Application for Study Protocol Evaluation نموذج التقدم للجنة أخلاقيات البحث العلمي بالكلية		
Researcher Name:		إسم الباحث
Faculty: Pharmacy		الكلية
University:		الجامعة
Department:		القسم العلمي
Mobile رقم المحمول		
E-mail البريد الالكتروني		
Master Thesis رسالة ماجستير	Yes	No
Ph.D. Thesis رسالة دكتوراه	Yes	No
Independent Research/ بحث ما بعد الدكتوراه مستقل	Yes	No
عنوان البحث أو الرسالة بالعربي		
Thesis or Research Title in English		
Will your Research/Thesis Involve?		

Experimental Animals حيوانات تجارب	Human Volunteers متطوعين	Cell line خط الخلايا	Unidentified human samples عينات بشرية غير معرفة

Primary Supervisor signature	PI Signature

العباسية – القاهرة – جامعة عين شمس – كلية الصيدلة – شارع منظمة الوحدة الأفريقية – خلف مستشفي عين شمس التخصصي
rec@pharma.asu.edu.eg 11566 الرقم البريدي

N.B. All forms must be typewritten, singed by the Chief supervisor and submitted via email to **rec@pharma.asu.edu.eg**

Application for Study Protocol Involving Human Subjects for Evaluation		Reviewer Opinion
Researcher Name:		
Faculty: Pharmacy		
University:		
Department:		
Mobile:		
E-mail:		
1. Thesis	**Independent Research**	
Thesis Type:		
Master	**PhD**	
Thesis/Research/Project Title:		
2. Summary of the thesis/research proposal (You should mention all the details regarding samples handling, injection if any, biological samples, anesthesia and method of intervention if need it, drugs, maximum 500 words)		
3.Study Scientific Significance		
***3.1*. Study Objectives**		
a.		
***3.2.* Demographic Data**		
3.2.1. Participants Age (Range in years for adults and in month(s) for children)		
18-70 years		
3.2.2. Participants Sex (M:F)?		
1:1		

3.2.3. Body Mass Index BMI (Range m2/k.g) (Requested/not Requested)	
29.9 – 18.5	

Study Protocol Involving Human Subjects (cont.)		**Reviewer Opinion**
3.3. **Approximated number (the least possible) of subjects?**		
3.4. **Have you conducted a sample size calculation?** **Define, state the reference scientific paper(s)**		
Yes	**No**	
3.5. **Why can't this research be carried out with animal/non-animal alternatives?**		
3.6. Is t**he Research having potential benefit(s) to participating subjects?** **If any state them.**		
Yes	**No**	
3.7. **Is this research based on preclinical trials (animal study)?** **If any state them.**		
Yes	**No**	
3.8. **Safety, expected risk(s) and Tolerability issues of the study to participants (Evidenced by references if possible, State them if Physical or Mental)**		
3.9. **State the Type of Sample/Biopsy obtained from participants,** **What is the procedure or precaution(s) to obtain such sample?**		

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Liquid biopsy; Blood, urine, CSF, effusion, exudate	
Tissue biopsy and if there is safety margin to be taken as well? Describe ?	

Study Protocol Involving Human Subjects (cont.)		**Reviewer Opinion**
3.10. **Is an informed Consent of the Involved Human Subjects or their guardians are taken?**		
Yes	**No**	
3.11. **If medication is to be taken; No**		
state the drug name with reference(s) for that.		
and the dosage used, with reference(s) for that.		
route of administration with reference(s) for that.		
and the duration for such medication use with reference(s) for that.		
4. **Commitment**		
4.1. **I do commit to provide a photocopy of plain informed consent form that will be used in the study**		
4.2. **I do commit to maintain the confidentiality of information and the safety of the human subjects involved in the research**		
5. **Research Setting**		
5.1. **Mention the setting (hospital/office) at which recruitment of human participants will be performed**		

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***5.2. S*pecify the license (A MUST)**	
***5.3. Specify a*ccreditation (OPTIONAL) of the setting**	
***5.4.* Mention the place at which the research will be conducted for the biochemical or molecular biology work**	
-	
***5.5. S*pecify the license type of this place**	

Study Protocol Involving Human Subjects (cont.)	**Reviewer Opinion**
***6.* Disposal**	
***6.1.* What is the disposal method used for solid tissue waste; pipettes, tissue culture flasks, and multiple well plates, …. after research end?**	
***6.2. S*pecify procedures to be applied and followed for disposal of biohazards (liquid waste as blood, urine, media and serum, after research end?)**	
Chief Supervisor electronic Signature إمضاء المشرف الرئيسي	
PI electronic Signature إمضاء الباحث الرئيسي	
Date Submitted/uploaded	

Reviewer Name:	**Reviewer signature:**
Reviewer Decision	

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Approved	Conditionally approved	Deferred	Not approved
Reviewing Date:			

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