

<p><u>Information Sheet</u></p> <p>Guidelines for Health Insurance Portability and Accountability Act (HIPAA), Protected Health Information (PHI) and Research</p>	<p>Advocate Health Care Institutional Review Board</p> <p>205 W. Touhy, Suite 203, Park Ridge, IL 60068-4202 Voice: 847-384-3534; Fax: 847-384-3537 E-Mail: IRBMail@AdvocateHealth.com</p>
Version: 1.0; Date: October 2006	

The Advocate Health Care Institutional Review Board (AHC IRB) office is providing the following guidelines regarding Health Insurance Portability and Accountability Act (HIPAA), Protected Health Information (PHI) and research.

NOTE

A person who participates in a research study is called a “subject.”

Federal HIPAA Requirement

By Federal law, all subjects enrolled in research on or after April 14, 2003, and subjects who are being re-consented because of protocol and/or consent changes, must explicitly authorize access to their private health information (PHI). To facilitate compliance with this HIPAA requirement, the IRB has developed a HIPAA Authorization form. Some investigators may choose to use a study specific, sponsor provided authorization form. Either form is acceptable.

HIPAA Authorization Approval Requirement

The AHC IRB **does not** need to approve a study's authorization form as long as it is a stand-alone document that does not alter in any way the currently approved informed consent. A copy of whichever form the investigator chooses to use, AHC's or sponsor's, should be filed with the IRB. If a sponsor's authorization form is used, its completeness has to be verified by the investigator against the AHC IRB HIPAA Authorization template.

NOTE

While the AHC IRB does not require prospective approval of the HIPAA form, some sponsors may require it. In such case, it is still advisable to make the Authorization a separate document rather than integrating it with the consent.

If the investigator opts to integrate the HIPAA Authorization into the body of the consent, then an amendment and the revised consent must be submitted to the AHC IRB in the usual manner.

Waiver of HIPAA Requirement

Under limited circumstances the IRB can approve a waiver of the HIPAA Authorization requirement, similar to a waiver of consent. This is sometimes requested for record review studies, for patient screening based on inclusion/exclusion criteria or for initial subject recruitment activities prior to signing a consent document. The AHC IRB has developed a form that can be submitted to request a waiver. A copy of the HIPAA Waiver approval should be left in any medical chart that it accessed for research purposes.

Completing the HIPAA Authorization Form

Study specific information required on the AHC template is on page 1 of the form and has to be completed by the investigator and/or study staff. Just as with Informed Consent documents, it is the investigator's responsibility to retain each subject's HIPAA Authorization on file and provide a copy to the subject.

Completing the HIPAA Waiver Form

The Advocate IRB “*Request to Waive Consent or Alter Authorization before Accessing Private Health Information for Research Purposes*” form has to be used to request a HIPAA waiver or alteration of authorization,. The investigator has to attach an abstract of the research study to the waiver form and briefly describe and discuss points listed on the waiver form (with reference to the numbers). For additional information on how to complete the form, refer to “HIPAA Waiver Instructions.”

HIPAA Authorization and HIPAA Waiver Forms

The AHC IRB HIPAA Authorization and HIPAA Waiver forms and HIPAA Waiver Instructions are available at: www.advocatehealth.com/researchethics under “Forms, Instructions, Policies and Guidelines.” The documents can also be requested via e-mail at: IRBMail@ AdvocateHealth.com.

Further questions should be directed to the AHC IRB office at 847-384-3534 or via e-mail at: IRBMail@ AdvocateHealth.com.

Selected HIPAA Definitions

► Authorization to Access Private Health Information

Uses and disclosures of PHI are permitted with an individual authorization, including an authorization for use and disclosure of PHI for research. HIPAA Authorization document must include a set of elements specified by the HIPAA Privacy Rule.

► Covered Entity

"Covered Entities" are: 1) Providers who transmit PHI electronically; 2) Health plans; and 3) Clearinghouses.

► De-identified PHI

"De-identified" information is not PHI. Information may be de-identified by a) removing all identifiers as specified in the Privacy Regulations, or b) an expert certifies that the risk is very small that the information (alone or in combination with other available information) could be used to identify the individual.

► Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule

The HIPAA Privacy Rule provides federal standards for protecting the privacy of individually identifiable health information (PHI) and became effective 04/14/03.

► Identifiers

The following identifiers of the individual or of relatives, employers, or household members of the individual, are considered PHI identifiers under HIPAA:

Names

2. Postal address

All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:

(1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and

(2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

3. Dates

All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;

4. Telephone numbers

5. Fax numbers

6. Electronic mail address

7. Social security numbers

8. Medical record numbers

9. Account numbers

10. Health plan beneficiary number

11. Certification/license numbers

12. Vehicle identifiers and serial numbers, including license plate numbers

13. Device identifiers and serial numbers

14. Name of relative

15. Web Universal Resource Locator (URL)

16. Internet Protocol (IP) address number

17. Biometric identifiers, including fingers and voice prints

18. Full face photographic images and any comparable images

19. Any other unique identifying number, characteristic, or code

► **Individual**

"Individual" means the person who is the subject of protected health information, including a) living persons, or b) deceased persons. Therefore, IHI that relates to any person, alive or dead, and is transmitted or maintained in any form or medium by covered entities is PHI subject to HIPAA protection.

► **Individually Identifiable Health Information (IIHI) / Protected Health Information (PHI)**

HIPAA governs use and disclosure of health information that is created or received by a covered entity or employer, and relates to the physical or mental health of an individual, or the provision of health care to an individual, or to the payment for the provision of health care to an individual, and identifies the individual or reasonably may be used to identify the individual. This information is referred to as *Individually Identifiable Health Information (IIHI)*. HIPAA governs the use and disclosure of IIHI by covered entities that is: 1) Transmitted electronically, or 2) Maintained in electronic media, or 3) Transmitted or maintained in any other form or medium. Such IIHI that is transmitted or maintained in any form or medium by covered entities is Protected Health Information (PHI).

► **Limited data set**

A limited data set is PHI that excludes all identifiers listed under "HIPAA PHI Identifiers," except for dates, zip codes and geocodes. Limited data sets can be used or disclosed, if covered entity (e.g. investigator) enters into a data use agreement with the limited data set recipient.

► **"Minimum necessary" requirement**

When using or disclosing PHI or when requesting protected health information from another covered entity, an investigator must make reasonable efforts to limit PHI to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request; only collect PHI essential to the study, and record as few identifiers as possible.

► **Use and Disclosure of PHI**

"Use" of PHI is within the workforce of the covered entity; "disclosure" of PHI goes outside this workforce.

► **Waiver or Alteration of HIPAA Authorization**

The IRB may waive or alter the HIPAA authorization upon request of an investigator, but only if the IRB determines that the study meets a set of specified by the HIPAA Privacy Rule criteria.

Helpful HIPAA Links

DHHS / Office for Civil Rights / Health Insurance Portability and Accountability Act (HIPAA):
<http://www.hhs.gov/ocr/hipaa/>

NIH / HIPAA Privacy Rule: Information for Researchers:
<http://privacyruleandresearch.nih.gov/healthservicesprivacy.asp>

NIH: Research Repositories, Databases, and the HIPAA Privacy Rule:
http://privacyruleandresearch.nih.gov/pdf/research_repositories_final.pdf

AAMC: Guidelines for Academic Medical Centers on Security and Privacy:
<http://www.aamc.org/members/gir/gasp/>