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| **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 Animalsحيوانات تجارب | Human Volunteersمتطوعين | Cell lineخط الخلايا | Unidentified human samplesعينات بشرية غير معرفة |
| **Primary Supervisor signature** | **PI Signature** |

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

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| **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** |  |
|  |  |
| ***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.ParticipantsSex (M:F)?** |  |
| 1:1 |  |
| **3.2.3. Body Mass Index BMI (Range m2/k.g) (Requested/not Requested)**  |  |
| 18.5 – 29.9 |  |

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| **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?** |  |
| Liquid biopsy; Blood, urine, CSF, effusion, exudate  |  |
| Tissue biopsy **and if there is safety margin to be taken as well?** **Describe ?** |  |
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| **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**  |  |
| ***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** |  |
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| **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?)** |  |
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| **Chief Supervisor electronic Signatureإمضاء المشرف الرئيسي**  |  |
| **PI electronic Signatureإمضاء الباحث الرئيسي**  |  |
| **Date Submitted/uploaded** |  |

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| --- | --- |
| **Reviewer Name:**  | **Reviewer signature:** |
| **Reviewer Decision**  |
| **Approved** | **Conditionally approved** | **Deferred** | **Not approved** |
| **Reviewing Date:**  |