REGULATORY APPRAISAL

MENTAL CAPACITY, WALES

THE MENTAL CAPACITY ACT 2005 (LOSS OF CAPACITY DURING RESEARCH PROJECT) (WALES) REGULATIONS 2007

Background

1. The Mental Capacity Act 2005 provides a statutory framework for people who may not be able to make their own decisions, for example because of a learning disability, an illness such as dementia or brain injury or mental health problems. The Act sets out who can take decisions, in which situations, and how they should go about this.

2. The Act enshrines in statute current best practice and common law principles concerning people who lack mental capacity and those who take decisions on their behalf. In Section 30 to 34, the Act also provides a statutory framework for research involving people who lack capacity to consent to their participation.

3. These Regulations deal with general research projects, which could be affected as a result of research subjects losing capacity during the course of such projects. These Regulations balance the importance of properly conducted research and the treatment and care of people who lack capacity with the need to protect their feelings and respect their current and previously expressed wishes and feelings.

4. These Regulations have been prepared to achieve congruence with the corresponding Regulations being developed in England by the Department of Health. A considerable amount of research takes place involving participants from both England and Wales and there are a number of joint initiatives underway to make the process for undertaking research for researchers more consistent, therefore, it is appropriate that cross-border research studies are subject to similar arrangements in both England and Wales.

Purpose and intended effect of the measure

5. In order to retain flexibility in certain aspects relating to research, regulation-making powers have been provided to cater for aspects such as transitional arrangements for existing research projects, especially for long-term studies that may involve people who consented but then lost capacity.

6. Section 34 of the Act provides a regulation making power, which may set out the arrangements to apply where a person had given consent to a study but who loses capacity before the end of the project.

7. These Regulations only apply where a person has consented prior to 31 March 2007 to take part in a research project, which started before 1 October 2007, but before the end of the project loses capacity to consent

to continuing in that project and where such consent would otherwise be necessary. The Regulations allow a researcher to continue to use information or material obtained prior to the research subject losing capacity to consent. The Regulations set out that information or data is either data within the meaning of the Data Protection Act 1998, or material that consists of or includes human cells or DNA. The continuation of the project is subject to meeting the requirements of Schedules 1 and 2. Schedule 1 requires that an 'appropriate body' has approved a protocol making appropriate provision for such research to be carried on (subject to certain safeguards being met, as referred to in the paragraphs below).

8. The appropriate body must be satisfied, in particular, that arrangements are in place to meet the safeguards in Schedule 2. Schedule 2 repeats the relevant safeguards set out in sections 32 and 33 of the Act (namely the requirement to consult carers on the wishes and feelings of the research subject, to withdraw from undertaking research in respect of a person who either appears to object or has made an advance decision or statement indicating that he or she wishes to be withdrawn from the project. Further safeguards are included, more particularly that the interests of the research subject must be assumed to outweigh the interests of science and society.

9. These Regulations do not apply to existing studies on which people were enrolled who lacked capacity at the time of enrolment (for example, ongoing projects involving adults with dementia or learning difficulties). Additionally, the Regulations will not apply to situations where researchers wish to go back to a person who lacks capacity in order to take more tissue or DNA samples or data. Such projects will need to have separate approval under section 30 of the Act when it is commenced in 2007.

Risk Assessment

10. Failure to make these Regulations would mean that the research studies already in place, in so far as they relate to persons who lose capacity, could no longer lawfully continue in Wales because there would be no legal basis for them. Furthermore, it would result in patients in Wales being treated differently to those in England.

Options

Option 1: Do Nothing

11. The Mental Capacity Act 2005 applies across England and Wales. Failure to make these Regulations would mean that the existing research projects involving people who lack the capacity to consent would not be able to lawfully continue.

Option 2: Make the Regulations

12. The purpose of the Regulations is to allow for the continuation of ongoing research involving persons who lose capacity, providing that safeguards are met, namely the provision of a protocol approved by an appropriate

body and making appropriate arrangements for consultation about a research subject's wishes and feelings.

Costs

13. The funding for the Mental Capacity Act 2005 in 2007-08 for Wales is £1.113m. There are no additional financial implications for the Welsh Assembly Government or others arising from the making of these Regulations. The Welsh Assembly Government have a service level agreement in place with the Central Office for Research Ethics Committees (COREC) (National Patient Safety Agency), which includes an operational, support and training service to Research Ethics Committees (RECs) in Wales. COREC provides help and leadership for RECs and the REC system by co-ordinating the development of operational and infrastructure arrangements in support of their work. The SLA totals £53,800 per annum, and new activities arising from the introduction of the Mental Capacity Act 2005 are covered within this service level agreement.

Benefits

14. The introduction of these Regulations will ensure that those individuals who lack capacity will receive greater protection as specified in the Mental Capacity Act 2005. It will assist in decisions being taken in their best interests.

Consultation

With Stakeholders

15. These Regulations were subject to formal consultation from 29 August 2006 to 6 November 2006. Views were sought on whether the proposed arrangements for research involving people who consented but then lost capacity are appropriate, in order to strike the right balance between the need to allow long-term research to continue whilst respecting the past and present wishes of participants.

