كلية الصيدلة-جامعة المنوفية

Faculty of Pharmacy, Menoufia University

لجنة أخلاقيات البحث العلمي

Scientific Research Ethics Committee (SREC-FP-MU)

Application Form

Date:	Ref. number	**MP**			/	
Reviewer:						
Decision:						

The Scientific Research Ethics Committee, Faculty of Pharmacy, Menoufia University (SREC-FP-MU) is responsible for ensuring that any research will be conducted by the faculty members and/ or students, or by other institutions cooperatively with our Faculty, meets the recognized ethical standards. If the applicant have made any changes in his 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.

The Application Form consists of 4 sections and 4 Annexes:

Section	Content	Mandatory/ Optional	Your mark
Section A	General Information, study description, and research procedures	Mandatory	
Section B	Research involving human participants	Optional	
Section C	Research involving animal use	Optional	
Section D	Research involving cell line	Optional	
Annex I	Patient informed consent form	Optional	
Annex II	Requesting a waiver of the informed consent process	Optional	
Annex III	Drugs, medicinal products, or medical devices	Optional	
Annex IV	Risk assessment form	Mandatory	

- ✓ This Application Form is divided into Sections. Section A and annex IV are mandatory. Other sections and annexes are optional. Please delete the non-applicable section(s) and/ or annex(es).
- ✓ **If the research will involve human participants, you must obtain another ethical approval from the place where the patients will be obtained.**
- ✓ The form should be word processed, printed, signed, scanned, and submitted *via* email to SREC.FPMU22@phrm.menofia.edu.eg. Please return a hard copy of the completed form to the Department of Graduate Studies and Research in the Faculty.

Section A

Title of the Research Study:
عنوان البحث باللغة العربية:

Part I: Applicant and supervisor/ researchers details

1. Name of the applicant:	اسم الباحث باللغة العربية:
2. Academic degree of the applicant:	الدرجة العلمية للباحث:
3. Status of the research: ☐ MSc ☐ PhD ☐ Independent research	
4. E-mail address:	
5. Mobile number:	
6. Department:	
7. Name and affiliation of supervisor(s)/ researcher(s):	اسم المشرفين أو الباحثين المشاركين وتخصصاتهم:

Part II: Originality of the research

We, the applicant and the supervisors, confirm that the ideas involved in the research plan are original and not fully copied form any other sources; seminars, theses, protocols, published or unpublished research papers.	Agree ☐ Refuse ☐

Part III: Summary of proposed research

What is the type of the proposed research?
i) Clinical ☐ If yes, fill section B (**research involving human participants**) **ii)** Experimental anim ☐ If yes, fill section C (**Research involving animal use)** **iii)** Cell line ☐ If yes, fill section D (**Research involving cell line)**
Brief background on the research topic. (Max = 300 word)

List the aims, objectives, and benefits of this proposed research. (Max = 100 word)
Brief outline of the proposed research design and methodology. (Max = 300 word)
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?
What is the anticipated date to finish this research?

Is this study sponsored or funded by a specific organization other than your University? If yes, mention the funding sources.
Have any collaborating internal or external schools, institutions, or departments whose resources will be needed, been informed and agreed to participate? If yes, mention them.
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 name		
Applicant signature		**Date**
Reviewer decision	☐ **Approved** ☐ **Conditionally approved** ☐ **Deferred** ☐ **Not approved**	**Required modification or reasons for rejection**
Reviewer name		
Reviewer signature		**Date**
Head of the 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 FP-MU, 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 FP-MU policies and procedures governing the ethical conduct of research.

Applicant Name:_____

Signature_____Date:_____

Section B

(This section is for the studies that involves human participants)

Part I: Human participants - selection and recruitment

How many participants will be involved?	
Have you conducted a sample size calculation? Define, state the reference scientific paper(s)?	
What are the main inclusion and exclusion criteria for the involved participants?	
Why can't this research be carried out with animal/non-animal alternatives?	
Is the research having potential benefit(s) to participating subjects? If any state them.	
Will any participants involved in this research study be simultaneously involved in any other research project?	
Will human participants receive compensation for participation in this study?	
What are the expected hazards on participants upon their approval to share in the project?	
State the type of sample/biopsy obtained from participants, What is the procedure or precaution(s) to obtain such sample?	
How are you going to follow up research participants? and for how long?	

