ALL INDIA INSTITUTE OF MEDICAL SCIENCES, JODHPUR

Guidelines/SOP for Industry Sponsored Clinical Trials of Drugs and New Devices

Research Section

AIIMS, Jodhpur

1. Preamble:

Clinical trial conducted in the AIIMS Jodhpur should follows the highest standard of ethics as per the national and international norms. The research should be in sync with the disease burden of the India.

2. Purpose and Scope:

- The proposed study should aim to
- Develop a new chemical entity or new drug which includes pre-clinical and clinical studies – all phases of clinical trial
- Investigate a new use/indication of the existing drug.
- Develop and/or testing new medical devices/ techniques and investigations to be used clinically.
- Develop and /or advanced technology for patient care, teaching and research.

3. Scientific merit: The study should be conducted to develop new drugs & molecules or newer uses of available drugs, new biological agents, vaccines and new medical devices. Clinical trial should be done preferably for the diseases common in the India as mentioned in the thrust areas identified by Govt. of India, ICMR, WHO and similar organizations.

4. Sponsors of the study:

- Original manufacturers of medical devices, drug molecules and investigational new drugs.
- Government, semi-Government and private research & development organizations in India and abroad.

5. Eligibility of investigators: The principal investigator should have a postgraduate degree in the concerned specialty and be a permanent employee of the Institute

6. Appointment of project staff: The Principal Investigator will appoint project staff as per the norms of the institute.

7. Responsibility of Principal investigator (PI)

The PI will be responsible and accountable for all scientific and financial aspects of project. PI will be submitting the research and synopsis proposal to the clinical research committee and institute ethics committee, AIIMS Jodhpur for approval as per guidelines of the institute (Ref. Annexure 1-6). Any query or communication of the Institute authorities will be done by the PI only.

In case of sponsored trial PI will also be responsible for preparing and execution of the agreement between Principal Investigator and sponsoring agency.

8. **Initiation of proposal in sponsored trial**

Authorized person of the industry/agency interested to carry out clinical trial/project at AIIMS Jodhpur, may approach the concerned department HOD/Faculty member with a request to conduct the trial. The concerned faculty will be the Principal Investigator and submit the proposal for Director's permission through Clinical research committee through proper channel.

Investigator Sponsor Agreement (ISA): The sponsor and the investigator should enter into an agreement before proposing the study. **The institute will NOT be a part of the agreement.**

The ISA should include the details of sponsors and investigators, obligations and responsibilities of sponsor and investigators, funding, Ethics committee and informed consent, duration of the study and agreement, protocol, subject enrolment, study conduct, study data, biological samples, study records, disclosure required by law, confidentiality agreement, monitoring, inspection and audit, issues related to invention, patents, intellectual property rights, publication rights, indemnification, liability and insurance, conditions for termination of project, governing law or any relevant details.
The PI of the trial/project is permitted to negotiate the terms and conditions of the trial/project with the funding agencies. It is preferable to retain the publication rights with the PI. The PI and other investigators are also permitted to attend the "Investigators' Meeting" with regard to development of methodologies and protocol of the clinical trial/project. **The finance for any activity of the project will not be borne by the Institution.**

It is the responsibility of the Principal Investigator to get the trial registered with Clinical Trial Registry of India.

9. Insurance: Insurance liabilities of all study participants against any anticipated or unforeseen injuries, illnesses etc. related to the study lies on PI/sponsor agency.

10. Funding: The details of funding including head-wise proposed expenditure, overhead charges for the institute, subject compensation should be submitted. All payment should be sent in the name of "The Director, AIIMS Jodhpur". (Ref. Annexure-3). ***Honorarium of any kind to Principal Investigator/ Co-Principal Investigator is not allowed.***

11. Institute fee (Institute overhead charges): For the projects with a total budget of up to INR five lakhs, the Institute Overhead charges would be 10% of the overall budget, whereas for the proposals with a budget of more than five lakhs it shall be 25% of the total cost of the project.
Fifty percent of the overhead charges will be provided to the principal investigator. The Principal Investigator in consultation with the Head of Department and other faculty members will use this money exclusively for research and academic purpose and for the infrastructure development of the parent and collaborating departments.
The institute fee for the Government sponsored projects (e.g., DBT, ICMR etc.) will be as per their norms.

12. Release of funds:
Once the funds deposited to the Institute, the Principal Investigator can maintain a current A/C jointly with the Co-I on the name of trial where an advance of not more than 25% can be transferred with a justification and the next amount shall only be released after the submission of Utilization Certificate of the earlier amount.

