HSPI The Open Access Publisher

APPS ISSN 2639-992X ARCHIVES OF PHARMACY AND PHARMACEUTICAL SCIENCES

Mini Review

Is the informed consent form only a symbolic document in clinical trials?

Buket Gungor*

Department of Pharmacology School of Medicine, Canakkale Onsekiz Mart University, Terzioglu Campus, 1700 Canakkale, Turkey

More Information

***Address for Correspondence:** Buket Gungor, Department of Pharmacology School of Medicine, Canakkale Onsekiz Mart University, Terzioglu Campus, 1700 Canakkale, Turkey, Email: buket.gungor@comu.edu.tr

Submitted: December 05, 2022
Approved: December 16, 2022
Published: December 19, 2022

How to cite this article: Gungor B. Is the informed consent form only a symbolic document in clinical trials? Arch Pharm Pharma Sci. 2022; 6: 035-036.

DOI: 10.29328/journal.apps.1001035

ORCiD: https://orcid.org/0000-0002-5802-1635

Being one of the basic principles of clinical research, informed consent is definitely a legal responsibility and ethical duty for health professionals. The purpose of obtaining informed consent is to enable the subjects to make an autonomous decision by providing them with accurate and clear information about the research at the stage of participation. Due to medical advancements and the increasing complexity of diagnostic and experimental methods in clinical research, the prepared Informed Consent Forms (ICFs) have become difficult to understand [1,2]. Viewing ICFs as just a necessary legal and symbolic document of participation in research often results in an insufficiently informed consent process for subjects [3]. Research shows that the rate of understanding the basic information in the consent forms prepared for the subjects participating in the clinical trials ranged from 52.1% to 75.8% [4].

The International Council for Harmonisation of Guideline for Good Clinical Practice (ICH-GCP), which includes directives on informed consent forms, has been published by regulators in order to establish necessary internationally accepted standards. Good Clinical Practice (GCP) reassures society that the rights, health and privacy of the volunteers participating in the trial will be protected. It provides the principal researcher with guidance on the information that should be in the ICF in clinical trials [5]. Informed consent forms include three critical and essential elements: voluntariness, disclosure of adequate information, and understanding by the subject with decision-making capacity. These critical elements must be present for ethically valid and genuine informed consent forms [6,7].

Volunteering is the ability of individuals to evaluate participation freely and independently, without any coercion, and according to their own values and background to make the most appropriate decision for them. Individuals' voluntariness, intellectual and emotional maturity, as well as the presence of a feared, incurable disease and thoughts about the disease, constitute the very factors that influence their decisions. In addition, people's religious beliefs, cultural values and economic situation also affect such participation [6].

Disclosure of sufficient information should include the information provided about the trial for valid informed consent, as well as the health conditions for which the trial is proposed, the purpose of the trial, treatment/intervention/research procedures, possible risks and benefits associated with research participation, alternative treatments, the guarantee that information will remain confidential, the right to withdrawal from the trial at any time, and the right to be informed when new information is obtained [5]. By stating all the possible side effects of a drug or the risks of the research drug, physicians may consider that they can make the research look unfavorable. On the other hand, in the event that they neglect to mention a side effect, this may invalidate the consent and they may be charged with malpractice or negligence [8].

The decision-making capacity of an individual is defined as "the ability to understand the nature and consequences of health-related information, and to formulate and communicate decisions" [6]. Decision-making capacity depends on one's cognitive abilities and is negatively affected by cognitive impairment. A number of appropriate approaches can be adopted to increase understanding, such as using simplified and easy-to-understand language, conveying information in the form of small and sequential pieces with a focus on important information, ensuring repetition of information, and providing ample time for asking questions and clarifying doubts [6].

In this process, information about the research should be presented to the subject in a clear and understandable way. However, a number of previous studies have reported that this aim cannot be fully achieved and ICFs prepared especially for subjects are very long and difficult to read and patients are likely to fail to understand the basic components of ICF [9-11]. In this context, one study showed that only half of the participants seem to have understood all the components of the ICF and that more than half were unaware that they had voluntarily participated in the research [12]. Researchers should not force, encourage or influence a patient to participate in the research during the participation phase. It should be ensured that clinical trial participation is voluntary and based on informed choices. Still, most patients tend to decide to participate in a clinical trial without reading or understanding the information they are provided with. Without knowing what they are dealing with, patients participate in clinical trials with complete confidence that only healthcare professionals will take care of them. For example, research has also shown that the level of detail of ICFs in cancer clinical trials does not affect the decision of patients to participate in clinical trials, but that further studies are needed to investigate whether or not shorter ICFs turn out to be more effective [13]. Another study compared simplified ICFs (containing plain language, short sentences, diagrams, pictures and bullet points) with standard ICFs and subjects using simplified ICFs had significantly higher levels of objective and subjective understanding, regardless of their health literacy [14].

