



# ETHICAL CONSIDERATIONS IN INTERNATIONAL NURSING RESEARCH: A REPORT FROM THE INTERNATIONAL CENTRE FOR NURSING ETHICS

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Ethical issues in international nursing research are identified and the perspectives of the International Centre for Nursing Ethics are offered in an effort to develop an international consensus of ethical behaviour in research. First, theoretical issues are reviewed, then initial conditions for ethical conduct are defined, and protocol design and procedure considerations are examined. A concerted effort is made to identify and avoid a western bias. Broad guiding principles for designing and reviewing research are offered: (1) respect for persons; (2) beneficence; (3) justice; (4) respect for community; and (5) contextual caring. A collaborative model of the researcher-participant relationship is suggested and discussed.

## Introduction

The International Centre for Nursing Ethics (ICNE) is a world-wide association of university research and teaching centres that focuses on issues of morality, professional ethics, philosophy of care, cultural and religious values, law and

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accountability in the field of nursing and related disciplines. The ICNE promotes international research, the development of ethics teaching, cross-cultural discussion and understanding, and ethical interprofessional and interagency cooperation. It runs regular conferences and seminars. This is the first of a series of articles produced by ICNE's teams of researchers and working groups.

The goals of this article are to identify ethical issues that nurse researchers and research ethics review committee members should consider regarding nursing research extending across national boundaries, and to stimulate discourse. Our hope is to move towards a broad consensus among nurses of all nations on norms of ethical conduct in international nursing research. The present discussion proceeds as follows: (1) specifying the scope of consideration; (2) reviewing theoretical issues that frame the topic; (3) defining initial conditions for research to be considered ethical; and (4) examining research protocol design and procedure considerations.

## Scope of consideration

Most recent efforts to examine issues in international research ethics in some developed countries focus on medical research. The executive summary of the US National Bioethics Advisory Commission's (NBAC) report, *Ethical and policy issues in international research*, specifically states 'the Commission's attention was focused on the conduct of *clinical trials* . . . in particular those trials such as Phase III drug studies' (p. ii).<sup>1</sup> In the UK, the Nuffield Council on Bioethics report, *The ethics of clinical research in developing countries*, lists the scope of research considered:

clinical trials of new drugs, vaccines and diagnostics, or improved clinical management strategies . . . basic clinical research studies on the natural history of a disease, the functioning of the body or on behaviour . . . Epidemiological studies may be aimed at identifying risk factors (p. 3).<sup>2</sup>

Although not excluding research of primary interest to nurses, these reports are clearly focused on medical research. A recent more comprehensive report from the Nuffield Council, *The ethics of research related to healthcare in developing countries*, does more to recognize the need to broaden consideration beyond clinical trials, stating:

In the developing world, research to find new or improved medicines and vaccines is often given high priority . . . but research to find better ways of delivering existing products and services to those in need is often equally or more important (p. 5).<sup>3</sup>

However, this Nuffield report still does not deal specifically with nursing.

This article addresses international nursing research, that is, research where investigators and participants are from different countries, rather than research targeting populations by race or ethnicity. Although cultural differences between researchers and participants are often an essential consideration in international research, it is not the only consideration. Furthermore, situations where researchers from one culture study persons from a distinctly different culture within national boundaries occur frequently in multi-ethnic countries like the USA and South Africa, or in countries with indigenous populations such as Australia and Finland. When research is conducted within national boundaries on minority

populations, there is a commonality of law and there may be a greater shared common sense of norms regarding authority and social goals.

There are many categories within the broad designation of international research, distinguished by different combinations of researchers and participants from developed and developing countries, and by varying types of collaborative arrangement between researchers, sites for recruiting, and origins of sponsorship. Some types of research that cross national boundaries have a higher potential for ethical difficulties than others. The two factors that determine the level of ethical concern are the degree of cultural difference between the involved countries and the potential for exploitation. Therefore, studies with principle investigators from a more developed country who are recruiting participants from a less well-developed country are of greater concern than collaboration between researchers of similarly developed countries collecting data for purposes of comparison, because of the greater potential for exploitation.

In the context of international HIV/AIDS research, UNAIDS identified factors that create conditions that make countries or communities potentially vulnerable to exploitation. These include:

- the level of the proposed community's economic capacity;
- limited experience with, or understanding of, scientific research in the country as a whole;
- limited local infrastructure, personnel and technical capacity for providing health care and treatment options;
- limited experience and capacity for conducting ethical and scientific review;
- an uncertain ability of individuals in the community to provide informed consent, for instance, as a result of class, gender and other social patterns.<sup>4</sup>

Method and data-gathering techniques of particular concern to nurses, such as interviewing, psychosocial intervention, participant observation, and other anthropological techniques, may be liable to different types of problems to quantitative health care research.<sup>5-7</sup> Although qualitative research does not usually involve the risk of physical harm, it carries a greater risk of social and psychological harm, particularly from breaches of privacy.<sup>8</sup> For example, Upvall and Hashwani<sup>9</sup> reported difficulties with informing participants in developing countries because in qualitative research the direction the inquiry takes cannot be fully anticipated in advance. Although it is becoming more accepted, qualitative research has often received less attention by research review committees because the medical establishment has traditionally considered this type of research to be of lesser value.<sup>10</sup> Current ethical and legal guidelines, developed by the western medical establishment and designed to regulate clinical drug trials, are often a poor fit with the realities of the qualitative research and methods more frequently used in nursing.<sup>11</sup>

