

**Sent:** Friday, April 11, 2003 09:20  
**Subject:** Important Memo from Wendy Baldwin - HIPAA: April 14, 2003 Deadline

**Importance:** High

## MEMORANDUM

**To:** University of Kentucky Researchers Conducting Research Involving Human Subjects  
**From:** Wendy Baldwin, Ph.D.  
Vice President, Research  
**Date:** April 11, 2003  
**Subject:** HIPAA: April 14, 2003 Deadline

New federal regulations will affect many researchers at the University of Kentucky. The new regulations, implementing the Health Insurance Portability & Accountability Act (HIPAA), are designed by the federal government to protect the use and disclosure of individually identifiable health information (also called protected health information or PHI), transmitted or maintained in any form. Protected Health Information is any information that relates to the past, present or future physical or mental health or condition of an individual. Compliance with these HIPAA privacy regulations is required by the 14th of April, 2003.

The UK Office of Research Integrity has sent out several notifications and offered several presentations dealing with HIPAA over the last few months. We realize how confusing this issue can be. The complexity of HIPAA has required a long time for the University to sort out the details. As the deadline rapidly approaches I wanted to give you a last reminder because the HIPAA requirements may affect your research program. It is important that you understand the obligations placed on the University as well as the liabilities, both criminal and civil, that you -- and we -- could face for non-compliance. If you need any assistance in understanding your obligations, please contact Helene Lake-Bullock, Research Compliance Officer, or Joe Brown, Research Privacy Officer. Their complete contact information follows at the end of this memorandum.

HIPAA is applicable to you if your college or department uses Protected Health Information in connection with certain covered transactions. Legal counsel with guidance from Deans and other UK leaders have determined which colleges and departments engage in covered transactions and thus are covered by HIPAA. To find out whether your department/college is covered by HIPAA, see [http://www.research.uky.edu/ori/HIPAA/HIPAA coverage.htm](http://www.research.uky.edu/ori/HIPAA/HIPAA%20coverage.htm). Because of its size and the diversity of its activities, the University of Kentucky (UK) is designated as a hybrid entity which means that some departments/colleges are regulated by HIPAA and others are not. An entity, or its covered departments or colleges, that is regulated by HIPAA is called a Covered Entity.

As a researcher, you have the following responsibilities:

1. If your research is regulated by HIPAA, you can NOT enroll new subjects, create, share or access Protected Health Information from a UK Covered Entity after April 14, 2003 until your procedures are HIPAA compliant.
2. You must determine if your research is regulated by HIPAA. See below for guidance.
3. If your research is regulated by HIPAA, it is your responsibility to ensure that all research procedures are HIPAA compliant. This might involve modifying your IRB approved protocol\*, setting up a system for accounting of disclosures (recording the release of Protected Health Information outside the Covered Entity), submitting assurances to clinic and hospital medical records, or obtaining HIPAA required agreements such as a data use agreement.

To assist you with HIPAA's research privacy requirements, UK's Office of Research Integrity has conducted a series of presentations on HIPAA. Contact the ORI if you interested in obtaining presentation handouts. Additional information is also available on its web site at <http://www.research.uky.edu/ori/HIPAA/main page.htm>.

What is covered by HIPAA?

PHI which is defined as any of the 18 HIPAA recognized identifiers (see below) in combination with health information. HIPAA recognized identifiers:

1. Names;
2. All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes;
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death;
4. Telephone numbers;
5. Fax numbers;
6. Electronic mail addresses;
7. Social security numbers;
8. Medical record numbers;
9. Health plan beneficiary numbers;
10. Account numbers;
11. Certificate/license numbers;
12. Vehicle identifiers and serial numbers, including license plate numbers;
13. Device identifiers and serial numbers;
14. Web Universal Resource Locators (URLs);
15. Internet Protocol (IP) address numbers;
16. Biometric identifiers, including finger and voice prints;
17. Full face photographic images and any comparable images;
18. Any other unique identifying number, characteristic, or code.

Is my research covered by HIPAA?

If you are employed in a UK Covered Entity component and create, access or share Protected Health Information, HIPAA applies to your research.

If in your research you collect Protected Health Information from a UK Covered Entity and your department/college is deemed outside of the Covered Entity, HIPAA applies to your access of the Protected Health Information.

Additional Information:

If you need a HIPAA application form, it is accessible on the ORI website at <http://www.research.uky.edu/ori/forms/HIPAA.htm>.

For questions regarding HIPAA in Research, contact Joe Brown, Research Privacy Specialist, at (859) 257-9084 or [jrbrow3@email.uky.edu](mailto:jrbrow3@email.uky.edu) or Helene Lake-Bullock, Research Compliance Officer, at (859) 257-5943 or [hbullo@email.uky.edu](mailto:hbullo@email.uky.edu).

For questions regarding HIPAA patient rights or accounting of disclosure, contact Brett Short, Privacy Officer, at (859) 323-9817 or [rbshor2@email.uky.edu](mailto:rbshor2@email.uky.edu).

For questions regarding HIPAA agreements such as Data Use Agreements or Business Associate Agreements, contact Ned Benson, Associate General Counsel, at (859) 323-1161 or [ejbens0@email.uky.edu](mailto:ejbens0@email.uky.edu).