1.0 Preamble

The difficulty faced in providing a suitable definition of research involving humans suggests that a more appropriate focus is to seek to define that which needs to be considered and approved by **UTAR Scientific and Ethical Review Committee** (SERC). Where activity involves human participation, definable human involvement has a purpose of establishing facts, principles or knowledge or of obtaining or confirming knowledge, the features of human involvement will be the focus of deciding whether it is research and so subject to review by SERC.

Where that involvement has a potential for infringing basic ethical principles, review by SERC is warranted. Such a potential arises: when that involvement could cause harm to the well-being of participants whether physically, psychologically, spiritually or emotionally; or in the exploitation of cultural knowledge and/or property where their involvement or the use of their personal or community-based information has a potential for infringing their privacy or of the confidentiality or ownership that attaches to that information; or where their involvement imposes burdens with little benefit.

Researchers, regulators, funding bodies, institutions, organisations and SERC will need to address these issues with deliberate care and caution and arrive at provisional descriptions of what constitutes research that merits ethical review. In this process, a sustained awareness of the characteristics of the evolving research environment and practice will be important. The adoption of such an approach to deciding whether an activity ought to be subject to review by SERC (and be thereby classified as research requiring SERC review) provides guidance rather than prescription to institutions in which such activities and research are conducted. It is the responsibility of each institution and to develop criteria to classify which of its activities are reviewable by its SERC and which are not.

The research environment in Malaysia is marked by an increase in the quantity and diversity of research that is being conducted and in the sources of funding for that research. Not only have there been major developments in traditional research fields during the last century, but new fields are continually opening up in a great many disciplines. Within research related to health, the continuous advance in knowledge of the predictors of health status increases the avenues of further research. The field of genetics is currently a clear example. In this changing context, UTAR regards the development and promulgation of an inclusive, relevant and reliable set of guidelines for the ethical design and conduct of all research involving humans as essential. Such guidelines become more important as the sources of funding and number of researchers multiply.

The conduct and outcomes of research involving humans has had and will continue to have benefits for society. Such research, in seeking new knowledge about the conditions for social wellbeing including the causes of social dysfunction, the origins and progress of disease or the efficacy of treatment or health care, plays an essential part in the beneficial future of

our society. Further, the opportunity that such research provides for the education of our students and researchers should not be underestimated. In the assessment of the ethical acceptability of any research project, a committee should pay regard to the importance and the benefits of research and assess and balance these against the burdens undertaken by those participating in research.

2.0 Statement of Applicability, Principles and General Policies

2.1 Applicability

2.1.1 This assurance is applicable to all activities which, in whole or in part involve research with human subjects if

- the research is sponsored by UTAR, or
- the research is conducted by or under the direction of any employee of UTAR in connection with his or her institutional responsibilities, or
- the research is conducted by or under the direction of any employee of UTAR using any property or facility of UTAR, or
- the research involves the use of UTAR's non-public information to identify or contact human research subjects or prospective subjects.

2.2 Ethical Principles

2.2.1 UTAR is guided by the ethical principles regarding all research involving humans as subjects as set forth in the report of the National Commission of the Protection of Human Subjects of Biomedical and Behavioural Research entitled Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the "Belmont Report").

2.2.2 In addition, the requirements set forth in Malaysian Guidelines for Clinical Practice, Ministry of Health Malaysia will be met for all research without regard to source of funding.

2.3 Institutional Policy

2.3.1 This institution acknowledges and accepts its responsibilities for protecting the rights and welfare of human/animal subjects of research covered by this assurance.

2.3.2 It is the policy of this institution that all research covered by this assurance will be reviewed and approved by SERC. The involvement of human subjects in research covered by this policy will not be permitted until SERC has reviewed and approved the research protocol and informed consent has been obtained. Furthermore, the SERC's

review of research on a continuing basis will be conducted at appropriate intervals but not less than once per year.

2.3.3 It is the policy of this institution that unless informed consent has been specifically waived by SERC, no research investigator shall involve any human being as a subject in research unless the research investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.

2.3.4 This SERC has the responsibility and authority to review, approve, disapprove or require changes in appropriate research activities involving human subjects.

2.3.5 This institution will comply with the policies which provide additional protections pertaining to research, development, and related activities involving fetuses, pregnant women, and in vitro fertilization of human oval, research involves children, individuals institutionalized as mentally disabled and other potentially vulnerable groups, and research involving prisoners.

2.3.6 This institution shall provide each individual at the institution conducting or reviewing human subject research (e.g., PI's, department heads, research administrators, SERC members) with a copy of this institutional assurance of compliance and copies of any future modifications which may be made to this assurance, with the exception of changes in SERC membership.

3.0 Implementation

3.1 Responsibilities of Research Investigators

3.1.1 Determination of human subject involvement

- Research investigators shall make a determination as to whether research will involve human subjects.
- When it is not clear whether the research involves human subjects, research investigators should seek assistance from the Director of IPSR and the SERC in making this determination.

3.1.2 Preparation of protocol

- Research investigators shall prepare a protocol giving a complete description of the proposed research. In the protocol, research investigators shall make provisions for the adequate protection of the rights and welfare of prospective research subjects and insure that pertinent laws and regulations are observed. This requirement is applicable even in cases where the research is exempt under section 9.5 of the Research Ethics & Code of Conduct.

