

CODE OF CONDUCT FOR HEALTH RESEARCH IN SRI LANKA



Education, Training and Research Unit and
National Health Research Council of Ministry of Health,
Nutrition and Indigenous Medicine

April 2018

CODE OF CONDUCT FOR HEALTH RESEARCH IN SRI LANKA

EDUCATION, TRAINING AND RESEARCH UNIT
AND
NATIONAL HEALTH RESEARCH COUNCIL
MINISTRY OF HEALTH, NUTRITION AND INDIGENOUS MEDICINE

April 2018

CODE OF CONDUCT FOR HEALTH RESEARCH IN SRI LANKA

ISBN 978-955-3666-13-0

EDUCATION, TRAINING AND RESEARCH UNIT
AND
NATIONAL HEALTH RESEARCH COUNCIL
MINISTRY OF HEALTH, NUTRITION AND INDIGENOUS MEDICINE

April 2018

MESSAGE FROM HON MINISTER OF HEALTH, NUTRITION AND INDIGENOUS MEDICINE

It is with great pleasure that I send this message on this historic occasion of launching of the Code of Conduct for Health Research in Sri Lanka.

During the recent past, the field of health care research in Sri Lanka has seen substantial advancement. Recognizing this trend, the Ministry of Health, Nutrition and Indigenous Medicine has successfully initiated several innovative ventures to promote an advanced research culture among healthcare professionals in the country.

Establishing National Health Research Council, granting of research allowance through the Research Allowance Scheme, establishing Research Management Committee of Medical Research Institute, granting funds for research are some of the key steps taken by the Ministry in last few years.

Development of the Code of Conduct for Health Research in Sri Lanka is yet another significant milestone in this journey.

The Code was developed by Education, Training and Research Unit and National Health Research Council, with participation of many key stakeholders in the field of health research in the country. The technical assistance was provided by the Monash University, Melbourne, Australia.

The Ministry expects all researchers and institutions across the disciplines to adapt the Code when conducting research in the future. The Code encourages those who conduct health research within the country, to adhere to a set of duties and responsibilities to promote integrity in research.

Further, the Code is a reference for any interested party who is seeking information on standards expected for responsible conduct of research in Sri Lanka.

I am confident that the Code of Conduct for Health Research in Sri Lanka will succeed in achieving its objectives and I wish it great success.

DR. RAJITHA SENARATNE
Minister of Health, Nutrition and Indigenous Medicine

MESSAGE FROM SECRETARY OF MINISTRY OF HEALTH, NUTRITION AND INDIGENOUS MEDICINE

It is indeed a pleasure to send this message on the occasion of launching of the Code of Conduct for Health Research of Sri Lanka.

I am delighted to note that Education, Training and Research Unit of the Ministry of Health has worked in collaboration with the National Health Research Council, all key stakeholders of health research activities of Sri Lanka and Monash University, Melbourne to make this Code a reality.

Deputy Director General, Education, Training and Research, Dr. Sunil De Alwis and his staff has worked with all relevant stakeholders for more than 6 months to finalize this valuable national document. The content of the code was subjected to public scrutiny in two stages and was revised based on their feedback before.

In the past the responsible conduct of research was guided by many existing non-binding guidelines, regulations, and declared policies of

individual research institutions. The availability of a comprehensive national document was a long felt need of the health and health related research community of the Sri Lanka. This Code fulfills that requirement and provides a set of duties and responsibilities for institutions and researchers to follow in order to promote integrity of health and health related research. When the integrity of research is maintained it will enhance the effectiveness of recommendations which is vital when converting research into policy.

I strongly believe that the Code will substantially contribute to promote research culture by building a platform among researchers and institutions to create the integrity.

I would like to extend my heartiest wishes to Dr. Sunil de Alwis, Deputy Director General of the Education, Training and Research Unit and National Health Research Council and the responsible staff for launching this Code.

JANAKA SUGATHADASA

Secretary

Ministry of Health, Nutrition and Indigenous Medicine



MESSAGE FROM DIRECTOR GENERAL OF HEALTH SERVICES

It is with immense pleasure that I am sending this message on the occasion of launching of the Code of Conduct of Health Research in Sri Lanka which is organized by Education, Training and Research Unit of the Ministry of Health, Nutrition and Indigenous Medicine in collaboration with the National Health Research Council.

In the recent past, the number of research being conducted and published has seen a gradual increase globally, regionally as well as in Sri Lanka. Importance of research has been accurately identified by the government of Sri Lanka and many steps have been taken to promote the research culture.

The task of ensuring the responsible conduct of research in health and health related disciplines falls on the Ministry of Health and National Health Research Council.

The Code of Conduct of Health Research fulfills this requirement by outlining the duties and responsibilities of institutions and researchers engaged in health research in Sri Lanka.

In the future, this Code is to be adapted by all those who conduct human health research within the country.

My Sincere thanks goes to the Education, Training and Research unit Ministry of Health, all the members of the National Health Research Council and World Health Organization. The technical assistance of Monash University, Melbourne, Australia is also highly appreciated.

On behalf of the Ministry of Health, I congratulate all the stakeholders who were behind this great achievement which will provide a better future for research world.

DR. ANIL JASINGHE
Director General of Health Services

MESSAGE FROM DEPUTY DIRECTOR GENERAL - EDUCATION, TRAINING AND RESEARCH

I am privileged to send this message on the occasion of launching the Code of Conduct of Health Research of Sri Lanka.

Over the years, health research has led to invaluable new knowledge and technology, which has had an enormous impact on the health and wellbeing of the people all over the world.

However, in pursuing new knowledge and development, one should not lose sight of the fact that health research is a complex process often involving human subjects and this creates complicated issues that are ethical, legal, political and social.

