MCA 2005 Consultation on Draft Research Regulations: A Response from HEAL UoS (Health Ethics and Law, University of Southampton).

About HEAL UoS:

This response is the product of discussion by members of HEAL UoS. This is an interdisciplinary group of academics and clinicians who are associated with the University of Southampton. It is **not** a formal response from the University as an institution but reflects the views of members of the network. On a number of points the range of views is recorded rather than a single conclusion on the consultation questions. As one might expect, not every individual is of the same view.

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Q1 – Views sought on whether the proposed arrangements for appointing the appropriate body that approves research are suitable?

We do not believe that, as currently constituted, all RECs have sufficient expertise and experience routinely to be approved as 'appropriate bodies' for research under Sections 30-32 of the MCA 2005. Assessing capacity in research contexts is a skilled exercise and our experience indicates that not all ethics committees have members with that experience.

In relation to paragraph 16 of the consultation, we believe the draft regulations need to set out explicitly the criteria for expertise to consider the ethics of research falling under the MCA 2005. In addition, paragraph 17 of the consultation document is insufficiently specific in defining the training and competences required.

We are aware of particular confusion about which disciplines have the skills to assess capacity. We are particularly concerned that Ethics Committees and lawyers often look to psychiatry as the most appropriate discipline when in fact psychiatrists deal with the abnormal. The more appropriate discipline to assess competence would seem to be psychology. We would therefore recommend that no REC should be approved as an appropriate body without psychological expertise (either by membership or co-option).

We believe that the training ought to facilitate/enhance ethics committee members' good understanding of the value of research that may not be obviously generalisable (e.g. small scale, qualitative or exploratory studies). Experience shows that RECs often underestimate the value of qualitative, psychological, small scale or exploratory research studies and may well overestimate the potential risks. This difficulty is exacerbated in relation to people with incapacity where RECs are, quite properly, risk averse. However,

the consequence of this is to deny individuals who lack capacity the benefits of such research.

Therefore, training in appropriate ways to assess the risks and benefits is required. Our experience in relation to non-clinical trials is that RECs tend to overestimate psychological risks and underestimate the potential benefits. For example, participants with Alzheimer's disease in a qualitative interview study exploring their coping with the disorder described the process of talking to the researcher as in itself helpful. These benefits were experienced despite the process at times being distressing but were still seen as of net assistance (Preston, Marshall & Bucks, 2006).

In a second example, one of our members has experience of an ethics committee ruling out, *on principle*, interview research with the recently bereaved. In our view, while it would always be appropriate to consider whether or not the possible distress is justified, whether it was or not would require consideration of a range of factors including the circumstance of the bereavement, the research methods being used, the skills and experience of the researchers, how the participants are being approached and the likely benefit of the research (Dyregrov, 2004; see also Scott et al., 2002).

Finally, the training would need to include consideration of the roles of the carers/family members and issues of confidentiality. Alongside these, we recommend that appropriate processes for informing and involving carers in research, even where they are not themselves research participants, be identified.

Q2 – Views sought whether the proposed arrangements for research involving people who consented but then lost capacity strike the right balance between the need to allow long-term research to continue whilst respecting the past and present wishes of participants?

We believe that the key principle is that the patient's wishes be honoured. Our recommendation is that, in a trial where it is likely that the participants will lose capacity, an LPA (Lasting Power of Attorney - welfare) should be appointed as part of the research recruitment process.

However, in circumstances where an LPA has not been appointed, we do not see how anybody other than someone to whom the participant has given a lasting power of attorney can be in a position to make a reliable judgment of what the participant's wishes and feelings would be. We would recommend that trial designs include discussion at the outset with the patient about whom should be consulted should the patient lose capacity. Such a person could legitimately be consulted even if they are not formally appointed with an LPA. In the absence of someone being identified by the participant, we believe that the protection provided by Section 33 (which stops anything being done to the patient to which they object) provides adequate safeguards.

We therefore believe that Schedule 2 to the draft MCA 2005 (Loss of Capacity during Research Project) (England) Regulations 2006 should be amended so as to indicate that only people appointed by the participant, either as the donee of an LPA or specifically as part of recruitment to the research project, can be a consultee.

In circumstances where the individual was not anticipated to lose capacity, we believe that respect for their autonomy requires that their consent should be regarded as of continuining validity unless they appear to object. In which case Section 33 of the MCA 2005 ('appears to object') already provides adequate protection.

References

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Scott, D.A., Valery, P.C., Boyle, F.M., Bain, C.J. (2002) 'Does research into sensitive areas do harm? Experiences of research participation after a child's diagnosis with Ewing's sarcoma' *Medical Journal of Australia*, 177, 507-10.