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**PROCEEDINGS OF**  
**“THE RESEARCH FORUM”**  
*An Open Forum on Research Ethics and Methodology*  
**2004**

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## **Message From The Dean**

The Ethical Review Committee of our faculty is the pioneering trend-setter in this field in Sri Lanka, having functioned for over 20 years. During this period it has grown in stature and has played a catalytical role in the establishment of other committee by national bodies such as the Sri Lanka Medical Association. The Ministry of Health has been establishing Ethical Review Committees in some of the Teaching Hospitals as well, during the last year. It is an opportune time to establish an apical body at national level to coordinate such activities.

*Prof. Sanath P Lamabadusuriya*

*Dean.*

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## **Message From The Chairperson, Ethical Review Committee**

There has always been a considerable debate as to the role of Ethics Committees in relation to ethical and scientific problems arising in research proposals. While some express the opinion that ethics committee should primarily focus on ethical aspects and scientific issues of the proposal should be dealt with by the scientist, others say that ethics committees must deal with both aspects. In practice ethics committees are faced with this dilemma all the time. It is in this respect that the ERC instituted a programme to focus on scientific and ethical issues in research proposals.

Dr. Vajira H. W. Dissanayake and his team have initiated a pioneering programme to address this core issue. I hope that this programme has benefited prospector researchers to present proposals with clarity in relation to both ethical and scientific aspects.

*Prof. Nalaka Mendis*

*Chairperson,*

*Ethical Review Committee.*

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## **Introduction**

The origins of the “Research Forum” could be traced back to the deliberations that took place at the Capacity Building Workshop on Research Ethics conducted by the Ethical Review Committee on March 8, 2004. At this workshop, which was well attended by Faculty members, a lively discussion took place on the scope of ethical review. The majority were of the opinion that research which is not methodologically sound could not be ethical. Many highlighted the need for a lively research debate in the Faculty, and the Ethical Review Committee took on the task of organising a “Research Forum” to fulfill that need with funding from the World Health Organisation.

This publication documents the proceedings of the “Research Forum” in the year 2004. We hope that this would serve as a useful quick reference guide for those who plan to submit proposals for ethical review in the future.

We wish to thank all those who helped in numerous ways to make the “Research Forum” a success.

*Dr. Vajira H. W. Dissanayake*

*Co-ordinator of the Research Forum.*

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## List of Research Forums

### 17<sup>th</sup> June 2004

***Moderator:***

Dr. Vajira H. W. Dissanayake

***Research Presentations:***

“Seroprevalence and selected factors associated with *Helicobacter pylori* among children and adults in Beruwala MOH area in Sri Lanka in year 2004.

Dr. T. P. R. Fernando

“Aetiological agents of bacteraemia and fungaemia in patients with neoplastic disease at Cancer Institute Maharagama.”

Dr. A.A.D. Priyanthi

***Brief Review:***

“Tips on ensuring confidentiality – what ethics committees look for”

Dr. Vajira H. W. Dissanayake

***No of participants:***

70

### 15<sup>th</sup> July 2004

***Moderator:***

Dr. Panduka Karunanayake

***Research Presentations:***

“A study of the efficacy and factors affecting drug compliance in the mass drug administration programme against filariasis in the Western Province of Sri Lanka”

Dr. G. S. A. Gunawardena

“Uniform Multi drug therapy trial –Sri Lanka”

Dr. W. A. S. Settinayake

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***Brief Review:***

“Scientific design and conduct of a study - tips on what ethics committees look for”

Prof. Dulitha Fernando

***No of participants:***

66

**19th August 2004**

***Moderator:***

*Dr. Vajira H. W. Dissanayake*

***Research Presentations:***

“Epidemiology of Invasive Pneumococcal disease among Children in Sri Lanka”

Dr. B. K. R Batuwanthudawa

“The outcome of bladder neck resection combined with bilateral prostatic diathermy thermotherapy”

V. Hasanthi Vithana

“A Descriptive Cross Sectional Study of Patients’ Knowledge and Attitudes on Informed Consent in Clinical Examination”

Dr. Nadeeka K. Rathnamalala

***Brief Review:***

“Recruitment of research participants and the informed consent process “

Dr. Vajira H. W. Dissanayake

***No of participants:***

47

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**28<sup>th</sup> October 2004**

