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NATIONAL COMMISSION FOR SCIENCE, TECHNOLOGY AND INNOVATION

National Training Guide for Institutional Ethics Review Committees

Upholding Ethical Standards in Research

January 2020

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FOREWORD

The National Commission for Science, Technology and Innovation (NACOSTI) is established by the Science, Technology and Innovation Act, No. 28 of 2013 (ST&I Act) as a State Corporation. NACOSTI is the successor the National Council for Science and Technology (NCST) which was established in 1977 by the Science and Technology Act Cap 250.

The objective of the Commission is to regulate and assure quality in Science, Technology and Innovation Sector and advise the Government in matters related thereto. The functions of NACOSTI are as outlined under section 6 (1) of the ST&I Act and include among others to: set the priorities in research, science and technology in Kenya; register and accredit research institutions in Kenya; approve all scientific research in Kenya; assure relevance and quality of ST&I programs in research institutes; and develop and Enforce Codes, Guidelines and Regulations in accordance with the policy determined under ST&I Act for the governance, management and maintenance of standards and quality in research systems.

In fulfilling its mandate of approving research and assuring quality in matters of research, NACOSTI has delegated the task of ethical clearance in research proposals to Institutional Ethics Review Committees (IERCs). These Committees are accredited by NACOSTI on the recommendation of National Bioethics Committee (NBC), an advisory body established in accordance with section 27 of the ST&I Act and ST&I Regulations 2014.

As of November 2019, there were thirty IERCs accredited by NACOSTI in hospitals, research institutions and universities. This number is expected to increase given the rapid expansion of universities and research institutions in the country. One of the critical requirements of accreditation, is the need for the chairperson and members of IERC to have basic training in research ethics. NACOSTI has noted that there are several institutions offering a variety of training in ethics. Most the courses are unregulated and do not provide the requisite knowledge and skills for effective discharge of the mandate delegated to IERCs.

It is in light of the above that NACOSTI recognized the need to provide standardized training for IERC members to improve on discharge of the delegated mandate. However, the achievement of the highest quality and ethical standards in research depends on the integrity, honesty and professionalism of all individuals involved in the research process.

PROF. TOM MIGUN OGADA
CHAIRPERSON, NACOSTI BOARD

PREFACE

The National Commission for Science Technology and Innovation (NACOSTI) through the Science, Technology and Innovation (ST&I) Act 2013, has been given a mandate of advising the Government on matters of Research, Science and Technology, coordinating the sector, accrediting research institutions, setting research priorities, licensing research and assuring quality .The objective of the Commission is to regulate and assure quality in Science, Technology and Innovation Sector and advise the Government in matters related thereto.

Several institutions are offering a variety of training in ethics. Most of the courses are unregulated and do not provide requisite knowledge and skills for effective discharge of the mandate delegated to IERCs. In order to have effective and regularized training for IERCs, it was agreed that a curriculum which addresses national and international needs be developed. Towards this end, NACOSTI constituted a multi-institutional and multi-disciplinary team to develop a curriculum which was subjected to the National Bioethics Committee and stakeholders for validation and approval.

This curriculum is intended to provide fundamental training appropriate for IERC members and individuals from different professional background with interest in research ethics so as to equip them with knowledge and skills in the review of research proposal within local and international policy and regulatory frameworks.

DR. MOSES. K. RUGUTT, PhD, OGW
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ABBREVIATIONS AND ACRONYMS

CIOMS	-	Council for International Organizations of Medical Sciences
CS	-	Cabinet Secretary
DG	-	Director General
EDCTP	-	European and Developing Countries Clinical Trials Partnership
IC	-	Informed Consent
ICH-GCP	-	International Conference on Harmonization – Good Clinical Practice
IERCs	-	Institutional Ethics Review Committees
IRB	-	Institutional Review Board
MTA	-	Material Transfer Agreement
NACOSTI	-	National Commission for Science, Technology and Innovation
NBC	-	National Bioethics Committee
NCST	-	National Council for Science and Technology
PAM	-	Post Approval Monitoring
SOP	-	Standard Operating Procedure
ST&I	-	Science, Technology and Innovation
UNESCO	-	United Nations Educational, Scientific and Cultural Organization
WHO	-	World Health Organization

Table of Contents

1.0 INTRODUCTION

The National Commission for Science, Technology and Innovation (NACOSTI) is established by the Science, Technology and Innovation Act, No. 28 of 2013 (ST&I Act) as a State Corporation. NACOSTI is the successor the National Council for Science and Technology (NCST) which was established in 1977 by the Science and Technology Act Cap 250.

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As of November 2019, there were thirty IERCs accredited by NACOSTI in hospitals, research institutions and universities. This number is expected to increase given the rapid expansion of universities and research institutions in the country. One of the critical requirements of accreditation, is the need for the chairperson and members of IERC to have basic training in research ethics. NACOSTI has noted that there are several institutions offering a variety of training in ethics. Most the courses are unregulated and do not provide the requisite knowledge and skills for effective discharge of the mandate delegated to IERCs.

