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| **National Authority on Tobacco and Alcohol****Application for Ethics Review (Part I) – Basic Information** |
| *for official use*  |
| Application No: |  |  |  |  |  |  |  |  |  |  | Date Received: |  |  | **/** |  |  | **/** |  |  |
|  |
| Reviewed By: |  | ERC Meeting Date: |  |  | **/** |  |  | **/** |  |  |
|  |
| Decision: |  | Date Informed: |  |  | **/** |  |  | **/** |  |  |

1. **Title of Project**

|  |
| --- |
| Add text |

1. **Investigators**

Applications from investigators based overseas will only be considered if the project is done in collaboration with investigators based in institutions in Sri Lanka who take equal responsibility for the conduct of the study and who will appear as co-authors in any publication arising out of the study.

|  |  |  |
| --- | --- | --- |
| **Title, Name, Designation and Affiliation of Investigators** | **Role** | **Signature** |
| Add text | Principal Investigator |  |
| Add text | Add text |  |
| Add text | Add text |  |
| Add text | Add text |  |
| Add text | Add text |  |

 Please note that a short curriculum vitae of all investigators should be attached to the application

1. **Conduct Details of the principal Investigator**

|  |  |
| --- | --- |
| Address: | Add text |
| Telephone numbers: | Add text |
| Fax number: | Add text |
| Email address: | Add text |

1. **Funding**

Name and Adress of Funding Source/s Amount

|  |  |
| --- | --- |
| Add text | Add text |

1. **Proposed Starting /ending dates \*+ and study setting**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Start Date |  | Add text |  |  | End Date |  | Add text |

|  |  |
| --- | --- |
| Study setting | Add text  |

\*From initial recruitment of participants until completion of all data collection

+Retrospective approval will not be given for projects already started or completed

1. **Has ethics approval for this study been requested earlier from NATA ERC or another similar committee?**

Yes [ ]  No[ ]

 If yes, give details (names of committees and outcome of review)

|  |
| --- |
| Add text |

Please note that for studies sponsored by foreign funding agencies or sponsors ethics review and approval is required from the country of the funding agency or the sponsor.

1. **Scientific review**

Has this research proposal been subjected to scientific review by any other committee?

Yes [ ]  No[ ]

If yes, give details (names of committees and outcome of review)

|  |
| --- |
| Add text |

1. **Clinical trials**
	1. What phase clinical trial is being conducted?

|  |
| --- |
| Phase I |[ ]
| Phase II |[ ]
| Phase III |[ ]
| Phase IV (post marketing) |[ ]
| Other |[ ]

 If OTHER specify:

|  |
| --- |
| Add text |

* 1. Is it a multicenter trial?

Yes[ ]  No[ ]

If yes, list the other trial sites

|  |
| --- |
| Add text |

* 1. Is the clinical trial registered with a clinical trials registry?

Yes[ ]  No[ ]

If yes, give details (Name of register and registration number)

|  |
| --- |
| Add text |

* 1. Data Safety Monitoring Board (only if available)

|  |  |
| --- | --- |
| Name and designation of members | Role |
| Add text | Add text |
| Add text | Add text |
| Add text | Add text |

 Please attach the curriculum vitae of all members of the DSMB

* 1. Details of Indemnity and Insurance coverage for participants, investigators, and ethics committee

|  |
| --- |
| Add text |

1. **Conflict of Interest**
	1. **Do you believe this project has a Conflict of Interest?**

Commercially

|  |
| --- |
| Add text |

Financially

|  |
| --- |
| Add text |

Intellectually

|  |
| --- |
| Add text |

Other (explain)

|  |
| --- |
| Add text |

* 1. **Does any member of the research team have any affiliation with the provide(s) of funding/support, or a financial interest in the outcome of the research?**

Yes[ ]  No[ ]

If yes, please explain

|  |
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| Add text |

* 1. **If there is a duality of interest identified above describe the interest and state whether it constitute a potential conflict of interest**

|  |
| --- |
| Add text |

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| --- |
| **National Authority on Tobacco and Alcohol****Application for Ethics Review (Part II) – Protocol Checklist** |
| *for official use*  |
| Application No: |  |  |  |  |  |  |  |  |  |  |  |  |
|  |
|  |

