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Health Research Governance Strategy in Sri Lanka


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

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Education, Training and Research Unit
and
National Health Research Council
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Message from the Honourable Minister of Health, Nutrition and Indigenous Medicine

Sri Lanka is well-known for its almost seven decade long free health care delivery system in keeping with changing demographics, disease burden and rapid technological advances. Considering the costs involved in the process there is a pressing need for evaluation frameworks to support decision-making on investment, and even disinvestment if necessary, in modalities of treatment and care.

I believe that in spite of all the challenges, we should strive to ensure that our people will continue to have access to an effective, efficient and sustainable health care system. Such a process would need evidence based information to fine tune service delivery modalities.

As we are aware, the government is now in the process of investing in building advanced health research capability in the country, while extending support to innovative research. On the other hand it is important to identify strategies to be developed to provide national leadership in promoting translation of research findings into clinical practice, policy and health services and systems.

As research provides the foundation for decision-making in health and health care, it is important that all research is accurate and reproducible. More robust guidance is needed for researchers and institutions on the nature of research misconduct and procedures for managing allegations of misconduct.

I am confident that development of this document will bring a change in the research governance strategy, which would promote and sets the standards for research, and continue to maintain research quality and public trust in the enterprise of research.

Hon. Dr. Rajitha Senaratne
Minister of Health and Nutrition and Indigenous Medicine
Democratic Socialist Republic of Sri Lanka

Message from the Secretary,
Ministry of Health Nutrition and Indigenous Medicine

It gives me great happiness to write this message on the occasion of launching of the Research Governance Strategy in Sri Lanka.

Research and research into policy and practice play a vital role in development of the nations in the entire world. It is a responsibility of the Ministry of Health, Nutrition and Indigenous Medicine to ensure that, the health research is conducted within the agreed set of standards, administrative processes, procedures and clearly defined legal and regulatory mechanism while meeting the national priorities. In this regard an emphasis is made to ensure to maintain standards and ethics in research culture.

I am sure that an enormous amount of work has gone into the development of this document, and I believe you will see the impact of it by promoting and managing research to generate relevant evidence through standardized manner. Further, this initiative will motivate and gratify the genuine researchers, funders, participants and public.

I convey my earnest gratitude to the Education, Training and Research Unit of the Ministry of Health, National Health Research Council, World Health Organization and Monash University, for their contribution and expertise to make this national task a reality. I am confident that the Health Research Governance Strategy established will pave the pathway for quality health research in Sri Lanka.

Wasantha Perera
Secretary to the Ministry of Health, Nutrition and Indigenous Medicine

Message from the Additional Secretary (Medical Services), Ministry of Health Nutrition and Indigenous Medicine

Our planet works in a common goal to achieve sustainable development goals in 2030. Health and wellbeing of communities in each country is a vital dimension of this journey. The value of conducting Health Research is underpinned to innovative approaches in facing the modern challenges of curative, preventive and community empowerment strategies of Sri Lanka, leaving no one behind the concept.

With the introduction of incentive mechanisms for the officers in the government service and the activities initiated by the Education Training and Research Unit of Ministry of Health, Nutrition and Indigenous Medicine, in collaboration with other government, non-government and international agencies, the number of researches conducted in health sector has been increasing steadily. In this context sound research governance strategy is of paramount importance to ensure standards of research through administrative, legal and regulatory mechanisms while protecting participants, researchers and research institutes, which Sri Lanka is lacking at present. The governing strategies will minimize poor performances, fraud and mis-conduct of the research while increasing the quality, integrity and transparency. Furthermore, it provides a platform to share the lessons learnt, absorbing the good practices, encouraging creative and innovative research to improve the health system and health care for the public.

Formulation of National Health Research Governance Strategy meets this long felt requirement of Sri Lanka. The Strategy will also be closely linked to the Code of Conduct of Health Research and the National Health Research Council Act which will be enacted shortly and will make an essential landmark of the research culture in Sri Lanka.

In this happy moment I would like to express my gratitude to the Education, Training and Research Unit of Ministry of Health, all the members of National Health Research Council, World Health Organization and Monash University, Melbourne, Australia for their administrative and technical contribution in making this Strategy a reality. This document paves the roadmap to a robust health research culture in Sri Lanka.

