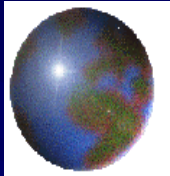


The Fundamentals of International Clinical Research



Practical Considerations for Fielding a Clinical Research Study

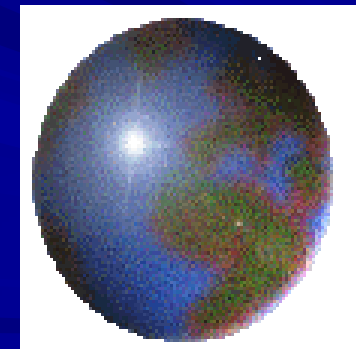
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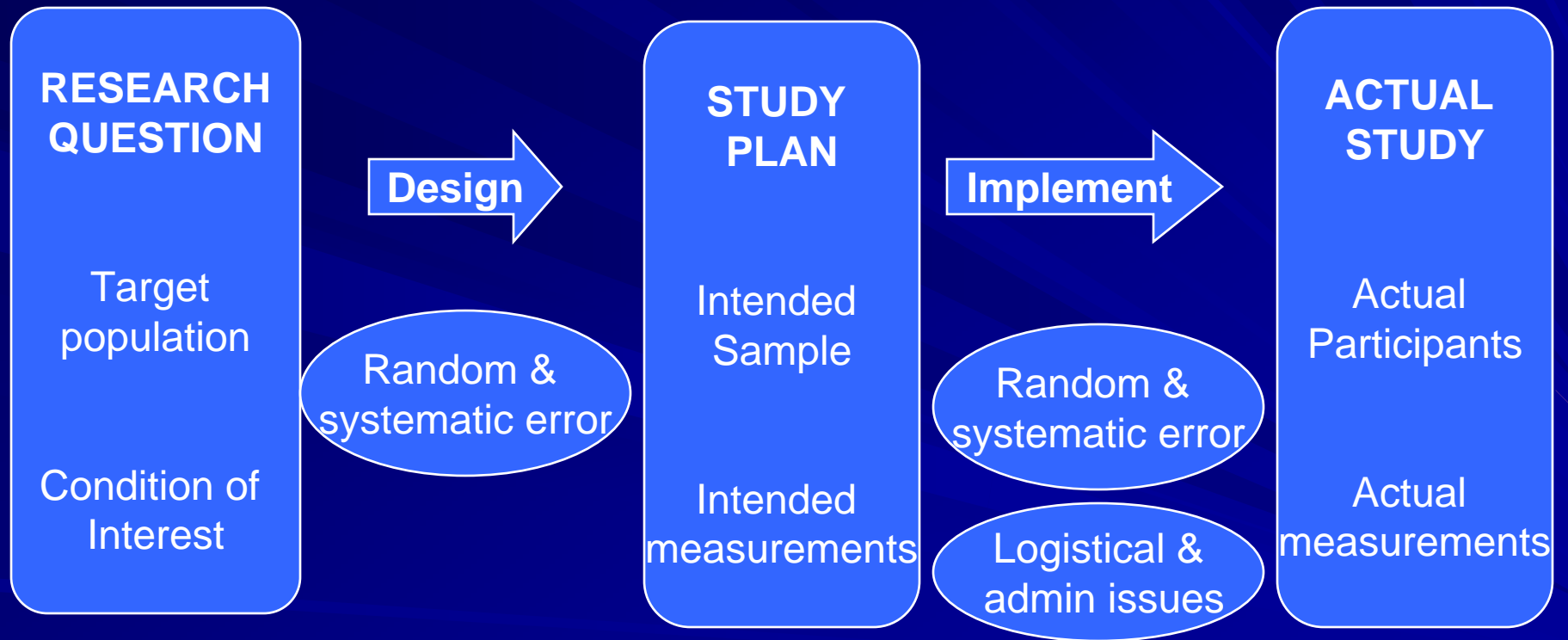


Where to Begin?

- **Protocol -**
 - **WHAT** are the protocol requirements?
- **Field / Site -**
 - **WHERE** will the study be implemented?
 - **WHO** will do what?
 - **WHAT** is the budget?



