## 1. Submission Checklist

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **S.No** | **Contents** | **Applicant Section** | | **Ethics**  **Committee**  **Section** | |  |
| **Yes** | **No** | **Yes** | **No** | **Comments** |
| 1. | Name of the applicant with designation |  |  |  |  |  |
| 2. | Name of the Institute/ Hospital / Field  area where research will be conducted |  |  |  |  |  |
| 3. | Approval of the Head of the  Department / Institution if applicable |  |  |  |  |  |
| 4. | Protocol of the proposed research |  |  |  |  |  |
| 5. | Ethical issues in the study and plans to  address these issues. |  |  |  |  |  |
| 6. | Proposal should be submitted with all relevant enclosures like proformae, case report forms, questionnaires, follow - up cards, etc. |  |  |  |  |  |
| 7. | Informed consent process, including patient information sheet and informed  consent form in local language(s). |  |  |  |  |  |
| 8. | For any drug / device trial, all relevant pre-clinical animal data and clinical trial data from other centers within the  country / countries, if available. |  |  |  |  |  |
| 9. | Current Curriculum vitae of all the  investigators |  |  |  |  |  |
| 10. | Regulatory Approval/ Submission  status |  |  |  |  |  |
| 11. | Source of funding and financial  requirements for the project |  |  |  |  |  |
| 12. | Insurance and Indemnity arrangements |  |  |  |  |  |
| 13. | Description of site facilities using in  the study including available  emergency facilities |  |  |  |  |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **S.No** | **Contents** | **Applicant Section** | | **Ethics**  **Committee Section** | |  |
| **Yes** | **No** | **Yes** | **No** | **Comments** |
| 14. | Investigator Undertaking |  |  |  |  |  |
| 15. | Agreement to comply with the relevant national and applicable international guidelines. |  |  |  |  |  |
| 16. | All payment, reimbursement and medical services to be provided to the  research subjects. |  |  |  |  |  |
| 17. | Plans for publication of results – positive or negative- while maintaining the privacy and confidentiality of the  study participants. |  |  |  |  |  |
| 18. | Information of other EC approval  Status of the study if applicable |  |  |  |  |  |
| 19. | Details of the study Team |  |  |  |  |  |
| 20. | Any other information relevant to the  study |  |  |  |  |  |