Standard Operating Procedures Institute Scientific Advisory Committee (ISAC)

All India Institute of Medical Sciences Bilaspur (HP)

Prepared by: On behalf of Members ISAC AIIMS Bilaspur	Reviewed by	Approved by
Prof(Dr) Anupam Parashar Member Secretary ISAC	**Prof (Dr) Dinesh Kumar Verma** Vice Chairperson ISAC	**Pruf (Dr) Vir Singh Negi** Chairperson ISAC
Anupam 29.08.2023	29/8/23	29/8/2023

Standard Operating Procedures

Institute Scientific Advisory Committee

All India Institute of Medical Sciences Bilaspur
Himachal Pradesh (174037)

Standard Operating Procedures

A. Purpose

The Institute Scientific Advisory Committee (ISAC) of AIIMS Bilaspur has been constituted to help prepare scientifically sound research proposals being considered for intramural and extramural funding.

The committee shall suggest appropriate changes in study design, methodology, and analysis methods to the research proposals submitted. After incorporating proposed modifications, the ISAC shall recommend submitting it to IEC for final approval.

B. Scope:

The Institute Scientific Advisory Committee (ISAC) of AIIMS Bilaspur will review scientific proposals conducted by AIIMS Bilaspur faculty and research studies being guided by the faculty members (except MD/MS/DM/MCh/PhD proposals which the individual Departmental PG Research Monitoring Committees review).

C. Procedures:

C.1 Proposal Submission process

1. For submission of the proposals to the ISAC AIIMS Bilaspur, the principal investigator will need to fill out the 'Project submission form for the Institute Scientific Advisory Committee (ISAC)'
2. The intramural and extramural proposals can be submitted to IEC AIIMS Bilaspur for final approval only after approval by the ISAC AIIMS Bilaspur.
3. All PIs must submit one print copy to the office of the Institute Scientific Advisory Committee (ISAC) of AIIMS Bilaspur and a soft copy of their research proposals on email id iscac@aiimsbilaspur.edu.in It is to be ensured that all pages that have been filled in ink and/or bear signatures are scanned and included in the electronic submission. Submissions without all relevant sections and signatures will be returned for resubmission.

C.2 Proposal Review Process

1. The research proposals submitted to the ISAC shall be reviewed by three reviewers among the members who are not in conflict with or not related to the project.
   For specialized projects like clinical trials, one or more internal/external additional subject experts may be invited as a member(s).
2. All proposals received till the 7th of each month will be submitted to three reviewers by the 15th of the month. The reviewers will be requested to give comments/ feedback within two weeks.
3. The comments/ suggestions given by the reviewers will be shared with the PI on email for clarification. The PI has to submit their point-wise reply to the reviewers' comments within seven days.
4. The reviewers will further review the replies submitted by the PI for the satisfaction of responses.
5. The PI will be asked to submit the revised manuscript after incorporating all changes as per the reviewers' suggestions
6. The revised manuscripts will be submitted to the ISAC for final approval.
7. ISAC will customarily meet four times per year, in person/virtually/ Hybrid mode, to review the study proposals.
8. Additional ad hoc meetings may be called as required.

C.3 Research review calendar

1. **Meeting dates:** Revised proposals submitted by 7th day of January/ 7th day of April/ 7th day of July/ 7th day of October will be taken up in the ISAC meetings to be held in the second week of February, May, August, and November respectively.

3. PIs will be invited to present their proposed research work at an ISAC meeting (if required). Investigators are advised to make a PowerPoint presentation of at most five minutes as per the template prescribed by the ISAC. It will be mailed to the concerned PIs once they submit a soft copy to the email ID iscac@aiimsbilaspur.edu.in

2. **Distribution of research proposals and documents to the ISAC members**

The date, time, venue, and documents relevant to the upcoming meeting will be communicated to the ISAC members, preferably 14 days before the meeting, and the final agenda of the meeting will be sent to the attending members a minimum of three working days before the meeting.

The Chairperson, the Vice Chairperson, or Member Secretary may agree to invite additional attendees to any ISAC meeting or item of discussion at the ISAC.

C4. Scoring of proposals

1. For the approval of the research proposal under an intramural grant from AIIMS Bilaspur, there will be a scoring system for the following parameters

a. Importance of research area

b. Novelty

c. Clinical application/ Public health relevance

d. Quality of research proposal

e. Innovation

f. Cost of the project

2. Selection will be based on the score given by the members, and the decision of the Institute Scientific Advisory Committee will be final.