Dr. Sunil De Alwis
Additional Secretary (Medical Services)

Message from the Director General of Health Services, Ministry of Health Nutrition and Indigenous Medicine

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

Health research provides us with the roadmap to tackle the increasing challenges which diseases and ill health place upon our nation. Its contribution to achieving health and wellbeing of the society, the growth of curative and preventive systems, knowledge economy of the country, to face international competition is enormous. While communicable diseases and nutritional disorders are still a burden to the country, noncommunicable diseases are on the increase along with current epidemiological and demographic trends. This is a time the country needs the best research.

Therefore, the government is determined to develop a set of standards, administrative procedures, processes, legal framework and regulatory mechanisms. National Health Research Council Act which will be enacted shortly, and The Code of Conduct of Health Research of the Ministry of Health will provide a legal and regulatory framework for this Strategy. The vision that this Strategy describe is underpinned by our determination to ensure good quality health research in an environment where all three parties; researchers, participants and research institutions are safe and secured. It is the icon of a country with a strong health research culture.

Further new research centres and institutions are increasingly establishing in academic, government and nongovernment institutions. Besides, the researchers in the current context are working beyond borders. In such a complex environment, this Strategy is a timely set intervention, and it will enhance the country's recognition in global research communities. Further, this governance document will pave clear guidance to all researchers, research institutions and their participants in human research.

The strategy fulfils a national requirement. This Strategy is to be adhered by all research institutions, researchers and participants involving in human research of the country. The Ministry of Health and the National Health Research Council will act upon establishing a monitoring and evaluation mechanism of all components of the health research governance described in this Strategy.

I am confident that the Health Research Governance Strategy of Sri Lanka will achieve its objectives. My sincere thanks go to the Education, Training and Research Unit, Ministry of Health, all the members National Health Research Council and the World Health Organization in making this a reality. The academic partnership of Monash University, Melbourne, Australia in the process of validation and finalisation is highly appreciated.

Dr. Anil Jasinghe
Director General of Health Services

Message from the Deputy Director General
(Education Training & Research),
Ministry of Health Nutrition and Indigenous Medicine

With the demographic transition of Sri Lanka, it is expected to increase the burden of non-communicable diseases while experiencing new and emerging threats of infectious diseases in the country. The delivery model of healthcare is evolving with more emphasis on the primary healthcare system. In order to face these contemporary challenges health research, need enhancement both by quantity and quality. A significant increase in the volume of health research has been already observed in the recent past. In order to ensure the quality of research with sound methodology and also due protection to the research participants and abiding by governing laws and regulations, more guidance is needed.

Lanka is a timely intervention to strengthen the conducting ethical and scientific health research in the country. It provides a broad overview on standards, administrative procedures and processes, and legal framework and regulatory mechanisms pertaining to health research in Sri Lanka.

Along with the forthcoming National Health Research Council Act, the Code of Conduct of Health Research published in 2018 and several other draft policies and guidelines on ethical conduct of research, human genetic data and stem cell research will provide the necessary background to ensure conducive environment for health research in Sri Lanka.

I am very much thankful to Dr. Sunil De Alwis, Additional Secretary (Medical Services) and the former Deputy Director General of Education, Training & Research for his leadership in this huge task. I am also thankful to Professor Rohini De Alwis Senevirathne, and all members of the National Health Research Council, Dr Nalika

Gunawardena and Dr Padmal de Silva of WHO Country Office, Dr Jayamini Ileperuma, Mrs. Marina Skiba, Dr. Tomas Zahora, and Prof John McNeil of Monash University, Australia for their technical guidance and active contribution to make this endeavour a success. I also acknowledge with sincere gratitude the team at Education, Training & Research Unit for their excellent contribution to make this effort a reality.

Dr. Sudath Samaraweera
Acting Deputy Director General (Education, Training & Research Unit)

Message from the Chairperson,
National Health Research Council

There is an exponential rise in the health research conducted in Sri Lanka as evident from the ever-increasing number of publications presented and published as abstracts, extended abstracts, and journal articles both in the print and electronic media. Hence, meaningful steps are required to ensure that the health research conducted is of high standard, good quality and the findings are utilized. The National Health Research Council (NHRC) as the apex body of health research in the country is tasked with the promotion, development, monitoring and maintaining the quality of health and health related research in the country. In order to ensure quality of research, standards are to be maintained explicitly in the areas of scientific and ethical conduct of research while maintaining transparency. There is also a need to conduct research within the existing administrative and legal framework in the country. Having published the Code of Conduct of Health Research in Sri Lanka (2018), Education Training and Research Unit of the Ministry of Health have, yet again joined forces to streamline and enhance the quality of health and health related research in Sri Lanka by producing this publication. The strategy, we hope will enable good governance of health research, as well as be conducive to encourage creative and innovative research, and to effectively transfer learning, innovations, technology and best practice to improve health of the people, health systems and health care.

