**CHECK LIST FOR SUBMITTING RESEARCH PROPOSALS TO RESEARCH CELL**

1. Title of the project : -------------------------------------------------------------------------
2. Name, Designation : -------------------------------------------------------------------------

& Address of Principal -------------------------------------------------------------------------

Investigator -------------------------------------------------------------------------

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sr. No.**  | **Particulars** | **PI Check****(Yes/No)** | **Research Cell Check****(Yes/No)** | **If No,** **Give reasons** |
| **1** | Noting page (2 blank pages with title of the project and PI Name)  |  |  |  |
| **2** | Check List for Submitting Research Proposal |  |  |  |
| **3** | Title Page and Acknowledgement |  |  |  |
| **4** | Covering Letter |  |  |  |
| **5** | Dully filled format for submission of research project (Proforma for IEC) |  |  |  |
| **6** | Proforma for Project Proposal (Funded/Non-Funded) |  |  |  |
| **7** | Project Specific Informed consent form1. English
2. Hindi/Vernacular
 |  |  |  |
| **8** | Project Specific Patient Information Sheet1. English
2. Hindi/Vernacular
 |  |  |  |
| **9** | Declaration by Principal Investigator |  |  |  |
| **10** | Project Specific Case Record Form |  |  |  |
| **11** | Any other document for consideration by IEC(viz collaboration with any Private Laboratory/Institute) |  |  |  |
| **12** | Permission to use copyrighted questionnaire and proforma |  |  |  |
| **13** | Brief CV of Principal Investigator |  |  |  |
| **14** | Soft copy in single file (pdf.) uploaded on researchcellaiimsrajkot@gmail.com |  |  |  |

**NOTE: Please attach Annexure – 7 of IEC (for IEC clearance) with this checklist.**

Date: Signature of Principal Investigator

**For office use only**

Date of receiving: Signature

(On behalf of IEC)

|  |  |
| --- | --- |
| **ANNEXURE – 7 (AN 07/01):** | **CHECK LIST FOR PROTOCOL SUBMISSION** |

**Checklist of Documents for Protocol Submission to the Institutional Ethics Committee AIIMS, Rajkot (to be filled in by the study team)**

Protocol submission for initial review (Tick accordingly)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Sr.****No.** | **Documents** | **Yes** | **No** | **Date by which it will be submitted, if pending** | **NA** |
| 1 | Letter to Member Secretary/ Chairperson |  |  |  |  |
| 2 | Summary of protocol (in not more than 500 words) |  |  |  |  |
| 3 | Protocol |  |  |  |  |
| 4 | Amendments to protocol, if applicable |  |  |  |  |
| 5 | Informed consent document in English |  |  |  |  |
| 6 | Informed consent documents in Regional languages (Total No:‐ \_\_\_\_\_\_\_) |  |  |  |  |
| 7 | Back translations of Informed consent documents |  |  |  |  |
| 8 | Back translation certificate |  |  |  |  |
| 9 | Amendments to the informed consent document |  |  |  |  |
| 10 | Case Record Form |  |  |  |  |
| 11 | Subject recruitment procedures: advertisement, notices or any other |  |  |  |  |
| 12 | Patient instruction card, identity card, diary etc. |  |  |  |  |
| 13 | Patient/Subject Questionnaire/s (No:\_\_\_\_\_) |  |  |  |  |
| 14 | Investigator Brochure |  |  |  |  |
| 15 | Insurance policy (Only one copy is needed for submission) |  |  |  |  |
| 16 | Investigator’s undertaking to DCGI (Only one copy is needed for submission) |  |  |  |  |
| 17 | DCGI approval (Only one copy is needed for submission) |  |  |  |  |
| 18 | Investigator’s agreement with sponsor (Copy ofthe Final Signed Document) |  |  |  |  |
| 19 | FDA marketing/manufacturing license for herbal formulations/ nutraceutics (Only one copy is needed for submission) |  |  |  |  |
| 20 | Related approval in case the study involves collaboration with any foreign laboratory/clinic/institution (Only one copy is needed for submission) |  |  |  |  |
| 21 | Bhabha Atomic Research Centre (BARC) approval in case study involves use of radioisotopes/ ionizing radiations (Only one copy is needed for submission) |  |  |  |  |
| 22 | Genetic Engineering Advisory Committee (GEAC) approval in case study involves use of gene therapy (Only one copy is needed for submission) |  |  |  |  |
| 23 | Director General of Foreign Trade (DGFT) approval in case study samples are to be sent abroad for analysis (Only one copy is needed for submission) |  |  |  |  |
| 24 | Administrative sanction from the Head of the Institution in case of collaborative studies with other institutions (one copy) |  |  |  |  |
| 25 | Signed and dated brief current curriculum vitae of the study team members (principal investigator, co‐investigator, study co‐coordinator) (one copy only) |  |  |  |  |
| 26 | Ethics Committee clearance of other centers (Total No \_\_\_\_\_) (one copy only) |  |  |  |  |
| 27 | Log of delegation of responsibility of the study team members  |  |  |  |  |
| 28 | Document Receipt Form (one copy only) |  |  |  |  |
| 29 | Current Status of Ongoing Studies conducted by principal investigator |  |  |  |  |
| 30 | Documentation of CTRI registration/ any other WHO platform registry (whenever applicable) (one copy only) |  |  |  |  |
| 31 | GCP training certificates of principal investigator and co-investigator (one copy only) |  |  |  |  |
| 32 | Any other Documents submitted |  |  |  |  |