

A meeting of IIPS-IRB was held on **09th May 2025, from 11:00 A.M. to 02:00 P.M.**, under the chairmanship of **Prof. D.P. Singh**. The committee discussed the ethical issues of five research proposals. The members of IIPS-IRB attended the meeting in hybrid mode is attached at **Annexure I**.

S. No.	Name of the project	Principal Investigator	Presentation Time	Discussion Time
1	Understanding Challenges & Barriers to IFA Adherence in Selected States in India: A provider's Perspectives (A multi-centric study)	Dr. Rajesh Kumar Aggarwal, Associate Professor and Former Director (Act), CRRID, PRC Chandigarh	11:00 A.M. to 11:15 A.M.	11:15 A.M. to 11:30 A.M.
2	Evaluation of Rashtriya Bal Swasthya Karyakram in Selected Districts of Haryana, Himachal Pradesh and Andhra Pradesh	Dr. Pawan Kumar Sharma, Research Assistant, CRRID, PRC Chandigarh	11:30 A.M. to 11:50 A.M.	11:50 A.M. to 12:10 P.M.
3	Primary Prevention and Management Strategy for Sickle Cell Disease among Particularly Vulnerable Tribal Groups under National Sickle Cell Anemia Elimination Mission: Comparative study of selected PVTG in Madhya Pradesh	Dr. Nikhilesh Parchure, Research Investigator, PRC, Sagar (M.P.)	12:10 P.M. to 12:30 P.M.	12:30 P.M. to 12:50 P.M.
4	An Evaluation of "Jiyo Parsi" Scheme in Reversing the Decline of the Parsi Population	Dr. Preeti Dhillon, Asst. Professor, IIPS	12:50 P.M. to 01:10 P.M.	01:10 P.M. to 01:30 P.M.
5	Unpacking Patterns, Drivers, and Consequences of Out Migration from the Middle Ganga Plain: A Longitudinal Approach	Prof. Archana K. Roy, Professor, IIPS	01:30 P.M. to 01:45 P.M.	01:45 P.M. to 02:00 P.M.

The meeting started at 11:00 A.M. The Chairperson and the Convener welcomed all members.

Project 1:

“Understanding Challenges & Barriers to IFA Adherence in Selected States in India: A provider’s Perspectives (A multi-centric study)”

Objective: The study aims to understand the procurement and supply chain of iron supplements and to assess the irregularities and non-availability of different items during the last two years at the selected facilities besides exploring the problems faced by the health workers in procurement and distribution of such iron supplements.

IRB Committee comments:

This multi-centric study offers a critical examination of the barriers to IFA adherence as reported by healthcare providers across selected Indian states. Its findings are poised to provide valuable insights that will help inform policy decisions, improve program implementation, and ultimately enhance maternal and child health outcomes.

The committee suggested the following point to be incorporated in the proposal by PI/s:

- Objective: If the proposal considers the beneficiaries' perspective, that would be good. Please include it in the objectives. Also, reframe the objective to specifically address knowledge assessment.
- Sample selection: Clearly explain the rationale and criteria used for selecting participants, including how the selection aligns with the objectives of the study. Presenters agreed upon non-selection of minors in the sample. Otherwise, they need to have an assent form as well.
- Sample size: The proposal includes only providers and beneficiaries; it is recommended to have a larger sample size to ensure more representation.
- Analysis: Please include a detailed analysis plan in the research proposal.

The PI/s is/are required to incorporate the above-mentioned points and submit a revised proposal as soon as possible for IRB review and clearance.

Project 2:

“Evaluation of Rashtriya Bal Swasthya Karyakram in Selected Districts of Haryana, Himachal Pradesh and Andhra Pradesh”

Objectives:

- 1) To assess the health system status of the RBSK programme (inputs, processes, outputs) in selected states as against the envisaged in national programme guidelines with a focus on leadership & governance, HR, service delivery, medicines & supplies, and Information systems.
- 2) To evaluate the knowledge, attitude, and practices of healthcare providers and frontline workers; and identify bottlenecks in providing services under RBSK.
- 3) To comprehend the factors that help and hinder the utilization of RBSK services.
- 4) To obtain a community feedback on the availability, affordability, accessibility, and quality of services under RBSK.
- 5) To examine the client satisfaction with the services provided under the RBSK Programme; and
- 6) To document good practices and human-interest stories for the implementation of the program.