The National Health Research Council developed this Health Research Governance Strategy in Sri Lanka between 2017-2019 with participation of stakeholders and, on behalf of the NHRC, I thank all who contributed to its development. 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 for the support extended to finalize it.

Snr. Professor Rohini de Alwis Seneviratne
Chairperson, National Health Research Council
Senior Professor of Community Medicine and Dean, Research & Development General Sir John Kotelawala Defence University, Sri Lanka

Acknowledgement

The "Health Research Governance Strategy in Sri Lanka" is intended to facilitate and to improve the quality of health research conducted in Sri Lanka. This document results from collaborative effort of the Ministry of Health, Nutrition and Indigenous Medicine, and the National Health Research Council of Sri Lanka.

The support and dedication of many intellectuals from many organizations who contributed to the successful publication is greatly valued. The leadership provided by Dr Sunil De Alwis Additional Secretary Medical Services and Prof Rohini de Alwis Seneviratne, Chairperson of the NHRC for the leadership given in this endeavour is acknowledged.

The WHO Representative in Sri Lanka, Dr. Razia Pendse and other officials of WHO, Sri Lanka office are acknowledged for supporting the development and printing of the Health Research Governance Strategy in Sri Lanka. A special word of thanks to Dr. Nalika Gunawardena and Dr. Padmal De Silva of the WHO country office in Sri Lanka for their technical support and contributions.

Sincere thanks are extended to Dr. Jayamini Illesinghe, Mrs. Marina Skiba, Dr. Tomas Zahora, and Prof John McNeil of Monash University, Australia for their contribution to finalize this. It is with gratitude we appreciate the Government of Australia for awarding "Australia Awards Fellowships 2017", during which this activity was initiated.

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Introduction

Research is defined as the attempt to explore the boundaries of knowledge in order to derive generalizable new knowledge by addressing clearly defined questions or hypotheses through application of systematic and rigorous methods. Undertaking quality research is considered essential for the advancement of medical sciences, improvement of health and wellbeing of the people and the health system. At the same time, health related research could pose an element of risk for the safety and wellbeing of the research participants and sometimes for the researcher. The public and participants in research have the rights to expect that research is aligned with national interests, is of high scientific and ethical standards, is carried out with accountable and transparent processes, is culturally appropriate, has been subject to robust monitoring during its conduct and that the generated evidence is translated into policy and practice for the good of all.

A country's research governance strategy is a key approach to promoting and setting a set of standards for research. The Health Research Governance Strategy of Sri Lanka will achieve its aims through an established system of standards and administrative, legal and regulatory mechanisms through which research is promoted and managed to generate relevant evidence, and to ensure that participants, researchers and research institutes are protected, and accountability is assured without undue hindrance and delays. The strategy further aims to forestall poor performance, detect adverse incidents, research misconduct and fraud, and to protect vulnerable groups. It ensures that lessons learnt are shared when poor practice is identified. Learning from adverse events will promote good practice, enhance the ethical and scientific quality of research, and safeguard the public. The strategy, while enabling good governance of health research, also provides a context to encourage creative and innovative research, and to effectively transfer learning, innovations, technology and best practice to improve health of the people, health systems and health care.

The legal framework and regulatory mechanisms to implement the strategy is provided by the National Health Research Council Act (NHRC Act) (awaiting enactment) while the Code of Conduct for Health Research in Sri Lanka, 2018, provides standards for researchers and research institutions engaged in health and health related research as a strategy for research governance. Furthermore, administrative circulars, codes and guidelines have been issued by the Ministry of Health (MOH) and other relevant government ministries which provide guidance to the process of decision making and the process by which the decisions made are implemented or not implemented.

The health research governance strategy was developed by the National Health Research Council of Sri Lanka (NHRC), and Ministry of Health in the period 2017-2019 in consultation with stakeholders and is applicable to all health and health related research with direct or indirect involvement of humans, conducted in Sri Lanka across all disciplines.

