Article

# An audit of the informed consent process in postgraduate dissertation studies at the College of Health Sciences, University of Nairobi, Kenya

**Miriam Carole Atieno Wagoro,** RN, MScN (Mental Health & Psychiatry Nursing), BScN, RPN, RM, RCHN, DAN, PG Dip Int Research Ethics
*School of Nursing Sciences, University of Nairobi, Kenya*

**Kirana M Bhatt,** MB ChB, MMed, MSc
*Department of Clinical Medicine and Therapeutics, School of Medicine, University of Nairobi, Kenya*

***Corresponding author:*** *M C Wagoro (atienomo@yahoo.co.uk)*

**Background.** Informed consent ensures respect for individual autonomy and safeguards against abuses of human participants. However, the high prevalence of poverty, inaccessibility of healthcare services, diseases, social insecurity and low literacy in developing countries such as Kenya increases participants' vulnerability to research exploitation and abuse. Biomedical and behavioural studies conducted on the vulnerable population in Kenya raise concerns about voluntary participation.

**Objective.** The purpose of this study was to assess the process of obtaining informed consent by postgraduate students in the College of Health Sciences at the University of Nairobi, Kenya.

**Method.** The study was observational, descriptive and quantitative. A convenience sample of 20 postgraduate students at the data collection stage was selected to participate in the study. Each student was observed during four episodes of administering informed consent, totalling 80 episodes of observed student-subject interaction. Data were collected for a period of 6 weeks by means of an observation checklist and analysed using the SPSS version 14 computer package. Descriptive statistics were used to answer the research questions.

**Results.** The main finding was that performance scores were better on the items that had a positive influence on patient participation than on those that would negatively influence patient participation.

**Conclusions.** The consent form was mainly used for the students' legal protection and not for the patients' benefit.

**Recommendation.** A further study on a large sample drawn from all the schools of the college is needed to confirm the practice of obtaining informed consent and compare performance in all the schools.

*S Afr J BL* 2012;5(1):45-50.

International research guidelines**1-**4 and researchers5,6 emphasise the universal recognition of informed consent as a precondition for ethical and scientific research involving human participants. Informed consent ensures respect for individual autonomy6 and safeguards against abuses of the participants. However, informed consent continues to be ignored3 and its practice remains an isssue of concern.[7,8] Institutional review boards that regulate clinical research focus on the protocol and content of the consent form, rather than on ensuring that the actual process of obtaining consent is appropriate.9 However, the World Health Organization10 recommends that institutional review boards monitor studies once they have begun. The author argues that monitoring of studies should include the enrolment of participants, which involves the process of informed consent administration.

In many studies, participants are exploited and the elements of informed consent are not fully observed. A high prevalence of poverty, inaccessible healthcare services and low literacy levels in developing countries are among the reasons for increased vulnerability of participants to research exploitation.[11] With the existing threats of HIV/AIDS, malaria and tuberculosis as the top killer diseases globally, biomedical research involving human participants is rapidly expanding.

Kenya is a resource-poor country with over 40% of the population unemployed and approximately 50% of people living below the poverty line.[12] Biomedical studies are increasingly being conducted on vulnerable Kenyan communities, and concerns about voluntary participation are on the increase. Evidence on whether researchers in Kenya obtain informed consent is lacking. An audit on the administration of informed consent would provide data on whether research participation in Kenya is voluntary. Since postgraduate students (PGSs) form 73% of biomedical researchers in Kenya,[13] an audit of their practice of obtaining informed consent would provide data on the quality of informed consent obtained.

## Method

A descriptive, quantitative study using a structured observation checklist was conducted among PGSs of the College of Health Sciences (CHS). A convenience sample of 20 PGSs was selected by the 'snowballing' technique, for logistical reasons and because of reluctance to participate. Data were collected for a period of 6 weeks. Four episodes of consent administration for each PGS were observed to take care of the Hawthorne effect. This is because observing the PGS administer the informed consent to four prospective participants would allow the researcher to observe and validate inconsistencies in behaviour that could occur as a result of being observed.

A sampling frame of all part 2 PGSs at the CHS was obtained from the respective schools' administrations. PGSs studying at Kenyatta National Hospital (KNH) were identified and visited in the clinical areas. The first PGS met was approached and given full disclosure of the research information and time to make a decision on participation. An appointment was subsequently arranged with the PGS, whose comprehension of information about the study was assessed using the questionnaire for objective responses before obtaining informed consent.

