

Budgeting for

a

Diverse Clinical Trial



Budgeting Basics

Key questions to ask yourself and team members

What will generate expenses?

What is the trial duration?

What is the patient burden?

What is the number of sites?

What is the accrual goal?

Components of a Successful Budget

Research Personnel

- Full-time coordinator and research staff members
 - Language requirement?
 - Competitive salaries will attract experienced recruiters
- Support for administrative staff at your institution and/or collaborating organizations
- A community advisory groups can be consulted to vet study design (often includes a fee or honorarium)

Reducing Patient Burden

- Reimbursement for transportation, parking, meals
 - Urban settings: provide a fixed amount on a transit card
 - For longer distances: provide mileage reimbursement
- Depending on duration of follow-up, you may need to account for childcare services and/or lodging
- Providing gift cards to local grocery store or movie theater is a best practice
- Consider providing after hours coverage and offering flexible follow-up visits

All suggestions must be first approved by your program officer and institution's IRB.

Must be itemized in submitted budget

Recruitment

- Passive methods: direct mailings, mass media outlets (e.g., newspaper postings, radio and poster announcements)
 - Posters and brochures in the waiting room are a best practice
- Active methods: telephone calls and interpersonal communication
 - Remember, on average, it takes 4 in-person visits to get a "Yes."
- Coordinator trainings (e.g., cultural competency)
- Translation services, translators, and bilingual staff are essential for non-English speaking populations

Retention

- Study memorabilia (e.g., mugs, magnets, pens, bags) improve retention rates
- Sending birthday and holiday cards is a best practice
 - Important to include phone number to call in case of change in address, contact information, or health status
 - Photo of the research team improves recognition and personal connection
- Successful retention of staff members can increase patient retention rates
- Provide a contact line for patients and providers
- Hold recognition events for community members and participants

As a general best practice, it is critical to communicate which procedures and tests are covered under Standard of Care and how insurance including Medicare/Medicaid would cover the costs



**Don't forget
about budgeting
for a "rainy day"
or hidden costs!**



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