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Lakeland Regional Health

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Owner	Trudy Wittenberg: 4388 Institutional Review Board Administrator
Department	HRPP/Research

Research: Waiver of Elements of Consent, Waiver of Documentation of Informed Consent, and Waiver of Written Authorization- AD.0168

PURPOSE

The purpose of this policy is to describe the requirements for the waiver of some or all of the elements of informed consent. It also describes the requirements for the waiver or partial waiver of subject authorization for use and/or disclosure of protected health information (PHI) pursuant to section 45 CFR § 164.512 of the Privacy Rule (HIPAA). Our policies guide our practices and ensure that we place people at the heart of all we do to deliver the best outcomes and safest care.

APPLICABILITY

This policy applies to Lakeland Regional Health's **Workforce** and **Research Personnel** engaged in research.

POLICY

I. **General**

A. Obtaining the informed consent of research subjects prior to participation is regarded as a cornerstone for the ethical conduct of research, and a fundamental protection for participants' rights. Federal regulations outline general requirements for informed consent in 45 CFR § 46.116, including eight (8) "basic" and six (6) "additional" elements to be addressed when obtaining informed consent (see policy, Informed Consent-AD.0122).

B. An IRB may approve a consent procedure which does not include, or which alters, some or all of the "basic" elements of informed consent, or waive the requirements to obtain informed consent; however, the study team must request a waiver or alteration of consent.

C. The informed consent process involves three (3) key features: (1) disclosing to potential research subjects the information needed to make an informed decision; (2) facilitating the understanding of what has been disclosed; and (3) promoting the voluntariness of

the decision about whether or not to participate in the research. Informed consent must contain all required elements and be obtained prior to initiation of the research study.

II. **Waiver of Informed Consent**

A. It is recognized that there is valuable research that would be difficult, or impossible, to conduct if consent were required; and that subjects can still be adequately protected in the absence of full consent. The waiver allows the interests of subjects to be balanced with societal interests in research, and both will be well served if this regulatory provision is understood and applied appropriately.

1. Federal regulations (HHS Final Rule/ 2018 Revised Common Rule (45 CFR PART 46) and HIPAA Regulations (45 CFR § 164)) allow the IRB to approve a consent/authorization procedure which does not include, or which alters, some or all of the elements of informed consent, or to waive the requirement to obtain any informed consent. Waivers of consent involve studies in which there are minimal risks to subjects. The proposed protocol must meet the following specific criteria found at 45 CFR § 46.116(d) and 45 CFR § 164.512(i)(1)(i):

a. The research involves no more than minimal risk to subjects;

b. The waiver or alteration will not adversely affect the rights and welfare of the subjects;

c. The research could not practicably be carried out without the waiver or alteration (obtaining consent is not practicable);

d. Whenever appropriate, the subjects or legally authorized representatives (LARs) will be provided with additional pertinent information after participation; and

e. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using identifiable private information or biospecimens in an identifiable form.

B. The IRB may also approve a waiver of informed consent for screening, recruiting, and determining eligibility if the following conditions are met:

1. The researcher will obtain information through oral or written communication with the prospective subject or LAR; or

2. The researcher will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens; and

3. The research is not regulated by the U.S. FDA.

C. According to the revised 2018 Common Rule, the LRH IRB may approve a proposal for the investigator to obtain information or biospecimens to screen, recruit, or determine eligibility of prospective subjects for a research study without obtaining informed consent. This is applicable if:

1. The information is obtained through oral or written communication with the subject or the subject's legally authorized representative, or

2. Identifiable private information or identifiable biospecimens are obtained by accessing records or stored identifiable biospecimens.

III. **Waiver of Documentation of Informed Consent**

A. If the proposed research activity plans to obtain consent without obtaining the subject's signature on a consent form, then the Researcher must request a waiver of documentation of consent. Waiving the requirement for a written form does not eliminate the requirement for informed consent. Subjects must be informed of the nature of the research, and their consent (or the consent of their legally authorized representatives (LARs)) must be obtained whenever appropriate. This type of waiver is useful for some telephone or internet surveys, questionnaires, or when signing the consent document could have a negative consequence for the subject.

B. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all of the subjects if it finds either that the:

1. Research presents no more than minimal risk, **AND**
2. Research involves procedures that do not require written consent when performed outside of a research setting, **OR**
    a. Principal risks are those associated with a breach of confidentiality concerning the subject's participation in the research; **AND**
    b. Consent document is the only record linking the subject with the research; **AND**
    c. Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern.
3. The IRB may also approve a waiver of documentation of informed consent for screening, recruiting, and determining eligibility if the following conditions are met:
    a. The researcher will obtain information through oral or written communication with the prospective subject or LAR; or
    b. The researcher will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens; and
    c. The research is not regulated by the U.S. FDA.

C. When the IRB considers waiving the requirement to obtain written documentation of consent, the IRB requires the investigator to submit a written description of the information that will be provided to subjects via an oral consent script, contact letter, phone script or similar document.

D. The IRB may require the use of an information sheet to be given to the potential subject or an oral script to be read to the potential subject. Investigators will use the information sheet or script to guide them through the informed consent discussion/process. The subject's signature on a consent form in not required. The script or information statement must be provided to the IRB at the time of original study submission for review and approval. The principal investigator and/or research staff will document the participant's consent, as well as the date, and the name of the person conducting consent in the study files.

E. In addition to describing the study, the script or information sheet must contain the basic elements of informed consent, as referenced in 45 CFR § 46.116(a) and 21 CFR § 50.25

(see policy, Informed Consent- AD.0122).

F. The script or information sheet should include the following information:
    1. State that the study involves research.
    2. Explain the purposes of the research and the expected duration of the subject's participation.
    3. If applicable: describe any foreseeable risk or discomfort to the subject.
    4. If applicable: describe any benefits to subjects or to others that may reasonably be expected from the research.
    5. If applicable: disclose alternatives.
    6. Describe the extent to which confidentiality of records identifying subjects will be maintained, where the records will be stored and who will have access to them.
    7. Provide contact information for answers to pertinent questions about the research, and participants' rights.
    8. Include that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which participants are otherwise entitled, and also that participants may discontinue participation at any time without penalty or loss of benefits to which they are otherwise entitled.

G. The IRB cannot grant a waiver of consent or documentation of consent if the research study involves the use of an investigational drug (IND) or device (IDE) that is regulated by the Food and Drug Administration (FDA) and is more than minimal risk. The only exception is for emergency use of a test article FDA 21 CFR § 50.23, or planned emergency research FDA 21 CFR § 50.24.

IV. Waiver or Partial Waiver of Written Authorization

A. One way to use or disclose protected health information (**PHI**) without authorization by the research participant is through a waiver of authorization. A waiver of research participants' authorization for use/disclosure of information must be approved by the IRB through full board or expedited review procedures (see Waiver of Authorization).

B. This provision of the Privacy Rule might be used to:
    1. Conduct records research;
    2. When researchers are unable to use de-identified information; or
    3. The research could not practicably be conducted if research participants' authorization were required.

C. The following criteria must be satisfied for the LRH IRB to approve a waiver of authorization under the Privacy Rule:
    1. The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the following elements:
        a. An adequate plan to protect the identifiers from improper use and disclosure;
        b. 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;

c. Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted under this rule;

d. The research could not practicably be conducted without the waiver; and

e. The research could not practicably be conducted without access to and use of the protected health information.

D. Provided the requirements of 45 CFR § 164.512(i)(2)(ii) are met, the IRB may grant an alteration or partial waiver of the Privacy Rule requirements. Examples include but are not limited to:

1. Waiver or alteration of one (1) or more of the required elements of authorization;
2. Waiver of the requirement to obtain authorization in writing such as when PHI is collected over the phone, fax, internet or email from study participants; and
3. Waiver to disclose PHI from one covered entity to another for the purposes of contacting and recruiting individuals into a study.

