

Research Ethics Committees identify and correct problems in applications to do cancer trials

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Researchers running cancer trials are often critical of the Research Ethics Committee (REC) process they have to go through to get their trials approved, complaining that it's too complex, burdensome and sometimes unreasonable. In the UK only 17% of research study applications are given immediate favourable opinion by RECs.

But a new study from the University of Leicester, recently reported in *The Lancet Oncology*, suggests that RECs may sometimes identify important problems in applications to conduct cancer trials.

The Leicester study, funded by the National Research Ethics Service, looked at 80 anonymised NHS REC decision letters concerning cancer trials, written between March 2004 and December 2006.

When reviewing applications to conduct cancer trials, the issue RECs are most likely to raise is that of informed consent. Committees are often concerned that the information that researchers propose to give patients may not be in language that can be easily understood. They also discourage researchers from presenting trials too enthusiastically, and seek to prevent researchers from providing misleading information. One Committee pointed out that the cancer drug side-effects were described as mild on the patient information sheet, but in the investigator's brochure it was noted that several patients had experienced serious adverse events thought to be related to the drug.

The study found that RECs identify a high rate of mistakes in applications, including missing information, ticking the wrong boxes, errors in the information provided and not following correct procedures.

The findings support the conclusion that RECs, though by their constitution somewhat bureaucratic, provide an important independent check on clinical trials by ensuring that investigators do not omit important information or underestimate risks in the information they give patients.

Professor Mary Dixon-Woods, of Medical Sociology in the Department of Health Sciences at the University, commented: "There have been a lot of complaints about REC procedures from researchers in recent years. They often find the process onerous and bureaucratic. However, this study is the first time anyone has systematically analysed what RECs are saying about cancer trial proposals.

"RECs are looking for evidence that researchers are sensitive to ethical issues, in particular to participants' interests, and that information given to potential participants explains the trial fully and truthfully. Researchers can improve their chances of success at ethical review by really good preparation."

Source: University of Leicester

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