It is in light of the above that NACOSTI recognized the need to provide standardized training for IERC members to improve on discharge of the delegated mandate. However, the achievement of the highest quality and ethical standards in research depends on the integrity, honesty and professionalism of all individuals involved in the research process.

1.1 Target Audience

This guide will be used for training IERCs members, IERC Administrators, Researchers, and Senior Management at the institutions mandated to carry out research.

1.2 Overall Goal

The aim of this course is to provide foundational training appropriate for IERC members and individuals from different professional background with interest in research ethics so as to equip

them with knowledge and skills in the review research proposals within local and international policy and regulatory frameworks.

1.3 Course Objectives

At the end of this course the trainees will be able to:

i. develop and review Standard Operating Procedures (SOPs) for IERCs;
ii. apply national and international research ethics guidelines;
iii. conduct scientific and ethics review of research proposals;
iv. monitor and evaluate approved research studies.

2.0 DESIGN AND STRUCTURE OF THE GUIDE

This guide consists of fourteen (14) modules.

Number of the Module	Module	Duration in Hrs
1.	Introduction to Research Ethics	2
2.	Ethical Principles in Research	2
3.	Research Study Designs	2
4.	Informed Consent in Research	2
5.	Research involving Vulnerable Populations	2
6.	Research Integrity	2
7.	Research involving animals	2
8.	Community engagement in Research	2
9.	Emerging Issues in Research	2
10.	Composition and Functions of Institutional Ethics Review Committees	2
11.	Research proposal review process	4
12.	Post Approval Monitoring	4
13.	Continuous Quality Improvement of IERCs	2
14.	Institutional Support for IERCs	2
Total		**30 hrs**

The program is modular and consists of 14 modules to be undertaken in 5 days of 7 hours each. It is envisaged that the entire guide would be covered in thirty (30) hours.

2.1 Obligations of trainers and trainees

2.1.1 Obligations of Trainers

Trainers for this course shall prepare the course material based on this training guide, avail copies of the training materials on time, and facilitate evaluation for the course. Appendix 1 provides the Evaluation questions.

2.1.2 Obligations of Trainees

The trainees for this course shall read the materials provided**,** attend and participate fully in the training sessions. Full attendance is required (100%) for all 14 Modules.

2.2 Mode of delivery

The trainers will be expected to utilize a variety of teaching strategies including: mini lectures, small and large group discussions, case studies, videos, vignettes, movies, stories, debates and mock IERC reviews.

3.0 INTRODUCTION

3.1 Module 1: Introduction to Research Ethics

Specific Objectives:

At the end of this module, trainees will be able to:

i. Describe the historical development of human research participant protection;
ii. Explain the policy and regulatory frameworks that govern international and national research; and
iii. Discuss the benefits of Research

Module Description:

This module is intended to equip the trainees with knowledge to trace the development of human research participant protection, apply international and national research ethics guidelines in human research participants' protection.

Module Content

3.1.1 Definitions

This topic covers definition of terms commonly used in research ethics including: Clinical trials, confidentiality, informed consent, assent, risk, ethics, research, research ethics, research participants

3.1.2 Philosophy and Research Ethics

Philosophical Theories: Consequentialism, Virtue, Ethics and Deontology.

3.1.3 Evolution of Research Ethics

Including: German clinical trials in 1930s-1940s, Tuskegee, Willowbrook, Majengo Sex Workers, Mother-to-child HIV transmission trials in Rakai Uganda among others

3.1.4 Evolution of Bioethics Committees and IERCs

Institutional, National, Regional and International Research Bodies

3.1.5 Legal and Regulatory frameworks governing research

Including: Belmont Report, Helsinki Declaration, Nuremberg Code, CIOMS, ICH-GCP Guidelines, Constitution of Kenya 2010, ST&I Act, 2013, Research Regulations

Learning and Teaching Methods:

Reading, Lecture, Group Activities, Videos, movies, Case Studies

References:

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18. Tribunals under Control Council Law No. 10. Nuremberg, October 1946–April 1949.
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20. www.unesco.org/new/en/social-and-human.../bioethics/bioethics-and-human-rights/

Case Studies: Majengo Sex Workers; Nyumbani Children's Home

4.0 CORE RESEARCH ETHICS

4.1 Module 2: Ethical Principles in Research

Specific Objectives:

At the end of this module trainees will be able to:

i. Describe the principles of research ethics;
ii. Discuss the application of ethical principles in research.

Module Description

This course equips the trainees with knowledge to apply the ethical principles in research.

Module Content

4.1.1 Definitions

Definition of terms including: Respect, beneficence, non-maleficence, justice, fairness, informed consent and assent, autonomy

4.1.2 Application of the Principle of Autonomy

Informed consent, Assent, Confidentiality, Privacy, Voluntary participation, Withdrawal.

4.1.3 Application of the Principle of Beneficence/Non-maleficence

Risk/benefit assessment, minimizing risks and maximizing benefits to both individuals and community; minimizing harm: physical, psychological, emotional and social

4.1.4 Application of the Principle of Justice

Fair selection of research participants, non-exploitation of vulnerable populations, sharing of benefits.

