INTERNATIONAL ETHICS

Research ethics review in government and academic institutions in Thailand

SOMBOON KIETINUN

Faculty of medicine, Thammasat University, Rangsit, Pathumtani 12120 THAILAND email: sbk@tu.ac.th

Abstract

This questionnaire-based study was conducted to collect information on the ethics review practices of research institutions in Thailand. One hundred and sixty-five out of 295 responses were received from institutions under the ministry of public health and 79 were received from 146 sent to academic institutions. Of these responses 114 and 64, respectively, reported conducting research involving human subjects. Thirty-four institutions in each group had ethics review committees. Key findings are summarised and suggest that many institutions are unable to follow practices such as ensuring independence of the ethics committee, including ethicists and community members, and monitoring research practice including the response to serious adverse events. The majority of respondents felt the need for a national research ethics review body for research involving human subjects.

The first ethics review committee (ERC) attached to an academic institution in Thailand was constituted in 1992. Since 1993, the ministry of public health promoted the setting up of ERCs within its institutions. The Forum for Ethical Review Committees in Thailand (FERCIT) was constituted in 2002, the same year that Thailand introduced national guidelines for biomedical research involving human subjects.

The objective of this research was to collect information on the ethics review practices of research institutions in Thailand. Structured questionnaires asking for general information, practices and opinions were sent to institutions attached to the ministry of public health (MOPH) and academic institutions believed to be conducting research involving human subjects.

Two hundred and ninety-five questionnaires were sent to institutions attached to the ministry of public health. One hundred and sixty five institutions replied, of which 114 reported conducting research studies. Institutions reporting conducting research included regional and provincial health centres and speciality hospitals. Only 34 of the 114 institutions reported having ethics review committees. Twenty-six reported using outside review committees and 49 stated that they did not conduct ethics review of their research. Five institutions did not respond to this question.

One hundred and forty six questionnaires were sent to academic institutions which could be expected to be conducting research involving human subjects. Seventy-nine replied, and 64 of these reported conducting research involving human subjects. Only 34 of the 64 institutions reported having ethics review committees. Nine stated that they used external ERCs and 17 stated that they did not conduct ethics review of their research. Four did not respond to this question.

All but one of the 34 MOPH committees had at least one medical doctor. Most also had representatives of other health care professions such as nurses, pharmacists and dentists. Ten committees had representatives from the community. More than half the institutions had committee members trained in medical ethics. Membership of ERCs in academic institutions was dominated by each institution's speciality – medicine, nursing, dentistry, pharmacy, and so on. A number of committee members had been trained in biomedical research ethics.

Ethics review committees should be independent in order to ensure the welfare of research subjects. In this study, it was found that many ERC members in both groups were appointed by the chief administrators of the institutions rather than by a higher authority.

The number of ERC members varied from three to 22. Most committees had around 12 members and invited specialists in particular fields when they needed to.

While the ERCs included sufficient numbers of scientific members, there was a shortage of community representatives and ethicists on the ERCs, though guidelines recommend that there be at least one member from the community on the ERC. Ten and nine ERCs in the MOPH and academic institutions respectively had members from the community. Barely half of the committees had received any training on how to conduct ethics review of proposals.

Few ERCs had regularly scheduled meetings and most of them met whenever there were proposals to review. The majority (20 and 25 in the MOPH and academic institutions respectively) did both ethics and scientific review.

In most guidelines, members of ERCs who have submitted proposals for ethics review are expected to leave the room when their proposals are being discussed or decided upon. However, this guideline was not followed by many ERCs (11 and six in the MOPH and academic institutions respectively). Given the hierarchical quality of institutions in many developing countries, this practice deserves to be reviewed.

Further, there is a need to ensure that proposals are discussed properly before a decision is taken. Fourteen and 21 ERCs of the MOPH and academic institutions respectively reported that

decisions were made by majority vote. Thirteen and nine in the MOPH and academic institutions respectively discussed the proposal till everybody was satisfied.

In 27 and 19 ERCs in the MOPH and academic institutions respectively, members were paid. It is suggested that institutions should pay reviewers, either from their annual budget or by charging the funders or researchers.

Twenty MOPH and 17 academic institutions had separate provision for supervision of research once it was approved. In other cases this was left up to the ERC, which had neither the resources to act, nor established procedures in place.

According to standard guidelines, if a serious adverse event (SAE) occurs during research, researchers are expected to report it immediately. Twenty-three MOPH and 22 academic institutions did not have an SAE reporting system. There is a need for clear guidelines for response to SAEs, as well as the infrastructure to follow up once a decision is made.

The majority of ERCs agreed that there is a need for a national body specifically responsible for ethics of research involving human subjects. At present in Thailand, there are a number of different bodies which play some role in research ethics review: university committees, hospital committees, the government ministry of health's own committee, committees of traditional Thai medicine and alternative medicine, and the department of food and drugs. Most of these committees work independently and there is no central organisation monitoring all research involving human subjects. The Thai Medical Council recently revised its regulations so that medical doctors who want to do research involving human subjects must have their protocols approved by an ethics review committee. The Nursing Council has also started to discuss research ethics involving human subjects. Therefore, it is important to have a central body to manage all research ethics involving human subjects.

The majority of respondents to this study felt the need for a national research council that includes representatives from all professional councils, medical doctors, nurses, pharmacists, traditional medical practitioners and so on. The running cost for this national body could from the government and from fees charged from the researchers or donor agencies.

Conclusion

The insights from this study should be used to conduct further research which could improve practice. The number of ERCs increased sharply in 2003-2004, and a study is needed to evaluate the quality of ERCs. There is also a need to train ethics review committees and researchers. Not all research proposals are reviewed, so there is a need to ensure that all research involving human subjects has been approved by ethical review committees. There is a need for ERCs to follow standard operating practice in terms of the composition of the committees, frequency, promptness and transparency of review. Institutions will also have to establish procedures to supervise research once it is approved by the ERC. A SAE reporting system is vital for clinical research, and must be established. Payment for reviewers may also be a significant matter for quality ethics review. There should be a national body to coordinate, cooperate and supervise research ethics involving human subjects. The national body should be either the National Research Institution or a professional organisation derived from all disciplines.

References

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This study was conducted with the approval of the ethics review committee of the faculty of medicine, Thammasat University.