Title: Informed Consent for Research and Authorization for the Use and Disclosure of Protected Health Information	**Policy Number:** A-COM-0004 **Policy Type:** Administrative **Effective Date of this Policy:** 01/21/19
Replaces (supersedes): **Title:**	**Policy Chronicle:** Date the Original Version of Policy was Effective: April 13, 2003 Most Recent Review (month/year): January 2019 Reviewer: Date: 01/2019 J. Glover Taylor, Director, Sponsored Research Administration Previous Reviews: June 2017 Previous Reviews: May 2014 Previous Reviews: March 2011 Previous Reviews: April 2003
Area of Operations: Institutional Review Board (IRB)	
Regulatory Agency: JCAHO/IM Dept. of Health & Human Services/HIPAA (45 CFR §164.514(e))	**THIS POLICY HAS BEEN REVIEWED AND APPROVED ELECTRONICALLY:** J. Glover Taylor Director, Sponsored Research Administration Lior Givon, MD, PhD Co-Chair, Institutional Review Board Patrick Wardell Chief Executive Officer
Keywords(s)	HIPAA PHI

I. Purpose

To define Cambridge Health Alliance guidelines, policies, and procedures, in accordance with federal and Massachusetts law, regarding the informed consent for research and the Health Insurance Portability and Accountability Act (HIPAA) authorization for the use and disclosure of protected health information (PHI) for research purposes.

II. Personnel: All Alliance Research Staff

III. Policy

Research involving human subjects may be subject to the “Common Rule” (codified for the Department of Health and Human Services at 45 C.F.R. § 46.). While the Common Rule provides for some research participant confidentiality protections, the HIPAA Privacy Rule adds substantially greater privacy protections for human subjects and establishes the conditions under which Protected Health

Information (PHI) may be used or disclosed by the Cambridge Health Alliance for research purposes.

Human subject research approved by the CHA IRB prior to January 21, 2019 may continue to be governed by the CHA *Informed Consent for Research and Authorization for the Use and Disclosure of Protected Health Information* policy effective prior to that date.

CHA's policy with respect to human subjects involved in research under the Common Rule and with respect to the use or disclosure of PHI for research purposes is as follows:

A. Informed Consent.

No research involving human subjects may be conducted unless:

(i) signed informed consent to participate in the research study is obtained from the research subject; or

(ii) a waiver of informed consent has been approved by the CHA Institutional Review Board (IRB) .

B. Privacy Rule.

1. General Rule.

No research involving uses or disclosures of a subject's PHI may be conducted unless:

(a) signed written authorization for use or disclosure of such information is obtained from the subject;

(b) a waiver of signed authorization has been approved by the IRB which serves as CHA's Privacy Board;

(c) the PHI has been de-identified;

(d) the PHI is used or disclosed in a limited data set in accordance with a data use agreement; or

(e) one of the exceptions listed in B.2 below applies.

2. Exceptions:

The following circumstances shall be exceptions to the Privacy Rule requirements of this policy:

(a) A subject's PHI may be disclosed to a person subject to the jurisdiction of the Food and Drug Administration (FDA) with respect to a FDA-regulated product or activity for which that person has responsibility, for the purpose of activities related to the quality, safety, or effectiveness of such FDA-regulated product or activity, including but not limited to:

(i) collecting or reporting adverse events, product defects or problems, or biological product deviations;

(ii) to track FDA-regulated products;

(iii) to enable product recalls, repairs, replacement, or reference activities; or

(iv) to conduct post marketing surveillance.

(b) PHI may be used by or disclosed to a researcher as necessary to prepare a research protocol or for similar purposes preparatory to research provided the researcher

represents to CHA that:

(i) the use or disclosure is sought solely for such purposes;

(ii) no PHI will be removed from CHA premises by the researcher in the course of the review; and

(iii) the PHI for which use or access is sought is necessary for the research purposes.

(c) PHI may be used by or disclosed to a researcher for research on decedents provided the researcher:

(i) represents to CHA that the use or disclosure is sought solely for research on the PHI of decedents;

(ii) provides to CHA, upon request, documentation of the death of the research subject; and

(iii) represents to CHA that the PHI is necessary for the research.