Once the study has been executed, PI should submit the final report to the sponsor as per the investigator sponsor agreement with a copy to the Director office through the Head of the Department.

13. Ethics committee approval: The ethics committee will take up proposals submitted to clinical research committee. A fee of INR 20,000/- (in favour of AIIMS IEC FEE) shall be levied upon the Sponsoring agency as fee for considering the proposal in IEC.

The proposal will first refer to Drug Trial Committee (DTC)) for approval. Dean (Research) will be the chairman of the committee. The committee constitution will be decided by the Director, with preferably member of the Department of Pharmacology as (Member Secretary). The Chairman can co-opt up to 2 subject experts related to the project. DTC will have monthly meeting on first Thursday of the month (or any other day as seems suitable to all). It will exclusively consider, discuss and approve proposals submitted for clinical trial of new drugs and new medical devices. DTC must ensure the study is conducted with respect to good clinical compliance and patient safety.

The proposal will be then referred to Ethics Committee of the institute. DTC will submit the decision to clinical research committee/IEC. The study should be approved by the Institute (Human) Ethics Committee before starting the study. PI will not start the study till he gets the approval from IEC. The Principal Investigator and Co-investigators will submit a six monthly progress report to Institute Ethics Committee. (Ref. Annexure-7).

14. Reporting of Serious Adverse Events/SAE data safely: Serious adverse events should be submitted to IEC/clinical research committee within 24 hours by PI (Ref. Annexure-8). IEC will assess the SAE and will report it within 30 days to the respective authorities. In case of sponsored trial it should be as per guidelines (Ref. Annexure 8 &9).

T**o assess the adverse events in clinical trials, a subcommittee for SAE termed as data safety monitoring committee DSMC will be constituted by IEC. Its function includes giving opinion on causality of SAE and submit it to DCGI within 14 days of occurrence with intimation to IEC. It will also decide the amount of compensation to be given to the patients with trial related injury along with monitoring of clinical trial. DSMC will prepare its own SOP which has to be ratified by IEC before implementation. The subcommittee should review the SAE during trial. When the risk is found to outweigh the potential benefits or when there is conclusive proof of definitive outcomes, physician must assess whether to continue, modify or immediately stop the study). Protocol of reporting has to be prepared.**

15. Drug Controller General of India (DCGI) permission: The sponsoring agents should submit drug controller's permission along with their proposal, wherever needed.

16. Health Ministry Screening Committee (HMSC) Permission: The approval from the HMSC, Govt. Of India should be obtained for multinational studies, wherever necessary.

17. Utilization of unspent balance: The Principal Investigator shall refund all the unspent money to the funding agency.

18. Closure of the study: At the time of closure of study, the Principal investigator should submit project completion report and also audited statement of accounts to the Director office through Clinical Trial Research Committee, within 4 months of completion of the study.

19. In case of any dispute related to clinical trial, the Director, AIIMS, Jodhpur decision is final.

20. Legal aspects: The ISA shall be governed by and interpreted in accordance with the laws of India and both Parties consent to the exclusive jurisdiction of the **Courts at Jodhpur, Rajasthan, India.**

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Checklist

SCTRC No:_____

(For Office use)

Checklist for enclosures: (Please submit five hardcopies and soft copy in single PDF)

Page No.

1. Research project proposal (a) Non-sponsored (b) Sponsored Clinical Trial	(Annex.1a & b)	Enclosed	Yes/No
2. Short summary (synopsis) of research Proposal	(Annex-2)	Enclosed	Yes/No
3. Application for project proposal approval		Enclosed	Yes/No
Including budget details	(Annex.3)	Enclosed	Yes/No
4. Informed consent Form/ Patient's information Sheet	(Annex –4)	Enclosed	Yes/No
5. Undertaking by the investigator	(Annex – 5)	Enclosed	Yes/No
6. Details of other funded projects –	(Annex – 6)	Enclosed	Yes/No
7. Format of clinical study report	(Annex-7)	Enclosed	Yes/No
8. Format of reporting ADR	(Annex-8&9)	Enclosed	Yes/No
9. Ethics committee approval (In case of multi-centric trial)		Enclosed	Yes/No
10. Insurance details		Enclosed	Yes/No
11. Request letter from sponsor		Enclosed	Yes/No
12. Investigator sponsor agreement (ISA) (As per guidelines of the Institute)		Enclosed	Yes/No
13. DCGI approval (if applicable)		Enclosed	Yes/No
14. HMSC permission (For multinational trial)		Enclosed	Yes/No
15. Demand draft (in favour of AIIMS IEC FEE) INR 20,000/- Draft No. & Date –		Enclosed	Yes/No
16. Any other documents enclosed (give details)		Enclosed	Yes/No

