

An online meeting of IIPS-IRB was held on Friday, 22 Dec, 2023, from 4:00 pm under the chairmanship of Prof. Vibhuti Patel. The committee discussed the ethical issues of three research proposals

1. “**SAHELI**: Study and Action on Hysterectomy: Evidence on Women’s Health through the Life Course in India” PI Dr. Dipti Govil
2. The Effect of Resettlement on Livelihood Rebuilding, Women Health and Demographic Behaviour The Study of Indira Sagar Irrigation Project in Bhandara District of Maharashtra- PI - Prof. D.A. **Nagdeve**
3. Baseline of Healthcare Indicators for Improving Healthcare Service Delivery in Pimpri Chinchwad Municipal Corporation (PCMC)" PI - Prof. D.A. **Nagdeve**

The following members of IIPS-IRB attended the online meeting and participated in the discussion:

Prof. Vibhuti Patel –
Chairperson

Prof A.K. Roy- Member

Prof. Gajanan Velhal - Member

Dr. Lalita Savardekar - Member

Prof. Aparajita Chattopadhyay -
Convener

Ms. Veena Johari - Member

Dr. Vahida Nainar - Member

The meeting started at 11.30 am. The Chairperson requested all members to start the proceeding for reviewing three projects circulated earlier. Mr. Raju Chavan couldn’t attend the meeting. Dr. Gajanan Velhal was not present when the last proposal was discussed.

The first presentation was on **SAHELI** project. The PIs talked about the formative research objectives and methodology. PIs of SAHELI Dr Dipti Govil from IIPS and Dr. Sapna Desai, Population Council India, made a presentation on the project. The objective of the formative research is to understand the context of hysterectomy in the study states. The information will enable to design survey tools for both quantitative survey and the longitudinal qualitative study to capture embedded social norms, causes, and effects of hysterectomy among women and use appropriate terms and concepts that are specific to each context. The project also aims to meet doctors and providers to understand supply side dynamics of hysterectomy that may be specific to these states. In the formative research SAHELI will conduct ~5 FGDs with women in groups of 6-10 women with and without hysterectomy. Women will be approached through community-based organizations in each state. The project aimed to capture information around social norms

concerned with menstruation and hysterectomy, cultural practices around menstrual hygiene, household and communal dynamics of decision making from the demand side of hysterectomy from the FGDs. For the formative research, they will obtain informed consent from all participants.

All members appreciated the endeavour and encouraged the PIs of the project to give evidence-based findings that could be used for developing protocols and programmes.

The suggestions by IRB board given on this project are as follows:

1. The medical audit mentioned in the project is not clear. What is the modality in doing so, needs detailing. The medical papers won't be available for majority of the patients. Even if the project wants to explore the pathways (alternative method tried, counseling done?), it would be difficult to get authentic papers on the process, progression or proper explanation for the decision. Whether triangulation of data will be done based on verbal responses, may not provide a clear picture. The project should try to present an unbiased demonstration of the entire scenario without being judgmental.
2. It is necessary to understand the women's request for hysterectomy. Literature states that women themselves push doctors in favor of hysterectomy for varying reasons.
3. How to define early hysterectomy? Need literature support to justify the age cut off or the way the research is defining early hysterectomy.
4. Terminology fixing and some rewordings (.. angle; unnecessary hysterectomy etc.) are needed.
5. How to address the time lag issue of women? Recall bias is natural. Do you need to restrict age of women?
6. It is difficult to assess causal effect from NFHS or LASI- at the most, association hysterectomy with NCD is possible from these data sets.
7. The cost benefit aspects of hysterectomy need elaborative understanding from both patients and medico's perspective. These factors vary over time and space.
8. Though it is stated that in-depth conversation, ethnographic exploration and patient journey mapping would be applied in the formative research and conclusions would be drawn, how far this study empirically would be helpful in policy or programme development needs clarity.
9. Approval for health testing, questionnaire etc. is requested to be put forth after conducting the formative research.

The project is approved with the condition to the above modifications and circulation of the modified draft to the IRB.

