



Privacy Board

Standard Operating Procedures

I. Background

The Health Insurance Portability and Accountability Act (“HIPAA”) generally requires specific compliance reviews and documentation by a Privacy Board in accordance with the HIPAA regulations when protected health information (“PHI”) managed by a University of Colorado Colorado Springs (“UCCS”) covered entity (“CE”) is used and/or disclosed for research purposes. The UCCS Privacy Board is critical for UCCS’s compliance with the HIPAA Privacy Rule (45 CFR 160 & 164).

Submissions to the UCCS Privacy Board are processed through expedited HIPAA Privacy Rule review procedures. Expedited review is permitted for research projects that are determined to involve no more than minimal risk to the privacy of the individuals who are the subject of the PHI for which use or disclosure is sought. A submission undergoes expedited review by the Chair or by a designated member of the UCCS Privacy Board, hereinafter referred to as “Board Member”.

II. Definitions

A. Altered HIPPA Authorization

A HIPAA Authorization, also known as an “Authorization”, in which some required elements are modified or removed and the UCCS Privacy Board determines that specific criteria within the HIPAA Privacy Rule have been met. For example, an alteration of the Authorization might be requested to remove the element that describes each purpose of the requested use or disclosure where the identification of the specific research project would affect the results of the project.

B. Application for a Waiver of Authorization or an Altered Authorization

A template used to apply for review by the UCCS Privacy Board for a waiver of Authorization(s) or an altered Authorization. The answers provided in the application assist the UCCS Privacy Board in determining if a full or partial waiver or an altered Authorization is appropriate under the HIPAA Privacy Rule for the particular research study.

C. Authorization

An Authorization is an individual's signed permission to use or disclose the individual's PHI that is described in the Authorization for the purpose(s) and to the recipient(s) stated in the Authorization. In order to be valid, an Authorization must contain all of the required elements and core statements outlined in the HIPAA Privacy Rule at 45 CFR 164.508(c). The signed Authorization must be retained for at least 6 years as per the privacy rule.

D. Data Use Agreement (DUA)

A data use agreement entered into by both the covered entity and the researcher, pursuant to which the covered entity may disclose a limited data set to the researcher for research, public health, or health care operations. See 45 CFR 164.514(e). A limited data set excludes specified direct identifiers of the individual or of relatives, employers, or household members of the individual. The data use agreement must:

1. Establish the permitted uses and disclosures of the limited data set by the recipient, consistent with the purposes of the research, and which may not include any use or disclosure that would violate the Rule if done by the covered entity;
2. Limit who can use or receive the data; and
3. Require the recipient to agree to the following:
 - a. Not to use or disclose the information other than as permitted by the data use agreement or as otherwise required by law;
 - b. Use appropriate safeguards to prevent the use or disclosure of the information other than as provided for in the data use agreement;
 - c. Report to the covered entity any use or disclosure of the information not provided for by the data use agreement of which the recipient becomes aware;
 - d. Ensure that any agents, including a subcontractor, to whom the recipient provides the limited data set agree to the same restrictions and conditions that apply to the recipient with respect to the limited data set; and
 - e. Not to identify the information or contact the individual.

E. Waiver of Authorization

A waiver granted by an IRB or UCCS Privacy Board when certain criteria, set forth in the HIPAA Privacy Rule at 45 CFR 164.512(i)(2), are met. Either of the following two types of waivers may be approved:

1. **Full Waiver:** Enables a research project to obtain PHI about research participants without obtaining signed Authorizations from research participants at any point during the project.
2. **Partial Waiver:** Enables a research project to obtain PHI about research participants without obtaining signed Authorizations from the participants for part of the research project, but not the entire research project. Examples of when Partial Waivers are appropriate include when PHI is necessary for recruitment/screening of potential research participants, after which PHI is no longer necessary or until a point at which Authorizations can be obtained from all research participants.

F. Internal Review Checklist

A template used by the UCCS Privacy Board to ensure uniform, consistent, and thorough reviews of a completed Application for a Waiver of Authorization or an Altered Authorization in determining compliance with the HIPAA Privacy Rule.

G. Principal Investigator (PI) Certification

A template used by the UCCS Privacy Board that must be signed by the PI upon approval of a Research Authorization Review and blank Authorization(s) for a research study. Among other requirements, the certification ensures that the PI will maintain, electronically and/or in hard copy, the signed Authorization for each research participant whose PHI is used or disclosed in the project and will provide any and/or all of the signed Authorizations to UCCS immediately upon request.

