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to lead him to wish to withdraw from the project if he had capacity in relation to the matter, R must ensure that P is withdrawn from it.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- (b) any other form of statement made by him and not subsequently withdrawn, of which R is aware.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

1

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.