In a final note about the scope of consideration, we acknowledge a historically long view of potential problems. History is filled with examples of events widely accepted at the time, even enjoying a semblance of local approval, but which, in retrospect, are seen as exploitive. The most dramatic of these may have been the slave trade during the eighteenth century. Researchers and reviewers cannot always be held accountable for the reactions of future generations but must remain alert for instances when present thinking and evidence are ample to

anticipate problems. In the words of one research participant, 'I fear your writings would hurt the feelings of village people if they could read; they will certainly hurt our great grandchildren who *will* read . . .' (p. 3).<sup>12</sup>

## Theoretical issues

A discussion of theoretical issues provides a background for the ethical consideration of specific design and procedure aspects of international nursing research. In any discussion of ethics with an international scope, an inherent tension exists between conceptions of ethics as a set of universal principles and ethics as contingent norms relative to culture. The position adopted by researchers and reviewers along the continuum between relativistic and universal ethics has practical implications. The degree of credence, acceptance and personal endorsement accorded to codes of ethics and guidelines intended to apply across national boundaries depends on an individual's beliefs regarding the balance between universalism and relativism or, from a more relativistic perspective, how well the 'universal' code of ethics fits with local custom.

Suggestions for approaches to the relativism issue in the international regulation of medical research have ranged from the emphasis on uniform international standards<sup>13</sup> to stressing ethical procedure to negotiate the specific content of protocols.<sup>14</sup> The ICNE adopts the intermediary position that general principles can be articulated with sufficiently broad international support to offer a framework for considering the various facets of the research process. Although providing a useful guide, these principles would also allow sufficient latitude to negotiate specific research activities when substantive variation in behavioural and ethical norms exists between the researchers and the local population being recruited. This is in accordance with Nagel's idea that '[morality involves] occupying a position far enough outside your own life to reduce the importance of difference between your self and other people, yet not so far outside that all human values vanish . . .' (p. 222).<sup>15</sup>

In endorsing the possibility of stating broad principles that can be widely accepted across national and cultural boundaries, it is essential that we do not assume that these principles are coincident with western values. Such 'ethical imperialism' in medical research has been widely criticized.<sup>16-18</sup> In relation to nursing, Davis states:

The use of western philosophical ethics, sifted through the USA's cultural lens, as a standard by which all else is compared, contrasted and judged, reflects a type of ethical influence that may be harmful. This influence combines attitudes and actions that essentially support the idea that all other people and cultures should have and use the same values and ethics as are found in America (p. 123).<sup>19</sup>

The ICNE suggests five broad principles to frame the initial discussion and development of guidelines for the ethical conduct of international nursing research: (1) respect for persons; (2) beneficence; (3) justice; (4) respect for community; and (5) contextual caring. To be useful in an international context, these principles must be understood in the broadest sense as overarching ideals of behaviour and not as prescriptive rules. The first three are the touchstones of the

western bioethics tradition<sup>20</sup> and are articulated with respect to research in the Belmont Report.<sup>21</sup> In this report the principle of 'respect for autonomy' is a key feature to the implementation of 'respect for persons.' Although the principle of respect for persons is inclusive enough to garner broad acceptance in the international community, the emphasis placed on respect for autonomy has been frequently criticized as idiosyncratic to the West and the USA in particular.<sup>19,22</sup> Thus the ICNE follows the Belmont Report in 'respect for persons' without the specification that the chief method of showing respect for competent persons is to respect their autonomy.

The next two suggested principles, beneficence and justice, are also part of the standard Western canon.<sup>20,23,24</sup> Beneficence, the principle that one should act for the benefit of others, encompasses both maximizing positive good and minimizing or preventing harm.<sup>21</sup> In the context of research ethics, justice means fair treatment of participants and communities, and the fair distribution of both the benefits and burdens of research at individual and community levels.<sup>25</sup>

The fourth principle, respect for community, goes beyond the standard application of western bioethics to the research situation requiring consideration of a wider context than concern for the individual participant. Researchers and research ethics committees should consider the effects of possible results on a community's self-conception, altered perceptions outside the community, changes to health care delivery methods by implementing results or potential problems with implementing results, as well as any effects on the entire community arising from individual participation. This principle recognizes that 'individualism (the cornerstone of western nursing) may often be inappropriate where the concept of *individual* rights does not exist' (p. 222).<sup>26</sup> This principle should serve as a guide for research in all countries and not be taken as a supplemental guide for considering research protocols only in nonwestern countries. Respect for community is intended as a corrective to the overly intense focus on individual rights found in most western guides to research ethics.

Although intrinsic tension can exist between the good of the individual and the community, it cannot be said that the solution always resides in the priority of one over the other. Always to value the good of the collective over the individual can lead to oppression,<sup>27</sup> while always to give priority to the individual over the community can lead to ethical isolation and the overemphasis of rights, as boundaries, to the detriment of attention to relationships and responsibilities.

