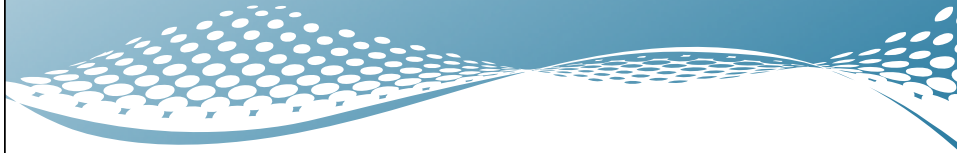




Recruitment Innovation Initiative



Financial Considerations

Develop a Financial Plan



- Project first year revenue
 - Types of Studies
- Payment
 - Industry research usually funded quarterly
 - In contract, negotiate monthly pay outs
- Costs
 - Consider sponsor contracting with CRO for additional employees
 - Recruitment costs – chart review

Budget



- Start up Expenses
 - Medical equipment
 - Licensing
 - Recruiting costs
 - Storage costs
- Operating Expenses
 - Salaries
 - Mileage
 - Medical supplies

Start-up Expenses



- Medical Equipment
 - Available or Need to Acquire
- Licensing
 - DEA
 - State licenses
 - Occupational licenses
- Recruiting Costs
 - Staff Needed – CRC, CRN, RA

Operating Expenses



- Salaries
- Benefits
- Mileage
- Office Space
- Office Supplies/Telephones/Fax
- Computer
- Continued Medical Education

Time Considerations



- Time Involvement
 - The time from identification to enrollment can be significant.
Expect approximately 7-9 hours per consented patient.
 - Identification – approximately 2-3 hours per day chart review
 - PI review for eligibility – 30 minutes
 - Contact and discussion with providers/physicians – 1 hour
 - CRC discussion with patient/family – 30 minutes
 - CRC and PI/Sub-I meet with patient/family for Informed Consent discussion – 1 hour
 - Completion of the screening visit – 2-3 hours

Budget Considerations



- Administrative
- Study Specific
- Miscellaneous

Keep in mind that Budget considerations may differ between Pharmaceutical and Academic palliative care research.

Budget – Administrative



- Initial Start-up Fee
 - Nonrefundable!
 - Covers the cost of pre-study review, regulatory document completion and staff training.
 - Typically invoiced at the time of CTA execution and IRB Approval.
- Coordinator Fee (per visit)
- PI Fee (per visit)
- Overhead (%)

Budget – Study Specific



- Informed Consent Execution Fee
- Amended Informed Consent Execution Fee
- Medical History (includes demographics)
- Physical Exam
- Vital signs
- ECG Fee
- Lab Collection Fee
- Drug Accountability
- Diary – Dispensing/Training/Review
- IVRS – Training
- Questionnaires (\$/each questionnaire)
- Patient Stipend
- Adverse Event Review
- Concomitant Medication Review

Budget – Miscellaneous Line Items



- Pharmacy Setup Fee (one time fee)
- Storage Fee (one time fee at study closure)
- Chart Review Fee (hourly rate)
- SAE Fee (per occurrence)
- Extra Phone and Teleconference fee (hourly rate)
 - Often required to attend mid-study conferences and additional trainings
- Shipping supplies/Charges
- Sponsor Audit – No Cause (per day for time of PI and SC)
- Per diem Document retrieval after Study Closure
- Mileage reimbursement
 - (ex. .505/mile not to exceed 50 miles round trip)

Investigator Initiated Budget Considerations



- NIH Grants
 - Personnel and Consultants
 - Equipment
 - Supplies
 - Travel
 - Other Expenses

NIH Grants – Personnel and Consultants



- Consider % of time and effort needed from each person to be listed on the project.
 - Will:
 - Each person be needed throughout the project?
 - Each person be needed all or part of a calendar year?
 - Personnel from other departments?
 - Graduate students be paid to work on the project?
 - Consultants be needed?

NIH Grants – Equipment, Supplies and Travel



- Equipment
 - Can you justify the need for equipment related to the project?
 - Justification must be tied to the research, not a process
- Supplies
 - General office supplies cannot be charged to federal grants.
 - Supplies can include:
 - Photocopying, library searches, project specific supplies
- Travel
 - How many trips will be needed?
 - How many people?
 - How often?

NIH Grants – Other Expenses



- Justification may be needed for other expenses related to the project.
 - Some additional expenses might include:
 - Programmer/Data Processing assistance
 - Postage & Telephone expenses
 - Printing costs
 - Financial Incentives (i.e. patient stipends, payment for chart review)
 - Videotaping
 - Graduate Student Tuition Support
 - Subscriptions
 - Meeting Expenses
 - Subcontracts
 - Indirect Costs (F&A rate)

Staff Considerations



- First Hire Employees
 - Salaried, exempt from overtime
 - Expectation – call is part of job requirements
 - Need to check with your State FLSA laws
 - If part time work needed, then hire non-exempt

Staff Considerations



- Contracted Employees
 - CRO/sponser covers costs
 - Interview first to make sure they fit with your culture and possess necessary skill set
 - Full time or part time
 - If you identify this person and CRO pays make sure finders fee is taken out of contract if they result in a FT hire

Pitfall – Hiring Expensive Staff



- An experienced CRC who is knowledgeable around regulatory issues, budgets, and adherence to protocols is the type of person you want to look for. This will not break the bank when you are trying to get started.
- Salary + benefits
 - CRC
 - CRN

Acquire Studies



- Subscriptions
 - Centerwatch
 - Biospace
 - ACRP
- Clinical trials.gov
- Networking
- Contracted agencies that find studies and assist with budget negotiations