



An online meeting of IIPS-IRB was held on 9<sup>th</sup> July 2024, from 11.00-1.15 pm under the chairmanship of Prof DP Singh. The committee discussed the ethical issues of three research proposals.

Sr. No.	Name of the project	Presenter	Presentation Time	Discussion Time
1	Collaboration of RBSK and RKSK with National TB Elimination Programme: An Assessment based on Selected States of India By-PRC Baroda	Mr. Koustav Gosh Mr. Prashant Sekhar	11:00 to 11:10	11:10-11:30
2	A Rapid Assessment to Review the Role of Panchayati Raj Institutions (PRIs) in TB Control Activities - A Pan-Indian Study By-PRC Sagar	Dr. Reena Basu Dr. Nikhilesh.Parchure	11:30 to 11:40	11:40-12.00
3	Exemplars of maternal and New-born health	Dr LK Diwedi Dr Manoj A Dr Guru V	12.00-12.15	12.15-12.30

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

Prof. DP Singh Chairperson

Prof A.K. Roy- Member

Prof. Aparajita Chattopadhyay Convener

Prof. Gajanan Velhal - Member

Dr. Lalita Savardekar - Member

Dr. S Das - Member

The meeting started at 11.00 am. The Convener welcomed all members and mentioned that revised IRB forms and SOP to be discussed after these proposal presentations. The first presentation was on: Collaboration of BSK and RKSK with National TB Elimination Programme Assessment based on Selected States of India.

The overall objective of the study is to assess the functioning of the collaborative programme in selected states of India. The specific objectives are: to examine the extent to which the collaboration programme has been successful in terms of implementation and to study the issues and gaps in implementation of the collaborative programme. The PIs talked about the methodology. The members appreciated the endeavour and encouraged the PIs of the project to give evidence-based findings the strengthen the programme.

The suggestions by IRB board given on this project are as follows:

1. Clear mentioning of the indicators. A checklist to be added with specific goals.
2. Consent forms were not submitted.
3. Training and monitoring details were not mentioned in detail.

**The project was conditionally approved, with the request of sharing the consent forms ASAP.**

The second project: A Rapid Assessment to Review the Role of Panchayati Raj Institutions (PRIs) in TB Control Activities - A Pan-Indian Study was aiming to conduct a rapid assessment to review the role of Panchayati Raj Institutions (PRIs) in TB elimination in 6 States/UTs - Karnataka, Kerala, Gujarat, Bihar, Himachal Pradesh and West Bengal. These are from 5 regions of the country where some activities with PRI's have been conducted since long, as stated by CTBD. Main objectives are to assess the knowledge of PRIs regarding NTEP and TB Mukta Panchayat Initiative, to understand process adopted by NTEP in collaboration with MoPR for certification PRIs for certification of GP as TB Mukta Panchayat, to assess the inclusion of TB related activities in Gram Panchayat Development Plan; explore the role of PRIs in creating community awareness and mobilization for promoting treatment behaviour for elimination of TB and challenges, assess the functions of members across all three tiers. (Gram Panchayat, Block Panchayat and District Panchayat) and corresponding members from NTEP, for achieving the goals of TB elimination, to assess monitoring mechanisms adopted by PRIs for treatment adherence, counselling, nutrition and follow ups; to examine inter-sectoral linkages of PRIs village health sub-committees and VHNSCs with frontline workers like ANMs, ASHAs, AWWs, Jan Aarogya Samitis, SHGs, schools and other local bodies for integrated action to achieve TB free panchayat.

IRB board experts appreciated this Pan India study and made the following comments;

1. It would have been better to check the reliability of the secondary data. Even a small sample, if collected to back check the data quality would have been a good contribution.
2. The project needs intense monitoring. PIs are requested to ensure it, this being a Pan India study
3. Please mention the potential risk of data collection.
4. Details of sample was asked. This is already reflected in the proposal:

Study Frame	Respondents (PRI)	a collection method	Sample Size (1 district)	Total (2 districts)
Gram Panchayat level	Sarpanch,/Panch	In-depth semi-structured interview (2 per GP*3GP)	6	12
	CHOs	(1 per GP*3GP)	3	6
Block/Janpad Panchayat	Chairperson/ Vice	Depth Interview (Key informant)	1	2
	Chairperson/ CEO/ STS	1 per treatment unit	1	2
Zila Panchayat	Chairperson/ Vice	Depth Interview (Key informant)	1	2
Health Department	DTO	In-Depth Interview	1	2
Gram Panchayat	JAS/VHNSC members/ Non PRI	Focus Group Discussion	2	4
<b>Total</b>			<b>15</b>	<b>30</b>

The PIs were asked to take care of the above points while conducting the research. However, one PI stated that they cannot make data quality check, yet another PI stated that they are doing the quality check and the project was already approved by MoHFW.

**The project was approved with the request of giving a short reply to the above points.**

The third project, Exemplars of Maternal and New-born health: Understanding the drivers of success in maternal and newborn mortality reduction in India, was seeking IRB approval for the second phase of the study. This project has received the IRB certificate in 2021. The documents of the project were submitted a week before and the IRB certificate 2021 was sent on 8<sup>th</sup> July. This 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. It stated that this is the first study to investigate the interrelated drivers of NMR and MMR reduction nationally and in states with different mortality levels, health systems and socio-demographic contexts. PI stated that the study will use mixed-methods. Quantitatively, publicly-available data will be analyzed including SRS, Million Death Study, NFHS, DLHS, HMIS, UN-IGME and GBDS. They will describe trends in maternal and newborn mortality, intervention coverage and equity, and health system changes since 2000, and conduct multivariate analyses on the contribution of key drivers of mortality reductions, as stated in the brief proposal.

The experts of IRB gave the following suggestions:

1. Please specify the aim of this extension study – the value addition, as the PI stated that the previous data-based analysis was already done.
2. Why to expand the sample size now? Whether any analysis is done based on which they are extending the sample?
3. Is it possible to check the online data collected with the offline face to face interaction-based data that you are planning to do? The reason is to understand the difference in quality of online and offline data and that could be a good contribution of the study
4. The project talked about ‘systematically investigate, document and compare the contribution of health policies...’- whether they are doing meta-analysis, systematic review? If so, in what way that is different from the previous work that they have done. It is not clearly understood as to what the proposal has submitted/ talked about and what is the aim of the extension research.
5. Need to spell out clearly the methodology of this study. No detail proposal of this extension work is shared.
6. If it is an internationally collaborative study and getting funding from abroad, need to get clearance from appropriate authority.

**PI is requested to submit a detailed reply with the explanation of the above points ASAP for IRB certification of this extension research work.**

The IRB committee discussed the revised form of IIPS IRB and the SOP related issues. The members are requested to send their comments in review mode/comments before 28<sup>th</sup> July, 2024. IIPS would be arranging a half day meeting off line to finalize the IRB form etc. and the possible date is 30<sup>th</sup> July 11.00 am 1.00 pm.

The meeting was concluded with vote of thanks.

Prof. D.P. Singh - Chairperson ----

*D.P. Singh*

Prof A.K. Roy- Member

- *A.K. Roy*

Prof. Aparajita Chattopadhyay - Convener -

*Aparajita Chattopadhyay*

Prof. Gajanan Velhal - Member - [consent through email]

Dr. Lalita Savardekar - Member - [Consent through email]

Dr. S Das- Member

- [Consent through email]