Health, Spirituality and Medical Ethics Journal
Qom University of Medical Sciences

Autumn 2022. Volume 9. Number 4

Research Paper

Researchers' Experiences of Obtaining Informed Consent to Participate in Human Research and Its Facilitating Factors: A Qualitative Study

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Please cite this article as Abbasinia M, Babaii A, Kazemnejad M, Amiri NZ, Researchers' Experiences of Obtaining Informed Consent to Participate in Human Research and Its Facilitating Factors: A Qualitative Study. Health Spiritual Med Ethics. 2022; 9(4):187-196. http://dx.doi.org/10.32598/hsmej.9.4.206.1

doi: http://dx.doi.org/10.32598/hsmej.9.4.206.1

Article info:
Received: 4 March 2023
Accepted: 31 May 2023
Publish: 01 Dec 2022

Keywords:
Informed consent, Ethics, Research, Qualitative study

ABSTRACT

Background and Objectives: Considering the lack of information about the ethical principles required to obtain informed consent, this issue should be given more attention by researchers. This study aims to extract the rich experiences of researchers regarding obtaining informed consent to participate in human research and its facilitating factors.

Methods: This qualitative study was conducted with the content analysis approach in 2023. Using targeted sampling, 17 researchers from the Qom University of Medical Sciences were selected, and quasi-structured and individual interviews were conducted until data saturation. Data were analyzed simultaneously with data collection using the Granheim and Lundman method.

Results: According to the results of this study, based on the nature of the study, researchers can use any of the written, oral, or electronic methods to obtain informed consent. The researchers believed that the principles of obtaining informed consent include voluntariness, avoiding coercion, the existence of two-way interaction between the researcher and the research samples, and providing necessary information to the research samples. According to researchers' experiences, the factors that facilitate obtaining informed consent include establishing effective communication with researchers and samples, the appropriateness of the text of the informed consent, preparing a multimedia file of the informed consent, holding training courses, and having clear and up-to-date instructions.

Conclusion: The principles of obtaining informed consent and the facilitating factors mentioned in this research can help researchers observe this critical aspect of ethics in research.

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Introduction

Informed consent, in the field of research, is defined as the voluntary agreement of individuals to participate in the research based on sufficient information about the research objectives and its consequences [1]. Informed consent is the ethical cornerstone of research because it is the practical application of the ethical principles of independence or respect for individuals [2]. Nevertheless, the ideal ways of obtaining informed consent have been less considered, and still, ethical challenges exist in this field [3]. The principles of obtaining informed consent have become more complex over time. The study results showed that only about 38% of researchers knew the content of ethics rules in health research [4]. Researchers' understanding of the principles of informed consent varies from ignorance to full awareness [5].

According to the different understandings of the researchers about the principles of informed consent, the way of obtaining informed consent can also be different [6]. A challenging topic among researchers is the basic and ethical principles of informed consent. Because of the required items to obtain informed consent [7], the methods of obtaining informed consent [8], the amount of information required by the participants to participate in the study [9, 10], and how much trust the participants in the researcher can affect their voluntary decision is always raised as ethical challenges of obtaining informed consent [11].

Several studies have been conducted on the principles of obtaining informed consent. These studies include the quality of the informed consent form [12, 13], the level of awareness of the samples about informed consent [14, 15], the effectiveness of the methods of providing information to obtain informed consent [16, 17], and the level of providing information to the participants for informed consent [18]. These limited studies do not provide insufficient information on the ethical principles required to obtain informed consent. Therefore, researchers should pay attention to the ethical and scientific principles in obtaining informed consent. Analyzing the rich experiences of researchers regarding obtaining informed consent to participate in human research and its facilitating factors can lead to a deep understanding of these conditions. This deep understanding can help research policymakers formulate more precise ethical principles to obtain the consent of research participants. Due to the limited information about the ethical principles required to obtain informed consent, this study was conducted to explain the experiences of researchers regarding obtaining informed consent to participate in human research and its facilitating factors.

