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(Wednesday 9:17am) 17 January 2001

Memorandum

To: Center for Clinical Trials faculty and staff

Fr: Curt Meinert

Re: Administration good practice policies and procedures (GPPP)

Definitions

center for coordinating centers (CCC) *n* - A **center** housing **coordinating centers** for two or more different **projects**.

consortium funding *n* - A type of **funding** in which monies received by a designated **center** are disbursed to other centers in a **multicenter study** according to terms set forth in a **consortium funding agreement** and involving **contracts** with (typically the case) or **grants** to those other centers. rt: **indirect distribution of funds**

evaluable study patient *n* - [**trials**] A **study patient** considered suitable for inclusion in some **tabulation** or **analysis** by virtue of having had some **event** or satisfying some condition during the course of **treatment** (eg, having a recurrence of a cancer; having received the **assigned treatment** and having taken it for a specified period of time). ant: **nonevaluable study patient** ***Usage note***: See note for **evaluable study patients**.

evaluable study patients *n* - [**trials**] The **subgroup** of **study patients** considered to **satisfy** certain conditions and, as a result, are retained for **analysis**. ***Usage note***: Generally, use of the term implies a violation of a basic **analysis principle** in that the subgroup used for making **treatment comparisons** is, itself, subject to **treatment-related selection bias**. As a result, treatment comparisons are likely to be **confounded** by the **selection variable** and, hence, the **treatment difference** noted, if any, may have more to do with selection bias than with the treatment being tested. The possibility of confounding exists whenever the selection variable is observed after the initiation of treatment (as with any **treatment compliance variable** in any analysis where only those patients receiving a specified amount of the treatment are selected for analysis).

head payment *n* - A **payment** based on person count, eg, a fee in the amount of $2,500 paid by a drug company to an **investigator** for each person **enrolled** into a **trial** and followed for 8 weeks.

P&P 1: Do not recruit personnel based on the promise of funding.

P&P 2: Do not dispatch staff to start work on implementing a trial before funding is in hand.

Comment

If it ain't over until the fat lady sings, then it ain't ready to start until she has money in hand. The "check is in the mail" won't do.

P&P 3: Do not staff at levels exceeding budgeted amounts.

P&P 4: Match funding and effort; scale back when funding is not adequate to support existing effort.

P&P 5: Do not overspend.

Comment

To avoid overspending, one has to have a timely means of tracking and projecting expenditures.

P&P 6: Avoid being the conduit for money flowing to clinics or other centers in trials.

Comment

Coordinating centers are neither well suited nor staffed for money handling. Assuming that function can detract from essential day-to-day operations of the CC. The activity is better located in a center having only disbursal responsibilities.

In those cases, when disbursing functions cannot be averted by the CC, the goal should be to vest disbursal responsibilities in people not otherwise involved in CC activities.

Responsibilities for disbursing money should not be accepted without a written understanding with the sponsor as to the nature of the duties and responsibilities.

P&P 7: When duties include disbursing money, establish safeguards to prevent mistakes or malfeasance; two signatures should be required to initiate a check requisition; at least one of the two signatories should be employed outside the CC.

P&P 8: Avoid being the purchasing agent for centers in the trial.

Comment

The rationale is the same as for P&P 6; avoid by placing money needed for purchases in individual center budgets. Do not serve as a purchasing agent if monies needed to cover the purchase have to be collected from individual centers (P&P 11).

P&P 9: Avoid being a supply center for centers in trials.

Comment

Rationale same as for P&P 6; avoid by having centers purchase directly. Resist centralizing purchases to achieve cost breaks. Usually, those breaks are modest and the "savings" are likely to be offset by efforts in the CC to arrange for purchases and shipments to local sites.

P&P 10: Avoid handling money.

Comment

Handling money exposes staff to temptation and risks that are best avoided. If money has to be handled, it should be in the form of checks or credit card vouchers; no cash.

P&P 11: Avoid serving as a collection agency.

Comment

The need to serve as a collection agency arises when clinics make expenditures that are to be reimbursed from the CC, eg, as in regard to travel to study meeting. Avoid as suggested in comment to P&P 9.

