

Nursing Research Series

Essentials of Science: Methods, Appraisal and Utilization

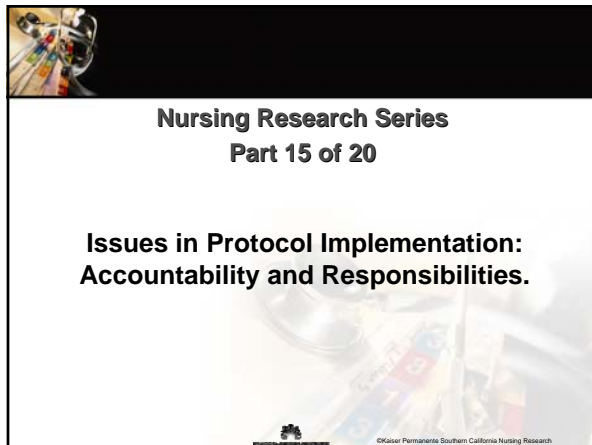


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*Essentials of Science:
Methods, Appraisal and Utilization*




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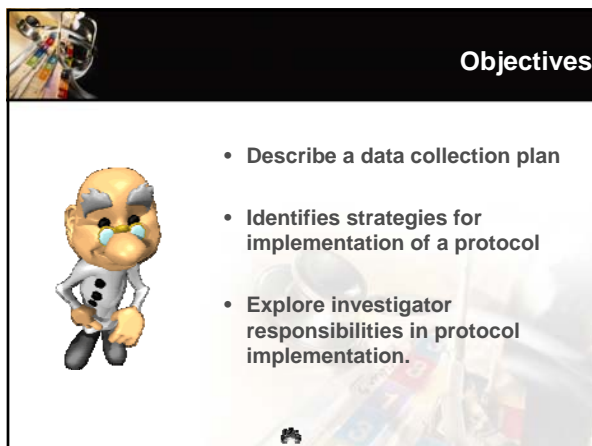


**Nursing Research Series
Part 15 of 20**


**Issues in Protocol Implementation:
Accountability and Responsibilities.**




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Objectives



- Describe a data collection plan
- Identifies strategies for implementation of a protocol
- Explore investigator responsibilities in protocol implementation.



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Data Collection Plan


- The blue print of the procedures for the research study.
- Includes:
 - Data Collection Protocols
 - Data Collection Forms
 - Data Management Procedures

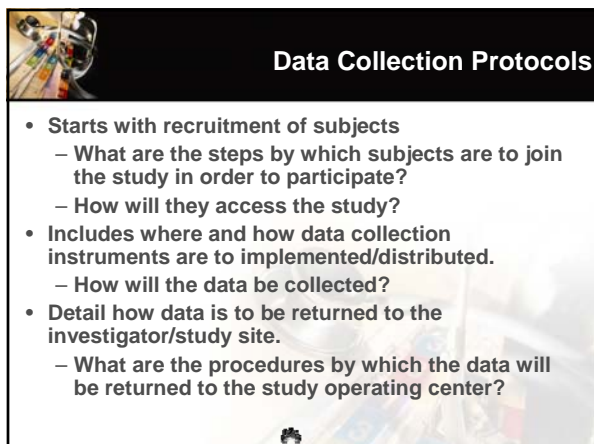




Data Collection Protocols


A detailed step by step procedure for where and how the data is to be collected





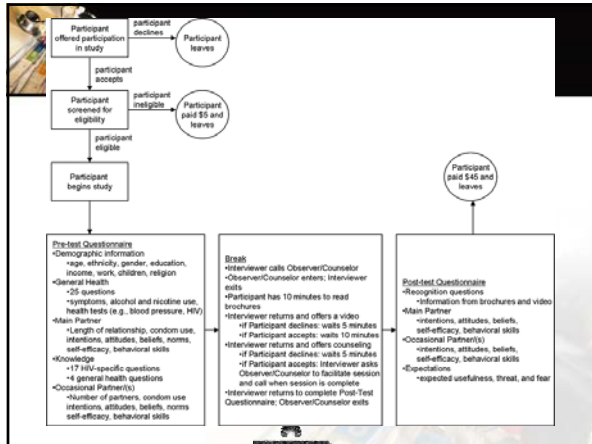
Data Collection Protocols

- Starts with recruitment of subjects
 - What are the steps by which subjects are to join the study in order to participate?
 - How will they access the study?
- Includes where and how data collection instruments are to implemented/distributed.
 - How will the data be collected?
- Detail how data is to be returned to the investigator/study site.
 - What are the procedures by which the data will be returned to the study operating center?



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Data Collection Protocols: Subject Recruitment

- Includes all recruitment materials
 - Brochures/Flyers
 - Advertisements
 - Posters
- Includes how recruitment materials are to be distributed.
 - Hand delivered by health care providers or study personal
 - Mailings
 - Newspapers/newsletters to be used.

Data Collection Protocols: Step by Step Description

- Includes a step by step description of how the data is to be obtained from the subjects.
 - Where and how questionnaires will be mailed.
 - If subjects are to come in for physical or psychological intervention, the mechanism by which that will occur is identified.
- Includes a prospectus on how to address any anticipated problems/difficulties during data collection.

