DLSMHSI-IEC Form 4L/V1/2012

Standard Operating Procedures Effective Date: October 2012

Member, IEC

Re: Site Visit Team Membership

Dear

I am pleased to inform you of your appointment as **MEMBER** of the IEC-Site Visit Team that is responsible for ensuring, through a study file and site profile review, the safety of study participants and adherence to specifications of the approved protocol and related documents.

As an IEC Site Visit Team Member, your responsibilities include, but not limited to the following:

- 1. Completing the Site Visit Report Form (Form 3G/V1/2012)
- 2. Ensuring that the investigators and study staff have adequate knowledge about the intervention under study
- 3. Confirming that only eligible participants are being/have been enrolled
- 4. Observing the informed consent process, if possible
- 5. Verifying that investigators and study staff are performing study-related tasks, and have not delegated these to unauthorized individuals
- 6. Collecting views of study participants, if possible
- 7. Discussing own findings with the Site Visit Team

The Protocol and Site Visit details are as follows:

	IEC Protocol Tracking No
Study Protocol No.	Protocol Approval Date: <dd mm="" yy=""></dd>
Study Initiation Date: <dd mm="" yy=""></dd>	Expected End Date: <dd mm="" yy=""></dd>
Title:	Version Number, Date
Name of Principal Investigator	Contact Nos.:
Sponsor/CRO	
STUDY SITE	Address
Date of Visit <dd mm="" yy=""></dd>	Time of Visit <hh:mm></hh:mm>

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

Signature Over Printed Name	 Date	
CONFORME OF SITE VISIT TEAM MEMBER:		
Chairman, DLSMHSI Independent Ethics Committee		
Truly yours,		
Truly yours,		
Thank you for your continued assistance and support.		
undersigned at (046) 461-6000 local 6042.		