H. Required Representations for Research on Decedent's Information

A template used by the UCCS Privacy Board when the researcher intends to conduct research that is *solely* on the PHI of decedents. The PI must initial and sign this template to document compliance with the representations required by the HIPAA Privacy Rule at 45 CFR 164.512(i)(1)(iii).

I. Required Representations for Review Preparatory to Research

A template used by the UCCS Privacy Board when the researcher intends to conduct a review of PHI to prepare for a research protocol or for similar purposes preparatory to research (*e.g.*, where PHI is needed to determine whether the proposed research project is feasible or to design the research study) and *agrees not to remove the PHI from UCCS in the course of the review*. The PI must initial and sign this template to document compliance with the representations required by the HIPAA Privacy Rule at 45 CFR 164.512(i)(1)(ii).

J. Research Authorization Review

A template used by the UCCS Privacy Board when the researcher has the ability to obtain written and signed Authorizations from all research participants to comply with the HIPAA Privacy Rule. The PI must submit a copy of the blank Authorization(s) to be used in the project and the completed Research Authorization Review template. The UCCS Privacy Board will conduct a review to determine that all core elements and required statements are provided in the blank Authorization(s) as required by the HIPAA Privacy Rule at 45 CFR 164.508(c).

III. Roles and Responsibilities

A. UCCS Privacy Board

The UCCS Privacy Board reviews research-related data requests to use and/or disclose PHI of individual research participants that is managed by UCCS for compliance with the HIPAA Privacy Rule. The UCCS Privacy Board is not an IRB and is not authorized to review and/or approve human subject's research regulated under the Federal Policy for the Protection of Human Subjects (45 CFR 46), also known as the "Common Rule." Board Members have been selected based on their demonstrated knowledge and understanding of research, the HIPAA Privacy Rule. As required by the HIPAA Privacy Rule the UCCS Privacy Board:

- Has members with varying backgrounds and appropriate professional competency as necessary to review the effect of the research protocol on the individual's privacy rights and related interests;
- Includes at least one member who is not affiliated with UCCS, not affiliated with any entity conducting or sponsoring the research, and not related to any person who is affiliated with any such entities; *and*
- Does not have any member participating in a review of any project in which the member has a conflict of interest.

1. Board Members' responsibilities include

- a. Taking required training.
- b. Attending UCCS Privacy Board meetings on an ad hoc basis;
- c. Conducting reviews of completed Applications for a Waiver of Authorization or an Altered Authorization;
- d. Collaborating on the HIPAA Privacy Rule, and research-related issues of interest to the UCCS Privacy Board; and
- e. Recusing themselves from UCCS Privacy Board reviews where they have or may appear to have a conflict of interest.

2. Training of Privacy Board Members

Collaborative Institutional Training Initiative ("CITI") training program offers computer-based training for board members. CITI training is self-directed instructional course that gives an overview of the HIPAA Privacy Rule. For complete instructions on how to access the CITI site and login please visit the Office of Sponsored Programs and Research Integrity <http://www.uccs.edu/osp/research-compliance/research-involving-human-subject-irb.html> under the "Training" section.

Before becoming a voting member, a new member will:

- a. Complete the above-mentioned tutorial within a three-month period. A certificate will be kept on file.
- b. Receive and review the UCCS Privacy Board Standard Operating Procedures.

Reference Materials will be available in the UCCS Compliance Office and available to members as requested.

B. UCCS Privacy Board Support Staff

The UCCS Compliance Office assigns staff to support the UCCS Privacy Board, hereinafter referred to as “Support Staff.” Support Staff provide administrative assistance on behalf of the UCCS Privacy Board by attending the UCCS Privacy Board Meetings, drafting email communications to the researchers and Board Members; maintaining files for all submissions to the UCCS Privacy Board; tracking submissions and pending requests for submissions; preparing the agenda and materials for UCCS Privacy Board meetings; and, assisting in the facilitation of board meetings.

C. Principal Investigator (“PI”)

The PI is the lead researcher for a particular well-defined project that is taking place at UCCS.

