# Research Ethics Manual

## Research Ethics and Intellectual Property Committee

2021

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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. Researchers 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 research.

## 2. What is ethics?

Ethics is a branch of philosophy that addresses questions about morality or the study of the disposition, character, or attitude of a specific person, group of people or culture, and ways of promoting or perfecting it. Bioethics is the morality of life sciences.

Ethics can also be considered as a moral principles system. They affect how people make decisions and lead their lives. Ethics, in this context, is concerned with what is good for individuals and society which is described by moral philosophy.

## 3. Scope of the guidelines

This guideline together with existing laws and regulations serve as the basis for the Research Ethics Committee (REC) to perform its function in ethical evaluation of proposed research. This manual is concerned only with ethical issues related to scientific research.

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

The Research Ethics committee (REC) of the Faculty of Pharmacy was established in November 2010. The Ethics committee ensures that the Faculty is following the ethical and safety measures in research. The REC is a member in the Egyptian Network of Research ethics committees (ENREC) and is registered in the US Office for human research protection (OHRP) as an active valid Institutional Review Board (IRB) with an IRB # 00010491. Additionally, the faculty has signed a collaboration protocol with Cairo University- Institutional Animal Care and Use Committee (CU-IACUC) to establish a framework for collaboration in the animal research ethics field so that the approval of any ethics proposal from MSA side is in turn accepted by Cairo University and vice versa.

The board of the REC includes faculty staff members from different specialties, and physician, in addition to a layman and a lawyer.

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.
- *Supporting and* safeguarding *the* wellbeing *of* animals *used for* scientific research
- *Taking into consideration the principle of justice.* The benefits and burdens of research should be distributed fairly among all researchers.
- Evaluating the ethical acceptability of research before the enrollment of the participants in a study; accordingly examining financial and scientific aspects.

## 5. Guidance on ethical approval for Research

- All the faculty staff members must assure that their personal research or those that carried out under their supervision follow the ethical principles in this manual.

- Since MSA University is going green, therefore the ethics committee has shifted to the use of electronic ethics application form and the whole process of evaluation is done online.

- Each researcher should obtain the approval of the REC before beginning the practical steps. He/she must fill an application form online [Application form for graduation project research (appendix I) or Application form for postgraduate research (Appendix II)] and present it to the 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 written approval (annex V) on the research protocol from REC. The decision is taken within two weeks of receiving the ethics application form.
- After reviewing the proposed research, the REC will reach one of the following decisions:
    1. **Approval**.
    2. **Approved after modification** – Researcher will not begin his/her work except after changing the protocol of work according to the specified conditions by the REC.
    3. **Disapproved** – 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 complementary ethics form (Appendix III) /Progress report (Appendix IV), describing these changes or research progress. The REC will then evaluate these changes ethically and reach one of the three previously mentioned decisions.

## 6. Guiding ethical principles

The following principles and values should be followed in all 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 governmental policies

Research 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 results and discussion 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 is 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 theses and manuscripts.

### 7.4 Investigator Competence

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

- 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 Ownership of and Access to Data

- Research data obtained in studies performed at MSA University belongs to it.
- 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 institutes.
- Researchers who left MSA could access the data which they helped in obtaining.
- Each researcher in a group project should have a written agreement with the principal investigator, about the parts of the project he or she might continue to explore after leaving the group.
- Unique divisible materials prepared in the course of the research, such as, but not limited to; intermediates in a chemical synthesis, cell lines and reagents … etc.

should be divided amongst the members of the 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 emerges from their work.
- An Invention Disclosure with the Technology Innovation Support Center should be made by researcher who has made a patentable finding.

### 7.6 Care and protection of researcher, research assistants, and environment

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 (such as but not limited to, chemical, biological, physical…. etc.) in his/her research and the possible means of protection (Risk assessment).

Risk assessment refers to the description of the overall process or method for:

- Identifying hazards and risk factors that have the potential to cause harm (hazard identification).
- Analyzing and evaluating the risk associated with that hazard (risk analysis, and risk evaluation).
- Determining appropriate ways to eliminate the hazard, or control the risk when the hazard cannot be eliminated (risk control).

### 7.7 Matters of Ethical concern in researches involving human

#### 7.7.1 Informed Consent

Human related researches that require ethical assessment and approval include:

- Invasive physical procedure, such as but not limited to the taking of blood samples
- Non-invasive procedures, such as but not limited to 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 nativelanguage that the participant can understand. This requirement is important to respect human dignity and integrity.

- Consent should be made in both 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.
- In the case of children participants, Informed consent should be obtained from their parents.

The four main requirements for informed consent are:

1. Disclosure;
2. Understanding or appreciation;
3. Voluntariness; and
4. Capacity to consent.

**1. Disclosure**

Disclosure refers to informing prospective participants by the nature of research to be done in detail and by appropriate language using patient information sheet.

**To obtain informed consent**, the following information must be disclosed to participants such as:

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 or not;

i. Participant have the right to be informed of new findings in the research;

j. The participant has the right to withdraw at any stage of the project:

k. The extent of maintaining their confidentiality;

l. The contact details of researchers. Researcher must inform participants with their contact detail, in case the participant require additional information or suffer anadverse event;

m. The qualifications of the researchers which make him/her suitable to conduct the research;

n. Participants should know that they have the right to decide the future use of specimens obtained from them.

**2. 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 understands and knows all the risks and benefits associated with the research. All participants' questions must be answered honestly.

**3. Voluntariness**

Researchers should obtain consent honestly. The consent will be invalid if given to researcher under compulsion.

**4. Capacity to consent**

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

### 7.7.2 Confidentiality

Personal data is data relating to living individuals. It includes, but not limited to: Names, contact details of participants, answers to questionnaires, photographs, video, etc and Human biological material, e.g. blood, tissue.

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, anonymizing 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 ensure the security and confidentiality of the data collected, researchers should:

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

**7.8 Matters of ethical concern in animal research.**

Researchers should only use animals in research when necessary and when they find that the expected knowledge obtained from the study is in the favor of harm/benefit balance. The use of animals in research, in MSA University, is regulated using the concept of 3R principles [Replacement-Reduction-Refinement] (Russel and Burch, 1959) as well as the following guidelines:

- Respect for life. All animals have to be treated in a way to maintain their dignity, basic needs of welfare life and species characterization.
- The researcher should provide the evidence of the absence of any alternative to animal experimentation (e.g. well established in-vitro method) before starting the experiment.
- Researchers are obliged to provide the animals with an appropriate environment which meets their physiological and behavioral needs including freedom of movement and appropriate social contacts and interactions.
- The animals should be kept in such a way that their physical functions and behaviors are not affected.
- The animals should be provided with suitable shelter, facilities and comfortable resting areas; ensuring that it is not exposed to adverse temperatures, weather conditions, or lack of oxygen.
- The number of animals, used in each research, should be kept to minimum, and the number of animals have to be calculated using a proper program for sample size calculation.
- Reducing pain and suffering for animals should be ensured by best possible treatment. Therefore, the use of anesthesia and analgesia is **obligatory** when invasive procedures are used.
- The appropriate termination criteria and proper disposal of animals must beclearly stated in the ethics application. The method used for euthanization should not be painful or cause animal distress

- All researchers who handles the animals should be well-trained and should have the moral and scientific responsibility for planning and justification of proper animal experimentation.

## 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 supervisor should provide the researchers a high quality trainingexperience. 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 to train them appropriately.
- Junior researchers have responsibilities to their supervisors and to the institution as well. They must adhere to this ethical guideline for researches, as well as safety guidelines.

## 9. Collaborations

Collaborative research includes researches between researchers 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 discussed 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 research group in another universities, institutions 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 Innovation Support Center of the university.
- In case of making practical work in a collaborating institution, the research should comply with the research ethics guidelines of that institution and external approval should be presented to the REC.

## 10. 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, confidentially, and fairly.

- 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.

