Risks and benefits in research on children

The 'Guidelines to aid ethical committees considering research involving children', see page 75, have been prepared by a working party of the British Paediatric Association, and circulated to all BPA members. The Editors of the Archives warmly welcome these guidelines, and have three particular reasons to do so.

Firstly, we have pointed out in a series of Editorials (1967, 42, 109; 1973, 48, 751; 1978, 53, 441) our continuing concern about the ethical problems of research in children, and we have described how we have developed our own guidelines for deciding whether research which we have been asked to publish is ethically acceptable. It is gratifying to see how close the thinking of the BPA working party is to our own. In 1973 we emphasised the idea of the risk/benefit ratio, though not without some trepidation—as we remarked in 1978 'The justification of the means by the end is notoriously slippery moral territory'. The risk/benefit ratio is the central concept of the BPA document; its value is that while it imposes very strict standards on the investigator, it avoids the extreme position of virtually forbidding all research on children.

Secondly, the authors of the document are to be congratulated on the very practical nature of their guidelines. They have bravely decided not just to deal in generalities but to give actual examples of problems that might arise in research. This greatly increases the value of the guidelines to the investigator planning a particular study.

Thirdly, the guidelines are accompanied by an announcement that BPA Council has set up a Standing Ethical Advisory Committee which will offer advice to local ethical committees on particular proposals for research in children. The usefulness of this committee will depend on how often it is consulted, but it could prove of great value. In 1973 we pointed out the limited influence which editors can exercise on the ethics of research: 'When we refuse a paper on ethical grounds, the work has already taken place, and though the authors may now have a clearer idea of what we regard as acceptable, no one else will, and this includes other potential research workers who might be contemplating a similar study'. The Standing Committee will have the great advantage of being consulted before the work is done. If they are consulted often enough, they will build up a body of 'case law' which will guide them in the future; furthermore if from time to time they publish examples of proposals put to them and decisions reached this would help to guide others. The examples should include proposed research judged unethical as well as ethical, and should, of course, not mention the names of the investigators. (The annual report of the Medical Defence Union is an example, from a different field, of how well this kind of thing can be done.)

The authors of the BPA guidelines will not expect these to remain unchanged; we pointed out in our 1978 Editorial how views on the ethics of research change according to the state of knowledge and the climate of opinion. For example, the rigid stand which we took on x-rays in normal children even in 1978 is countered in the BPA document by a technically better informed and less restrictive statement. However the fact that the guidelines will not all be permanent makes the effort of producing them even more courageous.