Learning and Teaching Methods:

Reading, Lecture, Group Activities, debates, Videos, movies, Case Studies

References:

1. Agulanna, C. (2010). *The Requirement of Informed Consent in Research Ethics*. European Journal of Scientific Research; 44 (2): 204-219.
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4.2 Module 3: Research Study Designs

Specific Objectives

At the end of this module, trainees will be able to:

i. Describe the types of study designs
ii. Discuss the use of each study design
iii. Outline the advantages and disadvantages of each study design.

Module Description

This module introduces the trainees to types of research study designs including descriptive studies, analytical studies, longitudinal studies, observational studies, interventional studies.

Module Content

4.2.1 Definitions

Definition of terms including: Randomization, blinding, placebo, clinical trials, control groups.

4.2.2 Introduction to study designs

Definition and examples of study design- Descriptive Studies, analytical studies, longitudinal studies, cross-sectional studies, observational studies, interventional studies.

4.2.3 Applications of study designs

i. Descriptive studies: Ethnographic, correlation research, case studies, casual comparatives, analytical
ii. Analytical studies: Observational studies and interventional studies;
iii. Longitudinal studies: Prospective studies, retrospective studies.
iv. Observational studies: Cohort and case-control studies.
v. Interventional studies : Clinical trials; randomized control trials and non-randomized, control trials; Phases of clinical trials: phase 1- 4; Advantages and disadvantages of deferent study designs.

4.2.4 Advantages and disadvantages of study designs

All research study designs have their pros and cons which need to be considered when designing a research study.

Learning and Teaching Methods

Reading, Lecture, Group Work, Role Modelling, Skit, Videos, Debate, Case Studies

References

1. De Vaus, D. A. (2001). *Research Design in Social Research*. London: SAGE.

2. Gorard, S. (2013). *Research Design: Creating Robust Approaches for the Social Sciences*. Thousand Oaks, CA: Sage.
3. International Ethical Guidelines for Health Related Research Involving Humans. Fourth Edition. Geneva. Council for International Organization of Medical Sciences (CIOMS): 2016 ISBN: 978-929036088-9. www.cioms.ch
4. Leedy, P.D. and Jeanne, E. O. (2013). *Practical Research: Planning and Design*. Boston, MA: Pearson.
5. Organizing your social sciences research paper: *Types of study designs*. http://libguides.usc.edu/writingguide/researchdesigns

4.3 Module 4: Informed Consent in Research

Specific Objectives:

At the end of this module, trainees will be able to:

i. Explain the importance of informed consent in research
ii. Explain the elements of informed consent and the process of obtaining informed consent form
iii. Describe contextually appropriate informed consent process

Module Description

This module introduces the trainee to the informed consent process, elements of informed consent, informed consent form and the informed consent process in diverse cultural contexts.

Module Content

4.3.1 Definitions

Consent, informed consent, assent, Legal Authority Representative, blanket consent

4.3.2 Purpose of Informed Consent

Obtaining informed consent is mandatory in research

4.3.3 Informed consent form and its elements

i. Sample of consent form
ii. Competence of participants
iii. Disclosure of information
iv. Voluntariness, withdrawal
v. Comprehension
vi. Compensation; coercion

4.3.4 Process of obtaining informed consent

The common rule, where, when and from whom obtain informed consent, translation and documentation

4.3.5 Special considerations

i. When can consent be waived?
ii. Contextual considerations
iii. Vulnerable Populations
iv. Materials Transfer
v. Assisted Reproductive Technologies
vi. Age of participants

4.3.6 Ethical Implications of the use of rewards/inducement for participation in research

Coercion

Learning and Teaching Methods:

Reading, Lecture, Group Activities, Skits, Role Modelling, Videos, Movies, Case Studies

References

1. Agulanna, C. (2010). *The Requirement of Informed Consent in Research Ethics: Procedure for Implementing a Crucial Ethical Norm in African Communal Culture*. European Journal of Scientific Research.
2. Blackmer, J. and Haddad, H. (2005). The Declaration of Helsinki. Canadian Medical Association Journal.
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4. Global Health Training Centre
5. https://globalhealthtrainingcentre.tghn.org/elearning/research-ethics/research-ethics-case-studies/voluntary-informed-consent/
6. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50&showFR=1&subpartNode=21:1.0.1.1.20.2
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4.4 Module 5: Research Involving Vulnerable Populations

Specific Objectives:

At the end of this module trainees will be able to:

i. Describe vulnerable populations and vulnerabilities
ii. Discuss ethical issues in research involving vulnerable groups

Module Description

This Module introduces the trainee to the ethical and legal issues arising from research involving vulnerable populations**.**

Module Content

4.4.1 Definitions:

Vulnerable populations, vulnerability, vulnerabilities, diminished decision-making capacity, legally authorized representative

4.4.2 Vulnerable Groups

Including pregnant women, embryos, fetuses, neonates, children, prisoners, the elderly, adolescents, institutionalized populations, economically disadvantaged and medical/mental/physical disabilities. It also includes those with differential power relations.

