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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** | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | |
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| **Application for:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Research | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | |
| Establishment of Database | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | |
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| **Study type:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Intervention | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | |
| Non intervention | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | |
| Undergraduate project: | | | | | | | | MBBS | | |  | | | | | BSc | | |  | | | | | | | | | | | | | | |
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| **Part I**  **Title of the Project** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| **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)** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 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? | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | |
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| **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 studies  4.1.4 Research database | | | | | | | | | | | | | | |  | | | | | | | | | | |
| 4.1.5 Other | | | | | | | | | | | | | | |  | | | | | | | | | | |
| **4.2 Is this for an academic degree?** | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | |
| 4.2.1 If for an academic degree, specify: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 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 address  of funding agency | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Amount | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 10.2 Do the study subjects have to incur any expenses by being participants in the study? | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | |
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| **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 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 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 | | | | | | | | | |
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| **12. Intervention study**  12.1 What phase clinical trial/intervention study is being conducted? | | | | | | | | | |
| Phase I |  | | | | | | | | |
| Phase II |  | | | | | | | | |
| Phase III |  | | | | | | | | |
| Phase IV |  | | | | | | | | |
| Others (Specify) |  | | | | | | | | |
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| 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 | | | | | | |
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| 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 | | | | | | | | | |
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| 12.5 What is the procedure for dealing with adverse events? | | | | | | | | | |
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| 12.6 What is the procedure for reporting adverse events? | | | | | | | | | |
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| **\* Attach documentary evidence**  12.7 What is / are the criteria for termination of the trial? | | | | | | | | | |
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| 12.8 Are the participants paid?  If yes, amount of money per participant per visit? | | | | | | |  | | |
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| 12.9 Are the investigators paid?  If yes, by whom and the amount? | | | | | | |  | | |
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| 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? | | | | | | | | | |
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| **13. Conflicts of Interest**  13.1 Declare any conflicts of interest that you may have in conducting this project (commercial/ financial/ intellectual/ other) | | | | | | | | | |
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|  | | | | | | | | | |
| 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 | | | | | | | | |  |
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| **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 | | | | | | |