Methods

Design

According to the study objectives, a qualitative method with a content analysis approach was used to conduct the study because the naturalistic paradigm and qualitative study methods discover the participants' perception of reality based on the context, in which it occurs and explain the different structures of a phenomenon [19].

Setting and participants

The study setting included hospitals affiliated with Qom University of Medical Sciences, Iran. The inclusion criteria included having at least five years of experience in researching humans, the ability to speak Persian, and having informed consent to participate in the study. Seventeen researchers were selected purposefully and included in the study.

Data collection

Data were collected using quasi-structured in-depth and face-to-face interviews with the researchers from March to November 2022. According to the participants' tendency, the interviews were conducted in a comfortable and quiet place. The interviews were conducted in Persian and the duration of the interviews was 40 to 50 minutes. The interview questions were as follows:

What methods do you use to communicate with the patient to obtain informed consent? What are your experiences on how to communicate with patients to obtain informed consent? What are your experiences in obtaining informed consent from patients? Following answers to the above questions, exploratory and in-depth questions were asked in this regard; for example, can you explain more? What does it mean? From interview 14, we reached data saturation, and no new code was created. For more certainty, three more interviews were also conducted.

Data analysis

All interviews were recorded with the permission of the participants. After each interview, the recorded content was immediately typed word by word and analyzed by Granheim and Lundman method. This method mainly focuses on the subject and the context and emphasizes the examination of differences and similarities in codes and classes. First, all interviews were read and re-read by the research team to understand the overall perspec-

tive of the topic to be developed. In the next step, all the relevant semantic units were extracted and the semantic units that deviated from the focus of the study were discarded. Then, semantic units were assigned to subcategories based on similarities and differences. The subclasses were also compared with each other and assigned to classes based on similarities and differences [20].

Trustworthiness

Lincoln and Goba criteria, including credibility, transferability, dependability, or confirmability were used for trustworthy [21]. For credibility, the extracted codes from each interview were checked with the interviewee and modified if needed, and the text of the interviews with the extracted codes and categories was provided to two professors and their corrective comments were applied in the coding process. For transferability, maximum variance sampling was performed (Table 1). For dependability, the long engagement of the researcher with the participants and continuous comparative analysis of the data was performed. After the initial formation, the codes were examined and compared several times, repeated and saturated codes were analyzed and classified, and the non-repeated codes were excluded from the classification and analysis. For confirmability, the codes and classifications were reviewed and approved by a faculty member out of the research team.

Results

In this study, 17 researchers participated. Most of the researchers were women (53%) with a PhD degree (70%) and had 10-20 years of research experience (65%) (Table 1).

The themes arising from the interviews are divided into four general categories: The nature of obtaining informed consent, methods of obtaining informed consent, the basic principles of obtaining informed consent, and factors that facilitate obtaining informed consent (Table 2).

The nature of obtaining informed consent

The nature of obtaining informed consent to participate in the study included two subcategories: The necessity of obtaining informed consent and the cases that require obtaining informed consent.

The necessity of obtaining informed consent

Most participants stated that obtaining informed consent is a beneficial process for the researcher and research samples. Performing this process creates confidence in research samples and increases their continued participation and cooperation to participate in the study. “When we communicate with the patients and tell them that we have a code of ethics and tell them in detail that our work is legal and what we want them to do, they cooperate better” [P12]. Also, the participants explained that the benefits of obtaining informed consent for patients include the obligation of researchers to respect the legal and ethical rights of the samples to participate in the study. “Informed consent is a moral obligation against no harm to patients” [P16]. “Informed consent is a way to ensure that patient’s rights are respected” [P6].

Cases that require obtaining informed consent

Informed consent is a key concept in human research ethics. The participants believed that in any research that includes human samples, informed consent should be obtained from each sample to participate in the study.

