Writing a Research Proposal

Joint Introductory Course on Field Epidemiology and Biostatistics
Bangkok, Thailand
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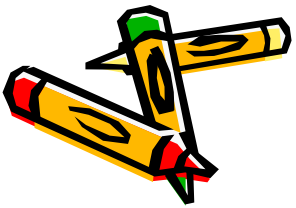
Steps in the research process

- Generate a research question
- Organize a team
- Draft a proposal/protocol
- Get TB Program and ethics approval
- Test on a small scale (pilot) and revise proposal
- Do study and analyze data
- Make conclusions for report and manuscript
- Disseminate information and plan action

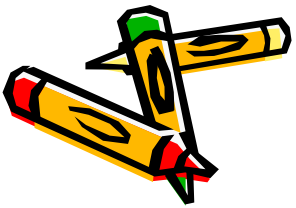
Why write a proposal?

- To organize your own thinking and plans
- To share your ideas
  - Why, what, and how you want to do something
- To ask for funds
- To obtain ethical clearance



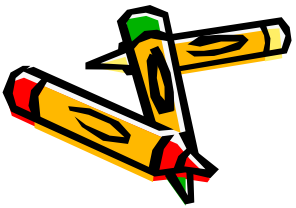
A good proposal…

- Focuses on a clear and specific research question
- Uses a structured format
- Is easy to read and understand
- Is detailed enough so any reader can understand
- Anticipates most questions and problems



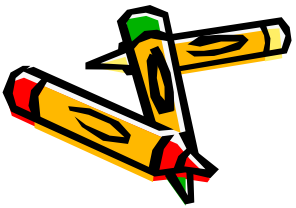
A good proposal

- Allows planning
- Helps secure support from supervisors and funders
- Makes doing the activity easy
- Makes doing the analysis easier
- Makes drawing conclusions easier
- Makes writing the report easier



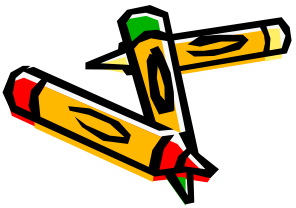
A proposal starts with an important idea

- A problem
- A question
- A hypothesis
  - Cause => Effect



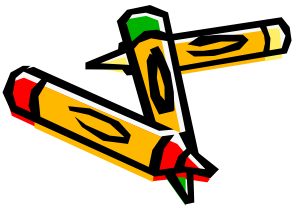
Examples of TB/HIV research questions

- Why are TB patients not tested for HIV?
- Why do TB/HIV patients interrupt treatment?
- Does treatment failure predict MDR TB in TB/HIV patients?
- Is there more stigma attached to HIV patients with TB?
- Is clinic-based DOT more cost-effective than home-based DOT for TB/HIV patients?



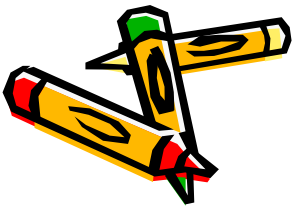
Components of a proposal

1. Background/Rationale
2. Objectives and hypothesis
3. Methods
4. Ethics/Protection of human subjects
5. Timeline
6. Budget
7. Investigators and responsibilities
8. Results dissemination
9. Appendices



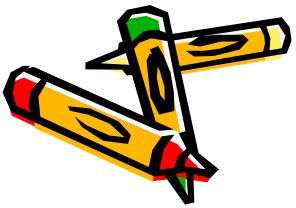
1. BACKGROUND/ RATIONALE

=> Why is it important to do this study?



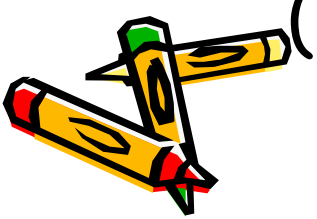
Background: Components

- General background of issue
- Literature review and previous data
  - Has anyone studied this question before?
  - If yes, are the answers relevant?
- Is it ethical to do it again? (Use of resources)
- Is it essential to do it again? (Justification)
  - What will THIS study contribute?
- What is the funding source?
- What is the intended use of the findings?