***Moderator:***

Dr. Vajira H. W. Dissanayake

***Research Presentations:***

“Difficulties that care givers have to face when they care for family members who are diagnosed as Schizophrenic patients”

Mrs. C. S. V. Pathirana

“Aetiology of anaemia in tertiary care hospitals in Sri Lanka”

Dr. L. V. Gunaratne

***Brief Review:***

“Community consideration in research”

Dr. M. W. Gunathunga

***No of participants:***

41

**18<sup>th</sup> November 2004**

**Moderator:**

Dr. Vajira H. W. Dissanayake

***Research Presentations:***

“A molecular-anthropology survey of the Sri Lankan population”

Mr. Ruwan Illeperuma

“A community based study of reproductive endocrine disorders among women in the reproductive age”

Dr. (Mrs.) Vindya Lakshmie Kumarapeli

***No of participants:***

27

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**9<sup>th</sup> December 2004**

***Moderator:***

Dr. Vajira H. W. Dissanayake

***Research Presentations:***

“A descriptive study of side effects of newer antipsychotic drugs”

Pubuduni Dantanarayana

“A descriptive study of the effects of mosquito coils on reproductive parameters of rats and foetal teratogenicity”

N. R. Ayesha

***Brief Review:***

“Care and protection of research participants”

Dr. Rohini Fernandopulle

***No of participants:***

29

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## **Brief Reviews**

### ***Protection of Research Participants' Confidentiality***

*by Dr. Vajira H. W. Dissanayake*

Confidentiality is keeping information given by or about an individual in the course of a professional relationship secure and secret from others. Confidentiality applies to personal information. Personal information is information relating to the physical or mental health of any person from which that person can be identified (eg Mr. A is schizophrenic or Mrs. B is diabetic). It may also apply to information such as race, religion, income, education level, etc. which may label a person as belonging to a certain group. But, the principle of confidentiality is not intended to justify withholding information from a person about themselves (eg: if a test for serum lipids is done, then it would be appropriate to pass on information of the results to the research subject as they may benefit from that information because any abnormal results are definitely linked with adverse health outcomes and there is proven intervention available in case the results are abnormal; in addition any normal result will be reassure the subject.)

When ever a researcher is collecting information keep in mind the principles laid down by the Caldicott committee(1):

- justify the purpose for using it;
- only use when absolutely necessary;
- use the minimum required;
- access should be on a strict 'need to know' basis;
- everyone who has access should be aware of their responsibilities;
- understand and comply with the law.

The following are some of the information/factors that ethical review committees look for in applications to ensure that the researchers are likely to protect the confidentiality of the participants (2).

- what data will be collected;

- 
- a description of the persons who will have access to personal data of the research participants, including medical records and biological samples;
  - the measures taken to ensure the confidentiality and security of personal information concerning research participants;
  - the extent to which the information will be anonymised (Information is anonymised if it does not identify, directly or indirectly the individual to whom it relates);
  - how the data/samples will be obtained, and the purposes for which they will be used;
  - how long the data/samples will be kept and how it will be dealt with at the end of the project;
  - to which countries, if any, the data/samples will be sent;
  - how consent will be obtained for the above (The adequacy of the process for obtaining consent, see section on consent).

Most research involves collection of information regarding subjects on a data collection booklet or on to a questionnaire. In many instances data collection booklets/questionnaires submitted for ethical review have data identifying research subjects and other personal information on the same page. An example is given in the next page:

**Seroprevalence and selected factors associated with *Helicobacter pylori* among children and adults in Beruwala MOH area in Sri Lanka in year 2004.**

Ref. No.....

Tick with 'X' the relevant cage where applicable, or fill appropriately.