Table 1. Characteristics of study participants

Characteristics		No.
Gender	Male	8
	Female	9
Educational level	Master	5
	PhD	12
Practice experiences (y)	<10	4
	10-20	11
	>20	2

Table 2. Researchers' views on the nature of informed consent

Classes	Sub-classes
The nature of obtaining informed consent	The necessity of obtaining informed consent
	Cases that require obtaining informed consent
Methods of obtaining informed consent	Obtaining a written informed consent
	Obtaining informed consent verbally
	Obtaining informed consent electronically
Basic principles of obtaining informed consent	Voluntary participation in the study
	Avoiding coercion
	Two-way interaction between the researcher and the research samples
	Providing essential information to research samples
Facilitating factors to obtain informed consent	Effective communication
	The appropriateness of the text of the informed consent
	Preparing a multimedia file of informed consent
	Conducting training courses and having certain and up-to-date instructions

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Therefore, in all descriptive, analytical, and experimental studies on humans, we should obtain informed consent to participate in the study. The participants stated that before starting the study, whether the person realizes or not that he/she has participated in the study, he should be informed about his/her participation in what study and the methods and interventions. They should also be informed about the benefits, disadvantages, and possible costs. After informing people, it is necessary to ensure informed consent to participate in the study. "All human beings have the right to decide whether to participate in a study" [P6].

Methods of obtaining informed consent

When researchers were asked to describe their experiences of how to obtain informed consent, they stated three written, verbal, and electronic ways.

Obtaining informed consent by written method

Most participants declared that for an intervention on the research samples, they use the written method to obtain informed consent to participate in the research. They stated that in obtaining written informed consent, forms were provided by the Ethics Committee of Universities and research centers. Researchers record their research information in these forms and provide them to the research samples so that after the study if they have consented to participate in the study, they can sign it. Most participants emphasized that while studying the relevant form, they are present next to the samples to answer their questions and doubts. Also, in the case of illiterate people, researchers read the form word by word for samples. "I always prepare an informed consent form and provide it to the samples. This form is reviewed by the University's Ethics Committee during the proposal defense process" [P15].

Obtaining informed consent verbally

Some participants stated that when no intervention is done on the research samples and the samples themselves complete the questionnaires, they use the verbal method to obtain informed consent. However, some participants stated that they use the written method in these cases. For this purpose, the participants prepare a written informed consent and explain its items orally to each sample. In this method, the participants emphasized answering the ambiguities and questions of the research samples. In the end, if any of the samples were willing to participate in the research, the data collection questionnaires were provided to them to complete. Some participants stated

that at the beginning of the questionnaires, they wrote a sentence with the following theme: "I was informed about the purpose, method, benefits, and disadvantages of the study and I participate in this study with informed consent". Then, they asked the samples to sign below this sentence. "Where the samples themselves want to complete a questionnaire, I am satisfied with obtaining verbal consent" [P08].

Obtaining informed consent electronically

A few participants stated that sometimes they use electronic methods to obtain informed consent. In this regard, they prepared the electronic form of informed consent to participate in the study in a multimedia format and provided it to the research samples using email or other social networks and asked them to sign the form in case of informed consent to participate in the study. "Sometimes I prepare the consent form electronically... In addition to the text, I also prepare video and audio about the objectives and method of the study and send to them" [P02].

Basic principles of obtaining informed consent

Voluntary participation in the study

According to the participants, three main components for obtaining informed consent included providing necessary information for each of the samples, ensuring that each of the samples understood the information provided, and voluntary participation in the study. The participants stated that they explained to the research samples the study objectives, the sampling method, the method, and the possible benefits and disadvantages of participating in the study. Then, they ensured that each of the samples understood the explanations provided and their participation was voluntary. "We used to explain to the patients what the purpose of our study was and what we wanted to do and how we wanted to do it... After ensuring that they understood our explanations and willingly participated in the study, we gave them a written consent form to read and sign" [P05].