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**Data Collection Protocols:
Return of the Data**

- Describes in detail how the data is to be returned to the investigator/study office.
 - Self address, return envelopes.
 - Subject returns for data collection.
 - Electronic data collection
 - Vendor Sites
 - Websites
- Indicates how the patient's risks are to be minimized during the data collection procedure.




Data Collection Forms

- Instruments or Tools
 - Self Reports
 - Observational Forms
 - Tape recordings
 - Video recordings
- Record/Case Report Forms
- Mining Databases
- Codebooks



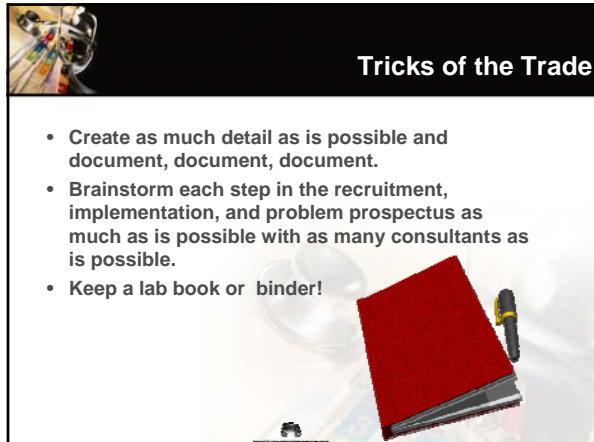
Data Management Procedures

- Data Entry
 - Who will be entering the data?
 - Who will have access to the data?
- Computerized Databases
- Tissue and Blood Banks
- Internet Security Procedures



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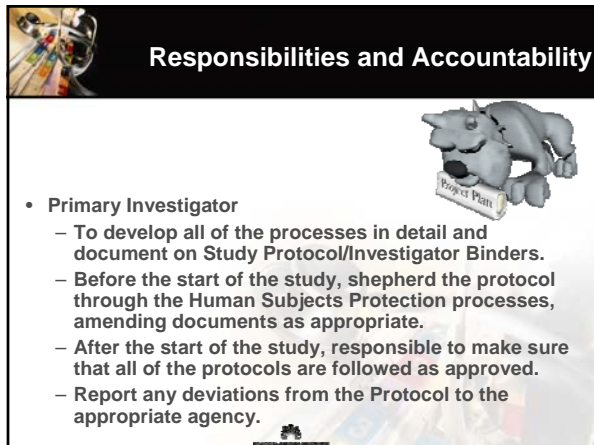
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Tricks of the Trade

- Create as much detail as is possible and document, document, document.
- Brainstorm each step in the recruitment, implementation, and problem prospectus as much as is possible with as many consultants as is possible.
- Keep a lab book or binder!

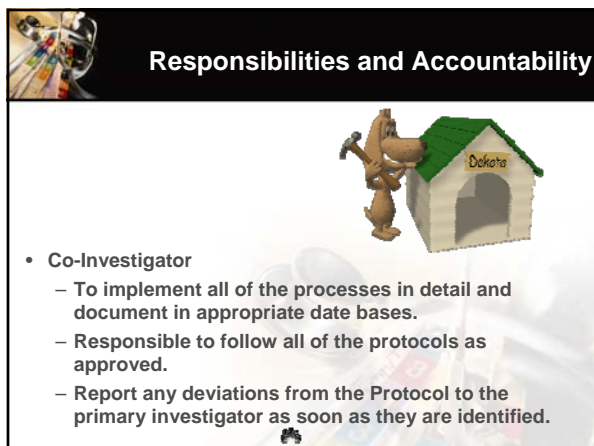
The slide features a background image of a red binder and a yellow highlighter. A small icon of a microscope is visible in the top left corner.



Responsibilities and Accountability

- Primary Investigator
 - To develop all of the processes in detail and document on Study Protocol/Investigator Binders.
 - Before the start of the study, shepherd the protocol through the Human Subjects Protection processes, amending documents as appropriate.
 - After the start of the study, responsible to make sure that all of the protocols are followed as approved.
 - Report any deviations from the Protocol to the appropriate agency.

The slide features a background image of a white dog sitting on a sign that says "Project Plans". A small icon of a microscope is visible in the top left corner.



Responsibilities and Accountability

- Co-Investigator
 - To implement all of the processes in detail and document in appropriate data bases.
 - Responsible to follow all of the protocols as approved.
 - Report any deviations from the Protocol to the primary investigator as soon as they are identified.

The slide features a background image of a dog standing next to a doghouse with a sign that says "DeKoko". A small icon of a microscope is visible in the top left corner.

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RESEARCH

There are risks in every scientific process.

These risks are mitigated through the development of an implementation process that is rigorous.

That rigor is evidenced though adequate protocol development.



References to Consider

- Burns, N. & Grove, S.K (2007). *Understanding Nursing Research, building an Evidence-Based Practice 4th Edition*. St. Louis, Missouri: Saunders.
- Harris, M. & Taylor, G. (2008). *Medical Statistics Made Easy, 2nd Edition*. Oxfordshire: Scion Publishing



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