ETHICS IN IMPLEMENTATION RESEARCH

FACILITATOR'S GUIDE

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

World Health Organization

MODULE 1

MODULE 2

MODULE 3

MODULE 4

MODULE 5

MODULE 6

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BACKGROUND

The focus of implementation research (IR) is on the systematic approach to understanding and addressing barriers to implementation and scale-up of effective and quality health interventions, strategies and policies. TDR undertakes a range of activities aiming to strengthen IR capacity in low- and middle-income countries, including the development of training tools, such as the IR Toolkit (https://www.who.int/tdr/publications/topics/ir-toolkit/en/).

The IR Toolkit highlights the importance of the submission of IR proposals to research ethics committees. Research ethics committees may not be familiar with reviewing IR protocols. The need was therefore identified to develop guidance for researchers and research ethics committees on the ethical implications of IR.

TDR and WHO's Global Health Ethics team have jointly developed a training course on the important ethical considerations in IR, with guidance for course facilitators and participants. The ultimate aim of these training materials is to help strengthen national and international capacity for review and conduct of IR.

This facilitator's guide is comprised of 6 modules:

Module 1 begins with an introduction to IR and an explanation of how IR differs from basic science, clinical research, epidemiology and surveillance. Overlaps with quality improvement and public health practice are also discussed.

Module 2 broadly discusses the ethical frameworks of medical ethics, research ethics and public health ethics and how these are all relevant to IR.

Module 3 addresses ethical issues related to the planning phase of IR, with an emphasis on the ethical principles and values underpinning the importance of community and stakeholder engagement.

Module 4 addresses the ethical issues related to the conduct of IR, with emphasis on ethical challenges raised with respect to autonomy of research subjects, promotion of justice, and data collection and management. Specific concerns regarding informed consent, standards of care and ancillary findings are discussed.

Module 5 addresses ethical issues in the post-IR phase, including obligations to disseminate research findings effectively and considerations regarding sustainability of successful interventions.

Module 6 permits consolidation of the learnings from prior modules using a case study to illustrate the relevance of the ethical considerations of IR in-depth.

All modules are intended to be interactive with didactic material interspersed with activities including case studies, role-playing and quizzes.

Additional cases for discussion and activity guides are included in 10 Annexes.

This facilitator's guide accompanies the participant's guide and contains all teaching materials, including explanations and notes for each slide and activity. It guides facilitators on the conduct of the training course and provides background information. A proposed agenda with time allotments for each module is provided to facilitate planning and conduct of the course.

The participant's guide contains all teaching materials and copies of activities without guidance explanations. The participant's guide is intended for distribution during the teaching course to maximize interaction and learning during sessions.

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LIST OF ABBREVIATIONS

ANC	Antenatal care
ARV	Antiretroviral
CAB	Community advisory board
GPS	Global Positioning System
HMM	Home–based management of malaria
HMIS	Health management information system
HSR	Health systems research
HSV	Herpes simplex virus
IC	Informed consent
ITN	Insecticide–treated net
IR	Implementation research
LF	Lymphatic filariasis
LMIC	Low– and middle–income country
MDA	Mass drug administration
MDG	Millennium Development Goal
OR	Operational research
PAR	Participatory action research
PMTCT	Prevention of mother–to–child transmission
QI	Quality improvement
RCT	Randomized controlled trial
RDT	Rapid diagnostic testing
SA	Situation analysis
SOP	Standard operating procedure
SOT	Special outreach team
STI	Sexually transmitted infection
TBA	Traditional birth attendant
WHO	World Health Organization

1. AGENDA OF THE COURSE

Below is a proposed template agenda for the two and a half-day course. Adequate time has been allocated for tea breaks. In the event of challenges in time management, tea breaks could be used as a buffer by shortening the break by 10 minutes at the most. Tea breaks can also be arranged to suit cultural norms and standards. Timings can be re-arranged to best suit the context, for example, if in a particular setting, the course should finish at 16.00, it could either start earlier, or be run over three days.

Day 1		
08:30–09:00	Registration of participants	
09:00–09:30	Opening Introduction of participants and facilitators Training objectives and overview	All
09:30–10:30	**Module 1.** Introduction to implementation research (IR) – interactive lecture	
10:30–11.00	Coffee break	
11:00–12:30	**Module 2.** Ethical considerations in IR Interactive lecture Small group activity	
12:30–13:30	Lunch	
13:30–15:00	**Module 2.** (Continued.)	
15:00–15:30	Coffee break	
15:30–17:00	**Module 3.** Ethical issues in planning IR Interactive lecture Small group work	
Day 2		
09:00–10:30	**Module 3.** (Continued.) Interactive lecture	
10:30–11:00	Coffee break	
11:00–11:30	**Module 3.** (Continued.) Role–play	Participants led by facilitators
11:30–12:30	**Module 4.** Ethical issues in conduct of IR	