

**RESEARCH ETHICS
FROM A
DEVELOPING WORLD
PERSPECTIVE**

SRI LANKAN TWIN REGISTRY

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We are grateful to Vijitha, Manel and the children, without whose support this would not have been possible.

This book is dedicated to everyone committed to creating an ethical society.

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WHY ANOTHER GUIDELINE ON BIOETHICS?

There are comprehensive guidelines for bio-medical and genetic research^{1,2,3,4} and some are from the developing world^{5,6}. Ours is not an alternative to the above mentioned, but complementary and supplementary to the existing ones. Philosophically we have taken a stand on some issues as researchers from the developing world.

We are encouraged by the recently published report by the Nuffield Council on Bioethics, recommending developing countries to take account of existing international and other national guidelines to create their own⁷.

The majority of bio-medical research has been predominantly motivated by concern for the benefit of already privileged communities. This is reflected by the fact that the WHO estimates that 90% of the resources devoted to research and development on medical problems are applied to diseases causing less than 10% of the current global suffering. The establishment of international guidelines that assist in strengthening the capacity for the ethical review of biomedical research in all countries contributed to redress⁸.

In Sri Lanka there are ethics review committees at five medical schools and also at five other academic bodies⁹. However we could not find a document to guide us on research ethics in Sri Lanka when we established the Sri Lankan Twin Registry¹⁰. There are influential international research collaborations established in Sri Lanka^{11,12,13,14,15,16,17}. However, lack of a broader ethical framework and guidance remains an issue.

This document came to light because biomedical ethics is still in its early stage of development in Sri Lanka¹⁸. Our document is not an exhaustive discussion on research ethics, and this proposal is open for further discussion. While it is important to seek generally applicable principles for biomedical research as far as possible, the international debate around some issues still continues. Although we first drafted this as a guide to the Sri Lankan Twin Registry,

the proposal has now been generalized to all biomedical research as advised by many who reviewed this document. Accordingly we have included a separate chapter for the issues important for the function of the Twin Registry.

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7. Nuffield Council on Bioethics. **Ethics of research related to healthcare in developing countries** 2002. Plymouth, UK. Researchers, sponsors and others who are involved in research related to healthcare are faced with diverse and sometime conflicting guidance. A number of developing countries (and many developed countries) have responded to this difficulty by developing their own national guidance to provide a framework for the review of the ethics of research related to healthcare in their countries. Such guidance, which should be based on an interpretation of the international guidance set out in this chapter, generally applies to both externally sponsored research and internally-funded research. Developing countries, who have taken this step, include South

Africa, Uganda, Nepal, Thailand, India, and Brazil. The development of expertise to formulate national guidance may also require education and training. We encourage developing countries to take account of existing international and national guidance and to create national guidance for its clear and unambiguous application. We take the view that, taken together, the development of national guidance and the strengthening of the process of review of the ethics of research related to healthcare will afford a further layer of protection to participants in externally-sponsored research studies and should be priorities for developing countries and sponsors of research.

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THE PROCESS OF DEVELOPING THIS DOCUMENT

The first draft of this document was written by Dr. A. Sumathipala and circulated among the Project Supervisory Committee members of the Sri Lankan Twin Registry. Amendments were made following the suggestions made by Dr. Sisira Siribaddana, Dr. Deepthi De Silva and Prof. Narada Warnasuriya. The amended draft was submitted to the Ethics Committee of the Sri Lanka Medical Association. Following their advice, changes in the presentation and format of this document were made. At the same time Dr. A. Sumathipala and Dr. Sisira Siribaddana made significant additions to its contents.

The revised draft was distributed among local and international experts in the field and interested academicians to obtain their views. We received valuable comments from some individuals as well as organisations.

We received valuable suggestions from the following local academicians Professor Diyanath Samarasingha, Professor of Psychiatry, Faculty of Medicine, Colombo, Prof Saroj Jayasingha, Professor of Medicine, Faculty of Medicine, Dr. Vasantha Bandara, Dental Surgeon, W.A.Wijewardene, Deputy Governor, Central Bank of Sri Lanka, Dr. Vinya Ariyaratne, CEO Sarvodaya, a NGO in Sri Lanka, Professor S.L Mendis, Dean Faculty of Medicine, University of Ruhuna and National Science Foundation of Sri Lanka.

We also received valuable comments from Karen J. Hofman, Acting Director, Division of Advanced Studies and Policy Analysis, Fogarty International Centre, National Institute of Health, USA.

On the issue of an ombudsman, we received views from Dr. Vikram Patel, Senior Lecturer, London School of Hygiene and Tropical Medicine and Sangath Centre, Goa, India; Dr. Martin Prince, Head of the Section of Epidemiology, Institute of Psychiatry, UK; Sophia Mukasa Monico, Co-ordinator, International HIV/AIDS Vaccine Network, ICASO, Canada; Nita Mawar, Assistant Director, SBR Unit, National

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We received valuable comments on the subsequent draft from **The Wellcome Trust's Biomedical Ethics Programme**, and also from **Dr. Richard Ashcroft**, Leverhulme Senior Lecturer in Medical Ethics at Imperial College, London. This document has been revised taking into consideration their comments as well as a recently published report, 'The Ethics of The Research Related to Health Care in Developing Countries', by the Nuffield Council on Bioethics.

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Background

Global situation

Health research is an essential prerequisite to the overall development of any country¹. National and international bodies concerned with research ethics need to confront the greatest ethical challenge, the enormous inequities in global health². Less than 10% of research funds are spent on the diseases that account for 90% of the global disease burden³. Though 93% of the world's burden of preventable mortality occurs in developing countries, too little research funding is targeted to health problems in developing countries; creating a dangerous funding differential⁴. Strengthening the health research capacity in developing countries is a critical element for achieving health equity⁵.

Sri Lankan situation

In Sri Lanka, lack of a research culture, inadequacies in research capabilities, absence of adequate incentives for research and near absence of a multidisciplinary and intersectional approach to research is a problem. However, there are influential international research collaborations taking place in Sri Lanka. Developing countries should reject the fallacy that they are only capable of carrying out basic and cheap research. There is a definitive place for advanced research to be carried out. Infant mortality rate alone will provide a good gauge for the need for research in genetic disorders. According to the WHO, any country with an infant mortality rate of less than 50, should invest in genetic research and investigation and treatment of genetic disorders. Sri Lanka has been cited as one of the countries in the South East Asian Region that need to develop an active programme of research in genetic disorders. Increasingly, genetics is extending beyond the confines of the research laboratory, and being incorporated as a part of primary care in all countries⁶.

Our vision

We aim to establish a research foundation, which brings together researchers from diverse disciplines to carry out research that will elevate the quality of life and achieve health equity and establish a partnership between the researchers and the public who should be the ultimate beneficiaries of these research endeavors.

Why a twin registry?

Twin research unites diverse disciplines and research methods. We will gradually extend our research efforts beyond twins.

Sri Lankan Twin Registry (SLTR) is an independent academic and research institution, with the aim of establishing a register for twins to facilitate research. We aim to establish a centre of excellence for twin, sibling, family and genetic studies.

The “twin method” can contribute to the understanding of genetic, environmental and developmental influence on human variation and disease. The information and knowledge gained through this research will aid in understanding the etiology of diseases and help in the prevention and treatment of them. Twin research unites diverse disciplines and research methods to form important multi-disciplinary collaborations. The governance of the SLTR is vested in a Supervisory Committee and its terms of reference are elaborated in the constitution of the SLTR⁷.

The revised Declaration of Helsinki⁸ emphasizes that the research is justified only if the population to be studied stand to benefit. Therefore a sister organisation of the twin registry, the **Multiple Birth Foundation**, was formed to organise twins, multiples and their families. Its aims are to raise the awareness of unique challenges and issues faced by the twins, multiples and their families and to initiate steps to build services to cater to their needs by working with professionals, statutory services and government policy makers.

New issues

Rapid progress of bioscience will create the need for continuing development of the national standards on ethics in research. Therefore we will encourage discussions on ethical issues and establishing consensus on policy and guidelines. We plan to work towards an ethical framework for the country for twin and genetic research and development of the national standards on ethics in research in all countries. We plan to work towards an ethical framework for the country for twin and genetic research.

