**Geir Wenberg Jacobsen** (born 1945), editor of the Journal of the Norwegian Medical Association and professor of public health at the Department of Public Health and General Practice, Norwegian University of Science and Technology. He served as deputy chair/acting chair of the Central Norway Regional Committee of Medical and Health Research Ethics in 1995–2001.

*Photo: Journal of the Norwegian Medical Association*

Despite the fact that the Health Research Act of 2008 appears to function quite well, some researchers still complain about complicated and lengthy procedures. Have the lawyers been given too much say?

# Did the Health Research Act turn out as intended?

The introduction of the Health Research Act (1) in 2009 severed a number of Gordian knots. One example: ten years earlier, I took over the responsibility for a prospective multi-centre study (2). At the time, it was a challenge to obtain approval from the Norwegian Data Protection Authority for the storage of personally identifiable data. The licence granted in 1986 specified that the data had to be deleted once the project had ended. All correspondence in the years until 2009 called for a completion date and deletion. The entry into force of the Health Research Act brought relief by reallocating the responsibility for further storage to the regional committees of medical and health research (REK). In the hearing round regarding the recommendations of the Nylenna Commission (3), the Norwegian Data Protection Authority noted that health information should not be stored any longer than necessary (4). The draft of the Act proposed deletion no later than 30 days after the notification of completion had been sent to the regional ethics committee, unless the information had been de-identified or anonymised (5). The Act authorises the regional ethics committee to approve storage for a period of up to five years, provided that this is deemed necessary (1, 6).

The Health Research Act was intended to improve the quality of medical and health research and simplify the formal procedures. The main impression is that the Act has brought clear improvements, but that some stumbling blocks remain (7). The idea that all project leaders should relate to only one single address remains to be realised – applications still need to be sent to a number of different bodies and authorities, including the Norwegian Medicines Agency, the Ministry of Health and Care Services and the Norwegian Social Science Data Services. Nor is there any guarantee that the regional ethics committees will deal with all applications that are submitted. Of the 2 713 cases that were addressed in 2013–2014, altogether 625 (23 %) were rejected on the grounds that they were «outside the mandate» (8). When such a substantial proportion falls outside the scope of the Act, it may be questionable whether this is warranted or whether the committee is actively seeking to reduce its workload (7). One issue is whether an approval by a regional ethics committee can be regarded as a stamp of quality that may be used to promote the project with regard to funding or publication, another issue is that it is sometimes difficult to distinguish research from quality assurance (9, 10). Thus, a heavy responsibility rests on the committee's lawyer, who is the person with the professional competence to decide whether an application should be processed or not. A rejected project may serve as an example. A hospital department had collected faeces samples and wanted to analyse the genomes of the microbes. The regional ethics committee rejected the project, stating that this was research on microbes, not people. As a consequence, the samples had to be destroyed immediately and the linkage to patient data had to be deleted (V. Skogen, personal communication). In addition, the researchers would most likely have run into problems when attempting to publish the results.

On the positive side, efforts are underway to prepare national guidelines for the regional ethics committees to avoid unequal treatment. The opportunity for direct processing of notifications of amendments to projects that have already been approved has helped make the scheme more flexible and less time-consuming. Previously, if a project failed to obtain approval, the researchers had no other opportunity than to resubmit the case to the same committee. It is therefore a major advantage that according to the new Act, the committees are government administration bodies and that a formal appeals procedure has been established for individual decisions. Appeals can be submitted to the National Committee for Medical and Health Research Ethics (NEM) if necessary.

Many things happened during the thirty years before the Act came into force. In 1979 two identical randomised studies started in the maternity wards in Trondheim and Ålesund. Their goal was to investigate the benefits of offering ultrasound examinations to all women twice during their pregnancy. The carrot offered to the pregnant women who were asked by their primary doctor to participate was that they could be selected to «have ultrasound». Women who let themselves be persuaded had thereby also consented to participate in the study. It was no more formal than that. A short time into the study period I had a phone call from a furious colleague: «Now I have referred five pregnant women, and none of them have been selected for ultrasound! If this continues, I refuse to go on with it!» The likelihood of such an outcome was extremely small, and the women were in any case included in the study as a control group. However, they are probably still ignorant of the fact that they helped answer one of the key questions related to pregnancy services at the time (11, 12).

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