

- (H) The Royal College of Physicians has advised that the use of anonymised left-over tissue for research is a traditional and ethically acceptable practice that does not need consent from patients or relatives and need not be submitted to a research ethics committee (Royal College of Physicians (1996) Guidelines on the practice of ethics committees in medical research involving human subjects, Third Edition, page 40), a view endorsed by the Nuffield Council on Bioethics in its report on Human Tissue (1995, *op.cit.*). The Nuffield Council states (Appendix 6, pp148-149) guidance for the referral of proposals for research on human tissue to research ethics committees, which is essentially consonant with that proposed here. An example of specific guidance based on these recommendations is: East London and the City Health Authority Research Ethics Committee: Notes on completing the Committee's short application form for research projects using archival or stored clinical material (1997). The authors of the Nuffield Report (1995, *op.cit.*) have suggested that general consent forms might usefully refer to the possibility that removed tissue may be used for the purpose of research, teaching or study but there remains a substantial body of opinion that express consent for usage for research is not vital (Royal College of Physicians, *op.cit.*).
- (I) In exceptional circumstances, it may be desirable and in the patient's best interests to report research results to the clinical notes, or, at least, where results are found, possibly unexpectedly, to have a bearing on health to the patient's medical adviser or to the patient, even without previously expressed (specific) consent. The risk of unauthorised disclosure must be balanced against the known risk to health of non-disclosure. Where not urgent, the advice of Chairman, LREC may be sought. In general, it is better to act through the patient's doctor rather than for a researcher to communicate directly with a patient or volunteer.
- (J) Case law in the UK clearly establishes the principle that, as with any medical intervention, consent is required for the removal of