IRB MEETING
22nd SEPTEMBER 2025

International Institute for Population Sciences
Mumbai 400088

Minutes of the Meeting

A meeting of IIPS-IRB was held on **22nd September 2025, from 04:00 P.M. to 06:00 P.M.**, under the chairmanship of **Prof. D.P. Singh**. The Chairperson, together with the Convener, warmly welcomed all members of the committee. As the composition of the IRB is revised, newly appointed members present at the meeting were invited to introduce themselves. Additionally, the Convener provided introductions for the IRB members who were unable to attend due to prior commitments. The diverse expertise represented within the committee was highlighted, emphasising the important role each member will play in upholding ethical standards in research.

The committee discussed the ethical issues of two research proposals.

S. No.	Name of the project	Principal Investigator	Presentation Time	Discussion Time
1	Medical Method of Abortion: A study of pharmacists and community health workers in Odisha	Dr. Harihar Sahoo, Associate Professor and Head, Department of Family and Generations, IIPS	04:00 P.M. to 04:30 P.M.	04:30 P.M. to 05:00 P.M.
2	Qualitative study of social frailty and cognitive health in older adults in Maharashtra (Undertaken as part of the ongoing research project titled "The cognitive consequences of social frailty: a mixed methods study of precarity and resilience among aging populations in India)	Dr. T. R. Dilip, Associate Professor, Department of Family and Generations, IIPS	05:00 P.M. to 05:30 P.M.	05:30 P.M. to 06:00 P.M.

Project 1:

"Medical Method of Abortion: A study of pharmacists and community health workers in Odisha"

The proposal was presented by Dr H Sahoo. The main objectives of the project are : To understand knowledge and attitudes towards Medical Method of Abortion (MMA) among pharmacists, ASHAs and ANMs; to identify barriers faced by these functionaries in facilitating MMA; to assess the influence of sociocultural stigma on their roles and practices and to develop a strategy for improving the capacity and integration of these stakeholders into reproductive healthcare service provisions.

IRB Committee comments:

Prof. (Dr.) Gajanan D. Velhal

1. Rationale and significance of the study should be clearly articulated.

2. It is recommended to clearly define and include the specific role of ASHA/ANM in the research proposal, focusing on whether they are expected to refer beneficiaries or provide detailed information.
3. Clarification required on the criteria for identifying, selecting, and contacting the ASHA workers as respondents.
4. A clear justification for the selection of districts to be included.

Dr. Lalita S. Savardekar

1. The methodology should clearly explain how information on unmarried women and partners to be captured.
2. Obsolete or outdated questions should be eliminated. Certain questions require reframing for clarity, while others can be reduced or removed.
3. Details required on who will conduct the survey and In-depth interviews (IDI).
4. The proposal should describe the details of the training for field investigators.

Ms. Sushmita Das

1. Ms. Sushmita strongly recommended conducting a pilot test of the questionnaire.
2. It is proposed that, although purposive sampling is the method for sample selection, additional criteria should be incorporated into the questionnaire to better guide the identification and selection of sample.
3. The questionnaire should be properly framed and, if required, certain questions may be eliminated.
4. It is recommended that field investigators be properly trained or experienced to ensure accuracy and consistency in the data collection.

Prof. Archana K. Roy

1. It is proposed to include the criteria for selection of the study participants in the research proposal.
2. Clarification required on how this study is expected to contribute to policy-making and what its importance will be in informing relevant policies.
3. Limitations of the study to be included in the proposal.
4. It is suggested to provide clear directives in consent that should be obtained.

Prof. D. P. Singh

1. Although purposive sampling is the sample selection method in the research, it is recommended to include stratification or a quota sampling approach for the selection of health workers to capture variations like seniority or experience, enhancing the depth of analysis.
2. Since the study involves tribal areas in Odisha, it is recommended to include local practices such as traditional exchanges and herbal medicine in the qualitative data to enrich the findings.

