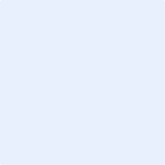
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| *Birla Institute of Technology and Science, Pilani - Wikipedia* | **(Annexure 3)**  **Continuing Review/ Annual report forma**  **Birla Institute of Technology and Sciences, Pilani K K Birla, Goa Campus**    **EC Ref. No*.(****for office use):* |

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| Title of study:    Principal Investigator (Name, Designation and Affiliation) |

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| --- | --- | --- |
|  | Date of EC Approval: Click here to enter a date. | Validity of approval: Click here to enter a date. |
|  | Date of Start of study: Click here to enter a date. | Proposed date of Completion: Click here to enter a date. |
| Period of Continuing ReportClick here to enter a date. | ---- to *------* Click here to enter a date. |
|  | Does the study involve recruitment of participants? Yes No   1. If yes, Total number expected      No. Screened:      No. Enrolled:     Number Completed:       No. on followup:       .   1. Enrolment status – ongoing / completed/ stopped 2. Report of DSMB*16* Yes No NA  1. Any other remark | |
|  | 1. Have any participants withdrawn from this study since the last approval? Yes No NA   If yes, total number withdrawn and reasons: | |
|  | Is the study likely to extend beyond the stated period*17*? Yes No  If yes, please provide reasons for the extension | |
|  | 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 : Click here to enter a date. | |
|  | (b) In case of amendments in the research protocol/ICD, was re-consent sought from participants?  If yes, when / how:       Yes No | |

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| --- | --- |
|  | *16In case there is a Data Safety Monitoring Board (DSMB) for the study provide a copy of the report from the DSMB. If not write NA.*  *17Problems encountered since the last continuing review application with respect to implementation of the protocol as cleared by the EC* |
|  | Is any new information available that changes the benefit -risk analysis of human participants involved in this study? Yes No  If yes, discuss in detail: |
|  | Have any ethical concerns occurred during this period? Yes No  If yes, give details |
|  | (a) Have any adverse events been noted since the last review? Yes No  Describe in brief:  (b) Have any SAE’s occurred since last review? Yes No  If yes, number of SAE’s :       Type of SAE’s:  (c) Is the SAE related to the study? Yes No  Have you reported the SAE to EC? If no, state reasons Yes No |
|  | Has there been any protocol deviations/violations that occurred during this period?  If yes, number of deviations  Have you reported the deviations to EC? If no, state reasons Yes No |
|  | In case of multicentric trials, whether reports of off-site SAEs have been submitted to the EC  Yes No NA |
|  | Are there any publications or presentations during this period? If yes give details Yes No    Any other comments: |

Signature of PI:  Click here to enter a date.

18Location implies page number in the ICD/protocol where the amendment is proposed.