Implementation



Key Topics

- **Staffing and Personnel**
- **Facilities and Equipment**
- **Participant Population**
- **Management Logistics**
- **Quality Control**
- **Financial Resources**
- **Community Involvement**

Staffing and Personnel

- Sufficient number of appropriately trained and qualified staff to meet study needs
- Ability of staff to absorb new workloads
- Training and certification
- Staff meetings/teamwork
- Adequate supervision and leadership

Staffing and Personnel

Staff you need depends on design

- Clinicians
- Lab staff
- Counselors
- Pharmacists
- Data staff
- Epidemiologists
- Administrative/regulatory
- Recruiters/tracers



Facilities and Equipment

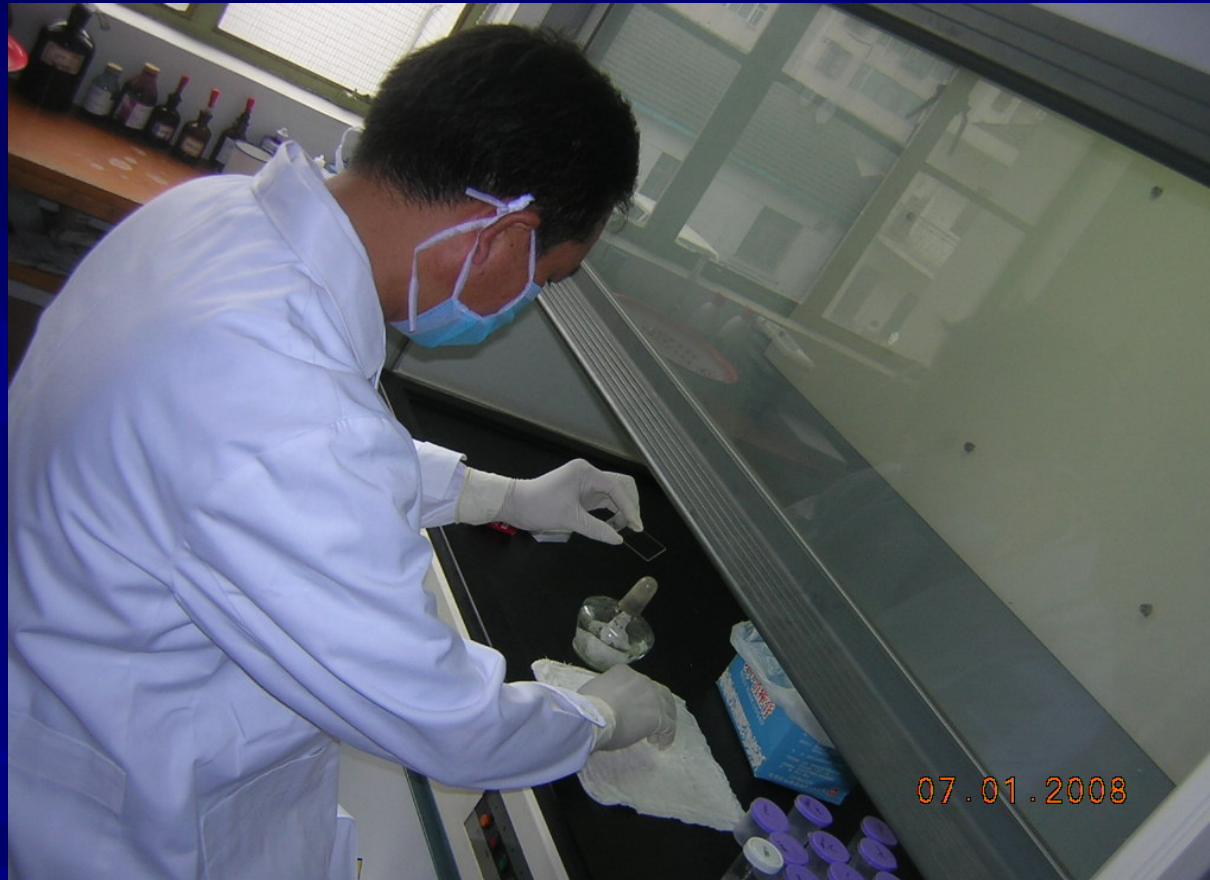
- **Study space**
 - Privacy important
 - Waiting area
 - Equipment/supplies
 - File storage
- **Office equipment**
- **Transportation**



Laboratory

- **Before study**
 - Proficiency testing
 - Normal ranges established
 - Storage space for specimens, refrigeration, etc.
 - Trained staff
- **During study**
 - Good tracking of specimens/labeling important!
 - Calibration and maintenance of equipment
 - Quality assurance testing
 - Safety for all staff

Protect Lab Staff



Pharmacy and Supply Storage

- Locked, restricted access
- Proper accountability
- Temperature controlled
- Trained staff



Office Space and Equipment

- **Administrative needs**
- **Phones, computers, fax**
- **Data storage**
 - **Need locked, secure storage areas**
- **Regulatory document storage**
 - **Requires dedicated space and staff**

Regulatory Files





Participant Population

- **Access to adequate number of qualifying participants**
- **Eligibility requirements of protocol**
 - Track why excluded on Screening Log
- **Competing protocols & studies**
 - Directing participants into studies
- **Creative recruiting**
 - Flyers, radio ads, street drama – all need IRB approval
- **Enroll with goal of retention**



