

Minutes of IIPS-IRB meeting held on February 09, 2021

An online meeting of IIPS-IRB was held on February 09, 2021, from 3.00 to 5.00 pm under the chairmanship of Prof. Vibhuti Patel. The committee discussed the ethical issues in two research proposals entitled End line Evaluation of SWABHIMAAN Project in the states of Bihar, Chhattisgarh, and Odisha, and a consumer survey on Identifying the Best Labeling System for the Front of Package Labels (FoPL) for Processed Foods 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 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.

End-line Evaluation of SWABHIMAAN Programme

At the chairperson's request, the Principal Investigator highlighted that the proposed end line study aims to estimate the improvements in the coverage of key nutrition-specific and nutrition-sensitive interventions and impact evaluation of the SWABHIMAAN programme. With cluster sampling, design effect of 1.5, and considering the non-response, an estimated sample of 800 adolescent girls and 1000 mothers of children under two years and their children and 300 pregnant women is required in control and intervention areas of each state. She further highlighted that the data collection techniques include quantitative methods. Quantitative data will be collected using Computer Assisted Personal Interviews (CAPI). A trained team of investigators will carry out data collection, and monitoring will also be done. Informed consent will be taken from the respondents before filling the tool. Quantitative data will be cleaned, validated, harmonized, and converted into different formats (SPSS and STATA). Major outcome variables will be nutritional indicators like stunting (adolescent girls aged 10-19 years), chronic undernutrition among mothers, pregnant women with MUAC 23 cm and above, access to nutrition and sanitation programmes. Further, PIs explained the standard operating procedures to protect survey teams and respondents from the risk of COVID infection.

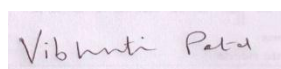
All the members of IIPS-IRB appreciated the proposal and put some queries and concerns about the plan for survey implementation during the COVID-19 situation. The chairperson opined that the study is simply the replica of the mid-term assessment of the SWABHIMAAN programme, which the IIPS-IRB already assessed. Most of the processes and protocols remain the same, and hence there should be a focus on strategies to initiate the survey in a COVID-19 pandemic situation. Once PIs re-emphasized the process and protocols in the context of COVID-19, the chairperson suggested that the term social distance should be replaced by physical distance. Prof. Velhal observed that the proposed study is the end line evaluation of the impact of interventions, what are the expected level of outcomes of interventions. PIs responded that the outcomes are mostly rooted in the capacity building of Self Help Groups (SHGs) and hence mostly in strengthening the process. Subsequently, Prof. Velhal enquired about the plan to link process indicators with outcomes indicators. PIs responded, in brief, the project strategies to integrate these two pieces of information to arrive at the implications of intervention in improving the nutritional status of various target groups. Prof. Savardekar raised precautions to be taken in anthropometric measures, especially because of the COVID-19 pandemic addressed by PIs.

Lastly, Prof. Singh opined that NFHS-5 fieldwork in the second phase states have some problems in response rate for which IIPS has been discussing suitable strategies. PIs of this study requested to share with them if some innovative strategies are developed to address the issues about lower response rates in anthropometric measures in community-based surveys. Prof. Nagarajan and Mr. Raju Chauhan gave their consent as the existing processes and protocols have already been approved at the time of mid-term evaluation.

Identifying the Best Labeling System for the Front of Package Labels (FoPL) for Processed Foods in India

As per the chairperson's instructions, the investigators of this consumer study presented the rationale, objectives, and methodology of the study highlighting that India is witnessing the rise in obesity and non-communicable diseases (NCDs) in an epidemic proportion. Both adult and childhood obesity has increased many folds in the last decade. The ease of access to energy-dense inexpensive processed foods low on nutrition is one of the key factors contributing to the rise in obesity and NCDs. In 2019, the Food Safety Standards Authority of India (FSSAI) had proposed an interpretive FOPL for all packaged foods. The labels included the percentage of recommended daily allowance (RDA) of total calories, saturated and trans-fats, sodium, and added sugar per 100gm of foods. The higher than the recommended levels of these nutrients were shown in brown colour. The FSSAI proposed regulation is shelved for now; however, it appears there is new interest from the government to revisit this issue and potentially issue regulations for the front of pack warning labels. Many labels have been used or proposed in other countries that could be tested in India to understand if they would be effective in the Indian context. Therefore, the **objective of this study is** to compare the warning label, nutriscore labels, multiple traffic lights, and GDA labels to no label in randomized control design in six geographical (urban and rural) location in India.

Members of IIPS-IRB appreciated the proposed study and raised their queries on different dimensions of the study. The chairperson enquired how the research team has arrived at the sample size of 420 respondents for each leg of the five-leg RCT design. The investigators responded that to capture the difference of 21 to 29 percent of awareness on warning levels with 95 percent confidence level, 80 percent power, and 10 percent non-response, the estimated sample size is about 2500, it comes to the estimate of 420 from six different regions. She further enquired about inclusion and exclusion criteria for balancing the compositional aspect of the sample in interviewing using CAPI, which was answered by the research team that the CAPI programme would randomize the target groups and restrict the quota following time location cluster approach. Prof. Savardekar enquired about the background information on such a study. It was responded that it is a multi-country study, and hence there is evidence from other countries. Still, in India, it would be similar to the COTPA act and MPOWER strategies to control tobacco use in the country. Prof. Velhal enquired about the study locations and types of products to be used for showing to the consumers. The research team members explained these issues. Lastly, the Chairperson suggested that the Informed Consent form should not contain the respondent's name, despite the minimal risk associated with such a consumer study. Prof. Nagarajan left the meeting with the chairperson's consent due to some other urgent meeting, and Mr. Raju Chauhan did not raise any concern. Prof. Singh did not raise any questions 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 the vote of thanks to the chairperson and all the members of IIPS-IRB.



Sd. Prof. Vibhuti Patel