Ethical Issues with Informed Consent

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1 Introduction

Informed consent is a vital step to any research project. It is the process in which a patient/participant consents to participate in a research project after being informed of its procedures, risks, and benefits (Bulger, 2002)[3]. Ideally, after fully comprehending the information about the project, the patient/participant gives full and conscious consent for the physician/scientist to continue with the procedure. There are many ethical issues that are entwined with the informed consent process. In order to fully appreciate the importance of this process, the history that led to its inclusion in research projects must be understood. Although informed consent is designed to make sure that a participant fully understands the procedures, benefits, and risks involved in an experiment, it is not without its flaws in its practical application. There are many covert communication barriers between participants and researchers that lead to misunderstandings. This prevents participants from making the fully autonomous decisions sought for in the informed consent process. Some of those barriers are related to cultural aspects such as language differences and religious dogma. Others are related to the faith that participants have in science such as false expectations. Having awareness of these types of barriers is crucial for both researchers and participants. Misunderstandings concerning the experimental procedures can lead participants to get involved in research projects that they dont approve of. Finding themselves in this situation can have great effects on the psychological and physical well-being of participants. For this reason, it is ethical for researchers to account and correct for the misunderstandings in the informed consent process. This would ensure that participants are treated according to the ethical standards set by the Belmont Report.

2 Brief History of Informed Consent

The events that led to the implementation of the principles behind the informed consent process in scientific research were some of the most terrible in human history. For example, the experiments conducted in Nazi Germany led to the creation of the Nuremberg Code after the war was over. Ever since then, the scientific community has continued to revise such principles in order to ensure the ethical treatment of participants. The Declaration of Helsinki and the Belmont

Report also attest to the ongoing need to refine the rules and regulations behind the informed consent process.

2.1 The Nuremberg Code

According to Bulger (2002)[3], the Nuremberg Code (published in 1949) was established for the purpose of having a standard by which to judge the Nazi scientists and physicians during the Nuremberg Trials. It established ten basic principles that were to be followed by everyone conducting research with human participants. Informed consent was established as a result of these principles. The Nuremberg Code states that all those who are participating in an experiment are required to give voluntary consent free of undue influence such as "coercion, fraud, duress, or deceit." However, the Nuremberg Code did not establish a method that would ensure that its rules were enforced by the physicians/scientists conducting research.

2.2 The Declaration of Helsinki

Bulger states that the principles set by the Nuremberg Code regarding informed consent were also present in the Declaration of Helsinki (established in 1964). However, it offered more protection to participants by establishing the need for "independent guidance" about an experiments protocol from scientists who were not involved in the research project. It also denied publication to all those research projects that were not externally reviewed.

2.3 The Belmont Report

According to Bulger (2002)[3], despite the attempts to ensure the safety of participants, unethical practices still occurred. For example, mentally disabled children at Willowbrook Home were given hepatitis for the purpose of studying the diseases natural progression. This led Congress to establish the National Research Act of 1974. Among the rules established by Congress was the creation of the Institutional Review Board (IRB) which reviews research proposals to determine if they are ethical and thus capable of being conducted. Congress also established a commission which would formulate the Belmont Reporta set of principles and guidelines that are to be followed in research involving human participants. The Belmont Report indentified three basic principles which are to be followed by all researchers. Among these is the ethical principle of respect for persons. This is the most important principle with regards to the consent process. This principle establishes that all human participants are to "be treated as autonomous agents capable of self-determination." This implies that all participants must give informed consent to be involved in a research project, they must be given adequate information about the project, they must understand the researchs protocol, and they must be able to withdraw from the project at any point.

3 Covert Communication Inefficiencies in Informed Consent

Despite the rules established by the Belmont Report, there are still many covert barriers to understanding the informed consent process which lead to ineffective communication between the researchers and the participants. The three discussed here are language barriers, religious influences, and false expectations.

3.1 Language Barriers

It is assumed that the individual who signs the consent form does so with full understanding of what is stated on the consent form. However, whether this is truly the case is very difficult to evaluate since there is no established method to measure the level of understanding that a participant has about the information given. Thus, it can be assumed that there is a degree of misunderstanding that occurs (USM Website). Many individuals sign the consent form without being fully aware of what they are signing. For example, a study conducted by Paul S. Appelbaum et al. (1982)[1] found that "research subjects systematically misrepresent the risk/benefits ratio of participating in research." They report that this is due to a failure to understand the research methodology. This study found that 69% of the participants failed to understand the meaning of randomization. This type of misunderstanding increases with patients who have limited English proficiency. According to the U.S. Census Bureau of 2006, out of the roughly 300 million people living in the United States, about 18% of the population speaks a language other than English. Knowing this information is crucial because research has shown that language barriers affect direct healthcare delivery (Crane, 1997). For example, Baker, Hayes, and Fortier (1998)[2] found that language barriers disturbed the doctor- patient relationship. Patients who did not speak the same language as their doctors had a greater tendency to skip their medications and to miss their appointments than patients who shared a common language with their doctors. They were also at larger risk of having drug-related medical complications as outpatients.