Data were collected using an observation checklist containing 9 elements of informed consent adapted from the US Code of Federal Regulations (45CFR 6.116[c&d]). Modification of the checklist was done to include demographic characteristics of the PGSs and methods used to elicit the elements. Each PGS was observed administering informed consent to 4 patients (4 episodes), totalling 80 episodes of observed interaction between PGSs and patients. Data input and analysis were done using the SPSS version 14 computer package. Descriptive statistics and clustered analyses were used to answer research questions.

### Ethical issues

The study was approved by the KNH/CHS Ethics and Research Committee (ERC) and the Vice-Chancellor of the University. Informed consent was obtained, and neither incentives nor compensation were given to PGSs since they were observed in the course of their normal research activity. No more than minimal risks were associated with the study. The PGSs were informed that the principal investigator was conducting this research as part of a course requirement and was therefore observing them in her capacity as a student of research ethics with no conflicting interests.

### Study limitations

The study employed a non-probability method in selecting a sample of 20 PGSs, mainly from the School of Medicine. Although there were limitations in methodology, such as the 'snowballing' sampling technique, the study did generate significant findings that need to be brought to the attention of bioethicists, research ethicists and institutional review boards. It can be treated as a pilot study, and the findings remain significant since the PGSs who agreed to participate may have been those who were confident about their performance, implying that they could be performing better than their colleagues who declined participation.

## Results

This study targeted all PGSs from the CHS, but only PGSs from the schools of Medicine and Pharmacy participated. PGSs from the schools of Nursing and Dental Sciences were not at the data collection stage at the time of this study. The School of Medicine had the majority of participants (85%), with only 15% of PGSs from Pharmacy. Study findings indicated that 90% of the PGSs had taken a course in research methods as part of the undergraduate course units and as a 2-week common course taught to all PGSs in the CHS.

To audit the practice of administration of informed consent, the extent to which each PGS elicited all 9 elements was assessed. Elements were categorised into the 3 fundamental conditions mandatory for informed consent, i.e. full and complete provision of information, comprehension of information, and voluntary participation. Each element contained sub-elements referred to as items, and it was considered elicited if a PGS addressed it irrespective of the number of episodes.

The performance score on the items was graded according to the number of times an item was elicited during the 4 episodes of consent administration. Since each student was observed on 4 episodes, a score of 4 points (100%) was given for an item elicited in all episodes. A zero (0%) score on an item indicated that it was not elicited at all. A grade was assigned to the score obtained on each element as follows: <50% = below average, 50 - 64% = average, 65 - 74% = above average, 75 - 84% = very good, and 85 - 100% = excellent.

### Category A. Full and complete provision of information

This category contained 4 elements, namely:

- Element 1: Introduction to research activity
- Element 2: Description of risks and benefits
- Element 4: Assurance of anonymity and confidentiality
- Element 5: Compensation for participation in research.

**Element 1: Introduction to research activity.** This element had 11 items. Performance on these items is described below and summarised in Fig. 1.

The best performance was recorded on item 1.11, which assessed the use of appropriate language. The majority (80%) of the

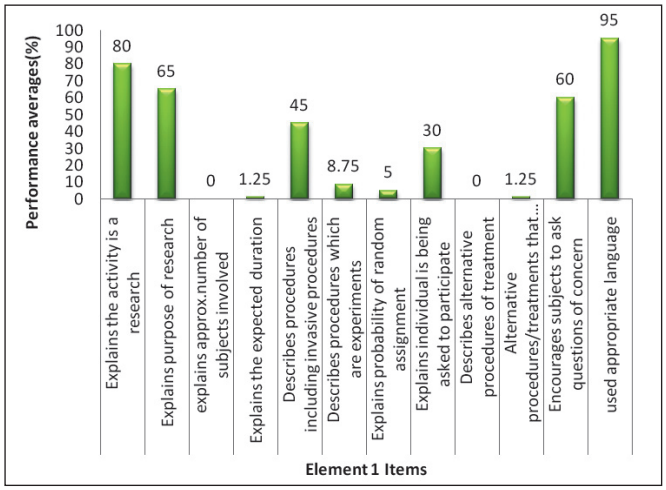


*Fig. 1. Performance on element 1: introduction to research activity.*

PGSs used official, national and the patients' traditional language of communication in all the 4 episodes – an excellent score of 95%.

