

# **Evaluation of a Protocol Budget**

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# Introduction

- \* **Determine:**
  - **Protocol requirements**
  - **Site resource requirements**
- \* **Establish protocol budget**

# Requirements

- \* **Duration**
- \* **Subjects**
- \* **Screening**
- \* **Clinical**
  - **Location**
  - **Infrastructure**
- \* **Laboratory**
- \* **Study Product**
- \* **Toxicity**
- \* **Data**

# Requirements

\* **Monitoring**

\* **Meetings**

- **Travel**

\* **Personnel**

\* **Equipment**

\* **Supplies**

\* **Institution**

\* **Subcontracts**

\* **Indirect Costs**

\* **Other**

# Duration — Protocol Requirements

- \* **On-study treatment / therapy**
- \* **Follow-up**

# Subjects — Protocol Requirements

- \* **Enrollment**
- \* **Screening**
- \* **Eligibility Criteria**
- \* **# of Visits**

# Subjects — Site Requirements

## \* Population Base

- Size
- Racial / Ethnic minorities
- Women
- Children
- Other special populations

# Subjects continued...

- \* **Community Advisory Boards**
  - **Financial support**
  - **Educational forums**
  - **Input / Perspective**

# Subjects continued...

- \* **Outreach and Recruitment**
  - **Strategy / Plan**
    - \* **women & minorities**
  - **Advertising**
    - **primary care providers**
    - **posters**
    - **mailings**

# Subjects continued...

- \* **Retention**
  - **Strategy**
  - **Tracking**
  - **Incentives**
    - \* **travel**
    - \* **pain**
    - \* **childcare**
    - \* **sustenance**

# Screening — Protocol Requirements

- \* **Clinical Evaluations**
- \* **Laboratory Evaluations**
- \* **Time Constraints**

# Clinical — Protocol Requirements

- \* **Study Visits**
  - # and length
    - \* **Staff expertise**
    - \* **Exams / Evaluations**
- \* **Special Procedures**
  - # and type

# Clinical — Site Requirements

- \* **Radiology**
- \* **Special Procedures**
- \* **Inpatient**
- \* **Other units**

# Clinical Location — Site Requirements

- \* **# of Clinics**
  - **Single / Multi-site**
- \* **Urban / Rural**
- \* **Domestic / International**
- \* **University / Private Clinic**

# Clinical Infrastructure — Site Requirements

- \* **Existing Space**

- **Clinical**
- **Laboratory**
- **Office**
- **Other units**

- \* **Renovations / Alterations**

- \* **Consistent**

# Laboratory — Protocol Requirements

- \* **Tests: # and type**
- \* **Specimens**
  - **Processing**
  - **Shipping**
  - **Storage**
- \* **Location: local, commercial, central**
- \* **Serial studies**

# Laboratory — Site Requirements

- \* **Specimen Preparation**
  - Serum, Plasma, Cells, Tissue
- \* **Shipping**
  - Packing materials, dry ice
  - Transportation
- \* **Storage**
  - Freezer space
  - Tracking & retrieval

# **Study Product — Protocol Requirements**

- \* Administration of drug / agent**
- \* # of drugs / agents involved**
- \* Route**

# Study Product — Site Requirements

- \* **Management**
- \* **Storage**
- \* **Accountability**
- \* **Subject**

# Toxicity — Protocol Requirements

- \* **Treatment & Evaluation**

- **Additional Visits**
- **Additional Labs**

- \* **Reporting**

- **Sponsor**
- **OHRP**
- **FDA**

- \* **Follow-up**

# Data — Protocol Requirements

- \* **Case Report Forms (CRFs)**
  - **Development / Programming**
- \* **Amount collected per visit**
  - **# Forms**
  - **# Pages**
- \* **Time Constraints**
- \* **Quality Management**

# Data Management — Site Requirements

## \* Staff

- Entry
- Management
- Quality Control & Assurance

## \* Equipment

- Computers
- Fax
- Copier

# Monitoring — Protocol Requirements

- \* **Clinical**

- Adherence to protocol
- Adherence to regulatory & GCP

- \* **Safety**

- SAE reporting

- \* **Data**

- Source documentation
- Endpoints

# Meetings — Protocol Requirements

## \* Length, Location, #

- Investigator
- Coordinator
- Committee
- DSMB

# Travel — Site Requirements

- \* **Meetings**
- \* **Presentations**
- \* **Field**
  - **Other sites**
  - **Outreach**

# Personnel — Site Requirements

- \* **Experience**
- \* **Commitments**
  - **Other research**
  - **Faculty**
  - **Attending**

# Personnel continued...

- \* **Investigator**
- \* **Coordinator**
- \* **Research Nurses**
- \* **Lab Scientists / Technicians**
- \* **Data Staff: entry, analyst, manager**
- \* **Statistician**

# Personnel continued...

## \* **Clinical:**

- **Physicians**
- **Mid-level providers**
- **Nurses**
- **Pharmacist**

## \* **Specialists / Consultants**

# Personnel continued...

- \* **Social Worker**
- \* **Monitor**
- \* **Quality Management**
- \* **Regulatory**
- \* **Administrators: Fiscal, secretarial**
- \* **Other**

# Equipment — Site Requirements

- \* **Clinical**
- \* **Laboratory**
  - **Freezers**
  - **Centrifuge**
- \* **Office**
  - **Computers**
  - **Furniture**
  - **Filing cabinets**

# Supplies — Site Requirements

- \* **Clinical**
- \* **Laboratory**
- \* **Office**
- \* **Mailing / Shipping**
- \* **Phone / Fax**

# **Institution — Site Requirements**

- \* Institutional Review Board (IRB)**
- \* Policies & Procedures**
- \* Regulatory**
  - Federal**
  - NIH Policies**
  - Good Clinical Practice (GCP)**

# Subcontracts — Site Requirements

- \* **Other Sites**
- \* **Monitoring**
- \* **Pharmacy**
- \* **Laboratory**
- \* **Data Management**
- \* **Record Storage**

# Indirect Costs — Site Requirements

## \* Facilities & Administration

### - Overhead

- \* utilities

- \* cleaning

- \* maintenance

### - % of direct costs

- \* personnel

- \* equipment

# Other

## Protocol Requirements

- \* **Study Management**
  - **Site**
  - **Overall**
- \* **Miscellaneous**

## Site Resource Requirements

- \* **Statistical Analyses**
- \* **Equipment Maintenance**



# Establishing a Protocol Budget

- \* **Information for prices / costs**
  - **Experience**
  - **Industry standard**
  - **?**
- \* **Include**
  - **Start-up**
  - **Screening & Follow-up**
  - **Close-out**

# Establishing a Budget continued...

- \* **Conserve costs while preserving safety and scientific integrity**
  - **Necessary**
  - **Negotiate rates**
  - **Subcontract**

# Establishing a Budget continued...

- \* **Determine how costs will be charged**
  - **Personnel**
    - \* **hourly rate**
    - \* **% time & benefits**
    - \* **per study visit**
  - **Labs**
    - \* **real time / batched**
    - \* **storage**

# **Establishing a Budget continued...**

**Determine the REAL cost of  
conducting a protocol**

# Establishing a Budget continued...

- \* **Line item for each resource**
- \* **Cost per patient**
  - **Spreadsheet**
  - **Subtotal categories**

# Summary

## \* Protocol Requirements

- Schedule
- Conserve costs
  - \* preserve safety & science
  - \* necessary not interesting

## \* Site Resource Requirements

- Establish costs
- Spreadsheet

# Contact

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