

HIPAA Policy 5032
Statement of Policy on Use and Disclosure of Protected Health Information for Research Purposes

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Scope

This policy applies to the University's Covered Components and those working on behalf of the covered components, designated as such for purposes of complying with the privacy provisions of the Health Insurance Portability and Accountability Act of 1996. The Covered Components are: (1) the Group Health Plan Component; and (2) the Covered Health Care Component, which includes the School of Nursing, the Department of Psychology clinics, Yale Health and the School of Medicine (except the School of Public Health and the Departments of Cell Biology, Cellular and Molecular Physiology, Comparative Medicine, History of Medicine, Immunobiology, Microbial Pathogenesis, Molecular Biophysics & Biochemistry, Neurobiology, Pharmacology, and WM Keck Biotechnology Resources Laboratory).

This policy applies to Yale University's Privacy Officer, the Privacy Officer's designees, and any persons requesting to create, access or use for research purposes any protected health information obtained or maintained by the covered components of Yale University. This policy does not affect Yale University's current policies governing Institutional Review Board approval and continuing review of research in accordance with the Yale University's policies and procedures available at <http://www.yale.edu/hrpp>

Policy Statement

Protected health information obtained or maintained by Covered Components of Yale University for research purposes may *not* be used internally or disclosed to any persons or organizations outside the Covered Component for research purposes without prior approval of Yale University's Privacy Officer or as expressly permitted by Yale University Policy.

Reason for the Policy

The purpose of this policy statement is to describe the requirements concerning the protection of the health information privacy of research subjects. The requirements were established by the federal law known as the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and subsequently amended under the Health Information Technology for Clinical Health Act (HITECH). The United States Department of Health and Human Services has passed comprehensive privacy regulations that implement and enforce the requirements of HIPAA. These regulations do not replace existing federal and state laws that currently govern human subjects research or protect patients' privacy, such as IRB requirements, but interact with these existing laws. This policy is supplemented by various additional Yale University Policies and Procedures designed to implement and

coordinate our Institutional compliance with federal and state privacy rules. Please direct any questions to the Yale University's Privacy Officer.

Definitions

Covered Component

Components of the University designated by Yale that are required to comply with the Administrative Simplification provisions of HIPAA because the component performs a covered function. There are two covered components at Yale: the Covered Employer Group Health Plan Component and the Covered Health Care Component.

Covered Entity

Covered entity means an entity that is subject to HIPAA. Yale University is the covered entity for HIPAA compliance purposes. Because Yale is a Hybrid Entity, only Yale's designated Covered Components are subject to HIPAA requirements.

Designated Record Set

Medical, clinical research and billing records about an individual maintained or used to make decisions about the individual and the individual's treatment. and subject to an individual's right to request access and amendment.

HIPAA Authorization

a specific type of permission given by the individual to use and/or disclose protected health information about the individual. The requirements of a valid authorization are defined in the HIPAA regulations. Yale recommends use of the Yale authorization form in Policy 5031 for patient requests, or the research authorization form in Policy 5032. Use of a modified form other than addition of required information requires review and approval by the privacy office.

Legally Authorized Representative

A person authorized either by state law or by court appointment to make decisions, including decisions related to health care, on behalf of another person, including someone who is authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure involved in the research.

Limited Data Set

Protected health information that excludes all of the 16 HIPAA specified direct identifiers of the individual or of relatives, employers, or household members of the individual, but retains geographic subdivisions larger than the postal address and elements of dates. Limited data sets may only be used for research, public health or for health care operations; and only with a data use agreement that limits the use of the data by the recipient.

Privacy Board

A review board that is responsible for approving HIPAA waivers of authorization. At Yale the IRB's serve as the privacy board.

Protected Health Information (PHI) is any individually identifiable health information, including genetic information and demographic information, collected from an individual, whether oral or recorded in any form or medium that is created or received by a covered entity (Yale School of Medicine (excluding the School of Public Health, the Animal Resources Center, and the basic science departments: Cell Biology, Cellular and Molecular Physiology, Comparative Medicine, History of Medicine, Immunobiology, Microbial Pathogenesis, MolecularBiophysics & Biochemistry, Neurobiology,Pharmacology and WM Keck Biotechnology Resources Laboratory), Yale School of Nursing, Yale Health, Department of Psychology Clinics and the Group Health Plan component)

PHI encompasses information that identifies an individual or might reasonably be used to identify an individual and relates to:

- The individual's past, present or future physical or mental health or condition of an individual; OR

- The provision of health care to the individual; OR
- The past, present or future payment of health care to an individual.