It is possible to assign contemporary positions or streams of thought in

bio-ethics more or less along the lines established in the classical Hellenistic period of Western philosophy⁹. The issues that dominate ethics in medical literature reflect the ethnocentric western philosophical and scientific tradition in which they are grounded. It is increasingly recognised that this philosophical and epistemological tradition is neither universal nor of overriding importance and that moral “rights” and “wrongs” are not absolute but may vary with the culture in which we live¹⁰.

Although culture is an extremely complex concept, and one that is difficult to adequately define, it is a major determinant of customs and social and moral norms, and plays a central role in shaping people’s values, beliefs, knowledge, behaviour and social interaction¹¹. Buddhist philosophy has several discourses on bio-ethics. These have contributed to the current debate on bio-ethics to such an extent that there is a journal¹² and several books¹³ devoted to Buddhism and bio-ethics. Inevitably Buddhist and Hindu philosophies have had a considerable influence on the ethical and moral values of Sri Lankan society. Buddhism can be viewed as a system of thought that has made a lasting and significant contribution in the history of moral thinking. Both in its origin and later development, ethical concerns have played a central role in Buddhism. This philosophy consists of a rich moral vocabulary, a distinct normative basis for moral action, doctrines that are of great significance to the moral philosopher and those interested in the development of moral ideas¹⁴.

New initiatives such as establishing a twin register and genetic facilities will inevitably create an essential need to bridge the existing divide between North-South bio-ethical philosophies. This draft document on bio ethics saw the light of day to fulfill this need.

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In the history of Indian thought, Buddhism evidently assumed the role of a moral reform movement, directing its moral critiques against the superstitions and rituals of both the sramana and brahmana traditions of 5th century B.C. The scriptures preserved under the Suttapitaka of the Theravada Pali cannon, which have parallels in the scriptures of other Asian Buddhist scriptural traditions preserved in languages such as Chinese and Tibetan, can be viewed as the most authentic sources for the reconstruction of the ethical doctrines of Buddhism.

CHAPTER 1

Outline Of The Document

Our ethical document is based on the following fundamental principles:

- * Foster international collaborations for mutually beneficial research, based on an agenda set by the developing world.
- * Capacity building in the developing world.
- * Third party to ensure freely given informed consent and ongoing monitoring of research.
- * Protect the national ownership from undue commercial exploitation.
- * A statutory framework robust enough to protect public interest but balanced enough to allow new developments.

Foster international collaborations for mutually beneficial research, based on an agenda set by the developing world.

Due to historical reasons, knowledge, skills, expertise, research funds and journals are available in the west and there is no doubt about the role of the developed world. Therefore North-South collaborations will be essential but South-South collaboration and net working is also essential to ensure maximum utilisation of capacity within the different regions of the developing world.

The partnership model for collaboration can produce high quality research with greater influence on national policy and practice. Expatriates having active links in both worlds will have a significant role to play¹.

Any North-South collaborations should be mutually respectful and beneficial partnerships. No collaboration in research should be entertained solely for economically cheap and easy research in the developing world. Exclusive rights should not be demanded nor agreed to by the donors or collaborators. Eventual economic and other gains should be ethically shared. However this sharing should not be for individual benefit but for the public good.

Capacity building in the developing world to reduce the global divide

It is essential that the developing countries should create a strong national research infrastructure so that they can define priorities for health research, influence national, regional and global health agendas, and lobby for equitable allocation of resources². International collaborative research projects should contribute to capacity building in the country. Successful building of research capacity depends on national governments incorporating capacity building into their national plans, i.e. in research infrastructure³. Health research capacity is the ability to define problems, set objectives and priorities, build sustainable institutions and organisations, and identify solutions to key national health problems. This definition encompasses research capacity at the levels of individuals, research groups, institutions, and nations³. Investment in research capacity would need to be made for the middle to long term, and it should be better co-ordinated and strategically deployed. It should be programme-based rather than project-based, and should make a more serious commitment to building local, national, and regional institutions⁴. Autonomous research institutions attract funding and reduces the administrative burden⁵.

Third party (ombudsman) to ensure freely given informed consent and ongoing monitoring of research

Informed consent is inadequate protection because of the asymmetry in knowledge and authority between researchers and subjects⁶. Clinicians should be mindful of the tremendous influence they have over their patients⁷. Due to this reason, especially in developing countries, it is difficult for patients to refuse to participate in research. The ombudsman's role may be helpful to decide whether the consent was really autonomous and voluntary. Ombuds-structure is not an alien concept. In the Helsinki Declaration, the 10th clause of the 12 basic principles states that, "When obtaining informed consent for a research project the physician should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case a physician who is not engaged in the investigation and who is completely independent of this official relationship should obtain the informed consent⁸".

Granting of ethical clearance alone is inadequate and ongoing monitoring of the progress, developments and adherence to the protocol is essential. The role of an ombudsman will be beyond ensuring freely given informed consent and also for monitoring any significant departures from the protocol for which the ethical clearance was granted⁹.

Protect the national ownership from undue commercial exploitation

Under no circumstances should exclusive rights or ownership for commercial exploitation be granted to any collaborator or funding agency. If there are research findings of any commercial value, the major proportion of financial returns should go to the relevant participating population. Compensation for participation in any commercially exploited research “could better take the form of ensuring technology transfer, scientific, technical and medical training, installation and ongoing maintenance of infrastructure such as laboratories, libraries, etc¹⁰”.

If any project has potential for commercial exploitation, it should be made clear at the outset in the ethical application and also to the participants during the informed consent process.

Statutory framework robust enough to protect public interest but balanced enough to allow new developments

We believe that there is a need for a central mechanism to implement the above proposals to safeguard the national interest and ownership. Therefore it has to be a statutory framework represented by the academics, research participants, relevant government organisations, opinion leaders, policy planners, and political leaders. However this mechanism should not be a bureaucratic hindrance to the advancement of science and technology, but should facilitate the process.

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CHAPTER 2

Ethical Considerations

Policy

1. Ethical researchers must pursue their scientific aims without compromising the rights and welfare of human subjects.
2. The four fundamental moral principles¹ are namely
 - (i) Autonomy: respect for decisions, which self regulate
 - (ii) Non maleficence: cause no harm, do no harm
 - (iii) Beneficence: prevent harm, do good
 - (iv) Justice: fairness

These moral principles form the core of western bio-ethics but is not alien and is easily applicable to Sri Lankan society, which is heavily influenced by the Buddhist and Hindu philosophies.

The Buddhist teachings consist of moral values, which have universal application. The supreme virtues of Buddhism can be summed up in negative terms as the absence of greed, malice and ignorance, and in positive terms as the perfection of compassion and wisdom. In practical terms it is an ethics of self-transformation. In formal terms, Buddhist ethics appear to contain some features common to consequentialist and utilitarian theories of ethics².

3. We endorse principles of ethical theory espoused by the Nuffield Council³ namely:
 - (i) *the duty to alleviate suffering*
 - (ii) *the duty to show respect for persons*
 - (iii) *the duty to be sensitive to cultural differences and*
 - (iv) *the duty not to exploit the vulnerable*
4. We endorse the Council for International Organisation of Medical Sciences (CIOMS) guidelines and recommendations⁴, which call for universal principles of ethical research. At the level of population, concerns with consent in population studies and differing cultural mores and values led to these recommendations. Although the medical care is not the same, research standards should be the same throughout the world⁵. Although there are fundamental human values which should form the basis of all

bio-ethical reflections, there should be some regard to other cultural values upon which all societies will not necessarily agree⁶. Therefore while being guided by international conventions on human research, we will also look into specific local needs and concerns with regard to ethical issues.

5. We will be guided by the principles of privacy⁷ and informed consent, confidentiality, maximising benefits, minimising harm, safeguarding against conflict of interests or competing interests, rights of the research participants and quality control.
6. Competence of the researcher is the first guiding ethical principle and is the essential prerequisite for ethical research. It is however, with the assurance of both appropriate training and quality control that respect for human dignity begins. Indeed, the implementation of other ethical principles depends on the assurance of competence⁸. Competence includes appropriate planning, training, pilot and field- testing and quality control through continual review⁸.
7. Ensure higher ethical standards in research, through increasing awareness within the scientific community and the public and capacity building at an individual, institutional and national level.

