



MINUTE

IRB MEETING
HELD ON 30 JAN 2024

International Institute for Population Sciences
Mumbai 400088



An online meeting of IIPS-IRB was held on Friday, 30 Jan 2024, from 10.10 AM-1.00PM. The committee discussed the ethical issues of eight research proposals

1. Global Adult Tobacco Survey (GATS-3)
2. The Mumbai migration project
3. Respectful Maternity Care among Women in Tamil Nadu
4. Study on effective utilization of health care services provided by Community Health Centres in Tamil Nadu
5. Tracking Progress in Girl Child Development through Welfare Schemes in Assam
6. Evaluation of the working of DEIC Haryana
7. Assessment of Mahergarh scheme in MH
8. Adequacy of Information Communicated Pre-General Surgery: A cross-sectional study in Sassoon Medical College and District Hospital Pune

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. Aparajita Chattopadhyay - Convener

Prof. Gajanan Velhal - Member

Ms. Veena Johari - Member

Dr. Vahida Nainar - Member

The meeting started at 10.10 am. The Chairperson requested all members to start the proceeding for reviewing the projects circulated earlier. Dr. Lalita Savardekar and Mr. Raju Chavan couldn't attend the meeting. Prof A K Roy attended the meeting during her leave period.

1. The first project Global Adult Tobacco Survey (GATS-3) is a project funded by the Government of India. Recognizing the importance of high-quality information on tobacco use to guide its tobacco control policy and programs, the Indian government has also been one of the first nations to undertake the Global Tobacco Surveys- both the Global Youth Tobacco Survey – done in 2003, 2006, 2009 and 2019 and the Global Adult Tobacco Survey of 2009-2010 and 2016-17. IIPS is the nodal agency and conducting the survey for years. Aim of the project is to obtain reliable estimates of various dimensions of tobacco use for systematic monitoring of adult tobacco use and its key tobacco control indicators. And to contribute to the understanding of the effectiveness of tobacco control measures, based on observed changes in relevant indicators since 2009-10 (GATS-1) and 2016-17 (GATS-2). The comments received from IRB members are as follows: to make the questionnaire customized based on space, i.e. any state specific question based on its socio-cultural practices related to tobacco needs to be included, for strengthening the research; consent form needs revision/addition, i.e. option of withdrawal, assent of the minor or parental consent. **It is requested to revise and**

resubmit the consent forms through email to the project support cell. IRB will convey their decision through email upon submission of the revised consent forms.

2. The Mumbai migration project aims to understand the characteristics, patterns, and reasons of inter-district migration and its association with regional disparity in Maharashtra in general and Mumbai in particular; to study the process of migration (in terms of economic and non-economic costs and role of network, individual and household decision making, push and pull dynamics) from different regions of Maharashtra to Mumbai; to study the interaction of migrants with the home community and its role in the social and economic mobility of the migrant; to examine the opportunities, vulnerabilities, and challenges (housing, education and health) faced by the inter-district migrants in Mumbai. Comments from IRB are: giving details on gender differential, region specific (MMRDA, MCGM, BMC) distribution. Question was raised on defining migration, as almost all residents of Mumbai would be migrant as per the research definition. As the focus of the project is on Mumbai slums, that should be highlighted across the proposal and in title. **The project is approved with due consideration of points raised by IRB.**

3. Respectful Maternity Care among Women in Tamil Nadu project mentioned about the necessity to look at the community level to understand the real situation of respectful maternity care. In view of this background, this study aims at exploring the practice of RMC among women and gaps in RMC service in Tamil Nadu, mainly aiming to understand the nature of mistreatment during antenatal, natal and postnatal care in ~~the~~ public and private health facilities through women's perceptions. IRB specified to include observation schedule; to lay down each component of maternity care to be measured as per WHO guideline. It was also noted that the file that was submitted for IRB clearance by the PI is getting combined with another project submitted by Dr V. Saravanakumar, and both projects have similar kind of objectives and thus need serious look. It was requested by IRB to send independent file to IIPS project cell and be distinct in making two projects different. IRB further commented to look into violence in the maternity ward and see a similar study conducted in Mumbai and improve the consent form. **The project can be approved by IRB, after fulfilling the above conditions. PI is requested to send new files with revisions for IRB approval.**

4. Study on effective utilization of health care services provided by Community Health Centres in Tamil Nadu stated that infrastructure facilities of Community Health Centres are well equipped with 30 bedded, functioning in government building, the utilization of CHCs are not satisfactory as most of the people prefer to avail maternal health services at the secondary level health facilities such as district hospital/sub district hospital or Medical college hospitals in Tamil Nadu. The district and Medical college hospitals are overcrowded, the normal delivery services need not be referred to higher facilities and may be handled at the block level health facilities. The infrastructure facility of the CHCs are satisfactory with 30 bedded with all equipment and medicine to provide maternal and health services. But the reason behind under-utilization of CHCs need to be examined with respect to infrastructure, manpower, equipment, medicine along with perception of users about satisfaction for utilizing the maternal and health services in

