These notes refer to the Mental Capacity Act 2005 (c.9) which received Royal Assent on 7 April 2005

MENTAL CAPACITY ACT 2005

EXPLANATORY NOTES

COMMENTARY ON SECTIONS

Part 1: Persons Who Lack Capacity

Research

Section 30: Research

96. This section and *sections 31* to *33*allow intrusive research to be lawfully carried out on, or in relation to, a person who lacks capacity, where the research is part of a research project approved by an appropriate body and it is carried out in accordance with the conditions set out in *sections 32* and *33*. The provisions are based on long-standing international standards, for example, those laid down by the World Medical Association and the Council of Europe Convention on Human Rights and Biomedicine.

97. This section relates to intrusive research, which means research that would normally need consent if it involved an adult with capacity. Clinical trials that are currently regulated under the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031) (or regulations succeeding or amending them) are excluded from the Act because those Regulations already make provision for trials involving participants who lack capacity. Research on anonymised medical data or tissue is also not included, but may be subject to controls under the Data Protection Act 1998 or the Human Tissue Act 2004.

98. The appropriate authority (the Secretary of State in relation to research in England and the National Assembly for Wales in relation to research in Wales) must specify an appropriate body for approving research projects, such as a Research Ethics Committee (REC).

Section 31: Requirements for approval

99. This section sets out the matters of which the appropriate body – such as an REC— must satisfy itself before approving a research project involving a person who lacks capacity.

100. Subsection *(2)* requires that the research must be connected with an impairing condition that affects the person participating in the research or with the treatment of the condition. Impairing condition means one that is, or may be, attributable to or causes or contributes to the impairment of or disturbance in the functioning of the person's mind or brain. This limits the sort of research projects that the person may be involved in but will include research into the effects of the impairment on his health and day-to-day life as well as into the causes or possible causes of the impairment and its treatment. *Subsection (4)* requires that there are reasonable grounds for believing that there is no alternative to the involvement of the person in the research, that is, it cannot be carried out as effectively if it only involves people who have capacity.

101. *Subsections (5)* and *(6)* deal with the anticipated benefits and risks of the research. There are two alternatives: either the research has the potential to benefit the person without

imposing a burden disproportionate to that benefit (this type of research is sometimes called "therapeutic research"); or the research is to provide knowledge of the causes of the person's condition, its treatment or the care of people who have the same or similar condition now or who may develop it in the future. In relation to this latter category, there must be reasonable grounds for believing that the risk to the person is negligible and the research must not interfere with the person's freedom of action or privacy in a significant way or be unduly invasive or restrictive. This latter category of research might include indirect research on medical notes or on tissue already taken for other purposes. It may also include interviews or questionnaires with carers about health or social-care services received by the person or limited observation of the person. And it could include taking samples from the person, e.g. blood samples, specifically for the research project.

Section 32: Consulting carers etc

102. Before any decision is taken to involve a particular person in approved research, the researcher must take reasonable steps to identify a person close to the person (this could include an attorney or deputy but not someone acting in a professional capacity or for payment, such as a paid carer) who is prepared to be consulted about the person's involvement in the research (*subsection (2)*). If there is no such person, then the researcher must nominate a person independent of the research in accordance with guidance issued by the appropriate authority (see paragraph 99).

103. *Subsection (4)* requires the researcher to give the consultee information about the research and to ask him or her for advice as to whether the person should take part in the research and what, in his opinion, the consultee's wishes and feelings would be about taking part in the research. If at any time the person consulted advises the researcher that in his opinion the person's wishes and feelings would be likely to lead him to decline to take part in the project then the researcher must ensure that the person does not take part in the project, or if it is already underway must ensure that the person is withdrawn from it. But the person may still receive treatment he was receiving during the research if withdrawal would create a significant risk to his health *(subsection (6)*).

104. *Subsections (8)* and *(9)* allow for action to be taken in relation to the research where treatment is to be provided to the person urgently and there is insufficient opportunity to consult. The researcher may proceed if he has the agreement of a doctor who is not connected to the project or in accordance with a procedure agreed by the appropriate body at the time of approval. However *subsection (10)* makes it clear that the researcher may only rely on *subsection (9)* while there is an urgent need to treat. Examples of this type of research may involve action by a paramedic or doctor to make measurements in the first few minutes following a serious head injury or stroke. These arrangements are similar to those provided for in the Clinical Trials Regulations.

Section 33: Additional safeguards

105. The purpose of *section 33* is to provide additional safeguards for the person participating in the research once the research has begun. It requires the researcher to respect any signs of resistance from the person (except where this would conflict with procedures designed to protect him from harm or injury), and not to involve the person in research that would be contrary to an advance decision or any other form of statement. The person's interests must be assumed to outweigh those of science and society *(subsection (3)*).

106. The person must be withdrawn from the project without delay if he indicates that he wishes to be withdrawn from it or if the researcher has reasonable grounds for believing that any of the requirements for approval of the project as set out at in *section 31(2)* to *(7)* are no longer met. As in *section 32*, the person may still receive treatment he was receiving during the research if withdrawal would create a significant risk to his health *(subsection (6)*).

Section 34: Loss of capacity during research project

107. This section provides for a transitional regulation-making power to cover research started before *section 30* comes into force and which involves people who had capacity when enrolled but who lose capacity before the end of the project. The regulations will lay down the conditions on which such research may continue; the research must meet prescribed requirements, the information or material used in the research must have been obtained before the loss of capacity and certain steps must be taken to protect the person participating *(subsection (2)*).

108. The regulations will set out these requirements and steps and may include safeguards similar to those provided for in *sections 31* to *33* but with any necessary alterations to the requirements for approval by an appropriate body, consultation with carers or the additional safeguards *(subsection (3)*). Regulations made by the Secretary of State will be subject to the affirmative procedure in Parliament (see *section 65*).