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INTRODUCTION

The scientific research enterprise, like other human activities, is built on a foundation of trust. Scientists trust that the results reported by others are valid. Society trusts that the results of research reflect an honest attempt by scientists to describe the world accurately and without bias. The level of trust that has characterized science and its relationship with society has contributed to a period of unparalleled scientific productivity. But this trust will endure only if the scientific community devotes itself to exemplifying and transmitting the values associated with ethical scientific conduct.

Researchers, public and private research organizations, universities and funding organizations must observe and promote the principles of integrity in scientific and scholarly research. Universities, institutes and all others who employ researchers, as well as agencies and organizations funding their scientific work, have a duty to ensure a prevailing culture of research integrity. This involves clear policies and procedures, training and mentoring of researchers, and robust management methods that ensure awareness and application of high standards as well as early identification and, wherever possible, prevention of any transgression.

The following should serve as foundation upon which the institution should develop its own responsible research framework that builds upon these principles, responsibilities, and guidelines. It is the responsibility of the institution and the collective researchers and staff to maintain the public’s trust and the integrity of research carried out and developed in University of Malaya.

1.0 GENERAL PRINCIPLES OF RESPONSIBLE RESEARCH

1.1 Responsibilities of the Institution

- Promote awareness of all manuals and legislation relating to the conduct of research.
- Provide documents setting out clearly the policies and procedures based on this manual.
- Actively encourage mutual cooperation with open exchange of ideas between peers, and respect for freedom of expression and inquiry.
- Maintain a climate in which responsible and ethical behavior in research is expected.
- Establish good governance and management practices by encouraging responsible conduct by researchers. Such practices promote quality in research, enhance the
reputation of the institution and its researchers, and minimize the risk of harm for all involved.

- The institution should provide an appropriate research governance framework through which research is assessed for quality, safety, privacy, risk management, financial management, and ethical acceptability in compliance with laws, regulations, manuals, and codes of practice governing the conduct of research in Malaysia.

- The institution must ensure the availability of the documents that help guide good research governance, conduct and management.

- Establish a clear policy on collaborative research projects with other organizations, which requires arrangements to be agreed before a project begins. As a minimum, these arrangements should cover financial management, intellectual property, authorship, publication, ethics approval, and ownership of equipment and data.

- The institution must have a well-defined process for receiving and managing allegations of research misconduct.

- There must be a process for regular monitoring of the institution’s performance with regard to these manuals.

a) Staff Training

- It is important that the institution provides induction, formal training and continuing education for all research staff, including research trainees.

- Training should cover research methods, ethics, confidentiality, data storage and records retention, as well as regulation and governance.

- Training should also cover the institution’s policies regarding responsible research conduct, all aspects of this manual, and other sources of guidance that are available. Institutions may make arrangements for joint induction and training with other institutions.

b) Promote mentoring

- The institution should promote effective mentoring and supervision of researchers and research trainees.

- This includes advising on research ethics, research design and methods, and the responsible conduct of research.

c) Ensure a safe research environment

- The institution must ensure a safe working environment in which to conduct each research project.
1.2 Responsibilities of Researchers

a) Maintain high standards of responsible research fostering a research environment of intellectual honesty and integrity, and scholarly and scientific rigor. Researchers must:

- respect the truth and the rights of those affected by their research.
- manage conflicts of interest so that ambition and personal advantage do not compromise ethical or scholarly considerations.
- adopt methods appropriate for achieving the aims of each research proposal.
- follow proper practices for safety and security.
- cite awards, degrees conferred and research publications accurately, including the status of any publication, such as under review or in press.
- promote adoption of this manual and avoid departures from the responsible conduct of research.
- conform to the policies adopted by their institutions and bodies funding the research.

b) Researchers should ensure that research findings are disseminated responsibly.

c) Researchers must comply with ethical principles of integrity, respect for persons, justice and beneficence.

d) Written approval from appropriate ethics committees, safety and other regulatory bodies must be obtained when required.

e) Researchers must respect the animals they use in research, in accordance with the Malaysian law, regulation, or institutional policies.

f) Researchers should conduct their research so as to minimize adverse effects on the wider community and the environment.

