Enrolling in Clinical Research While Incarcerated: Influences on Participants' Decisions

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Background

As participants in federally funded studies, prisoners in the United States are afforded special protections beyond those governing traditional human subjects research. While these rules have been in place since 1976, surprisingly little empirical attention has been paid to how prisoners arrive at decisions to participate in modern research. The prevailing ethical concerns for clinical research involving prisoners are that they will be coerced or unfairly exploited. The present study sought to fill this gap by identifying a more comprehensive range of factors as identified by prisoners themselves. We hypothesized that participants would endorse a broad range of factors including a desire for treatment, altruism, compensation, and for entertainment, and that few, if any, would describe being coerced into enrolling.

Methods

We conducted semi-structured interviews with 55 incarcerated participants from 6 clinical studies to identify a broader and comprehensive range of influences on their enrollment decisions. We used NVivo 10 for all coding and analyses and for an identified factor to be included in the final results. Both coders had to agree on its presence. At the completion of the coding process, a code frequency list was generated. Coding saturation was evaluated and considered reached when no new factors appeared in a transcript group. Coding quality was evaluated by inter-rater agreement determined by comparing 10 randomly selected transcripts.

Results

The average age of participants was 40.5 years, 54.2% were male, 44.4% were White non-Latino, and 63.8% had completed high school or less. Identified factors favoring enrollment included a desire for treatment, a perception of limited alternative options, altruism, compensation, and others. Although some factors raised concerns about potential exploitation, participants still felt free to decline participation, and none expressed perceptions of coercion. Pressure from others, when present, was viewed as encouraging rather than threatening. Factors against enrollment were also identified, including previously unrecognized influences such as being pressured by correctional staff not to enroll.

Conclusion

These results suggest enrollment decisions are informed by complex and often conflicting motives. An absence of perceived coercion suggests informed consent for these participants is adequate while the presence of additional influences, particularly dissuasion from enrollment, raise novel concerns regarding clinical research with prisoners. While the sample size of 55 participants represents a strength of this study, these findings are limited by the inclusion of studies conducted within only a single state correctional department. The policies and culture of other state or federal correctional systems may produce different influences from those identified here. Similarly, we only interviewed participants from 6 clinical studies and only those who elected to enroll in clinical trials. Future research should include participants who have elected not to enroll in clinical trials, more correctional facilities, and a wider range of clinical trials.