CAMBRIDGE HEALTH ALLIANCE Title: Informed Consent for Research and Authorization for the Use and Disclosure of Patient Health Information	Replaces (supercedes) Title:	Policy Number: **A-COM-0004** Policy Type: **Administrative** Effective Date: 04/13/03
Area of Operation(s): Institutional Review Board (IRB)	Policy Chronicle: Date Original Version of Policy was Effective: 04/13/03 Date of Previous Review/Revision to the Policy: 04/13/03 Date of Most Recent Review/Revision to the Policy: 07/01/06 Signature of Most Recent Reviewer/Reviser: _____ Printed Name of Most Recent Reviewer/Reviser: Glover Taylor	
Regulatory Agency/Standards: JCAHO/IM Dept. of Health & Human Services/HIPAA (45 CFR §164.514(e)	Approvals: Chair, Institutional Review Board:_____ Stephen Pinals, MD Chief Executive Officer:_____ Dennis Keefe	
Keyword(s):	Informed Consent, Authorization, HIPAA, Disclosure, Research	

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 authorization for the use and disclosure of protected health information.

II. Personnel: All Alliance Research Staff

III. Policy

Research involving human subjects is subject to the Common Rule (codified for the Department of Health and Human Services at 45 C.F.R. § 46 et al.). While the Common Rule provides for some patient confidentiality protections, the 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. The **Cambridge Health Alliance'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) an 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 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) an informed consent for use or disclosure of such information is obtained from the subject;
(b) a waiver has been approved by the IRB;
(c) the health information has been de-identified;
(d) the health information 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 an 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) Protected health information 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 the **Cambridge Health Alliance** that:
(i) the use or disclosure is sought solely for such purposes;
(ii) no protected health information will be removed from the **Cambridge Health Alliance's** premises by the researcher in the course of the review; and
(iii) the protected health information for which use or access is sought is necessary for the research purposes.
(c) Protected health information may be used by or disclosed to a researcher for research on decedents provided the researcher:
(i) represents to the **Cambridge Health Alliance** that the use or disclosure is sought solely for research on the protected health information of decedents;
(ii) provides to the **Cambridge Health Alliance**, upon request, documentation of the death of the research subject; and
(iii) represents to the **Cambridge Health Alliance** that the protected health information is necessary for the research.

IV. Procedure

A. Informed Consent:
Informed Consent is the process by which information is presented to an individual, to enable such individual to voluntarily decide whether or not to participate as a research subject. An informed consent is documented by the use of a written consent form approved by the IRB and signed by the subject. Such consent form will be provided to a subject in either of the following manners prior to such subject's participation unless a waiver of informed consent is approved by an IRB:

(i) Written. A written consent document that embodies all of the elements of the Common Rule and Privacy Rule is signed by the subject, a copy of which is given to the subject; or

Oral. Oral consent may be used only in exceptional circumstances where written consent cannot be practically administered and oral consent will provide adequate opportunity for subjects to make an informed decision. Use of oral consent is subject to prior approval by the IRB. A short form written consent document, stating that the necessary elements of the informed consent have been presented orally to the subject or the subject's legal representative, is signed by the subject or the subject's legal representative, a witness to the oral presentation and the person obtaining the consent, and a copy of the summary is given to the subject.

1. Informed Consent Criteria. The informed consent shall be written in understandable language (Sixth Grade level) and contain the following criteria:
   (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.

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

2. Additional Criteria. 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 consent;
   (c) any additional 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; and
   (f) the approximate number of subjects involved in the study.

3. Exculpatory Language. The informed consent shall not contain any exculpatory language or release of **Cambridge Health Alliance**, an investigator, sponsor or other institution.