A very good score of 80% was observed on item 1.1, which assessed whether the PGSs explained to the patients that they were participating in a research activity. This item was elicited by all PGSs in varying numbers of episodes. Almost half (45%) of the PGSs elicited the item in all 4 episodes. Seventeen PGSs (85%) elicited the item in more than 50% of the episodes. The researcher was, however, surprised at the below-average (30%) performance on a related item 1.7, which required the PGSs to explain to the patients that they were being asked to be study participants. Although item 1.7 was elicited in varying episodes by half (50%) of the students, only 3 (15%) of them elicited it in the 4 episodes and half (50%) of them completely failed to elicit it.

Item 1.2 recorded an above-average score of 65%, which was the third-best performance. The item required PGSs to explain the purpose of research to their patients. Eleven (55%) PGSs elicited this item in more than half of the episodes and 25% of the PGSs explained it in all the episodes.

The remaining 8 items recorded below-average scores (<50%). The lowest scores were recorded on items 1.3 and 1.8. Item 1.3 required the PGSs to explain to the patients the approximate number of patients involved in the study, while item 1.8 required the PGSs to describe alternative procedures and courses of treatment available and their advantages. No PGSs elicited these items at all.

**Element 2. Description of risks and discomforts.** This element had 6 items. The general performance on these items was below average (Fig. 2).

Item 2.1 involved describing foreseeable physical risks and discomforts to the patient. It recorded a score of below average (42.5%), yet it was the item with the highest performance on the element. More than half of the PGSs described risks and discomfort to patients in varying numbers of episodes. It is worth noting that only 3 (15%) of the PGSs described the risks to their patients in all 4 episodes, while 7 (35%) did not elicit this item at all.

Items 2.2, 2.3, 2.4 and 2.5, which required the PGSs to describe foreseeable social, emotional, economic risks or discomforts and how they would be minimised, recorded a dismal performance (Fig. 2).

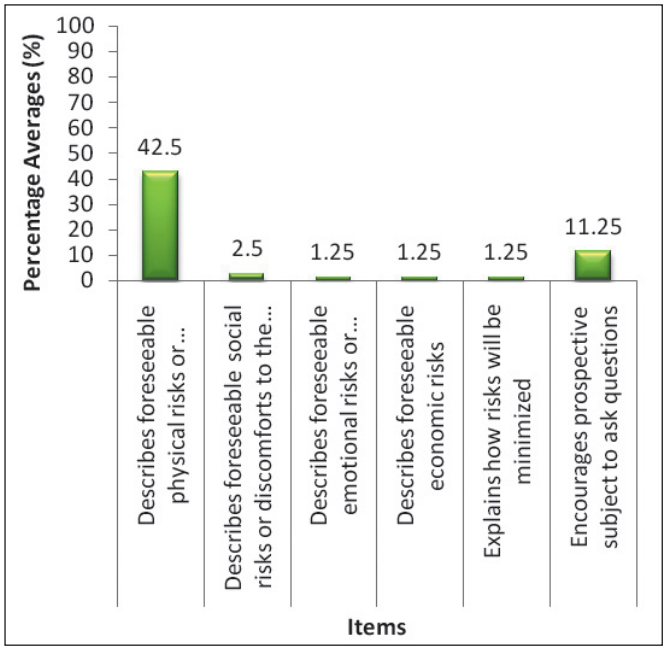


*Fig. 2. Performance on element 2: description of risks and discomfort.*

**Element 4. Assurance of anonymity and confidentiality.** This element had 2 items. They required explanation to patients about maintaining confidentiality during the research process and in publication. Forty per cent of the PGSs explained about confidentiality of records during the research process in varying number of episodes. However, no PGSs explained about confidentiality during publication of data in any episode.

**Element 5. Compensation for participation in research**. This element contained 3 items that required the PGSs to explain and describe availability of compensation, medical treatment and the risks if injury occurred. The performance in all these 3 items was below average, with the highest score 13.75%.