Information is deemed to identify an individual if it includes either the patient's name or any other information that taken together or used with other information could enable someone to determine an individual's identity. (For example: date of birth, medical records number, health plan beneficiary numbers, address, zip code, phone number, email address, fax number, IP address, license numbers, full face photographic images or Social Security Number see [Policy 5039](#) for a list of [HIPAA Identifiers](#))

PHI excludes individually identifiable health information in education records covered by the Family Educational Right and Privacy Act (FERPA) (records described in 20 USC 1232g(a)(4)(B)(iv)) and employment records held by a covered entity in its role as employer. PHI also excludes information related to individuals who have been deceased for more than 50 years. (see also definitions of "health information" and "individually identifiable health information")

Psychotherapy Notes

Notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the individual's medical record. Psychotherapy notes exclude 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. See [Policy 5031](#).

Research

Research is any systematic investigation (including research development, testing, and evaluation) that is designed to contribute to generalizable knowledge.

Summary Health Information

Information that summarizes the claims history, claims expenses, or type of claims experienced by individuals for whom a plan sponsor has provided health benefits under a group health plan; and from which identifying information has been deleted, except that the geographic information need only be aggregated to the level of a five digit zip code.

See the [HIPAA Glossary](#) for a complete listing of HIPAA terms

Policy Sections

5032.1 - Requirements

Certain requirements apply to the use and disclosure of PHI in connection with research. As a general rule, the use or disclosure of PHI for research purposes may be authorized only:

- for reviews preparatory to research;
- for research on the PHI of a decedent;
- if, prior to April 14, 2003, the subject has given his or her informed consent to participate in the research, or if the requirement for such informed consent was waived by an IRB;
- if the researcher has obtained the individual's authorization;
- if an IRB or a Privacy Board approves a waiver of individual authorization;
- if the recipient of a limited data set has entered into a data use agreement with Yale University (See [Form 5032](#) - Research Authorization Form and Procedure [5032 PR1](#) Determining Whether "Human Subject Research" Activity Involves Use/Disclosure Of "Protected Health Information")
or

- if the use or disclosure is consistent with institution's policy on AE reporting, study monitoring, regulatory reporting, public health, required by law, health oversight, serious threat to health/safety, or similar situations.

The specific requirements for each of these exceptions are discussed below. *An individual authorization or a waiver should be requested if there is any doubt about whether any other exception is applicable.* Any questions should be directed to Yale University's Privacy Officer.

Special rules apply to research involving psychotherapy notes, as explained in Policy [5031](#), Authorization Requirements for Use and Disclosure of Protected Health Information, Including Verification of Identification

5032.2 - General Prohibition and Exceptions

The use or disclosure of PHI for research purposes may not be authorized unless at least one of the following conditions applies:

1. Reviews Preparatory to Research. The Privacy Officer may permit the use and disclosure of PHI (*except* psychotherapy notes) to develop a research protocol or for similar purposes preparatory to research. Researchers should be aware that this exception does *not* permit the continued use or disclosure of the PHI once the Principal Investigator has determined to go forward with the study.

- EXAMPLE: The examination of medical records to determine whether the holder of the PHI has information about a sufficient number of prospective research participants that would meet the eligibility criteria for enrollment in a research study constitutes a review preparatory to research.
- EXAMPLE: The use of PHI to contact eligible subjects for recruitment purposes would not be permitted under this exception.

In order to permit a use or disclosure of PHI under this exception, the Holder of PHI must obtain representations from the 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 PHI from the covered component's premises in the course of the review or make any notes that include PHI; and
- the PHI for which use or access is sought is necessary for the research purposes.

Researchers seeking access to PHI for preparatory reviews should sign the Yale Request Form For Access To Protected Health Information For Research Purpose.

During the preparatory review, those granted access may only record information in a form that is "de-identified." They may not take any other notes or take away any PHI from the location where information is stored. Appendix A describes the information that must be removed to constitute de-identified information.