Guidelines:

Research undertaken should comply with the following guidelines,

1. To be guided by the declaration on medical research, its recommendations guiding the physicians in bio-medical research involving human subjects⁹, adopted by the 18th World Medical Assembly, Helsinki, Finland, 1964, and its' amendments at the 29th Assembly in Tokyo, Japan in 1975, and at the 35th Assembly, Venice, Italy in 1993 and the 5th Amendment¹⁰.
2. To be guided by the international ethical guidelines for bio-medical research involving human subjects, 2002, by the Council for International Organisations of Medical Sciences and the World Health Organisation¹¹.
3. To be guided by the Statement on the Principled Conduct of

Genetic Research⁸.

4. To be guided by the Nuffield Council on Bioethics³ report on the ethics of research related to health care in developing countries.
5. Main areas of ethical concerns include, quality of the research and competence of the researcher, informed consent, confidentiality and data protection, rights of the research participants, access to human specimens and genetic material, compensation and commerciality, patenting, funding and conditions for funding, and responsibility and authorship of publication of results.

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 - (i) Autonomy: the meaning asserts rather than claims, a right of non-interference to make decisions for oneself, to be self-determining. In appraising the autonomous action of others, it is said that we should allow them the same right to their choices and actions as we have to our own. This perspective is often referred to as the 'principle' of respect for persons because it promotes the view that the individual is both responsible for, and the rightful determiner of his or her own life.
 - (ii) Non maleficence: the non-infliction of harm, or the duty of non- maleficence is often described as the foundation stone of social morality and is to be found in the Hippocratic oath.
 - (iii) Beneficence: can be defined as 'active well doing', altruism, conduct aimed at the good and the well being of others.
 - (iv) Principle of justice: in the general sense, justice refers to de facto standards and expectations which any society holds concerning relations between the member/s of that society and, further more, concerning that which is due rendering to any member of that society. That is quite beyond the laws which govern any society. There are standards and social mores which suggest that people should live up to their obligations to one another.
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11. Council for International Organisations of Medical Sciences (CIOM, 2002). International ethical guidelines for biomedical research involving human subjects. Geneva.

CHAPTER 3

Informed Consent

Policy:

1. In parallel with advances in medicine there has been a shift in bio-ethics from a paternalistic ethic governed by doctors to one based on the patients' autonomy and integrity¹.
2. Consent² is informed when it is given by a person **who understands the purpose and the nature of the study**, what participating in the study requires the patient to do and to risk, and what benefits are intended to result from the study³. It should be reiterated that there may not be any personal benefit at all to the participant.
3. Genuine consent to participate in research must be obtained from each participant.
4. For the consent to be valid there should be personal competence, procedural competence and material competence⁴.
5. Informed decision to participate can be individual, familial, or at the level of communities and populations. Under certain conditions with proper authority, anonymous testing for epidemiological purposes and surveillance could be an exception to consent requirements⁵. **However ethics committee approval must be in place before research may go ahead without seeking individual consent⁶.**
6. When it is not possible to request informed consent from every individual to be studied, the agreement of a community group may be sought, but the representative should be chosen according to the nature, traditions and political philosophy of the community or the group³. **However ethics committee approval must be in place before research may go ahead without seeking individual consent and this approval should include a choice of a community representative⁷.**

Guidelines:

Research to be undertaken should comply with the following guidelines:

1. The Principal Investigators (PI) should be responsible to ensure that the research participants selected for a particular study provides freely given informed consent. A designated

member of the research team could obtain the informed consent but an independent third party (**an ombudsman**) such as a representative of the research participants or the community, or any other person independent to the research team, should be present as an observer to ensure that the process of informed consent is genuinely carried out, preferably in sensitive, high risk and complex research. The decision to appoint an ombudsman should preferably be decided by the ethics review committee who approve the research.

We believe that, involving an ombudsman is a better way of eliminating potential untoward compliance arising because of the authoritative position held by the clinicians and adherence to the informed consent process. An ombudsman could also monitor any significant departure from the protocol for which the ethical clearance was granted.

Involving an ombudsman is not compulsory in all research projects and will depend on the sensitivity, complexity of the project and the degree of potential harm to the research participant. **(This ombudsman role will be further researched and developed)**

2. If the research participants are less than 18 years of age (minor), informed consent of the parents or the responsible adult will be obtained. However if the minor does not consent then that decision will be respected, even if the responsible adult consents.
3. Even if the research participants are above the age of 18 but unable to provide valid informed consent in conditions such as with the mentally handicapped and serious mental disorders, extra precautions should be taken to protect the rights of the participants. In these instances, even obtaining consent from parents or the responsible adult (care givers) should be carried out with extra care⁸. In these cases, having an impartial third party approach could reduce medical vulnerability⁹. (Ombudsman's role).
4. Details of the project should be explained in the language which is best understood by the research participant, based on the information leaflet supplied by the applicant, with the protocol

approved by the relevant ethics committee/s. This should also include information about the process of taking samples (if relevant) including risks, if any, the general purpose for which the samples will be taken and immediate benefits or disadvantages of the volunteer or the society. Guarantee of confidentiality and their right to refuse to participate without any detriment to their future health care should be reiterated in the information leaflet. This section should also be read in conjunction with the chapter on collection, storage and access of human biological material including genetic material (**chapter 6**).

5. If the data collection is entirely by post, an information leaflet should be posted with a form to provide informed consent in writing. The ombudsman will have no role in this situation, but ethical clearance would be sufficient.
6. Research participants who agree to participate will be made explicit so that they can withdraw at any stage of the project.
7. Informed consent has to be obtained in writing on the form specifically designed for this purpose.
8. Informed consent given to participate in a project is valid only for that specific project unless otherwise specified at the time of making the ethical review application. If the investigators plan to obtain more general consent, for example retention of samples for purpose of future use, this should be disclosed to the ethical review body as well as to the potential participants about: (**refer to chapter 5, 6, 8**).
 - a. the plan for storage of any left over human biological material
 - b. request consent for storing or destroying it
 - c. the fact that no further investigations will be performed without the written consent of the individual whose human biological material DNA is being tested.

References and End Notes

1. Aslka Syse. Norway: valid (as opposed to informed) consent. *Lancet*. 2000; 356:1347-8
-
- Personal competence: person concerned (or the representative) must have formal competence to take the decision in question and must possess the mental capacity to consent. Specific provisions about representation are

required in the case of a minor or incompetent patient.

Procedural competence: the consent given must not be influenced by defects in the contractual assent. The consent must be of the quality that the situation requires.

Material competence: the consent must relate to an issue to which the patient validly may consent. Penal codes usually define what a person validly may consent to.

2. Alderson.P, Goodey. C. Theories of Consent. *BMJ*; 1998; 317:1313- 1315.
3. Council for International Organisations of Medical Sciences (CIOM, 1991). **International guidelines for ethical review of Epidemiological Studies**. Geneva.
4. Nuffield Council on Bioethics (1995). Human Tissue; ethical and legal issues: Paragraph 6.02. Nuffield Council on Bioethics, London
5. Wertz DC. et al. **Guidelines on Ethical Issues in Medical Genetics and Provision of Genetic Services**. World Health Organisation.Geneva.1995.
6. US regulations make provision for waiver of consent under 5 conditions:
 1. all components of the study involve minimal risk or any component involving more than minimal risk must also offer the prospect of direct benefit to participants;
 2. the waiver is not otherwise prohibited by state, federal or international law;
 3. there is an adequate plan to protect the confidentiality of the data;
 4. there is an adequate plan for contacting participants with information derived from the research, should the need arise;
 5. in analyzing risks and potential benefits, the institutional review board specifically determines that the benefits from the knowledge to be gained from the research study outweigh any dignitary harm associated with not seeking informed consent.
7. Nuffield Council on Bioethics. Ethics of research related to health care in developing countries. 2002. Plymouth.UK
8. **MRC ethics series guidelines**. Ethical conduct of research on the mentally incapacitated. 1993
9. Report and recommendations of the National Bioethics Advisory Commission. Ethical and policy issues in research involving human participants. Bethesda, Maryland, USA. 2001

CHAPTER 4

Data Collection, Documentation, Storage And Access To Databases

Policy:

1. Even if a register or a database is population-based, as far as individual research projects are concerned, voluntariness is the hallmark. Inclusion in a register or in a database will not compel registrants to participate in research, unless they wish to do so. The research participant will have the right to decide to or not to participate in specific research activity. (Also see **Chapter 3** on inform consent section **G2**)
2. Genetic, disease specific or population-based databases are powerful research tools. These enormously powerful research tools should be used with extreme caution. All possible steps should be taken to prevent potential abuse. It should be ensured through conducting high quality research, combined with the best possible ethical standards. (Also refer to **Chapter 2, G1- G5**).
3. Data collection, data storage and access to the data should be governed by the fundamental principles of respecting and observing the rights of the research participants, maintaining confidentiality and protecting personal, medical and genetic information of research participants.
4. Privacy and protection against unauthorised access should be ensured by confidentiality of information. Coding of information, procedures for controlled access, policies for transfer and conservation of data, samples and information should be developed.
5. Issue of confidentiality and access could be addressed at two levels¹:
 - (i) Confidentiality and access to database, either collected for specific projects or already stored. (Also refer to **Chapter 5** Policy on the Collection, Storage and Access to Human Genetic Material)
 - (ii) Maintaining the privacy of the registrants themselves and the confidentiality of the individual data.
6. Careful and responsible documentation of all research and

its data is one of the fundamental needs of ethical research. The retention of accurately recorded and retrievable results is of utmost importance for the progress of scientific inquiry².

