Lifespan-wide Policy

Subject:
IRB POLICY FOR:

USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

File Under:

Issuing Department:
Research Administration

Latest Revision Date:

Original Procedure Date:

Approved By:

_____
(Director)

_____
(Executive)

SCOPE OF POLICY

This policy applies to any Lifespan Institutional Review Board and to the Lifespan Office of Research Administration that administers such Boards (collectively referred to herein as the "IRB"), acting as the designee of the Lifespan Privacy Officer, and to any person who requests access to or use for research purposes of any protected health information obtained by a Lifespan affiliate, including but not limited to persons who are Lifespan affiliate staff members and medical staff members. The term "affiliate staff member" includes all Lifespan employees, medical or other students, trainees, residents, interns, volunteers, consultants, contractors and subcontractors at the affiliates. The term "medical staff member" includes physicians as well as allied health professionals.

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STATEMENT OF POLICY

Protected health information obtained by the Lifespan affiliate may *not* be used internally or disclosed to any persons or organizations outside the hospital for research purposes without the prior approval of the IRB. This policy outlines the circumstances in which the IRB may or may not approve the use or disclosure of protected health information for research purposes. The IRB may designate one or more persons to act on its' behalf in any or all aspects covered by this policy. All references to the IRB in this policy include the IRB designees. All requests for access to protected health information for research purposes must be made and reviewed in accordance with the procedures explained below.

IMPLEMENTATION OF POLICY

Certain requirements apply to the use and disclosure of protected health information in connection with all research involving human subjects. As a general rule, the IRB may *not* authorize the use or disclosure of protected health information for research purposes except:

- for reviews preparatory to research;
- for research on the protected health information of a decedent;
- if the hospital has obtained the informed consent of the individual to participate in the research, or a waiver of such informed consent, prior to April 14, 2003 (this exception ceases to apply if informed consent is sought from the individual after April 14, 2003);
- if the information is "completely de-identified;"
- if the information is partially de-identified into a "limited data set" and the recipient of the information signs a data use agreement to protect the privacy of such information;
- if the hospital has obtained a valid authorization from the individual subject of the information; or
- if an IRB approves a waiver of the individual authorization requirement.

The specific requirements for each of these exceptions are discussed below.

Special rules apply to the use and/or disclosure for research purposes of psychotherapy notes. Additional information on research involving psychotherapy notes can be found in Appendix F of this policy.

The IRB must determine that one of the exceptions outlined above and described in more detail below applies before permitting the use or disclosure of any protected health information for research purposes. *The IRB should require either an individual authorization or a waiver of authorization if there is any doubt about whether any other exception is applicable*. All research activities must also comply with other applicable policies and regulations relating to research (such as DHHS and FDA regulations for research) and with any additional requirements that apply to the specific types of information identified above as having special rules. Finally, to the extent Lifespan staff and medical staff provide treatment to subjects as part of a research study, they must follow other affiliate policies to the extent those policies apply to the provision of health care to individuals. Any questions should be directed to Peggy McGill, Lifespan Director, Office of Research Administration.

A. Research Defined

For purposes of this policy, *research* includes any systematic investigation (including research development, testing, and evaluation) that has as its *primary purpose* the development of or contribution to *generalizable knowledge*.

- *Generalizable knowledge*. Knowledge may be generalizable even if a research study only uses protected health information held within the hospital and the results are generalizable only to the population served by the hospital. Research is therefore not limited to clinical trials funded by government sponsors (such as the National Institutes of Health) or commercial sponsors. Quality assurance and utilization management activities do not typically result in generalizable knowledge and thus ordinarily would not be governed by this policy

- *Primary purpose*. The development or contribution to generalizable knowledge must be the *primary purpose* of the investigation for this policy to be applicable. In some instances, the primary purpose of the activity may change as preliminary results are analyzed. An activity that was initiated as an internal outcomes evaluation, for example, may produce information that the affiliate administration intends to generalize. *If the purpose of a study changes and the results will be generalized, the IRB must document the change in status of the activity to establish that the requirements of this policy were not violated*

If an activity would be considered "research" under other applicable policies, it should be considered research for purposes of this policy.

