Why a research ethics committee for social science?

Reflections on three years of experience at the Royal Tropical Institute, Amsterdam

Prisca Zwanikken & Pauline Oosterhoff

The open-ended nature of anthropological research processes and methods such as participatory observation can be at odds with the demands of ethical review boards, which often require a fully worked-out proposal. However, clearance by an ethical review board is increasingly a requirement for all social scientists. Proponents argue that clearance is a logical necessity for compliance with international human rights standards and increased requests from national authorities. Critics argue that these boards are preventing original research because they require fully worked-out studies, which may lead to duplication in the field or run the risk of rigidly following a pre-defined protocol in the field. This article examines the Royal Tropical Institute's (KIT), Amsterdam, experiences of establishing and using a Research Ethics Committee. A review of KIT's Research Ethics Committee showed that almost half of the 21 studies presented needed to be adjusted based on the committee's review. This study employed participant observation, review of policy documents, interviews and questionnaires.

[ethical review boards, research, methods, social sciences, The Netherlands]

Background

Obtaining the approval of an ethical review board (ERB) is a standard procedure for medical researchers involved in research with human subjects. Increasingly, social scientists are also being asked to submit their work to ethical review boards, especially for work in the health sector. The WHO Operational Guidelines for Ethics Committees that Review Biomedical Research (WHO 2000) for example, includes social science health research under 'social investigations'. And the 2008 update of the International Guidelines for Ethical Review of Epidemiological Research, first published in 1991, covers observational studies (CIOMS 2009). This study looks at both what is behind this increasing demand and the actual experiences of a review board based on the experiences of the Royal Tropical Institute (KIT) in The Netherlands.

The history of the emergence of a consensus on ethical review boards for medical science is well documented. The uncovering of the abuse of medical science by German Nazis as well as the Tuskegee experiment – where African-Americans were deliberately denied effective treatment for syphilis – made it clear that the ethics of medical science needed structural improvement (Brody 1998). Several ethical codes, including the Nuremberg Code, the Declaration of Helsinki and the Belmont Report, responded to concerns about these abuses (World Medical Association 2002). Institutional review boards began to be used in the US and the UK in 1966 after H. Beecher published in the New England Journal of Medicine 22 questionable examples of research, including experiments with heart catheterization with little therapeutic value, and drugs trials without patient's consent. In Canada similar problematic unethical medical testing led to more legal restrictions on clinical research. In the Halushka case, for example, a patient enrolled in a trial was not informed about the medical risks and suffered a heart attack (Glass 2006).The Council for International Organizations of Medical Sciences (CIOMS) started to collaborate with WHO in the late 1970s to study ethics in research and how the Helsinki declaration, first issued in 1964 and amended in 1975, could be applied in low-income countries. In 1982 CIOMS/WHO published 'Proposed International Guidelines for Biomedical Research in Human Subjects', which was revised in 1993 and 2002 (CIOMS/WHO 1982, CIOMS/WHO 1993, CIOMS/WHO 2002). The 'International Guidelines for Ethical Review of Epidemiological Research' was published in 1991, and covered public health research (CIOMS 1991). Although there are differences in the emphasis and level of detail in the key documents, there is now agreement within medical science research that ethical approval is required in order to prevent abuses, especially of the poor and that access to optimum care needs to be assured (Katz 2006; Office for Human Research Protections 2005).

Recently debates about medical research ethics have intensified because of a growing awareness about wider global inequities in health and wealth, and concerns with trials, notable HIV medicines in resource-poor settings (Levine et al. 1991; Molyneux & Geissler 2008). As a response to these concerns the regulations and guidelines of ethical review boards on individual studies have been refined. Local and national institutions, such as ethical review committees and community advisory boards, have also been expanded and strengthened (Emanuel et al. 2004; Weijer et al. 1999).

Rather than just expanding 'universal' individual informed consent procedures, through local ethical review boards that are based on a biomedical western model and philosophy, it is important to acknowledge the power relations and meanings of the historical diversity of practices within countries (Van der Kloot Meijburg 1994). And it is useful to have an understanding of the construction and meaning of consent in different socioeconomic and cultural settings. The focus on individual rights and consent, for example, can be meaningless in cultural contexts where strategic life and health-related choices and decisions are made in a familial and/or community context, or when people feel they are under economic pressure, which could cause them to participate for financial reasons (Oosterhoff 2009; Lindegger et al. 2006; Molyneux et al. 2004). Without such a proper understanding of local contexts, ethics committees may serve mainly to protect the institution rather than operate in the interests of either sub-

ject or researcher. The recent emphasis on detail in the ethical review guidelines and procedures reflect an awareness of the problems of applying what seem to be universal principles of justice and law in different cultural, political and legal contexts, but also increase the bureaucratic requirements of research in these contexts.