1. PI’s responsibilities include:
 - a. Taking required CITI training and abiding by the HIPAA Privacy Rule (See C2 below).
 - b. Preparing the research project and any required paperwork to submit to the UCCS Privacy Board.
 - c. Answering any questions that the UCCS Privacy Board may have related to the project / research.
 - d. Keeping the UCCS Privacy Board informed of any changes related to the project / research.

2. Training of Investigators

Collaborative Institutional Training Initiative (“CITI”) training program offers computer-based training for members. CITI training is self-directed instructional course that gives an overview of the HIPAA Privacy Rule. For complete instructions on how to access the CITI site and login please visit the Office of Sponsored Programs and Research Integrity <http://www.uccs.edu/osp/research-compliance/research-involving-human-subject-irb.html> under the “Training” section.

Reference Materials will be available in the UCCS Compliance Office and available to members as requested.

IV. Templates

The UCCS Privacy Board designed the following templates to assist in obtaining information necessary for its HIPAA Privacy Rule compliance reviews:

1. Request for Waiver of Elements of Authorization or an Altered Authorization
2. Authorization (Permission) to Use or Disclose (Release) Identifiable Information for Research (Authorization template).

3. HIPAA Authorization for Research Checklist
4. PI Certification
5. Required Representations for Research on Decedent's Information
6. Activities Preparatory to Research Request for Waiver of Authorization

One additional template, the Internal Review Checklist, is used internally by the Board Members in their review and is not otherwise provided to the PI for completion. These templates are provided for viewing at <http://compliance.uccs.edu/?cat=69>, and are maintained and updated, as needed, by Support Staff with the approval of the Chair.

V. Tracking UCCS Privacy Board Submissions

Support Staff maintain the following:

- (1) UCCS Privacy Board Submissions Received; and (2) Folders with Study-specific approvals and meeting minutes.

VI. Procedures

A. Receipt of UCCS Privacy Board Submissions

Submissions to the UCCS Privacy Board can be made in one of two ways:

1. The PI may make submissions to the Office of Sponsored Programs and Research Integrity. For detailed information related to the UCCS IRB please visit their website at <http://www.uccs.edu/osp/research-compliance/research-involving-human-subject-irb.html>. The Office of Sponsored Programs and Research Integrity will then forward any Privacy Board Information requests along with IRB application, protocol, level of review assigned by the IRB (full board, expedited or exempt) and assigned IRB number to the UCCS Privacy Board. Once the information is received, the UCCS Privacy Board Support Staff will then email the PI confirming receipt of their submission.
2. The PI may email submissions directly to the UCCS Privacy Board if there is no IRB review required (*e.g.*, accessing PHI preparatory to research).

Support Staff provide preliminary review of the submission for completeness and confirm pertinent documents have been received and/or that templates have been signed, dated, and otherwise initialed or completed. If Support Staff receives an incomplete submission, Support Staff will email the PI on behalf of the UCCS Privacy Board and track until the submission is complete.

Once the submission is deemed complete, Support Staff assigns a completed Application for review based on the type of review requested and the level of review assigned by the IRB. Please see the *Privacy Board Review Process* flowchart

B. Review of UCCS Privacy Board Submissions

The PI certification, attached to the email, is properly initialed, signed, and returned to the UCCS Privacy Board. Upon receipt of an appropriately completed PI Certification, Support Staff prepares an email to be sent by the Chair acknowledging receipt of the PI Certification and indicating approval of the blank Authorization(s). The PI are further advised that if the blank Authorization(s) is(are) modified or if any new Authorizations are used in the course of the project, such Authorizations must be submitted to the UCCS Privacy Board for review/approval prior to use in the research project.

1. Review of Required Representations for Review Preparatory to Research

Support Staff reviews information about the research project for consistency with the representations that the use or disclosure of PHI is sought solely for purposes preparatory to research and that the PHI will not be removed from UCCS. The information abstracted in the course of the review of PHI, from the Covered Entity or Covered Component. Furthermore, may not be disclosed under any circumstances to anyone outside of the Covered Entity or Covered Component. Support Staff will follow-up with the PI to confirm the template is appropriate. Support Staff prepares an email that is sent by the Chair to the PI acknowledging acceptance and approval of the Required Representations for Review Preparatory to Research template. Support Staff also notifies the UCCS Privacy Board and the Office of Sponsored Programs and Research Integrity of the approval.

