# RESEARCH MONITORING PROCESS

# ERIC AKUM ACHIDI (PhD) Professor of Chemical Pathology & Immunology

#### Presentation Outline

- What is research Monitoring?
- Who are the stakeholders in monitoring
- What are the different levels of research monitoring
- Research Monitoring versus Research Audit
- What is the research monitoring situation in UB?

#### WHAT IS RESEARCH MONITORING?

"The act of overseeing the initiation, progress and close-out of a research project by designated stakeholders, and of ensuring that it is executed, documented, and reported in accordance with agreed guidelines and any regulatory requirements"

## What is the Purpose of Monitoring?

- To ensure that the research protocol approved in the awarded project and agreement signed is correctly and fully executed in accordance with regulatory requirements.
- ❖ Protection of rights and wellbeing of human participants, animals, plants, other living things and the environment.
- Ensure that research data are accurate, complete and verifiable

## What is the Purpose of Monitoring?

Ensure that challenges or problems encountered during the research cycle are identified on time so that solutions are found and implemented on schedule.

## Who are the Stakeholders in Research Monitoring?

- The PI
- Funder/Sponsor
- Study Population (if relevant)
- ❖ The host Institution (Grant Office, IRB, Biosafety Committee etc)
- The Government

## What is the Extent and Nature of Research Monitoring?

- Monitoring should be done taking into consideration the following:
  - Research Objectives & their indicators
  - Goal & timelines
  - Research Design
  - Size and complexity of project
  - Outcome measures (Deliverables)
  - \*Risks
  - Ethical compliance
  - Finances (rythym, eligible costs compliance, procurement etc)

### LEVELS OF MONITORING (I)

- Coordinating centre/day-to-day monitoring by PI, Grant manager/coordinator (Internal monitoring) to ensure that:
  - Data collected are consistent with protocol
  - Data is being collected by competent and 'authorised' staff
  - No key data is missing (Data completeness)
  - Ethical requirements are respected
  - Summarily: Review daily/weekly progress of work, identify challenges encountered and execute contingency plans

## LEVELS OF MONITORING (II)

#### FUNDERS

- Ensures that grant funds have been disbursed to the grantee institution
- Monitors progress of work of grantee using annual/midterm reports and timelined deliverables
- Monitors financial rhythm of expenditure,
   appropriate use of funds (e.g budget lines)
- Project close-out

May recommend AUDIT

### LEVELS OF MONITORING (III)

- Host Institution
  - GRANT OFFICE monitors:
    - Progress of work (annual/final reports, Pl's compliance with grant agreement etc)
    - Financial Issues (disbursements, procurement, reports etc)
  - IRB monitors compliance with ethical guidelines
  - Biosafety Committee monitors research activities to protect the environment

### LEVELS OF MONITORING (IV)

#### **Study Population**

May choose to verify what is being done with samples collected from the field including documentation that ensures confidentiality

### LEVELS OF MONITORING (V)

#### Government

Some studies may involve use of materials or equipment that hinges on national security e.g use of drones to facilitate vaccine delivery

Other studies may involve use of new products whose harmful effects have not been cleared by the machinery of the state e.g drugs, vaccines etc

#### **MONITORING vs AUDIT**

- ❖ Monitoring can be viewed as some form of Quality Control procedure during which a stakeholder (PI, Funder or Institution) reviews the research process to ensure compliance with protocol & high quality/reliable results.
- It is an ongoing process
- **❖** Auditing is some form of Quality Assurance performed by an independent body that is usually planned and systematic either at midterm or closeout of project.
- Internal or external audit

## The Research Monitoring Situation in UB

- **❖** There exist a Research and Cooperation Service: Its Monitoring role???
- ❖ There exist an IRB and ERC: Monitoring of the implementation of research projects for ethics compliance???
- There is no Biosafety Committee????

There is need for a dedicated grant office with staff trained in the management of externally funded grants in UB given the growing number of externally funded grants

## THANK YOU?

