

MENTAL CAPACITY ACT 2005

EXPLANATORY NOTES

COMMENTARY ON SECTIONS

Part 1: Persons Who Lack Capacity

Research

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.