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Completeness of consent forms in research proposals submitted to an ethics review committee

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Abstract

This was a descriptive cross-sectional study which analysed the consent forms submitted to the ethics review committee at the faculty of medicine of the University of Kelaniya, Sri Lanka, between January 2007 and December 2008. Of the 145 consent forms reviewed, 94.5% (137) explained the purpose of the study, 77% (111) included a statement that participation was voluntary, 44% (64) stated that refusal of participation did not affect care, 65.5% (95) mentioned the ability to withdraw consent at any time, 79% (115) that confidentiality of records would be maintained and 45.5% (66) that further clarifications were possible. Thirty nine (75%) of 52 eligible consent forms described the potential benefits and 19% (18) of 93 consent forms explained that there were no benefits to the participants. Twenty eight (59%) of 47 eligible consent forms described possible risks or discomfort to patients and 30% (29) of 98 consent forms explained that there were no risks to the participants.

In conclusion, essential elements of the consent forms were missing in this study. It is recommended that a checklist of compulsory elements to include on forms be used before proposals are submitted to an ethics review committee.

Introduction

Scientific research has given rise to important social benefits as well as to some troubling ethical issues. The voluntary consent of the human subject is essential prior to any study. This is stated as the first precept of the Nuremberg code and is followed by nine other precepts (1). The Belmont Report describes the purpose of consent as the mechanism to ensure that participants understand the research study and voluntarily agree to participate (2).

By ensuring the prevalence of voluntary or informed consent, violations of the patient's or participant's well-being can be more easily detected, not only by external authorities but by the patients/participants themselves. This is because in any clinical trial, a conflict of interest naturally arises between the desire to advance our knowledge, and the health and happiness of the person participating in the trial (3). Moreover, by creating greater transparency into the way in which medical research is carried out, the more conscious involvement of participants may also furnish deeper insights into the research under consideration.

In order to ensure that a participant understands a proposed research study, there must be a comprehensive discussion between the investigator and the participant. This process is documented and reinforced by a written consent form. Informed consent is not valid unless the participant, or the participant's legally authorised representative, comprehends the information in the consent document (3). Any biomedical research involving human participants or human tissue samples should get approval from an ethical review body before commencement (3-5). This is done by submitting a research proposal containing the consent form translated into the languages which the prospective participants can easily understand (5).

The consent form should provide all the information needed for an individual to make an informed decision. In order for that, the consent form must contain adequate information to give the complete picture of the research to the participant (3,5,6).Apart from this written form, a verbal explanation and sufficient time to consider and ask questions should also be

provided (5,6). This whole process, including the invitation to participate in a research study, should be presented in a way that avoids the undue influences mentioned earlier (2,5,6). The extent to which consent forms written up for medical research allow their participants to be in a state of informed consent can be defined as the 'completeness' of that form.

The completeness of consent forms utilised in medical research in Sri Lanka has seldom been investigated. Such a study can result in the correction of some of the deficiencies in the consensual procedures. The objective of this study was to assess the completeness of the consent forms submitted for ethics approval at the University of Kelaniya in Sri Lanka.

Methods

This was a descriptive cross-sectional study which analysed the consent forms submitted to the ethics review committee at the faculty of medicine at the University of Kelaniya, Sri Lanka, between January 2007 and December 2008. The consent forms submitted with undergraduate research proposals were excluded.

A record sheet was developed, based on the appropriate international guidelines regarding consent forms. It consisted of an array of elements, including whether confidentiality was being respected and whether there was time for deliberation, which were defined as necessary for facilitating informed consent. Using this sheet, we assessed the presence or absence of each element on the consent forms submitted for ethical approval during the study period. The aptness of the language used on the forms was not factored in.

Data were obtained by two investigators working independently, and consensus reached by discussion if there were any divergent findings. The data analysis was then performed by using SPSS, version 16. The proportion of studies which included each of the elements on the record sheet was calculated as a percentage.

Ethics clearance for this study was granted by the ethics review committee at the faculty of medicine of the University of Kelaniya

Results

0ut of the 145 consent forms reviewed, 126 (87%) were observational studies, 8 (5.5%) were clinical trials and 11 (7.5%) were other experimental studies. Postgraduate trainees were the principal investigators of 61 (42%) proposals and the remaining were academic staff members of the University.

