

UNIVERSITI TUNKU ABDUL RAHMAN			
Policy Title : <b>RESEARCH ETHICS &amp; CODE OF CONDUCT</b>			
Policy Number : <b>POL-IPSR-R&amp;D-004</b>	Rev No: <b>0</b>	Effective Date: <b>14/6/2011</b>	Page No <b>1 of 29</b>

## 1.0 Preamble

Universiti Tunku Abdul Rahman (*hereinafter* referred to as **UTAR**) is committed to the advancement of knowledge and research which is one of its critical goals in its aspiration to become the premier university. However, UTAR is also committed to inculcating among the UTAR community high moral values. Those conducting research enter into a social contract requiring them to be responsible and accountable for their activities. The right to conduct research is a privilege which is conditional on the rights and wellbeing of human participants, other living creatures and the good of the community being put foremost, in conformity with long established broad principles guiding research practice. UTAR *Research Ethics & Code of Conduct* (*hereinafter* referred to as **CODE**) provides a framework of standards intended to guide researchers, and the faculties/institutions in which they work, in acceptable research practices.

The CODE will assist those involved to establish research governance that promotes and supports a culture of responsible and accountable research practice and identifies the responsibilities of both faculties/institutions and researchers in areas including data and records management, publication of findings, authorship, conflict of interest, supervision of students and research trainees, research misconduct and ethical practice in research involving humans and other animals.

## 2.0 Implementation

- 2.1 The CODE is applicable to all **Researchers** of UTAR.
- 2.2 The President of UTAR (*hereinafter* referred to as **President**) is empowered to make exemptions from any section of the CODE if deemed appropriate.
- 2.3 The decision of the President on all matters regarding the interpretation of the CODE, or on any matter(s) not specified in the CODE is final.

## 3.0 Definition

- 3.1 The existence of many definitions of **Research** demonstrates how difficult it is to define it comprehensively. This document adopts the following definition written for the broad audience involved in the *Research Assessment Exercise* for Britain's universities:

**Research** is an original investigation undertaken to gain knowledge and understanding and makes it widely available. It includes work of direct relevance to the needs of commerce and industry, as well as to the public and voluntary sectors; scholarship; the invention and generation of ideas, images, performances and artefacts including design, where these lead to new insights; and the use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products and processes,

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*including design and construction. It excludes routine testing and analysis of materials components and processes, as distinct from the development of new analytical techniques. It also excludes the development of teaching materials that do not embody original research.*

- 3.2 SERC – refers to UTAR Scientific and Ethical Review Committee**
- 3.3 Researcher** is defined as anyone who is practising **Research** (as in 3.1) and includes all staff, either gainfully employed or with honorary positions, and students carrying out **Research** at or on behalf of UTAR.
- 3.4 Student** is defined as anyone enrolled in UTAR’s programmes including Bachelor, Master or Doctoral programmes.
- 3.5 Research Trainee** is defined as anyone, either gainfully employed or honorary, undertaking research activities under the supervision of an experienced Researcher of UTAR and with explicit permission from UTAR.
- 3.6 Good Research Governance** is defined as a system that sets standards of research practice, provides mechanisms to deliver those standards, provides for monitoring and assessment of research practice and applies to all **Researchers**. It is intended to improve research quality and, where research involves humans, foster participant safety by enhancing ethical and scientific quality, promoting good practice, reducing adverse events, ensuring lessons are learned and preventing poor performance and research misconduct.
- 3.7 Integrity** – A genuine search for knowledge, adherence to recognized principles of research conduct, honest conduct, and the dissemination and communication of results.
- 3.8 Respect for persons** – A regard for the welfare, rights, perceptions, customs and cultural heritage of participants (both individuals and collectives).
- 3.9 Beneficence** – Responsibility of the researcher to minimize risks or discomfort to participants (UTAR absolutely endorses the principle that respect for the dignity and well-being of participants must take precedence over the expected benefits to knowledge).
- 3.10 Justice** – A fair distribution of the benefits and burdens associated with participation in the research, and any inclusion / exclusion of subjects on the basis of gender, race, age, etc is essential to the purposes of the research;
- 3.11 Consent** – Informed and voluntary consent of potential participants in research.

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- 3.12 Research merit and safety** – research must be justifiable on the basis of its potential contribution to knowledge.

## **4.0 General Principles for Responsible Practice in Research**

- 4.1** Researchers have an obligation to society, funding agencies, their disciplines/fields, their colleagues and those whom they supervise or train, to maintain high standards of intellectual honesty and integrity in the conduct of their research, and in their dealings with other researchers.
- 4.2** Researchers must act with respect for the truth and for the rights of those affected by their research, to ensure they are conducting their research with integrity. Personal ambition and expectation of economic gain or material advantage must not compromise ethical, societal or scholarly considerations.
- 4.3** Researchers must be aware of, and appropriately manage, actual or potential conflicts of interest, whether financial or non-financial. This will generally require open disclosure and discussion, with the involvement of supervisors, managers and colleagues.
- 4.4** Researchers must be alert to and eschew plagiarism, deception, and the fabrication or falsification of results, each of which is a serious departure from responsible research conduct.
- 4.5** Researchers must respect those affected by their research and be mindful of the consequences of their research, adhering strictly to ethical and legal principles.
- 4.6** Researchers must be aware of and adhere to ethical principles of integrity, respect for persons, justice, beneficence and truthfulness. Responsible researchers demonstrate respect for the dignity, privacy and cultural differences of human participants, and avoid harming them. Respect also must extend to sentient and insentient animals and the environment used in research. Research must therefore comply with all relevant guidelines, including this document and all relevant laws.
- 4.7** Where research requires approval by SERC or by other safety or regulatory committees, research must not proceed without such approval.
- 4.8** Researchers must contribute to the monitoring of research by the institution through processes which include provision of regular reports as required by the institution and through the prompt notification of adverse or untoward events.
- 4.9** Researchers must report cases of suspected misconduct, and do so in a responsible, timely and appropriate manner as directed by institutional procedures.

## **5.0 Study Design & Ethical Approval**

- 5.1** Good research should be well justified, well planned, appropriately designed,

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and ethically approved. To conduct research to a lower standard may constitute misconduct.

