

27 May 2010

Dr Robert Frost
Academy of Medical Sciences
10 Carlton House Terrace
London SW1Y 5AH

Dear Rob

Call for evidence: Review of the regulation and governance of medical research

I am writing in response to your call for evidence to inform the Academy of Medical Sciences' current review of the regulation and governance of medical research.

Drawing on the recently published report of the Nuffield Council on Bioethics, *Dementia: ethical issues*, I would like to raise a number of points in relation to research on dementia. Paragraph and chapter numbers in brackets refer to the Council's report.

Policies for allocating funds for research

We are struck by the fact that the major research funding bodies within the UK do not appear to have explicit policies according to which they allocate funds between different conditions, focusing rather on research excellence and the 'importance' of the topic. While it is clearly appropriate that funding bodies support important and high quality research, criteria such as these do not, alone, ensure a just distribution between the needs of different parts of the population.

We believe that major research funders should be more explicit as to how they divide their research funds between areas of research that have the capacity to benefit very different groups of the population. Given the social and economic impact of dementia, we believe that a more explicit approach to research priorities would be likely to lead to significant increases in research funding for dementia. If such an increase were not to be matched by research applications of the necessary high standard, then active steps should be taken to develop and promote research capacity in the relevant areas (paragraph 8.17).

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On the question of how funding should be prioritised *within* dementia research, we recognise that it is difficult to give one type of research priority over others. However, **we recommend that relevant research funders consider ways in which the level of funding for dementia research could be increased in the following areas: health services research into how people with dementia and their carers can best be supported to live well, how mainstream services can best be adapted to their needs, and how good practice can more readily be implemented; more meaningful outcome measures for assessing the effect of particular forms of treatment or service; research into how best to improve the provision of support for ethical decision making; all forms of research for the non-Alzheimer's dementias; and research into preventative strategies.**

Involving people with dementia in research

There are clearly good ethical reasons, based on concern for people's autonomy and well-being, for ensuring that strong safeguards are in place to protect people who lack capacity from being harmed by research. However, at the same time there is a risk that, if the procedural bar is set too high, people with dementia will be excluded altogether from research. This, in turn, would be discriminatory: it would prevent people with dementia from acting altruistically when they have autonomously expressed a wish to do so, and would reduce the chance of better treatment and care both now and in the future. **We believe that the current legal safeguards are an appropriate way of protecting people with dementia from harm. However, we believe that action should be taken to make it easier to allow those who have expressed a wish to take part in research to do so** (paragraph 8.44). In particular, we highlight the following:

- The importance of good clinical trial networks which bring together clinicians and people with dementia who are interested in helping with clinical trials of promising interventions.
- The importance of researchers carefully considering the possible effects of the trial on the person with dementia *beyond* the end of the trial period.
- The potential benefits of people using advance decisions and advance care planning to state their views and wishes regarding their participation in research in the future. Such views and wishes could, with appropriate safeguards, provide a basis for participation in research at a time when the person lacks capacity to consent.

- The difference between the systems in England/Wales and Scotland as regards the power of welfare attorneys to consent to research: in Scotland welfare attorneys have this power while in England and Wales they do not.

We recommend that the UK Departments of Health should commission research on the feasibility of developing some form of (non-binding) advance statement on research participation which could influence decisions on research participation after loss of capacity.

We recommend that serious consideration be given to enable the role of the welfare attorney in England and Wales to be explicitly extended to include decisions over research, both within the Mental Capacity Act and the Clinical Trials Regulations. In the meantime we recommend that the Mental Capacity Act Code of Practice should provide guidance on the role of the welfare attorney in decisions about participation in research governed by the Mental Capacity Act.

We further recommend that the mental capacity Codes of Practice should include clear guidance on the procedures to be followed when capacity is lost during involvement in a research project covered by the Act, to minimise the risk of research results being compromised as a result of people dropping out of research despite their initial wish to participate. (Paragraph 8.44)

The general principles of research governance and consent are, we believe, broadly correct. The practice, however, can place unnecessary barriers in the way of research in dementia. In particular:

- **The bureaucratic procedures around research ethics approval can be cumbersome for researchers. We encourage current attempts by the Department of Health to simplify the procedures, particularly in the context of low-risk research.**
- **The ability of people with dementia to give, or withhold, valid consent to research should not be underestimated. The information provided both in written and verbal form, however, may need to be provided in a different form for people with some cognitive impairment compared with people without such impairment. Both researchers and ethics committees should adapt the informing process in a way to enable, rather than to exclude, people with dementia in making a valid decision as to whether or not to participate in research (paragraph 8.45).**

The Council's report *Dementia: ethical issues* is available to download at www.nuffieldbioethics.org/dementia. A copy will also be posted to you, along with a hard copy of this response.

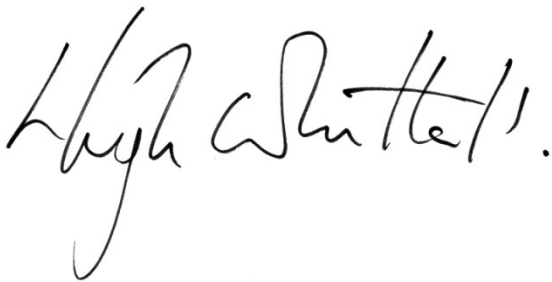
Donation of human tissue for research

The Academy may also be interested to know that the Council has set up a Working Party to consider the ethical issues raised by the donation of human bodies in medical treatment and research, which met for the first time in January 2010. Among other issues, the group is considering the issues raised by the donation of human bodily materials for research, for example related to increasing supply, obtaining consent, and ownership and control.

The group is currently holding a public consultation which closes on 13th July. A report with recommendations for policy and practice will be published in autumn 2011. Further information is available at: www.nuffieldbioethics.org/bodies.

Please do not hesitate to contact me if you would like further information or assistance.

Yours sincerely

A handwritten signature in black ink that reads "Hugh Whittall". The signature is written in a cursive style with a large, sweeping initial 'H'.

Hugh Whittall
Director