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Commentary IV Good epidemiological practice: ethical review is essential

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The Swiss society for public health publishes very useful guidelines for good epidemiological practice, prepared for "the betterment of epidemiology in Switzerland". Unfortunately a crucial point is omitted in the text: research protocols should undergo ethical reviews. This is however a general and universal obligation to investigators and institutions, for any research on human subjects (Levine 1996). The international guidelines, such as the Helsinki declaration (World Medical Association 2000), the guidelines from CIOMS (1991; 2002) and from WHO (2000) are very clear, as are the Swiss guidelines for medical research (SAMW 1997). The same principles strictly apply to research carried out in developing countries (CIOMS 1991; WHO 2000; Nuffield Council on Bioethics 2002).

Our experience during the past 12 years at the research ethics committee for epidemiology and public health is that some investigators still don't respect this rule. Some examples are national studies on health and behaviours, or some projects by students. Other projects have been submitted after completion of the study, because ethical review was requested by the editors. This of course was not acceptable to the committee. Even projects by health authorities are not systematically reviewed. In one occasion, we were told that a project was ethical, since it was requested by the government....

Ethical reviews often contribute favourably to the quality of projects. Firstly, submitting a project obliges investigators to

write a formal protocol. Surprisingly, a number of projects are carried out without this fundamental element. Secondly, in most cases corrections are requested and recommendations are made. The main issues are about information of participants, confidentiality of data and formulation of questions in questionnaires. Quite frequently the ethical review helps the investigators overcome ethical and legal obstacles to the study. For instance, a study on child sexual abuse prevalence, research in genetic epidemiology or projects involving participation through the Internet could hardly be carried out without the approval of the committee.

Compared with clinical research, epidemiology is often considered to involve relatively minor risks. However, when small risks are applied to many persons, the damage can be very significant. The study of healthy people also raises specific ethical issues.

In general, epidemiologists have good, even excellent intentions. However, the issues at stakes in medical research are very complex and sometimes unidentified by the researchers. Any research project can involve significant risks and can raise complex ethical and legal questions. It is crucial that all projects in epidemiology and public health are reviewed by ethics committee in order to safeguard the rights and welfare of research subjects and to improve the quality of research.

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References

Council for International Organizations of Medical Sciences (CIOMS) (1991). International guidelines for ethical review of epidemiological studies. Geneva: CIOMS. http://www.cioms.ch.

Council for International Organizations of Medical Sciences (CIOMS) (2002). International ethical guidelines for biomedical research involving human subjects. Geneva: CIOMS, WHO. http://www.cioms.ch.

Levine RJ (1996). The institutional review board. In: Coughlin SS, Beauchamp TL, eds. Ethics and epidemiology. New Xork: Oxford University Press.

Nuffield Council on Bioethics (2002). The ethics of research related to healthcare in developing countries. London: Nuffield Council on Bioethics. http://www.nuffieldbioethics.org.

Schweizerische Akademie der medizinischen Wissenschaften (SAMW) (1997). Directives pour la recherche expérimentale sur l'être humain. Basel: SAMW. http://www.samw.ch/content/Richtlinien/f_Forschungsunters.pdf.

World Health Organization (2000). Operational guidelines for ethics committees that review biomedical research. Geneva: WHO. www.who.int/tdr/publications/publications/

World Medical Association (2000). Declaration of Helsinki – ethical principles for medical research involving human subjects. Edinburgh: WMA. http://www.wma.net/e/policy/b3.htm.

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