The final guiding principle, contextual caring, entreats the researcher to behave towards each participant as a person within an ethical relationship of caring concern grounded in the researcher's personal values. This differs from beneficence, the abstract principle that one's behaviour should be guided by the desire to do good for others.<sup>20</sup> In contextual caring one acts in accord with personal caring concern for the concrete specific other within one's immediate scope. The call to caring behaviour is more difficult to prescribe than a beneficence because it is more closely bound to an individual's emotional reactions; however, there is increasing recognition that emotion is inextricably bound to moral good.<sup>28,29</sup> The principle of caring concern encourages the consideration of what good can and may be done for another to whom one feels responsible beyond the obligatory dictates of what must and must not be done.<sup>30-33</sup>

## **Initial conditions for ethical conduct of international nursing research**

There are three initial conditions for the ethical conduct of international research: (1) that the local community has an early opportunity and an ongoing mechanism to provide input into the purposes, goals and methods of the research; (2) that the research design generates knowledge that has the potential to benefit the community or population providing the participants; and (3) that there is an ethically justifiable reason to target the population from which participants will be recruited. Although these conditions can be applied broadly to research in general, they are particularly vital to prevent exploitation in less developed countries.

Although the concept of local input has broad endorsement,<sup>34-36</sup> ethical considerations remain regarding the details of how local input should be obtained. Determining who is appropriate to provide local input regarding cultural norms and practices (i.e. who speaks for a culture or community) remains an issue. An example of a potential problem would be using local scientists as co-investigators who may be influenced by the possibility of enhancing their personal reputations by working with US or European scientists.<sup>2,11,37</sup> In the study commissioned by the National Bioethics Advisory Committee<sup>1</sup> of researchers from the USA and other countries who have conducted international studies, one of the informants described a situation where the presence of western researchers conferred significant status on a local research assistant. In referring to the local person, who assisted with recruitment, the researcher says: 'They actually call him master, they have a high level of respect for the guy' (p. B-25).<sup>38</sup> The point illustrated here is somewhat different from the NBAC report, where the quote is used to show the degree of commitment researchers have towards obtaining local input; however, the statement also speaks to the potential conflicts created when local persons are working with foreigners who are perceived as powerful. The ability to gain and wield this status could potentially work to the detriment of a local individual's role as community advocate.

The practical aspects of local input are solved to a degree when the local country requires committee review of research as prescribed by the Helsinki Declaration.<sup>39</sup> In countries that do not have this requirement, researchers should assist in moving towards establishing the infrastructure.<sup>1,3,40</sup> However, when participating in 'capacity building', care must be taken not simply to recreate western derived procedures and ethical standards where they may not be appropriate. The Council for Organizations for Medical Sciences guidelines<sup>40</sup> stipulate that this is to be avoided by providing funds to, but not allowing direct involvement by, local authorities.

Although local committee review, such as that performed by an institutional review board in the USA or a local research ethics committee in the UK, greatly helps in assessing a specific protocol's adherence to local norms, this does not fully solve the issue of local input regarding what should be researched and with what method and conceptual framework. Other avenues of local input may also be appropriate, such as local nurses, community leaders, or advocacy agencies, who may need to be consulted to appreciate fully the community's perception of priorities in health care concerns and the appropriateness of the procedures of specific protocols.

However, considerations of respect for the community and the sense of unique local perspective to which the researcher may not be privy must be balanced with the researcher's scientific autonomy and integrity. Part of this balance would be a consideration of why an outsider conducts this particular research in this particular locale: is it a matter of technical know-how in performing something for the local community that they would otherwise do for themselves, or does the researcher have some unique interest, possibly born from his or her position as an outsider?

In an effort to build local capacity towards just and effective negotiations with foreign researchers, one conceptual guide for a method to gain true consensus between the parties is offered by Habermas'<sup>41</sup> conditions of discourse:

- All participants in the discourse must have the same chance to speak so that at all times they may open and perpetuate discourse through address and reply, question and answer.
- All participants must have the same chance to put forward interpretations, assertions, recommendations, explanations and justifications.
- Discourse allows only for speakers who have an equal chance to express views, feelings and wishes, and make them known without omission or deception.
- All participants have an equal chance to employ regulative acts of speech, such as to command, to resist, to allow, to forbid and to make and retract promises.

Foreign research efforts would be expected to work towards fulfilling these conditions and for assessing progress by reference to the conditions.

The second condition for carrying out research using a population sample outside one's own country is the intention to generate knowledge of direct benefit to the population from which the sample is drawn. This requirement helps to prevent exploitation. Specific groups should not be targeted because of convenience, particularly if the convenience is in the form of reduced regulatory requirements or easy recruitment based on power differentials between the researcher and the participants. The abuses of the Tuskegee study, in which the natural progress of syphilis was allowed to continue in African-American men after treatment was available, were made possible by such a power differential.<sup>42</sup>

Local benefit is a well-established standard in guides to research on specific populations (e.g. US regulations on using prisoners as participants<sup>43</sup>) and guidelines for the use of international samples.<sup>1,3,40</sup> This requirement has a fairly straightforward application in clinical drug trials but it may require some reflection in the ethical justification of certain types of nursing research.

An honest declaration of local benefit further requires that any intervention that may be shown to be successful is affordable and practical in the local milieu. Although this stipulation is often applied to drug research, much nursing research involves testing person-to-person interventions, which can also be economically costly and may need to be implemented or administered by personnel with training that is largely unavailable in the local community.

