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|  | Ethics Review Committee CINEC Campus |   |
| **Application Form for Scientific and Ethical Review**  |

**For Office Use Only:**

Application Number: CINEC/ERC/20\_\_\_/\_\_\_\_\_\_ Date Received: \_\_\_/\_\_\_/\_\_\_

Name of the Applicant: Rev/Prof/Dr/Mr/Ms\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**This application should be forwarded by the principal investigator who requests ethical approval for a research project. All the co-investigators should provide signed consent to submit the application to ERC, CINEC Campus. Application guidelines are available at CINEC website. Trainees, trainers, extended faculty and staff of any recognized academic/ research/industry institute are eligible to apply for ERC approval from CINEC Campus.**

**Part A – Administrative Details**

1. **Title of the Research Project:**
2. **Details of the Investigators:**

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| Title, Name, Designation and Affiliation  | age55image17536age55image17856Roleage55image18784age55image19104 | age55image19576Signature age55image20768 |
|  | Principal Investigator  |  |
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1. **Contact Details of the Principal Investigator:**

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| --- | --- |
| 3.1 Postal Address  | age56image3880age56image5272 |
| 3.2 Email Address  |  |
| 3.3 Telephone  | age56image9856age56image10984 |

1. Nature of the study:

 Observational/non-interventional Clinical trial (investigator initiated) Research database/information system Sponsored clinical trial
Other

1. Proposed starting (initial date of enrolment of participants) and ending (completion of data collection) dates (retrospective approval will not be given to the projects already started)

 Start Date: End Date:

1. Has the relevant Board of Study/Specialty Board approved the research project (if applicable)?

 Yes: No:
 If Yes, Board of Study/Specialty Board: Details:

1. Has ethics approval for this study been requested earlier from ERC CINEC or another ERC? (if you have received ethics approval already, please attach a copy of the approval)

 Yes: No:
 Details:

1. Funding (if any)

Name and Address of the funding source: Amount:

1. Do you believe the proposed project has conflicts of interest?

 Yes: No: If Yes, Details:

**Part B – Protocol Check List**

Under each category, indicate the protocol section of the research proposal. If a particular category in not relevant to your study, indicate it as ‘NA’

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|  | **Scientific validity**  | age57image7512Protocol page/s age57image8584age57image8904 | age57image9520**Reviewer Evaluation**  |
| age57image10744age57image11064Acceptable  | age57image12304Comments age57image13072 |
| age57image13528Yes  | age57image14608age57image14928No  | age57image16152N/A  |
| 1  | Title  |  | age57image19976 | age57image20600age57image20920 | age57image21688 | age57image22296 |
| 2  | Research problem  |  | age57image25712 | age57image26336age57image26656 | age57image27424 | age57image28032 |
| 3  | Research questions/ hypothesis  |  | age57image31488 | age57image32112age57image32432 | age57image33200 | age57image33808 |
| 4  | Objectives  |  | age57image37184 | age57image37808age57image38128 | age57image38896 | age57image39504 |
| 5  | Study setting  |  | age57image42920 | age57image43544age57image43864 | age57image44632 | age57image45240 |
| 6  | Study design  |  | age57image49872age57image50352 | age57image50840age57image51160age57image51640age57image51960 | age57image52424age57image52904 | age57image53368age57image53848 |
| 7  | Study population (giving inclusion exclusion criteria)  |  |  |  |  |  |
| 8  | Sample size  |  | age57image60392 | age57image61016age57image61336 | age57image62104 | age57image62712 |
| 9  | Sampling method  |  | age57image66128 | age57image66752age57image67072 | age57image67840 | age57image68448 |
| 10  | Measurements / variables  |  | age57image71904 | age57image72528age57image72848 | age57image73616 | age57image74224 |
| 11  | Study instruments  |  | age57image77640 | age57image78264age57image78584 | age57image79352 | age57image79960 |
| 12  | Procedures to ensure quality of data  |  | age57image83536 | age57image84160age57image84480 | age57image85248 | age57image85856 |
| 13  | Plan for analysis  |  | age57image89312 | age57image89936age57image90256 | age57image91024 | age57image91632 |
| 14  | Ethical considerations  |  | age57image95048 | age57image95672age57image95992 | age57image96760 | age57image97368 |
| 15  | Budget (if relevant)  |  | age57image100824 | age57image101448age57image101768 | age57image102536 | age57image103144 |
| 16  | Work plan and time frame  |  | age57image107896age57image108376 | age57image108864age57image109184age57image109664age57image109984 | age57image110448age57image110928 | age57image111392age57image111872 |
| 17  | Justification for a replication study, if your study is a replica  |  | age57image115920 | age57image116704age57image117024 | age57image117632 | age57image118240 |

