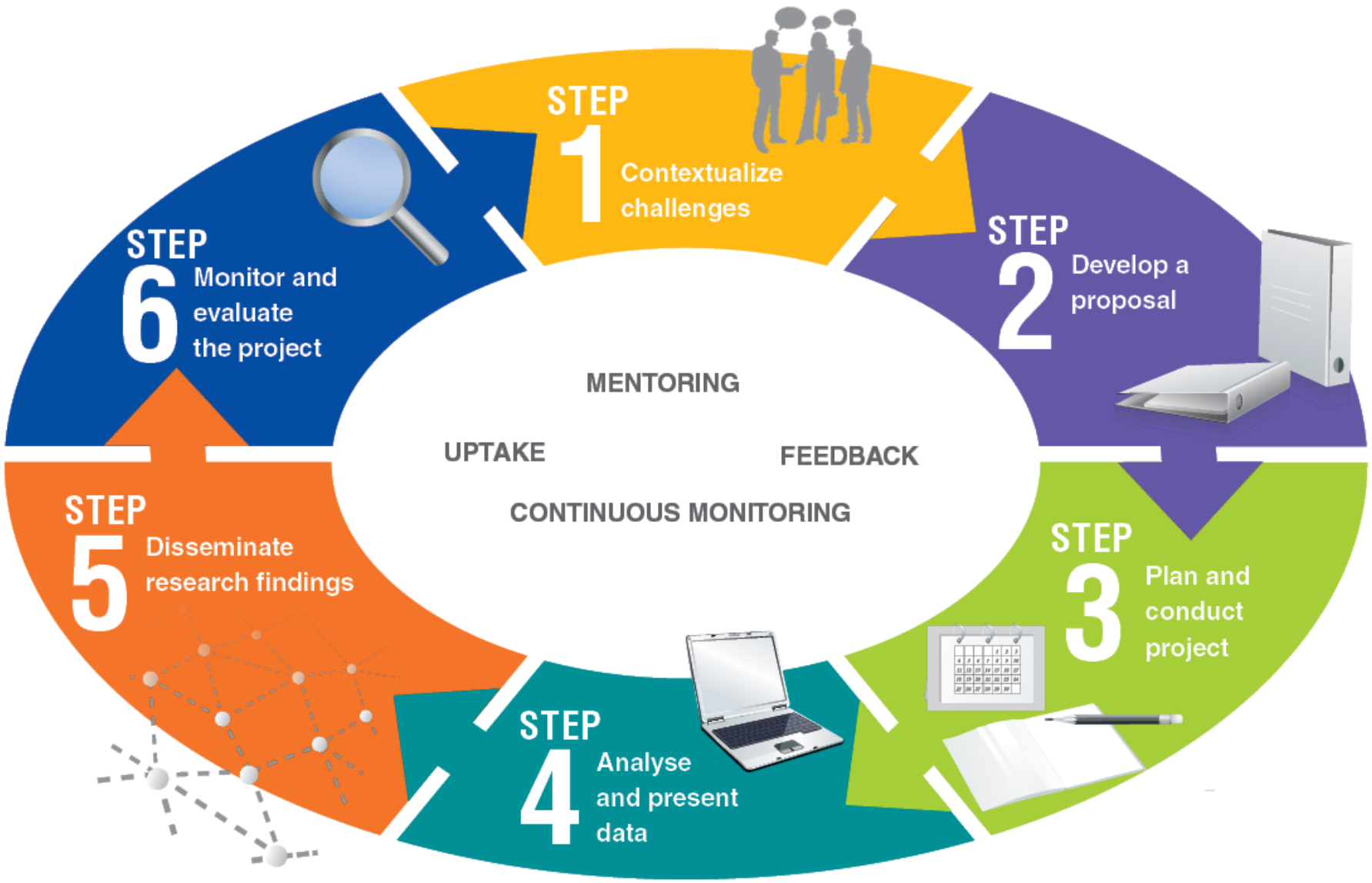
Module 3:
Planning to conduct the research

TDR For research on diseases of poverty
UNICEF • UNDP • World Bank • WHO

World Health Organization

Six steps in the IR process



Outline of the Presentation

- **Objective**
- **Expected outcomes**
- **Key concepts**
  - Seeking ethical clearance
  - Project implementation process
  - Good practices in research

Objective

Increase your understanding of the planning process for implementing a research project

Expected outcomes

After this module you will be able to:

- Describe the ethical requirements and processes required to successfully submit a project protocol for ethical review
- Describe the related ethical processes in a project cycle
- Systematically describe the steps taken to implement a research project
- Comprehend the value of good practices in the full cycle of a research project

Key concept 1: Seeking ethical clearance

What are your experiences with seeking ethical approval?