17. Details of Investigators & Signature

Name:
Designation:
Department:
Signature with seal & Date:

Co-Investigators:
Name:
Designation:
Department:
Signature with seal& Date:

(Annexure-1(a))

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RESEARCH PROJECT PROPOSAL (Non-sponsored)

GENERAL INFORMATION

1.Name of the Investigator:

2.Department/Division:

3.Designation:

4.Name of the Co-Investigator:

5.Title of the Project:

6.Year of start of the study:

7.Year of Proposed Termination:

8.Is the study Inter-institutional (National/International):

9.Is the study Interventional:

10. Are the non-drug interventions to be used professionally accepted

(Annexure-1 (b))

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RESEARCH PROJECT PROPOSAL (Sponsored Clinical Trial)

GENERAL INFORMATION

1. Name of the Investigator :
2. Department/Division:
3. Designation:
4. Name of the Co-Investigator:
5. Title of the Project:
6. Year of start of the study:
7. Year of Proposed Termination:
8. Is the study Inter-institutional (National/International):
9. Is the study Interventional:
10. Sponsor's Name:
11. Are the non-drug interventions to be used professionally accepted?
12. Are the drugs to be used approved for these indications by DCGI? (Enclose the approval letter for the drug from DCGI for trial on human)

(Annexure-2)

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SYNOPSIS OF RESEARCH PROPOSAL

1. Title of the study:

2. Background information & justification (100-200 words):

3. Objectives

    a. Overall

    b. Specific

4. Trial design:

5. Materials and Methods:

a) Trial subjects:

b) Type of study
(RCT/Cohort study/ case control/Prospective clinical study/Others)

c) Inclusion Criteria

d) Exclusion Criteria

e) Number of groups to be studied, their names & Definition (Control, Treatment I, Treatment II, etc)

f) Sample size in each group and sample size determination methods

g) Interventions

h) Methodology:

(Including sampling method, randomization, intervention and their standardization, variable to be studied, proposed statistical methods, etc.)

i) Evaluation of efficacy & Safety:

j) Anticipated adverse events:

k) Ethical Issues:

(Annexure-3)

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APPLICATION FOR PROJECT PROPOSAL APPROVAL

CTRC No: _____
(FOR OFFICE USE)

1. Title:
2. Principal Investigator:
3. Designation:
4. Department:
5. Sponsor's name and address:
6. Proposed date of starting of project:
7. Duration of project:
8. Budget details/Plan:

S. No	BUDGET HEADS	AMOUNT in Rs. (LAKH)
1	Equipment	
2	Equipments maintenance charges	
3	Salaries	
4	Hospital expenses (Investigation, Hospital stay charges, etc)	
5	Subject compensation (Transport, means etc)	
6	Travel (investigator's meet, conferences, project work, etc)	
7	Contingencies (Xerox, stationary, postage, telephone, fax, etc)	
8	Consumables	
9	Miscellaneous	
10	Others	
11	Insurance charges (for investigators, patients/volunteers)	
	TOTAL COST OF STUDY CONDUCT	
12	Institutional over heads (25%)/As per guidelines Pt no. 14	
	GRAND TOTAL	

9. Intradepartmental/Interdepartmental:
   (If interdepartmental)
   a) State names of the collaborating departments:
   b) Whether consent obtained from them:
10. 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):
   d) State whether you have enclosed a copy of the original research protocol submitted by the co-ordinating institution.

(Annexure –4)

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INFORMED CONSENT FORM/PATIENT'S INFORMATION SHEET

1. Checklist for study Subject's informed consent documents

1.1 Essential Elements:

1. Statement that the study involves research and explanation of the purpose of the research
2. Expected duration of the Subject's participation
3. Description of the procedures to be followed, including all invasive procedures and
4. Description of any reasonably foreseeable risks or discomforts to the Subject
5. Description of any benefits to the Subject or others reasonably expected from research. If no benefit is expected Subject should be made aware of this.
6. Disclosure of specific appropriate alternative procedures or therapies available to the Subject
7. Statement describing the extent to which confidentiality of records identifying the Subject will be maintained and who will have access to Subject's medical records
8. Trial treatment schedules (s) and the probability for random assignment to each treatment (for randomized trials)
9. Compensation and /or treatment(s) available to the Subject in the event of a trial-related injury
10. An explanation about whom to contact for trial related queries, rights of Subjects and in the event of any injury
11. The anticipated prorated payment, if any, to the Subject for participating in the trial (For funded project)
12. Subject's responsibilities on participation in the trial
13. Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the Subject is otherwise entitled
14. Any other pertinent information