In Sri Lanka, during the recent years we have witnessed a new-found resurgence in the field of health research. In addition, the global health research community is recognizing our country as a potential setting for conduct of scientific research and this has brought in a new set of challenges and concerns to the authorities.

It is in this backdrop that the Education Training and Research unit of the Ministry of Health, the

focal point for development of health research in this country, embarked on the development of a Code of Conduct of Health Research of Sri Lanka. I take great pride and joy in leading a team of young and enthusiastic group of individuals who are committed to developing an innovative health research culture in Sri Lanka. Their effort was the foundation of the success of this endeavor. In addition, the contribution of many institutions and individuals, also should be greatly appreciated.

The National Health Research Council, The World Health Organization, Monash University, Melbourne in Australia provided invaluable support. Many academics and experts in the field of health research and associated specialties contributed in many ways, providing invaluable knowledge and insight. Without the support of these institutions and individuals this endeavor would not have been possible.

The Code of Conduct of Health Research of Sri Lanka is now a reality. Today we rejoice the results of our effort. Tomorrow let us all work together to make Sri Lanka a global leader in health research.

DR SUNIL DE ALWIS
Deputy Director General
Education, Training and Research

MESSAGE FROM CHAIRPERSON, NATIONAL HEALTH RESEARCH COUNCIL

Research in recent past has shown an exponential increase in many ways and for several reasons. This increase is related to increased quest for scientific evidence, availability of diverse sources of funding, monetary, professional and academic awards and rewards for research and enhanced opportunities for publication from increasing number of journals published both in print and or online. Every year an ever-increasing cohort of new graduates add to the potential researcher-base, needing training, guidance and mentoring in research. The advances in information technology, ease of communication, and investment opportunities for research partnerships have expanded the horizons of research leading to local and foreign collaborative research, inter and trans disciplinary research, transfer of technology and biological material across borders. In this milieu, it is expected that this Code will provide research institutes and organizations, researchers and funding agencies a reference to safeguard the

institute, the researcher and the participants, and at the same time produce high quality research. It provides guidance to conduct research with responsibility and integrity, with due regard to scientific rigour and ethical norms and outlines the duties and responsibilities of institutions and individuals to promote integrity in research.

The National Health Research Council developed this Code of Conduct for Health Research in 2017-2018 with participation of stakeholders and on behalf of the NHRC I thank all who contributed to its development and validation. The legal framework for the Code will be provided by the NHRC Act which will be enacted in the near future. I also wish to thank the World Health Organization, Sri Lanka and the Department of Epidemiology and Preventive Medicine of the School of Public Health and Preventive Medicine of Monash University and the for the support extended in the validation and finalization.

SNR. PROFESSOR ROHINI DE ALWIS SENEVIRATNE
Chairperson, National Health Research Council

ACKNOWLEDGEMENT

This is to acknowledge that it would not have been possible to publish the Code of Conduct for Health Research in Sri Lanka without the enormous support and dedication of many intellectuals. The continuous contribution, collaboration and guidance of many experts in the fields of research and ethics led to the completion of this task.

The WHO Representative in Sri Lanka, Dr. Razia Pendse and other officials of WHO, Sri Lanka office are acknowledged for supporting the process of validation and printing of the Code.

A special word of thanks to Dr. Nalika Gunawardena and Dr. Padmal De Silva of the WHO country office in Sri Lanka for the technical support and contributions until this became a publication.

Sincere thanks are extended to a group of experts for their contribution in finalizing the Code, namely, Dr. Jayamini Illesinghe, Mrs. Marina Skiba, Dr. Tomas Zahora, and Prof John McNeil of Monash University, Australia.

TABLE OF CONTENTS

	Page no.
Introduction to the Code of Conduct for Health Research in Sri Lanka	1
Aim and Principles of the Code	2
Part 1: Principles and practices for encouraging the responsible conduct of research for institutions and researchers	3
1.0 Formulation of research proposals	3
1.1 Responsibilities of institutions	3
1.2 Responsibilities of researchers	3
2.0 Management of research data and primary materials	4
2.1 Responsibilities of institutions	4
2.2 Responsibilities of researchers	5
3.0 Conduct of research	6
3.1 Responsibilities of institutions	6
3.2 Responsibilities of researchers	8
4.0 Collaborative research	9
A. Collaborative research between individuals and institutions within the country	10
4.1 Responsibilities of institutions	10
4.2 Responsibilities of researchers	11
B. Collaborative research with other countries	12
4.3 Responsibilities of institutions	12
4.4 Responsibilities of researchers	14
5.0 Conflict of interest	14
5.1 Responsibilities of institutions	14
5.2 Responsibilities of researchers	15

6.0 Supervision of research	15
6.1 Responsibilities of institutions	16
6.2 Responsibilities of supervisors of research trainees	16
6.3 Responsibilities of research trainees	17
7.0 Peer review	17
7.1 Responsibilities of institutions	18
7.2 Responsibilities of peer reviewers	18
7.3 Responsibilities of researchers	19
8.0 Dissemination of research findings, publication and responsible authorship	19
8.1 Responsibilities of institutions	20
8.2 Responsibilities of researchers	20
Part 2: Research misconduct, breaches of the Code and allegations of misconduct or breach	22
Glossary	24

INTRODUCTION TO THE CODE OF CONDUCT FOR HEALTH RESEARCH IN SRI LANKA

Research, by its very nature and definition, is a search for knowledge, or for an answer to a problem through systematic thinking, planning, conduct and reporting.