4.4.3 Categories of vulnerabilities:

Cognitive or communicative vulnerability; Institutional vulnerability; Differential vulnerability; Medical vulnerability; Economic vulnerability; Educational Vulnerability, Social vulnerability; Legal vulnerability; Study vulnerability.

4.4.4 Ethical issues that need to be considered in research involving vulnerable populations

Competence, Disclosure of information, Voluntariness, Comprehension, Compensation, dissemination of findings, sharing of benefits and incidental findings

4.4.5 Additional protections to consider to minimize the possibility of coercion or undue influence

Monitoring and evaluation by the project team, Monitoring of Post approval compliance by IERC

Learning and Teaching Methods:

Reading, Lecture, Group Activities, Debate, Videos, Movies, Role Modelling, Skit, Case Studies

References

1. Jester V et al. 2007. A new brief instrument for assessing decisional capacity for clinical research. Arch Gen Psychiatry. 64(8):966-74
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10. Vreeman R etal. 2012. Community Perspectives on Research Consent Involving Vulnerable Children in Western Kenya. Journal of Empirical Research on Human Research Ethics, Vol. 7, No. 4,

4.5 Module 6: Research Integrity

Specific Objectives:

At the end of this module, trainees will be able to:

i. Define research integrity and research misconduct
ii. Discuss research misconduct
iii. Discuss ethical issues in research misconduct
iv. Discuss dissemination and publication ethics

Module Description

This Module introduces the trainees to research integrity, research misconduct, ethical issues in conducting research and disseminating findings

Module Content

4.5.1 Definition

Including: research integrity, research misconduct, falsification, fabrication, plagiarism, guest authorship/ghost authorship, conflict of interest, non-publication of data, retraction

4.5.2 Principles of research integrity

Honesty, Accountability, Professional courtesy and fairness, and good stewardship

4.5.3 Good Research Practices

Conducive research environment, mentoring, appropriate research procedures, safeguards against misconduct, securing data, collaborative working

4.5.4 Research misconduct

Research falsification, fabrication and plagiarism.

4.5.5 Publication Ethics in Research

Authorship, non-publication of data, Dissemination disclosure, disclaimer, salami slicing/sneaky publication practices, predatory journals

4.5.6 Consequences of Research Misconduct

Including: Retraction, blacklisting, suspension, denial of research funds

Learning and Teaching Methods:

Reading, Lecture, Group Activities, Videos, Movies, Role Modelling , Debate, skit, Case Studies

References:

1. All European Academies. (2017). European Code of conduct for research integrity. Revised Edition, Berlin Germany. Retrieved from http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf
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4.6 Module 7: Research involving animals

Specific Objectives:

At the end of this module, trainees will be able to:

i. Discuss the legislation, regulations and guidelines on the use of animals in research
ii. Discuss the historical development of animal rights and research ethics
iii. Describe principles of research in animal husbandry, care and use;
iv. Discuss the guiding principles of animal research ethics
v. Review of protocols in animal research

Module Description:

This module introduces the trainees to the legislation, regulations and guidelines on the use and care of animals in research; principles of research in animal husbandry; care and use; guiding principles of animal research ethics and review of protocols in animal in research.

Module Content

4.6.1 Definitions

Including: Animal rights, animal research ethics, animal husbandry, animal care, animal use, ethology, laboratory animals, animal welfare and speciesism

4.6.2 Legislation, regulations, guidelines on the use of animals in research

International and national laws and guidelines on use of animals in research

4.6.3 Historical development of animal rights and research ethics

Evolution of animal rights movement and animal research ethics

4.6.4 Ethics and 3R principles of research in animal husbandry, care and use

Justification of the research, the three Rs(replace, refine and reduce), the five animal freedoms (freedom from hunger and thirst, freedom from discomfort, freedom from pain, injury and disease, freedom to express normal behavior, freedom from fear and distress), humane endpoints, unlimited access to food and water, acquisition of laboratory animals, transport, care and housing of research animals, experimental procedures, field research, educational use of research animals;

4.6.5 Review of ethics in research involving animals

Research animal breeding, housing and care, ethology; vulnerability, disposal and environmental safety

Learning and Teaching Methods:

Reading, Lecture, Group Activities, Videos, Movies, Skits, Role Play, Case Studies

References

1. Festing S & Wilkinson R. 2007. The ethics of animal research. Talking Point on the use of animals in scientific research. EMBO Reports. European Molecular Biology Organization. 8:6.
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4.7 Module 8: Community Engagement in Research Word research missing

Specific Objectives:

At the end of this module, trainees will be able to:

i. Discuss the importance of community engagement
ii. Describe the principles of community engagement
iii. Describe strategies of Community Engagement
iv. Discuss ethical issues in Community Engagement

Module Description

This module introduces the trainee to the importance of community engagement in research as well as principles, strategies and ethical issues therein

Module Content

4.7.1 Definition

Including: Community; Community Engagement; Community Participation, Community Involvement and Community Advisory boards; types of community groups; stakeholders; research teams; public engagement, community entry, community gatekeepers.