- EXAMPLE: A researcher may review medical charts and other identified information but may not copy or record any identified information. A researcher may make other notes, such as a tally of the number of records meeting certain inclusion criteria.

2. Research on the PHI of a Decedent. The Privacy Officer may permit the use and disclosure of the PHI (*except* psychotherapy notes) of a decedent who has been deceased for fifty years or less for research purposes. In order to permit such a use or disclosure, the Holder of PHI must obtain representations from the Principal Investigator that the use or disclosure is being sought *solely* for research on the PHI of a decedent *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 Holder of PHI's request, documentation of the death of any individuals about whom information is sought. The Yale University Request Form For Access To Protected Health Information For Research Purposes must be signed by researchers seeking to engage in research on the PHI of a decedent. Note that health

information of individuals who have been deceased for more than 50 years is not subject to the HIPAA requirements and does not require the representations described above,

- EXAMPLE: A researcher may *not* request a decedent's medical history to obtain health information about a decedent's living relative. A researcher *may* request a decedent's medical history for an outcomes study relating to treatment previously administered to the decedent.

3. Consents and Waivers of Consent Obtained Prior to April 14, 2003. If informed consent has been waived for a study before April 14, 2003, investigators may continue to use and disclose the subjects' PHI in connection with the study without obtaining a Research Authorization from the subjects. For studies that require informed consent, those subjects who, prior to April 14, 2003, have executed an informed consent to participate in the project, do not have to sign a research authorization unless the subject is re-consented after April 14, 2003. In either case, any limitations on the use and disclosure of PHI contained in the informed consent form or imposed by the IRB must be honored.

4. Subject Authorization for Research. The Privacy Officer may allow the use and disclosure of PHI according to the terms of a completed and signed Research Authorization form. Permissible uses and disclosures are limited to those described in the authorization. Use or disclosure of psychotherapy notes for research is permissible only if the subject signs an authorization that encompasses *only psychotherapy notes* and no other PHI.

- EXAMPLE: If a subject signs a Research Authorization form that permits disclosure of that subject's entire medical and research record to a research sponsor, the Privacy Officer may permit Case Report Forms with the subject's initials and visit dates to be disclosed to the sponsor.
- EXAMPLE: A single Research Authorization form may not authorize a disclosure of medical records and psychotherapy notes.

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. If the Principal Investigator has any questions or concerns when preparing the Research Authorization form, the Principal Investigator should consult with the Privacy Officer. (See [Form 5032](#) - Research Authorization Form and Procedure [5032 PR1](#) Determining Whether "Human Subject Research" Activity Involves Use/Disclosure Of "Protected Health Information")

No one may be enrolled in any study within a covered component requiring a Research Authorization without signing the Research Authorization form. Nevertheless, 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 Privacy Officer or to the Privacy Officer designee who has assessed, or who will assess, the Principal Investigator's request for permission to use or disclose PHI for research.

5. IRB or Privacy Board Approval of Waiver. The Privacy Officer may allow the use and disclosure of PHI (*except* psychotherapy notes) for research purposes if either an IRB or a Privacy Board grants a partial or total waiver of the authorization requirement. If the IRB or Privacy Board grants only a *partial waiver* – that is, if it requires a Research Authorization for some research activities and not others – the Privacy Officer must require a signed Research Authorization form for all aspects of the protocol not covered by the waiver.ⁱ

- EXAMPLE: If an IRB grants a partial waiver of authorization to allow Dr. Jones to obtain the PHI of another of Dr. Smith's patients so that Dr. Jones can recruit those patients for her study, Dr. Jones would still have to obtain authorizations from the subjects to use or disclose PHI in connection with the performance of the study.

Note: Disclosures of PHI pursuant to a waiver must be tracked according to Policy [5003](#) and Procedure [5003](#) on Accounting for Disclosures, whereas disclosures of PHI pursuant to an authorization need not be tracked. Investigators should carefully consider the administrative burden of tracking these disclosures before applying for a waiver.

Note: A waiver of individual authorization under this policy is *not* a waiver of the requirements of informed consent for participation in the study or of any other requirement in any other policy. An IRB (but not a Privacy Board) may also waive or alter informed consent requirements, but the IRB must review a request to waive or alter informed consent requirements *separately* from a waiver of authorization under criteria set forth in the IRB's guidelines for investigators.