Guidelines:

1. Database or a register should preferably have a separate computer/s for storing the data.
2. The database or a register should be based in the country of origin (Sri Lanka) and the original database should not be released or allowed to be taken out of the country of origin.
3. Regular backup copy updated should be kept for use in emergency situations where the data are lost from the computer due to technical problems.
4. It should have a coded login number and a password, which will only be known to designated persons within a registry or database. Only these designated persons will have direct access to the database information.
5. No other person should be authorized to access the database without prior approval.
6. Unauthorized retention of personal copies of the database is prohibited.
7. The researchers should agree to maintain the confidentiality of data.
8. The registries or managers of databases should assist researchers in drawing random samples for approved projects and also in contacting the research participants for data collection.
9. The registries or managers of databases should inform the research participants selected for a specific study and also obtain the informed consent as described in **Chapter 3**. Registrants should also be reminded that all contact will be through the

registry database managers, and any unauthorised access should be brought to the notice of the respective registries or database managers. Consent given for one study will not be valid for another.

10. All collaborators with any such database or registry should try to share the data with the registry. This data should be stored in a computer maintaining the central database. Investigators of authorized research projects can retain copies of the primary data for his/her own use. However in no instance should primary data be destroyed while investigators and readers may raise questions answerable only by reference to such data².
11. Individual research participants should have the right to obtain his/her personal data for non-commercial purposes, especially for medical reasons.
12. The Registry to the best of its ability should not deliberately try to recruit the same research participant for more than one study. This is with an aim not to abuse their goodwill or contribution, as it will affect the quality of the data collection.
13. Any other data protection laws of the country should also be observed if it is appropriate and wherever possible.

References:

1. Knopers BM, Hirtel M, Lormeau S. Ethical issues in international collaborative research on the Human Genome. *Genomics*; 1996; 34:272-282. 12
2. **Guideline for investigators in scientific research.** Prepared by Harvard Medical School. 1988. USA.

CHAPTER 5

Collection, Storage And Access To The Human Biological Material Including Genetic Material

Policy:

1. Biomedical researchers have long studied human biological materials- such as cells collected in research projects, biopsy specimens obtained for diagnostic purposes, and organs and tissues removed during surgery- to increase knowledge about human diseases and to develop better means of preventing, diagnosing and treating these diseases. Today, new technologies and advances in biology provide even more effective tools for using such resources to improve medicine's diagnostic and therapeutic potentials. Yet, the very power of these new technologies raise a number of ethical issues. The novelty of this field means that the potential harm to individuals who are the subjects of research, are poorly understood and hence can be over or underestimated¹.
2. While protecting the rights and interests of the subjects through proper guidelines and principles, the **scientific community has a duty and responsibility to carry out scientific research on human subjects.**
3. The researchers should be guided by the "Statement on the Principled Conduct of Genetic Research"², the National Bioethics Advisory Commission, and the publication by the British Medical Association: "Human Genetics - choice and responsibility"³, MRC guidelines on " Human tissue and biological sample collections for use in research"⁴.
4. Researchers should maintain confidentiality, and protect from exploitation of genetic data of research participants. All research involving the use of genetic material should require informed consent. (Also refer to **Chapter 3**)
5. Issue of confidentiality and access may be addressed at two levels⁵.
 - (i) Confidentiality and access to samples either collected for specific projects or already banked. (Also refer to **chapter 4** Policy on the Data Collection, Storage and Access to the databases)
 - (ii) Maintaining the privacy of the sampled populations themselves and the confidentiality of the individual data.

6. All human biological material if collected during a research project involving an existing database/registry, should preferably be stored in that particular registry or laboratory. Permission should not be given for this material to be taken out of the country. However, the data originating from such research will be the property of the researchers and can be taken out of the country.
7. Recent experience in Iceland shows that the creation of large-scale databases of personal information linked to DNA collections can be highly controversial⁶. Therefore before establishing such databases, discussions and consensus generation in academic circles and in interested parties of the public, concerning the possible use and misuse of such research resources is needed.
8. When informed consent to the use of human biological materials is required, it should be obtained separately from informed consent to clinical procedures¹.
9. Guideline for genetic research will also be based on other current and international local policies and guidelines. These guidelines will be updated to maintain any further development of ethical practices.
10. As genetic research may require foreign expertise, guideline of international collaboration, funding and commercial exploitation will have to be considered in conjunction with this section. **(Chapters 6,7,8)**
11. The emphasis of this document is confined to genetic research in general but can be extended to twin, sibling and family studies⁴. **Human stem cell research, cloning, pre-implantation genetics and other advances are not dealt with here.** These will also be considered for consensus development in the future.

Guidelines:

1. All proposals involving genetic testing of human biological material should be referred to a research ethics committee.

Ethics Committee approval should also be obtained from all countries collaborating in research, including where that collaboration takes the form of funding only.

2. Collection of samples from research participants should be specified by type, volume and frequency of sampling in the project proposal and in the information leaflet for the research participants. Minimal invasiveness and low sample frequency is encouraged and adherence to the written protocol will be expected. Any changes (for example in the case of sample loss or failure to extract DNA) should be notified to the responsible committees/ombudsman overseeing the project. Re-sampling may be permitted with the consent of the research participants concerned.
3. The use of samples for testing specific genetic disorders without prior counselling of research participants should not be carried out. If medically relevant information regarding the present or future health of participants is likely to be generated, this should be made explicit in the proposal and the consent sheet.
4. The participants should be informed in simple language using an information leaflet containing the following:
 - a. The purpose of the specimen collection and any likely benefits and disadvantages of this research to the volunteer or the registry/database
 - b. Guarantee of confidentiality and their “right to refuse” without detriment to their future healthcare
 - c. Describe any risk of the procedure
 - d. The type, volume and frequency of the samples
 - e. Named investigator or contact who can answer any queries about the project, including the address, phone number and email address
 - f. The plan for storage of any leftover genetic material
 - g. Request consent for storing or destroying it
 - h. Explain that no further investigations will be performed without the written consent of the individual whose DNA is being tested

5. Participants who agree to participate should be asked to sign a consent form and indicate their preference either for storage or destruction of DNA after the investigation is completed.
6. The research participants who consent to genetic testing as approved by an ethical committee, should be contacted by the registry or database managers or by the researcher if approval is given for the investigator to do so. A representative of the registry of database manager or an ombudsman will have the right to supervise/inspect the specimen collection.
7. Any specimen collected for a specific project can only be used for the specific project for which the ethical permission was granted, unless prior approval has been obtained as specified in **Chapter 3 section G 8**.
8. Leftover specimens can be stored with the written consent of the individual (or destroyed if the individual does not consent). Further investigations using these samples will require a new application to an ethical committee with the endorsement of the registry or the managers of a database. Following the above approval, a fresh informed consent should be obtained from the research participants.
9. Once a genetic database is established and samples are stored centrally, further sampling may not be necessary. However the other aspects of the research projects will be required to go through the same procedures to obtain ethical approval. Obtaining informed consent will also be essential for projects using identified samples.
10. Following are the categories of genetic and other human biological materials¹:
 - (a) Stored collections (repository)¹
 - (i) Unidentified collections: For these specimens identifiable personal information was not collected or, if collected, was not maintained and cannot be retrieved by the repository.
 - (ii) Identified specimens: These specimens are linked to personal information in such a way that the person from whom the material was obtained could be identified by name, personal

identification number or clear pedigree location (i.e. his or her relationship to a family member whose identity is known).