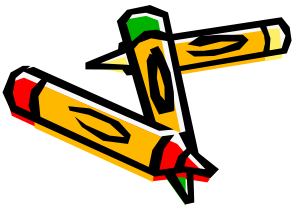
Sources of information

- Peer-reviewed books and articles, official statistics (best)
  - *Lancet, New England Journal of Medicine, Journal of the AMA, Bulletin of WHO, PanAmerican Journal of Public Health, International Journal of TB and Lung Disease, American Journal of Public Health, etc.*
- Health services reports (good)
- Personal communications/anecdotal evidence (fair)



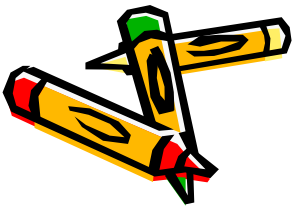
2. OBJECTIVES AND HYPOTHESIS

=> What is the purpose of this study?



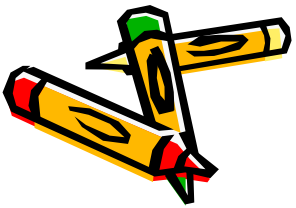
Objectives and hypothesis

- Objectives
  - Statement of what you will do, short and clear
  - May be primary and secondary objectives
  - Must be specific, measurable, and attainable
- Hypothesis:
  - Cause => Effect
  - Concise, clear, specific



Objectives: Examples

- Measure body mass changes in patients on TB/HIV treatment in district X in 2004
- Identify the barriers to clinic access by TB/HIV patients in rural areas in 2004
- Compare the treatment outcomes of male and female patients at health centre Y during 2003
- Determine whether previous TB treatment is a risk factor for anti-TB drug resistance
- Compare the cost of home-based DOT to clinic-based DOT in province Z

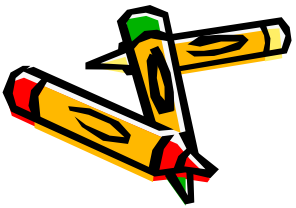


3. METHODS

=>"How are you going to do the study?"

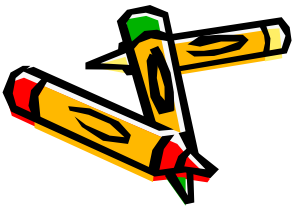
=>"Who are you studying?"

=>"When will you do the study?"



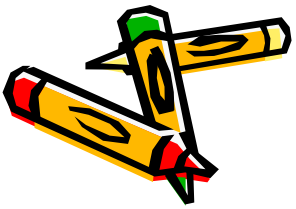
METHODS Components

Design
Intervention (if applicable)
Study population
Case definition
Study sample
Enrollment procedures
Data collection and variables
Data analysis
Limitations
Pilot study
Training



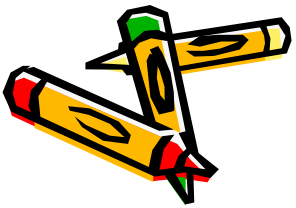
3.1 Design

- Descriptive study?
- Analytical study? (Asking WHY?)
  - Cross-sectional
  - Case-control
  - Cohort
- Is it testing an intervention?
  - Randomized controlled trial
- Prospective or retrospective?



3.2 Intervention(s)

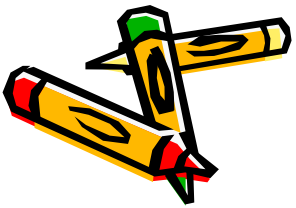
- Refers to the intervention received by the study participants
- May have been administered in the past (retrospective study)
- Can be more than one per study (describe all)
- One can be the common standard of care, or no care
- Description must be detailed enough



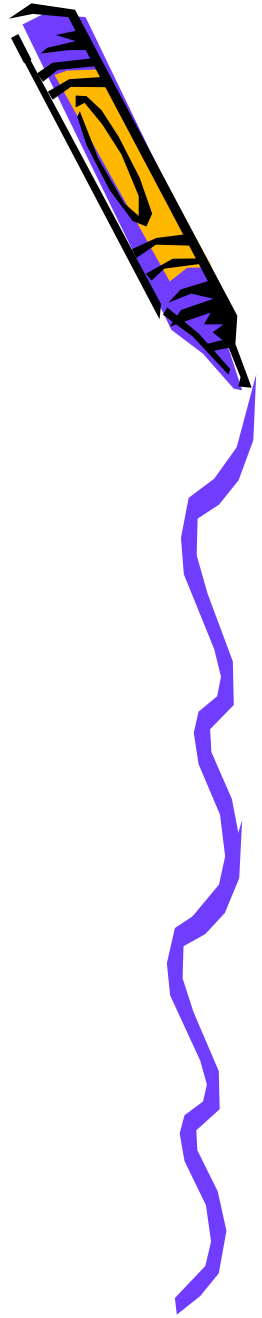
Intervention: Example

"The anti-TB drug regimens used in Country A and referred to in this study, are defined as follows:

