題名:臨床牙科寶鑑: 鹵素光樹脂聚合機. Chapter 10: 6
作者:董德瑞; 李勝揚
貢獻者:牙醫學系
上傳時間:2009-11-23T02:57:46Z
摘要:This essay explores the meaning and implications of informed consent in xenotransplantation clinical trials from both ethically justifiable and international perspectives. In international and national codes and guidelines involving human subject research and in the laws of many nations, the informed consent of research subjects is obligatory. Its moral foundations include and also extend beyond respect for individual persons as autonomous agents in Western nations. Axioms regarding the value of human life and duties to protect innocent and vulnerable persons from harm, duress, and deceit underlie Western individualism and are broadly shared in many non-Western cultures. Accents on family and/or community consent in China and other nations are compatible with individual consent as long as family and community consent supplement, rather than replace, individual consent. Reflecting its moral foundations, informed consent in medical research is rightly characterized as "voluntary" or "freely given" informed consent because it encompasses researchers~ disclosure and subjects~ comprehension of all the relevant information about the protocol that reasonable persons would want to know in order to freely and affirmatively enroll in the research. The interplay between these conceptual foundations of informed consent and the realities of xenotransplantation research defines what the nature and functions of consent should be in xenotransplantation clinical trials. Because these trials involve a complex body of medical information, numerous procedures, numerous risks (associated with failure rates, immunosuppression, xenogeneic infections, and so on) and the subject~s obligation to abide by

extensive national and international precautionary guidelines, informed consent should be enacted as an organized, sequential, thoughtfully paced, jargon-free process of communication. The features and functions of consent forms or consent documents should accord with this process. Rather than being virtually equated with informed consent, consent documents should be utilized as templates of relevant, essential, and understandable information that contribute to comprehension and voluntary enrollment. In xenotransplantation clinical research, the consenting process must cover a large number of topics, including treatment choices, participation information, study procedures, information about risks associated with immunosuppression, xenogeneic infections, discomforts, and other matters. In addition, due to infectious risks, subjects are obliged to 10 post-protocol responsibilities. Two of the three unique moral issues regarding informed consent in xenotransplantation trials involve what to do to minimize post-protocol infectious risks and what to do about international and national guidelines that affirm the subject~s right to withdraw from participation in medical research at any time. The third moral issue centers on issues involving the enrollment of children and mentally incapacitated adults. The other chapters in this consensus statement demonstrate that, morally and logically, favorable harm-benefit determinations precede considerations of informed consent. When these harm-benefit assessments are favorable enough to warrant the onset of clinical trials, informed consent emerges as a pivotal moral precondition for these trials.