P&P 12: Avoid being a reimbursement center for travel and related expenditures of personnel located at other study sites.

Comment

Avoid as suggested in comment to P&P 9; place monies in budgets of study centers.

P&P 13: If clinics are provided with head forms of payment, specify the basis for determining payment before implementation.

Comment

The time to argue and debate is before such systems are in place. Avoid schemes where payments are provided only for "evaluable" patients and schemes tied too tightly to visit completion rates.

P&P 14: In long-term trials in regard to computing equipment, budget for replacement and upgrades of computing equipment.

Comment

The useful "life" of ordinary PCs is about 3 years; budget for replacements and upgrades over the life of the trial.

P&P 15: Create and maintain the means to develop and train personnel in the CC.

Comment

Having the wherewithal to train and develop staff is essential for recruitment and retention of staff and in maintaining proficiency over the life of a trial. However, acquiring the monies needed for training is difficult. The likelihood is that requests to cover those costs from study funds will fall on deaf ears. The NIH is wont to argue that those cost should be covered by the institution housing the CC from indirect costs.

It possible sometimes, by finagling, to plan study meetings or site visits, in connection with scientific meetings. Usually, in those cases the costs for travel and lodging can be covered from study funds. Also, it is generally possible to get permission to use study funds for persons to travel to scientific meetings if they are on the program to make presentations related to the trial.

The rules for travel to professional meetings varies by funding agency and mode of funding. Generally, there are more degrees of freedom with the grant mode of funding than with the contract mode of funding. Hence, it is wise, when possible, to strive for arrangements where key people in the CC are funded from multiple sources. The diversity of funding provides bridges for people when funding sources dry up and, at the same time, provides a wider ranges of options for supporting travel needed for professional development.

P&P 16: In centers with more than one trial, establish revolving accounts to cover common items such as telephones, photocopying, and general office supplies.

Comment

Monies flowing to the revolving accounts come from the budgets of the different coordinating centers housed in the center. The "fair share cost" of the different coordinating centers is a function of the FTEs or is some percentage of the total per year direct cost of the various CCs.

P&P 17: Prior to submitting a funding request, carry out a series of budget analyses to ensure a properly balanced and apportioned budget.

Comment

The FTEs in a budget should be broken down by type. There should be an appropriate mix of senior and junior people.

Similarly, there should be some balance in FTEs devoted to different functions such as listed below:

- Directorate
- Administrative
- Design and implementation
- Biostatistical and analysis
- Data processing
- Quality control
- Secretarial

The fraction of FTEs devoted to direction, leadership, and administration can be expected to be around 20% of the total FTEs.

The fraction of costs (direct) represented by personnel (salaries and fringe benefits) versus all other direct costs in the CC generally is somewhere between 65% and 80% of the total. Fractions above 80% are generally symptomatic of an "other expenses" starved operation, assuming "other expenses" to include the following:

- General office supplies
- Cost for purchase and upgrades of software
- Purchase and upgrades of computing hardware (assuming a 3 year life expectancy)
- Equipment maintenance agreements
- Photocopying

- US postage; UPS; Fed Ex
- Phones (voice and data)
- Books and journals
- Travel; study related and one professional meeting per year per FTE

Another analysis, possible only in cases where one has access to the total budget (eg, as is generally the case with investigator-initiated proposals), relates to the overall budget. Generally, the proportion of the total direct cost devoted to coordinating center functions can be expected to run between 10% and 25% of the total direct cost. Fractions less than 10% are usually symptomatic of under funded coordinating centers. Fractions over 25% may be symptomatic of under funded clinical operations.

It is useful also when the entire budget is available to calculate monies going for quality control and assurance. The fraction should be somewhere around 10% of the total direct cost.

P&P 18: Retain administrative records for a period of not less than 3 years beyond the cessation of funding for the trial.

P&P 19: Retain study records for a period of not less than 7 years beyond cessation of funding for the trial and for at least 2 years beyond the last publication.