In nursing research where the objective is to learn more about cultural attitudes and customs regarding health, it must be presumed that the intent is for that knowledge to lead to better local health care. The connection between understanding a culture and giving quality nursing care will be direct in many studies;

examples are those by Åstedt-Kurki *et al.*<sup>44</sup> and Konishi and Davis.<sup>45</sup> However, in some cases, the presumption of benefit through cultural understanding may be inferential.

In meeting the third initial condition for conducting international nursing research, the justification of targeting participants from another country, the following criteria should be considered: (1) the phenomenon under consideration is biologically unique to that group or relates to a phenomenon that is biologically unique to that group (e.g. thalassaemia, sickle cell anaemia); (2) the phenomenon, although culturally mediated, is widely known to be group specific (e.g. the effect of local diet or sexual practices); (3) there is an empirically demonstrated rationale for targeting a specific group (e.g. there is a demonstrated difference in incidence, rate of detection or recovery); (4) extensive normative data exist that do not include the targeted population – if it is reasonable to believe that the targeted population may vary from the general population described by the data; or (5) comparative data between groups would be helpful to mutual understanding or in designing treatment, service delivery or education (e.g. efforts to understand differences in ethical concepts cross-culturally).

## Design and procedure considerations

The ethical conduct of research requires careful design, including specific attention to enrolling and maintaining participants, assessing benefit and risk, maximizing benefit, minimizing risk, and ensuring confidentiality, all in a way that respects both individuals and the community, and also fosters contextual concern.

### Enrolment and maintenance

In the West this would mean a discussion of informed consent; however, for this document we prefer to frame this topic as the consideration of conditions for ethical entry into a protocol and continuation of the person's participation in research. Informed consent as a formalized documented process is a relatively new concept, even in those countries where it is established as a norm. Informed consent, first widely endorsed as a formal condition for the ethical conduct of research after the Nuremberg Code, was issued in the context of the 1945–1949 war crimes trials. Its first statement of principle is: 'The voluntary consent of the human participant is absolutely essential' (p. 181).<sup>46</sup> However, this did not become a regulatory requirement for all publicly funded research in the USA until the 1970s.<sup>20</sup> Despite its relatively recent codification, the conceptual basis of informed consent is deeply embedded in a long tradition of the individual as the locus of decision making originating in fifth century BC Athens.<sup>20,47</sup>

Although many research situations exist where written and documented informed consent, as understood in parts of the West, may be the most appropriate means for ensuring the ethical enrolment of persons into a study, it is ethnocentric to assume that a procedure so closely tied to a particular way of thinking is acceptable to people from all other traditions.<sup>19,48</sup> Because individualism is so deeply embedded in the western understanding of humanity and ethics, the use of alternatives to informed consent remains perhaps the most difficult issue for

western people to confront and, thus far, ethical guidelines and literature considering international research ethics consistently include a strong endorsement of individual informed consent.<sup>1,3,49,50</sup>

Obtaining proper informed consent, as it is conceived in the West, requires shared assumptions about the nature of decision making, and at least some degree of shared understanding of the meaning of the research and the nature of the risks and benefits involved in the particular study. Reliance on informed consent is problematic when the assumptions of researchers and participants differ in any of these areas. Although the therapeutic misconception (a person's belief that the researcher is acting for his or her benefit in the manner expected of clinicians) frequently occurs in the USA,<sup>51-53</sup> the researchers participating in the NBAC study<sup>38</sup> suggested a widespread occurrence of the therapeutic misconception in research in developing nations. Some of these researcher participants noted that the word 'research' did not exist in the native language and was translated as 'medicine'.<sup>38</sup>

With growing experience in cross-national research there has been increased interest in potential alternative strategies, such as the consent of community leaders.<sup>38</sup> In the NBAC study of international researchers, 51% said they enrolled participants with the consent of community leaders and 19% enrolled them with the consent of a family member.<sup>38</sup> In any arrangement where one person's deliberations determine the inclusion of another person in a study, the possibility of individual dissent presents a problem. Situations may occur where some individuals, although acknowledging that either a collective or a paternalistic decision-making process is their cultural norm, disagree with that norm and prefer that the usual process should not hold sway over them. Culture is dynamic and dissent fosters change. Women in many industrialized countries would not be allowed to vote if dissent against cultural assumptions and accepted procedural norms could not occur. Culture is not a fixed entity and individuals make their own interpretation of cultural norms and the value of those norms.

Researchers and members of review committees must strike a balance between overvaluing western ideals in the form of written, individually-signed informed consent documents, while not supporting oppression in the name of cultural relevancy. The use of a male family member to provide consent for a female member's participation because males in that culture are the sanctioned decision makers presents such a dilemma.

## **Benefit and risk**

In the western tradition, the central purpose of informed consent is to respect and promote a person's autonomous decision to assess the balance between the benefits and risks of participating in a protocol. Thus individual variation is recognized and allowed within a shared cultural paradigm. However, even within the context of honouring individual variation in the assessment of benefit and risk, a great deal of overlap in culture is required. Information disclosure is the key procedure in informed consent, with the standard used being what a reasonable person would want to know.<sup>20</sup> Therefore, the researcher must share enough assumptions with the potential participant to anticipate what information needs to be disclosed for effective informed consent. Therefore, ethical and practical considerations in protocol design are enhanced by greater

knowledge of local custom and significant local input.

