LOUISIANA STATE UNIVERSITY
HEALTH CARE SERVICES DIVISION
BATON ROUGE, LA

POLICY NUMBER: 7520-24

CATEGORY: HIPAA Policies

CONTENT: Use and Disclosure of Protected Health Information for Research

APPLICABILITY: This policy is applicable to Health Care Services Division Administration and Lallie Kemp Medical Center to include employees, physician/practitioner practices, vendors, agencies, business associates and affiliates. This policy will also apply to LSU System health care components, including but not limited to, IRBs and/or Privacy Boards established thereunder, hospitals, physician/faculty practices, and clinics.

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LSU HEALTH CARE SERVICES DIVISION
PRIVACY POLICIES AND PROCEDURES For CLINICAL RESEARCH
HUMAN SUBJECT/PATIENT POLICY: Use and Disclosure of Protected Health Information for Research

I. POLICY STATEMENT

This policy will provide guidance for the use and disclosure of protected health information (PHI), as described in the Health Insurance Portability and Accountability Act (HIPAA) of 1996, for research purposes including:

A. Instances where a written authorization is required before PHI may be used or disclosed;
B. Instances where written authorization of the patient is not required before PHI may be used or disclosed, but a review of the use or disclosure of PHI must be performed and approved by a qualified board; and
C. Instances where written authorization of the patient is not required before PHI may be used or disclosed, but the researcher must provide written assurances that the PHI will be protected.

Note: Any reference to Health Care Services Division (HCSD) also applies and pertains to Lallie Kemp Medical Center.

II. IMPLEMENTATION

This policy and subsequent revisions to the policy shall become effective upon approval and signature of the HCSD Chief Executive Officer (CEO) or Designee.

III. DEFINITIONS

A. Accounting of Disclosures- A research subject has the right to receive a written accounting of certain research disclosures of his/her PHI to individuals or entities outside of the HCSD facilities or clinics. This right applies to all disclosures made during research performed under a waiver of authorization or involving deceased individuals. This right includes any such disclosures during the six years prior to the date on which the accounting is requested after April 14, 2003. Note that disclosures are not permitted under a preparatory to research project nor is an accounting required when research is pursuant to a HIPAA-compliant authorization or involves de-identified data or limited data sets with a data use agreement.

B. Authorization - A written document completed and signed by the individual that allows use and disclosure of PHI for specified purposes other than treatment, payment or health care operations.

C. **Common Rule –** The Federal Policy for the Protection of Human Subjects that is currently in effect, as described in 45 CFR part 46(A). The Common Rule provides protections for individuals and establishes the role of Institutional Review Boards (IRB) in achieving those protections.

D. **De-identified Information** – Health information that does not identify an individual and data from which there is no reasonable basis to believe that the information can be used to identify an individual. All identifiers have been removed pursuant to federal Privacy Rule § 164.514 (b) (2). De-identified information is not considered PHI and is not subject to HIPAA. To de-identify information, you must remove all of the following elements:

1. Names
2. Address – (All geographic subdivisions smaller than a State including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census: (initial 3 digits if geographic unit contains less than 20,000 people, or any other geographical codes).
3. Dates (except for years)

    a. Birth Dates
    b. Admission Dates
    c. Discharge Dates
    d. Date of Death
    e. Ages >89 and all elements of dates (including year) indicative of such age, EXCEPT that such ages and elements may be aggregated into a single category of >90

4. Telephone Numbers / Fax Numbers
5. E-mail Addresses / Web Universal Resource Locators (URLs) / Internet Protocol (IP) Address Numbers
6. Social Security Numbers
7. Medical Record Numbers
8. Health Plan Beneficiary Numbers
9. Account Numbers
10. Certificate / License Numbers
11. Vehicle Identifiers and Serial Numbers
12. Device Identifiers and Serial Numbers
13. Biometric Identifiers (e.g. finger or voice prints)
14. Full face photographic images and any comparable images
15. Any other unique identifying number, characteristic, or code

E. **Designated record set—**A group of records regarding an individual that are maintained by a HCSD facility or clinic and that include medical and billing

records which are used in whole or in part to make decisions about individuals. (NOTE: records that are strictly research records that are kept separately are not part of the designated record set.)

