I. Background

This committee was charged with recommending a set of patient identifiers to be routinely required for submission in typical cooperative group therapeutic clinical trials. A secondary charge was to consider patient identifiers that might be required in skills verification programs required to train or certify specialists prior to allowing their participation in certain clinical trials.

A survey of the NCI-funded cooperative groups was performed to determine which patient identifiers (as defined by the Privacy Rule) are currently collected and will continue to be collected after the implementation of the HIPAA Privacy Rule. The purpose of the survey was to assess the extent to which patient-identified information will continue to be collected and to provide information to other working groups assigned tasks at the NCI January 8, 2003 meeting.

II. Survey Results (See attached file)

The plans for each of the independent cooperative groups are remarkably similar with respect to the patient-identifying information they plan to collect for patients enrolled in their NCI cancer treatment trials. Of the 18 items identified by the Privacy Rule, the cooperative groups consistently identified 5 which will be part of their collection set. They are:

1. **Patient Names**: All cooperative groups plan to collect patient initials. Several of the groups will continue to allow full names to be optionally submitted.

2. **Geographic Information**: All cooperative groups collect zip code and country to be in compliance with federal requirements for this information.

3. **Elements of Dates**

4. **Social Security Number**

5. **Medical Record, Prescription Numbers, and Other Unique Identifying Numbers**

All of the cooperative groups which also conduct quality of life studies, cancer control studies, cancer prevention studies and other ancillary studies indicated a need to continue to collect additional information in order to ensure data integrity for those special studies. This additional information most commonly includes full names, addresses and telephone numbers of the patients.
III. Conclusions

A commonly shared position among all committee members was that the submission of identifiable data (by HIPAA definition) will be required in virtually all clinical trials conducted by the cooperative groups. Transfer of certain identifiers and dates is critical to maintain acceptable levels of data quality as well as scientific validity. A list of common patient identifiers that will be routinely required in most therapeutic trials includes the following:

- Patient Initials
- Geographic information as currently required by NCI
- Dates (relating to diagnosis, relevant medical history, treatment, tests, recurrence or other protocol-defined events, birth date, date of death)
- Social Security Number
- Medical Record Numbers, including Pathology Report Numbers

The commonality of survey responses supports the point-of-view that an enterprise-wide authorization is feasible and appropriate.

In certain circumstances, collection of additional items of PHI will be necessary to ensure data integrity. These additional requirements are study-specific and should be detailed in the protocol-specific informed consent document.

**Skills Verification:** For selected studies, it is necessary to collect information on non-study patients whose records are reviewed for purposes of investigator skills verification. In some cases, this may be accomplished with the transfer of completely de-identified data; but in other cases, the transfer of identifiable information will be necessary, as for example the transmission of dates to document currency of required skills acquisition activities. In such cases, the cooperative groups will consider utilizing limited data sets. When this is not possible, an IRB waiver will be requested or the patients whose records were used in the credentialing process will be requested to provide authorization.

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