

Providing Access to Protected Health Information for Research Purposes

Overview

Under HIPAA, Yale University is required to follow federal restrictions on the use (i.e. internal access by Yale "workforce" members) and disclosure (i.e. any other sharing of data) of protected health information for "research" purposes. Research is distinguished from health care provider "operations" that may involve retrospective review of patient data for solely internal purposes (i.e. no publication or outside presentation is anticipated). Examples of "operations" include self-initiated quality improvement measures and medical staff credentialing or peer review. If you have questions regarding whether requested data will be involved in "research", please contact Yale Privacy Officer or designee or review the Statement Of Policy On Use And Disclosure Of Protected Health Information For Research Purposes.

Where PHI Is Located and Who Is Responsible for Protecting Its Privacy

Protected health information is located in many discrete locations throughout the "campus" of the Yale School of Medicine and the Yale School of Nursing, at Yale Health, and in Psychology Department clinics (e.g., in faculty offices, in clinical and research laboratories, and in other clinics and care-giving sites). Protected health information resides in written and electronic records, in tissue banks and data bases, on films, slides, and many other media. All persons who have contact with protected health information have a responsibility to guard its privacy. However, additional responsibility rests with the on-site managers or "keepers" of identified data (which includes medical records "departments", office sites, collections, and banks) to ensure that Yale does not access PHI for research purposes without an authorization, a waiver, or assurances that the access is for reviews preparatory to research or for research on decedents. Yale University has adopted policies and requirements for documenting a requester's authority to receive or review data for research purposes, and the frontline responsibility for enforcing those policies will, in many cases, reside with an onsite data manager.

What is "Protected Health Information" or PHI?

The requirements described in this Procedure relate only to data that include "protected health information." If you suspect that a requester is seeking information that may not be PHI, you will find a discussion and decision tree in the Yale University Procedure, "Determining Whether 'Human Subject Research' Involves Use/Disclosure of 'Protected Health Information.'" Steps to Follow in Responding to a Request for Access

- A. Review the requester's documentation, by answering the questions below on a copy of this form. If the answer to any of the questions is "NO", you need to consult with the Yale Privacy Officer or designee before allowing access to the requested information. If the answer to all of the questions is "YES", you may provide the information as described below.
- B. Identify and copy the requested protected health information.
[Note: Copies are not permitted for Reviews Preparatory to Research. Reviews Preparatory to Research must be conducted ON THE PREMISES using the original record, unless another method is approved in writing by the Yale Privacy Officer. You should also provide the researcher with a list of "Identifiers" if the request is for a Review Preparatory to Research and remind the researcher that he or she may not copy or remove any PHI from the premises and may only record de-identified information.]
- C. Mark "Approved" on the Request Form in the appropriate space, and sign your name as the "Reviewer."

- D. Copy the Request Form (with the approval notation), attach the copy to the information that is being provided, and deliver the information to the requester.
- E. Attach a copy of your answers to the questions listed below to the original Request Form and file all of the documentation in a safe place.

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- 1. _____ Has the requester completed a Yale-Approved Request Form?
[A copy of an approved Request Form is attached. Other forms may be approved by the Yale Privacy Officer from time to time.]
 - 2. _____ Did the requester mark the correct Research Type box and corresponding Requester Assurances boxes
 - 3. _____ Is the documentation required by the Request Form attached to the Form?
 - 4. _____ Do the request and the supporting documentation clearly specify the requested information?
 - 5. _____ If request is pursuant to authorization or waiver (#s 1 or 2 on the Request Form), does the information requested match the approved release supported by the attached documentation?
 - 6. _____ If request is pursuant to authorization or waiver (#s 1 or 2 on the Request Form), are the persons who will be given access to the information identified (either by name or category) in the Authorizations or in the HIPAA Waiver?
 - 7. _____ Does the Request Form have an original signature of the named requester? Proxy signatures (by someone on behalf of another) are NOT ALLOWED. [Verify the requester's identity from a photo-identification card if he/she is not someone known to you.]

Approved: Yes No

Signature of Reviewer _____ Date _____