
Delivered to the ministry 21 December 2004 from a committee headed by Prof. Magne Nylenna.

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1. Background

A good health service, the effective treatment of disease and health-promotion measures that work are dependent on reliable knowledge. This knowledge can be obtained through systematic, scientific studies. Fast-growing expectations of the health service and a greater demand for transparency have increased the interest of the Norwegian public in medical and health research. Research is a fundamentally positive and useful activity on which both today’s and tomorrow’s patients rely. Good research is a prerequisite for better health.

Medical and health research ranges from experiments on healthy volunteers to the testing of new medicines and from studies of tissue samples and biochemical processes to surveys of general health conditions in major population studies. Medical and health research involving human beings, human biological material or health data must meet special requirements regarding professional conduct, due care and ethical awareness.

Much of the public debate on medical and health research concerns the difficulties these activities can lead to. While people used to be mainly concerned about the possible harm caused by clinical trials, there is possibly more focus today on the danger of violating personal integrity. From “to avoid harming”, the objective has become “to avoid harming and wronging”.

There are many good reasons why medical and health research is regulated. By ‘regulated’ we mean subject to all the rules and behavioural norms which affect and steer the way the research is conducted. The intention of these rules and norms is to protect human dignity by preventing harm and violation of integrity. This ensures the confidence of
research participants and the general public that medical and health research is ethically and scientifically justifiable. Regulation is based on a balance between the special interests of the research participants, society, the research, the researchers, the industry and others. These interests are for the most part identical. Ideally, the rules and norms should promote good research and pave the way for healthy freedom of research.

2. Terms of reference

In June 2003, the Government appointed a committee to go through the regulation of medical and health research. The committee wrote a report based on the following three main tasks within the committee’s terms of reference:

- to survey how medical and health research in Norway is regulated today
- to consider the suitability of this regulation
- to propose possible changes in the current regulation

3. The situation today

Norway uses fewer resources on research than other countries it is natural to compare it with. The level of scientific production in Norway in the field of medicine and health-related disciplines is low compared with other OECD countries and lower than any other Nordic country, in spite of the fact that the prerequisites for conducting medical and health research in Norway are good. There are few examples of serious violation or undesirable consequences of such research. Although it is not easy to prove that regulation has been a barrier to good, significant research, it is important both for researchers and the authorities to ensure that regulation of research is not unnecessarily complicated and resource-intensive.

There are two essential elements in the regulation of research: legislation (laws, regulations, etc.) and the bodies which administer the legislation (authorities, approval bodies, etc.)

The current legislation is unnecessarily fragmented. The Committee has identified about twenty-five Acts which regulate medical and health research in one way or another. There are also professional norms and an increasing number of international conventions and directives. This makes the rules and norms inaccessible and over-complex. Furthermore, regulation often has other primary objects than to ensure good research. Preventing violation of personal integrity and unjustifiable research is often the most important object. This negative approach can have the effect of weakening confidence in what is fundamentally a socially beneficial activity. There is thus a danger that regulation will have unintentional consequences and create unnecessary barriers.
Furthermore, the regulations are enforced by about ten control and supervisory bodies with partially overlapping duties. Researchers have to relate to a number of different public authorities and other bodies when working on one and the same research project. This is perceived both by researchers and by public bodies as unnecessary bureaucratisation.

4. **Promote, improve and simplify**
By comparing and analysing the legislation, conventions and declarations that are in force today, the Committee has identified a number of general principles for medical and health research (see box). These are fundamental norms which the Committee wishes to uphold.

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<th>General principles relating to</th>
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<td>• Human dignity</td>
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<td>• Methods</td>
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<td>• Risk/benefit</td>
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<td>• Freedom of research</td>
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<td>• Professional conduct and responsibility</td>
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<td>• Scientific quality</td>
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<td>• Community of interests</td>
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In this Report, the Committee puts forward some recommendations based on these norms and principles. Its recommendations are intended to ensure an appropriate and clear regulation of medical and health research, with a simpler authority structure. With reference to the current situation, the Committee sees the need to promote, improve and simplify medical and health research. This should mainly be done through two initiatives:

- a separate act on medical and health research (“one Act”) and
- coordination of the different bodies to which researchers have to relate (“one letterbox”).

5. **“One Act”**
The Committee holds the view that one coherent Act should be passed on medical and health research – an Act relating to medical and health research (the Health Research Act). Such an Act will be an easy-to-follow, pedagogical aid for researchers and provide a collective set of rules for their research. Draft legislation with comments has been drawn
The Committee’s draft takes into account the international nature of medical and health research and the international regulations in this field.

The Committee’s draft covers medical and health research which involves human beings, human biological material or health data and is based on the principles in the Declaration of Helsinki, the Norwegian Biobank and Biotechnology Acts and Acts relating to the Processing of personal Data and Personal Health Data Filing Systems and the Processing of Personal Health Data.

The object of the draft is to promote good, ethically justifiable medical and health research.