## Category B. Comprehension of information

This category comprised two elements:

- Element 6: Offering answers to questions
- Element 9: Assessment of participant understanding of information.

**Element 6** contained 4 items. The performance on this element was below average, with a range between 46.25% and 3.73%. Item 6.2, which assessed whether the PGSs allowed time for patients to ask questions, recorded the highest score. The majority

(80%) of the PGSs allowed time for questions in varying number of episodes. Thirty per cent of them allowed for time in only 1 episode while 20% allowed for time in all 4 episodes. It is worth noting that no PGS assessed patients' understanding of information, as required in element 9.

### Category C. Voluntary participation

This last category had three elements:

- Element 3: Description of benefits
- Element 7: Non-coercive disclaimer
- Element 8: Option to withdraw.

**Element 3. Description of benefits.** The element had 4 items concerned with description of direct, indirect, future and clinical benefits. It was encouraging that all PGSs described the research benefits to their patients, although in varying numbers of episodes. The majority (75%) of the PGSs described direct benefits in at least 3 episodes. The performance on this item was very good (77.5%). Items 3.1 and 3.4, on future benefits of research to others and making patients aware of no clinical benefits, respectively, recorded below-average scores. However, item 3.2, on description of indirect benefits, was not elicited at all. Fig. 3 shows a summary of these scores.

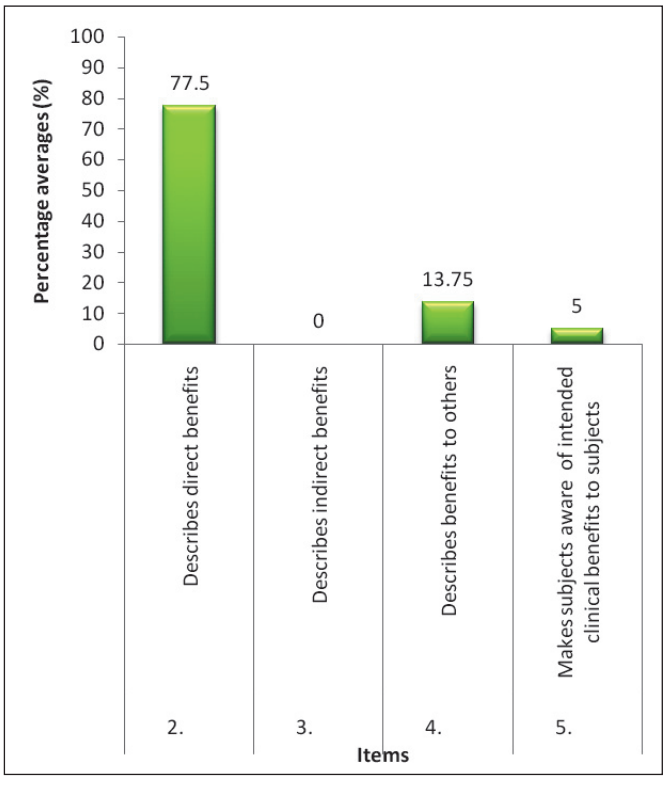


*Fig. 3. Performance on element 3: description of benefits.*

**Element 7. Non-coercive disclaimer.** Element 7 had 2 items. The first item required the PGSs to explain to the patients that participation was voluntary. More than half (70%) of the PGSs elicited this item in varying number of episodes. Three PGSs (15%) elicited this item in all 4 episodes while 6 PGSs (30%) elicited the item in 3 episodes and 6 (30%) did not elicit the item at all. The second item, explaining that there would be no penalties or loss of benefits for refusal to participate, was not elicited by any PGSs.

**Element 8. Option to withdraw.** The element had 2 items which were not elicited at all by any PGS. These items required the PGS to explain to patients the option to discontinue research at any time they wanted. The PGS was also required to explain that the patient would be stopped from participation at any time if his/her health was at risk.

## Discussion

### Introduction to research activity

Performance on the items 'explanation of research activity' (80%), 'use of appropriate language' (95%) and 'encouraging patients to ask questions' (60%), could imply that the majority of the patients were aware of their participation in research activity. However, it is not clear whether the patients understood the nature of the research they were participating in, since their understanding was not evaluated. Research has shown that patients may be aware they are taking part in a study without understanding its nature.[14] In some studies,[10,15,16] participants mentioned the need to check their understanding of information at every step of the research process. Explaining the approximate number of participants involved in the study and describing alternative procedures to participants were the only items in the element not elicited at all. While it may be argued that describing the alternative procedures could have been missed out completely because of the nature of the research, namely prevalence studies that did not require such description, explaining the number of participants, which is relevant to all research studies, was also missed out completely for reasons that are not clear.