g) A researcher who considers that research misconduct may have occurred must act in a timely manner, having regard to the institution’s policies.

h) Appropriate community involvement in research should be encouraged and facilitated by research institutions and researchers especially in research affecting or of concern to vulnerable populations.
2.0 MANAGEMENT OF RESEARCH DATA

2.1 Responsibilities of the Institution

a) Retain research data and primary material

- The institution must have a policy on the retention of materials and research data that is consistent with practices in the discipline, relevant legislation, codes and manuals.

b) Provide secure research data storage and record-keeping facilities

- The institution must provide facilities for the safe and secure storage of research data and for maintaining records of where research data are stored.

c) Date retention and storage time requirements

In general, the minimum recommended period for retention of research data is 5 years from the date of publication. However, in any particular case, the specific type of research should determine the period for which data should be retained. For example:

- for short-term research projects that are for assessment purposes only, such as research projects completed by students, retaining research data for 12 months after the completion of the project may be sufficient.

- for most clinical trials, retaining research data for 15 years or more may be necessary.

- for areas such as gene therapy, research data must be retained permanently (e.g. patient records).

- if the work has community or heritage value, research data should be kept permanently at this stage, preferably within a national collection.

- A policy is required that covers the secure and safe disposal of research data and primary materials when the specified period of retention has finished.

d) Data Ownership

- There must be a policy on research data ownership and storage.

- This policy must cover all situations that arise in research, including when researchers move between institutions or employers and when data are held outside Malaysia.

- Agreements covering ownership and storage of research data should be reviewed whenever there is movement or departure of research staff.

- Wherever possible and appropriate, research data should be held in the researcher’s department or other appropriate institutional repository, although researchers should be permitted to hold copies of the research data for their own use.
In projects that span several institutions, an agreement should be developed at the outset covering the storage of research data and primary materials within each institution.

e) Identify ownership of research data and primary materials

- The institution must have a policy on the ownership of research materials and data during and following the research project. The ownership may also be influenced by the funding arrangements for the project. As a general rule, the most satisfactory arrangement will be that the materials and data retained at the end of a project are the property of the institution that hosted the project, another institution with an interest in the research, or a central repository.

f) Ensure security and confidentiality of research data and primary materials

- The institution must have a policy on the ownership of, and access to, databases and archives that is consistent with confidentiality requirements, legislation, privacy rules and other manuals. The policy must guide researchers in the management of research data and primary materials, including storage, access, ownership and confidentiality; ensure that researchers are informed of relevant confidentiality agreements and restrictions on the use of research data; and must be secure, and information technology personnel must understand their responsibilities for network security and access control.

2.2 Responsibilities of Researchers

a) Retain research data and primary materials

- When considering how long research data and primary materials are to be retained, the researcher must take account of professional standards, legal requirements and contractual arrangements.

- Researchers should retain research data and primary materials for sufficient time to allow reference to them by other researchers and interested parties. For published research data, this may be for as long as interest and discussion persist following publication.

- Research data should be made available for use by other researchers unless ethical, privacy, or confidentiality matters prevent this.

- Research data should be retained for at least the minimum period specified in the institutional policy.

- If the results from research are challenged, all relevant data and materials must be retained until the matter is resolved. Research records that may be relevant to allegations of research misconduct must not be destroyed.
b) Manage storage of research data and primary materials

- Researchers must manage research data and primary materials in accordance with the policy of the institution.

c) Maintain confidentiality of research data and primary materials

- Researchers given access to confidential information must maintain that confidentiality. Primary materials and confidential research data must be kept in secure storage.

- Confidential information must only be used in ways agreed with those who provided it. Particular care must be exercised when confidential data are made available for discussion.

3.0 SUPERVISION OF RESEARCH TRAINEES INTRODUCTION

All research trainees must receive training on research ethics, this manual, and the research policies of the institution concerned. This should have high priority for completion early in their careers. Researchers and supervisors must ensure that the role model they provide to junior colleagues is positive and conducive to a research culture of excellence, integrity, professionalism and mutual respect.

In return, research trainees must understand that in undertaking research they are joining an endeavor that requires dedication and accountability. Thus, research trainees also have responsibilities under this section.