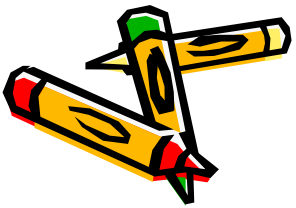
- Standardized treatment for MDR TB: Three months of PZA, EMB, ethionamide, kanamycin, and ciprofloxacin, followed with 15 months of PZA, EMB, ethionamide, and kanamycin. Treatment is administered daily and under direct observation.
- Individualized treatment for MDR TB: A treatment regimen of at least 18 months duration that includes at least five drugs, to which the organism has shown *in vitro* susceptibility. It is administered daily under direct observation."



3.3 Study Population

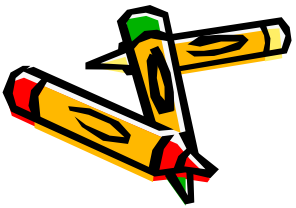


- Exactly WHO will be studied
  - Time, place, person
- Inclusion & exclusion criteria
  - Stated exclusions – eg children, recent arrivals, prisoners, extrapulmonary TB



Study Population: Example

"The study population is made up of adult TB patients in Country A who began treatment for MDR TB between August 1996 and March 2002. These patients are distributed throughout Country A, however a majority of them are residents of the capital.



Inclusion and exclusion: Example

Participants Inclusion Criteria

- Patients who started treatment with second-line drugs between August 1996 and March 2002. Patients with HIV disease, a history of renal insufficiency, hepatitis, or diabetes will be analyzed separately due to these medically complicating factors.

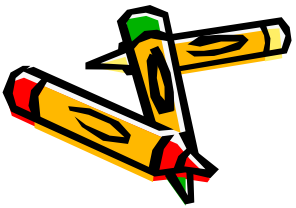
Participant Exclusion Criteria

- Children <= 18 years old, pregnant women, and/or those for whom treatment outcomes cannot be determined with certainty.

Justification of Exclusion

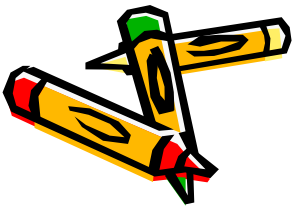
- Establishing a culture-confirmed treatment outcome for children is much more difficult than for adults. As this evaluation relies on knowing treatment outcomes, children have been excluded. Lastly, MDR TB treatment and MDR TB treatment outcomes are more complex for pregnant women, and thus pregnant women have been excluded from this evaluation.

Estimated Number of Participants: 2700



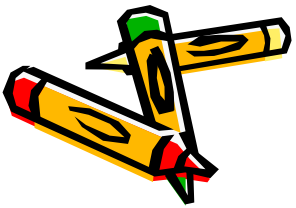
3.4 Case Definition

- Criteria for classifying subjects as cases or controls
- Does not need to be a TB case (depends on the study question)



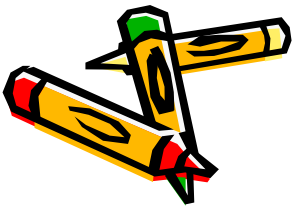
Case Definition: Example

- For the purposes of this study, a patient who received MDR TB treatment is a patient who was enrolled in a second-line drug regimen for at least 1 day.



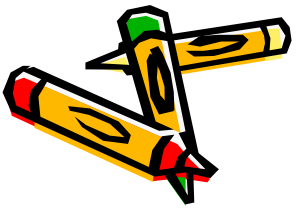
3.5 Study Sample

- Describe the sampling frame
  - E.g.: clinic's patient registry
- Describe the sampling method
  - Random, systematic, cluster, etc.
- Stratification?
- Indicate the sample Size (n=xx)
  - Computer, table, formula, or statistician
  - Based on estimated proportion of what is being measured, precision and variation required



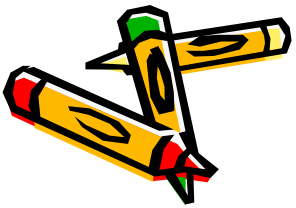
3.6 Participant enrollment

- How will eligible participants be identified
- Will study participants be assigned a study ID number?
- Who will talk to the eligible participants to ask them to participate?
- Will a form be filled at the time of enrollment?



