# **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).