F. **Individually Identifiable Health Information** – Information, including demographic information, that:

1. Is created or received by a healthcare provider, health plan, employer, or healthcare clearinghouse
2. Relates to the past, present, or future physical or mental condition of an individual, the provision of healthcare to an individual, or the past, present or future payment for the provision of healthcare to an individual
3. Identifies the individual (or there is a reasonable basis to believe the information can be used to identify the individual)

G. **Limited data set—**means PHI that excludes the following direct identifiers of the patient, or of the patient's relatives, employers, or household members:

1. names
2. postal address information, other than town or city, state, or zip code
3. telephone numbers
4. FAX numbers
5. Electronic mail addresses
6. Medical record numbers, including prescription numbers and clinical trial numbers
7. Health plan beneficiary numbers
8. Account numbers
9. Certificate/license numbers
10. Vehicle identifiers and serial numbers, including license plate numbers
11. Device identifiers and serial numbers
12. Web Universal Resource Locators (URLs)
13. Internet Protocol (IP) address numbers
14. Biometric identifiers, including finger and voice prints
15. Full face photographic images and any comparable images

(NOTE that this list of identifiers is **not** the same as that for de-identified information).

H. **Protected Health Information (PHI)-** for purposes of this policy means individually identifiable health information held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper, or oral. Includes demographic data that relates to:

1. The individual's past, present or future physical or mental health or condition;

2. The provision of health care to the individual, or;
3. The past, present, or future payment for the provision of health care to the individual, and that identified the individual or for which there is a reasonable basis to believe it can be used to identify the individual. PHI includes many common identifiers such as name, address, birth date, social security number, etc.

I. **Research** – A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge, including research studies that involve treatment.

J. **Research databases**— PHI collected and maintained solely for research purposes is a research database. In contrast, PHI collected and maintained solely for treatment, payment, and operations is not a research database.

IV. RESPONSIBILITY

All HCSD facilities and clinics within the scope of this policy that participate in research in which patients' PHI is used or disclosed, will have procedures in place to assure PHI is used or disclosed in accordance with applicable state and federal laws, regulations, and rules. Researchers should be guided by the following principles:

A. A researcher has the obligation to identify when the intended use or disclosure of PHI is for research, as defined above.

B. Individual authorization is generally required to request, access, review, use or disclose PHI for research purposes, except in limited circumstances described in the sections, below. Authorizations forms must be reviewed by the IRB and/or Privacy Board.

C. In those research circumstances where an individual authorization is excepted (*i.e.* preparatory to research, research on decedents, or under a waiver of authorization) satisfaction of LSU's IRB's policies and procedures must be met prior to such activities.

D. Each HCSD facility or clinic engaged in research activities will establish administrative and management infrastructure to implement this policy.

E. These provisions are intended to supplement, rather than replace, the existing IRB policies and procedures.

V. PROCEDURE

A. Use of an Institutional Review Board (IRB) and/or Privacy Board

1. Any HCSD facility or clinic which participates in and provides data for research projects shall use an IRB of record and/or Privacy Board for the purposes of minimizing risks, including privacy risks, to research participants. The purpose and functions of an IRB are as described in 45 CFR part 46 (A) (the Common Rule).

2. The IRB and/or Privacy Board will conduct reviews and approvals of uses and disclosures of PHI and waivers or alterations of an authorization to use or disclose PHI for research purposes.

B. Receipt and Processing of Research Requests

1. HCSD facilities or clinics may use or disclose PHI for research regardless of the source of funding. The research may be conducted either with a patient's authorization or without the patient's authorization in limited circumstances and under certain conditions.

2. Requests for use of patients' PHI in research projects will be submitted in writing to the IRB and/or Privacy Board. The research request must describe with sufficient specificity the PHI necessary, as well as how it will be used for the research.

3. The IRB and/or Privacy Board will evaluate the request to determine whether the health care component will grant access to patients' PHI. Based on the type of research, the required uses and disclosures of PHI, and assurances provided by the principal investigator, the IRB and/or Privacy Board will determine the necessity for authorizations, waivers, or alterations of authorizations.

4. The IRB and/or Privacy Board chair, or designee, will notify the requestor of denial or approval and under what circumstances the approval is made. The IRB action on the request will be maintained by the Research Office with other documents related to that protocol.

5. HCSD facilities or clinics are responsible for adhering to the requirements for providing an accounting of disclosures for research purposes. The principal investigator may be required to provide the facility with information necessary to construct an accounting of disclosures. Researchers need to understand that their contact information will be provided to patients whose health information was used in their research with a waiver of authorization, if the patient so request. See Policy # 7525 Accounting of Disclosures of Protected Health Information for further information.