3.1 Responsibilities of the Institution

a) Set standards for supervision and mentorship

- The institution must ensure that each research trainee, whether part of the institution or from elsewhere, has an appropriately qualified and trained supervisor.

- It follows that the ratio of research trainees to supervisors must be low enough for effective intellectual interaction.

b) Induct research trainees

- The institution must ensure that research trainees understand the importance of responsible research conduct.
• The institution must provide induction and training for all research trainees. This training should cover research ethics, occupational health and safety, and environmental protection, as well as technical matters appropriate to the discipline.

• The institution must maintain the availability of key documents on the responsible conduct of research, including this manual, institutional manuals on the conduct of research, requirements for research involving humans and animals, privacy and confidentiality, and the institution’s mechanisms for dispute resolution.

3.2 Responsibilities of Researchers, Supervisors, and Research Assistants/Staff:

a) Ensure training

• Supervisors of research trainees should ensure that training starts as soon as possible in the career of a researcher.

• Training should encompass discipline-based research methods and other relevant skills, such as the ability to interact with industry and to work with diverse communities.

b) Mentor and provide support

• The research supervisor should guide the professional development of research trainees. This involves providing guidance in all matters relating to research conduct and overseeing all stages of the research process, including identifying the research.

c) Ensure valid and accurate research

• Supervision includes oversight of the research outcomes from those under supervision. A supervisor must be satisfied that the research methods and outcomes of researchers and research trainees under their supervision are appropriate and valid.

d) Ensure appropriate attribution

• Researchers and supervisors must ensure that research trainees receive appropriate credit for their work.

e) Seek guidance

• A research trainee must demonstrate a professional attitude towards the research. Frequent sessions with the supervisor are important, requiring the cooperation of both parties.

• The trainee should not wait until approached by the supervisor but should play an active part in maintaining an appropriate schedule of meetings.
f) Undertake induction and training

- A research trainee should complete all induction and training courses as soon as possible after embarking on research in the institution.

4.0 DISSEMINATION AND PUBLICATION OF RESEARCH FINDINGS

Dissemination of findings is a very significant part of research. This includes passing on the benefits from the research to other researchers and commonly to the community. While most granting agencies require a report at the conclusion of the funding period, making the findings available to the broader academic, clinical and general community is important. Publication in journals is probably the most common form of dissemination along with conference presentations.

There are many other types of dissemination such as web documents, leaflets, public presentations or media interviews. The potential users of research findings are not just academics. Clinicians, policy makers, funders, educators and members of the public may also be interested in the work and its implications for their area of responsibility.

4.1 Responsibilities of the Institution

a) Promote responsible publication and dissemination of research findings

b) Protect confidentiality and manage intellectual property

c) Support communication of research findings to the wider public.

4.2 Responsibilities of Researchers

a) Disseminate all research findings

Researchers have a responsibility to their colleagues and the wider community to disseminate a full account of their research as broadly as possible.

b) Ensure accuracy of publication and dissemination

All reasonable steps must be taken to ensure that published reports, statistics and public statements about research activities and performance are complete, accurate and unambiguous.
c) Cite the work of other authors fully and accurately

Researchers must ensure that they cite other relevant work appropriately and accurately when disseminating research findings.

d) Multiple submissions of research findings

Publication of multiple papers based on the same set(s) or subset(s) of data is not acceptable, except where there is full cross-referencing within the papers (for example, in a series of closely related work, or where a complete work grew out of a preliminary publication and this is fully acknowledged).

e) Obtain permission for republishing

Researchers must take all reasonable steps to obtain permission from the original publisher before republishing research findings.

f) Disclose research support accurately

Publications must include information on the sources of financial support for the research. Financial sponsorship that carries an embargo on such naming of a sponsor must be avoided.

g) Register clinical trials

Researchers must register clinical trials with a recognised register to promote access to information about all clinical trials.

h) Acknowledge the work

Publications involving either a student enrolled with the University, or a University staff member must acknowledge the work was carried out at the University by using the university by-line.