## References

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


1. BBSRC Statement on safeguarding good scientific practice, revised (2013).

2. Canadian Center for Occupational Health and Safety. https://www.ccohs.ca/oshanswers/hsprograms/risk_assessment.html(access date 10/8/2020)

3. Ethics Education Programme (Bioethics Core Curriculum) Sector for Social and Human Sciences UNESCO.

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

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

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

7. MRC Ethics Guide: Medical research involving children. Medical Research Council, (2004).

8. 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

9. Russell, W.M.S. and Burch, R.L., (1959). The Principles of Humane Experimental Technique, Methuen, London. ISBN 0900767782
10. UNESCO: Universal declaration 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( access date:10/8/2020)

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

12. http://worldanimal.net/our-programs/model-law-project/part-2-proposal-for-the-wording-of-a-new-animal-welfare-act/chapter-3-keeping-of-animals-care-of-animals. (access date 10/8/2020)

# Appendices

# Graduation Project
# Ethics Application Form

COMMENTS

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|---|---|---|---|
| **Date submitted:** | | **Ref:** | |
| **Reviewers:** | | **Decision:** | |

# Research Ethics Committee-Faculty of Pharmacy
# Application Form

**Note for the applicant**

The MSA Faculty of Pharmacy Research Ethics Committee (REC) is responsible for ensuring that any research undertaken by faculty members or students, or by other institutions when in collaboration with the University, meets recognized ethical standards. Where ethical issues exist in a research proposal the research should not commence until approval has been obtained from the REC.

**The Application Form consists of 3 sections and 4 Annexes:**

| TABLE OF CONTENTS | MANDATORY / OPTIONAL | Used Sections & Annex are marked with ✓ |
|---|---|---|
| SECTION A: General Information, study description, research procedures General information, study description, research procedures and Supervisor Declaration | MANDATORY | |
| SECTION B: Researches involving human participants | Optional | |
| SECTION C: Researches involving animal use | Optional | |
| Annex I Patient consent form | Optional | |
| Annex II Participant Information sheet | Optional | |
| Annex III Medicinal products/Cosmetics/Food supplement and Medical devices | Optional | |
| Annex IV Risk Assessment form | MANDATORY | |

**This Application Form is divided into Sections.**

Section A is Mandatory. Sections B and C are optional.

For any inquiries, please consult the Head of the ethics committee, Dr.Reham Wasfi (Room G009) or the committee members.

## General rules applying to research projects carried by graduating students in the faculty of Pharmacy

**a) The authorship for any articles based on results of this research must be according to the International Committee of Medical Journal Editors (ICMJE) which stated that authorship should be for contributors who share in all the following points**

**i) Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND**

**ii) Drafting the work or revising it critically for important intellectual content; AND**

**iii) Final approval of the version to be published; AND**

**iv) Able to defend the article and responsible for accuracy of work**

**b) If the applicant have made any changes in his/her project that differs from that in the first submitted ethics application form, he/she must submit a complementary form with that changes and he should obtain another approval from the committee.**

| COMMENTS |
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# Research Ethics Committee-Faculty of Pharmacy
# Application Form

## Section A

| | |
|---|---|
| Title of the Research Study: | |
| Project code: | |

**Part I: Applicant and Supervisor Details**

| | |
|---|---|
| 1. Name of Applicants (students) | |
| ID of MSA students (if applicable) | |
| 2. Status (Undergraduate, MA or MSc) | |
| 3. E-mail Address | |
| 4.Telephone Number | |
| 6. Department | |
| 7. Supervisor's name | |
| 8. Supervisor's affiliation | |
| 9. Supervisor’s E-mail address | |

**Section II:Summary of Proposed Research**

| |
|---|
| 9. Brief outline of the proposed project (include project design and methodology). |
| |
| 10. List the study aims, objectives and benefits of this proposed research. |
| |
| 11. What do you consider to be the main ethical issues which may arise with the proposed study and what steps will be taken to address these? |
| |

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| 12- Have any collaborating internal or external schools or institutions or departments whose resources will be needed, been informed and agreed to participate? |
|---|
| |

| 13- Brief outline of the work carried by collaborating institutions or departments. What do you consider to be the main ethical issues in that work? (Describe the steps taken to address these ethical issues in the specified part of the ethics application form) |
|---|
| |

| | | |
|---|---|---|
| Applicant's Signature | | |
| Supervisor's Signature | | Date |
| Head of the Research Ethics Committee | | Date |

## Supervisors Declaration

| For the project under the title: | |
|---|---|
| Carried by: | |
| Supervisor Name: | |

**As the supervisor for this project I hereby declare that I am aware of my obligation to respect all the matters mentioned in the introduced ethics form, also to ensure that the students have done all the work according to all the mentioned rules.**

**In particular, I will**
**- Not change any step of the research plan, except after informing the ethics committee via a written form and acquire their permit.**
**- Respect the confidentiality / restriction of any information brought to my attention during the performance of this research work.**
**- Make sure that any experiment done in a facility outside MSA will follow all ethical and safety rules and all experiments carried by this facility will be mentioned in the ethics form.**
**- Not make any information available to the public, even after completion of my assignment.**

| Supervisor Signature: | | Date |
|---|---|---|

## Section B

| a. HUMAN PARTICIPANTS - SELECTION AND RECRUITMENT |
|---|
| Please describe: |

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# Research Ethics Committee-Faculty of Pharmacy
# Application Form

| | |
|---|---|
| **1. How many participants are to be involved?** | |
| **2. What are the main inclusion and exclusion criteria for involved participants?** | |
| **3. Will any participants involved in this research study be simultaneously involved in any other research project?** | |
| **4. Will human participants receive compensation for participation?** | |

**b. HUMAN PARTICIPANTS – INFORMED CONSENT**

| **This part for the case of clinical trials** | |
|---|---|
| **1. Will informed consent be obtained? ) If no, please justify** | |
| **2. How will informed consent be obtained and by whom?** | |
| **3. Will participants be informed of their right to refuse to participate and their right to withdraw from this research study? Please elaborate.** | |
| **4. Will there be a time interval between giving information and seeking consent?** | |
| **5. Will any research participants be under the age of 18?** | |

**c. Data Protection and Confidentiality**

**Researchers must abide by the provisions of the Data Protection Act and the University Data Protection Policy**

**1. Will the research involve any of the following activities at any stage (including identification of potential research participants)? (Tick as appropriate)**

| | | | |
|---|---|---|---|
| | Examination of medical records by those outside the research facility , or within the facility by those who would not normally have access | | |
| | Electronic transfer by magnetic or optical media, e-mail or computer networks | | |
| | Sharing of data with other organizations | | |
| | Export of data outside the country | | |
| | Use of personal addresses, postcodes, faxes, e-mails or telephone numbers | | |
| | Publication of direct quotations from respondents | | |
| | Publication of data that might allow identification of individuals | | |
| | Use of audio/visual recording devices | | |
| | Storage of personal data on any of the following: | | |
| | | | Manual files |
| | | | MSA computers |
| | | | Home or other personal computers |
| | | | Laptop computers |

**2.What measures have been put in place to ensure confidentiality of personal data? Give details of whether any encryption or other anonymisation procedures have been used and at what stage?**

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3. Where will the analysis of the data from the study take place and by whom will it be undertaken?

4. Who will have control of and act as the custodian for the data generated by the study?

| | | |
|---|---|---|
| Applicant's Signature | | |
| Supervisor's Signature | | Date |
| Head of the Research Ethics Committee | | Date |

## Section C

This part is for the studies that involves lab animals

### I. What is the purpose of using animal in this study?

| | |
|---|---|
| 1.Field study/capture or study of free-living (including feral) animals | |
| 2.Behaviour observations | |
| 3.Harvesting of tissues from dead animals | |
| 4.Dissection of dead animals | |
| 5.Surgical procedures | |
| 6. Administration of pharmaceutical agents | |
| 7.Infection with microbial agents and/or parasites/ testing of toxins [i] | |
| 8.Production of antisera | |
| 9.Feeding studies, including diet modification | |
| 10.Animals with altered genetic make-up(manipulated, modified, naturally occurring mutation) | |
| 11. Other Procedures: if selected, please write details in the box below | |

### II. Calculation of animal sample size

| | |
|---|---|
| 1. How many animal groups will be included? | |

2. Recommended methods for calculation of sample size:

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**3. Provide your calculation details here**

**4. What is the source of numbers used in your calculations? Hypothesis or a previous study and if a previous study put link for this study**

## III. Animal Housing

**a) Housing**

Standards of animal housing and management can have a significant impact on animal well-being. Explain where animals will be housed and the type of housing. Points to consider are the maximum/minimum animals per cage/pen, isolation, group housing (stocking rates, sexes), shelter, bedding, hiding areas, environmental enrichment, conditioning period, day to day husbandry of the animal/s, eg diet, and how the normal environment of native animals is approximated.

