**Application to obtain aDMINISTRATIVE CLEARANCE FROM THE miNISTRY OF HEALTH**

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| 1 | Title of the Research | |  | | | | | | |
| 2 | Details of the Principal Investigator | | | | | | | | |
| 2.1 | Name with Initials | |  | | | | | |
| 2.2 | Full name | |  | | | | | |
| 2.3 | NIC No | |  | | | | | |
| 2.4 | Designation | |  | |  | |  | |
| 2.6 | Place of work | |  | |  | |  | |
| 2.7 | Permanent Residential Address | |  | | | | | |
| 2.8 | Mobile Telephone No | | 1. 2. | | | | | |
| 2.9 | Residential Tel. No | |  | | | | | |
| 2.10 | Official Tel. No. | |  | | | | | |
| 2.11 | Email Address | |  | | | | | |
|  | | | | | | | | | |
| 3 | Details of Co-investigators | | | | | | | | |
| No | Name | | | Designation | NIC No | | Contact No | | Email Address |
| 1 |  | | |  |  | |  | |  |
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**List of documents (hard copies) to be submitted for administrative clearance from the Ministry of Health**

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| **No** | **Component** | **Availability**  **(Please √)** |
| 1 | **Proposal** |  |
|  | 1. Detailed proposal |  |
|  | 1. Information sheet (In all three languages) |  |
|  | 1. Consent form (In all three languages) |  |
|  | 1. Study instruments – eg. Questionnaire (In all three languages) |  |
| 2 | Certificate of Ethics Clearance (For clinical trials - from a CTEC-NMRA recognized ERC) |  |
| 3 | **Financial Details** |  |
|  | a.Detailed Budget |  |
|  | b. Details of source of Funding |  |
| 7 | **Agreements including Intellectual Property Rights (If relevant)** |  |
|  | 1. Collaborative Agreement |  |
|  | 1. Memorandum of Understanding |  |
|  | 1. Data Transfer Agreement |  |
|  | 1. Material Transfer Agreement |  |
|  | 1. Any other (Please specify) ……………………………………………………. |  |
| 5 | **For Clinical trials** |  |
|  | 1. evidence of registration in the Sri Lanka clinical trial registry of SLMA |  |
|  | 1. For a new drug /new device/new indication for existing drugs - \*NMRA - CTEC approval |  |
|  | 1. Participant Insurance certificates (If relevant) |  |
| 6 | No objection certificate from head(s) of the institution(s) of the study sites /PDHS/RDHS |  |
| 7 | Request letteraddressed to DDG/ ET&R |  |
| 11 | **Soft copies to be submitted in separate folders**  **Folder (I)**   1. Study proposal with Details Budget 2. Information sheet /consent form 3. Study instruments 4. Ethics Clearance Certificate   Folder (II) – All the relevant Agreements & Insurance Certificates  Folder (III)– Other documents |  |

\*Clinical Trial Evaluation Committee (CTEC)-NMRA

**For inquiries please contact the Research Unit.**

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