Use and Disclosure of Protected Health Information for Research Policy

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Responsible Office:	Academic Affairs
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I. Policy Statement

The University of Louisiana at Monroe's Use and Disclosure of Protected Health Information for Research Official Policy establishes the requirements for disclosing and using information for research purposes.

II. Purpose of Policy

To 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:

- Instances where a written authorization is required before PHI may be used or disclosed;
- 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
- 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.

III. Applicability

This policy is applicable to all faculty and staff.

IV. Definitions

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 ULM health care components. 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.

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.

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.

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 protected health information (PHI) and is not subject to the Health Insurance Portability and Accountability Act (HIPAA). To de-identify information, you must remove all of the following elements:

- Names
- 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).
- Dates (except for years)
- Birth Dates
- Admission Dates
- Discharge Dates
- Date of Death
- 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
- Telephone Numbers / Fax Numbers
- E-mail Addresses / Web Universal Resource Locators (URLs) / Internet Protocol (IP) Address

Numbers

- Social Security Numbers
- Medical Record Numbers
- Health Plan Beneficiary Numbers
- Account Numbers
- Certificate / License Numbers
- Vehicle Identifiers and Serial Numbers
- Device Identifiers and Serial Numbers
- Biometric Identifiers (e.g. finger or voice prints)
- Full face photographic images and any comparable images
- Any other unique identifying number, characteristic, or code

Designated record set - A group of records regarding an individual that are maintained by a ULM health care component 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.)

Individually Identifiable Health Information - Information, including demographic information, that:

- Is created or received by a healthcare provider, health plan, employer, or healthcare clearinghouse.
- 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
- Identifies the individual (or there is a reasonable basis to believe the information can be used to identify the individual)

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

- names
- postal address information, other than town or city, state, or zip code
- telephone numbers
- FAX numbers
- Electronic mail addresses
- Medical record numbers, including prescription numbers and clinical trial numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) address numbers
- Biometric identifiers, including finger and voice prints
- Full face photographic images and any comparable images
  (NOTE that this list of identifiers is not the same as that for de-identified information).

Protected Health Information (PHI) - means individually identifiable health information, whether oral or written, that is transmitted by electronic media; maintained in any medium; or transmitted or maintained in any other form. PHI excludes individually identifiable health information in student education records covered by the Family Educational Rights and Privacy Act (FERPA) and records held by a covered entity in its role as employer.

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

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.

V. Policy Procedure

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

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

1.2 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.

2.0 Receipt and Processing of Research Requests

2.1 ULM health care components 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.

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

2.3 The ULM IRB 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 ULM IRB will determine the necessity for authorizations, waivers, or alterations of authorizations.

2.4 The IRB 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.

2.5 ULM health care components 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.
The Researcher's contact information will be provided to patients whose health information was used in their research with a waiver of authorization, if the patient so requests.

2.6 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. A signed copy of the authorization must be given to the participant.

3.0 Research That Does Not Require Authorization But Does Require IRB Review

3.1 ULM health care components 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.

3.2 Reviews Preparatory to Research under Privacy Rule 164.512(i)(1)(ii). The principal investigator shall submit to the IRB Chair, or designee, a Request for Review- Projects Using Human Subjects form for review and approval which describes the research and contains written representations that:

3.2.1 Use or disclosure is sought solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research;

3.2.2 No PHI is to be removed from the ULM health care components 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;

3.2.3 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 Minimum Necessary Information Policy.

3.2.4 If IRB policies are more restrictive than HIPAA, you must follow the IRB policies.

3.3 Waiver of Authorization.

3.3.1 Approval of Waiver of Authorization. ULM health care components 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.

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

3.3.2.1 Identification and date of action. A statement identifying the IRB and the date on which the alteration or waiver of authorization was approved.

3.3.2.2 Waiver criteria. A statement that the IRB has determined that the alteration or waiver, in whole or in part, of authorization satisfies the following criteria:

- 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:
- There is an adequate plan to protect the identifiers from improper use and disclosure;
- 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; and
- 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; and
- 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;
- The research could not practicably be conducted without the alteration or waiver; and
- The research could not practicably be conducted without access to and use of the PHI.

3.3.2.3 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;

3.3.2.4 Review and approval procedures. A statement that the alteration or waiver of authorization has been reviewed and approved by the IRB following the requirements of the Common Rule, including the normal review procedures described in applicable federal policies including the Department of Health and Human Services (DHHS) regulations (45 CFR part 46.108(b)) or equivalent 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

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

4.0 Research That Requires Authorization For Use and Disclosure of PHI

4.1 If any ULM health care component 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.

4.2 Any ULM health care component 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.

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

4.3.1 A description of the information to be used or disclosed that identifies the information in a specific and meaningful manner.

