

**RESEARCH CONFIDENTIALITY**

**August 2007**

**Policy 7.1.01**

**Policy:**

If you are involved in any privately funded research you may have an obligation to keep certain information confidential. If the research is a clinical trial, do not share confidential information about the trial in writing unless the exact wording has been approved in writing by: 1. the sponsoring agency, and 2. the KUMC Human Subjects Committee (HSC), and 3. the KUMC Research Institute (KUMCRI). For specific stipulations regarding publication, refer to the original, signed contract.

**Purpose:**

When KU Medical Center Research Institute enters into a research contract with a faculty member and a funding source, there is almost always a confidentiality agreement section that binds all parties to non disclosure of certain information without written approval of the other parties. In clinical trial research, this is always the case. The investigator, and anyone involved in the trial who received information regarding the protocol, must keep all information strictly confidential.

Information which is usually confidential includes the name of the company, the drug information, the protocol number, the dosage, etc. Most companies will not allow the title of the trial to be posted or advertised on lists. Listing of trials for the purpose of recruitment of patients, even when only done in the corridors or offices of the clinics, does not maintain confidentiality. Some staff have chosen to list the title of the trials on their CV as evidence of their research experience. The aforementioned examples must have written approvals. An example of the type of general information that can be shared is, "A multi center, double-blind study for a long-acting beta agonist for subjects with asthma".

Care must be taken when sharing information verbally with others on the staff or in situations where staff can be overheard by patients, visitors, or other unauthorized persons. Companies are very serious about confidential information. Protection of human subjects' information is very seriously monitored by the HSC. Breach of contract by disclosure of confidential information is a very serious offense for the KUMCRI and KUMC.

As of April 13, 2003, the U.S. Department of Health and Human Services required compliance with regulations mandated in HIPAA. These requirements stipulate that researchers be aware of, and follow, the HIPAA Privacy and Security Rules.

**Procedures:**

Approval must be received in writing by the sponsoring agency, the KUMC Human Subjects Committee (HSC), and the KUMC Research Institute, Inc. before confidential information can be shared.

All KUMC Research Institute staff must sign a confidentiality agreement.

**Definitions:**

HSC: Human Subjects Committee.

**Responsible Parties:**

This policy shall apply to all KUMC faculty (regardless of appointment type), staff, postdoctoral fellows, students, trainees, and any other persons at KUMC, University of Kansas Physicians Incorporated and its affiliates, and KU Hospital staff involved in conducting and/or coordinating or managing research at KUMC, and all KUMC Research Institute personnel.

**Exemptions:**

None.

**Related Policies and Links:**

KU Medical Center Office of Compliance <http://www2.kumc.edu/researchcompliance/human.htm>

National Institute of Health, HIPAA Privacy Rule [http://privacyruleandresearch.nih.gov/clin\\_research.asp](http://privacyruleandresearch.nih.gov/clin_research.asp)

The National Human Research Protection Advisory Committee <http://www.hhs.gov/ohrp/nhrpac/documents/nhrpac14.pdf>

**Contacts:**

Vice Chancellor for Research: 913-588-7068

Associate Vice Chancellor for Research Administration: 913-945-6636

**History:**

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