



Mental Capacity Act 2005

2005 CHAPTER 9

PART 1

PERSONS WHO LACK CAPACITY

Research

31 Requirements for approval

- (1) The appropriate body may not approve a research project for the purposes of this Act unless satisfied that the following requirements will be met in relation to research carried out as part of the project on, or in relation to, a person who lacks capacity to consent to taking part in the project (“P”).
- (2) The research must be connected with—
 - (a) an impairing condition affecting P, or
 - (b) its treatment.
- (3) “Impairing condition” means a condition which is (or may be) attributable to, or which causes or contributes to (or may cause or contribute to), the impairment of, or disturbance in the functioning of, the mind or brain.
- (4) There must be reasonable grounds for believing that research of comparable effectiveness cannot be carried out if the project has to be confined to, or relate only to, persons who have capacity to consent to taking part in it.
- (5) The research must—
 - (a) have the potential to benefit P without imposing on P a burden that is disproportionate to the potential benefit to P, or
 - (b) be intended to provide knowledge of the causes or treatment of, or of the care of persons affected by, the same or a similar condition.
- (6) If the research falls within paragraph (b) of subsection (5) but not within paragraph (a), there must be reasonable grounds for believing—

Status: This is the original version (as it was originally enacted).

- (a) that the risk to P from taking part in the project is likely to be negligible, and
 - (b) that anything done to, or in relation to, P will not—
 - (i) interfere with P's freedom of action or privacy in a significant way, or
 - (ii) be unduly invasive or restrictive.
- (7) There must be reasonable arrangements in place for ensuring that the requirements of sections 32 and 33 will be met.