Faculty of Pharmacy
Research Ethics Committee

RESEARCH ETHICS MANUAL

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1. Introduction & Background:

The birth of the concept 'research ethics' began with desire to protect the right of human subjects involved in research. The Universal Declaration on Bioethics and Human Rights that was developed by the UNESCO in 2005, includes the principles that should be respected in any research involving human participants.

MSA University encourages research, in the pharmaceutical field, by offering well equipped research laboratories to researchers and undergraduate students. Researcher working in the pharmaceutical field should be aware of the basic ethical principles and policies, which are made to ensure safety and dignity of participants, care of animals used in research and finally research integrity. Hence, the ethics committee in the faculty of pharmacy has prepared this ethics manual to serve as a guideline for researchers helping them in maintaining the integrity of their researches.

2. What is ethics?

Ethics is a branch of philosophy that addresses questions about morality.

3. Scope of the guidelines

This guideline together with existing laws and regulations serve as basis for the Research Ethics Committee (REC) to perform its function in ethical evaluation of proposed researched.

This manual is concerned only with ethical issues related to scientific research.

4. The role of the Research Ethics Committee (REC)

The aim of the REC in reviewing pharmaceutical based research is:

- *Protecting the rights, safety, and well-being of research participants.* The goals of research should not supersede the health of participants.
- *Taking into consideration the principle of justice.* The benefits and burdens of research should be distributed fairly among all researchers.
- *Evaluating proposed researches ethically* before the beginning of the research and also reviewing all modifications and amendments to approved research

5. Guidance on ethical approval for Research

Faculty staff must ensure that their researches or researches carried under their supervision are conducted following ethical principles in this manual.

Each researcher should obtain the REC approval before beginning the practical steps. He/she must fill an application form [Application form for graduation project research or Application form for postgraduate research] and present it to REC. The application form consists of three sections: **Section A (Obligatory)**: This section should be filled with information on the applicants, research aim, objectives, protocol of work and information about any collaborating institution. **Section B (optional)**: for researches involving human participants. **Section C (optional):** This section should be filled for researches that involve working on animals.

Researchers are not allowed to begin their research except after receiving a written approval on the research protocol from REC. The approval should be obtained within two weeks of receiving the ethics application form.

After reviewing proposed researches the EC will reach one of the following decisions:

1. **Approval** .
2. **Conditional Approval** – Researcher will not begin his/her work except after changing the protocol of work according to the specified conditions by the REC.
3. **Not Approved** – the researcher will not be allowed to begin this research due to reasons mentioned by the EC.

When the researcher decides to make any changes in the research protocol of previously approved research, he/she must fill a special form [complementary ethics form /Progress report] describing these changes or research progress. The REC evaluate these changes ethically and make one of the three previously mentioned decisions.

6. Guiding ethical principles

The following principles and values should be followed in each research carried out in MSA:

6.1 Integrity

Researchers must always be honest.

6.2 Respect for persons

Researchers must treat participants and research subjects with respect. Obtaining informed consent from participant is an important form of respecting persons.

6.3 Beneficence

Researchers must make efforts to secure the well-being of participants.

6.4 Non-malfeasance

Researchers should always think of maximizing possible benefits and minimizing possible harms. The health conditions of researchers (pregnancy and allergy) should be taken into considerations

6.5 Justice/Fairness

Researchers should not only consider the benefits of the individual or organization but rather they should consider the benefits for the wider community

7. Matters of ethical concern in research

7.1 Respect for the Law and system of government

Researches execution should comply with the Constitution of the Arab Republic of Egypt and Egyptian laws.

7.2 Relevance & integrity

- Any fabrication of research results or negligence for true observations is considered serious forms of misconduct.

- If the researcher wants to make changes on an approved protocol, he/she must obtain the REC approval. Disregarding the committee approval in this stage may lead the REC to stop the research.
- Meticulous record-keeping is a permanent reference for the researcher that helps him/her to disprove any allegation or falsification of data.

