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| **Ethics Review Committee****SIDCER(Strategic Initiative for Developing Capacity in Ethical Review)recognized ERC****Faculty of Medicine, University of Kelaniya, Ragama, Sri Lanka****FWA00013225** |
| ***For office use only*** |
| **Application No** | **P** |  |  |  |  | **Date received** | D D | M M | Y Y Y Y |
| **Names of the Reviewers** |
| **Reviewer 1** |  |
| **Reviewer 2** |  |
| **Reviewer 3** |  |
|   |
| **Application for:** |
|  |
| Research |  |
| Establishment of Database |  |
|  |  |
| **Study type:** |
|  |
| Intervention |  |
| Non intervention  |  |
| Undergraduate project: | MBBS |  | BSc  |  |
|  |  |  |  |  |
| **Part I****Title of the Project** |
|  |
|  |
| **2. Investigators****2.1 Principal investigator** |
| Name |  |
| Qualifications |  |
| Designation |  |
| Official address |  |
| Telephone |  |
| E-mail address |  |
| Signature  |  |
| **2.2 Other investigators 01/ Supervisor** |
| Name |  |
| Qualifications |  |
| Designation |  |
| Official address |  |
| Telephone |  |
| E-mail address |  |
| Signature  |  |
| **Other investigators 02/ Supervisor** |
| Name |  |
| Qualifications |  |
| Designation |  |
| Official address |  |
| Telephone |  |
| E-mail address |  |
| Signature  |  |
| **Other investigators 03/ Supervisor** |
| Name |  |
| Qualifications |  |
| Designation |  |
| Official address |  |
| Telephone |  |
| E-mail address |  |
| Signature  |  |
|  **(If there are any more investigators please add their details in an additional sheet)** |
|  |
| 2.3 Is the principal investigator affiliated to the University of Kelaniya?  |  |
| 2.4 Are any of the other investigators affiliated to the University of Kelaniya?  |  |
| 2.5 Is ERC, Faculty of Medicine, University of Kelaniya the closest Ethics Review Committee to the study site? |  |
| 2.6 Is this an industry sponsored study? |  |
| **\*\*\*If the answers to all above questions (2.3-2.6) are ‘No’, please note ERC, Faculty of Medicine, University of Kelaniya is unable to accept your application.** |
|  |
| **3. Select all that applies to this study** |  |
| 1. Does this research involve collection or use of individual level data?
 |  |
| 1. Does this research involve collection or use of community level data that are on sensitive topics?
 |  |
| 1. Are all data to be used in the research in the public domain?
 |  |
| 1. Is this an audit carried out using existing data?
 |  |
| 1. Are participants in this study considered as a vulnerable group?
 |  |
| 1. Is the risk involved to the participants minimal?
 |  |
| 1. Does the research involve use of biological material?
 |  |
|  |
| **4. Nature of the research project** **4.1 Specify the type of study** |
| 4.1.1 Observational/non interventional study: |  |
| Investigator initiated |  |
| Industry sponsored |  |
| 4.1.2 Clinical trial: |  |
| Investigator initiated |   |
| Industry sponsored |  |
| 4.1.3 Other interventional studies4.1.4 Research database |  |
| 4.1.5 Other |  |
| **4.2 Is this for an academic degree?**  |  |
| 4.2.1 If for an academic degree, specify:  |
|  |
|  |
| 4.2.2 Degree awarding University:  |
| 4.2.3 Registration status | Registered  |  | Pending |  |
| Date of Registration |  |
|  |
| **5. Proposed dates of commencement and completion the study** |
| *[From initial recruitment of participants until completion of all data collection]*Date of commencement  *Click here to enter a date.*Date of completion Click here to enter a date. |
| **6. Has ethical review for this study been requested earlier from this Ethics Review Committee?**If yes, |  |
| Reference number |  |
| Decision\* |  |
| Date |  |
| \* Attach documentary evidence |
| **7. Has ethical review for this study been requested from any other Ethics Review Committee?**If yes, |   |
| Reference number |  |
| Decision \* |  |
| Date |  |
| \* Attach documentary evidence |
| **8. Has this project been subjected to scientific review?**If yes, |  |
| Name and address of the committee |  |
| Decision \* |  |
