



(Wednesday 5:24am) 29 November 2000

Memorandum

To: Center for Clinical Trials faculty and staff

Fr: Curt Meinert

Re: Numbered memo good practice policies and procedures (GPPP)

Definitions

numbered policy and procedure memorandum n - [trials] A **policy and procedure memorandum** issued to update the **study protocol**, provide clarification or interpretation of the protocol, clarify the meaning of items on **data collection forms**, instruct in regard to methods and procedures to be followed in data collection, and instruct centers in regard to communications with **local institutional review board**; numbered to underscore importance, separate from other policy and procedure memoranda, and facilitate reference, filing, and tracking. rt: **policy and procedure memorandum**

policy and procedure memorandum (PPM) n - [trials] A memorandum distributed to **centers** in a trial detailing policy or procedure for the trial and issued from the **coordinating center, office of the chair, or sponsor**. rt: **numbered policy and procedure memorandum**

P&P 1: Use numbered memoranda to:

- Inform centers of interim revisions to the study protocol (revisions occurring following release of the latest version of the protocol and to be incorporated into the next version of the protocol)
- Announce changes to the study protocol and effective dates
- Announce suspension of enrollment or treatment protocol and effective date
- Distribute reports of serious adverse events for distribution to local IRBs
- Distribute prototype consent forms to centers
- Instruct centers re study methods and procedure
- Distribute policy statements
- Clarify or interpret study definitions or items on data collection forms
- Announce changes in the investigatorship or participating centers

P&P 2: Content and format requirements of numbered memos:

- Date of issue: Printed in the upper right hand corner of the 1st page and headers of continuation pages; suggested format for 1st page: *(Friday 8:59am) 20 October 2000* or *(Friday) 20 October 2000*; suggested format type for continuation pages: *20 October 2000*

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- *To* portion of memo: Indicate to whom directed (by position, eg, Center directors and coordinators, group, eg, Steering committee and treatment effects monitoring committee, or by name, eg, Rudy Randoff, Randoff Rudy, Hazel Sogby, and Dudley Dudley)
- *From* portion of memo: Indicate place (eg, ADAPT Coordinating Center) and person of issue (optional)
- *Re* portion of memo: Indicate content (see P&P 4)
- Header for continuation pages: Give date of issue, shortened subject matter title, and page number
- Distribution of memo: Indicate distribution in distribution list at end of memos; list persons by center
- cc recipients: List by name following distribution list
- Internal distribution list, including files folder numbers or names
- Attachments: List individually (ie, one line per attachment); list in sufficient detail to ensure unique identification; indicate recipients receiving numbered memo only (ie, absent attachments; usually the case for persons in cc list)
- Footer; last page of memo: Electronic file name and address; date and time

P&P 3: Produce and distribute numbered memos on letterhead of issuing center.

Comment

Avoid production and distribution via e-mail. E-mail was invented largely as a surrogate for telephone conversations. It is not well suited for official communication, nor are e-mail word processors well suited to producing anything other than ordinary conversational style communications. If e-mail is used, use as indicated in P&Ps 9 - 11.

P&P 4: Provide centers with cumulative listings of numbered memos.

Comment

The purpose is to provide clinics with a convenient summary of memos and a tool for retrieval. The list may be updated with each issue (as an attachment to each new numbered memo) or at regular intervals over the course of the trial. The list should be arranged in ascending or descending order by memo number and should indicate the subject matter of memos (verbatim from the *Re* portion of memos) and dates of issue.

P&P 5: Instruct study personnel in regard to function and use of numbered memos.

Comment

This is best done at a kick-off training meeting followed by a numbered memo about numbered memos (Memo # 1); memo should indicate purpose of numbered memos, where they issue from, how issued and distributed, where filed, and how used.

P&P 6: Issue numbered memos from a single point, generally the coordinating center.

Comment

Arrangements allowing for two or more points of issue are likely to result in confusion at clinics.

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P&P 7: Require centers to maintain a notebook containing numbered memos; inspect notebooks during site visits to determine whether up to date.

P&P 8: Distribute numbered memos by mail, courier, or as attachments to e-mail notices.

P&P 9: If distribution is accomplished by placement of numbered memos on a study web site, use e-mail to notify recipients of the placement.

Comment

This mode of distribution has some obvious advantages over mail or courier. It is faster, less expensive, and easier. Preparation of packets for mailing or courier entails a fair amount of effort for copying, stuffing, and posting.

Distribution as an e-mail attachment is not recommended (because recipients may not have the software needed to open and print attachments). The better approach is by placement of memos on a study specific web site in PDF format. PDF files can be opened independently of the word processing language used to create them and the print copy will be a replica of the memo, as produced at the distributing center.

P&P 10: When distribution is accomplished by placement on a study specific web site, require center coordinators to produce a print copy of such memos for inclusion in the notebook referenced in P&P 7.

P&P 11: When issuing e-mail notices of numbered memos, include the distribution list of the numbered memo in the body of the e-mail notice.

Comment

Technically, the *To* portion of e-mail memo indicates distribution, but those lists are hardly reader friendly.

P&P 12: Instruct center coordinators that their duties include ensuring that numbered memos are distributed and seen by all relevant personnel in their centers.

P&P 13: Retain hard copy of numbered memos and related hard copy correspondence for a minimum of 5 years following completion of the trial.

P&P 14: Establish internal procedures for clearing numbered memos for release.

Comment

The usual procedure is to require memo to undergo internal review before release and to require sign-off by the center director or deputy center director before they can be released.

P&P 15: Numbered memos intended to communicate official study policy or procedure should be cleared by study officers before distribution.

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P&P 16: Establish internal procedures for deciding whether a topic or issue requires a numbered memo; use ordinary letters for topics or issues not rising to the level numbered memos.

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