(b) Research samples¹.

- (i) Unidentified samples: Sometimes termed “anonymous,” these samples are supplied by a registry or database to the investigators from a collection of unidentified human biological specimens.
 - (ii) Unlinked samples: Sometimes termed “anonymized,” these samples lack identifiers or codes that can link a particular sample to an identified specimen or a particular human being.
 - (iii) Coded samples: Sometimes termed “linked,” or “identifiable,” these samples are supplied by a registry or a database to the investigators from identified specimens with a code rather than personally identifying information, such as name or identity card number etc.
 - (iv) Identified samples: These samples are supplied by a registry or from a database from identified specimens with a personal identifier (such as a name or person number) that would allow the researcher to link the biological information derived from the research directly to the individual from whom the material was obtained¹.
11. Human biological material and genetic data storage (a) Access to all such data, which are stored by registries or databases, should be restricted to designated individuals of the registry or database and will only be via a designated representative. The designated individual should be requested to sign a written agreement with the supervisors of a registry or the managers of a database on the conditions under which this right has to be recorded in a logbook or a database maintained at all times in the registry
- (b) Human biological material and genetic material stored at the registry or a database if released, should be done without the identification of the name or the address of the research participants. But information regarding their age, ethnic origin, location or gender can be given. (Coded samples).
 - (c) Collection of other relevant data (for example medical history, biochemistry) should be permitted if approved by the ethics committee and permitted by the registry.

12. For the above mentioned unidentified samples, individual informed consent may not be possible because these samples come from stored unidentified collections mentioned in section **G 10 (a)(i)** in this chapter. However, any fresh research project requesting the use of such samples are still required to submit a written project proposal, which should be reviewed by the relevant ethics committee.
13. Research conducted with unlinked, coded or identified samples is research on human subjects and therefore will have to undergo all normal procedures specified in this document.

References:

1. National Bioethics Advisory Commission. Research involving human biological materials: ethical issues and policy guidance. Executive summary. 1999. Rockville, Maryland, USA.
2. National Bioethics Advisory Commission. Research involving human biological materials: ethical issues and policy guidance. Vol. 1 report and recommendations of the National Bioethics Advisory Commission. 1999. Rockville, Maryland, USA.
3. British Medical Association. Human Genetics- choice and responsibilities. 1998. Oxford University Press, Oxford, UK.
4. www.mrc.ac.uk/pdf-tissue_guide_fin.pdf
5. Knopers BM, Hirtel M, Lormeau S. Ethical issues in international collaborative research on the Human Genome. *Genomics*; 1996; 34:272-282.
6. Kaye J, Martin P. Safeguards for research using large scale DNA collections. *BMJ* 2000; 321: 1146-9
7. www.mrc.ac.uk/pdf-tissue_guide_fin.pdf

CHAPTER 6

Funding

Policy:

1. Any researcher is under obligation to ensure that the research which is undertaken, is conducted and the results are published “for the public good”. Therefore they should make all possible efforts to secure funding from research charities, donations, from charitable organisations and individuals.
2. However the research institutions throughout the world are under enormous pressure due to the limitation of charitable funding. Only 5% of global research funds are devoted to studying the developing world’s health problems¹. Availability of national funding is also limited. Therefore, researchers may be confronted with situations to secure funding and other support from non-charitable organisations, mainly from business establishments, either with or without any specific area of interest relevant to research.
3. Researchers should be sensitive to the potential complications arising from such funding, particularly from the potential conflict of interest/competing interests² between the research interests of academics and commercial interest of business organisation. Therefore it is advisable to lay down and agree on unambiguous terms and conditions in advance for accepting or not accepting such funding, with a view to prevent/limit any possible misuse/abuse or exploitation of the research participants. The main areas of concern are:(1) ownership of data, (ii) ownership of human biological material, (iii)commercial exploitation and patenting. All these issues are dealt with in this document and should be taken into consideration.
4. Funding from non-charitable sources should be considered on a case-by-case basis and the process of decision-making should be fully transparent. Arriving at a decision should be in accordance with the first four principles discussed in

Chapter 1. It should be a collective decision by the managers of the database or registry. The source of the non-charitable funding and the amount should be disclosed to the relevant ethical committee.

5. The above policies should be read in conjunction with the chapters on informed consent, data collection, documentation, storage and access to the database, collection, storage and access to human biological material including genetic material, commercial exploitation and the chapter on ethical consideration.

Guidelines:

1. Neither any individual in the management of the registry or database nor any researcher given permission by an ethics committee for a research project, may enter into any agreement with any commercial enterprises that will, in any way, allow commercial exploitation of any knowledge gained as a result of research being conducted, if this has not been disclosed to the ethics review committee and also disclosed to the research participants at the time of obtaining informed consent. However if the research findings are commercially valuable, the researchers should obtain clearance from the same ethics committees involved in the prior approval of the research, and the managers of the database or the registry before proceeding further.

References:

1. Jesus Marie J, Lozano JM, Duley L Erasing the global divide in health research. *BMJ*;1997;314:390.
2. Smith R. Beyond conflict of interest. *BMJ*; 1998; 317:291-292.

CHAPTER 7

Commercial Exploitation

Policy:

Our policy on this aspect will be governed by our opinions and interpretation of two main concepts, namely compensation and commerciality.

1. On principle, the issue of **compensation** can be viewed from two different angles. One is “a payment for initial participation” and the other is “that of participating in the eventual economic benefit.”¹
2. Individual or group **compensation for initial participation** can be considered as an inducement for participation². However an appropriate payment for research participants for traveling and subsistence could be considered and agreed, in advance. This subsistence payment for the research subjects should be based on the **wage-payment model**³. It operates on the notion that the participation in research requires little skill but takes time and effort and requires endurance of uncomfortable procedures. The basis is that all subjects performing similar functions will be paid similarly and the payment is based primarily on the time the subjects spend participating in the research. Application of the wage payment model would lead to the payment of fairly low, standardised hourly wages, augmented by an increase for particularly uncomfortable or burdensome procedures.
3. The payment is **not made** “on the basis of the sale of blood or other bodily tissues but on the basis of their co-operation in a scientific programme⁴. Undue inducement through compensation for individual participants will not be encouraged⁵.
4. At present, the wage payment model is considered as the model of choice, which coupled with commitment to rigorous research, will most effectively balance the increasing need for human research subjects. It will also guarantee adequate protection to those who make such research possible. This model

has advantages of the wage payment model over market and reimbursement models.

5. The ethics of incentives is yet a permanent problem⁶. This issue is extensively discussed in the Nuffield Council of Bioethics guidelines⁷. This guideline discusses the relationship between harmfulness, proportionality and vulnerability.
6. The 2000 version of the Declaration of Helsinki now offers an unambiguous ethical road map for research, especially in the developing countries⁸. Accordingly, at the conclusion of any research study every patient entered to the project should be assured of the best-proven prophylactic, diagnostic and therapeutic methods identified by that study⁹. However this revision has sparked a debate on ‘uniform care requirement’¹⁰. While being aware of the advantages and disadvantages of the ‘uniform care requirement’, we believe that ethical committees in the developing countries should follow the Nuffield Council on Bioethics guidelines on Ethics of Research related to Health Care in Developing Countries⁷ **Chapter 7** ‘Standards of Care’ closely.
7. We take the view that **compensation for participation** in any commercially exploited research “could better take the form of ensuring technology transfer, scientific, technical and medical training, installation and ongoing maintenance of infrastructure such as laboratories, libraries, etc¹.”
8. The principle of reciprocity of partnerships will be respected. However, the researchers under no circumstances should agree to **exclusive rights** for commercial exploitation by any funding agencies. Researchers and research institutions should agree on a percentage figure for the sharing of eventual economic gains if and when the patents are developed, provided the researchers agree on commercial exploitation of the findings.
9. If the Ethics Committee grants permission to any project that is commercially exploitable, it should be made clear at the outset to the participants and must be part of the recruitment and informed consent¹¹.