Avoiding coercion

All participants emphasized the non-coercion of obtaining informed consent. They also emphasized that the samples should not be under pressure to convince them to participate in the study. Considering that sometimes the researcher also plays the role of the patient's doctor, the participants stated that in these cases, the doctor should make sure that the patient has freely chosen to participate in the study, because the patients may be bound to participate in the study due to not completing the treatment course and or shame with their doctor. "Sometimes patients only express their consent to participate in the study because they fear that the continuation of their treatment will be justified by the problem without obtaining sufficient information" [P11].

Two-way interaction between the researcher and the samples

Informed consent is a two-way interaction between the researcher and the samples. In addition to allowing the participant to independently decide to participate in the study, it also provides the researcher with the opportunity to check whether the participant understands the conditions of the study and whether he can participate in the study. "During the interaction with the participants and before obtaining informed consent, it is possible to find out whether this participant can actively participate in the study and help provide the data needed for analysis" [P07].

Providing essential information to samples

The participants of this study stated that in both written and verbal methods, each sample received complete information about the person in charge of the study, how to communicate with the person in charge of the study, having a code of ethics from the vice president of research of the university for sampling, the study objectives, the method of conducting the study, possible risks and the method of their compensation, the freedom to participate in the study, the possibility of opting out of continuing to participate in the study in any of the stages of the study, and not interfering and affecting the individual's treatment process by participation or non-participation in the study. "I will explain to them the objectives, the method, and the possible risks... I will explain to them who is responsible and how to compensate them if any danger happens to them... I will also give them my number if they have any questions to call me" [P14].

Facilitating factors to obtain informed consent

Effective communication

The participants of this study believed that the basis of negotiation with humans is to communicate effectively with them. They stated that most samples do not have enough time and patience to read the informed consent form, "Today, people do not have the patience to read long materials" [P09]. Therefore, before delivering the form, it is better to establish a good human relationship

with them and verbally explain the items in the form to them. Also, researchers should be careful to use effective communication techniques, such as getting feedback to ensure that they have understood the research samples of the presented content correctly. In this case, if a person has a question or a misunderstanding, he/she can be convinced at that moment. According to the experiences of the participants of this study, communicating effectively with the research samples and explaining the items in the informed consent form compared to when we give the form to the samples to study by themselves, the probability of their cooperation to participate in the study increases. "If we give them the form to read by themselves, they often refuse to participate in the study, but when we explain to them that this form is a consent form and what is written in it, their cooperation improves" [P10]. The participants also emphasized continuing to have a proper relationship with the samples. "I have to constantly explain what we do for him... If they don't understand why we are doing what we are doing, in the study in the middle of the study, they stop participating" [P17].

Appropriateness of the text of the informed consent

When we asked the participants about the characteristics of the informed consent form, most of them emphasized that they design this form based on their level of understanding of the research samples. "When my samples are ordinary people, I try to write the form contents more simply and I use less medical terms, but if my samples are, for example, nurses, I try to use academic terms" [P08]. They believed that the use of complex terms confuses the samples and reduces their cooperation. "The use of complex concepts confuses people... they fear that their treatment change and not be cured... They say that we are not laboratory rats" [P01]. They also adjust the amount of information provided in the form according to the level of understanding of the research samples. The more the understanding of research samples about the research topic is higher, they provide the more comprehensive explanations in the form. "Providing information beyond people's understanding can confuse people and reduce the possibility of their cooperation" [P04]. Some participants also stated that to facilitate the reading of the long informed consent form, at the beginning of the form, they provide a summary of the information in the form [P16].

Preparing a multimedia file of informed consent

One of the participants stated that to facilitate the access of illiterate people to the information on the informed consent form, he prepared the audio and video file of this form and gave it to the research samples. When the number of research samples is large, using this method can lead to saving time in conducting the study. «I sent the audio file of the consent form to the samples who were illiterate, and if they had any questions, I answered their questions, therefore the time of my study was shortened» [P13].

