## Format for Six monthly progress of Project

**IEC Proposal No**. :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Study title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Name of the Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Designation / Department: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Duration of Study: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date of IEC Approval:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Non-Funded/Funded & Name of funding Agency\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date of Starting of the Study: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Period of six monthly progress report:** From \_\_\_\_\_\_\_\_\_\_\_\_\_\_ to \_\_\_\_\_\_\_\_\_\_

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| The progress report shall incorporate following elements:  1. Status of study: Initiated/Not initiated  If initiated, Ongoing/Prematurely Terminated/Completed  If not initiated, give reason  If prematurely terminated, give reason  2. Summary of Protocol participants (at our site)   1. No. of participants approved by IEC 2. No. of participants screened 3. No. of participants who refused to consent 4. No. of participants recruited 5. No. of ongoing participants 6. No. of completed participants 7. No. of patients withdrawn 8. Reason for withdrawal   3. Any amendments in protocol/Informed Consent Document since last review  If yes, whether communicated to IEC  4. Any Serious Adverse Event at our site  If yes,  Number \_\_\_\_\_\_\_, whether communicated to IEC  5. Any new information or the information evolved from your study that might affect IEC’s evaluation of risk/benefit analysis  If yes, given details on separate sheet  6. Any change of investigator (Addition or withdrawn)  If yes, Name\_\_\_\_\_\_\_\_\_\_  Whether communicated to IEC  7. Is report of interim data analysis available?  If yes, submit on separate sheet.  Adverse Effect if any:  Amendment if any:  If discontinuation, give reasons:  Progress: |

Signature of Principal Investigator : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date & Seal : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Note:**

1. The report should be **typeset as per the format** and must be **signed alongwith seal & date by Principal Investigator.**
2. Kindly submit the report along with **covering letter** addressed to “The Chairman, Institute Ethics Committee, AIIMS Raipur”, at the IEC Office, Room No. 2103, Academic Section, 2nd Floor, Medical College Complex, AIIMS Raipur, Chhattisgarh 492099.