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| **UCSI UNIVERSITY**  **Ethical Clearance Application Form**  **Description: Latest-UCSI-Vertical**   |  |  |  |  | | --- | --- | --- | --- | |  | New Submission |  | Resubmission | | |
| **A** | **DETAILS OF RESEARCH PROJECT** |
| **A(I)** | **Title of Research Project** |
| **A(ii)** | **Start Date: Expected Date of Completion:**  *\*The proposed start date must be a minimum of one month after the scheduled ethics meeting* |
| **A(iii)** | **NMRR Registration ID *(If Applicable)*:** |
| **A(iv)** | **This study involves minimal risk** Yes No  *\*”Minimal risk” is defined as the potential harms and discomforts to participants are no greater than those encountered in daily life or during routine physical or psychological examinations* |
| **A(v)** | **Study Design:**  Cross-sectional Study Case Report    Qualitative Study Case-controlled Study  Mixed Method Study Case Series  Prospective Cohort Retrospective Cohort  Randomized controlled trial Quasi-experimental  Other, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **B** | **DETAILS OF RESEARCHER** |
| **B(i)** | Name of Project Leader: IC / Passport Number: |
| **B(ii)** | **Faculty/School/Centre/Dept (Please provide full address):** |
| **B(ii)** | **Position (Please tick** *( √ )***):**    **Professor** **Assoc. Prof.** **Asst. Prof / Lecturer** |
| **B(iv)** | **Type of Service (Please tick** *( √ )***):**  **Permanent Contract (State contract expiry date):** |
| **B(v)** | **Office Telephone No.:** **Handphone No.:** |
| **B(vi)** | **E-mail Address:** |

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| **B(vii)** | **Other Researchers:**  *(Please include maximum 5 pages of curriculum vitae for each researcher)* | | | | | | | | | | | |
| **Bil** | **Name** | | **Faculty /Department** | **Role** | | | | | **Phone** | | **E-mail** |
| 1 |  | |  |  | | | | |  | |  |
| 2 |  | |  |  | | | | |  | |  |
| 3 |  | |  |  | | | | |  | |  |
| **C** | **Human Study** | | | | | | | | | | | |
| **C(i.)** | **Human Subject Involvement** | | | | | | | | | | | |
| **No.** | **Item** | | | **Remarks/ Brief Description** | | | | | | | |
| **1.** | **Protocol of Research Project** | | |  | | | | | | | |
|  | 1. Summary of Research Proposal | | |  | | | | | | | |
|  | 1. Purpose | | |  | | | | | | | |
|  | 1. Background rationale | | |  | | | | | | | |
|  | 1. Hypothesis or problem statement | | |  | | | | | | | |
|  | 1. Methodology/Procedure | | |  | | | | | | | |
|  | 1. Procedures involve invasion of the body (*e.g. touching, contact, attachment of instruments, withdrawal of specimens*) | | |  | | | | | | | |
| 1. Description of all procedures involving subjects, in sequential order (*e.g. self-administered surveys, interviews, questionnaires, physical measurements*) | | |  | | | | | | | |
| 1. A copy of questionnaires | | |  | | | | | | | |
| 1. Venue of research | | |  | | | | | | | |
| 1. A copy of permission/approval letter to conduct the research | | |  | | | | | | | |
| 1. A copy of investigator brochure | | |  | | | | | | | |
| 1. A copy of ethics approval letter from other ethics committee | | |  | | | | | | | |
|  | 1. A copy of the case report form (CRF). | | |  | | | | | | | |
| **2.** | **Informed Consent Form** | | |  | | | | | | | |
|  | 1. Appropriate language | | |  | | | | | | | |
| 1. Criteria should include reading and understanding of subject information sheet | | |  | | | | | | | |
| 1. Signage from participants or parents/ guardians (*if subjects are underage*) | | |  | | | | | | | |
| **3.** | **Study Population** | | |  | | | | | | | |
|  | 1. Description of criteria for subject recruitment | | |  | | | | | | | |
| 1. Number of subjects | | |  | | | | | | | |
| 1. Gender | | |  | | | | | | | |
| 1. Race | | |  | | | | | | | |
| 1. Age range | | |  | | | | | | | |
|  | 1. Any special characteristics 2. Inclusion criteria 3. Exclusion criteria | | |  | | | | | | | |
|  | 1. Relationship between investigator and subjects | | |  | | | | | | | |
| 1. Remuneration for participation | | |  | | | | | | | |
|  | 1. Insurance / protection of subject for any medical incidence | | |  | | | | | | | |
| **4** | **Feedback to subjects** | | |  | | | | | | | |
|  | 1. Provision made for arrangements to inform subjects of the outcome of the result | | |  | | | | | | | |
| **5** | **Potential benefits of the study** | | |  | | | | | | | |
|  | 1. Direct benefits to subjects involved in study | | |  | | | | | | | |
| 1. Potential/ benefits to the scientific community/ society that would justify the use of human subjects | | |  | | | | | | | |
| **6** | **Competency of Investigators in carrying out project study/ procedures** *(describe prior experience / qualification / certification)* | | |  | | | | | | | |
