

SCHEDULE 1

Regulation 3(c)

Requirements which the project must satisfy

1. A protocol approved by an appropriate body and having effect in relation to the project makes provision for research to be carried out in relation to a person who has consented to take part in the project but loses capacity to consent to continue to take part in it.
2. The appropriate body is satisfied that there are reasonable arrangements in place for ensuring that the requirements of Schedule 2 will be met.

SCHEDULE 2

Regulation 3(d)

Steps which the person conducting the project must take

1. R must take reasonable steps to identify a person who—
 - (a) otherwise than in a professional capacity or for remuneration, is engaged in caring for P or is interested in P's welfare, and
 - (b) is prepared to be consulted by R under this Schedule.
2. If R is unable to identify such a person he must, in accordance with guidance issued by the Secretary of State, nominate a person who—
 - (a) is prepared to be consulted by R under this Schedule, but
 - (b) has no connection with the project.
3. R must provide the person identified under paragraph 1, or nominated under paragraph 2, with information about the project and ask him—
 - (a) for advice as to whether research of the kind proposed should be carried out in relation to P, and
 - (b) what, in his opinion, P's wishes and feelings about such research being carried out would be likely to be if P had capacity in relation to the matter.
4. If, at any time, the person consulted advises R that in his opinion P's wishes and feelings would be likely to lead him to wish to withdraw from the project if he had capacity in relation to the matter, R must ensure that P is withdrawn from it.
5. The fact that a person is the donee of a lasting power of attorney given by P, or is P's deputy, does not prevent him from being the person consulted under paragraphs 1 to 4.
6. R must ensure that nothing is done in relation to P in the course of the research which would be contrary to—
 - (a) an advance decision of his which has effect, or
 - (b) any other form of statement made by him and not subsequently withdrawn,of which R is aware.
7. The interests of P must be assumed to outweigh those of science and society.
8. If P indicates (in any way) that he wishes the research in relation to him to be discontinued, it must be discontinued without delay.
9. The research in relation to P must be discontinued without delay if at any time R has reasonable grounds for believing that the requirement set out in paragraph 1 of Schedule 1 is no longer met or

that there are no longer reasonable arrangements in place for ensuring that the requirements of this Schedule are met in relation to P.

10. R must conduct the research in accordance with the provision made in the protocol referred to in paragraph 1 of Schedule 1 for research to be carried out in relation to a person who has consented to take part in the project but loses capacity to consent to continue to take part in it.