# Annexure 1: Research funded by foreign agencies/companies

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|  | | **Applicable** | | **Section in Protocol & page** |
| **Yes** | **No** |
| 1. | Justification for conducting the study in Sri Lanka |  |  |  |
| 2. | Relevance of the study to Sri Lanka |  |  |  |
| 3. | Post research benefits to Sri Lanka |  |  |  |
| 4. | The steps taken to mitigate effects on the environment and on cultural and social customs, practices, and taboos in Sri Lanka |  |  |  |
| 5. | The sharing of rights to intellectual property |  |  |  |
| 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 |  |  |  |
| 7. | How the results of research will be conveyed to relevant authorities in Sri Lanka |  |  |  |
| 8. | The agreement between the sponsor/funding agency and the investigator |  |  | Please  Attach |
| 9. | The materials transfer agreement, if biological material is to be transferred abroad |  |  | Please  Attach |

**Annexure 2: Clinical trials**

|  |  |  |  |  |
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|  | | **Applicable** | | **Section in Protocol & page** |
| **Yes** | **No** |
| 1 | What phase clinical trial is being conducted? |  |  |  |
| 2 | Is it a multicentre trial?  If yes, list the other trial sites |  |  |  |
| 3. | Justification for withdrawing any therapy from participants to prepare them for the trial |  |  |  |
| 4. | Justification for withholding standard therapy from trial participants (e.g. control group) |  |  |  |
| 5. | Justification for standard of care providing care which  is not the standard of care |  |  |  |
| 6. | Procedure for dealing with adverse events |  |  |  |
| 7. | Procedure for reporting adverse events |  |  |  |
| 6. | Measures in place for management of trial related injuries |  |  |  |
| 7. | Provisions for safety monitoring |  |  |  |
| 8. | Provisions/criteria for termination of the trial |  |  |  |
| 9. | Provisions for making the trial drugs and therapeutic measures available to participants after the trial if found to be effective |  |  |  |
| 10 | Details of data Safety Monitoring Board |  |  | If applicable, please provide details below |
|  | **Name and Designation of Members** | | **Role** | |
|  | |  | |
|  | |  | |
|  | |  | |
|  | |  | |
| 11 | Details of Indemnity and Insurance coverage for participants, investigators and ethics committee |  |  | If applicable, please provide details below |
|  |  | | | |
| 12 | If Patient recruitment is not taking place in foreign collaborating institution |  |  | If YES, please explain why |
|  |  | | | |
| 13 | Are the participants paid? |  |  | If YES, amount of money per participant per visit |

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| 14 | Are the investigators paid? | | |  |  | If YES, by whom and the amount |
|  |  | | | | | |
| 15 | Is the clinical trial registered with a clinical trials registry? | | Yes | | | No |
| If Yes | | | | | |
| Name of register |  | | | | |
| Registration No. |  | | | | |
| 16 | Has this protocol been approved by the Subcommittee on Clinical Trials (SCOT) of the Ministry of Health, Sri Lanka. | | Yes | | | No |
| If Yes | | | | | |
| Approval No. |  | | | | |

Please attach following documents (if applicable):

Ethics approval from the sponsoring country or country of the overseas principal investigator Curriculum vitae of all members of the DSMB

Related documentary evidence

# Annexure 3: Community based research

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| --- | --- | --- | --- | --- |
|  | | **Applicable** | | **Section in Protocol & page** |
| **Yes** | **No** |
| 1. | The impact and relevance of the research on the community in which it is to be carried out |  |  |  |
| 2. | The steps taken to consult with the concerned community during the design of the research |  |  |  |
| 3. | The procedure used to obtain community consent |  |  |  |
| 4. | The contribution to capacity building of the community |  |  |  |
| 5. | The procedure for making available results of research to the community |  |  |  |

**Annexure 4: Establishment and maintenance of research database**

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| --- | --- | --- | --- | --- |
|  | | **Applicable** | | **Section in Protocol & page** |
| **Yes** | **No** |
| 1. | A list of data collected |  |  |  |
| 2. | Method of data collection |  |  |  |
| 3. | Type of the research projects to be undertaken |  |  |  |
| 4. | Procedure to obtain consent from patients for use of data |  |  |  |
| 5. | Data management process (including governance structure) |  |  |  |
| 6. | The methods employed to ensure data security |  |  |  |
| 7. | Procedure for amendment and termination |  |  |  |
| 8 | Data collection and/or follow-up period |  |  |  |