Guidance for accessing health data, including Protected Health Information (PHI)

This guidance will assist researchers in understanding their options for accessing health-related data regulated under the Health Insurance Portability and Accountability Act (HIPAA), including Protected Health Information (PHI), and how Chapman Institutional Review Board (IRB) and the Privacy Board (PB) will review such projects. See more about what is and is not considered PHI and a list of the 18 identifiers on the HIPAA PHI details page.

PHI refers to information comprising personally identifiable health information derived from or generated in clinical settings, or so-called HIPAA-covered entities. Hospitals, medical centers, doctor's offices, clinics, and private practices delivering health-related services (and billing insurance) are considered HIPAA-covered entities that are subject to the HIPAA Privacy Regulation. Read more about the HIPAA privacy rule on the OHRP website.

Chapman may receive PHI from HIPAA-covered entities for research purposes under certain circumstances, as described under Procedures. PIs should be aware that:

- PHI received or maintained by Chapman may not be used internally or disclosed to any persons or organizations outside Chapman for human subjects research purposes without prior approval by the IRB/PB as described in this policy.
- All references to the IRB/PB in this policy include the IRB/PB's designees unless expressly excluded.
- All requests for access to PHI for research purposes must be made and reviewed in accordance with the procedures described below.
- As a condition of protocol approval, the Chapman IRB/PB will require evidence that the Principal Investigator (PI), Co-PIs, Primary Contact, and any research study team members deemed by the PI have completed CITI HIPAA training within the last three years.

Note that personally identifiable health information provided directly to Chapman researchers by individual human subjects about themselves is not PHI.

Procedures

As a general rule, the IRB/PB may only authorize the use or disclosure of PHI under any one of these circumstances:

1. if the information is completely de-identified; or
2. if the information is partially de-identified into a "limited data set" and the recipient of the information signs a data use agreement to protect the privacy of the information; or
3. if the participant provided their informed consent to participate in the research and a signed authorization statement allowing the Chapman PI to receive the PHI; orif the data provider can demonstrate it received consent and authorization from the participant to use PHI for the research purpose; or
4. if the study is eligible for exemption category 4 (i.e., secondary research for which consent is not required); or
5. if an IRB/PB approves a waiver of the individual privacy authorization requirement;
6. for research on the protected health information of a decedent.

The specific requirements for each of these options are discussed below. In addition, special limitations apply to the use or disclosure of psychotherapy notes for research purposes. Contact the IRB if these circumstances apply to your proposed study.

The IRB/PB must determine that one of the options summarized above and described in greater detail below applies before permitting the collection, use, or disclosure of PHI for research purposes. If there is any doubt about the scope of the original consent or authorization, IRB/PB should require either an updated individual authorization or consent or provide a waiver of authorization or consent before the study may commence. All Chapman research activities also must comply with other applicable Chapman policies relating to research and with any additional requirements that apply to the specific types of information involved in the study (e.g., agreement terms).

1. <u>Accessing De-identified Data</u>

Chapman PI can accept de-identified medical information provided by a HIPAA-covered entity. De-identified data is defined as *Health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual is not individually identifiable health information*[1].

[1] https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-C/part-164/subpart-E/section-164.514#p-164.514(a)

The data must be completely de-identified following 45 CFR and 164.514(a)-(c) of the Rule, and therefore, is not considered "human subject" data under the OHRP regulations and does not require IRB approval. Contact the IRB if you have questions about whether the data is de-identified.

2. **Limited Data Sets**

Covered entities are authorized under HIPAA to share "limited data sets[2]" with researchers under specific Data Use Agreement terms. A limited data set includes only a small number of

PHI identifiers, but is still PHI and subject to the requirements of the Privacy Regulations. IRB review and approval are needed before the PI may receive the data. The Chapman PI must agree to the terms of the Data Use Agreement by signing the agreement to acknowledge the terms before Chapman's authorized signatory signs the data use agreement.

3. **Participant's Authorization to Share PHI**

   IRB/PB review and approval are required for the IRB study and the data safety monitoring plan. PIs are responsible for following human subjects and data privacy requirements described in the study application and agreements with participants and data providers.

   a. When PHI will be collected as part of a new study, PIs may ask participants to share their PHI with the Chapman team for purposes of the project using a separate *"Authorization to the Use or Disclosure (Release) of Personal Health Information for Research Purposes."* PIs may use or disclose the data only as described in this Authorization Form, even if the IRB/PB would normally approve other uses and disclosures of the data. The research participant may revoke their authorization, which will be honored unless the data has previously been published or presented. Going forward, the PI cannot use the PHI for further data analyses, publications, or presentations.

