Southwest
Oncology Group
A National Clinical Research Group

MEMORANDUM

To: Southwest Oncology Group Members
Other Cooperative Group Representatives (for circulation)

From: Southwest Oncology Group Operations Office and Statistical Center

Date: April 1, 2003

Subject: HIPAA Implementation in SWOG

The Health Insurance Portability and Accountability Act (HIPAA) **Privacy Rule** goes into effect on April 14, 2003. The Privacy Rule places restrictions on how Covered Entities may use and disclose Protected Health Information (PHI). This memorandum serves to notify you of new policies and procedures developed within the Southwest Oncology Group to acknowledge this new regulation. Attached are the HIPAA Fact Sheet for IRBs, Privacy Boards, and Institutions, as well as the Southwest Oncology Group's model Patient Authorization form, which explain how HIPAA affects our Group in detail. In summary, please be aware of these key points:

- The Southwest Oncology Group Operations Office and Statistical Center are **not** covered entities. Therefore, we are not mandated to comply with the HIPAA Privacy Rule standards. However, we recognize that our members are, so we are complying with the regulation as much as possible.

- The Southwest Oncology Group is not a Business Associate of any of its members.

- **All patients (initially) registered to SWOG-coordinated studies on or after April 14, 2003 must have signed a patient authorization form** so that PHI may be released to us.

- **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 which say that a consent form signed prior to April 14 may act as an authorization after April 14.

- We expect that your patient authorization forms will be specific to your institution's requirements, and comply with local laws. SWOG has provided a ***model*** authorization form which you may download from the http:\\swog.org website (members page), and modify as needed..

- Ongoing protocols will **not** be amended to include a patient authorization form. The model patient authorization form on our website serves as the template for ongoing studies. New protocols will include study-specific patient authorization forms.

- With the exception of patient initials and dates, the only PHI we collect is at registration. These data are stored under an additional layer of security in the Southwest Oncology Group database, and access is severely restricted. Some older forms may still request full patient name, but we continue to require that **only initials be provided** now and in the future on all data submitted. This will be enforced at the Statistical Center. Repeated infractions will be reported to the institution's Privacy Officer.

- With the exception of patient initials and dates, no PHI will be released by the Southwest Oncology Group, except as required by law. We may utilize PHI internally for research purposes only.

- Other Cooperative Groups are implementing similar policies and procedures.

These points are further explained in the attached documents. Please read them carefully. Questions may be addressed to Dana Sparks at the Operations Office (210) 677-8808 or Angela Ribble at the Statistical Center (206) 652-2267.

National Cancer Institute Cooperative Clinical Trials Groups
Southwest Oncology Group

HIPAA Fact Sheet for IRBs, Privacy Boards, and Institutions

Cooperative Groups are networks of investigators and institutions located in academic centers and the community that work together to conduct clinical cancer research. Activities in the Cooperative Groups are largely funded as federal programs through the National Cancer Institute (NCI), one of 25 institutes and centers in the National Institutes of Health.

More than 1,500 institutions and thousands of professionals participate in Cooperative Group trials and activities. Together these members enroll more than 28,000 patients on cancer clinical trials each year and account for approximately 60 percent of all patients enrolled each year in cancer clinical trials in the U.S.

The introduction of the Privacy Rule (HIPAA) has implications for the conduct of these Cooperative Group cancer clinical trials. We have prepared this Fact Sheet to describe how HIPAA impacts researchers like us, and our relationship with institutions like yours.

The Southwest Oncology Group is Not a Covered Entity

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. The Southwest Oncology Group does not provide treatment because it does not provide its research subjects with care, services or supplies for treatment purposes.[1]

The Southwest Oncology Group is Not a Business Associate

Researchers are not business associates of covered entities.[2] To be your Business Associate, a person or entity must perform a function on your behalf 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.[3] Furthermore, research is not one of the additional special services for which HHS requires a business associate agreement.[4] Therefore, as a research organization, the Southwest Oncology Group is not your business associate.

You Do Not Need to Have a Business Associate Agreement With the Southwest Oncology Group

Because the Southwest Oncology Group is not a business associate of yours, you do not need to have a business associate agreement with us. Furthermore, the HHS Office of Civil Rights has stated that disclosures of PHI from a covered entity to a researcher for research purposes do not require a business associate agreement.[5] Business associate agreements are only required if a

person or entity is conducting a function or activity regulated by the Administrative Simplification Rules on behalf of a covered entity.[6] Usually such functions or activities are for treatment, payment, or healthcare operations. Research is not such a function. Therefore, you do not need to have a business associate agreement with the Southwest Oncology Group.