However, a conceptual framework for ethical enrolment into international research studies needs to go beyond fitting cross-national situations into a western paradigm through better anticipation of local norms in assessing benefit and risk. Awareness of the potential for a fundamental disconnection in the values people use to weigh the risk–benefit balance must be acknowledged and maintained. We therefore suggest that there should be emphasis on informed consent at the entry into a protocol as the decision point for individuals to balance the risks and benefits, and more emphasis on the maintenance of an ongoing relationship. Even in those countries where people share initial assumptions, there is an increased recognition that an individual's risk–benefit assessment fluctuates, leading to more emphasis on informed consent as a process rather than as a one-time interaction.<sup>54</sup>

## **Confidentiality**

Control over the way one is viewed by others is a fundamental mechanism of personal identity that sets the foundation for social relations.<sup>55,56</sup> Thus, the assurance and maintenance of confidentiality in research serves both ethical and practical functions. Researchers respect participants by granting them control over personal information and protecting them when they are vulnerable from unwarranted revelations. This demonstrates researchers' respect for both the participant and the community. Confidentiality is also of practical concern because researchers often seek information that participants would prefer to keep private from the community at large; thus they will not reveal such information unless the promise of confidentiality is credible. In this way researchers have a responsibility not only to the individuals in a specific protocol but also to the culture, community and future researchers for maintaining the credibility of assurances of confidentiality.<sup>57</sup>

The embarrassment and shame that individuals experience when others observe behaviours or personal characteristics that are considered to be aberrant or undesirable lead them to seek privacy.<sup>58,59</sup> Privacy also allows persons some opportunity to express characteristics and desires that they do not wish revealed to others. An inability to maintain some secrecy about aspects of the self can result in a profound loss of identity.<sup>57</sup> Despite variations in the content of what is considered as private, all cultures maintain and value this concept.<sup>60</sup>

The international research situation is problematic because norms in the assessment of what embarrasses or shames vary considerably among cultures.<sup>58</sup> Research ethics guidelines written from the western perspective deal with confidentiality mostly in terms information and record keeping, generally echoing the way in which medical records are handled. Western guidelines are also problematic because some cultures rely more on oral communication and tradition than on written record keeping. Therefore, international researchers need to attend to the broader concept of privacy, which encompasses confidentiality of information as well as privacy of person. Such attention is particularly significant in anthropological or other research that describes people, their behaviours or their social environment.

In international research, researchers are inevitably outsiders who are

intending to reveal information about the local community to a large foreign audience. To respect the community, researchers must attend to its privacy as a whole to maintain the community's control over its presentation to the world. Nursing researchers must be especially vigilant of privacy needs because of their focus on the psychosocial aspects of care.

### **Alternative models of the research relationship**

With the increasing globalization of health care research, now is the time to re-examine the heavily western influenced bioethical literature that tends to focus on either individual informed consent or substitute procedures that are justified in the ethical terms of informed consent. An ethical model emphasizing the relationship between researchers and participants may be more congruent to the international situation where many researchers find that the cultural gap ensures that participants cannot be truly 'informed' in the same manner as a person who shares the researchers' basic assumptions.<sup>38</sup>

One effect of the emphasis on informed consent is that it fosters a 'willing object' approach to the researcher-participant relationship; that is, the sense that, as long as the person knows what he or she is getting into and agrees, then enrolment is ethical. A collaborative model of the researcher-participant relationship, first offered by Katz<sup>61</sup> as early as 1973, is an alternative conception of researchers' relationship with participants that offers more flexibility with greater accountability. This model was more recently endorsed by a 1998 Canadian Tri-Council Policy Statement: 'Such collaboration entails an active involvement by research subjects, and ensures both that their interests are central to the project or study, and that they will not be treated simply as objects' (p. i.7)<sup>62</sup> (see Table 1). A shift to a collaborative model for assessing ethics in the conduct of research receives empirical support from a study by Verheggen *et al.*<sup>63</sup> in which it was shown that participants place more weight on verbal discussion of the protocol and any prior relationship with the clinician conducting the study than on the written informed consent. The effective implementation of a collaborative model of research ethics would draw on Moody's<sup>64</sup> concept of negotiated consent, which placed emphasis on the concrete process of communication in the natural context that may involve family, social network, local institutions or any other party relevant to the potential participant.

The collaborative model is more realistic in international and cross-cultural settings than trying to adapt the western contractual approach. The distinction between the participant as a willing object in contrast to a collaborator is blurred in situations where researchers and participants share norms and cultural assumptions, because the researcher can safely assume that the participant would not agree to take part without endorsing the research goals. This supposition is not warranted when participants' fundamental conceptions of benefit, risk, research and the nature of decisions vary from those of the researcher.