i) Manage confidentiality

Sometimes the confidentiality requirements of a sponsor can prevent or delay peer review until after the research results are delivered to the sponsor. In such cases, the researcher must explain to the sponsor that the work has not been subject to peer review.

j) Responsibly communicating research findings in the public arena

Researchers may be interviewed by the media, invited to participate in debates, and approached by individuals for comment. It is important that all these activities are considered and supported where possible to minimise misunderstanding about research outcomes.
5.0 AUTHORSHIP AND CONTRIBUTORSHIP

An “author” is generally considered to be someone who has made substantive intellectual contributions to a published study, and biomedical authorship continues to have important academic, social, and financial implications. An author must take responsibility for at least one component of the work, should be able to identify who is responsible for each other component, and should ideally be confident in their co-authors’ ability and integrity. In the past, readers were rarely provided with information about contributions to studies from persons listed as authors and in acknowledgments.¹

Some journals now request and publish information about the contributions of each person named as having participated in a submitted study, at least for original research. Editors are strongly encouraged to develop and implement a contributorship policy, as well as a policy on identifying who is responsible for the integrity of the work as a whole.

While contributorship and guarantorship policies obviously remove much of the ambiguity surrounding contributions, they leave unresolved the question of the quantity and quality of contribution that qualify for authorship. The following criteria are recommended for authorship; these criteria are still appropriate for journals that distinguish authors from other contributors. Authorship credit should be based on:

1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;

2) drafting the article or revising it critically for important intellectual content;

3) final approval of the version to be published.

Authors should meet conditions 1, 2, and 3. When a large, multicenter 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/contributorship defined above, and editors will ask these individuals to complete journal-specific author and conflict-of-interest disclosure forms.

When submitting a manuscript authored by a group, the corresponding author should clearly indicate the preferred citation and identify all individual authors as well as the group name. Journals generally list other members of the group in the acknowledgments. The United States National Library of Medicine (NLM) indexes the group name and the names of individuals the group has identified as being directly responsible for the manuscript; it also lists the names of collaborators if they are listed in acknowledgments.

- Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute authorship.
- All persons designated as authors should qualify for authorship, and all those who qualify should be listed.
Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

5.1 Responsibilities of the Institution

a) Have criteria for authorship

The institution must have a policy on the criteria for authorship consistent with this code, seeking to minimise disputes about authorship and helping to resolve them if they arise.

5.2 Responsibilities of Researcher

a) Follow policies on authorship

Researchers should adhere to the authorship criteria in their institution’s codes and policies.

b) Agree on authorship

Authorship of a research output is a matter that must be discussed between researchers at an early stage in a research project, and reviewed whenever there are changes in participation.

c) Include all authors

Researchers must offer authorship to all people, including research trainees, who meet the criteria for authorship listed above.

d) Do not allow unacceptable inclusions of authorship

Authorship should not be offered to those who do not meet the requirements set out below:

- being head of department, holding other positions of authority, or personal friendship with the authors.
- providing a technical contribution but no other intellectual input to the project or publication.
- providing routine assistance in some aspects of the project, the acquisition of funding or general supervision of the research team.
- providing data that has already been published or materials obtained from third parties, but with no other intellectual input.
e) Acknowledge other contributions fairly

Researchers must ensure that all those who have contributed to the research, facilities or materials are properly acknowledged, such as research assistants and technical writers.

f) Extend the authorship policy to web-based publications

Authors of web-based publications must be able to take responsibility for the publication’s content and must be clearly identified in the publication. Where the research is published, including electronically, one author must be given principal status with the responsibility for signing a Statement of Authorship form ensuring that all co-authors are in agreement with their inclusion and that no person entitled to authorship has been excluded.

g) Maintain signed acknowledgments of authorship for all publications

The department of the executive or senior author must retain the written acknowledgment of authorship discussed above in the form of an original hand-written signature. Where it is not practical to obtain an original signature, it is acceptable to use faxed or emailed consent. This also applies to published conference abstracts and similar publications. If an author is deceased or cannot be contacted, the publication can proceed provided that there are no grounds to believe that this person would have objected to being included as an author.