It can be seen that more than three-quarters of the consent forms informed the participants about the purpose of the study, that participation was voluntary, and the extent to which their answers were protected through confidentiality (Table 1). On the other hand, the anticipated duration of the study, the purely voluntary nature of participation, and the lack of any repercussions on the quality of care through non-participation were too often omitted. Few forms informed participants about how to gain a more sound understanding of the study, with just 66 (45%) providing the means of clarification (Table 1).

Thirty nine (75%) of 52 consent forms where the research would benefit the participants described these potential benefits. Eighteen (19%) out of the remaining 93 consent forms explained that there were no benefits to the participants. Similarly, 28 (59%) of 47 consent forms where there were possible risks/of discomfort to the participants described possible risks or discomfort to participants and 30% (29) of the remaining 98 consent forms explained that there were no risks to the participants.

Of seven consent forms where participants had to bear a participation cost, four (57%) notified participants about this cost. Of the remaining 138 consent forms where there were no costs involved to the participants, 17 (12%) stated that there were no costs involved.

Of the 145 consent forms, 31 (21%) affixed a section for assessing participants' understanding about his/her role and the consent process. With regard to the section for assessing participants' understanding about his/her role and the consent process most of the required elements were not met (Table 2). However, 138 (95%) consent forms provided space for the participant's signature, 80% (n=116) for the date, 95 (65%) for the participant's name and 79 (54%) for the signature of the investigator.

Of the eight clinical trial consent forms, most failed to be sufficiently informative and complete in terms of the drug and the randomisation procedures involved (Table 3). Thirty seven (25%) proposals were supposed to collect specimens for investigations. With regard to those studies where samples were collected, the completeness of the forms was relatively better (Table 4). More than half included details about where the samples would be deposited and the amount of sample that would be taken, and almost 90% indicated the type of specimen that would be required. However, significantly, few assured participants that the samples would not be used in any unrelated experiments, or described the method of sample collection.

Only 48% (15) of 31 consent forms where physical examination of the patient was necessary described the procedure to be used for physical examinations. Twenty four studies were funded by international sponsors, of which only 10 (42%) included a statement on sponsorship. Children below 16 years of age were the study participants of 33 proposals, of which 29 (88%) consent forms sought/provided means of seeking the consent of the parents. Fifteen proposals were on pregnant mothers of which 2 (13%) stated that there might be possible risks to the foetus and 3 (23%) proposals included a statement that there were no possible risks to the foetus.

Discussion

Most of the results would seem to confirm the stereotypical perception that the notion of informed consent, at least in the medical context, is a dimly appreciated value. Another study

– referring to the use of informed consent forms in clinical practice – has also confirmed that a significant number of consent forms were incorrectly or insufficiently completed (7).

It is evident that many consent forms were designed solely to extract the signatures of participants. This suggests that these forms were only being proffered to participants in a purely cursory, dutiful manner. Nonetheless, it is encouraging to see a mention of the voluntary nature of participation and confidentiality clauses in more than 75% of the forms.

Just as in the study of Swedish doctors (8), such trends may indicate that many researchers were intentionally withholding or distorting information in order to be able to enlist more participants. Otherwise, negligent omission of important facts such as the potential side-effects of the trials, the possibility of withdrawing from the trials, and the ability to decline participation, would seem to be highly unacceptable and unethical conduct.

By informing the participants, for example about the type of physical examinations that they must undergo, or the types of samples they are required to provide, the researcher is attempting not to impose upon the personal preferences, aversions and beliefs of his/her participants. By informing the participants of any foreign sponsorship and its obligations, or the intended future commercial applications of the study, the researcher is respecting the moral values of the participants, and their right to be adequately remunerated for their participation.

