

Seattle Cancer Care Alliance

Administrative Policies and Operating Procedures

Section: Privacy

Policy Title: Use & Disclosure of Protected Health Information (PHI) for Research

Purpose/Background

To state the policy of the Seattle Cancer Care Alliance (SCCA) with respect to the Health Insurance Portability and Accountability Act (HIPAA) requirements for the use and/or disclosure of protected health information for research.

The Privacy Rule permits the SCCA, a covered entity, to use or disclose PHI for research under the following circumstances and conditions:

- For reviews preparatory to research if certain representations are obtained from the researcher
- For research solely on decedents' information if certain representations are obtained from the researcher
- If the subject of the PHI has granted specific written permission through an Authorization
- If the SCCA receives appropriate documentation that the IRB has granted a waiver or an alteration of the Authorization requirements
- If the PHI has been de-identified in accordance with the standards set by the Privacy Rule (in which case the health information is no longer PHI)
- If the information is released in the form of a limited data set, with certain identifiers removed, and with a data use agreement between the researcher and the covered entity
- If informed consent of the individual to participate in research, an IRB waiver of such informed consent, or other expressed legal permission to use or disclose the information for the research is grandfathered by the transition provisions.

Definitions

Disclosure of protected health information means the release, transfer, and provision of access to or divulging of such information outside of the entity holding the information.

Institutional Review Board (IRB) is a committee formally designated to review research involving human subjects. The IRB approves the initiation of new research and conducts reviews of ongoing research, and shall have sole discretion to approve an alteration to or waiver, in whole or in part, of the individual Authorization required by the Privacy rule.

Protected Health Information means, generally, health information that is individually identifiable (i.e., patient-specific) and that is created, maintained, used or disclosed by or for the SCCA. More specifically, the term refers to information that:

- (i) identifies or could reasonably be used to identify the individual; and
- (ii) relates to:
 - a. an individuals' physical or mental health or condition;
 - b. the provision of health care to an individual, or
 - c. payment for health care provided to an individual

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute “Research” for the purposes of this policy, whether or not they are supported or funded under a program that is considered research for other purposes. This definition includes activities preparatory to the conduct of research; for example, activities conducted in support of a grant or proposal preparation, pilot studies, and feasibility studies.

Limited Data Set means a set of patient health information from which certain individually identifiable information has been removed. See SCCA policy “*De-identification of Protected Health Information (PHI)*” for a list of the sixteen direct identifiers that must be excluded from a Limited Data Set.

Data Use Agreement means a written agreement between the SCCA and the person or entity requesting patient health information (i.e., researcher) in the limited data set for research, health care operations, or public health purposes. See SCCA policy “*De-identification of Protected Health Information (PHI)*” for more on Data Use Agreement.

Researcher’s Representation means a written statement from the researcher attesting to specific criteria or conditions.

Policy

The SCCA will adhere to all federal and state regulatory requirements concerning the use and/or disclosure of Protected Health Information (PHI) for research purposes. To do so, the SCCA will adhere to:

- (i) regulatory requirements for obtaining patient Authorization prior to the use and/or disclosure of protected health information for research purposes;
- (ii) regulatory requirements pertaining to review by the Institutional Review Board of an Authorization waiver or alteration request;
- (iii) regulatory requirements for documenting the disclosure of protected health information for research purposes;
- (iv) regulatory requirements for patient access to protected health information for research purposes, including allowable restrictions to patient access

I. Authorization Requirements for the Use and Disclosure of PHI for Research

Individual patients must provide voluntary and informed Authorization (Authorization language may be embedded in a research consent document) before protected health information about that individual is used and/or disclosed for research purposes. This standard does not apply where the HIPAA privacy regulations provides an exception to the Authorization requirements (see below for *Exceptions to Authorization*). The research Authorization is study-specific (i.e., study participant will provide separate Authorization for each study), unless otherwise allowed by the IRB, and must include the following criteria:

- a) a description of how protected health information will be used or disclosed for the research study;
- b) a description of the research participant’s access rights to his or her own protected health information, including a statement about any restrictions on the participants’ ability to access his or her own protected health information;

- c) a date or event describing when the Authorization expires (statements such as “the end of the research study” or “there is no expiration” are permitted);
- d) a statement describing the individual’s right to revoke the Authorization, including a description of how the individual may revoke the Authorization and any exceptions to the individual’s right to revoke the Authorization;
- e) the signature of the research participant and date. If a personal representation of the individual signs the Authorization, a description of the representative’s authority to act for the individual must also be provided.

