

# Roles and Responsibilities of Different Stakeholders in Health Research.

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# Introduction

- ▶ At the core of any health research system are the:
  - Researchers: who undertake the research
    - The diverse body that funds it
      - Those organizations that host it

# What is Health Research?

□ Research that is done to learn more about human health

■ Goals:

- to find ways to improve human health
- to find better ways to prevent and treat diseases

*An important way to help improve the care and treatment of people world wide.*

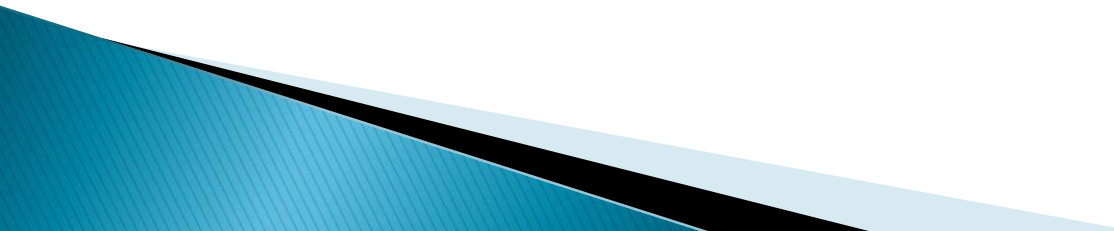


# Stakeholder: Definition

- ▶ Can be defined as “organizations and individuals that are involved in a specific activity because they participate in producing ,consuming,managing,regulating or evaluating the activity”

# Specific stakeholders groups

□ These stakeholders range from a broad spectrum that includes:

- Research participants,
  - research team,
  - sponsors,
  - regulators,
  - monitors,
  - government agencies,
  - academic institutions,
  - ethics committees or IRB's etc.
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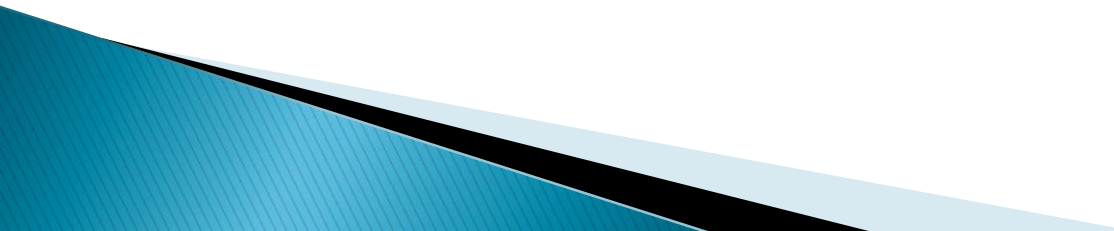
# Health research Stakeholders

## □ The Initiator

- Research **sponsors** are the primary stakeholders who initiate the research process
  - Pharmaceutical or biotechnology companies in the business of making drugs ,biologics or medical devices.
- They may also be **Academic Institutions** ( UDSM,MUHAS,KCMC,KCRI) or even **Government agencies** eg NIMR

# Health research Stakeholders

## □ Sponsor Roles:

- Protocol development
  - Selecting qualified investigators
  - Providing all information needed to properly conduct the investigation
  - Monitoring and ensuring that the study is conducted in accordance with protocol
  - Ensuring complying with regulatory bodies
  - Informing FDA/TFDA and participating investigators of any AE and risks.
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# Health research Stakeholders

## The Researchers

- “research team”-PI,Co-PI,research coordinators, site managers, lab personnels,technicians,analysts,pharmacists,research assistants, data managers ,research nurses ,QA/QC people,etc.
  - This team of professionals is led by the **principal investigator**.

## Roles:

- Ensure that an investigation is conducted according to the regulations
- Obtaining the informed consent of each subject
- Reporting any adverse events to the sponsor and the IRB's



# Health research Stakeholders

- ▶ As the research team works on the study, there is a certain level of **interaction** that occurs between the IRB, the sponsor and TFDA/FDA.
- ▶ **Reasons:**
  - Common goal of completing the study
  - To ensure that the study is conducted ethically while preserving the safety and wellbeing of subject.

# Health research Stakeholders

## □ The Enforcer (National Regulatory Bodies)

- The FDA/TFDA is the main regulatory authority stakeholder in charge of **protecting** the public health by assuring the **safety** and **efficacy** of drugs, biologics and medical devices.
  - NIMR
- Performs Audits and Inspections .

# Health research Stakeholders

## □ The Safety Squad

### ○ IRB's /Ethics Committees

- Main Role: Protecting Research Participants

### ■ By:

- Conduct initial review to see if the study can be done ethically and safely
- Analyze study protocol and assess the risks and benefits\_(decision)
- Several reviews through the study period

□ *While the investigator is interested in conducting the study ,the IRB/EC is mostly interested in maintaining subject welfare*

# Health research Stakeholders

## □ The Community(You and I)

### ▶ **Role:** Consumer-new drugs....

- Is the community informed on the findings after the study is done?

### ▶ CAB-Promote community engage in health research

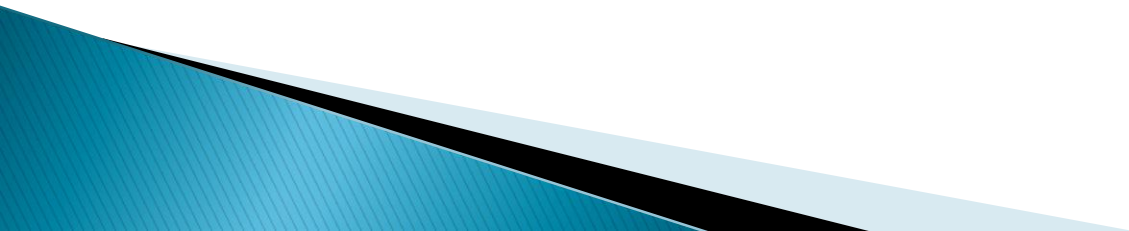
### ▶ Provide formal systematic channels by which communities can have inputs in research

# Stakeholders relationship in health research.

All the groups interact with and influence each other but consistently ,  
researchers

feel pressure from many of the other stakeholders.

- Conflict of interest between Clinicians who are researchers-how do you separate those hats?



# Conclusion



- ▶ Regardless of type of stakeholder or position, health research is a very cooperative field. Many aspects of it rely on much collaboration, partnership and forming alliances.
- ▶ Different types of research findings can influence development of health care policies, change the existing policies ,hence diseases management ,prevention and control for the better health and safe living in this world
- ▶ **Teamwork** is an essential skill since it is a field where you work with all kinds of people with different professions and knowledge.

## References:

<http://www.nimr.or.tz>

GCP Regulations and Guidance Doc-21CFR 312.60

<http://mzagzoug.hubpages.com/hub/Stakeholders--Roles-in-Clinical-Research>

■ Thank You.