**b) Site where procedures are to be carried out**

**c) Holding time**

What is the maximum time for which any individual animal will be held?

**d) Monitoring by Investigators**

Write in details how the wellbeing of animals will be assessed throughout the project including: Details of the method and frequency of monitoring animals during and after procedures. What will be done if a problem is identified? Please include the criteria used for intervention, treatment, or withdrawal of the animals from the project. Who will be responsible for the management of veterinary and other emergencies?

**e) Fate of Animals**

What will happen to animals at the completion of each experiment? If animals are to be euthanized,

- How will this be done? Who will euthanize the animals?

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- **After the end of the experiment the animals will be anesthetized, the animals will be euthanized by cervical dislocation and that will be done in the presence of supervisor. The blood and liver samples will be collected and stored till time of analysis.**
- **The dead animals will be delivered to the sanitation companies and disposed according to the official biological waste disposal system.**

**f) Risks**

Please specify any special risks to other animals or humans arising from the project

**•Risk of rat bite.**
**•Risk of syringe injury.**
**•Blood contamination risk.**
**•Injury of rat**

| | | |
|---|---|---|
| **Applicant's Signature** | | **Date** |
| **Supervisor's Signature** | | **Date** |
| ***Signature of the Head of pharmacology department in MSA** | | **Date** |
| **Head of the Research Ethics Committee** | | **Date** |

***This signature is required only If this part of practical work will be done in the Animal House of MSA**

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Research Ethics Committee-Faculty of Pharmacy

# Annex I

## Patient Consent Form

| | |
|---|---|
| **Title of Research:** | |

| | |
|---|---|
| - I confirm that I have read and understand the Information Sheet for the above study, have had the opportunity to ask questions, and understand what I am expected to do as a volunteer.<br>- I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my rights being affected.<br>- I would like/not like my own results reported back to me, understanding that no interpretation may be possible.<br>- I do/do not agree that photographs and video material recorded during the study may be used for illustration purposes in reports and any subsequent journal articles. This is on the understanding that, while every effort will be made to preserve my anonymity, this cannot be guaranteed.<br>- I do/do not agree that samples provided during the study may be stored beyond the study duration for further research. I understand that these samples will be made anonymous and not traceable back to me. | أؤكد أنني قد قرأت وفهمت ورقة معلومات عن الدراسة المشار إليها أعلاه، فقد أتيحت لى الفرصة لطرح الأسئلة ، وفهمت ما يتوقع مني أن افعله كمتطوع.أنا أفهم أن مشاركتي هي طوعية وأنني حر في الانسحاب في أي وقت ، دون إبداء أي سبب، من دون أن تتأثر حقوقي. - أود / لا أود أن اعرف نتائج . - اوافق / لا أوافق على أن يمكن استخدام الصور ومواد الفيديو التي سجلت خلال دراسة لأغراض التوضيح في التقارير والمقالات الصحفية. هذا على أساس أنه، في حين استخدامها سيتم بذل كل جهد ممكن للحفاظ على عدم كشف عن هويتى. - - اوافق / لا أوافق على أن يمكن تخزين العينات المقدمة أثناء الدراسة تتجاوز مدة الدراسة لإجراء مزيد من البحوث. |
| **Participant signature:** | **توقيع المشارك:** |
| | |

### Consent form for children and illiterate

**I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily for (child) to participate as a participant in this study and understand that I have the right to withdraw her/him from the study at any time without in any way affecting our care at this Centre.**

| | | |
|---|---|---|
| **Print Name of Parent or Guardian** | | **Date** |
| **Signature of Parent of Guardian** | | **Date** |

### If illiterate

**A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.**

**I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.**

| | | |
|---|---|---|
| **Print name of witness** | | **Date** |
| **Signature of witness** | | **Date** |

> Click Here To Download Annex I

Research Ethics Committee-Faculty of Pharmacy

# Annex I

## Patient Consent Form

**I have accurately read or witnessed the accurate reading of the consent form to the Parent/guardian of the potential participant and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.**

| | | |
|---|---|---|
| **Print name of researcher** | | **Date** |
| **Signature of researcher** | | **Date** |

**A copy of this Informed Consent Form has been provided to the parent or guardian of the participant _____ (initialed by researcher/assistant)**

COMMENTS

| OFFICE USE ONLY | | | |
|---|---|---|---|
| Date submitted: | | Ref: | |
| Reviewers: | | Decision: | |

# Annex II
# Participant Information Sheet

| |
|---|
| Invitation: You are invited to participate in a research study under the title: |
| |
| Conducted by (please include the names of the students and their ID numbers): |
| |
| Supervised by (please include the supervisor name and affiliation): |
| |
| |
| |
| This research has been approved by the ethics committee of the Faculty of Pharmacy-MSA University. Before you decide whether or not to participate in this study, please make sure that you are fully aware with the details of the study and what exactly is required from you and how would your participation affect the study. Please take the time to read the following parts before you sign the participant consent form. Your participation in this research is voluntarily and you are free to withdraw at any time, without providing reasons. |
| What is the purpose of this research? Write a brief outline on this study. |
| |
| What is required from the participant? And why is he/she been invited? |
| |
| What are the risks associated with the proposed procedure(s)? |
| |
| What is the expected time for finishing the research? |
| |
| I declare that I have read all the information in the participant information sheet and agree to participate in this research |

| | |
|---|---|
| Participant signature: | |

| | |
|---|---|
| If you find any problem in this research you can contact the following researcher | |
| Name: | |
| Contact information: | |
| Researcher declare that he/she is responsible for preserving the confidentiality of collected data and participant's personal information | |
| Researcher (students) signature: | |

# ملحق II
# ورقة معلومات للمشاركين في البحث

COMMENTS

| OFFICE USE ONLY | | | |
|---|---|---|---|
| Date submitted: | | Ref: | |
| Reviewers: | | Decision: | |

## Annex II
## Participant Information Sheet

| رسالة دعوة: أنت مدعو للمشاركة في دراسة بحثية بعنوان: |
|---|
| |
| اسماء الباحثين: |
| |
| |
| |
| هذا البحث تم الموافقة عليه من قبل لجنة الأخلاقيات التابعة لكلية الصيدلة. قبل أن تقرر ما إذا كنت ترغب في المشاركة في هذه الدراسة، فمن المهم بالنسبة لك أن نفهم لماذا يتم اجراء هذا البحث وما سينطوي.عليه ... يرجى أخذ الوقت الكافي لقراءة ما يلي قبل التوقيع على استمارة موافقة المشاركين. مشاركتكم في هذا البحث هو طوعي وأنت حر في الانسحاب في أي وقت، دون إبداء أسباب. |
| ماهى اهداف هذا البحث؟ اكتب باختصار خطوات البحث. |
| |
| ما هو الدور المطلوب من المشارك؟ و لماذا تم دعوتكم للمشاركة؟ |
| |
| ما هي المخاطر المرتبطة بهذا الإجراء؟ |
| |
| الوقت المتوقع لانتهاء البحث |
| |
| أقر بأنني قد قرأت جميع المعلومات الواردة في ورقة المعلومات مشارك وافقت على المشاركة في هذا البحث |
| توقيع المشارك: |
| |
| |
| |
| |
| إذا وجدت أي مشكلة في هذا البحث يمكنك الاتصال بالباحث. |

| | |
|---|---|
| الأسم: | |
| معلومات الإتصال: | |
| يقر الباحث بمسؤليته على الحفاظ على سرية المعلومات المجمعة و البيانات الشخصية للمشاركين. | |
| توقيع الباحث: | |

COMMENTS

| OFFICE USE ONLY | | | |
|---|---|---|---|
| **Date submitted:** | | **Ref:** | |
| **Reviewers:** | | **Decision:** | |

# Annex III

## Annex III Medicinal products/Cosmetics/Food supplement and Medical devices

**This annex needs only to be completed if relevant to research. It should be completed when Drug or medicinal products or medical devices are used on Human participants or animals.**

| **Title of Research:** | |
|---|---|

| | |
|---|---|
| **1. Is the study initiated /sponsored by pharmaceutical or other industrial company?** | |
| **2. Does the study involve:** | |
| - Pre-marketing use of a product? | |
| - A new use for marketed product? | |
| - Studying the effect of marketed product? | |

