As a researcher, what should you do if you discover something that may have an effect on the research participants' health?

Research ethics – a perennial topic of discussion

In 2008, the principles of medical research ethics were collected and presented in the Health Research Act, on the basis of the principle of one act, one mailbox (1). The act has largely functioned according to its intentions, and the authorities have not expressed any desire for a general revision. This notwithstanding, medical research ethics is constantly facing new and unforeseen challenges, in practice as well as in principle.

We have seven regional committees of medical and health research ethics (REK). These committees constitute independent government administration units. Efforts are made to ensure the goal of equal treatment across all committees by having, for example, a joint application portal, various shared arenas for discussion of principles of research ethics and by having appeals decided by The National Committee of Medical and Health Research Ethics (NEM), of which the undersigned is chair.

The Health Research Act divided Norwegian research into two categories. Projects that are intended to «generate new knowledge about health and disease» pursuant to Section 1 shall be subject to prior ethical review by a regional committee of research ethics, and approval by the committee is required for implementation of the project. All other research projects can be implemented without any such prior approval, and the distinction between projects that are encompassed by or fall outside the scope of the Health Research Act has been subject to widespread debate.

The health services are legally bound to undertake quality assurance. Such work thus falls outside the scope of the Health Research Act and shall not be subject to approval by a regional ethics committee, even when research methods are used for purposes of quality assurance. Differing practice between committees, however, has required harmonisation. Shared guidelines were therefore prepared; these have previously been presented in the Journal of the Norwegian Medical Association (2).

Research that involves a risk of health injury represents another problem of where to draw the boundary. If such trials are not intended to «generate new knowledge about health and disease» they currently fall outside the scope of the act and thereby also outside the mandate of the regional ethics committees (3). Examples of this are a number of physiological projects, including in sports. The National Committee for Medical and Health Research Ethics has taken the initiative for a legal amendment that will require prior approval of all research projects that involve a risk of health injury.

After the Second World War, the interest in research ethics in general and medical research ethics in particular has concentrated on protection of research participants. This is and should remain the fundamental element in the Helsinki Declaration as well as the Health Research Act. In November 2014, the EU adopted what has come to be called the Rome Declaration on Responsible Research and Innovation (RRI), which defines responsible research and innovation as «the ongoing process of aligning research and innovation to the values, needs and expectations of society» (4). The social responsibility of research has not yet found an expression in key documents pertaining to medical research ethics. This represents a challenge, nationally as well as internationally.

Even though no revision of the Health Research Act has been planned, efforts are continuously undertaken to improve the processing of applications by the committee system. In this issue of the Journal of the Norwegian Medical Association, Roger Bjugn presents a project in which he has investigated a specific, but important question pertaining to requirements for research protocols (5). He has reviewed applications to and rulings by the regional ethics committee regarding projects at Oslo University Hospital in 2011 to see how often the management of research findings with implications for the research participants is described in explicit terms. This could include unintended findings, such as an aneurysm detected by diagnostic imaging of the brain, as well as «intended» findings of clinically relevant hypertonia in population studies. Bjugn points out that researchers who undertake such studies are obligated to have a plan for managing what are often referred to as «findings with a possible clinical relevance». Here, Bjugn refers to the so-called Oviedo Convention (6), in which the requirement for managing relevant research findings arises from the duty of care defined by the convention.

Information on management of findings with possible clinical implications was found in 21 out of 57 projects in which the researcher interacted directly with humans, of which six of fifteen projects included genetic tests. The author is cautious in drawing conclusions and notes that this question may have been considered without having been reported in the documentation. He nevertheless proposes to include a separate item in the questionnaire, which will be a simple measure to undertake. Bjugn's findings primarily pertain to the four committees in the south-eastern region. Familiarity with the committee system indicates, however, that practices may vary from one committee to another. Practices may also have changed since 2011 in light of the increasing focus on unintended findings, especially with regard to genetic tests.

The findings in Bjugn's project are so clear, however, that they ought to be followed up, and this topic will be discussed in joint meetings of the regional ethics committees and the national committee. An amendment to the application form is a simple measure that nevertheless may contribute to further formalisation. On the other hand, formalisation of approval procedures may also be conducive to abrogation of responsibility, with researchers believing that their ethical responsibility is limited to writing a correct application to the regional ethics committee. Perhaps we may achieve the same goal by taking the article's findings seriously and focusing greater attention on the management of clinically relevant research findings.

Dag Bruusgaard
dag.bruusgaard@medisin.uio.no

>>>

Dag Bruusgaard (born 1940), MD, PhD, former part-time general practitioner, Professor Emeritus at the Department of General Practice, University of Oslo, and chair of The National Committee for Medical and Health Research Ethics.
The author has completed the ICMJE form and declares no conflicts of interest.

References

1. LOV-2008-06-20-44. Lov om medisinsk og helsefaglig forskning. https://lovdata.no/dokument/NL/lov/2008–06–20–44 (11.4.2015).
2. Lekven J, Gisvold SE, Hardang J. Hvilke prosjekter skal legges frem for regional etisk komité? Tidsskr Nor Legeforen 2012; 132: 2366–7.
3. Bruusgaard D. Hva skal fremlegges for regional etisk komité? Tidsskr Nor Legeforen 2012; 132: 2366–7.
4. Europakommisjonen. Responsible research and innovation. http://ec.europa.eu/research/science-society/document_library/pdf_06/responsible-research-and-innovation-leaflet_en.pdf (11.4.2015).
5. Bjugn R. Forskningsfunn med kliniske implikasjoner. Tidsskr Nor Legeforen 2015; 135: 755–8.
6. Additional protocol to the Convention on human rights and biomedicine concerning biomedical research. Strasbourg: Council of Europe, 2005. http://conventions.coe.int/Treaty/en/Treaties/Html/195.htm (11.4.2015).