It is also important to note that an inappropriately worded informed consent form could be favourable to the spread of false notions like the 'therapeutic misconception', the seemingly unshakeable conviction among participants that trials are for the benefit of the participants. Therapeutic misconception arises wherever the participants misunderstand the primary purpose of a clinical research as therapeutic (9). It exists when individuals do not understand that the purpose of clinical research is to produce generalisable knowledge, regardless of whether the participants enrolled may potentially benefit from the intervention under study. Appelbaum *et al*. found that 51% had unrealistic beliefs about the likelihood of benefit to themselves of participating in the study (10). King *et al*. found many consent forms combined unclear statements such as: "You may or may not benefit." (11) Kimmelman and Levenstadt found similar problems with misleading language in many of the consent forms (12). Joffe *et al* uncovered the same misconception among providers, as much as among participants (when they tell cancer patients that clinical trials constitute medical treatment) (13). The effects of this attitude among researchers in Sri Lanka would be an issue worth investigating in the future.

A standardised consent form template may be a way of improving the completeness of consent forms. Further, a major limitation of our study is that it focused on the completeness of the consent form and not the 'quality' of the consensual process. The exploration of all the factors that contribute to the consensual process including completeness make up the quality of that process. This would involve assessing the provider-participant interaction, and the comprehensibility of the language used in the forms (14-16).

A more comprehensive investigation of these aspects would be a fertile area for further research to better understand and develop informed consent in Sri Lanka.

Conclusion

In this study of consent forms submitted to a university ethics review committee in Sri Lanka, most of the vital information to be included on a consent form was missing. It is recommended that investigators should be educated about the purpose and the necessary content of a consent form. Providing a standardised consent form with instructions, or a check list for investigators prior to submission to an ethics review committee, would be one means of improving the consent process.

Table 1: Proportion of consent forms that included the required elements

Element	Met n (%)	Not met n (%)
Title of the project	98 (67)	47 (33)
Purpose of the study	137 (94.5)	08 (5.5)
Expected duration of participation	31 (21)	114 (79)
Voluntary nature of participation	111 (77)	35 (23)
Non-participation will have no effect on quality of care	64 (44)	81 (56)
Possibility for consent to be withdrawn at any time	95 (65.5)	50 (35.5)
Withdrawal of consent will not result in loss of the benefits patients are entitled to	48 (33)	97 (67)
Confidentiality of the information supplied	115 (79)	30 (21)
Possibility for further clarifications	66 (45.5)	79 (54.5)
Section to assess participants' understanding of their role	31 (21)	114 (79)

Table 2: Completeness of elements in the section for assessing participants' understanding of their role and the consent process

Element	Met n (%)	Not met n (%)
Have you read the information sheet?	09 (06)	136 (94)
Have you had an opportunity to discuss the study and ask any questions?	20 (14)	125 (86)
Have you got satisfactory answers to all your questions?	07 (05)	138 (95)
Have you received enough information about the study?	25 (17)	120 (83)
Who explained the study to you?	03 (02)	142 (98)
Do you understand that you are free to withdraw from the study at any time?	28 (19)	117 (81)
Have you had sufficient time to come to your decision?	04 (03)	141 (97)
Do you agree to take part in this study?	27 (19)	118 (81)
Provision of space for the participant's signature	138 (95)	07 (05)
Provision of space for the date	116 (80)	29 (20)
Provision of space for the participant's name	95 (65.5)	50 (34.5)
Provision of space for the witness's name	27 (19)	118 (81)
Inclusion of a participant's copy of the consent form	07 (05)	138 (95)
Explanation of the investigator's statement	09 (06)	136 (94)
Provision of space for the investigator's signature	79 (54)	66 (46)

Table 3: Completeness of elements in consent forms for randomised controlled trials

Element	Met n (%)	Not met n (%)
Description of randomisation	04 (50)	04 (50)
Description of use of placebo *	02 (40)	03 (60)
Description of potential side-effects	04 (50)	04 (50)
Description of route of administration	03 (37.5)	05 (62.5)
Description of frequency of drug to be taken	01 (12)	07 (88)
Description of dosage of the drug	01 (12)	07 (88)
Description of restrictions such as dietary or medication *	03 (60)	02 (40)

* Missing data due to non-applicability of the particular elements

Table 4: Completeness of elements in consent forms for collection of specimens

Element	Met n (%)	Not met n (%)
Type of specimen	33 (89)	04 (11)
Specified amount	19 (51)	18 (49)
Method of collection	12 (32)	25 (68)
Final disposition	01 (03)	36 (97)
The specimen will not be used for purposes other than those specified	03 (08)	34 (92)

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