Three aspects of shifting emphasis in research ethics from an individual-orientated basis to a more relational approach include: (1) assessment of participant investment in the goals of the research; (2) less stress on the participants' entry into protocols and more on their ability to exit after enrolment; and (3) more weight on ensuring that the protocol includes an ongoing process of

**Table 1** Comparison of approaches to the researcher–participant relationship

	'Willing object' approach	Collaborative approach
Nature of relationship	Participants agree to allow themselves to be used by the researcher	Participants collaborate with researcher towards the goal of the protocol
Source of harm	The protocol itself	Problems in the relationship
Point at which ethical participation is assured	Point of entry	Attention to maintaining ethical relationship throughout duration of protocol
Chief technique for respecting participants	Informed consent	Attention to informed and willing participation throughout
Examples of specific harms targeted by the model	The experimental intervention causing direct harm Uninformed participation Inappropriate risk or burden	Coercion Deception Participant's feeling that treatment was less than what was deserved.
Type of benefit emphasized	Therapeutic effect of intervention	Altruistic or personal interest in advancing knowledge

working in collaboration with willing participants.

Research as a collaborative relationship incorporates the principle suggested by Jonas to move beyond informed consent and identify participants who are themselves, for whatever reason, invested in the goals of the research.<sup>65</sup> Annas and Grodin's suggestion 'that researchers should presume that valid consent cannot be obtained from impoverished populations in the absence of a realistic plan to deliver the intervention to the population' (p. 563)<sup>66</sup> follows this principle, although somewhat paternalistically, assuming that researchers can decide what is best for the community. The assessment of participant investment includes the typical informed consent requirement of telling participants the purpose of the research, and would also encompass being knowledgeable of their values, especially when cultural norms and values differ between them and the researchers. This moves the research enterprise towards an expectation of contextual concern in relationship rather than a contractual connection.

Collaboration also means a sustained relationship with ongoing clarification of research goals and the expectations of both the researcher and the participant, as well as an ongoing assessment of the participants' continued endorsement of the goals and methods and their willingness to meet expectations. Emphasis on

participant investment should lead to increased importance of procedures to allow participants to end their co-operation, rather than focusing on enrolment. In this way, techniques that honour cultural norms of leadership or familial decision making could be used if they were balanced with the possibility of individual dissent.

In summary, the conceptual basis of western bioethics, with its individualistic emphasis on informed consent, may be too narrow to ensure an ethical basis for the recruitment, enrolment and continued participation, risk–benefit analysis, and respect for the privacy of participants in international research. The basis for ethical participation in such research is broadened, not by discarding informed consent, but by expanding the foundation of research ethics to the research relationship as a collaboration between participant and researcher, and then asking under what conditions that relationship is ethical. In cases where researchers and participants share cultural assumptions, typical informed consent procedures will often ensure an ethical basis for the relationship, but, where assumptions vary, the broader relational view provides a more flexible conceptual framework for devising techniques to ensure ethical participation. This goes beyond tinkering with typical western-style informed consent to provide a more workable and ethical approach.

## Conclusion

In general we advocate a flexibility of approach, an emphasis on the ethical conduct of researchers, as driven by researchers' responsibilities to the participants within a collaborative relationship, an attention to detail that demonstrates respect for the local community (such as accurate translation and knowledge of the local situation) through researchers' own efforts and the judicious reliance on local input. The goals of the ICNE here, as elsewhere, are twofold: to demonstrate the possibility of a dialogue moving towards an ethical framework that is inclusive enough to achieve widespread consensus; and to further that pursuit through inclusion of the widest possible range of ethical paradigms from the international community.

## References

- <sup>1</sup> National Bioethics Advisory Commission. *Ethical and policy issues in international research: clinical trials in developing countries*, 2 vols. Rockville, MD: US Government Printing Office, 2001. Available from: URL: <http://www.georgetown.edu/research/nrcbl/nbac/pubs.html> [Accessed 30-Oct-2002]
- <sup>2</sup> Nuffield Council on Bioethics. *The ethics of clinical research in developing countries*. London: Nuffield Council on Bioethics, 1999. Available from: URL: <http://www.nuffieldbioethics.org/filelibrary/pdf/clinicaldiscuss1.pdf> [Accessed 30-Oct-2002]
- <sup>3</sup> Nuffield Council on Bioethics. *The ethics of research related to healthcare in developing countries*. London: Nuffield Council on Bioethics, 2002. Available from: URL: <http://www.nuffieldbioethics.org/publications/developingcountries/rep0000000942.asp> [Accessed 30-Oct-2002]
- <sup>4</sup> Joint United Nations Programme on HIV/AIDS. *Ethical considerations in HIV preventive vaccine research: UNAIDS guidance document*. Geneva: UNAIDS, 2000. Available from: URL: <http://www.unaids.org/publications/documents/vaccines/vaccines/Ethicsresearch.pdf> [Accessed 30-Oct-2002]

