

## Privacy Rule Overview

Protected Health Information (PHI) is private information that is subject to special treatment under the HIPAA Privacy Regulations. PHI can only be used or disclosed in research if one of the following applies:

1. Written Authorization has been obtained from the patient-participant.
2. DFCI IRBs (which serve as the Privacy Boards for DFCI and DF/HCC human research) approve and document a formal Waiver of Authorization.
3. DFCI IRBs receive a satisfactory representation from the investigator that the research involves only a Review Preparatory to Research.
4. DFCI IRBs receive a satisfactory representation from the investigator that the research involves only Decedents' Information.
5. DFCI IRBs determine that the research involves only De-identified Information.
6. DFCI IRBs determine that the research involves only a Limited Data Set(s) accompanied by Data Use Agreement.

Privacy Rule requirements are in addition to human subject protection requirements. The following chart provides a brief overview of the six mechanisms identified above:

Mechanism	Minimum Necessary Standard	Accounting of Disclosures	Submission Requirements	Documentation Requirements	Retention Requirements
Authorization	Does Not Apply	No	IRB for processing	Patient-Participant Authorization(s)	6 years
Waiver/Alteration of Authorization	Applies	Yes, but simplified if 50 or more	IRB for required determinations	IRB Documentation	6 years
Review Preparatory to Research	Applies	Yes, but simplified if 50 or more	IRB for approval	PI Representation & IRB Approval	6 years
Research Using Decedents' Info	Applies	Yes, but simplified if 50 or more	IRB for approval	PI Representation & IRB Approval	6 years
Research Using De-Identified Info	Does Not Apply	No	IRB for approval	PI Representation (or Statistician's Determination) & IRB approval	6 years
Research Using Limited Data Set	Applies	No	IRB for approval	PI Representation & Data Use Agreement & IRB approval	6 years

**Minimum Necessary Standard.** A Covered Entity must use, disclose, or request the least amount of information needed for the intended purpose. If the entire medical record is desired, it must be justified as the minimum necessary. Although the Minimum Necessary Standard does not apply to Uses or Disclosures under an Authorization, all Uses and Disclosures are limited to the purposes described in the Authorization.

**Accounting for Disclosures.** The Privacy Rule generally grants individuals the right to a written "Accounting of Disclosures" of their PHI made in the six years prior to their request for an Accounting. Accountings are required for Disclosures made under a Waiver of Authorization; research on Decedents' Information; and Reviews Preparatory to Research.

**PHI from Other Covered Entities.** DF/HCC institutions have entered into an "Organized Health Care Arrangement." Under the agreement, the sharing of PHI between DF/HCC sites for DF/HCC supported research is not considered sharing outside of this Covered Entity. Investigators must observe the Privacy Rule requirements of any Covered Entity from which they access PHI. If the investigator removes PHI from another Covered Entity, then the DF/HCC Privacy Rule requirements also apply. Privacy Rule requirements are in addition to any human subject protection requirements with the DF/HCC and the other entity.

## Social & Behavioral Research – General Information

HIPAA governs the use or disclosure of Protected **Health** Information.  
HIPAA is not applicable to research that does not involve **health** information.  
HIPAA Privacy Rule requirements are in addition to IRB human subject protection requirements.

Social and Behavioral research may or may not involve the use of Protected Health Information, and thus may or may not be subject to the HIPAA Privacy Rule.

**Example 1:** Research studying how social interactions between colleagues at work affect productivity would **not** ordinarily **involve** the use or disclosure of **health** information and would, therefore, not be governed by the HIPAA Privacy Rule.

**Example 2:** However, if the research also studies how an individual's history for treatment of emotional disorders or blood glucose levels affects productivity, the research **would involve health** information and, therefore, would require compliance with the HIPAA Research Privacy provisions. In this case, one of the following six mechanisms for using or disclosing Protected Health Information must be invoked.

Most often, the Social and Behavioral research will involve health information (if unsure, please contact OHRS) and, therefore, will be governed by the HIPAA Privacy Regulations. This means that one of the following must be obtained to use or disclose Protected Health Information.

Written Authorization from the patient-participant;

OR

A Waiver of Authorization approved by the DFCI IRB;

OR

A satisfactory representation (assurance) from the PI to the IRB that the research involves only:

De-identified Information, *or*

A Limited Data Set along with an accompanying Data Use Agreement; *or*

A Review Preparatory to Research, *or*

Research Involving Decedents' Information.