3. The member of the Institute Scientific Advisory Committee submitting the research proposal will not be eligible for scoring their project.

C5. Procedures for the conduct of the meeting

1. **Conditions to be fulfilled for conducting the meeting**

   The quorum should consist of the Chairperson or Vice-chairperson and 50% of the members.

2. The Chairperson/Vice Chairperson will initiate the meeting after ensuring that a quorum is complete.

3. At his discretion, the Chairperson may delegate the responsibility of conducting the meeting to the Member Secretary, as per the agenda laid down for the meeting.
4. The Chairperson will ask the members if anyone has any conflict of interest with the research projects tabled for the meeting and, if so, to declare the conflict.
5. The Member Secretary will ask the members whether any points need to be discussed regarding the minutes of the previous meeting. If no issues are raised, the minutes will be considered confirmed.
6. The Member Secretary will present the agenda of the meeting for discussion.
7. The meeting shall generally proceed in the order detailed in the agenda. However, the Chairperson may allow alterations to the order of issues depending on the situation.
8. The meeting date and agenda will be circulated to the relevant investigators via email. If required, the investigators will be informed and requested to be available for the meeting date.
9. If a meeting is to be rescheduled due to unavoidable circumstances, the date and time will be emailed to the ISAC members and investigators.
10. Decisions will include approvals, disapprovals, requests for study modifications/ budget modifications, and suspension or termination of an ongoing study.
11. The decisions should be clear and provide recommendations for revising the proposal.
12. A rejection decision on an application will be clearly explained with appropriate reasons.
13. If minor modifications are required as suggested in the ISAC meeting, the revised project proposal will be reviewed and approved by the Member Secretary or a sub-committee of the ISAC on behalf of the full board. The Member Secretary will report the decision in the next board ISAC meeting.
14. The ISAC Secretariat will draft a summary of the discussions and decisions taken in the meeting within seven working days after the meeting.
15. The ISAC secretariat will issue the final approval letters.
16. The Principal Investigator will submit an annual report of all the approved projects to ISAC AIIMS Bilaspur. PI is also required to submit a copy of any abstract submitted / paper published to ISAC along with the annual report.

17. The ISAC will review the Intramural grant projects annually for satisfactory progress. If the progress is unsatisfactory without any valid reason, the committee may terminate the intramural grant.

Annexure 1

Project submission form for the Institute Scientific Advisory Committee (ISAC)

Project submission form

(To be filled by office)
Project number:
Date of submission:

A. Project details

1. Project title:
2. Principal investigator:

3. Department and designation:
4. Contact details
   - Telephone number:
   - Email:
   - Fax:
5. Co-investigators with department and designation:

6. State whether Intradepartmental or Interdepartmental
   a. If the study is interdepartmental
   b. Name of the collaborating departments
   c. State whether consent has been obtained from them

7. Details in case of Inter-institutional projects
   a. Name of the co-ordinating Institution
   b. Is a copy of the protocol submitted to co-ordinating centre enclosed?

8. Funding Details
    a. Type of Study
        Non-funded ☐
        Intramural ☐
        Extramural ☐
    b. In case of funded
        i. Funding agency Government ☐
        Private ☐
        AIIMS Bilaspur ☐
        ii. Name of Funding agency_____
        iii. Estimated Budget in INR_____
            1. Extramural fund (sanctioned for AIIMS Bilaspur)_____
            Total (if Multicentric)_____
            2. Intramural Fund (Funding sought)_____

B. <u>Project details</u>

Sr No.	Section	Recommendation
1.	**Title of the project/ study**	
2.	**Rationale** (not more than 500 words)	Explain the scientific background and rationale for the study/ investigation being reported.
3.	**Research question/ Hypothesis/ Aim of study**	State research question, including any prespecified hypotheses.
4.	**Objective of study**	State specific objectives (Primary Objectives & Secondary Objectives)

5.	**Review of Literature**	Briefly describe (Not more than 1000 words)
6.	**Project description**	
a)	Study setting	Describe the setting, locations, and relevant details, including periods of recruitment, exposure, follow-up, and data collection
b)	Study design	Present key elements of study design ➢ Descriptive- Longitudinal/ Cross-sectional ➢ Analytical- Case-control/ Cohort/ Cross-sectional ➢ Intervention/clinical trial ➢ Systematic review/ meta-analysis
		➢ Quantitative ➢ Qualitative ➢ Mixed Method
c)	Inclusion & exclusion criterion	Give the eligibility criteria for participants/ sample/ study.
d)	Sample size	Explain how the study/ sample size was arrived at. ➢ assumptions ➢ method used
e)	Sampling strategy	Explain the sources of participants/sample and method of selection of participants/ sample.
f)	Study duration	Describe the relevant details, including periods of recruitment, exposure, follow-up, and data collection.
g)	Methods/ procedure	Provide details. (**Note** - add Annexure A for intervention study AND Annexure B for systematic review/ meta-analysis under this section only).
h)	Data collection	Describe the method of data collection.
i)	Follow up (if any)	Describe the method and periods of follow-up.