One of the strengths of social sciences is to understand these broader socio-economic, cultural, historical and political contexts. The principles and political legality of ethical review, such as avoiding harm, can be shared by many social and medical scientists (Foster 2001; see also e.g. Code of Ethics, American Anthropological Association 1998). Just as happened in the medical field, controversies and abuses in the research practice of social sciences led to increased attention to interpersonal relationships, and concern with justice and the political implications of the research followed by calls for more regulation. For example, the controversy around the US military's Project Camelot and its cancellation in 1965 sparked discussions and led most of the major social science associations to formulate their guidelines (Barnes 1979: 158-168; Solovey 2001). Other well known ethically controversial research includes Humphries' (1970) with his 'tearoom trade', which traced and interviewed without informed consent men having sex with men and according to some exposed their hidden identity, the Stanford Prison experiment by Zimbardo (1973), and the obedience to authority experiment by Milgram (1964). As a response to these ethical issues and abuses social science research institutes in various countries such as Australia and Canada have started to look at procedures that can help improve research quality and develop guidelines for social research (Australian Government 2009; Dunn 2009).

A key area of contention and misunderstanding between social scientists and medical professionals is the difficulties of combining open-ended qualitative methods with the often detailed ethical rules and requirements of ethic review committees that focus on the scientific method of biomedicine (Romm 2001; Hoeyer et al. 2005). Participatory qualitative approaches and methods can generate quantitative as well as qualitative data (Chambers 2007). But the difficulties of replicating social science research, the instability of concepts and definitions and the fact that unlike most medical researchers social scientists often work alone, raised many questions about the reliability and duplicability of their research. A biomedical scientist might find puzzling and alien the fact that a female researcher could redo the work of their male colleagues or visa versa in the same setting and find completely different results (see for example Weiner 1976).

To address the criticism that anthropological methods rely too much on an individual, some anthropologists have started to share data or do joint analyses of the same data. Misunderstandings about qualitative methods among bio-medical researchers could possibly be addressed by having more social scientists become board members themselves to increase the capacity of ERBs to understand social science methods and support the spirit of innovation that should lead all research (Marshall 2003). Many guidelines and committees also require that ERB should be multi-disciplinary to reduce biases and gaps caused by overrepresentation of one discipline. However this is not always the case in practice, raising questions about the capacity of these boards to assess qualitative methods (Theobald & Nhlema-Simwaka 2008).

However ERB's whether for clinical trials or for social science research, run the risk of bureaucratic procedures that reflect other broader political concerns that researchers encounter when dealing with ERBs in various countries. In the US a focus on legal threats may override the 'benefits to society' (*S*hea 2000). And in some communist states such as Laos, China and Vietnam researchers working on any topic in minority ethnic areas, are confronted with compulsory paperwork for ethical clearances by national or provincial ERBs and other authorities. These requirements are often justified in the name of security of the researchers and the populations, but can prevent fieldwork in minority areas on almost any topic, reflecting local power relations (Turner 2010).

Ethical review boards in The Netherlands

Official medical ethical and ethical review boards in The Netherlands were created later than in comparable countries, the number has been growing, and there are many historical differences between these boards reflecting different disciplinary traditions and values (Van der Kloot Meijburg1994). Laws governing medical experiments with animals were approved more than two decades before (1977) the laws on research involving human subjects (1999). In practice, however, many hospitals have had ethical committees since the 1970s and 1980s, for example the ethical committee at the VU Medical Centre (at Vrije Universiteit, Amsterdam) started in 1970 (Vrije Universiteit Amsterdam 2010).

The creation of hospital medical ethical committees grew when the Ministry of Health, Welfare and Sports began licensing hospitals in 1984 (Bergkamp, cited in Berden 1993). A law covering medical experiments was first drafted in 1987 (Berden 1993). In 1997 a medical research project that involved mentally challenged people raised concerns among ethics and health practitioners, and this may have contributed to the finalization in 1998 of the law on medical-scientific research (WMO) with human subjects, which protects ill and healthy subjects of medical-scientific research. Based on this law, the Central Committee on Human-Related Research was created in 1999 and oversees medical ethical committees in The Netherlands.