**Epidemiology Research.** Epidemiology research targets specific health outcomes, interventions, or disease states and attempts to reach conclusions about cost-effectiveness, efficacy, interventions, or delivery of services to affected populations. Some epidemiology research is conducted through surveillance, monitoring, and reporting programs — such as those employed by the Centers for Disease Control and Prevention (CDC). Other epidemiology research may employ retrospective review of medical, public health, and/or other records. Depending upon the nature of the data collected, epidemiology research may be subject to the HIPAA Privacy Rule only, to IRB human subject protection requirements only, or to both.

### Biomedical Research – General Information

HIPAA governs the use or disclosure of Protected **Health** Information.  
HIPAA is not applicable to research that does not involve **health** information.  
Privacy Rule requirements are in addition to IRB human subject protection requirements.

Usually, the biomedical research will involve health information (if unsure, please contact OHRS) and, therefore, is governed by the HIPAA Privacy Regulations. This means that to use or disclose the Protected Health Information, one of the following must be obtained:

Written Authorization from the patient-participant;

OR

A Waiver of the Authorization approved by the DFCI IRB.

OR

A satisfactory representation (assurance) from the PI to the DFCI IRB that the research involves only:

De-identified Information, *or*

A Limited Data Set along with an accompanying Data Use Agreement; *or*

A Review Preparatory to Research, *or*

Research involving Decedents' Information.

**Epidemiology Research.** Epidemiology research targets specific health outcomes, interventions, or disease states and attempts to reach conclusions about cost-effectiveness, efficacy, interventions, or delivery of services to affected populations. Some epidemiology research is conducted through surveillance, monitoring, and reporting programs — such as those employed by the Centers for Disease Control and Prevention (CDC). Other epidemiology research may employ retrospective review of medical, public health, and/or other records. Depending upon the nature of the data collected, epidemiology research may be subject to the HIPAA Privacy Rule only, to IRB human subject requirements only, or to both.

## Screening Records to Identify and/or Contact Prospective Participants

For clinical trials, researchers often review medical records, clinic appointment logs and other documents to identify and/or contact prospective participants who meet specified enrollment criteria. This screening constitutes a **Use** or **Disclosure** of **Protected Health Information** and is covered by the HIPAA Privacy Rule. Since the identity of the prospective participants is usually not known until the researchers have reviewed the records, obtaining an Authorization is usually not practicable. Researchers ordinarily have two options for screening records in compliance with Privacy Rule requirements.

**Option A.** Investigators can request a **Waiver of Authorization** to identify and/or contact prospective participants by applying to the DFCI IRB when all of the following circumstances are satisfied:

- 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 presence of the following elements: (1) an adequate plan to protect the identifiers from improper use and disclosure; AND (2) an adequate plan to destroy the identifiers at the earliest opportunity consistent with the 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 (3) 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, or for other research for which the use or disclosure would be permitted under the Privacy Rule; AND
- The research could not practicably be conducted without the waiver; AND
- The research could not practicably be conducted without access to and use of the Protected Health Information.

**Note: If the screening information is to be used to contact prospective participants, or if it is to be shown or given to the sponsor or others, the request for Waiver of Authorization must specify how and by whom prospective participants will be contacted, and/or how and why the information will be disclosed.** A submission to the DFCI IRB is also required for review of human subject protection requirements.

**Option B.** A more limited option is to propose a **"Review Preparatory to Research."** Investigators can submit to the IRB a representation of a **Review Preparatory to Research** when all of the following circumstances are satisfied:

- The Use or Disclosure is being sought solely to review Protected Health Information as necessary to prepare a research protocol or for similar purposes "preparatory to research;" AND
- No Protected Health Information is to be removed from the Covered Entity by the researcher in the course of the review; AND
- The Protected Health Information for which use or access is sought is necessary for the research purposes.

**Note: Under this option, personnel at DF/HCC sites may record information with identifiers, but the information may not be removed from DF/HCC sites at any time, and IRB Human Subject approval is required. Only members of the workforce at DF/HCC sites may contact prospective research participants under this option. Prospective participants may not be contacted by sponsors or any other persons who are not personnel of the covered entity.**

Information may also be accessed through use of a De-identified Data Set or a Limited Data Set.