IV. Procedure

A. Informed Consent:

Informed Consent is the process by which information is presented to an individual or their legally authorized representative, to enable such individual to voluntarily decide whether or not to participate in a research study. Informed consent is documented by the use of a written consent form approved by the IRB and signed by the subject or their legally authorized representative. Such consent form will be provided to a subject or their legally authorized representative prior to such subject's participation, unless a waiver of informed consent is approved by the IRB.

Written: A written consent document that embodies all of the elements of consent outlined in this policy (and where applicable, the Common Rule, the Privacy Rule, and/or FDA research regulations (21 CFR 50)), is signed by the subject, a copy of which is given to the subject; or if a written consent is not feasible, a waiver of consent may be requested from the IRB. If approved, a waiver of consent may authorize alternative methods of obtaining consent that are consistent with the consent processes described in the IRB Operations Manual.

1. General Requirements for Informed Consent (whether written or oral):

(a) Before involving a human subject in research, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.

(b) Informed consent is to be sought only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate, and that minimize the possibility of coercion or undue influence.

(c) The information that is given to the subject or the legally authorized representative shall

be in language understandable to the subject or the legally authorized representative (seventh-grade reading level).

(d) The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

(e) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

Key information includes:
- Consent is being sought for research; participation is voluntary.
- Purposes, expected duration of participation, study procedures.
- Reasonably foreseeable risks or discomforts to subjects.
- Benefits to subjects, others that may reasonably be expected.
- Alternatives, if any, that might be advantageous.

(f) Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

(g) Exculpatory Language. The informed consent shall not include any exculpatory through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, CHA or its agents, or another institution from liability for negligence.

[NOTE: Although the Common Rule allows for Broad Consent, this option may not be used at CHA.]

2. Basic Elements of Informed Consent. The informed consent shall be written in understandable language (Seventh Grade level) and contain the following:

(a) a statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of experimental procedures;

(b) a description of reasonably foreseeable risks and discomforts to the subject;

(c) a description of any benefits to the subject or to others which may be reasonably expected from the research;

(d) a disclosure of appropriate alternative treatments that might be advantageous;

(e) a statement describing the extent to which the confidentiality of records will be

maintained;

(f) an explanation of whether compensation will be paid and if injury occurs, whether treatment is available and where further information may be obtained;

(g) an explanation of whom to contact about the research, the subject's rights and any research related injury; and

(h) a statement that participation in the research study is voluntary, and refusal to participate or discontinuance with the study carries no penalty or loss of benefits to which the subject is otherwise entitled.

(i) for any research that involves the collection of identifiable private information or identifiable biospecimens, a statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility.

[NOTE: For more information on how to write an Informed Consent and for institutional templates, please visit the CHA IRB website on staffnet. Search for "IRB"]

3. Additional Elements of Informed Consent. The informed consent should also provide one or more of the following provisions when applicable:

(a) a statement that the treatment or procedure may involve currently unforeseeable risks to the subject (or to the embryo or fetus for subjects who are or may become pregnant);

(b) anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or legally authorized representative's consent;

(c) any costs to the subject that may result from participation in the study;

(d) the consequences of a subject's decision to withdraw from the research and procedures of how a subject may terminate his or her participation;

(e) a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject;

(f) the approximate number of subjects involved in the study;

(g) a statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;

(h) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and

(i) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.,* sequencing of a human germline or somatic specimen with

the intent to generate the genome or exome sequence of that specimen).

Form. A copy of the CHA template **"Informed Consent and Authorization to Use and Disclose Protected Health Information for Research"** that meets these standards can be found on the CHA IRB website on staffnet (search: IRB website).

4. Revocation of Consent/Permission: A study participant or his/her legally authorized representative can revoke the subject's consent to participate in the research and/or authorization to use and disclose the subject's PHI. This can be done by the subject or his/her legally authorized representative telling a member of the study team that the subject no longer wishes to participate in the study.