### Description of risks and discomforts

The PGSs seemed to have described mainly physical risks to patients, and recorded below-average (42.5%) performance. They may have found physical risks and discomfort easier to explain, since the majority of them conducted cross-sectional studies in which most of the participants had their physiological parameters observed without having to go through interventional procedures. Besides, invasive procedures performed (such as drawing samples) carried minimal risks, being part of routine care that the patient would receive in the absence of research.

Items on description of social risks, emotional risks, economic risks and how risks would be minimised recorded the lowest score (≤3%). Although the failure of PGSs to explain economic risks could be due to pressure of time, patients were recruited done in the course of clinical duties with many patients in the queue, lack of knowledge by the PGSs could not be ruled out. The PGSs were expected to anticipate patients' anxiety associated with disclosing personal information and uncertainty on cost implications during participation, and address them accordingly. Low scores on the element could be attributed to association of risks with clinical trials and not with cross-sectional surveys that formed the majority (80%) of the PGSs' studies.

### Assurance of anonymity and confidentiality

Participants value anonymity and confidentiality, and this influences their participation in research. It appears that PGSs were concerned with research as part of the course requirement and not with regard to publishing findings, which could explain their failure to mention confidentiality on published data. The findings were consistent with a study in which only 30% of the participants remembered being informed that data collected in the study would be used solely for the purpose for which consent was obtained.[6]

### Compensation for research participation

Study findings indicated that the issue of compensation was not discussed with patients most of the time. It therefore appears that participants were not influenced by financial inducements. However, it should be noted that patients may participate in research even though they are not paid, since to them participation would mean securing free health care.[11] Participation could also be due to fear of the consequences of refusal because of the paternalistic clinician-patient relationship.[10] Given that KNH is a national public referral hospital, participation as a means to achieving cheap treatment and avoiding the long queue could not be ruled out.

### Offering answers to questions

The researcher observed that the PGSs recruited patients during the busy clinical schedules of attending to allocated patients. This could explain the below-average (46.25%) performance on this element. It was also observed that patients asked few questions, probably implying that they understood all the information presented. It could also be argued that the paternalistic nature of the clinician-patient relationship intimidated patients, and that the rapid delivery of information of 9 - 11 minutes left patients with very little time to ask questions.

### Description of benefits

Performance on explaining direct benefits had a very good score of 77.5% compared with that on making participants aware of no clinical benefits (5%). This performance is consistent with findings by other researchers that 53.7% of participants recalled being given information on benefits only, compared with 5.2% who recalled information on risks.[6] Although some research findings indicate that researchers usually emphasise benefits to limit refusal by prospective participants, misconceptions among participants who expect more medical or therapeutic benefits than explained by the researcher have also been reported.[16,17]

### Option to withdraw

Although participants were told that participation was voluntary, they were neither told the consequences of non-participation nor given the option to withdraw. These omissions, in addition to emphasis on direct benefits, might have positively influenced participation in the research. These findings are similar to those of a study in which only 21% of participants remembered being told that they could withdraw their consent for a study at any time without giving reasons.[6]

## Conclusion

Responsible conduct of research is critical in protecting the rights of Kenya's vulnerable population. The University of Nairobi recognised this fact and introduced research methodology as a common course for all PGSs of the CHS. Moreover, all protocols are approved by the KNH/UoN ERC to ensure protection of participants. A consent form containing all elements is one of the criteria set for approval of protocols. It is expected that all the PGSs who participated in the study would have had their consent forms approved.

However, the PGSs did not ensure that some of the basic elements of informed consent were satisfactorily completed, and they performed better on the items that had a positive influence on subjects' participation than on those that would negatively influence participation. The researcher noted that some PGSs might have failed to elicit some of the items in the elements for informed consent because of the nature of research that did not require them to elicit such items, as mentioned in the discussion. It seemed that the consent form was mainly used to satisfy a college requirement and as a legal protection tool by the PGSs, rather than for the purpose of obtaining informed consent in the true sense of the term.

