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ASPECTS OF RESEARCH

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Foreword

It has been customary for Steering Committees to organise, annual seminars. "Aspects of research" was the chosen theme for one such activity. This was initiated and organised by the Committee for Medicine, Veterinary Science & Dentistry.

One of NARESA's main activities is the provision of research grants awarded on a selective basis of priorities. The objective is to promote scientific & technological research relevant to the needs of the country.

In training for research, there is a potential for developing human resources for science & technology development. Young scientists have obtained masters degrees and Ph.Ds on NARESA grants.

During the course of research for which NARESA has awarded a grant, there is continuous evaluation of progress. The results achieved are expected to enhance the resource of scientific knowledge required for development of National Science and technology capability.

This seminar was directed to fulfil the strengthening of some aspects of research. The publication of these presentations should be helpful to reiterate the points made by the resource persons. Further, it is hoped that it will go beyond the walls of NARESA to hundreds of scientists who could not participate in that exercise.

Priyani E. Soysa

Prof. Priyani E. Soysa
Director General

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TRAINING IN RESEARCH

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Research may be broadly defined as the Call of Truth, and if I may borrow from Ravindranath Tagore's essay on the call of Truth - it gives expression to an inward freedom and sense of inquiry which refuses to submit to the rule of things as they always have been, but is determined to find out the truth and bring about change that has never been before.

A training in research then is a training of both mind and attitude towards a different approach, a different way of thinking such that an individual can

(a) identify a need, problem or unexplained phenomenon
(b) find out what others have done to address the problem
(c) critically evaluate where others have failed or what strategies have not been used by them
(d) innovate new and realistic strategies which will give one unambiguous results
(e) plan the best way of analysing ones results
(f) draw ones conclusions, and
(g) identify future work which may be required to confirm, or clarify ones work or which will further explain new aspects that emerged from ones work.

At what stage should this training begin?

It begins automatically during pre-school days eg. when a child by trial and error learns little tricks and ploys that will help him get his way. Unwittingly he has researched his environment and planned his strategy accordingly.

This kind of `finding out' could be reinforced at primary school and in a sense this was the thinking behind the introduction of `parisaraya' or environmental studies into the curriculum in primary schools in Sri Lanka. Here, instead of formal teaching in geography, history, civics and nature studies, the student was guided to find out for himself or herself, collect specimens, draw maps and maintain a record book.

At secondary, and senior school levels there should be ample opportunity for developing the facility of independent thinking, and self study, but does this happen in Sri Lankan schools? - Chunks of theoretical subject matter have been introduced to the A level curriculum forcing students into a feverish life of notecopying in school and tuition classes thereafter until they flop tired into bed. In a somewhat clumsy effort to create equal opportunity, practical examinations for A-level science students were dispensed with as a temporary measure. It has however become a permanent feature of our examination system. This decision reduced the importance of the laboratory and all that it offers towards the development of practical skills; and towards developing the ability to observe, record and conclude. Considering all this, the A-level evaluation is a test of re-call of subject matter learnt around the marking schemes of previous years. The system kills instead of fostering individuality, freedom of thought and expression and the capability of solving problems. Many students with these capabilities are shut out of Universities.

Similarly in the Universities, large batches have to be handled; there is limited small group teaching; and exercises in problem solving, literature surveys, and planning and executing of projects are minimal. There is little opportunity with this mass production of graduates and limited teacher cadres to probe the minds of students and to foster in them an attitude of inquiry.

This basically is the background of the average research student to-day in Sri Lanka and supervisors or trainees are faced with the formidable task of instilling in them some research orientation.

Instilling Research Orientation

In many instances research students are employed as research assistants on projects that supervisors have planned and obtained funds for. This happens is many parts of the world but the biggest draw back in this set up is that the research student can be made use of as a glorified technician instead of receiving a true training in research. It is relevant to highlight deficiencies in training that I have consistently found when examining local M. Phil and PhD theses.

(1) A wealth of results are inadequately analysed and discussed
(2) They fail to critically evaluate their own work
(3) They draw firm conclusions where clearly there is only suggestive evidence.
(4) There is no evidence of wide reading in relevant areas around the subject so that the subject is seen in its wider perspective.
(5) At times the wider significance of their own work eludes them.
(6) They are unable to defend their theses with confidence.

(7) They display ignorance of how references should be quoted and bibliographies should be compiled.

Supervisors may be conversant with the techniques and methodology of research, but this does not necessarily mean that they know how to train a student for research. A trainer or supervisor has certain obligations by the student. eg:-

(1) To initially assess background knowledge and skills of the students.

(2) To identify deficient areas and rectify them through short term training stints or by enrolling on available lecture courses.

(3) To guide on reading on the related wider aspects of the chosen subject and to ensure he is aware of the sources of information available.

(4) To ensure that the student knows how to do literature searches and that he catalogues and classifies his references in a methodical way

(5) To develop the student's ability to present and write with clarity and good sequence.

(6) To develop the student's analytical ability.