The volume of research being conducted and published has seen a gradual increase not only globally and regionally, but also in Sri Lanka. The recognition by the Government of Sri Lanka of the importance of research has had a significant positive influence on the volume of funded, conducted, presented and published research.

The role of the National Health Research Council (NHRC) of Sri Lanka, the apex body governing the scientific and ethical conduct of relevant health research and the utilization of research findings, is to ensure the responsible conduct of research.

This Code was developed by the National Health Research Council of Sri Lanka in 2018, in consultation with stakeholders, to be relevant to all human health research conducted within the country, across all research disciplines.

The Code outlines the duties and responsibilities of institutions and researchers to promote integrity in research. Furthermore, the responsible conduct of research is embodied in many existing non-binding codes of conduct, guidelines, regulations and declared policies of individual research institutions.

It is encouraged that all research institutes in the country make compliance with the Code a prerequisite for approval of research degrees and grants. It is encouraged that all researchers undertaking such research abide by the Code.

This Code is also a reference for people outside the research community who require information on the standards expected for the responsible conduct of research in Sri Lanka.

AIM AND PRINCIPLES OF THE CODE

The aim of the Code of Conduct for health research is to ensure that all research activities involving humans are performed only for the purposes of human health and social benefit, with outcomes that inform health promotion, disease prevention and patient management, and improve the health system. The onus is on the institution and the researchers to adhere to the responsibilities specified in the Code. The Code establishes the desired standard of conduct and provides guidance to researchers on essential practices for research integrity.

The Principles underlying this Code include

- Honesty and Integrity
- Accountability
- Respect for human participants in research, as well as for the environment and culture
- Transparency

The Code of Conduct that follows is based on the above stated aim and principles.

This Code consists of two main parts:

Part 1: Principles and practices for encouraging the responsible conduct of research, for institutions and researchers]

Part 2: Research misconduct, breaches of the Code and allegations of misconduct or breach

Part 1: Principles and Practices for encouraging the responsible conduct of research, for institutions and researchers

1.0 Formulation of research protocols

The research protocol is a summary document of a research plan. It outlines the topic, research question, aims and objectives, study design and methods, plan for data analysis, sources of funds and timeline. The research protocol also outlines the steps taken to address ethics issues in the conduct of the research.

1.1 Responsibilities of institutions

To encourage formulation of research protocols that promote responsible conduct of research, the institution should:

- 1.1.a Provide published guidelines, procedures and policies based on this Code. These include the format for the protocol and the processes and procedures to follow when submitting proposals and obtaining administrative, ethics and legal approvals.
- 1.1.b Publicise national and institutional research priorities.
- 1.1.c Advertise and award research grants in a transparent manner.
- 1.1.d Ensure that the proposals are submitted by researchers/teams with relevant expertise/qualifications.
- 1.1.e Have a transparent peer review mechanism for proposal evaluation in the form of a Scientific Review Process or Committee, and an Ethics Review Committee.

1.2 Responsibilities of researchers

To ensure that the formulated research protocol promotes responsible conduct of research, the researcher should:

- 1.2.a Adhere to the published guidelines, procedures and policies of the institution when formulating the research protocol.

- 1.2.b Obtain ethics clearance for the protocol and for any subsequent modifications.
- 1.2.c Obtain any other required authorizations, permissions and clearances.
- 1.2.d Register protocols for interventional studies, cohort studies and registries at the National level.

2.0 Conduct of research

Responsible conduct of research requires that research be conducted according to the approved research protocol, following good research practices and research ethics guidelines. Research should be conducted honestly, accurately, objectively and efficiently to ensure research integrity. This will result in high quality, generalizable, reproducible research that leads to meaningful improvements in health and wellbeing.

2.1 Responsibilities of institutions

To ensure that high quality research is conducted with integrity institutions should

- 2.1.a Ensure that the researchers have the necessary qualifications and competence for the conduct of the research. In the event that the health research is an interventional study on humans, a cohort study or a registry study, at least one of the researchers should be a medical doctor registered with the Sri Lanka Medical Council.
- 2.1.b Provide researchers with training in good research practices, including good clinical practice (GCP) and good laboratory practice (GLP) where relevant, as well as training in statistical analysis, data interpretation and research ethics. All research trainees must receive training on this Code and the research policies of the institution concerned.
- 2.1.c Provide opportunities for researchers to update their research skills throughout their research career.
- 2.1.d Provide training in scientific review and ethics review for members of such committees.

2.2 Responsibilities of researchers

To ensure that high quality research is conducted with integrity, researchers should:

- 2.2.a Obtain skills of good research practice, including good clinical practice and good laboratory practice, where relevant.
- 2.2.b Either gain the necessary ancillary skills to conduct the particular research, including the required statistical analysis, or include suitable experts as co-investigators.
- 2.2.c Adhere to the approved research protocol. Obtain prior approval for any modifications to the protocol.
- 2.2.d Use standard definitions, reproducible methods and standardised materials prepared using good manufacturing practices. Calibrate and validate equipment, instruments, reagents, kits, tests, questionnaires and other data collection tools, computer models etc. Use positive and negative controls when required.
- 2.2.e Use statistical tests correctly with sufficiently stringent criteria for statistical significance. Interpret results accurately.
- 2.2.f Collect and record all data meticulously and store primary materials appropriately and retain them for inspection for the relevant period of time as specified in 3.1.a..
- 2.2.g Ensure the rights, health and wellbeing of research participants by following research ethics guidelines and complying with any additional requirements of the Ethics Review Committee.
- 2.2.h Conduct and report the study with the highest standards of objectivity, transparency and independence, sans bias, fabrication, falsification, exaggeration, misrepresentation or misinterpretation.
- 2.2.i Account for all research funds using standard accounting practices.