The fact that current ICFs are not well understood by patients and that they are long and difficult to read seriously undermines the ethical foundations of clinical research. However, while the ICFs protect patients, they also legally protect those who conduct and organize the research. Moreover, it is also worrying that subjects do not understand fully the key components of informed consent, raising questions about patients' participation in joint medical decision-making. ICFs should be shortened in length, technical terms should be avoided, and the focus should be on improving the ICF to make it more readable and understandable to the patient. In addition, researchers should encourage patients to participate in the conversation by asking open-ended questions, giving the subjects enough time and staying in constant communication.

The preparation of the ICFs in the form of questions and answers is a way of shortening them and the researchers need to be trained so that they prepare the ICFs in such a way that they contain both the minimum necessary information and present this information in a way that the volunteers can understand it. Moreover, the use of innovative technologies such as videos in the informed consent process and the gamification of this process, in the form of questions and answers, is likely to increase a volunteer's comprehension of the ICF.

References

1. Cheung WY, Pond GR, Heslegrave RJ, Enright K, Potanina L, Siu LL. The contents and readability of informed consent forms for oncology clinical trials. Am J Clin Oncol. 2010 Aug;33(4):387-92. doi: 10.1097/COC.0b013e3181b20641. PMID: 19884804.
2. Ennis L, Wykes T. Sense and readability: participant information sheets for research studies. Br J Psychiatry. 2016 Feb;208(2):189-94. doi: 10.1192/bjp.bp.114.156687. Epub 2015 Sep 17. PMID: 26382948; PMCID: PMC4837385.
3. Sreenivasan G. Does informed consent to research require comprehension? Lancet. 2003 Dec 13;362(9400):2016-8. doi: 10.1016/S0140-6736(03)15025-8. PMID: 14683665.
4. Tam NT, Huy NT, Thoa le TB, Long NP, Trang NT, Hirayama K, Karbwang J. Participants' understanding of informed consent in clinical trials over three decades: systematic review and meta-analysis. Bull World Health Organ. 2015 Mar 1;93(3):186-98H. doi: 10.2471/BLT.14.141390. Epub 2015 Jan 22. PMID: 25883410; PMCID: PMC4371493.
5. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. Integrated addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2). Current Step 4 version. 2016. www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html. Date of access:23.09.2022.
6. Gupta UC, Kharawala S. Informed consent in psychiatry clinical research: A conceptual review of issues, challenges, and recommendations. Perspect Clin Res. 2012 Jan;3(1):8-15. doi: 10.4103/2229-3485.92301. PMID: 22347696; PMCID: PMC3275995.
7. Kadam RA. Informed consent process: A step further towards making it meaningful! Perspect Clin Res. 2017 Jul-Sep;8(3):107-112. doi: 10.4103/picr.PICR_147_16. PMID: 28828304; PMCID: PMC5543760.
8. Abdussalam M. Informed consent in clinical practice and biomedical research. In: Mansourian BP (Editors), Global Perspectives In Health. (2), EOLSS, Geneva, Switzerland. 2009; 221-234.
9. Schumacher A, Sikov WM, Quesenberry MI, Safran H, Khurshid H, Mitchell KM, Olszewski AJ. Informed consent in oncology clinical trials: A Brown University Oncology Research Group prospective cross-sectional pilot study. PLoS One. 2017 Feb 24;12(2):e0172957. doi: 10.1371/journal.pone.0172957. PMID: 28235011; PMCID: PMC5325585.
10. Gungor B, Aylin M, Asena A, Somuncuoglu EI, Bozkurt NB, Ucku SR, Gelal A. Evaluation of Legal Legislation Compliance and Readability of Clinical Trial Informed Consent Forms. Ther Innov Regul Sci. 2020 Mar;54(2):468-475. doi: 10.1007/s43441-019-00078-2. Epub 2020 Jan 8. PMID: 32072599.
11. Pietrzykowski T, Smilowska K. The reality of informed consent: empirical studies on patient comprehension-systematic review. Trials. 2021 Jan 14;22(1):57. doi: 10.1186/s13063-020-04969-w. PMID: 33446265; PMCID: PMC7807905.
12. Falagas ME, Korbila IP, Giannopoulou KP, Kondilis BK, Peppas G. Informed consent: how much and what do patients understand? Am J Surg. 2009 Sep;198(3):420-35. doi: 10.1016/j.amjsurg.2009.02.010. PMID: 19716887.
13. Almodallal Y, Duong Q, Satele D, Novotny P, Cook KD, Chauhan C, Daiss MK, Le-Rademacher J, Looker S, Martin N, Smestad MF, Winham SJ, Mandrekar SJ, Jatoi A. Randomized, Double-Blind Trial on the Impact of Word Count in Cancer Clinical Trial Consent Forms. JCO Oncol Pract. 2021 Oct;17(10):e1460-e1472. doi: 10.1200/OP.21.00071. Epub 2021 Jun 14. PMID: 34125586.
14. Kim EJ, Kim SH. Simplification improves understanding of informed consent information in clinical trials regardless of health literacy level. Clin Trials. 2015 Jun;12(3):232-6. doi: 10.1177/1740774515571139. Epub 2015 Feb 19. PMID: 25701156.