E. HIPAA Attestations from Investigator's Work Preparatory to Research:

An investigator may conduct work preparatory to research without Written Authorization, provided that they provide the IRB with an attestation. Work preparatory to research are activities required for planning or to determine the feasibility of a study before developing or submitting a protocol to the IRB. For example, an investigator may be interested in studying a rare condition but does not know if there are enough prospective subjects available to perform the study. They may submit a certification for Work Preparatory to Research in order to determine if the project is feasible. The IRB receives the investigators certification and will check it for appropriateness; it does not issue an approval. The investigator will receive the IRB's acknowledgment of receipt.

F. Use of Decedent's PHI:

Research that involves the use of decedents PHI is not regulated by the Common Rule but is covered by HIPAA. Investigators may use the PHI of decedents without Written Authorization, provided that they provide the IRB with an attestation that certifies that the PHI is necessary for the research and that the PHI will not be used for any other purposes. The IRB receives the investigators certification and will check it for appropriateness; it does not issue an approval. The investigator will receive the IRB's acknowledgment of receipt.

V. **Documentation of Waiver of HIPAA Authorization**

A. When the IRB grants a waiver or partial waiver of Written Authorization, it will provide documentation of its determinations as required by 45 CFR § 164.512(ii):

1. Identification that the waiver was granted by the IRB, and the date on which the alteration or waiver was approved; and
2. A statement that the IRB determined that the alteration or waiver of Written Authorization, in whole or in part, satisfied the criteria of Section IV.C of this policy; and
3. A brief description of the protected health information for which use or access was determined to be necessary by the IRB; and
4. A statement that the alteration or waiver of HIPAA Authorization was reviewed and approved under expedited or full IRB review procedures.