Often scant attention is paid to many of the aspects listed above until the student finally begins writing up his thesis. While the supervisor fills his obligations, opportunities could be provided for presentation and discussion of both ongoing and concluded research. These opportunities could be provided by University departments, and institutions such as SLAAS, NARESA, SLMA, CISIR, CARP etc.

Publication could be encouraged by linking it to promotional prospects in research institutes. At present I think this is only a feature in the Universities.

Scientific bodies such as NARESA and SLAAS and the Universities could pay a more meaningful role in the development of curricular and research training in schools.

These bodies could identify and be clear about the deficiencies in the system. They should participate in decision making and vigorously question detrimental decisions on educational policy.

Finally, there is a tendency in Sri Lanka to view 'research' as an exercise reserved for post graduates and a means to an end which is a qualification such as an M Phil or a PhD. Quite often, those who obtain these research degrees either believe they have achieved their goal in life and do not exercise the training they have received after this perceived end has been achieved. However, in more developed countries, a research degree such as even a PhD is perceived as a training in research - the beginning of a journey in search of Truth.

COST BENEFIT ANALYSIS IN RESEARCH

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Research in business involves identifying a management problem/ opportunity; translating that problem/ opportunity into a research design and collecting and analysing and reporting the information specified in the research problem.

Management problem deals with decisions Managers must take. A research problem deals with providing information that will help the management to make a better decision.

A research design is the specification of procedures for collecting and analyzing the data necessary to help identify or react to a problem or opportunity, such that the difference between the cost of obtaining various levels of accuracy and the expected value of the information associated with each level of accuracy is maximised.

This definition emphasises four aspects, namely

(a) specification of procedures,
(b) the data are to be collected to help, identify or react to a problem or opportunity,
(c) information has value,
(d) varying levels of accuracy of information can be generated in response to be same problem,
(e) the goal of applied research design is to generate the most valuable information in relation to the cost of generating the information.

Research problem design process involves specifying the types of information that are needed by the management. It involves four inter related steps.

(a) management problems/ opportunity classification,
(b) situation analysis,
(c) model development and
(d) specification of information requirements.

STEPS IN THE RESEARCH DESIGN PROCESS

Step	Description
1. Define the Research Problem	Specify the information required to help react to the management problem
2. Select the data collection method(s)	Determine whether secondary data, a survey, or experimentation will produce the required data and choose the form of the selected method(s) to use.
3. Select the measurement technique	Determine whether and how to use questionnaires, attitude scales, observation, and/ or projective techniques.
4. Select the Sample	Determine who and how many respondents or objects to measure
5. Select the analytical approach	Determine the appropriate means of analyzing the data to provide the required information.
6. Specify the time and financial cost	For each research approach, develop time and financial cost estimates.
7. Estimate the value of the information to be provided by the research	Using either informal judgement or the expected value approach, determine whether any of the research approaches provide information judged to be worth more than its cost. If so pick the best informational buy. If not, and no other designs seem feasible, cancel the project.

8. Prepare the research proposal

Summarise the results of the preceding seven steps in the form of a research proposal.

The basic goal of problem definition and opportunity classification is to ensure that the decision makers initial description of the management decision is accurate and reflects the appropriate area of concern for research.

The situational analysis focuses on the variables that have produced the stated management problem or opportunity. It is not an arm chair exercise in logic. It involves giving careful attention to company records, appropriate secondary sources such as census data, industry sale figures, economic indicators and so on; and interviews with knowledgeable individuals both internal and external to the firm.

Situation model describes the outcome that are desired, identifies the variable which determine whether the objective/s will be met and indicates how the variables relate to the objective/s.

In cost benefit assessment of a research project the problem definition specifying the objective of research must be explicit. In estimating the time and financial requirements or the cost of research the researcher has to estimate the research requirements. These requirements are classified into broad categories, time and finance. Time refers to the period required to complete the project. The financial requirement is the monetary representation of personal time, computer time and materials requirements. The time and financial requirements are not independent. On some occasions time and money are inter-changeable.

Financial Requirements: Estimates of financial requirements must include the direct and indirect manpower costs, materials, transportation, overhead, and other costs. Commercial research organizations, particularly those that specialize in specific types of research, are often able to derive accurate rules of thumb.

Time -Cost Analysis: It is frequently possible to substitute financial resources for time. For example, it may be possible to gather information by personal interview or by mail. Although a number of variables may affect this decision, cost and time frequently play a major role. Personal interviews are generally faster and more expensive than mail questionnaires. However, if time is more critical in a given research project than the additional cost, personal interviews can be substituted.

The Cost of Delay: A very real cost of research can be the loss in earnings that would have been realized if a decision had been made immediately rather than waiting for a research project to be conducted. Although this is an opportunity rather than an out-of-pocket cost, it nonetheless should be taken into account in estimating the overall cost of a prospective research project.

