



The HIPAA Privacy Rule and Research Position Statement

The Association of Academic Health Centers (AAHC) believes the negative impact of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule on research has created the need for a new regulatory framework to govern, protect, and enhance the privacy of research participants while at the same time ensuring the advance of the nation's research enterprise. The protection of the privacy and confidentiality of patients and research participants is a fundamental tenet of research. However, the HIPAA Privacy Rule, since its implementation in 2003, has had a profoundly negative impact on the type and pace of research undertaken throughout the nation. Many researchers are deterred from pursuing important lines of inquiry necessary to advance science, thus slowing the progress towards new cures and treatments for illness and disease, ultimately doing harm to patients both present and future. The AAHC believes that the chilling effect the Privacy Rule has had on research will only be magnified by the added provisions mandated in the Health Information Technology for Economic and Clinical Health (HITECH) Act, signed into law by President Obama in February 2009 as part of the American Recovery and Reinvestment Act (ARRA).

The AAHC recommends that Congress authorize the Secretary of Health and Human Services to create the new regulatory framework to protect the privacy of research participants. The framework should include the creation of a certification process for institutions to qualify as "safe harbor" entities similar to what occurs in Canada and the United Kingdom. In order to be certified, an institution must show evidence of sound data security practices as well as established criteria for researchers with respect to ethical research practices and protection of privacy and confidentiality. Academic health centers, where the vast majority of research is conducted in the United States, are in the vanguard, developing new methods for data security and the protection of patient privacy. The new framework should recognize the significant safeguards already in place at these institutions by allowing them to be certified as "safe harbors" while simultaneously providing institutions and researchers with the flexibility to pursue innovative lines of scientific inquiry. **The AAHC recommends that once this new framework for privacy of research participants is established, research should be exempted from the Privacy Rule.**

By its nature, the regulatory process does not move quickly enough to keep pace with technology; the technical knowledge necessary to bypass the safeguards in the HIPAA Privacy Rule is unfortunately already available. Adding more detailed and prescriptive

regulations will neither deter those who are determined to breach the privacy of others or keep pace with technologies designed to accomplish that goal. **Thus, the new framework should establish significant penalties for the intentional and malicious breach of privacy as well as a solid mechanism to enforce such penalties.**

The AAHC recognizes that the establishment of a new framework and the exemption of research from the Privacy Rule will take time. **In the interim, the AAHC recommends that the U.S. Department of Health and Human Services take immediate action to harmonize the HIPAA Privacy Rule with the Common Rule and all other federal regulations governing research.** Areas of inconsistency include but are not necessarily limited to:

- Differing deidentification standards;
- The ability for research participants to authorize their information to be used for future research; and
- The exemption for activities preparatory to research in the Privacy Rule.

Furthermore, the Common Rule (45 CFR 46) should be harmonized with Food and Drug Administration (FDA) human subject protection regulations (21 CFR 50). Eliminating the several areas of inconsistency would break down some of the existing barriers for institutions, researchers, and patients alike, and facilitate the transition to a framework that is compatible with the unique needs of the research environment.

Ultimately, the best way to protect the privacy and safety of human research participants is to ensure that all research conducted in the United States adheres to a uniform set of regulations. **Thus, AAHC recommends that Congress develop legislation to ensure that the Common Rule and the new framework extend to all research conducted in the United States regardless of its funding, sponsor, or location.**

The Association of Academic Health Centers believes a new framework to protect the privacy of research participants is required to ensure that the United States remains preeminent in biomedical research in the future.