FORMAT FOR SUBMISSION OF PROJECTS INVOLVING RESEARCH IN HUMAN
SUBJECTS FOR CLEARANCE BY ETHICS COMMITTEE OF AIIMS

Submit fourteen (14) copies of the Research Project along with Covering letter and ‘soft copy’
on CD with the following information to the Member Secretary, Institution Ethics Committee at
Room No. 102, 1st Floor, Old OT Block, AIIMS, Tel No. 4579. The Principle Investigator must
submit protocol through Head of Department.

No research project shall be / can be started unless ethics clearance/approval is obtained. Please
bear in mind that no retrospective / post facto ethical clearance can be provided to research
projects which were neither submitted nor wetted by the Institution Ethics Committee.

All submissions should be made in the prescribed Format of the Institution Ethics Committee
with signatures of all the investigators. The submission must be accompanied with Participant
Informed Consent Form (PICF) and Participant Information Sheet (PIS), both in English and
Hindi, in a simple layman’s language, in a narrative form, directed to Participant /LAR,
covering all the points given on the website, before it can be considered for placing before the
Institution Ethics Committee. Also ensure that all the pages are numbered.

Project Submission Time: Submissions will be received on all days. Proposals received till
15th of any month will be processed in the coming Institution Ethics Committee meeting and
those received after 15th will be processed in the next Institution Ethics Committee meeting. All
meetings of Institution Ethics Committee will be held as far as possible on first Monday of Jan,
Feb, March, April, May, June, July, August, September, October, November, and December.

While submitting replies raised by the Institution Ethics Committee, the candidates are advised
to mention the Institution Ethics Committee reference number/s and also attach a copy of the
comments of the Institution Ethic Committee. Moreover if the approval is required in a
particular format, the same may be submitted in a CD.

Amendment Submission: While submitting amendments in protocols a covering letter should
be provided clearly stating the changes and a certificate by the PI that the changes made in the
protocol will not hamper the safety of the subject in anyway.

The research projects / proposal submitted should be as follows:

<table>
<thead>
<tr>
<th>1. Full Title of Study:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1a. AIIMS Temporary Research Section Number for all Clinical Trials which are privately funded</td>
<td></td>
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<tr>
<td>2. Name of Investigators / co-investigators (permanent AIIMS Staff) with designation and departments</td>
<td>Signatures</td>
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<tr>
<td>2.1</td>
<td>2.1</td>
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<td>2.2</td>
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<tr>
<td>2.3</td>
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</tbody>
</table>
2.4 _____________________________
2.5 ________________________________
(Expand if more co-investigators)

3. Objectives of the study
3.1 ____________________________________________
3.2 ____________________________________________
3.3 ____________________________________________
3.4 ____________________________________________
3.5 ____________________________________________

4. Justification for conduct of this study

5. Methodology
5.1. Number of Patients:
5.2. Inclusion criteria
a)___________________________________________
b)___________________________________________
c)___________________________________________
d)___________________________________________
5.3. Exclusion criteria
a)___________________________________________
b)___________________________________________
c)___________________________________________
d)___________________________________________
5.4. Control(s) ________________________________
5.5. Study design ______________________________
5.6. Dosages of drug ___________________________
5.7. Duration of treatment _______________________
5.8. Investigation specifically related to projects________
5.9 Permission to use copyrighted Questionnaire/proforma
5.10. Others ________________________________

6. Permission from Drug Controller General of India (DCGI)
   1. ☐ Required  2. ☐ Not required
   3. ☐ Received  4. ☐ Applied when:

7. Permission from DGFT if applicable
   1. ☐ Required  2. ☐ Not required
   3. ☐ Received  4. ☐ Applied when:

8. a) Safety measures for proposed interventions
    b) Results of relevant laboratory tests
    c) Result of studies in human
    a)___________________________________________
    b)___________________________________________
    c)___________________________________________

9. Plans to withdraw standard therapy during conduct of research
   ☐ Yes  ☐ No
   Remarks:_____________________________________

Remarks:_____________________________________

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<tbody>
<tr>
<td>10.</td>
<td>Plan for provision of coverage for medical risk(s) during the study period</td>
</tr>
<tr>
<td>11.</td>
<td>How you will maintain confidentiality of subject?</td>
</tr>
<tr>
<td>12. <strong>Total Budget (Approx. in Rs.)</strong></td>
<td>Who will bear the cost of investigation / implants drugs / contrasts?</td>
</tr>
<tr>
<td>13.</td>
<td>Participant Information Sheet <em>(mark √ if yes)</em></td>
</tr>
</tbody>
</table>
|   | Attached English version  
|   | Attached Hindi version  
|   | Certified that Hindi version is a true translation of English version |
| 14. **Participant Informed Consent Form** *(mark √ if yes)* | Attached English version  
|   | Attached Hindi version  
|   | Certified that Hindi version is a true translation of English version |
| 15. | Conflict of interest for any other investigator(s) (if yes, please explain in brief) |
|   | 1. _______________________________ Yes No |
|   | 2. _______________________________ Yes No |
|   | 3. _______________________________ Yes No |
|   | 4. _______________________________ Yes No |
| 16. | Whether any work on this project has started or not? |
|   | *(mark √ if yes, X if no)*  
|   | (Please enclose a separate certificate to this effect). |
| 17. | Attached documents *(If any)* |
|   | 17.1 Covering letter, through proper channel.  
|   | 17.2 Copy of the detailed protocol is mandatory.  
|   | 17.3 Brief CV of Investigators (including No. of projects with Principal Investigator)  
|   | 17.4 Investigator’s Brochure  
|   | 17.5 Undertaking that the study shall be done in accordance with ICMR and GCP guidelines  
|   | 17.6 In case of multicentric study, IEC clearance of other centres must be provided  
|   | 17.7 Definite undertaking as to who will bear the expenditure of injury related to the project  
|   | 17.8 In case an insurance cover is intended, Insurance certificate must be provided (as per ICMR guidelines)  
|   | 17.9 Permission as mentioned in column 5.9  
|   | 17.10 Certificate/undertaking as mentioned in column 16  
|   | 17.11 Investigator should provide undertaking what they will do with the leftover sample tissue  
|   | 17.12 Others |
| 18. | In case of clinical trials CTRI status |