OFFICE USE ONLY		
Date submitted:	_____	**Ref:** _____
Reviewers:	_____	
Decision:	**Approved/ Approved after corrections/Rejected**	

Research Ethics Committee-Faculty of Pharmacy

Application Form for post graduate studies

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 3 Annexes:

-For any inquiries, please consult Dr.Reham Wasfi (Room G009) or join the ethics committee weekly meeting every Tuesday from 1:00 to 2:00 or send an email to msapharmrec@gmail.com

-The form should be word processed. You can receive a soft copy of the application form by sending an email to the previously mentioned email address.

-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: M.Sc. / Ph.D/ Post doctoral/other

Part I: Applicant and Research Details

1. Name of applicant (from MSA) and affiliation:	
2- Collaborating researchers (non MSA affiliated)	
3. E-mail Addresses:	
4- Telephone Number	
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?
i) Clinical ……Fill Section B (**Researches involving human participants**) **ii)** Experimental…….Fill Section C (**Researches involving animal use)** iii) **Other**
8. 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?
15. What is the anticipated date to finish this research?
16. Is this study sponsored or funded by a specific organization other than MSA University? What is the estimated budget?

13- Have any collaborating internal or external schools or institutions or departments whose resources will be needed, been informed and agreed to participate?
14- 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)

		Date
Applicant's Signature		
Reviewer's Signature		
Head of the Research Ethics Committee		

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.
- Abide by all of the MSA University policies and procedures governing the ethical conduct of research.

Applicant Name:_____

Signature_____Date:_____

Section B

1) HUMAN PARTICIPANTS - SELECTION AND RECRUITMENT

Please describe:

a) How many participants are to be involved?	
b) What are the main inclusion and exclusion criteria for involved participants?	
c) Will any participants involved in this research study be simultaneously involved in any other research project?	
d) Will human participants receive compensation for participation?	
e) What are the expected hazards on participants upon their approval to share in the project?	
f) How are you going to follow up research participants? and for how long?	

2) HUMAN PARTICIPANTS – INFORMED CONSENT (for the case of clinical trials)

a) Will informed consent be obtained?) If no, please justify	
b) How will informed consent be obtained and by whom?	
c) Will participants be informed of their right to refuse to participate and their right to withdraw from this research study? Please elaborate.	

d) Will there be a time interval between giving information and seeking consent?	
e)Will any research participants be under the age of 18	

3. Data Protection and Confidentiality

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

3.1 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

3.4 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

3.5 Where will the analysis of the data from the study take place and by whom will it be undertaken?
3.6 Who will have control of and act as the custodian for the data generated by the study?

		Date
Applicant's Signature		
Reviewer's Signature		
Head of the Research Ethics Committee		

Section C

This part is for the studies that involves lab animals

What is the purpose of using animal in this study?

1. Field study/capture or study of free-living (including feral) animals	**YES / NO**
2. Behaviour observations	**YES / NO**
3. Harvesting of tissues from dead animals	**YES / NO**
4. Dissection of dead animals	**YES / NO**
5. Surgical procedures	**YES / NO**
6. Administration of pharmaceutical agents	**YES / NO**
7. Infection with microbial agents and/or parasites/ testing of toxins [i]	**YES / NO**
8. Production of antisera	**YES / NO**
9. Feeding studies, including diet modification	**YES / NO**
10. Animals with altered genetic make-up (manipulated, modified, naturally occurring mutation)	**YES / NO**
Other. Other Procedures: if selected, please write details in the box below	**YES / NO**

- **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?

f) Risks

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

Applicant's signature	
*Signature of the Head of pharmacology department in MSA	

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

Annex I Risk assessment

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**
• **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.			
• **Chemical hazards** e.g.: Toxic by inhalation, irritant ,corrosive, flammable, explosive Include routes of exposure: skin sensitization, sensitization by inhalation…			
• **Personal safety** e.g: physical or verbal attack , disability or health problem, getting lost or stranded by transport, cultural or legal differences			

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**
• **Biological agent hazards** *Any micro-organism , cell culture or human endoparasite including any which have been genetically modified may cause infection , allergy, toxicity and other hazards of human health This includes bacteria ,viruses ,fungi and parasites *Routes of exposure should be included e.g.: blood borne infection, skin contact….			
• **Environmental impact** E.g.: pollution and waste, deposition of rubbish…..			
• **Other hazards**			