### Recommendations and implications for research ethics

A large-scale study is needed, with the sample drawn from all the schools of the college to confirm the practice and compare performance in all the schools.

There is a need for additional educational programmes on bioethics for postgraduate students to create greater awareness of the informed consent process and all its elements.

**Acknowledgements.** I thank the University of Cape Town's Centre for Bioethics for awarding me the scholarship to take the course in international research ethics; the faculty members of the Centre for mentorship and encouragement; Professor Ann Robertson for her invaluable inputs and constant support; the postgraduate students who agreed to participate in the study; and the reviewers of the manuscript.

**References**

1. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Washington, DC: Department of Health, Education and Welfare, 1978. http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm (accessed 29 September 2008).
2. Council for International Organizations of Medical Sciences. International Ethical Guidelines for Biomedical Research Involving Human Subjects, 2002. http://www.Cioms.Ch/Guidelines (accessed 19 December 2011).
3. Marshall PA. Ethical Challenges in Study Design and Informed Consent for Health Research in Resource-poor Settings. Special Topics in Social, Economic and Behavioural (SEB) Research. WHO Report Series; No. 5, TDR/SDR/SEB/ST/07.1. Geneva: World Health Organization, 2007.
4. World Medical Association. Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects, 2008. http://www.Wma.Net/E/Policy/B3.Htm (accessed 28 September 2008).
5. Minnies D, Hawkridge T, Hanekom W, Ehrlich R, London L, Hussey G. Evaluation of the quality of informed consent in a vaccine field trial in a developing country setting. BMC Med Ethics 2008;9(1):15.
6. Oduro AR, Aborigo RA, Amugsi D, et al. Understanding and retention of the informed consent process among parents in rural northern Ghana. BMC

Med Ethics 2008;9(9):12. http://www.Biomedcentral.Com/1472-6939/9/12 (accessed 30 September 2008).
7. Mabunda G. Ethical issues in HIV research in poor countries. J Nurs Scholarships 2001;33(2):111-114.
8. Buchanan D, Sifunda S, Naidoo N, Shamagonam J, Reddy P. Assuring adequate protections in international health research: a principled justification and practical recommendations for the role of community oversight. Oxford Journal of Public Health Ethics 2008;1(3):246-257.
9. Benatar SR. Reflections and recommendations on research ethics in developing countries. Soc Sci Med 2002;54(7):1131-1141.
10. World Health Organization. Research Ethics Committees: Basic Concepts for Capacity-Building, 2009. http://www.who.int/eth/Ethics_basic_concepts_ENG.pdf (accessed 3 June 2010).
11. Joubert G, Steinberg H, van der Ryst E, Chikobvu P. Consent for participation in the Bloemfontein vitamin A trial: how informed and voluntary? Am J Public Health 2003;93(4):582-584.
12. Obyerodhyambo O. How informed can consent really be in poor countries? Science 2005;309(5732):205-336. http://www.scidev.www-staging.pixl8-hosting.co.uk/en/editor-letters/how-informed-can-consent-really-be-in-poor-countri.htm (accessed 24 September 2008).
13. Central Bureau of Statistics, Ministry of Health, Kenya Medical Research Institute, Centers for Disease Control, ORC Macro. Kenya Demographic and Health Survey, 2003. Calverton, MD: CBS, MOH and ORC Macro, 2004. *www.measuredhs.com/pubs/pdf/FR151/FR151.pdf (accessed 3 June 2008).*
14. Patel V. Clinical Trials in Kenya (Stichting Onderzoek Multinationale Ondernemingen). Amsterdam: Centre for Research on Multinational Corporations, 2006.
15. Hill Z, Agyemang C T, Danso S O, Kirkwood B. Informed consent in Ghana: what do participants really understand? J Med Ethics 2006;34(1):48-53.
16. Pedroni JA, Pimple KD. A Brief Introduction to Informed Consent in Research with Human Subjects: Poynter Center for the Study of Ethics and American Institutions. Bloomington, IN.: Indiana University Press, 2001.
17. Marshall P. Informed consent process in international health research. Journal of Empirical Research on Human Research Ethics 2006;1(1):25-42.