



Re:

<i>Study Protocol No.</i>	<i>IEC Protocol Tracking No</i>
<i>Protocol Submission Date: <dd/mm/yy></i>	<i>Date of Initial Review:</i>
<i>Title:</i>	<i>Version Number, Date</i>
<i>Sponsor/CRO</i>	

Dear

Thank you for submitting the above protocol for scientific and ethical review by the IEC which is constituted and operated in accordance with the Declaration of Helsinki, National Ethical Guidelines for Health Research, Council for International Organizations of Medical Sciences (CIOMS), and the International Conference on Harmonization/Good Clinical Practice (ICH/GCP).

The IEC is pleased to inform you that the above study protocol has been granted **APPROVAL** for implementation, in its meeting held on _____, with the following IEC members in attendance.

The approval is valid for one (1) year from the date of this letter or for the duration of the study whichever is earlier. Specifically, approval relates to the following:

- 1.
- 2.



Please be advised that any change in the protocol or informed consent document that may affect the scientific and/or ethical aspects of this IEC-approved study must be promptly reported and must use the assigned IEC Protocol Code to all the succeeding transactions, and that an on-site visit may be conducted if deemed necessary. Moreover, continued approval is contingent upon the submission of the following post-approval requirements, whichever is applicable.

1. **Protocol Amendment Submission** (IEC FORM 3A/V1.2012) – must be filed within 7 days of the modification
2. **Continuing Review Application** (IEC FORM 3B/V1/2012) – must be filed 60 days prior to expiry date of current IEC approval
3. **Final Report** (IEC FORM 3C/V1/2012) – must be filed within 90 days after study completion
4. **Non-Compliance (Deviations/Violations) Report(s)** (IEC FORM 3D/V1/2012) - must be reported not later than 7 days of discovery for Major non-compliance; minor/administrative deviations can be submitted with the Continuing Review Application
5. **Early Study Termination Application** (IEC FORM 3E/V1/2012) – must be filed within 15 days of the termination
6. **SAE Report** (IEC FORM 3F/V2/2014) – for *on-site* SAE and in the event of death, must be reported within *24 hours when Principal Investigator is informed of the event*; for *off-site* SAE and in the event of death, must be reported within *24 hours when Principal Investigator receives report from the Sponsor*.

Should you have any question or need further clarification/information, please feel free to contact the undersigned at (046) 481-8000 local 8042.

The IEC wishes you great success in this endeavor.

Respectfully yours,

Chairman, DLSMHSI Independent Ethics Committee