JOHNS HOPKINS
U N I V E R S I T Y

Center for Clinical Trials

Department of Biostatistics
Department of Epidemiology
Department of International Health

Department of Medicine
Department of Ophthalmology
Oncology Center

(Friday 6:27am) 29 December 2000

Memorandum

To: Center for Clinical Trials faculty and staff

Fr: Curt Meinert

Re: Record retention and storage good practice policies and procedures (GPPP)

Definitions

primary record *n* - 1. The main or principal **record** in relation to some process or procedure. 2. **source record** rt: **secondary record**

record *n* - 1. A group of related **data items** or **fields** treated as a unit, eg, a **patient chart** or completed **data collection form**. 2. A **paper** or **electronic** document that contains or is designed to contain a set of facts related to some occurrence, transaction, or the like. 3. The state or fact being **recorded**. 4. Official document. rt: **primary record**, **secondary record**, **source record**

secondary record *n* - 1. A **record** of **secondary** importance or relevance in relation to some specified use, process, or procedure. 2. A record completed from a **primary** or **source record**. rt: **primary record**, **source record**

source document *n* - 1. The **original** (defn 2) of a **document**. 2. A document from which other things flow, arise, or depend. rt: **primary document**, **secondary document** ***Usage note***: Traditionally, the **medical chart** is regarded as the source document in **clinical trials**. Under that view, all information recorded on **study forms** derives from the medical chart. However, in reality medical charts exist only for trials done in clinical settings, and even then are rarely so detailed and reliably completed to enable one to complete **study forms** from the charts. Most **data collection** in trials is form driven and is done in **real time**. Therefore, the **medical record** in trials is the composite of information contained in medical charts, when they exist, and the completed study forms.

source record *n* - 1. The **original** (defn 2) of a **record**. 2. A record containing **original data**. 3. **source document** rt: **primary record**, **secondary record**

P&P 1: Regard completed data collection forms as medical records; store in a secure locked area with limited access.

P&P 2: Store to meet commitments for storage specified in IRB submissions.

Room 5010 • 615 North Wolfe Street • Baltimore, Maryland 21205 • 410 955-8175 • Fax: 410 955-0932
E-mail: cctmail@jhsph.edu • Web site: http://www.jhsph.edu/Research/Centers/CCT

P&P 3: In the CC, file and store forms containing personal identifiers in locked files; file and store apart from other data collection forms.

P&P 4: Retain data collection forms and corresponding electronic datasets for a minimum of three years after the last publication, completion of the trial, or cessation of funding, which ever is the greater.

P&P 5: Retain data collection forms and corresponding electronic datasets for a minimum of ten years following the completion an FDA audit or inquiry concerning the adequacy or accuracy of study data.

P&P 6: Records placed in "cold storage" should be housed in a facility equipped for storage of medical records; facility should be secure and attended; access should be limited to personnel responsible for operation of the facility.

P&P 7: For records placed in "cold storage", produce a document deposited with the records and retained on-site that indicates the following:

- Address of location where records are stored
- Case-by-case or file-by-file inventory of contents; detail should be sufficient to enable custodians to retrieve designated forms by going to a designated case and location within a case
- Procedures for accessing records
- Persons having authority to access records

The above mentioned document should be filed in at least two separate and distinct locations on-site; its location should be known to at least two people in the coordinating center.

P&P 8: Destruction of data collection forms should be in accordance with State and local laws.

P&P 9: Do not write consent documents in which promises are made as to when study forms will be destroyed.

Comment

Such promises may be difficult to keep, especially if it takes longer to do the trial than planned (often the case).

P&P 10: Do not write consent documents promising severance of linkage to study subjects.

Comment

Severance of linkage is not be in the best interests of study subjects in trials where there is risk of late-term, ill-effects arising from agents or drugs used in the trial. It may be necessary or prudent in such cases to re-establish contact with study subjects, years after separation from the trial, to inform them of potential risks or to examine them for evidence of ill-effects.

Resist requests from IRBs for severance, especially requests that lead one to made time-specific promises of severance to study subjects. Trials rarely proceed on the timetables envisioned when initially reviewed and approved by IRBs.

P&P 11: Retain study documents, including the study protocol, copies of data collection forms, study handbooks and manuals, minutes of meetings, and performance and treatment effects monitoring reports for at least as long as the data collections forms are retained.

P&P 12: Retain administrative records related to funding and study expenditures for a period not less than that required by funding agencies or the institution housing the center; generally at least three years following cessation of funding.

P&P 13: Designate the location of official study repositories and related relevant information (including names of responsible persons) for the following:

- Original copies of completed study forms
- Study databases
- Study protocols
- Study handbooks and manuals
- Study publications
- Minutes of meetings of the Steering Committee
- Minutes of TEMC meetings
- Treatment effects monitoring reports