4.7.2 Framework for Community Engagement

Legal, statutory and ethical requirements

4.7.3 Introduction to community engagement

Purpose of Community Engagement; Forms of community engagement: formal and informal; Importance of community engagement; sharing benefits, dissemination of findings

4.7.4 Principles of Community Engagement:

Respect, mutual understanding, integrity, transparency, accountability, and mutual benefits; investigator partnership; inclusivity, relevant to community needs; Capacity building, recognition, continuous communications; Transparency, compliance with policies and by laws, dissemination of results to the community; Translation of research into actions in the community, sustainability

4.7.5 Strategies of Community Engagement:

Designing strategies for community engagement: formal and informal: community groups, community advisory boards, community mapping, media, heterogeneous community gatherings, (‘*mabaraza’*) and drama.

4.7.6 Ethical Issues in community engagement

Informed consent, benefit sharing, data sharing, capacity building, superior-subordinate relations , contextual considerations, dissemination of findings, involvement of multiple voices, incidental findings, post research obligations

Learning and Teaching Methods:

Reading, Lecture, Group Activities, Videos, Movies, Skits, Role Playing, Case Studies

References

1. Akwanalo C, Njuguna B, Mercer T, Pastakia SD, Mwangi A, Dick J, Dickhaus J, Andesia J, Bloomfield GS, Valente T, Kibachio J, Pillsbury M, Pathak S, Thakkar A, Vedanthan R, Kamano J, Naanyu V. Strategies for effective stakeholder engagement in strengthening referral networks for management of hypertension across health systems in Kenya. *Glob Heart.* 2019 Jun;14(2):173-179
2. Mikesell, L., Bromley, E., & Khodyakov, D. (2013). Ethical community-engaged research: a literature review. *American journal of public health*, *103*(12), e7–e14. doi:10.2105/AJPH.2013.301605
3. Ross, L. F., Loup, A., Nelson, R. M., Botkin, J. R., Kost, R., Smith, G. R., Jr, & Gehlert, S. (2010). Human subjects protections in community-engaged research: a research ethics framework. *Journal of empirical research on human research ethics: JERHRE*, *5*(1), 5–17.
4. Tindana, P. (2007). Grand Challenges in Global Health: Community Engagement in Research in Developing Countries. PLoS Medicine. http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.280.3087&rep=rep1&type=pdf

4.8 Module 9: Emerging Issues in Research

Specific Objectives:

At the end of this module, trainees will be able to:

i. Identify emerging issues in research
ii. Discuss emerging issues in research
iii. Discuss the ethical and legal issues in Research

Module Description

This module introduces trainees to ethical issues emerging from advances in technology and research

Module Content

4.8.1 Technological advancement and Research

Assisted Reproductive Technology: Stem Cell research, cloning, Bio banking, frozen embryos, gene editing, DNA studies among others

Handling of biological material: Transfer, storage and future use of biological samples

Advances in Technology: Synthetic Biology, Cloning: Data Protection: Big data, Artificial intelligence

Learning and Teaching Methods:

Reading, Lecture, Group Activities, Videos, movies, Role Playing, Skit, Case Studies

References:

1. Caufield, T. (2007). *Stem cell research ethics: Consensus statement on emerging issues*.
2. Coughlin, S.S. (2006). *Ethical issues in epidemiologic research and public health practice.* Emerg. Themes Epidemiol.
3. Knowles, L. P., and Kebnick, G.E. (2007). *Reprogentics: Law, Policy and Ethical issues*. USA: John Hopkins University Press.
4. Libby, B. (2017). *Big data and data sharing: Ethical issues*. UK: Data Service.
5. Mastroinanni, A.C., Faden, R., and Federman, D. (1994). *Women and Health Research. Ethical and legal issues of including women in clinical studies*. New York, NY: National Academy Press
6. UNESCO (2007). *The ethics and politics of nanotechnology.* UNESCO, Paris, France.
7. UNESCO (2015). *Global Bioethics: What for? 20th Century of UNESCO Bioethics Programme*. UNESCO, Paris, France 2015.
8. World Health Organization (WHO) (2013). *Ethical issues in patient safety research: Interpreting existing guidelines*. Geneva, Switzerland.

5.0 INSTITUTIONAL ETHICS REVIEW COMMITTEES

5.1 Module 10: Composition and Functions IERCs

Specific Objectives:

At the end of this module, trainees will be able to**:**

i. Describe the composition and functions of IERCs;
ii. Discuss the process of appointment of IERCs members;
iii. Develop and review standard operating procedures.

Module Description:

This module equips the trainees with the knowledge and skills operationalize functions of IERCs and demonstrate competency in developing standard operating procedures (SOPs)

Module Content

5.1.1 Definitions

Definition of terms including: IERCs, SOPs, Appointing Institution.

