



## Science Policy News August 2013

### **Update on Human Subjects Research: HIPAA and HITECH**

The HIPAA/HITECH rule was recently released with an effective date in late March 2013. This article highlights changes and provisions likely to be of concern to the ASIP membership. The Health Insurance Portability and Accountability Act (HIPAA) of 1996 included many components designed to address patient privacy issues. The 2009 Health Information Technology for Economic and Clinical Health Act (HITECH) further built upon HIPAA, clarifying privacy requirements as it fostered the growth of electronic health records. Together, HIPAA and HITECH regulate how patient information can be conveyed to and used by healthcare workers and researchers. HIPAA/HITECH apply when information or samples are gathered from patients.

Researchers in the United States who work in institutions that receive US Federal funds must also comply with the Common Rule (encapsulated in Title 45 Code of Federal Regulations (CFR) 46, last revised in 1991), which establishes the basic bioethical requirements for human subjects research. The purview of the Common Rule extends beyond patient care data and addresses all research conducted on human subjects by agencies of the United States Department of Health and Human Services as well as other federal departments such as The Department of Energy and The Department of Defense. Each of the participating agencies requires the use of Institutional Review Boards (IRBs) to oversee human subjects research. IRBs must operate under the requirements of the Common Rule.

HIPAA/HITECH expand upon the requirements of the Common Rule when the research is conducted on patients or where samples were gathered from patients in the healthcare setting. As a result, researchers conducting studies using samples from patients must comply with both the requirements of HIPAA/HITECH and the Common Rule.

Many of the 2013 revisions of HIPAA/HITECH ease previous restrictions and their resulting administrative requirements are more harmonious with the Common Rule. Researchers should work with regulatory affairs professionals to understand further how these changes may apply within your organization and their alignment with other relevant state, local or national regulations. An executive summary of the major changes to HIPAA/HITECH relevant to researchers is provided below.

### **Compound Authorizations may be used in specific circumstances.**

The new rule adds some flexibility to authorizations for the use of protected health information (PHI) in research. This is a positive development, representing further compatibility between



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the Common Rule and HIPAA's provisions. Previously, conditioned and unconditioned authorizations could not be combined in the same document. Conditioned authorizations are those requiring the patient's consent before treatment, payment, and enrollment in a health plan or benefit eligibility. Unconditioned authorizations are those agreements that do not link treatment, payment, enrollment in a health plan or benefit eligibility to the patient's consent. Previously, an authorization could not blend conditioned and unconditioned authorizations. For example, authority to treat was presented in one document and consent to participate in a research study was found in another document. Compound authorizations – combining conditioned and unconditioned authorizations – are now allowed in specific sets of circumstances. The Final Rule requires that a compound authorization clearly differentiate between the conditioned and unconditioned components. The individual is provided with an opportunity to opt in to the research activities described in the unconditioned authorization. "Opt out" authorizations are insufficient; for example, one should not use a form requesting that an individual initial here if they do not want information used. It is important to note that compound authorizations allowing access to psychotherapy PHI may only be combined with other authorizations for use of psychotherapy notes.

### **Compound Authorizations may be used to consent to future research. Authorizations need not be study specific.**

Authorizations for future use should sufficiently describe the purposes in a way that an individual might expect their information to be used in the future and/or disclosed. Consent may be provided for biobanking activities as well as secondary future research. Consent for these activities may be contained within the compound authorization. This brings HIPAA's requirements in line with the Common Rule.

Genetic Information is now explicitly included as part of the definition of health information. Furthermore, the Final Rule states that genetic information cannot be disclosed to covered entities for underwriting purposes except issuers of long-term care policies; this is currently part of GINA – the Genetic Information and Nondiscrimination Act of 2008. It makes specific note that genetic information may not be used for activities such as underwriting by health plans; eligibility determinations; premium calculation; and exclusion of pre-existing conditions. The law specifies various terms to further delineate what is meant by genetic information, including defining the following:

- Family member includes a dependent or any other person who is a first-degree, second-degree, third degree, or fourth-degree relative with each degree level further defined in the regulation. Relatives by affinity (such as marriage or adoption) are treated the same as relatives by consanguinity (having a common biological ancestor). Relatives by less than full consanguinity (such as half-siblings sharing a single parent in common) are treated the same as relatives by full consanguinity (such as siblings who have both parents in common).



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- Genetic information includes information about the following: the individual's genetic tests; the genetic tests of family members; the manifestation of a disease or disorder in family members; or genetic services. It also includes genetic information concerning a fetus carries by the individual or family member who is a pregnant woman and any embryo legally held by an individual or family member utilizing an assisted reproductive technology. It specifically excludes information about the sex or age of any individual.
- A genetic service includes a genetic test, genetic counseling or genetic education.

### **The definition of research did not change.**

Research continues to be defined as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

### **Protected Health Information (PHI) excludes information from an individual who died over 50 years ago.**

Consent for use of PHI is required for decedents whose death has been within the last 50 years. This change will ease researchers' ability to use decedent's information over time.

*This article was prepared by Jennifer Dreyfus, MBA, M. Bioethics, who is a consultant to the ASIP Public Affairs Working Group.*

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*[http://www.asip.org/publications/newsletter/documents/ASIPPathways\\_August2013.pdf](http://www.asip.org/publications/newsletter/documents/ASIPPathways_August2013.pdf)*