## Screening Non-DF/HCC Site Records to Identify and/or Contact Prospective Participants

For clinical trials, researchers often review medical records, clinic appointment logs and other documents to identify and/or contact prospective participants who meet the enrollment criteria. This screening constitutes a **Use or Disclosure of Protected Health Information** and is covered by the HIPAA Privacy Rule. Since the identity of the prospective participants is usually not known until the researchers have reviewed the records, obtaining an Authorization is usually not practicable. In instances where researchers are reviewing records **at another Covered Entity**, the privacy requirements set forth by that Covered Entity should be followed. However, as a general guideline, researchers will have two options when conducting pre-screening such that they comply with the Privacy Rule requirements:

**Option A.** Investigators can request a **Waiver of Authorization** from the IRB or Privacy Board at the other Covered Entity when all of the following circumstances are satisfied:

- 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 presence of the following elements: (1) an adequate plan to protect the identifiers from improper use and disclosure; AND (2) an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for regaining the identifiers or such retention is otherwise required by law; AND (3) 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, or for other research for which the use or disclosure would be permitted under the Privacy Rule; AND
- The research could not practicably be conducted without the waiver; AND
- The research could not practicably be conducted without access to and use of the protected health information.

**Note: The request for Waiver of Authorization must specify how and why the information will be disclosed to you, as well as how and by whom prospective participants will be contacted.** Submissions to the DFCI IRB and the IRB at the other Covered Entity are also required for review of human subject protection requirements.

**Option B.** A more limited option is to propose a **“Review Preparatory to Research.”**

Investigators can submit to the other Covered Entity's IRB or Privacy Board a representation of a **Review Preparatory to Research** when all of the following circumstances are satisfied:

- The Use or Disclosure is being sought solely to review Protected Health Information as necessary to prepare a research protocol or for similar purposes “preparatory to research;” AND
- No Protected Health Information is to be removed from the Covered Entity by the researcher in the course of the review; AND
- The Protected Health Information for which use or access is sought is necessary for the research purposes.

**Note: DFCI personnel may not remove the information from the Covered Entity at any time and may not contact prospective research participants under this option.** Submissions to the DFCI IRB and the IRB at the other Covered Entity are also required for review of human subject protection requirements.

Information may also be accessed through use of a De-identified Data Set or a Limited Data Set.

## Retrospective Studies Using Existing Identifiable Health Information

Many studies involve the collection and use of existing identifiable health information. Often under the Human Subject Protection regulations, these studies can be reviewed by an IRB member using an expedited review procedure. The Privacy Rule also applies to the Use and Disclosure of existing identifiable health information (Protected Health Information), and researchers have the following options to meet the Privacy Rule requirements:

**Option A.** Investigators of the institution can **request a Waiver of Authorization** by applying to the DFCI IRB when all of the following circumstances are satisfied:

- 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 presence of the following elements: (1) an adequate plan to protect the identifiers from improper use and disclosure; AND (2) an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for regaining the identifiers or such retention is otherwise required by law; AND (3) 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, or for other research for which the Use or Disclosure would be permitted under the Privacy Rule; AND
- The research could not practicably be conducted without the waiver; AND
- The research could not practicably be conducted without access to and use of the protected health information.

**More limited options include the following:**

**Option B.** Investigators can submit to the IRB a **representation that the information has been De-identified** when all of the following circumstances are satisfied:

- An expert has determined that the risk is very small that the information could be used, either alone or in combination with other reasonably available information to identify an individual; OR
- (1) The many requisite identifiers of the individual or of the relatives, employers, or household members of the individual are all removed; AND (2) DF/HCC institutions do not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a participant of the information.

**Note:** If codes are maintained to **re-identify** the De-identified information, then the following circumstances must also be satisfied:

- The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual; AND
- The code or record identification is not used or disclosed for any other purpose and the mechanism for re-identification is not disclosed.

**Option C.** Investigators can submit a **representation to the IRB that the research involves a Limited Data Set** when all of the following circumstances are satisfied:

- The many requisite identifiers of the individual or of relatives, employers, or household members of the individual are all removed; AND
- A Data Use Agreement has been obtained which stipulates that the recipient will use or disclose the information only for the limited purposes described in the agreement.

**NOTE: For all options, a submission to the DFCI IRB is also required for review of human subject protection requirements.**

## Retrospective Studies Using Existing De-Identified Health Information

Many studies involve the collection and use of existing “De-identified” health information, often from a data registry or tissue repository. It is very important to distinguish “De-identified” information (as defined under the HIPAA Privacy Rule) from “non-identifiable” or “anonymous” information (as used under the human subject protection regulations). In the case of “non-identifiable” or “anonymous” information, there is no way to link the information to the individual from whom it was derived. However, “De-identified” information may include a code or link that permits the information to be “re-identified,” i.e., linked back to the individual from whom it was derived. Thus, “De-identified” information is potentially identifiable and cannot be considered “anonymous” from a human subject protection standpoint.

