Continuing Review / Annual report format

Surat Municipal Institute of Medical Education and Research (SMIMER)

Opp. Bombay Market, Umarwada, Surat - 395 010. (Gujarat - India).

Ph: (0261) 2368040 to 43; Fax: (0261) 2343241

Title of study: .....

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Principal Investigator (Name, Designation and Affiliation): .....

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1. Date of EC Approval: dd mm yy Validity of approval: dd mm yy
2. Date of Start of study: dd mm yy Proposed date of Completion: dd mm yy

   Period of Continuing Report: dd mm yy ---- to ------ dd mm yy
3. Does the study involve recruitment of participants? Yes ☐ No ☐

   (a) If yes, Total number expected..... Number Screened:..... Number Enrolled: .....

   Number Completed:..... Number on followup:.....

   (b) Enrolment status – ongoing / completed/ stopped

   (c) Report of DSMB[16] Yes ☐ No ☐ NA☐

   (d) Any other remark.....

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   (e) Have any participants withdrawn from this study since the last approval? Yes ☐ No ☐ NA☐

   If yes, total number withdrawn and reasons: .....

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4. Is the study likely to extend beyond the stated period ?[17] Yes ☐ No ☐

   If yes, please provide reasons for the extension. .....

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5. Have there been any amendments in the research protocol/Informed Consent Document (ICD) during the past approval period?

   If No, skip to item no. 6 Yes ☐ No ☐

   (a) If yes, date of approval for protocol and ICD : dd mm yy

   (b) In case of amendments in the research protocol/ICD, was re-consent sought from participants? Yes ☐ No☐

   If yes, when / how: .....

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