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Ask first, investigate later

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There will be fewer problems for everyone if all required permissions have been obtained before the data collection starts. Afterwards it may be too late.

Foto Einar Nilsen

«Ask first, dig later», the former Norwegian telecommunications agency exhorted us. This was back when the telephone book was a real book and not a website, and all electronic signals passed through cables. A torn cable gave the telecommunications agency a lot of work, and the subscribers concerned could be left with no telephone connection for days or even weeks – problems that could have been easily avoided with a simple advance enquiry.

Research freedom is the freedom to dig for new knowledge. This freedom is essential to good research. Nevertheless, society is obligated to regulate the ways in which this digging for knowledge is done. There are numerous good reasons for this, and they have has been described in this journal on several occasions (1) – (3). Medical research is therefore strictly regulated, by international conventions as well as national legislative acts and regulations. By offering protection against indiscriminate decisions such regulations also establish predictability for the individual researcher.

In Norway, most of the regulations in this field were incorporated into the Health Research Act of 2008 (4). By itself, the Act is obviously not very suitable as a practical guide for researchers, but it has resulted in a simplification of the application procedures. It has become a great deal clearer who one is supposed to ask before the project is initiated. As a main rule, all medical and health-related research projects should be given prior approval by one of the regional

committees for research ethics (REK) (5). All research involving human beings also requires informed, documentable consent from those concerned (5). In addition, one must ask oneself a few simple control questions before the data collection can start:

- Is this a prospective clinical study? If so, it most likely needs to be registered in one of the international study databases (1). With a view to preventing selective publishing this registration must be done before the first patient is included.
- Does the study include collection, registration and/or storage of personal data? If so, it must be reported to the Data Protection Ombudsman (6). This applies regardless of whether the study is defined as quality assurance or as research.
- Does the study include testing of drugs or medical equipment? If so, an application must be submitted to the Norwegian Medicines Agency or the Directorate of Health respectively (7).

The simplest way to ensure that all this has been taken care of is to prepare a research protocol. In addition to being an aid to the researcher, a systematic protocol is useful at all stages of the project – when applying for permissions and funding, for embedding the project at the hospital or in an organisation, or when the results are due for publication. Such a protocol may be useful even in projects that only involve quality control. There are numerous good templates for research protocols available. An article published in this journal in 2002 provides useful advice on their design (8). But even if all prior permissions have been obtained and the project is scientifically interesting, a researcher may encounter difficulties in publishing the study. This is because all medical journals have an independent obligation to undertake an ethical assessment of the completed project. This obligation is laid down in the Declaration of Helsinki (9) and in the journals' commitment to collaborate within the International Committee of Medical Journal Editors (ICMJE) (10) and the Committee on Publication Ethics (COPE) (11). There is an obvious reason for this: The governmental agencies, such as the regional ethics committees and the data protection ombudsmen, give prior approval to plans, while the journals assess what has been done. These roles are complementary.

To remain within the allegory in the title: Even though you have been given prior permission to dig, the journals must make sure that you have not torn any cables along the way. One example is provided by quality assurance projects, which according to the law may be initiated without approval by the regional ethics committee and without the consent of the patients (4). When it comes to publication, however, the distinction between quality assurance and research is less interesting (2) – because the journals must invariably assess whether the work that has been undertaken complies with generally accepted standards of publication ethics, irrespective of how the project was defined at the outset. The journals are also obligated to undertake assessments of publication ethics that go beyond national legislation. If there is a possibility that individual patients

could be identified, they must provide consent for publication. As a rule, this is strictly enforced. In this journal we require that our standard consent form is used (12).

Good research projects are not necessarily large or complex. Important new knowledge may often be dug up with the aid of simple methods. This notwithstanding, the required permissions must always be obtained before the project can start. As editors of this journal, we totally dislike having to reject a manuscript on the grounds that these matters have not been taken care of. Ask before you investigate. Afterwards it may be too late.

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