Annexure No. 3 A

Institutional ethical committee Sambalpur University

Initial Review Submission Form for Research Proposal

1. Cover Letter to Secretariat IEC-SU for Consideration of application
2. Title of the research proposal
3. Name of the Principal Investigator with qualification and designation
4. Name of the Co-Investigator(s) with qualifications and designation
5. Name of the Institute / Hospital / Field area where research will be conducted
6. Forwarding letter from the Head of the Department / Institution / Guide.
7. Protocol of the proposed research: (includes and not limited to) clear research objectives,rationale for undertaking the investigations in human participants in the light of existing knowledge, inclusion and exclusion criteria for entry of participants. Precise description ofmethodology of the proposed research, including sample size (with justification), type of study design (observational, experimental, pilot, randomized, blinded etc.), intended intervention, dosages of drugs, route of administration, duration of treatment and detailsof invasive procedures if any, Plan to withdraw or withhold standard therapies in the course of research. Plan for statistical analysis of the study. Ethical issues in the study and plans to address these issues.
8. Proposal should be submitted with all relevant enclosures like proforma, case report forms, questionnaires, follow-up cards, participant recruitment procedures and brochures,if any, Informed consent process, including patient information sheet and informed consent form in English and local language(s). Investigator's brochure for trial on drugs/ devices/ vaccines/ herbal remedies and statement of relevant regulatory clearances. Source of funding and financial requirements for the project.
9. For any drug / device trial, all relevant pre-clinical animal data and clinical trial data from other centers within the country / other countries, if available.
10. Usefulness of the project / trial
11. Expected ‘benefits’ to volunteers / community. ‘Benefits’ to other categories if any
12. Explain all anticipated ‘risks’ (adverse events, injury, discomfort) of the project. Efforts taken to minimize the ‘risks’. Proposed compensation and reimbursement of incidental expenses and management of research related and unrelated injury/ illness during and after research period. Description of the arrangements for indemnity, if applicable in study-related injuries and description of the arrangements for insurance coverage for research participants, if applicable.

13. Agreement to report all Serious Adverse Events (SAE) to IEC-SU.
14. Other financial issues including those related to insurance.
15. An account of storage and maintenance of all data collected during the trial.
16. Research proposals approval by scientific advisory committee
17. For international collaborative study details about foreign collaborators and documents for review of Health Ministry's Screening Committee(HMSC) or appropriate Committeesunder other agencies/ authority like Drug Controller General of India (DCGI)
18. For exchange of biological material in international collaborative study a MoU/ MaterialTransfer Agreement between the collaborating partners.
19. Statement of conflicts of interest, if any.
20. Agreement to comply with the relevant national and applicable international guidelines, Good Clinical Practices (GCP) protocols for clinical trials.
21. All significant previous decisions (e.g., those leading to a negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided
22. A statement on, probable ethical issues and steps taken to tackle the same like justification for washout of standard drug, or the use of placebo control.
23. Curriculum vitae of all the investigators with relevant publications in last five years.
24. Plans for publication of results / positive or negative / while maintaining the privacy and confidentiality of the study participants.
25. Any other information relevant to the study.
26. Signature of the Principal Investigator with date.
27. Project Sanction Letter by various R&D Organizations/ National funding agencies /State funding agencies /NGOs, etc.
28. Application processing fees for IEC Clearance of Rs.2500/- to be deposited along with the IEC application in the form of demand draft in the name of IEC-SU, State Bank of India.

Note: The above information and enclosures should be furnished wherever necessary depending upon the nature of study proposal

Institutional Ethics Committee Sambalpur University

Ongoing Approved Research Review Submission Form

1. Reference number
2. Cover Letter to Secretariat IEC-SU for Consideration of application
3. Month / Year of approval
4. Number of ongoing review
5. Title of the research proposal
6. Name of the Principal Investigator (PI) with qualification and designation
7. Name of the Co-investigator(s) (Co-PI) with qualification and designation
8. Duration of the Project
9. Source of funding & financial allocation for the project / trial
10. Has subject recruitment begun?
11. If subject recruitment has not begin, give reasons and proceed to No:20
12. How many subjects have been screened?
13. How many subjects have been recruited?
14. How many more to be recruited
15. Is subject recruitment continuing?
16. Are there any 'drop outs'?
17. Are subjects still receiving active intervention?
18. Have there been any adverse events? If yes, give details
19. Have there been any Serious Adverse Events adverse events? If yes, give details.
20. Have there been any unanticipated study-related problems?
21. Is there any new risk or benefit information? If yes, give details.
22. Are there any interim changes to the protocol or consent form? If yes, give detailsincluding submission of revised protocol and consent form for approval
23. Does the scientific literature indicate changes in knowledge relevant to the conduct of thestudy?
24. List of attachments for review, if any
25. Remarks, if any
26. Signature of the Principal Investigator with date.

Note: The above information and enclosures should be furnished wherever necessary depending upon the nature of study proposal.

