

Overcoming Consent Form Obstacles in Qualitative Research

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Abstract

The quality of the researcher's data is the cornerstone of research excellence. In qualitative research the connection that is established between the researcher and the participants dictates the quality and quantity of the data. The consent form is a necessary part of social science research involving human subjects and can be utilized as a tool to establish trust. The appearance of the document, the language used and amount of time given to read the document affect the level of understanding of the participant. This paper proposes that researchers avoid legalese, aim the language of the documents at the population one is trying to attract, allow sufficient time to read, listen or view the information and provide an opportunity for potential participant feedback. By being open and forthcoming to participants researchers will receive the same from participants and achieve their research data collection goals.

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Introduction

The power of qualitative research is its ability to reach the human essence of a given phenomenon. When dealing with methodologies that involve observation or interview procedures, interaction with participants is essential and unavoidable. In methodologies involving the interviews it is the depth to which one is able to reach with the participants that dictates the quantity and quality of the data that one can retrieve. Thus, establishing a connection with the participants is a crucial aspect of the research. Meaningful ‘connections’ can only be established through a high level of trust. As researchers, we are often at a disadvantage because there is no prior relationship that one can use to form the basis of trust. Reputation of the researcher or organization they work or study in can assist in the building of trust but a key instrument in quickly establishing an aura of trust is the ‘consent form’ procedure.

The consent form procedure is a procedure by which the researcher or research team enlightens participants about the project and gets their approval to for participation in the study. It has become an accepted practice that researchers are required by their universities to gain approval from an ethics review board when dealing with human subjects and part of that approval relies on the explanatory statement and consent form. The need for ethics approval arose from the unethical behaviour that was highlighted by the atrocities committed in the name of science by the Nazis during World War Two. A code of ethics by which research on human subjects is governed was the universal result (Christians, 2000; Lindoff & Taylor, 1995). The use of a consent form demonstrates the researcher’s ethical standards and concerns regarding the responsibilities that the researcher has towards the participants.

The consent form procedure indicates to the participant what the research is about; why it is being done; who is doing it; sponsoring organization (e.g. academic institution); how it will be accomplished and what protection will the participant receive. The level of protection that the participant receives from the researcher will influence the level of participation. Guaranteeing anonymity, limited access to data given, secure storage of data and privacy when conducting the research provides the participant with a sense of trust within the project and the researcher.

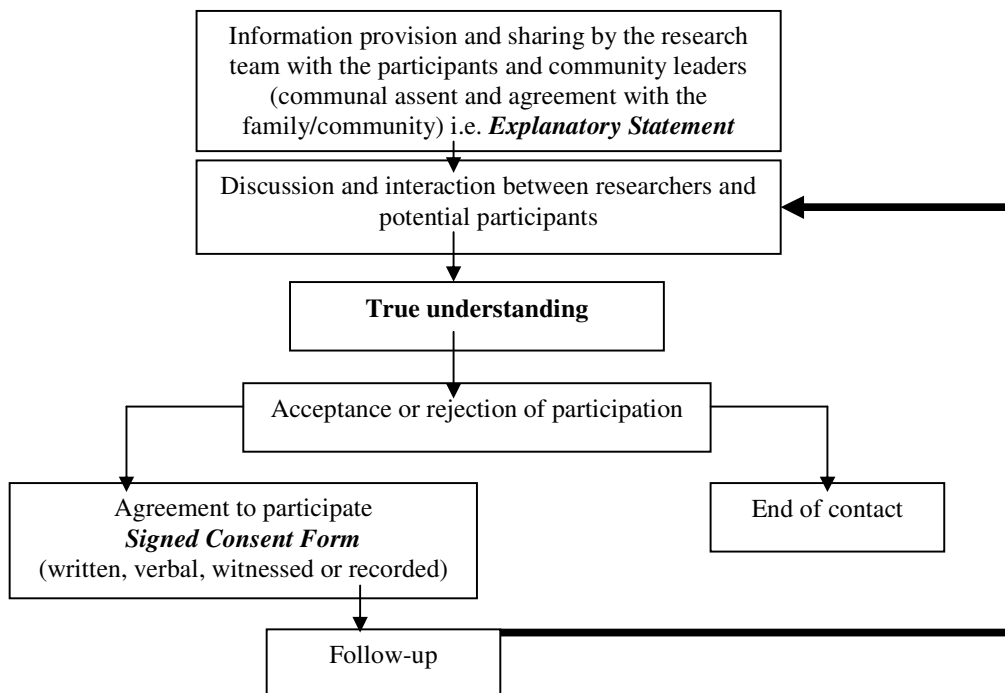
The difficulty of the consent form process is the amount of information that needs to be set out in a few documents. It is therefore important to choose your words carefully and develop a short description of your study in layman's terms so that it is easy for anyone to understand (Flory & Emanuel, 2005; Mann, 1994; WHO, 2005; Wogalter, et al., 1999). However, no matter how well written the explanatory statement or consent form is participants may have questions regarding the researcher, the methodology or the study itself. A researcher should never fail to answer a question unless it divulges the identity of another participant. The more open you are as a researcher about your research project, the more open the participants will be in the interview process. Your willingness to talk about the process will encourage a more open and trusting environment.