The key components, namely, standards, administrative procedures and processes, and the legal and regulatory mechanisms to ensure good governance of health research in Sri Lanka are outlined in the Figure 1. A brief description of provisions under each of these strategic areas are presented under Sections 1, 2 and 3.

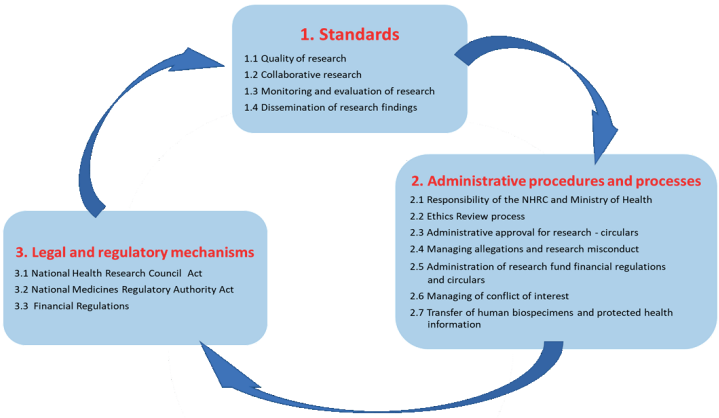

Figure 1: Key components of health research governance in Sri Lanka

01 - Standards

Good governance of health research entails setting up standards relevant to the promotion of research, quality of research, conduct of collaborative research, monitoring and evaluation of conduct of research and dissemination of research findings to guide health researchers and research institutions in the country.

The Code of Conduct for Health Research in Sri Lanka published in 2018 (referred to hereafter as the Code) provides guidance to researchers and research institutions on expected standards.

1.1 Quality of research

Ensuring high quality and promotion of research requires maintaining standards relevant to the formulation of research proposals, management of research data and primary materials, ethical conduct of research, management of conflicts of interest, and management of funds.

Research training has to be included in the basic curricula for all health professionals. Comprehensive technical guides on health research need to be compiled and made available for perusal by any person undertaking health research.

Quality research culture is grounded on the principles of honesty, accountability, creativity, valuing the diversity within the society, and respect for participants' dignity, rights, safety and well-being.

To ensure quality of research, these standards are to be maintained explicitly in the areas of:

- scientific conduct of research
- ethical conduct of research
- transparency
- conforming to administrative and legal requirements

1.1.1 Scientific conduct of research

All those involved in managing and conducting research projects have to be qualified by education, training and experience, or have to be competent to perform their tasks under the supervision of a suitably qualified person.

The research project has to be scientifically sound, and the design and the procedure of the research are to be clearly described and justified in the research protocol. The research is to be designed, reviewed, managed and undertaken in a way that ensures originality, integrity, quality and transparency.

Independent and impartial review of the research protocols by peers is considered to be the backbone of research governance. The expert scrutiny of research protocols is important during its development and as part of the ethical review process of the protocol. Once it is approved it should be followed without change or deviation. If a change is needed then the change is presented for ethical review again as an amendment to the protocol, which, then undergoes review before the amendment is approved.

1.1.2 Ethical conduct of research

The research conducted has to be guided by ethical principles in all aspects. A research project is expected to commence, especially data collection, only if a nationally accepted research ethics committee has reviewed and approved the research protocol. The duty of care owed by health and social care providers continues to apply when their patients and service users take part in research.

The research participants are afforded respect and autonomy, taking into account their capacity to understand and their cultural and religious beliefs. When participants' explicit consent is sought, it must be voluntary and informed. Appropriate methods should be used to obtain consent from patients, subjects, communities and / or guardians while ensuring that adequate time is given to make

a decision to consent or not consent. Where consent is refused or withdrawn, the person or community that has been approached must not suffer any inconvenience or reprisal.

The safety and well-being of the individual prevails over the interests of science and society. Before a research project is initiated, any anticipated benefit of the research has to be weighed against the foreseeable risks and inconveniences.

All information collected for or as a part of the research project has to be recorded, handled and stored appropriately and in such a way and for such time that it can be accurately reported, interpreted and verified, while the confidentiality of information and identity of the individual research participants remain appropriately protected. The data and biospecimens collected are managed in a transparent way that demonstrates commitment to their appropriate use for research and appropriate protection of privacy.