- What are the IRB/ERC submission requirements in your institution?
- How long does it take to receive approval in your institution? What are the possible reasons for not having approval after the first review?
- Does your IRB/ERC charge you a few for the review?

Key concept 1: Seeking ethical clearance

Submission of the research protocol for ethics review

Documents typically required:

- Cover letter
- Research protocol (not proposal)
- Risks and benefits
- Recruitment process and target population
- Proposal for returning research results
- Proposal for post-study obligations
- CV of principle investigator and research team members
- Proposed dissemination plan

Key concept 1: Seeking ethical clearance

- **Ethical issues to be considered during project implementation**
  - Informed consent
  - Privacy, confidentiality, anonymity
  - Ethical clearance during implementation
    - Periodic ethics reviews
    - Interim ethics review
    - Final ethics reviews

What are the essential elements of an informed consent form?

Elements of an informed consent form

Part 1: Information sheet
Introduction of the investigator and his/her institution.
Purpose of the research.
Type of research intervention.
Participant selection.
Voluntary participation.
Procedures (interview, focus group discussions (FGD), where interview will take place, privacy and confidentiality issues).
Duration of the procedures/interview, the length of the intervention including follow-up.
Anticipated risks.
Benefits at different levels (individual, community or society levels).
Reimbursements (if necessary).
Confidentiality (note: FGDs provide particular challenge to confidentiality, because once something is said in the group, it becomes common knowledge).
Sharing of results (process that will be used to share the research results).
Right to refuse or withdraw.
Who to contact (e.g. for any additional information).
Part 2: Certificate of consent
This section must be written in the first person.
Should include a few brief statements about the research and be followed by a statement, indicating that the participant has read or the information has been read to him/her, they understand and are participating voluntarily.
If the participant is illiterate, but provides oral consent, a witness must sign.
The researcher or person going over the informed consent must sign each consent form.

Example of Comments from IRB

Dear Sir/Madam,

PROTOCOL TITLE: ……..

This is to inform you that the protocol number ……. has been presented to the Institutional Review Board and the study was deferred until you address the comments below.

The following comments are to be addressed by the PI

1) The PIs CV is not attached to the document as required in the checklist for submission.
2) Although the protocol has a consent form, it does not relate in any way to the study.
3) Sources of information and data cited have not been stated and some references are not listed in the reference section.
4) The conceptual framework has no source and it is not explanatory, PI should indicate whether it is original or adapted.
5) The Hypothesis is not clearly stated
6) PI should explain the basis for the sample size and the population.
7) Techniques and Tools have been mixed up, they should be differentiated.
8) PI needs to clearly specify data analysis plan especially for qualitative data collected.
9) The statement on Page xx under Ethics statement:' The research involves no human specimen' is wrong because, the research involves interviewing and observing people.
10) The budget on piloting improvement should be clarified. PI should explain how and when this intervention would be done.
11) PI should explain the table xx.
12) In the Executive Summary, it is important to state upfront the reason for the purposive selection of those particular hospitals. This is stated later in the document and must appear in the Executive Summary.

Reflection activity

A researcher was conducting a study on ~~a~~ patients in a half-way home. The study involved daily visits by a health worker to the half-way home to administer treatment by intra muscular injections. With limited access to transportation, the health worker was unable to make the necessary daily trips to the half-way home. Should the health worker train the researcher to give the daily injections?

What are the ethical issues (if any) raised by this situation?

How can the issue(s) be addressed?

