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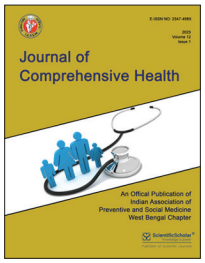

CME/View Point/Book Review

The Unsung Heroes

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Researchers often face major challenges in recruiting participants for trials, either inside the walls of a hospital or the open space of a community. "Trial participants" are the individuals who volunteer and are at the core of all research efforts. This is a tribute to those heroes.

International guidelines for safeguarding research participants, such as the Declaration of Helsinki, and the International Council for Harmonization Good Clinical Practice, ensure ethical conduct, risk minimization, equitable treatment, and protection of participants' rights, safety, and well-being.[1] The members of the Institutional Review Board and Institutional Ethics Committee play a key role in protecting the trial participants including data safety.[2] While all good research follows ethics and standard guidelines; many times the experiences and the perspectives of the trial participants go unsought, unheard, and their efforts under-appreciated. The "how" of recruiting participants bothers the inquisitive minds. The words, "Yes, I shall participate in the trial" when vibrates against the tympanum of a researcher, joy knows no bounds. A multicenter study done by Pillai *et al*. reports that the majority of the participants of a trial knew many aspects of the research that they were a part of. Very few reported having signed a consent form.[3] Another study reported that the trial participants were not aware of which phase or type of trial they were recruited on.[4] Hence, the researchers must ensure that due diligence is exercised while administering the informed consent. Many times people participate in trials for altruistic reasons – the advancement of science and benefit to the human race.[5,6] Both healthy volunteers and diseased participants in trials enable medical sciences to come up with solutions to a variety of health problems. Especially with the pandemic creating havoc, the world did have those warriors, who were ready to get jabbed, swallow a tablet, and donate plasma to curb the virus. Sometimes these heroes are forgotten, and they are not hailed as "COVID warriors" like the rest of the health workforce. It takes courage to participate in a research trial, braving the known and unknown adverse reactions and outcomes. Being managed by unknown faces of the trial team and being exposed to exploratory medications in a "clinical trial ecosystem" is another challenge. Further, their investment of personal time and not being sure of the trial outcomes, either beneficial or harmful, adds to the psychological stress. How often are the above aspects and the contribution of the study participants to the advancement of science acknowledged? How often are these stakeholders made aware of the research outcomes? The "subjects" in the trial environment get bracketed as mere "new recruitment," "mid-way," and "final follow-ups" and not as one of the core stakeholders of the process. Researchers fill fields as "missing data" for drugs not taken or investigations not done. The reasons for reluctance in participation and lost to follow-up are not delved deep into by the researchers. Trial participants most often interact with the study coordinators and research assistants and rarely with the lead investigators. It will be better for the cause of the research if the trial leads can consciously address this gap and if this is done consistently across the trials in various research ecosystems, has the potential to be

a harbinger of positive change. This in the long run also will pave the way for conducting clinical trials with relative ease (overcoming the resistance) and styme the misconceptions (by building trust) in the research processes. Families too, play a key role in deciding participation. Imagine your family member being part of a clinical trial. What would be the thoughts running in your mind? Would you even allow them to give consent? If not for the cooperation of the family members, many trials would not have participants. In certain trials, letting a family member be part of a trial is almost equal to a family member being sent to fight in the army. Do we ever wonder about the family's emotional stress?

We would like to leave the readers with a few questions to ponder upon! How many times have you thought of a participant who participated in your trial, post-completion of the study? How many times have you contacted a trial participant after the completion of the study? The biggest question is do we thank them enough?

We would like to take this platform to say a big thank you to all those who have ever been part of a trial! We will remember you and your family in our daily prayers. Addressing them as "participants" and not as "subjects" would be the stepping stone in honoring these great souls. We urge the researchers to express gratitude to their participants, recognize their sacrifices, and make them feel valued even if it takes a little extra time and effort. A salute to the unsung heroes! In a way, they too are frontline workers! Medical science would not be what it is today, if not for your signature on that consent sheet and cooperation through the course of the trial.

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REFERENCES

1. World Health Organization. WHO GCP Principles; 2005. p. 118. Available from: https://apps.who.int/iris/bitstream/handle/10665/43392/924159392x_eng.pdf [Last accessed on 2024 Oct 09].
2. Available from: https://www.04_irb_independent_ethics_committee_27102017 [Last accessed on 2024 Oct 09].
3. Pillai GS, Sheeba CS, Barman M, Sen A, Sundaram N, Dickson M, *et al*. Knowledge and Awareness of Clinical Trials among Trial Participants in India: A Multicentric QuestionnaireBased CrossSectional Study. Indian J Ophthalmol 2024;72:275-80.
4. Joshi V, Oka G, Kulkarni A, Bivalkar V. Public Awareness and Perception of Clinical trials: Quantitative Study in Pune. Perspect Clin Res 2013;4:169-74.
5. Doshi MS, Kulkarni SP, Ghia CJ, Gogtay NJ, Thatte UM. Evaluation of Factors that Motivate Participants to Consent for Non-therapeutic Trials in India. J Med Ethics 2013;39:391-6.
6. Shah JY, Phadtare A, Rajgor D, Vaghasia M, Pradhan S, Zelko H, *et al*. What Leads Indians to Participate in Clinical Trials? A Meta-analysis of Qualitative Studies. PLoS One 2010;5:e10730.

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