The basic guiding principle in business research is that it is expected that the value of information to be obtained will be greater than the cost of obtaining it. The intuitive approach to decision making is a judgemental process. In opting for investing in business research it is possible to specify exactly what kinds of considerations that need to be taken into account such as

(a) the alternative action that could be taken,
(b) the possible state of the market and their pay offs,
(c) the degree of uncertainty concerning which state of the market is the actual state,
(d) the ability to forecast the actual state of the market given the research findings,
(e) the risk preferences of the decision making.

There are two other aspects that need to be considered in discussing cost benefit of research projects namely,

(a) the non-quantifiability of the benefits,
(b) difficulty of estimating the pay off period as the research findings will yield both short term and long term benefits. The long term benefits will depend on many other variables which can influence the market behavior.

In assessing cost benefit of research, it is also required to choose the degree of refinement required.

Otherwise the effort may far outweigh the results. There is also no need to belabour obvious answers or foregone conclusions. The following points need to be considered in assessing the benefit of research.

(a) What precisely is the issue to be analyzed and resolved? Has the problem been clearly spelled out?

(b) Which factors, relationships, and trends will likely to be helpful in analyzing the problem at hand?

(c) What ways can be found to get a quick "ballpark" estimate of a possible result ?

(d) How reliable are the available data, and how is this likely to affect results?

(e) How exact does the answer have to be, and how much effort should be expended in refining results?

(f) What are the limitations of the tools themselves, and how is this likely to affect results?

Whether or not the research agency's responsibilities extend to the interpretation of the data and recommendations for further policy is a matter to be agreed when the original briefing is given. The insight which researchers have gained into the clients' activities and the markets in which they operate, would appear to qualify them to offer unique guidance based on objective findings.

Finally, research findings from studies of a non-continuous nature can soon lose its value through the passage of time. Delay in dealing with survey findings may reduce the effectiveness of research, especially when the pace of change in a market is quickening.

Managerial attitudes to marketing research too impact cost benefit assessment. Some Managers think that marketing research could be turned on and off like a tap. There are others who expected marketing researchers `to jump when they said jump' and `at the drop of a hat to provide immediate answers to sometimes lunatic questions'.

Management information costs money and involves the use of scarce resources. It is important, therefore, to check that the value of the information will be greater than the costs involved in its collection and processing.

The simplest method of deciding whether or not to enter a particular market would be to toss a coin; the chances of a correct decision would be 50 - 50, so on the basis of a Rs. 500000/= markets launch the estimated possible loss would be Rs. 250000/=

But this simplistic approach is likely to be modified by the fund of knowledge and experience which management may already possess. This `background knowledge' is, as observed earlier, a necessary constituent of management decision making and, in some cases, it may be adequate. The more novel the product and the more dynamic the marketing environment, the greater the risk in making decisions on this basis.

To continue the example given above and assuming that present information is judged to be sufficient for management to make a correct decision on 60-40 basis, the estimated cost of making a wrong decision could be calculated thus: Rs. 500000/= x 40% = Rs. 200000/=.

The research is expected to improve the profitability of success. In computing the value of marketing research, the estimated cost of making a wrong decision has to be made. Research by providing more, accurate, uptodate information reduces the probability of market failure.

In dealing with day-to-day problems, managers may be accustomed to making three levels of estimates of the outcome of decisions: an expected, an optimistic, and a pessimistic one. They may, in a relatively informal way, attach probabilities to these projections. Bayesian decision theory offers a formal procedure for enabling management to make an efficient choice from among various alternatives.

TECHNOLOGIES IN RESEARCH

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Research is basically the search for new information/ data which needs to be established or confirmed. It might also involve determining the cause of a phenomenon or detection of a new process. The nature of research varies from discipline to discipline and a wide variety of technologies are used for the purpose. In this short address I cannot go into the types of technology but I should like to answer the questions that confronts the researcher in deciding on the type of technology that is most suitable for his/ her purpose.

(1) Create or Modify Technology

The researcher may need to develop a new technology or modify an existing technology to solve the research problems confronting him. Once a new test has been established he will then need to evaluate it with known positives and negatives to make sure that the test is giving the desired quantal result. He may need to calibrate using known values to make sure that it gives valid quantitative data.

(2) Choice of Test

More often the researcher has to choose among established tests what is best for his particular purpose. He needs to consider the characteristics of the test, the particular situation in which the test has to be applied, and other criteria such as cost and ease of performance.

(2.1) Characteristics of the test

The most important characteristics are sensitivity and specificity

Sensitivity refers to the ability of the test to pick up the true positives. If it picks up all the true positives then it is 100% sensitive. If it picks up only some of the true positives (say a) and fails to detect other true positives (say b) then the sensitivity (s) is given by the formula;

$$s = \frac{a}{a+b}$$

Specificity refers to the ability to detect true negatives and where some of the true negatives (say c) are detected and the remaining true negatives are undetected, i.e. false positives, (say d), then the specificity (f) is given by the following formula;

$$f = \frac{c}{c+d}$$

The ideal test would be 100% sensitive and 100% specific, i.e. capable of picking up all the true positives and true negatives. But in practise tests which are very sensitive tend to be less specific and vice versa. Therefore, tests have to be chosen according to the characteristics which are important for the particular purpose.

