



Uganda Virus Research Institute

Plot 51-59, Nakiwogo Road, Entebbe
P.O. Box 49, Entebbe-Uganda
Tel: +256 414 320 385 / 6
Fax: +256 414 320 483
Email: directoruvri@uvri.go.ug



Managing activities and planning as an investigator by Emily N Kabuye



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Study Staff

- PI
- Co-PI
- Study coordinator
- Research clinician
- Research nurses
- Counselors
- Data manager
- Data clerk
- QA Coordinator



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Study Staff-2

- Pharmacist
- Social Scientist
- Lab manager
- Lab techs
- Community /advisor/educator
- Outreach worker/ Recruiter
- IT
- Driver
- Accountant/ Administrator



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Research Activities

Pre-Study On study Post- Study	Pre-Study On study Post- Study	Pre-Study On study Post- Study
Grant writing	Informing collaborators/ stakeholders	Close out visit
Creating source docs/ CRFs	Finance	Final financial reporting
Writing SOPs	Sponsor reports Dissemination	Dissemination
EC approval	Follow up of participants	Analysis
Sensitization	Data entry	Writing manuscripts
Recruitment	QA/ QC	
Pharmacy- obtaining IP	Annual EC approval	
Laboratory- testing kits	DSMB	

Important study documents

- Protocol (amendments, signature pages)
- Statement of investigator
- Contract with funders
- Insurance for pts
- Confidentiality agreements
- Investigator brochures
- Ethics documents (submissions, approvals, amendments), Budget
- Operation manual
- SOPs
- All communications

Important study documents-2

- meeting minutes
- AE/SAE reporting
- Source docs/ CRF
- Pharmacy documentation
- Laboratory registers



Things to organize before starting research

- Logistics
- Forming a research team
- Preparing field documents
- Training the research team
- Supervision & documenting
- progress



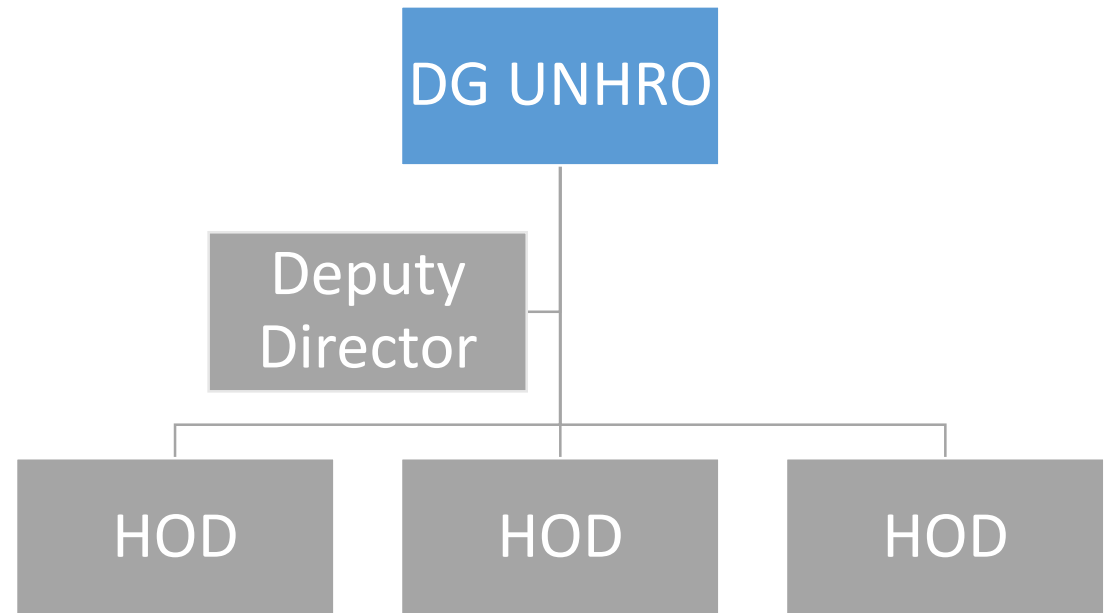
Logistics of Study Activities

- Will participants be
- visited/examined at their
- homes or asked to come to a
- central location?
- How will samples be stored
- and transported to a
- laboratory?
- How will people be traced?
- How will confidentiality be
- maintained?