Explanatory Statement

As shown in Figure 1 a preliminary step to the consent form process is informing the participant about the objectives of the research project. In most social science research projects this is done through an explanatory statement which is given to the participant by either the researcher (i.e. in person or via email or mail) or a third party (i.e. an explanatory statement be in the form of a written letter. Several researchers have pointed out other affective methods of imparting information to participants such as audio visual techniques (power point presentation, video), an interactive computer program or an audio recording (Bhutta, 2004; Flory & Emanuel, 2004).

These methods are especially affective when dealing with individuals that may be illiterate or possess little education or not fluent in the chosen language of the study (Bhutta, 2004, Creed-Kanashiro, et al., 2005). However, in a study by Flory and Emanuel (2004) they stated that the most effective method was through expanded discussions with the participants. This concurred with Fletcher and Hunter's (2003) findings regarding gaining parental consent for research involving children.

Figure 1. Conceptual framework for the process of obtaining informed consent.



Source: Adapted from 'Beyond informed consent' by Z. A. Bhutta, 2004, *Bulletin of the World Health Organization* 82 (10) p. 772.

An explanatory statement should include the following:

- Purpose of research
- Selection criteria
- Voluntary nature of participation
- Research procedure (e.g. interview, focus group, etc.)
- Time requirement
- Risk/discomfort
- Benefits for participant, researcher, and society
- Incentives (i.e. financial compensation)
- Confidentiality
- Refusal or withdrawal rights
- How the results will be disseminated (e.g. published in a journal, book, etc.)
- Contact information – researcher and organization.

Some of these points are restated in the consent form but are important aspects that the participant needs to be aware of thus by repeating them it signals the importance of those points (e.g. confidentiality and the refusal or withdrawal rights).

Creating an Understanding

The objective is to create an understanding of the research project and research protocols so that the participant is aware of what they will take part in. Thus, each part of the consent form process provides the participant with information that not only informs but also builds trust in the researcher and the process. The purpose of the research is reiterated at the beginning of the consent form and provides the participant with a brief description about the objectives of the research. For example, in the study described in the consent form in Appendix 1 the participant was informed that the research focused on community and job retention. This once again provides the participant with the opportunity to make a decision whether or not their particular situation or knowledge is applicable to study.

Informing the participant why the research is being done is important so that they have an understanding of how their participation is going to advance understanding. By briefly outlining in the explanatory statement and consent form what the study delves into one also hopes to capture the interest of the participant. A heightened sense of interest in the participant will open new avenues that they are willing to talk about and may provide the researcher with other contacts and perhaps other willing participants.

The knowledge of who is doing the research and for whom, can impose ethical dilemmas for the researcher and the participants. Graduate student research provides the participants with an opportunity to assist a student in getting a degree. Most individuals are more than willing to assist an individual to be successful in school (perhaps because of their own personal experience in the school system). Also the association with a university or academic institution adds legitimacy to not only the research but the researcher as well. However, the area of research and extent of participation may increase the possibility of an ethical dilemma (e.g. medical research or research that involves personal data of a sensitive nature).

Further, ethical problems may arise when there is an outside sponsoring organization. People may doubt the true aim of the research when an outside sponsoring organization is involved. Potential participants may believe they are merely being manipulated for the gain, financial or political, of the sponsoring organization. Therefore, a researcher may end up with biased results because the only individuals that may wish to participate will hold favourable views towards the sponsoring organization. Through the informed consent process the researcher has the opportunity to reassure the participant of the validity of the project and eliminate participant doubt. Thus, to remove the ethical dilemma the researcher informs potential participants and willingly answers any questions in regards to the project and its aims.

