

7 April 2014

Health and Disability Ethics Committee Chairs and Members
c/o Health and Disability Ethics Committees Secretariat

Dear Health and Disability Ethics Committee Chairs and Members,

As some of you will know, the Ministry has recently become aware of concerns regarding ethics committees' approval of research involving participants who lack the capacity to consent to participate. Health Legal wishes to remind committees of their obligations when considering such applications.

The Standard Operating Procedures for Health and Disability Ethics Committees require committees to check that proposed research meets established ethical standards that aim to protect participants, including the National Ethics Advisory Committee (NEAC) Ethical Guidelines for Intervention Studies. In regard to non-consensual studies, the guidelines state that:

6.27 The ethical standards for non-consensual studies that are stated in these Guidelines are intended for application only to studies that are lawful.

Research involving participants who do not have the capacity to consent (and where no-one legally authorised to give consent on behalf of the participant does so) is not lawful unless it satisfies Right 7(4) of the Code of Health and Disability Services Consumers' Rights (the Code). Committees do not have the authority to give consent on behalf of participants.

Investigators must satisfy the committee that the proposed research is lawful before the committee approves an application. Committees are not required or able to give legal advice to investigators; it is the responsibility of the investigator to ensure that the research is lawful. However it is open to the committees to note any uncertainty about the legality of the particular research in question and to suggest that the researcher seeks formal legal advice (see para 15 *Standard Operating Procedures for Ethics Committees*).

The Committees should make clear in approval letters that giving ethical approval does not relieve researchers and sponsors of their responsibility to ensure that their research is conducted lawfully.

Yours sincerely,



Phil Knipe
Chief Legal Advisor