- 2.2.j Comply with this Code and any relevant national, professional and institutional policies, laws, regulations, guidelines and procedures.

3.0 Management of research data and primary materials

Responsible conduct of research includes the proper management and retention of the research data and primary materials. Adequate policies need to be in place to address concerns of ownership of research data and primary material, storage, retention beyond the end of the project and provision of access to the research community. While it might not be practical to keep all the primary materials, information extracted from the materials must be retained for lengthy periods. What is retained may be decided based on the objectives of the researcher or may be influenced and determined by law, funding agency, publisher or by convention in the discipline. The potential value of the materials for further research should be taken into consideration when dealing with this.

3.1 Responsibilities of institutions

The research institutions play a key role in ensuring responsible management of research data and primary materials.

3.1.a Retention of research data and primary materials

Each institution undertaking research must have a documented policy on the retention of materials and research data. The institutional policy must be aligned with the Code, guidelines, regulations and declared policies of each individual research institution and should be within the legal framework.

In general, the minimum recommended period for retention of research data is 5 years from the date of publication. However, the actual period should vary based on the type of research, such as:

- Clinical trials – minimum of 15 years
- Cohort studies – retained permanently
- Gene therapy – clinical records retained permanently
- Where research has community or heritage value – retained permanently

If the research project includes more than one type of research, the longer period of retention should apply.

The institutional policy should include procedures for the secure and safe disposal of research data and primary materials when the specified period of retention has finished.

3.1.b Identification of ownership of research data and primary materials

Each institution must have a policy on the ownership of research data and primary materials, during and following the research project. The ownership may also reflect the funding arrangements for the project. The Code encourages that the materials and data retained at the end of a project should be the property of the institution that hosted the project.

3.1.c Provision of secure research data storage and record-keeping facilities

It is the responsibility of each institution undertaking research to provide facilities for the safe and secure storage of research data and primary materials.

In this regard:

- Each institution must have a clearly documented policy on research data storage. This policy must cover all situations that arise in research, including when researchers move between institutions and when data are held outside Sri Lanka.
- All research protocols should have a section pertaining to the storage of research data, including course of action to be taken in the case of departure or movement of research staff from the institution.
- Whenever possible, the research data should be maintained and stored in the same institution under the institutional repository, with a clear guideline on access to the data. Where the data is stored in external locations, arrangements and process of access to data need to be documented.

- Where the research spans several institutions, clear agreement needs to be made at the beginning of the project on the process and mechanism of data storage within the institutions.
- The capacity for hosting the data in a secure environment and providing access as required needs to be taken into consideration when deciding on the data storage location.

3.1.d Ensuring the security and confidentiality of research data and primary materials

Each institution must have a policy on ensuring the security and confidentiality of databases and archives that is consistent with legislation, privacy rules and other guidelines. Institutional policy needs to be in line with the legal framework in relation to the ownership, storage and ensuring the security and confidentiality of the research data and primary materials.

3.2 Responsibilities of researcher

The researchers also play a key role in ensuring responsible management of research data and primary materials.

3.2.a Retention of research data and primary materials

When considering how long research data and primary materials are to be retained, the researcher must take into account the professional standards, legal requirements and contractual arrangements as well as the following:

- Research data should be retained for at least the minimum period specified in the institutional policy.
- Research data should be made available for use by other researchers unless this is prevented by ethical, privacy or confidentiality matters.
- If the results from research are challenged, all relevant data and materials must be retained until the matter is resolved.
- Research records that may be relevant to allegations of research misconduct must not be destroyed.
- The institutional policy on the storage and safe disposal of primary materials and research data must be followed.

3.2.b Storage of research data and primary materials

Researchers must manage research data and primary materials in accordance with the policy of the institution. To achieve this, researchers must:

- Maintain a clear and accurate documentation system with records of the research methods and data sources, including any approvals granted, during and after the research process.
- Maintain a catalogue of research data in an accessible form. Retain research data, including electronic data, in a durable, indexed and retrievable form
- Manage research data and primary materials according to institutional policy, ethics principles and relevant legislation.
- Ensure that research data and primary materials are kept in safe and secure storage

3.2.c Maintaining confidentiality of research data and primary materials

Researchers given access to confidential information must maintain that confidentiality. Primary materials and confidential research data must be kept in secure storage. Confidential information must only be used in ways agreed to by those who provided it. Particular care must be exercised when confidential data are made available for discussion.

4.0 Collaborative research

Research can involve a wide range of collaborations between individuals, between institutions and between countries. Collaborative research needs thorough planning. Else, it may raise issues regarding ownership of the research, sharing of intellectual property, managing research findings, conflicts of interest and commercial use of deliverables.

Research collaboration will be described in relation to two areas: Collaborative research between individuals, communities and institutions within the country, and collaborative research with other countries.

A. Collaborative research between individuals, countries and institutions within the country

4.1 Responsibilities of institutions

When conducting collaborative research between individuals, communities and institutions within the country, there are several responsibilities that should be fulfilled by the collaborating institutions.

4.1.a Establishment of agreements for each collaboration

Institutions involved in a collaborative research project should ensure that an agreement is reached among the collaborators. The agreement should be in writing. It must cover intellectual property, confidentiality and copyright issues; storage and sharing of generated data, sharing commercial returns, responsibility for ethics and safety clearances; and reporting to appropriate agencies. It should specify the plan for authorships and the procedures to be followed by the partners when disseminating the research outcomes. Further, it is necessary to specify the ownership of data of collaborative research in the event of a premature end or on completion of the research.