The participant must have an understanding of how the research will be accomplished and how the data will be collected from them. In the example case it is made clear that the research will be conducted through a series of interviews in which they will participate. They are also informed that the interviews will be taped for which their permission is required. If they do not wish to be audio taped or videotaped they may still consent to the interview process by allowing researcher to take notes. If this is the case then the researcher amends the consent form or provides a space to show that participant has agreed to the process but declines to be taped.

To ensure an interview that will provide the researcher with data that has a significant level of the depth the researcher needs to ensure a level of protection that will allow the participant to divulge information with the fear of no reprisals. The researcher must assure the participant that their identity will be kept confidential. The guarantee of anonymity will open avenues of trust and put the participant in a relaxed environment. Therefore, it is essential to explain to the participant how this will be carried out. For example, if their data is used in a published report then they will be given a pseudonym in order to protect their identity and any identifiable characteristics will be removed before publication. One may go as far as offering to allow the participant to read the document before publication to ensure confidentiality.

A further step that can be taken to demonstrate the level of confidentiality is to explain the limited access to the data given by the participant. In most cases this will be the research team and transcribers (it is important to state if the transcribers will be individuals other than the research team). The participant needs to understand that the data gathered from them will be accessible only to those individuals mentioned above and when it is not in use will be stored in a secure location.

Once the consent form is written and put into use problems may arise. What if the participants cannot write or read. In today's global economy the industrialized nations have witnessed a high level of immigration. The level to which these individuals understand the English language varies. It is therefore important that the researcher reviews the consent form with the participant before the participant signs the document. This review not only ensures that the participant understands what is presented in the explanatory statement and consent form but also provides the opportunity for the researcher to gain a verbal consent. Once the participant has agreed to participate and has signed the consent form the researcher should turn on their audio or video recording device, ask the participant if they understand the consent form and if they signed the consent form voluntarily. This procedure will provide the researcher with an audio copy of the participant's verbal consent. If the participant signs the document using a mark other than their signature (given name and surname) then the researcher needs to verify that the mark through which they have signed the consent form with is representative of their agreement to participate.

This method of gathering verbal consent can appease individuals who are still concerned about confidentiality. An individual may feel that their signature reveals their identity and therefore, may not wish to sign the document, but may be willing to participate. Thus, by allowing them to sign the document with a pseudonym but taping their verbal consent and recording an acknowledgement of their signing the document the researcher does not lose a willing participant and still maintains evidence of willing participation.

If the individual will not consent to audio or video taping but still signs the consent form then the researcher has no option but to rely on their note taking ability during the interview process. If the individual will not consent to audio or video taping and also refuses to sign the consent form then the researcher would be wise to not conduct the research with that individual. The refusal by the individual would leave the door open for that particular individual to refute the findings of the research project and bring the reliability of the findings into doubt.

As stated earlier, it is becoming increasingly likely that researchers will have to deal with the reality that English may not be the mother tongue of some of the participants. This language barrier will cause problems in assuring that the participant is giving 'informed' consent. The language barrier may also cause problems during the interview process. Participants may have difficulty expressing their true feelings and experiences in a language other than their mother tongue. Steps should be taken to ensure that they understand the process and the questions to be

asked, which may involve the use of an interpreter. The ideal situation would be that the interviewer could speak required language or an alternative is to recruit an interviewer from the chosen field that is fluent in the language. Preparation of the consent form (if the language barrier concern is known of in advance) in the native tongue of the participant will also demonstrate respect for the participant, increase the level of understanding, and illustrate the level of commitment to the project that the researcher has.

When a participant stops the interview for any reason and does not wish to continue their participation their permission is required to use the data from the interview already conducted. Turn off the recording devices when the individual expresses their desire to end the interview then ask why. Although some participants may not wish to respond, others may provide insight as to why they stopped that may help avoid the same situation from occurring in other interviews. It is a learning process and one can only learn by asking questions.

Legal Aspects

One of the unwanted and often ignored feature of research are the legal aspects that may arise. Commonly found in the medical profession, especially in emergency care situations, is the use of a consent form to protect caregivers from litigation. In social science research the consent form once again offers protection to not only the academic institution but the researcher as well. The consent form offers a legally binding document and in conjunction with a taped verbal agreement offers irrefutable evidence of informed and voluntary participation.