| Date |  |
| \* Attach documentary evidence |
| **9. Estimated budget of your project\*** |
| Less than Rs.100,000 |  |
| Rs.100,000 - Rs.300,000  |  |
| Rs.300,000 - Rs. 1 Million |  |
| Rs. 1 Million - Rs. 5 Million |  |
| Over Rs. 5 Million |  |
| **\* Include budget in the proposal****10. Funding status** |
| 10.1 Status  |  Planning to apply |  Decision pending |  Funding secured |  Self funded |
| 10.1.1 If funded:  |  |
| Name and addressof funding agency |  |
| Amount |  |
|  |
| 10.2 Do the study subjects have to incur any expenses by being participants in the study? |   |
|  |
|  |
| **11. Collaborative research** 11.1 List the collaborating institutes and its role |
|  | Institution | Recruitment | Lab facility | Logistics | Intellectual | Any other |
| 1. |  |  |  |  |  |  |
| 2. |  |  |  |  |  |  |
| 3. |  |  |  |  |  |  |
| \* Attach documentary evidence |
| 11.2 Has this study been submitted to an ERC / similar body in the country/ countries of foreign collaborator/s?If yes, |   |
| a) |
| Name and address of the committee |  |
| Decision \* |  |
| Date |  |
| b) |
| Name and address of the committee |  |
| Decision \* |  |
| Date |  |
| c) |
| Name and address of the committee |  |
| Decision \* |  |
| Date |  |
| \* Attach documentary evidence If no, give reason/s |
|  |
| 11.3 What is the relevance of this study to Sri Lanka? |
|  |
|  |

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| 11.4 Are biological samples to be transferred abroad?If yes,  |  |
| 1. Attach the material transfer agreement
2. Describe the fate of the biological sample at the conclusion of the study
 |
|  |
|  |
| **12. Intervention study**12.1 What phase clinical trial/intervention study is being conducted?  |
| Phase I  |   |
| Phase II |   |
| Phase III |   |
| Phase IV |   |
| Others (Specify)  |   |
|  |
|  |
| 12.2 If it is a clinical trial, is it registered with a clinical trial registry (CTR)? |  |
| 12.2.1 In which CTR is this registered? |
| Name of the registry |  |
| **\*Please provide evidence of registration once it is completed**  |
| 12.3 Is it a multicenter trial?If yes, list the other centers. |  |
| Country | Center | Effective date of joining the trial |
|  |  |  |
|  |  |  |  |
| 12.4 Has ethical approval been obtained to conduct the study in centers given in 12.3 from relevant bodies? \*\*If yes, attach documentary evidence  |   |
|  |
| \*If no, give justification |
|  |
|  |
| 12.5 What is the procedure for dealing with adverse events? |
|  |
| 12.6 What is the procedure for reporting adverse events? |
|  |
| **\* Attach documentary evidence**12.7 What is / are the criteria for termination of the trial? |
|  |
|  |
| 12.8 Are the participants paid? If yes, amount of money per participant per visit? |  |
|  |
|  |
| 12.9 Are the investigators paid?If yes, by whom and the amount? |  |
|  |
| 12.10 Details of insurance coverage for participants |
|  |
| **\*Attach documentary evidence**12.11 If Patient recruitment is not taking place in foreign collaborating institution explain why? |
|  |
| **13. Conflicts of Interest** 13.1 Declare any conflicts of interest that you may have in conducting this project (commercial/ financial/ intellectual/ other) |
|  |
|  |
| 13.2 Does any member of the research team have any affiliation with the providers of funding/ support or financial interest in the outcome of research? If yes, explain |  |
|  |
|  |
| **14. Declaration of Applicant**1. As the Principal Investigator of this project, my signature confirms that I will ensure that all procedures performed under the project will be conducted in accordance with all relevant national and international policies and regulations that govern research involving human participants. 2. I understand that if there is any deviation from the project as originally approved I must submit an amendment to the ERC for approval prior to its implementation. 3. I have submitted all significant previous decisions by this or any other ERC and/or regulatory authorities relevant for the proposed study. 4. I declare that I am not seeking approval for a study that has already commenced or has already been completed. 5. I will submit progress reports/reports of adverse events and side effects/ final report as requested by the ERC. |