6. Authorizations are obtained in addition to the IRB approved documents for the research, and a copy is placed on the participant's medical record along with the IRB-approved documents.

C. RESEARCH THAT DOES NOT REQUIRE AUTHORIZATION BUT DOES REQUIRE IRB AND/OR PRIVACY BOARD REVIEW

HCSD facilities or clinics may use or disclose PHI for research purposes in certain circumstances without obtaining the patient's written authorization or providing an opportunity for the patient to agree or object.

1. **Reviews Preparatory to Research under Privacy Rule 164.512(i)(1)(ii)**.

   The principal investigator shall submit to the IRB and/or Privacy Board Chair, or designee, a Principal Investigator's Certification of Review Preparatory to Research form for review and approval which describes the research and contains written representations that:

   a. Use or disclosure is sought solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research;
   b. No PHI is to be removed from the HCSD facilities or clinics and/or performance sites by the principal investigator or other researchers working with or under his/her direction during the course of the review; and
   c. The PHI for which use or access is sought is necessary for research purposes. The principal investigator must identify the minimum necessary PHI for the access request or must justify access to the entire medical record, if necessary. See Policy # 7512 Minimum Necessary Standard for Use and Disclosure of PHI.
   d. If IRB policies are more restrictive than HIPAA, you must follow the IRB policies.

2. **Research on Decedent's Information under Privacy Rule 164.512 (i) (1) (iii)**.

   The principal investigator shall submit to the IRB and/or Privacy Board Chair, or designee, a Principal Investigator's Certification of Request for Decedent's Information form which describes the research, including:

   a. Written representations that the use or disclosure is sought solely for research on the PHI of decedents;
   b. Documentation of the death of such individuals, if requested by the IRB and/or Privacy Board Chair, or designee; and
   c. Representation that the PHI for which use or disclosure is sought is necessary for the research purposes.

3. **Waiver of Authorization.**

a. Approval of Waiver of Authorization HCSD facilities or clinics may use or disclose PHI for research if it obtains IRB approval of an alteration to or waiver, in whole or in part, of the individual's authorization required for use or disclosure of PHI.

b. Documentation of Waiver Approval. For a use or disclosure of PHI to be permitted based documentation of approval of an alteration or waiver, as described above, the documentation must include all of the following:

1. Identification and date of action. A statement identifying the IRB and/or Privacy Board and the date on which the alteration or waiver of authorization was approved.

2. Waiver criteria. A statement that the IRB and/or Privacy Board has determined that the alteration or waiver, in whole or in part, of authorization satisfies the following criteria:

aa. The use or disclosure of PHI involves no more than minimal risk to the individuals based on, at least, the presence of the following elements;

bb. There is an adequate plan to protect the identifiers from improper use and disclosure;

cc. There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law;

dd. There are adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI is permitted;

ee. The research could not practicably be conducted without the alteration or waiver; and

ff. The research could not practicably be conducted without access to and use of the PHI.

3. Protected health information needed. A brief description of the PHI for which use or access has been determined to be necessary and without which the research could not practicably be conducted as determined by the IRB and/or Privacy Board regulations of another federal agency, or the expedited review procedures described in applicable federal policies including DHHS regulations (45 CFR part 46.110) or equivalent regulations of another federal agency; and

4. Required signature. The documentation of the alteration or waiver of authorization must be signed by the IRB chair or designee.

D. RESEARCH THAT REQUIRES AUTHORIZATION FOR USE AND DISCLOSURE OF PHI

1. If any HCSD facility or clinic uses or discloses PHI for the purpose, in whole or in part, of research involving human subjects that component must obtain an authorization for the use or disclosure of such information. See Form: Authorization to Use and Disclose PHI for Research which is required unless IRB approval has been granted for an alteration.

2. Any HCSD facility or clinic may condition the provision of research-related treatment on provision of an authorization for the use and disclosure of PHI for such research. Ordinary (non-research) patient care may NOT be conditioned on participation in the research or provision of an authorization to use and disclose PHI.