All information about treatment, care or other services provided as part of the research project and their outcomes are recorded, handled and stored appropriately and in such a way and for such time that it can be understood, where relevant, by others involved in the participant's care. At the same time all information is accurately reported, interpreted and verified, while the confidentiality of records of the participants remains protected

The intended deviation from normal treatment, care or other services is adequately supported by the available information. This information include evidence from previous research.

The research proposal or protocol and the participant information sheet explain special arrangements, if any, for provision of treatment after the research intervention period has ended. For example, whether the treatment will continue or change, whether the care or other services that were introduced for the purposes of the research will continue or change.

Big Data is a novel area of research that has recently emerged due to the availability of large volumes of data in an electronic form, (for example, credit card purchases of particular drugs in pharmacies). Research using such information will require special attention and possibly different criteria. The current document will not address this in detail, other than state that researchers are expected to ensure confidentiality of personal information. Guidelines will be developed on this area in the future.

1.1.3 Transparency

In order to avoid waste, information about research projects (other than those for educational purposes) are to be made publicly available before they start, unless a deferral is agreed to by or on behalf of the research ethics committee.

Other than research for educational purposes and early phase trials, the findings, whether positive or negative, are to be made accessible, with adequate consent and privacy safeguards, in a timely manner after they have finished, in compliance with any applicable regulatory standards.

1.1.4 Administrative and legal requirements

Conforming to administrative and legal requirements provides processes that guide decision making and their implementation and contributes towards the quality of research. This is dealt with in more detail in Section 02.

1.2 Collaborative research

Health research often requires the contribution of multiple disciplines and leads to a wide range of collaborations within institutions, between institutions, and with institutions from other countries. In Sri Lanka, the Code provides guidance to researchers and research institutions on maintaining standards in collaborative research by ensuring that:

- Collaborating parties enter into agreement for each collaborative research project including provision for access to research materials, ownership of data, intellectual property rights for patents and publication, managing disagreements, and management of conflicts of interest.

- Appropriate ethics and administrative clearance and approvals have been obtained for all research.

- The rights of. the clients and research participants are safeguarded when obtaining, transporting and storing of biospecimens and data. This must be done in accordance with the national standards and protocols.

- Sri Lanka's cultural and religious beliefs, ethnic harmony and values are respected and preserved.

- Sri Lankan indigenous genomic and genetic information is preserved and protected.

- Sri Lanka's indigenous medical knowledge is preserved, protected and the intellectual property is not compromised.

- Sri Lanka's biodiversity is preserved and protected.

- Sri Lanka's carbon footprint is minimized during the process of research.

- Research findings are disseminated in a timely manner and translation of research findings into policy and practice is promoted.

1.3 Monitoring and evaluation of research

Monitoring is a process that helps improve performance and achieve results. The Code specifies that each research institution should have arrangements to monitor whether the research is conducted in accordance with the approved protocol in keeping with the highest ethical standards. Institutions bear the ultimate responsibility for monitoring the research conducted by their researchers. The frequency and type of monitoring should reflect the degree of risk to research participants.

The researchers are also assigned the responsibility of monitoring their own research, as they are in the best position to observe any adverse events or unexpected outcomes. They are responsible for notifying the review body of the mechanisms for monitoring which are in place, and for convincing the review body that these are appropriate to the research. They should report such events or outcomes promptly to the relevant institution(s) and ethics review committees and take prompt steps to deal with any unexpected risks. In clinical research, especially clinical trials, research sponsors also have such responsibilities.

In clinical trials the protocol will specify the conditions under which the researcher will discontinue the trial, and the monitoring of research should aim at complying with the protocol.

As stipulated in the Code, in order to maintain standards, the monitoring of research is required to:

- Ensure that research institutions establish a mechanism in the form of a review body to monitor the research conducted by its researchers.
- Instil mechanisms by which the researchers are able to report the results of monitoring of research to the review body and or ethics review committee.

- Establish a process of investigating non-compliance to the requirements of monitoring of research or not taking appropriate actions where indicated.

- Ensure that ethics review committees monitor the progress of the research projects approved by them by using a standard format that should be made available to all researchers to submit their regular progress and by undertaking detailed reviews on a sample of approved protocols.

The evaluation mechanisms, and institutions and persons responsible for the evaluation of the research have to be explicitly named in the research protocol. Those who are assigned such responsibility are required to carry out the evaluation within the parameters of the approved protocol.

