

Regulatory Authorities – Botswana Perspective

Ernest MOSEKI



Outline

- ❑ National Regulatory body
- ❑ Other Regulatory bodies



National IRB

- ❑ HRDC – Health Research Development Committee is in the Health Research Unit – MoH
- ❑ HRU are secretariat
- ❑ Chairperson is PS Health Services
- ❑ Members = volunteers



Membership

- ❑ HRU staff (Secretariat)
- ❑ Volunteers
 - Various MoH specialists
 - Referral hospital staff
 - UB staff
 - Community member



Meetings

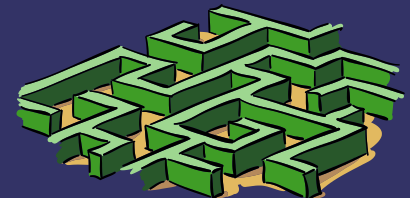
- ❑ Once in two months
- ❑ 1/3 members form a quorum
- ❑ Meeting ½ day
- ❑ Adhoc meeting



Review Process

- ❑ Submission done 6 weeks prior to meeting
- ❑ No payment
- ❑ Proposal given to a primary reviewer depending on area of specialty
 - ❑ Sends comments to the secretariat after review
 - ❑ Comments discussed further at the full meeting

- ❑ Minimal risk study can be expedited



Turn Around Time

- ❑ 10 Working days after a full committee meeting
 - ❑ But can take more than that
 - ❑ Reviewers may not have sent in comments
 - ❑ Secretariat busy with other MoH business



Clinical Trial With unregistered drugs

- ❑ Parallel submission to Drug Regulatory Unit (DRU)
- ❑ Request additional often not easy to obtain information –
GMP certificate, stability data



Other Bodies

- ❑ University of Botswana
 - ❑ Well staffed and resourced
- ❑ 2 hospitals



Ke a leboga

Asante sana