10. For those who are helping in a research study and whose' government salaries are miserably small, incentives may be obligatory if they are to be persuaded to assist. Their help has to be paid for, but these payments can bring jealousy and discord among colleagues⁶.
11. Patent law has structural effects on the development of economies and is more suited to countries with well-established industries. Additionally, the lack of skilled intellectual property lawyers in some countries will most likely result in these countries not being able to take the full advantage of the patenting systems. Therefore the enforcement of patent law must be balanced by other arguably compelling ethical and legal considerations for the benefit of the developing nations.

Guidelines:

1. For the research participants who are being studied, ordinary thoughtful care should include a bare minimum for transport and subsistence. Such payments should not be considered as incentives⁵. The amount has to be agreed to by the researcher in advance, at the protocol review stage.
2. The researchers under no circumstances should agree to **exclusive rights** for commercial exploitation by any funding agency. Researchers, research institutions, managers of the databases or registries should decide on a percentage figure for sharing of economic gains if and when the patents are developed, provided the above mentioned parties agree on commercial exploitation of the findings in advance.

References:

1. Knopers BM, Hirtel M, Lormeau S. Ethical issues in international collaborative research on the Human Genome. *Genomics*; 1996; 34:272-282.
2. Knopers BM, Chadwick R. The Human Genome Project. Under an international microscope. *Science*; 1994; 265: 2035.
3. Dickert N, Grady C. What's the price of a research subject? Approaches to payment for research participation. *NEJM*. 1999; 341:200-3

4. Subcommittee on population genetics of the UNESCO International Bioethics Committee. Draft report on “Bioethics and Human genetic Research”. (1995)_<http://www.charm.net/~rafi/19932.html>.
5. Ethics statements of the Human Genome Organisation, available at: <http://www.hugo-international.org/hugo/statements.html>
6. Parry E. The ethics of clinical research in developing countries. *J R Coll Physicians Lond.* 2000; 34: 328-9
7. Nuffield Council on Bioethics. Ethics of research related to healthcare in developing countries. Nuffield Council on Bioethics. London, UK. 2002.
8. Ramsay S. World Medical Association strengthens Declaration of Helsinki. *Lancet.* 2000; 356:1336.
9. Editorial. Fifth Amendment for the Declaration of Helsinki. *Lancet* 2000; 356:1123
10. Killen J., Grady C., Folkers GK., Fauci AS. Ethics of clinical research in the developing world. *Nature Reviews Immunology.* 2002; 2: 210-215.
11. The Human Genome Diversity Project, North American Committee. Draft “Model Ethical Protocol for Collecting DNA Samples. 1995.

CHAPTER 8

International Collaborations

Policy:

1. Collaboration is a true partnership with sharing of knowledge, expertise, skills and resources. It is a mutually profitable exchange and not a dependent relationship that can be exploited.
2. Research in developing countries are influenced by a semi-colonial model¹; i.e. “postal research” where developing countries courier biological samples to the west, “parachute research” whereby western researchers travel to developing countries and take back biological samples, and “annexed sites research” led and managed by expatriate staff. Undoubtedly these annexed sites have produced some of the most influential and innovative research in tropical medicine, and many of the best researchers are trained in these annexed sites. There are several disadvantages of this type of research. Merger of “annexed sites” with appropriate national partners would be preferable and mutually beneficial¹. This is the “partnership model”, which produce high quality research at lower cost, with greater influence on national policy and practice. In this model, local academic leaders manage the research. Expatriates having active links in both worlds will have a significant role to play¹. The risks in the start-up phase of any partnership may also be higher, but in the longer term the developmental impact of a balanced and equal research partnership is much greater, and the scope for broader, multi-disciplinary research increases¹.
3. In an era where geographical boundaries are becoming a misnomer, the role of an expatriate academic is crucial in capacity building in the developing world. Physical presence in a particular country is not a prerequisite to share one’s expertise in developing and improving the conditions in that country. Therefore, there is a need to surpass the territorial boundaries and barriers to reach such repositories of scientific wealth, in order to develop one’s own country. The only condition required is a programme committed to the agenda.

4. The “partnership model” has four broad principles for truly co-operative research partnership between outside and inside researchers and organisations². These are:
 - (I) Mutual trust and shared decision making
 - (II) National ownership
 - (III) Early planning for translating research findings into policy practice
 - (IV) Development of national research capacity
5. International collaborative research projects should ensure a substantial contribution to the development of knowledge, skills, technology and scientific equipment in Sri Lanka. The local partners should preferably decide what is considered “substantial”, depending on the proposal and potential benefits for the collaborators and donors.
6. No collaboration will be entertained solely for “economically cheap and easy research in the developing world.”
7. As per the revised Declaration of Helsinki³, population involved should benefit from the research. Any clinical study carried out should be done against best-proven method, and there should be access to the therapy at the end of the study. We believe that ethical committees in the developing countries should follow the Nuffield Council on Bioethics guidelines on Ethics of Research related to Health Care in Developing Countries⁴ Chapter 7 ‘Standards of Care’ closely. (Please refer also to **Chapter 7 p6**)
8. Collaborations are actively encouraged to bring together diverse disciplines and expertise together to promote projects with multi-disciplinary inputs as this is essential to investigate into the aetiologies of multifactorial origin.
9. North-South collaborations will be essential but South-South collaboration and net-working is also essential to ensure maximum utilisation of capacity within the different regions of the developing world.

10. In addition, this may serve to increase the ‘voice’ of the developing world in debates on international health research issues, a concern that has been expressed in relation to the formulation of international guidelines⁵.

Guidelines:

1. International researchers should have a local collaborator.
2. The international collaborators should have ethical clearance from their home institution as well as from a local Ethical Committee. When there are disagreements between the Committees (developing and sponsoring country), the two committees should directly correspond to discuss the issues.
3. International collaboration should be based on the scientific merit of the project, ethical considerations and mutual benefit of the collaboration.

References:

1. Costello A, Zumla A. Moving to research partnership in developing countries. *BMJ* 2000; 321:827-9.
2. Swiss Commission for research partnership with developing countries. Guidelines for research in partnership in developing countries. Bern; The Commission, 1998.
3. Editorial. Fifth Amendment for the Declaration of Helsinki, *Lancet* 2000; 356:1123 (www.wma.net)
4. Nuffield Council on Bioethics. Ethics of research related to health care in developing countries. Nuffield Council on Bioethics. London UK. 2002.
5. The Global Forum on Bioethics in Research, Cape Town 20-22 February 2002; ‘The politics of ethical consensus finding’, editorial, *Bioethics*, vol 16 number 2, 2002, ppiii-v.

CHAPTER 9

After Completion Of The Research

Policy:

1. Completion of data collection and analysis or even writing up research will not end the ethical responsibility of an investigator. There are other matters, which should follow the research. One of the important responsibilities will be to provide a feed- back to the participants. In intervention research, if the tested intervention is effective, the investigator should, (to the best of his ability) offer the intervention to the control group. Extending the intervention to the general public should also be on the agenda. Therefore service development should be a long-term aim of a research project. Not integrating research findings in to practice is a sad aspect in our part of the world and we should try to avoid it.
2. There is a possibility of existing illnesses in research subjects which come to light during research projects. This may occur at an individual level or group level. When research results are disclosed to a subject, it will be the responsibility of the investigator to provide appropriate medical advice or referral. Such disclosures occur when the findings are reconfirmed and proven to be scientifically valid. Therefore the researchers should in their protocols describe anticipated findings and circumstances that might lead to a decision to disclose the findings to a subject, as well as a plan on how to manage such disclosure. Subjects may be benefited through a feedback of the outcome of the research¹. However we acknowledge the right of the research participants not to know the results. This is particularly appropriate when feedback concerns a diagnosis for which no treatment or intervention would be available.
3. Investigators' plans for disseminating results of research should include, when appropriate, the provisions to minimise the potential harm to individuals of associated groups¹. Research on samples that implicate groups may place group members at risk of harm. For example, research revealing that a racial or an ethnic group is prone to a particular disease could be used to

stigmatize or discriminate against group members. Consultation with group members before designing and implementing research on groups may be an effective way to understand and reduce risk¹.

Guidelines:

1. Disclosure of the results of research to subjects should preferably occur only when the following conditions are satisfied¹.
 - (a) Findings are scientifically valid and confirmed.
 - (b) The findings have significant implications for the subjects' health concerns
 - (c) A course of action to ameliorate or treat this condition is readily available

Reference:

1. National Bioethics Advisory Commission. Research involving human biological materials: ethical issues and policy guidance. Executive summary. 1999. Rockville. Maryland, USA.