1. **Title of Protocol**

|  |
| --- |
| Add text |

1. **Name of Principal Investigator**

|  |
| --- |
| Add text |

1. **A list of documents submitted for review**

|  |  |  |
| --- | --- | --- |
| **Title of document** | **Version** | **Date** |
| Add text | Add text | Select date |
| Add text | Add text | Select date |
| Add text | Add text | Select date |
| Add text | Add text | Select date |
| Add text | Add text | Select date |
| Add text | Add text | Select date |
| Add text | Add text | Select date |

1. **Protocol checklist**

Please indicate the following:

|  |  |  |  |
| --- | --- | --- | --- |
| **Collaborative partnership** | **Applicable** | **Protocol section Number** | **Reviewer checked** |
|  | Yes | No |  |  |
| 1. | The collaborations you have established with institutions where the study is to be conducted |[ ] [ ]  Add text | Add text |
| 2. | The collaborations you have established with the community where the study is to be conducted  |[ ] [ ]  Add text | Add text |
| 3. | The benefits to institutions, communities, and participants in your research |[ ] [ ]  Add text | Add text |

 Reviewers’ comments:

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| --- |
| Add text |

|  |  |  |  |
| --- | --- | --- | --- |
| **Social value** | **Applicable** | **Protocol section Number** | **Reviewer checked** |
|  | Yes | No |  |  |
| 1. | The beneficiaries of your research and the benefit to them |[ ] [ ]  Add text | Add text |
| 2. | The plan for dissemination of study findings  |[ ] [ ]  Add text | Add text |

 Reviewers’ comments:

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| --- |
| Add text |

|  |  |  |  |
| --- | --- | --- | --- |
| **Scientific validity** | **Applicable** | **Protocol section Number** | **Reviewer checked** |
|  | Yes | No |  |  |
| 1. | The scientific importance of your study in relation to improving health care and/or knowledge on the subject |[ ] [ ]  Add text | Add text |
| 2. | The justification for a replication study, if your study is a replication study |[ ] [ ]  Add text | Add text |
| 3. | How the sample size was calculated  |[ ] [ ]  Add text | Add text |

 Reviewers’ comments:

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| Add text |

|  |  |  |  |
| --- | --- | --- | --- |
| **Assessment of Risks/Benefits**  | **Applicable** | **Protocol section Number** | **Reviewer checked** |
|  | Yes | No |  |  |
| 1. | The risk to research subjects |[ ] [ ]  Add text | Add text |
| 2. | Benefits to research subjects |[ ] [ ]  Add text | Add text |
| 3. | Steps taken to minimize risks |[ ] [ ]  Add text | Add text |
| 4. | Steps taken to enhance benefits |[ ] [ ]  Add text | Add text |
| 5. | Justification of the potential benefits against the risks |[ ] [ ]  Add text | Add text |
| 6. | Support provided to the research participants (medical, psychological and other) |[ ] [ ]  Add text | Add text |

 Reviewers’ comments:

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| Add text |

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| --- | --- | --- | --- |
| **Consent**  | **Applicable** | **Protocol section Number** | **Reviewer checked** |
|  | Yes | No |  |  |
| 1. | The procedure for approaching the relevant community |[ ] [ ]  Add text | Add text |
| 2. | The information (written/oral) provided to the community |[ ] [ ]  Add text | Add text |
| 3. | The procedure for initial contact of participants |[ ] [ ]  Add text | Add text |
| 4. | The information (written/oral) provided to the participants |[ ] [ ]  Add text | Add text |
| 5. | The procedure for obtaining informed consent |[ ] [ ]  Add text | Add text |
| 6. | The procedure for ensuring that participants have understood the information provided |[ ] [ ]  Add text | Add text |
| 7. | The procedure for obtaining proxy consent |[ ] [ ]  Add text | Add text |
| 8. | The procedure for obtaining assent |[ ] [ ]  Add text | Add text |
| 9. | The procedure for consenting if the child reaches consenting age during the study  |[ ] [ ]  Add text | Add text |
| 10. | The procedure for consenting if the participant acquires capacity to give consent during the study |[ ] [ ]  Add text | Add text |
| 11. | The procedure for re consenting if data or specimens that have been collected are to be used for other research projects that may be in the same (Extended Consent) or a different (Unspecified Consent) field of study |[ ] [ ]  Add text | Add text |
| 12. | The procedure for withdrawing consent |[ ] [ ]  Add text | Add text |
| 13. | The justification for waiver of consent or waiver of written consent  |[ ] [ ]  Add text | Add text |
| 14. | Incentives/rewards/compensation/reimbursement provided or not provided to participants and their accompanying persons  |[ ] [ ]  Add text | Add text |
| 15. | The procedure for re consenting if the research protocol changes during the course of research  |[ ] [ ]  Add text | Add text |