2. Review of Required Representations for Research on Decedent's Information

Support Staff reviews information about the research project for consistency with the representation that the research is solely on the PHI of decedents, and follows up with the PI as needed in order to confirm that the template is appropriate with respect to the research conducted in the project. Once the review is complete, Support Staff prepares an email that is sent by the Chair to the PI acknowledging acceptance and approval of the Required Representations for Research on Decedent's Information template. Support Staff also notifies the UCCS Privacy Board and the Office of Sponsored Programs and Research Integrity of the approval.

3. Review of the Research Authorization Review Template and Blank Authorization(s)

Support Staff reviews *Authorization (Permission) to Use or Disclose (Release) Identifiable Information for Research (Authorization template)* submitted to the UCCS Privacy Board, which will be used in the research project. The review determines whether all core elements and required statements set forth in the HIPAA Privacy Rule at 45 CFR 164.508(c) are included in any Authorization used in the project. The template is designed to help the PI address these needs prior to submission. Where an Authorization for use in a research project is deficient, Support Staff emails the PI listing any deficiencies and provides an explanation for appropriate revisions to be made and the Research

Authorization Review template and blank Authorization(s) can be resubmitted to the UCCS Privacy Board for approval. When blank Authorizations meet the regulatory requirements, Support Staff prepares an email that is sent by the Chair to the PI indicating the blank Authorization(s) submitted for use in the project will be approved. Support Staff will notify the UCCS Privacy Board and the Office of Sponsored Programs and Research Integrity the Research Authorization Review and blank Authorization(s) are approved.

4. Review of Request for Waiver of Elements of Authorization or an Altered Authorization

Support Staff reviews the *Request for Waiver of Elements of Authorization or an Altered Authorization* for completeness and follows up with the PI if necessary. Once the form is deemed complete, Support Staff assigns the review to the UCCS Privacy Board Chair or designee if the project was marked as either exempt or expedited (i.e. minimal risk) by the IRB. If the project was marked as full board review by the IRB, then Support Staff notifies the UCCS Privacy Board of the review and assigns it to the next scheduled UCCS Privacy Board meeting. All of the meeting documents will be sent via email to the Board Members for review and discussion at the next meeting.

C. Meeting Administration

Except when an exempt or expedited review procedure is used, the UCCS Privacy Board will review proposed *Request for Waiver of Elements of Authorization or an Altered Authorization* at convened meetings where a quorum is present. The UCCS Privacy Board will meet monthly as needed in conjunction with the UCCS IRB meetings, or at some other frequency determined by UCCS Privacy Board Chair.

1. Quorum

- a.** A quorum is defined as one half of the number of regular Board Members plus one.
- b.** A quorum consists of regular Board Members and includes: at least one Board Member who is not associated with the University.
- c.** If a Board Member abstains from voting, the Board Member may be used to establish a quorum.
- d.** Special consultant(s) are not used to establish a quorum.
- e.** If a Board Member recuses him/herself from deliberations and voting, the Board Member may not be used to establish quorum for the duration of review of the item from which the member is recused. A Board Member experiencing a COI must recuse him/herself. Recused Board Members leave the board room during voting discussion.

2. Meeting Materials Sent Prior to UCCS Privacy Board Meetings

- a.** All UCCS Privacy Board Members will be sent documentation required for review approximately one week in advance of the meeting to allow time for adequate review. These include:

- Agenda: a meeting agenda will be prepared by the Support Staff and distributed to UCCS Privacy Board Members prior to each meeting. A copy of the agenda and attached materials will be maintained on file with the meeting minutes.
- Minutes: Documentation shall be in sufficient detail to show attendance at the meeting, actions taken by the UCCS Privacy Board, the vote on actions including the number of Board Members voting for, against, and abstaining or recusing, and the basis for requiring changes in or disapproving the request for waiver or alteration of the research authorization.

3. Telephone Use

- a. Convened meeting using speaker phone:
Should a Board Member not be able to be physically present during a convened meeting, but is available by telephone, the meeting can be convened using a speakerphone. In this manner, all Board Members will be able to discuss the protocol even though one member is not physically present. Board Members participating by such speakerphone may vote, provided they have had an opportunity to review the material.
- b. Meetings Conducted Via Telephone Conference Calls:
 - On occasion, meetings may be convened via a telephone conference call. A quorum (as defined above) must participate for the conference call meeting to be convened. To allow for appropriate discussion to take place, all Board Members must be connected simultaneously for a conference call to take place -- "telephone polling" (where members are contacted individually) will not be accepted as a conference call.
 - Board Members not present at the convened meeting or participating in the conference call may not vote on an issue discussed during a convened meeting (no voting by proxy).

