

Designing and compiling a generic informed consent form for human volunteers participating in research

Yousefinejad Ostadkelayeh A. (M.Sc.)¹, Larijani B. (M.D.)², Majdzadeh S.R. (Ph.D.)³, Madadi A. (B.S.)⁴, Zabiheyan M. (M.D.)⁵, Parsapour A.R. (M.D.)⁵, Tamini H. (M.Sc.)⁶, Soleimani H. (M.Sc.)⁷, Zamani G. (Ph.D.)⁸, Nikbakht A.R. (Ph.D.)⁹.

1- Expert in Internal Medicine and Surgery Education, Research Deputy, Tehran University of Medical Sciences, Tehran, Iran.

2- Professor, Department of Internal Medicine, Faculty of Medicine, Tehran University of Medical Sciences, Tehran, Iran.

3- Associate Professor, Department of Statistics and Epidemiology, Faculty of Public Health, Tehran University of Medical Sciences, Tehran, Iran.

4- Bachelor's degree, Tehran University of Medical Sciences, Tehran, Iran.

5- General Practitioner, Tehran University of Medical Sciences, Tehran, Iran.

6- Instructor, Faculty of Rehabilitation, Tehran University of Medical Sciences, Tehran, Iran.

7- Expert, Tehran University of Medical Sciences, Tehran, Iran.

8- Assistant Professor, Department of Statistics and Epidemiology, Faculty of Public Health, Tehran University of Medical Sciences, Tehran, Iran.

9- Assistant Professor, Department of Internal Medicine & Surgery, Faculty of Nursing & Midwifery, Tehran University of Medical Sciences, Tehran, Iran.

Abstract

Introduction: Performing research on (human) volunteers may involve useful or harmful effects. To preserve the volunteers' dignity, numerous world associations have issued declarations such as Nuremberg's, Helsinki's, Belmont's report, etc. One of the four ethical principles in research is respecting volunteers' rights and the most obvious aspect of this respect materializes in obtaining the volunteers' informed consent.

Materials & Methods: This informed consent form has been compiled by a Delphi quality study which 15 experts have participated in its designation and compilation. At first, the experts replied the questions posed by the researchers on the frame and contents of the form. Then, the replies were summarized and once again were sent to the experts for a second revision. Eventually, the final form was edited by a Persian language expert.

Results: The final result of this research is an informed consent form which includes three main parts: introduction, body and places provided for signatures.

Conclusion: Compilers of this form find it a suitable and useful way to obtain volunteers' informed consent. This form has been prepared for all researchers in different fields of medical science and the authors welcome any comments, suggestions or criticisms by professors and specialists.

Key Words: Research, Human subjects, Volunteer, Informed consent.

Corresponding Author: Yousefinejad Ostadkelayeh, Ali., NO. 23, Dameshgh Street, Vali-e-Asr Avenue, Tehran, Iran, P.O. Box 14155-5799.

E-mail: Ali_yousefinejad@razi.tums.ac.ir