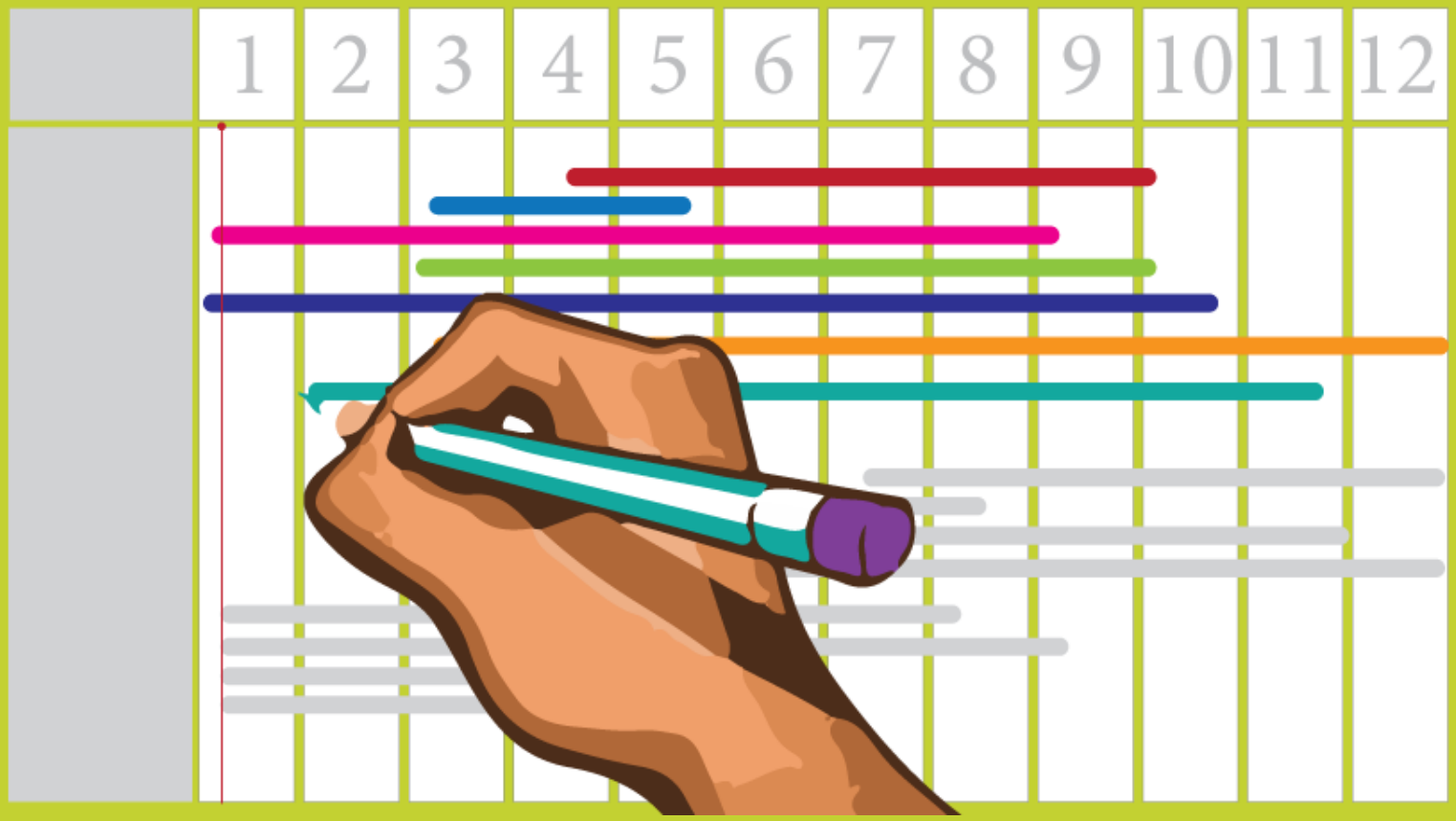
Key concept 2: Project implementation

- **Conducting and monitoring proposed activities**
- **Updating and revising the research plan**
- **Activities**:
  - Assembling the research team
  - Applying for logistical needs
  - Allocation of activities and tasks
  - Establishing: research sites, timelines, procedures for data collection.
  - Closure and evaluation of the project
  - Reporting and dissemination of the research processes and findings

Monitoring the project

Measure... analyse... react...

Updating and revising the research plan



Key Concept 2: Project Implementation

Starting the Implementation Process

Include the entire research team in the launch

Review:

- Project goals
- Objectives
- Indicators
- Work plan

Key Concept 3: Good practices in IR

- Documenting the processes
  - What is happening?
  - Why is it happening this way?
  - Is this expected?
- Training of implementers
- Pre-testing of instruments
- Data management
  - Recording
  - Storage
  - Back up files
  - Data protection
  - Data sharing

Application of key concepts

Example project: **Key Findings from an evaluation of the mothers2mothers program in KwaZulu-Natal, South Africa**

Concept 1: Ethical procedures
Concept 2: Programme implementation processes
Concept 3: Good practices in implementation research