

Format for Six monthly progress of Project

IRC Proposal No. : _____

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 _____

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)
 - a) No. of participants approved by IEC
 - b) No. of participants screened
 - c) No. of participants who refused to consent
 - d) No. of participants recruited
 - e) No. of ongoing participants
 - f) No. of completed participants
 - g) No. of patients withdrawn
 - h) 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 Any change of investigator (Addition or withdrawn)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.