II. Institutional Review Board (IRB) Review

Institutional Review Boards affiliated with the SCCA are charged with reviewing requests to alter the Authorization requirement, and requests to waive the Authorization requirement. All human subject research, including those that are exempted under the Privacy Rule from Authorization requirement, must be reviewed by an IRB. Investigators and/or research staff are responsible for providing written documentation of IRB review and approval, as appropriate, to the SCCA when requesting use and/or disclosure of PHI for research purposes. *(Contact the SCCA Research Implementation Office for information regarding IRBs that are affiliated with the SCCA.)*

Drug and alcohol abuse treatment records included in PHI are subject to more stringent protections and the SCCA will apply the stringent requirements. The designated IRBs shall serve as the broker of access to these records for research purposes to comply with the requirements of state and federal regulations.

III. Exceptions to Authorizations for the Use and Disclosure of PHI for Research

Waiver or Alteration of the Authorization Requirement

For some types of research, it may be impractical for researchers to obtain written Authorization from research participants. The Privacy Rule allows for the waiver or alteration of the Authorization requirement by an IRB. The SCCA will permit the use and disclosure of PHI for research purposes without a signed Authorization (or with an altered Authorization), if it receives proper documentation from the researcher that an affiliated IRB has granted a waiver (or an alteration) of the Authorization requirement. The researcher must provide documentation of, among other things, the IRB’s determination that the following criteria have been met:

- The PHI use or disclosure involves no more than a minimal risk to the privacy of individuals based on at least the presence of (1) An adequate plan presented to the IRB to protect PHI identifiers from improper use and disclosure; (2) an adequate plan to destroy those identifiers at the earliest opportunity, consistent with the research, absent a health or research justification for retaining the identifiers or if retention is otherwise required by law; and (3) adequate written assurances that the PHI will not be reused or disclosed to any other person or entity except (a) as required by law, (b) for authorized oversight of the research study, or (c) for other research for which the use or disclosure of the PHI is permitted by the Privacy Rule.
- The research could not practicably be conducted without the requested waiver or alteration.
- The research could not practicably be conducted without access to and use of the PHI.

Individual(s) accessing PHI under a waiver of authorization will adhere to the SCCA requirements to meet and account for disclosures of all PHI accessed in accordance with SCCA policy *“Accounting of Disclosures of Protected Health Information (PHI)”*.

De-Identified Health Information. Individual Authorization is not required for the use or disclosure of de-identified health information for research because de-identified data is not PHI and, therefore, not subjected to the Privacy Rule. The data must be de-identified in accordance with SCCA’s policy *“De-Identification of Protected health Information (PHI)”* and a designated IRB has reviewed and approved the creation of the de-identified data set.

Limited Data Sets. Individual Authorization is not required for use or disclosure of health information in a limited data set, provided the health information is used or disclosed for research purposes and meets the criteria for limited data set. A signed data use agreement must be in place between the investigator and the SCCA, in accordance with the SCCA policy *“De-identification of Protected Health Information (PHI)”* and a designated IRB has reviewed and approved the creation of the limited data set.

Activities Preparatory to Research.

The SCCA may permit researchers to review PHI in medical records or elsewhere to prepare a research protocol, or for similar purposes preparatory to research. This review allows the research to determine, for example, whether a sufficient number or type of records exists to conduct the research. No PHI shall be removed from the SCCA facility or information systems. To allow a researcher to conduct a review preparatory to research, the SCCA must receive from the researcher representation that:

- The use or disclosure is sought solely to review PHI as necessary to prepare the research protocol or other similar preparatory purposes.
- No PHI will be removed from the SCCA facility or information systems during the review.
- The PHI the researcher seeks to use or access is necessary for the research purposes.

Screening activities, feasibility, and/or pilot studies that involves the use of human subjects either directly or through individually identifiable health records or other data such as samples, specimens, or autopsy materials, require review and approval by an IRB affiliated with the SCCA.

Research Involving Decedent’s PHI. The use of PHI of individuals who are no longer alive requires IRB review and approval. The IRB may require consent from a legally authorized surrogate or may authorize a waiver of consent in accordance with state law RCW 70.02. Documentation of the death of the individual about whom information is sought must be available to the SCCA upon request.

IV. Security Requirements

All individuals performing research must meet the SCCA policy for General Computing and Access to Electronic Systems.