IRB Committee comments:

This is an insightful and impactful project that will thoroughly assess the program's effectiveness and impact. The findings will help strengthen the program's implementation, ensuring better health outcomes for children through early detection and intervention.

The committee suggested the following point to be incorporated in the proposal by PI/s:

- Analysis: Replace "percentile analysis" with "frequencies and percentages" for clarity and accuracy.
 - Timeline: Justification for how a thorough program evaluation will be achieved within the short two-month timeframe.
 - Feedback: Clarification on community feedback and beneficiary feedback is needed.
 - Data: An Explanation for ensuring the validity and reliability of the collected data is required.
 - Sample selection: Justification for selecting only three states for the study.
- Consent: Please review and align the consent form content with standard guidelines available on the IIPS IRB website.

The PI/s is/are required to incorporate the above-mentioned points and submit a revised proposal as soon as possible for IRB review and clearance.

Project 3:

“Primary Prevention and Management Strategy for Sickle Cell Disease among Particularly Vulnerable Tribal Groups under National Sickle Cell Anaemia Elimination Mission: Comparative study of selected PVTG in Madhya Pradesh”

Objectives:

- 1) To document the processes adopted for the two PVTGs under the Sickle Cell Anaemia Elimination Mission.
- 2) To estimate the coverage of Sickle Cell Disease screening among two PVTGs.
- 3) To study the gaps in SCD screening at health facility level and at community level.
- 4) To study the acceptance of two PVTGs regarding SCD screening.
- 5) To study the coverage of pre-marital counselling and pre-conception screening.
- 6) To understand the facilitating and inhibiting factors of SCD care and support system.

IRB Committee comments:

It is a highly valuable study that will play a pivotal role in addressing a critical health issue. By conducting a comparative study of selected PVTGs in Madhya Pradesh, it will provide evidence-based strategies to improve prevention, early detection, and management of sickle cell disease, ultimately improving health outcomes for these vulnerable communities.

The committee suggested the following point to be incorporated in the proposal by PI/s:

- Sample: Explanation of the approach for ensuring that the sample is representative and how the findings will be generalized.
- Consent: Review and align the consent form content with standard guidelines available on the IIPS IRB website.

The PI/s is/are required to incorporate the above-mentioned points and submit a revised proposal as soon as possible for IRB review and clearance.

Project 4:

“An Evaluation of “Jiyo Parsi” Scheme in Reversing the Decline of the Parsi Population”

Objectives: The overall aim of the study is to evaluate the effectiveness of the “Jiyo Parsi” scheme in reversing the decline of the Parsi population, including an examination of the key facilitators and barriers, as well as identifying areas for future improvement to achieve the intended outcomes. Specific objectives are:

- 1) To evaluate the effectiveness of the "Jiyo Parsi" scheme in achieving its intended outcomes, specifically stabilizing the birth rate and reversing the decline in the Parsi population.
- 2) To assess the geographic and demographic coverage of beneficiaries over time.
- 3) To gauge the satisfaction levels of beneficiaries and understand their expectations for the future.
- 4) To examine the efficiency of the scheme, identify any bottlenecks in its implementation, and explore potential areas for future improvements.

IRB Committee comments:

This project evaluating the *"Jiyo Parsi" Scheme* will significantly contribute to understanding the effectiveness of initiatives aimed at reversing the decline of the Parsi population. By assessing the scheme's impact, it will provide valuable insights to refine and strengthen policies, ensuring the long-term sustainability and growth of the Parsi community.

The committee suggested the following point to be incorporated in the proposal by PI/s:

- Data collection: Data to be collected up to the current point in time.
- Data availability: Given the sensitive nature of the study, ensure thorough verification of data availability.
- Sample selection: Clarification of cross marriages was requested.
- Sample size: The process used to determine the sample size and whether simple random sampling is being used should be clearly outlined.
- Study design: Data coverage within Mumbai may not yield significant variation, as Mumbai has the wealthiest segment of the Parsi population.
- Criteria: The criteria used to gather information for the study should be clearly defined.

The PI/s is/are required to incorporate the above-mentioned points and submit a revised proposal as soon as possible for IRB review and certification.

