Criteria for approving research under sections 30-33 of the Mental Capacity Act

	Criterion	*Evidence**
1	The research is connected with an impairing condition affecting participants who are unable to consent, or with the treatment of the condition.	SQ1
2	The research could not be carried out as effectively if it was confined to participants able to give consent.	SQ2
3	Either of the following apply: (a) The research is of potential benefit to participants without imposing a disproportionate burden (b) The research is intended to provide knowledge of the causes or the treatment or care of the condition affecting the participants or of a similar condition. If (a) does not apply, the following criteria must also be met: (c) The risk to participants is negligible (d) The research will not significantly interfere with their freedom of action or privacy (e) The research is not unduly invasive or restrictive.	 A18, SQ4 A9, SQ5 A16, SQ6 A14, A17, SQ6 A14, A17, SQ6
4	Reasonable arrangements are in place to consult another person ("consultee") for advice on whether the participant should take part and on what the participant's wishes and feelings might be. In particular: (a) Steps will be taken to identify a consultee who is engaged in caring for the participant or is interested in their welfare, but not in a professional capacity or for remuneration (b) If a person cannot be found under (a), arrangements are in place for a consultee *who has no connection with the project* to be nominated by the appropriate authority (e.g. NHS Trust, local authority social services department, private care home).	SQ7, SQ9
5	Appropriate information is to be provided to consultees about: (a) their role and responsibilities, including possible consultation throughout the project (b) the project.	Information sheet

6	If a participant might need to be treated urgently, appropriate arrangements are in place to seek agreement from a doctor who is not connected in the project where practicable. If not practicable, other appropriate arrangements are in place to decide on the inclusion of the participant.	SQ8
7	The REC is satisfied that a participant will be withdrawn if the consultee so advises or the participant indicates they wish to be withdrawn (unless the discontinuation of treatment would put their health at significant risk).	SQ12
8	The REC is satisfied that nothing will be done in the course of the research: (a) to which participants appear to object (unless it is to protect them from harm or reduce/prevent pain or discomfort) (b) which would be contrary to an advance decision or statement made by a participant.	 SQ13 SQ14
9	The REC is satisfied that the research will be conducted in such a way that the interests of participants will outweigh those of science and society.	Discussion with researcher

* Key: A = Question in Part A of on-line REC application form
SQ = Question in supplementary form for section 30 approval (form MCA1)