- 5 Orb A, Eisenhauer L, Wynaden D. Ethics in qualitative research. *Image J Nurs Sch* 2001; **33**: 93–96.
- 6 Schoepf BG. Ethical, methodological and political issues of AIDS research in Central Africa. *Soc Sci Med* 1991; **33**: 749–63.
- 7 Whitaker B, van der Arend A, Harman G. Factors affecting the timing of ethical approval of research in humans: a survey of hospital and university ethics committees in Australia and The Netherlands. In: Pelkonen M, Perälä M, Niemelä T eds. *Knowledge development: Clinicians and researchers in partnership. Proceedings of the 9th Biennial conference of the Workgroup of European Nurse Researchers*, vol. 1; 1998 July 5–8; Helsinki, Finland. Helsinki: Oy Edita Ab, 1998; 134–45.
- 8 Byrne M. The concept of informed consent in qualitative research. *AORN J* 2001; **74**: 401–403.
- 9 Upvall M, Hashwani S. Negotiating the informed-consent process in developing countries: a comparison of Swaziland and Pakistan. *Int Nurs Rev* 2001; **48**: 188–92.
- 10 Glenister D. Nursing research ethics: some problems and recommended changes. *Nurs Times Res* 1996; **1**: 184–90.
- 11 Levine R. *Ethics and the regulation of clinical research*, second edition. New Haven, CT: Yale University Press, 1986.
- 12 Pandey U. Would you like to listen or not? *Anthropol Newsletter* 1992; (May): 3.
- 13 Levine R. Informed consent: some challenges to the universal validity of the western model. *Law Med Health Care* 1991; **19**: 207–13.
- 14 Christakis N, Panner M. Existing international ethical guidelines for human subjects research: some open questions. *Law Med Health Care* 1991; **19**: 214–21.
- 15 Nagel T. *The view from nowhere*. New York: Oxford University Press, 1986.
- 16 Angell M. Ethical imperialism? Ethics in international collaborative clinical research. *N Engl J Med* 1998; **319**: 1081–83.
- 17 Benatar SR. Imperialism, research ethics, and global health. *J Med Ethics* 1998; **24**: 221–22.
- 18 Forde OH. Is imposing risk awareness cultural imperialism? *Soc Sci Med* 1998; **47**: 1155–59.
- 19 Davis AJ. Global influence of American nursing: some ethical issues. *Nurs Ethics* 1999; **6**: 118–25.
- 20 Beauchamp T, Childress J. *Principles of biomedical ethics*, fifth edition. New York: Oxford University Press, 2001.
- 21 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 participants of research*. Washington: OPRR Reports. A6-14; 1979. Available from: URL: <http://ohrp.osophs.dhhs.gov/humanparticipants/guidance/belmont.htm> [Accessed 30-Oct-2002]
- 22 Takala T. What is wrong with global bioethics? On the limitations of the four principles approach. *Camb Q Healthc Ethics* 2001; **10**: 72–77.
- 23 Benjamin M, Curtis J. *Ethics in nursing*, third edition. New York: Oxford University Press, 1992.
- 24 Hall J. *Nursing ethics and law*. Philadelphia, PA: Saunders, 1996.
- 25 Frankena W. *Ethics*, second edition. Englewood Cliffs, NJ: Prentice-Hall, 1973.
- 26 Lützn K. Nursing ethics in the next millennium: a context sensitive approach for nursing ethics. *Nurs Ethics* 1997; **4**: 218–26.
- 27 Arendt H. *The origins of totalitarianism*. New York: Harcourt, 1973
- 28 Nortvedt P. *Sensitive judgment: nursing moral philosophy and the ethics of care*. Oslo: Tano Aschehoug, 1996.
- 29 Vetlesen A. *Perception, empathy, and judgment: an inquiry into the preconditions of moral performance*. University Park, PA: Pennsylvania State University Press, 1994.
- 30 Benner P, Wrubel J. *The primacy of caring*. Menlo Park, CA: Addison-Wesley, 1989.
- 31 Gastmans C, Dierckx de Casterlé B, Schotsmans P. Nursing considered as moral practice: a philosophical-ethical interpretation of nursing. *Kennedy Inst Ethics J* 1998; **8**: 43–69.
- 32 Gastmans C. Care as a moral attitude in nursing. *Nurs Ethics* 1999; **6**: 214–23.
- 33 Gilligan C. Remapping the moral domain: new images of self in relationship. In: Gilligan C, Ward J, Taylor J, eds. *Mapping the moral domain*. Cambridge, MA: Harvard University Press, 1988, 3–20.
- 34 Eades SJ, Read AW. The Bibbulung Gnarnep project: practical implementation of

