Round table A:

Informed consent From Theory to practice

Experiences from the participants

- Written consents more useful
- Oral consents associated with problems when death or side effects occur
- Need to have local language intellect translate the written consent for non illiterates
- Development of consent need local intellect to participate.

Experiences cont.

- Witness should know the vernacular language and should be one who is not study staff
- Institution which is doing the study should be explained in the process of doing consent
- Witness is a challenge for the confidentiality hence need to define confidentiality (confined to study team)

Contents for Ifakara HSV study

- A study to minimize HIV transmission from partner who is HIV + ve to one who is –ve
- One of the common viral STI(HVS-2) which increase HIV transmission
- Testing drug for treating HSV-2 to see if it will reduce the HIV transmission
- Conducted by NEU & SWU (Tz) funded by NIH

Contents cont.

- Study involve 200 couples ½ will have drug and other half receive similar tablet (not with the drug), because we are not sure if the drug will work
- Participants will receive the drug by chance
- You won't know what you receive and we (researcher) will not know what type of tablet received.

Contents cont.

- You and your partner will be screened for HIV and HSV-2
- You will participate in the study if one of you is HIV +ve and HSV -2 +ve other is not
- If eligible you and your partner will be return every one month for 12 months
- At the beginning and after every 3 months you will have blood drawn (show tubes)

Contents cont.

- Collect urine, genital swabs
- Men will provide semen at three months
- You will undergo HIV risk reduction counselling at each visit
- Risks
- Drug side effects (list)
- Stigma from society

Contents cont.

- Risks (ctd..)
- Family tension, psychological pain because of knowledge of discordance
- Physical pain/discomfort in drawing blood
- Pain, discomfort, embarrassment in genital examination

Contents cont.

- Benefits
- Knowledge of you and your partner's HIV status
- Treatment of STIs
- If study proves efficacy of drug, you and society will get the drug (years and amount)

Contents cont.

- No alternative advantages for participation were identified.
- The research team will have access to your clinical records. Funding agencies and govt institutions eg FDA may also have access to study records BUT
- No individual names will be mentioned in records and publications/reports.

Contents cont.

- There will be treatment of drug side effects and injuries from study procedures at no charge.
- Travel compensation at TSh 5000.
- In case of any queries or comments with regard to the research, contact the project director at …. (address and phone #). You can also contact the Ethics committee at..

Contents cont.

- It is important for you to participate, BUT remember that it is VOLUNTARY.
- You can withdraw from the study at any time, there will be no penalty.
- Provision for signature, thumb-print, witness, etc