For example in the case of screening for results of the Human Immuno Deficiency Virus (HIV) which is the cause of AIDS, Blood Banks and other screening centres use a highly sensitive test such as a sandwich ELISA so that all true positives are detected. But some true negatives are also detected as false positives. The result is an over estimation of numbers that are positive for HIV infections and if a researcher uses these figures he will be misled. By repeating the test and also using other tests (supplementary) which operate on a different principle eg. competitive ELISA or particle agglutination test and even highly reliable (confirmatory) tests such as Western Blot or immunofluorescence the false positives are eliminated. This permits a proper determination to be made of the numbers of true HIV positives.

In practise it is not necessary to use all these tests because one or two reliable tests can eliminate all the false positives. In deciding the cost should also be taken into consideration.

Another example of the importance of sensitivity in deciding on the test was seen in testing for Hepatitis B virus infection. Earlier there were many tests which varied in their degree of sensitivity. eg. ID (+), IEOP(++), RPHA(+++), ELISA (+++), RIA(++++). Under these circumstances if one was performing a research project to determine the prevalence of Hepatitis B carriers in the community the only valid results would be by using RIA. However, in more recent times the sensitivity of the ELISA has been improved to equal the RIA. As this test is cheaper, has a longer shelflife, is safer and requires less equipment and facilities the ELISA has now become the accepted test for research purposes, whereas it was not earlier.

(2.2) The situation

In the examples of HIV testing given above even using the best tests for antibody some infected individuals can be missed as they may be infected but have not yet developed antibody. It will be possible to detect some of these by using a test that detects a virus component (antigen) such as P24. But even this may not be detected in some of those infected and therefore the best course is to test the individual again after 6 months or more when usually they would have developed antibody.

Another example showing the need to take the particular situation into consideration is demonstrated by the type of testing required to determine the prevalence of Japanese Encephalitis (JE) virus infection. It is very difficult, expensive and time consuming to do the specific test (neutralization, NT) for this virus. Therefore, one might use a simpler haemagglutination inhibition (HI) test. Unfortunately this test will give a positive result not only for a JE infection but also for a Dengue infection. However, as Dengue does not occur in the rural areas (at the moment) where JE occurs it would suffice to do the HI test for JE in the rural areas. Then a small sample of the HI positives can be confirmed by NT testing for JE and, if they are all positive then by extrapolating the HI test could be taken as an indicator of JE prevalence in that rural area.

3. Ensure reproducibility

This means that whenever the particular test is done even months or years apart, the results must be comparable. To ensure this the test kits used should be properly standardized. The conditions in which each test are carried out and the procedures should be consistent. The personnel performing the test should be of a similar ability and their performance should be uniformally good. Even then some degree of person to person variation can occur. The ideal would be for one competent person to do the tests at all times. The comparability of the results can be ensured by the use of adequate controls (positive and negative). Finally it is important that the test procedure or the test itself should not be changed during the course of the research project.

4. Quality Control and Calibration

Whatever the technology the instruments should be calibrated regularly to ensure accurate readings. There should be both internal and external quality control to ensure that the results obtain are accurate.

GETTING THE MESSAGE ACROSS

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Introduction

Are scientists, on the whole, worse at communicating their ideas than other categories of professionals and academics ? Although that question may be unanswerable with any degree of certanity, I know of no evidence to suggest that scientists are peculiarly inept at conveying their thoughts to others. All the same, there is no gainsaying that scientists could do with more attention to the fascinating art of communication.

I believe that irremediably bad communicators are few. Most people who do not communicate well simply have not tried hard enough. Some of them have not been told of their deficiency, perhaps out of a misplaced sense of politeness or friendship, or for fear of reprisals that may visit the potential critic. Others have not been told how to remedy their deficiencies. A third group comprises those who have been told all these, but choose to ignore them because of false pride or a sense of their infallibility.

Mastering the principles of effective communication requires much contemplation and practise. It also requires that one should welcome criticism and suggestions for improvement. The rest of this article is devoted to some of the principles central to effective communication by scientists.

Basic principles

Two fundamental aspects of effective communication can be simply stated in the form of questions: What is the message ? For whom is the message intended? Some examples may help to clarify.

The message may be, for example,

i) a research proposal for submission to a funding agency

ii) the results of research intended for oral or poster communication to a scientific body

iii) the results of research intended for publication in a scientific journal

iv) a press release for the general public

v) a review or situation report for policy makers with the object of modifying public policy

It ought to be clear from the examples given above that, to be acceptable and effective, the message must be given in a form, style, language and structure appropriate for the intended purpose and the medium. In other words, the message, the medium, the content and the presentation must all be carefully contemplated and crafted. A press communique written or delivered in the manner of a scientific article for a learned society is unlikely to attract anything other than an uncomprehending and cursory glance from members of the lay public.