4. Form. A copy of the **Cambridge Health Alliance's "Informed Consent Form for Research and Authorization to Use and Disclose Protected Health Information"** that meets these standards can be found on the CHA IRB website on staffnet. Click on the link below:

   http://staffnet/Academic/ResearchAdministrationHumanSubjectsProtectionIRB.asp

5. Revocation by Patient. The patient can revoke his/her consent to participate in the research and/or authorization to use and disclose of the patient's health information. A copy of the **Cambridge Health Alliance's "Revocation of Informed Consent for Research and/or Authorization to Use and Disclose of Protected Health Information"** that meets these standards can be found on the CHA IRB website staffnet. Click on the link below:

   http://staffnet/Academic/ResearchAdministrationHumanSubjectsProtectionIRB.asp

B. Authorization:

In addition to informed consent, under the Privacy Rule, authorization for the use and disclosure of protected health information for research purposes must be obtained from the research subject, unless a waiver of authorization is approved by an IRB or Privacy Board, the information is de-identified, the protected health information 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, all Research staff of **Cambridge Health Alliance** shall use the Informed Consent and Authorization to Use and Disclose of Patient Health Information 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 the **Cambridge Health Alliance** to condition treatment, payment, enrollment or eligibility for benefits on the authorization by stating either that:

(1) The research team of **Cambridge Health Alliance** 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 **Cambridge Health Alliance** is permitted to place such conditions, then an explanation of the consequences of the participant's refusal to sign the authorization.

3. The authorization is written in plain language.

4. The principal investigator of **Cambridge Health Alliance** provides the individual with a copy of the signed authorization.

C. Waiver of Informed Consent/Authorization:

When relying on a waiver or alteration of an informed consent to participate in a research study, the IRB [or Privacy Board, as applicable] shall document the following:

1. Criteria for Approving a Waiver of Informed Consent under the Common Rule
An IRB can approve a waiver of informed consent if:
(a) The research is to be conducted by or subject to the approval of state or local government officials, and is designed to study:
(i) a public benefit or service program;
(ii) procedures for obtaining benefits or services under those programs;
(iii) changes or alternative to those programs or procedures; and
(iv) changes to payment methodology; or

(b) For other research purposes:
(i) the research involves no more than minimal risk to the subjects;
(ii) the waiver or alteration does not adversely affect the rights and welfare of the subjects; and
(iii) whenever appropriate, the subjects are provided with additional pertinent information after the conclusion of their participation in the study.

2. Criteria for Approving Waiver of Authorization for the Use and Disclosure of Patient Health Information under the Privacy Rule
(a) The **Cambridge Health Alliance's** IRB or Privacy Board shall approve the waiver or alteration of the informed consent only if it can document that the following criteria for the waiver or alteration have been met:
(i) The use or disclosure of protected health information 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 protected health information will not be reused or disclosed to any other person or entity except as required by

law, for authorized oversight of the research project, or for other research 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 protected health information.

(b) The **Cambridge Health Alliance's** IRB or Privacy Board shall approve the waiver or authorization only if, in addition to the documentation required above, the **Cambridge Health Alliance's** IRB or Privacy Board includes in the waiver or alteration approval document the following:

(i) a brief description of the protected health information to be used or disclosed;
(ii) a statement that the alteration or waiver of authorization has been reviewed and approved by the IRB [or Privacy Board] 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 protected health information to the Privacy Office for tracking purposes.

(e) A sample of the **Cambridge Health Alliance's "Request for Waiver or Alteration of Informed Consent Authorization"** that meets these standards can be found on the CHA IRB website on staffnet. Please click on the link below.

http://staffnet/Academic/ResearchAdministrationHumanSubjectsProtectionIRB.asp

D. De-identification:

The **Cambridge Health Alliance** is not required to satisfy the informed consent requirement if an IRB or Privacy Board 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 the **Cambridge Health Alliance** 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 determined by HIPAA guidelines 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 **Cambridge Health Alliance** 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 the **Cambridge Health Alliance** does not use or disclose the code for any other purpose and does not disclose the mechanism for re-identification.

E. Limited Data Set:

The **Cambridge Health Alliance** may use protected health information to create a limited data set, or disclose protected health information to a business associate to create a limited data set, for research purposes so long as the **Cambridge Health Alliance** obtains satisfactory assurance, in a data use agreement, that the limited data set recipient will only use the protected health information 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 the **Cambridge Health Alliance** 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 **Cambridge Health Alliance** 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. Please click on the link below:

   http://staffnet/Academic/ResearchAdministrationHumanSubjectsProtectionIRB.asp