Although there is diversity in terminology and practice, 'medical-scientific research' in Dutch law seems to be defined more from a biomedical than a social science point of view. Interpreted broadly, it could include all research involving humans, including behavioral science research, leaving these laws rather abstract. Following this law on medical-scientific research with human subjects the Faculty of Psychology at the University of Maastricht also used a broad definition when it installed an Ethical Committee for Psychology that would have to approve research that could violate the integrity of people in any way (Ethische Commissie Psychologie 2009). Another example of social science ethical review is the creation in 2007 of a Commission for Behavioral Research at the Faculty of Social Sciences in Nijmegen to review research (Witteman 2010). The Faculty of Law at the Free University Amsterdam recently formed an Ethical Committee too. All these review mechanisms

are recent, even though guidelines for the ethical conduct of research have existed for much longer, such as the 2003 'Ethical Code for the use of Personal Data' by the Social Sciences Council.

The Medical Ethical Committee of the Leiden University Medical Centre considers research by students as part of research by staff and therefore that research is reviewed. Most of the other Dutch committees however consider only research conducted by staff, not by students. For students working on health issues this can pose a problem if they would like to publish their work in a health-related academic journal, as these journals often require ERB clearance. Dutch researchers working on medical and health issues in developing countries face the additional challenge that medical ethics committees (MECs) in The Netherlands frequently refuse to review research carried out in developing countries because they do not see this as part of the role of Dutch MECs. This leaves organizations that conduct social science research (either through staff or students) in low- and middle-income countries vulnerable to criticism from both the Dutch and the national authorities.

Methods

This article examines some of these issues based on the experiences of the Royal Tropical Institute's Research Ethics Committee for students and staff during 2007-2010. The study used participant observation, review of policy documents, interviews and questionnaires.

– Review of policy documents: Helsinki Declaration on Human Rights, as well as National Guidelines on Research Ethics, WHO guidelines, and both guidelines and experience from the Liverpool School of Tropical Medicine.
– Participatory observation took place at meetings with key stakeholders.
– Review of the correspondence between key stakeholders, notably the director of KIT, the director of KIT Development Policy and Practice, and the area leaders in health and education (director of the Master's programmes).
– Survey of all students and staff who have used the REC through a semi-structured questionnaire asking the following: Did the review help to improve the quality of the study? Did the review process cause undue delay? Did the review help to safeguard the subjects' human rights? Did they feel restricted by changes they had to make to fieldwork? Did they lack feedback while in the field?

They were also asked whether they discovered any duplication in the field (same topic or same participants) and whether the research question still seemed relevant once they were in the field. Seven out of the 16 students and five out of the six staff who had submitted proposals to the REC responded to the questionnaire.

Limitations of the study

For the data collection of this study we combined roles of a health management professional and a medical anthropological researcher, based on the lead author's experiences combining health education management and participation in the development of an ethical review committee. Combining roles of management with research has distinct advantages and disadvantages (Oosterhoff 2009). One of the limitations of the study is that following the requirements of the ethical committee the proceedings of the committee are confidential and not part of the public domain. Although one of the authors has been participating in the meetings of the ethical committee, which has contributed to her understanding, the proceedings she observed during these meetings cannot be described in this article. Secondly to protect the confidentiality of those who submitted their research for review and who answered the questionnaire details that would possibly reveal their identity cannot be published.

Thirdly, as the authors are linked to the ethical review board at the KIT, in particularly for the former students, there are power relations that may have influenced the responses. And fourthly, related to that is the problem of representativeness; only 12 of the 22 researchers answered the questionnaire.

Although, we are as, described above not able to share names and other details of who responded and who did not, we are able to share that responses included both people whose work had been rejected and whose work had been accepted.

Results

Process of development of the ERB

A number of reasons let to the development of the ERB. First, the Royal Tropical Institute (KIT) as a knowledge, research and training institute is committed to ethical research and wants to ensure that research conducted under its name adheres to international ethical standards. Second, from a more practical perspective, existing medical ethics committees frequently refuse to review research carried out in developing countries because they do not see this as part of the role of the MECs in The Netherlands. KIT already had established an agreement with the MEC of the Academic Medical Centre (AMC), who would review any research involving medical actions on human subjects.