3. For the uses and disclosures to be permitted, the authorization must be valid and contain the following core elements and required statements:

    a. A description of the information to be used or disclosed that identifies the information in a specific and meaningful manner.
    b. The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure.
    c. The name or other specific identification of the person(s), or class of persons, to whom the facility may make the requested use or disclosure.
    d. A description of each research purpose of the requested use or disclosure.
    e. A statement that the facility may condition research-related treatment on the provision of the individual's signature of authorization and in the event conditioning is required; make a further specification of the consequences to the individual of a refusal to sign the authorization.
    f. An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. The statement "end of the research study", "none", or similar language is sufficient if the authorization is for a use or disclosure of PHI for research in which the end date is not known, uncertain or as in the event of the creation and maintenance of a research database or research repository, an expiration date is not applicable.
    g. State that the individual has the right to revoke the authorization in writing, except to the extent that the health care component has taken action in reliance thereon; or to the extent that information in this section is included in the Notice of Privacy Practices, a reference to the facility's Notice.
    h. A statement that information used or disclosed pursuant to the authorization may be subject to re-disclosure by the recipient and no longer protected by the HIPAA regulations.
    i. The individual's signature and date; if the authorization is signed by a personal representative of the individual, a description of such

representative's authority to act for the individual must be documented.

j. A copy of the signed authorization must be provided to the patient or his/her personal representative.

k. **See the following website for the HIPAA Authorization form to be used to authorize the use of an individual's PHI.**

https://www.lsuhsc.edu/administration/academic/ors/hipaa.aspx

Click on the applicable authorization form (Under the Forms section)

E. REVOCATION OF AUTHORIZATION TO USE AND DISCLOSE PHI FOR RESEARCH

1. An individual may revoke an authorization at any time. The revocation must be in writing, submitted to the Primary Investigator or Co/Sub-Investigator, and specify which authorization is revoked.

2. Any records custodian receiving the request to revoke an authorization must discontinue any further release of the individual's PHI as permitted by the initial authorization. However, the revocation does not apply to actions already taken in reliance on the initial authorization.

3. As appropriate, the Primary Investigator or his/her designee and/or any records custodian will notify other health care components of the LSU System or its business associates that may have relied upon the authorization of the revocation.

4. The HCSD facility or clinic is permitted to continue using and disclosing PHI that was obtained prior to the time the individual revoked his/her authorization, as necessary to maintain the integrity of the research study. For example, use or disclosure of PHI to account for a subject's withdrawal from the study, as necessary to incorporate the information as part of a marketing application submitted to the FDA, to conduct investigations of scientific misconduct, or to report adverse events. However, the health care component is not permitted to continue disclosing additional PHI to a researcher or to use for its own research purposes information not already gathered at the time the individual withdraws the authorization.

F. Document Retention and Production Fees

1. All HCSD facilities or clinics must retain documentation of:

- IRB and/or Privacy Board decisions,
- Waivers and alterations of authorizations,

- Research authorizations
- Informed consent

Authorizations and any associated waivers, alterations, informed consents, restrictions or revocations should be included in the patient's medical record and/or research record. Such records should be retained for six years from the date of their creation or the date when they last were in effect, whichever is later.

2. Any HCSD facility or related IRB and/or Privacy Board may establish a fee schedule to compensate for the use of facilities, personnel time, software, hardware or other equipment for:

a. Reviewing requests for research information (Application Fee)
b. Generating the information required (including personnel time, and computer system usage)
c. Aggregating data/information
d. Other specified activities related to processing the request for research information, or any costs related to participating in the research.

G. Guidance on Sufficient Descriptions of the Purpose of a Use or Disclosure for Future Research Authorizations

Authorizations for the use or disclosure of PHI for *future* research must include a description of each purpose of the requested use or disclosure. The statement "at the request of the individual" is a sufficient description of the purpose when an individual initiates the authorization and does not, or elects not to, provide a statement of the purpose. The authorizations do not need to specify each specific future study if the particular studies to be conducted are not yet determined. Rather, the authorization must adequately describe such purposes such that it would be reasonable for the individual to expect that his or her PHI could be used or disclosed for such future research.

H. Other *Considerations* for Handling PHI Related to Research

1. A HCSD facility or clinic may use or disclose PHI for retrospective research studies only if such use or disclosure is made either with patient authorization or a waiver of patient authorization pursuant to the IRB and/or Privacy Board.

2. Research recruitment is neither marketing nor a health care operations activity. Treating physicians and patients may continue to discuss the option of enrolling in a clinical trial without patient authorization and without an IRB waiver of authorization. If a researcher without an

independent treatment relationship with a patient wants to recruit that patient, an authorization is required and must be obtained by the treating physician. An authorization or a waiver is required if the health care component wants to disclose the PHI to a third party, outside of the covered entity or HCSD facilities or clinics, for purposes of recruitment in a research study.