Communications intended to modify public policy

Communications intended to modify public policy are usually aimed at policy and decision makers. The principal object here is to convince them. So such communications should ideally take note of some or all of the following. They should

i) be brief and reader-friendly

ii) be scientifically accurate and objective

iii) take into account socio-economic implications (eg. what would be the social and economic costs of implementing a new or modifying an existing policy ?)

iv) examine relevant cultural and religious aspects (eg many policy decisions such as slaughtering of animals, drug abuse, traffic and motoring regulations, abortion, contraception, homosexuality, health of workers etc, often have strong religious and cultural implications).

v) take note of political realities; remember, politics is the art of the possible.

To increase clout, it might be legitimate to use the media, approach individual politicians or `ginger groups', NGOs, and interested voluntary groups and associations, but only after careful consideration of the likely positive and negative consequences of such an approach. These approaches could be collectively referred to as campaigning, and that usually requires enormous skill, tact, organisation, energy and resources.

Communications intended for policy makers and politicians should have a fine balance between reasoning and rhetoric. They should preferably tilt more towards advocacy rather than polemic.

Communications intended for the mass media and the public

Communications aimed at the mass media (ie the public), should be crafted with some or all of the following in mind. They should

i) be as simple, brief and reader-friendly as possible

ii) pay particular attention to relevant cultural and religious sensitivities.

iii) use short rather than long sentences, and familiar rather than exotic or difficult words eg

try, not endeavour

everywhere, not ubiquitous

needs, not requisites

short-lived, not transitory

iv) use positive sentences eg.

a) Say, Rickets is common in India

Or, Many children in India have rickets

(depending on which is more appropriate)

Not, Rickets is not rare in India

b) Say, To recover soon the patient must eat a good diet

Not, If the patient does not take a good diet, he will not recover anytime soon.

v) use the same word each time for a thing, because using different words may confuse (eg. recently in a brief article in the press all these words were used to mean one fluid: semen, sperm, male sperm (!), ejaculate and seminal fluid)

vi) use active verbs eg.

a) Say, Jack built this house.

Or, This is the house that Jack built.

Not, This is the house that was built by Jack.

b) Say, Pasteur proposed the theory and Lister confirmed it

Not, The theory was proposed by Pasteur and confirmed by Lister

vii) avoid mixing metaphors or using apparently conflicting descriptions eg.

a) 'Mixing' metaphors I smell a rat, I see it floating in the air. Let us nip it in the bud.

b) Conflicting adjectives She is a little tall and pretty ugly (Say, she is tall and ugly).

viii) Use few pronouns, and make sure that the text makes clear what the pronouns refer to. eg.

Say, Tell the mother to give the syrup to her child three times a day. (Note, only one pronoun and that clearly refers to the mother)

Not, Tell her to give it to him three times a day. (Note, three pronouns, and none of them quite clear)

ix) avoid unnecessary comparatives eg.

distinctly better	=	better
somewhat similar	=	similar
reasonably fresh	=	fresh
considerably safe	=	safe
notoriously unreliable	=	unreliable

x) Keep tenses simple eg

a) Say, Mary ate poorly in the last week.

Not, Mary had been eating poorly in the last week

b) Say, patients with tuberculosis lose weight.

Not, patients with tuberculosis would have lost weight

c) Say, A child with measles has a rash

Not, A child with measles will have a rash

xi) explain in clear, logical sequence

xii) use special journalistic techniques where appropriate eg start with a 'real life' situation; pose a question etc.

a) How can teachers contribute to generating curiosity in children?

b) Ranjith returned from school one day with fever, a hoarse voice and a rash.

Communications to scientific bodies and journals

Communications to scientific bodies and journals should conform to the requirements of these associations or journals. Generally, the IMRAD format is useful. The acronym stands for introduction, methods, results and discussion.

Introduction - Why, precisely why did you undertake the study?

Methods - should be described in adequate detail for another worker to repeat the study

Results And - What did you find ?

Discussion - What do your results mean ?

Most journals also require a summary or structured abstract in 200 to 500 words. Some authors tend to think that such uniformity stifles style; while this may be so for a minority, clarity and brevity are greatly enhanced by structured articles for a vast majority of authors, readers, reviewers and science journalists.

Journals often carry a variety of articles eg editorials, research papers, reviews, meta-analyses, personal views and letters. Authors must learn how to select the appropriate journal and type of article, and adjust to the house-style of the journal.

ETHICS OF RESEARCH

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Research may be defined as a class of activities designed to develop or contribute to generalizable knowledge i.e. theories, principles or relationships, or the collection of information on which they are based, that can be corroborated by accepted scientific methods of observation and inference. Ethics may be very simply explained as rules of conduct or actions which are considered to be morally "right".

In my presentation today, I propose to deal briefly with ethical considerations applicable to the fields of human biomedical research, animal experimentation and social science research.

General Ethical Considerations

There are some ethical aspects which can be applied to all types of research irrespective of the field.

- **Purpose of research** - The research conducted should have some beneficial results and as far as possible should not cause any harm.

- **The scientific worker** - The person undertaking research should be competent to do so. eg. Helsinki II requires that "biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person".