The Committee's proposal introduces the requirement of internal control and organisation of the research. Medical and health research must be organised in the form of a research project under the direction of a responsible person or body (most often an institution or business enterprise) with systems responsibility and be managed by a qualified project manager who has the day-to-day responsibility. Furthermore, a research protocol with specified contents must be drawn up for each project.

Medical and health research must in principle be based on informed, voluntary, express and documented consent of a competent person. The consent rules must ensure that the research participants are allowed to decide themselves whether they will take part in the research. The Committee’s draft introduces the concept of “broad consent” for consent to use human biological material or health data for specified, broadly defined research purposes. The Committee proposes legal authorisation of the possibility of exemption from the consent requirement, for example for research in clinical emergency situations and for research which uses human biological material and health data which has already been collected in connection with diagnoses and treatment.

It is in everyone’s best interest to have complete openness around medical and health research. The Committee’s draft gives the project manager the right and obligation to publish the results of the research. The results must be presented in an objective and accountable way, thus ensuring that both the positive and the negative finds are made public. In special cases, publication may be postponed for a time-limited period, for example because of patenting.

6. “One letterbox”
The current control and supervisory system is mainly based on guidance and advance control. Coordination and simplification of the processing of applications to initiate medical and health research projects is absolutely necessary. It will normally be sufficient for researchers to relate to one body.
In light of the current system, it is natural for the regional committees for medical research ethics to undertake this task. The committees will then be able to continue the committee system tradition of giving advice and guidance to researchers and research communities. The Committee wishes to give the regional committees for medical and health research ethics (which will be their new name) more authority and freedom to exercise discretion than is the case today. The Committee proposes a clarification of current practice in a number of areas. This means, for example, formalising the pre-assessment which now ends in a recommendation or a non-recommendation of the project. For all practical purposes, the committees’ activities must be regarded as the public exercise of authority and their decisions must be regarded as an approval or a rejection. According to general principles of administrative law, these decisions should be authorised by law, made as individual decisions and be subject to appeal. The Committee recommends that the National Committee for Medical and health Research Ethics should, in addition to its present tasks, be able to deal with appeals against decisions by the regional committees. The Ministry of Education and Research has proposed authorising the committees in law, which is in line with the Committee’s recommendations.

In order to be able to undertake more comprehensive tasks than before, the regional committees must be given more expertise and more capacity. This applies in particular to the committees’ secretariats. It presupposes the development of appropriate electronic systems and websites for information and communication. This will benefit researchers, the administration and the general public.

In the case of medicines testing, the Norwegian Medicines Agency has specific duties in the advance approval process pursuant to the Regulations regarding clinical trials of medicines for human use, which are based on the EU Medicines Directive. These Regulations were issued in pursuance of the Norwegian medicinal Products Act. The Committee wishes to uphold these duties, but believes that the Regulations should be authorised by the Health Research Act.

The Norwegian Board of Health should have the main responsibility for supervising medical and health research. The Data Inspectorate and the Norwegian Medicines Agency should supervise their own particular areas. Post-research control is taken care of through, for example, greater transparency and the requirement of a final report to the regional committee for medical and health research ethics.

7. **Summary**
The Committee recommends a new Act, where the object is to **promote** good, ethically justifiable medical and health research. Important research-promoting elements in this Act
are more clearly defined rights for researchers and an obligation on the part of the sponsor to safeguard the free, truth-seeking nature of research.

The Committee achieves its intention to improve medical and health research by setting more comprehensive and more explicit standards for research than those in force today. Significant quality-enhancing measures are: the introduction of a responsible person or body with systems responsibility, more stringent requirements regarding the qualifications of the project manager and a statutory requirement regarding a research protocol along with an obligation to pass on information/results and clearly defined provisions regarding transparency and access.

Gathering all the control provisions together in one Act will achieve both simplification and a better overview for researchers, research participants, the authorities and the general public. Clearer requirements regarding the organisation of the research offers the possibility of, for example, more flexible and more practical consent rules depending on the nature of the project. The possibility of granting broad consent gives the research participants greater freedom of manoeuvre and the researchers more chance of carrying out projects where developments may raise new problems en route, for example study methods that were not available at the start of the project. Establishing the regional committees for medical and health research ethics as the only point of contact for researchers will clearly simplify matters. The committees’ wider authority to exercise discretion and differentiate requirements depending on the special nature of the project and risk of harm will promote, improve and simplify the research. Combined with an efficient communication system, this will speed up and simplify the advance approval of medical and health research projects. Seen as a whole, the consequences of the Committee’s recommendations will give a clear health-related, socio-economic gain.

Regardless of legislation, assessment and supervisory bodies and other regulation mechanisms, the individual researchers’ values, attitudes, professional standards and ethical awareness will always be of prime importance. Sufficient attention must be given to basic ethical and legal principles in the education of researchers. A continuous, open and general debate on the appropriate limits for medical and health research and the way in which research is conducted must be encouraged.