



Re:

<i>Study Protocol No.</i>	
<i>Protocol Submission Date:</i>	
<i>Title:</i>	<i>Version Number, Date</i>
<i>Name of Principal Investigator</i>	
<i>Sponsor/CRO</i>	
<i>Study Site</i>	

Dear

This has reference to the above protocol in which the proposed amendments were submitted to the DLSMHSI-IEC for review and approval.

We wish to inform you that the **De La Salle Medical and Health Sciences Institute – Independent Ethics Committee** reviewed your study protocol amendments during its regular meeting and is requesting further clarification.

As a result of the review, DLSMHSI-IEC action is **MAJOR MODIFICATIONS PRIOR TO APPROVAL / MINOR MODIFICATIONS PRIOR TO APPROVAL**. Recommended revisions and/or clarifications are summarized below:

1.

A resubmission within 90 days of receipt will be highly appreciated, otherwise the study will be declared closed for DLSHSI-IEC records. Please note that the recommended revisions must be:



De La Salle Medical and Health Sciences Institute
Dasmariñas, Cavite 4114

INDEPENDENT ETHICS COMMITTEE

Cavite (046) 481-8000/ Manila (02) 988-3100 Local 8042

DLSMHSI-IEC Form 4H/V1/2012
Standard Operating Procedures
Effective Date: October 2012

1. Integrated in a revised version of the protocol or other study documentation, with the revisions tabbed and clearly highlighted. Include a footer in all pages that indicates the Version Number and Date of the revised version.
2. Summarized in a cover letter indicating in which the page/section/paragraph of the revised version the specific revisions may be found

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

The DLSMHSI-IEC looks forward to hearing from you soon.

Respectfully yours,

Chairman, DLSMHSI Independent Ethics Committee