EXPLANATORY STATEMENT

STATUTORY RULES 1989 No //8

Issued by the Authority of the Minister for Community Services and Health.

Australian Institute of Health Act 1987 Australian Institute of Health Ethics Committee Regulations

Section 32 of the <u>Australian Institute of Health Act 1987</u> (the Act) provides that the Governor-General may make regulations, not inconsistent with this Act, prescribing matters required or permitted by this Act to be prescribed.

Subsection 16(1) of the Act provides that the Institute shall appoint a committee to be known as the Ethics Committee. Subsection 16(2) provides that the functions and composition of the Ethics Committee (the Committee) shall be as prescribed.

There are no previous Regulations in relation to the Committee. It is envisaged that the present Regulations will allow the Committee to have regard to relevant ethical principles in monitoring adherence by the Institute to ethical standards, through the provision of written reports and opinions to the Institute.

The Regulations prescribe the functions and composition of the Committee. In pursuance of its functions the Committee is to form and revise opinions as to the ethical acceptability of activities engaged in or proposed to be engaged in by the Institute and associated bodies. In doing so the Committee is to have regard to the Declaration of Helsinki, any relevant ethical principles formulated by the National Health and Medical Research Council, and any other matters that the Committee considers to be relevant. The Declaration of Helsinki embodies recommendations of the World Medical Assembly guiding medical doctors in bio-medical research relating to human subjects.

The Committee will be required to inform the Institute of its opinions and provide an annual written report of the Committee's operations to the Institute.

The members of the Committee are to consist of the Director of the Institute, a University graduate in medicine with post graduate medical experience, a tertiary institution graduate in social science with post graduate research experience, a nominee of the Registrars of Births, Deaths and Marriages, a Minister of religion, a legal practitioner of the High Court or a Supreme Court, and a man and a woman not being members of, or employed by, the Institute but able to represent general community attitudes. One of the members shall be appointed Chairperson by the Institute.

The Regulations came into operation on the date of notification in the Gazette.

S.R. 143/89