HIPAA Permits You to Release Protected Health Information to the Southwest Oncology Group

You may release PHI to the Southwest Oncology Group with the study subject's permission. This type of permission is termed an 'authorization.' Patient authorizations may take many forms, depending on your institution requirements and local laws, but they must include certain required elements.[7] Since some PHI must be released to the Southwest Oncology Group as part of data submission requirements, all initial patient registrations to Southwest Oncology Group trials initiated April 14, 2003 or later will request the date the patient signed an authorization form. If the patient refuses to sign an authorization, they will not be allowed to participate in the trial.[8] The Cooperative Groups, working with the NCI, have developed a model authorization form which SWOG members can download from the SWOG website and modify according to your needs.

The study consent form acts as an authorization for subjects consented prior to April 14, 2003. According to the HIPAA Transition Provisions, a covered entity may use and disclose protected health information that was created or received for research, either before or after the compliance date, if the covered entity obtained the informed consent of the individual to participate in the research.[9] Patients consented prior to April 14, 2003 do not need an additional authorization signed to release PHI, unless required by local law. If a re-consent is required by the study after April 14, 2003, authorization would be required at that time.

Recommendations for Authorizations

It is expected that the patient authorizations will be worded so as to allow the release of PHI to the Southwest Oncology Group for the life of the study. While the authorization may be integrated within other documents related to the study, we recommend 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's Groups, in collaboration with OHRP and the FDA, 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 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.

Patient Identifiers to be Collected

For most Southwest Oncology Group studies, the collection of patient identifiers will be limited to the following items. The collection of this information is critical to maintain acceptable levels of data quality as well as scientific validity.

Patient Identifier	**Reason**
Patient Initials	Allows researchers to verify the accuracy of research case numbers across multiple pieces of information submitted throughout the life of the study. Full patient name is only requested at the time of registration, and is optional, but recommended.
Social Security Number	The SSN is required to access the national death index, which may be used by researchers. The SSN is only requested at the time of registration, and is optional, but recommended.
Elements of Dates	All dates relevant to the study will be collected to insure the appropriate analysis of the data including dates of diagnosis, treatment, disease response/progression, death, etc.
Zip Code	Federal requirement
Country	Federal requirement
Photographs	May be necessary for certain studies that have central radiation therapy review.

The Southwest Oncology Group Protects the Security of the PHI You Release to Us

We have developed policies and procedures to ensure the confidentiality of the PHI you release to us. We train our employees in HIPAA privacy procedures, and have designated an individual who is responsible for ensuring the procedures are followed. All Southwest Oncology Group employees sign confidentiality pledges.

No case report forms created after January 2000 collect any PHI except for patient initials and dates. Only the patient registration program collects identifiable patient information (full name and SSN, both of which are optional; zip code and country which are required by federal law). These data items are stored under an additional layer of security in the Southwest Oncology Group database. Access to these data items is severely restricted, and only granted as needed to perform necessary job functions.

With the exception of patient initials and dates, PHI is redacted from any data released by the Southwest Oncology Group, except as required by law.

Implementation of the HIPAA Privacy Rule Within the Southwest Oncology Group

A model Southwest Oncology Group patient authorization form can be found on the members page of the Group's website at http://swog.org. The patient authorization form must be modified to include language specific to your institution and local laws. If you choose to use it, the model patient authorization form is clear where institution-specific language must be inserted. Patient authorization forms must meet certain requirements[7], and these requirements will be verified at audit.

We will be asking for the date an authorization was signed by the patient or their legal representative as part of the registration process for all initial registrations to SWOG-coordinated studies starting April 14, 2003. Revised Registration Forms will be included as part of future protocol amendments to ask for the date of authorization. Language about the patient authorization requirement will also be added to the Eligibility Section as part of future protocol amendments.

All new Southwest Oncology Group protocols activated April 15, 2003 and later will include a study-specific model patient authorization form that is separate from the Informed Consent. If a patient transfers to your institution after April 14, 2003, you may need re-authorization from that patient to release data.

As stated above, a consent form signed prior to April 14, 2003 acts as an authorization form for release of PHI after that date (as local law allows). Therefore, if a re-consent is necessary after April 14, a patient authorization form may need to be signed at that point.

Questions may be referred to Dana Sparks at the SWOG Operations Office (210) 677-8808 or Angela Ribble at the SWOG Statistical Center (206) 652-2267.

References

[1] 45 C.F.R § 160.3; 65 Fed. Reg. 82477

[2] Standards for Privacy of Individually Identifiable Health Information, Office of Civil Rights HIPAA Privacy, pps. 43, 47, December 3, 2002, collected 12/11/2002 at http://benefitslink.com/articles/finalprivacy20021203.pdf (*hereinafter* "HIPAA Questions & Answers").

