

Pre-Research Certification

Investigators who need to access University of Colorado Denver Medical Records, Databases or Tissue Banks to use protected health information ("PHI") of individuals to assess the feasibility of conducting a study, to design a research study, or to formulate a research hypothesis must submit this form to the keeper of the information accessed and to the HIPAA Privacy Officer (campus box F497) to comply with the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). PHI accessed in this manner may not be used to recruit subjects.

Investigator's Name: _____

Date: _____ Date(s) Access/Use Will Occur: _____

School / Department or Unit: _____

E-mail Address and Phone Number: _____

Investigator's Home Institution: TCH DHMC NJMRC UCH UCD UPI

VAMC Other: _____

List Any Co-Investigators or Coordinators For Whom You Are Also Requesting Access:

Description of Research: (Use additional sheets if needed) _____

Description of PHI You Will Be Using: (Use additional sheets if needed) _____

Description of Location of PHI:

_____ (Name of Institution) Medical Records

Database; (please provide name and location of database) _____

Tissue Bank; (please provide name and location of tissue bank) _____

Other _____

The Investigator makes the following certifications:

1. The access/use sought is solely to prepare a research protocol or for similar purposes preparatory to research;
2. No PHI will be removed from UCD;
3. The PHI sought is necessary for the research; and,
4. No PHI will be recorded in any form.

By signing this document, I certify that the above stipulations are correct in accordance with the Health Insurance Portability and Accountability Act of 1996. I understand that any misrepresentation of the above information could result in criminal liability. I understand that information obtained through the review preparatory to research cannot lead to publication. I agree that this review is for formulation of a research protocol/idea only and if a research project comes out of this review I will be required to submit a protocol to COMIRB per COMIRB guidelines.

Investigator's Signature: _____ Date: _____

Once completed, please remit this form to the UCD HIPAA Privacy Officer, Campus Box F497, and a copy of this form to the keeper of the information accessed. Please retain a copy of this form for your records.