DLSMHSI-IEC Form 4J/V1/2012

Standard Operating Procedures Effective Date: October 2012

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Re:

Study Protocol No.	IEC Protocol Tracking No
Protocol Approval Date: <dd mm="" yy=""></dd>	<protocol application="" continuing="" final<br="" review="" withdrawal="">Report/ SAE Report/ Site Visit Repor/t Non-Compliance Report/ Early Study Termination/ Queries/Complaints > Submission Date:</protocol>
Title:	Version Number, Date
Sponsor/CRO	

Dear

This has reference to the <Protocol Withdrawal/ Final Report/ SAE Report/ Site Visit Report Non-Compliance Report/ Early Study Termination/Queries/Complaints> received by the IEC for review and approval.

Upon review of the , the IEC has decided, in its regular meeting, to REQUEST FURTHER INFORMATION/RECOMMEND FOR FURTHER ACTION/(OTHERS, SPECIFY). . Specifically, the following are requested:

1.

2.

A response/submission within 90 days of receipt will be highly appreciated, otherwise the study will be declared closed for IEC records.

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 looks forward to hearing from you soon.

Truly yours,

Chairman, DLSMHSI Independent Ethics Committee