

BKLWRMC&H

(AX-V /SOP /V)

Project Submission Form for review by Local IEC

A. Project details:

| | |
|---------------------------|----------------------------------|
| Project No. | (Will be allotted by IEC office) |
| Date of Submission | |
| Title: | |
| PI: | |

Please complete the questionnaire for submitting the research proposal for BKLWRMC&H- IEC

Is it a trial? Yes/No (Tick as appropriate)

If No go to Sr. No. 18 in the table below.

If Yes Continue

(Please fill the applicable Y= Yes/N= No)

| Sr. No. | Detail | Yes | No |
|---------|--|-----|----|
| | Controlled trials | | |
| 1 | Is this a randomized controlled trial? | | |
| 2 | Is this a non-randomized controlled trial? | | |
| 3 | Is this a controlled trial that seeks new indication for establishing drug, process or a procedure? | | |
| | Uncontrolled trials | | |
| 4 | Is this a prospective trial testing new intervention, drug, or device on patients? | | |
| 5 | Is this a prospective trial designed to test new (unproven) indication for established drug, process, procedure or device on patients? | | |
| 6 | Is this a pilot trial on new intervention, drug, and device on patients? | | |
| | Trial involve transfer of data/ material from BKLWRMC&H | | |
| 7 | Is this a multi-centre trial? | | |
| 8 | Is this trial involves transfer of patients' data to another site (including industry)? | | |
| 9 | Is this trial involves transfer of patients' blood, serum, DNA, tissue to another site? | | |

| | | | |
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| 10 | Is this a phase IV/ marketing trial undertaken on behalf of the industry? | | |
| | Community or screening trials | | |
| 11 | Will this trial be undertaken in the community? | | |
| 12 | Will this trial involve the screening? | | |
| | Trials involving genomics & proteomics | | |
| 13 | Does this trial involve conducting genomics or proteomics studies on patients' specimens? | | |
| | Trials with conflict of interest | | |
| 14 | Will this trial involve development of a device, drug or test lead to profits or patent? | | |
| 15 | Is this a prospective follow-up study (documentation of parameters only) of patients being offered standard treatment at BKLWRMC&H? | | |
| 16 | Is this a phase II-IV trial restricted to standard intervention/ treatments published in EBM booklet? | | |
| 17 | Is this a feasibility study for introduction of new treatment, recently shown in major international studies, to be beneficial / superior and need to be started at BKLWRMC&H? | | |
| | | | |
| 18 | Is this a retrospective or prospective analysis of charts , data or audit of procedures / tests / treatments? | | |
| 19 | Is this a retrospective or prospective review of pathology specimen (may involve some additional staining techniques)? | | |
| 20 | Is this a retrospective or prospective review of radiology reports and their clinical correlation? | | |
| 21 | Is this a retrospective or prospective review of laboratory reports and their clinical correlation? | | |
| | Procedure / demonstration at workshops etc. | | |
| 22 | Are you demonstrating an experimental procedure which is 'not established standards of care' at a workshop, or a public meeting? | | |
| 23 | Are you performing a procedure in workshop at BKLWRMC&H by non-BKLWRMC&H staff member? (Please check other requirements also) | | |
| | Intramural Funding | | |
| 24 | Are you seeking intramural funding? | | |
| 25 | Does this project use additional resources of BKLWRMC&H beyond the usual patients' work-up (e.g. IHC, molecular profiling, MRI etc. which is not a routine part of work-up)? | | |

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| | Extramural Grants | | |
| 26 | Are you submitting application for extra-mural grant for this project? | | |
| 27 | Is this project partly or wholly supported by grants from sponsored industry? | | |
| 28 | Is this a phase IV/ marketing trial undertaken on behalf of the industry? | | |
| | Modification in approved project | | |
| 29 | Are you seeking modification/s in the BKLWRMC&H- IEC approved trial? | | |
| | Patient to bear the cost of project | | |
| 30 | Are patient going to bear the cost of experimental intervention or drug therapy? | | |
| 31 | Does patient has to undergo additional blood sample collection, biopsy, endoscopy, procedure etc.? | | |
| 32 | Does patient has to bear the cost of complications arising from treatment? | | |
| 33 | For the trial purpose, does the patient has to spend Rs. 5000/- or more above the usual expenses (for any reason such as drug therapy, additional investigation, prolonged stay or repeated travel)? | | |