4. Meeting Actions

a. Approvals

If a Full Waiver is approved, The UCCS Privacy Board will agree to the *Request for Waiver of Elements of Authorization or an Altered Authorization* as long as it contains all required provisions set forth in the HIPAA Privacy Rule at 45 CFR 164.512(i)(2). Support Staff prepares an email / letter that will be sent by the Chair to the PI which will include the following information:

- i. Identify the approval by the UCCS Privacy Board’;
- ii. Date on which the waiver or alteration was approved;
- iii. A statement that the UCCS Privacy Board has determined that all of the specified criteria for a waiver or an alteration were met;

- iv. A brief description of the PHI for which use or access has been determined by the IRB or UCCS Privacy Board to be necessary in connection with the specific research activity;
- v. A statement that the waiver or alteration was reviewed and approved under normal or expedited review procedures.
- vi. The required signature of the UCCS Privacy Board chair or the chair's designee.

Support Staff then notifies the UCCS Privacy Board and the Office of Sponsored Programs and Research Integrity of the approval.

If a Partial Waiver is approved, if the Partial Waiver is approved by the Privacy Board, Support Staff prepare an email / letter that is sent by the Chair to the PI which will include the following information:

- i. i. Identify the approval by the UCCS Privacy Board’;
- ii. Date on which the waiver or alteration was approved;
- iii. A statement that the UCCS Privacy Board has determined that all of the specified criteria for a waiver or an alteration were met;
- iv. A brief description of the PHI for which use or access has been determined by the IRB or UCCS Privacy Board to be necessary in connection with the specific research activity;
- v. A statement that the waiver or alteration was reviewed and approved under normal or expedited review procedures.
- vi. The required signature of the UCCS Privacy Board chair or the chair's designee.

Support Staff then notifies the UCCS Privacy Board and the Office of Sponsored Programs and Research Integrity of the approval.

b. Denials

In the event the Privacy Board a *Request for Waiver of Elements of Authorization or an Altered Authorization* application, Support Staff promptly notifies the Office of Sponsored Programs and Research Integrity of the denial. Support Staff also prepares an email that is sent by the Chair to the PI outlining the document deficiency(ies) and asking the PI to follow-up with the UCCS Privacy Board to address this matter. Support Staff tracks the communications related to the submission until the deficiency(ies) contained in the approved waiver documentation has (have) been resolved. At that point, Support Staff prepares an email for the Chair to send to the PI acknowledging the acceptance and reliance upon the UCCS Privacy Board approved waiver.

D. Extensions, Renewals, and Modifications

UCCS Privacy Board approvals document HIPAA compliance in support of a specific research-related privacy requests. The duration of any approval by the UCCS Privacy Board is linked to the related UCCS IRB Approval or the expiration in which the PI states. When

there is a request to extend, renew, or modify a research-related expiration date in which the UCCS Privacy Board provided prior approval, it is the responsibility of the UCCS IRB to notify the UCCS Privacy Board. Where there is a substantial change in the project that may affect any of the UCCS Privacy Board's prior approvals, Support Staff will contact the PI for further information to determine whether further review is required or if prior approved documentation is sufficient to support the extension, renewal and/or modification.

E. Lack of Response from the PI and/or Government Sponsor

During the course of a review, if Support Staff and/or the Board Member are not obtaining responses from the PI within a reasonable amount of time, Support Staff will notify the UCCS Privacy Board to try to resolve the issues. If a **No Action** letter is to be sent by the UCCS Privacy Board, Support Staff prepares an email / letter that will be sent by the Chair to the PI and Office of Sponsored Programs and Research Integrity informing them that the UCCS Privacy Board's file related to the Privacy Board Review has been **inactivated**.

VII. Misconduct

Allegations of Privacy or Research Misconduct will be handled according to either the IRB policies or the HIPAA policies, depending on the situation of the allegation.

VIII. References

HIPAA Privacy Rule, 45 CFR Parts 160 and 164