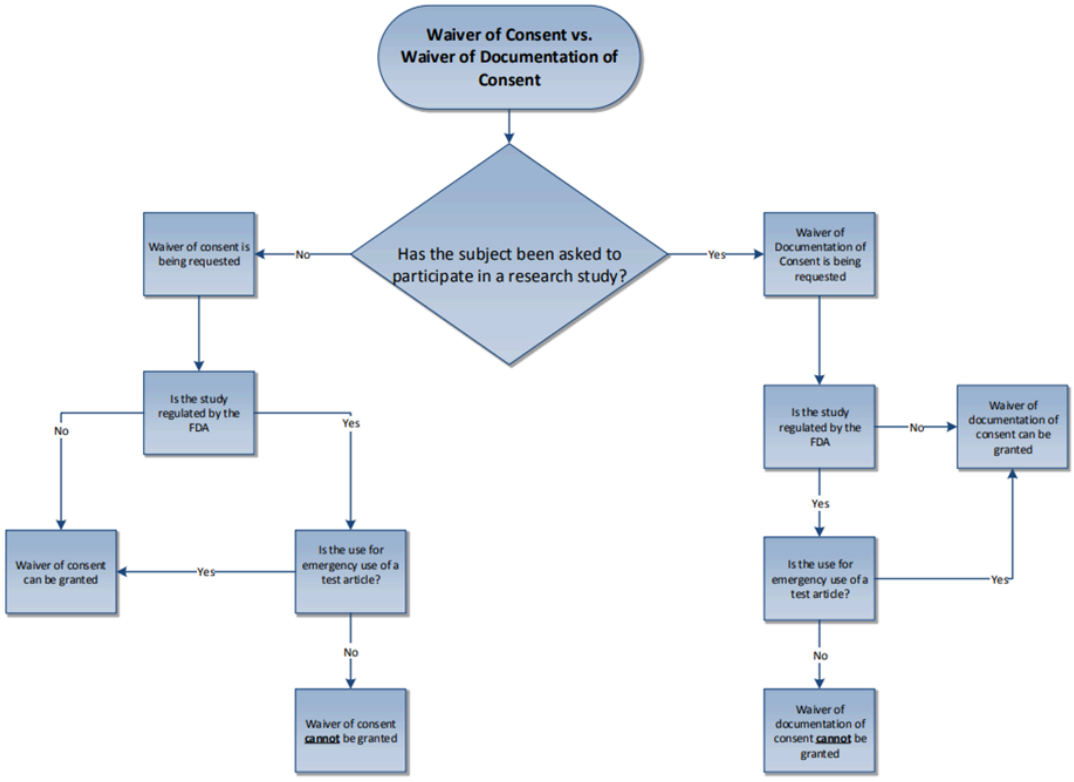
PROCEDURE

I. **Waiver of Informed Consent vs. Waiver of Documentation of Consent**

A. The waiver request(s) must be submitted at the time of the initial submission and will be reviewed by the IRB and if it meets the appropriate criteria, will be approved and documented in the response letter and in IRBNet. See Figure 1 for the process of determining if a waiver of informed consent or waiver of documentation of informed consent is appropriate.

1. Waiver of Informed Consent.
2. Waiver of Documentation of Informed Consent.

II. **Figure 1:**



III. **Waiver or Partial Waiver of Written Authorization**

The waiver request(s) must be submitted at the time of the initial submission and will be reviewed by the IRB and if it meets the appropriate criteria, will be approved and documented in the response letter and in IRBNet. See Figure 2 for the process of determining if a waiver or partial waiver of authorization is appropriate.

IV. Application for IRB Waiver of Authorization or Altered Authorization Under the HIPAA Privacy Rule

Figure 2:

Screening Activity	HIPAA Waiver
Reviewing medical records for eligibility prior to contact	No waiver
Checking availability of stored biospecimens	No waiver
Collecting information directly from potential subject – verbal or written	Waiver
Prospective testing or procedures to determine eligibility	Waiver
Collecting medical record data for retrospective	Waiver

The waiver request(s) must be submitted at the time of the initial submission and will be reviewed by the IRB and if it meets the appropriate criteria, will be approved and documented in the response letter and in IRBNet.

DEFINITIONS

FDA: Food & Drug Association.

HIPAA: Health Insurance Portability and Accountability Act.

IRB: Institutional Review Board.

LAR: Legally Authorized Representative.

Minimal Risk: probability and magnitude of harm or discomfort anticipated are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

PHI: Private Health Information.

Research Personnel: All individuals designing or directing research, serving as a principal or co-investigator, enrolling research subjects (including obtaining subjects' informed consent or screening potential subjects), or making decisions related to eligibility to participate in research, analyzing or reporting research data, analyzing or reporting adverse events, or submitting manuscripts concerning the research publication.

Workforce: All LRH employees, volunteers, trainees/students, contractors, and Medical Staff.

REFERENCES

21 CFR § 56.116

45 CFR § 164.512(i)(2)(ii)

45 CFR § 46.116

IRBSOP706_WaiverConsent&HIPAA_012219 (chop.edu)

uiuc_policies_and_procedures_manual_05.10.2021.pdf (illinois.edu)

Waiver of Documentation for Informed Consent Form | Office for the Protection of Research Subjects (illinois.edu)

Waiver of Informed Consent Form | Office for the Protection of Research Subjects (illinois.edu)

Approval Signatures

Step Description	Approver	Date
	Danielle Drummond: 0001 President & Chief Executive Officer - LRHS	03/2024
	Jonn Hoppe: 1011 Executive VP, Chief Legal Officer-General Cou	03/2024
	Timothy Regan: 0009 President - LRMC/Chief Medical Officer	03/2024
	Renee Reed: 4064 Senior Attorney	03/2024
	Deana Nelson: 4080 SVP - Administration and Corporate Initiative	03/2024
	Georgia Ann Keriazes: 0729 QI/ Due Pharmacist	03/2024
	Andrew Bugajski: 4387 AVP - Research and Sponsored Studies	12/2023