



**14<sup>th</sup> IRB MEETING**  
**17 JANUARY, 2025**

**International Institute for Population Sciences**  
**Mumbai 400088**

**Minutes of the Meeting**

## 14th IRB MEETING MINUTES DATED 17/01/2025

A meeting of IIPS-IRB was held on **17<sup>th</sup> January 2025, from 11:00 A.M. to 02:30 P.M.**, under the chairmanship of **Prof. D.P. Singh**. The committee discussed the ethical issues of six research proposals and IIPS IRB SOP-related matters. The members of IIPS-IRB attended the online meeting and participated in the discussion attached at **Annexure I**.

S. No.	Name of the project	Principal Investigator	Presentation Time	Discussion Time
1	Experience of Pensioners from Kerala: Study on MEDISEP	Dr. Nikhil P.N, Research Officer, PRC, Kerala	11:00 A.M. to 11:30 A.M.	11:30 A.M. to 11:45 A.M.
2	A study on factors impacting NRC services and NRC linkages to community in six selected states in India	Dr. Oommen P. Mathew, Research Investigator, PRC, Kerala - PI	11:45 A.M. to 12:00 P.M.	11:30 A.M. to 12:15 P.M.
3	Providers' Perspective on Enablers and Barriers of RKSK Programme in Selected Districts in Kerala	Dr. Suresh Kumar S, Documentalist, PRC, Kerala	12:15 P.M. to 12:30 P.M.	12:30 P.M. to 12:45 P.M.
4	Concurrent Assessment of Service Satisfaction among Elderly for The National Programme for Health Care of the Elderly (NPHCE) at Various Levels of Healthcare in India	Ms. Sagarkanwar Premsinhji Rajput, Research Investigator, PRC, Baroda	12:45 P.M. to 01:00 P.M.	01:00 P.M. to 01:15 P.M.
5	Assessing access and utilization of maternal health care among female migrants in Mumbai	Dr. Reshmi R.S., Assistant Professor, IIPS, Mumbai	01:15 P.M. to 01:30 P.M.	01:30 P.M. to 01:50 P.M.
6	SAHELI: Study and Action on Hysterectomy: Evidence on Women's Health through the Life Course in India	Dr. Dipti Govil, Assistant Professor, IIPS, Mumbai	01:50 P.M. to 02:10 P.M.	02:10 P.M. to 02:30 P.M.

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

**Project 1:**

**“Experience of Pensioners from Kerala: Study on MEDISEP”**

Objective: To explore Kerala state pensioners’ perception on health insurance and their experiences with MEDISEP.

**IRB Committee comments:**

This project is a valuable initiative that provides essential insights into pensioners' healthcare needs and experiences in Kerala. It is crucial to enhance the MEDISEP scheme and ensure better welfare and support for pensioners across Kerala. The committee suggested the following point to be incorporated in the proposal by PI/s:

- Objective: Expand the objective and include perspectives of both beneficiaries and healthcare providers.
- Methodology: Provide detailed description of the methodology including Study area, variables information, sampling design, sample size, inclusion and exclusion criteria of the selection of participants and hospital. Also present the sampling design with the flow chart for better clarity.
- Data Analysis and expected outcomes: to be described in detail.
- Permissions: Prior permission from hospital management is to be taken and submitted with revised 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. The IRB Committee gives conditional approval provided the above-mentioned suggestions are incorporated.

**Project 2:**

**“A Study on Factors impacting NRC services and NRC linkages to community in six Selected States in India”.**

Objectives:

1. To identify the enabling factors and barriers for access to NRC services

2. To assess the feasibility of community follow ups and linkages with community protocol for community management of malnutrition in children by MWCD, for ensuring continuum of care from NRC to community
3. To assess the compliance to NRC technical protocols
4. To evaluate the compliance to NRC counselling post discharge from NRC at one month and six-month intervals
5. To list the challenges faced by NRCs in six different states in administrative and technical domains.