| **7** | **Subject information sheet** *(letter of information separate from consent form describing disease / condition to be evaluated in the research study)* | | |  | | | | | | | |
|  | 1. Language and proper translations | | |  | | | | | | | |
| 1. Disease evaluated | | |  | | | | | | | |
| 1. Drug evaluated | | |  | | | | | | | |
|  | 1. Aim of study | | |  | | | | | | | |
|  | 1. Expected outcome | | |  | | | | | | | |
| 1. Alternative treatment available | | |  | | | | | | | |
| 1. Side effects of participating in the study | | |  | | | | | | | |
| 1. Organisation and funding of research | | |  | | | | | | | |
| 1. Remuneration of subjects | | |  | | | | | | | |
| 1. Confidentiality of Information | | |  | | | | | | | |
| **8** | **Funding of project study and approval status** | | |  | | | | | | | |
|  | 1. University | | |  | | | | | | | |
| 1. Government | | |  | | | | | | | |
| 1. Private/ Company | | |  | | | | | | | |
| 1. Others | | |  | | | | | | | |
| **C(ii)** | **Ethical Issues Questionnaire**  The following questionnaire is to help alert you to the major types of ethical issues in your research. Please answer **ALL** questions.  If you tick (√ ) ‘Yes’ to any of the questions, please include a brief description here and provide full details and all necessary justifications in your proposal. Please also explain and justify other ethical issues where applicable. | | | | | | | | | | | |
|  | **SUBJECT’S PROFILE** | | | | | No | | Yes | | Brief Description | |
| 1 | Are any of these subjects from a particularly vulnerable group? (*e.g. young children, mentally challenged etc.)* | | | | |  | |  | |  | |
| 2 | Are any of these subjects from a minority/ culturally identifiable/ disadvantaged group? *(e.g. orang asli etc.)* | | | | |  | |  | |  | |
| 3 | Are any of these subjects in constant requirement of / is highly dependent on medical care? | | | | |  | |  | |  | |
| 4 | Are any of these subjects unable to give or are incapable of giving consent? (*i.e. consent will be obtained indirectly from a legal guardian etc.)* | | | | |  | |  | |  | |
| 5 | Are the subjects given any form of payment/ incentive to participate? | | | | |  | |  | |  | |
|  | **PRIVACY AND CONFIDENTIALITY** | | | | |  | |  | |  | |
| 6 | Will you be collecting data that will potentially disadvantage a subject? *(e.g. handicaps etc.)* | | | | |  | |  | |  | |
| 7 | Does any of the data that is collected has the potential to cause discomfort, embarrassment, or psychological harm to the subjects?  (*e.g. sexual orientation etc*.) | | | | |  | |  | |  | |
| 8 | Does your research involve measures undeclared to the subjects?  (*e.g. covert observations etc.)* | | | | |  | |  | |  | |
| 9 | Will the collected data be made available to other parties not involved in the research? (*e.g. government agencies)* | | | | |  | |  | |  | |
|  | **RISK OF HARM** | | | | |  | |  | |  | |
| 10 | Will you be collecting biological samples e.g. body fluids? *(if ‘No’, go to Question 13)* | | | | |  | |  | |  | |
| 11 | What type of biological samples?  *(Please indicate amount and frequency)* | | | | |  | |  | |  | |
| 12 | Is the collection method invasive and has the potential to cause harm, physical pain or discomfort etc.? | | | | |  | |  | |  | |
| 13 | Will the subjects be subjected to physically invasive examinations or exercise regimens? | | | | |  | |  | |  | |
| 14 | Is there any form of novel procedure/ medication involved? | | | | |  | |  | |  | |
| 15 | If ‘Yes’ to No.14, and an effective treatment is already available, is a placebo group included and justified? | | | | |  | |  | |  | |
| 16 | Is there any kind of risk to the subject if he/she chose to withdraw? | | | | |  | |  | |  | |
|  | **OTHER ETHICS ISSUES** | | | | |  | |  | |  | |
| 17 | Are there any other ethical issues not highlighted in this checklist? | | | | |  | |  | |  | |
| 18 | Does this study require approval from another country/institute/agency/premise? | | | | |  | |  | |  | |
| 19 | If ‘Yes’ to No.18, please confirm whether the approval letter has been attached to this submission. | | | | |  | |  | |  | |
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| **D.** | **DECLARATION BY APPLICANT** | | | | | | | | | | | |
|  | **I hereby declare that all information stated here are accurate, and UCSI Institutional Ethics Committee (IEC) has the right to reject or to cancel the offer without prior notice if there is/are any inaccurate information given.**    **Date : Applicant’s Signature :** | | | | | | | | | | | |
| **E.** | **APPROVAL BY HEAD OF RESEARCH AND POSTGRADUATE STUDIES** | | | | | | | | | | | |
|  |  | | **Approved** | | |  | | **Resubmission** | | | | |
| **Comments:**  **Date : Signature :** | | | | | | | | | | | |