1.4 Dissemination of research findings

Ensuring standards of dissemination of research findings is an integral part of good governance of research in a country. It is a key step that facilitates translating research findings into practice, guiding future research and passing on the benefits of research to the people, the health system and the society.

The Code provides guidance to researchers on essential practices in relation to maintaining standards in dissemination of research findings by promoting and fostering an environment and a culture of honesty and integrity in the dissemination of research findings.

Protecting the intellectual property rights including patents of the country, institutions, researchers and sponsors is a requirement.

In publishing research, authors need to maintain accuracy and authenticity, and adherence to accepted criteria for authorship.

Authors have to ensure that they adhere to accepted norms in relation to citing other researches and acknowledge contributors.

Opportunities for researchers to disseminate research findings to all stakeholders have to be created by all those involved in research.

02- Administrative procedures and processes

An institution, an organization or an individual that conducts health and related research on humans is required to follow the administrative procedures and processes in relation to governance of health research. These include obtaining ethics clearance and administrative clearance and conforming to the financial guidelines of the institution in the management of research funds. Research should also be implemented within the legal and regulatory framework relevant to health research.

2.1 Responsibility of the NHRC, Sri Lanka

The NHRC, Sri Lanka has been established to provide a framework for the regulation, co-ordination, monitoring, development and management of health research in the country. Under the 13th amendment to the constitution, the conduct of research is a subject that is not devolved to the provincial councils. The role, functions and duties of NHRC in health research governance are outlined in part two of the NHRC Act.

2.2 Obtaining ethics clearance

Institutions which grant ethics clearances should have established institutional ethics review committees (IERCs) with requisite processes and procedures. The principles on which clearance is granted are based on the international guidelines, namely, those of the Council of International Organizations of Medical Sciences (CIOMS) and the World Medical Association's Declaration of Helsinki. The NHRC is currently in the process of formulating national guidelines for ethical research on humans. Further, the

proposed National Health Research Ethics Committee under the NHRC Act will provide overall governance mechanisms for ethics of health research.

International collaborative research will be required to obtain ethical review clearance from both local and partner institution ethics review committees. If the international guidelines are in conflict with the local guidelines, the local guidelines will be considered as final.

2.3 Administrative approval for research

The researchers should obtain approval from the relevant administrative authorities prior to commencement of research. The researchers and the sponsors are responsible and are expected to familiarize themselves with relevant circulars and legislation relevant to managing and conducting the research in accordance with the law of the land, the NHRC Act, the Code and the ethical guidelines.

Sanctions for non-compliance with these principles may include appropriate administrative, contractual or legal measures as defined by the funders, employers, relevant professional and statutory regulators, and other relevant bodies.

The Ministry of Health has the responsibility to ensure that research conducted is generally within the expected administrative requirements and information is obtained on all health research projects carried out at public and private sector health institutions and in community settings. The Circular No ETR/E/NHRC-Mts/11/2015 and ETR/E/NHRC-Mts/2017 (currently under revision) released on 01.10.2016 and 03.10.2017 respectively, describe the need for obtaining Ministry clearance prior to conducting health and health related research in healthcare institutions and community settings.

2.4 Managing allegations and research misconduct

The Code has specified in detail what should be identified as research misconduct and breaches of the Code of Conduct. Misconduct includes plagiarism and infringements in intellectual rights. It is essential that a transparent mechanism be available at national and institutional levels to accept, accommodate, review and recommend punitive action to those found to have committed research misconduct and breached the Code.

Identification of research misconducts and breaches of the Code may be through complaints via ethics review committees, scientific review committees or public complaints as well as complaints from participants, media, research governing bodies or professional organizations.

Complaints shall be accepted in the form of written documents. Verbal complaints are also accepted in cases where the complainant is illiterate. Further, an allegation could 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 the complaints.

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 and are also within the provisions of NHRC Act.

2.5 Administration of research funds

Making funds available is necessary and important to encourage researchers to take on research. Institutions and other organizations that fund research need explicit policies to ensure that allocation of funds is carried out in a transparent manner, by objective and fair assessment of protocols following open advertisement.

Formulation of a needs-based and prioritized national health research agenda is necessary to direct limited financial resources available for research and to address health needs of the people and the problems in the health system. Such health research priorities at national and institutional levels have to be publicized and also need periodic review.