The agreement may take one of the following forms: a legal contract signed by the chief executive officer, an exchange of letters, a research management plan signed by all parties or research management plans signed by appropriate authorized representatives from all parties. Where disparities are evident within institutional policies, precedence should be given to the legal framework of Sri Lanka.

Each institution must ensure that its researchers are aware of and understand the policy and agreements governing the joint research collaboration.

4.1.b Management of access to research materials

The institution should direct the collaborators to identify a mechanism to manage research data, primary materials and other items to be retained at the end of the project.

4.1.c Management of disagreements

The institution must have a published policy and guidelines for managing disagreements that arise in collaborative research due to breaches of the agreement.

The collaborative agreement should spell out clearly and in detail the process of managing breaches that may arise during the period of agreement, from conceptualizing the research proposal to dissemination of findings and up to destruction of stored data.

4.1.d Management of conflicts of interest

The institution should have a mechanism for managing conflicts of interest that may arise in collaborative research (see section on conflict of interest)

4.1.e Investigation of allegations of misconduct

The institution should have a mechanism to investigate allegations of misconduct that may arise in collaborative research (see Part 2 of the Code).

4.2. Responsibilities of researchers**4.2.a Management of conflicts of interest**

The researcher should cooperate with the institutional mechanism for managing conflicts of interest that may arise in collaborative research (see Part 2 of the Code).

4.2.b Investigation of allegations of misconduct

The researcher should cooperate with the institutional mechanism to investigate allegations of misconduct that may arise in collaborative research (see Part 2 of the Code).

B. Collaborative research with other countries

Research practices differ between countries, but research conducted in Sri Lanka should make every effort to comply with this Code. This section deals with collaborative research projects that involve:

- An Institution in Sri Lanka collaborating with an institution of another country
- Individual researcher in Sri Lanka collaborating with an institution of another country
- Institution from Sri Lanka collaborating with a Principal Investigator from another country

4.3 Responsibilities of institutions

When conducting collaborative research with other countries, there are specific responsibilities that should be fulfilled by the collaborating institutions, in addition to the responsibilities listed in section 4.1 above.

4.3.a Obtaining scientific clearance

Institutions involved in collaborative research project/s with other countries should ensure that the research protocol has been submitted to the Scientific Review processes of the collaborating Sri Lankan institution.

4.3.b Obtaining ethics clearance

Institutions involved in a collaborative research project should ensure that ethics clearance is obtained from an Ethics Review Committee registered with the National Health Research Ethics Committee. For clinical trials it should be obtained from Ethics Review Committees approved by the Ministry of Health, inclusive of Ethics Review Committees recognized by the Subcommittee on Clinical Trials (SCOCT) of National Medicinal Regulatory Authority of the Ministry of Health, Sri Lanka.

4.3.c Registering clinical trials

Institutions involved in a collaborative research project involving clinical trials need to register the clinical trial in the Sri Lanka Clinical Trial

Register irrespective of it being registered in the collaborating country. The said clinical trial registration number should be communicated to the Ethics Review Committee and to the Administration of the institution.

4.3.d Declaration of funding sources

Institutions must disclose all details of funding arrangements for the joint project. Competing interests of the collaborating institutions should be clearly declared and the Scientific and Ethics Review Committees should ensure that these interests do not influence the conduct of the study.

4.3.e Obtaining administrative clearance

When conducting internationally collaborative research which involves transfer of human biological material, the institution should obtain administrative clearance from an appropriate authority of the Ministry of Health on the recommendation of the NHRC. The institution also needs to obtain Ethics clearance from a recommended Ethics Review Committee prior to applying for administrative clearance. On application for administrative clearance, the following documents need to be submitted:

- Collaborative agreement with the Sri Lankan organization
- Funding arrangements
- Certificates of ethics clearance (local and from the collaborating institutions / countries)
- Certificate / letter of scientific review
- Research protocol
- Dissemination of research findings Clinical trial registration number in the case of interventional studies

4.3.f Storage of data

Institutions involved in collaborative research must have a documented policy on the storage of digitized data including: location of server, duration and data sharing policy and also on removal of stored data from the server. When data collection is being conducted within Sri Lanka, storage of data should be in a secured server under the local collaborator.

4.3.g Report of the findings

A report of the collaborative research with other countries should be submitted to the Head of the institution, upon completion of the research.

4.4 Responsibilities of researchers

When conducting collaborative research between individuals and institutions in other countries, the collaborating local and foreign researchers should fulfil several responsibilities.

4.4.a Compliance with agreements on collaborative research

Researchers involved in collaborative research must be aware of and comply with all sections of the relevant collaborative research agreement, specifically:

- Management of research data and primary materials
- Authorships in publications
- Declaring conflicts of interest
- Dissemination of research findings

5.0 Conflict of interest

A conflict of interest arises where there is a divergence between a researcher's personal interests and professional responsibilities. Conflicts of interest have the potential to compromise judgments and decisions that should be made impartially. Such compromise could undermine community trust in research.

Institutions and researchers must recognize that conflicts of interest (on individual or institutional level, including but not limited to financial matters) can inappropriately affect research. Conflicts of interest must be identified, declared and addressed in order to avoid poor practice in research or potential misconduct.

5.1 Responsibilities of institutions

To facilitate identification, declaration and management of conflicts of interests, the institution should:

- Have a policy on conflicts of interest that is clearly written and readily available to all staff. The policy should aim to cover the full range of possible conflicts of interest and be reviewed regularly to enable relevant amendments.
- Ensure that heads of organizations and other senior staff are informed of potential or actual conflicts of interest at the institutional level and disclose them so that they can be addressed.
- Ensure that the person concerned does not take part in the decision-making processes.
- Keep records of how each conflict is managed in the proceedings of meetings.