  The researcher should display ethical responsibility such as integrity in conducting and publishing the research, fairness towards co-workers and colleagues, and respect for subjects and materials used.

- **Scientific method** - The scientific methodology used should be valid. It is now considered unethical to conduct experiments which are scientifically invalid. This view is taken by the World Health Organisation.

- **Ethical review** - All research proposals should be submitted to an independent ethical review committee for approval before research is begun. The research protocol should indicate the ethical considerations involved. Many scientific journals now insist on ethical approval as a condition for publication of results.

Animal Experimentation

Important advance in both human and veterinary medical science depend largely on animal experimentation. Indeed international ethical codes for human experimentation insist that new substances or devices should not be used for the first time on human beings unless they have been previously tested on animals and are presumed to be reasonably safe. The same principle applies to experimental surgery.

Different countries have different approaches to the use of animals in research, depending on the legal systems and cultural background. Some countries do not have any relevant legislation or even self-regulatory mechanisms. Therefore international guiding principles have been proposed for the use of vertebrate animals in research. These guidelines apply to intact live vertebrates.

International guiding principles for biomedical research involving animals

Basic principles :

- Should use methods other than animals wherever appropriate eg. mathematical models, computer simulation and in-vitro biological systems.
- Should be undertaken only if relevant for human or animal health and advancement of biological knowledge.
- The animals selected should be appropriate and the minimum number required to obtain scientifically valid results.
- Should treat animals as sentient and avoid or minimize discomfort, distress and pain.
- Should consider use of sedation, analgesia or anaesthesia as required.
- At the end of the experiment, or if appropriate during an experiment, animals should be painlessly killed if they suffer severe pain, distress or disability that cannot be relieved.
- Best possible living conditions should be maintained for research animals under supervision of experienced veterinarians.
- Best possible living conditions should be maintained for research animals under supervision of experienced veterinarians.

- Head of the institution should ensure competency of investigators conducting procedures on animals.

In addition to the above guidelines, the following provisions should be ensured by a national advisory council or other competent body:-

Acquisition - specialised breeding establishments should be the source of commonly used experimental animals.

Transportation-the animals should be transported under human and hygienic conditions.

Housing - animals should be housed to safeguard the general health of the animals. Attention should be paid to allocation of adequate space, maintenance of hygiene and provision of proper facilities for disposal of animal waste and dead animals.

Nutrition - adequate supply of food to maintain health and free access to potable water should be provided.

Veterinary care- should be available for health surveillance & disease prevention.

Records - should be kept of all experiments with animals and should be available for inspection.

Biomedical Research Involving Human Subjects

The Nuremberg Code of 1947 was the first international declaration on research involving human subjects, resulting from the Nuremberg War Crime Trials of physicians & scientists who had conducted biomedical experiments on prisoners in concentration camps during the Second World War. This code stressed that "voluntary consent" of the subject was essential for research in humans. The World Medical Association issued a modernised version of the Hippocratic Oath, the Declaration of Geneva, in 1948, but this did not make any reference to medical experimentation. The W.M.A. introduced a code of ethics in human experimentation in the Declaration of Helsinki in 1964 (Helsinki I). Helsinki I provided guidelines for medical doctors conducting clinical research, which was categorised into therapeutic and non-therapeutic clinical research. An important condition laid down was that "Informed consent" had to be obtained from the subject.

A revised version of the Declaration, issued in 1975 in Tokyo, (Helsinki II), broadened its scope to include "biomedical research involving human subjects". Helsinki II made a distinction between a) medical research combined with professional care (clinical research) and b) non-therapeutic (non-clinical) biomedical research, and included the following important provisions:

- In clinical research, exceptions to informed consent was permitted.
- Experimental protocol should be submitted to a "specially appointed independent committee for consideration, comments & guidance".
- Protocol should include a statement giving ethical considerations.
- Experiments not in accordance with ethical principles should NOT be accepted for publication.

Helsinki II has been widely accepted as the basic document in its field. Other important documents in this field are the Belmont Report (Report of the National Commission for the Protection of Human Subjects of Biomedical & Behavioral Research) issued by the Department of Health, Education & Welfare of the United States Government, and "Guidelines on the Practice of Ethics Committees in medical research involving human subjects" issued by the Royal College of Physicians, London U.K. in 1984.

The basic ethical principles governing biomedical research on human subjects are contained in Helsinki II. Ethical Review Committees should ensure that these basic principles are complied with:

- Investigators must be scientifically qualified and competent to carry out the proposed research
- Proposed research must be properly designed
- Benefit must be assessed in relation to risk
- Selection of subjects must be equitable.
- Subject's privacy must be respected
- Extent to which subjects are protected against possible hazards of intervention must be considered.