Ensuring that research funds are managed and utilized effectively and efficiently, and in accordance with the approved budget proposal in the research protocol are the main strategies with regard to the financial governance of research.

The disbursement of funds for research, both local and foreign, is expected to be carried out in accordance with the administrative and financial regulations of the institution, the relevant ministry and the government.

2.6 Managing conflicts of interest

The National Medicines Regulatory Authority (NMRA) Act (2015) refers to conflict of interest as including any dealing with any company or undertaking which engages in manufacturing, importation, distribution or sale of medicines, medical devices, borderline products or investigational medicinal products.

Conflicts of interest in relation to funding and fiduciary conflict of interest and duty have to be declared. Conflicts of interest include issues that arise on an individual level (e.g. funding of the researcher by pharmaceutical companies), project level (e.g. funding of project by a pharmaceutical company), institutional level (e.g. links of contributing organizations to tobacco industry) and national level (e.g. research which may compromise national security or the biodiversity of the environment).

Research institutions and organizations must facilitate identification, declaration and management of conflicts of interest through published policy or guidelines on the full range of possible

conflicts of interest. These have to be brought to the attention of all researchers so that they can abide by the directions provided by the institutions and ethics review committees.

2.7 Transfer of human biospecimens and protected health information

Researchers should be aware of the commercial potential of biospecimens and genetic information. For example, the genetic information and therapeutic response of a cohort of patients having a particular disease will be invaluable to pharmaceutical companies developing targeted drugs (i.e. personalized or precision medicine).

The researchers who propose to transfer biospecimens, information with or without data (also named the biospecimen resource or provider), to an approved end user or recipient have to declare such intentions to the ethics review committees and receive approval. The transfer of material is possible only after a material transfer agreement has been duly signed by all parties. Both the provider and the recipient have to be aware that only de-identified information is sent and that the individual from whom specimens, information or data are collected cannot be identified. The recipient has a responsibility to abide by the conditions in the agreement including that the material will be used solely for the purpose agreed, will be destroyed once the purpose has been served and that the recipient will acknowledge the biospecimen source as the source of the material/information/data in oral presentations, journals and other publications.

Such material transfer agreement developed by the research institution/organization should be made available to all researchers when required.

The ownership of patents, intellectual property rights including authorship of publications, and other such rights have to be stated and agreed upon at the planning stage and are expected to be favourable to Sri Lanka.

03 - Legal framework and regulatory mechanism

3.1 National Health Research Council Act

Good research governance requires a fair legal framework with impartial, transparent decision making and enforcement. The envisaged NHRC Act (awaiting enactment) has provided for good research governance by explicitly identifying powers, functions and duties of the National Health Research Council. The NHRC is empowered to promote, develop, monitor and maintain the quality and also ensure standards of health research. The Council will promote and develop responsible and ethical conduct of research and thus protect the rights and welfare of subjects of research, animals and the environment.

There is provision to establish a National Health Research Ethics Committee (NHREC) which will in turn establish and regulate of institutional ethics review committees and investigate misconduct of research. The Act will also enable the Council to investigate and take action against research misconduct and breeches of the Code. In addition, the Act will provide for the Council to investigate and initiate actions against those who are suspected of research misconduct and of breaching the Code.

The Council will function to grant approval for transfer of biospecimens/information/data to an approved recipient and the conditions of use of such information and matters related to intellectual property, authorship and other relevant conditions.

The Council will facilitate or coordinate the evaluation and review of the performance of research institutions, laboratories and research programmes and projects.

3.2 National Medicines Regulatory Authority Act no 05, 2015

An objective of the National Medicines Regulatory Authority Act No 05 of 2015 is to regulate all matters pertaining to the conduct of clinical trials in Sri Lanka. The NMRA Act also provides for the establishment of a division, namely, The Clinical Trials Registration Division, with the responsibility to regulate and control all aspects pertaining to clinical trials carried out in Sri Lanka as authorized and regulated by the NMRA.

The objectives of the NMRA Act (2015) are to ensure that all activities related to registration, licensing and importation of investigational medicinal products are carried out in a transparent, sustainable and equitable manner.

3.3 Financial Regulations

The financial transactions related to health research have to be carried out in accordance with the conditions and requirements stipulated in the Finance Act No. 38 of 1971 and the Financial Regulations (FR) of the Democratic Socialist Republic of Sri Lanka.