- 5.2 Laboratory and clinical research should be driven by protocol; pilot studies should have a written rationale.
- 5.3 Research protocols should seek to answer specific questions, rather than just collect data.
- 5.4 Protocols must be carefully agreed by all contributors and collaborators, including, if appropriate, the participants.
- 5.5 The final protocol should form part of the research record.
- 5.6 Early agreement on the precise roles of the contributors and collaborators, and on matters of authorship and publication, is advised.
- 5.7 Statistical issues should be considered early in study design, including statistical calculations, to ensure there are neither too few nor too many participants.
- 5.8 Formal and documented ethical approval from an appropriately constituted research ethics committee is required for all studies involving people, medical records, and anonymised human tissues.
- 5.9 Use of human tissues in research should conform to the highest ethical standards.
- 5.10 Fully informed consent should always be sought. It may not always be possible, however, and in such circumstances, an appropriately constituted research ethics committee should decide if this is ethically acceptable.
- 5.11 When participants are unable to give fully informed consent, research should follow international guidelines, such as those of the Council for International Organizations of Medical Sciences (CIOMS).
- 5.12 Animal experiments require full compliance with local, national, ethical, and regulatory principles, and local licensing arrangements.
- 5.13 Formal supervision, usually the responsibility of the principal investigator, should be provided for all research projects: this must include quality control, and the frequent review and long term retention of all records and primary outputs.
- 5.14 When reporting experiments on humans subjects, authors should indicate whether the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation and with the Helsinki Declaration of 1975.
- 5.15 When reporting experiments on animals, authors should be asked to indicate whether the institutional and national guide for the care and use of laboratory animals was followed.

## **6.0 UTAR Scientific and Ethical Review Committee**

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SERC is to play the role in the regulation of research involving human or animal subjects / samples from human body or animals since investigators should not be the sole judges of whether their research conforms with generally acknowledged ethical codes.

Research is for advancement of knowledge and it should be carried out in the interests of community and its priorities. The interventions are justifiable if its objectives and studies are designed with a view to obtain information from as few subjects as possible and be exposed to a minimum of risk and inconvenience. The main principles of medical ethics are beneficence (the duty of the patient, subservient only to the larger good of the community); autonomy (respect for the patient's rights to self-determination); non-maleficence (the duty not to inflict harm or injury, which should always be considered together with beneficence); and justice (the patient should be given what is his or her due, within the limits of legal or societal concerns)

## **7.0 SERC Authorities and Responsibilities**

### **7.1 SERC's review and approval of research**

- The SERC shall have the responsibility to review and the authority to approve, modify or disapprove all activities or proposed changes in previously approved activities.
- The SERC shall approve research based on the SERC's determinations that the following requirements are satisfied:
  - Risks to subjects are minimized:
    - by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
    - whenever appropriate by using procedures already being performed on the subjects for diagnostic or treatment purposes.
  - Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of knowledge that may reasonably be expected to result. In evaluating risks and benefits, the SERC shall consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies the subjects would receive even if not participating in the research). The SERC shall not consider long-range effects of applying knowledge gained in the research as among those research risks that fall within the purview of its responsibilities.
  - Selection of subjects is equitable. In making this assessment the SERC shall take into account the purposes of the research, the setting in which the research will be conducted, and the population from which subjects will be recruited.

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- Informed consent will be sought from each prospective subject or the subject's legally authorized representative.
- Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

## 7.2 Documentation of informed consent

- The SERC shall require documentation of informed consent by use of a written consent form. It may however, waive the requirement to obtain a signed consent form for some or all subjects if the SERC decided that:
  - The only record linking the subject and the research would be the consent document and the principle risk would be the potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research and the subject's wishes will be taken into consideration; or
  - The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
- When the documentation requirement is waived, the SERC may require the research investigator to provide subjects with a written statement regarding the research.

## 7.3 Waiver or alteration of informed consent

- The SERC may approve a consent procedure which does not include, or waive the requirement to obtain informed consent provided the SERC finds that:
  - The research involves no more than minimal risk to the subjects;
  - The waiver or alteration will not adversely affect the rights and welfare of the subjects;
  - The research could not practicably be carried out without the waiver or alteration.

## 7.4 Observation of the consent process and the research

- The SERC shall have the authority to observe or have a third party observe the consent process and the research.

## 7.5 Frequency of review

- The SERC shall determine, in its review of research protocols, which projects will require SERC review more often than monthly.
- Except as may be otherwise provided in this assurance, all convened SERC meetings shall be conducted under and pursuant to UTAR Laws and Regulations.

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- Convened meeting of each SERC shall occur:
  - at the request of the R&D Committee and Commercialisation of UTAR when it determines that the SERC needs to review a proposal or application; and
  - at the call of the chairperson when the chairperson judges the meeting to be necessary or advantageous.

#### 7.6 Monitoring

- The SERC has the responsibility to ensure that the conduct of research approved by the SERC is monitored by procedures and/or by utilizing existing mechanisms within the faculties/institution which will ensure the achievement of the goals for monitoring as determined by the SERC.
- The SERC shall conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year.
- As a minimum the SERC must require at regular periods, at least annually, reports from principal researchers on matters including:
  - progress to date or outcome in the case of completed research;
  - maintenance and security of records;
  - compliance with the approval protocol; and
  - compliance with any conditions of approval.
- The SERC may recommend and/or adopt any additional appropriate mechanism for monitoring including random inspections of research sites, data and signed forms, and/or interview, with their prior consent, of research participants.

#### 7.7 Verification of change

- The SERC shall determine which projects need verification from sources other than the research investigators that no material changes have occurred since previous SERC review.

#### 7.8 Authority to suspend or terminate approval of research

- The SERC shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with the SERC's decisions, conditions and requirements or that has been associated with unexpected serious harm to subjects the consequence of which suspension or termination shall result in the suspension or termination of the research.

#### 7.9 Information dissemination and reporting requirements

- The SERC shall have the authority and be responsible for promptly reporting information to the IPSR, the R&D and Commercialisation Committee or both on a variety of issues. In conjunction with this requirement the SERC must be prepared to receive and act on information received from a variety of sources, such as human subjects, research investigators, the IPSR or other institutional staff

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which may be one of the following.

- Any serious or continuing non-compliance by research investigators with the requirements of the SERC.
- Injuries to human subjects - information received by the SERC concerning injuries to subjects.
- Unanticipated problems--information received by the SERC concerning unanticipated problems involving risks to subjects or others.