The general principles laid down in Helsinki II can be regarded to be of universal validity. However, there are certain limitations particularly with regard to how these principles may be applied in special circumstances of technologically developing countries. Therefore, the World Health Organisation (WHO) and the Council for International Organisations of Medical Sciences (CIOMS) have produced a document which covers these aspects eg. issues specific to research involving communities rather than individuals, externally sponsored research and the limitations of the informed consent procedure. This document, titled "International Ethical Guidelines for Biomedical Research Involving Human subjects" has been revised in 1993, (annexure). Certain areas such as human genetic research, embryo and fetal research and fetal tissue research are not covered in the CIOMS document.

Clinical research frequently involves the use of human tissues such as blood, semen, eggs, urine or saliva. In some cases, such specimens are collected specifically for use in research. At other times, procurement of human samples for use in research is "opportunistic" and this situation requires special ethical attention. A special situation of "opportunistic" use of human materials is research proposed on "leftover specimens," originally obtained for some other diagnostic, therapeutic or research purpose. The scientific and Ethical Review group of the Special Programme for Research Development and Research Training in Human Reproduction has drafted guidelines to help researchers to deal with ethical issues relating to the above situations.

Guidelines for ethical review in Health Systems Research - include the following

- Researcher should not use a position of authority or exert moral pressure to obtain consent.
- Whatever ethical considerations are applicable to individuals should be carried over to the community as far as possible.
- Should safeguard confidentiality of health - related records by having an established policy for control and access.
- Should attempt to communicate findings to decision makers quickly.

Social Sciences Research

The scope of Social Sciences or the Behavioural Sciences includes aspects of behaviour and behaviour influencing activities such as teaching - learning and their evaluation, communication and human psychology. Such behavioural studies include those pertaining to individuals, interacting groups or populations. Therefore, in addition to the general ethical considerations described earlier, many ethical principles described in the Helsinki Declaration are also applicable to research in Social Sciences.

When studying any form of human behavior, ethical considerations are of paramount importance, and codes of ethics for the conduct of research have been prepared by many professional organisations eg. American Sociological Association, American Psychological Association, etc. Two principles that are embodied in all these codes are 1) the right to privacy and 2) the relationship between individual cost and scientific benefit. Therefore, informed consent, freedom to decline and confidentiality are extremely important. When the principle of benefit vs. risk is considered, the possibility of causing psychological harm or discomfort rather than physical harm, should be kept in mind. Other ethical aspects which have more relevance in social science research include the use of deception as part of methodology, dehoaxing and desensitization, use of special populations and financial incentives.

References

1. Declaration of Helsinki (Revised) 1975. W.M.A.

2. The Belmont Report, CPRR Reports, 1979.

3. Human Experimentation and Medical Ethics. XVth CIOMS Round Table Conference.
Ed. Z. Bankowski and N. Howard - Jones, 1982.

4. Planning Educational Research, Borg & Gall. Longmans, Ny. 1989.

5. Ethics in Health Systems Research. S.R. Kottegoda, World Health Forum Vol. 11, 1990.

6. Draft of National Guidelines for ethical conduct of scientific research. NARESA - 1992

7. International ethical guidelines for biomedical research involving human subjects. CIOMS, Geneva, 1993.

ANNEXURE

International ethical guidelines for biomedical research involving human subjects

Geneva, Council for International Organizations of Medical Sciences (CIOMS), 1993.

Informed consent of subjects

1. *Individual informed consent*

For all biomedical research involving human subjects, the investigator must obtain the informed consent of the prospective subject or, in the case of an individual who is not capable of giving informed consent, the proxy consent of a properly authorized representative.

2. *Essential information for prospective research subjects*

Before requesting an individual's consent to participate in research, the investigator must provide the individual with the following information, in language that he or she is capable of understanding:

—that each individual is invited to participate as a subject in research, and the aims and methods of the research;
—the expected duration of the subject's participation;
—the benefits that might reasonably be expected to result to the subject or to others as an outcome of the research;
—any foreseeable risks or discomfort to the subject, associated with participation in the research;
—any alternative procedures or courses of treatment that might be as advantageous to the subject as the procedure or treatment being tested;
—the extent to which confidentiality of records in which the subject is identified will be maintained;
—the extent of the investigator's responsibility, if any, to provide medical services to the subject;
—that therapy will be provided free of charge for specified types of research-related injury;
—whether the subject or the subject's family or dependants will be compensated for disability or death resulting from such injury; and
—that the individual is free to refuse to participate and will be free to withdraw from the research at any time without penalty or loss of benefits to which he or she would otherwise be entitled.

3. *Obligations of investigators regarding informed consent*

The investigator has a duty to:

—communicate to the prospective subject all the information necessary for adequately informed consent;
—give the prospective subject full opportunity and encouragement to ask questions;
—exclude the possibility of unjustified deception, undue influence and intimidation;
—seek consent only after the prospective subject has adequate knowledge of the relevant facts and of the consequences of participation, and has had sufficient opportunity to consider whether to participate;
—as a general rule, obtain from each prospective subject a signed form as evidence of informed consent; and
—renew the informed consent of each subject if there are material changes in the conditions or procedures of the research.