All research institutions that administer and manage finances for research should clearly lay down processes, procedures and systems governing financial management of such funds. The guidelines, checklists and forms for utilization of funds have to be made known and made available to the researchers who receive research funds. The financial plan pertaining to a research project should be drawn up by the researcher based on the objectives, research outputs, deliverables and other activities associated with them and as approved by the agency /organization that granted the funds. They should obtain the approval of the research management committee or any other body set up at the institution for such purposes for the financial plan. All researchers have to familiarize themselves with these requirements and ensure that they abide by them.

The research institution should monitor the physical and financial progress of the research in accordance with the stated deliverables and the financial plan and ensure submission of progress reports of the research and financial management at stipulated intervals. Any deviation from the approved budget proposals should be done with a justification and approval of the funding agency/sponsor and with the concurrence of the research institution.

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6. Finance Act, no 38, 1971, Democratic Socialist Republic of Sri Lanka, 1971.

7. The Financial Regulations of the Democratic Socialist Republic of Sri Lanka, 1992.

List of Contributors

1. Dr. Sunil De Alwis	Additional Secretary (Medical Services), Ministry of Health; Former Secretary to NHRC; Former Chairperson of Research Committee of MRI; Member of the Professional Panel to Evaluate Research Proposals of National Science Foundation; Focal point for Policy and Coordination Committee (PCC) of the UNDP/ UNFPA/ UNICEF/ WHO/ World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP)
2. Prof. Rohini de Alwis	Chairperson, National Health Research Seneviratne Council; Dean, Research & Development, and Senior Professor in Community Medicine, Sir John Kothalawala Defense University; Emeritus Professor, Community Medicine, University of Colombo.
3. Dr. Sudath Samaraweera	Secretary, National Health Research Council; Member, Ethics Review Committee, Medical Research Institute, Colombo; Deputy Director General, Education, Training & Research (Actg.), Ministry of Health
4. Dr. Nalika Gunawardena	Member, National Health Research Council; National Professional Officer WHO; Consultant Community Physician.

5. Dr. Padmal De Silva	National Professional Officer WHO; Consultant Community Physician; Former Head, Research Unit, National Institute of Health sciences
6. Dr. Chamila Priyangi Abeywickrema	Coordinator, National Health Research Council; Medical Officer, Education Training & Research Unit, Ministry of Health
7. Dr. Umanga Sooriyaarachchi	Member, National Health Research Council; Consultant Community Physician, Education Training & Research Unit, Ministry of Health
8. Dr. Sumal Nandasena	Specialist in Public Health and Community Medicine, National Programme for Tuberculosis Control & Chest Diseases (NPTCCD)
9. Dr. Samantha Prabath Ranasinghe	Developer of e-learning Research Methodology module for Health Professionals of Sri Lanka; Ex Deputy Director-Training, Education Training & Research Unit, Ministry of Health
10. Dr. Chandima Suranji Dahanayake	Ex Director Research (Actg.), Education Training & Research Unit, Ministry of Health.
11. Dr. Dileep De Silva	Member, Research Management Committee, Ministry of Health; Con.sultant Human Resource Coordinating Unit, Ministry of Health.
12. Dr. Saumya Janakanthi Kumari	Member,National Health Research Council; Former Director, Institute of Indigenous Medicine, Sri Lanka.

13. Prof. Ajith Nagahawatta	Member, National Health Research Council; Chair Professor of Microbiology & Chairperson, Ethics Review Committee, Faculty of Medicine, University of Ruhuna
14. Prof. Anoja Fernando	Member, National Health Researc.h Council; Member, UNESCO International Bioethics Committee; Emeritus Professor, University of Ruhuna
15. Prof. Saroj Jayasinghe	Member, National Health Research Council; Chair Professor of Medicine & Founder Head,Department of Medical Humanities, Faculty of Medicine, University of Colombo; Hon. Consultant Physician, National Hospital Sri Lanka
16. Prof. Samath Dharmaratne	Member, National Health Research Council; Head and Chair Professor of Community Medicine, Department of Community Medicine & Director, Health Emergency and Disaster Management Training Centre (HEDMaTC), Faculty of Medicine, University of Peradeniya
17. Dr. Champika Wickramasinghe	Member, Research Management Committee & Deputy Director General, Non-Communicable Diseases, Ministry of Health
18. Dr. Lal Panapitiya	Member, Research Management Committee & Deputy Director General, Medical Services, Ministry of Health