**1) Drug and Medicinal product**

A medicinal product is: (a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

| **a) Details of the medicinal product:** | | | |
|---|---|---|---|
| **Approved Name** | **Active ingredient** | **Strength** | **Manufacturer** |
| | | | |
| **b) Dosage regimen used:** | | | |
| **Dosage & Frequency** | | **Route** | |
| | | | |
| **c) Is this dosage regimen** | | | |
| - The recommended dose regimen by the manufacture | | | |
| - New dose regimen | | | |

| **d) What are the possible side effects?** |
|---|
| |
| **e) What is the pharmacological action of this drug?** |
| |
| **f) What are the arrangements for dispensing medicinal product? (please give details)** |
| |

**2) Medical devices**

- Is the focus of this study/trial to investigate/evaluate a medical device?
- If yes, what is the name of the medical device or device nomenclature (system of naming the medical device)?
- If yes, please provide a general description of the medical device and the medical use in patients.
- If an application to conduct a clinical investigation of a medical device

| OFFICE USE ONLY | | | |
|---|---|---|---|
| Date submitted: | | Ref: | |
| Reviewers: | | Decision: | |

COMMENTS

| (a) Does the device have a CE mark? | |
|---|---|
| • If the device has a CE mark, is it proposed to use the device within the terms of its CE mark or outside the terms of its CE mark? | |
| • If outside, please elaborate: | |
| | |
| • CE mark* number: | |
| | |
| • What are the possible hazards and adverse effects? | |
| | |
| • Who will fit or apply the device for participant? | |
| | |

**NOTE: CE Marking on a product is a manufacturer's declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation, in practice by many of the so-called Product Directives.**

| SIGN HERE TO APPROVE THE FILLED CONTENT IN ANNEX IVa | | OFFICE USE ONLY | | | | COMMENTS |
|---|---|---|---|---|---|---|
| Supervisor signature: | | Date | | Ref: | | |
| | | Reviewers: | | Decision: | | |

| Equiment / Tool / Biological agent /Waste | Hazards inherent in the task or process Include all the significant hazards that are expected or are foreseeable in the context of the work or process that is being undertaken and where it will be done | Person (s) at risk | Precautions (control measures) include precautions for all individuals /groups that may be affected by the hazards you have identified e.g. staff, students, passersby… | Current Risk Rating | | | Further control measures required and by whom | Final Current Risk Rating | | | Remarks |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Likelihood | Severity | Risk rating | (Only required for "Medium" and "High" risk ratings) | Likelihood | Severity | Risk rating | |
| **Equipment and physical hazards E.g.: tools, machinery, work at height, electricity, high pressure, high temperature , UV , laser Only significant hazards need to be recorded.** | | | | | | | | | | | |
| | | | | | | (0) | | | | (0) | |
| | | | | | | (0) | | | | (0) | |
| | | | | | | (0) | | | | (0) | |
| | | | | | | (0) | | | | (0) | |
| | | | | | | (0) | | | | (0) | |
| **Personal safety**<br>**e.g: physical or verbal attack , disability or health problem, getting lost or stranded by transport, cultural or legal differences** | | | | | | | | | | | |
| | | | | | | (0) | | | | (0) | |
| | | | | | | (0) | | | | (0) | |
| **Biological agent hazards**<br>***Any micro-organism , cell culture or human endoparasite including any which have been genetically modified may cause infection ,**<br>**allergy, toxicity and other hazards of human health This includes bacteria ,viruses ,fungi and parasites**<br>***Routes of exposure should be included e.g.: blood borne infection, skin contact….** | | | | | | | | | | | |
| | | | | | | (0) | | | | (0) | |
| | | | | | | (0) | | | | (0) | |
| | | | | | | (0) | | | | (0) | |
| | | | | | | (0) | | | | (0) | |
| **Environmental impact**<br>**E.g.: pollution and waste, deposition of rubbish…..** | | | | | | | | | | | |
| | | | | | | (0) | | | | (0) | |
| | | | | | | (0) | | | | (0) | |
| **Other hazards** | | | | | | | | | | | |
| | | | | | | (0) | | | | (0) | |

| TO APPROVE THE FILLED CONTENT IN ANNEX IVb | | OFFICE USE ONLY | | | |
|---|---|---|---|---|---|
| | | Date submitted: | | Ref: | |
| Supervisor signature: | | Reviewers: | | Decision: | |
| Supervisor signature: | | | | | |
| Reviewer signature: | | | | | |

"Chemical hazards e.g.: Toxic by inhalation, irritant ,corrosive, flammable, explosive Include routes of exposure: skin sensitization, sensitization by inhalation… "

| Chemical Compounds | Hazards inherent in the chemical Including all the significant hazards that are expected or are foreseeable in the context of the work or process that is being undertaken and where it will be done | Person (s) at risk | Precautions (control measures) include precautions for all individuals /groups that may be affected by the hazards you have identified e.g. staff, students, passersby… | Current Risk Rating | | | Further control measures required and by whom | Final Current Risk Rating | | | Co mea in ca acci l sp |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Likelihood | Severity | Risk rating | (Only required for "Medium" and "High" risk ratings) | Likelihood | Severity | Risk rating | |

| TO APPROVE THE FILLED CONTENT IN ANNEX IVb | | OFFICE USE ONLY | | |
|---|---|---|---|---|
| | | Date submitted: | | Ref: |
| Supervisor signature: | | Reviewers: | | Decision: |
| Supervisor signature: | | | | |
| Reviewer signature: | | | | |

Annex IVb - Risk Assessment Form

"Chemical hazards e.g.: Toxic by inhalation, irritant ,corrosive, flammable, explosive Include routes of exposure: skin sensitization, sensitization by inhalation… "

| Chemical Compounds | Hazards inherent in the chemical Including all the significant hazards that are expected or are foreseeable in the context of the work or process that is being undertaken and where it will be done | Person(s) at risk | Precautions (control measures) include precautions for all individuals /groups that may be affected by the hazards you have identified e.g. staff, students, passersby | Current Risk Rating | | | Control measures in case of accidental spillage | Storage | Disposal | Link to relevant MSDS | Remarks |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Likelihood | Severity | Risk rating | | | | | |
| | | | | | | 0 | | | | | |
| | | | | | | 0 | | | | | |
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| | | | | | | 0 | | | | | |
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| | | | | | | 0 | | | | | |
| | | | | | | 0 | | | | | |
| | | | | | | 0 | | | | | |
| | | | | | | 0 | | | | | |

# Risk Matrix

**Risk rating is calculated by multiplying value of likelihood and severity/impact**

**A value should be assigned for the likelihood of an incident occurring based on the hazard from 1 to 5 and a value for theseverity / impact of the hazard from 1 to 5. e.g. 3 x 2 = 6 (low hazard).**

| | | | | | | |
|---|---|---|---|---|---|---|
| SEVERITY / IMPACT | 5 CATASTROPHIC | 5 | 10 | 15 | 20 | 25 |
| | 4 MAJOR | 4 | 8 | 12 | 16 | 20 |
| | 3 SERIOUS | 3 | 6 | 9 | 12 | 15 |
| | 2 MODERATE | 2 | 4 | 6 | 8 | 10 |
| | 1 MINOR | 1 | 2 | 3 | 4 | 5 |
| | | 1 RARE | 2 UNLIKELY | 3 POSSIBLE | 4 LIKELY | 5 ALMOST CERTAIN |
| | | LIKELIHOOD | | | | |

**Risk score = likelihood of the hazard to cause harm impact**

| High | Medium | |
|---|---|---|
| **Low Rating 15 or more** | **Rating 8 - 12** | **Rating 1 – 6** |
| **Immediate action is required to control and/or lower the level of risk. Exposure to** | **Urgent review of the equipment,activities, system of work within the workplace with the aim of lowering the risk to the next level.** | Usually, no further actionwill be required except formonitoring to ensure the risk does not change. However, if it is possible to reduce the risk levels still further, by using controls that are “reasonably practicable”,then this |

# REVIEWER CHECKLIST

**OFFICE USE ONLY**

| | | | |
|---|---|---|---|
| **Date submitted:** | | **Ref:** | |
| **Reviewers:** | | **Final Decision:** | |

