



MINUTE

IRB MEETING
HELD ON 27 Feb 2024

International Institute for Population Sciences
Mumbai 400088



An online meeting of IIPS-IRB was held on Tuesday, 27 Feb 2024, from 10.10 AM-1.15 PM. The ~~committee~~ discussed the ethical issues of nine research proposals. One proposal was not presented.

1. A Study of Early Marriages in Assam (ASEMA)
2. Menstrual Health Management (MHM)
3. Study to Assess Private Delivery Preference and Out of Pocket Spending for Delivery in Tamil Nadu.
4. Prevalence of anemia and compliance to weekly iron-folic acid supplementation programme amongst school going adolescents in Maharashtra
5. Prevalence of Mental Health Problems and Treatment Seeking Behaviour among School Going Adolescents in Jammu and Kashmir
6. Low Birth Weight babies and Poshan Sudha Yojana: Examining the linkages in selected districts of Gujarat
7. Exploring Adolescent School Children's Perspectives on Mental Health and Well-being
8. An Assessment of Pradhan Mantri Surakshit Matritva Abhiyan (PMSMA) Scheme in selected districts of Uttar Pradesh”
9. Kinship Structure and Spouse selection practices among youth a study from Udaipur: An Exploration
10. Health infrastructure and service delivery at Nutritional Rehabilitation Centres (NRCs): An investigation in selected District Hospitals in Karnataka- This project was not presented and hence not approved.

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

1. Prof. D.P Singh (Chairperson)
2. Prof. Aparajita Chattopadhyay (Convener)
3. Prof. Archana K Roy (Member)
4. Dr. Lalita Savardekar (Member)
5. Prof. Vaishali Kolhe (Member)
6. Ms. Sushmita Das (Member)
7. Dr. Vinod B Joshi (Legal-Member)

The Chairperson requested all members to start the proceeding for reviewing the projects circulated earlier. Convener welcomed all members, especially the new members who joined IIPS IRB. Dr. Prof. Gajanan Velhal and Mr. Raju Chavan couldn't attend the meeting. Prof A K Roy attended the meeting during her leave period.

1. The first project **A Study of Early Marriages in Assam (ASEMA)** 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 during 2021-23 . This project made all revisions as suggested by the IRB members in the last meeting held on 30th Jan 2024. IRB asked whether the project suggests to take actions against those who had early marriage and the PI clarified that the project is only to understand the reasons for early marriage. The committee members approved the project with a request to add qualitative components if possible, to actually understand the reasons leading to early marriage in different parts of Assam.
2. **Menstrual Health Management of Adolescents in Mumbai Slums** aims to address MHM practices in Mumbai slums. In general, the research aims to explore young girls' issues related to MHM, WaSH exposure and young men's perspectives on MHM, and explore the pros and cons in menstrual health practices of adolescents in slums. Its objectives are to map and measure the KAP, parental behavior, social and environmental obstacles and gender

roles of adolescent boys/men and girls/women related to MHM. The study will further explore the self-reported menstrual health problems, treatment, and help seeking behavior of girls/women. Mixed method approach will be adopted and qualitative data will be gathered from the local school authorities and health workers of the locality on MHM. The project submitted all documents, i.e. consents, assent, questionnaire, KI guidelines as per ethical guiding principle along with research proposals and IRB form. Members accepted the project and approved for conducting the field work.

3. **Study to Assess Private Delivery Preference and Out of Pocket Spending for Delivery in Tamil Nadu** aims to understand the percentage of women who utilized antenatal care services at public health facilities using private health facilities for delivery in districts of Tamil Nadu using NFHS -5, to find out the OOPS for delivery by women at private health facilities who availed Antenatal care services at Public health facilities; to explore the reasons for using private health facility for delivery using qualitative methods. IRB members asked to elaborate the sample selection, more clarity in objectives, private public components. Consent is needed from facility and for individual. Further, it was noted that the project presented by the PI in the last IRB meeting on similar issues (health care) was not yet cleared due to non-submission of relevant revised documents. Hence, IRB can give clearance of projects one by one, depending on the revisions and resubmissions of relevant documents. IRB requested the PI to resubmit the project, and relook into the consent forms.

4. **Prevalence of anemia and compliance to weekly iron-folic acid supplementation programme amongst school going adolescents in Maharashtra** wants to study the prevalence and trend of anemia among school going adolescents (15-19 years) in Maharashtra state using secondary data; to study the coverage of iron and folic acid supplementation in Maharashtra ; to study the compliance and non-compliance of WIFS among study participants of the study area and to identify barriers to compliance with the iron-folic acid supplementation program among school-going adolescents in Maharashtra; to access the perception of frontline health workers, teachers and other stakeholder about WIFS initiatives. IRB suggestions are the following: to cover the heterogeneity of the state, the research can think of adding more districts, and explore issues related to the programme through qualitative research, if budget is the constraint in expanding sample size for quantification; the compliance and non-compliance part need more specification on varying issues like availability and accessibility at facility, at school and for that how to select samples and how to operationalize validity of data need elaboration; compliance card may not be sufficient to understand the programme on anaemia; selection of children considering gender component are not highlighted, ensuring inclusion of those who are not included in the programme needs expansion. The project needs a bit of elaboration and accordingly revision of consent and assent forms (for minors), the consent for health workers, teachers and stakeholders are necessary. IRB requested the PI to resubmit the project, and relook into the consent forms.