Suspension or termination of SERC approval – if the SERC decides to suspend or terminate approval of research protocols a statement of the reasons for the SERC's action shall be given promptly to the research investigator, the IPSR and the R&D and Commercialisation Committee.

#### **7.10 SERC Records**

- The SERC shall prepare and maintain adequate documentation of SERC activities, including the following:
  - Copies of all research proposals reviewed, scientific evaluation, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by research investigators and reports of injuries to subjects.
  - Minutes of SERC meetings, which shall be in sufficient details to show the names of attendees at the meetings; actions taken by the SERC; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; a written summary of the discussion of controversial issues and their resolution; and dissenting reports and opinions. If a member in attendance has a conflicting interest regarding any project, minutes shall show that this member did not participate in the review, except to provide information requested by the SERC.
  - Records of continuing review activities.
  - Copies of all correspondence between the SERC and the research investigators.
  - A list of SERC members.
  - Statements of significant new findings provided to subjects.
- The SERC shall provide for the maintenance of records relating to a specific research activity for at least 7 years after termination of the last SERC approval period for the activity.
- SERC records shall be maintained in the IPSR and shall be accessible for inspection and copying by authorized representative of funding agencies at reasonable times and in a reasonable manner, or shall be copied and forwarded to funding agencies when requested by authorized representatives of the agencies.



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### 7.11 Complaints

- The SERC shall establish mechanisms for receiving and promptly handling complaints or concerns about the conduct of an approved research project.
- The SERC must nominate a person to whom complaints from research participants, researchers, or other interested persons may be made in the first instance. The appointed person or the SERC shall attempt to resolve the complaints. Where a complaint made cannot be resolved, the SERC must refer the matter to the R&D Committee.

## 8.0 SERC Standard Operating Procedure

- 8.1 The following documents are required:
- full study protocol
  - volunteers/patient's information sheet
  - volunteers/patient's consent form
  - brief CVs of researchers (description of involvement is required)
- 8.2 For commercial link research, the following documents are required:
- detailed information regarding the products to be tested
  - letter of indemnity/insurance coverage
  - financial contract
  - statement on intellectual property right
- 8.3 For commercial link research, a processing fee will be charged to the company. The exact amount depends on the volume of materials to be screened. The SERC shall determine the amount.
- 8.4 Decision on ethical approval is made by consensus. Should the committee fail to reach a consensus; the final decision is made by a simple majority vote.
- 8.5 The Letter of Approval is signed by the chairperson and contains the following:
- the date of the meeting
  - the documents reviewed by the committee
  - the decision of the committee
  - the reasons for disapproval (in applicable)
  - the names of the investigators approved to do the research
  - the venue where the research is to be conducted
  - the expected date of commencement and duration of the research
  - the numbers of patients/volunteers involved in the research
- 8.6 The documents stated in 8.5 shall be submitted by the secretariat of SERC to IPSR within 5 working days after the meeting.
- 8.7 IPSR shall notify the researcher the status of the application within 3 working days after receiving the documents in 8.5 from the secretariat.
- 8.8 The IPSR shall monitor the progress and the final report of the project.

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## **9.0 SERC Procedures on Expedited Review**

### **9.1 SERC receives protocol:**

- The SERC chairperson shall receive all non-exempt research protocols from the IPSR.

### **9.2 Determination of review procedure**

- The SERC chairperson shall determine whether the research protocol meets the criteria necessary for an expedited review process.
- The SERC chairperson refers all research protocols to either full committee review or expedited review.

### **9.3 Expedited review**

- The eligibility of some research for review through the expedited procedure is in no way intended to negate or modify the policies of this institution.
- The SERC may use the expedited review procedure to review minor changes in previously approved research during the period for which approval is authorized.
- The only other research for which an SERC may use an expedited review procedure is that which involves no more than minimal risk to the subjects and in which the only involvement of human subjects will be in one or more of the following categories:
  - Collection of hair and nail clippings, in a no disfiguring manner deciduous teeth; and permanent teeth if patient care indicated a need for extraction.
  - Collection of excreta and external secretions including sweat, un-cannulated saliva, and placenta removed at delivery and amniotic fluid at the time of rupture of the membrane prior to or during labour.
  - Recording of data from subjects 18 years of age or older using non-invasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example x-rays, microwaves).
  - Collection of blood samples by venipuncture, in amounts not exceeding 20 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.
  - Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is

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accomplished in accordance with accepted prophylactic techniques.

- Voice recording made for research purposes such as investigations of speech defects.
  - Moderate exercise by healthy volunteers.
  - The study of existing data, documents, records, pathological specimens, or diagnostic specimens.
  - Research on individual or group behaviour or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the research investigator does not manipulate subjects' behaviour and the research will not involve stress to subjects.
  - Research on drugs or devices for which an investigational new drug exemption or an investigation device exemption is not required.
- Expedited review shall be conducted by the SERC chairperson or by one or more of the experienced SERC members designated by the chairperson to conduct the review.
  - The SERC member(s) conducting the expedited review may exercise all of the authorities of the SERC except that the reviewer(s) may not disapprove the research. The reviewer(s) shall refer any research protocol which the reviewer(s) would have disapproved to the full committee for review. The reviewer(s) may also refer other research protocols to the full committee whenever the reviewer(s) believes that full committee review is warranted.
  - When the expedited review procedure is used, the SERC chairperson or member(s) conducting the review shall inform SERC members of research protocols which have been approved under the procedure.
  - At the convened SERC meeting, any member may request that an activity which has been approved under the expedited procedure be reviewed by the SERC in accordance with non-expedited procedures. A vote of the members shall be taken concerning the request and the majority shall decide the issue.

#### **9.4 Full committee review**

- Research protocols scheduled for review shall be distributed to all members of the SERC prior to the meeting.
- When it is determined that consultants or experts will be required to advise the SERC in its review of a protocol, the research protocols shall also be distributed to the consultants or experts prior to the meeting.
- A majority of the membership of the SERC constitutes a quorum and is required in order to convene a meeting for the review of research protocols.

