DLSMHSI-IEC Form 40/V1/2012

Standard Operating Procedures Effective Date: October 2012

## Re:

| Study Protocol No.                            | IEC Protocol Tracking No  |  |
|---|---|--|
| Protocol Approval Date: <dd mm="" yy=""></dd> | Submission Date: <dd mm="" yy=""> Date Received: <dd mm="" yy=""></dd></dd> |  |
| Title:  | Version Number, Date  |  |
| Sponsor/CRO                                   |   |  |

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This has reference to the

received by the IEC for review and approval.

Upon review of the , the IEC has decided, in its regular meeting, to **DISAPPROVE** the study. Specifically, the following are bases for such decision:

1.

2.

An appeal and resubmission within 90 days of receipt will be granted, 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.

Truly yours,

Chairman, DLSMHSI Independent Ethics Committee