

**Annexure 19 A**

**Reminder letter by the IEC to principal investigator**

**Name of Principal Investigator:-**

**Department:-**

**Ref: - Project no. Title: XXXXXX**

The above referenced project was approved by the IEC on XXXXXXXX and is due for Continuing Annual/ Periodic Review by the IEC. You are requested to submit an Annual/ Periodic status report in the prescribed format which is enclosed (Continuing Review Application Form) at the earliest, on or before XXXXX. (1 month period)

Signature with date \_\_\_\_\_

Member Secretary/ Chairperson \_\_\_\_\_

<b>No.:Date of IEC approval:</b>
<b>Title:</b>
<b>Investigator : Department :</b>

**Annexure- 19B  
Continuing Review Application Form**

<p><b>Summary of protocol participants:</b></p> <p>_____ No. of participants screened</p> <p>_____ No. of participants approved by IEC</p> <p>_____ No. of recruited participants</p> <p>_____ No. of ongoing participants</p> <p>_____ No. of completed participants</p> <p>_____ No. of participants who refused to consent</p> <p><b>Have any participants been withdrawn from this study?</b> Yes No</p> <p>If no, (state the number and reasons for drop-outs of each participant, attach separate sheet if needed)</p>	<p><b>Has any information appeared in the literature, or evolved from this or similar research that might affect the IEC/IEC's evaluation of the risk/benefit analysis of participants involved in this protocol?</b> Yes No</p> <p>If Yes (attach separate sheet if needed) <b>Whether reports of SAEs so far have been reviewed by the IEC-</b> _____</p> <p><input type="checkbox"/> Whether reports of SAEs at other sites have been submitted to the IEC- _____</p> <p><b>Have any participating investigators been added or withdrawn since last review?</b> Yes No</p> <p>If Yes (Identify all changes in the attached narrative)</p> <p><b>Is report of interim data analysis available?</b></p> <p>Yes (submit as an attachment) No</p> <p><b>Is report of the data safety and monitoring board available?</b></p> <p>Yes (submit as an attachment) No</p> <p><b>Have any investigators developed equity or consultative relationship with a source related to this protocol which might be considered a conflict of interest?</b></p> <p>Yes (Append a statement of disclosure) No</p>
<p><b>Have there been any amendments in protocol/ Informed Consent Document since the last review?</b></p> <p>Yes No</p> <p><b>Were these protocol/ Informed Consent Document (ICD) amendments approved by IEC?</b></p> <p>Yes No</p> <p>If no, mention the amendments not approved</p>	<p><b>Which protocol amendment is the site following at present</b> _____</p>

**Date:** \_\_\_\_\_

**Signature of the Principal Investigator with Date:** \_\_\_\_\_

**Assessment of Continuing Review Report by the IEC**

**To be reviewed by**

- Chairperson /Member Secretary only and informed to the IEC members at Full Board
- Full Board
- Any 2 IEC members and informed to the IEC members at Full Board

1. Names of IEC members: \_\_\_\_\_

2. \_\_\_\_\_

**Signature with date**

**Chairperson/Member Secretary**

**IEC Decision on the Continue Review Report**

**Date - -----**

**Decision**

Approved and the project can be continued without any modifications

Modifications recommended - requiring protocol resubmission

State the recommendations:

Protocol should be discontinued

State the reasons for discontinuation

Date of Full Board discussion

**Signature of reviewer/s with date:** \_\_\_\_\_

**Signature with date**

**Chairperson / Member Secretary**