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 3 Annexes:

TABLE OF CONTENTS	MANDATORY /OPTIONAL	Mark used
SECTION A **General Information, study description, research procedures**	MANDATORY	
SECTION B **Researches involving human participants**	Optional	
SECTION C **Researches involving animal use**	Optional	
Annex I Patient consent form	Optional	
Annex II Risk Assessment form	Mandatory	
Annex III Medicinal products/Cosmetics/Food and Foodstuffs	Optional	

-This Application Form is divided into Sections.
Section A is **Mandatory.** Sections B and C are optional.
-For any inquiries, please consult the coordinator of the committee Dr.Reham Wasfi (Room G009) or join the ethics committee weekly meeting every Wednesday from 10 to 11.-The form should be word processed. It can be obtained from the e-learning website (ethics committee).-Return one hard copy of the completed form to: Faculty of Pharmacy-Ethics committee.

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.**

Section A

Title of the Research Study:

Part I: Applicant and Supervisor Details

1. Name of Applicant (student):	
2. Status (Undergraduate, MA or MSc):	
3. E-mail Address:	
4- Telephone Number	
6. Department:	
7. Supervisor's name and affiliation :	
8. Supervisor’s E-mail address:	

Section II: Summary of Proposed Research

9. Brief outline of the proposed project (include project design and methodology). Limit = 300 words.
10 List the study aims , objectives and benefits of this proposed research Limit = 100 words.

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?
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)

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

Supervisors Declaration

For the project under the title:

Carried by :

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 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?	

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

3.2 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
3.3 Where will the analysis of the data from the study take place and by whom will it be undertaken?

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

		Date
Applicant's Signature		
Supervisor'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	
Supervisor'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*

This Section is optional. Please delete if this section does not apply.

Annex I

Patient Consent Form

Project Title	
-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. -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. -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 الكشف 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 _____

Signature of Parent of Guardian_____

Date _____

Day/month/year

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_____ AND Thumb print of participant

Signature of witness _____

Date _____

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_____

Signature of researcher _____

Date _____

Day/month/year

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

Annex II 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**			

This Section is optional. Please delete if this section does not apply.

Annex III: Drugs or Medicinal products or 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? Y/N
2. Does the study involve - Pre-marketing use of a product Y/N - A new use for marketed product Y/N - Studying the effect of marketed product? Y/N

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 Y/N - New dose regimen Y/N			
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 <u>medical device?</u>**
- **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?** Within / Outside	• **If the device does not have a CE mark, is this study being undertaken for the purposes of obtaining a CE mark?** Yes / No
• **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.**

October University for Modern Sciences and Arts

MSA University

Annex IV

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 signature:**	

ملحق IV

ورقة معلومات للمشاركين فى البحث

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:

_____