NATIONAL CANCER INSTITUTE COOPERATIVE CLINICAL TRIALS GROUPS

HIPAA FACT SHEET

[LIST PARTICIPATING COOPERATIVE GROUPS]

FOR IRB’s, 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.

[Name of Cooperative 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. [NAME OF COOP GROUP] does not provide treatment because it does not provide its research subjects with care, services or supplies for treatment purposes.¹

[Name of Cooperative 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”). 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, [NAME OF COOP GROUP] is not your Business Associate.
You Do Not Need To Have A Business Associate Agreement With [Name of Cooperative Group].

Because [Name of Cooperative 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 protected health information from a covered entity to a researcher for research purposes do not require a business associate agreement. 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. 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 [NAME OF COOP GROUP].

HIPAA Permits You To Release Protected Health Information To [NAME OF COOP GROUP] With A Subject’s Authorization

You may release PHI to [NAME OF COOP GROUP] with the study subject’s permission. This type of permission is termed an Authorization. The subject’s Authorization must meet certain requirements. The cooperative groups, working with the NCI, have developed a model authorization form (Permission Form). If a patient refuses to sign an authorization, they may not be allowed to participate in a cooperative group trial.

Recommendation for Authorizations

While the Authorization may be integrated within other documents related to the study, we recommend that the authorization for the release of PHI be obtained prior to seeking the patient’s informed consent for participation in a trial.

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 IC 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.
NCI’s 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.

When a patient authorizes the release of their PHI, all types of protected health information may be collected by the researcher.

**Patient Identifiers to be Collected**

For most cooperative group studies, the collection of patient identifiers will be limited to the following items. However, for certain studies it may be necessary to collect additional information. The collection of this information is critical to maintain acceptable levels of data quality as well as scientific validity.

<table>
<thead>
<tr>
<th>Patient Identifiers</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Initials</td>
<td>Allows researchers to verify the accuracy of research case numbers across multiple pieces of information submitted throughout the life of the study.</td>
</tr>
<tr>
<td>Zip Code</td>
<td>Federal Requirement</td>
</tr>
<tr>
<td>Country</td>
<td>Federal Requirement</td>
</tr>
<tr>
<td>Elements of Dates</td>
<td>All dates relevant to the study will be collected to insure the appropriate analysis of the data including dates of diagnosis, treatment etc.</td>
</tr>
<tr>
<td>Social Security Number</td>
<td>The SSN allows for more efficient searching of patient data and provides a means of tracking patients for study follow-up data collection. Additionally, the SSN is required to access the national death index, used by researchers</td>
</tr>
<tr>
<td>Medical Record, Prescription and Other Unique Identifying numbers</td>
<td>This allows the researchers another level of information to insure the accuracy of the data. It also maintains the appropriate link to the institution submitting the data and ensures that the appropriate records are audited</td>
</tr>
</tbody>
</table>
[NAME OF COOP GROUP] ensures 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. They include who has access to protected information and how it will be used within [NAME OF COOP GROUP]. We train our employees in [NAME OF COOP GROUP]’s privacy procedures, and have designated an individual who is responsible for ensuring the procedures are followed. To see a copy of our policy for protecting Protected Health Information you can visit our website at INSERT URL.

References

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


3 HIPAA Questions & Answers, pp. 43-47; 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.