- Research investigators shall include samples of proposed informed consent forms with the protocol.

3.1.3 Scientific merit and ethical consideration review

- Departmental Heads through appropriate procedures established within their respective departments, are responsible for reviewing research protocols for ethical considerations and scientific merit.

3.1.4 Submission of protocol to IPSR

- Research investigators shall be responsible for insuring that all research involving human subjects is submitted to the IPSR.

3.1.5 Submission of a supplement to an original protocol to the IPSR.

- Research investigators shall be responsible for submitting a supplement to the original protocol to the IPSR when:
  - it is proposed to involve human subjects, and the activity previously had only indefinite plans for the involvement of human subjects, or
  - it is proposed to involve human subjects, and the activity previously had no plans for the involvement of human subjects, or
  - it is proposed to change the involvement of human subjects and that involvement is significantly different from that which was initially approved by the SERC.

3.1.6 Complying with SERC decisions

- Research investigators shall be responsible for complying with all SERC decisions, conditions and requirements.

3.1.7 Obtaining informed consent

- Research investigators are responsible for obtaining informed consent, and for insuring that no human subject will be involved in the research prior to the obtaining of the consent.
- Unless otherwise authorized by the SERC, research investigators are responsible for insuring that legally effective informed consent shall:
  - be obtained from the subject or the subject's legally authorized representative;
  - be in language understandable to the subject or the representative;
  - be obtained under circumstances that offer the subject or the representative sufficient opportunity to consider whether the subject should or should not participate; and
  - not include exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the research investigator, the sponsor, the institution or its agents from liability of negligence.

3.1.8 Providing basic elements of informed consent

- Unless otherwise authorized by the SERC, research investigators at a minimum shall provide the following information to each subject:
  - A statement that the study involves research, an explanation for the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
  - A description of any reasonable foreseeable risk or discomforts to the subject;
  - A description of any benefits to the subject or to others which may reasonably be expected from the research;
  - A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
  - A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
  - For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
  - An explanation of whom to contact for answers to pertinent questions about the research and research subjects' right, and whom to contact in the event of a research-related injury to the subject; and
  - A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

3.1.9 Providing additional elements of informed consent

- When required by the SERC, the research investigator shall provide one or more of the following additional elements of information to each subject:
  - A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
  - Anticipated circumstances under which the subject's participation may be terminated by the research investigator without regard to the subject's consent;
  - Any additional costs to the subject that may result from participation in the research;
  - The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

- A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
- The approximate number of subjects involved in the study.

3.1.10 Documentation of informed consent

- Research investigators shall be responsible for insuring that informed consent is documented by the use of a written consent form approved by the SERC and signed by the subject or the subject's legally authorized representative, unless this requirement is specifically waived by the SERC.
- Research investigators shall ensure that each person signs the written consent form is given a copy of that form.
- Research investigators may use a consent form which is either:
  - A written summary read to the subject or the subject's legally authorized representative, but in both events, the research investigator shall give either the subject or the representative adequate opportunity to read the form before signing it, or:
  - A "short form" written consent document stating that the elements of informed consent have been presented orally to the subject or the subject's legally authorized representative. When the "short form" is used, research investigators shall insure that:
    - a witness is present at the oral presentation,
    - the short form is signed by the subject or the representative,
    - the witness signs both the short form and a copy of the written summary of the oral presentation,
    - the person obtaining consent signs a copy of the summary,
    - a copy of both the short form and summary is given to the subject or the representative, and
    - the written summary of what is to be said to the subject or the representative receives the prior approval of the SERC.

3.1.11 Retention of signed consent documents

- Research investigators are responsible for placing the consent documents signed by human research subjects in a repository approved by the SERC.

3.1.12 Submission of progress reports on the research

- Research investigators are responsible for reporting the progress of the research to the IPSR, every 6 months in the manner prescribed by the SERC.

3.1.13 Submission of injury reports and reports of unanticipated problems involving risks

- Research investigators are responsible for reporting promptly to the IPSR any injuries to human subjects.

- Research investigators are responsible for reporting promptly to the IPSR any unanticipated problems which involve risks to the human research subjects or others.

3.1.14 Reporting changes in the research

- Research investigators are responsible for reporting promptly to the IPSR proposed changes in the research activity.
- Changes in research during the period for which SERC approval has already been given shall not be initiated by research investigators without SERC review and approval, except where necessary to eliminate apparent immediate hazards to the subject.

3.1.15 Reporting of non-compliance

- Research investigators are responsible for reporting promptly to the IPSR and the SERC any serious or continuing non-compliance with the requirements of this assurance of the determinations of the SERC.

3.1.16 Attending SERC meetings

- To facilitate the review of research and the protection of the rights and welfare of human subjects, research investigators are encouraged to attend SERC meetings when invited by the SERC.

3.1.17 Notifying the IPSR concerning investigational new drugs

- The research investigators shall be responsible for notifying the Malaysian Ministry of Health (MOH) and the IPSR whenever it is anticipated that an investigational new drug or device exemption will be required.