B. General Prohibition on Use and Disclosure and Exceptions

The IRB may not authorize the use or disclosure of protected health information for research purposes unless at least one of the following exceptions applies:

1. Reviews Preparatory to Research. The IRB may permit the use and disclosure of protected health information to develop a research protocol or for similar purposes preparatory to research, such as to aid study recruitment (*e.g.*, to determine whether the hospital has information about prospective research participants who would meet the eligibility criteria for enrollment in a research study). Researchers should be aware that this exception does *not* permit the continued use or disclosure of the protected health information once the Principal Investigator (the individual responsible for the scientific, technical, and administrative aspects of the project, *e.g.*, for NIH-funded research, the person named at Item 3a, Form PHS 398) has determined to go forward with the study. For example, though the Principal Investigator could use protected health information to contact eligible subjects for recruitment purposes, the Principal Investigator would need to seek their authorization to use or disclose their protected health information for the research study. It is important to note that only researchers who are covered by Lifespan's Joint Notice of Privacy Practices may use this exception to contact prospective research subjects.

In order to permit a use or disclosure of protected health information under this exception, the IRB must obtain representations from the Principal Investigator that:

- the use or disclosure is sought solely to prepare a research protocol or for similar purposes preparatory to research;
- no researcher will remove any protected health information from the hospital's premises in the course of the review; and
- the protected health information for which use or access is sought is necessary for the research purposes.

During the preparatory review, those granted access should, if possible, record information only in a form that is "de-identified"; if the recorded information is identifiable, it must remain on hospital premises at all times. Appendix A describes the information that constitutes de-identified information. Appendix C includes a researcher certification form that should, when possible, be signed by researchers seeking access to protected health information for preparatory reviews.

2. Research on the Protected Health Information of a Decedent. The IRB may permit the use and disclosure of the protected health information of a decedent for research purposes. In order to permit such a use or disclosure, the IRB must obtain representations from the Principal Investigator that the use or disclosure is sought *solely* for research on the protected health information of a decedent (*e.g.*, researchers may not request a decedent's medical history to obtain health information about a decedent's living relative) *and* that the information for which use or disclosure is sought is necessary for the research purposes. Moreover, the Principal Investigator must provide, at the IRB's request, documentation of the death of any individuals about

whom information is sought. Appendix D includes a researcher certification form that should, when possible, be signed by researchers seeking to engage in research on the protected health information of a decedent.

3. Informed Consents or Waivers of Informed Consent Obtained Prior to April 14, 2003. The IRB may approve the use or disclosure of protected health information for a specific research project provided that one of the three following requirements are met:

i. Express Legal Permission For Use And Disclosure Of Protected Health Information. If the researcher has obtained, prior to April 14, 2003, express legal permission from the individual that *specifically authorizes* a use or disclosure of protected health information for purposes of the research project, the IRB may permit such use or disclosure for purposes of that project. However, any restrictions on the use and disclosure of health information provided in such express legal permission must be honored.

ii. General Informed Consent. If the researcher has obtained, prior to April 14, 2003, the individual's *informed consent* to participate in a specific research project, the IRB may permit a use or disclosure for purposes of that project even though the informed consent *does not* specifically authorize the use or disclosure of protected health information for purposes of the research project. However, any restrictions on the use and disclosure of health information provided in such informed consent must be honored.

iii. Waiver Of Informed Consent. If the researcher has obtained, prior to April 14, 2003, an IRB waiver of the informed consent requirement (in accordance with the Common Rule) for a specific research project, the IRB may permit a use or disclosure of the individual's protected health information for purposes of that project. However, if the researcher obtains an individual subject's informed consent at any time after April 14, 2003, the researcher will also be required to obtain the individual's Research Authorization (as provided in this policy) at that time.

4. Completely De-identified Information. The IRB may allow completely de-identified information to be used and disclosed for research purposes without restriction. Information may only be considered completely de-identified when either (1) a qualified statistician documents his or her determination that the risk of identification is very small, or (2) the information meets the requirements described in Appendix A of this policy. If the IRB has any doubts as to whether protected health information has been completely de-identified within the meaning of this policy, the information should be treated as though it were *not* completely de-identified and neither used nor disclosed for research purposes without meeting another exception.

5. Limited Data Set. The IRB may allow the use and disclosure for research purposes of a *limited data set* including a partially de-identified subset of the individual's protected health information, provided that the person using or receiving the information has signed a Data Use Agreement through which he or she agrees to protect the privacy of the information received. Appendix B of this policy provides more information about the identifiers that must be removed from an individual's protected health information in order to create a *limited data set*.

6. Subject Authorization For Research. The IRB may allow the use and disclosure of protected health information pursuant to a completed and signed Research Authorization form. Permissible uses and disclosures are limited to those described in the authorization, even though those permissible uses and disclosures may be more limited than what the hospital's Notice of Privacy Practices describes.