0. Date : .....

1. Name : .....

2. Date of birth : .....

3. Sex : .....

4. Postal address : .....

5. Ethnicity S  M  T  Others

6. Highest educational level:

No Schooling	<input type="checkbox"/>
Up to grade 6	<input type="checkbox"/>
From grade 6 up to O/L	<input type="checkbox"/>
From O/L up to A/L	<input type="checkbox"/>
University or Higher	<input type="checkbox"/>

7. Occupation : .....

8. Monthly income:

Less than Rs. 2000	<input type="checkbox"/>
Rs. 2000 - Rs. 3999	<input type="checkbox"/>
Rs. 4000 - Rs. 5999	<input type="checkbox"/>
Rs. 6000 - Rs. 7999	<input type="checkbox"/>
Rs. 8000 or more	<input type="checkbox"/>

To avoid this, design a separate sheet for subject identification information and place it in front with clear instructions that it should be torn out of the main data collection booklet/questionnaire, and stored away under lock and key. An example is given below:

**Inherited Factors in Pre-eclampsia in Sri Lanka Study**

PHENOTYPIC DATA  
Pre-Eclamptic Woman

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Subject Study Number:    /    / 03

Name: .....

Address: .....

Telephone number: .....

Hospital number: .....

A/V/C Clinic number: .....

P/B/C Clinic number: ..... Name: .....

Date of birth: .....

**Data Protection and Confidentiality**

After completion of this page, ensure that the subject study number is entered on all pages of this booklet. Then detach this page and store separately from the rest of the booklet.

Subject Study Number:    /    / 03

Date of entry to study:  -  -

Date of ascertainment

Date of birth:  -  -

RACE:  0. Not Know

1. Sinhalese

2. Sri Lankan Tamil

3. Indian Tamil

4. Malay

5. Moor

6. Burgher

7. Other, Specify:

Smoker:  0. No

1. Stopped during index pregnancy

2. Smoked during index pregnancy

**Data Protection and Confidentiality**

After completion of this page, ensure that the subject study number is entered on all pages of this booklet. Then detach this page and store separately from the remainder of the booklet.

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***Scientific Design and Conduct of the Study***  
*by Prof. Dulitha Fernando*

Definition of Research includes the following four areas:

- Trying to answer a problem/question;
- Collection of data;
- Analysis of data; and
- Interpret data.

The following five areas highlight key issues of what Ethical Review Committee look for:

- Informed consent;
- Good research design;
- Competent investigator;
- Equitable selection of subject; and
- Compensation for research induced injury.

How to proceed in formation of a research proposal and what Ethics Committees look for:

- Start with question;
- Then form the objectives of the study;
- From the objectives decide what information is needed; and
- Decide how the information would be obtained (Validity of results will depend on how you get the information).

Methodological issues as relevant to ethical review:

- Study design

The researcher must know the methods to get the required information to achieve the objectives and know the best method to achieve it.

Designs commonly used include:

- Descriptive;
- Analytic; and
- Experimental trials.

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Researcher has to choose a study design which will give the best information.

If expected out come is not reached the study is unethical.

- In whom are you going to do the study
  - Inclusion criteria;
  - Exclusion criteria;
  - Sample size; and
  - How to deal with non responders, dropouts, etc.
- Study Instruments  
Information could be collected by any of the following methods:
  - Questionnaire;
  - Clinical examination;
  - Investigator; and
  - Combination of above.

But, does it really measure what you want to measure?

Concerns are:

- Is the study design appropriate?
- Are there alternative approaches?
- Study instrument appropriate?
- How to ensure quality of data?

Different types of approaches have to be used to ensure quality.  
If quality of data is not good then results are of no use.

To conclude key points in the presentation include:

- Is the study design appropriate?
- Is the investigator competent?
- Are the measurements you are going to make adequate and appropriate and how this is going to be done?
- How to ensure quality of data?

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Relative importance of these vary with the type of study you intend to do.

If you pay attention to above areas you can probably get though ethical clearance from a methodological point of view (ethics has not been addressed in this presentation).

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## ***Recruitment of Research Participants and the Informed Consent Process***

*by Dr. Vajira H. W. Dissanayake*

Given below is a check list of what ethics committees look for in an ethical clearance application to make their decision regarding the appropriateness of the selection of research participants and the recruitment process itself including the process of obtaining informed consent. This list is taken from reference (2).

### *Recruitment of research participants*

- The characteristics of the population from which the research participants will be drawn (including gender, age, literacy, culture, economic status and ethnicity) and the justification for any decisions made in this respect.
- The means by which initial contact and recruitment is to be conducted.
- The means by which full information is to be conveyed to potential research participants or their representatives.
- Inclusion criteria for research participants.
- Exclusion criteria for research participants.

