

## **17. THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT**

Requirements for the release of identifiable health information by covered entities (e.g., certain health providers, health plans, and health clearinghouses) were set forth by the Health Insurance Portability and Accountability Act (HIPAA) of 1996, which became effective on April 14, 2003.

The Coordinating Center will work with the Study Centers to ensure that authorizations to release identifiable health information meet the HIPAA requirements. These authorizations must include a description of the information that will be used or disclosed; who may use or disclose the information; who may receive the information; the purpose of the use or disclosure; the expiration date (if there is no expiration date, it must be explicitly stated as such); notice that the authorization may be revoked; notice that the information may be disclosed to others not subject to the Privacy Rule (redisclosures may not be protected); notice that an individual may refuse to sign the authorization (if any treatment or payments are conditional upon the individual's signing the authorization, the individual must be informed of this); and the individual's signature and date.

These requirements for authorizations may be combined in a consent form or may be a separate document. A Privacy Board (or IRB serving as a Privacy Board) may authorize the release of identifiable health information if additional risks are not created for Study subjects.