However the AMC did not review any research that did not involve medical activities on human subjects or which was outside the AMC. Third, international research journals increasingly require that studies have been reviewed by an ERB. Fourthly, various international guidelines require the review of all research involving human participants, not just clinical research. Fifthly, KIT staff saw that an ethical review board could provide staff and students with another perspective, more feedback and additional quality control. Sixth, clearance at an institutional level would be practical as it helps students and staff to obtain clearance by national authorities. This is related to the fact that clearance by the host institute, such as the KIT, is increasingly required

by local review committees before these local ERB proceed with their appraisals. And lastly, most of the institutions in the tropEd network that teach a Master's program in International Health already have an ERB which, among other things, reviews research proposals by their Master's students. KIT staff was sensitive to questions about the lack of such a board at the Institute to review social science research by and on behalf of KIT in low- and middle-income countries.

It was decided in 2007 that all research that did not involve medical activities on human subjects or which was outside the AMC MEC's remit should be reviewed by a KIT ERB, including social sciences research by staff and students working in low- and middle-income countries. It was not a formal agreement, but KIT decided it needed such a board and AMC felt it was part of KIT's role and responsibility and not theirs. In 2007 the ethical review board was created, called the Research Ethics Committee (REC), which was formally inaugurated in 2009. The board is composed of social scientists, epidemiologists, public health specialists; and lay members and an ethicist from outside KIT. Initially the forms and procedures that were developed, used examples from both WHO and other European institutes that have ERBs. The framework of rules, the criteria, the development of forms, guidelines and the formation of the REC are based on the 1) Council for International Organizations of Medical Sciences: international guidelines for biomedical research involving human participants (CIOMS, 2002), 2) the guidelines on reproductive health research of the WHO Special Programme of Research Development and Research training, (WHO, 4th edition, 2003), and 3) the general WHO Research Ethics Committee, Rules of procedure (WHO, 2005). All members of the REC as well as interested staff at KIT were trained by a renowned ethicist to assess proposals on their ethical merits for one day in two different sessions. Expertise to the board was delivered by one of the KIT staff who is a member of the *Ethical* Review Committee of the *human reproduction* program of WHO and by a public health ethicist from the University of Utrecht who is also a standing member of the REC.

Tasks and functions of the REC at KIT

The review of a research proposal consists of a technical and ethical assessment which looks at nine criteria of the research, which are operationalized as follows:
1 The need for the study is checked by the description in the problem statement and the rationale; the description of the context and by a literature review that uses primary and secondary sources. Local relevance is also judged by the clearance of the local ethical committee, which in some countries is also required after the international clearance by the institute that leads the research.
2 The research design and instruments to be used: such as the recruitment and the number of subjects, the criteria for subject selection, exclusion and study discontinuation: the design depends on the type of research and on its scientific merits against the paradigm and the rules of that design. Sampling and instruments need to lead to the desired results as formulated in the objectives and be an efficient use of time and/or money for both researchers or respondents.

3 Qualifications of the researchers: this depends on the type of research: i.e. for qualitative research the experience in using and writing articles on qualitative research is judged through the curriculum vitae submitted, which should demonstrate appropriate research experience depending on the types of research.

4 Adequacy of research facilities on site: mostly what is reviewed is the budget, computers and time. Whether the research facilities have enough human resources is also checked by the cv and the number of staff.

5 Risks and anticipated benefits to participants and/or their community: this is judged as discussed in CIOMS guidelines. It is a balance between the objective in comparison to the risk the patients/ respondents are exposed to. For example if women are asked about their sexual experience; they might feel distressed because of a rape exposure. Interviews can have positive psychological effects for some, releasing feelings, but for others a need for referral and counselling may arise. Public selection of participants for focus groups in a public space may inadvertently reveal characteristics of these individuals which they consider private.

6 Full and timely disclosure of relevant information to subjects: the proposal needs to state that the results will be shared with subjects and relevant stakeholders, in an appropriate way. If the intervention in a case-control study clearly works better, the research needs to be stopped and information needs to be provided to the public and other stakeholders in appropriate language.