#### **9.5 The following categories of research are entitled to speedy review by IPSR without going through SERC (research protocols qualify for exemption):**

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- 9.5.1) Research conducted in established or commonly accepted education settings, involving normal education practices, such as:
- research on regular and special education instructional practices, or
  - research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- 9.5.2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
- information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
  - any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- 9.5.3) Research involving the use of education tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under the previous paragraph if:
- the human subjects are elected or appointed public officials or candidates for public office; or
  - statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- 9.5.4) Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, and if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.
- 9.5.5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
- public benefit or service programs;
  - procedures for obtaining benefits or services under those programs.

## **10.0 Data and Records Management**

- 10.1** *Data* is used to describe sufficient information from the work to enable the published results to be defended, enable other researchers to follow what was done, and ascertain whether the findings were genuine, analysed appropriately, and not fabricated.

While the original material – such as ore, biological materials, questionnaires, or tape recordings – may not need to be kept (except as required by legislation or discipline convention), a durable record of the relevant information derived from them (e.g. assays, test results, electronically recorded responses, or transcripts) should be kept. In some cases, retention of the original material for

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others to use may be required.

- 10.2** Researcher conducting research is responsible for the storage of data collected, and for maintaining clear and durable records concerning the location of stored data.
- 10.3** Researchers have primary responsibility for the appropriate and secure management of data and records.
- 10.4** Researchers should keep clear and accurate records of the procedures followed (including any approvals granted) before, during and after the research process.
- 10.5** Researchers must accord primary research records such as laboratory note books the same level of care and protection as data.
- 10.6** Researchers must manage their data so as to comply with relevant privacy legislation and protocols.
- 10.7** Researchers are responsible for ensuring appropriate security of any confidential material.
- 10.8** When data are obtained from limited access databases or via a contractual arrangement, written indication of the location of the original data, or key information regarding the database from which they were collected, must be retained by the researcher.
- 10.9** Researchers must make available for discussion data that form the basis of publications of any kind. Where confidentiality provisions apply (for example, where the researchers have given undertakings to third parties, such as the subjects of the research), it is necessary for data to be kept in a way that reference to them by third parties can occur without breaching such confidentiality.
- 10.10** When researchers are given access to information of value to others, such as in the peer review process, strict confidentiality must be maintained.
- 10.11** Researchers must be aware of professional standards, legal requirements and contractual arrangements in determining how long data must be retained.
- 10.12** Researchers must hold data for sufficient time to allow reference to them by other researchers and interested parties. For published data, this may be for as long as interest and discussion persists following publication.
- 10.13** Researchers must retain all relevant material while there is any likelihood that results from the work may be challenged. Data that have been subjected to challenge (and all relevant material) must be retained until any matter is resolved.
- 10.14** Researchers must retain data that are the basis for publications in a durable form and under the control of the institution where all or most of the work was undertaken.

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- 10.15** Researchers must ensure that data are stored securely in order to protect the privacy of participants and in accordance with such confidentiality agreements as may apply.
- 10.16** Researchers must ensure that computing systems, especially those which are accessible through networks, are secure. Security and confidentiality must be assured in a way that copes with use by multiple researchers and the departure of individual researchers.
- 10.17** Data should be appropriately analysed, but inappropriate analysis does not necessarily amount to misconduct. Fabrication and falsification of data do constitute misconduct.
- 10.18** All sources and methods used to obtain and analyse data, including any electronic pre-processing, should be fully disclosed; detailed explanations should be provided for any exclusions.
- 10.19** Methods of analysis must be explained in details, and referenced, if they are not in common use.
- 10.20** The post hoc analysis of subgroups is subject to permission obtained from SERC as well as from the participants.
- 10.21** The discussion section of a paper should mention any issues of bias, and explain how they have been dealt with in the design and interpretation of the study.
- 10.22** Researchers must ascertain whether confidentiality agreements apply to any given research project.
- 10.23** Researchers must make known to the head of the research institution (or nominated representative), details of any confidentiality agreement before such agreement is signed.

## **11.0 Publication Of Results**

- 11.1** Publication forms an essential part of the research process. It informs other researchers, professional practitioners and the wider community of the results of the research. Section 11.0 should be read in conjunction Section 12.0 on authorship and Section 13.0 on peer review.
- 11.2** Researchers, in consultation with the President or nominee must oversee confidentiality agreements to protect intellectual property rights between UTAR, the researcher and a sponsor of the research. Faculties/institutions must ensure that where such agreements limit free publication and discussion, an approved process is instigated to ensure that limitations and restrictions are explicitly agreed and understood by all concerned parties.
- 11.3** Researchers have responsibilities to their colleagues and the wider

community to publish the results of their research, if circumstances allowed.

- 11.4** An author, who submits substantially similar work to more than one publisher, whether at the same time or subsequently, must disclose this to the publishers at the time of submission.
- 11.5** Researchers must not re-publish without full disclosure and cross referencing, and must have received permission to do so from the original publisher.
- 11.6** Researchers must ensure the accuracy and integrity of the results they publish.
- 11.7** Researchers must take all reasonable steps to ensure that published reports, statistics and public statements about research activities and performance are accurate and unambiguous.
- 11.8** Researchers must be aware that integrity and accuracy in publications of results also extends to the accurate listing of publications in applications (for positions, research grants, awards etc), curricula vitae and public statements. This also applies to accurately describing the state of any publication (“in preparation”, “submitted”, “accepted”) of research funding (“applied for”, “granted”, “funding period” etc) and of awards conferred, including where any of these relate to more than one researcher.
- 11.9** Researchers must correct the record in cases where misleading or inaccurate statements have been made as soon as they are aware of the error.
- 11.10** Publications should include information on the sources of financial support for the research, and should include a disclosure of any potential conflicts of interest.
- 11.11** Information on research funding should be provided / stated within any type of publication (e.g., commercial company, charity or government department). The conditions of the funding from commercial firms, private foundations and government have the potential to bias and otherwise discredit the research.
- 11.12** The role of the research study sponsor, as well as the role of all parties contributing to the research and publication, in designing the research, recruiting investigators/authors, collecting the data, analyzing the data, preparing the manuscript or controlling publication decisions should be stated in the publication, unless this is obvious from the list of authors/contributors.
- 11.13** Other sources of financial support for publications should be clearly identified in the manuscript, usually in an acknowledgement.
- 11.14** Researchers must take great care when reporting research findings to the media. Such findings must be subjected to peer review and with the express consent of the SERC or Vice President-RDC before reporting. The status of research findings, whether preliminary, complete, peer

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reviewed or otherwise must be explicitly disclosed.