 Reviewers’ comments:

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| Add text |

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| --- | --- | --- | --- |
| **Confidentiality**  | **Applicable** | **Protocol section Number** | **Reviewer checked** |
|  | Yes | No |  |  |
| 1. | How the data and sample will be obtained |[ ] [ ]  Add text | Add text |
| 2. | How long data and samples will be kept |[ ] [ ]  Add text | Add text |
| 3. | Justification for collection of personal identification data |[ ] [ ]  Add text | Add text |
| 4. | Who will have access to the personal data of the research participants |[ ] [ ]  Add text | Add text |
| 5. | How the confidentiality of participants will be ensured |[ ] [ ]  Add text | Add text |
| 6. | The procedure for data and sample storage |[ ] [ ]  Add text | Add text |
| 7. | The procedure for data and sample disposal  |[ ] [ ]  Add text | Add text |

 Reviewers’ comments:

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| --- |
| Add text |

|  |  |  |  |
| --- | --- | --- | --- |
| **Rights of participants** | **Applicable** | **Protocol section Number** | **Reviewer checked** |
|  | Yes | No |  |  |
| 1. | Procedures for subjects to withdraw from the research at any time |[ ] [ ]  Add text | Add text |
| 2. | Peocudure for subjects to ask questions and register complaints  |[ ] [ ]  Add text | Add text |
| 3. | The contact person for research subjects |[ ] [ ]  Add text | Add text |
| 4. | Provisions for participants to be informed of results  |[ ] [ ]  Add text | Add text |
| 5. | Provisions to make the study product available to the study participants after research |[ ] [ ]  Add text | Add text |

 Reviewers’ comments:

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| Add text |

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| --- | --- | --- | --- |
| **Fair participant selection**  | **Applicable** | **Protocol section Number** | **Reviewer checked** |
|  | Yes | No |  |  |
| 1. | The justification for the selection of the study population |[ ] [ ]  Add text | Add text |
| 2. | The inclusion and exclusion criteria  |[ ] [ ]  Add text | Add text |

 Reviewers’ comments:

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| Add text |

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| --- | --- | --- | --- |
| **Responsibilities of the researcher**  | **Applicable** | **Protocol section Number** | **Reviewer checked** |
|  | Yes | No |  |  |
| 1. | The provision of the medical services to research participants  |[ ] [ ]  Add text | Add text |
| 2. | The provisions for continuation care after the research is completed |[ ] [ ]  Add text | Add text |
| 3. | Declaration of conflicts of interests and how the investigators plan to manage the conflicts |[ ] [ ]  Add text | Add text |
| 4. | The ethical/legal/social and financial issues relevant to the study |[ ] [ ]  Add text | Add text |

 Reviewers’ comments:

|  |
| --- |
| Add text |

|  |  |  |  |
| --- | --- | --- | --- |
| **Vulnerable populations**  | **Applicable** | **Protocol section Number** | **Reviewer checked** |
|  | Yes | No |  |  |
| 1. | Justification for conducting the study in this population  |[ ] [ ]  Add text | Add text |

 Reviewers’ comments:

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| --- |
| Add text |

|  |  |  |  |
| --- | --- | --- | --- |
| **Research funded by foreign agencies/companies**  | **Applicable** | **Protocol section Number** | **Reviewer checked** |
|  | Yes | No |  |  |
| 1. | Justification for conducting the study in Sri Lanka |[ ] [ ]  Add text | Add text |
| 2. | Relevance of the study to Sri Lanka |[ ] [ ]  Add text | Add text |
| 3. | Post research benefits to Sri Lanka |[ ] [ ]  Add text | Add text |
| 4. | The steps taken to take into account cultural and social customs, practices, and taboos in Sri Lanka |[ ] [ ]  Add text | Add text |
| 5. | The sharing of rights to intellectual property  |[ ] [ ]  Add text | Add text |
| 6. | The fate of data and biological samples including whether they will be transferred abroad and what will happen to them after the conclusion of the study |[ ] [ ]  Add text | Add text |
| 7. | How the results of research will be conveyed to relevant authorities in Sri Lanka |[ ] [ ]  Add text | Add text |
| 8. | The agreement between the sponsor/funding agency and the investigator |[ ] [ ]  Please attach  | Add text |
| 9. | The materials transfer agreement if biological materials is to be transferred abroad  |[ ] [ ]  Please attach | Add text |

 Reviewers’ comments:

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| --- |
| Add text |

|  |  |  |  |
| --- | --- | --- | --- |
| **Community based research**  | **Applicable** | **Protocol section Number** | **Reviewer checked** |
|  | Yes | No |  |  |
| 1. | The impact and relevance of the research on the community in which it is to be carried out |[ ] [ ]  Add text | Add text |
| 2. | The steps taken to consult with the concerned community during the design of the research |[ ] [ ]  Add text | Add text |
| 3. | The procedure used to obtain community consent |[ ] [ ]  Add text | Add text |
| 4. | The contribution to capacity building of the community |[ ] [ ]  Add text | Add text |
| 5. | The procedure for making available results of research to the community  |[ ] [ ]  Add text | Add text |

 Reviewers’ comments:

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| Add text |

|  |  |  |  |
| --- | --- | --- | --- |
| **Clinical trials**  | **Applicable** | **Protocol section Number** | **Reviewer checked** |
|  | Yes | No |  |  |
| 1. | Justification for withdrawing any therapy from participants to prepare them for the trial |[ ] [ ]  Add text | Add text |
| 2. | Justification for withholding standard therapy from trial participants (e.g. control group) |[ ] [ ]  Add text | Add text |
| 3. | Justification for providing care which is not the standard of care |[ ] [ ]  Add text | Add text |
| 4. | Procedure for dealing with adverse events |[ ] [ ]  Add text | Add text |
| 5. | Procedure for reporting adverse events |[ ] [ ]  Add text | Add text |
| 6. | Provisions for safety monitoring  |[ ] [ ]  Add text | Add text |
| 7. | Provisions/criteria for termination of the trial |[ ] [ ]  Add text | Add text |
| 8. | Provisions for making the trial drug available to participants after the trial if found to be effective |[ ] [ ]  Add text | Add text |

 Reviewers’ comments:

|  |
| --- |
| Add text |

|  |  |  |
| --- | --- | --- |
| **Information sheet (IFS)/Informed Consent From (ICF)****Check list**  | **Section IFS/ICF** | **Reviewer checked** |
|
| List the sections in IFS/ICF where you have dealt with the following: |  |  |
| 1. | Purpose of the study | Add text | Add text |
| 2. | Voluntary participation | Add text | Add text |
| 3. | Duration, procedures of the study and participant’s responsibilities | Add text | Add text |
| 4. | Potential benefits | Add text | Add text |
| 5. | Risks, hazards, and discomforts | Add text | Add text |
| 6. | Reimbursements | Add text | Add text |
| 7. | Confidentiality | Add text | Add text |
| 8. | Termination of study participation  | Add text | Add text |

 Reviewers’ comments:

|  |
| --- |
| Add text |

 Are the investigator’s qualifications and experience appropriate to conduct the study?

Yes [ ]  No[ ]

Recommendation: Approve [ ]  Reject [ ]  Conditional Approval (Please state the conditions) [ ]

 Reviewers’ comments:

|  |
| --- |
| Add text |

 Reviewer: ……………………………………Signature: ……………………………Date: …. /…./….

|  |
| --- |
| **National Authority on Tobacco and Alcohol****Application for Ethics Review – Document Checklist** |
| *for official use*  |
| Application No: |  |  |  |  |  |  |  |  |  |  |  |  |
|  |
|  |

