Policy Name:

Policy on Research Authorizations

Purpose for creation of policy:

To create a method for handling protected health information used or disclosed for research purposes by researchers at the University of Louisville when the research subject has not signed a required HIPAA authorization.

Consequences, if any of not following the policy:

No researcher will be allowed to continue to use or disclose any protected health information from or about a study subject, obtained without that subject’s permission through a signed HIPAA authorization.

Original author / office:

Privacy Office

Original document (is this draft replacing another document):

Original Document

When will it undergo review again:

Will undergo review on August 3

To whom does the policy apply:

The policy applies to all University of Louisville Institutional Review Board approved research protocols, which require a signed HIPAA authorization from the subject before protected health information from or about the subject can be used or disclosed.

Is there an appeal process:

No.

Specified time for comment from Faculty Senate:

Comment from Faculty Senate is requested no later than August 4, 2004.
Purpose: Create a method for handling protected health information used or disclosed for research purposes by researchers at the University of Louisville when a required HIPAA authorization has not been signed by the research subject.

Policy: No researcher will be allowed to continue to use or disclose any protected health information from or about a study subject, obtained without that subject’s permission through a signed HIPAA authorization. Any such protected health information in the possession of the researcher must be eliminated from the researcher’s files. The researcher will not be permitted to use the information for the research project. Whether said information must be completely destroyed and the appropriate disposition if not destroyed will be determined by the Institutional Review Board in consultation with the University Privacy Officer.

The researcher must contact all third parties with whom he/she shared such protected health information. The research must use his/her best efforts to get the third party to either return the protected health information to the researcher for appropriate disposition or obtain an assurance from the third party that such information has been destroyed. The researcher must assure that any disclosures by a covered entity of protected health information made without the required authorization are appropriately accounted for in the covered entity’s records.

The researcher must make and document any necessary communications with the subject regarding the subject’s continuing participation in the study.

Applicability: University of Louisville Institutional Review Board approved research protocols, which require a signed HIPAA authorization from the subject before protected health information from or about the subject can be used or disclosed.