6. Data Use Agreement. The Privacy Officer may allow the use and disclosure of a limited data set (*unless* it contains psychotherapy notes) for research purposes if Yale University has a data use agreement in place with the recipient of the limited data set. Requests for uses and disclosures of a limited data set for research purposes should be made to the Office of Grant and Contract Administration using the Data Use Agreement Form. The data use agreement should conform to Procedure [5032 PR.1](#).

7. Use and Disclosure Consistent with Other Policies. Other uses and disclosures of PHI may be allowed in connection with research if the use or disclosure is specifically permitted by Policy [5031](#) and Procedure [5031](#) Authorization Requirements for Use and Disclosure of Protected Health Information, Including Verification of Identification.

- EXAMPLE: Uses and disclosures of PHI in connection with administering routine treatment to a research subject as part of a study protocol would be permitted by Policy [5031](#) and Procedure [5031](#) on Authorization Requirements for Use and Disclosure of Protected Health Information, Including Verification of Identification, even without a Research Authorization or an IRB or Privacy Board waiver.
- EXAMPLE: Unanticipated adverse device effects (for a study under an IDE) or adverse events caused by a study drug (for a study under an IND) may be reported to a research sponsor, even without a Research Authorization or an IRB or Privacy Board waiver, according to Policy [5031](#), as an FDA-related disclosure].

5032.3 - Subject Recruitment

Using or disclosing a patient's PHI for research recruitment purposes is generally permissible only with a Research Authorization or an IRB or Privacy Board waiver of the authorization requirement, except that **treating** providers may discuss with their own patients the option of enrolling in a study without a Research Authorization or waiver. Treating providers may *not* disclose PHI (including a patient's identity) to anyone else for purposes of recruitment in a research study without a Research Authorization or waiver.

A Research Authorization permitting anyone other than the patient's treating physician to obtain the patient's contact information and to contact that patient for recruitment purposes must specify what information will be used or disclosed for recruitment purposes, the person(s) who will receive such information, and all other items required by the Research Authorization form.

5032.4 - Individual Access and Accounting

Individuals generally have a right to access all their PHI maintained by the covered component or its business associates. All subject requests for access to PHI obtained in the course of research should be referred to the institution's Records Department or the holders of PHI for processing in accordance with Policy [5003](#) and Procedure [5003](#) on Accounting for Disclosures, which provides detailed guidelines for responding to such requests. The Records Department or the holders of PHI will determine, with assistance from the researcher and the Privacy Officer, whether access to PHI may be denied under the exception described in this section of this policy.

Individuals also have a right to an accounting of certain "disclosures" (but not "uses") of their PHI, as described more fully in Policy [5003](#) and Procedure [5003](#) on Accounting for Disclosures. A "disclosure"

occurs when information is released, transferred, accessed by, or divulged in any other manner *outside* the health care component, and includes disclosures between legally separate entities that are members of an organized health care arrangement. A disclosure for research purposes need not appear in an accounting list if it is made:

- To the subject, of his or her own information;
- Pursuant to a Research Authorization;
- As part of a limited data set, if the recipient has signed the Data Use Agreement;
- "Incident to" an otherwise-permissible use or disclosure (e.g., the calling of a subject's name in a waiting room may not trigger accounting obligations);
- For the facility's in-patient directory or registry, or to persons involved in the individual's care or other notification purposes, as provided in Policy [5031](#) - Authorization Requirements for Use and Disclosure of Protected Health Information, Including Verification and Identification;
- For national security or intelligence purposes, as provided in Policy [5031](#), Authorization Requirements for Use and Disclosure of Protected Health Information, Including Verification and Identification];
- To correctional institutions or law enforcement officials, as provided in Policy [5031](#) - Authorization Requirements for Use and Disclosure of Protected Health Information, Including Verification and Identification];or
- That occurred prior to April 14, 2003.

More information on the procedures for tracking of research-related disclosures can be found Yale University Policy [5003](#) on Accounting for Disclosures.