The Research Authorization form must be completed by the Principal Investigator for the research subject's review and signature. It is the responsibility of the Principal Investigator to ensure that the Research Authorization form covers the uses and disclosures necessary for the research study. Instructions on preparing the Research Authorization form are included with the form.

When obtaining a Research Authorization, an individual's ability to receive research-related treatment as part of a research study may be conditioned upon the individual's agreement to sign the Research Authorization form

However, in presenting the Research Authorization form to prospective subjects, researchers should never suggest that failure to sign the form will limit access to any treatment that may be available *outside* the study. Any questions about the availability of such treatment outside the study should be referred to the prospective subject's physician(s). Any other questions about the Research Authorization form should be directed to the IRB or to the IRB's designee who has assessed, or who will assess, the Principal Investigator's request for permission to use or disclose protected health information for research.

7. IRB Approval Of Waiver. The IRB may allow the use and disclosure of protected health information for research purposes if the IRB grants a partial or total waiver of the authorization requirement. If the IRB grants only a *partial waiver* – that is, if it modifies or waives only some elements of the Research Authorization form – the IRB must condition the use and/or disclosure of any protected health information for research purposes on compliance with any authorization requirements not waived and as modified. For example, if an IRB grants a partial waiver of authorization to allow a researcher who is not covered by the Lifespan Joint Notice of Privacy Practices to obtain protected health information to recruit potential research participants, the researcher would still have to obtain authorizations from the subjects to use or disclose protected health information for the study itself.

If a Principal Investigator intends to apply to an IRB for a waiver of these authorization requirements, he or she should first present the full IRB application package to the IRB for an assurance that the requested use or disclosure will be permitted. Documentation of IRB waiver must be in writing and include:

- the name of the IRB
- the date on which the waiver was approved;
- the signature of the IRB chair, or other member designated by the chair;
- a statement that the IRB has determined that the waiver satisfies the required criteria;
- a brief description of the protected health information that the IRB has determined is necessary for research purposes; and

  EXAMPLE: If the IRB approves only the use or disclosure of *certain information* from individuals' medical records, and not individuals' *entire* medical records, this must be stated on the document certifying IRB approval.

- a statement that the waiver has been reviewed and approved under either normal or expedited review procedures and that all applicable procedures were followed.

Note: A waiver of individual authorization under this policy is *not* a waiver of the requirements of informed consent for the project or of any other consent required by the hospital's policies. The IRB may waive or alter informed consent requirements, but the IRB must review a request to waive or alter informed consent requirements *separately* under criteria set forth in the Common Rule.

C. Individual Access

Individuals generally have a right to access all their protected health information maintained by the hospital or its business associates. Any patient requesting access to protected health information obtained in the course of research (including protected health information that may be contained in research records) should be directed to submit his or her request to the hospital's Records Department for processing in accordance with the hospital's policy *Patient Access to Protected Health Information*, which provides detailed guidelines for responding to such requests. The Records Department will determine, with assistance from the researcher and

the IRB, whether access to protected health information should be denied under any of the exceptions described in that policy.

D. Documentation

The IRB must retain any writings or documentation required by this policy for *six years* from the date of its creation or the date when it last was in effect, whichever is later.

VIOLATIONS

The IRB has general responsibility for implementation of this policy. Members of a Lifespan affiliate's staff and medical staff who violate this policy will be subject to disciplinary action up to and including termination of employment, contract or medical staff privileges with Lifespan or the Lifespan affiliate. Anyone who knows or has reason to believe that another person has violated this policy should report the matter promptly to his or her supervisor or the IRB. All reported matters will be investigated, and, where appropriate, steps will be taken to remedy the situation. Where possible, the IRB will make every effort to handle the reported matter confidentially. Any attempt to retaliate against a person for reporting a violation of this policy will itself be considered a violation of this policy that may result in disciplinary action up to and including termination of employment or contract with Lifespan.

QUESTIONS

If you have questions about this policy, please contact your department supervisor or the IRB immediately. It is important that all questions be resolved as soon as possible to ensure protected health information is used and disclosed appropriately.

APPENDIX A

COMPLETE DE-IDENTIFICATION

Information is completely de-identified if *none* of the following 18 types of identifiers is contained in the information *and* if no one accessing the information has *actual knowledge* that the information could be used – alone or in combination with other information – to identify any individual who is the subject of the information. Note that this does not prohibit coding records so that they may later be re-identified, so long as the code does not contain information about the subject of the information (for example, the code may not be a derivative of the individual's Social Security Number) and is not used or disclosed for any other purpose, and so long as the re-linking mechanism (e.g., the subject log or coding algorithm) is not disclosed to any persons or organizations outside the hospital.

