

4th September 2006

Joanna Edwards
Department of Health
Wellington House
Waterloo Road
London SE1 8UG

Dear Ms Edwards,

1. Thank you for giving us the opportunity to respond to the consultation of the Department of Health on the draft regulations under the Mental Capacity Act 2005. A Report published by the Council, *Mental disorders and genetics: the ethical context* (1998) (copy enclosed), recommended that further consideration be given to the details of legislation and regulation to safeguard the interests of people with mental incapacity with respect to participation in research. Therefore, in general, we welcome the proposed regulations on appointing an 'appropriate body' to advise on the ethics of research involving people with mental incapacity, and the regulations relating to the loss of capacity during research. Detailed responses to each of the draft regulations are provided below.

Regulations defining the appropriate body

2. In the Report *Mental disorders and genetics: the ethical context* (1998), the Council proposed that the interests of people with mental incapacity taking part in non-therapeutic research in particular should be protected through legislation. The definition of intrusive research in the Mental Capacity Act is wider than health or medical research, for example, it includes social care research studies and other non-therapeutic research. Under the draft regulations on the 'appropriate body', this kind of research would be subject to ethical review in relation to people who lack capacity to consent to it. We welcome the added protection that this is likely offer.
3. The Report also concluded that the expertise of existing research ethics committees to consider non-therapeutic research involving people with mental incapacity may need to

Chairman
Professor Sir Bob Hepple QC, FBA

Deputy Chairman
Professor Peter Smith CBE

Members
Professor Margot Brazier OBE
Professor Roger Brownsword
Professor Sir Kenneth Calman KCB FRSE
Professor Peter Harper
The Rt Revd Lord Harries of Pentregarth DD
FKC FRSL
Professor Søren Holm
Professor Peter Lipton
Lord Plant of Highfield
Mr Anatole Kaletsky
Dr Rhona Knight
Professor Sir John Krebs FRS
Professor Hugh Perry
Dr Alan Williamson FRSE

Director
Professor Sandy Thomas

Deputy Director
Dr Catherine Moody

Assistant Director
Mr Harald Schmidt

be broadened (paras 7.11-7.18). The draft Regulations include the criterion that appropriate bodies should have expertise encompassing the ethics of research falling under the Mental Capacity Act. As non-therapeutic research is covered by the Act, we would expect appropriate bodies to seek to gain expertise in this area.

Regulations regarding loss of capacity during research

4. The Report *Mental disorders and genetics: the ethical context* (1998) concluded:

Another, more real concern is that the capacity of the person to consent, and therefore the validity of that consent, may fluctuate with the course of the disorder, for example in dementia. The possibility that the potential participant's capacity to consent to the research might change during the course of that research, with proposed contingencies for dealing with that, should be presented to a research ethics committee at the outset and appropriate procedures agreed with participants (para 7.10).

When a participant loses capacity to consent to continue before the conclusion of a research project, the draft regulations specifies that: 'the appropriate body must be satisfied that there are reasonable arrangements in place for ensuring that the requirements of Schedule 2 will be met'. Schedule 2 sets out steps that the researcher must take to gain consent to continue from a person interested in the welfare of the participant. Although we welcome the interests of people with mental incapacity being protected through legislation in this way, we note with concern that the Council's conclusion, **that researchers present to a research ethics committee contingencies for dealing with loss of capacity at the outset and appropriate procedures agreed with participants**, has not been met.

5. The Department of Health might also like to note the following recommendation from the Report *Mental disorders and genetics: the ethical context* (1998) about individuals who are intermittently competent, as this has not been addressed in the draft regulations:

7.5 For many individuals with mental disorders, mental capacity varies and it is desirable, and almost always

possible, to involve them in relevant genetic research at a time when they are competent to consent on their own behalf. The Working Party recommends that individuals who are intermittently competent should only be approached about participation in research when competent. In these circumstances, the problems in obtaining informed consent from individuals suffering from psychiatric disorders are not qualitatively different from those encountered in research on other medical disorders.

Please do not hesitate to contact us if you require clarification on any of the information contained in this letter, or further copies of the Council's Reports.

Thank you again for the opportunity to respond to the consultation.

Yours sincerely,

A handwritten signature in blue ink that reads "Sandy Thomas". The signature is written in a cursive style.

Professor Sandy Thomas
Director