Annexure 3B

FORMAT FOR SUBMISSION OF PROJECTS INVOLVING RESEARCH IN HUMAN SUBJECTS FOR CLEARANCE BY ETHICAL COMMITTEE OF SAMBALPUR UNIVERSITY

Submit five (5) copies of the Research Project along with Covering letter and 'soft copy' on email ***iec.su@suniv.ac.in*** along with a blank CD with the following information to the Member Secretary, Institution Ethics Committee at Room No._, _____Sambalpur University, Tel No.____ . The Principal Investigator must submit protocol forwarded through the 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 waited 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 Concerned local Language, **in a simple layman's language, in a narrative form, directed to Participant, 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 working days. Proposalsreceived till 15th of preceding 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, March, May, July, September, and November. The frequency will change depending upon the Load and will be updated on the website: www.suniv.ac.in

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.

Form to be filled by the Principal Investigator (PI) for submission to Institutional Ethics Committee (IEC), Sambalpur University

(For attachment to each copy of the proposal)

Serial No of IEC Management Office:

Proposal Title:

	Name, Designation, Department & Qualifications	**Address Tel & Fax Nos. Email ID**	**No of projects already with Investigator**	**Signature**
PI				
Co-PI / Collaborators 1.				
2.				
3.				
4.				
5.				

6.				
	Please attach detailed Curriculum Vitae of all Investigators (with subject specificpublications limited to previous 5 years).			

Tick appropriately

Sponsor Information :							
1. Indian	a) Government	☐	Central	☐	State	☐	Institutional ☐
	b) Private	☐					
2. International	Government	☐	Private	☐	UN agencies	☐	
3. Industry	National	☐	Multinational	☐			
Contact Address of Sponsor:							
Total Budget :							
Who will bear the cost of investigation / implants drugs / contrasts?	1. ☐ Patient 2. ☐ Project 3. ☐ Exempted 4. ☐ Other Agencies (Name)_____						

1.Type of Study : Cross sectional case control cohort Clinical Trial Review Participating Centre : Single center Multi-centric Others (Specify)		
2. Status of Review: New Revised		
3. Clinical Trials: **Drug /Vaccines/Device/Herbal Remedies :**		
i. Does the study involve use of : Drug Devices ☐ Vaccines Indian Systems of Medicine/ Alternate System of Medicine Any other ☐ NA		
ii. Is it approved and marketed In India UK & Europe ☐ USA Other countries, specify ☐		
iii. Does it involve a change in use, dosage, route of administration?	Yes	No
If yes, whether DCGI's /Any other Regulatory authority's Permission is obtained?	Yes	No
If yes, Date of permission :		
iv. Is it an Investigational New Drug?	Yes	No
If yes, IND No:		
a). Investigator's Brochure submitted	Yes	No
b). *In vitro* studies data	Yes	No
c). Preclinical Studies done	Yes	No
d). Clinical Study is : Phase I Phase II Phase III ☐ Phase IV ☐		

e). Are you aware if this study/similar study is being done elswhere ? **If Yes**, attach details	Yes	No

4. Brief description of the proposal – Introduction, review of literature, aim(s) & objectives, justification for study, methodology describing the potential risks & benefits, outcome measures, statistical analysis and whether it is of national significance with rationale (Attach sheet with maximum 500 words):

5. Subject selection:

i. Number of Subjects :

ii. Duration of study :

iii.	Will subjects from both sexes be recruited	Yes	No
iv.	Inclusion / exclusion criteria given	Yes	No

v. Type of subjects Volunteers ☐ Patients ☐

vi. Vulnerable subjects Yes ☐ No ☐
(Tick the appropriate boxes)

pregnant women	☐	children	☐	elderly	☐
fetus	☐	illiterate	☐	handicapped	☐
terminally ill	☐	seriously ill	☐	mentally challenged	☐
economically & socially backward	☐	any other	☐		

vii. Special group subjects Yes ☐ No ☐
(Tick the appropriate boxes)

captives	☐	institutionalized	☐	employees	☐
students	☐	nurses/dependent	☐	armed forces	☐
any other	☐	staff	☐		

6. Privacy and confidentiality

i. Study involves - Direct Identifiers ☐
Indirect Identifiers/coded ☐
Completely anonymised/ delinked ☐

ii.	Confidential handling of data by staff	Yes	No
7. Use of biological/ hazardous materials		Yes	No
i.	Use of fetal tissue or abortus		
ii.	Use of organs or body fluids	Yes	No
iii.	Use of recombinant/gene therapy	Yes	No
	If yes, has Department of Biotechnology (DBT) approval for rDNA products been obtained?	Yes	No
iv.	Use of pre-existing/stored/left over samples	Yes	No
v.	Collection for banking/future research	Yes	No

vi. Use of ionizing radiation/radioisotopes **If yes,** has Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?	Yes Yes	No No
vii. Use of Infectious/bio hazardous specimens	Yes	No
viii. Proper disposal of material	Yes	No
ix. Will any sample collected from the patients be sent abroad? **If Yes, justify with details of collaborators**	Yes	No
a) Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration?	Yes	No

b) Sample will be sent abroad because (Tick appropriate box):

Facility not available in India ☐
Facility in India inaccessible ☐
Facility available but not being accessed. ☐
If so, reasons…

