

**Policy Memorandum No. 31**

**Subject:** HIPAA Policy

**Departments Affected:** All  
Name

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**HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)  
PRIVACY RULE POLICY**

The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule went into effect April 14, 2003. The Privacy Rule places restrictions on how Covered Entities may use and disclose Protected Health Information (PHI). This policy serves to document the policies and procedures developed within SWOG to acknowledge this regulation.

- The SWOG Operations Office and Statistical Center are **not** covered entities. Therefore, the Group is not mandated to comply with the HIPAA Privacy Rule standards. However, it is recognized that our member institutions are, so the Group will comply with the regulations as outlined below. Covered entities include healthcare plans, healthcare clearinghouses, and healthcare providers. Researchers are not covered entities, in part because they are not healthcare providers unless they provide treatment along with their research and bill for their services using a HIPAA Standard Transaction. SWOG does not provide treatment because it does not provide its research subjects with care, services or supplies for treatment purposes (45 C.F.R § 160.3; 65 Fed. Reg. 82477).
- SWOG is not a Business Associate of any of its members. Researchers are not business associates of covered entities. (Standards for Privacy of Individually Identifiable Health Information, Office of Civil Rights HIPAA Privacy, pp. 43, 47, December 3, 2002, collected 12/11/2002 at <http://benefitslink.com/articles/finalprivacy20021203.pdf>.) To be a Business Associate, a person or entity must perform a function involving Protected Health Information (PHI). The department of Health and Human Services (HHS) has taken the position that when an entity conducts research, it does not perform a function "on behalf of" a covered entity and, therefore, researchers are not business associates. (Standards for Privacy of Individually Identifiable Health Information, Office of Civil Rights HIPAA Privacy, pp. 43, 47, December 3, 2002, collected 12/11/2002 at <http://benefitslink.com/articles/finalprivacy20021203.pdf> [45 C.F.R. § 160.103].) Furthermore, research is not one of the additional special services for which HHS requires a business associate agreement. Those special services are actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services (45 C.F.R. § 160.103).
- **All patients (initially) registered to Group-coordinated studies on or after April 14, 2003, must have signed a patient authorization form** so that PHI may be released to the Group.

- Recommendations for Authorizations

It is expected that patient authorizations will be worded so as to allow the release of PHI to SWOG for the life of the study. While the authorization may be integrated within other documents related to the study, the Group recommends that the authorization form and Informed Consent document be kept separate for the following reasons:

- The important distinctions between privacy risks and risks of study treatment are better maintained.

- There may be times when it is necessary for the physician to release PHI to determine whether a patient is eligible for a particular trial. In these cases, it will be necessary to have a signed authorization prior to having the patient enroll in the trial and sign an Informed Consent.
  - NCI Cooperative Groups, in collaboration with the Office for Human Research Protections and the Food and Drug Administration, developed and have generally adopted and employed a consistent approach to a study informed consent template. Different institutions may wish to adopt different approaches to the content of the HIPAA authorization. Combining this with the model consent would risk sacrificing some of the consent consistency.
  - HIPAA regulations allow the institution to deny participation in a clinical trial, should the patient refuse to sign an authorization to release PHI to the researcher. Further, it is required by the regulation that this fact be included in the authorization for release of PHI. Including this language in the informed consent document could appear to "coerce" the patient into agreeing to the release of PHI in order to participate in the trial.
  - Informed consent documents must be approved by the appropriate Institutional Review Board (IRB). If the authorization is combined with the informed consent, the IRB must approve the language. The IRB is not required to approve the separate authorization.
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- **PHI for patients registered to SWOG-coordinated studies prior to April 14, 2003, may be released without further authorization**, according to the HIPAA Transition Provisions that say that a consent form signed prior to April 14 may act as an authorization after April 14.
  - It is expected that patient authorization forms will be specific to each institution's requirements, and comply with local laws.
  - Ongoing protocols as of the implementation date were not amended to include a patient authorization form. The model patient authorization form on our website serves as the template for ongoing studies. Protocols activated after April 14, 2003, will include study-specific patient authorization forms.
  - Any PHI data collected are stored under an additional layer of security in the SWOG database, and access is severely restricted. With the exception of patient initials and dates, SWOG will release no PHI, except as required by law. It may utilize PHI internally for research purposes only, and PHI may be released back to the submitting participant or institution under appropriate circumstances.