If you have any questions, concerns, suggestions regarding the studies for (02355) 264149 extn: 495, email: asyadav13@gmail.com or dr.suvarnanpatil@gmail.com

| | | |
|----------------|--|------------|
| Name of PI: | | Signature: |
| Name of CO-PI: | | Signature: |

Project Submission Form for review by IEC

B. Project Fact Sheet

| | |
|---|--|
| Project No. (To be filled by the Secretariat) | |
| Date of receipt by IEC | |
| Project Title | |
| Key Words title (2-4 options) | |
| Principal Investigator | |
| Number of ongoing studies in which PI is involved? (as PI only) | |
| Contact number Principal Investigator | |

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| Co-Principal Investigators (if any) | |
| Co-investigators | |
| Site/sites where study is to be conducted i.e. BKLWRMC&H / ACTREC / Both. (Please specify). | |
| Tick the type of study applicable | <input type="checkbox"/> Investigator Initiated study <input type="checkbox"/> Pharmaceutical Study <input type="checkbox"/> Thesis <input type="checkbox"/> Others |
| Agency or Sponsor or funding resource | |
| Total estimated budget in Rs. | |
| Duration of the Project (months) | |
| Suggested date of starting the study | |
| Total number of subjects to be accrued in study (including BKLWRMC&H, if multi-institutional study) | |
| Number of subjects from BKLWRMC&H to be accrued | |
| Will biological products be sent out of the country?(Yes/No) If yes attached the copy of regulatory clearance obtained [DCGI/ ICMR /Health Ministry Screening Committee (HMSC)] | |
| Any Conflict of interest, (Yes/No) If Yes Please specify | |
| Signature of PI | |
| Date of submission | |

Investigators Declaration

| | |
|-----|--|
| 01. | This research project (including collection of blood or tissues samples for research) will not be started until the final approval of the IEC has been obtained. |
| 02. | We agree to undertake research proposal involving human subjects in accordance with the Schedule Y (Drugs & Cosmetics Act 1940), ICH-GCP and ICMR ethical guidelines, 2006. We will not modify the research protocol, consent, etc without prior approval by the IEC. |
| 03. | The investigators agree to obtain a properly informed and understood consent for all trial subjects before their inclusion in the trial in the informed consent form that is approved by the IEC. Participants will receive an 'information sheet' which will detail the project design in simple understandable layperson's language. |
| 04. | The investigators agree to report within a week all serious adverse events (SAE) associated with the trial in the SAE form to the IEC. In the event of a death of the trial subject, the Secretary, IEC and DSMSC, will be informed within 24 hours. |
| 05 | The investigators agree to submit status report atleast annually of the trial in the appropriate form. A final report will be submitted at the end of the trial. |
| 06 | Full details on funding and a proposed budget are included with the trial proposal. The proposed budget is presented on the specific budget sheet of this form. |
| 07 | We understand that the IEC is concerned about transparent financial transactions during the trial. A report on how the trial funds were utilized will be presented to the EC along with the final project report at the end of the trial. |
| 08 | The investigators agree to transfer 10% of the total budget to BKLWRMC&H as service charges and Estimated Professional charges for clinical services. (15% at the end of the study on actuals). This will not apply to intramural projects, those projects co-sponsored by BKLWRMC&H/ CRI/ ACTREC/ DAE and ICMR/ DBT /DST/WHO/IAEA funded projects. |
| 09 | The investigators agree that the grant money will be spent in accordance with the budget proposal only. The funds will not used for any other purposes without prior approval from the IEC. Thirty percent of the surplus grant if left over at the end of the study will be credited to BKLWRMC&H. The remaining 70% of the surplus grant money may be used by the investigators for conducting intramural research, improving teaching facilities in the department, providing financial assistance to investigators for conferences, etc after obtaining permission from the IEC. |
| 10 | For all research proposals that are sponsored by a pharmaceutical or biomedical company, we the investigators will ensure that the Sponsor Company will underwrite all expenses such that neither the hospital nor the study participants are made to spend while participating in the trial. The investigators will also ensure that in the event of complications arising directly due to the trial or litigation, the cost of management or legal fees will be borne by the Sponsor Company totally. |
| 11. | The investigators will declare any financial gain from the commercial sponsor and any conflict of interest in the drug or product by way of consultations, shareholding, |