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|  | **Social Value**  | Protocol page/s age57image123760age57image124080 | age57image124968**Reviewer Evaluation**  |
| age57image126768Acceptable  | age57image128008Comments age57image128776 |
| Yes  | age57image130864age57image131184No age57image132112age57image132432 | age57image132904N/A age57image133832 |
| 1  | Benefits of the study to the community/society  |  |  |  |  | age57image141024 |
| 2  | Plan for dissemination of study findings  |  |  |  |  |  |
| 3  | Scientific importance of the study  |  |  |  |  |  |

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| age57image155704age57image155864age57image156344age57image156504 | **Risk Benefit Assessment**  | Protocol page/s age57image159464age57image159784 | **Reviewer Evaluation**  |
| Acceptable  | Comments age57image164048 |
| Yes  | No  | N/A  |
| age57image168168age57image1684881 age57image169416age57image169736 | Potential risks to the participants  |  |  |  |  |  |
| 2  | Potential benefits to the participants  |  |  |  |  |  |
| 3 | Justification for risks against benefits  |  |  |  |  |  |
| 4 | Steps taken to minimize risks  |  |  |  |  |  |
| 5 | Support provided to participants (medical, educational, other)  |  |  |  |  |  |

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|  | **Participants rights and consent**  | age58image26448age58image26768Protocol pages age58image27840age58image28160 | age58image28776**Reviewer Evaluation**  |
| age58image30000age58image30320Acceptable  | age58image31560Comments age58image32328 |
| age58image32800Yes age58image33728 | age58image34224age58image34544No age58image35472age58image35792 | age58image36264N/A age58image37192 |
| 1  | Procedure for recruiting the participants  | age58image39872 |  |  |  | age58image41624 |
| 2  | Information provided to the participants  | age58image45152age58image45632 | age58image46096age58image46576 | age58image47064age58image47384age58image47864age58image48184 | age58image48648age58image49128 | age58image49592age58image50072 |
| 3  | Procedure for requesting informed consent  |  |  |  |  |  |
| 4  | Procedure for requesting proxy consent  | age58image56000 | age58image56608 | age58image57232age58image57552 | age58image58320 | age58image58928 |
| 5  | Procedure for requesting assent (subjects between 12y to 18y)  | age58image61928 | age58image62536 | age58image63160age58image63480 | age58image64248 | age58image64856 |
| 6  | Procedure for withdrawing consent  | age58image67552 | age58image68160 | age58image68784age58image69104 | age58image69872 | age58image70480 |
| 7  | Incentives provided to participants  | age58image73864age58image74344 | age58image74808age58image75288 | age58image75776age58image76096age58image76576age58image76896 | age58image77360age58image77840 | age58image78304age58image78784 |
| 8  | Procedure for participants to ask questions / register complaints  | age58image81784 | age58image82392 | age58image83176age58image83496 | age58image84104 | age58image84712 |
| 9  | Participants right to decline consent without losing entitled benefits  |  |  |  |  |  |

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|  | **Confidentiality and Privacy**  | age58image95544age58image95864Protocol page/s age58image96936age58image97256 | age58image97872**Reviewer Evaluation**  |
| age58image99096age58image99416Acceptable  | age58image100656Comments age58image101424 |
| age58image101896Yes age58image102824 | age58image103320age58image103640No age58image104568age58image104888 | age58image105360N/A age58image106288 |
| 1  | Steps to ensure confidentiality of data  | age58image109008 |  |  |  | age58image110760 |
| 2  | Justification for collecting personal identification data  | age58image113640 | age58image114248 | age58image114872age58image115192 | age58image115960 | age58image116568 |
| 3  | Steps taken to ensure privacy during data collection  |  |  |  |  |  |
| 4  | How long data and samples will be kept  |  |  |  |  |  |
| 5  | Who will have access to the data  |  |  |  |  |  |
| 6  | Procedure for storage of data and samples  |  |  |  |  |  |
| 7 | Procedure for disposal of data |  |  |  |  |  |