5.1.2 Categories of IERCs

Animal IERCS, Social Science Research Committees, Biomedical Sciences IERCs, Agricultural IERCs

5.1.3 Composition of IERCs

Membership, Qualifications /expertise, size, constitutional considerations (e.g. Gender, Regional and Ethnic Balance), Succession Planning

5.1.4 Functions of IERCs

Review research proposals: ethical clearance to safeguard participants, evaluate risks and benefits of research, evaluating the process and materials used for seeking informed consent, assessing the recruitment process and compensation, develop SOPs, compilation, storage and management of data, resolution of complaints, capacity building, monitoring and evaluation of approved research studies, document prepare annual reports, examine compliance with all regulatory requirements, applicable guidelines and laws

5.1.5 Appointment of IERCs members

The role of appointing authority and Chairperson of the IRECs, Tenure, conditions of appointment and terms of reference

5.1.6 IERCs mode of operation

Conducting meetings, reviewing and approval of protocols, monitoring and evaluation of approved studies, submission of reports to the regulatory body, suspension and termination of studies, dispute resolutions, handling of appeals

5.1.7 Training of IERC members

Types and levels of Training, Continuous training for IERC members, Responsibility for training.

Learning and Teaching Methods:

Reading, Lecture, Group Activities, Video Clips, Case Studies

References

1. Bhatt A. Ethics committee composition. Perspectives in Clinical Research. October-December, 2012, Vol 3, Issue 4
2. Council of Europe. 2010. Guide for Research Ethics Committee Members. Steering Committee on Bioethics
3. https://www.coe.int/t/dg3/healthbioethic/activities/02_biomedical_research_en/Guide/Guide_EN.pdf
   https://www.who.int/ethics/Ethics_basic_concepts_ENG.pdf
4. NACOSTI (2017). *Guidelines for Accreditation of Institutional Ethics Review Committees in Kenya.* National Commission for Science, Technology and Innovation (NACOSTI)
5. Standard Operating Procedures Research Ethics Committee, Department of Correctional Services, South Africa, February 2019. www.docs.gov.za
6. UK Health Departments Research Ethics Service: Standard Operating Procedures for Research Ethics Committees. https://Res_Standard_Operating_Procedures_Version_7.3_September_2018.pdf
7. WHO. 2009. Research ethics committees. Basic concepts for capacity-building. Geneva
8. World Health Organization. Product Research and Development Team. (2000). Operational guidelines for ethics committees that review biomedical research. World Health Organization. https://apps.who.int/iris/handle/10665/66429

5.2 Module 11: Review Process of Research Proposals

Specific Objectives:

At the end of this module trainees will be able to:

i. Describe the key elements of a research proposal
ii. Distinguish the different types of review
iii. Discuss the ethics review process and the outcomes of review
iv. Describe the ethical concerns in behavioral and social science research

Module Description

This course introduces the trainee to ethical review process of proposals, decision making and communication of decisions

Module Content

5.2.1 Definitions:

Including: Research, research proposal, human participant research, Behavioral Science; Social Science, expedited review

5.2.2 The key elements of a research proposal, what to look for and why

Title
Investigators (details and signatures)
Acknowledgement
Abstract
Introduction
Problem statement/justification
Aims and specific objectives
Methodology
Literature Review
Ethical considerations
Data management
Data analysis
Dissemination plan
Appendices: Work plan, Budget, Informed Consent Form
Approvals

5.2.3 Types of Review

Full Review, Amendments, Modifications, Renewals, Exempt, Expedited

5.2.4 Decision making process

Allocation of proposals to reviewers, Full committee meeting, Discussion of the proposal, deliberations by committee members, decision making and communication of outcome

5.2.5 Guidelines for reviewing social science research

There are guidelines that are specific to social science research. However, these guidelines need to be used together with other guidelines described in Module 1.

5.2.6 Concerns in the review of social science research:

Freedom of Research and Society; Respect for Individuals; Regard for groups and Institutions, The Research Community; Science Communication; appropriateness of tools, Fair Selection of Participants; screening and recruitment, consenting process, ethical clearance.

Learning and Teaching Methods:

Reading, Lecture, Group Activities, Videos, Mock Reviews, Mentorship, Case Studies

References

1. Author & year missing Ethics Assessment in Different Fields in Social Sciences. *Ethics Assessment in Different Fields in Social Sciences*. Retrieved from http://satoriproject.eu/media/2.d-Social-Sciences.pdf
2. Blackmer, J. and Haddad, H. (2005). *The Declaration of Helsinki*. Canadian Medical Association Journal. 173(9): 1052-1053
3. International Ethical Guidelines for Health Related Research Involving Humans. Fourth Edition. Geneva. Council for International Organization of Medical Sciences (CIOMS): 2016 ISBN: 978-929036088-9. www.cioms.ch
4. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1979). *The Belmont Report: Ethical Principles and Guidelines for the protection of Human Subject of Research.* http://ohsr.od.nih.gov/guidelines/belmont.html
5. THE NUREMBERG CODE [from Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10. Nuremberg, October 1946–April 1949. Washington, D.C.: U.S. G.P.O, 1949–1953.]