CHAPTER 10

Policies And Guidelines Mainly Related To The Sri

Lankan Twin Registry

These guidelines should be read in conjunction with other chapters and the institution. The research undertaken at or in collaboration with the SLTR should comply with the proposed guidelines presented in this document.

Informed Consent:

1. The Registry will be responsible to ensure that the twins selected for a particular study provide freely given informed consent. A designated member of the research team will obtain the informed consent but a designated person (**ombudsman**) of the Multiple Birth Foundation or a representative of twins or any other person independent to the research team will be present as an observer to ensure that the process of informed consent is genuinely carried out.
2. Enrollment in the twin register (voluntary or population-based registers), as far as individual research projects are concerned, voluntariness is the hallmark. Inclusion in the Register will not compel them to participate in research, unless they wish to do so. The twins and/or their responsible adults will have the right to decide to or not to participate in specific research activity. Determining the zygosity of twins is a fundamental right of the twins¹ as well as an essential prerequisite for twin research. Therefore ethical clearance is not required. However the consent of the twins and/or their parents/guardians is needed.

Collection, Storage And Access To Human Biological Material Including Genetic Material:

1. It is the policy of the Committee to encourage genetic research² of high quality, performed locally, maintaining ethical standards spelt out in this document. To implement this policy, our vision is to establish the registry's own genetic laboratory as facilities for genetic research compatible with international standards are limited locally at present. We aim to achieve this only through non-commercial charitable funding.

Funding:

1. The activities directly linked to the expansion of the Registry include, establishing a **Volunteer Twin Register**, any activity or data collection that will contribute to the establishment of the **Population Based Register**, zygosity determination of twins, man power and expertise development, establishing the infrastructure, activities connected with the promotion of the Registry and dissemination of information related to the Registry.
2. The registry will secure funding for the above functions, and the funding obtained for a specific propose must not be used for activities other than those specified in the grant application without obtaining permission from the grant awarding body.
3. The supervisory committee will decide overhead costs for projects originating through the Registry. This will be considered on a project-to-project basis based on a sliding scale.
4. With the expansion of the Registry, the Committee will establish a separate grant that could be used to consider funding for projects that are not directly linked to the Registry or its expansion as specified in section II. This fund will be used to encourage high quality research originating from individuals.

Commercial exploitation:

1. The research and the results of the research should not be commercially exploited in any way without the prior written agreement of the Committee. Such an agreement may be refused at the Registry's absolute discretion or granted subject to conditions decided by the Committee.
2. Neither any individual in the Committee nor any researcher given permission to carry out a twin study may enter into any agreement with any commercial enterprise that will, in any way, allow commercial exploitation of any knowledge gained as a result of research being conducted through the Registry, without first obtaining approval of the Supervisory Committee in writing. This approval should have been obtained before starting the research.

International Collaborations:

1. International researchers should have a local collaborator. If they do not or cannot find such a collaborator, the Registry will consider to be the collaborator or will assist in finding a suitable collaborator.
2. International collaboration should be the sole discretion of the Committee, based on the scientific merit of the project, ethical considerations and mutual benefit of the collaboration.
3. The benefits for twins through any outcome of twin research or related activity should be channelled through the Multiple Birth Foundation.

Dissemination of Results, Authorship and Acknowledgments:

1. Authorship for projects originating from The Committee should also follow the same guidelines for authorship. However it should add the statement ‘on behalf of the Sri Lanka National Twin Registry’ after the list of authors. Members of The Committee should be listed and acknowledged at the end of the paper, similar to the *BMJ* papers³.
2. All research projects connected with the registry will have to be closely supervised and scrutinized by designated member/s of The Committee. Due to the nature of the official responsibility, they will also be accepting responsibility jointly with the other authors, for the intellectual content of the publication. “Ministers must take ultimate responsibility for everything done in their departments and editors for all that in their journal⁴”. No person can be held accountable without offering credit for accountability. Hence the quality of the contribution will be substantial and their entitlement for authorship should not be considered as “gift authorship”.
3. Authorship for publications on the establishment of the Population based Twin Register, should follow the same guidelines as for other projects. Every individual research project that contributes to the development of the Population Based Register should be acknowledged in these publications.

4. Any research project carried out through the Registry should duly acknowledge the Registry and the members who contributed, but would not necessarily qualify for authorship

References and End Notes:

1. Declaration of Rights & Statement of Needs of Twins and Higher Birth Order. Adopted by the Council of Multiple Birth Organisation of International Twin Society. 1995. <http://kate.pc.helsinki.fi/twin/Right>
2. Genetic research - includes analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites, in order to detect heritable genotypes, mutations, phenotypes or karyotypes. The purpose of this research includes assessing the prevalence, penetrance and expressivity of these heritable traits within the overall population, a particular sub population, or an individual.
3. Rahi JS, Dazateux C, on behalf of the British Congenital Cataract Interest Group. National cross sectional study of detection of congenital and infantile cataract in the United Kingdom: role of childhood screening and surveillance. *BMJ*.1999; 318:362-365.
4. Smith R. Authorship: time for a paradigm shift? *BMJ* 1997; 314:992.

CHAPTER 11

Dissemination Of Results, Authorship And Acknowledgments

Policy:

1. Dissemination of the findings is an essential component of any research for numerous reasons. Such efforts will provide opportunities for the results to be discussed by peer groups, and also to explore the validity and the usefulness of the findings. A published article is the primary means whereby new work is communicated¹. Therefore researchers should make best possible efforts to disseminate their work and make them available to the scientific community, as wide as possible.
2. Scientific papers include a list of authors. Arguments over authorship are becoming increasingly common^{1,2}. These are partly due to scientists not addressing the root of the problem: lack of clarity and openness about the authorship, resulting in roles and expectations undefined and undisclosed, waste of time and being poorly resolved¹.
3. There is currently an extensive debate in editorial circles on what constitutes authorship^{2,3,4}. Therefore the researchers should be sensitive to such issues raised and discussed by the academic community. At the end of this chapter, a brief review on the current views about authorship and contributorship is provided.
4. In principle we agree with the concept of contributorship. However current practice of authorship is something that cannot be discarded until more research is done. Even an excellent research project, if poorly written, will not convey the scientific message. Similarly, well written but poorly designed and conducted research will be less valued scientifically.
5. Therefore the final product, the scientific paper, should be viewed as an end product of a process of collective contribution. However embedded within this collective contribution is an essential component of a relative contribution by each participant. Hence there has to be a realistic aim to limit the contribution by some who will have to be credited with acknowledgment, while some are credited with authorship and contribution. Contributors will

have to decide where to draw the line between contributors and those who will be acknowledged³.

6. Considering issues, concerns, and opposing and contradicting views on authorship, the best policy would be to be proactive rather than reactive. Researchers from developing countries should have their own criteria and guidelines.
7. Following *BMJ*'s³ suggestion to experiment with the new idea, it is best to take into consideration both the current policies and guidelines on the authorship, as well as the principle of proposed contributorship.

Guidelines:

1. Authorship for publications should preferably be decided on the guidelines given below. They are based on the “Uniform Requirements for Manuscripts submitted for Biomedical Journals” (revised) and also taking into consideration the principle of contributorship, which include contributors and guarantors^{1,3}.
2. Until such time as the international scientific community and journals agree on the new theme of replacing authors with contributors and guarantors, there is no option other than to mention the authors and follow the guidelines of the I.C.M.J.E⁵ However publications to the journals (*BMJ*, *Lancet*, *JAMA* or any other journal), which will publish the lists of contributors and guarantors, should reveal such details as necessary.
3. Even in the case of papers submitted to the journals which will only publish the names of authors, the principles of contributors and guarantors should be used to decide who should qualify for the list of ‘authors’. The main principle would be to decide on pre-agreed criteria as to who has “added usefully to the work.^{1,3}”
4. In doing so we will assess the contribution (added usefully to the work) using two independent broader criteria. They are: (i) qualitative contribution, (ii) quantitative contribution. However these two criteria may be overlapping at times, but also may be mutually exclusive at other times. A scientific paper

is the end product of a process that has a collective contribution which may be qualitative or quantitative. (intellectual⁶ and practical⁶).