According to the United States Department of Health and Human Services webpage, federal regulation 45CFR46.116 states that informed consent has to be given in a language that is understood by the participant or their representative, but misunderstandings can still occur because of inadequate language translations. The quality of the interpretation is almost as important as the informed consent itself. Misunderstandings can occur because of incorrect translations. Research has shown that the use of untrained translators in clinical settings tend to make frequent errors that in some cases result in dangerous misinterpretations (Vasquez, 1991) For example, one of the authors of this paper experienced a situation in a hospital in El Paso, TX in which liver was translated as kidney by an untrained translator. According to Woloshin et al. (1997), errors during translation may cause misdiagnosis, resulting in a decrease in the quality of healthcare and patient satisfaction. For example, Tocher and Larson (1998) found that more than half of the non-English speaking patients rated

the instructions from their physician as poor. Vasquez (1991) reports another problem with the use of untrained translators such as other employees in a hospital. This can result in violation of the patient confidentiality which can strain the participant-researcher relationship. Research has also shown that words or phrases translated from English to another language can result in drastic and erroneous change of meaning (Toucher and Larson, 1998)[7]. Untrained translators fail to realize how words that are spelled almost the same in other languages dont necessarily have the same meaning as they do in English. The word realize in English and its Spanish counterpart realisar serve as a good example. The English word realize means coming to awareness about the situation at hand. The Spanish word realisar means the accomplishment of an endeavor. However, many untrained translators will translate realize as realisar.

3.2 Religious Influence

The informed consent process is designed to give every participant the liberty to decide whether to accept or refuse the recommended medical treatment (Bulger, 2002). However, researchers designing such a form must consider the negative effects that participants might experience due to religious beliefs when participating in researcher projects. Having a full understanding of the methods involved in the experiment will enable a person to adequately judge if they want to participate in the experiment. Researchers must consider how the methodology of the experiment can come into conflict with the rules of behavior set by a participants religion. For example, the Jehovah Witness religion places strict rules of conduct on its followers when it comes to the type of medical attention they can receive. According to Pimentel Perez (2002)[6], this religious group has both moral and physical retributions towards the patients that do not follow the rules of conduct. Jehovah Witnesses are not allowed to receive any blood transfusions and organ transplants of any kind. However, it is important to note that Jehovah Witness are currently making changes to their rules in order to permit the use of certain amount of blood for surgical procedures. They believe that such procedures will contaminate the body. One of their main arguments against blood transfusion and organ transplant is written in The Atalaya of Sion magazine founded by Charles Taze Rusell in the years 1879 and 1881:

> "The blood of a person is the person itself, the excess, and drinking habits, the venoms that can put someone in the edge of suicide, murder and robbery is in the blood. The low moral values and sexual promiscuity, the complexes of inferiority and sexual crimes... this entire are transmitted during blood transfusion (as cited in Pimentel Perez, 2002)."

One can understand how experiments involving stem cell research and gene therapy would be condemned by the Jehovah Witness religion. Participants belonging to this religion need to fully understand the methodology of an experiment to see if it is in violation of their religions rules. Knowing this information will permit them to make a more adequate decision.

3.3 False Expectations

Even when there are no language barriers or religious impediments to thwart the communication relationship between researcher and participant, misunderstanding can still occur due to a participants false expectations of the experiment outcome. Lee et al. (2001)[5] conducted a study to investigate the discrepancies between the success rates for stem cell transplantation given by the researcher/physician and the success rates as they were understood by the patient. This study measured the expectations of 313 participants involved in a stem cell transplant. There were three groups of participants: 1) early stage patients; 2) intermediate stage patients; and 3) advanced stage patients. Physicians determined the amount medical information they would give participants. All the participants receiving treatment signed an informed consent form with general information about their treatment. However, this information was not specific enough considering the dangers involved in stem cell transplantation. According to Lee et al., the information on the consent form did not include "quantitative estimates of morbidity or mortality." For this study, patients receiving treatment were asked to complete a survey concerning their treatment expectations. Their physicians were also asked to complete a survey concerning the likelihood of treatment success. Both results were compared to analyze the discrepancies. They were also compared to the actual treatment results. This study found that there were discrepancies between patient-physician expectations 48-93% of the time. It also found that 78% of the patients had higher expectations about treatment success than their physicians. It was also found that the discrepancies between actual outcomes and expectations were higher among those patients in higher disease levels. Patients in intermediate and advanced levels "greatly underestimated actual mortality [rates]." These results show how patients do not really understand the risks involved in participating in experimental treatments. Although the patients in this study were aware of potential treatment-related deaths, they did not grasp the likelihood of this occurring. Their hopes and expectations did not permit them to fully understand what they were consenting to.