4.3.2 The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure.

4.3.3 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.

4.3.4 A description of each research purpose of the requested use or disclosure.

4.3.5 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.

4.3.6 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.

4.3.7 State that the individual has the right to revoke the authorization in writing, except to the extent that the healthcare component has acted 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.

4.3.8 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.

4.3.9 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.

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

5.0 Revocation of Authorization To Use And Disclose PHI For Research

5.1 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.

5.2 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.
5.3 As appropriate, the Primary Investigator or his/her designee and/or any records custodian will notify other health care components of the ULM or its business associates that may have relied upon the authorization of the revocation.

5.4 The ULM health care component 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.

6.0 Document Retention and Production Fees

6.1 All ULM health care components must retain documentation of IRB decisions; waivers and alterations of authorizations; research authorizations; and informed consents.

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

6.3 Any ULM health care component IRB may establish a fee schedule to compensate for the use of facilities, personnel time, software, hardware or other equipment for:

6.3.1 Reviewing requests for research information (Application Fee)

6.3.2 Generating the information required (including personnel time, and computer system usage)

6.3.3 Aggregating data/information

6.3.4 Other specified activities related to processing the request for research information, or any costs related to participating in the research.

7.0 Other Considerations for Handling PHI Related to Research

7.1 A ULM health care component 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.

7.2 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 ULM health care components, for purposes of recruitment in a research study.

7.3 The health care component 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 on Limited Data Set.

7.4 The patient may inspect or obtain copies of his/her PHI to be used and disclosed for research purposes unless an individual's access to protected health information created or obtained by any ULM health care component 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:

7.4.1 The individual has agreed to the denial of access when consenting to participate in the research that includes treatment, and

7.4.2 The ULM health care component engaged in research has informed the individual that the right of access will be reinstated upon completion of the research.

7.5 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:

7.5.1 A statement that the patient may refuse to sign the authorization;

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

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

7.6 A ULM health care component 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.

7.7 If a ULM health care component 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.

7.8 ULM health care components 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.

7.9 Accounting of Disclosures must be done in accordance with the Policy on Accounting of Disclosures of PHI. Special considerations are given to the following:

7.9.1 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:

7.9.1.1 the information required above for the first disclosure during the accounting period;

7.9.1.2 the frequency or number of the disclosures made during the accounting period; and

7.9.1.3 the date of the last such disclosure during the accounting period.

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

- the name of the protocol or other research activity;
- 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;
- a brief description of the type of PHI disclosed;
- 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;
- the name, address, and telephone number of the entity that sponsored the research and of the researcher to whom the information was disclosed; and
- 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.

7.10 Minimum Necessary. Any ULM health care component 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.

7.10.1 For all uses, disclosures or requests that are made for research purposes, the ULM health care component 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.

7.10.2 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 Review. See HIPAA Minimum Necessary Information Policy.

7.10.3 However, if the ULM health care component 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.

7.11 Limited Data Sets. The use of a limited data set should be considered when requests for PHI are submitted for research studies. See Policy on 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.

7.12 De-identified Information. In certain instances, research studies may involve requests for deidentified information. In these instances, conversion of PHI to de-identified information must be conducted according to facility policy. See Policy on De-identification of Protected Health Information. De-identification of data for research purposes must be approved by the IRB.

7.13 Case Studies—Researchers must obtain an authorization from the participant before publication of a case study, if the case study uses or discloses protected health information.

8.0 Transition Provisions

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

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

8.1.1.1 A researcher may continue to use or disclose the PHI created or received prior to April14, 2003.

8.1.1.2 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 review.

8.1.2 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 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.

8.1.3 The researcher may then use the IRB 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.

VI. Enforcement

The Vice President of Academic Affairs will be responsible for enforcement of this policy.

VII. Policy Management

The Vice President of Academic Affairs will be responsible for enforcement of this policy.

VIII. Exclusions

None

IX. Effective Date

This policy is effective upon the date signed by the University President.

X. Adoption

This policy is hereby adopted on this 8th day of November 2023.

Recommended for Approval by:

Dr. Mark Arant, Provost

Approved by:

Dr. Ronald L. Berry, President

XI. Appendices, References and Related Materials

N/A

XII. Revision History

Original Adoption Date: November 8, 2023