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| | etc as detailed in the BKLWRMC&H Conflict of Interest Policy. |
| 12. | The investigators will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the Institutional Ethics Committee. BKLWRMC&H, approved protocol. |
| 13. | All data collected during the research project, including those supported by commercial sponsors (e.g. pharmaceutical company), will remain the property of BKLWRMC&H or as per the Clinical Trial Agreement. |
| 14. | The salaries to staff employed for the research project will be as shown in the budget sheet and at par with the prevailing BKLWRMC&H salary scales. |
| 15. | The study documents will be made available to members of the IEC any time for random verification and monitoring. The study documents must ensure archived for 15 years post study close out or until the sponsor confirms that the records are no longer required; whichever is earlier. |
| 16. | The investigators promise to ensure that there is no falsification of data when compared to the source documents. We agree to clarify any doubts or discrepancies that may arise during the data monitoring evaluation. |
| 17. | All the findings and conclusions of the proposed project such as review of case records, analysis of forms of treatment, investigations, etc will be first presented to the staff members of BKLWRMC&H before they are released or presented elsewhere. |
| 18. | The investigators will not issue any press release before the data and conclusions have been peer-reviewed by the BKLWRMC&H staff or published in a peer-reviewed journal. |
| 19. | All serious injuries arising from the trial will be the responsibility of the Investigators. The investigators agree to cover any expenses for injury and/or compensation arising from the study as per the national regulations/institutional policies.. |
| 20. | The investigators will constantly inform the IEC about amendments in the study protocol, data collection forms, informed consent forms, budget expenses, salaries, other trial documents, etc. as and when they occur. No changes in the study protocol or conduct of the study will be carried out without prior approval of the IEC. |
| 21. | The investigators realize that the IEC is particular that all aspects of the study are in accordance with the Schedule Y (Drugs & Cosmetics Act 1940), ICH-GCP and ICMR ethical guidelines, 2006. The investigators will comply with all policies and guidelines of the BKLWRMC&H and affiliating/collaborating institutions where this study will be conducted, as well as with all applicable laws regarding the research |

We the investigators of the proposed trial have read all the statements listed above and agree to observe / undertake these IEC requirements while conducting our proposed project/ trial

We understand that serious protocol violations and/or non-compliance during the trial by the investigators may result in withdrawal of project approval by IEC

Study Team Undertaking with Duties & Delegation

| | CC No. if available | Investigator Name | Email | Status (PI, Co-PI, CI) | *Role & responsi bility | Conflict of Interest Yes/No If Yes Please specify | Sign & date |
|---|------------------------|----------------------|-------|---------------------------------|-------------------------------|---|----------------|
| 1 | | | | | | | |
| 2 | | | | | | | |

- Choose from the following list.

| | |
|---|--|
| A. Concept B. Design C. Screening of patients D. Selection & Recruitment and consenting of patients E. Laboratory investigations F. Laboratory report interpretation G. Treatment decision H. Patient evaluation I. AE and SAE management, evaluation and reporting | J. Examination of patients on follow-up K. Data collection and monitoring of data L. Interpretation of data M. Statistical analysis & Interpretation N. Maintaining patients file and master file of project O. Drafting final report P. Publication Z. Any other, please specify |
|---|--|

Note: Investigators may clarify any of the points in this undertaking with the IEC secretariat

Financial Disclosure Form for Researchers

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|-------------------------|
| Project entitled: |
| Name of PI: |
| _____ |

1. Employment or Leadership Position

Check yes if you or an immediate family member currently holds any full-time or part-time employment or service as an officer or board member for an entity having an investment, licensing, or other commercial interest in the research study under consideration

Yes No If yes, amount received in last 12 months in Rs.

2. Consultant or Advisory Role

Check yes if you or an immediate family member holds or has held any consultant or advisory arrangements with an entity having an investment, licensing, or other commercial interest in the research study under consideration,

Yes No If yes, amount received in last 12 months in Rs.

3. Stock Ownership

Check yes if you or an immediate family member currently holds any ownership interest in any company (publicly traded or privately held) that has an investment, licensing, or other commercial interest in the research study under consideration

Yes No If yes, amount received in last 12 months in Rs.

4. Honoraria

Check yes if you or an immediate family member has been paid directly any honoraria (reasonable payments for specific speeches, seminar presentations, or appearances) from an entity that has an investment, licensing, or other commercial interest in the research study under consideration

Yes No If yes, amount received in last 12 months in Rs.