5.3 Module 12: Post Approval Monitoring (PAM) of approved protocols

Specific Objectives:
At the end of this module, trainees will be able to:

i. Describe components of post approval monitoring
ii. Conduct audit visits of approved studies
iii. Provide feedback of post approval monitoring

Module Description
This Module introduces trainees to the process of post approval monitoring of ongoing research projects to ensure compliance to guidelines that govern conduct of research

Module Content

5.3.1 Definitions
Including: Audit visits, monitoring, post approval monitoring and evaluation

5.3.2 Useful indicators for post approval monitoring
Research team composition, qualifications and expertise, screening and recruitment, consent process, verification of informed consent and documentation, privacy and confidentiality, methodology, publications from the study, recruitment, enrollment and follow up of participants, report of adverse events, storage of study documents and data, compensation, approval documents, community engagement, project team concerns

5.3.3 Types of Post Approval Visits
For Cause visits: These are PAM visits requested by the IERB or other relevant institutional officials due to concerns regarding the study. They can be focused or investigative in nature depending on the concerns noted/reported.

Routine visits: These are PAM visits that are not driven by any concerns. The IERC may select and visit a study based on a criteria such as risk level of the study or enrollment of vulnerable populations. Routine visits can be targeted or preventative/educational

Preparatory review: A PAM can be requested by the research team to get assistance with preparation for an external audit or in anticipation of recruitment.

5.3.4 Preparation and implementation of post approval visit

1. Develop a planning tool; develop a checklist of resources, identify the audit team

2. Audit the Consent Process, violations and deviations; audit of safety compliance and reports; audit of protocol amendments and annual reports; provide feedback

Learning and Teaching Methods:
Reading, Lecture, Group Activities, Video, Role Modelling, Case Studies

References

1. Australian Government (2014), *Monitoring approved research*. National Health and Medical Research Council. Retrieved from (https://www.nhmrc.gov.au)
2. Djuidje NM, Ateudjieu J, Fokunang C, Chi PM, Kwedi S, Tchakoa J &Kaptue L.(2011).*Active Monitoring of the Implementation in Cameroon of Research Protocols* Approved by the Cameroon National Ethics Review Committee. Conference: Sixth EDCTP Forum, At Addis Ababa, Ethiopia
3. Heath, J.E. (1979). *The IRB's Monitoring Function: Four Concepts of Monitoring. IRB: Ethics and Human Research, 1(5):1*
4. Linden-Laufer, S. (1997). *Monitoring Approved Research Protocols - A Question of Balance. Medicine and Law: World Association for Medical Law*, 16(4): 655-677
5. Phiri-Shana, M.E., Musesengwa, R. Ruzario, S.Gutsire-Zinyama, R.B. ,Gunda, R. (2012). *'Challenges in Regulating HIV Prevention Research.in Zimbabwe'*, A Case Study of a National Ethics Committee*:BMC Retrovirology*,

5.4 Module 13: Continuous Quality Improvement of Institutional Ethics Review Committees

Specific Objectives:

At the end of this module, trainees will be able to:

i. Describe the importance of continuous quality management of IERCs;
ii. Discuss modes of assessment of performance of IERCs
iii. Discuss mitigating measures for continuous quality improvement

Module Description

This module introduces the trainee to continuous quality management of IERCs, modes of assessment and how to ensure continuous quality improvement

Module content

5.4.1 Definitions

Including**:** Quality, quality management, quality improvement, continuous quality improvement**,** monitoring, evaluation, compliance.

5.4.2 Benefits of continuous quality improvement of IERCs

Efficiency, cost effectiveness, reduction of waste, dispute resolution, increased customer base, customer satisfaction, reduced turnaround time, job satisfaction and quality research

5.4.3 Strategies for Continuous quality improvement

Setting and implementation of standards, use of data for decision-making, benchmarking, customer satisfaction survey

5.4.4 Types of Reports for continuous quality improvement

Self-assessment Reports, Annual Reports, Customer Satisfaction Survey Reports, Post Approval Monitoring Reports

Learning and Teaching Methods:

Reading, Lecture, Group Activities, Video Clips, Case Studies

References

1. Jaoko, W., Bukusi, E. and Davis, A.M. (2016). An Evaluation of the Middle East Research Training Initiative Tool in Assessing Effective Functioning of Research Ethics Committees. Journal of Research Human Research Ethics. Vol.11 (4) pp.357-363. doi: 10.1177/15562461665952. Epub 2016 Sep 18

2. NACOSTI (2017). Guidelines for Accreditation of Institutional Ethics Review Committees in Kenya. National Commission for Science, Technology and Innovation (NACOSTI).
3. Sleem,H. Abdelhal, R.A.A., Al- Abdallat, Al-Naif et al.(2010).Development of an Accessible Self-Assessment Tool for Research Ethics Committees in Developing Countries. Journal of Empirical Research Human Research Ethics. Vol.5 (3). pp.85-98. doi: 10.1525/jer.2010.5.3.85

5.5 Module 14: Institutional Support of IERCs

Specific Objectives:

At the end of this module, trainees will be able to:

i. Describe the primary responsibilities of administrators;
ii. Discuss the challenges experienced by IERC secretariat
iii. Discuss the role of host institutions in supporting IERCs
iv. Discuss institutional strategies for development of a conducive environment for functionality of IERCs

Module Description:

This module gives an overview of the composition and functions of IERC secretariat. It examines strategies that institutions can use to strengthen the operations of IERCs

Module Content

5.5.1 Definitions

Institutional Support, host institutions, IERC secretariat and IERC administrators

5.5.2 Roles of the secretariat

Receiving, acknowledging, recording and documentation of proposals; pre-screening of proposals, organizing meetings and taking minutes, storing and archiving, communication of decisions

5.5.3 Procedures on management of IERCs

Scheduling meetings and Agenda preparation, screening for types of review, documenting and communicating meeting decisions, Record keeping, Post approval responsibilities (MTAs, Permits, progress reporting, Audits/Inspections, Reporting to regulatory agencies, communicating with participants), receiving and processing of complaints.

