

Responsibilities of PIs, Academic Supervisors, Institutions, Sponsors, funders, participants and Communities in Health Research

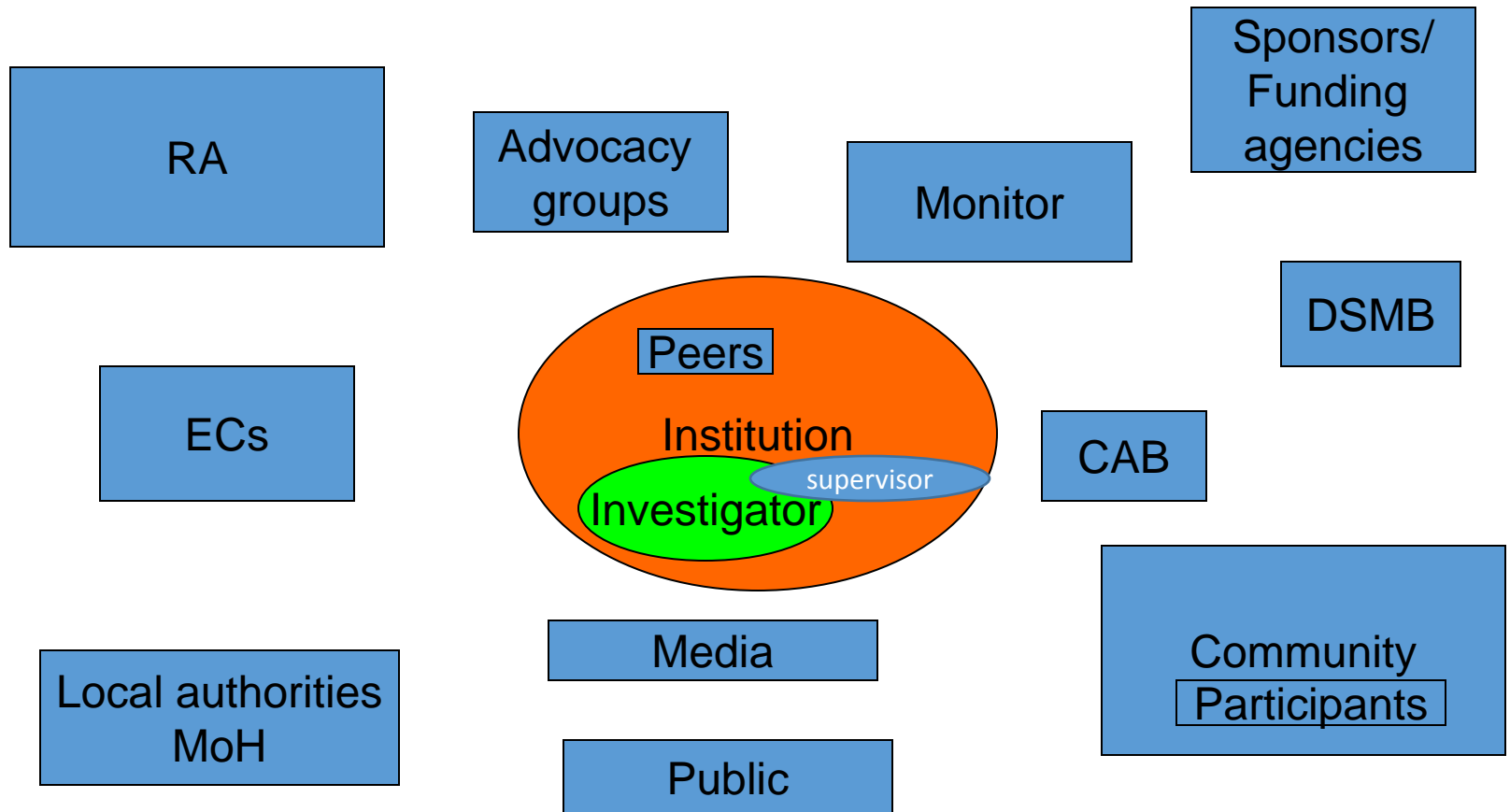
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Outline

- Discuss the specific responsibilities of Stakeholders in health research
 - Researcher/Investigator and supervisors
 - Sponsor
 - Funders
 - Participants
 - Communities

Various players in Research



Who is a Researcher/Investigator

- **A researcher/Investigator** is the individual who undertakes a research study.
- GCP - “Investigator” is: **the person who takes responsibility for the conduct of the trial or study and the study site.**
- Principal Investigator (PI): Person leading the team of researchers/investigators
 - **Held accountable for everything that happens during the course of the study/trial (good or bad)**

Issues for the investigators

- Qualified by education, training, and experience
- Clinical trials- licensed investigators and study team members
- Complying with approved protocol, institutional policies and national regulations.
- Conflict of interest
- Conflict of commitment

Responsibilities-Before Research

- Design a scientifically and ethically sound research
- Ensure adequate logistics for proposed research
- Negotiate MTAs and other benefits/issues
- Seek approvals
 - EC
 - NRA
 - Product importation,
 - Product registration
- Enrolling eligible subjects
- Eliciting/documenting informed assent/consent

Responsibilities-During Research

- Compliance with protocol approved by IRB/IEC
- Fulfill all reporting requirements
- Assign personnel to perform various study related activities
- Account for all study activities including unscheduled activities.
- Data management:
 - collection, cleaning, entry, analyses, summarization, archiving
- Responsible use of resources
- What are the other responsibilities researchers take on when they conduct research in resource poor countries?
 - Ancillary care

Responsibilities-After Research

- **Preparing/disseminating reports**
- **Publishing results**
- **Repacking results for utilization**
- **Benefit sharing – patents etc**
- **Providing/access: research related health care**

Important!!!!