Holding training courses and specific and up-to-date instruction

Researchers mostly reported that their knowledge of informed consent was gained from on-the-job experience or self-study. Considering the importance of obtaining informed consent and the need to be up-to-date in this field, some researchers stated that academic training about the need to obtain informed consent and its research methods is necessary for them, especially young researchers. They stated that they often do not have access to the guides of informed consent or the existing guides do not answer all their needs and questions. Therefore, they emphasized that several training workshops should be held every year to familiarize researchers with informed consent, and based on the materials presented and researchers› questions, clear instructions should be placed on the university›s research site and research centers. «The concept of informed consent and its methods are changing day by day... Our information is very out-of-date... The first step to ensure the accurate implementation of informed consent is to teach its principles in workshops and prepare up-to-date guidelines» [P09].

Discussion

This study was conducted to explain the experiences of researchers regarding obtaining informed consent to participate in human research and its facilitating factors. Although informed consent is the cornerstone of ethics in research, few studies have investigated researchers' experiences in this field. The participants emphasized that in all studies on humans as samples, informed consent must be obtained to participate in the study. They stated that obtaining informed consent to participate in research is one of the basic ways to ensure research samples and the Research Ethics Committee of Universities and research centers comply with ethical standards while conducting research. Manti and Licari stated that informed consent can be waived in certain situations; for example, in situations where obtaining informed consent is impossible or if the research does not violate the principle of self-determination [22]. Laurijssen et al. argued that some situations can make conventional informed consent truly impractical, such as untraceable participants or harm to participants. At the same time, researchers have

an ethical responsibility to design an infrastructure, in which consent can be obtained, even if they encounter difficulty in obtaining consent. Furthermore, researchers should seek to minimize harm to participants when harm may occur as a result of the consent process [7].

The researchers stated that they use three written, verbal, and electronic methods to obtain informed consent to participate in the study. They believed that in cases where no intervention is on the samples or the samples themselves complete a questionnaire, they use the verbal method and in other cases, the written method. However, some researchers stated that in any case, they use the written method to obtain informed consent to participate in the study. In addition, a small number of researchers stated that they send the informed consent form electronically to the research samples. The results of a study showed that written consent was not used by nearly 40% of researchers in their latest studies. In this study, many respondents recommended that human subject regulations should provide more flexibility in ways of documenting informed consent [13]. In a study, researchers stated the benefits of getting verbal satisfaction, including speeding up work. However, most researchers who were directly responsible for obtaining consent emphasized obtaining written consent, especially in trials. They were concerned that the lack of a signed consent form could put them at greater risk of litigation [23].

The researchers emphasized that participation in the study should be voluntary and the researchers should be careful that the research samples are not forced to participate in the study due to the fear of disrupting the completion of the treatment course and having shame with them. The researchers also reported that informed consent is a two-way interaction between the participant and the researcher. In addition to allowing the participant to independently decide to participate in the study, it also provides the researcher with the opportunity to check whether the participant understands the conditions of the study and whether he/she can participate in the study. Bhutta believes that in developing countries, instead of ensuring the true understanding and voluntary participation of research samples, the emphasis is on obtaining informed consent. He recommends that current guidelines should be revised to ensure the understanding of the research samples from research information and voluntary participation in the study [15]. It is sometimes emphasized that a mechanism to measure understanding should be included in research studies as part of the informed consent process [13].