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|  | **Fair participant selection and vulnerability**  | age59image4408age59image4728Protocol page/s age59image5800age59image6120 | age59image6736**Reviewer Evaluation**  |
| age59image7960age59image8280Acceptable  | age59image9520Comments age59image10288 |
| age59image10760Yes age59image11688 | age59image12184age59image12504No age59image13432age59image13752 | age59image14224N/A age59image15152 |
| 1  | Justification for selection of study population  | age59image17872 |  |  |  | age59image19624 |
| 2  | Justification for conducting the study in a vulnerable population  |  |  |  |  |  |

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|  | **Responsibilities of the researcher**  | age59image33120age59image33440Protocol page/s age59image34512age59image34832 | age59image35448**Reviewer Evaluation**  |
| age59image37088Acceptable  | age59image38328Comments age59image39096 |
| Yes  | age59image41184age59image41504No age59image42432age59image42752 | N/A  |
| 1  | Ethical, legal, financial issues related to the study  | age59image47832age59image48312 |  | age59image49800age59image50120 |  | age59image51288age59image51768 |
| 2  | Any conflicts of interest and how the researcher plans to manage them  |  |  |  |  |  |
| 3  | Permissions from relevant institutions / authorities  | age59image58120 |  | age59image59448age59image59768 |  | age59image61240 |
| 4  | Collaborations with the relevant stakeholder  | age59image64768age59image65248 |  | age59image66872age59image67192age59image67672age59image67992 |  | age59image69592age59image70072 |
| 5  | Provision of medical / psychological care to the participants  |  |  |  |  |  |
| 6  | Qualifications of the research team to handle the research study  |  |  |  |  |  |

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|  | **Foreign funded studies**  | age59image87528age59image87848Protocol page/s age59image88920age59image89240 | age59image89856**Reviewer Evaluation**  |
| age59image91080age59image91400Acceptable  | Comments age59image93408 |
| age59image93880Yes age59image94808 | age59image95304age59image95624No age59image96552age59image96872 | age59image97344N/A |
| 1  | Justification for conducting the study in SL  | age59image101032 |  |  |  | age59image102784 |
| 2  | Relevance of the study to SL  | age59image105560 | age59image106168 | age59image106792age59image107112 | age59image107880 | age59image108488 |
| 3  | Post research benefits to SL  |  |  |  |  |  |
| 4  | The sharing of intellectual property rights  |  |  |  |  |  |
| 5  | How the results will be conveyed to authorities in SL  |  |  |  |  |  |

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|  | **Information Sheet / Consent Form**  | age60image5040Section in Info. sheet consent form age60image6584age60image6904 | age60image7392age60image7712**Reviewer Evaluation** age60image9104 |
| age60image9416age60image9736Acceptable  | Comments age60image11408 |
| age60image11864Yes  | age60image13360No  | age60image14584N/A  |
| 1  | Purpose of the study  | age60image17728 | age60image18336 | age60image19376 | age60image20144 | age60image20752 |
| 2  | Voluntary participation  | age60image24056age60image24536 | age60image25000age60image25480 | age60image26376age60image27280 | age60image27744age60image28224 | age60image28688age60image29168 |
| 3  | Duration of the study and responsibilities of the participants  |  |  |  |  |  |
| 4  | Potential benefits  | age60image35032 | age60image35640 | age60image36680 | age60image37448 | age60image38056 |
| 5  | Risks, Hazards, Discomforts  | age60image40712 | age60image41320 | age60image42360 | age60image43128 | age60image43736 |
| 6  | Incentives / Reimbursements  | age60image46392 | age60image47000 | age60image48040 | age60image48808 | age60image49416 |
| 7  | Confidentiality  | age60image51992 | age60image52600 | age60image53640 | age60image54408 | age60image55016 |
| 8  | Contact person for the participants  | age60image58440age60image58920 | age60image59384age60image59864 | age60image60760age60image61664 | age60image62128age60image62608 | age60image63072age60image63552 |
| 9  | Understanding of information provided by the researcher  |  |  |  |  |  |
| 10  | Agreement of the participant to provide information / samples  | age60image69720 | age60image70328 | age60image71368 | age60image72136 | age60image72744 |
| 11  | Consent for dissemination of research findings  | age60image76312age60image76792 | age60image77256age60image77736 | age60image78632age60image79536 | age60image80000age60image80480 | age60image80944age60image81424 |
| 12  | Appropriate translation of the information sheet  |  |  |  |  |  |
| 13  | Appropriate translation of the consent form  |  |  |  |  |  |

**Decision of the reviewer:**

Approved Conditional approval Approve with revisions Reject

**Comments of the Reviewer**:

Name of the Reviewer: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of the Reviewer: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_