3.7 Variables

- List each variable necessary for the analysis
  - Dependent, independent, control…
- Describe what it will look like and how it will be created
  - Type (dummy, index, scale, categorical, etc.)
  - Values
  - Source of information
  - Any recoding, calculations involved, etc.

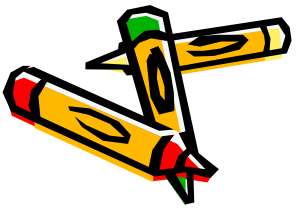


Variables: Examples

- Socio-demographic characteristics
  - Gender, age, etc.
- Culture dates and results
- Treatment outcomes
- Drug expiry dates
- Distance between patient's house and clinic
- Number of patients per DOT worker
- Patient's accurate knowledge of TB transmission
- Quality of TB services at clinics

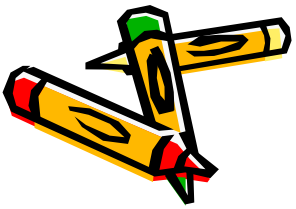
3.8 Data collection

- Design questionnaire/data collection forms
- Describe the data collection process
  - Who will collect/abstract the data?
  - How many data collectors?
  - Who will supervise the data collection?
- Describe data entry process
  - Who will enter the data?
  - Software used?
  - How will the data quality be checked?



Sources of data

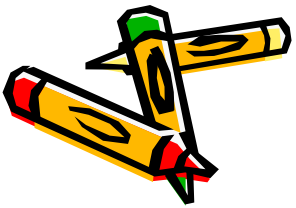
- Records
  - Patient histories, lab registry, personnel roll, etc.
- Interviews or surveys
- Observations
- Tests/instruments



3.9 Data analysis plan

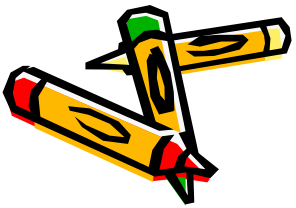
- Software used
- Statistical approach
  - Univariate – frequencies
  - Bivariate – x by y tables
  - Multivariate (regression)
- Planned tables and figures

Refer to objectives and research question!



3.10 Limitations

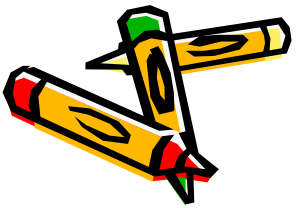
- Description of bias you might expect
  - Self-report bias
  - Recall bias
  - Lag-time bias
  - Selection bias
- Limitations in design that you cannot fix
- **Can you estimate true cause -> effect?**



3.11 Pilot Study

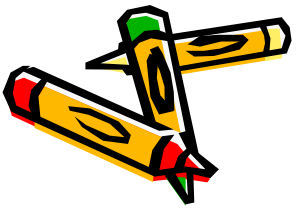
- Purpose: to check study procedures:
  - Understanding (survey questions)
  - Acceptability
  - Feasibility
  - Time, distances
  - Further training needs

- Describe where, when and how pilot testing will occur



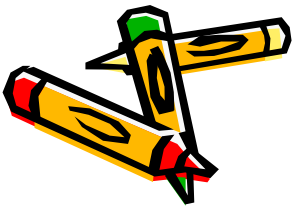
3.12 Training

- Purpose of training
- Who will be trained, by whom
- What you will train them to do
- When training will occur
- Where training will take place



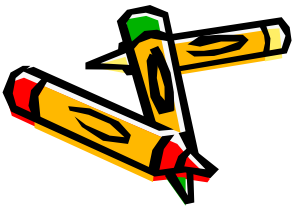
4. HUMAN SUBJECTS PROTECTION

- Describe all measures taken to protect study participants from harm
  - Describe possible harm – pain, risks, embarrassment, costs, costs & risks to health services
  - (How) will informed consent be obtained?
  - How will confidentiality/privacy be protected
  - What will be done if a problem arises



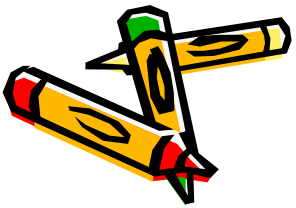
Informed consent

- Needed for research with human subjects
- Must follow three principles
  - Participation is voluntary
  - Participant must be able to understand the purpose of the research, in language that is understandable
  - Participation must NOT be coerced



