PROTOCOL REVIEW APPLICATION

To the Principal Investigator:

Please obtain an electronic copy of this Form, fill-out the requested information, and make your submission both in electronic version and hard copy. Print in letter-sized paper with printer default set at A4.

<table>
<tr><th colspan="2">I. PROTOCOL INFORMATION</th><th>IEC Protocol Tracking No.
(to be assigned by IEC)</th></tr>
<tr><td colspan="2">Title</td><td>Version Number, Date</td></tr>
<tr><td colspan="2">Study Protocol No.</td><td>Protocol Submission Date</td></tr>
<tr><td>Principal Investigator</td><td>Name:

Contact Nos.:</td><td>☐ DLSMHSI Faculty
☐ DLSMHSI Student
☐ DLSMHSI Resident/Fellow
☐ Non-DLSMHSI (indicate):</td></tr>
<tr><td>Status of Review</td><td colspan="2">☐ New
☐ Revised/Amended
(Please indicate version and date of version in resubmitted document footer)</td></tr>
<tr><td>Research Category</td><td colspan="2">☐ Research involving human participants
☐ Animal Research
☐ Others (indicate)</td></tr>
<tr><td>Type of Study</td><td>☐ Pre-Clinical
☐ Clinical
☐ Observational
☐ Interventional (Clinical Trial)
☐ Phase ____
☐ Non-Clinical
☐ Epidemiological
☐ Document-based
☐ Socio-behavioral
☐ Controlled laboratory studies
☐ Herbal/CAM Research
☐ Diagnostics
☐ Medical Device
☐ Genetic/genomic research
☐ Operations/Process Research
☐ Others (indicate)</td><td>☐ Single-Center
☐ Multi-Center; No. of Study Sites ____
☐ Screening
☐ Interim Analysis
☐ Randomized
☐ Stratified randomized
☐ Single-blind
☐ Double blind
☐ Open-labeled
☐ Parallel
☐ Cross-over
☐ Placebo-controlled
☐ Treatment-controlled
☐ Use of:
☐ Blood samples
☐ Tissue samples
☐ Genetic materials</td></tr>
<tr><td>Purpose and Duration of Study:</td><td>Purpose:
☐ Academic requirement
☐ Independent research work
☐ Contract research
☐ Collaboration/Joint venture
☐ Others (indicate)</td><td>Duration (in months): _____</td></tr>
</table>

<table>
<tr>
<td>Total No. of Participants in the

Study _____

Gender
☐ Male
☐ Female

Age Groups
☐ <18 yrs
☐ Adults (18-65yrs)
☐ Elderly (>65yrs)</td>
<td>Groups of participants:
☐ Healthy Volunteers
☐ Patients
☐ Women of child-bearing potential
☐ Others (indicate)</td>
<td>Vulnerable Participants:
☐ In-utero
☐ Pre-term Newborns (up to ≤37weeks)
☐ Newborns (0-27days)
☐ Infant & Toddlers (28days-23months)
☐ Children (2-11years)
☐ Adolescents (12-17years)
☐ Elderly (>65years)
☐ Pregnant women
☐ Illiterate
☐ Seriously ill
☐ Terminally ill
☐ Handicapped
☐ Mentally challenged
☐ Others (indicate):</td>
</tr>
<tr>
<td colspan="3">PROTOCOL SYNOPSIS (maximum of 500 words) clearly describing the following:
1. Justification for the Study
2. Study Design/Methodology
3. Participant Selection including vulnerability
4. Risks & Benefits
5. Respect for the dignity of the study participants</td>
</tr>
<tr>
<td>Previous Approval from other Technical/ Ethics Committees

☐ Approval Start and End Date
☐ Not Applicable</td>
<td colspan="2">☐ Name of Technical Review Committee/ Ethics Review Committee

_____</td>
</tr>
<tr>
<td>Funding Source:</td>
<td colspan="2">☐ Investigator
☐ DLSMHSI
☐ Others (indicate):</td>
</tr>
</table>

I declare that I have:

- ☐ *NO Conflict of Interest in any form (personal, professional, financial, proprietary) with sponsor, the study, or the site*
- ☐ *personal/family interest in the study results*
- ☐ *proprietary interest in the study (patent, trademark, copyright, licensing etc)*

I declare that the above study has not commenced or been completed.

I declare that the information provided above is true and correct to the best of my knowledge.

I understand that it will require 30-60 days for the IEC to review and grant approval.

_____ _____

Signature Over Printed Name of Principal Investigator *Date*