This legal aspect gives way to a problem that has arisen with the use of consent forms; the belief that it will inhibit a free-flowing interview process due to the cumbersome and legal standing jargon. Fine, Weis, Weseen, and Wong (2000) contend that the use of a consent form, in it least one case, caused “hesitations, monosyllabic answers, and reluctance to speak.” They presented the consent form with the following passage:

Thanks for doing this. As you know, I an interview and women about their experiences on welfare but also tried to get pictures of their lives. This is a consent form and you may want to read it first. If you agree to abide by whatever is written there, please sign it. And I am going to tape record this. Also, if you do not feel comfortable with what ever, to say you're going to skip it, okay? (Fine et.al., 2000)

The problem may not be the consent form because similar to one presented at the end of this paper there it is a little or no legal jargon to be found. How the researchers presented the consent form may have been the cause of the problem. By using terminology such as “agree to abide by what ever is written there” (Fine, et al., 2000) it may cause the participant to believe that they are being manipulated and thus, introduce a level of distrust. It is important that the participant feel that they are in control of the interview procedure. They should be made aware that they can ask questions about the procedure, about the questions, and that they can feel free to refuse to answer questions or stop the interview at any given time with out fear of reprisal. The greater sense of control that they feel they have over the interview the more willing they will be to open up to the interviewer. By giving this control and trust to the participant the researcher creates a powerful research tool.

Conclusion

When dealing with legal documents it is quite common that individuals do not read the forms prior to signing them (Mann, 1994; Wogalter et al., 1999); thus, they are not well informed. A group of researchers found that the appearance of the document, the language used and amount of

time given to read the document affected the level of understanding. Their recommendations concur with the ones proposed in this paper; avoid legalese, aim it at the population one is trying to attract, allow sufficient time to read, listen or view the information and provide an opportunity for potential participant feedback (Wogalter et al., 1999).

Further, to avoid an ambiguous or confusing explanatory statement and consent form, pre-test them. Have colleagues read it over and ask for their response. Do they understand what the study is about? Do they understand the level of confidentiality? Do they understand their rights as a participant? At the same time you can pre-test interview questions.

When used with the proper steps and attitude the consent form process becomes a valuable tool the researcher uses to encourage an open and engaging environment for the participant thereby assisting the researcher to achieve their goals. The consent form process provides the participants with information on the research project and an outline of their rights as participants. The consent form should demonstrate to the participant that they control the interview process. They can stop at any time and they can ask questions at any time. The consent form protects the participant, the researcher and the institution.

This paper has outlined some of the problems that may arise with the consent form process and the interview process. Problems with understanding, with literacy, language barriers and mistrust can be overcome with imagination and common sense. The consent form process should be used as another tool to build trust and facilitate a bond between the researcher and participant that leads to deeper and richer data.

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Appendix 1: Example of a Consent Form

Community, Employee, and Organization Interaction: Why we stay!

The overall objective of this research project is to gain a deeper understanding of the role of community involvement in the relationship between an employee and the organization they work for and how that relationship affects retention.

I have read the explanatory letter and understand the objectives of the study. I also understand that I am free to ask any questions at any time about the nature of the study and the methods that the Researcher is using. I understand that I can contact the Researcher, NAME, at any time through the address/phone number/email listed below.

I understand that any data that the Researcher extracts from the interviews for use in reports or published findings will not, under any circumstances, contain names or identifying characteristics. I understand that my anonymity will be protected. I understand that all information received from me will be kept confidential.

My participation in this interview is voluntary. I may choose not to answer some or all of the questions with no consequences. I can stop the interview at any time with no consequences. I have the right to say no to the entire interview with no consequences. I have the right to choose that the interview not be used in any reports or published findings. I will be notified of any report or published findings and, if I wish, I will be provided with a copy of any report or published findings regarding the results of this interview.

I understand that the data from this interview will be kept in a secure storage and accessible to only the Researcher. I also understand that the data will be destroyed after two years from this date unless I consent for it to be used in future research.

I hereby consent to this interview.

Yes _____ No _____

I hereby grant permission to be taped.

Yes _____ No _____

I hereby grant permission for data from this interview to be kept for an indefinite period of time for future research.

Yes _____ No _____

Participant _____ Date _____

Researcher _____ Date _____

Contact:

NAME, Qualification, Organization

Address

Office Phone Number, Fax Number, Email Address

If you have any other concerns please feel free to contact:

Organization Name,

Address

Office Phone Number, Fax Number, Email Address