

**IOWA HEALTH SYSTEM – DES MOINES  
INSTITUTIONAL REVIEW BOARD**

***Information for Investigators***

**USE AND DISCLOSURE OF  
PROTECTED HEALTH INFORMATION FOR RESEARCH  
WITH AUTHORIZATION**

**This guidance document is dated 19-March-03  
and updates previous documents**

20030319

The Privacy Rule of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which goes into effect on April 14, 2003, sets out the requirements for using and disclosing and Protected Health Information (PHI) of human subjects participating in research. HIPAA also requires that investigators obtain either the written authorization of research subjects to use and disclose their PHI or a waiver of authorization from an Institutional Review Board or a Privacy Board organized in accordance with HIPAA before using or disclosing and PHI of the human subjects. The Institutional Review Board of Iowa Health System – Des Moines will function as the HIPAA-mandated Privacy Board for research purposes.

***Protocols approved before April 14, 2003***

All subjects who consent to participate in research projects on or after April 14, 2003 must also authorize use and disclosure of their PHI.

Investigators have 3 choices:

1. Amend the currently approved consent form by excising the section dealing with Privacy/Confidentiality and include HIPAA language. (See next section: “New protocols approved after April 14, 2003.”) Research subjects will sign the form in only one place. The amended Consent and Authorization Form must be submitted to the IRB for review. In most cases, review will be expedited. If you are considering this option, please be advised that the IRB is testing a new format for the Consent & Authorization Form; the language will be simpler and the format should be easier to follow. The template for the new format is located on this website. Any Consent & Authorization Form that is approved before April 14, 2003 will be valid at least through the next round of continuing review of the protocol.
2. Retain the current Consent Form and use an Authorization Form. Research subjects will sign two forms. It is important that the language of the Confidentiality/Privacy section of the approved Consent Form be consistent with the Authorization Form. Your Authorization Form must be submitted to the IRB Office for review, which usually can be expedited. A sample form containing HIPAA-compliant language is attached and is also available for download as an MSWord file.
3. Retain the current Consent Form but excise the section on Confidentiality/Privacy and use an Authorization Form. Research subjects will sign two forms. The amended Consent

Form and the Authorization Form must be submitted to the IRB Office for review, which usually can be expedited.

***New protocols approved after April 14, 2003***

The language in the attached form should be used in place of the Privacy/Confidentiality Section of a traditional Consent Form. The Consent and the Authorization are combined in a single document, which the subject signs in only one place. However, please see suggested language that would immediately precede the signature.

Investigators wishing to use separate forms for Consent and Authorization may do so, however the Consent form should make no reference to Privacy or Confidentiality beyond saying that the subject is covered in a separate form. Both forms must be submitted to the IRB.

***Protocols approved under continuing review after April 14, 2003***

The previously approved Consent Form should be revised to incorporate language in the attached form, which may be used in place of the Privacy/Confidentiality Section. The Consent and the Authorization are combined in a single document, which the subject signs in only one place. However, please see suggested language that would immediately precede the signature.

*Please note the following points:*

- Consent to participate and authorization to use and disclose PHI are different things.
- The forms must be completed with **elements that are protocol-specific as indicated by yellow highlight [..]**; be sure to fill in all the appropriate spaces.
- If it is necessary or advisable to describe how the security of information about a research subject will be maintained (eg, in a triple-locked cabinet; 128-bit encoding; certificate of confidentiality), then this should be explained in the Consent/Authorization Form.
- The subject must receive a copy of the signed Authorization form or the combined Consent & Authorization form.
- Not all investigations qualify as “research”: For example, if the purpose of an investigation is analyze or improve healthcare delivery in the institution then it can be considered part of healthcare operations and an authorization to use and disclose PHI is not required. However, if there is a reasonable probability that the results of the investigation might be published or otherwise disseminated beyond the institution, then the investigation should be considered research.
- Not all research protocols involving human subjects require the HIPAA authorization. For example, surveys conducted on hospital employees and studies of educational interventions might not use Protected Health Information, and so would not be covered by the Act.
- In the pages that follow, **instructions to the investigator are shown in red print**; delete these passages from your final document.