Q Why do I have to apply for ethical approval before I can begin my research?

A All research is undertaken with the ultimate aim of using the findings to benefit people. That benefit can take the form of improvements in treatment and care or advances in knowledge and understanding – even negative findings can make a contribution to the development of new and effective treatments. It is inevitable, however, that research involving human participants involves some degree of risk to those involved, be they the participants or the researchers.

Potential harm may range from minor temporary discomfort to permanent damage. It is not possible to protect all participants from this and, although research ethics committees (RECs) are not totally averse to risk, they will want to know what the risks are and what actions researchers may take if harmful events do occur. They will also want to know how researchers will protect themselves from harm.

The history of research ethics has repeatedly demonstrated what happens when they are not taken seriously. Probably the best known and most extreme examples are the events that occurred during the years of Nazi power in the 1930s and 1940s. The pain and suffering caused in the name of research and science have been well documented.

Development of ethical codes

After the fall of the Nazis and the end of the Second World War, many involved in this research were tried in Nuremberg and found guilty of crimes against humanity. The Nuremberg Code, published soon after, was an attempt to prevent such events from happening again. Two decades later the Declaration of Helsinki was published by the World Medical Association and adopted widely around the world. Both documents made it clear to researchers what was ethically acceptable and how participants should be recruited and treated.

However, these international codes did not put an end to unethical and harmful research; this is one of the clearest examples of how such research was followed by a reaction that failed to put an end to further unethical research. This cycle has been repeated many times – the most recent and best publicised example being the retention of deceased children’s organs at Liverpool’s Alder Hey Hospital without the informed consent of the children’s parents. This event resulted in the Research Governance Framework for Health and Social Care and the Human Tissue Act 2008. It is too early to say whether these have put an end to unethical research and there are concerns that the answer will again be “no”.

The role of RECs

The primary focus of all RECs, whether in the NHS (coordinated by the National Research Ethics Service) or in universities, is to protect potential research participants from harm. They do this by balancing the possible risks against the possible benefits of research. As noted above, no research involving human participants is without risk and RECs do not expect all possible risks to be eliminated. However, in addition to knowing what the risks are and how they will be minimised, RECs want to be sure that people being invited to participate in research are aware of those risks and can make an informed decision about participating based on the information they are given. All too often participant information sheets are poorly written and do not include the information people need to be able to make informed and autonomous decisions.

A brief examination of the history of research ethics demonstrates that people get hurt when researchers do not take research ethics seriously. Independent review of research involving human participants by an appropriate REC has become the minimum standard required before research can begin.

Seeking ethical approval should not be treated as a chore or a hoop through which researchers must jump before they can begin their research. Rather, preparing for ethical review should be treated as an important and integral part of the research process. It is often the process of preparing for ethical review that helps researchers focus on exactly how they will undertake the different stages of their research, from recruiting participants through to disseminating their findings. Researchers should embrace and value the process of ethical review.

Leslie Gelling is reader in nursing at Anglia Ruskin University, Cambridge

Useful reading


www.nursingtimes.net / Vol 107 No 30/31 / Nursing Times 02.08.11 23