

TOPIC 6.

FOLLOWING THE RULES AND INSTRUCTIONS AS PART OF A TEAM

Following Study Protocol and Reporting

Study Protocol and Reporting

Course Objective:

- ❖ Demonstrate understanding of the importance of study protocol adherence and documenting efforts



What is a Study Protocol?

- ❖ A **study protocol** is a document that describes, in detail, the plan for conducting the clinical **study**.
- ❖ The **study protocol** explains the **purpose of the study** as well as **how to do** it.
- ❖ It is the blueprint for all members of the research team to follow.



Protocol Deviation

- ❖ Accidental or unintentional **changes** to, or not following the research protocol that
 - does not increase risk or decrease benefit or;
 - does not have a significant effect on the subject's rights, safety or welfare; and/or on the integrity of the data.
- ❖ **Deviations** may result from the action of the subject/participant, researcher, or research staff, like a CHW.

Activity: Examples of a protocol deviation and why is a problem

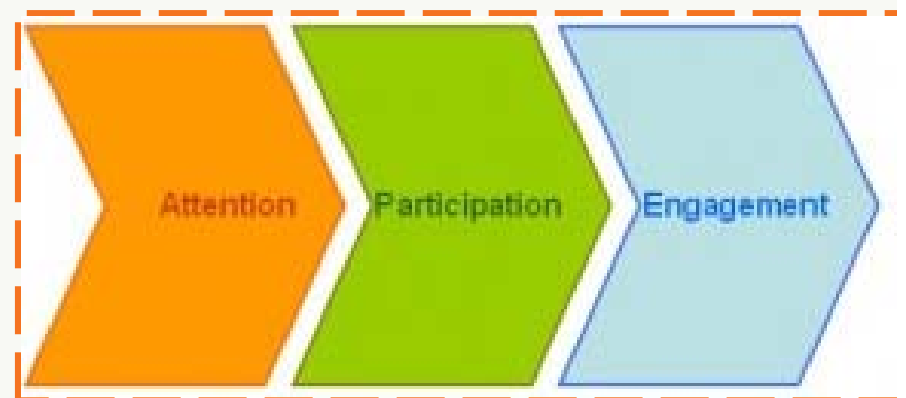
- ❖ A rescheduled study visit
- ❖ Failure to collect an additional self-report questionnaire
- ❖ Subject's refusal to complete scheduled research activities

Discuss why these are problems and how would you as a CHW, handle them in your team



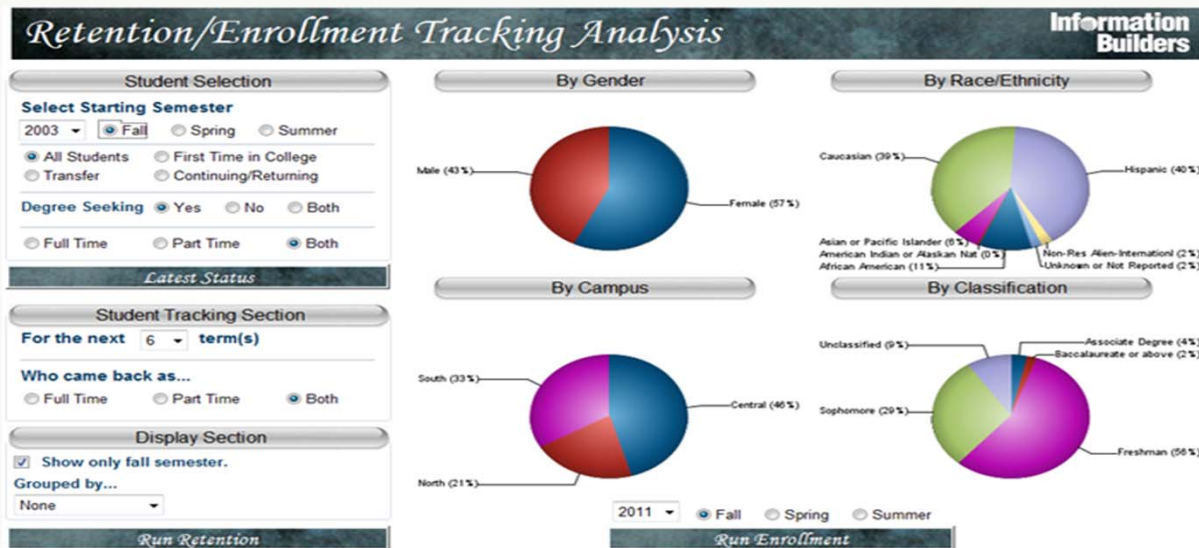
CHW Role in a research study protocol

- ❖ Facilitate increased participant
 - Recruitment
 - Participation
 - Retention
- ❖ Ensuring that research **procedures are culturally appropriate** for the target population
- ❖ Provide feedback **about the feasibility** of using outcome assessments in the target population



