

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 4. Example of a HIPAA Waiver of Authorization

Waiver of HIPAA Authorization	PI Name:		
Protected Health Information (PHI) is defined as “Individually identifiable health information that a health care provider, health plan, health care clearinghouse, or employer creates or receives, and includes information about the past, present, or future physical or mental health of a person, the provision of health care to a person, or the payment for the provision of care to that person.”			
1. Check the protected health information (PHI) that will be used:			
<table style="width: 100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> Patient's name <input type="checkbox"/> All dates (except year) that are directly related to an individual (eg DOB, discharge date) <input type="checkbox"/> Telephone numbers <input type="checkbox"/> E-mail addresses <input type="checkbox"/> Medical record numbers <input type="checkbox"/> Account numbers <input type="checkbox"/> Vehicle identifiers and serial numbers <input type="checkbox"/> Web URLs (http://...) <input type="checkbox"/> Biometric identifiers (including finger and voice prints) <input type="checkbox"/> Full-face photographic images and any comparable images <input type="checkbox"/> Any other unique identifying number, characteristic, or code </td> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> Geographic subdivisions smaller than a state <input type="checkbox"/> Fax numbers <input type="checkbox"/> Social security numbers <input type="checkbox"/> Health plan beneficiary numbers <input type="checkbox"/> Certificate/license numbers <input type="checkbox"/> Device identifiers and serial numbers <input type="checkbox"/> IP address numbers </td> </tr> </table>		<input type="checkbox"/> Patient's name <input type="checkbox"/> All dates (except year) that are directly related to an individual (eg DOB, discharge date) <input type="checkbox"/> Telephone numbers <input type="checkbox"/> E-mail addresses <input type="checkbox"/> Medical record numbers <input type="checkbox"/> Account numbers <input type="checkbox"/> Vehicle identifiers and serial numbers <input type="checkbox"/> Web URLs (http://...) <input type="checkbox"/> Biometric identifiers (including finger and voice prints) <input type="checkbox"/> Full-face photographic images and any comparable images <input type="checkbox"/> Any other unique identifying number, characteristic, or code	<input type="checkbox"/> Geographic subdivisions smaller than a state <input type="checkbox"/> Fax numbers <input type="checkbox"/> Social security numbers <input type="checkbox"/> Health plan beneficiary numbers <input type="checkbox"/> Certificate/license numbers <input type="checkbox"/> Device identifiers and serial numbers <input type="checkbox"/> IP address numbers
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2. Describe where the specific PHI will be accessed from:			
3. Describe any contact the study personnel will have with the subject: (ie, office visits, phone calls, mailings, e-mails, etc)			
IN ORDER FOR THIS WAIVER TO BE APPROVED, THERE MUST BE NO MORE THAN MINIMAL RISK TO PRIVACY OF THE SUBJECT, BASED ON THE ANSWERS TO THE FOLLOWING QUESTIONS:			
4a. How will subject identifiers be protected?			

4b. What is the plan to destroy the identifiers ASAP? [Please state if there is a health or research justification for retaining the identifiers of if retention is required by law.]		
4c. Will the data be made available to anyone other than the study personnel? If so, to whom? And if so, why?		
	YES	NO
5. Can this project be done without PHI?		
6. Why is it not possible to get the authorization of the subjects whose PHI you want to use?		

CONFIRMATION:

I confirm that the PHI will not be reused or disclosed except as required by law, for authorized oversight of the research, or for other research that has been reviewed and approved by the IRB with specific approval regarding access to this PHI.

PI Signature

Date

This protocol has been reviewed under expedited procedures and the use and disclosure of PHI and:

_____ **meets the above criteria. Alteration, or waiver, in whole or in part, of authorization has been satisfied by the presence of the above criteria and is granted.**

_____ **does not meet the criteria for approval of Waiver of Authorization**

Signature of IRB Chair

Date

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