V. Failure to Comply

Failure to comply with the specified requirements or misuse or misappropriation of health information for research purposes may result in disciplinary action. (See SCCA policy *“Sanctions for the Failure to Follow Applicable Privacy Policy or for a Breach of Patient Confidentiality or Security”*).

Procedures

Use of electronic PHI for research is tracked and auditable via the various software systems that contain PHI. Auditable software systems include ORCA/Mindscape, IDX, Gateway, Labvision, CODI and others. The requirements listed in the policy section above are still applicable and must be followed. A copy of the signed consent form or the IRB-approved waiver of consent is required when requesting access to hard copy medical records.

If you have questions about whether you must account for the disclosure of PHI for research or other aspects of this policy when you are accessing and using PHI for research, please contact the Research Implementation Office at 288-1287 or 288-6607.

Use of residual clinical specimens for research:

1. Requestor will contact the laboratory in possession of the residual clinical specimen.
2. A laboratory representative will provide the requestor with the Use of Residual Specimens for Research worksheet located in the O:\Forms folder.
3. The requestor will complete the form and submit it to the lab staff.
4. Lab staff will review the form for completeness. If questions or concerns, lab staff will contact their lab supervisor, the Research Implementation Office or the Privacy Officer.
5. If the request has been approved by an IRB using a participant consent or authorization, no accounting of disclosure is required. Laboratory staff will provide the requested specimens to the requestor and send the completed Use of Residual Specimens for Research worksheet to the Integrity Program at G6-060.
4. If the request has been approved by an IRB using a **waiver of consent** or authorization, an accounting of disclosure is required. Laboratory staff will obtain the following information and forward it to the SCCA Health Information Management (HIM) Release of Information (ROI) area [G6-202] to centrally track all accountings of disclosure at the SCCA:
 - Name(s) and U-number(s) of research participant(s)
 - A summary of what is being or was disclosed to the requestor
 - Date of PHI being disclosed (can also be a date range)
 - To whom the PHI is being disclosed
 - Purpose of disclosure
 - Date PHI disclosed to requestor
 - Name and contact number of SCCA staff person handling request and documenting disclosure
5. Documentation of PHI disclosed will be recorded and maintained by Health Information Management and filed in the designated record set.

References

- I. Privacy APOP: Accounting of Disclosures of PHI/Designated Record Set.
- II. 45 CFR Part 160 and 164; Section 164.512(i) – “Uses & Disclosures for Which Consent, Authorization or Opportunity to Agree or Object is Not Required – Research Purposes”.

- III. RCW 70.96A.150 – Drug and Alcohol Abuse Treatment Records; 42 C.F.R. Part 2.
- IV. References specific to Policy Section I. A.: 7 CFR 1c.107, 10 CFR 745.107, 14 CFR 1230.107, 15 CFR 27.107, 16 CFR 1028.107, 21 CFR 56.107, 22 CFR 225.107, 24 CFR 60.107, 28 CFR 46.107, 32 CFR 219.107, 34 CFR 97.107, 38 CFR 16.107, 40 CFR 26.107, 45 CFR 46.107, 45 CFR 690.107 **or** 49 CFR 11.107
- V. References specific to Policy Section II. A. 3. (a) – Normal Review Procedures: 7 CFR 1c.108(b), 10 CFR 745.108(b), 14 CFR 1230.108(b), 15 CFR 27.108(b), 16 CFR 1028.108(b), 21 CFR 56.108(b), 22 CFR 225.108(b), 24 CFR 60.108(b), 28 CFR 46.108(b), 32 CFR 219.108(b), 34 CFR 97.108(b), 38 CFR 16.108(b), 40 CFR 26.108(b), 45 CFR 46.108(b), 45 CFR 690.108(b) **or** 49 CFR 11.108(b).
- VI. References specific to Policy Section II. A. 3. (a) – Expedited Review Procedures: 7 CFR 1c.110, 10 CFR 745.110, 14 CFR 745.110, 14 CFR 1230.110, 15 CFR 27.110, 16 CFR 1028.110, 21 CFR 56.110, 22 CFR 225.110, 24 CFR 60.110, 28 CFR 46.110, 32 CFR 219.110, 34 CFR 97.110, 38 CFR 16.110, 40 CFR 26.110, 45 CFR 46.110, 45 CFR 690.110 **or** 49 CFR 11.110.

Attachments

Attachment A: Use of Residual Specimens for Research Worksheet

Approval

Director:	Julie Hamilton	Approval Date:	05/19/06
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