### *The informed consent process*

- A full description of the process for obtaining informed consent, including the identification of those responsible for obtaining consent, the time-frame in which it will occur, and the process for ensuring consent has not been withdrawn.
- The adequacy, completeness and understandability of written and oral information to be given to the research participants, and, when appropriate, their legally acceptable representatives.

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- Clear justification for the intention to include in the research individuals who cannot consent, and a full account of the arrangements for obtaining consent or authorization for the participation of such individuals.
  - Assurances that research participants will receive information that becomes available during the course of the research relevant to their participation (including their rights, safety and well-being) the provisions made for receiving and responding to queries and complaints from research participants or their representatives during the course of a research project.

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## ***Community Considerations***

*by Dr. M.W. Gunathunga*

### Issues

- What is the “community”?
- Why consider community issues?
- Why do we need to go to the community?
- Ethical issues.
- Matters related to quality of data.
- Commitment.

### What is the “Community”?

- Geographical areas (provinces, districts, urban, rural, schools, etc.);
- Occupational groups;
- Age groups (infants, pre-school, school, adolescent, antenatal, working, retired, elderly);
- Institutions, etc.

### Why consider community issues?

- For planning research;
- To maintain quality of data; and
- For safety of data collectors and community.

### Why do we need to go to the community?

- True source;
- No alternative;
- Healthy/Apparently healthy people;
- Incidence/Prevalence; and
- Controls.

### Examples:

- Descriptive studies:
  - Objective: Epidemiology of abdominal obesity in relation to coronary heart disease in an adult population: Ref. No. EC-03-77
  - Objective: A study of risk factors for dental caries in 15 year old children in the district of Colombo, and problems

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encountered by their care givers in providing oral health care: Ref. No. EC-03-74

- Experimental studies (vaccine trials, community trials. Eg: Water fluoridation study, Study by Lint in Salisbury)

Ethical issues:

- Meeting only selected members;
- Without appointment (Stranger at home);
- Invasive procedures;
- Behaviour of the data collector;
- Feedback from the researcher;
- Disruption of daily life; and
- Attire.

Matters related to quality of data:

- Length of the questionnaire;
- Workload per day;
- Refreshments/Transport;
- Dealing with unfinished work;
- Supervision; and
- Completing questionnaires same day.

Commitment:

- Selecting data collectors – committed people;
- Working in rough terrain;
- Living few days with people (qualitative research);
- Revisits;
- Patience/Status (eg: questions on ethnicity etc.);
- Language; and
- Payments for work.

Given below is a list of issues with regard to community considerations, which ethics committees would look at when reviewing an application. This list is taken from reference (2).

- The impact and relevance of the research on the local community and on the concerned communities from which the research participants are drawn.

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- The steps which had been taken to consult with the concerned communities during the course of designing the research.
  - The extent to which the research contributes to capacity building, such as the enhancement of local healthcare, research, and the ability to respond to public health needs.
  - A description of the availability and affordability of any successful study product to the concerned communities following the research.
  - The manner in which the results of the research will be made available to the research participants and the concerned communities.

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***Care and Protection of Research Participants***  
*by Dr. Rohini Fernandopulle*

Scientific research

- has produced substantial social benefits  
but
- has also posed some troubling ethical questions

Main sources of guidance

- Nuremberg Code;
- Declaration of Helsinki;
- Belmont Report; and
- International Ethical Guidelines for Biomedical Research involving Human Subjects.

They were written in response to specific events to avoid future scandals

Basic principles

- Respect for person;
- Beneficence;
- Justice; and
- Fair patient selection.

*Respect for person*

- Individuals should be treated as autonomous agents (free to act independently).
- Subjects should enter into the research voluntarily and with adequate information about the benefits and risks.
- Persons with diminished autonomy are entitled to protection.

*Beneficence*

- Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm but also by making efforts to secure their well being.  
Two general rules:
  - Do no harm.
  - Maximize possible benefits and minimize possible harms.

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### *Justice*

- Who ought to receive the benefits of research and bear its burden?

An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly.

### *Fair patient selection*

- Requires that the scientific goals of the study not vulnerability, privilege or other factors unrelated to the purpose of the research be the primary basis for determining the groups and individuals that will be recruited and enrolled.

