Proforma for research activities at Jhargram Govt Medical College & Hospital, (JGMCH), Jhargram (Other than drug trial)

Instruction: **Submit 1+ 1 copies (1 hard+1 soft) of the research documents along with the application form and the covering letter needs to be submitted to the PRINCIPAL, Jhargram Govt Medical College & Hospital, (JGMCH), Vidyasagarpally, Jhargram West Bengal, India**

No research project shall be/can be started unless ethics and administrative approval is obtained. Proposal must contain the telephone no and email id of principal /co investigator for further communications.

Principal investigator/co investigator should inform the progress of the study monthly after obtaining ethical clearance and at the end of the study, otherwise ethics committee has the right to enquire the same from the investigators or visit the site. Study completion report must be reported to Principal JGMCH.

1. Title of the Research:
2. Name of the Investigator / Principal Investigator :
3. Department/Division:
4. Designation:
5. State:

a) The number of ongoing research projects as principal investigator:

b) Source and amount funds in each of his/her research project:

6. Name of the Co-Investigators :

(Qualification, Designation Department)

7. CV of each investigator(in case if the investigator belongs outside the institute): NA

8. Is the study Intradepartmental/ Interdepartmental :

If interdepartmental

a. State names of the collaborating departments :

b. Whether consent obtained from them:

If inter-institutional:.

a. State the name of co-ordinating institution:

b. State the name of the collaborating institution:

c. State whether consent obtained from the collaborating institutions (Enclose copies):

9. State whether you have enclosed a copy of the original research :.

protocol submitted by the co-ordinating institution:

10. Duration of Proposed Study:

11. Date of start of the study:

12. Month and year of Proposed Termination:

13. Is the study Interventional:.

14. Have the investigator(s) received any special training for carrying out this study or intervention?

15. Telephone (mobile), email id of principal/co-investigators :

16. Objectives

    a. Overall

    b. Specific

17. The study design

18. Study duration and place of study

19. Sample size and sampling method

20. Methodology (Details about every parameter studied)

21. The population studied: Inclusion and exclusion criteria (explanation if vulnerable Population included deliberately)

22. The detailed methods

    a. How will the subjects be recruited.

    b. How will the study/ intervention be carried out.

    c. What outcome will be measured and how.

    d. Specify if procedure involves banking of biological samples, HIV testing, genetic testing.

    e. Plan of data analysis – including by whom and how.

    f. Please mentioned whether data will be analysed to understand politically and socially sensitive group differentials- gender, cast class, ethnicity, race.

23. Systemic in place for reduction, management of anticipated and unanticipated risks, discomfort, adverse events/toxicity and their monitoring.

a. Describe all possible risks and discomfort for subject/participant due to use of intervention and/or interaction procedures/data collection methods proposed.

b. risk reduction: Describe steps you have taken or propose to take to minimise such risk, discomfort or for early recognition of side effects and their management.

c. Does the project require appointment of a data safely Monitoring board(DSMB)?.

If so, give the following details:.

d. Data and Safely Monitoring:

i. Define adverse effects in the study

ii. How and to whom you propose to report them

iii. Describe rules for stopping the study due to adverse effects.

iv. Describe Data and Safely Monitoring Plan of your project.

24. Privacy and Confidentiality:

a. Measures to provide privacy to subjects/participants while conducting study:

b. What level of confidentiality promised:.

c. What are the likely consequences to the subject/participant in the event of violation of confidentiality.

d. The types of identifiable information on subject/participant collected :.

e. How will they be masked/removed:

f. How will this data be stored and its safe keeping ensured.

25.Benefits of the study:

a. Benefits to the subjects to the study:

b. Benefits, if any to the society.

c. Risk/Benefit analysis to be presented.