7 Clarity of the consent documentation and process. Consent forms are asked to be described in a neutral way, in easy and understandable language, explaining possible side effects, discomfort, complications and/or benefits; stating how confidentiality will be maintained; clarification to the participants that he/she is free to decline to participate or to withdraw at any time without suffering any disadvantage or prejudice; stating name and contact details where complaints can be directed to; and providing contact details for counseling or other referral where appropriate. In case of 'mystery clients', i.e. researchers who pose as clients, not revealing their identity as researchers, to collect data, one of the questions is the extent to which a researcher has the right to do this without the service provider being informed. Such methods can be advantageous to collect data on differential treatment of various clients by health staff, for example different treatment of sex workers and government workers at reproductive health services. However, the results of such data collection methods may not be acceptable to the health staff, who needs to be involved in the improvement of the quality of these services. Currently the guideline is to inform the service providers that during some period of time 'mystery clients' may visit. Such tensions between the means, the process and the end, the objective and aims of the study are contentious areas of inquiry.

8 Undue inducements and barriers to voluntary subject participation: is reviewed by looking at the recruitment procedures and the consent form. The recruitment needs to be carefully described by who and how it is done. The criteria to judge the consent form are the appropriate language, should not be too long, contain enough information and how the study is done. The signing of the consent form is by the person itself, if the person is not possible or able to do so, than a witness. If it is

clearly argued why a signature is not appropriate or not possible, verbal consent can be accepted. KIT followed the WHO guidelines that stipulate that a consenting adult can be a woman alone, and there is no need for consent of the partner, unless there is a clear and direct effect on the partner (i.e. male pill and side effects which have bearings for the female partner). Undue inducement is reviewed by looking at the reimbursements which should not be higher than time and transport costs.

9 Adequate protection of the confidentiality of data: The risks and benefits to their privacy need to be clear to participants, as described in the consent form (Research Ethics Committee 2007).

As this was a new institution, for the committee and the staff the finalization of these criteria, their operationalisation and the functioning of the committee were interactive, reflexive and mutual learning processes. Since its inception the KIT REC met nine times (thrice in 2008; four times in 2009, and twice in 2010). The forms with which proposals are submitted were adapted four times. The first change was related to the questions on the forms as people did not find them clear, the second was that the form required the signature of the advisor in case the study is performed by a student, after a study was submitted and rejected for review without the supervisor having seen it.

A third change involved a shift from anonymous to open review. The review process was anonymous at first in order not to bias the members of the committee as they may know some of the students or staff personally. However this anonymity did not work well in practice. Through the CVs it was clear sometimes to the members of the committee who a certain person was and this made it de facto an open review process. The fourth addition was that the REC added a request for a signature of a local supervisor. The REC itself felt that it had sometimes limited insight into the specifics of specific local situations, and therefore might not be able to understand the situation sufficiently and function in the interests of either subject or researcher. It was therefore recently decided that when a student submitted a project for review, they would also need to find an additional local supervisor of the fieldwork, and the curriculum vitae of this supervisor needs to be part of the submission to the REC. A fifth change was made to address the question of addressing unexpected events with ethical implications that occur in the field during the study. As the REC is based in The Netherlands there are practical issues related to possible delays in communication from the field and technical issues such as the above mentioned limited insight of the REC in local situations. One logical solution seemed to be to identify a local ethics committee or local ethics review board that would be in charge of taking action if so required in case of ethical problems or complaints regarding the implementation of a research. To avoid conflicting decisions by two boards, the REC required that it would be notified if there are any complaints and/or problems. It was also decided that while it should be clear on the consent form that the local institution or local supervisor must be available for participants to turn to in case of problems, the committee should also be informed. Of course this raises questions about the sharing of responsibilities, and other practical issues such as language and other communication barriers between a local board and the REC at the KIT. The sixth adaptation was the request to clarify

how to acknowledge and incorporate concerns about social and cultural sensitivities and local power structures. Originally one of the criteria was that justice and equity were to be adhered to. However, after discussion, justice and equity proved to be difficult to operationalise, reflecting the difficulties of translating universal human rights into specific and highly diversified local conditions. The reformulation improved recognition of local diversity but the contradicting need of having clear guidelines and acknowledging local diversity remains difficult and clearly cannot be resolved with more rules and regulations. The ERB works in the spirit of the law, rather than the letter of the law, as the interpretations of human rights can differ under the circumstances, making a universally applicable text rather unpractical. In practice, REC members looked at human rights related aspects of the research: beneficence, non-malevolence, freedom to say no, right to full information, confidentiality as best as they could based on their experience as individual experts and as a multidisciplinary group, with specific and additional questioning by the expert in medical ethics.

