SLUG: COMMENT
TITLE: Ethical obstacles in health systems research in India: need for focused guidelines
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Annexure 1: Application of guidelines to the study context

Points to consider	Applying guidelines to the study context	Tensions observed in the field work	Reflections points
Is it research?	The study clearly defined the elements of research. The study was approved by REC to avoid uncertainties. The field work was done to achieve scalable information and not just to inform local change.		
What aspects are research?	While the research was based on the routine practice, identifying barriers to implementation of nutrition programmes included a checklist of infrastructure available and interviewing the participants to understand the issues faced by the frontline worker i.e., AWW in providing the routine services. This was done to understand the reasons from the health systems perspective to understand the malnutrition problem in areas of majorly tribal regions.		
Is REC review required?	REC approval was sought and received prior to commencement of data collection in the community involving AWW, CDPOs, District level officers, and community participants	REC approval was a requirement as per university norms for study involving human participants. The REC required a proper consent form to be submitted in English and local language. The form was duly scrutinised and recommendations were made with respect to the approach of the study and the biases the health system would bring. The study was guided by the key informant's input for choosing the	Biases in the study and the key informant's power to influence the researcher. The researcher's position with respect to the study.

		AWCs. The key informants had the power to influence the study to show a better picture of their areas than what might be the truth. But with the biases that the approach brought with it, there was no anganwadi level data available in publicly available sources. Therefore, IEC gave their approval.	
Are there adequate plans to manage any conflicts of interest?	The PI is an independent researcher and no conflict of interest were observed.		
Where relevant what is the study intervention?	No interventions were done.		
Who are research participants?	Research participants were both members of the health system, and community members. 3 categories of participants were identified • Key informants- to select the appropriate AWCs, District level officers and CDPOs were interviewed • Anganwadi worker- To identify the key barriers to nutrition programmes • Guardians of beneficiary children- to attain triangulation of findings	There exists a tension to think that the participant has voluntarily agreed to participate when their overseer has asked them to be a participant or given them an option to opt out. It also causes bias when the employee is put into spotlight, they may feel obliged to give specific answers which they may feel is what their overseer might want them to say. Another issue was difficulty in maintaining confidentiality of Key informants.	An important aspect of interviewing participants is obtaining consent. The consent must be understood by the participant, addressing all their questions with respect to their role in the study and their willingness to participate independently has to be established. The issue arises when their overseers instruct employees to participate. In such a situation a tension arises for the researcher to gauge the situation and interpret the voluntariness of the consent provided.
From whom is informed consent required, or is a waiver of consent appropriate?	Separate consent forms were made for the three types of participants. The informed consent consisted of the following information: • Their involvement in the study was explained	Confidentiality was difficult to be maintained when CDPOs were present while interviewing AWW Answers thus given would affect their jobs.	While it was attempted to provide privacy while interviews were conducted, in about half of the interviews conducted the key informant (CDPO) who is also the overseer of AWW accompanied the PI to the AWC. This led to difficulty in maintaining confidentiality of the participant as well as inability to provide the AWW with the adequate privacy. This

	• Confidentiality of participants maintained throughout the process • Participation would not affect their jobs in any way. • The information collected was devoid of identifiers and stored in a password protected device accessible only to PI. • The participants had the right to refuse participation or answer any question any part of the interview. • The original recordings with identifiers would be destroyed after 6 months from data collection. • PI's contact details and the IEC committee chair-person's contact details.		phenomenon can either harm the participants if they reveal something that their overseer might not approve of. This might result in a range of issues including hostile work environment, loss of job, social isolation or harm on their basic human rights. On the other hand, the participant might use this opportunity to provide information in such a way to please their overseer to gain promotion at work. This information may not be reflective of the truth the researcher sets out to find through their research and could also deprive the community of the benefits the research could result in.
Is permission from a "gatekeeper" required?	Gatekeepers were encountered at every stage of the data collection process. An official permission from CEO/Collector was obtained in order to then get permission from ICDS program officer who provided with a list of CDPOs and their contact details along with a written permission for the mentioned period to visit the AWCs in the district. CDPOs also in a few talukas acted as a gatekeeper, restricting the PI from visiting the specific AWCs by taking the PI to the centers and being present during the interviews.	In situation where gatekeepers are so closely involved in the study, it becomes difficult to not only maintain confidentiality of the participants but also leads to control of information being provided.	The PI gained access to the participants in the study by taking permission from the health officials and administrative heads of the district. This route of entry is one that puts the researcher in a position where they might have to comply to guidance provided by these health officials. Therefore, they act as gatekeeper to access information at the Anganwadi centers. The researcher is then exposed to the study setting from the perspective of the system. The officials then have control on the data to be disclosed. From the researcher's perspective, gaining information from study participants fulfils the research obligation and the ethical obligation to gain accurate findings. But this may not always be feasible for the health authorities as CDPO 7 says "*This is a difficult place and I am getting to learn also. But this can be very tricky. One time one person came like you and recorded our data. Then he leaked our recordings. We were answerable to the district officer and higher reporting when it was all over the news. So I didn't let you record. It is only*