26. Informed consent

a. Describe the process:

i. How, where, when and by Whom the informed consent will be

obtained:

ii. Additional plans/needs for informed consent in case the study involves special population such as neonates, children, adolescents, pregnant women, prisoners, etc :.

iii. How you will access that information is correctly understood by the participant.

b. Content:

i. Statement that consent is for a study/research/experiment,

ii. And explanation of the purpose of research and nature of procedure.

iii. All foreseeable risks/discomforts to participants due to research must be enumerated:

iv. Any benefits to be expected should be mentioned:

v. Alternative procedures or courses of treatment in case subject does not want to participate.

vi. The extent of confidentiality protection provided:

vii. Explanation of provision of compensation for injury caused to participant during the study.

viii. Whom to contact to know more about the study and participant's rights:

ix. A statement that participation is voluntary:

x. A statement that participant can withdraw consent and from : the study at any time without any facing penalty.

xi. The reimbursement of expenses and compensation provided to trials subjects for participation:

xii. The post-trial benefits would be given to the trial subjects.Whether the investigational drug of odd device will be provided to the study participants/subjects if it is found to

be effective.

27. Financial:

a. Type of funding- Contract/Grant, Subcontract,

Gift/donation of drugs/devices:

b. Source of funding:

Government:Central/State/Local/Intramural:..

c. Private foundation: Indian/Foreign

d. Industry:Private/public/Other

e. Other/unfounded/non funding required

f. Compensation to trial subjects-give details.

g. Other studty participants,investigators and institution protected by insurance coverage to cover litigation costs and compensation?

h. If yes, specify the amount and conditions of coverage.

i. Provide a copy of insurance document

j. Budgets details(show fund allocation to various heads-manpower, material, etc.)

[For extra mural research Programme, as per ICMR guidelines 5% of the total cost of the project needs to be deposited to the Institution as overhead expenses.]: As per protocol

28. Statement on Conflict of Interests – The financial and other interests of any of the investigators and/or close relative(s) and outcome of the study. No conflict.

29. List of attachments:

a. Full proposal, with protocols/instruments for data collection and budget in detail.

b. I accept ultimate responsibility for the conduct of this study, the ethical performance of the project, and the protection of the rights and welfare of the human subjects who are directly or indirectly involved in this project.

c. I will comply with all policies and guidelines of Jhargram Govt Medical College & Hospital where this study will be conducted as well as with all applicable loss regarding theresearch.

d. I ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the IEC-JGMCH, Kolkata for the approved protocol.

e. I will not modify this IEC certified protocol or any attached materials without first obtaining approval for an amendment to the previously approved protocol.

30. Name and signature of investigator with date.

31. Name and signature of the head of the department of the principal investigator with date

32. Name and signature of all co-investigators with date.

33. Name and signature of the head of the department of each of the co-investigator with date.

Checklist for enclosures

(To be filled by the Investigator)

1) Research proposal form	Enclosed Yes/No
2) Short summary (synopsis) of research proposa	Enclosed Yes/No
3) Informed consent documents(patient information sheet Informed consent form etc) as per Appendix V of schedule-Y	Enclosed Yes/No
4) Compensation for the injury or death"	Enclosed Yes/No
5) Principal investigator's certification	Enclosed Yes/No
6) Any other documents enclosed(give details) 7) Signature of the investigators: 8) Signature of all the co-investigators: 9) Signature of Head of the Department of the investigators 10) Signature of Head of the Department of each of the investigators co-investigators: (To be filled by the Investigator) 1. Project Title: 2. Name of the Investigator with designation : 3. Department /Division: 4. Name of Co-Investigators:	Enclosed Yes/No

(Qualifications, Designation & Department) 5. Sponsor's Name:	

(For Office use)

EC NO_____Date of receiving the proposal:

:

Signature of Member-Secretary, EC

10. Ethics Committee approval No and date:

11. Date of submission of copy of ISA submitted to Office of Dean(Research):

12. Year of start of the study:

13. Year of proposed termination of study:

14. Year actually finished:

15. Project completion report submission date:

Signature of Principal