4 Possible Improvements Techniques for Informed Consent

Given the importance that informed consent is for both the protection of human rights and the validity of research experiments, it is important and ethical to try to amend the problems caused by the misunderstanding of information. Four methods suggested are: 1) conducting a demographic analysis of the research projects geographical location; 2) hiring professionals to translate all the information related to the experiment; 3) taking extra time to fully explain the informed consent form; and 4) administering small quizzes about the information covered in the consent form.

4.1 Demographic Analysis

Researchers can amend problems due to language barriers by anticipating the language proficiency of their participants. One way to do this is by analyzing the ethnic composition of the region where the research is conducted. As our nation grows more diverse, more languages are spoken other than English. Location is an important clue that informs a researcher of the potential problems participants will have with reading and understanding a consent form. For example, in a border city such as El Paso where a large number of the population speaks Spanish, a consent form written in English may pose a problem. Researchers conducting experiments in El Paso should be aware of this and have a professional translate the informed consent form to Spanish.

4.2 Professional Translators

Having a properly translated consent form is crucial for participants that do not speak English. Baker, Hayes, and Fortier (1998) reported that almost 52% of Spanish speaking patients in large hospitals thought that the presence of an interpreter was seriously needed. If patients/participants speak a different language than the one used by the physician/researcher, how legitimate is the consent they give when they are not able to fully understand all aspects of the consent form? A professionally translated document that explains the procedure to patients who do not speak English is another way to help alleviate the problem of language barriers. According to the guidelines for developing consent forms given in the University of Minnesotas website, a translated consent form is called a "short form." The "short form" is a short version of the original consent form but it is in the native language of the participant. This form is accompanied with a partial oral presentation of the information contained in the consent form. The short form must also be submitted to the IRB for approval. For consent to be valid, the participant, the representative/translator, and a witness must all sign the consent form. The University of Southern Mississippis website advices that translators use the language proficiency of a fourth through eighth grade reading level when translating consent forms. They must use the simplest terms available to explain the information about the experiment. The

translated consent form must remain as close to the original document as possible. The University of Minnesota also states that all concepts must be translated into their proper terms. Translations must be precise to avoid confusion in the participant. The patients right to be autonomous agents must always be respected if a researcher is to behave ethically.

4.3 Increasing Explanation Time

Another method that researchers can use to avoid misunderstandings is taking extra time to explain the content of the consent form in detail. Lee et al. (2001)[5] suggest that researchers could analyze potential areas in their research projects where misperceptions can occur. Once they identify such areas, they can explain

the material in more detail. For example, in the case of false expectations, physicians can expect patients to be overconfident about therapy success rates. To correct for this discrepancy, physicians can emphasize to participants the therapys actual success rates. Lee et al. also suggest that extra time be taken to further educate participants about aspects of the research project that they might not fully understand. For example, in the case of potential conflicts of interests due to religious creed, researchers can take the time to educate the participant about these conflicts of interests. They can also address any misconceptions about the research/medical project. For example, researchers can inform Jehovah Witness participants that criminal behavior patterns are not passed on to the person receiving blood transfusions.

4.4 Testing for Misunderstandings

Another method that can be implemented to the informed consent process is testing for understanding. A short quiz after the informed consent form is explained would help researchers identify potential problem areas. Questions on the short quiz should focus on the important aspects of the research project such as its methodology, purpose, risks, and benefits. Researchers can use the erroneous answers as a guide for conducting further explanation sessions. For example, if a participant missed a question concerning the direct benefits that he/she will receive, researchers can address the matter in more detail to dispel most misconceptions. This will ensure that the researcher is acting ethically by respecting the full autonomy of the participant.

5 Concluding Remarks

The informed consent process is a very important aspect of both research and clinical experiments. Ideally, it is a guideline set up by many documents such as the Nuremberg Code, the Declaration of Helsinki, and the Belmont Report to influence scientists to behave ethically at all times. It promotes the rights of a participant as autonomous beings to ensure that they are treated with justice, beneficence, and respect. For this to occur, a participant must fully understand the nature of the experiment. In practice, however, this does not always occur. The process can be taken very lightly by both researchers and participants. In order for the consent process to be valid, participants need to realize and understand its importance. Neglecting its importance can lead to unethical behavior and the loss of participants rights. One of the major problems with the informed consent process in practice is the occurrence of misunderstandings between the participants and the researchers. Such misunderstandings can occur due to factors such as language barriers, conflicts with religious dogma, and false expectations. These factors can affect the quality of participant-researcher interaction. Thus, researchers should pay greater attention to this issue so that participants can be better informed and have greater comprehension about the

informed consent documents that they are required to sign. Furthermore, researchers should take all the steps necessary to ensure that participants fully understand what is being stated in the consent form. For example, researchers can make demographic analysis to anticipate potential language barriers, they can hire professionals to translate all required information, they can take extra time to explain confusing information in detail, and they can administer small quizzes assessing the level of comprehension about the consent form. Implementing such methods can prevent unintended behaviors that are unethical by ensuring that participants have full autonomy over their decisions. It can also ensure that the principles outlined by decrees such as The Belmont Report are seriously acknowledged and respected.

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