Part II: Human participants – informed consent

Will informed consent be obtained? If no, please justify	
How the informed consent will be obtained and by whom?	
Will the participants be informed of their right to refuse to participate and their right to withdraw from this research study anytime they want?	
Will there be a time interval between giving information and seeking consent?	
Will any research participants be under the age of 18?	

Part III: 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 the participants.
- ☐ Use of audio/visual recording devices.
- ☐ Storage of personal data on any of the following:
    - ☐ Manual files
    - ☐ FP-MU- Computers
    - ☐ Home or other personal computers
    - ☐ Laptops

Part IV: Disposal (Environment Friendly Research Work)

What is the disposal method used for solid tissue waste; pipettes, and multiple well plates,…after research end?	
*S*pecify procedures to be applied and followed for disposal of biohazards (liquid waste as blood, urine, media and serum) after research end?	

Section C

(This section is for the studies that involves experimental animals)

Part I: What is the purpose of using animals in this study?

1. Field study/capture or study of free-living (including feral) animals	**Yes / No**
2. Behavior 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 [1]	**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**

Part II: General information

What is the species of the used animals?	
How many animals will be used?	
What is the maximum/minimum animals per cage?	
What are the housing conditions available?	
What is the type of feed given to animals?	
Who will be responsible for the care of animals during the weekdays?	
Who will be responsible for the care of animals during the weekends and holidays?	
Are you euthanizing animals at the end of the study? If yes, What will be the method used to euthanize the animals?	
What is the maximum time for which any individual animal will be held?	
Place where you will conduct the experimental work: -Animal house place -The biochemical/molecular biology lab	

Part III: Disposal (Environment Friendly Research Work)

What is the disposal method used for solid tissue waste; pipettes, and multiple well plates,…after research end?	
*S*pecify procedures to be applied and followed for disposal of biohazards (liquid waste as blood, urine, media and serum) after research end?	
What is the method of disposal of used animals after research?	

Section D

(This section is for the studies that involves cell line)

Part I: General information

What is the cell line name and no. to be used?	
Mention the origin of the cells used? i.e. primary to culture by yourself Or ready-to-use-purchased cell line?	
Mention from where will you purchase the cell line?	
For primary culture; mention the animal to be used or the hospital name to obtain the human sample?	
State chemicals, biological agents, and physical hazards in culturing work?	
Is the research involving viruses; adenovirus or lentivirus? Explain?	
Mention the lab biosafety level?	
Is there any radiation work? Explain steps, precautions and protection facilities available?	
Who will be responsible for the care of cells during either storage periods? Or sub-culturing?	
Are there contaminants used during cell culturing? Explain.	
Mention the place where you will conduct the experimental work	

Part II: Disposal (Environment Friendly Research Work)

What is the disposal method used for solid waste; pipettes, tissue culture flasks, and multiple well plates, after research end?	
What is the disposal method used for cell culture liquid waste media and serum, after research end?	

Annex I
Patient Informed Consent Form

(This Section is optional. Please delete if it is not applicable)

Volunteer Participant Name		
Gender	Male	Female
Age		
Address		
Telephone		
Research Title in English:		
Researcher Name		
Master Thesis	Yes	No
Ph.D. Thesis	Yes	No
Independent Research	Yes	No
The scientific background and the aim of conducting the research Please explain in simple language in at least eight lines about the scientific background of the research and what is the importance of research for science and society.		
What will be done in detail		
Duration of the research		
Location of the research		
Total Number of research participants		
Sick	Healthy	
Mention the method of selecting research participants, especially in clinical trials		
-Details of the research steps that the subscriber will be exposed to including		
times of the visit,		

the place of research
place of taking samples
various diagnostic methods
various treatments that the participant will be exposed to during the search
-**Please write each of the risks that may occur to the participant from any procedure in the research including:**
treatment
Diagnosis (for example taking a blood sample may result in a slight bruise and pain)
Expected benefits from the research:
direct benefits:
indirect benefits:
If there are no direct benefits to the subscriber, write (there is no direct benefit from participating in the research, but the search result will benefit other patients)
Compensation in case of risks: if any
Available alternatives if you refuse to participate in this research:
When there is any question for the participant, s/he can contact:
The principal investigator:
Mobile:
Or the principal investigator Representative:
Mobile:
Or the Reporter/Chair of the Ethics Committee:
Mobile:

N.B.

1- The volunteer has the right to withdraw from the research at any time without any negative consequences

2- The volunteer must obtain a copy of this declaration

I acknowledge that I have read, understood and agreed to the procedures to be carried out through this research.
Research participant or his legal representative Name:
Signature:
Date:

Witnesses in case the participant is unable to read and write
Name:
Signature:
Date:

I undertake to maintain the confidentiality of the research participant's information
Principal Investigator Name:
Signature:
Date:

Applicant name		
Applicant signature		**Date**
Reviewer decision	☐ **Approved** ☐ **Conditionally approved** ☐ **Deferred** ☐ **Not approved**	**Required modification or causes of rejection**
Reviewer name		
Reviewer signature		**Date**
Head of the Committee		**Date**

نموذج الموافقة المستنيرة لإجراء بحث طبي على مشارك متطوع

اسم المشارك المتطوع	
ذكر	**أنثي**
السن	
العنوان	
التليفون	
عنوان البحث باللغة العربية:	
اسم الباحث	
يتم إجراء هذا البحث توطئة لرسالة	
ماجيستير	**دكتوراة**
• **مشروع بحثي غير ممول**	
• **مشروع بحثي ممول**	
تسمية الجهة الممولة (إذا وجدت)	
الخلفية العلمية والهدف من إجراء البحث	
برجاء الشرح بلغة مبسطة فيما لا يقل على ثمانية أسطر عن الخلفية العلمية للبحث وما هي أهمية البحث للعلم والمجتمع.	
ما سوف يتم إجراؤه بالتفصيل:	
مدة البحث	
مكان إجراء البحث	
عدد المشاركين الكلي في البحث	
عدد المشاركين المرضى	**عدد المشاركين الأصحاء**
ما هو أسلوب اختيار المشاركين في البحث وخاصة في التجارب الإكلينيكية	
تفاصيل خطوات البحث التي سيتعرض لها المشترك بما يشمل:	
مرات الزيارة	
مكان البحث	

مكان سحب العينات	
العلاجات المختلفة التي سيتعرض لها المشارك أثناء البحث:	
برجاء كتابة كل من المخاطر المتوقع حدوثها للمشترك من أي إجراء في البحث بما يشمل :	
العلاج	
أو التشخيص (مثل سحب عينة الدم يمكن أن ينتج عنه كدمة بسيطة وألم)	
الفوائد المتوقعة من البحث:	
الفوائد المباشرة	الفوائد غير المباشرة
إذا كانت لا توجد فوائد مباشرة للمشترك يكتب (لا توجد فائدة مباشرة من الاشتراك في البحث لكن نتيجة البحث ستفيد مرضى آخرين)	
التعويضات في حالة حدوث مخاطر: إن وجدت	
البدائل المتاحة في حالة رفضك الاشتراك في هذا البحث:	
عند وجود أي استفسار للمشارك يمكنه الاتصال بـ	
الباحث الرئيسي (الاسم)	
التليفون:	
ممثل عن الباحث الرئيسي (الاسم):	
التليفون:	
مقرر أو رئيس لجنة الأخلاقيات (الاسم)	
تليفون:	

تنبيهات

1. **من حق المتطوع الانسحاب من الدراسة بأي وقت دون أي عواقب سلبية**
2. **يجب حصول المتطوع على صورة من الإقرار**