Researchers have the following options to meet the Privacy Rule requirements when using “De-identified” information. A submission to the DFCI IRB is also required for review of human subject protection requirements.

**Option A.** Investigators can **request a Waiver of Authorization** by applying to the DFCI IRB when all of the following circumstances are satisfied:

- 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 presence of the following elements: (1) an adequate plan to protect the identifiers from improper use and disclosure; AND (2) an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for regaining the identifiers or such retention is otherwise required by law; AND (3) 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, or for other research for which the use or disclosure would be permitted under the Privacy Rule; AND
- The research could not practicably be conducted without the waiver; AND
- The research could not practicably be conducted without access to and use of the protected health information.

**Option B.** A more limited option is a specific request to use “**De-Identified Information.**” Investigators can submit a **representation to the DFCI IRB that the information has been De-identified** when all of the following circumstances are satisfied:

- An expert has determined that the risk is very small that the information could be used, either alone or in combination with other reasonably available information to identify an individual; OR
- (1) The requisite identifiers of the individual or of the relatives, employers, or household members of the individual are removed; AND (2) DF/HCC institutions do not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.

**Note:** If codes are maintained to **re-identify** the de-identified information, then the following circumstances must also be satisfied:

- The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual; AND
- The code or record identification is not used or disclosed for any other purpose and the mechanism for re-identification is not disclosed.

Information may also be accessed through use of a Limited Data Set.

**NOTE: For all options, a submission to the DFCI IRB is also required for review of human subject protection requirements.**

## Research on Decedent's Information

The Human Subject Protection regulations apply to research involving "living human beings." Accordingly, Human Subject Protection requirements typically do not apply to research involving decedents unless the research also involves information that identifies living individuals. However, the Privacy Rule does apply to decedents' information. Researchers have the following options to meet the Privacy Rule requirements:

DFCI investigators can submit a **representation that the research involves Decedents' Information** to the DFCI IRB when all of the following circumstances are satisfied:

- The information is solely for research on the protected health information of decedents; AND
- Documentation of the death of such individual is available at the request of the covered entity; AND
- The protected health information is necessary for the research.

Decedents' Information may also be accessed through use of a Waiver of Authorization, a De-identified Data Set, or a Limited Data Set.



## Overview of Accounting of Disclosures

**Accounting of Disclosures.** The Privacy Rule generally grants individuals the right to a written "Accounting of Disclosures" of their Protected Health Information made in the six years prior to their request for an Accounting. Accountings do not go back before April 14, 2003. In general, an Accounting of Disclosures must be provided within 60 days of receipt of the request.

**Required Accountings.** According to the Privacy Rule, an Accounting of Disclosures is required for:

1. Routinely Permitted Disclosures (e.g., under public health authority, to regulatory agencies, to persons with FDA-related responsibilities) with limited exceptions (e.g., law enforcement, national security, etc.)
2. Disclosures made pursuant to:
  - a. Waiver of Authorization
  - b. Research on Decedents' Information
  - c. Reviews Preparatory to Research

**Elements of Accounting.** When an Accounting of Disclosures is made, the Accounting must include the following elements:

1. All Disclosures of the individual's Protected Health Information made by the Covered Entity, including Disclosures to or by the Covered Entity's Business Associates
2. Date of each Disclosure
3. Name and address, if known, of the person or entity receiving the information
4. Brief description of the Protected Health Information disclosed, and
5. Brief statement of the purpose of and basis for the Disclosure, or a copy of the written request for the Disclosure.

**Elements of Simplified Accounting for Multiple Disclosures to the Same Person/Entity.** Where multiple Disclosures of an individual's Protected Health Information have been made to the same person or Entity for a single purpose, a full Accounting of the first Disclosure is required as described in the section above. Accounting for subsequent Disclosures may be accomplished by providing the following:

1. The frequency, periodicity, or number of Disclosures made.
2. The date of the last Disclosure.

**Elements of Simplified Accounting of Disclosure of Protected Health Information for 50 or More Individuals.** Where Disclosures of Protected Health Information for 50 or more individuals have been made for a single purpose, the Accounting may be accomplished by providing the following:

1. Name of the protocol or research activity
2. Brief description of the purpose of the research and criteria for record selection.
3. Brief description of the type of Protected Health Information disclosed.
4. Dates or time periods when Disclosure may have taken place.
5. Name, address, and phone number of sponsoring entity and research investigator.
6. Statement as to whether other Disclosures of the individual's Protected Health Information have been made.