- 11.15** Where there is confidential reporting or use of research that has not been subjected to peer review, researchers have an obligation to explain fully the status of the work to the SERC, the Vice President-RDC or nominee and the scrutiny to which it will be subjected.

## **12.0 Authorship**

- 12.1** Authors are responsible for the publication of the results of research. To claim to be an author requires that a person is directly involved in the creation of the work – conceiving it, analysing and interpreting the data on which it is based, writing or revising its intellectual content, and taking responsibility for it once published. Authorship should honestly reflect the contribution to the work being published. No person who is an author, consistent with this definition, may be excluded as an author without their permission in writing.

Researchers must comply with authorship criteria appropriate to their discipline, and/or according to the requirements of the journal their work is to be published in. Similarly, the policies outlined here should also be adhered to in relation to grant applications. The following paragraphs should be read in conjunction with Section 11.0 on Publication of Results.

- 12.2** Collaborating researchers must discuss authorship of a publication or other research output at an early stage in a research project, and must review their decisions on authorship whenever there are changes in author participation.
- 12.3** Researchers must not deviate from acceptable execution of duties and responsibilities of authorship. Expressly unacceptable are:
- Gift authorship (granting authorship for reasons of friendship, position of authority etc. without their having met the criteria above);
  - Relinquished authorship (inducing or forcing persons to be removed from authorship where they do meet the criteria above);
  - Ghost authorship (being a writer who has had no input into the physical or intellectual work involved in the research);
  - Honorary authorship. (as for example granting authorship to a person simply because that person is Head of Department), and
  - Omission from authorship of those who have made substantial intellectual contributions.
- 12.4** The following are *not* sufficient to justify authorship:
- participating solely in acquisition of funding;
  - participating solely in collection of data; or
  - supervising the overall activities of the research group.
- 12.5** At least one author must accept responsibility for each part of an article critical to its main conclusion. An author's role in a publication or other research output must be sufficient for that person to take public responsibility for at least that part of the output to which that person



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contributed.

- 12.6** The right to authorship is not tied to either position or profession, and does not depend on whether the contribution was paid or voluntary. A researcher's name would not normally warrant inclusion as an author in situations where their participation related solely to the acquisition of data, the acquisition of funding or where their role in the research related only to general overall supervision.
- 12.7** When a large, multi-center group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript. These individuals should fully meet the criteria for authorship defined above and editors will ask these individuals to complete journal-specific authors and conflicts of interest disclosure forms.
- 12.8** When submitting a group author manuscript, the corresponding author should clearly indicate the preferred citation and should clearly identify all individual authors as well as the group name.
- 12.9** Journals will generally list other members of the group in the acknowledgements.
- 12.10** Researchers must ensure that others who have made substantial contributions to the research and those individuals and organisations who have provided facilities or material are acknowledged.
- 12.11** All contributors who do not meet the criteria for authorship should be listed in an acknowledgements section. Examples of those who might be acknowledged include a person who provided purely technical help, writing assistance, or a department chair who provided only general support. Editors should ask authors to disclose whether they had writing assistance and to identify the entity that paid for this assistance. Financial and material support should also be acknowledged.
- 12.12** Groups of persons who have contributed materially to the paper but whose contributions do not justify authorship may be listed under a heading such as 'clinical investigators' or 'participating investigators', and their function or contribution should be described – for example, 'served as scientific advisors', 'critically reviewed the study proposal', 'collected data', or 'provided and cared for study patients'. Because readers may infer their endorsement of the data and conclusions, all persons must give written permission to be acknowledged.
- 12.13** Names of sponsors of research must be disclosed.

## **13.0 Peer Review**

- 13.1** Peer review is accepted by the research community as an essential element of quality assurance in a range of processes from assessing grant applications, to reviewing performance, to the selection of staff. Peer review supports honesty and integrity in research and can sometimes help detect departures from the principles of the CODE (eg double

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publication, errors and misleading statements). However, it cannot act as the sole overseer of research integrity as peer reviewers rarely have access to all relevant information.

- 13.2** Researchers have a responsibility to participate in peer review processes for research when required.
- 13.3** Researchers involved as peer reviewers of research applications and/or publications must:
- Act in confidence and must not disclose any matter regarding the application or publication without the express permission of both the author(s), sponsor or UTAR
  - Be fair, impartial and not introduce irrelevant considerations
  - Disclose all real or potential conflicts of interest, and any other relevant matters that may affect the judgement of the application or publication
  - Not disclose to an outside party the outcome of any process in which they are involved
  - Ensure that they are informed about the policies and selection criteria to be applied
  - Not violate the issue of plagiarism of research idea
- 13.4** Researchers applying for research support or submitting papers for publication must:
- Ensure that their applications/publications are accurate and honest
  - Not omit relevant material or make claims not capable of verification
  - Not approach any person involved as a peer reviewer in an attempt to influence the decision making process.
  - Disclose all other sources of research support for all applicants
  - Disclose all sources of funding in regard to any publication

## **14.0 Supervision Of Students And Research Trainees**

- 14.1** All new researchers should receive proper training appropriate to the discipline(s) involved, in research ethics, and in research project management. Researchers act as role models for trainee researchers and need to ensure that the model they provide is positive and conducive to a research culture of excellence, honesty, integrity and discipline.
- 14.2** Researchers acting as supervisors must have the expertise as well as appropriately qualified to supervise each of the student or research trainee, provide guidance in all matters of research conduct and guidelines, including those covering ethical requirements for studies on humans or animals, requirements for privacy and confidentiality, and occupational health and safety matters, if applicable.
- 14.3** Supervisors must ensure that training in research conduct, both formal and practical, to be commenced as soon as possible in the career of a researcher. Subject to the availability of resources, training should encompass not only discipline-based research, but also industry research interactions, and skills relevant to working with diverse

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communities.

- 14.4** The supervisor must seek to ensure the validity of research data obtained by a research trainee under his/her supervision. Supervisors must take responsibility for overseeing all stages of the research process, including developing a hypothesis or research objective, preparing applications for funding, selecting methods for research and data collection and recording, and summarising, analysing and reporting findings.
- 14.5** Researchers must not exploit research students and junior colleagues.
- 14.6** Researchers must not put research students or junior researchers at risk. Risks can include chemical hazard, infectious disease and psychological trauma.