6.0 PEER REVIEW

Peer review is both a set of mechanisms and a principle at the heart of the system for evaluating and assuring the quality of research before and after it is funded or published. It involves subjecting research proposals and draft presentations, papers and other publications to critical evaluation by independent experts (peers). The reviewers are usually appointed by the funding body or the editors of a journal or other formal channel for communication to which the work has been submitted.

Peer review is applied to a number of activities in the research process, particularly in the context of higher education. There is considerable variety of practice, and it is a merit of the system that there is no single model of good practice. But peer review is employed in:

- the evaluation of applications for funding, to determine which applications are successful.
- the review of reports submitted by researchers once their funding award has come to an end.
- to assess whether a project has been completed satisfactorily.
- the evaluation of draft conference presentations, journal articles and monographs, before they are published, to assess whether they meet quality standards.
• the evaluation of publications once they have been published, through reviews and review articles.
• the evaluation of the quality of work produced by individuals, teams, departments and institutions to help determine appointments, promotions and levels of funding.

6.1 Responsibilities of the Institution

a) Encourage participant in peer review

6.2 Responsibilities of Peer Reviewers

a) Conduct peer review responsibly

It is important that participants in peer review:

• are fair and timely in their review.
• act in confidence and do not disclose the content or outcome of any process in which they are involved.
• declare all conflicts of interest, do not permit personal prejudice to influence the peer review process, and do not introduce considerations that are not relevant to the review criteria.
• do not take undue or calculated advantage of knowledge obtained during the peer review process.
• ensure that they are informed about, and comply with, the criteria to be applied.
• do not agree to participate in peer review outside their area of expertise.
• give proper consideration to research that challenges or changes accepted ways of thinking.

6.3 Responsibilities of Researchers

a) Do not interfere during the peer review process

Researchers whose work is undergoing peer review must not seek to influence the process or outcomes.

b) Participate in peer review

Researchers in receipt of public funding have a responsibility to participate in peer review processes.

c) Mentor trainees in peer review

Supervising researchers have a responsibility to assist trainee researchers in developing the necessary skills for peer review and understanding their obligation to participate.
d) **Declare conflicts of interest**

Peer reviewers must declare all relevant conflicts of interest.

### 7.0 CONFLICT OF INTEREST

Conflict of interest in research can be defined as:

“A conflict of interest involves the abuse  actual, apparent, or potential of the trust that people have in professionals. The simplest working definition states: A conflict of interest is a situation in which financial or other personal considerations have the potential to compromise or bias professional judgment and objectivity. An apparent conflict of interest is one in which a reasonable person would think that the professionals judgment is likely to be compromised. A potential conflict of interest involves a situation that may develop into an actual conflict of interest. It is important to note that a conflict of interest exists whether or not decisions are affected by a personal interest; a conflict of interest implies only the potential for bias, not a likelihood. It is also important to note that a conflict of interest is not considered misconduct in research, since the definition for misconduct is currently limited to fabrication, falsification, and plagiarism.”

In research, the conflict of interest may affect, or be seen to effect, not only the collection, analysis, and interpretation of data, but also the hiring of staff, procurement of materials, sharing of results, choice of licencees, choice of protocol, involvement of human participants, or the use of statistical methods. It may also be financial benefits or non-financial.

### 7.1 Responsibilities of the Institution

It is the role of an institution to manage conflicts of interest. The following points should be observed:

a) **Ensure that the policy is clearly written and readily available to all staff.**

b) **Encourage a full disclosure by those involved of the circumstances giving rise to concerns about conflicts of interest.**

c) **Ensure that where the circumstances constitute a conflict of interest, or may lead people to perceive a conflict of interest, the person concerned must not take part in the decision – making processes.**

d) **A record must be kept of how each conflict is managed in the proceedings, even if confidential information must be omitted.**
e) The policy should aim to cover a full range of possible interests and should be reviewed regularly.

7.2 Responsibilities of Researchers

Full disclosure must be made to the appropriate line manager such as head of department, dean or Deputy Vice Chancellor (Research & Innovation). A well-documented systematic procedure determines the effective management or elimination of conflict of interest.