Prof. Aparajita Chattopadhyay

1. Obtaining a prescription from a doctor is essential for the issuance of any medication for abortion. To explore the prevalence of abortion practices conducted without a prescription, one might consider formulating a set of questions that can somewhat capture this issue and give a rough estimate.
2. Understanding the risks associated with Population research is crucial. Pl change your statement of No risk, wherever mentioned (Say in Annexure 1, page 3).
3. Your objective states 'developing a strategy'. Developing a comprehensive strategy may require implementing an intervention to validate the effectiveness of this strategy. It is important to outline the specific methods you will use to assess its success. Otherwise, remove the term and say suggestive measures to be given.

Dr. Shireen J. Jejeebhoy

This is an important study that will shed light on MMA service provision by three community-based providers, namely ANMs, ASHAs and pharmacists, all of whom play somewhat different roles in the provision of MMA.

Some comments, technical and on ethical issues that investigators may want to consider are as follows:

Technical

1. The proposal appears to equate ANMs and ASHAs in the provision of MMA services. Is this appropriate? Can the proposal describe the expected role of these two categories of providers and justify the fielding of identical instruments to both?
2. The small sample size proposed is justified because of financial constraints but raises concerns. The plan is to conduct this project in two average districts of Odisha, interviewing just 150 providers in all for the quantitative component and 25 for the qualitative. Half of all interviews will be conducted in each district and presumably, the three categories of workers will be equally distributed too. Hence, overall just 50 providers from each category will be interviewed, half per district. Mention is also made of rural-urban distinctions. Is this really enough for the sub-group analysis proposed?

   Why not consider conducting the study in just one average district, perhaps in just rural areas, to ensure greater homogeneity and increase the sample size within the same budget? I believe it is essential to increase the sample size so that separate analyses may be conducted on each category of provider.
3. I am not sure how tin-depth interview sample will be selected. Since almost all the questions in the IDI guidelines assume that the respondent has had experience delivering services to women seeking MMA, I suggest that the IDI sample is drawn purposively from the survey sample, and

includes those who reported some experience providing one or more MMA service. We are also not told who will conduct the IDIs, is it the same person who will do the survey? How much training will they receive etc.

4. There is no information on the training of survey and in-depth interview field investigators. What kind of training will they receive? In quantitative and qualitative components?

Ethical

1. Consent forms suggest that the IDI will take just 30-40 minutes. The guideline is long (5-6 pages) and contains multiple questions and sub-questions. To my mind, an IDI will take about 1.5-2 hours, and investigators may want to modify the consent form accordingly (or reduce the number of questions). Investigators may want to review this lengthy guideline and drop questions that are not absolutely essential.
2. Several providers who supply MMA to women without a prescription may fear consequences. Perhaps it would be helpful to indicate that no matter what information the respondent provides, that information would remain confidential and secure and would have no consequences for the respondent (or something like that). Although this is said, it may need to be more strongly worded. This is especially relevant for pharmacists.
3. Consent forms should share the entire study design with the respondent. So for example, in the IDI consent form, mention of the survey should be made and vice versa.
4. In all consent forms, why is the name and signature of the "participant/guardian" sought? I assume that all respondents will be adults, so please delete the mention of "guardian".
5. There is always some risk so rather than saying no risk is foreseen, you might say there is a slight risk that the interview will be overheard etc but that interviewers will take all steps to ensure this doesn't happen.
6. If the IDI sample is to be drawn from the survey respondents, the consent form will need to be appropriately modified (some participants may be selected for more in-depth discussion etc, and they should consent to being approached again…

Comments on guidelines, survey questionnaires

1. Guideline p 62: question on which kind of women seek abortion – you might add "unmarried women and girls"?
2. P.63: "Do you understand the difference…" is self-evident. Why not ask whether they know what MMA is and what it entails.
3. P63 and elsewhere: The guidelines assume that providers are aware of MMA specifically and not some other medication supposed to cause abortion. Unless the sample is drawn from among those who were aware and had provided MMA services specifically, some additional probes are needed to ensure that the respondent is talking about MMA and nothing else.