| **……………………………………………………………………**Signature of the Principal Investigator | **……………………………………………………………**Date |
|  |
| **15. Consent from all investigators**We, the undersigned hereby confirm that we have consented to be co-investigators of the project titled ………………………. ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………… |
| **Name** | **Institutional Affiliation** | **Signature** |
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| **Part II – Protocol Checklist****Title of the Project:** |
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|  |
|  | **Page** |
| 1 | Title  |  |
| 2 | Summary of the project |  |
| 3 | Introduction/ background  |  |
| 4 | Objectives of the study |  |
| 5 | Justification |  |
| 6 | Review of literature |  |
| 7 | Budget |  |
| **Methodology** |
| 8 | Study design |  |
| 9 | Place of study |  |
| 10 | Duration of the study |  |
| 11 | Study population |  |
| 12 | Sample size and calculation of sample size |  |
| 13 | Inclusion criteria |  |
| 14 | Exclusion criteria |  |
| 15 | Study instrument/s |  |
| 16 | Pilot study |  |
| 17 | Sampling/ recruitment procedure |  |
| 18 | Description of procedure |  |
| 19 | Data collection |  |
| 20 | Data analysis |  |
| 21 | Maintenance and fate of data  |  |
| 22 | Dissemination of results |  |
| **Ethical issues** |
| 23 | Assessment of risks/ benefits |  |
| 24 | Procedure for obtaining consent |  |
| 25 | Informed consent form |  |
| 26 | Participants Information sheet |  |
| 27 | Justification for including vulnerable population |  |
| 28 | Fair participant selection |  |
| 29 | Procedures to protect the rights of participants |  |
| 30 | Confidentiality/Privacy |  |
| 31 | Voluntary participation right to refuse or withdraw without penalty |  |
| 32 | Safety monitoring |  |
| 33 | Responsibilities of the researchers |  |
| 34 | Provision of medical and psychological support to participants |  |
| **Biological Samples** |
| 35 | Justification for using biological sample/s |  |
| 36 | Procedures for collection, storage and disposal of biological sample/s |  |
| 37 | Consent for collecting biological sample/s |  |
| 38 | Protection of the rights of local collaborator |  |
| 39 | Justification for transfer of data and /or biological/ genetic materials to the country of foreign collaborator |  |
| 40 | Fate of transferred data and biological/ genetic material |  |
| **Clinical trial** |
| 41 | Investigator brochure  |  |
| 42 | Clinical record forms  |  |
| 43 | In case of multi centre studies listing of overseas centre(s) and ERC/IRB approval status if relevant and copies of ERC/IB approval letters from other centers  |  |
| 44 | Principle investigators’/ coordinating PI’s curriculum vitae and evidence of Good Clinical Practice training  |  |
| 45 | Product liability letter or insurance certificate  |  |
| 46 | Patient recruitment procedures  |  |
| 47 | Patient’s diary cards (if required in non clinical trial proposals as well) Justification for use of placebo  |  |
| 49 | Criteria for termination of participants from the trial |  |
| 50 | Criteria for termination of the trial |  |
| 51 | Adverse event monitoring, management and reporting |  |
| 52 | Justification for withholding/ withdrawing standard therapy |  |
| 53 | Provision for making the trial drug available after completion of the trial |  |
| **I understand that the application for ethics clearance will not be accepted unless all necessary documents are submitted and are in correct format. I hereby state that I have declare all conflicts of interests related to project financial or otherwise and I am not seeking approval for a study that has already commenced or has already been completed.**  |
|  | Date | DD | MM | YYYY |
|  |  |  |
| Signature of the Principal Investigator |