**Research Ethics Committee-Faculty of Pharmacy Application Form**

**The Application Form consists of 3 sections and 4 Annexes:**

| | TABLE OF CONTENTS | Used Sections & Annex are marked with ✓ | Decision | Supervisor Signature | Student(s) Signature | Reviewer Signature | Head of Ethics Committee Signature | Head of Pharmacology Department Signature |
|---|---|---|---|---|---|---|---|---|
| M | SECTION A: General Information, study description, research procedures General information, study description, research procedures | | | Not signed | Not signed | Not signed | Not signed | |
| M | SUPERVISOR DECLARATION | | | Not signed | | | | |
| | SECTION B: Researches involving human participants | | | Not signed | Not signed | | Not signed | |
| | SECTION C: Researches involving animal use | | | Not signed | Not signed | | Not signed | Not signed |
| | Annex I Patient consent form | | | | | | | |
| | Annex II Participant Information sheet | | | | | Not Checked | | |
| | Annex III Medicinal products/Cosmetics/Food supplement and Medical devices | | | | | Not Checked | | |
| M | Annex IVa Risk Assessment form | | | Not signed | | | | |
| M | Annex IVb Risk Assessment form | | | Not signed | | | | |

# Graduation Project
# Complementary Ethics Application Form

COMMENTS

| OFFICE USE ONLY | | | |
|---|---|---|---|
| Date submitted: | | Ref: | |
| Reviewers: | | Decision: | |

## Research Ethics Committee-Faculty of Pharmacy
## Complementary Form for Research project

| | |
|---|---|
| Project title | |
| Project code | |
| Department | |
| Applicant Name(s) | |
| Applicant ID(s) | |
| Supervisor | |

**This form should be filled by applicants to state the modifications in their project. This form must be delivered to the ethics committee: (1) in the beginning of second part of research project (for all projects) and (2) in case of any modifications (if any) in the information submitted in the original ethics application form in part one.**

| | |
|---|---|
| Is there any modifications in protocol of work | |
| Other modifications in the research | |
| Is there any documents that you are going to attach to this form | |

**Write the modifications that you are going to make in your project.**

| | | |
|---|---|---|
| Applicant's Signature | | Date |
| Supervisor's Signature | | Date |

**This part is filled by the Ethic**

**Is this modification considered?**

**The ethics committee comment and recommendations on these modifications**

**This part is filled by the Ethics committee after fulfilling the**

| OFFICE USE ONLY | | | | COMMENTS |
|---|---|---|---|---|
| Date submitted: | | Ref: | | |
| Reviewers: | | Decision: | | |
| This research is | | | | |
| Head of the Research Ethics Committee | | Date | | |

| COMMENTS |
|---|
| |

| OFFICE USE ONLY | | | |
|---|---|---|---|
| Date submitted: | | Ref: | |
| Reviewers: | | Decision: | |

**Fill this part in case of changing the number of animals from those calculated in part one**

## Annex I

| II. Calculation of animal sample size |
|---|
| 1. How many animal groups will be included? |
| 2. Recommended methods for calculation of sample size: |
| |
| 3. Provide your calculation details here |
| |
| 4. What is the source of numbers used in your calculations? Hypothesis or a previous study and if a previous study put link for this study |
| |
| |

| SIGN HERE TO APPROVE THE FILLED CONTENT IN ANNEX IVa | | OFFICE USE ONLY | | | | COMMENTS |
|---|---|---|---|---|---|---|
| Supervisor signature: | | Date | | Ref: | | |
| | | Reviewers: | | Decision: | | |

| Equiment / Tool / Biological agent /Waste | Hazards inherent in the task or process Include all the significant hazards that are expected or are foreseeable in the context of the work or process that is being undertaken and where it will be done | Person (s) at risk | Precautions (control measures) include precautions for all individuals /groups that may be affected by the hazards you have identified e.g. staff, students, passersby… | Current Risk Rating | | | Further control measures required and by whom | Final Current Risk Rating | | | Remarks |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Likelihood | Severity | Risk rating | (Only required for "Medium" and "High" risk ratings) | Likelihood | Severity | Risk rating | |
| **Equipment and physical hazards E.g.: tools, machinery, work at height, electricity, high pressure, high temperature , UV , laser Only significant hazards need to be recorded.** | | | | | | | | | | | |
| | | | | | | (0) | | | | (0) | |
| | | | | | | (0) | | | | (0) | |
| | | | | | | (0) | | | | (0) | |
| | | | | | | (0) | | | | (0) | |
| | | | | | | (0) | | | | (0) | |
| **Personal safety**<br>**e.g: physical or verbal attack , disability or health problem, getting lost or stranded by transport, cultural or legal differences** | | | | | | | | | | | |
| | | | | | | (0) | | | | (0) | |
| | | | | | | (0) | | | | (0) | |
| **Biological agent hazards**<br>***Any micro-organism , cell culture or human endoparasite including any which have been genetically modified may cause infection ,**<br>**allergy, toxicity and other hazards of human health This includes bacteria ,viruses ,fungi and parasites**<br>***Routes of exposure should be included e.g.: blood borne infection, skin contact….** | | | | | | | | | | | |
| | | | | | | (0) | | | | (0) | |
| | | | | | | (0) | | | | (0) | |
| | | | | | | (0) | | | | (0) | |
| | | | | | | (0) | | | | (0) | |
| **Environmental impact**<br>**E.g.: pollution and waste, deposition of rubbish…..** | | | | | | | | | | | |
| | | | | | | (0) | | | | (0) | |
| | | | | | | (0) | | | | (0) | |
| **Other hazards** | | | | | | | | | | | |
| | | | | | | (0) | | | | (0) | |

| TO APPROVE THE FILLED CONTENT IN ANNEX IVb | | OFFICE USE ONLY | | | |
|---|---|---|---|---|---|
| | | Date submitted: | | Ref: | |
| **Supervisor signature:** | | Reviewers: | | Decision: | |
| Supervisor signature: | | | | | |
| Reviewer signature: | | | | | |

"Chemical hazards e.g.: Toxic by inhalation, irritant ,corrosive, flammable, explosive Include routes of exposure: skin sensitization, sensitization by inhalation… "

| Chemical Compounds | Hazards inherent in the chemical Including all the significant hazards that are expected or are foreseeable in the context of the work or process that is being undertaken and where it will be done | Person (s) at risk | Precautions (control measures) include precautions for all individuals /groups that may be affected by the hazards you have identified e.g. staff, students, passersby… | Current Risk Rating | | | Further control measures required and by whom | Final Current Risk Rating | | | Co mea in ca acci l sp |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Likelihood | Severit | Risk rating | (Only required for "Medium" | Likelih | Severit | Risk | |

| | | | | | |
|---|---|---|---|---|---|
| | TO APPROVE THE FILLED CONTENT IN ANNEX IVb | | OFFICE USE ONLY | | |
| | | | Date submitted: | | Ref: |
| Supervisor signature: | | | Reviewers: | | Decision: |
| Supervisor signature: | | | | | |
| Reviewer signature: | | | | | |

Annex IVb - Risk Assessment Form

"Chemical hazards e.g.: Toxic by inhalation, irritant ,corrosive, flammable, explosive Include routes of exposure: skin sensitization, sensitization by inhalation… "

| Chemical Compounds | Hazards inherent in the chemical Including all the significant hazards that are expected or are foreseeable in the context of the work or process that is being undertaken and where it will be done | Person(s) at risk | Precautions (control measures) include precautions for all individuals /groups that may be affected by the hazards you have identified e.g. staff, students, passersby | Current Risk Rating | | | Control measures in case of accidental spillage | Storage | Disposal | Link to relevant MSDS | Remarks |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Likelihood | Severity | Risk rating | | | | | |
| | | | | | | 0 | | | | | |
| | | | | | | 0 | | | | | |
| | | | | | | 0 | | | | | |
| | | | | | | 0 | | | | | |
| | | | | | | 0 | | | | | |
| | | | | | | 0 | | | | | |
| | | | | | | 0 | | | | | |
| | | | | | | 0 | | | | | |
| | | | | | | 0 | | | | | |