**Application Checklist**

I declare that I have attached the following documents (Please tick the check box and confirm):

|  |
| --- |
| 1. Application form: Part I [3 copies] [ ]
 |
| 1. Application form: Part II [3 copies] [ ]
 |
| 1. The complete research protocol including a section on ethics considerations [3 copies] [ ]
 |
| 1. Information sheet for research participants (Should be provided in all three languages: Sinhala, Tamil, and English – if the participant is being interviewed or is filling up the form) [3 copies each] [ ]
 |
| 1. Consent form (Should be provided in all three languages: Sinhala, Tamil, and English) [3 copies each] [ ]
 |
| 1. Assent form (Should be provided in all three languages: Sinhala, Tamil, and English) [3 copies each] [ ]
 |
| 1. Data collection booklets/forms/questionnaires (Should be provided in all three languages: Sinhala, Tamil, and English) [3 copies] [ ]
 |
| 1. Indemnity/Insurance coverage (required for clinical trials) [ ]
 |
| 1. Clinical trial contract (required for clinical trials) [3 copies] [ ]
 |
| 1. Summary and flowchart (required for clinical trials) [3 copies] [ ]
 |
| 1. Certificate of GCP training for at least one member of the research study [3 copies] [ ]
 |
| 1. Materials transfer agreement (required for all research involving transfer of biological samples abroad) [ ]
 |
| 1. Ethics approval from sponsoring country or country of the overseas investigator (if any) [ ]
 |
| 1. Brief curriculum vitae of all investigators [3 copies] [ ]
 |
| 1. Curriculum vitae of all DSMB members [ ]
 |
| 1. Agree to submit soft copies of all documents after receiving the ERC reference number [ ]
 |
| 1. A receipt for the appropriate payment to the accounts department [ ]
 |

**I understand that the application for ethics clearance will not be accepted unless all documents are submitted. I declare that I am not seeking approval for a study that has already commenced or has already been completed. I understand that at least two months are required for this ethics review and granting ethics clearance.**

………………………………… ... ……………………..

Signature of principal Investigator Date

|  |
| --- |
| **National Authority on Tobacco and Alcohol****Application for Ethics Review – Document Receipt Checklist** |
| *for official use*  |
| Application No: |  |  |  |  |  |  |  |  |  |  |  |  |
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**THIS WILL BE FILLED AND HANDED OVER TO THE APPLICANT BY THE ERC STAFF MEMBER ACCEPTING THE APPLICATION**

The ERC confirms that the following documents were handed in by the applicant

|  |
| --- |
| 1. Application form: Part I [3 copies] [ ]
 |
| 1. Application form: Part II [3 copies] [ ]
 |
| 1. The complete research protocol including a section on ethics considerations [3 copies] [ ]
 |
| 1. Information sheet for research participants (Should be provided in all three languages: Sinhala, Tamil, and English – if the participant is being interviewed or is filling up the form) [3 copies each] [ ]
 |
| 1. Consent form (Should be provided in all three languages: Sinhala, Tamil, and English) [3 copies each] [ ]
 |
| 1. Assent form (Should be provided in all three languages: Sinhala, Tamil, and English) [3 copies each] [ ]
 |
| 1. Data collection booklets/forms/questionnaires (Should be provided in all three languages: Sinhala, Tamil, and English) [3 copies] [ ]
 |
| 1. Indemnity/Insurance coverage (required for clinical trials) [ ]
 |
| 1. Clinical trial contract (required for clinical trials) [3 copies] [ ]
 |
| 1. Summary and flowchart (required for clinical trials) [3 copies] [ ]
 |
| 1. Certificate of GCP training for at least one member of the research study [3 copies] [ ]
 |
| 1. Materials transfer agreement (required for all research involving transfer of biological samples abroad) [ ]
 |
| 1. Ethics approval from sponsoring country or country of the overseas investigator (if any) [ ]
 |
| 1. Brief curriculum vitae of all investigators [3 copies] [ ]
 |
| 1. Curriculum vitae of all DSMB members [ ]
 |
| 1. Agree to submit soft copies of all documents after receiving the ERC reference number [ ]
 |
| 1. A receipt for the appropriate payment to the accounts department [ ]
 |

The application number appearing on top of this page has been assigned to this application. Please quote the number in all correspondence with the committee.

………………………………… ……………………

Authorized Signatory for ERC Date