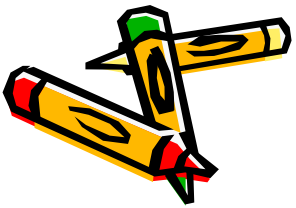
Consent Form: Essential Components

- Describe nature of research and procedures
- Describe nature and duration of participation
- Risk & benefits (physical, psychological, social)
- Stress that participation is voluntary
- Must state that the participant can stop taking part at any time
- Describe how you will protect confidentiality
- Name of contact who can answer questions about the study

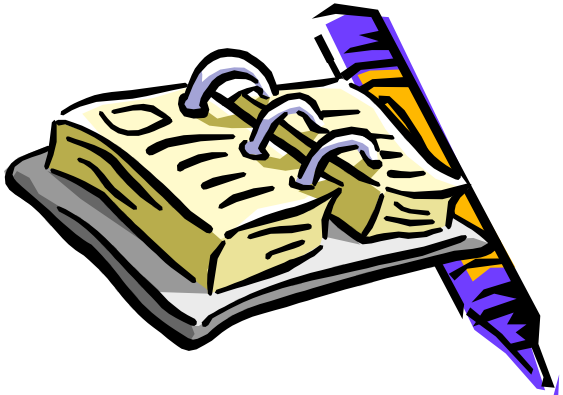


Examples of protective measures

- Writing consent forms in simple language
- Translate consent forms into participants' native language
- Not writing patients' name on data collection forms
- Keeping filled forms in locked cabinets
- Destroy pages containing identifiers once data is entered
- Training data collectors to maintain confidentiality



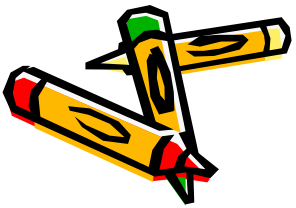
5. TIMELINE



- Work back from deadline
- Proposal writing — Month 1-2
- Recruiting, training of field workers & piloting — Month 3
- Finalizing interview format — Month 3
- Permission, ethical clearance, funding — Month 5
- Data collection — Month 6-8

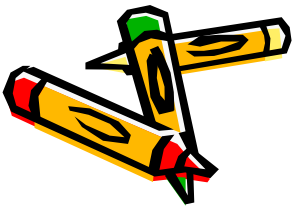
TIMELINE Continued

• Data collection	Month 6-8
• Data entry & cleaning	Month 8, 9
• Analysis	Month 9, 10
• Report writing	Month 11
• Deadline for report	Month 12
• Community meetings	Month 12-14
• Conference presentation	Month 12-14



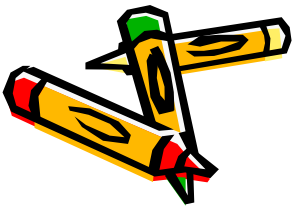
6. BUDGET

- **What resources will be needed to conduct the study?**
- Salaries: Different personnel categories
  - (Amount) x (duration) = Total
- Training (equipment, space, refreshments, etc.)
- Travel (airfare, bus fare, hotel, per-diem)
- Office accommodation and furniture
- Equipment (computer, printer, software)



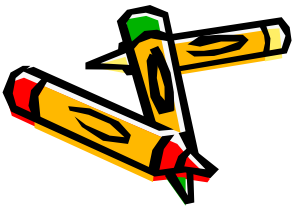
BUDGET Continued

- Stationary, photocopies, printing
- Telephones, faxes, couriers, postage
- Report dissemination
  - Written
  - Conference attendance
  - Community meetings – hire of hall, refreshments
- Administrative charges



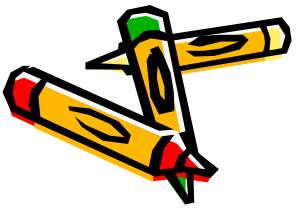
7. INVESTIGATORS and RESPONSIBILITIES

- Name, title, affiliation
- Contact information for each
  - Address, phone, fax, e-mail
- Describe in detail who will do what



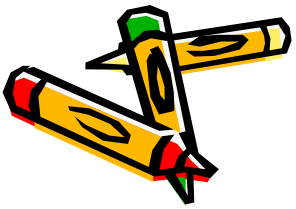
8. RESULTS DISSEMINATION

- To whom will results be reported?
- Unethical NOT to report research (whatever the results)
- Variety of forums
  - conference, publication, report, community meeting



9. APPENDICES

- Information sheet and consent form
- Data collection instrument(s)
- Other relevant documents



Questions?