أقر أنني اطلعت وفهمت الإجراءات التي ستتم من خلال ها البحث ووافقت عليها
اسم المشارك في البحث أو الممثل القانوني عنه:
التوقيع:
التاريخ:
اسم الشاهد في حال المشارك غير قادر على القراءة والكتابة:
التوقيع:
التاريخ:
أتعهد أنا الباحث بالحفاظ على سرية المعلومات الخاصة بالمشارك في البحث
اسم الباحث الرئيسي
التوقيع:
التاريخ:

اسم المتقدم		
توقيع المتقدم		**التاريخ**
قرار المراجع	☐ **منح الموافقة الأخلاقية** ☐ **موافقة مشروطة ببعض التعديلات** ☐ **تأجيل الموافقة** ☐ **لا يتم منح الموافقة الأخلاقية**	**التعديلات المطلوبة أو أسباب الرفض**
اسم المراجع		
توقيع المراجع		**التاريخ**
توقيع رئيس اللجنة		**التاريخ**

Annex II
Requesting a Waiver of the Informed Consent Process

(This Section is optional. Please delete if it is not applicable)

A proposal which does not include an informed consent IC process may be approved by the REC under certain conditions.	
Explain why the research involves NO more than minimal risk to the subjects.	
Explain how the research involves NO more than minimal risk to the subjects.	
Explain why the waiver will NOT adversely affect the rights and welfare of the subjects.	
Is the research team collecting identifiable private information and/or identifiable biospecimens?	
Yes	No
If yes, explain why the research could not practicably be carried out without using such information or biospecimens in an identifiable format.	
Explain why the research could not be practicably be carried out without the waiver of informed consent.	
If a waiver of informed consent is approved by the REC, will subjects be provided with additional pertinent information after participation?	
Yes	No
Explain/describe why:	

Applicant name		
Applicant signature		**Date**
Reviewer decision	☐ **Approved** ☐ **Conditionally approved** ☐ **Deferred** ☐ **Not approved**	**Required modification or reasons for rejection**
Reviewer name		
Reviewer signature		**Date**
Head of the Committee		**Date**

Annex III
Drugs, medicinal products, or medical devices

(This Section is optional. Please delete if it is not applicable)

Is the study initiated /sponsored by pharmaceutical or other industrial company?	Yes/ No
Does the study involve:	
Pre-marketing use of a product	Yes/ No
A new use for marketed product	Yes/ No
Studying the effect of marketed product?	Yes/ No

1. Drug and medicinal product

The medicinal product is any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or 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:			
Dosage and frequency		Route of administration	
It is the recommended dose regimen by the manufacture? Yes/ NO			
If it is a new dose regimen, mention the reference.			
C. What are the possible side effects?			
D. What is the pharmacological action of this drug?			
E. What are the arrangements for dispensing medicinal product? (please give details)			

2. Medical devices

A medical device can be any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination for a medical purpose.

<table>
<tr><td>What is the name of the medical device or device nomenclature (system of naming the medical device)?</td><td></td></tr>
<tr><td>Provide a general description of the medical device and the medical use in patients.</td><td></td></tr>
<tr><td colspan="2">Does the device have a CE mark?</td></tr>
<tr><td>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</td><td rowspan="3">If the device does not have a CE mark, is this study being undertaken for the purposes of obtaining a CE mark?

Yes / No</td></tr>
<tr><td>If outside, please elaborate:</td></tr>
<tr><td>CE mark number:</td></tr>
<tr><td>What are the possible hazards and adverse effects?</td><td></td></tr>
<tr><td>Who will fit or apply the device for participant?</td><td></td></tr>
</table>

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 IV
Risk Assessment

(This Section is Mandatory)

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.: toxicity by inhalation, irritant ,corrosive, flammable, explosive. Routes of exposure: skin sensitization, sensitization by inhalation,…etc.			
Personal safety e.g: physical or verbal attack, disability or health problem, getting lost or stranded by transport, cultural or legal differences.			

Biological agent hazards Any micro-organism , cell culture or human endoparasite including any 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,…etc.			
Environmental impact e.g.: pollution and waste, deposition of rubbish,…etc.			
Other hazards			