Moreover, the researcher should:

a) understand the policy of the institution.

b) maintain records of activities that may lead to conflict of interest.

c) when invited to join a committee, review current activities for actual or apparent conflicts and bring possible conflicts of interest to the attention of those concerned.

d) disclose any actual or apparent conflict of interest as soon as it becomes apparent.

8.0 RESEARCH COLLABORATION

Collaboration has been intrinsic to the research process for the past 50 years, but collaboration per se usually refers to researchers who work within the same discipline, either within an institution or in different institutions. Multidisciplinary research is a form of collaborative research that involves researchers working across disciplines, either within an institution or in different institutions.

A physician working with an engineer to manufacture a new imaging device, or an epidemiologist working with a political scientist on a tobacco-control initiative, is an example of a cross-disciplinary research project. When the pharmaceutical industry works with a medical center to perform a clinical trial of a new drug, it is a collaboration across industry and academia. Each of these interactions creates different expectations and requires a variety of modes of communication to ensure that the collaboration is successful.

8.1 Responsibilities of the Institution

a) Establish agreements for each collaboration

The joint research should ensure that an agreement is reached with the partners on the management of the research. The agreement should:

- be in writing.
follow the general principles of the code of ethics.
cover intellectual property, confidentiality and copyright issues, sharing, commercial returns, responsibility for ethics, safety clearances and reporting.
address the protocols to be followed by the partners.
include dissemination of research outcomes.

b) Manage conflicts of interest
Every institution must have a policy to deal with this matter.

c) Manage access to research materials
The collaborating parties should manage the research data efficiently.

8.2 Responsibilities of Researchers

a) Comply with multi-institutional agreements
Joint researchers must be aware of all written agreements and comply with them.

b) Declare conflict of interest
Researchers must disclose as soon as possible any actual apparent conflicts of interest related to the project.

9.0 MISCONDUCT IN RESEARCH

Misconduct in research (for example, fabrication, falsification, and plagiarism) damages the scientific enterprise, is a misuse of public funds, and undermines the trust of citizens in science and in government.

Various definitions of these terms are possible. For example, the United States government defines research misconduct in a way that has been adopted in some other countries:

- Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
- Fabrication is making up results and recording or reporting them.
• Falsification is manipulating research, materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

• Plagiarism is the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit, including those obtained through confidential review of others’ research proposals and manuscripts.

• Research misconduct does not include honest errors or honest differences of opinions.

9.1 Responsibilities of the Institution

a) Policies on allegations

Institutions must have a written policy on receiving complaints or allegation related to misconduct in research. It should recognize the following categories:

- Failure to implement the code.
- Research misconduct.

All allegations must be addressed appropriately and allegations of a minor nature that are contested can become major issues if they are not handled appropriately.

A person who is the subject of an allegation must be treated fairly and be provided with opportunities to respond to allegations in writing.

A person who makes an allegation must also be treated fairly and according to any legislative provisions for whistleblowers during and following investigation of the allegations.

b) Reviewing employer-employee agreements

The process for handling research misconduct must be relevant to the workplace agreements and the law.

c) Appointing a designated person and advisers to look into research integrity issues

Institutions must appoint a designated person, other than the Vice Chancellor, to whom allegations of research misconduct must be directed, and one or more persons as advisers in research integrity.

9.2 Responsibilities of departmental or research centre

The most effective way of preventing research misconduct is to establish a responsible research environment. When the misconduct among researchers arise, supervisors and heads
of department should be the first point of contact or senior mentor, such as an adviser in research integrity.

Departments / Centres are expected to:

- Establish and maintain a responsible research environment in which a high standard of research practice is expected.
- Declare any actual or apparent conflicts of interest relating to an alleged breach of the manuals.
- Manage, if possible, breaches of the Code that do not constitute research misconduct in accordance with university policy.
- Keep full records of the process used to investigate and resolve allegations of breaches of the Code.

9.3 Responsibilities of Researchers

Researchers are expected to:

- Report potential research misconduct cases in a timely manner in accordance with University policy.
References


END NOTES

1 International Committee of Medical Journals Editor. (2010). Ethical Considerations in the Conduct and Reporting of Research: Authorship and Contributorship. Manuals is accessible at: http://www.icmje.org/ethical_1author.html


Update: 21/7/2014