



Department of Biostatistics
Department of Epidemiology
Department of International Health

Department of Medicine
Department of Ophthalmology
Oncology Center

(Wednesday 6:03am) 31 January 2001

Memorandum

To: Center for Clinical Trials faculty and staff

Fr: Curt Meinert

Re: Meeting good practice policies and procedures (GPPP)

Definitions

research group *n* - The entire set of personnel involved in the conduct of a **research project** such as a **study**; in **multicenter trials** includes **center directors** and support staff, representatives from the **sponsoring agency**, and **study committee** members. syn: investigative team, **investigative group**, **study group** (not a recommended syn, see usage note for **study group**), **study staff**

steering committee (SC) *n* - A **committee** of an organization responsible for directing or guiding the activities of that organization. In **multicenter trials**, the committee responsible for conduct of the **trial** and to which other **study committees** report. Usually headed by the **study chair** and consisting of persons designated or elected to represent **study centers**, disciplines, or activities. One of the **key committees** in **multicenter** structures. rt: **executive committee**
Usage note: Sometimes used interchangeably with **executive committee**; not recommended (see **executive committee** for comment).

treatment effects monitoring committee (TEMC) *n* - [**trials**] A standing **committee** in the structure of **single** or **multicenter trials** responsible for the periodic review of accumulated **data** for evidence of **adverse** or **beneficial treatment effects** during the **trial** and for making recommendations for modification of a **study treatment**, including termination, when appropriate. One of the **key committees** in the organizational structure of a multicenter trial. Usually constituted such that voting privileges are restricted to members not directly involved in the execution of the trial and not associated with participating **centers** or **sponsors** of the trial. Others, such as **officers of the study** or other key **study investigators**, if included as members, serve without vote. Voting members are appointed by the **sponsor** (defn 2) or **research group**, often with the advice and consent of the other party. The committee reports to the appointing authority and usually to the other party via the appointing authority or directly. syn (not recommended): **data monitoring committee**, **data and safety monitoring committee**, ethical committee, **ethics committee**, **safety monitoring committee** rt: **advisory-review and treatment effects monitoring committee**, **external treatment effects monitoring committee**, **internal treatment effects monitoring committee** *Usage note:* The committee may be variously named. One of the more common synonyms is **data monitoring committee**. Though acceptable, it is

Memo re Meeting good practice policies and procedures
(Wednesday 6:03am) 31 January 2001

not recommended because of its nondescript nature and possible confusion with other types of monitoring. Also common is the name **safety monitoring committee**; not recommended because of the implied emphasis on **safety**. The committee may have a compound name when the treatment monitoring function is vested in a committee having other broad responsibilities, eg, **advisory-review and treatment effects monitoring committee** or **data and safety monitoring committee** (not recommended).

P&P 1: Plan and budget for face-to-face meetings of the SC, Research Group, and TEMC along the following lines:

- SC: At least 4 in year 1; at least 2 per year thereafter to completion of the trial
- Research Group: 1 training meeting in year 1; at least 1 (preferable 2) meeting(s) per year thereafter to completion of data collection
- TEMC: 1 meeting in year 1; 2 meetings per year thereafter to completion of the trial

Comment

Ask and ye shall receive. Maybe. But it is a cinch that if you do not ask *ye shall not receive*. Travel budgets, too often, are trimmed because of the mistaken belief that the affairs of the trial can be conducted without much travel. Ironically, the most important meetings are those of the research group, but they are usually the most difficult to fund.

P&P 2: In regard to meetings of the SC, TEMC, and Research Group:

- Choose and announce meeting dates as far in advance as feasible
- Once organized, maintain an advance schedule of meetings extending at least one year into the future and that provides dates for at least the next two meetings of a group
- Avoid choosing dates for future meetings during meetings (generally a waste of time and designed to disenfranchise people not in attendance or lacking calendars)
- Avoid picking dates to please a few at the expense of many
- Choose dates to maximize attendance; accept less than perfect attendance
- Pick dates to avoid travel during heavy travel periods
- Avoid changing dates once dates are chosen

Comment

The further away a date, the easier it is to schedule. Accordingly, a fair amount of time can be saved and aggravation avoided by scheduling meetings of the SC, RG, and TEMC well in advance.

P&P 3: In regard to meeting sites:

- Choose in favor of locations serviced by major airports
- Choose to minimize time away from home
- Choose in favor of hotels near hub airports for "fly-in" meetings
- Choose in favor of downtown hotels for multi-day meetings
- Avoid travel to out of the way, exotic places (likely to be seen as "extravagant" in the eyes of the general public)

Comment

Memo re Meeting good practice policies and procedures
(Wednesday 6:03am) 31 January 2001

When planning meeting sites, keep in mind that most people traveling to meetings arrive minutes before the start of meetings and leave for home before the last words have been spoken.

P&P 4: In regard to SC meeting dates, choose independent of meetings of related societies; avoid piggybacking.

Comment

Put two pigs under a blanket, and they both get away. Translation: Sandwiching meetings of the SC into the schedule of society meetings makes for bad SC meetings.

Having meetings immediately before or after society meetings is not much better. Most societies have business meetings and workshops on days preceding the main meeting. After the society meeting people are tired and want to get home. In any case, only a fraction of the people on a SC are likely to attend any given society meeting. Hence, many are required to travel for a few.

P&P 5: In regard to use of conference phone in place of face-to-face meetings, limit to one hour duration, to updates and briefings, and to noncontentious issues and matters.

P&P 6: In regard to meetings remember:

- Talk expands to fill time
- A meeting without an agenda is a waste of time
- The light switches in meeting rooms are nowhere to be found
- The screen is never visible from the podium
- Microphones never work and when they do there is feedback hum
- The light on the podium will not work and if it does it will be too dim to be useful
- The last speaker in a program is always short changed
- A slide that requires an apology is not worth showing
- In regard to projection equipment: Whatever can go wrong will
- Those who assume that meeting places will have the software and hardware needed to project electronic slides enjoy living on the edge
- Empty stomachs make for bad meetings
- Tired brains produce bad decisions; decide nothing after 6 PM
- Bad arrangements make for bad meetings
- Most meeting rooms are too hot or cold (layer your clothes)
- The hotel model for what constitutes sufficient leg and elbow room is a 4 foot 2 inch, 90 pound, person
- Restlessness in meetings increases with crowding

\GPPP\Mtg.WPD