1.2 Additional elements, which may be required

a. Statement of foreseeable circumstances under which the Subject's participation may be terminated by the Investigator without the Subject's consent.
b. Additional costs to the Subject that may result from participation in the study.
c. The consequences of a Subject's decision to withdraw from the research and procedures for orderly termination of participation by Subject.
d. Statement that the Subject or Subject's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the Subject's willingness to continue participation will be provided.
e. A statement that the particular treatment or procedure may involve risks to the Subject (or to the embryo or fetus, if the Subject is or may become pregnant), which are currently unforeseeable
f. Approximate number of Subject enrolled in the study

(Annexure –4)

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Informed Consent Form

Title of the project : _____

Name of the Principal Investigator : _____Tel. No. _____

Patient/Volunteer Identification No. : _____

I, _____ S/o or D/o _____
R/o _____
give my full, free, voluntary consent to be a part of the study "_____", the procedure and nature of which has been explained to me in my own language to my full satisfaction. I confirm that I have had the opportunity to ask questions.

I understand that my participation is voluntary and am aware of my right to opt out of the study at any time without giving any reason.

I understand that the information collected about me and any of my medical records may be looked at by responsible individual from _____ (Company Name) or from regulatory authorities. I give permission for these individuals to have access to my records.

Date: _____ _____

Place: _____ Signature/Left thumb impression

This to certify that the above consent has been obtained in my presence.

Date: _____ _____

Place: _____ Signature of Principal Investigator

1. Witness 1

_____
Signature
Name: _____
Address: _____

2. Witness 2

_____
Signature
Name: _____
Address: _____

2. Format of informed consent form for Subjects participating in a clinical trail

Informed Consent form for to participate in a clinical trial

Study Title:

Study Number:

Subject's Initials:_____ Subject's Name_____

Date of Birth / Age:_____

		Please initial box (Subject)
(i)	I confirm that I have read and understood the information sheet dated_____ for the above study and have had the opportunity to ask questions.	
(ii)	I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
	I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.	
	I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s)	
	I agree to take part in the above study.	

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:_____

Date: _____/_____/_____

Signatory's Name: _____

Signature of the Investigator: _____ Date: _____/_____/_____

Study Investigator's Name: _____

Signature of the Witness _____Date: _____/_____/____

Name of the Witness: _____

(Annexure – 5)

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UNDERTAKING BY THE INVESTIGATOR

1. Full name, address and title of the Principal Investigator (or Investigator(s) with qualification

2. Name and address of the institute medical college, hospital or other facility where the clinical trial will be conducted.

3. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.

4. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator.

5. Commitments:

I. I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary Ethics Committee and regulatory approvals have been obtained.

II. I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval / favorable opinion from the Ethics Committee of the amendment, except where necessary to eliminate an immediate hazard(s) involved are only logistical or administrative in nature.

III. I agree to personally conduct and/or supervise the clinical trial at my site.

IV. I agree to inform all Subjects, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the GCP guidelines are met.

V. I agree to report to the Sponsor all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory and GCP guidelines. (For funded projects)

VI. I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.

VII. I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.

VIII. I agree to maintain adequate and accurate records and to make those records available for audit / inspection by the Sponsor, Ethics Committee, Licensing Authority or their authorized representatives, in accordance with regulatory and GCP provisions. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.

IX. I agree to promptly report to the Ethics Committee all changes in the clinical trial activities and all unanticipated problems involving risks to human Subjects or others.

X. I agree to inform all unexpected serious adverse events to the ethics committee & Sponsor (for funded projects) within seven days of their occurrence.

XI. I will maintain confidentiality of the identification of all participating study patients and assure security and confidentiality of study data.

XII. I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials.

6. Signature of Investigator with Date

(Annexure – 6)

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Details of other funded projects

1. Name of the Principal Investigator / Co-Principal Investigator)
2. The number of ongoing research projects as principal investigator /Co-Principal Investigator)
3. Title of each project with duration
4. Source and amount of funds in each of his/her research project with following details:
    a) Fees
    b) Honorarium
    c) Financial support details
    d) Provision for compensation details

(Annexure – 7)

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PROJECT REPORT

STRUCTURE, CONTENTS AND FORMAT FOR CLINICAL STUDY REPORTS

1. Title Page: -
This page should contain information about the title of the study, the protocol code, name of the investigational product tested, development Phase, indication studied, a brief description of the trial design, the start and end date of patient accrual and the names of the Sponsor and the participating Institutes (Investigators).

