

Minutes of IIPS-IRB Meeting held on July 20, 2021

An online meeting of IIPS-IRB was held on Tuesday, July 20, 2021, from 11.00 am 1.30 pm under the chairmanship of Prof. Vibhuti Patel. The committee discussed the ethical issues in two research proposals entitled *Coping mechanism during COVID-19 Pandemic in unorganized Sector: A Qualitative Investigation in Mumbai and Neighbouring Cities* and *Young Wives: An Exploratory Study of Married Women Below Twenty and the Socio-Cultural Determinants of their Contraceptive Behaviour in Low Resource Settings in India*. The following six members of IIPS-IRB attended the online meeting and participated in the discussion:

Prof. Vibhuti Patel	- Chairperson
Prof. S.K. Singh	- Convener
Prof. Gajanan Velhal	- Member
Dr. Lalita Savardekar	- Member
Prof. R. Nagarajan	- Member
Dr. Raju Apnalaya	- Member

The convener of the meeting welcomed the Chairperson and all the members and requested the Chairperson to start the proceeding. Principal Investigators of the project were invited to make a brief presentation of the research proposal, focusing on objectives, methodology, and strategies of human subject protection. At the Chairperson's request, the Principal Investigator of the project "*Coping mechanism during COVID-19 Pandemic in unorganized Sector: A Qualitative Investigation in Mumbai and Neighbouring Cities*" made a brief presentation on the project. The presentation of the project was completed by Principal Investigator (PI) Prof. Dhananjay Bansod, along with the other two PIs. During the presentation, the qualitative survey tools for Key-informant interview (KI) and In-depth interview (IDI) were discussed. The expert committee of IRB has given few suggestions to improve the tools. All the members of IIPS-IRB appreciated the proposal and put some queries and concerns about the plan for survey implementation during the COVID-19 situation.

The Chairperson highlighted that the occupational health precautions could also include examinations like Thermometer, Oximeter, etc. Gender balance should be maintained among the respondents. Some of the reproductive issues can also be addressed for women respondents. ILO Health Report, section 202 can be referred. Prof. S. K. Singh highlighted that this excellent study should select the wards for key informant interviews (KII). The research team should outline some inclusion and exclusion criteria for the selection of entrepreneurs. Respondents' reactions to the lockdown period can explore more separately for KI and IDI. Prof. Singh further highlighted that motivation and expectation should be asked individually, and Social Protection Schemes should also address tools. As this exploration will divide the events and processes adopted in the last two years into three broad periods, it will be better to encourage the respondent to react more to how their life cycle has changed. Five to six FGDs also should be done along with the homogeneous groups.

Dr. Lalita Savardekar highlighted that the interviewer should be mature enough to tackle the situation for sensitive questions. The informed consent should be read out while recording the responses, and photographs also can be taken after the permission of the respondent. She categorically highlighted that the research team should ensure that the training for the investigators should be given very thoroughly to avoid refusal, aggressive reaction, and violence, etc. In addition, she offered two suggestions to the research team. First, to minimize the refusal problems and partially complete, the sample size should be good enough. Second, survey tools should also cover treatment at-home treatment and visiting general practitioners in addition to visiting COVID-19 hospitals. Professor Gajanan Velhal and Prof. Nagarajan also appreciated the study. They suggested the PIs ensure adequate quality checks measured in collecting qualitative data on this vital issue. Mr. Raju Chauhan did not offer any suggestions to the research team.