3. The facility or clinic may disclose PHI to a registry for research purposes, including those sponsored by academic and non-profit organizations, if such disclosure: is required by law, made pursuant to an IRB waiver of authorization, made pursuant to the individual's authorization, or consists only of a Limited Data Set. See Policy # 7509: Limited Data Set and Policy # 7505: Use and Disclosure for Which an Authorization Is Not Required.

4. The patient may inspect or obtain copies of his/her PHI to be used and disclosed for research purposes unless:

    a. An individual's access to protected health information created or obtained by any HCSD facility or clinic in the course of research that includes treatment of the individual may be temporarily suspended for as long as the research is in progress. Denial of access based on a research restriction is allowed if:

        i. the individual has agreed to the denial of access when consenting to participate in the research that includes treatment, and
        ii. the HCSD facility or clinic engaged in research has informed the individual that the right of access will be reinstated upon completion of the research.

5. Additional information that may be provided to the patient at the time the request for authorization is offered for signature to use and disclose PHI for research purposes includes, but is not limited to:

    a. A statement that the patient may refuse to sign the authorization;

    b. A description of the extent to which such PHI will be used or disclosed to carry out treatment, payment, or health care operations;

    c. A description of any PHI that will not be used or disclosed.

6. An HCSD facility or clinic may not include a limitation affecting its right to make a use or disclosure that is required by law, or (A) is necessary to prevent or lessen a serious and imminent threat to the health or safety of a

person or the public; and (B) is to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat.

7. If a HCSD facility or clinic has provided or intends to provide the individual with the Notice of Privacy Practices, the authorization must refer to the Notice and state that the statements made regarding research and authorization within the Notice are binding. Performance sites are responsible for providing the Notice of Privacy Practices upon their first encounter with the individual patient.

8. HCSD facilities or clinics have the right to define a subset of protected health information created for research. The health care components may provide additional protections for, or place stricter limits on, use and disclosure of this subset of records created for research.

9. *Accounting of Disclosures* must be done in accordance with Policy #7525: Accounting of Disclosures of PHI. Special considerations are given to-the following:

    a. *Multiple Disclosures*: If during the period covered by the accounting, the researcher has made multiple disclosures of PHI to the same person or entity for a single purpose (*e.g.* a sponsored project) or pursuant to a single authorization, the accounting for such multiple disclosures may provide:

        i. the information required above for the first disclosure during the accounting period;
        ii. the frequency or number of the disclosures made during the accounting period; and
        iii. the date of the last such disclosure during the accounting period.

    b. *Research Disclosures Involving 50 or More Subjects:* If the research involved 50 or more subjects, the accounting for any disclosures may provide:

        i. the name of the protocol or other research activity;
        ii. a description, in plain language, of the research protocol or other research, including the purpose of the research and the criteria for selecting particular records;
        iii. a brief description of the type of PHI disclosed;
        iv. the date or period of time during which such disclosures occurred, or may have occurred, including the date of the last such disclosure during the accounting period;

v. the name, address, and telephone number of the entity that sponsored the research and of the researcher to whom the information was disclosed; and

vi. a statement that the protected health information of the individual may or may not have been disclosed for a particular protocol or other research activity.

10. *Minimum Necessary*. Any HCSD facility or clinic may rely, if such reliance is reasonable under the circumstances, on a requested disclosure as the minimum necessary for the stated purpose when documentation or representations that comply with the applicable standards for use and disclosure of PHI are provided by the researcher requesting the information for research purposes.

a. For all uses, disclosures or requests that are made for research purposes, the HCSD facility or clinic may not use, disclose or request an entire medical record, except when the entire medical record is specifically justified as the amount that is reasonably necessary to accomplish the purpose of the use, disclosure or request.

b. The documentation required as representation of the minimum necessary PHI required for a research study may be satisfied by one or more written statements, provided that each is appropriately dated and signed as required under section **Research Studies that Do Not Require Authorization But Do Require Documentation of the IRB and/or Privacy Board Review.** See Policy #7512: Minimum Necessary Standard for Use and Disclosure of Protected Health Information.

However, if the HCSD facility or clinic has knowledge that the documentation of IRB approval was fraudulent with respect to the PHI needed for a research study, it may not rely on the IRB's documentation as fulfilling the minimum necessary requirement.

11. *Limited Data Sets.* The use of a limited data set should be considered when requests for PHI are submitted for research studies. See Policy #7509: Limited Data Sets for requirements in preparing PHI as well as ensuring that a Data Use Agreement is obtained from the data recipient. Limited Data Sets for research purposes must be approved by the IRB.