1. Names
2. All geographic subdivisions smaller than a State, including:
   - street address
   - city
   - county
   - precinct
   - zip codes 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: (1) the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people, and (2) the initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
3. Telephone numbers
4. Fax numbers
5. E-mail addresses
6. Social Security numbers
7. Medical record numbers
8. Health plan beneficiary numbers
9. Account numbers
10. All elements of dates (except year) for dates related to an individual, including:
    - birth date
    - admission date
    - discharge date
    - date of death
    - all ages over 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 age 90 or older
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) address numbers
16. Biometric identifiers, including finger and voice prints
17. Full face photographic images and any comparable images
18. Any other unique identifying numbers, characteristics, or codes

APPENDIX B

CREATION OF LIMITED DATA SET

The IRB may approve the use and disclosure of a limited data set for research purposes if the person who would use or receive the information has signed a Data Use Agreement through which the person agrees to protect the privacy of the information received.

A limited data set may be created by removing from the individual's protected health information the following direct identifiers of the individual or of relatives, employers or household members of the individual:

1. Names;
2. Postal address information, other than town or city, State, and zip code;
3. Telephone numbers;
4. Fax numbers;
5. Electronic mail addresses;
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, including license plate numbers;
12. Device identifiers and serial numbers;
13. Web Universal Resource Locators (URLs);
14. Internet Protocol (IP) address numbers;
15. Biometric identifiers, including finger and voice prints; and
16. Full face photographic images and any comparable images.

Note: Limited data sets may also be used and disclosed for the hospital's or the recipient's health care operations and for public health purposes, but requirements for the use and disclosure of a limited data set for these non-research purposes are set forth in Lifespan's policies on use and disclosure of a limited data set pursuant to a data use agreement for these other purposes. Any questions concerning use and disclosure of a limited data set for research purposes should be directed to the IRB or his or her designee.

APPENDIX C

RESEARCHER REQUEST
FOR
REVIEWS PREPARATORY TO RESEARCH

Researcher Name:

____

Last First MI

This form must be completed by any researcher seeking access to protected health information in preparation for research. The researcher completing this form should remember to print his or her name above and sign and date the form.

INFORMATION REQUESTED

Please describe in the space below the protected health information you would like to review.

____

SPECIFIC REPRESENTATIONS

I seek access to the above protected health information solely to prepare a research protocol or for similar purposes preparatory to research.

I will not remove any of the above information from the hospital's premises during the course of my review.

I affirm that access to the above protected health information is necessary for my review preparatory to research.

I understand that if I record any protected health information in a way that may directly or indirectly be used to identify particular individuals (*e.g.*, addresses, telephone numbers, etc.), I will use such information (1) only when I am on hospital premises and (2) only for the purpose of contacting potential research subjects. Furthermore, I will not disclose such protected health information to anyone other than the individual who is the subject of the information.

I understand that I may not continue to use and disclose the protected health information described above without further permission from the IRB once the Principal Investigator has determined to go forward with the study.

By signing below, you represent that all of the above statements are true.

_____
Signature of Researcher

_____
Print Name

_____
Date

APPENDIX D

<u>RESEARCHER REQUEST</u>
<u>FOR</u>
<u>PROTECTED HEALTH INFORMATION OF DECEDENTS</u>

Researcher Name:

____
Last First MI

This form must be completed by any researcher seeking access to a decedent's protected health information for research on that decedent. The researcher completing this form should remember to print his or her name above and sign and date the form.

INFORMATION REQUESTED

Please describe in the space below the protected health information (including the name of the decedent or decedents) you would like to review.

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SPECIFIC REPRESENTATIONS

I seek access to the above protected health information solely for research *on the protected health information of the decedent(s) named above*. I understand that I may not request a decedent's medical history to obtain information about another living person such as a decedent's living relative.

I affirm that access to the above protected health information is necessary for my research purposes.

I agree to provide, at the IRB's request, documentation of the death of the decedent(s) named above.

By signing below, you represent that all of the above statements are true.