## **15.0 Disclosure Of Conflicts Of Interest**

- 15.1** A conflict of interest exists where there is a divergence between the individual interests of a researcher and his/her professional obligation to UTAR such that an independent observer might reasonably question whether the professional actions or decisions of that person are influenced by their own interests.

Conflict of interest is a serious issue in research as it can compromise the validity of the research process by influencing impartial judgement. While financial conflicts of interest are foremost in the public mind, other potential conflicts of interest include political or philosophical commitments, private benefits significantly dependent on research outcomes and significant personal or professional advantage.

A perception that a conflict of interest exists can be as serious as an actual conflict, raising concerns about the integrity of researcher. As such, the perceived conflict of interest will be treated as though the conflict exists until proven otherwise.

- 15.2** Conflicts of interest include, but are not limited to, any affiliation with, or financial involvement in, any organisation or entity with a direct interest in the subject matter or materials of their research.
- 15.3** Researchers have a responsibility to disclose at the time of proposing or reporting research any potential conflict of interest that may influence or be seen to influence any aspect of the conduct of the research. This responsibility extends to matters related to research including investigations, publication, media reports, grant applications, and applications for appointment or promotion. The most satisfactory means of managing conflicts of interest is for the researcher to remove him or herself from the process.

## **16.0 Research Misconduct**

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## 16.1 Definition

Research misconduct includes any conduct that jeopardizes research integrity and erodes the trust and confidence of the public in research. It includes fabrication, falsification, plagiarism or deception in proposing, carrying out or reporting results of research and deliberate, dangerous or negligent deviations from accepted practice in carrying out research. It includes failure to follow agreed protocol if this failure results in unreasonable risk or harm to humans, other sentient beings or the environment, and facilitating of misconduct in research by collusion in, or concealment of, such actions by others. It includes any plan or conspiracy or attempt to do any of these things.

Misconduct in this context does not include honest errors or honest differences in interpretation or judgment in evaluating research methods or results, or misconduct (including gross misconduct) unrelated to the research process.

Ongoing carelessness in record-keeping or in the preparation of grant applications or publications may, constitute misconduct, if it is of gross degree or repeated after admonishment. However, it does include the facilitation of misconduct in research by collusion in, or the concealment of, such actions by others. It also includes any plan or conspiracy or attempt to do any of these things.

## 16.2 Confidentiality

Allegations must be investigated in the strictest confidence. All those who are involved in the procedures for investigating an allegation, including witnesses, representatives and persons providing information, evidence and/or advice, have a duty to maintain strict confidentiality.

## 16.3 Responsibilities of Researchers

All members of UTAR have a responsibility to report any incident of suspected research misconduct, whether this has been witnessed, or is suspected. Every member of the University should understand, however, that any allegation which is found to be unproven and which has been frivolously or maliciously made may result in disciplinary action being taken against the member of staff who made the allegation.

16.3.1 A researcher suspecting possible misconduct has occurred or is occurring should first seek advice in confidence from the Dean of Faculty/Institute, on research integrity. Dean of Faculty/Institute will decide whether or not the matter requires further investigation.

16.3.2 If the Dean of Faculty/Institute has co-authored published material with the person against whom the allegation has been made (hereafter referred to as the **respondent**), or is the supervisor of a research project in which the person is the employer, or is the supervisor, or has some other professional connection with the person's research, the researcher should seek advice in confidence from amongst the Vice President appointed by the President. The Vice President will decide

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whether or not the matter requires further investigation.

- 16.3.3 In any case involving a UTAR staff, the matter will be investigated in conformity with the provisions of and procedures set out in the Statues and Ordinance of UTAR and/or any other written laws of the Country.
- 16.3.4 Researchers should be aware of the possibility of misconduct in research, both their own and that of others. Researchers must acknowledge their responsibility to bring alleged cases of research misconduct to the attention of the designated authority.
- 16.3.5 Researchers should be aware of the research governance framework within which they work and in particular the provisions relating to research misconduct.

#### **16.4 Responsibilities of Faculties/IPSR**

- 16.4.1 Faculties/IPSR shall name *advisers in research integrity* for consultation by staff and students who suspect misconduct or who are uncertain about what constitutes misconduct in particular situations. Faculties/IPSR should make available a range of persons able to provide independent advice to staff who wants to discuss their concerns with someone in order to determine whether there is a basis for making a formal report.
- 16.4.2 Faculties/IPSR must have procedures to investigate allegations of research misconduct independent of those for personal grievances and other forms of misconduct. The procedures for investigating allegations of research misconduct must provide for fair, prompt, judicious and confidential investigation.
- 16.4.3 The procedures must provide for the appointment of a person or persons to whom allegations of research misconduct are to be directed. There must be written procedures for that person or persons to follow including taking steps to secure all relevant documents.
- 16.4.4 Faculties/IPSR must ensure procedural fairness whenever misconduct is alleged. Fairness must apply to both those raising issues of misconduct and those being accused.
- 16.4.5 There must be provision for a preliminary investigation of an allegation of research misconduct. The preliminary investigation must provide for a written statement of any allegations to be provided to the person(s) against whom such allegations are directed, and for a written response from that person to be received and considered. A preliminary investigation should be limited to advising the institution whether a *prima facie* case exists that research misconduct has occurred. Confidentiality in the conduct of this investigation is paramount.

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- 16.4.6 On receipt of advice that a *prima facie* case of research misconduct exists, IPSR must forthwith notify any agency currently funding the research of the situation, on the understanding that the agency will not consider terminating its support until after the case has been proven.
- 16.4.7 The IPSR must make arrangements for a formal investigation where the preliminary investigation finds that a *prima facie* case exists.
- 16.4.8 If, after the formal investigation, research misconduct is established, those findings must be reported forthwith to any funding agency that supported work in respect of which such misconduct occurred, or any agency which is currently supporting the person found to have engaged in research misconduct (whether or not an appeal has been lodged).
- 16.4.9 Where relevant, IPSR must also notify forthwith other interested parties including professional registration authorities, scientific journals and any other media through which the research in question was reported.
- 16.4.10 There must be provision to continue any such investigation, even if the person accused of such misconduct resigns from the institution, in order to establish the facts. Distortions of the research record must be rectified, whether or not the persons involved remain in the institution.
- 16.4.11 Faculties/IPSR must establish a process for appeals against findings of research misconduct.
- 16.4.12 Institutional procedures and guidelines must be framed in such a way as to protect the interests of all interested parties. Such fair dealing must consider the protection of persons making allegations in good faith and of persons accused of misconduct. "Interested parties" include:
- a person bringing an allegation;
  - a person against whom an allegation is made;
  - staff, students and trainees working with persons making an allegation, or with persons against whom an allegation is made;
  - journals and other media reporting the research which is connected to the suspected, alleged, or found misconduct;
  - funding bodies supporting persons or research involved; and the public.