5.2 Responsibilities of researchers

To facilitate the management of conflicts of interests, the researcher should use the following approach:

- Be familiar with any policy documents/ guidelines on conflicts of interest relevant to the institution and the country.
- Comply with their institution's policy for addressing conflicts of interest, as well as any external requirements relating to conflicts of interest, such as those of funding bodies.
- Disclose any potential or existing conflicts of interest according to the institution's policy.
- Maintain detailed records of activities that may lead to conflicts of interest (e.g. consultancies, membership of committees, membership of advisory groups, financial benefits etc.).
- Agree to abide by any direction given by their institution or any relevant Ethics Review Committee in relation to a conflict of interest.

6.0 Supervision of research

The supervisor's behaviour should provide a role model to junior colleagues that is positive and conducive to a research culture of excellence, integrity, professionalism and mutual respect. The research trainee must understand that undertaking research means participating in an endeavour that requires dedication and accountability.

6.1 Responsibilities of institutions

To facilitate research supervision, the institution should:

6.1.a Assign and approve supervisors

The institution must ensure that each research trainee has an appropriately qualified and eligible supervisor with adequate time to supervise the trainee.

6.1.b Ensure that supervisors are given adequate time for supervision of trainees

The institution should ensure that supervisors of research trainees have adequate time to carry out research supervision.

6.2 Responsibilities of the supervisors of research trainees

To ensure effective research supervision, the supervisor should:

6.2.a Ensure adequate training in research

The supervisor of a research trainee should ensure that training starts as soon as possible in the trainee's career and that the trainee is given adequate and committed contact time. The supervisor should ensure that the trainee undertakes the necessary training on research ethics, this Code and the research policies of the institution concerned as early as possible. Further, the supervisor should ensure that the trainee undergoes training in discipline-based research methods, specific research methods required by the planned research and other relevant skills required to ensure responsible conduct of the research.

6.2.b Guide the professional development of the trainee

The supervisor should guide and support the professional development of the trainee by providing guidance, linking to training opportunities and overseeing all stages of the research process.

6.2.c Certify validity and accuracy of research

Supervision includes oversight of the conduct of the research. The supervisor must certify that the methods and outcomes of research conducted by all trainees under his/her supervision are appropriate and valid.

6.2.d Attribute credit for research

The supervisor must ensure that research trainee receives appropriate credit for his/her work.

6.2.e Ensure dissemination of results

The supervisor should ensure that the trainee disseminates the research findings in an acceptable and responsible manner. Particular attention should be paid to avoiding plagiarism, maintaining academic integrity, and ensuring that the student acknowledges other the work and contributions of other people, institutions and funding agencies.

6.3 Responsibilities of research trainees

The research trainee is also responsible for ensuring that the research supervision is effective. The research trainee should:

6.3.a Seek guidance

The research trainee must demonstrate a professional attitude towards research. It is the responsibility of the trainee to seek guidance at each step of the research. The trainee should utilise all the allocated contact times with the supervisor.

6.3.b Undertake training

The research trainee should complete training on research ethics, this Code and the research policies of the institution concerned at the commencement of the training. The trainee should also undergo training on discipline-based research methods, specific research methods required by the planned research project and other training to acquire the skills required to ensure responsible conduct of the research. The trainee should take advantage of any available training opportunities for professional development.

6.3.c Seek guidance on dissemination of findings

It is the responsibility of research trainee to seek the guidance of the supervisor in disseminating findings in an acceptable and responsible manner.

7.0 Peer review

“Peer review” describes a process of independent and impartial assessment of one’s research work by others working in the same or a related field. Peer review is an essential component of the research process that contributes to identifying and correcting errors in research methodology and misinterpretation of research findings. The peer review process is an important part of research management in the assessment of grant applications, in selecting material for publication, in the

review of performance of researchers and teams, and in the selection of staff. All research institutions and researchers are encouraged to take part in the peer review process as it provides expert scrutiny of a project and helps maintain high standards and encourage accurate, thorough and credible research reporting.

7.1 Responsibilities of institutions

To ensure responsible peer review of research the institution should:

7.1.a Encourage participation in peer review

The institution undertaking research should recognise the importance of the peer review process and foster researchers' participation in the peer review process within the institution. Each institution should have a documented mechanism of undertaking peer review within the institution.

7.1.b Mentor researchers in peer review

The institution should undertake training and mentoring of researchers and research trainees in developing the necessary skills for peer review and ensure that they understand their obligation to participate.

7.2 Responsibilities of peer reviewers

7.2.a Conduct peer review responsibly

It is important that all participants in peer review,

- are fair and unbiased in their review
- are timely in completing their review
- are thorough and constructive in their review
- maintain confidentiality of the content of the protocol they are reviewing and the outcome of any review
- declare any conflicts of interest
- are non-judgmental and do not permit personal prejudice to influence the peer review process
- do not take advantage of knowledge obtained during the peer review process
- ensure that they are informed about, and comply with, the criteria to be applied
- do not agree to participate in peer review outside their area of expertise
- give proper consideration to research that challenges or changes accepted ways of thinking

- disclose any undue influence that is exerted on them during or after the peer review process

7.3 Responsibilities of researchers

Responsible implementation of the peer review process requires the contribution of the researchers.

It is important that the researcher:

7.3.a Does not interfere with the peer review process

The researcher should not influence the peer review process or the reviewers in any way.

7.3.b Participates in peer review

The researcher has a responsibility to get trained in and to participate in peer review.

8.0 Dissemination of research findings, publication and responsible authorship

Timely dissemination of research findings is an important part of the research process. It facilitates translating research findings into practice, guiding future research and passing on the benefits of research to health care services and to society. This Code applies to the dissemination of research findings through publications in journals as well as mass media, the internet and other communication platforms.