5. Research Funding

Check yes if you or an immediate family member currently conducts any clinical research project(s) funded, in whole or in part, or has received any post study awards by an entity that has an investment, licensing, or other commercial interest in the research study under consideration

Yes No If yes, amount received in last 12 months in Rs.

6. Patent or Royalty interests

Check yes if you or an immediate family member has received any patent or royalty from an entity having an investment, licensing, or other commercial interest in the research study under consideration

Yes No If yes, amount received in last 12 months in Rs.

7. Other Remuneration

Check yes if you or an immediate family member has received any trips, travel, gifts, or other in-kind payments at any point from an entity having an investment, licensing, or other commercial interest in the research study under consideration

Yes No If yes, amount received in last 12 months in Rs.

I hereby agree to recuse myself from any deliberations and actions involved in the approval or re-approval of a protocol for which I have a real or apparent conflict of interest, and from discussions of these matters unless my presence for discussions is requested by the IEC Chair.

- I hereby declare that I have no conflict of interest in my project.
- I have above conflict of interest:

| | |
|------------------------|-------------|
| Signature of PI | Date |
|------------------------|-------------|

Consent of Head of the PI's Department
Date:.....

I have reviewed the above project submitted by
Principal Investigator from my Department. I endorse the project and have 'no objection'
for submission for consideration by Institutional Ethics Committee.

I concur with the participants / investigators included in the study.
I have reviewed the financial and non financial disclosure

Yes No

PI has conflict of interest
 Yes No

| | | |
|------------------|------|------------|
| Signature & date | Name | Department |
|------------------|------|------------|

Consent from Disease Management Group(DMG) / Working Group
Date:

The above project submitted by , Principal Investigator, has been discussed in theworking group and has been

accepted to be submitted for submission for Institutional Ethics Committee consideration.

The investigators / participants included in the study are acceptable to the members.

I have reviewed the financial and non financial disclosure

Yes No

PI has conflict of interest

Yes No

| | |
|------------------|--|
| Signature & date | Name (Convener or senior member of DMG/ working group) |
|------------------|--|

C. Project Submission Overview

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|---|--|
| Title | |
| Short Title | |
| Names of all Investigators (underline principal investigator) | |
| Introduction/ background Give the background, including human or animal research relevant to the design of the proposed study. When new techniques or procedure are to be used, provide a description of preliminary work. When an investigation drug is to be used, animal data and phase I or II data on the drug should be included. A summary of how the study may help in the future should be included in the protocol. | |
| Aims/ Objectives Clearly state the aims or objectives of the study. Whenever possible this should be in the form of a hypothesis. | |
| Design of the Study | |
| Phase-I, Phase-II, Phase-III, Phase-IV, NA | |
| Randomized [Double or single blind], Open | |
| If multicentric, is BKLWRMC&H the co- | |

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| coordinating centre? | |
| Please tick if applicable Epidemiological [] Survey [] Observational [] Case control [], Thesis [] Any other (Specify) | |
| <p>Study methodology Explain, in sequence, the conduct of study and all data collection procedures. Describe the involvement of human subjects including initial evaluation procedures and screening tests, phases, medical/surgical procedures and sequence of the study. Separate standard and experimental aspects of the study as much as possible. Give brief account of procedures for treatment, dose adjustments, etc. Describe the randomization procedure, if applicable. Specify if procedure involves banking of biological samples. Define stop points and criteria for withdrawing subjects from the study.</p> | |
| <p>Eligibility (Explain inclusion and exclusion criteria; To be stated clearly in the summary) (specific explanation if participants will include Minor, Pregnant woman, Neonate, Person incompetent to give informed consent, Normal / Healthy volunteer, Student, Staff of the institute).</p> | |
| How many subjects will be screened? How many subjects are likely to be enrolled? | |
| Describe benefits to the subject/participant in this study. Also describe the benefits, if any, to the society. | |
| <p>Power estimates Describe power calculations, if the study involves statistical comparisons between two or more groups. Mention evidence to support that adequate number of subjects can be enrolled during the study period</p> | |