			that you showed me the permission I let you see the anganwadi." This goes to show the power with the researcher after data is collected. The officials face adverse effects of letting researchers into the field. The power that the researcher holds and the integrity that the researcher possesses. In such a situation, a tension is created where the researcher must make a decision if they want to keep data confidential also concealing important data that could possibly benefit the society, or they must reveal the data to include uncomfortable truth that may cause harm to the higher officials as well. What level of data must be altered, and how much data must be concealed to fulfil the research obligations, and ethical obligations to participants as well as do collective good i.e., social responsibility.
Is group or community engagement required?	Interview with guardians of beneficiaries was done only for triangulation of findings. Therefore, community engagement was not done.		
Are there adequate plans for protection of privacy and confidentiality?	The interview recordings had identifiers; interview transcripts were devoid of any identifiers. Although the name of the district was specified, the role of the district level officers was not specified. All transcripts and codes were stored in a password protected laptop.	Difficult was faced in maintaining confidentiality when privacy could not be attained.	Although consent forms were designed in such a way that the participants know their rights, it was difficult to maintain privacy and confidentiality of the study. The AWWs interviewed in presence of their overseer replied in shorter and objective sentences. The AWWs that were interviewed in complete privacy elaborately described the functioning of the AWCs, the problems they faced and stories of children that were successfully brought out of the AWCs and the children that were rushed to the hospitals by the AWWs. These stories were more closer to the truth than the shorter, to the point answers that were given by the participants in presence of CDPOs who either using verbal or nonverbal means influenced the information being provided and sometimes even answered questions asked to the AWWs.

Are the potential benefits and risks of the study acceptable?	In the current context, the data collection procedure was not an interventional one. The data collection involved interviews and a check list of the infrastructure. The study was an attempt at understanding and identifying a complex and notorious child malnutrition problem that has existed since a long time. Quantitative studies have reported a consistent and considerable number of deaths among children below the age of 6. Therefore the knowledge gained from a qualitative study to understand the concept reasons for malnutrition from the health system's perspective could improve the approach of provision of nutrition service delivery in Anganwadi centers. This also meant that the participants from the system would be at risk of social isolation, or professional harm. Maintaining confidentiality at different levels of the health systems is therefore a difficult task.		Calculating risks and benefits in the studies like the one described in this commentary is pretty much in the hands of the researcher. Ethical guidelines followed and prescribed by the IEC ie. The ICMR guidelines were used to conduct data collection. Guidelines not specific to health systems do not capture the power relations that exist in the study setting. In countries like India where rural areas have various socio-cultural and political influences on the community; the health systems that aid in health care delivery exists with their own hierarchy and therefore on the truths that the researcher seeks in the study setting are also subsist in the same structures and are relevant for the researcher. It becomes researcher's responsibility to anticipate these tensions/conflicts and make these extremely complex decisions. And even when these decisions are taken after a lot of consideration, it may still cause harm that the researcher could not have anticipated as an outsider. How then must we streamline this process of result dissemination for all the researchers that conduct research in the health system?
Are concerns about justice and equity adequately addressed?	The study addresses a chronic malnutrition issue. Although the district was a tribal dominated one, the tribal groups were not targeted. AWCs were identified based on good and not-so-good performance. The AWWs although participated in the study, it is very difficult to assess if it was voluntary because the CDPOs had either informed them to participate prior to PI's arrival or accompanied the PI to the AWC.		Although the district had a tribal dominated population, data collection was not specific to tribal population. Having tribal groups as the main focus of the study could benefit the specific community, but the selection of such a population could also lead to discrimination against the participants especially when overseers are present during the interviews. The study involved data collection in the good AWCs and not-so-good AWCs. No data with respect to the caste of population was collected.
Where relevant, are there satisfactory plans for access to	There were no intervention.		

interventions after the study, and rollout of successful interventions on a wider scale?			