B. HIPAA Authorization:

In addition to informed consent, under the HIPAA Privacy Rule, authorization for the use and disclosure of PHI for research purposes must be obtained from the research subject, unless a waiver of authorization is approved by the IRB, the information is de-identified, the PHI is disclosed in a limited data set pursuant to a data use agreement, or one of the authorization exceptions set forth in Part 1.B.2 above applies.

1. When requesting an authorization from a subject, Research staff of CHA shall use the **"Informed Consent and Authorization to Use and Disclose Protected Health Information for Research"** form that contains:
   (a) a description of the information to be used or disclosed;
   (b) identification of the persons or class of persons authorized to make the use or disclosure;
   (c) the identification of the persons or class of persons to whom the information may be disclosed;
   (d) an expiration date or expiration event that relates to the individual or the purpose of the disclosure, which expiration date or event may be "none", "end of research study" or similar language;
   (e) a description of each purpose of the requested use or disclosure;
   (f) a statement of the right to revoke the authorization in writing, procedures to revoke the authorization and exceptions to the right to revoke,
   (g) a statement that information used or disclosed pursuant to an authorization may be subject to re-disclosure and may no longer be protected by the federal privacy protections;
   (h) the signature of the subject and date; or if the authorization is signed by a personal representative of the subject, a description of such representative's authority to act for the subject;
   (i) a statement regarding the ability or inability of CHA to condition treatment, payment, enrollment or eligibility for benefits on the authorization by stating either that:

(1) The research team of CHA may not condition treatment, payment, enrollment or eligibility for benefits on whether the participant signs the authorization when such prohibition applies, or

(2) The research team of CHA is permitted to place such conditions, then an explanation of the consequences of the participant's refusal to sign the authorization.

2. The authorization is written in plain language.

3. The principal investigator of CHA provides the individual with a copy of the signed authorization.

C. Waiver of Informed Consent/HIPAA Authorization:

When relying on a waiver or alteration of informed consent to participate in a research study, the IRB shall find and document the following:

1. Criteria for Approving a Waiver of Informed Consent under the Common Rule

An IRB may not omit or alter any of the *General Requirements for Informed Consent*.

(a) *Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials*.

An IRB can approve a waiver or alteration of informed consent if:

i. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials, and is designed to study, evaluate, or otherwise examine:
   - a public benefit or service program;
   - procedures for obtaining benefits or services under those programs;
   - possible changes in or alternatives to those programs or procedures; or
   - possible changes to payment methodology or levels of payment for benefits or services under those programs; and

ii. The research could not practicably be carried out without the waiver or alteration.

(b) *General waiver or alteration of consent.*

An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent for research, provided the IRB finds and documents that:

(i) the research involves no more than minimal risk to the subjects;

(ii) the research could not practicably be carried out without the requested waiver or alteration;

(iii) if the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

(iv) the waiver or alteration does not adversely affect the rights and welfare of the subjects; and

(v) whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

(c) *Screening, recruiting, or determining eligibility.*

An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:

(i) the investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or

(ii) the investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

(d) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds any of the following:

(i) That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;

(ii) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or

(iii) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

2. Criteria for Approving Waiver of Authorization for the Use and Disclosure of PHI under the HIPAA Privacy Rule

(a) The CHA IRB shall approve the waiver or alteration of signed authorization only if it can document that the following criteria for the waiver or alteration have been met:

(i) The use or disclosure of PHI involves no more than minimal risk to the individuals or their privacy, based on:

(a) an adequate plan to protect identifiers from improper use and disclosure;

(b) an adequate plan to destroy the identifiers at the earliest opportunity (unless there is a health or research justification for retaining identifiers or such retention is otherwise required by law); and

(c) adequate assurances that the PHI will not be reused or disclosed to any other person or entity except as required by law, for authorized oversight of the research project, or for other research permitted under this policy.

(ii) The research could not practicably be conducted without the alteration or waiver, and

(iii) The research could not practicably be conducted without access to and use of the PHI and the PHI to be accessed is the minimum information necessary to conduct the research.

(b) CHA's IRB shall approve the HIPAA waiver or authorization only if, in addition to the documentation required above, the CHA Privacy Board includes in the waiver or alteration approval documentation of the following:

(i) a brief description of the PHI to be used or disclosed;

(ii) a statement that the alteration or waiver of authorization has been reviewed and approved by the IRB under normal or expedited procedures; and

(iii) the signature of the Chair of the IRB or other member, as designated by the Chair.