4. Several questions are better off as survey questions and not IDI. For instance knowledge questions (for example p.63 – are you aware of the law? Is a prescription legally required; is husband's consent required etc).
5. P.64 – question on whether worker feels differently about various types of service seekers. This needs to be unpacked much more.
6. P.68-70 important questions, should be crux of IDI

Survey questionnaire, health workers

1. Again, should questionnaires for ANMs and ASHAs be different?
2. Q301: this should be multiple response
3. In many questions (325, 326, 402, 414 for example), responses are MR, but interviewer told to "probe". Does this mean each of the response categories will be asked? If so, chances of saying yes to various options increases, so better to just ask "anything else?"
4. Q305: why not ask the health worker what she does on her first interaction with a client seeking abortion
5. Are Q306 and 312 similar, can they be merged.
6. Along with 313, should you ask whether nmostly women or men come?
7. Q335 and more: many times women visit a provider just to be assured that the abortion is taking place/will take place. Should that be an option? And a question asking what proportion visit them for complications just needing reassurance
8. 404: why not add an option "anyone" or "any woman"?
9. 406: before asking about the two drugs, why not ask what meds are given to help women terminate pregnancy? Health worker may not know mife-miso per se. Likewise, she herself may adhere to common myths (416) so I would ask these myths individually, and ask whether she believes this, and then whether the community does
10. Several questions could be deleted – eg 501, 503
11. Section 6, why not simply 601-623 (Y/N?), and consider reducing this set.

Pharmacists

Many comments above may apply here too

1. 112: include more pharmacy related training?
2. 201: a rural pharmacy may not even serve 50, so why not have a lower limit
3. 207: sometimes pharmacists offer some ayurvedic medicine, or allopathic off-label medicine so need to first ask what they do
4. 212 – would be good to also ask what proportion of MA clients are husbands/partners
5. 213- add a specific option about whether unmarried girls/partners also come

6. Some of the questions in Section 3 on side effects, knowledge of pregnancy etc – are they appropriate for a pharmacist? Is there reason to believe they would be aware of these things?
7. 317: maybe this should be MR?
8. 501: is not useful unless you probe what the role is
9. Section 6 questions – as for health workers
10. 703: are the responses appropriate for a question on "challenges"? Could you ask whether anyone to whom the pharmacist sold MMA drugs came back saying they didn't work or wanted their money back?

The PI/s is/are required to submit a revised proposal/guidelines as soon as possible for IRB review and necessary action.

Project 2:

"Qualitative study of social frailty and cognitive health in older adults in Maharashtra (Undertaken as part of the ongoing research project titled "The cognitive consequences of social frailty: a mixed methods study of precarity and resilience among aging populations in India)"

The presentation was made by Dr T R Dilip. Mental health among older adults needs greater research and programme attention, and this project aims to supplement what we know. It is undertaken in collaboration with the Sri Chithra Institute of Medical Science and Technology (SCTIMST) via a grant from the Indian Council of Medical Research (ICMR, New Delhi. Apparently, as part of an ongoing study using secondary data (LASI), this project will provide in-depth qualitative insights from fieldwork in one district of Maharashtra. Approval is sought for this qualitative component, comprising 75 in-depth interviews with 60 older adults & 15 health system staff members.

The main objectives are: to explore the lived experiences of the elderly with respect to multiple intersecting precarities; to examine how multiple socioeconomic and material need insecurities intersect and affect social frailty especially in the dimensions of social resources, social actions and social functioning of the elderly, and to examine the possible mechanisms through which social frailty affects cognitive health. Further, the research aims to explore the situation of older adults with regard to precarities; examine links of multiple social disadvantage and social frailty, and the mechanisms through which social frailty affects cognitive health.

IRB Committee comments:

The IRB committee reviewed and suggested the following points to be included in the proposal.