4. *Inducement to participate*

Subjects may be paid for inconvenience and time spent, and should be reimbursed for expenses incurred, in connection with their participation in research; they may also receive free medical services. However, the payments should not be so large or the medical services so extensive as to induce prospective subjects to consent to participate in the research against their better judgment ("undue inducement"). All payments, reimbursements and medical services to be provided to research subjects should be approved by an ethical review committee.

5. *Research involving children*

Before undertaking research involving children, the investigator must ensure that:

—children will not be involved in research that might equally well be carried out with adults;
—the purpose of the research is to obtain knowledge relevant to the health needs of children;
—a parent or legal guardian of each child has given proxy consent;
—the consent of each child has been obtained to the extent of the child's capabilities;
—the child's refusal to participate in research must always be respected unless according to the research protocol the child would receive therapy for which there is no medically-acceptable alternative;
—the risk presented by interventions not intended to benefit the individual child-subject is low and commensurate with the importance of the knowledge to be gained; and
—interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual child-subject as any available alternative.

6. *Research involving persons with mental or behavioural disorders*

Before undertaking research involving individuals, who by reasons of mental or behavioural disorders are not capable of giving adequately informed consent, the investigator must ensure that:

—such persons will not be subjects of research that might equally well be carried out on persons in full possession of their mental faculties;
—the purpose of the research is to obtain knowledge relevant to the particular health needs of persons with mental or behavioural disorders;
—the consent of each subject has been obtained to the extent of that subject's capabilities, and a prospective subject's refusal to participate in non-clinical research is always respected;
—in case of incompetent subjects, informed consent is obtained from the legal guardian or other duly authorized person;

—the degree of risk attached to interventions that are not intended to benefit the individual subject is low and commensurate with the importance of the knowledge to be gained; and
—interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual subject as any alternative.

7. *Research involving prisoners*

Prisoners with serious illness or at risk of serious illness should not arbitrarily be denied access to investigational drugs, vaccines or other agents that show promise of therapeutic or preventive benefit.

8. *Research involving subjects in underdeveloped communities*

Before undertaking research involving subjects in underdeveloped communities, whether in developed or developing countries, the investigator must ensure that:

—persons in underdeveloped communities will not ordinarily be involved in research that could be carried out reasonably well in developed communities;
—the research is responsive to the health needs and the priorities of the community in which it is to be carried out;
—every effort will be made to secure the ethical imperative that the consent of individual subjects be informed; and
—the proposals for the research have been reviewed and approved by an ethical review committee that has among its members or consultants persons who are thoroughly familiar with the customs and traditions of the community.

9. *Informed consent in epidemiological studies*

For several types of epidemiological research individual informed consent is either impracticable or inadvisable. In such cases the ethical review committee should determine whether it is ethically acceptable to proceed without individual informed consent and whether the investigator's plans to protect the safety and respects the privacy of research subjects and to maintain the confidentiality of the data are adequate.

Selection of research subjects

10. *Equitable distribution of burdens and benefits*

Individuals or communities to be invited to be subjects of research should be selected in such a way that the burdens and benefits of the research will be equitably distributed. Special justification is required for inviting vulnerable individuals and, if they are selected, the means of protecting their rights and welfare must be particularly strictly applied.

11. *Selection of pregnant or nursing (breastfeeding) women as research subjects*

Pregnant or nursing women should in no circumstances be the subjects of non-clinical research unless the research carries no more than minimal risk to the fetus or nursing infant and the object of the research is to obtain new knowledge about pregnancy or lactation. As a general rule, pregnant or nursing women should not be subjects of any clinical trials except such trials as are designed to protect or advance the health of pregnant or nursing women or fetuses or nursing infants, and for which women who are not pregnant or nursing would not be suitable subjects.

Confidentiality of data

12. *Safeguarding confidentiality*

The investigator must establish secure safeguards of the confidentiality of research data. Subjects should be told of the limits to the investigators' ability to safeguard confidentiality and of the anticipated consequences of breaches of confidentiality.

Compensation of research subjects for accidental injury

13. *Right of subjects to compensation*

Research subjects who suffer physical injury as a result of their participation are entitled to such financial or other assistance as would compensate them equitably for any temporary or permanent impairment or disability. In the case of death, their dependants are entitled to material compensation. The right to compensation may not be waived.

Review procedures

14. *Constitution and responsibilities of ethical review committees*

All proposals to conduct research involving human subjects must be submitted for review and approval to one or more independent ethical and scientific review committees. The investigator must obtain such approval of the proposal to conduct research before the research is begun.

Externally sponsored research

15. *Obligations of sponsoring and host countries*

Externally sponsored research entails two ethical obligations:

—An external sponsoring agency should submit the research protocol to ethical and scientific review according to the standards of the country of the sponsoring agency, and the ethical standards applied should be no less exacting than they would be in the case of research carried out in that country.

—After scientific and ethical approval in the country of the sponsoring agency, the appropriate authorities of the host country, including a national or local ethical review committee or its equivalent, should satisfy themselves that the proposed research meets their own ethical requirements.