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

|  |  |  |
| --- | --- | --- |
| 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 |  |  |  |  |  |
| 2 |  |  |  |  |  |
|  3 |  |  |  |  |  |
|  4 |  |  |  |  |  |
|  5 |  |  |  |  |  |

**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
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|  | 1. For a new drug /new device/new indication for existing drugs - \*NMRA - CTEC approval
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|  | 1. Participant Insurance certificates (If relevant)
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| 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 CertificatesFolder (III)– Other documents |  |

\*Clinical Trial Evaluation Committee (CTEC)-NMRA

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

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