# Risk Matrix

**Risk rating is calculated by multiplying value of likelihood and severity/impact**

**A value should be assigned for the likelihood of an incident occurring based on the hazard from 1 to 5 and a value for the severity / impact of the hazard from 1 to 5. e.g. 3 x 2 = 6 (low hazard).**

| | | | | | | |
|---|---|---|---|---|---|---|
| SEVERITY / IMPACT | 5 CATASTROPHIC | 5 | 10 | 15 | 20 | 25 |
| | 4 MAJOR | 4 | 8 | 12 | 16 | 20 |
| | 3 SERIOUS | 3 | 6 | 9 | 12 | 15 |
| | 2 MODERATE | 2 | 4 | 6 | 8 | 10 |
| | 1 MINOR | 1 | 2 | 3 | 4 | 5 |
| | | 1 RARE | 2 UNLIKELY | 3 POSSIBLE | 4 LIKELY | 5 ALMOST CERTAIN |
| | | LIKELIHOOD | | | | |

| Risk score = likelihood of the hazard to cause harm ximpact | | |
|---|---|---|
| **High** | **Medium** | **Low** |
| Rating 15 or more<br><br>Immediate action is required to control and/or lower the level of risk. Exposure to the identified hazard is prohibited or severely restricted | Rating 8 - 12<br><br>Urgent review of the equipment, activities, system of work within the workplace with the aim of lowering the risk to the next level. | Rating 1 – 6<br>Usually, no further action will be required except for monitoring to ensure the risk does not change. However, if it is possible to reduce the risk levels still further, by using controls that are “reasonably practicable”, then this should be done. |

# Postgraduate
# Ethics Application Form

COMMENTS

| OFFICE USE ONLY | | | |
|---|---|---|---|
| **Date submitted:** | | **Ref:** | |
| **Reviewers:** | | **Decision:** | |

# Research Ethics Committee-Faculty of Pharmacy
# Application Form

**Note for the applicant**

The MSA Faculty of Pharmacy Research Ethics Committee (REC) is responsible for ensuring that any research undertaken by faculty members or students, or by other institutions when in collaboration with the University, meets recognized ethical standards. Where ethical issues exist in a research proposal the research should not commence until approval has been obtained from the REC.

**The Application Form consists of 3 sections and 4 Annexes:**

| TABLE OF CONTENTS | MANDATORY / OPTIONAL | Used Sections & Annex are marked with ✓ |
|---|---|---|
| SECTION A: General Information, study description, research procedures General information, study description, research procedures and Supervisor Declaration | MANDATORY | ☐ |
| SECTION B: Researches involving human participants | Optional | |
| SECTION C: Researches involving animal use | Optional | |
| Annex I Risk Assessment form | Optional | |
| Annex II Participant Information sheet and Patient Consent Form | Optional | |
| Annex III Information Sheet on drug or medicinal products used in animal research | Optional | |
| | | |

**This Application Form is divided into Sections.**

Section A is Mandatory. Sections B and C are optional.

- For any inquiries, please consult Dr.Reham Wasfi (Room G009) or send an email to rwasfi@msa.eun.eg
- The form should be word processed.
- Return one hard copy of the completed form by hand to: Faculty of Pharmacy-Ethics committee

## Section A

| | |
|---|---|
| **Title of the Research Study:** | |
| **Grade of protocol:** | |

**Part I: Applicant and Supervisor Details**

| | |
|---|---|
| **1. Name of Applicant (from MSA) and affilation** | |
| **ID of MSA students (if applicable)** | |
| **2. Collaborating researchers (non MSA affiliated)** | |
| **3. E-mail Address** | |
| **4.Telephone Number** | |

COMMENTS

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|---|---|---|---|
| Date submitted: | | Ref: | |
| Reviewers: | | Decision: | |

# Research Ethics Committee-Faculty of Pharmacy
# Application Form

| | |
|---|---|
| 5. Responsibilities of research investigator: | |
| 6. Name of sponsors/funding organization and address: | |
| 7. Name and address of collaborating institutes: | |

**Section II:Summary of Proposed Research**

**8.What is the type of proposed research?**

**9. Brief background on the research topic and rational for making this research. Write references of literature cited. Limit = 300 words.**

| | |
|---|---|
| References: | |

**10. List the study aims , objectives and benefits of this proposed research Limit = 100 words.**

**11. Brief outline of the proposed research (include research design and methodology). Add a graphic outline of the study design (optional) Limit = 300 words.**

**12. What do you consider to be the main ethical issues which may arise with the proposed study and what steps will be taken to address these issues?**

COMMENTS

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| Date submitted: | | Ref: | |
| Reviewers: | | Decision: | |

# Research Ethics Committee-Faculty of Pharmacy
# Application Form

**13. What is the anticipated date to finish this research?**

**14. Is this study sponsored or funded by a specific organization other than MSA University? What is the estimated budget?**

**15. Have any collaborating internal or external schools or institutions or departments whose resources will be needed, been informed and agreed to participate?**

**16. Brief outline of the work carried by collaborating institutions or departments. What do you consider to be the main ethical issues in that work? (Describe the steps taken to address these ethical issues in the specified part of the ethics application form)**

| | | |
|---|---|---|
| Applicant's Signature | | Date |
| Head of the Research Ethics Committee | | Date |

## Applicant Declaration

| | |
|---|---|
| For the Research under the title: | |
| Carried by: | |

**I declare that I am aware of my obligation to respect all the matters mentioned in the introduced ethics form.**

**In particular, I will**
**- Not change any step of the research plan, except after informing the ethics committee via a written form and acquire their permit.**
**- Respect the confidentiality / restriction of any information brought to my attention during the performance of this research work.**
**- Make sure that any experiment done in a facility outside MSA will follow all ethical and safety rules and all experiments carried by this facility will be mentioned in the ethics form.**
**- Not make any information available to the public, even after completion of my assignment.**

| | | |
|---|---|---|
| Supervisor Signature: | | Date |

## Section B

**a. HUMAN PARTICIPANTS - SELECTION AND RECRUITMENT**

COMMENTS

| OFFICE USE ONLY | | | |
|---|---|---|---|
| **Date submitted:** | | **Ref:** | |
| **Reviewers:** | | **Decision:** | |

# Research Ethics Committee-Faculty of Pharmacy
# Application Form

**Please describe:**

| | |
|---|---|
| **1. How many participants are to be involved?** | |
| **2. What are the main inclusion and exclusion criteria for involved participants?** | |
| **3. Will any participants involved in this research study be simultaneously involved in any other research project?** | |
| **4. Will human participants receive compensation for participation?** | |

**b. HUMAN PARTICIPANTS – INFORMED CONSENT**

**This part for the case of clinical trials**

| | |
|---|---|
| **1. Will informed consent be obtained? ) If no, please justify** | |
| **2. How will informed consent be obtained and by whom?** | |
| **3. Will participants be informed of their right to refuse to participate and their right to withdraw from this research study? Please elaborate.** | |
| **4. Will there be a time interval between giving information and seeking consent?** | |
| **5. Will any research participants be under the age of 18?** | |

**c. Data Protection and Confidentiality**

**Researchers must abide by the provisions of the Data Protection Act and the University Data Protection Policy**

**1. Will the research involve any of the following activities at any stage (including identification of potential research participants)? (Tick as appropriate)**

| | | | |
|---|---|---|---|
| | Examination of medical records by those outside the research facility , or within the facility by those who would not normally have access | | |
| | Electronic transfer by magnetic or optical media, e-mail or computer networks | | |
| | Sharing of data with other organizations | | |
| | Export of data outside the country | | |
| | Use of personal addresses, postcodes, faxes, e-mails or telephone numbers | | |
| | Publication of direct quotations from respondents | | |
| | Publication of data that might allow identification of individuals | | |
| | Use of audio/visual recording devices | | |
| | Storage of personal data on any of the following: | | |
| | | | Manual files |
| | | | MSA computers |
| | | | Home or other personal computers |
| | | | Laptop computers |

**2.What measures have been put in place to ensure confidentiality of personal data? Give details of whether any encryption or other anonymisation procedures have been used and at what stage?**

**3. Where will the analysis of the data from the study take place and by whom will it be undertaken?**

COMMENTS

| OFFICE USE ONLY | | | |
|---|---|---|---|
| Date submitted: | | Ref: | |
| Reviewers: | | Decision: | |

## Research Ethics Committee-Faculty of Pharmacy
## Application Form

**4. Who will have control of and act as the custodian for the data generated by the study?**

| | | |
|---|---|---|
| Applicant's Signature | | Date |
| Supervisor's Signature | | Date |
| Head of the Research Ethics Committee | | Date |

## Section C

**This part is for the studies that involves lab animals**

**a. What is the purpose of using animal in this study?**

| | |
|---|---|
| 1.Field study/capture or study of free-living (including feral) animals | |
| 2.Behaviour observations | |
| 3.Harvesting of tissues from dead animals | |
| 4.Dissection of dead animals | |
| 5.Surgical procedures | |
| 6. Administration of pharmaceutical agents | |
| 7.Infection with microbial agents and/or parasites/ testing of toxins [i] | |
| 8.Production of antisera | |
| 9.Feeding studies, including diet modification | |
| 10.Animals with altered genetic make-up(manipulated, modified, naturally occurring mutation) | |
| 11. Other Procedures: if selected, please write details in the box below | |

**Animal Housing**

**a) Housing**

Standards of animal housing and management can have a significant impact on animal well-being. Explain where animals will be housed and the type of housing. Points to consider are the maximum/minimum animals per cage/pen, isolation, group housing (stocking rates, sexes), shelter, bedding, hiding areas, environmental enrichment, conditioning period, day to day husbandry of the animal/s, eg diet, and how the normal environment of native animals is approximated.