_____
Signature of Researcher

_____
Print Name

_____
Date

APPENDIX E

IRB OR PRIVACY BOARD WAIVER PROCESS

IRBs may grant waivers of the research authorization requirement described in this policy. The purpose of this Appendix is to assist researchers in submitting waiver requests to an IRB by providing a brief description of the role of the IRB and explaining what the IRB is required by federal law to consider when evaluating such requests

Composition of IRBs. To approve a waiver request under HIPAA, an IRB must be established in accordance with the Common Rule. A Privacy Board must:

- include members of varying backgrounds and appropriate professional competency as necessary to review the effect of the research protocol on the individual's privacy rights and related interests;
    - include at least one member who is not (1) affiliated with the hospital, (2) affiliated with any entity conducting or sponsoring the research, or (3) related to any person who is affiliated with either the hospital or an entity conducting or sponsoring the research; and
    - ensure that members who may have a conflict of interest abstain from participating in the review.[i]

Criteria IRB Must Consider. To obtain a waiver of authorization, an IRB should keep minutes of its meetings documenting that the requested waiver satisfies *each* of the following criteria:[ii]

- the use or disclosure involves no more than minimal risk to the individuals because:
    - there is an adequate plan to protect the "identifiers" (the types of information listed in Appendix A of this policy);
    - there is an adequate plan to destroy the "identifiers" at the earliest opportunity, unless there is a health (*i.e.*, individual care) or research justification for retaining the identifiers or their retention is required by law; *and*
    - there are adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except (1) as required by law, (2) for authorized oversight of the research project, or (3) for other research for which the use or disclosure of protected health information is otherwise permissible under this policy.

      EXAMPLE: IRBs should obtain adequate written assurances that the protected health information will not be disclosed to an individual's employer for employment decisions without the individual's authorization.
- the research could not practicably be conducted without the waiver; *and*
    - The difference between impossibility and impracticability is important. In a research study that involves thousands of records, it may be *possible* to track down all potential subjects, but doing so

may entail costs that would make the research *impracticable*. Authorization may not, however, be waived simply for convenience.

- If a researcher is to have direct contact with research subjects during the course of the research, the researcher should be able to seek and obtain authorizations for the use and disclosure of the research subjects' protected health information for the research study. Because most clinical trials *could* practicably be conducted without a waiver, research involving treatment *will ALMOST NEVER be eligible for an IRB or Privacy Board waiver*.

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

  - If a researcher can practicably use de-identified health information or a limited data set for a research study, a waiver of authorization should not be granted.

- **Review Procedures.** If the Principal Investigator applies to an IRB to approve a waiver as described above, the IRB will follow the Common Rule's normal or expedited review procedures as applicable.

APPENDIX F

USE AND DISCLOSURE OF PSYCHOTHERAPY NOTES FOR RESEARCH PURPOSES

Special restrictions apply to the use and disclosure of psychotherapy notes for research purposes. *Psychotherapy notes* are notes recorded (in any medium) by a mental health professional that (1) document or analyze the contents of conversation during a private counseling session or a group, joint, or family counseling session and (2) that are kept separately from the rest of the individual's medical record. *Psychotherapy notes* do not include medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date.

In general, the use or disclosure of psychotherapy notes for research is permissible *only* if:

- the subject signs a Research Authorization, *and*

- the Research Authorization encompasses *only psychotherapy notes* and no other protected health information. Thus, if medical records are requested in addition to psychotherapy notes, two Research Authorizations will be required.

Because the rules for psychotherapy notes are more protective of privacy than the general HIPAA research rules, the following exceptions in the policy are *not applicable* to the use and disclosure of psychotherapy notes for research purposes:

- reviews preparatory to research,

- research on the protected health information of a decedent, and

- IRB or Privacy Board approval of waiver of authorization.

Note that the transition exceptions allowing continued use and disclosure of an individual's protected health information (including psychotherapy notes) are still applicable in this area. Thus, use and disclosure of such information for research purposes is permitted if an express legal permission, informed consent, or waiver of informed consent has been obtained from the individual prior to April 14, 2003 and the individual is not re-consented after April 14, 2003.

As explained in this policy, individuals generally have a right to access all their protected health information maintained by the hospital or its business associates. Individuals have *no* right, however, to access any psychotherapy notes. Any questions about the hospital's policy on access to psychotherapy notes should be directed to the hospital's Records Department.

Additional information on the use and disclosure of psychotherapy notes can be found in Lifespan general policies regarding *Privacy of Psychotherapy Notes*. Note, however, that this policy controls with respect to the use and disclosure of psychotherapy notes *for research purposes*.

[i] According to the Privacy Rule commentary, hospital employees requesting protected health information for research purposes are "not *necessarily* conflicted," even if those employees may benefit financially from the research.

[ii] These criteria were significantly modified through the August 2002 modifications to the Privacy Rule. *See* 45 C.F.R. § 164.512(i)(2)(ii) (as promulgated in 67 Fed. Reg. 53,182 (Aug. 14, 2002)). In general the criteria were modified to reduce internal inconsistencies and to align the criteria more closely with the requirements for waiver of informed consent under the Common Rule.