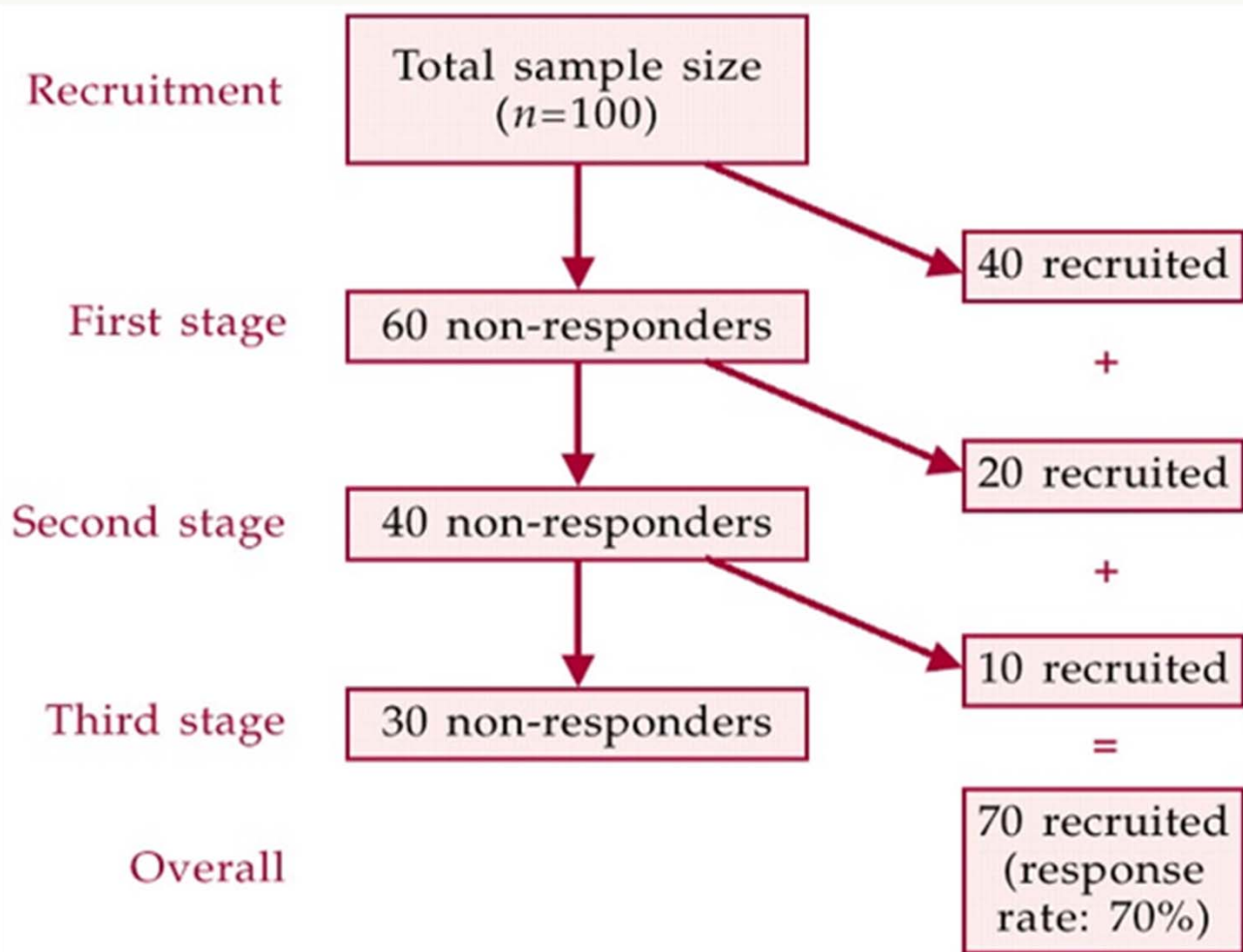
Tracking Study Participants

- ❖ **Tracking systems** vary from simple **paper logs** of follow-up phone calls to elaborate **computer-based** systems that track every aspect of participation, from information at baseline/starting point to a final follow-up contact.



A tracking system may be used by CHWs for multiple purposes

- Track participant's **current participation status** (e.g., refuses contact; location unknown, etc.);
- **Access and update contact information** on the participant and his/her proxies, relatives, friends, and health care providers;
- **Schedule follow-up activities**, such as annual mailings or appointment reminders;
- **Track responses** to follow-up contacts and completion rates;
- Automatically produce letters or forms (e.g., **appointment reminders**);
- **Generate reports** that prompt follow-up activity (e.g., a list of participants needing telephone follow-up due to nonresponse to a mailed survey);
- **Generate mailing labels** with the most up-to-date address;
- **Track results** of activities to search for **participants who cannot be located**; and
- **Provide summaries** of response rates.



Collaboration in the Research Team



- ❖ Exchange Information
- ❖ **Ongoing Communication**
- ❖ Cross Training
- ❖ **Share Resources**
- ❖ Enhance Capacity of Another Team Member

Questions?



❖ Next topic:

- How to report study results and to whom?