Authorship must be based on substantial contributions to one or more of the following:

- Conceptualization and design of the project
- Analysis and interpretation of research data
- Drafting significant parts of the work or critically revising it so as to contribute to the interpretation of research data

The right to authorship requires substantial intellectual involvement and should not be tied to one's position or profession and should not depend on whether the contribution was paid for or voluntary. To qualify as an author, it is not enough to have provided materials or routine technical support, or to have collected the measurements on which the publication is based.

A person who qualifies as an author must not be included or excluded as an author without their permission.

8.1 Responsibilities of institutions

To promote dissemination of research findings, publication and responsible authorship, the institution should:

8.1.a Promote responsible dissemination of findings

The institution should promote and foster an environment and a culture of honesty, integrity and validity in the dissemination of research findings.

8.1.b Protect and manage intellectual property

The institution must have a policy to protect the intellectual property rights of the institution, researchers and sponsors. The policy should prevent undue delays and restrictions in publication.

8.1.c Have criteria for authorship

The institution should publish guidelines for authorship based on substantial contribution to research concept, design, methods, data collection, data analysis, writing and interpretation. In case of journal publications, the International Committee of Medical Journal Editors' guideline or the guidelines of the journal can be followed. Each journal may also have its own criteria/conditions/guidelines for authorship, which need to be considered.

8.1.d Create opportunities for researchers to disseminate research findings

8.2 Responsibilities of researchers

To promote dissemination of research findings, publication and responsible authorship, the researcher should:

8.2.a Disseminate all findings in a timely manner

The researcher should take every effort to disseminate a full account of the findings in different forms of publications or presentations, without undue delay, to all target groups and stakeholders including sponsors, policy makers, health personnel, community and society.

8.2.b Follow policies on authorships

The researcher should adhere to institutional/journal guidelines when offering authorship to collaborators. Researchers must offer authorship only to those who are eligible as stipulated in the guidelines, and ensure that all eligible people, including research trainees, who meet the criteria for authorship are offered authorship.

8.2.c Comply with agreements on authorship

The researcher should comply with the agreements on authorship when engaging in collaborative research.

8.2.d Cite the work of other researchers

The researcher should respect the intellectual property rights of others and cite the previous work of other researchers when it has been used.

8.2.e Acknowledge other contributions

The researcher must ensure that all those who have contributed to the research, facilities or materials are properly acknowledged.

8.2.f Ensure accuracy and authenticity of published research

The researcher must ensure that research findings are accurately and properly reported so as not to mislead the audience. Publications should include a disclosure of conflicts of interest of all authors and information on all sources of financial and in-kind support. Multiple publication of the same research findings should be avoided and submission of findings similar to those already published should disclose this fact.

8.2.g Retract publications when applicable

The researcher should retract publications that contain demonstrated unreliable findings, unethical research, plagiarism and research misconduct.

Part 2 : Research misconduct, breaches of the Code and allegations of misconduct or breach

This part of the Code describes research misconduct and breaches of the Code and addresses how to manage allegations that research has not been conducted responsibly. Here, the term research misconduct is used for more serious or deliberate deviations while the term breach is used for less serious deviations from this Code.

The following behaviours or actions are considered as research misconduct:

- Intentional use of research findings to fulfil goals or purposes other than what is stipulated in the protocol.
- Misconduct in relation to the collection of data.
- Fabrication, falsification, conscious misinterpretation or misrepresentation of data, deception in proposing, carrying out and reporting the results of research
- Plagiarism, misleading ascription of authorship including listing of authors without their permission, inappropriate omission of authors and including as authors those who have not contributed to the research, lack of appropriate acknowledgment of the work of others
- Failure to declare or manage any conflict of interest.
- Unauthorised deviation from the research protocol approved by the Ethics Review Committee
- Wilful support, assistance, concealment or facilitation of research misconduct by others.
- Failure to provide adequate guidance or mentorship for researchers or trainees under supervision.
- Inappropriate utilisation of funds by researchers, including not conforming to the policies of the funding agency.

The following elements are considered as breaches of the Code of Conduct:

- Non-adherence to appropriate security and safety measures for participants and researchers
- Deviation from the approved research protocol with no prior approval for changes in methodology or in the analysis of results

- Failure to maintain research records or an inappropriate destruction of research records, data and source materials
- Any other deviations from the Code

Managing allegations of research that has not been conducted responsibly requires that misconduct or breaches are identified, investigated and managed through an established framework within institutions.

Identification of research misconduct / breaches of the Code

Identification of research misconduct and breaches of the Code may be done through complaints by Ethics Review Committees or Scientific Review Committees, public complaints, complaints from research project participants, the media, research governing bodies or professional organizations.

Allegations of misconduct or breach

The Code proposes the establishment of a framework within each institution to investigate the allegations and to guide the management of proven misconduct and breaches. The framework should make provisions to conduct the following:

- Acceptance of allegations
- Conducting inquiries
- Enforcement of disciplinary and administrative actions for proven misconduct and breaches of the Code

A complaint should be received in the form of a written document. If the complainer is unwilling to make a written submission, a verbal complaint will be accepted instead. An allegation can also be investigated if the incident has been discussed in professional bodies, social media or mass media.

It is the responsibility of the relevant institution, NHRC and the Ministry of Health to attend to a complaint. Conducting inquiries and enforcement of disciplinary and administrative actions for the proven misconduct and breaches of the Code should be based on institutional policies and guidelines.