**b) Site where procedures are to be carried out**

COMMENTS

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|---|---|---|---|
| **Date submitted:** | | **Ref:** | |
| **Reviewers:** | | **Decision:** | |

## Research Ethics Committee-Faculty of Pharmacy
## Application Form

**c) Holding time**

What is the maximum time for which any individual animal will be held?

**d) Monitoring by Investigators**

Write in details how the wellbeing of animals will be assessed throughout the project including: Details of the method and frequency of monitoring animals during and after procedures. What will be done if a problem is identified? Please include the criteria used for intervention, treatment, or withdrawal of the animals from the project. Who will be responsible for the management of veterinary and other emergencies?

**e) Fate of Animals**

What will happen to animals at the completion of each experiment? If animals are to be euthanized,
- How will this be done? Who will euthanize the animals?

**f) Risks**

Please specify any special risks to other animals or humans arising from the project

| | | |
|---|---|---|
| **Applicant's Signature** | | **Date** |
| **Supervisor's Signature** | | **Date** |
| ***Signature of the Head of pharmacology department in MSA** | | **Date** |
| **Head of the Research Ethics Committee** | | **Date** |

***This signature is required only If this part of practical work will be done in the Animal House of MSA**

| SIGN HERE TOAPPROVE THE FILLED CONTENT IN ANNEX Ia | | OFFICE USE ONLY | | | | COMMENTS |
|---|---|---|---|---|---|---|
| | | Date submitted: | | Ref: | | |
| Researcher signature: | | Reviewers: | | Decision: | | |
| Reviewer signature: | | | | | | |

## Annex Ia
## Risk Assessment Form

| | Equiment / Tool / Biological agent / Waste | Hazards inherent in the task or process Include all the significant hazards that are expected or are foreseeable in the context of the work or process that is being undertaken and where it will be done | Person (s) at risk | Precautions (control measures) include precautions for all individuals /groups that may be affected by the hazards you have identified e.g. staff, students, passersby… | Remarks |
|---|---|---|---|---|---|
| **Equipments and tools** | | | | | |
| 1 | | | | | |
| 2 | | | | | |
| 3 | | | | | |
| 4 | | | | | |
| 5 | | | | | |
| **Personal safety**<br>**e.g: physical or verbal attack , disability or health problem, getting lost or stranded by transport, cultural or legal differences** | | | | | |
| 1 | | | | | |
| 2 | | | | | |
| **Biological agent hazards** | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| **Environmental impact**<br>**E.g.: pollution and waste, deposition of rubbish…..** | | | | | |
| | | | | | |
| | | | | | |
| **Other hazards** | | | | | |
| | | | | | |

| SIGN HERE TO APPROVE THE FILLED CONTENT IN ANNEX Ib | | OFFICE USE ONLY | | | | COMMENTS |
|---|---|---|---|---|---|---|
| | | Date submitted: | | Ref: | | |
| Researcher signature: | | Reviewers: | | Decision: | | |
| Reviewer signature: | | | | | | |

**Annex Ib**

**Risk Assessment Form**

| "Chemical hazards e.g.: Toxic by inhalation, irritant ,corrosive, flammable, explosive Include routes of exposure: skin sensitization, sensitization by inhalation… " | | | | |
|---|---|---|---|---|
| Chemical Compounds | Hazards inherent in the chemical Including all the significant hazards that are expected or are foreseeable in the context of the work or process that is being undertaken and where it will be done | Person(s) at risk | Precautions (control measures) include precautions for all individuals /groups that may be affected by the hazards you have identified e.g. staff, students, passersby… | Remarks |
| | | | | |

COMMENTS

| OFFICE USE ONLY | | | |
|---|---|---|---|
| Date submitted: | | Ref: | |
| Reviewers: | | Decision: | |

## Annex IIa

(used in Clinical trial or clinical research)

## Part 1: Participant Information Sheet

| |
|---|
| Invitation: You are invited to participate in a research study under the title: |
| |
| Conducted by (please include the names of the students and their ID numbers): |
| |
| Supervised by (please include the supervisor name and affiliation): |
| |
| |
| |
| This research has been approved by the ethics committee of the Faculty of Pharmacy-MSA University. Before you decide whether or not to participate in this study, please make sure that you are fully aware with the details of the study and what exactly is required from you and how would your participation affect the study. Please take the time to read the following parts before you sign the participant consent form. Your participation in this research is voluntarily and you are free to withdraw at any time, without providing reasons. |
| What is the purpose of this research? Write a brief outline on this study. |
| |
| What is required from the participant? And why is he/she been invited? |
| |
| What are the risks associated with the proposed procedure(s)? |
| |
| What is the expected time for finishing the research? |
| |
| I declare that I have read all the information in the participant information sheet and agree to participate in this research |

| | |
|---|---|
| Participant signature: | |
| | |
| If you find any problem in this research you can contact the following researcher | |
| Name: | |
| Contact information: | |
| Researcher declare that he/she is responsible for preserving the confidentiality of collected data and participant's personal information | |
| Researcher (students) signature: | |

## ملحق II

## ورقة معلومات للمشاركين في البحث

| |
|---|
| رسالة دعوة: أنت مدعو للمشاركة في دراسة بحثية بعنوان: |
| |
| اسماء الباحثين: |

COMMENTS

| OFFICE USE ONLY | | | |
|---|---|---|---|
| Date submitted: | | Ref: | |
| Reviewers: | | Decision: | |

## Annex IIa

(used in Clinical trial or clinical research)

## Part 1: Participant Information Sheet

هذا البحث تم الموافقة عليه من قبل لجنة الأخلاقيات التابعة لكلية الصيدلة. قبل أن تقرر ما إذا كنت ترغب في المشاركة في هذه الدراسة، فمن المهم بالنسبة لك أن نفهم لماذا يتم اجراء هذا البحث وما سينطوي.عليه ... يرجى أخذ الوقت الكافي لقراءة ما يلي قبل التوقيع على استمارة موافقة المشاركين. مشاركتكم في هذا البحث هو طوعي وأنت حر في الانسحاب في أي وقت، دون إبداء أسباب.

ماهى اهداف هذا البحث؟ اكتب باختصار خطوات البحث.