- guidelines on ethics in indigenous health. *Med J Austr* 1999; **170**: 433–36.
- 35 Kaufert J, Commanda L, Elias B, Grey R, KueYoung T, Masuzumi B. Evolving participation of aboriginal communities in health research ethics review: the impact of the Inuvik workshop. *Int J Circumpolar Health* 1999; **58**: 134–44.
- 36 Macaulay AC, Cross EJ, Delormier T, Potvin L, Paradis G, McComber A. Developing a code of research ethics for research with a native community in Canada: a report from the Kahnawake schools diabetes prevention project. *Int J Circumpolar Health* 1998; **57**(suppl 1): 38–40.
- 37 Figueroa JP. Is serious research possible in the Caribbean? *Ethn Dis* 1991; **1**: 368–78.
- 38 Kass N, Hyder A. Attitudes and experiences of US and developing country investigators regarding US human subjects regulations. In: . National Bioethics Advisory Commission. *Ethical and policy issues in international research: clinical trials in developing countries*, vol. 2. Rockville, MD: US Government Printing Office, p. B1-B220; 2001. Available from: URL: <http://www.georgetown.edu/research/nrcbl/nbac/clinical/Vol2.pdf> [Accessed 30-Oct-2002]
- 39 World Medical Association. *The Helsinki Declaration: ethical principles for medical research involving human subjects*, 2000. Available from: URL: <http://www.wma.net/e/policy/17c.pdf> [Accessed 30-Oct-2002]
- 40 Council for International Organizations for Medical Sciences. *CIOMS international ethical guidelines for biomedical research involving human subjects*, revised draft, 2002. Available from: URL: [http://www.cioms.ch/frame\\_guidelines\\_january\\_2002.htm](http://www.cioms.ch/frame_guidelines_january_2002.htm) [Accessed 3-May-2002]
- 41 Horster D. (Thompson H, trans.). *Habermas: an introduction*. Philadelphia, PA: Pennbridge Books, 1992.
- 42 King P. Twenty years after. The legacy of the Tuskegee syphilis study. The dangers of difference. *Hastings Cent Rep* 1992; **22**(6): 35–38.
- 43 Department of Health and Human Services, National Institutes of Health, Office for Protection from Research Risk. *Protection of human subjects*. Code of Federal Regulations, Title 45, Part 46 [Federal Register 56:28003-28032. Appendix 4, A4-35 – A4-49]; June 18, 1991. Available from: URL: <http://ohrp.osophs.dhhs.gov/humanparticipants/guidance/45cfr46.htm> [Accessed 30-Oct-2002]
- 44 Åstedt-Kurki P, Friedemann M, Paavilainen E, Tammentie T, Pounonen-Ilmonen M. Assessment of strategies in families tested by Finnish families. *Int J Nurs Stud* 2001; **38**: 17–24.
- 45 Konishi E, Davis A. The right-to-die and the duty-to-die: perceptions of nurses in the West and in Japan. *Int Nurs Rev* 2000; **48**(1): 17–28.
- 46 Government Printing Office. *Trials of war criminals before the Nuremberg military tribunals under control council law no. 10, v. 2*, Nuremberg, October 1946 – April 1949. Washington, DC, 1949. Available from: URL: <http://ohsr.od.nih.gov/nuremberg.php3> [Accessed 30-Oct-2002]
- 47 Meier C. (Kimber R, Kimber R, trans.). *Athens: a portrait of the city in its golden age*. New York: Metropolitan Books, 1998.
- 48 Thomasma D. Proposing a new agenda: bioethics and international human rights. *Camb Q Healthc Ethics* 2001; **10**: 299–310.
- 49 Wang C, Huch M. Protecting human research participants: an international perspective. *Nurs Sci Q* 2000; **13**: 293–98.
- 50 Council of Europe. *Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine: convention on human rights and bio-medicine*, 1997. Available from: URL: <http://conventions.coe.int/treaty/en/treaties/html/164.htm> [Accessed 30-Oct-2002]
- 51 Appelbaum P, Roth L, Lidz C, Benson P, Winslade W. False hopes and best data: consent to research and the therapeutic misconception. *Hastings Cent Rep* 1987; **17**(2): 20–24.
- 52 Advisory Committee on Human Radiation Experiments. *The human radiation experiments*. New York: Oxford University Press, 1996. Available from: URL: <http://tis.eh.doe.gov/ohre/roadmap/achre/report.html> [Accessed 30-Oct-2002]
- 53 Daugherty C, Ratain M, Grochowski E et al. Perceptions of cancer patients and their physicians involved in Phase I trials. *J Clin Oncol* 1995; **13**: 1062–72.
- 54 Jonsen AR, Siegler M, Winslade WJ. *Clinical ethics*, fourth edition. New York: McGraw-Hill, 1998.
- 55 Goffman E. *The presentation of self in everyday life*. Woodstock, NY: Overlook Press, 1973.

- <sup>56</sup> Reiman J. Privacy, intimacy, and personhood. In: Schoeman F, ed. *Philosophical dimensions of privacy*. Cambridge: Cambridge University Press, 1984, 330–61.
- <sup>57</sup> Bok S. *Secrets: on the ethics of concealment and revelation*. New York: Vintage, 1983.
- <sup>58</sup> Levy R. Self and emotion. *Ethos J Soc Psychol Anthropol* 1983; **11**: 128–34.
- <sup>59</sup> Lynd H. *On shame and the search for identity*. New York: Harcourt, Brace, 1958.
- <sup>60</sup> Moore B. *Privacy: studies in social and cultural history*. Armonk, NY: Sharpe, 1984.
- <sup>61</sup> Katz J. The regulation of human research – reflections and proposals. *Clin Res* 1973; **21**: 785–91.
- <sup>62</sup> Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada. *Tri-council policy statement on ethical conduct for research involving humans*, 1998. Available from: URL: <http://www.nserc.ca/programs/ethics/english/ethics-e.pdf> [Accessed 30-Oct-2002]
- <sup>63</sup> Verheggen F, Jonkers R, Kok G. Patients' perceptions on informed consent and the quality of information disclosure in clinical trials. *Patient Educ Counsel* 1996; **29**: 137–53.
- <sup>64</sup> Moody H. *Ethics in an aging society*. Baltimore, MD: Johns Hopkins University Press, 1992.
- <sup>65</sup> Fethe C. Beyond voluntary consent: Hans Jonas on the moral requirements of human experimentation. *J Med Ethics* 1993; **9**: 99–103.
- <sup>66</sup> Annas G, Grodin M. Human rights and maternal–fetal HIV transmission prevention trials in Africa. *Am J Public Health* 1998; **88**: 560–63.