[2] Per 45 C.F.R. § 164.514(e), a limited data set is defined as protected health information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual: (i) Names; (ii) Postal address information other than town or city, State, and zip code; (iii) Telephone numbers; (iv) Fax numbers; (v) Electronic mail addresses: (vi) Social security numbers; (vii) Medical record numbers; (viii) Health plan beneficiary numbers; (ix) Account numbers; (x) Certificate/license numbers; (xi) Vehicle identifiers and serial numbers, including license plate numbers; (xii) Device identifiers and serial numbers; (xiii) Web Universal Resource Locators (URLs); (xiv) Internet Protocol (IP) address numbers; (xv) Biometric identifiers, including finger and voice prints; (xvi) Full face photographic images and any comparable images.

b. HIPAA-covered entities, as the data provider, may provide Chapman with data sets, including PHI. When data for research already exists at a covered entity (e.g., in the form of medical records), the PI can request that the institution share the data with Chapman for research purposes. This is permitted under HIPAA regulations.

   The participant must supply Chapman with authorization to use PHI, and informed consent before Chapman may use it for research. Such authorizations are typically allowed for in the data-sharing agreement. The data-sharing agreement is typically signed after the IRB/PB approves the application. The Chapman PI must agree to the terms of the Data Use Agreement by signing the agreement to acknowledge the terms.

4. **The study is eligible for exemption category 4.**
   Exemption category 4 refers to using identifiable private information (e.g., PHI) or biospecimens for a proposed study, when such information or biospecimens have been/will be primarily gathered for a purpose other than the proposed study. There are four (4) subcategories possible under category 4 (see the IRB's Initial Review of Human Subject Research). Of the four subcategories, Chapman's IRB is not eligible to use the third subcategory since Chapman University is not a HIPAA-covered entity. Use of the third subcategory is only possible by an external IRB (i.e., IRB other than Chapman's) *and* a reliance agreement is established between Chapman and such external IRB.

5. **Request an IRB waiver of the participant's authorization**. The IRB/PB reviews all requests for waivers of authorization for compliance with the regulations, and when appropriate (see criteria below), can approve partial or full waivers of authorization. Waivers of authorization are most commonly used for record review studies where the researchers review records with PHI for information not initially contemplated in signed informed consent.

   Waivers may also be appropriate in an emergency if the PI can demonstrate that PHI is needed, but requesting the participant's authorization would not be feasible or create harm to the person. This is rare at Chapman.

HIPAA requires that waivers meet all of the following criteria:

- The use or disclosure of PHI involves no more than minimal risk.
- Granting of the waiver will not adversely affect privacy rights and welfare of the individuals whose records will be used.
- The project could not practicably be conducted without a waiver.
- The project could not practicably be conducted without use of PHI.
- The privacy risks are reasonable relative to the anticipated benefits of research.
- An adequate plan to protect identifiers from improper use and disclosure is included in the research proposal.
- An adequate plan to destroy the identifiers at the earliest opportunity, or justification for retaining identifiers, is included in the research proposal.
- The project plan includes written assurances that PHI will not be re-used or disclosed for other purposes.
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

6. Research Using Decedents' Data

Decedent Research under the State of California Regulations

The State of California regulations protects the health information of the deceased and death data files. Therefore, Chapman's policy requires the IRB/PB to review research involving death data files and medical records under certain circumstances (even though, for IRB purposes, human subject data is defined as data from a living individual). For example, decedent research that requires access to PHI, even if identifiers will not be recorded and stored, must be submitted for IRB review. However, if the researcher does not access PHI (i.e., only access completely de-identified information), IRB review and approval are not required since the decedent's identity cannot be determined.

Required Reviews for Decedent Research

- If the decedent study does not include having direct access to PHI, IRB review and approval are not required because the deceased individuals cannot be identified.
- Decedent research involving direct access to individually identifiable PHI, even if identifiers are not recorded as part of the study, must request and receive IRB/PB approval before the study commences. In most cases, the study will be handled via the expedited review process.