7.3 Plagiarism

- Authors who plagiarized others data and ideas and claim that they are their own are committing theft of intellectual property. Plagiarism is research misconduct.
- Plagiarized data in research include reviews and methodology sections from other publications.
- Author should cite work of others including the work in which he is a co-author.
- Researcher should cite work of others even if it was unpublished.
- Utilization of privileged information such as manuscript received for peer review is a serious form of plagiarism and theft for intellectual property.
  The University offer subscription to turnitin® application which facilitate checking the originality of presented thesis and assignment

7.4 Investigator Competence

Only qualified and competent investigators are allowed to conduct the research. The following attributes should be found in researchers to be suitable for conducting research:

- Certification
- Technical and research competence;
- Knowledge and experience in the required field;
- Ability to identify ethical issues.
- Can face ethically challenging situations in a responsible and appropriate way.
- Honesty and Integrity;

7.5 Informed Consent

Human related researches that require ethical assessment and approval include:

- Invasive physical procedure, such as the taking of blood samples
- Non-invasive procedures, such as interviews, questionnaires, surveys, observation
- Accessing personal data and /or tissue

Researchers must obtain informed consent from the research participant before beginning research (Patient consent form). The consent form should be written in native language that the participant can understand. This requirement is important to respect human dignity and integrity.

- Consent should be made both by written and verbal form.
- When the participant is illiterate, a literate witness must confirm that the researcher has informed the participants of all relevant information (consent form for children and illiterate).
- In case of children participants, Informed consent should be obtained from their parents (consent form for children and illiterate)

The four main requirements for informed consent are:

(a) Disclosure;

(b) Understanding or appreciation;

(c) Voluntariness; and

(d) Capacity to consent.

A. Disclosure

Disclosures of the nature of research to prospective participants must be done in detail and by appropriate language.

To obtain informed consent, the following information must be disclosed to participants;

a. That their participation in research is voluntary;
b. The aim of the research
c. The expected time period of his/her participation in the research;
d. The nature of the experiments to which he/she will be subjected;
e. What will be his/her responsibilities upon participation in research?;
f. The possible risks and hazardous that he/she may encounter from his/her participation in this research.;
g. The benefits that he/she might gain during participation in the research;
h. What will happen in case of participant's injury during participation in research i.e Whether a compensation will be given to participant ot not.;
i. Participant have the right to be informed of new findings in the research;
j. That participant has the right to withdraw at any stage of the project ;
k. The consequences of their withdrawal from research;
l. The extent of maintaining their confidentiality;
m. The contact details of researchers. Researcher must inform participants with their contact detail, in case the participant require additional information or suffer an adverse event;
n. The qualifications of the researchers which make him/her suitable to conduct the research;
o. Participants should know that they have the right to decide the future use of specimens obtained from them

B. Understanding or appreciation

Age, maturity, intelligence, education, and belief system must be considered in the method used to obtain informed consent. The researcher must have the confidence that the participant understand and know all risks and benefits associated with the research. All participants' questions must be answered honestly

C. Voluntariness

Researchers should obtain consent with honesty. The consent will be invalid if given by researcher under compulsion.

D. Capacity to consent

Accepted consent is the one given by participant who is legally and factually capable to consent.

7.6 Ownership of and Access to Data

- Research data obtained in studies performed at the University of MSA belong to the University of MSA.
- Any member of the research group has the right to access data collected in the research.
- A principal investigator who leaves the University could make a copy of data to be able to continue the research in other institute.
- Each researcher in a group project should make a written agreement with the principal investigator, about which parts of the project he or she might continue to explore after leaving the group.
- Researchers who left MSA to another institution could access the data which they helped to obtain.
- Unique divisible materials prepared in the course of the research, such as intermediates in a chemical synthesis, cell lines, and reagents,….etc, should be divided among members of a research group. An agreement between researchers in group research should be made for non-divisible items.
- A written agreement should be made within group research to specify the rights of each researcher if a patent emerge from their work.

- An Invention Disclosure with the Office of Technology Management should be made by researcher who has made a patentable finding.

7.7Confidentiality

Personal data is data relating to living individuals. The personal data includes: Names, contact details of particpants, answers to questionnaires, photographs, video, etc and Human biological material, e.g. blood, tissue.

In this case consent form should be obtained from participants after providing them with necessary information.

The investigator must preserve the confidentiality of participants' personal data by making access to this data limited as possible and removing information that might lead to identification of participants, anonymzing data or by other means. Researcher should sign a declaration for preserving confidentiality of participants. This part of the declaration included in the ethics application form.