Management Logistics

- **STRONGLY ENCOURAGED:** “rehearse” with all staff, all procedures prior to starting screening
 - Use **flow sheets or checklists** to guide staff
 - Practice data collection with “mock” patients
 - Time how long each activity takes
- Plan how specimens will be labeled, transported, stored
- Inventory supplies needed and ensure availability

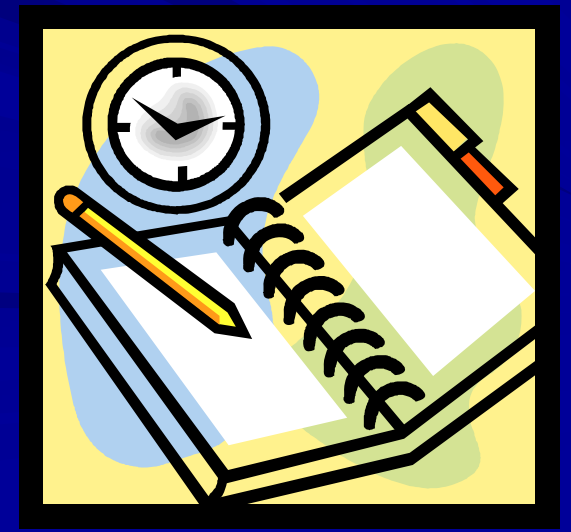
Managing Participant Flow

Who does what where?

- Client screening / counseling
- Informed consent
- Physical exam, interview, survey
- Laboratory specimens
- Follow-up visits / tracking
- Write details in Manual of Procedures or SOPs

Managing Follow-up and Tracking

- Plan for retention **BEFORE** enrollment begins
- Make it easy for participants
- Remind participants—calls, letters, visitors
- Have convenient hours for appts.
- Track patients who fail to return



Managing Paper

- Participant files and folders
 - Storage of source documents
 - Completing CRFs: Who? Where? When?
 - QA—Who? When? Where?
 - Storage of CRFs
 - Paper flow system for data entry
 - Paper flow for queries (correcting forms)



Quality Control

- DMID Quality Management Plan for medium and high risk protocols
- Missing data or low retention lead to wrong conclusions
- Build in ongoing qc for all data, including lab
- Exams and interviews must be conducted in same way by all staff with all patients
- Write **Operations Manual, SOPs, work instructions** to guide staff
- Train, supervise, monitor performance

Financial Resources

Budgeting approaches:

- Primary Objective is priority
- Include staff training costs
- Remember the “little” things—file cabinets, shipping, paper
- Scale back as needed
- Budget for the unexpected

Community Involvement

- **Involve local clinics, leaders, potential participants**
- **Form partnerships with local investigators**
- **Provide useful information to community**
- **If approached sincerely can boost acceptance of research, enhance enrollment**
- **Can build foundation for future studies**

Summary

- **Work out logistics, write SOPs, MOP**
- **Standardize data collection, including lab data**
- **Train staff, monitor, provide leadership**
- **Build in ongoing quality control**
- **Ensure supplies, space available and secure**
- **Stay on budget and on time**
- **Work with local community**

Group B

Practical Considerations for Implementing a Clinical Research Study

An HIV sero-conversion study is underway in your district. The study involves blood draws every 3 months for a year. All HIV tests are free for participants, and participants received an incentive for enrolling. Enrollment was completed very quickly. Six months after enrollment started, the investigator looks at retention data and discovers that about 35% of participants have missed one or both of the follow-up blood draws. After discussing with study staff, he discovers two things unknown to him previously. One, many of the study enrollees are migrant workers and have left the province for the work season. Two, a local community leader has printed a newspaper article stating that taking blood specimens will affect the fertility of men and women.

1. What can the investigator do now to improve retention in the study? Indicate whether or not these actions would need IRB approval.

2. What design features should the investigator consider changing for this study or the next one? Indicate whether or not these changes would need IRB approval for this study.

Group D

Practical Considerations for Implementing a Clinical Research Study

The primary outcome variable in your diarrheal study is weight of infants enrolled in the study. As the principal investigator, you observe the screening of the first 10 babies into the study and notice the following when the staff performs the baseline weight measurement.

- a. When babies are scared, they try to climb off of the scale and the staff must hold them on the scale to complete the measurement.
- b. If the baby is squirmy, the pointer on the scale swings up and down wildly.
- c. Some of the babies are weighed immediately after feeding, some are hungry; some are weighed with heavy clothing, some naked.
- d. When you weigh a 5-kilogram weight to test the accuracy of the scale, the mean weight is 5.3 kg.

All of these affect the accuracy of your outcome data. Write detailed instructions for staff about how to weigh babies for the study.

