

**AX1-V6.1/SOP 07/V6.1  
Form B**

**Continuing Review Application Form/Annual Status Report Form  
(Basic Human study)**

TMC Project No:
<b>PROTOCOL TITLE:</b>

**Principal Investigator:**

**Co- Investigator (s) :**

**Phone no:**

**Email Id:**

**Institute:** ACTREC/TMH

**Date of TMC IEC approval :** \_\_\_\_\_ **Approval valid upto:** \_\_\_\_\_

**Mention overall duration of study (in years/months) approved by IEC at the time of study approval:**

**Start Date of study:**

If the start date is > 6 months from the IEC approval date kindly provide the reasons for the same

**Duration of study:**

**Period of Report of the current CRA :** \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_ to  
\_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

**Funding Source :**

**Account no :**

<p><b>1) Project Status</b></p> <p><input type="checkbox"/> Ongoing</p> <ul style="list-style-type: none"><li><input type="radio"/> Active accrual on going</li><li><input type="radio"/> Accrual completed /Follow-up</li><li><input type="radio"/> Analysis on going</li></ul> <p><input type="checkbox"/> Not started/Not initiated</p> <p>If 'Not started' state reasons</p> <hr/>
<p><b>2) Provide the date of last status review report submitted to TMC- IEC for this project : __/__/_____ <input type="checkbox"/> NA</b></p>
<p><b>3) Have there been any Protocol amendments since the last status report?</b></p> <p><input type="checkbox"/> Yes                      <input type="checkbox"/> No</p> <p>If 'YES', Were these Protocol Amendments approved by TMC- IEC?</p> <ul style="list-style-type: none"><li><input type="radio"/> YES    If 'YES', please provide date of approval _____</li><li><input type="radio"/> NO</li></ul> <p><b>Note:</b> Kindly attach a sheet with the list of amendments to be approved/approved by the TMC-ACTREC IEC in a tabular column with details of amendment no. with date, date of submission to TMC-IEC and date of approval by TMC-IEC.</p>
<p><b>4) Have there been any Informed Consent document amendments since the last status report?</b></p> <p><input type="checkbox"/> Yes            <input type="checkbox"/> No            <input type="checkbox"/> NA</p> <p>If 'Yes', were these informed consent document amendments approved by TMC-ACTREC IEC?</p> <ul style="list-style-type: none"><li><input type="radio"/> YES    If 'YES', Please provide date of approval _____</li><li><input type="radio"/> NO</li></ul> <p><b>Note:</b> Kindly attach a sheet with the list of amendments to be approved/approved by the TMC-IEC in the tabular column with details of Amendment no. with date, Date of submission to TMC-IEC and Date of approval by TMC-IEC.</p>
<p><b>5) Summary of Protocol participants:</b></p> <ul style="list-style-type: none"><li><input type="radio"/> Total patients/samples to be recruited at TMC (IEC ceiling)_____</li><li><input type="radio"/> Total number of samples screened since protocol began : _____</li></ul>

<ul style="list-style-type: none"><li>○ Total Screen failures since protocol began: _____</li><li>○ Total participants accrued / samples collected since protocol began _____</li><li>○ New participants accrued /samples collected since protocol began: _____</li><li>○ Date of accrual of last participant / Samples: _____</li><li>○ Number of active participants/Sample (analysis going on) _____</li><li>○ Number of samples analyzed: _____</li><li>○ Any other: _____</li></ul>
<p><b>6) Is the recruitment on schedule?</b></p> <p><input type="checkbox"/> <b>Yes</b>      <input type="checkbox"/> <b>No</b>      <input type="checkbox"/> <b>NA</b></p> <p>(If 'NO', please attach a sheet giving reasons and your plans to improve accrual)</p>
<p><b>7) Have there been any changes in the participant population, recruitment or selection criteria since the last status report was submitted to TMC- IEC?</b></p> <p><input type="checkbox"/> <b>Yes (Kindly attach a sheet explaining the changes)</b></p> <p><input type="checkbox"/> <b>No</b></p> <p><input type="checkbox"/> <b>NA</b></p>
<p><b>8) Were any samples not suitable for analysis during the last one year (only the report period.)?</b></p> <p><input type="checkbox"/> <b>Yes (Kindly attach a sheet stating reasons)</b></p> <p><input type="checkbox"/> <b>No</b></p> <p><input type="checkbox"/> <b>NA</b></p>
<p><b>9) Have any participating investigators been added or deleted since the last status report was submitted to TMC- IEC?</b></p> <p><input type="checkbox"/> <b>Yes (Kindly attach a sheet with details)</b></p> <p><input type="checkbox"/> <b>No</b></p> <p><input type="checkbox"/> <b>NA</b></p>
<p><b>10) Have any new collaborating sites (institutions) been added or deleted since the last status report was submitted to TMC- IEC?</b></p> <p><input type="checkbox"/> <b>Yes (Kindly attach a sheet with details)</b></p> <p><input type="checkbox"/> <b>No</b></p> <p><input type="checkbox"/> <b>NA</b></p>