## **17.0 Responsibilities of the IPSR**

- 17.1 Institution determinations concerning exemptions, sponsorship, and certification.
- The IPSR shall receive from the research investigators all research

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protocols which involve human subjects.

- The SERC is responsible for reviewing the preliminary determinations of research investigators and for making final institutional determination whether research protocols qualify for exemption from coverage in 9.5.
- The IPSR shall forward all non-exempt research protocols to the SERC for review.
- The IPSR shall review all exempted research as well as all non-exempt research which has been reviewed and approved by SERC to recommend to the SENATE whether the institution shall support or sponsor such research.
- When the SERC approves a protocol on condition that the research investigator make modifications to the protocol, the IPSR shall not forward the protocol to any funding body until the IPSR has determined that such modifications are made. As appropriate, the SERC or the IPSR may negotiate protocol modifications with the research investigator. Each protocol submitted to funding body by the IPSR must include:
  - certification that the research was reviewed and approved by the SERC; or
  - notification that the research was determined to be exempt from coverage under 9.5 or that coverage was waived.
  - The IPSR shall keep research investigators aware of decisions and administrative processing affecting their respective protocols and shall return all disapproved protocols to the research investigators.

#### 17.2 Retention of signed consent documents

- The IPSR shall designate procedures for the retention of the signed consent documents. These documents shall be retained for at least three years after termination of the last SERC approval period.

#### 17.3 Reporting requirements

- The IPSR shall be responsible for promptly reporting information, as appropriate, to the SERC, the R&D and Commercialisation Committee, and research investigators on a variety of issues. Information may flow from sources such as human subjects, research investigators, SERC's or other institutional staff. Specifically, the IPSR shall:
  - report promptly to the R&D Committee and Commercialisation any instances of injuries to subjects and unanticipated problems involving risks to subjects or others;
  - report to the SERC information received concerning non-compliance by research investigators, injuries to subjects, unanticipated problems involving risks, changes proposed in research activities and the progress of research;

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- maintain information concerning the SERC's reasons for the termination or suspension of SERC approval; and
- report promptly any changes in SERC membership to the R&D Committee.

## **18.0 Ethical Practice in Research Involving Humans and Other Animals**

### **18.1 Research Involving Human Participants**

- 18.1.1 In research involving human participations, researchers should ensure the privacy and confidentiality of personal information relating to the participants in research, safety of the research participants, and that the research fulfils any legal requirements.
- 18.1.2 Approval from SERC is required for all research that involves
- human participants
  - medical records or
  - human biological samples
- 18.1.3 Approval is required to be obtained from SERC for the following research activities:
- studies requiring extra procedures to be carried out on the subjects, that is any procedure which would not have been normally carried out in the course of the subject's stay/visit to the medical centre, and which is proposed to be carried out because of the study
  - clinical trials
  - studies, whether retrospective or prospective, using patient data outside of the researcher's Department
  - questionnaire/surveys involving patients and/or their relatives
  - invasive medical or paramedical procedures
- 18.1.4 In the following cases, approval from SERC should also be obtained, namely
- research with children, prisoners and adults not competent to give consent
  - research that may impose an undue disadvantage upon participants.
- 18.1.5 The following researches may not require ethical review by the SERC.
- Research solely involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures and data collection in the public domain
  - Researches involving diagnostic and therapeutic procedures that are an accepted part of treatment and are recognized as a current practice by the appropriate professional body
  - Non-invasive medical or paramedical procedures
- However, the research activities involved should adhere to the Declaration of Helsinki.
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18.1.6 The application procedure is stipulated in the Guidelines to Applications for SERC review.

## **18.2 Research Involving Human Tissues**

18.2.1 Samples of human tissue, including blood and other body fluids, are collected from persons in hospitals and other health care institutions in a variety of circumstances. Samples collected for diagnostic purposes in the course of treatment may also be used for teaching or quality assurance activities and for research. Pathologists have traditionally exercised, and should continue to exercise, discretion in the use of clinical samples in the interpretation and development of laboratory procedures. After the original purpose for which samples were collected has been achieved, the residual tissue may be discarded. Hospitals and pathology laboratories are required by law to retain archival samples for diagnostic or forensic purposes. Accordingly, most hospitals have collections of stored samples, the use of which in research may lead to important advances in the understanding and treatment of disease.

18.2.2 Where human tissue is to be used in any research, SERC needs to be satisfied that the research proposal conforms to the guidelines in the following:

- Genetic research that uses human tissue
- Use of fetal tissue, reproductive tissue and tissue from autopsy for research.

18.2.3 The application procedure is stipulated in the Guidelines to Applications for SERC review.

## **18.3 Clinical Trials**

18.3.1 A clinical trial is a study involving humans to find out whether an intervention, including treatments or diagnostic procedures, which is believed may improve the health status of human being or mortality rate, actually does so. A clinical trial can involve testing a drug, a surgical or other therapeutic or preventive procedure, or a therapeutic, preventive or diagnostic device or service. Any intervention, including so-called “natural” therapies and other forms of complementary medicine, can be tested in similar way. Other related disciplines also conduct research which involves similar ethical considerations to those raised in clinical trials.

In pharmaceutical and medical device trials there are established codes of good clinical research practice which define clearly what is meant by a clinical trial for those purposes. Clinical Trials has principal application in the context of medical clinical trials but should also apply to any other intervention claiming therapeutic benefit, wherever provided or conducted.

The aims of every trial must be precisely stated in a protocol presented to and approved by (SERC) and every trial must be conducted by researchers with suitable experience, qualifications and competence and, where applicable, adequate training in relevant

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procedures including the use of any device being on trial.

