

Online Supplementary Material

Pace WD, Staton EW, Holcomb S. Practice-based research network studies in the age of HIPAA. *Ann Fam Med*. 2005;3(Suppl 1):S38-S45.

http://www.annfammed.org/cgi/content/full/3/suppl_1/S38

Supplemental Appendix 3. Example of a Pre-Research Certification Form

Pre-Research Certification

*Investigators who need to access **ABC's data** 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 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: _____

List any coinvestigators 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) _____

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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 ABC;
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 ABC's institutional review board.

Investigator's Signature: _____ Date: _____

Adapted with permission from the Colorado Multiple Institutional Review Board (COMIRB), <http://comirbweb.uchsc.edu>.