2. Study Synopsis (1 to 2 pages): A brief overview of the study from the protocol development to the trial closure should be given here. This section will only summarize the important conclusions derived from the study.

3. Statement of compliance with the 'Guidelines for Clinical Trials on Pharmaceutical Products in India – GCP Guidelines' issued by the Central Drugs Standard Control Organization, Ministry of Health, Government of India.

4. List of Abbreviations and Definitions

5. Table of contents

6. Ethics Committee:
This section should document that the study was conducted in accordance with the ethical principles of Declaration of Helsinki. A detailed description of the Ethics Committee constitution and date(s) of approvals of trial documents for each of the participating sites should be provided. A declaration should state that EC notifications as per Good Clinical Practice Guidelines issued by Central Drugs Standard Control Organization and Ethical Guidelines for Biomedical Research on Human Subjects, issued by Indian Council of Medical Research have been followed.

7. Study Team:
Briefly describe the administrative structure of the study (Investigators, site staff, Sponsor/ designates, Central laboratory etc.).

8. Introduction:
A brief description of the product development rationale should be given here.

9. Study Objective:
A statement describing the overall purpose of the study and the primary and secondary objectives to be achieved should be mentioned here.

10. Investigational Plan:
This section should describe the overall trial design, the Subject selection criteria, the treatment procedures, blinding / randomization techniques if any, allowed/ disallowed concomitant treatment, the efficacy and safety criteria assessed, the data quality assurance procedures and the statistical methods planned for the analysis of the data obtained.

11. Trial Subjects

A clear accounting of all trial Subjects who entered the study will be given here. Mention should also be made of all cases that were dropouts or protocol deviations. Enumerate the patients screened, randomised, and prematurely discontinued. State reasons for premature discontinuation of therapy in each applicable case.

12. Efficacy evaluation

The results of evaluation of all the efficacy variables will be described in this section with appropriate tabular and graphical representation. A brief description of the demographic characteristics of the trial patients should also be provided along with a listing of patients and observations excluded from efficacy analysis.

13. Safety Evaluation

This section should include the complete list

13.1 All serious adverse events, whether expected or unexpected and

13.2 unexpected adverse events whether serious or not

The comparison of adverse events across study groups may be presented in a tabular or graphical form. This section should also give a brief narrative of all important events considered related to the investigational product.

14. Discussion and overall Conclusion

Discussion of the important conclusions derived from the trial and scope for further development.

15. List of References

16. Appendices

List of Appendices to the Clinical Trial Report

a Protocol and amendments
b Specimen of Case Record Form
c Investigators' name(s) with contact addresses, phone, email etc.
d Patient data listings
e List of trial participants treated with investigational product
f Discontinued participants
g Protocol deviations
h CRFs of cases involving death and life threatening adverse event cases
i Publications from the trial
j Important publications referenced in the study
k Audit certificate, if available
l Investigator's certificate that he/she has read the report and that the report accurately describes the conduct and the results of the study.

(Annexure – 8)

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Data Elements for reporting serious adverse events occurring in a clinical trial

1. Patient Details

Initials & other relevant identifier (hospital/OPD record number etc.)*

Gender

Age and/or date of birth

Weight

Height

2. Suspected Drug(s)

Generic name of the drug*

Indication(s) for which suspect drug was prescribed or tested

Dosage form and strength

Daily dose and regimen (specify units - e.g., mg, ml, mg/kg)

Route of administration

Starting date and time of day

Stopping date and time, or duration of treatment

3. Other Treatment(s)

Provide the same information for concomitant drugs (including non-prescription/OTC drugs) and non-drug therapies, as for the suspected drug(s).

4. Details of Suspected Adverse Drug Reaction(s)

Full description of reaction(s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction*.

Start date (and time) of onset of reaction

Stop date (and time) or duration of reaction

De-challenge and re-challenge information

Setting (e.g., hospital, out-patient clinic, home, nursing home)

5. Outcome

Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted

For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; Any post-mortem findings.

Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations etc.

6. Details about the Investigator*

Name

Address

Telephone number

Profession (specialty)

Date of reporting the event to Licensing Authority:

Date of reporting the event to Ethics Committee overseeing the site:

Signature of the Investigator

Note: Information marked * must be provided."

(Annexure – 9)

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SCHEMETIC LAYOUT OF REPORTING OF SERIOUS ADVERSE EVENT