**Appendix ‘I’**

 Guidelines for submission of proposals to the Ethical Committee

1. **List of Document to be Submitted to IEC for Drug Trial Protocol/ Clinical Trial.**

**The hard copy of protocol with each document & 10 soft copy of CD**

1. Application forwarded by the HOD/institution
2. Invitation Letter from the sponsor
3. Summary of the protocol
4. Index of documents with stickers at appropriate places
5. C.V of the Principal Investigator & Co-Investigator updated, signed and dated .
6. ICP-GCP Certificate of PI
7. DCGI clearance
8. Indemnity Bond/Insurance Coverage
9. Written Informed Consents from Hindi & English.
10. Patient Information Sheet.
11. Funding/financial disclosure.
12. copies of the Protocol
13. Crossed cheque/ Draft worth Rs.40000/- in the name of Indian Fertility society
14. Clinical Trial Agreement (CTA)
15. CTRI Registration number for the study
16. Soft copy of approved protocol (PDF format in CD)
17. Contact no.& E-mail ID
18. One file folder
* All documents are found to be complete.
1. Proposal is received at least 2-weeks prior to the date for Ethical Committee Meeting.
2. No more than 12 projects have already been received for IEC meeting.
* **List of documents for Amendments in already approved protocols**
1. Summary of the amendment ( to be incorporated )
2. Processing Fees 10000/-
3. Copies of detailed documents.

(B) **List of Document to be Submitted to IEC for Academic study /IFS follow \_**

**\_**

1. Application forwarded by the HOD/Institution Head. (signed with stamp)
2. Summary of the protocol
3. Index of documents with stickers at appropriate places
4. Recommendations letter from Departmental Scientific Committee consisting of three faculty members other then Principal Investigator and Co-investigator on departmental letter head with date**. (signed with stamp)**
5. Current C.V of the Principal Investigator & Co-Investigator updated, signed and dated.
6. List of study team (signed with stamp)
7. Written Informed Consents from Hindi & English.
8. Patient Information Sheet Hindi & English
9. Protocol
10. Crossed cheque/ Draft worth **Rs.10000/-** in the name Indian Fertility society
11. Budget details
12. CTRI Registration number (After IEC approval )
13. Soft copy of approved protocol (PDF format in CD)
14. Contact no.& E-mail ID
15. One file folder
16. **List of documents for Serious Ad**
17. **Serious Event in already approved protocol.**
18. Patient’s details - Initials and other relevant identifier (hospital /OPD record number etc.)
19. Suspected Drug
20. Indication (s) for which suspected drug was prescribed of tested
21. Daily dose and regimen (specify unit of measure ,e.g.mg.ml.mg/kg)
22. Route of administration
23. Starting date and time or duration of treatment
24. Date of reaction
25. Stop date and time of duration of reaction
26. De-challenge and re-challenge information
27. Information on recovery and any sequel, result of specific test and /or treatment.
28. Medical history allergy, drug or alcohol abuse, family history, findings from special investigators
29. Clinical investigator details –Name ,address, telephone ,E-mail
30. Signature of the investigator
31. Crossed cheque/ Draft worth **Rs. 5,000/- in** the name of Indian Fertility Society

|  |  |  |
| --- | --- | --- |
| **S..No** | **Documents for submission Academics study& IFS fellow**  | **Yes/No/ Any clarification**  |
| 1 | PI Name ,Designation & Department , Address |  |
|  |
|  |
|  |
|  |
|  |
|  |
| 2 | Email & Phone No. |  |
|  |
| 3 | Application forwarded by the HOD /Institution Head. (signed with stamp) |  |
| 4 | Departmental Scientific Committee. (signed with stamp) |  |
| 5 | Current C.V of the Principal Investigator & Co-Investigator updated , signed and dated  |  |
| 6 | Index of documents with stickers at appropriate places |  |
| 7 | List of study team (signed with stamp) |  |
| 8 | Crossed cheque/ Draft worth Rs.10000/- in the name of “ Indian Fertility Society ”as Processing fee OR Undertaking for processing fee |   |
| 9 | Summary of the protocol |  |
| 10 | Protocol |  |
| 11 | Written Informed Consents from Hindi & English. |  |
| 12 | Patient Information Sheet Hindi & English |  |
| 13 | Budget details  |  |
| 14 | Type of study  |  |
| 15 | No. of ongoing project  |  |
| 16 | No. of complete project |  |

|  |  |  |
| --- | --- | --- |
| **S..No** | **Documents for Clinical Trial** | **Yes/No/ Any clarification**  |
| 1 | PI Name ,Designation & Department , Address |  |
| 2 | Email & Phone No. |  |
|  |
| 3 | Application forwarded by the HOD. (signed with stamp) |  |
| 4 | Departmental Scientific Committee**.(signed with stamp)** |  |
| 5 | Current **C.V** of the Principal Investigator & Co-Investigator updated signed and dated 1. PI qualification
2. Experience of clinical trial
3. **ICH-GCP certificated**
 |  |
|  |
|  |
|  |
| 6 | Index of documents with stickers at appropriate places |  |
| 7 | List of study team (signed with stamp |  |
| 8 | Crossed cheque/ Draft worth **Rs.40000/- or Internationally collaborative funded studies Rs.(INR) equivalent to USD 1000.00** in the name of **“Indian Fertility Society”** as Processing fee  | Cheque no.:Dated:   |
| 9 | Invitation letter from the sponsor  |  |
| 10 | Summary of the protocol |  |
| 11 | Protocol |  |
| 12 | Written Informed Consents from Hindi & English. |  |
| 13 | Patient Information Sheet Hindi & English |  |
| 14 | DCGI clearance |  |
| 16 | Indemnity Bond/Insurance Coverage |  |
| 17 | Clinical Trial Agreement (CTA) |  |
| 18 | Funding details  |  |
| 19 | Type of study  |  |
| 20 |  New DRUG clinical trial : **Y/N, if yes mention indication of drug**  |  |
| 21 | No. of ongoing project  |  |
| 22 | No. of complete project  |  |
| 23 | Power point presentation  |  |

|  |  |
| --- | --- |
| **Documents for Clinical trial Amendment**  | **Yes/No/ Any clarification**  |
| PI Name ,Designation & Department  |  |
|  |
|  |
| Email & Phone No. |  |  |
| Amendment No.  |  |
| Crossed cheque/ Draft worth **Rs.10000/-** in the name of **“Indian Fertility Society ”**  as Processing fee |  |
| Summary of the protocol changes |  |
| Protocol |  |
| Type of study  |  |
| No. of ongoing project  |  |
| No. of complete project  |  |
| PI Sign & Date  |  Member Secretary (IEC) & Date \_\_\_\_\_\_\_\_ |