ما هو الدور المطلوب من المشارك؟ و لماذا تم دعوتكم للمشاركة؟

ما هي المخاطر المرتبطة بهذا الإجراء؟

الوقت المتوقع لانتهاء البحث

أقر بأنني قد قرأت جميع المعلومات الواردة في ورقة المعلومات مشارك وافقت على المشاركة في هذا البحث

توقيع المشارك:

إذا وجدت أي مشكلة في هذا البحث يمكنك الاتصال بالباحث.

| | |
|---|---|
| الأسم: | |
| معلومات الإتصال: | |

يقر الباحث بمسؤليته على الحفاظ على سرية المعلومات المجمعة و البيانات الشخصية للمشاركين.

| | |
|---|---|
| توقيع الباحث: | |

COMMENTS

| OFFICE USE ONLY | | | |
|---|---|---|---|
| **Date submitted:** | | **Ref:** | |
| **Reviewers:** | | **Decision:** | |

# Annex IIb

## Part 2: Information on drugs or Medicinal products

**This annex needs only to be completed if relevant to research. It should be completed when Drug or medicinal products or medical devices are used on Human participants.**

| **Title of Research:** | |
|---|---|

| | | |
|---|---|---|
| **1. Is the study initiated /sponsored by pharmaceutical or other industrial company?** | | |
| **2. Does the study involve:** | | |
| | - Pre-marketing use of a product? | |
| | - A new use for marketed product? | |
| | - Studying the effect of marketed product? | |

**1) Drug and Medicinal product**

A medicinal product is: (a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

| **a) Details of the medicinal product:** | | | |
|---|---|---|---|
| **Approved Name** | **Active ingredient** | **Strength** | **Manufacturer** |
| | | | |
| **b) Dosage regimen used:** | | | |
| **Dosage & Frequency** | | **Route** | |
| | | | |
| **c) Is this dosage regimen** | | | |
| - The recommended dose regimen by the manufacture | | | |
| - New dose regimen | | | |

| |
|---|
| **d) What are the possible side effects?** |
| |
| **e) What is the pharmacological action of this drug?** |
| |
| **f) What are the arrangements for dispensing medicinal product? (please give details)** |
| |

**2) Medical devices**

- Is the focus of this study/trial to investigate/evaluate a medical device?
- If yes, what is the name of the medical device or device nomenclature (system of naming the medical device)?
- If yes, please provide a general description of the medical device and the medical use in patients.
- If an application to conduct a clinical investigation of a medical device

| **(a) Does the device have a CE mark?** | |
|---|---|
| **• If the device has a CE mark, is it proposed to use the device within the terms of its CE mark or outside the terms of its CE mark?** | |
| **• If outside, please elaborate:** | |
| | |
| **• CE mark* number:** | |

| OFFICE USE ONLY | | | |
|---|---|---|---|
| **Date submitted:** | | **Ref:** | |
| **Reviewers:** | | **Decision:** | |

COMMENTS

| |
|---|
| |
| **• What are the possible hazards and adverse effects?** |
| |
| **• Who will fit or apply the device for participant?** |
| |

**NOTE: CE Marking on a product is a manufacturer's declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation, in practice by many of the so-called Product Directives.**

## Annex IIc

## Part 3: Patient Consent Form

| Title of Research: | |
|---|---|

- I confirm that I have read and understand the Information Sheet for the above study, have had the opportunity to ask questions, and understand what I am expected to do as a volunteer. - I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my rights being affected.
- I would like/not like my own results reported back to me, understanding that no interpretation may be possible. (answer yes/No)
- I do/do not agree that photographs and video material recorded during the study may be used for illustration purposes in reports and any subsequent journal articles. This is on the understanding that, while every effort will be made to preserve my anonymity, this cannot be guaranteed. (answer agree/not agree)
- I do/do not agree that samples provided during the study may be stored beyond the study duration for further research. I understand that these samples will be made anonymous and not traceable back to me. (answer agree /not agree)

| Participant signature: | توقيع المشارك: |
|---|---|
| | |

### Certificate of Consent for children

**I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily for (child) to participate as a participant in this study and understand that I have the right to withdraw her/him from the study at any time without in any way affecting our care at this Centre.**

| | | |
|---|---|---|
| Print Name of Parent or Guardian | | Date |
| Signature of Parent of Guardian | | |

### Certificate of Consent for illiterate

**I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.**

| | | |
|---|---|---|
| Print name of witness | | Date |
| Signature of witness | | |
| Thumb print of participant | | Date |

### Statement by the researcher/person taking consent

**I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:**

| | |
|---|---|
| | |
| | |
| | |

**I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.**

**A copy of this Consent Form has been provided to the participant.**

| | | |
|---|---|---|
| Print Name of Researcher/person taking the consent | | Date |
| Signature of Researcher/person taking the consent | | |

COMMENTS

| OFFICE USE ONLY | | | |
|---|---|---|---|
| **Date submitted:** | | **Ref:** | |
| **Reviewers:** | | **Decision:** | |

# Annex III

## Information on drugs or Medicinal products used in animal research

**This annex needs only to be completed if relevant to research. It should be completed when Drug or medicinal products or medical devices are used on human or Animal.**

| **Title of Research:** | |
|---|---|

| | |
|---|---|
| **1. Is the study initiated /sponsored by pharmaceutical or other industrial company?** | |
| **2. Does the study involve:** | |
| - Pre-marketing use of a product? | |
| - A new use for marketed product? | |
| - Studying the effect of marketed product? | |

**1) Drug and Medicinal product**

A medicinal product is: (a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

| **a) Details of the medicinal product:** | | | |
|---|---|---|---|
| **Approved Name** | **Active ingredient** | **Strength** | **Manufacturer** |
| | | | |
| **b) Dosage regimen used:** | | | |
| **Dosage & Frequency** | | **Route** | |
| | | | |
| **c) Is this dosage regimen** | | | |
| - The recommended dose regimen by the manufacture | | | |
| - New dose regimen | | | |

| **d) What are the possible side effects?** |
|---|
| |
| **e) What is the pharmacological action of this drug?** |
| |
| **f) What are the arrangements for dispensing medicinal product? (please give details)** |
| |

**2) Medical devices**

- Is the focus of this study/trial to investigate/evaluate a medical device?
- If yes, what is the name of the medical device or device nomenclature (system of naming the medical device)?
- If yes, please provide a general description of the medical device and the medical use in patients.
- If an application to conduct a clinical investigation of a medical device

| **(a) Does the device have a CE mark?** | |
|---|---|
| **• If the device has a CE mark, is it proposed to use the device within the terms of its CE mark or outside the terms of its CE mark?** | |
| **• If outside, please elaborate:** | |
| | |
| **• CE mark* number:** | |

| OFFICE USE ONLY | | | |
|---|---|---|---|
| **Date submitted:** | | **Ref:** | |
| **Reviewers:** | | **Decision:** | |

COMMENTS

| |
|---|
| |
| **• What are the possible hazards and adverse effects?** |
| |
| **• Who will fit or apply the device for participant?** |
| |

**NOTE: CE Marking on a product is a manufacturer's declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation, in practice by many of the so-called Product Directives.**

| OFFICE USE ONLY | | | |
|---|---|---|---|
| **Date submitted:** | | **Ref:** | |
| **Reviewers:** | | **Decision:** | |

# Research Protocol Approval

| | |
|---|---|
| **Title of Research:** | |
| **Carried by:**<br>**(Applicant's name and affiliation)** | |

**The ethics committee on behalf of the Faculty of pharmacy has reviewed the above mentioned research submitted to the committee and has decided the following:**

| | |
|---|---|
| **Decision:** | |

**<u>The Committee has considered the relevant requirements outlined in:</u>**

- **The Declaration of Helsinki**
- **The National Statement on Ethical Conduct on Human Research 2007;**
- **The National Occupational Health and Safety Commission guidelines;**
- **National Code of Practice for the Preparation of Material Safety Data Sheets;**
- **Code of Research Conduct and Research Ethics of the MSA University**

**Comments:**

| | | |
|---|---|---|
| **Head of the Research Ethics Committee** | | **dd/mm/yyyy** |

# Postgraduate
# Progress Report

| OFFICE USE ONLY | |
|---|---|
| **Date submitted:** | **Ref:** |
| **Submission number:** | |
| **Reviewers:** | |
| **Decision:** | |

# Research Ethics Committee-Faculty of Pharmacy

## Progress Report

| | |
|---|---|
| **Research title** | |
| **Applicant (s) and affiliation (s)** | |
| **Department** | |

**This form should be filled by applicants to state the modifications in their running research. This form must be delivered to the ethics committee: (1) once a year , (2) in case of any modifications (if any) in the information submitted in the original ethics application form in part one and (3) any serious unexpected adverse events.**

| | |
|---|---|
| **Is there any modifications in protocol of work** | Yes/No |
| **Other modifications in the research** | Yes/No |
| **Are there any documents that you are going to attach to this form** | Yes/No |

Write the modifications that you are going to make in your research.

| |
|---|
| |

| | |
|---|---|
| **Applicant signature** | |
| **Reviewers signature** | |

**This part is filled by the Ethics committee**

**Is this modification considered major** ☐

**Minor** ☐

**The ethics committee comment and recommendations on thesemodifications**

| |
|---|
| |

---

**This part is filled by the Ethics committee after fulfilling the recommendationsof the Ethics committee**

**This research is approved** ☐ **or not approved** ☐

| | |
|---|---|
| **Reviewer's signature** | |
| **Head of the ethics committee signature** | |