Dr. Sudipta Mondal, Principal Investigator of the collaborative project between PCI, New Delhi; IIPS, Mumbai, and the University of Austine, USA, presented in brief the background, context, objectives, and methods of the project entitled "*Young Wives: an Exploratory Study of Married Women Below Twenty and the Socio-Cultural Determinants of their Contraceptive Behaviour in Low Resource Settings in India*". Dr. Mondal highlighted that the research project aims to study the socio-cultural norms, including gender roles, that determine the Family Planning (FP) behaviors of young couples and their decisions related to delaying the first pregnancy among such couples in Jharkhand and Assam regions in India; both areas are known for the high incidence of early marriage

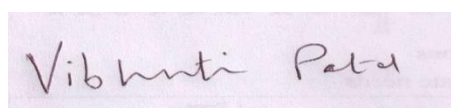
and conception (NFHS-4, 2015-16). The central hypothesis is that a set of socio-cultural and ecological factors play an essential role in separating family planning (FP) doers (adopters) from non-doers (non-adopters) in the same geography. The primary research question involves determining the most critical socio-cultural and ecological factors that can help explain the differential attitude and practices around FP in couples in resource-poor settings. Our objective is to identify predictors of FP adoption by studying the complex cultural ecologies of health, particularly fertility-related beliefs and gender norms, and how they interact with the FP decisions of young couples. In addition, to explain the design and methods for the study, Dr. Mondol categorically mentioned that the study would draw complementary insights from both qualitative and quantitative approaches to triangulate findings. Members of IIPS-IRB appreciated the proposed research and raised their queries on different dimensions of the study.

The Chairperson enquired whether the investigators speak the local language? and what will be the sample size for the qualitative study? Dr. Mondal responded that PCI India has staff positioned in Jharkhand and is aware of the languages spoken in both states, including Hindi, Santhali, Assamese, and Bengali. Investigators will speak the local language for data collection. In response to the second question, he informed the members that the qualitative/ethnography phase of the study would focus on data collection from 20 households that meet our selection criteria (10 each doer/non-doer) from ten selected villages across both states. Young wives, husbands, and mothers-in-law will be requested to the participant from all households. A sequential design will be adopted, where the quantitative phase will follow the qualitative phase.

Dr. Lalita Savardekar enquired that the age of young wives who will be involved in the study is 15 to 19 years. In the light of Section 376 of IPC, how will the study take care of married girls below 18 years? PI responded that as a part of the research protocol, consent would be sought from all respondents, and the data will be collected from only those who agree. This binds the research team to maintain the confidentiality of all data collected. Hence, data will only be used for research purposes by the team. Any case of early marriage or pregnancy of girls before the age of 18 years cannot be reported under the POCSO Act since it will be a breach of confidentiality. The research team has prior experience conducting studies with minor girls in Bihar and Jharkhand on gender-related issues. They have encountered such scenarios and have not reported such cases. Prof. Nagarajan highlighted that this is one of the emerging issues while researching young women and hence required due care. The PI agreed with the suggestion and assured that these issues would be given due consideration during the training of investigators who will be responsible for collecting qualitative as well as quantitative data. The Chairperson cited examples of other community-based research on young women tackling such issues during the training program. She specifically suggested mitigation measures as approaching respondents through community institutions such as Village Organizations, with the permission of State Rural Livelihood Mission. The research team can have a community advisory board for any difficulty in the field. The respondents may contact the board for any queries.

Prof. Velhal enquired that there is a lot of research on family planning in the country, which is still unknown, that this research will throw light on? The PI responded that the research study would focus on the cultural ecology of health and social and gender norms determining family planning behavior among young Indian couples. The study also adopts a systems-level approach – looking at the family as a unit, an entire ecosystem. As a part of the research methodology, the doer/non-doer analysis will be undertaken. In the same ecosystem and geographic area, there will be cases where some young wives can adopt contraceptive methods while others aren't. It will help understand the socio-cultural and ecological factors behind adopting or not adopting modern FP methods for young couples in low-resource settings. Prof. Singh did not raise any questions about being a member of the research team for this study.

With the consent of all the members, the Chairperson announced the proposal to be approved. The certificate of approval of the project proposal will be issued with a soft copy of the Chairperson's signature. The meeting ended with a vote of thanks to the Chairperson and all the members of IIPS-IRB.



Signed by Prof. Vibhuti Patel, Chairperson, IRB, IIPS, Mumbai 5-8-2021