Review of research proposals

The board reviewed 22 studies, six from staff members and 16 from students. Of these only three were approved immediately, eleven were approved after amendments, two were withdrawn, one was rejected, three were exempted, one was deferred to the Medical Ethical Committee of the AMC, and one is still in process.

The research sites were in Asia, Africa and South America, including Sierra Leone, Senegal, Namibia, Zambia, Tanzania, Brazil, Thailand and two multi-country studies. Most of the studies (20/22) were exploratory descriptive studies (some using a case study approach) and two cross-sectional surveys. Study methods included focus group discussions, semi-structured and in-depth interviews, observations (structured and non-structured), reviews of patient records, Venn diagrams, time lines, and mapping. One study was rejected because the principal investigator would not be on site when the study was to be conducted. One study was withdrawn due to time constraints, and the other due to the unstable political situation in the country.

Review of process by students and staff

Seven of the twelve respondents of whom five students) reported that the process of the ERB did improve the study. Nobody proposed to abolish an ethical review board, questioned the relevance of an ethical clearance, or the importance of human rights and public health research. Respondents focused on practical aspects as positive aspects of the ERB process. It helped them to think through and reflect on more aspects of the study, both on practical and theoretical aspects, and on linking personal interests and individual studies with local needs.

Students and staff reported:

The ethical review made me reflect on the inclusion criteria and the steps that are required to have permission and informed consent for the interviews that I conducted. It was a

good necessary exercise to follow the steps of the committee to make the research ethically coherent and not undermining local priorities (student, study exempted, with one month delay).

It helped me in thinking about ethical aspects which I didn't take into consideration yet (student, accepted with 6 months delay).

It helped me in improving the selection and recruitment procedures (staff, accepted with no delay).

However not all agreed that the ERB helped them reflect and improve their understanding of theoretical concepts of plan their research better even though their work was accepted.

The course coordinator) made me submit my proposal to the REC. This took me a lot of time, and also of my external supervisor. The work has not added to the proposal, but has added a lot of frustration at a very inconvenient time for both of us (student, study exempted, one month delay).

People whose proposals were rejected were not necessarily negative about the review board. In order to be able to supervise the research in practice, including looking at how ethical issues are dealt with REC requires that the principal researcher ie the student or the staff responsible is in country when the study is carried out.

I was sad to know that my proposal was rejected. However now I believe it's was the right decision from the REC to not approve the research in absence of the principal investigator which could have harmed the research participants (student, proposal rejected because student unable to be in-country during study).

Delays

As a result of the committee's clear set of procedures (including an option for expedited review), all proposals were reviewed within two months, in line with the regulations. The average time between first submission and final approval was two months, with a range of 0.5 month to 6 months. The meetings of the REC were planned as such that there was enough time for a student to submit, and if needed resubmit before going on field work in case for those students who are taking the master's fulltime (ie meeting in April, field work in June). Amendments could be reviewed by the two reviewers by e-mail for approval and reported back during the next REC meeting.

The question whether the ERB caused a delay resulted in a mixed response among staff and students, Six (two of whom students) reported it did not cause any delay; four remarked that they were well aware of the dates; one of the students remarked that it added pressure to the time, but it helped her to complete the thesis on time.

Of the five (four of whom students) who reported a delay one was due to a mistake in procedures at the REC: informally the secretary had written that the proposal was approved, but the official letter was forgotten and only sent months later. One student was not clear on having to fill out the form, one because the time path was unclear to her, i.e. the duration it would take after the meeting or after requests for changes and took longer than she expected and one had a delay because it was a multi country study which also required local approvals in these countries which took longer than was anticipated. One student did not answer the question.

Flexibility and relevance

The ERB tried to help researchers think through the whole process in the field to make the study more relevant and hopefully avoid having to make drastic changes in the field. In a proposal on nutrition questions about local relevance and gender equity by the ERB did help the study according to the researcher: "I took into account the specific requirement of the REC in the elaboration of my proposal and it allowed me to refine it".. The study was initially deferred mostly because it was seen to reinforce gender inequities but was accepted after revision. The focus of the proposal was only on mothers, who already participated in the nutrition projects, while the literature suggests that men and communities play a role in women's norms and decisions and should thus be included as respondents. The respondent remarked she hadn't realized that her bias was towards the mothers, and she included the fathers and other family members in her study. For her having to write the proposal for the REC helped her to refine and improve the proposal.