18.3.2 The SERC must consider all aspects of the design of a clinical trial and be satisfied that:

- the trial is directed to answering a specific question or questions;
- there is a scientifically valid hypothesis being tested which offers a realistic possibility that the interventions being studied will be at least as effective as standard treatment;
- where the research is therapeutic, and is therefore intended and likely to be of direct benefit to participants, there is an acceptable balance between the risks and benefits of the trial;
- the methodology provides:
  - a rationale for the selection of appropriate participants;
  - an appropriate method of recruitment;
  - adequate, understandable information for the purpose of obtaining participant consent;
  - a clear description of the intervention and observation to be conducted; and
  - a sample size adequate to demonstrate clinically and statistically significant effects.
- it has access to adequate expertise or advice to consider the safety of the drugs, medical devices or other intervention under investigation.

18.3.3 The SERC, before granting approval to a clinical trial, must be satisfied that the protocol conforms to:

- Malaysian Guidelines for GCP,
- ICH GCP 1996,
- WHO GCP,
- Declaration of Helsinki, 2000,
- The Belmont Report 1979,
- ICH E2A, ICH E2B, ICH E2B(M),
- ICH 2C, ICH 2C (Addendum),
- ICH E9,
- ICH 135/95, and
- ISO 14155 Clinical Investigations of Medical Devices.
- MOH – Guidelines on Stem Cells Research

Note: (GCP – Good Clinical Practice; ICH – International Conference on Harmonisation; WHO – World Health Organization; ISO – International Organization for Standardization)

18.3.4 The use of a placebo alone or the incorporation of a non-treatment control group is ethically unacceptable in a controlled trial where:

- other available treatment has already been clearly shown to be effective; and
- there is risk of significant harm in the absence of treatment.

If there is genuine uncertainty about the net clinical benefit of treatment, a placebo controlled trial or a trial with a no-treatment arm may be considered.

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- 18.3.5 A researcher must inform the SERC of any business or other similar association which may exist between a researcher and the supplier of a drug or surgical or other device to be used in the trial.
- 18.3.6 The SERC must examine those aspects of the budgets of clinical trials which raise ethical issues, including capitation fees, payments to researchers, institutions or organisations involved in the research, current and consequential institutional or organisational costs and costs which may be incurred by participants. It should be satisfied that:
- payment in money or kind would not cause researchers to apply pressure to individuals so as to obtain their consent to participate;
  - payment in money or kind could not influence the findings of the research;
  - there will be disclosure to the research participants of relevant aspects of those budgets; and
  - funding is sufficient to conduct and complete the trial so that participants are not disadvantaged by premature cessation.
- 18.3.7 The SERC must be satisfied, before approving a clinical trial, that arrangements exist to ensure adequate compensation to participants for any injury suffered as a result of participation in the trial.
- 18.3.8 The SERC must require the researcher:
- to conduct the trial in compliance with the approved protocol;
  - to provide reports of the progress of the trial to the SERC at a frequency directed by the SERC that is related to the degree of risk to participants, but at least annually;
  - to inform the SERC of, and seek its approval of, amendments to the protocol including any:
    - proposed or undertaken in order to eliminate immediate hazards to participants;
    - that may increase the risks to participants; or
    - that significantly affect the conduct of the trial.
  - to inform the SERC of all serious or unexpected adverse events that occur during the trial and may affect the conduct of the trial or the safety of the participants or their willingness to continue participation in the trial;
  - to inform the SERC as soon as possible of any new information from other published or unpublished studies which may have an impact on the continued ethical acceptability of the trial or which may indicate the need for amendments to the trial protocol;
  - to inform the SERC, giving reasons, if the trial is discontinued before the expected date of completion;
  - to confirm the existence of or establish a system for tracking the participant, with consent, for the lifetime of the device in relation to trials with implantable medical devices, and to report any device incidents to the SERC;
  - to discontinue a trial if :

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- there are or have been substantial deviations from the trial protocol;
- side effects of unexpected type, severity, or frequency are encountered; or
- as the trial progresses, one of several treatments or procedures being compared proves to be so much better, or worse, than other(s) that continuation of the trial would disadvantage some of the participants.

18.3.9 The application procedure is stipulated in Guidelines to Applications for SERC review.

## **18.4 Research Involving the Use of Animals**

18.4.1 All experimental work should seek where possible to avoid the use of animals, and the researcher must have advance sound scientific reasons for their use, explaining in proposals for support why no realistic alternative exists. Approval from SERC is required for research involving animals.

18.4.2 Investigators who use animals for research have a moral and professional obligation to treat the animals humanely and consider their welfare when planning projects and conducting experiments.

18.4.3 Investigators have direct and primary responsibility for all matters related to the welfare of the animals under their control, including the general husbandry and housing of those animals as well as the specific experimental manipulations.

18.4.4 Research involving the use of animals should be designed so that:

- The objective is feasible, and clearly defined.
- Species with the most appropriate physiology for the work are used. Where possible, simple organisms should be used.
- The number of animals used in an experiment must be the minimum sufficient to create adequate statistical power to answer the question posed.
- The severity of the procedures performed upon animals is kept to the minimum. The experiment must be as short as possible, and analgesia/anaesthesia used to minimise pain wherever possible.

18.4.5 The application procedure is stipulated in Guidelines to Applications for SERC review.

## **19.0 Dispute Resolution**

### **19.1**

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Disputes arising under this Code of Conduct shall in the first instance be referred to Vice President -RDC for resolution. Should a satisfactory resolution not obtained, the dispute shall then be referred to the President for a decision. If the agreement is unable to reach, the final decision shall be decided by arbitration under the arbitration rules of Malaysian Institute of Arbitrators or its successor and using the said Institute's facilities. The appointing authority shall be the President of the Malaysian Institute of Arbitrators.

## **20.0 Review of Research Ethics & Code of Conduct**

- 20.1** The University shall have the discretion to waive or vary any of the provisions of these rules in a particular case. A waiver on one occasion and for a particular case shall not be deemed to be a waiver or variation of the same or any other provision on a future occasion or for a future case.
- 20.2** The University reserves the right to review this Code of Conduct from time to time. Issues arising shall be considered in the light of all relevant circumstances including the policies in place at that time.