Prof. (Dr.) Gajanan D. Velhal

1. The study involves gerontological changes among senior citizens, whose experiences vary widely based on their living conditions, making it difficult to identify all barriers within the

general senior population. Instead of a broad focus, it is recommended to prioritize the most vulnerable groups to better identify and address their specific challenges.

2. It is strongly recommended that greater clarity be provided on how participants will be enrolled.
3. It is proposed to clearly specify and define the scope of the study to ensure focused research and effective identification of relevant issues.

Ms. Sushmita Das

1. It is recommended to include clear criteria for the selection of participants in the research proposal.

Dr. Lalita S. Savardekar

1. It is proposed that the participant selection criteria be clearly defined based on the study objectives.
2. If the study population includes transgender individuals but the sample size is small, it is recommended to limit categorization to male and female to ensure meaningful analysis; or either clarify how transgender participants will be included, how many are expected, and whether a separate IDI format will be developed for them.
3. It is recommended to provide clarity on oral versus written consent and how this will be documented consistently across respondents.

Prof. Aparajita Chattopadhyay

The life course approach is emerging in ageing research. The research on aging is increasingly incorporating these methodologies. This shift reflects a broader understanding of how various life stages and experiences influence the aging process. However, the proposal needs clarity in different aspects. A few comments you may consider for refining the proposal:

1. Failing to understand the basis of selection for IDIs. You stated that there would be 3 levels. Could you pl elaborate? Initially, you mentioned the precarity framework of 4 dimensions. Then you said classification by Gender (M F Trans), then by birth, caste, impoverishment, education, smoking, etc. If you are getting so many combinations, then how could you apply a standard IDI for all to understand social frailty? And in case you need to unfold the life story, you must have a different set of questions for this varied population.
2. Would suggest adding a 'multilevel' structure to your approach, as you mentioned in your proposal.
3. The IDI guideline does not well capture the life course events, and the story-building potential for such a diverse 75 IDIs. Not sure if these 75 cases are suitable for IDI or as case studies. If you really need to develop life stories, then a case study would give you better ideas. You mentioned grounded theory to be applied in your study. I am not sure how IDIs of a similar set of questions will reveal recurring themes of resilience, grief, and the persistent pursuit of a meaningful life, even in the face of the difficulties associated with ageing.

4. Pl note, LASI has asked in detail about the Functional health questions (ADL, IADL). LASI also poses questions on helpers. If the respondent says Yes to any ADL/IADL constraints, the relationship of the helper with the respondent. LASI has some questions on early life scenarios through which you can link the current frailty, and the papers are published on that. LASI has family medical history and a detailed set of social connectedness on a subsample.
5. Then why for Raigarh? Could it have been done in a village and in an urban area?
6. In the Conceptual frame, you mentioned that the social frailty is particularly 'relevant in a post-pandemic context". Could not find its relevance and how does it get addressed in your guidelines.
7. What do you mean by 'declining social protection'? Are you capturing this aspect? How?
8. Pl remove my name from all the participant information sheets- You can add the IRB secretariat and IRB email, if at all essential. Otherwise, the PI's details and the Director's Office address are usually given for further information.
9. Pl note, as per the administrative guideline (No.P/TVS/3663/2025) dated 15 Jan, Prof T V Sekher will no longer be a PI of any project, either funded within the institute or externally funded. However, he can be associated with the project currently engaged in." Kindly note, your participant information sheets mentioned Prof TV Sekher as the first researcher. Pl modify.
10. Some research on life course using LASI data may be helpful, and you might have come across these studies already. We hope that your research will enhance the insights we gain from LASI.
    https://pubmed.ncbi.nlm.nih.gov/37050953/
    https://geographicinsights.iq.harvard.edu/sites/g/files/omnuum10546/files/ssm_2025_life_course_social_mobility_and_cognitive_function_among_middle-aged_and_older_adults_in_india.pdf
    https://bmcgeriatr.biomedcentral.com/articles/10.1186/s12877-025-05727-w

