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Paper: Equity

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

The voluntary consent of human subjects is essential prior to any medical research. A consent form should provide all the information needed for an individual to make an informed decision. In order for that to occur, the consent form must be replete with all the necessary information to give a complete picture of the research study to the participant.

The objective of this paper is to assess the completeness of consent forms submitted for ethical approval.

This was a descriptive cross sectional study which analysed the consent forms submitted to the Ethics Review Committee of the Faculty of Medicine of 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 used to extract data.

Of 145 consent forms reviewed, 94.5% (137) explained the purpose of the study, 77% (111) included a statement that participation was voluntary, 44% (64) refused participation and did not affect care, 65.5% (95) gave ability to withdraw consent at any time, 79% (115) stated that confidentiality of records would be maintained, and 45.5% (66) said 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. Only 48% (15) of 31 eligible consent forms described the procedure of physical examination and 21% (31) used a separate section to assess the participant's understanding of her/his role.

We conclude that essential elements of the consent forms were missing, and recommend that a checklist of compulsory elements to be included on forms be used, before proposals are submitted to the Ethics Review Committee.