

LETTER

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A response to Al et al. *Trials* 2023;24:233

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Abstract

In their recent paper, Al and colleagues (*Trials* 2023;24:233) argue that manipulation of the methods of recruitment using well-known techniques in order to increase enrollment can be ethically acceptable. This brief response challenges that notion as an affront to voluntariness and a devolution of the ethics of human subjects research to the “ethics” of the marketplace.

Keywords Informed consent, Refusal, Psychological manipulation, Voluntariness

To the Editor:

In their recent paper, Al and colleagues [1] argue that, at least with nonvulnerable subjects, manipulation of the methods of recruitment using well-known techniques in order to increase enrollment can be ethically acceptable. They do add that researchers attempting to use such methods should study their practices (perhaps to ensure they do not rise to the level of coercing or unduly influencing potential subjects), and disclose their methods and purpose to relevant ethics committees. The examples they provide demonstrate the use of manipulation of information (setting social norms, framing of benefits and losses), and “leveraging” the trust patients place in their physicians to bolster recruitment.

The paper appears to be premised on a strong assumption that research participation is the correct normative choice for potential subjects and that researchers (and ethics review boards) are therefore justified in purposefully using psychological manipulation to influence potential subjects’ decisions, biasing people toward

participation. If we start from an opposite assumption, say one in which subjects are to be protected from research risks, then ethics boards “should” be promoting methods to dissuade potential subjects from taking part. In my opinion, neither assumption is wholly correct, so methods having the express purpose and intent of biasing people one way or the other seem illegitimate and dangerous.

A review of reviews conducted several years ago suggested that, across a broad range of human subjects research, something on the order of 30% of potential subjects refuse to participate, ranging from zero to nearly 100% [2]. This rate of refusal is not shocking to established researchers. Perhaps the descriptive should set the norm; I for one worry about recruitment methods when researchers report no or few refusals. Having served on 3 different Institutional Review Boards, I worried too when I heard reviewers conclude that they personally wouldn’t participate, but if “patients” are willing to take part, they won’t stand in their way. Informed consent is imperfect, but putting researchers’ and ethics reviewers’ hands on the scale to tip the balance is paternalism run amok and presents a serious risk to voluntariness [3, 4].

Al et al. justify the use of manipulative methods in part on the basis that “behavioral influence strategies could be considered *prima facie* autonomy-respecting if it is comparable to other uncontroversial behavioral influence strategies to which an individual is routinely exposed in their daily life,” (pg. 4) drawing an analogy to minimal risk, “daily-life” standards for waiver or modification of

This comment refers to the article available online at <https://doi.org/10.1186/s13063-023-07258-4>.

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informed consent. We citizens are bombarded on a daily basis with multimedia marketing and targeted advertising, all of which draw on the well-established tools of propaganda [5–7]. I for one hope that research ethics will not devolve to the “ethics” of the marketplace. Moreover, while it might be argued that these methods might be used simply to enhance the likelihood of potential subjects paying attention and hearing or reading a research pitch (or consent form), people are completely free to give “uninformed refusals.” [8].

I suggest that a better approach is to try to help potential subjects make the best decisions they can under the circumstances, drawing on their own values, hopes, and tolerances for risk and uncertainty. This may increase or decrease recruitment, but in the end, research should serve the interests of subjects as much as, if not more than, other stakeholders, because we ask the most of subjects — they have the most to lose and not necessarily the most to gain.

Acknowledgements

not applicable.

Author's contributions

JFM conceived of this letter, wrote each draft, and accepts responsibility for its content.

Funding

None.

Availability of data and materials

Not applicable.

Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Competing interests

Since 1997, JFM has been a paid expert witness in 3 civil cases involving the adequacy of informed consent and IRB review in research, twice for defense and once for plaintiff, as well as a 4th case involving the definition of human subjects research. In the last 3 years, JFM has received financial compensation for service on several Data and Safety Monitoring Boards for the NIH and the American College of Radiology Imaging Network, and for service on a pharmacogenomics ethics advisory board for Merck. JFM received partial salary support as moderator of the IRBForum (<https://community.primr.org/home>) by a grant from Public Responsibility in Medicine & Research (PRIMR) from 2012 through 2020.

Received: 17 May 2023 Accepted: 3 August 2023

Published online: 13 August 2023

References

1. Al P, Hey S, Weijer C, Gillies K, McCleary N, Yee ML, Inglis J, et al. Changing patient preferences toward better trial recruitment: an ethical analysis. *Trials*. 2023;24:233. <https://doi.org/10.1186/s13063-023-07258-4>.

2. Baker FX, Merz JF. What gives them the right? legal privilege and waivers of consent for research. *Clin Trials*. 2018;15:579–86.
3. Nelson RM, Merz JF. Voluntariness of consent for research: an empirical and conceptual review. *Med Care*. 2002;40(Suppl):V69–80.
4. Appelbaum PS, Lidz CW, Klitzman R. Voluntariness of consent to research: a conceptual model. *Hastings Cent Rep*. 2009;39:30–9.
5. Stanley J. *How propaganda works*. Princeton NJ: Princeton Univ. Press; 2015.
6. Rutherford P. Introduction: advertising as propaganda. In: *Endless propaganda: the advertising of public goods*. Toronto CA: Univ. of Toronto Press; 2000. p. 3–16.
7. Noddings N. Advertising and propaganda. In: *Critical lessons: what our schools should teach*. New York: Cambridge Univ. Press; 2006. p. 170–97.
8. Vorholt V, Dickert NW. Uninformed refusals: objections to enrolment in clinical trials conducted under an Exception from Informed Consent for emergency research. *J Med Ethics*. 2019;45:18–21.

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