

CHALLENGES OF IRB MANAGEMENT IN
TANZANIA
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General information.

- Tanzania Institutional Review Boards or Research Ethics Committees are designated by Institutions
- They review, approve the initiation of and conduct periodic review of biomedical research involving human subjects
- The Primary purpose of such review is to assure the protection of the rights and welfare of the human subjects

- The evaluation of research proposals focuses special attention to:-
 - Equity in distribution of benefits and burdens to ensure that the selection of subjects is equitable in relation to benefits and burden
 - Risk/benefits ratios: this is to ensure that the risks to subjects are minimal and reasonable in relation to anticipated benefits

- Conflict of interest *ie* to ensure that there is no conflict of interest by researchers, participants or sponsors
- Adequacy of information for participants and protection of freedom within consent including informed consent

- Educate and assist researchers and community in understanding and appreciating ethics of researches
- Monitor and audit researches

Some of the Challenges facing IRBS in Tanzania

Challenges from outside Tanzania:

- Pressure from collaborating institutions in terms of:-
 - Inadequacy of the initially provided scientific information in research projects by the collaborating side may later be questionable by international collaborator leading to discontinuation of the project
 - Time frame for ethical clearance of joint projects, may take too long eg **KI/MUCHS, Havard/MUCHS**

- Different understanding of some **Ethical issues** from the collaborating institutions (developed countries) eg. Consent process, confidentiality including disclosure of Confidential matters
- Occasional poor involvement of local researchers in the project design for projects developed in the West eg overlap of research districts

Challenges from within Tanzania

- Ethics committee receive patchy information in research proposals making evaluation difficult
- Little coordination and different handling procedures of Research issues between IRBs in Tanzania
- Nearly all Public Research health institutions in Tanzania have their own IRBs but there is little coordination and uniformity
- This leads to Duplication, waste of resources and poor sharing of the findings

- Lack of centralized data base of research activities from different IRBs
- Lack of accountability of researchers in cases where only one IRB was involved in the process of ethical clearance of collaborative research without the awareness of the partner IRB
- Can the partner IRB be able to monitor activities? Where is the researcher supposed to be accountable in case of misconduct??
- Those who receive ethical clearance from one IRB on time for inter-institutional collaborative researches but **delayed by** other partner IRB **should they proceed or wait?**
- Problems in realizing a Quorum during planned IRB meetings leading to postponement of meetings

- Lack of adequate and continued education regarding the ethics by IRBs, researchers and other stakeholders
- Inadequate facilities for documentation and archiving IRB materials including procedures for constitution, operating procedure for IRBs, regular reports, etc

Follow-up Challenges.

- Difficult in establishing following-up procedures of all studies for which a positive decision has been reached due to lack of training, inadequate manpower and infrastructure and finances