Minutes of IIPS-IRB meeting held on May 18, 2021

An online meeting of IIPS-IRB was held on May 18, 2021, from 11.30 to 2.00 pm under the chairmanship of Prof. Vibhuti Patel to discuss the ethical issues in two research project proposals entitled " Exemplars in Maternal and New-born Health: Understanding the drivers of success in maternal and new-born mortality reduction in India" and "An assessment of the implementation process of large scale surveys to strengthen the quality of data ecosystem in India" The following six members of IIPS-IRB attended the online meeting and participated in the discussion:

1. Prof. Vibhuti Patel (Chairperson)
2. Prof. S.K. Singh (Convener)
3. Prof. Gajanan D. Velhal
4. Prof. Lalita Savardekar
5. Prof. R. Nagarajan
6. Mr. Raju Chauhan

The meeting convener welcomed the chairperson and all the members and requested the Chairperson to start the proceeding. Principal Investigators of the project were invited to briefly present the research proposal, focusing on objectives, methodology, and strategies of human subject protection. Principal Investigator of the Exemplars of Maternal and New-Born Health highlighted that this study would provide crucial evidence to build a deeper understanding of the critical drivers of the reduction in Maternal and New-Born Mortality in India over the last two decades. She highlighted during her presentation that the study aims to systematically investigate, document, and compare the contribution of health policies, programs, and contextual changes that contributed to the rapid reduction in maternal and newborn mortality in India nationally and sub-nationally since 2000. This is the first study investigating the interrelated drivers of NMR and MMR reduction nationally and in states with different mortality levels, health systems, and socio-demographic contexts.

It was categorically highlighted that the study would use mixed methods. Quantitatively, publicly available data will be analyzed, including SRS, Million Death Study, NFHS, DLHS, HMIS, UN-IGME, and GBDS. The qualitative methods will include document review and primary data collection using key informant interviews (KIIs) with 70-120 purposively selected participants, including policymakers, government officials, professional or academic experts, and private and non-governmental sector stakeholders service at different times from 2000 to present. The KII questions will not cover sensitive topics or involve vulnerable groups. The project will canvass suitably developed informed consent form having provisions of voluntary participation, and maintaining confidentiality, so that participation in the survey should not affect participants personally or professionally. The indirect benefits and benefits to society would be contributing knowledge on improving maternal and newborn health.

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 enquired whether the study implementation plan has factored in the detrimental effect of COVID -19, especially the third wave having a potential impact on children. The PI clarified that all the KII would be conducted virtually using social media platforms following specifically designed standard operating procedures. Therefore, there is no risk of getting COVID infection due to the process of survey implementation.
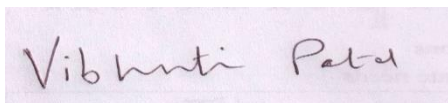
The chairperson raised a follow-up question highlighting that COVID has a definite impact on maternal and neonatal mortality. PIs clarified that they have interest in analysing the key drivers of maternal and neonatal mortality reduction since 2000. If NFHS-5 data may be available in the public domain, it may be feasible to explore this vital issue.

Professor Velhal made two observations: first, probably the per capita income may be considered the driver of maternal and neonatal deaths for the proposed study. Second, what new the study will bring as many drivers of MMR and NNMR have been discussed in previous studies. It was explained by the PI that the task will be conducted in a group of states with high and low mortality. Further, a decomposition analysis will help ascertain whether changes in population composition or educational changes are the key drivers of declining MMR and NNMR in India after 2000. Prof. Nagarajan raised the issue of timing and process of KII, especially given the COVID-19 situation. It was clarified by the PI that KII will be conducted before November 2021 using a virtual platform, and hence varying COVID-19 situations may not affect the process. Prof. Savardekar enquired whether the study, though already approved by the IRB of the University of Manitoba, will be put up for the approval of the Ministry of Health and Family Welfare? It was clarified that as BMGF has sponsored the study, the approval of HMSC of ICMR is not mandatory. This issue has been informed by NHRC, New Delhi, which is the collaborator of this study. With the consent of all the members, the chairperson announced the proposal to be approved.

Chairperson requested PIs of the second project proposal entitled "An assessment of the process of implementation of large-scale surveys to strengthen the quality of data ecosystem in India to make a brief presentation on objectives, method, and human subject protection strategies. It was highlighted that a deeper understanding of effective survey implementation strategies and protocols is an essential component of assessing data quality and data ecosystem, resulting in a reduction of non-sampling error in large-scale surveys. Over the years, most of the large-scale surveys in India, such as the National Family Health Survey (NFHS), District Level Household Survey, Longitudinal Aging Survey, and National Sample Surveys (NSO), have been evolving to address various dimensions of the data quality issues. In the recent rounds of NFHS (2015-16), the expanding contents and coverage of the survey have resulted in about a six-fold increase in the sample size, which may have adverse implementation for the quality of data, especially the risk of increasing non-sampling error. IIPS has adopted several innovative strategies for survey implementation and developed software-based applications to address the data quality. Still, no one has yet conducted any study to assess the efficiency and effectiveness of those approaches, especially from the interviewer's perspectives. Against this backdrop, the proposed research provides the first-ever opportunity to evaluate the survey implementation process from the interviewer's perspectives and its implications for strengthening the data ecosystem in the country.

The specific objectives of the study are to document the best practices adopted by different largescale surveys in India to maintain the data quality and strategies to ensure its effectiveness in survey implementation; to capture the approach adopted by the FIs to ensure completion of the survey within the assigned time frame at the PSU level; to find out the significant problems during training by the field staff (FIs, HIs, Supervisors, and Project Officers) and their linkages with data quality. The study will be using a method mix approach where interviewers will be interviewed using a structured interview schedule. In contrast, supervisors and survey managers will be interviewed using qualitative checklists using virtual platforms.

All the members of IIPS-IRB appreciated this joint effort by IIPS and Population Council, primarily due to the involvement of IIPS in many large-scale surveys in the country where data produced by the Institute are used in policy decisions and formulating newer programs in the area of population, health, and nutrition. Chairperson opined that such a project might help assess operational and conceptual issues affecting data quality. Dr. Nagarajan raised the conflict of interest if IIPS being the nodal agency, will be conducting such a study. It was clarified that the proposed research would encompass all the large-scale surveys in the country rather than only those conducted by IIPS. Second, all the respondents, who have been employees of various survey agencies, will be ensured that their frank opinion on the process will be kept confidential and used only to improve future surveys. Hence, there is no conflict of interest. Prof. Velhal enquired about the expected outcomes of the study and how the data will be analyzed. The PIs explained that IIPS and other nodal agencies like NCEIR, UNICEF, NSSO, and RGI had constantly adopted innovative approaches to strengthen the data quality. Hence, the proposed study will provide an opportunity to assess the effectiveness of those measures from the interviewer's perspectives. The quantitative data will be analyzed using STATA, while qualitative data will be analyzed using Atlat-Ti or NVIVO software. Prof. Lalita Savardekar appreciated the proposal. 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 the vote of thanks to the chairperson and all the members of IIPS-IRB.

Prof. Vibhuti Patel

Chairperson, IIPS-IRB   23-5-2021