

RECOMMENDATIONS FOR RESEARCH ON PEOPLE WHO LACK CAPACITY

1. The recommendation is to adopt the main features of sections 30 – 34 of the MCA so that research may only be undertaken on people who lack capacity provided the following conditions are satisfied:
 - a) The research is approved by an *ethics committee*.
 - b) *An Impairing condition*: the research must be connected with the cause or treatment of the condition affecting the potential research participant.⁸³²
 - c) The *necessity condition*: research of a similar nature cannot be carried out with comparable effectiveness on an adult who is capable of consenting to participate.⁸³³
 - d) *Balancing the benefits and burdens of research*: the research must have either (a) the potential to benefit the person without imposing a disproportionate burden, or (b) is intended to provide knowledge of the causes or treatment of, or care of persons affected by, the same or similar conditions.⁸³⁴
 - e) There is *minimal risk*: If the research falls into category (b) above, there must be reasonable grounds for believing that both the risks to the person from taking part in the project are likely to be negligible, and it will be minimally invasive or restrictive.⁸³⁵
 - f) *Consultees*: researchers must take reasonable steps to identify an appropriate person who is interested in the participant's welfare and can advise the researcher of the participant's likely wishes and feelings – if they had capacity – about taking part, and their continued involvement in the research; as well as the ability to appoint independent advocates.⁸³⁶
 - g) *Additional safeguards for "dissent"*: nothing may be done to the person in relation to research to which the person appears to object, or which is contrary to any effective prior statement.
 - h) *Emergency care research*: an opinion from an independent doctor, or, if this is not practicable, following an agreed process with an ethics committee.
 - i) *Innovative treatment and practice*: is included within the scope of ethical review.

⁸³² Mental Capacity Act 2005, s 31(2).

⁸³³ Mental Capacity Act 2005, s 31(4).

⁸³⁴ Mental Capacity Act 2005, s 31(5).

⁸³⁵ Mental Capacity Act 2005, s 31(6).

⁸³⁶ Mental Capacity Act 2005, ss 32(2) and (4).