(d) When relying on a waiver of authorization approval by the IRB, the Principal Investigator must report all use of PHI to the CHA HIPAA Privacy Office for tracking purposes.

A sample of the CHA's **"Informed Consent and Authorization to Use and Disclose Protected Health Information for Research"** that meets these standards can be found on the CHA IRB website on staffnet (search: IRB website).

A. De-identification:

CHA is not required to satisfy the informed consent requirement if the IRB determines that the health information is de-identified. Health information is de-identified only if:

1. a person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable determines that the risk is very small, that the information could be used alone or in combination with other reasonable available information by an anticipated recipient to identify a subject and documents the methods and results of the analysis that justify the determination, or

2. the following identifiers of the subject or relatives, employers, or household members of the subject are removed and CHA does not have any actual knowledge that the information could be used alone or in combination with other information to identify the subject. Such identifiers as defined by HIPAA are:
   (a) Names;
   (b) Geographic subdivisions smaller than a state (except the initial three digits of a zip code if the division contains more than 20,000 people);
   (c) All elements of dates except year (and for ages greater than 89, age unless grouped together into a single category of age 90 or older);
   (d) Telephone numbers;
   (e) Facsimile numbers;
   (f) Electronic mail addresses;
   (g) Social security numbers;
   (h) Medical record numbers;
   (i) Health plan beneficiary numbers;
   (j) Account numbers;
   (k) Certificate/license numbers;
   (l) Vehicle identification numbers;
   (m) Device identifiers;
   (n) Web universal resource locators;
   (o) Internet protocol addresses;
   (p) Biometric identifiers (e.g., finger/voice prints);
   (q) Full face photographic and any comparable images;
   (r) Any other unique identifying number characteristic or code, provided, however, that a code used by CHA to re-identify the de-identified information is permitted so long as the code is not derived from or related to information about the subject and CHA does not use or disclose the code for any other purpose and does not disclose the mechanism for re-identification.

A. Limited Data Set:

CHA may use PHI to create a limited data set, or disclose PHI to a business associate to create a limited data set, for research purposes provided CHA obtains satisfactory assurance, in a data use agreement, that the limited data set recipient will only use the PHI for limited purposes.

1. A limited data set is protected health information that excludes the following direct identifiers of

the subject or of relatives, employers, or household members of the subject:

(a) Names,
(b) Postal address information,
(c) Telephone numbers,
(d) Fax numbers,
(e) Electronic mail addresses,
(f) Social security numbers,
(g) Medical record numbers,
(h) Health plan beneficiary numbers,
(i) Account numbers,
(j) Certificate/license numbers,
(k) Vehicle identification numbers and serial numbers (including license plate numbers),
(l) Device identifiers and serial numbers,
(m) Web Universal Resource Locators,
(n) Internet Protocol address numbers,
(o) Biometric identifiers (including finger and voice prints), and
(p) Full face photographic images and any comparable images.

2. A data use agreement between CHA and the limited data set recipient must:
   (a) establish that the recipient will only use and disclose the limited data set information for purposes of research, public health or health care operations;
   (b) establish who is permitted to use or receive the limited data set;
   (c) provide that the recipient will:
      (i) not use or further disclose the limited data set information other than as permitted by the data use agreement or as otherwise required by law;
      (ii) use appropriate safeguards to prevent use or disclosure of the limited data set information other than as provided for by the data use agreement;
      (iii) report to CHA any use or disclosure of the limited data set information other than as provided for in the data use agreement;
      (iv) ensure that any agents, including a subcontractor, to whom the recipient provides the limited data set information agrees to the same restrictions and conditions that apply to the recipient; and
      (v) not identify the limited data set information or contact the subjects.

3. The **Cambridge Health Alliance's "Limited Data Set Use Agreement"** can be found on the CHA IRB website on staffnet (search: IRB website).

Approver	Approved (initial)	Not Approved (initial)
Glover Taylor	JGT	
Patrick Wardell	PRW	
Lior Givon	LG	