5. **Prevalence of Mental Health Problems and Treatment Seeking Behaviour among School Going Adolescents in Jammu and Kashmir** aims to estimate the prevalence of different mental health issues among school going adolescents age 14-18 years, and to identify the factors associated with mental health problems among adolescents; to study the treatment seeking behavior among the adolescents for their mental health problems and to study the variation in perceived mental health issues among the adolescents. IRB's comments are: the project is important and highly sensitive as it is dealing with minor population and mental health issues. So, how to ensure the safety and support for those children if they are mentally unwell? This 'support' component is a must as per research ethical guidelines in mental health research and is done through referral. The consent and assent form need thorough revision, once the parent and the child agree to conduct interviews, then only the interview can start. The PI needs to make provisions for helping out mentally ill children, if asked for. IRB requested the PI to

resubmit the consent and assent forms and look into the IRB forms by marking all required fields.

6. **Low Birth Weight babies and Poshan Sudha Yojana: Examining the linkages in selected districts of Gujarat** wants to study the prevalence and determinants of LBW in the study districts based on secondary data (NFHS-V); To study the prevalence and determinants of LBW in the selected districts based on primary data after the introduction of PSY and to examining the linkages between LBW and PSU in selected district of Gujarat. The suggestions from IRB are as follows: the rationale for selecting the districts is to be given, as the current selection does not capture the heterogeneity of the state; the impact assessment in objectives are not going well with the sample selection, analysis, or the entire write up of the project. The consent form also needs more detailing. IRB requested the PI to resubmit the project, and relook into the consent forms; risks and benefits need mentioning in consent.
7. **Exploring Adolescent School Children's Perspectives on Mental Health and Well-being in Kerala** aims to explore adolescent school children's perspectives on various aspects of mental health and well-being. By utilizing a quantitative research design, the study seeks to gather insights into the prevalence of mental stress, socio-demographic factors, and coping mechanisms among adolescents. IRB's comments are as follows: the project is highly sensitive as it is dealing with minor population and mental health issues. How to ensure the safety and support for those children if they are mentally ill needs elaboration. This 'support' component is a must as per research ethical guidelines and hence the PI needs to address that issue through referral. The consent and assent forms need to be included/ needs thorough revision. Further, the project is very similar to the one presented by PRC, J-K. The objectives are very broad and the title of the project itself is written in the first objective. Hence, specification and narrowing down of the ideas are essential to answer the research questions that the project is trying to address requested the PI to resubmit the consent and assent forms; risks and benefits need mentioning in consent and look into the IRB forms by marking all required fields.
8. **An Assessment of Pradhan Mantri Surakshit Matritva Abhiyan (PMSMA) Scheme** in selected districts of Uttar Pradesh aims to assess the facility level preparedness to cater services under PMSMA scheme; To ascertain the beneficiary satisfaction under PMSMA; to identify the potential factors of PMSMA scheme and suggest appropriate strategies, policies and effective mechanism for accelerating the status of health and nutritional security of pregnant women in Uttar Pradesh. The project was appreciated with the following comments: some of the questions are broad based; to calculate prevalence, it needs specification; how to ensure validity of the data that the project is collecting from facilities; as these are in service facility and working personnel will give the report, how to ensure the sensitivity and reliability of the data; whether audit is to be performed on product availability; the sampling for facilities are not clear, inclusion and exclusion criteria need elaboration; the consent forms are not comprehensive- for every kind of facility, consent is needed; for individual interview, consent is required with risks and benefits need mentioning in consent. IRB requested the PI to revise the project, and relook into the consent forms; risks and benefits need mentioning in consent.
9. **Kinship Structure and Spouse selection practices among youth a study from Udaipur: An Exploration** aims to study the changes in kinship structure and marriage patterns in Udaipur; To understand perception and practice of selection of partners among youth in Udaipur; To understand the evaluation of kinship structures driven by marriage among youth. The project though important, was not very clear in terms of usefulness, research questions, expected outcome, ; whom to interview and related consents; the aims that was presented for this research needs mixed method approach and if it is an interview of 3 generations, then need elaboration of sampling selection and separate consent form; further PI explained kinship role in influencing marriage- which may not

come out from the questionnaire that she presented. IRB requested the PI to resubmit the project, and relook into the consent forms; risks and benefits need mentioning in consent.

10. Health infrastructure and service delivery at Nutritional Rehabilitation Centres (NRCs): An investigation in selected District Hospitals in Karnataka: **Absent**

IRB clearance certificate will be issued, if the projects that needs to be resubmitted are approved by the committee. It was requested to give a training session by faculty concerned of IIPS dealing with PRC on project proposal writing, and explaining modalities in filling up the IRB form. IIPS IRB web page is updated in the last three months and it will add details of filling up the IRB form shortly <https://www.iipsindia.ac.in/content/institutional-review-board>

The meeting was concluded with a vote of thanks.

D.P. Singh

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