Regarding the necessary information required for research samples, the researchers emphasized that to obtain informed consent to participate in the study, information about the person in charge of the study, how to communicate with the person in charge of the study, having the code of ethics from the research deputy of the university for sampling, and the objectives of the study, the method of conducting the study, the possible risks and the method of their compensation, the freedom to participate in the study, the possibility of withdrawing from continuing to participate in the study at any stage of the study, and the fact that participation or non-participation in the study does not interfere and affect the individual's treatment process, should be provided to the research samples. Informed consent to participate in research is the same as obtaining informed consent in performing treatment procedures, including informing, understanding, being voluntary, having the authority to do the work, and the place of signature [2]. Too much information can be exhausting and in some cases, it can impair decision-making [24]. In a study, researchers stated that participants rarely read documents related to obtaining informed consent in detail, and these very long and complex documents did not lead to standardized understanding [5]. No agreement exists on the amount of information required to obtain informed consent. However, most of the studies agree on providing information about the nature and purpose of the research, the method of conducting the study, the possible risks of participating in the study, and the freedom of participating in the study [22].

The researchers of this study believed that effective communication with the research samples can be effective in obtaining the consent of the samples to participate in the study. Dawson and Kass also emphasized the positive impact of relationships between the research team and the study population to obtain informed consent [25]. The researchers also stated that the appropriateness of the text of the informed consent and the preparation of the multimedia file of the informed consent can be effective in improving the information conveyed to the samples to make an informed decision to participate in the study. Giving people more information and time to reflect is associated with lower satisfaction rates. It seems that an optimal level of information can lead to a better understanding of the study while creating less anxiety in the samples and leading to greater satisfaction [26]. In contrast to the findings of our study, Synnot et al. stated that the value of audiovisual interventions as a tool to help enhance the informed consent process for individuals intending to participate in clinical trials is largely unclear; however, trialists should continue to explore in-

novative ways to provide information to potential trial participants during the informed consent process [27]. Flory and Emanuel also found that efforts to improve comprehension through the use of multimedia content forms have had only limited success. Having a study team member or an unbiased mentor spend more time individually talking with study participants appears to be the most effective way to improve research participants› understanding. However, further studies are needed to decide in this regard [16].

According to the results of our study, holding training courses and clear and up-to-date guidelines can facilitate the process of obtaining informed consent to participate in the study for researchers and research samples. Institutional Review Boards also believe that the existing informed consent forms are long and complicated and efforts should be made to update the guidelines for obtaining informed consent to participate in the study [28]. The results of Knight's study showed that teaching research ethics is essential in developing the researcher's awareness and creating critical thinking about ethical issues in different fields of research [4]. Lin et al. also explained that improving the process of obtaining informed consent requires the creation of a structured and standardized informed consent process and adequate training in the principles of obtaining informed consent for researchers [8].

Conclusion

The researchers reported that obtaining informed consent is a necessary process for all studies involving human samples. During this process, it is ensured that the research samples receive the necessary information about the research and participate in the study consciously. Most researchers reported that they used a written method to obtain informed consent. Some also stated that they use oral and electronic methods for this purpose. The researchers believed that the basic principles of obtaining informed consent include voluntariness, avoiding coercion, the existence of two-way interaction between the researcher and the research samples, and providing necessary information to the research samples. According to researchers' experiences, the factors that facilitate obtaining informed consent include establishing effective communication with research samples, the appropriateness of the text of the informed consent, preparing a multimedia file of the informed consent, holding training courses, and clear and up-to-date instructions. The basic principles of obtaining informed consent and its facilitating factors mentioned in this research can help researchers in observing this crucial aspect of ethics in research.

Ethical Considerations

Compliance with ethical guidelines

This research was approved by the Ethics Committee of the Qom University of Medical Sciences (Code: IR.MUQ.REC.1400.203). Ethical principles of research, such as informed consent, anonymity, confidentiality, and to the possibility of withdrawal from the research were considered. Also, before starting the interview, the participants were informed about the objectives, confidentiality of information, and recording of the interview.

Funding

This research did not receive any grant from funding agencies in the public, commercial, or non-profit sectors.

Authors' contributions

All authors equally contributed to preparing this article.

Conflict of interest

The authors declared no conflict of interest.

Acknowledgments

The authors thank the Research Administration of Qom University of Medical Sciences and all participants who participated in the study.

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