GLOSSARY

Authorized representative	An authorized representative is a neutral or legal person acting on behalf of a research institution or a researcher in carrying out certain tasks required in the research agreement.
Breach of contract	Breach of contract is a legal cause of action and a type of civil wrong, in which a binding agreement or bargained-for exchange is not honoured by one or more of the parties to the contract by non-performance
Breach of the Code	Failure to comply with the code
Collaborative research	Collaborative research can be defined as two or more researchers working together to achieve the common goal of producing new scientific knowledge.
Collaborator	Collaborator is defined as a researcher working together with other researchers to achieve the common goal of producing new scientific knowledge.
Conflict of interest	Conflict of interest is a situation in which a person is in a position to derive benefit to self or the institution from actions or decisions made in getting involved in the research.
Data	Refers to facts and statistics collected together for reference or analysis.
Ethics Review Committee	An institutional review board (IRB), also known as an independent ethics committee (IEC), ethical review board (ERB), or research ethics board (REB), is a type of committee that applies research ethics by reviewing the methods proposed for research to ensure that they are ethical.

Institution	An institute is either a training establishment which requires trainees to conduct research or an establishment which grant administrative, scientific or ethics approval for research
Misconduct	Misconduct refers to any improper action by a staff member in his official capacity; any conduct by a staff member, unconnected with his official duties, tending to bring the Organization into public discredit; any improper use or attempt to make use of his position as an official for his personal advantage; any conduct contrary to the terms of his oath or declaration. Wrongdoing in research - intentional, fraudulent or grossly negligent behavior such as fabrication, falsification, plagiarism, deliberate misrepresentation or other practices by a staff member or collaborator that seriously deviate from this Code
Primary materials	Primary research materials include all types of materials generated and utilized in the scope of scholarly research
Research	Is defined as the development of new knowledge with the aim of understanding health challenges and mounting an improved response to them.
Research agreement	Research agreement refers to the binding legal document agreed upon by two or more researchers, researcher and an research institution or two or more research institutions within the country or outside of the country
Research institution	A research institute is an establishment endowed for doing research. Research institutes may specialize in basic research or may be oriented to applied research.

Research protocol	A research protocol is a detailed set of activities for the project you propose and these activities are supported by evidence from other research and from your preliminary investigations.
Supervisor	A research supervisor is a person who directs and oversees the work of a postgraduate research student.
Trainee	A trainee is commonly known as an individual taking part in a trainee program or a graduate program within a company or an organization after having graduated from university or college.
Researcher	A person who carries out academic or scientific research.
Scientific Review Committee	A group of doctors, scientists, researchers and other experts that reviews the detailed plan of a clinical trial for scientific quality and correct study design.

CONTRIBUTORS

Dr. Adimali Kankanamalage Sunil Bernard De Alwis	Secretary, National Health Research Council, Sri Lanka, Deputy Director General, Education Training & Research Unit, Ministry of Health, Chairperson Board of study, Medical Administration, Post Graduate Institute of Medicine, Sri Lanka.
Prof. Samath Dhammindha Dharmaratne	Member, National Health Research Council, Sri Lanka, Professor in Community Medicine, Faculty of Medicine, Peradeniya.
Dr. Panapitiyage Wijayalal Chandrasiri Panapitiya	Member, Research Management Committee, Ministry of Health, Director, Medical Suppliers Division.
Dr. Don Sudath Dharmapriya Samaraweera	Member, Research Management Committee, Ministry of Health, Member Ethics Review Committee, Medical Research Institute, Colombo, Director, National Cancer Control Programme, Sri Lanka.
Dr. Maduwage Dileep Kumarasinghe De Silva	Member, Research Management Committee, Ministry of Health, Consultant Community Dental Surgeon, Head of Human Resource Coordinating Unit, Ministry of Health.
Dr. Gamage Samantha Prabath Ranasinghe	Developer of e-learning Research Methodology module for Health Professionals of Sri Lanka; Deputy Director- Training, Education Training & Research Unit, Ministry of Health.
Dr. Shiranee Champika Wickramasinghe	Member, Research Management Committee, Deputy Director General, Non-Communicable Diseases, Ministry of Health.
Prof. Sunitha Rohini de Alwis Seneviratne	Chairperson, National Health Research Council, Sri Lanka; Senior Professor in Community Medicine from Faculty of Medicine, Sir John Kothalawala Defense University
Dr. Liyanaarachchilage Chandima Suranji Dahanayake	Member, National Health Research Council, Sri Lanka; Director Research, Education Training & Research Unit, Ministry of Health.
Dr. Manatungage Bhashinie Umanga Diyasena Sooriyaarachchi	Member, National Health Research Council, Sri Lanka; Consultant Community Physician, Education Training & Research Unit, Ministry of Health.
Dr. Matiwala Walawwe Saumya Janakanthi Kumari	Member, National Health Research Council, Sri Lanka; Former Director, Institute of Indigenous Medicine, Sri Lanka.
Dr. Chamila Priyangi Abeywickrema	Coordinator, National Health Research Council, Sri Lanka; Medical Officer, Education Training & Research Unit, Ministry of Health.
Dr. Yatagama Lokuge Sumal Nandasena	Member, Ethics Review Committee, National Institute of Health Sciences; Member Ethics Review Committee, Sri Lanka Medical Association; Deputy Director (Field Services) National Institute of Health Sciences, Sri Lanka.
Dr Nalika Gunawardena	Member, National Health Research Council, Sri Lanka; National Professional Officer WHO, Consultant Community Physician
Dr Padmal De Silva	National Professional Officer WHO, Consultant Community Physician Former Head, Research Unit, National Institute of Health sciences



9 789553 666130

ISBN 978-955-3666-13-0