j)	Statistical analysis	
	I. Variables (independent/ dependent)	Clearly define the exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable.
	II. Outcomes	Clearly define prespecified primary and secondary outcome measure.
	III. Statistical tests	Describe all statistical methods, including those used to compare groups for primary and secondary outcomes, subgroup analysis and dealing with missing data etc.
7.	**References**	Add references as per Vancouver style.

8. Enclosures

c. Data collection proforma ☐

d. Questionnaire (s) ☐

e. Patient Information Document ☐

f. Copy of signed original protocol (For multi centric studies) ☐

g. Copy of signed consent letter from coordinator (For multi centric studies) ☐

h. Any other (Specify)_____

Signatures with dates

Principal investigator **PI's HOD**

Co-investigator(s) **Co-investigator's(s) HOD**

Annexure A – Additional information for intervention study/ randomized trial

No.	Section	Recommendation	Yes/No
1.	Trial design	Description of trial design (such as parallel, factorial) including allocation ratio.	
2.	Interventions	The experimental and control interventions for each group	
3.	Randomization - Sequence generation	Method used to generate the random allocation sequence and type of randomization.	
4.	Randomization - Allocation concealment mechanism	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	
5.	Randomization - Implementation	Who will generate the allocation sequence, who will enroll participants, and who will assign participants to interventions	
6.	Blinding	If done, who will be blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how.	
7.	Trial registration	Trial registration with clinical trial registry of India (CTRI)	

Annexure B - Additional information for systematic review or meta-analysis

No.	Section	Recommendation	Yes/No
1.	Information sources	Specify all databases, registers, websites, organizations, reference lists and other sources to search or consult to identify studies.	
2.	Search strategy	Describe the full search strategies for all databases, registers and websites, including any filters and limits that will be used**.**	
3.	Selection process	Specify the methods that will be used to decide whether a study met the inclusion criteria of the review.	
4.	Data collection process	Describe the methods that will be used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	
5.	Risk of bias assessment	Describe the methods that will be used to assess risk of bias in the included studies.	
6.	Effect measures	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used for the synthesis or presentation of results.	
7.	Synthesis methods	a) Describe any methods used to tabulate or visually display results or synthesize results of individual studies and syntheses. b) In case of meta-analysis, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	

Annexure 2

Institute Scientific Advisory Committee
All India Institute of Medical Sciences Bilaspur (H.P.)
Study assessment form for Reviewer

Protocol number:		Date (dd/mm/yy):	
Protocol title:			
Principal investigator:			
Department:			
Type of Study	International	National ➢ Inter-institutional ➢ Intra-institutional	

Please mark and comment on the items that are applicable to the study.
(Suggestions/ comments may be mentioned in the row below each point)

1.	Whether the Objectives of the study clearly defined?	Yes/ No
	If No, What should be improved?	
2.	Is the study design appropriate for answering research question?	Yes/No
3.	Is the patient/ study population clearly defined?	Yes/No
4.	Is the sampling methodology/ selection of patients clearly defined?	Yes/No

5.	Is sample size appropriately calculated?	Yes/No
6.	Whether data collection methods adequately described?	Yes/No
7.	Whether the data measurements tools proposed to be used are validated?	Yes/No
8.	Does the data analysis describe how the data will be utilized to answer the research objectives?	Yes/No
9.	Does the patient information document describe the relevant information required by the study population?	Yes/No
10.	Any other suggestion which needs to be incorporated by the investigator?	

Reviewer's signature with date: _____

Annexure 3

Institute Scientific Advisory Committee
All India Institute of Medical Sciences Bilaspur (H.P.)
Decision Form

Protocol number: _____
Decision date: _____

Protocol title:	
Principal investigator:	
Department:	
Final decision	• Approved for submission to IEC • Revision with minor modifications / amendments • Revision with major modifications and resubmission • Not approved Reason(s):

Member Secretary
(Signature and date)