5032.5 - Documentation

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

5032.6 - Resignations of Investigators or Research Staff

In the event that a Yale investigator or research staff member leaves Yale and wishes to copy or remove research data created or acquired by Yale, he or she must request permission from his or her department head and the Privacy Officer. The Privacy Officer will make each determination related to privacy rules on a case-by-case basis, considering at least the following:

- does the data include PHI;
- who, besides the departing investigator or staff member, will have access to the removed or copied data, including any other institution with which the departing investigator or staff member will become affiliated;
- the feasibility of permitting the copying or removal of only de-identified, coded data, with the key to the code remaining at Yale;
- whether such copying or removal is contemplated in the Research Authorization signed by each subject;
- the feasibility of requesting additional authorizations from the subjects;
- review of any representations to, or agreements made by Yale with, the transferors of the data to Yale; and
- whether such copying or removal would be inconsistent with any representations made in the context of a waiver/decedents application.

The Privacy Officer will then inform the departing investigator or research staff member of the terms and conditions under which research data may be copied or removed. Research data may be copied or removed from Yale *only* pursuant to those terms and conditions.

5032.7 - Violations

The Privacy Officer has general responsibility for implementation of this policy. Members of the medical staff and covered components staff who violate this policy will be subject to disciplinary action up to and including termination of employment or contract with Yale University. .ii 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, the Privacy Officer, or the chairperson of the reviewing IRB. All reported matters will be investigated, and, where appropriate, steps will be taken to remedy the situation. Where possible, the University 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 Yale University.

5032.8 - Questions

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

Procedures

[5003 PR.1](#) - Accounting for Disclosures

[5031 PR.1](#) - Authorization Requirements for Use and Disclosure of Protected Health Information, Including Verification of Identification

[5032 PR1](#) - Determining Whether "Human Subject Research" Activity Involves Use/Disclosure Of "Protected Health Information"

Forms and Exhibits

[Form 5032](#) - Research Authorization Form

[Exhibit 5039](#) - De-identification

[Exhibit 5039](#) - Limited Data Set

[Form 5039](#) – Data Use Agreement

[Form 5039](#) – Data Use Agreement for Internal Research Uses

Related Information

Policy [5003](#) - Accounting for Disclosures

Policy [5031](#) - Authorization Requirements for Use and Disclosure of Protected Health Information, Including Verification and Identification

Contacts

Subject	Contact	Phone
HIPAA Compliance	Chief HIPAA Privacy Officer	203-432-5919
Information Security	Central Campus Help Desk Medical School Campus Help Desk	203-432-9000 203-785-3200
Research Compliance	Human Investigation Committee and Human Subjects Committee	203-785-4688

Roles and Responsibilities

Office of the Provost

responsible for University compliance issues including HIPAA

Office of General Counsel

interprets HIPAA regulations; reviews and approves all HIPAA related contracts including contracts with Business Associates or for research contracts

University Information Security Officer

individual responsible for overseeing information security and ensuring compliance with security requirements of HIPAA

Chief HIPAA Privacy Officer

individual responsible for overseeing and ensuring HIPAA compliance throughout Yale University; coordinates compliance related activities through the following deputies in each of the covered schools, departments, or other entities:

- Deputy Privacy Officer, School of Medicine
- Deputy Privacy Officer, School of Nursing
- Deputy Privacy Officer, Yale Health Services
- Deputy Privacy Officer, Yale Health Plan/Benefits Office
- Deputy Privacy Officer, Department of Psychology Clinics

Procurement Office

identifies Business Associates and ensures appropriate contracts in place

Grants & Contracts Administration

Responsible for negotiating data use agreements and research related contracts.

Institutional Review Boards (HIC, HSC)

Responsible for review and approval of waivers of authorization for research purposes.

Footnotes:

- i The Privacy Rule also permits an IRB or Privacy Board to waive only some of the *elements* of authorization. For ease of administration, however, this policy only permits the IRB or Privacy Board to waive *all* the authorization requirements for the whole study (a total waiver) or for only part of the study (a partial waiver).
- ii A covered entity may refer to disciplinary action procedures already established in its policy manuals. Alternatively, it may establish disciplinary action procedures that respond specifically to violations of this policy. The Privacy Rule advises that covered entities may choose to vary the severity of the sanction (ranging from a warning to termination of employment or contract) according to the severity of the violation (e.g., intentional violations, unintentional violations, or a pattern or practice of violations). 65 Fed. Reg. at 82562.

The official version of this information will only be maintained in an on-line web format. Any and all printed copies of this material are dated as of the print date. Please make certain to review the material on-line prior to placing reliance on a dated printed version.
