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The PHG Foundation's Response to the consultation by the Department of Health: 'Guidance on nominating a consultee for research involving adults who lack capacity to consent.'

Introduction

1. The PHG Foundation is an independent charity and the successor body to the Public Health Genetics Unit and the Cambridge Genetics Knowledge Park. It works to gain maximum health benefit through the responsible and evidence based application of biomedical science. Our objectives include fostering a social and regulatory environment which is receptive to the application of biomedical science for health, but at the same time imposing an appropriate, equitable and proportionate regulatory burden.

General Comments

2. We welcome the forthcoming implementation of the Mental Capacity Act and the clarity that the Act will provide to health care professionals, carers and researchers. We have a longstanding interest in the regulation of research involving those lacking capacity to consent[1] taking the view that legitimate research, particularly that carried out as a matter of urgency in Accident and Emergency departments or in intensive care units, should not be precluded or made more onerous by the introduction of a formal legal framework, subject to appropriate safeguards.

3. We support the proposed Guidance on the basis that it reinforces these safeguards, in particular the need for researchers to respect core ethical principles, be subject to independent ethical scrutiny and to be seen to act with probity and integrity. In our view, the Guidance will be helpful in promoting public trust in, and support for bio-medical research by seeking to make the selection of nominated consultees for research demonstrably transparent.

Detailed Comments

Fluctuating Capacity

4. However, we are concerned that insufficient account has been taken of research involving those with fluctuating capacity. Although specific provisions[2] in the Mental Capacity Act allow for research to continue even if research subjects lose capacity during a research project, these provisions have limited application, as they provide only for continued use of material or information obtained before the participant's loss of capacity. They do not allow for the ongoing collection of data

[1] Publications include K. Liddell, D. Menon, and R. Zimmern (2004) The human tissue bill and the mental capacity bill *BMJ* 328;1510-1511.
[2] Section 34 Mental Capacity Act 2005 and the Mental Capacity Act 2005 (Loss of Capacity during Research Project) (England) Regulations S.I. 2007 No. 679.

or material within a project and apply only to projects started before 1 October 2007. Moreover, the establishment of a functional definition of capacity within the Mental Capacity Act implies that a significant number of research projects may simultaneously involve both activities for which a prospective subject may be competent to consent and others for which they will lack competence.

5. The Guidance does not clarify the role of the nominated consultee in the context of fluctuating capacity. One question is the extent to which the consent of a nominee is regarded as enduring notwithstanding P regaining competence. Legal precedent suggests that such consent could be regarded as enduring. For example, the Human Tissue Act[3] establishes that consent given by a parent for the retention, storage and use of human material from a child for research purposes is regarded as enduring notwithstanding the child attaining competence. There is no obligation in the Human Tissue Act or Codes of Practice which requires those using tissue to seek renewed consent from the child who has attained competence, or even to inform them of their parents actions.

6. In other situations, such as where P loses and gains competence many times in a very short period, the lack of guidance as to the durability of the consent given by the nominee may impose a considerable practical burden. The Mental Capacity Act requires that those seeking consent consider as far as reasonably practicable when and if P is likely to regain capacity[4] in the future. However, this obligation may be difficult to reconcile with research protocol and it may be impractical to seek renewed consent from the nominee every time the research participant loses capacity. Prospective researchers are now required to provide additional information to NRES (in the form of a supplementary questionnaire) as part of their application for ethical review which questions the burden placed upon nominees during the course of research, and the incidence and treatment of fluctuating capacity amongst research participants[5]. This suggests a need for specific advice in this area.

7. In our view this advice should include clarification as to the arrangements that are permissible in the event of fluctuating capacity. One way forward may be to adopt a presumption that the ongoing participation of the research subject in the trial is legitimate, despite periods of intervening capacity, rebuttable upon any material change of circumstances and/or veto by the research subject (when capable) or the nominee. The Guidance could also be more explicit about other mechanisms by which a consistent approach to participation in research could be achieved without the need for nominated consultees, such as encouraging the competent research subject to make an advance decision to continue participating in research or to grant a lasting power of attorney.

Ensuring independence

8. It would be helpful if the Guidance could clarify whether a treating clinician or carer would be disqualified from acting as a nominated consultee, if they had previously approached a potential personal consultee, with a view to enrolling P in the

[3] Human Tissue Act 2004, section 2(3).
[4] Section 4(3) and 4(4), Mental Capacity Act 2005.
[5] National Research Ethics Service, MCA1- supplementary information form (section 30) Version 1, 25 June 2007.

research. Namely, does the interpretation of the phrase ‘connected with the research’ extend to communications made on behalf of the research team by treating clinicians as envisaged by page 7 of the Guidance?

Ensuring that research is free from potential influence

9. We question whether ‘seniority’ is the ethically relevant issue in securing that a prospective nominated consultee is ‘free from potential influence’ (page 10). Our concern is that these words, broadly interpreted, could result in all those who are ‘junior to a member of the research team’ being excluded from acting as proposed nominated consultees, with the result that it may be impossible to proceed with research in many of the emergency situations that are contemplated by the Guidance. We would prefer to see the wording explicitly exclude situations in which there is a possibility of a potentially coercive relationship or where a member of a research team has direct managerial responsibility for the proposed nominated consultee.

10. We would like to see the potential remit of the consultee on page 9 being extended to consideration of P’s past views and preferences rather than being limited to current concerns: the use of the present tense in this context may be unduly restrictive.

PHG Foundation
14 September 2007