**IRB Committee comments:**

This is an insightful and impactful project that thoroughly examines critical factors shaping NRC services. Its findings are essential for improving the effectiveness of NRC processes and strengthening the connection between these services and local communities across India. The committee suggested the following point to be incorporated in the proposal by PI/s:

- Methodology: Provide detailed description of the methodology including Study area, variables information, sampling design, sample size, inclusion and exclusion criteria of the selection of participants and mentioned states. Also present the sampling design with the flow chart for better clarity.
- For a multisite approach: Selection criteria, type and locality of NRCs, specific and total sample size of the participants per NRC per state.
- Categorization: State-wise number of ANMs, social workers and medical officers.
- Consent Form: Key components such as potential risks and discomforts, potential benefits, participation fees, contact information of the PI/ Research Team, consent statement and signature to be mentioned. Prepare consent forms in local languages of all the mentioned states.
- Specify indicators for community linkages of NRC services.
- Permissions: Prior permissions from NRC in-charge medical officer/ Staff Nurse/ Dietician in charge of NRC, ANM/ ASHA/ AWW worker at the community level is to be taken and submitted with revised 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. The IRB Committee gives conditional approval provided the above-mentioned suggestions are incorporated.

**Project 3:**

**“Providers’ Perspective on Enablers and Barriers of RKSK Programme in Selected Districts in Kerala”.**

**Objectives:**

1. To understand the functioning of RKSK programme in Kerala.
2. To understand the facilitators and barriers affecting implementation of RKSK programme in Kerala through providers’ perspective.
3. To analyse the RKSK programme in Kerala through beneficiary point of view.

**IRB Committee comments:**

It is a highly valuable study that offers crucial insights into the challenges and strengths of the RKSK programme. Its findings will play a key role in enhancing the programme’s effectiveness and ensuring better youth health services in the region. The committee suggested the following point to be incorporated in the proposal by PI/s:

- Methodology: Provide detailed description of the methodology for each objective including Study area, variables information, sampling design, sample size, inclusion and exclusion criteria of the selection of participants and hospital. Also present the sampling design with the flow chart for better clarity.
- Abbreviations: Full forms of each abbreviation to be mentioned for better understanding.
- Consent from: Contact information of the PI/ Research Team, consent statement and signature in FGDs consent form to be mentioned.
- LAR: Legally Authorized Representative (LAR) on behalf of a study participant to be incorporated in the informed consent.
- Who will be providing data related to highest and lowest percentages of adolescents utilising programme – Is it at state level or individual district level with written document or only by asking to higher authorities verbally.

- Please mention who would be participating in FGDs and the places for FGDs.

The PI/s is/are required to incorporate the above-mentioned points and submit a revised proposal as soon as possible for IRB review. The IRB Committee gives conditional approval provided the above-mentioned suggestions are incorporated.

**Project 4:**

**“Concurrent Assessment of Service Satisfaction among Elderly for The National Programme for Health Care of the Elderly (NPHCE) at Various Levels of Healthcare in India”.**

Objectives: To assess the satisfaction level of elderly patients with the healthcare services provided under NPHCE at various facility levels (SC, PHC, CHC and DH) in five states of India. The sub-objectives are as follows:

1. To identify the determinants of Satisfaction levels among the respondents
2. To identify the reasons of dissatisfaction among the dissatisfied respondents

**IRB Committee comments:**

It is a vital project that evaluates the quality of healthcare services for the elderly across various levels in India. The findings will play a crucial role in improving the NPHCE and ensuring better healthcare delivery for this important demographic group. The committee suggested the following point to be incorporated in the proposal by PI/s:

- Objective: Expand the objective and include perspectives of both beneficiaries and healthcare providers.
- Methodology: Provide detailed description of the methodology including Study area, variables information, sampling design, sample size, inclusion and exclusion criteria of the selection of participants and the selected 5 states. Also present the sampling design with the flow chart for better clarity.
- Permissions: Prior permissions from SHC (sub-health centre), PHC (primary health centre), CHC (community health centre) and DH (district hospital)/ SDH (sub-district hospital) is to be taken and submitted with revised proposal.
- Consent Form: Thumb impression for the witness to be included.
- Study design: Submit a combined proposal from all the mentioned PRCs for approval.

