

Understanding how the perception of risks and benefits influences cancer clinical trial withdrawal outcomes

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While people with cancer have options to participate in cancer clinical trials (CCTs), it can be challenging when they encounter difficulties

enrolling and remaining in the trial. Trial withdrawal, although every participant's right, can thwart study goals and hamper advancing novel treatments.

Until now, little attention has focused on what influences retention after participants are enrolled in a trial, especially the role of perceived [benefits](#) and burdens. A new investigation from the University of Pennsylvania School of Nursing (Penn Nursing) has examined the association between patients' perceived benefits and burdens of research participation and CCT retention. It found that the studied patients perceived important benefits from CCT participation, which was associated with trial retention, even among those who also perceived substantial burdens.

"The findings of how perceptions of benefits and burdens were associated with CCT withdrawal outcomes provide novel and foundational evidence of the importance of understanding these perceptions for trial retention," explains Connie M. Ulrich, Ph.D., RN, FAAN, Lillian S. Brunner Chair in Medical and Surgical Nursing, Professor of Nursing and Professor of Medical Ethics and Health Policy at Penn Nursing. Ulrich is the lead investigator of the study.

The study found that when perceived benefits were equal to or greater than perceived burdens, participants were less likely to withdraw than those who perceived the burdens to be greater than the benefits. How participants think about benefits and burdens in a research trial may differ from how researchers and IRBs discern the trial's acceptability.

"Protection of human participants is critical, but more research is needed on how participants perceive benefits, the different types and categories of benefits, and implications of perceived benefits for [retention](#) to elucidate the role of benefits compared with the risks and burdens that participants are asked to bear," says Ulrich.

The results of the study have been published in *JAMA Network Open*.

More information: Connie M. Ulrich et al, Association of Perceived Benefit or Burden of Research Participation With Participants' Withdrawal From Cancer Clinical Trials, *JAMA Network Open* (2022).
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