

CHARGING MEMORANDUM

Task Force H (TF-H): HIPAA-Research Task Force

The broad mission of the HIPAA-Research Task Force (TF-H) is to review compliance and integrity issues relating to the implementation of the Health Insurance Portability and Accountability Act (HIPAA) in respect to research activities, especially those involving human subjects, at the University, and to provide advice and recommendations. In so doing, this Task Force should become generally familiar with current HIPAA regulatory requirements, with ethical and other external standards (including Kentucky state law requirements) that relate to human research, and with relevant University policies and practices. The HIPAA-Research Task Force will identify and inventory institutional needs and vulnerabilities, and associated compliance risks, and make recommendations respecting any matters under review, with the objective of minimizing risks, enhancing compliance, and facilitating the responsible conduct of research.

The HIPAA-Research Task Force will provide its advice and recommendations to university officials and committees, as appropriate. In consultation with others, it will establish timelines and milestones for the accomplishment of its tasks. In conducting its review, it will give consideration to the matters identified below:

1. Guidelines, policies and forms applicable to HIPAA implementation and HIPAA requirements, and to research involving human subjects in research;
2. Appropriate mechanisms for monitoring and auditing compliance with HIPAA requirements and for other appropriate forms of oversight;
3. Appropriate measures, including sanctions and discipline, for the enforcement of University policies relating to the implementation of HIPAA in respect to research activities, and for handling instances of non-compliance. In this connection the HIPAA-Research Task Force should coordinate its recommendations with the Human Studies Task Force (TF-E), and with the Monitoring, Auditing and Response Task Force (TF-F), which have, respectively, over-arching responsibility for recommendations concerning policies for the protection of human subjects in research, and for coordinating the development of research monitoring and auditing mechanisms, generally, and for research misconduct policies and procedures;
4. Appropriate training and certification requirements for University faculty and staff concerning HIPAA and research. In this connection, the HIPAA-Research Task Force should coordinate its recommendations with the Research Standards and Training Task Force (TF-G), which has responsibility for developing the overall program for training and certification in the responsible conduct of research;
5. The level of commitment and support by all concerned at the University for policies involving the implementation of HIPAA in connection with research at the University;
6. Ways to streamline procedures and facilitate compliance relating to the implementation of HIPAA in connection with research..