The second presentation was on **'The Effect of Resettlement on Livelihood Rebuilding, Women Health and Demographic Behaviour The Study of Indira Sagar Irrigation Project in Bhandara District of Maharashtra'**. The proposal stated that the site features 92 m high and 653 m long concrete gravity dam. The dam fulfils the irrigation and electricity needs of the destination and its adjoining areas. The project is still incomplete and there are alleged irregularities in construction of dams, rehabilitation of affected people, environmental clearances, and finances. About 93 villages will be affected, of which 35 will be completely submerged due to the project. These 93 villages from three districts consists of 16,000 project affected families - Nagpur 8,312; Chandrapur 1,542 and Bhandara 6,000. The major source of

income for the affected families was agriculture. The government has decided to support them with allied agriculture services like livestock rearing, skill training for youth and goat farming. The overall objective of this project is to study the effects of resettlement due to an irrigation project on livelihood rebuilding, health and demographic behaviour through changes in social and economic variables at the community and at household levels in Bhandara district.

The project was appreciated and the suggestions by IRB board given on this project are as follows:

1. The gender aspect of resettlement project must be highlighted. Men and women do experience differential impacts of development project.
2. How would you explore health status of women? What is the age cohort? If it is a household survey of all members then would you be asking health in general and RH in particular?
3. As the age range is huge- take care of the length of the questionnaire- it must not exhaust respondents.
4. 'anonymized and delinked' are mentioned in the form. You can anonymize the response, but can not delink- as we have a code and that code is a reflection of that particular household. So, legally, we can not delink it completely. Better to delete the delink word.
5. The consent form must have the statement on withdrawal from the interview at any time.
6. Please mention the contact details of person from Ethical board, in case respondent wants to talk directly on any issue.
7. For health section, please mention "reported health".

The project is approved with the condition to the above modifications and circulation of the modified draft to the IRB.

The third proposal was on '**Baselining of Healthcare Indicators for Improving Healthcare Service Delivery in Pimpri Chinchwad Municipal Corporation (PCMC)**'. PCMC has resolved to undertake the implementation of the project through Social Impact Bond route wherein, an experienced private sector player would upfront finance and implement the project and would be paid only if the identified outcome indicators are met. Hence, there is a need to clearly setup a baseline of the identified outcome indicator and targets for such indicators can be set accordingly and measured and verified when the target is achieved. The objectives of the baseline survey are to provide a baseline to establish the level of operation efficiency and the capacity it is catering considering 100% of the population being the target, establish a base line against which the project would be monitored and assessed for its projected progress; to establish the preparedness to adopt the revised guidelines/methods to improve/augment process/facilities through data analysis.

The project was appreciated as it is policy driven project with the long-term objective to improve the health services. The suggestions of IRB members are as follows:

The proposed project is for the medical audit of health care services.

It is desirable that PI specifically spell out that the project will pay special attention to intersectionality vulnerable and marginalized populations and capture their responses.

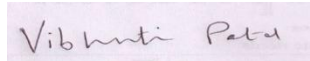
The project is approved subject to accurate response to Question 5.vi of the IRB form. Since it was made clear during the presentation and the discussion that the proposal involves working with economically and socially marginalized communities, the stated response in the form is not correct.

Convener requested to confirm a suitable date for the next meeting in mid-February. All 3 proposals presented in the meeting was a backlog of this year as the last meeting was held in June 23. The internal members of the committee were altered in November end 2023. The earliest date conveyed by the Chairperson for scheduling this was in Dec 23 and this meeting was scheduled accordingly.

The proposed date of the forthcoming meeting would be communicated by the Chairperson to IIPS. Convener requested to have a least three meetings yearly based on number of project proposal submission. Two project proposals will be submitted shortly through internal approval, for IRB clearance. The agenda and documents (approved through e office of IIPS) will be circulated at least 2 weeks before the scheduled meeting date.

The meeting was concluded with a vote of thanks.

Prof. Vibhuti Patel –
Chairperson



Prof. Aparajita Chattopadhyay -
Convener



Prof A.K. Roy- Member (Consent through e-mail)

Prof. Gajanan Velhal - Member (Consent through e-mail)

Dr. Lalita Savardekar – Member (Consent through e-mail)

Ms. Veena Johari- Member (Consent through e-mail)

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