Dr. Shireen J. Jejeebhoy

Some comments, technical and on ethical issues that investigators may want to consider are as follows:

1. Is Raigad district really representative of Maharashtra on average? Could investigators provide some justification for this selection, and why an average district is more appropriate than a less developed district?
2. The sample and phases of interviews are unclear – do investigators mean that two interviews will be held with each study participant, or that one interview will be held that encompasses two components (formative interviews and in-depth interviews).
3. Apparently, men, women and transgender individuals will be selected. How will transgender individuals be identified in ways that don't stigmatise? 5 interviews will be held with each group distinguished by social disadvantage and status-related factors such as education,

smoking, etc. Again, how will these specific categories of people be identified in non-stigmatising ways?

4. Who are the interviewers? Same sex or doesn't it matter? Please clarify.
5. In describing data collection and analysis plans, step 3 is to develop an interview guide – this is unclear. There is already an interview guide contained in this proposal – is this a different guide? And will investigators return to the IRB for approval of this additional guide? Actually, the steps 3,4,5 on p. 17 need to be explained in greater detail.
6. Will findings from the qualitative work proposed supplement the LASI study data, with which this study is linked? Please describe.
7. Consent form – how will you explain terms such as cognitive well-being?
8. Is there a need to say "especially considering your age"? Why not just say some questions may make you uncomfortable?
9. Who is the guardian of the elderly participant? Unclear – do you mean primary carer and if so why not call them so?
10. In describing the procedures, what is meant by "you will be asked to complete an interview schedule"? Do you mean "have a discussion with me" or "answer some questions I will put to you regarding your experiences and insights"?
11. In case the study participant does not wish to sign the consent form, please provide for the investigator to sign that he/she has informed the participant and the participant has consented.
12. Can you say there is no cost for participating? After all, time costs are incurred.
13. Will you be tape-recording or taking notes – if so this should be mentioned in the consent form.

Questions for IDIs with older persons

1. This is an IDI – should you be asking the participant to quantify their health status, why not allow them to describe it in words?
2. Q2 asks if they have a problem, and Q3 onwards seems to be written for those who have a problem – what about those who reported no problem, being independent, etc. Shouldn't there be questions appropriate for them?
3. The social function Qs 1-3 are very general and quite abstract; could they be clarified?

Questions for IDIs with health system functionaries

The PI/s is/are required to submit a revised proposal/guidelines as soon as possible for IRB review and necessary action.

. *** Meeting ended with a vote of thanks ***

Prof. D.P. Singh, Chairperson – DPSingh.

Prof. Aparajita Chattopadhyay, Convener - 26/9/25

Prof. Archana K. Roy, Member – Archana K Roy

Dr. Shireen J. Jejeebhoy, Member – Consent provided via Email dated 26/09/2025

Prof. (Dr.) Gajanan D. Velhal, Member – Consent provided via Email dated 26/09/2025

Dr. Lalita S. Savardekar, Member – Consent provided via Email dated 28/09/2025

Ms. Sushmita Das, Member – Consent provided via Email dated 26/09/2025

Adv. Ashwin C. Thool, Member – Consent provided via Email dated 30/09/2025

Prof. (Dr.) Deepak Raut joined the meeting for a moment but had to leave due to other commitments.

Prof. M. Sivakami could not join the meeting due to prior commitments.

List of attendees

S. No.	Name of the official	IRB Committee
1	Prof. D.P. Singh	Chairperson
2	Prof. Aparajita Chattopadhyay	Convener
3	Prof. Archana K. Roy	Member
4	Dr. Shireen J. Jejeebhoy	Member
5	Prof. (Dr.) Gajanan D. Velhal	Member
6	Dr. Lalita S. Savardekar	Member
7	Ms. Sushmita Das	Member
8	Adv. Ashwin C. Thool	Member
9	Mrs. Avni Goel	Member Secretary (R.O.)