<p><b>11) Were there any protocol deviations/violations in the study?</b></p> <p><input type="checkbox"/> Yes (Kindly attach a sheet with details)</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> NA</p>
<p><b>12) Is interim data analysis report available?</b></p> <p><input type="checkbox"/> Yes (If 'YES', kindly submit as an attachment)</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> NA</p>
<p><b>13) Has there been any presentation/publication related to the data generated in this study?</b></p> <p><input type="checkbox"/> Yes (Kindly attach a sheet enclosing the details)</p> <p><input type="checkbox"/> No</p> <p>If 'YES' then has this been intimated to the TRAC office?</p> <p><input type="checkbox"/> Yes    <input type="checkbox"/> No    <input type="checkbox"/> NA</p>
<p><b>14) Has any information appeared in the literature, OR evolved from this OR similar research that might affect the TMC- IEC evaluation of the risk/benefit analysis of human subjects involved in this protocol?</b></p> <p><input type="checkbox"/> Yes (If 'YES' kindly attach a sheet providing the details)</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> NA</p>
<p><b>15) Was the study Monitored by Data Monitoring Committee (DMC)?</b></p> <p><input type="checkbox"/> Yes (If 'YES' kindly attach a sheet providing the details)</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> NA</p> <p><b>If Yes, When was study last monitored?</b> Date of monitoring _____</p> <p>Monitored by _____</p> <p>Number of subjects monitored _____</p>
<p><b>16) Is the DMC report available?</b></p> <p><input type="checkbox"/> Yes ( If 'YES', submit as an attachment)</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> NA</p>

**17) Did the Data monitoring team have any adverse comments regarding the study?**

- Yes (If, 'YES', please attach a copy of their comments)
- No
- NA

**18) Scientific and Technical Progress**

**a) Progress made against the Approved Objectives, Targets & Timelines during the Reporting Period.**(Attach a separate sheet of detailed work progress report till date, including tables/figures and experimental data generated last one year and future objectives )

**b) Summary and Conclusions of the Progress made so far** (minimum 100 words, maximum 200 words)

**c) Details of New Leads Obtained, if any:**

**19) Is the project likely to finish in the stipulated time? If no please mention reason for not being able to complete the work in stipulated time, what percent of work is pending and the period of extension (months/year(s)) is required to complete the project. How many prior extensions sought? (in numbers)**

**20) Have any investigators developed an equity or consultative relationship with a source related to this protocol which might be considered as conflict of interest?**

- Yes (If YES, kindly append a statement of disclosure for the same)
- No
- NA

**21). Details regarding the budget: (kindly attach account statement sheet duly signed by Accounts Officer)**

Total budget proposed for the project: Rs. \_\_\_\_\_

Total budget sanctioned for the project: Rs. \_\_\_\_\_

Total amount utilized for the Project: Rs \_\_\_\_\_

**If funds unutilized, to state the reason:** \_\_\_\_\_

**If extramural funding was sought, name the funding source and amount.**

Funding Source: \_\_\_\_\_

Amount : Rs. _____
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**SIGNATURES:**

**Principal Investigator:**

**Date:**