

Guidelines for Budget Elements - Clinical Trial Research

The following items are intended to serve as a guide to Principal Investigators and administrative staff in clinical trial budgeting, and particularly in determining whether per patient enrollment fees will be adequate to cover the entire costs of the trial. Often, investigators develop a planning agreement with a pharmaceutical organization even before the clinical trial agreement is developed, in which the following types of costs can be budgeted. This phase is often overlooked and, therefore, uncompensated, although it is often one of the phases of the study when the investigator makes the most significant intellectual contributions.

Pre-Trial Development Costs / Planning Agreement

- Principal Investigator time and/or Consultant Fee
- Coordinator time
- Secretarial time
- Miscellaneous (telephone, copy costs, etc.)

Clinical Trial Budget:

• Start-up Costs:

- Screening of patients for enrollment:
- personnel costs (should include such costs as PI time, Coordinators, evaluators, secretary, data manager/data entry, programmers, consultants)

• Patient-related costs:

- respondent honoraria (does it include travel, parking, lodging?)
- lab fees
- in-patient or out-patient costs (should include room rent if out-patient)
- anesthesiologist and surgery or Operating Room fees
- enrollment fees (e.g., Emergency Department)
- specialist professional fees
- pharmacy (including study management fee)

• Miscellaneous costs:

- biostatistical or other analytical costs
- computer time
- equipment maintenance
- WIRB fees when changes in protocols require additional fees
- Dry ice/shipping costs/fax and phone costs
- laboratory and specialized equipment supplies
- computers