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| by the investigators. | |
| <p>Variables to be estimated (e.g. response, survival, toxicity, age, etc) Enumerate the variables, outcomes and end points that will be measured. Try to separate variables as response and explanatory variables. Describe the type and frequency of tests, admissions, outpatient visits, etc used to obtain these variables or variables.</p> | |
| <p>Analysis of the variables Describe how the variables obtained during the study will be statistically analyzed. e.g. Univariate comparison or Cox- proportional hazards model, etc</p> | |
| Describe all possible risks and discomfort for subjects due to use of intervention and /or data collection methods proposed. Describe expected degree and frequency of such risks, discomfort, side effects of drug etc. | |
| If the procedures in the trial are invasive or potentially harmful, describe what arrangements have been made for treatment of the complications arising from the trial? | |
| Who will bear the cost of treating the complications arising from this trial? | |
| Does your study involve testing of drug/s, device/s and/or biologics? | Yes [] No [] |
| Are they already approved by the regulatory authorities and available in the market or are they new ones? | Already approved [] New one [] |
| Does your study involves modified or new claims, namely, indications, dosage forms (including sustained release dosage form) and route of administration of already approved drugs and combination of two or more drugs | Yes [] No [] |
| Who has prepared and /or is manufacturing the drug/s, device/s and biologics under investigation? | |

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| Who holds the patent or IND/IDE of the drug/s, device/s and biologics under investigation? | |
| What are the reasonable possibilities of the availability after the study of the investigational drug(s), device(s) and biologics for the study participants/subjects if it is found to be effective? | |
| Does your study require permission from regulatory authorities? | Yes [] No [] |
| If yes, | |
| (i) from DCGI | Yes [] No [] |
| (ii) from the ICMR | Yes [] No [] |
| (iii) From other govt. departments | Yes [] No [] |
| If yes, specify the department Whether permission is obtained | Yes [] No [] |
| Does your study require you to send human biological material outside India? | Yes [] No [] |
| If yes, have you obtained permission of the director, BKLWRMC&H & DCGI? | Yes [] No [] |
| Has BKLWRMC&H and the foreign party signed agreement/MOU for that? If yes, attach a copy of agreement/MOU | Yes [] No [] |
| If study will be conducted fully or partially outside the BKLWRMC&H, please describe the need for permission from institution(s), health centre(s), local government/administrative bodies, etc. | |
| Have you define adverse events in your study, and what rules you will use for stopping the study due to adverse events. (Please note that SAEs have to be reported to IEC as per national regulations and SOPs.) | Yes [] No [] |
| In what way will you ensure the confidentiality and privacy of the subjects? | |
| If some procedures in this trial are emotionally upsetting describe what arrangements have been made for psychological counseling? | |
| Describe (i) How, where, when and by | |

| | |
|--|--|
| <p>whom the Informed Consent will be obtained. (ii) how much time the subject/participant will be given to consider participation and decide, (iii) describe additional plans/needs for informed consent in case the study involves special population such as minors, pregnant mothers, neonates, etc. (iv) Describe how you will assess that information is correctly understood by the participant.</p> | |
| <p>Who will be maintaining the trial records and where? For how long will the data be stored? Give details of where they will be stored, who will access</p> | |
| <p>Does your study have provisions for monitoring the data to ensure the safety of participants?</p> <p>Who is responsible for monitoring and ensuring the safety of participants?</p> | <p><input type="checkbox"/>Yes <input type="checkbox"/>No <input type="checkbox"/>NA</p> |
| <p>Post trial access will be provided</p> <p>If yes, describe briefly arrangements for pot trial access.</p> | <p><input type="checkbox"/>Yes <input type="checkbox"/>No <input type="checkbox"/>NA</p> |
| <p>Does any of the investigators/research staff and /or their close relative/s have any the financial and other interests of with the sponsor/s and outcome of the study?</p> <p>Describe briefly, if any, the financial and other interests of any of the investigators/research staff and /or their close relative/s, with the sponsor/s and outcome of the study.</p> | <p><input type="checkbox"/>Yes <input type="checkbox"/>No</p> |
| <p>Have you made provision for insuring yourself, and BKLWRMC&H against any legal action that may arise out of this project?</p> | |
| <p>Have you made provision for insuring trial</p> | |

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| subjects for any accidental unforeseen trial related injury? | |
| How is it intended the results of the study will be reported and disseminated? | Please tick in the box <input type="checkbox"/> Peer reviewed scientific journals - <input type="checkbox"/> Other publication - <input type="checkbox"/> Conference presentation - <input type="checkbox"/> Internal report - <input type="checkbox"/> Submission to regulatory authorities <input type="checkbox"/> Access to raw data and right to publish freely by all the investigators in study or by independent steering committee on behalf of all investigators OtherPlease specify..... |

| | | |
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| Name of PI: | Signature: | Date: |
| Name of CO- PI: | Signature: | Date: |

