RESEARCH

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As part of their duty to protect life and health to an acceptable professional standard, surgeons have a subsidiary responsibility to strive to improve operative techniques through research to assure themselves and their patients that the care proposed is the best that is currently possible. Y et there is moral tension between the duty to act in the best interests of individual patients and the duty to improve surgical standards through exposing patients to the unknown risks that any form of research inevitably entails. The willingness to expose patients to such risks may be further increased by the professional and academic pressures on many surgeons to maintain a high research profile in their work. For this r eason, surgeons (and physicians, who face the same dilemmas) now accept that their research must be exter nally regulated to ensure that patients give their informed con sent, that any known risks to patients are far outweighed by the potential benefits and that other forms of protection for the patient are in place (e.g. proper indemnity) in case they are unexpectedly harmed. The administration of such r egulation is through research ethics committees, and surgeons should not participate in research that has not been approved by such bodies. Equally , special provisions will apply to research involv ing incompetent patients who cannot provide consent to par ticipate, and research ethics committees will evaluate specific proposals with great care. In practice, it is not always clear as to what constitutes ‘research’ that should be subjected to regulation, as compared with a minor innov ation dictated by the contingencies of a particular clinical situation. Surgeons must always ask them selv es in such circumstances whether or not the innovation in question falls within the boundaries of standard procedures in which they are trained. If so, what may be a new technique for them will count not as research but as an incremental improve ment in personal practice. Nevertheless, major innovations in operative procedure are scrutinised by national regulatory authorities; in the UK by the National Institute for Health and Care Excellence (NICE). This process of scrutiny has been designed to ensur e that the innovation is safe, e ffi cacious and cost-e ff ective. It is regarded (by the NHS) as a mandatory step when introducing a new interventional procedure. Equally , surgeons know that exigencies of operative surgery sometimes demand a novel and hitherto undescribed manoeu vre to get the surgeon (and the patient) out of trouble. Providing your solution is necessary , proportionate to the circumstances, performed in good faith and would pass the scrutiny of your peers as reasonable, it is unlikely that any subsequent criticism of your actions could be sustained. If a proposed innovation passes the criteria for research, it should be approved by a research ethics committee. Such sur gical research should also be subject to a clinical trial designed to ensure that findings about outcomes are systematically com pared with the best a vailable treatment and that favourable gical skill among researchers) that cannot be replicated (see also Chapter 12).

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