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

(Thursday 9:59pm) 15 June 2000

Memorandum

To: Center for Clinical Trials faculty and staff

Fr: Curt Meinert

Re: Operation good practice policies and procedures (GPPP)

Definitions

knowledge assessment test *n* - [**trials**] 1. A **test** administered to a **study candidate** to assess adequacy of **consent**. 2. A test administered to study personnel to assess their knowledge and understanding of the basic design and operating features of a trial, especially when administered in relation to training and certification of study personnel.

study credit roster *n* - A list or roll of names of persons, institutions, businesses, agencies, or organizations having some role, function, or association with a **study**; such a list as appearing at the end of a **study manuscript**.

study curriculum vitae *n* - A tabular-like listing, akin to that of the **curriculum vitae** of a person, relating to a **study**; containing historical facts concerning the study and a listing of significant accomplishments, including a listing of **presentations** and **publications** emanating from the study. rt: **curriculum vitae**

P&P 1: Establish and maintain language and notation conventions as discussed in *Notation and terminology good practice policies and procedures.*

P&P 2: Establish and maintain the study CV and study credit roster; see *Publication and presentation good practice policies and procedures.*

P&P 3: Create and maintain numbered memo system as detailed in *Communication good practice policy and procedures.*

P&P 4: Create and maintain:
- List of participating centers (past and current)
- List of standing and ad hoc committees (past and current)
- Credit roster

P&P 5: Maintain a paper and electronic file of outgoing correspondence.

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 6: Maintain a chronological file of incoming and outgoing correspondence; retain such files for a minimum of 2 year; thereafter purge as necessary to keep files to manageable sizes.

Comment

Such files are invaluable for finding letters and memos that have not yet been filed, mis-filed, or "lost".

P&P 7: Maintain a master file of IRB approvals and related incoming and outgoing correspondence.

P&P 8: Maintain a tracking and alarm system to ensure compliance with IRB requirements.

Comment

IRBs routinely notify investigators of the need to submit renewal applications, but those systems are not foolproof. In any case, a lapsed approval is a lapsed approval in the eyes of OHRP. The question of who is to "blame" is irrelevant. It is the responsibility of investigators to ensure proper and active IRB approvals.

An alarm system can be built using automated e-mail notices timed to be sent to the Director of the Center, the Coordinator, and Office Manger 60 days prior to the impending expiration date.

P&P 9: Create and maintain a file of IRB approvals for participating centers; monitor to detect and avoid lapsed approvals.

P&P 10: Create and maintain slide sets summarizing design and operating features of the trial; do likewise for results as they become available for distribution.

P&P 11: Create and maintain a study archive of key study documents including the following:

- Protocol (all versions)
- Numbered memos
- Study forms (all versions)
- Study handbooks and manuals (all versions)
- Study CV
- Credit roster
- Slide sets
- Study publications

P&P 12: Establish procedures for clearing manuscripts for submission to journals.

P&P 13: In regard to manuscripts submitted for publication, establish and maintain files containing the following:

- Copy of manuscripts as submitted (paper and electronic)
- Letters of submission
- Author assurances and disclosures

- Reviewers and editors comments
- Response to reviewers and editors
- Letters of acceptance or rejection
- Supporting datasets

P&P 14: Maintain a file of the following:
- Meeting notebooks and related materials
- Performance monitoring reports
- Treatment effects monitoring reports
- Minutes of meetings
- Site visit reports

P&P 15: Establish policy and procedures for:
- Rifting or adding a clinic
- Receiving and acting upon recommendations from the TEMC
- Dealing with suspicion or charges of fraud in data collection
- Requests for information about the study
- Requests for data from the study

P&P 16: Maintain a list of ideas for papers; review periodically with investigators at study meetings.

P&P 17: Maintain a list of commissioned papers; review and update periodically.

P&P 18: Maintain list of archived and distributed datasets.