20 Medical research

Medical research aimed at understanding and preventing disease or improving its diagnosis and treatment is generally welcomed by society, especially where it is conducted primarily with altruistic motives. Such research may carry risks for the human participants involved. Experience has shown that even well-motivated researchers may at times pursue their research inappropriately, to the detriment of the research participants. To protect research participants, international and national codes of research ethics have been in place for more than 50 years. In Australia, health and medical research is now overseen by nationally accountable research governance systems in hospitals and medical research institutes [1,2]. A key element of this governance is the prospective ethical review of research proposals by human research ethics committees (HRECs). This chapter summarises the ethical principles of human research, the governance of research, the expected standards of good research practice, the responsibilities of clinical researchers, and research misconduct involving doctors. Overlapping with research are clinical audit and quality assurance studies, in which doctors are increasingly expected to participate, and which can raise similar ethical issues.

20.1 Codes of ethics in clinical research

The stimulus for the development of international codes of medical ethics, specifically in regard to research, was the gross abrogation of accepted standards involved in so-called medical research by doctors in Nazi Germany before and during the Second World War. The first international code of research ethics, *Recommendations guiding medical doctors in biomedical research involving human subjects*, was adopted by the World Medical Association (WMA) in 1964 at its 18th Assembly in Helsinki and is now better known as the *Declaration of Helsinki*. The document has been revised on seven occasions, and the most recent revision was completed in 2013 [3]. While still relevant to Australian health and medical research, the Declaration is no longer the key guide, having been supplanted by the *National statement on ethical conduct in human research* (the 'National Statement') [4] and the *Australian code for the responsible conduct of research* ('the Code') [5]. These two documents are issued conjointly by the National Health and Medical Research Council (NHMRC), the Australian Research Council and Universities Australia.

The National Statement requires institutions and researchers to have any proposed human research reviewed and approved by an HREC. This review and approval is designed to ensure that all such research meets the key ethical requirements of research merit and integrity, justice, beneficence and respect for humans, to provide proper protection for the participants. The Code requires institutions and researchers to fulfil responsibilities for issues including researcher training, data storage, intellectual property, authorship, copyright and publication of research findings. The Code also contains definitions of research misconduct and specifies procedures to address allegations of such conduct.

Like the *Declaration of Helsinki*, the National Statement and the Code are revised periodically, in a process that involves broad public consultation. The National Statement is supported by codes for research in specific contexts such as assisted reproductive technology and gene therapy, and codes for research involving specific populations, such as Aboriginal and Torres Strait Islander Australians [6]. These documents are available on the NHMRC website (http://www.nhmrc.gov.au). These specific guidelines are consistent with the key ethical principles for medical research drawn from the National Statement and the Code, as described in this chapter.

20.2 Research governance

Research governance describes the policies and procedures by which institutions (including hospitals, universities and research institutes) seek to assure the safety, quality and ethical propriety of the research they sponsor or conduct [1,2,7]. Research governance is a much broader subject than research ethics, although the role of HRECs is a core component of governance [1,8]. Research governance in Australia is now guided by the National Statement [4] and the Code [5]. For clinical research, these documents derive their authority from the *National Health and Medical Research Council Act 1992* (Cwlth). Receipt of NHMRC funding of research is dependent on institutions and their staff complying with the guidelines in these two documents. When an institution accepts an NHMRC-funded research grant on behalf of a researcher, a deed of agreement is signed with the NHMRC binding the institution to follow the guidelines. The *Therapeutic Goods Act 1989* (Cwlth) makes it illegal for a clinical trial of an unregistered therapeutic agent to begin before the trial protocol has been approved by a properly constituted HREC, as provided for in the National Statement.