Research Team

- What man power is necessary to carry out the research?
- Think through the logistics of the desired field team:
- How will they flow in the research center?
- Can they be accommodated in the vehicle along with equipment?
- Develop job descriptions for personnel including educational requirements and experience
- Organograms- helpful to show relationships and lines of



Logistics-Logistics of Study Activities-3

- If large equipment and sensitive testing necessary, central location
- House to house allows you to be sure you have documented all people eligible which is not possible with a central location
- Issues of confidentiality in doing house to house
- Increased participation in house to house
- What is an ideal central location?
- Is it a church, a village dispensary, a tent set up in the village or a research center in town?

Field Documents

- Sample Staff Responsibility Log
- Protocol
- Manual of Operations
(MOP)/ Field Procedure Manual
- Standard Operating
- Procedures (SOPs)
- Tracking Logs



Training the Team

- Essential for producing quality research results!
- The more knowledge the team has on the study, the more likely they will do quality work.
- Don't underestimate the role of any member on the team.
- Everyone is contributing toward producing quality research.





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Training can be

- Study protocol
- Standard Operating Procedures (SOPs)
- Good Clinical Practice (GCP)
- Good Clinical Laboratory Practice (GCLP)
- Research ethics
- Confidentiality



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Importance of SOPs

- Manage compliance obligations ,
Incorporates regulations, GCPs, and institutional, requirements
- Create operational efficiency
- Ensures processes have been examined and optimized
- Training staff Acts as a resource to keep everyone on the same page at all times
- Ensures the team knows their regulatory obligations and how to best meet them using available resources
- Implementation of :
- Common standardizes processes amongst all studies
- Provides a level of formal accountability for team/members
- Prevents noncompliance on a systemic level



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SOPs in terms of investigations and audits (Persp):

- The process of creating SOPs enhances awareness and working knowledge.
- Training staff on SOPs ensures everyone is doing things the same way.
- Should you have an investigation or audit, an SOP-trained staff should have no problems.
- Should you have an investigation and no SOPs, you could be vulnerable to findings. Results of most audits usually include recommendations or requirements to create SOPs.

Standard Operating Procedures (SOPs)

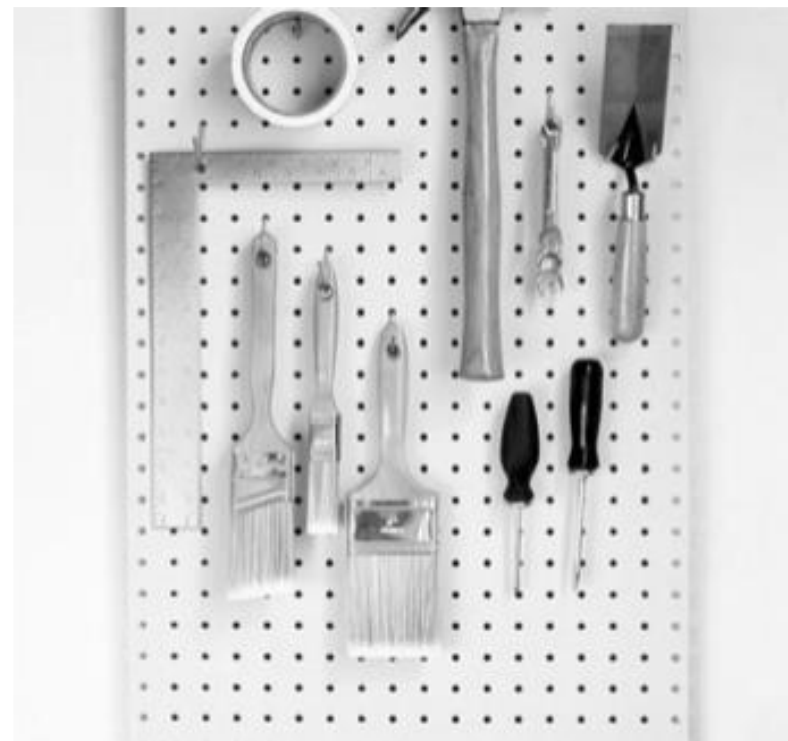
SOP -is detailed, written instructions to achieve uniformity of the performance of a specific function”

- ICH GCP 1.55



Limitations of SOPs

- They can't help if you don't use them.





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I thank you





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Group work

- You have been hired as the research coordinator (or manager) of a large multicenter phase III clinical trial of ARV based microbicide for prevention of HIV transmission among women in a fishing Community in Uganda. The study will be conducted at a community based study clinic.
 1. What study staff would you hire?
 2. Identify aspects/ activities of the research you need to organize or assure are happening- pre-study, during study and post study?
 3. What documents must be maintained in the research coordinator/manager's files for this study?