8. Consent : *Written ☐ Oral ☐ Audio-visual ☐

i. Consent form : (tick the included elements)

Understandable language	☐	Alternatives to participation	☐
Statement that study involves research	☐	Confidentiality of records	☐
Sponsor of study	☐	Contact information	☐
Purpose and procedures	☐	Statement that consent is voluntary	☐
Risks & Discomforts	☐	Right to withdraw	☐
Benefits	☐	Consent for future use of biological material	☐
Compensation for participation	☐	Benefits if any on future commercialization	☐
Compensation for study related injury	☐	eg. genetic basis for drug development	

*If written consent is not obtained, give reasons:

ii. Who will obtain consent ? PI/Co-PI ☐ Nurse/Counsellor ☐
Research staff ☐ Any other ☐

9. Will any advertising be done for recruitment of Subjects? (posters, flyers, brochure, websites – if so kindly attach a copy)	Yes	No
10. Risks & Benefits: i. Is the risk reasonable compared to the anticipated benefits to subjects / community / country?	Yes	No
ii. Is there physical / social / psychological risk / discomfort? **If Yes,** Minimal or no risk ☐ More than minimum risk ☐ High risk ☐	Yes	No

Iii.Is there a benefit a) to the subject ? Direct ☐ Indirect ☐ b) Benefit to society ☐		
11. Data Monitoring i. Is there a data & safety monitoring committee/ Board (DSMB)?	Yes	No
ii. Is there a plan for reporting of adverse events? **If Yes,** reporting is done to : Sponsor ☐ Ethics Committee ☐ DSMB ☐	Yes	No
iii. Is there a plan for interim analysis of data?	Yes	No
vi. Are there plans for storage and maintenance of all trial database? **If Yes,** for how long ?	Yes	No
12. Is there compensation for participation? **If Yes,** Monetary ☐ In kind ☐ Specify amount and type:	Yes	No
13. Is there compensation for injury? **If Yes,** by Sponsor ☐ by Investigator ☐ by insurance company ☐ by any other ☐	Yes	No
14. Do you have conflict of interest? (financial/nonfinancial) **If Yes, specify :**	Yes	No
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	
15. Participant Information Sheet *(mark √ if yes)*	☐ Attached English version ☐ Attached Odia version ☐ Certified that Odia version is a true translation of English version	
16. **Participant Informed Consent Form** *(mark √ if yes)*	☐ Attached English version ☐ Attached Hindi version ☐ Certified that Odia version is a true translation of English version	
17. Whether any work on this project has started or not?	☐ *(mark √ if yes, X if no)* *(Please enclose a separate certificate to this effect).*	
18. In case of clinical trials CTRI status		

Checklist for attached documents:

Covering letter, through proper channel.	☐
Project proposal – 02 Copies	☐
Curriculum Vitae of Investigators	☐
Brief description of proposal	☐
Patient information sheet	☐
Informed Consent form	☐
Investigator's brochure for recruiting subjects	☐
Copy of advertisements/Information brochures	☐
Copy of clinical trial protocol and/or questionnaire	☐
Institutional Ethics Committee clearance	☐
Institutional Animal Ethics Committee clearance	☐
CPCSEA clearance, if any	☐
HMSC/DCGI/DBT/BARC clearance if obtained	☐
Undertaking that the study shall be done in accordance with ICMR and GCP guidelines	☐
In case of multi-centric study, IEC clearance of other centres must be provided	☐
Definite undertaking as to who will bear the expenditure of injury related to the project	☐
In case an insurance cover is intended, Insurance certificate must be provided (as per ICMR guidelines)	☐
Permission to use copyrighted Questionnaire/proforma	☐
Investigator should provide undertaking what they will do with the leftover sample tissue	☐
Certificate/undertaking as mentioned in column 17	☐
Others	☐

Institute Ethics Committee, Sambalpur University, Jyoti Vihar

Format for submission of revised/additional documents, protocols and information regarding already approved projects to be submitted by the Principal Investigator (PI)(Two copies of this form along with the revised documents to be submitted)

1. IEC Reference No:

2. Approval Date and Number:

3. Title:

4. Principal Investigator:

5. Purpose of this submission:

6. New documents being submitted: Please list the documents being submitted along with the differences from the previously approved documents in a tabular form as below:

S. No.	List of Documents being submitted	List the modifications/revisions made from previously approved proposal, wherever applicable

Place:
Date:

Signature PI/Collaborator _____
Name:

Annexure 4C

Six monthly progress of Project

Institute Ethics Committee Reference No._____

Study title:_____

Name of the Principal Investigator _____

Designation / Department _____

Duration of Study _____

Date of Starting of the Study _____

Period of Six monthly progress report: from_____to _____

Progress:

Side Effect if any:

Amendments if any:

Discontinuation reasons:

Progress:

Signature of Principal Investigator _____

Date:_____

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 birthWeight

Height

2. Suspected Drug(s)

Generic name of the drug*

Indication(s) for which suspect drug was prescribed or testedDosage 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 nonprescription/OTCdrugs) 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 reactionDe 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 fromspecial 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."*