PHI for research preparations.

VI. Research on PHI on Decedents

A. In the event that the DHS facility determines that access to PHI is needed solely to conduct research on the PHI of decedents, the DHS facility may permit researchers to access PHI without Authorization and without IRB or Privacy Board approval of a waiver of Authorization, if the requirements of this Section are met.

B. The DHS facility must ensure that the researchers review and sign the attached form entitled, "Representations of Researcher to Review Protected Health Information of Decedents Held by...." (Attachment B). In signing the form, the researchers will provide the following representations to the DHS facility:

1. Only the PHI of decedents will be reviewed for the research;

2. Review of the PHI is necessary for the research; and

3. At the DHS facility's request, the researcher will provide documentation of death of the individuals whose PHI will be reviewed.

VII. Documentation Retention

A. All documents required to be created or completed under this policy shall be maintained for at least six (6) years after the completion of the research in by the DHS facility and in the IRB or Privacy Board.

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

REFERENCES:

45 Code of Federal Regulations §§ 164.508 and 264.512(l)
DHS Policy No. 361.3, "Use and Disclosure of Protected Health Information without Authorization"
DHS Policy No. 361.7, "Right of an Individual to Agree or Object to the Use and Disclosure of Protected Health Information"
DHS Policy No. 361.19, "De-identification and Re-identification of Protected Health Information/Limited Data Sets"

ATTACHMENT A

MODEL REPRESENTATIONS OF RESEARCHER
TO REVIEW PROTECTED HEALTH INFORMATION HELD BY
_____ (THE "DHS FACILITY") TO
PREPARE FOR RESEARCH

1. Name of requesting individual:

_____

2. Date of request:

_____

3. Describe the health information that is the subject of the request to review:

_____

_____

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

_____

_____

By signing this form, I hereby represent to the DHS facility 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 DHS facility 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: _____

Signature: _____

Date: _____

ATTACHMENT B

MODEL REPRESENTATIONS OF RESEARCHER
TO REVIEW PROTECTED HEALTH INFORMATION OF
DECEDENTS HELD BY _____ (the "DHS facility")

1. Name of requesting individual:

_____

2. Date of request:

_____

3. Describe the health information that is the subject of the request to review:

_____

_____

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

_____

_____

By signing this form, I hereby represent to the DHS facility 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 DHS facility so requests, I will provide documentation of death of the individuals whose health information I will review.

Researcher's Name: _____

Signature: _____

Date: _____