

2 September 2005

Mr Chris Humphreys
Director, Civil Law Policy
Department of Justice
Level 4, 55 St Andrews Place
MELBOURNE VIC 3000

Dear Mr Humphreys,

RESPONSE TO THE
MEDICAL RESEARCH PROCEDURES INVOLVING PATIENTS UNDER A
LEGAL INCAPACITY CONSULTATION PAPER

Thank you for the opportunity to comment on the above Consultation Paper.

In general, Health Issues Centre believes the proposed changes are practical and quite logical. We suggest the following changes around consent. It is important that the proposal does clearly defines the following:

- that consent means 'informed consent' in all processes of participation including when the patient regains capacity (55.2) and when the patient does not regain capacity and a person responsible is located (55.3)
- how information about the medical research procedure would be given prior to obtaining consent
- how to determine if the patient or the person responsible fully understands what they consented for
- whether the consent should be verbal or written
- how to record the consent

Please do not hesitate to contact me if you require further clarification.

Yours sincerely,

Charin Naksook
Senior Project Officer