[3] HIPAA Questions & Answers, pp. 4347; 45 C.F.R. § 160.103

[4] Those special services are actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services. *See* 45 C.F.R. § 160.103.

[5] HIPAA Questions & Answers, pg.47

[6] 45 C.F.R. § 160.103

[7] *See* 45 C.F.R. § 164.508

[8] *See* 45 C.F.R. § 164.508

[9] HIPAA Questions & Answers, pg. 89

Authorization to Use or Disclose (Release)
Identifiable Health Information For Research

Institution: please address all red text.

1. What is the purpose of this form?

The **Southwest Oncology Group** is an organization that does research to learn about the causes of cancer, and how to prevent and treat cancer. Researchers would like to use your health information for research. This information may include data that identifies you. Please carefully review the information below. If you agree that researchers can use your identifiable health information, you must sign and date this form to give them your permission.

2. What health information do the researchers want to use?

The researchers want to abstract and use the portions of your medical record that they will need for their research. If you enter a Southwest Oncology Group research study, information that will be used and/or released may include your complete medical record, and in particular, the following:

- the history and diagnosis of your disease
- specific information about treatments you received
- information about other medical conditions that may affect your treatment
- medical data, including laboratory test results, tumor measurements, CT scans, MRIs, X-rays, photographs of radiation therapy target areas, and pathology results
- information on side effects (adverse events) you may experience, and how these were treated
- long-term information about your general health status and the status of your disease
- tissue and/or blood samples, associated data related to the analysis of the samples

You may request a blank copy of the Southwest Oncology Group data forms from **[title/position]** to learn what information will be shared.

3. Why do the researchers want my health information?

[name of site] will collect your health information and share it with the Southwest Oncology Group if you enter a Cooperative Group research study, or to evaluate your eligibility for a study. The Southwest Oncology Group researchers will use your information for the following cancer research study(ies).

[title and details of study as required by your institution]

4. Who will be able to use my health information?

[name of site] will use your health information for research. As part of this research, they may give your information to the following Groups taking part in the research. **[name of site]** may

also permit staff from these Groups to review your original records as required by law for audit purposes.

- the Southwest Oncology Group
- **[name of participating Group, if applicable]**
- **[name of member institution, if applicable]**
- the Cancer Trials Support Unit (CTSU), a research group sponsored by the National Cancer Institute to provide greater access to cancer trials **[if applicable]**
- public health agencies and other government agencies (including non-U.S.) as authorized or required by law
- other people or organizations assisting with Southwest Oncology Group research efforts.
- central laboratories, central review centers, and central reviewers. The central laboratories and review agencies may also give your health information to those groups listed above.

5. How will information about me be kept private?

The Southwest Oncology Group will keep all identifiable health information confidential to the extent possible, even though they and other federal research groups are not subject to the same federal privacy laws governing clinical centers. The Southwest Oncology Group will not release identifiable health information about you to others except as authorized by this form, or required by law. If your identifiable health information must be shared with other organizations, the privacy laws that govern those organizations would apply.

6. What happens if I do not sign this authorization form?

If you do not sign this authorization form, you will not be able to take part in a research study for which you are being considered.

7. If I sign this form, will I automatically be entered into the research study?

No, you cannot be entered into any research study without further discussion and separate consent. After discussion, you may decide to take part in the research study. At that time, you will be asked to sign a separate research consent form.

8. What happens if I want to withdraw my authorization?

You can change your mind at any time and withdraw this authorization. This request for withdrawal must be made in writing. Beginning on the date you withdraw your authorization, no new identifiable health information will be used for research. However, researchers may continue to use the health information that was provided before you withdrew your permission.

If you sign this form and enter the research study, but later change your mind and withdraw your authorization, you will be removed from the research study at that time.

To withdraw your authorization, please contact the person below. **[He/she]** will make sure your written request to withdraw your authorization is processed correctly.

[title of contact person, address, phone and fax number]

9. How long will this authorization last?

If you agree by signing this form that researchers can use your identifiable health information, this authorization has no expiration date. However, as stated above, you can change your mind and withdraw your permission at any time.

10. What are my rights regarding my identifiable health information?

You have the right to refuse to sign this authorization form. You have the right to review and/or copy records of your health information kept by **[name of site]**. You do not have the right to review and/or copy records kept by the Southwest Oncology Group or other researchers associated with the research study.

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Signatures

I agree that my identifiable health information may be used and disclosed for research purposes described in this form.

Signature of Patient or Patient's Legal Representative:

_____ Date:_____

Printed Name of Legal Representative (if any):_____

Representative's Authority to Act for Patient:_____

Signature of Person Obtaining Authorization:_____

Printed Name of Person Obtaining Authorization:_____