To keep security and confidentiality of the data, researchers should:

- Keep this data in a secure place such as locked cabinet or password-protected files
- Do not share the data with persons outside the research group.
- Transfer the data in a secure manner.
- Keep data till end of research and then disposed securely.
- Anonymise data once collected and researcher should ensure that data is published only in anonymised form.
- Personal data of participants should not be used in another purpose other than research.

7.8 Care and protection of research staff

The safety of researchers must be ensured by adequate safety measures. Training on safety procedures must be done for all staff. Researchers must be aware of the possible

health hazards (chemical, biological , physical,….etc) in his/her research and also means of protection (Risk assessment manual).

7.9 Care and protection of animals

Researchers should not use animals in research only when necessary and when they find that the expected knowledge obtained from this study is valuable.

- Conscious animals must not be used in research unless the potential benefit of the research outweighs the moral and ethical concerns raised by utilizing such animals.
- Researchers should offer, for the animals, the conditions which meet their needs.
- The number of animals, used in each research, should be kept to minimum.
- Reducing pain and suffering for animals should be ensured by best possible treatment.
- Anesthesia should be used for any painful procedure done to the animal
- Studies including animals should end as early as possible. Animals which experience disease or suffering should be euthanized. The method used for euthanization should not be painful or cause animal distress.
- Anyone who handles the animals should be trained properly.

8 . Responsibilities of Research Supervisors and Junior Researchers

Both research supervisors and junior researchers have ethical responsibilities.

- The researcher should be well trained on the necessary skills and knowledge required for working as research investigator.
- The primary supervisor should provide suitable research environment for the researcher to acquire both the conceptual and technical skills of the field.
- The mentor should provide the researchers a high quality training experience. It is the responsibility of the mentor to guide the research students during their work and interact personally with researcher on a regular basis to give timely feedback regarding research findings and progress.

- The number of researchers in lab should be limited to the number that allows the supervisors and mentors to train them appropriately.
- Junior researchers have responsibilities to their supervisors and to the institution as well. Junior researchers must adhere to this ethical guideline for researches, as well as safety guidelines.

9. Collaborations

Collaborative research includes researches between investigators with distinct capabilities working together on a specific research.

- MSA University encourages research collaboration within the university as well as with other institutions.
- Rules for collaborations should be discusses among all participants from the beginning.
- Written agreements should be made whenever the collaborations involve exchange of biological materials.

Written agreements should be made for any collaboration between laboratories in MSA and an outsider group (another university and/or research centers). This agreement provides a protected environment for long-term collaborations and protects the intellectual property rights to MSA inventions. These agreements are handled by the Technology Transfer Office of the university.

- In case of making practical work in a collaborating institution, the research should comply with the research ethics guidelines of that association and external approval should be presented to the EC

10. Research Misconduct

- Recording, analyzing and presenting data should be done with honesty and integrity.

- Any sort of deception in writing research data as misreporting or exclusion of outlying data points is research misconduct.

The administration of MSA University deals with allegations of scientific misconduct seriously. The procedures followed by the administration of MSA University are intended to process allegations of scientific misconduct promptly, confidentiality, and fairly.

References

The following documents have been taken into consideration and/or referred to for the policy review.

1. Ezekiel J. Emanuel et al., (2011). The oxford textbook of clinical research ethics. Oxford University press.

2. Elliott C. Kulakowski and Lynne U. Chronister (2006). Research Administration and Management. Jones and Barlett international.

3. IACUC Guidelines for the Humane Euthanasia of Laboratory Animals (2013). University of Texas.Office of research support in the university of texas guideline

4. MRC Ethics Guide: Medical research involving children. Medical Research Council, 2004

5. BBSRC Statement on safeguarding good scientific practice, revised, 2013

6. National Research Council: Guide for the Care and Use of Laboratory Animals, National Academy Press, Washington D.C., 2011, ISBN 978-0-309-15401-7

7. UNESCO: Universal decalaration on bioethics and human rights(2005) **Office of International Standards and Legal Affairs. http://portal.unesco.org/en/ev.phpURL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html**

8. UK Research Integrity Office (UKRIO) Code of Practice for Research, 2009