Most respondents (seven of the twelve, four of whom staff) reported to feel free enough to make changes, two found that changes were not needed and one reported that it was not clear how, whom and when to ask for changes and one did not respond.

Respondents all thought their studies were locally relevant, not just a response or an interaction with international debates. They perceived their study to be locally relevant, as it originated from the work they had been doing locally (2), one because it was based on an assignment of a local organisation. Two others responded that the proposal was developed together with local people, or because they consulted extensively through e-mail with different levels of actors locally beforehand and during the process of development.

Conclusion

The development of the KIT ethical review process took place in a wider global as well as national Dutch context of intensified debates about the medical ethics of trials in developing countries, and the increased emphasis on regulations and guidelines of ethical review boards and support for the strengthening of ethical review committees in resource-poor settings.

KIT, an institute based in Northern Europe that works exclusively in low- and middle-income countries, was particularly sensitive about the context of the broader socio-economic inequalities in which research was being conducted in these countries. Faced with a gap in The Netherlands to review social science research outside The Netherlands, KIT responded by forming its own review board, the Research Ethics Committee. The review board has an extensive list of areas that it reviews, both technically and ethically.

Almost half of the 22 studies reviewed since the committee was formed needed to be adjusted based on the review, and although the committee did take initial decisions within the two months specified in its terms of reference, proposals that needed to be revised took on average two months but up to six months. Staff experienced overall slightly less delay than students, which might be because they had more experience with an ERB, or they could easily ask an experienced colleague to check before the work was sent in.

It could and has been argued that it is a universal right of people in the South that a study is reviewed by an ERB in the North and that therefore these rules and guidelines for review should be the same. However the review confirmed some of the practical and theoretical bottlenecks observed by others on the operationalization of universal guidelines. An institute in the North cannot reasonably be expected to know the local conditions all over the world. But this would be needed to be able to address specific socio-cultural and political conditions.

Transferring the responsibility to the South, after an initial review in the North, may seem logical and practical for both sides. This review of the KIT's review board however made it clear that this can be a bureaucratic and fairly complicated process. The study showed that many of the respondents found the review process useful and that there was respect for the principles of an ethical review. A number of researchers found that it helped them to link theory to practice. The findings reconfirmed the need for a REC – reviewing the literature and the experiences – but also reconfirmed the tension between universal rights and guidelines and specific local conditions, between the need to be firm and clear yet flexible. We did not interview REC's in the South but it would be rather useful for this discussion to learn how they view the clearance from the North. The review also helped to clarify the need for KIT to balance between the need to be as clear as possible about procedures and working in the spirit of ethical and human rights laws and principles. It would be useful to make such a distinction of the spirit and the practice of laws and regulations of ERB clear to future and current public health practitioners.

Whether the ERB improves the local relevance of the research is not very clear, mostly because feedback mechanisms to the people who participated, whether as respondents or as stakeholders are not specified. Transferring the responsibility to the South may increase local relevance. However the tension between adherence to guidelines and the necessary flexibility and adaptation of research may not be solved. There is no reason to assume that ERBs in the South are more sensitive to the requirements of qualitative anthropological research methods when they are encouraged to

adopt procedures from resource-rich settings that are weak in reviewing open ended qualitative research methods.

It remains for the ERB to find an appropriate balance between carrying out very strict and rigorous ethical reviews based on agreed protocols while at the same time ensuring that social science research remains relevant and of a high standard by allowing sufficient freedom for researchers to adapt and continuously evolve their research based on preliminary findings.

Note

Prisca Zwanikken, is area leader for education at the Royal Tropical Institute (KIT) in Amsterdam and specialist in public health, human resource development and training. She has extensive experience in developing and organizing degree and short courses in public health, including quality assurance and curriculum development. She is the program director of the both the Master's in Public Health (ICHD) as well as the Master's in International Health at KIT and is involved in capacity building and training programs in a number of countries. She is a member of the Research Ethics Committee of KIT. E-mail: P.Zwanikken@kit.nl.

Pauline Oosterhoff is Senior Health Advisor and trainer at the Royal Tropical Institute (KIT) in Amsterdam. She has over 15 years of international experience in public health, media production and research. She has master's degrees in political science and international public health and a PhD in medical anthropology. She has worked extensively on sexual and reproductive health and HIV/AIDS, human rights, micro-credit, indigenous and minority peoples' access to health, and harm reduction. Her regional focus is Asia. E-mail: pauline_oosterhoff@yahoo.com.

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