Decedent Research under HIPAA

Under the Common Rule and FDA requirements, the IRB/PB does not review research on data relating to decedents. However, under the HIPAA Privacy Rule, access to identified information on decedents requires that the researcher make certain representations. The IRB/PB has assumed the role of assuring that those representations are made. Therefore, the IRB/PB may permit the use and disclosure of the PHI of a decedent for research purposes if the PI submits to the IRB/PB representations that the use or disclosure is sought solely for research on the protected health information of a decedent (e.g., researchers may not request a decedent's medical history to obtain health information about a decedent's living relative) and that the information for which use or disclosure is sought is necessary for the research purposes. Researchers must complete, sign and submit the PI Representations for Decedent Research form to the IRB to file before the project may commence.

Accessing Public Records

PIs wishing to obtain state death data files containing personal identifying information should:
- Submit an application to the IRB/PB for review, and
- Obtain approval from the California Department of Public Health Vital Statistics Advisory Committee (VSAC) and the California Health and Human Services Agency's Committee for the Protection of Human Subjects (CPHS).

CDC National Death Index (NDI) - The CDC NDI is a database of all the deaths in the United States. NDI is available to investigators solely for statistical purposes in public health and medical studies. An application must be submitted to NDI to obtain this information, and PIs must provide an IRB approval letter. Follow the instructions above to obtain IRB approval from Chapman.

Researchers should follow the requirements of other institution(s) holding those records.

Protecting PHI

PIs must submit a full-length Data Safety and Monitoring Plan for full board review projects involving collection and access to PHI. Plans will include the following protections unless the PI justifies why it cannot be done, and the IRB approves an alternate scheme.

- Demonstrate that the team will collect the minimum PHI necessary to accomplish your project.
- State how long you will need access to the PHI, and the plan for destroying PHI as soon as practical.
- Demonstrate that the team will limit physical and electronic access to devices and PHI whenever possible.
- Laptops, tablets, phones, or other data collection devices and computers used to access PHI must be encrypted.
- Storage of data in OneDrive
- Files must be password protected.
- Information may only be stored on phones, tablets, and other mobile devices for a short time (less than 24 hours) before transferring the data to a secured cloud server. This is because mobile devices are more susceptible to loss or theft. After that, PHI must be deleted from collection devices entirely.
- PHI in paper format must be stored in a locked Chapman office or lab and in a locked file cabinet that only authorized researchers can access.
- Avoid sending PHI through email whenever possible. If you must send PHI through email, use SECUREMAIL.

Data Safety and Monitoring Plans are not required for studies using limited data sets or de-identified data.

Reporting Adverse Events, Including Data Breaches

Any breach of confidentiality or release of identifiable participant information must be reported to the IRB/PR immediately and no later than five working days from the discovery or sooner as required by other agreements, e.g., a data-sharing agreement. Chapman may be required to report such breach to the participant depending on the terms of the consent and the data provider based on the terms of any agreement. See the policy on Incident Reporting for more information.

Record Keeping

The Office of Research will track data-sharing agreements and link that information to the IRB study record in Cayuse for reference.

HIPAA requires that certain records be maintained in both healthcare and research contexts. PIs accessing PHI from a HIPAA-covered entity may be asked to provide information to the covered entity about CU IRB/PB-approved use and any disclosure of PHI outside of Chapman. Authorizations for use of PHI should be kept in research records for at least six years. Though not required, a good practice would be to keep signed informed consent documents together with research authorization forms. Limited Data Sets are not subject to HIPAA's accounting/tracking requirements.

When disclosures of PHI occur (i.e., when information is sent to people outside the Chapman workforce), the PI must keep a record of what information was sent, the date of disclosure, and to whom. An audit trail of disclosures should be kept and made available on request by a study participant so that they can see what information about them was sent to an outside organization or person. For more information, see https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-C/part-164/subpart-E/section-164.528

Revision history:

24Apr2024 - removed language requiring annual IRB review for all expedited review and full board studies involving PHI

18Mar2024 – added a determination of exemption under the 2018 Requirements as a path to using PHI for research

07Aug2023 – corrected error on page 2 (i.e., text should not have read that review of a Privacy Board is needed for limited data sets)

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