Project 5:

“Unpacking Patterns, Drivers, and Consequences of Out Migration from the Middle Ganga Plain: A Longitudinal Approach”

Objectives:

- 1) To analyze the evolution of migration over the past decade, including trends in internal, international, seasonal, return, potential, and non-migration, with a special focus on post-COVID shifts in migration patterns.
- 2) To identify the key socio-economic, demographic, and cultural determinants influencing migration strategies and decisions, particularly among poor, landless, and socially marginalized groups.
- 3) To estimate changes in remittance flows across regions and time, and to examine their long-term social and economic effects on household livelihoods, poverty alleviation, and local development.
- 4) To assess the impact of male migration on left-behind families, focusing on
 - i. The education, nutrition, and emotional development of children
 - ii. The physical and psychological health of elderly parents, including dependency and care arrangements
 - iii. The autonomy, mental well-being, coping strategies, and caregiving roles of left behind women.
- 5) To explore shifts in gender roles and household dynamics, including changes in decision making power, resource control, and leadership among women in migrant households.
- 6) To identify policy and programmatic gaps in the inclusion and support of migrant families, and to recommend concrete measures to strengthen grassroots data systems (e.g., migration registers at the village or block level), ensure better welfare outreach, and build community based support structures.
- 7) To pilot and evaluate a localized migration governance model, including a Migration Registration System and Migration Information Centre, which can serve as a scalable framework for managing migration data and delivering services to migrant families in rural sending areas.

IRB Committee comments:

The project using a longitudinal approach will provide crucial insights into the factors driving migration and its long-term impacts. The findings will help inform policy and interventions

aimed at addressing migration-related challenges, ensuring more effective regional development and migration management strategies.

The committee suggested the following point to be incorporated in the proposal by PI/s:

- Title: Consider revising the project title to include the term "rural" for better clarity.
- Reduce the hypotheses.

The IRB certificate in the prescribed format of ICSSR was a prerequisite for submission of the research proposal. Accordingly, the project coordinators applied for ethical clearance from the IRB, as it was an essential component for applying to ICSSR for funding of the project. IRB agreed to issue the certificate with the approval of the competent authority for applying to the ICSSR funding.

Generic suggestion:

- Inclusion of "Government of India" logo in the research proposals is strictly prohibited.
- It is strongly recommended to schedule a comprehensive training programme covering IRB protocols, compliance with SOPs, anticipated challenges and related topics to ensure a better understanding by the applicant. In this connection, it is to be mentioned that Prof. T. V. Sekher, Chairperson, IIPS PRC Scientific and Advisory Committee (PSAC) has already taken a training of PRC members on IRB issues, consent form details, ethical clearance guidelines, etc along with Prof US Mishra, in May 2024 in Bengaluru. Additionally, a virtual meeting to review the progress of PRC projects was held on 20th February 2025. In addition, IRB secretariat reviews the forms and the research proposals once submitted and provides feedback in advance. Yet, acceptance of suggestion from IRB secretariat by PIs of projects is optional.

The meeting was concluded with a vote of thanks.

Prof. D.P. Singh, Chairperson –



Prof. Aparajita Chattopadhyay, Convener –



Prof. Archana K. Roy, Member –



Prof. Gajanan Velhal, Member – Consent from Email dated 19/05/2025

IRB MEETING MINUTES DATED 09/05/2025

Dr. Lalita Savardekar, Member – Consent from Email dated 18/05/2025

Ms. Sushmita Das, Member – Consent from Email dated 19/05/2025

Dr. (Mrs.) Manjiri M. Rane, Member Secretary -



Annexure I

S. No.	Name of the official	IRB Committee
1	Prof. D.P. Singh	Chairperson
2	Prof. Aparajita Chattopadhyay	Convener
3	Prof. Archana K. Roy	Member
4	Prof. Gajanan Velhal	Member
5	Dr. Lalita Savardekar	Member
6	Ms. Sushmita Das	Member
7	Dr. (Mrs.) Manjiri M. Rane	Member Secretary
8	Ms. Rinju	R.O. (PRC)
9	Ms. Bhavika Shinde	UDC, Admin.
10	Mrs. Avni Goel	R.O. (IRB & NEP)