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HIPAA and the Cooperative Groups

The National Cancer Institute (NCI) Cancer Clinical Cooperative Groups are working with the NCI to coordinate and clarify the implementation of the HIPAA regulations, as they relate to Cooperative Group research.

Several of our member institutions have expressed concern regarding the submission of research data to the Southwest Oncology Group when the new Privacy Act takes effect on April 13, 2003.

Cooperative Group investigators will be seeking individual authorizations from participants in Cooperative Group trials. Within the next few weeks, the Cooperative Groups will be releasing the following information to the member institutions and investigators:

- A model authorization form for the release of protected health information (PHI)
- A fact sheet for institutions outlining the relationship of the NCI Cooperative Groups to the Privacy Act
- A fact sheet for patients outlining their rights under HIPAA, as they relate to Cooperative Group clinical trials.

We are also developing information sheets describing the transmission of biology samples, scans and other information required for Cooperative Group research, but the timing of release of these materials may be later in the spring of this year.

At a meeting of the Groups and NCI representatives, there was discussion of whether or not the authorization should be incorporated in the same document as the model informed consent. Several lines of reasoning suggested that the HIPAA authorization and the model informed consent should be separate:

- The important distinctions between privacy risks and risks of study treatment are better maintained.
- Combining the forms would require that all of the consent documents for open trials be revised to include authorization for new patients. If there is a separate authorization, no revision to the informed consent is required.
- 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.
- The groups, in collaboration with OHRP and FDA, developed and have generally adopted and employed a consistent approach to a study informed consent template. At least at present, 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. Some individuals felt that including this language in the informed consent document could appear to "coerce" the patient into agreeing to release of PHI in order to participate in the trial.

For these reasons the NCI Cooperative Group approach will be to recommend that the authorization for the release of PHI be a separate and distinct document from the Informed Consent for participation in a Cooperative Group Clinical trial.

If you have questions, please contact the Southwest Oncology Group Operations Office.