D. Budget Sheet for the Proposed Study

| | | |
|---|--|------------------------------------|
| 1 | Title of the Project: | |
| 2 | Principal Investigator | |
| 3 | Designation and address of the PI | |
| 4 | Co-investigators: | |
| 5 | Source of funding | |
| | Government: | Central [], State [], Local [] |
| | Intramural | |
| | Private Foundation: | Indian [], Foreign [] |
| | Industry: | Private [], Public [], Other [] |
| | Other: | |
| | No funding required | |
| | Address, phone, fax. E-mail of sponsor with the name of the contact person | |
| 6 | Total Budget for the entire project in Rs. | |
| 7 | Duration of the Project in months | |
| 8 | Proposed date of starting the project | |

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| 9 | Direct payments to investigators, if any | |
| 10 | Any other benefits to the investigators | |
| 11 | Conflict of Interests, if any | |
| 12 | Type of project funding | |
| | Intramural from BKLWRMC&H | |
| | Non profit agency/trust funded | |
| | Pharma./ industry sponsored | |
| | Others –specify | |

| | | |
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| Name of PI: | Signature: | Date: |
| Name of CO- PI: | Signature: | Date: |

Detailed Budget for the Proposed Study*

| 1. Source of funding | Please specify | | | |
|---|----------------------|----------------------|----------------------|-------|
| | 1 st Year | 2 nd Year | 3 rd Year | Total |
| Items | | | | |
| 2. Salaries-personnel (Numbers) | | | | |
| Research Nurse | | | | |
| Doctor (Research Fellow) | | | | |
| Data operator | | | | |
| Any other specify | | | | |
| 3. Equipment and Hardware | | | | |
| - | | | | |
| 4. Drugs and Consumables | | | | |
| - | | | | |
| 5. Clinical Investigations | | | | |
| - | | | | |
| 6. Hospitalization | | | | |
| - | | | | |
| 7.Travel expenditure for investigators | | | | |
| - | | | | |
| 8. Travel expenditure for trial subject and one attendant | | | | |
| 9. Honorarium to doctors/technicians | | | | |
| 10. Insurance | | | | |
| i. for investigators | | | | |
| ii. any unforeseen, accidental trial related injury | | | | |
| 11. Any other expenditures | | | | |
| 12.Miscellaneous (<5% of budget) | | | | |
| 13. Total | | | | |
| 14. BKLWRMC&HRMCAH Service Charge (10% of total) (BKLWRMC&H, DAE, ICMR, DBT, DST, IAEA, WHO, IARC etc. funded project are exempted) | | | | |
| 15. Estimated Professional charges for clinical services. (15% at the end of the study on actual) | | | | |
| Grand Total | | | | |

| | | |
|---------------|------------|-------|
| Name of PI: | Signature: | Date: |
| Name of CO-PI | Signature: | Date: |

Note:

- PI should devise incremental budget whenever necessary.
- Please provide the complete break-up of item nos. 3, 4 & 5 on separate sheet.

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| Project No. | |
| Trial Register No. | |
| Project Title (To be filled by PI) | .. |
| Revised Title if any (To be filled by IEC) | |
| Principal Investigator | .. |

Institutional Ethics Committee Approval

The members of the **Institutional Ethics Committee** met on at BKLWRMC&H and reviewed the above named project with all the documents submitted. The **Institutional Ethics Committee** after careful deliberations has granted final approval to the project. The above mentioned project/ study may now be undertaken at BKLWRMC&H in accordance with the study protocol submitted by the investigators, subject to fulfilling local and other institutional regulations.

| | |
|------------------------|------------------|
| Member Secretary | Chairperson..... |
| Name: | Name:..... |
| Date..... | Date..... |

Instructions:

- This form must be printed and not handwritten.
- Fill the form completely (If there are any questions/queries, please contact the IEC office 02355-264149 EXT: 495)
- Make sure to include the e-mail address and contact numbers of the PI, Co-investigators.
- Please submit the documents as per the checklist (AX2-V3/SOP03/V3) to ensure all requirements for submission are fulfilled for timely review by IEC.

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- Submit the submission form (Part A,B,C,D)along with the supporting documents to the IEC office.