LISPOP
Laurier Institute for the
Study of Public Opinion and Policy

Informed Consent and Participant Outcomes

Matthew R. Arp
Research Associate, LISPOP, Wilfrid Laurier University

Abstract

Informed Consent Forms (ICFs) are an essential component of survey research used to provide participants with necessary information and the impact of participating in the study. With increased legal and ethical liability to participants, the length of ICFs has increased over recent decades. This methods note explores the impact of ICF length on participant outcomes and participant preferences.

Keywords: Survey Research, Informed Consent Forms, ICFs

Suggested Citation: Arp, Matthew R. (2020). "Informed Consent and Participant Outcomes." Methodology Briefs. Laurier Institute for the Study of Public Opinion and Policy. Waterloo, Canada

Introduction

Informed Consent Forms (ICFs) are an essential component of research involving human subjects. ICFs provide participants with general information about the study, participant expectations, risks/benefits, compensation/expenses and privacy safeguards. In an effort to provide additional information for ethical and legal purposes, the length of ICFs have significantly increased over recent decades.[1]

ICF Outcomes

The increasing lengths of ICFs is a concern to researchers, since it is correlated with a reduction in participant understanding of pertinent information included within the ICF. Some research has concluded that the relationship between ICF length and negative outcomes is causal in nature. These findings have validated such concerns, finding a link between ICF length and participant understanding, with shorter ICFs leading to higher levels of comprehension.[2]

However, there is a substantial body of literature that challenges these findings, which calls into question the causal relationship between ICF length and the impact on participant outcomes. This body of research contends that participant understanding and comprehension is not directly caused by the length of the ICF. Rather, negative participant outcomes including participant understanding, concerns, trust, satisfaction and consent rates are poor regardless of ICF length.[3] One prominent theory for poor outcomes is the desensitization of participants towards the content of ICFs due to overexposure to legal disclaimers, such as terms of service, which are more frequently encountered in recent years.

ICF Preferences

While outcomes of participants appear to be independent of the ICF length, scholarship has also dissected the relationship between ICF structure and comprehension. The inclusion of particular elements (or the format) of the ICF does not have a demonstrable effect on comprehension or response rates.[4] That being said, participants do have preferences on the inclusion and exclusion of certain elements. The areas of the most concern for participants are foreseeable risks, direct benefit and adverse effects. The areas of least concern are remuneration, conflicts of interest and funding sources.[5] Participants also prefer ICFs that are more concise, while disgruntled by "repetitive", "too detailed" and "laborious" information.[6] Research has also found that participants favour the use of highlighting and utilizing bullet points, bold text and shorter sentences.[7] However, the use of highlight and bold text should be selective and limited to individual words or phrases as opposed to entire sentences or paragraphs.[8]

Conclusion

The literature is in agreement that more concise ICFs and the inclusion of certain stylistic elements are preferred by respondents, even if they do not result in statistically significant improvements in comprehension, consent rates or response rates compared to longer ICFs. It should also be noted that the research cited herein varied drastically in their

definitions of "concise" and "standard", with "concise" ICFs ranging from 2 pages to 16 pages. With respect to style, there is a consensus about emphasizing sections that are unique to the particular study being conducted and using appendices and/or aggregation as a method of shortening the ICF.

Biographical Information

Matthew R. Arp earned his Ph.D. in Political Science from West Virginia University. His research interests include great power conflict and international norm creation. He joined LISPOP as a research associate with a background in large-N data collection, including the During-Conflict Justice (DCJ) and Northern Ireland Research Initiative (NIRI).

[1] Ilene Albala, Margaret Doyle, and Paul S. Appelbaum, "The Evolution of Consent Forms for Research: A Quarter Century of Changes," *IRB: Ethics & Human Research* 32, no. 3 (2010): 7–11; Nancy E. Kass et al., "Length and Complexity of US and International HIV Consent Forms from Federal HIV Network Trials," *Journal of General Internal Medicine* 26, no. 11 (2011): 1324; Amy Corneli and Jeremy Sugarman, "Reducing Consent Form Length: Stakeholder Support, Evidence-Based Strategies, and Regulatory Requirements," *IRB: Ethics & Human Research* 39, no. 2 (2017): 18–20.

[2] Emma Beardsley, Michael Jefford, and Linda Mileshkin, "Longer Consent Forms for Clinical Trials Compromise Patient Understanding: So Why Are They Lengthening?," *Journal of Clinical Oncology* 25, no. 9 (2007): e13–e14; Graham M. Dresden and M. Andrew Levitt, "Modifying a Standard Industry Clinical Trial Consent Form Improves Patient Information Retention as Part of the Informed Consent Process," *Academic Emergency Medicine* 8, no. 3 (2001): 246–252; Mary E. Enama et al., "Randomization to Standard and Concise Informed Consent Forms: Development of Evidence-Based Consent Practices," *Contemporary Clinical Trials* 33, no. 5 (2012): 895–902; Leanne Stunkel et al., "Comprehension and Informed Consent: Assessing the Effect of a Short Consent Form," *IRB* 32, no. 4 (2010): 1.

[3] Kenji Matsui et al., "A Randomized Controlled Trial of Short and Standard-Length Consent Forms for a Genetic Cohort Study: Is Longer Better?," *Journal of Epidemiology*, 2012, 1203220305–1203220305; Neal W. Dickert et al., "Reframing Consent for Clinical Research: A Function-Based Approach," *The American Journal of Bioethics: AJOB* 17, no. 12 (2017): 3–11, https://doi.org/10.1080/15265161.2017.1388448.

[4] Evan K. Perrault and David M. Keating, "Seeking Ways to Inform the Uninformed: Improving the Informed Consent Process in Online Social Science Research," *Journal of Empirical Research on Human Research Ethics* 13, no. 1 (2018): 50–60..

[5] Juntra Karbwang et al., "What Information and the Extent of Information Research Participants Need in Informed Consent Forms: A Multi-Country Survey," *BMC Medical Ethics* 19, no. 1 (2018): 79.

[6] Amy Corneli et al., "Evidence-Based Strategies for Shortening Informed Consent Forms in Clinical Research," *Journal of Empirical Research on Human Research Ethics* 12, no. 1 (2017): 14–25.

[7] Perrault and Keating, "Seeking Ways to Inform the Uninformed."

[8] K. A. Priestley et al., "Are Patient Consent Forms for Research Protocols Easy to Read?," *BMJ : British Medical Journal* 305, no. 6864 (November 21, 1992): 1263–64.