16. Key stakeholders were invited to comment on the draft Regulations, including: healthcare professionals, the voluntary sector, NHS Trusts, Local Health Boards and local authorities, Research Ethics Committees, organisations representing healthcare professionals, community health councils and other regional and national stakeholder organisations representing people who lack capacity. A list of consultees is attached at Annex A. One formal consultation response was received, of which no substantial alterations were suggested. The response was not relevant to these Regulations, but focused on the IMCA Regulations and has been covered in the Regulatory Appraisal submitted with those Regulations. As a result, no amendments to the policy have been made.

Consultation

With Subject Committee

17. These Regulations were notified to the Health and Social Services Committee, via the list of forthcoming legislation, on 25 May 2005

(HSS(2)-07-05(p.1a) item no: HSS 02 (05)) and have remained on the list ever since. The Regulations were identified for detailed scrutiny.

18. The Health and Social Services Committee considered the Regulations at its meeting on 13 December 2006. No amendments to the Regulations were proposed.

19. The Committee was content with the Regulations as drafted. No points of clarification were raised by the Committee in relation to these Regulations. A transcript of the committee discussion is attached at Annex B.

Review

20. The relevant Research Ethics Committees will receive training on their remit under the Regulations. Review and monitoring procedures are currently being developed within existing standards and processes in place for Research Ethics Committees. The Welsh Assembly Government will also review the Regulations after 3 years.

Summary

21. These proposed Regulations particularly deal with research projects, which could be affected as a result of research subjects losing capacity during the course of such projects. The provisions under section 30 to 34 balance the importance of properly conducted research and the treatment and care of people who lack capacity with the need to protect their feelings and respect their current and previously expressed wishes and feelings. The purpose of the Regulations is to allow for the continuation of ongoing research involving persons who lose capacity provided safeguards are met. Such safeguards include the existence of a protocol and arrangements ensuring that there are appropriate arrangements for consultation about a research subject's wishes and feelings.

ANNEX A

Letter to stakeholders regarding consultation on the Mental Capacity Act 2005 draft Research Regulations

List of Welsh Stakeholders:

NHS Trust R&D Directors

NHS Trust R&D Managers

R&D committee members

Active Researchers

Research nurses/coordinators

Patient and Carer representative groups

LHB R&D leads

Higher Education Institute R&D offices

REC Chairs & Coordinators

Annex B

Is-ddeddfwriaeth: Deddf Galluedd Meddyliol 2005
Secondary Legislation: Mental Capacity Act 2005

[2] **Rhodri Glyn Thomas:** Mae nifer o faterion i'w trafod o ran is-ddeddfwriaeth. Mae'r cyntaf ar Ddeddf Galluedd Meddyliol 2005, ac mae Helen Mary Jones yn dymuno codi pwynt o eglurhad.

Rhodri Glyn Thomas: There are many issues to be discussed in terms of secondary legislation. The first is on the Mental Capacity Act 2005, and Helen Mary Jones wishes to raise a point of clarification.

[3] **Helen Mary Jones:** Does the Government have any intention to make provision, under section 41, to offer an independent advocate even to those individuals who may have families or carers available?

[4] **The Minister for Health and Social Services (Brian Gibbons):** The main provision under this legislation is made if the person is at risk from violence or abuse, particularly in an adult situation. In those circumstances, even though there may be relatives to hand or available, there is discretion for the use of independent mental capacity advocates.

[5] **Helen Mary Jones:** The concern has been raised in a number of contexts—with vulnerable adults and children—that the interests of families and carers do not always coincide with what is best for the service user, even though they may have the best of intentions. Of course, in the kind of situations that we are talking about here, it is possible that the risk of abuse may arise from within the family. Will you say a bit more about who will have the discretion and how it might be exercised? If you have a situation where you have a family member who is articulate and able to use his or her voice and a service user who is not, my concern is where that discretion will kick in and whose discretion it will be.

[6] **Brian Gibbons:** By definition, the potential victims will not be able to speak up for themselves because if they were able to do so, they would not be in that situation. It will be at the discretion of the local health board or the local authority. There are two situations in which it will be mandatory to have the advocate in place and two situations in which there will be discretion, one of which is a review of a change of accommodation and so on. However, this is the second situation. The answer is that we will be relying on the professionalism of the local health board or the local authority to make that decision. I think that whoever is involved, be it a social worker or whoever, as in many of these situations, we are dependent on the professional judgment of the lead worker.

[7] **Helen Mary Jones:** That is helpful, Minister, and obviously that is a judgment on which we can normally rely. Am I right in understanding that there will be a specific code of practice on how these guidelines will be used? In that context, can you clarify whether there will be a separate code for Wales or whether it will be a joint code, and whether it will allow for the provision of advocacy in the language of choice?

[8] **Brian Gibbons:** That goes without saying. In Wales, Welsh would obviously be a big part of it, but in other parts of the United Kingdom, or in England as compared with Wales, the choices would be different.

[9] **Helen Mary Jones:** I would just say that there are occasions, sometimes, Minister, where things that go without saying go without doing as well, so it was a point worth raising.