The PI/s is/are required to incorporate the above-mentioned points and submit a revised proposal as soon as possible for IRB review. The IRB Committee gives conditional approval provided the above-mentioned suggestions are incorporated.

**Project 5:**

**“Assessing access and utilization of maternal health care among female migrants in Mumbai”.**

Objectives: The project aims to investigate barriers to accessing health care for women migrants, a demographic for whom migration can impact health care access.

1. To identify the socioeconomic and cultural factors associated with access and utilization of maternal health care among female migrants.
2. To understand migrant women’s attitude towards utilization of maternal health care.

Ultimately, this project will provide information to aid future efforts, including programming and policies for improving maternal health care for female migrants in India.

**IRB Committee comments:**

This project highlights the healthcare challenges faced by migrant women. Its findings will be instrumental in improving maternal healthcare access and support for this vulnerable population in Mumbai. The committee suggested the following point to be incorporated in the proposal by PI/s:

- Methodology: Provide detailed description of the methodology including Study area, variables information, sampling design, sample size, inclusion and exclusion criteria of the selection of participants and hospital care workers. Also present the sampling design with the flow chart for better clarity.
- Data Analysis and expected outcomes: to be described in detail.
- Permissions: Prior permissions from hospital management is to be taken and submitted with revised proposal.
- Consent from: Key components such as potential risks and discomforts, potential benefits, participation fees to be included. Written consent is required from health care workers. Prepare consent forms in local language also.

- Define clearly, who would be considered female migrant. Those who have gone to Mumbai for delivery purpose in last five years, are they going to be considered?. Add few more criteria's like stay in Mumbai for at least 10 months in a year, migrates with husband, job transfer to Mumbai etc.
- Mention place of interviews for female migrants.

The PI/s is/are required to incorporate the above-mentioned points and submit a revised proposal as soon as possible for IRB review. The IRB Committee gives conditional approval provided the above-mentioned suggestions are incorporated.

**Project 6:**

**“SAHELI: Study and Action on Hysterectomy: Evidence on Women's Health through the Life Course in India”.**

It is to be noted that the IIPS IRB committee has already approved the project proposal on 02.01.2024 when it was presented for formative research. This presentation in IRB was focussed on approval of Research Tool and Questionnaire to be used in the main survey.

Objectives: the study aims to investigate the prevalence, determinants and consequences of unnecessary hysterectomy in India and to suggest feasible health policy, clinical and community-based intervention strategies to reduce unnecessary hysterectomy by addressing evidence gap in the research.

**IRB Committee comments:**

It is an important project that provides valuable evidence on the impact of hysterectomy on women's health throughout their life course in India. Its findings will be pivotal in shaping policies and interventions to improve women's health and well-being. The committee suggested the following point to be incorporated in the proposal by PI/s:

- **Consent:** Key component such as no participation fee to be incorporated.

The PI/s is/are required to incorporate the above-mentioned points and submit a revised proposal as soon as possible for IRB review. The IRB Committee gives conditional approval provided the above-mentioned suggestions are incorporated.



## Other Matters

### Suggestions to include in SOP Document:

- For multicentre study, it is highly recommended to have a single proposal with one main centre to make it uniform and more ethical.
- All the points including details of participation fees need to be incorporated in the informed consent form.
- Page number on every page and full forms of each abbreviation is to included. (Already mentioned in the SOP).

The meeting was concluded with a vote of thanks.

Prof. D.P. Singh, Chairperson –



Prof. Aparajita Chattopadhyay, Convener – Consent from Email

Prof. Archana K. Roy, Member -



Dr. Gajanan Velhal, Member – Consent from Email

Dr. Lalita Savardekar, Member – Consent from Email

Ms. Sushmita Das, Member – Consent from Email

Mrs. Manjiri M. Rane, Member Secretary -



**Annexure I**

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