Researcher/Investigator must protect the safety and well-being of research participants/communities before during and after research.

Supervisors Roles in Graduate research

- Graduate students classified as researchers
- A graduate student as an independent researcher in the making
- Graduate research – impact & resource implications.
- Publications from graduate students work count in institutional profiles
- Supervision issues –what is the role of supervisors?
- Graduate students who do not publish.....

Changing Landscape for Graduate Studies

- More graduate students in academic institutions
- Emphasis on research degrees
- Supervision as a duty for academic staff – not a favour
- New trend in academic institutions – Research & Graduate Studies
- Funding for graduate studies
- Training of supervisors to improve supervision of students
- Allocation of supervisors may present challenges in institutions (by number or ability?)

Realities about Supervising graduate students

- Post graduate research is a form of apprenticeship taken under the supervision of senior faculty members.
- Supervisors should possess recognised subject expertise.
- Supervisors should have the necessary skills and experience to monitor, support and direct research students' work.
- Research students should receive support and direction sufficient to enable them to succeed in their studies.
- The progress made by research students should be consistently monitored and regularly communicated to the students

Interesting paper on supervision

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Post Graduate Students' Experiences with Research Supervisors

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KEYWORDS Postgraduate Students. Supervisors. Research. Universities. Challenges

ABSTRACT This study examined the experiences and challenges of post graduate students with research supervisors. The study adopted an interpretive qualitative research methodology and a case-study research design. Data were collected through face-to-face interviews with 40 post graduate students from 2 South African Universities in the Eastern Cape Province. In addition, questionnaires were also used as the main instrument of obtaining the feedback from the students. The study found that only a few students claimed satisfaction with their supervisors. However, it is noticed that a significant percentage (75%) of respondents are not satisfied at all with supervisors' feedback in relation to their research work. Their insufficient knowledge of the relevant field, change of supervisors due to transfer to other institutions, lack of supervisory support and supervisor's other work load have been identified as challenges facing some of the post graduate students in this study. The study recommends training of supervisors in research supervision. Issues to be addressed in the training of supervisors should include training in research methodology, technical expertise, managing the supervision relationship, quality control, providing constructive criticism and feedback and ethical concerns.

Interesting data.....

- Worldwide the completion rate for post graduate students ranges from poor to dismal (Lubbe et al. 2005).
- Up to half of the students who begin post graduate studies do not complete their studies at all (Golde and Dore 2001).
- About 40% of the postgraduate students reported that they would pick a different topic if they could start all over again (Golde and Dore, 2001)
- About 46% stated that they would select a different supervisor if they were given the opportunity to do so (Golde and Dore, 2001).
- About a third of the respondents noted that they would select a different field if they had to redo their post graduate studies (Lubbe et al. 2005).

Questions

- What are the qualities of a good student?
- What are the qualities of a good supervisor?
- What is the difference between supervision and mentoring?

Institutions

- House Investigators for accountability
- Put up policies to protect science, participants and institution.
- Provide an enabling environment
 - grant management skills
 - Provide infrastructure and support services
 - Setting up and supporting IRB

Funders and Sponsors

- What is the difference between funders and sponsors?
- Why do some organisations prefer to become funders and not sponsors?

Sponsor

Individual/company/institution/organization that finances research and participates in its initiation and management.

1 Research funding to cover

- 1.1 Res implementation/management costs
- 1.2 Res related health care to participants
- 1.3 Compensation for participation costs
- 1.4 Insurance cover for injuries
- 1.5 Res capacity building/technology transfer

2 For clinical research, sponsor responsible for:

- 2.1 Investigational product: GMP manufacturing, packaging, labeling, coding, and handling of supplies
- 2.2 Identification/selection of investigators/expertise
- 2.3 Providing information on investigational product
- 2.4 Submitting notifications to RA/REC, incl SAEs

Research Participants

- Provide data – king in research
- Follow study procedures
- Researcher can terminate participation under what conditions.
- Family, Guardians, significant others and community leaders role in providing access to individual

Communities

- Participants in Research through:
 - community leaders/representatives
 - CABs
 - Source of participants
- Protecting individual participants
- Providing access to research participants
 - Community assent/permission
- Provide input on the development and initiation of Research
- Provide inclusive community insight to researchers on needs to direct a needs-driven and locally relevant research.
- Promote and assist in recruiting participants
- Evaluate the impact of research

Conclusion

- Investigators need to appreciate the various stakeholders and the roles they play
- Researchers should not view ethics, as a regulatory requirement but as a duty to all stakeholders.
- Investigators/research team members bear the ultimate ethical responsibility for their work with fellow humans.

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