12. *De-identified Information*. In certain instances, research studies may involve requests for de-identified information. In these instances, conversion of PHI to de-identified information must be conducted according to facility policy. See Policy #7511: De-identification of

Protected Health Information. De-identification of data for research purposes must be approved by the IRB. See the required Certification Form for De-Identification.

13. *Research Databases:* Researchers who create or maintain their own research databases, which contain PHI, must maintain the HCSD facilities or clinics' HIPAA-compliant privacy and security measures and must have IRB approval.

14. *Case Studies*—Researchers must obtain an authorization from the participant before publication of a case study.

15. *Sale of PHI* – Disclosures for research purposes are excepted from the remuneration prohibition to the extent that the only remuneration received by HCSD or HCSD Business Associate is a reasonable cost-based fee to cover the cost to prepare and transmit PHI for research purposes. Reasonable cost-based fees may include both direct and indirect costs, including labor, materials, and supplies for generating storing, retrieving, and transmitting the PHI; labor and supplies to ensure the PHI is disclosed in a permissible manner; and as well as related capital and overhead costs. However, fees charged to incur a profit from the disclosure of PHI are not allowed.

I. Compound Authorizations

Compound authorizations – An authorization for use or disclosure of PHI may not be combined with any other document to create a compound authorization, except as follows:

1. An authorization for the use or disclosure of PHI for a research study may be combined with any other type of written permission for the same or another research study. This exception includes combining an authorization for the use or disclosure of PHI for a research study with another authorization for the creation or maintenance of a research database or repository, or with a consent to participate in research.
2. An authorization for a use or disclosure of psychotherapy notes may only be combined with another authorization for a use or disclosure of psychotherapy notes.
3. A conditioned authorization is one that conditions treatment or payment on the patient agreeing to authorize use of their PHI. Such an authorization is generally not allowed, but is allowed in relation to research studies. Research studies may also use unconditioned authorizations.
4. HCSD may choose to combine conditioned and unconditioned authorizations (compound authorizations) for research, provided that the authorization clearly allows the individual to **opt-in** to the unconditioned

research activities. Such combined conditioned and unconditioned authorizations may be used for any type of research study, with the exception of studies that involves the use or disclosure of psychotherapy notes. For research that involves the use or disclosure of psychotherapy notes, an authorization for a use or disclosure of psychotherapy notes may only be combined with another authorization for a use or disclosure of psychotherapy notes.

5. Individuals may revoke their authorization in writing. In the case of compound authorizations, where it is not clear exactly to which research activities the individual's revocation applies, written clarification must be obtained from the individual in order for the revocation to apply only to certain of the research activities identified in the authorization, or the entire authorization must be treated as revoked.
6. Revocations and clarifications must be maintained and documented in a manner that will ensure uses and disclosures of PHI for the activity to which the revocation applies discontinue.
7. This provision allows HCSD to combine such authorizations with informed consent documents for research documents.

J. TRANSITION PROVISIONS:

For research involving PHI and carried out according to a protocol reviewed and approved by the IRB prior to April 14, 2003:

1. If the protocol included a research informed consent or a waiver of informed consent:

    a. A researcher may continue to use or disclose the PHI created or received **prior** to April14, 2003.
    b. A researcher operating under a waiver of informed consent may continue to enroll new subjects and create, receive, use, and disclose PHI after April 14, 2003, with no further action until the next scheduled IRB and/or Privacy Board review.
2. If the protocol reviewed prior to April 14, 2003 was approved as an "exempt" protocol without documentation of a waiver of consent, the researcher needs to contact the IRB and/or Privacy Board for appropriate revision of the protocol. Until that occurs, PHI created or received prior to April 14, 2003 may **not** be used or disclosed after April 14, 2003.

3. The researcher may then use the IRB and/or Privacy Board approval notice in conjunction with individual research informed consent forms, if informed consent was not waived, to access, use, and/or disclose PHI according to documentation procedures adopted by the administrative and management infrastructure of the individual IRB and/or Privacy Board.

VI. EXCEPTION

The HCSD CEO or designee may waive, suspend change, or otherwise deviate from any provision of this policy deemed necessary to meet the needs of the agency as long as it does not violate the intent of this policy, state and/or federal laws, Civil Services Rules and Regulations, LSU Policies/Memoranda, or any other governing body regulations.

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