5. The ‘qualitative’ contributions are as listed below. In broader terms this would be the intellectual contribution. They include:
 - (a) Formulation of an original, idea/ research question hypotheses/innovative idea/ and continuing of its development
 - (b) Contributing to the development of the research methodology to be used to investigate into the above
 - (c) Drafting or contributing to the draft or critically reviewing or revising it for intellectual content or scientific validity or accuracy of the proposal/protocol, including the statistical component of the design
 - (d) Literature search **and** selecting relevant material, literature review, design of the review
 - (e) Data extraction, analysis of the data, interpretation of the data **and** statistical analysis
 - (f) Setting up databases or software programs and similar intellectual contributions directly relevant to the specific piece of research
 - (g) Writing the first draft in whole or part, **or** contributing, revising subsequent drafts or in the final draft including approval of the final draft. Contribution in terms of any one of the above from **8(a) to (g)** should qualify for “authorship”. This contribution should be **substantial**⁶.

6. The specific ‘quantitative’ contributions are as listed below. In broader terms this would be the components involving the implementation of the research project. These may or may not necessarily demand intellectual contribution. Even in the absence of a significant intellectual contribution, the following categories of contributors would qualify for ‘authorship’. They would include the activities considered essential for the successful completion of research without which a publication would not have resulted. However the contribution must be substantial.
 - (i) Substantial involvement in the data collection. This should be specifically considered in larger studies where data collection

- is substantial, and also in studies using qualitative research techniques, in which a significant intellectual contribution will have to be made by the person who is involved in the data collection.
- (ii) If the study is a multi-centre study and there are large numbers of data collectors, whose contribution is not substantial, only an acknowledgement may suffice.
 - (iii) Active contributions for obtaining funding for the specific piece of research, if that effort has incurred substantial planning or significant time commitment
 - (iv) Co-ordinating the project, providing close supervision or negotiating with relevant authorities to collect or obtain data should also qualify because these contribute to the integrity and a guarantee to the project, provided this contribution is substantial.
7. Any contribution, which does not fall into any of the above categories, should be duly acknowledged under the heading of acknowledgment. These include secretarial assistance and any similar assistance.
 8. Subjects who contributed by participating in the research cannot be named, as this will be against confidentiality. However the participants in qualitative research, particularly an expert panel or a nominal group, could be named under acknowledgment. Although such a group provides a form of intellectual contribution with opinions or interpretations, they will not qualify for authorship, as it is no more than participating in a research project as subjects.
 9. The first author should be the one most closely associated with work⁶ irrespective of the position or academic credentials.
 10. There are varying practices to select the order of the co-authors^{1,6,7}.
We will list co-authors to reflect the rank order of contribution⁶.
 11. Rank order of the list will be decided collectively by the

co-authors.

References:

1. Rennie D, Yank V, Emanuel L. When Authorship Fails. A proposal to Make Contribution Accountable. *JAMA*. 1997; 278(7): 579-585.
2. Smith R. Editor. *BMJ*. Personal Communication. 1999.01.29.
3. Smith. R. Authorship is dying; Long live contributorship. *BMJ*.1997; 315:696.
4. Letters to the editor. *BMJ*.1997; 315:744-748.
5. International Committee of Medical Journal editors. Uniform Requirements for Manuscripts Submitted to Biomedical Journals. *Ann Intern Med*.1997; 126:34-47.
6. Bhopal R, Rankin J, McColl E, et al. The vexed question of authorship: views of researchers in a British medical faculty. *BMJ*.1997; 314:1009-1012.
7. Rennie D, Flanagan A. Authorship! Authorship! Guest, Ghost, Grafters and the two sided Coin. *JAMA*.1994; 271(6) 469- 471.

Appendix One

Current Debate On Authorship

The first attempt in the recent past to establish guidelines for the format of manuscripts submitted to the Biomedical Journal was made in 1978, by a small group of editors at an informal meeting. This group, named the Vancouver Group, later expanded and evolved into the International Committee of Medical Journal Editors (I.C.M.J.E) who meet annually. The “Uniform Requirements for Manuscripts Submitted for Biomedical Journals” were produced by them (I.C.M.J.E) ^{1,2}. The above guidelines state that: “All persons designated as authors should qualify for authorship. The order of authorship should be a joint decision of the co-authors. Each author should have participated in the work to take public responsibility for the content. Authorship credit should be based only on substantial contribution to

- (a) Conception and design, or analysis and interpretation of data (b) Drafting the article or revising it critically for important intellectual content
- (c) In the final approval of the version to be published the above conditions (a), (b), and (c) must all be met. Participation solely in the acquisition of funding or the collection of data does not justify authorship. General supervision of the research group is not sufficient for authorship.” Any part of an article critical to its main conclusions must be the responsibility of at least one author. On the Policy on Acknowledgments, The “Uniform Requirements” suggest in relation to acknowledgments that: “Immediately following the text of an article, one or more statements should specify:
 - (a) Contribution that need acknowledging but do not justify authorship, such as general support by a department chair
 - (b) Acknowledgment of technical support
 - (c) Acknowledgments of financial and material support specifying the nature of support
 - (d) Financial relationships that may pose a conflict of interest.

Persons who have contributed intellectually to the paper but whose contributions do not justify authorship may be named and their functions or contribution described- for example, ‘scientific adviser’, ‘critical reviewer of study proposal’, ‘data collection’ or ‘participation in clinical trial’.

There are some issues and concerns raised by academics on authorship³. Current definitions of authorship are not well known^{4,5} and are often not accepted even when they are known⁵, proliferation of numbers of authors, practice of gift authorship and the I.C.M.J.E. criteria being too restrictive so that technicians, research assistants would be excluded from authorship, are some of these issues³.

The above mentioned issues were discussed at a meeting³ at the University of Nottingham, sponsored by *BMJ* and *Lancet*. The conference agreed with Drummond Rennie, Deputy Editor, *JAMA*, that authorship brings both credit and responsibility and cannot have one without the other³. The question was how to construct a definition of authorship that gave credit to those who deserve it and responsibility for the honesty and accuracy of research report to those who should take it^{3,4}.

As the solution to these issues, Drummond Rennie⁴, suggested replacing “authorship” with “contributors” and “guarantors” and disclosing the exact nature of the contribution alongside the research report (film credit approach). The aim is to give credit to those who deserve it and responsibility to those who should take it. He goes onto describe what the anticipated problems would be in using this system and how co-authors should decide their relative contribution and also how they should decide on the accountability. He has also taken care to discuss what the anticipated problems would be in using the proposed criteria.

The above suggestions have received mixed reactions⁶ and the scientific community is divided on the issue^{3,7}. The Vancouver group decided that there was not enough evidence to justify an immediate change in definition of authorship³. However they revised the 1993 statement adding “editors may ask the authors to describe what each contributed; this information should be published”⁷.

Advocators of Contributorship believe, it will make possible for people to agree over who did what^{4,8}. This may not be that straight forward, because the perceived quantity (size) and the quality of contribution could vary on individual expectations, attitudes, and their own estimation of the relative value of the contribution.

There are two issues to be anticipated. One is exclusion of a person

from authorship when it is deserved and the other is demand or claim for authorship when it is not deserved. *BMJ* encourages researchers to experiment with this new idea⁸ proposed by Rennie⁴.

References:

1. International Committee of Medical Journal Editors. Uniform Requirement for Manuscripts Submitted to Biomedical Journals. *JAMA*.1993; 268:99.
2. Macintyre S.(Editorial). Conventions, Ethics and Laws in Journal Publishing. *Social Science and Medicine*. 1997; 45 (1):1-2.
3. Editorial. Definition of authorship may be changed. *BMJ*.1996; 312: 1501-1502.
4. Rennie D, Yank V, Emanuel L. When Authorship Fails. A proposal to Make Contribution Accountable. *JAMA*. 1997; 278 (7): 579-585.
5. Bhopal R, Rankin J, McColl E, et al. The vexed question of authorship: views of researchers in a British medical faculty. *BMJ*. 1997; 314: 1009-1012
6. Letters to the editor. *BMJ*. 1997; 315: 744-748.
7. Editorial. What Does Authorship Mean in a Peer reviewed Medical Journal? *JAMA*.1996; 276:75.
8. Smith R. Authorship is dying; Long live contributorship. *BMJ*.1997; 315:696.