the CHCs. The study would provide useful inputs to the policy makers and the implementers to identify the reasons hindered for the low performance of Community health centres, for taking corrective measures on bottlenecks, disparities and suggest ways to improve the standards which will help in improving the utilization of CHCs. IRB members gave the following comments: how to capture effectiveness is not clear; what are the indicators- based on which the project is capturing it? Further, CHC has so many dimensions of health- why only maternal care is emphasized is not clear. Whether the project is interested to do an audit? If so, how? No specific indicators are given to measure effectiveness- it needs to have a base to capture efficacy. Further, consent form has not mentioned withdrawal options- needs revision. This project looks similar to the previous project mentioned above. It was also noted that the file that was submitted for IRB clearance by the PI is getting combined with another project submitted by Dr Kavitha, and both projects have similar kind of objectives and thus need serious look. It was requested by IRB to send independent file to IIPS project cell and be discrete in making two projects different. **The project can be approved by IRB, after fulfilling the above conditions. PI is requested to send new files with revision for IRB approval.**

5. Tracking Progress in Girl Child Development through welfare schemes of Assam aims to assess the levels and trends in age at marriage in Assam and its districts; to examine the patterns and disparities in age at first marriage across the population sub-groups of Assam during 2021-23; to measure impact the girl child welfare programmes have on their age at first marriage in Assam. The project already received funding and needs factsheet production at the earliest. IRB members gave the following comments: the current project is on girl child marriage – so how come the title is on welfare scheme assessment! The title and objectives are not going hand in hand. IRB commented that either focus on development indicators and do the project accordingly or, make the title clear focusing on child marriage. The question was raised on measurement of sub groups- it needs clarity in definition, selection, spatial extent, measurement. The consent form is not clear, in case respondent is not an adult how to go for the survey. **The project was requested to be revised, tuning the objective of the first phase and the content given; resubmitted for IRB approval.**

6. The project on the evaluation of the working of DEIC Haryana focuses on developmental delays that are common in early childhood affecting at least 10 percent of the total children. These delays, if not intervened timely, may lead to permanent disabilities like cognition, hearing and vision. In this context, the Ministry of Health and Family Welfare, Government of India is committed to improve survival outcome of children, through early identification and management of 4Ds' Program under Rashtriya Bal Swasthya Karyakram (RBSK). The project received the following comments: How to define "working" needs clarity; whether it is a process or outcome evaluation is not clear. Project needs to look into 3 levels of evaluation process. Consent form needs revision- mentioning on withdrawal, contact details, introduction. It was requested not to use sensitive words, value loaded expressions as the study is dealing with

sensitive population. **It is requested to revise and resubmit the consent forms through email to the project support cell. IRB will convey their decision through email upon submission of the revised consent forms.**

7. The next project on as assessment of Maherghar scheme in MH deals with acritical aspect of programme. The broad objective of the study is to assessment of scheme in Maharashtra aiming to evaluate the adequacy of the infrastructure and services under the MaherGhar Scheme in Maharashtra; to understand the views/opinions of the health personnel and beneficiaries about the overall functioning of the Maher Ghar Scheme and the issues faced by them and to identify the gaps in the implementation of the MaherGhar Scheme. IRb suggested to think critically and ask questions that can help understanding the implementation gaps. It was recommended to have case studies and revision of the consent form and resubmit the same for IRB approval. The form needs to mention, withdrawal, videography/ witness, if unable to put signature. **It is requested to revise and resubmit the consent forms through email to the project support cell. IRB will convey their decision through email upon submission of the revised consent forms.**

8. The last project Adequacy of Information Communicated Pre-General Surgery: A cross-sectional study in Sassoon Medical College and District Hospital Pune; aims to explore the importance of quality of communication given to the patient, preferences, patient understanding and discussion of risks/benefits/time factor based on the communication and informed consent before the actual surgery. It aims to assess the adequacy of the pre and post-operative information communicated by the surgeons/physicians to the patients/relatives; to understand surgeon/physicians perspectives of the adequacy, appropriateness and challenges in communication to the patients; to find the gaps (if any) and suggestion to improve the quality of communication to ensure the patients are completely informed before undergoing the procedure and its consequences. IRB comments are: necessity to get permission and do the project through proper channel. Without sanction of the concerned authorities, the project, even if having IRB certificate, can not be progressed Further, consent for <18 years were pointed; reason to chose Pune and a particular hospital were sorted. **The project was approved conditional to clearance from different authorities.**

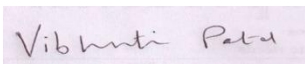
The meeting was concluded with a vote of thanks. The next IRB meeting is proposed to be in the last week of Feb, preferably offline for ease of administration.

Prof. Vibhuti Patel

Chairperson

Prof. Aparajita Chattopadhyay

Convener



Prof A.K. Roy- Member (on CCL,attended meeting, consent through e-mail)

Prof. Gajanan Velhal – Member (consent through e-mail)

Ms. Veena Johari – Member (consent through e-mail)

Dr. Vahida Nainar – Member (consent through e-mail)