Applications of the principles in conduct of research

- Informed consent;
- Risk benefit assessment;
- Selection of research subjects; and
- Respect for potential and enrolled subjects.

### *Informed consent*

Consists of three elements:

#### Information

Give sufficient information on:

- research procedure, and their purposes;
- risks and anticipated benefits;
- alternative procedures; and
- a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research.

#### Comprehension

- The ability to understand is a function of intelligence, rationality, maturity and language, important to adapt the presentation of the information to the subjects capacities.
- It is the responsibility of the investigators to ascertain that the subject has understood the information.

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### Voluntaries

- An agreement to participate in research constitutes a valid consent only if voluntarily given.
- free of coercion and undue influence.

### *Assessment of risks and benefits*

#### Consider risk of

- psychological harm;
- physical harm;
- legal harm;
- social harm; and
- economic harm.

and the corresponding benefits.

#### Assessment of justifiability of research:

- Brutal or inhumane treatment is never morally justifiable.
- Risks should be reduced to those necessary to achieve the research objective.

### *Selection of research subjects*

- Fair procedures and outcomes in selection of research subjects
- Two levels: Individual and Social

#### Individual

- Should not offer potentially beneficial research only to some patients who are in favour or select only undesirable persons for risky research.

#### Social

- Distinction be drawn between classes of subjects that ought and ought not to participate in any particular kind of research based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened classes.

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## Conclusion - Basic principles for medical research

- It is the duty of the doctor to protect life, health, privacy and dignity of the human subject.
- Research should be conducted only by scientifically qualified persons.
- Should be preceded by careful assessment of risks and burdens in comparison with foreseeable benefits to the subject or to others.
- Do only if benefits clearly outweigh the risks - stop the research if risks outweigh the potential benefits.
- Subjects must be volunteers, informed and free to withdraw - steps to be taken if research participants withdraw.
- The benefits risks burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic and therapeutic methods.
- At the conclusion of the study every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study.
- Their right to safeguard their integrity must always be respected. Respect their privacy, confidentiality and minimise impact of the study on the subject's physical and mental integrity and on the personality of the subject.
- The physician should fully inform the patient which aspects of care are related to the research, and what to expect.
- Patient should be informed of the rewards compensation to the participants / researchers.
- Inform any conflicts of interests.

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## Points to Ponder

In this section we have listed out some questions that were asked from researchers by the participants. A short discussion follows where necessary. These issues may be relevant to your projects as well.

- “You are using 10ml of blood from adults and 5ml of blood from children to do the same test, why?”  
*If you are performing the same test or procedure in different groups of people in different ways, then it is necessary to justify why.*
- “You want to use an invasive test on a child when a non invasive test is available, why?”  
*Ethical approval was not given for the part of this project that involved the use of children as research subjects, as it required obtaining blood from healthy children for a test of which the benefits for children were not clear. If your study involves children, then you need to ask is it really necessary to subject the children to it.*
- “Do you need informed consent for routine testing?”  
*No test is routine.*
- “Did you mention the use of animals in your research in the ethical review application?”  
*In this application the applicants have failed to mention that they will be using sheep in the test protocol in a new test that they were introducing as a part of the overall study protocol. When animals are used for research, welfare of such animals is an important consideration in the ethical review process.*
- “Can the hypothesis of a qualitative study change in the light of findings?”  
*Yes, hypothesis will develop and take a final form.*

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- “How do you select a sample size for a quantitative study?”  
*Sample size may not matter in quantitative studies.*
  - “Should loss of confidentiality be listed as a potential risk?”  
*Yes*
  - “Are Muslims a racial group?”  
*No, A Muslim is a person who follows the Islamic faith. The two main racial groups in Sri Lanka that follow the Islamic faith are Moors and Malays.*

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## References

1. Protecting and using patient information: a manual for Caldicott Guardians. <http://www.dh.gov.uk/assetRoot/04/06/81/36/045068136.pdf>
2. Governance agreements for NHS Research Ethics Committees. <http://www.dh.gov.uk/assetRoot/04/05/86/09/0458609.pdf>

## Acknowledgements

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- the researchers who presented their project for peer review through the “Research Forum”.
- the invited moderator and the invited guest speakers who presented brief reviews on various aspects of research ethics and methodology.
- the participants who contributed to the discussion.