

Ethical considerations

Day 2

The general conduct of biomedical studies

- The centrality of the voluntary participation of subjects with their informed consent
- Ethical review

Example in TB Survey

- be protected from any harm related to testing procedures and stigma associated with tuberculosis (TB);
- participate in the benefits of the survey, and have access to free treatment services if diagnosed with TB;
- be informed of the procedures and risks; and
- freely choose whether or not to participate in the study, and not in any way be coerced into TB testing by promises of benefits such as free treatment.

Review

- Ethical considerations
- Scientific Soundness

Opposite comments from different reviewers

Externally sponsored studies

(1) the initiating agency should submit the study protocol to ethical review, in which the ethical standards should be no less exacting than they would be for a study carried out in the initiating country; and (2) the ethical review committee in the host country should satisfy itself that the proposed study meets its own ethical requirements.

WHO requires internal clearance for all studies involved in.

Some dilemmas

- Basic TB prevalence survey does not force anything beyond medical practice
 - Symptom screening,
 - CXR – widely used in health screening program: IOM, visa applicant, WHO recruitment
 - Diagnosis (and treatment)- standard practice in
- TB is one of the diseases that should be notified
- DST (MDR) and HIV testing
 - Gap between global recommendations and real accessibility/practice

You need to answer

- How will you take informed consents?
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- Is there ethics committee in the country or institution? Where will you submit your protocol?
- Is there any international assistance (finance and/or technical)?
- How will you keep and utilize data that are linked to individuals as a nature of TB survey? (others: see page 278 Annex 39)

Involvement of Minors

- Under 18y of age
 - Guardian's approval is often required
- Young migrated workers in urban slum
 - Unable to participate is disadvantage when they have higher risk?

Similar discussions among pregnant
excluding pregnant from a scientific study is
fair or not

Confidentiality

- Interview: interview at home does not guarantee confidentiality
- Being TB suspected
- Feedback of the results: letter
- TB patient

False positive diagnosis

- **Study (Active case detection) and Clinical Practice (Passive case detection)**
- **Study Lab results and clinical management in local health setting**