5.5.4 The role of host institutions in supporting IERC operations

Appointment of IERC members in consultation with the Chairperson, provision of office space; equipment, communication facilities, secretariat staff, operational finances, facilitate capacity building of IERC members, reviewers and the secretariat

Learning and Teaching Methods:

Reading, Lecture, Group Activities, Case Studies

Reference

1. Emmanuel, E., Grady, C., Lie, R., Miller, G.F., Crouch, A.R. and Wendler, D. (2011).The Oxford Textbook of Clinical Research Ethics. https://www.books.google.co.ke/books https://www.ncbi.nlm.nih.gov/books/NBK310666/pdf/Bookshelf_NBK310666.pdf
2. Kass NE, Hyder AA, Ajuwon A, Appiah-Poku J, Barsdorf N, Elsayed DE, et al. (2007) The Structure and Function of Research Ethics Committees in Africa: A Case Study. PLoS Med 4(1): e3. https://doi.org/10.1371/journal.pmed.0040003
3. NACOSTI (2017). *Guidelines for Accreditation of Institutional Ethics Review Committees in Kenya.* National Commission for Science, Technology and Innovation (NACOSTI).
4. WHO. 2011. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants. Geneva.
5. World Health Organization (WHO) (2000). *Operational Guidelines for Ethics Committees on Biomedical Research.* Switzerland 2000:TDR/PRD/ETHICS/2000.1

Appendix 1: Training Evaluation and Learning Self-Assessment

Training Guide for Institutional Ethics Review Committees in Kenya

Training Evaluation and Learning Self-Assessment

1. Please rate this training in terms of **Trainer's Expertise, Clarity, Time Management, Organization of the Presentation** and **Responsivenes**s to your research needs. Provide any additional feedback in the **Comments** section. Circle the appropriate numbers.

RATING SCALE: 1 = LOW 3 = MEDIUM 5 = HIGH

Trainer Name(s)	Expertise					Clarity					Responsiveness					Time Management					Organization of the Presentation				
	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5
	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5
	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5
	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5
	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5
Comments:																									

2. Please review the following list of knowledge and skills statements. Give some thought to what you knew before this training and what you learned here in the two days. Circle the number that best represents your knowledge and skills **before** then **after** this training.

RATING SCALE: 1 = LOW 3 = MEDIUM 5 = HIGH

Before Training					Self-assessment of Knowledge and Skills Related to:	After Training				
1	2	3	4	5	Module 1: Introduction	1	2	3	4	5
1	2	3	4	5	Module 2: Ethical Principles in Research	1	2	3	4	5
1	2	3	4	5	Module 3: Research study designs	1	2	3	4	5
1	2	3	4	5	Module 4:Introduction to Informed consent	1	2	3	4	5
1	2	3	4	5	Module 5:Research involving vulnerable population	1	2	3	4	5
1	2	3	4	5	Module 6:Research Integrity	1	2	3	4	5
1	2	3	4	5	Module 7:Research Involving animals	1	2	3	4	5
1	2	3	4	5	Module 8: Community Engagement ethics	1	2	3	4	5
1	2	3	4	5	Module 9: Emerging issues in Research	1	2	3	4	5
1	2	3	4	5	Module 10: Composition and Functions of Institutional Ethics Review Committees (IERCs)	1	2	3	4	5

1	2	3	4	5	Module 11: Research proposal Review process	1	2	3	4	5
1	2	3	4	5	Module 12: Post Approval Monitoring	1	2	3	4	5
1	2	3	4	5	Module 13: Continuous Quality Improvement of IERCs	1	2	3	4	5
1	2	3	4	5	Module 14: Institutional Support for IERCs	1	2	3	4	5

OVERALL EVALUATION OF PRESENTATION

3. Please take a moment to answer the following questions. Your comments are an **important contribution** as we design this training to meet your professional and research needs.

What will you do **differently** in your practice/service setting as a result of this training?

What do you feel were the **strengths** of this training?

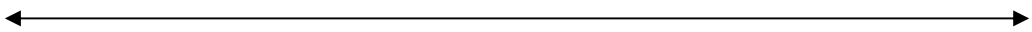
What do you feel were the **weaknesses** of this training?

How can we **improve** this training?

What **additional** do you have regarding this training?

4. Please rate the following statements using a 1 through 5 scale where:

1 = Disagree Strongly **5 = Agree Strongly**



____ I can **apply the information** learned in my practice/service setting.
____ The training met my professional **educational needs**.
____The trainers **actively involved** me in the learning process.

____ As a result of this training, I feel **more confident** in my capacity to develop training materials.

Any additional comment: