CYNULLIAD CENEDLAETHOL CYMRU

OFFERYNNAU STATUDOL

2007 Rhif 837 (Cy.72)

GALLUEDD MEDDYLIOL, CYMRU

Rheoliadau Deddf Galluedd Meddyliol 2005 (Colli Galluedd yn ystod Prosiect Ymchwil) (Cymru) 2007

NODYN ESBONIADOL

(Nid yw'r nodyn hwn yn rhan o'r Rheoliadau.)

Caiff y Rheoliadau hyn eu gwneud o dan adrannau 30, 34, 64 a 65 o Ddeddf Galluedd Meddyliol 2005 (p.9) ("y Ddeddf"). Maent yn darparu ar gyfer ymchwil penodol, sy'n ymwneud â phobl heb y galluedd i gydsynio iddo, i gyflawni'n gyfreithlon yr hyn y byddai fel arall yn rhaid cydymffurfio â gofynion adran 30 o'r Ddeddf.

Mae'r Rheoliadau hyn yn gymwys o ran cyflawni ymchwil yng Nghymru.

Mae rheoliad 1 yn darparu i'r Rheoliadau ddod i rym ar 1 Gorffennaf 2007 at ddibenion galluogi ceisiadau ar gyfer cymeradwyo protocolau ymchwil o dan y Rheoliadau i gael eu gwneud a'u penderfynu ac at bob diben arall ar 1 Hydref 2007.

Mae rheoliad 2 yn darparu bod y Rheoliadau'n gymwys pan fo prosiect ymchwil wedi dechrau cyn 1 Hydref 2007 a bod person ("P") wedi cydsynio, cyn 31 Mawrth 2008, i gymryd rhan yn y prosiect ond ei fod wedyn wedi colli'r galluedd i barhau i gydsynio.

Mae rheoliad 3 yn darparu y gellir cyflawni ymchwil sy'n defnyddio gwybodaeth neu ddeunydd a gasglwyd cyn i P golli galluedd. Rhaid bod yr wybodaeth neu'r deunydd naill ai'n ddata o fewn ystyr Deddf Diogelu Data 1998 (p.29) neu'n ddeunydd sy'n gelloedd dynol neu'n DNA neu'n eu cynnwys. Yn ychwanegol, mae'n darparu bod yn rhaid cydymffurfio â gofynion Atodlenni 1 a 2.

NATIONAL ASSEMBLY FOR WALES

STATUTORY INSTRUMENTS

2007 No. 837 (W.72)

MENTAL CAPACITY, WALES

The Mental Capacity Act 2005 (Loss of Capacity during Research Project) (Wales) Regulations 2007

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made under sections 30, 34, 64 and 65 of the Mental Capacity Act 2005 (c.9) ("the Act"). They provide for certain research, relating to people without capacity to consent to it, to be carried out lawfully where otherwise the requirements of section 30 of the Act would have to be complied with.

These Regulations apply in relation to research carried on in Wales.

Regulation 1 provides for the Regulations to come into force on 1 July 2007 for the purpose of enabling applications for approval of research protocols under the Regulations to be made and determined and on 1 October 2007 for all other purposes.

Regulation 2 provides that the Regulations apply where a research project began before 1 October 2007 and a person ("P") consented, prior to 31 March 2008, to take part in the project but has subsequently lost capacity to continue to consent.

Regulation 3 provides that research may be carried out using information or material collected prior to P's loss of capacity. The information or material must be either data within the meaning of the Data Protection Act 1998 (c.29) or material which consist of or includes human cells or DNA. In addition, it provides that the requirements of Schedules 1 and 2 must be complied with.

Mae Atodlen 1 yn darparu bod yn rhaid bod corff priodol wedi cymeradwyo protocol ar gyfer y prosiect o ran ymchwil sydd i'w gyflawni ynglŷn â pherson sydd wedi cydsynio i gymryd rhan ac yna wedi colli galluedd. Rhaid bod y corff priodol hefyd wedi'i fodloni bod trefniadau rhesymol ar gael i sicrhau y byddir yn cydymffurfio ag Atodlen 2.

Diffinnir 'corff priodol' yn rheoliad 1 drwy gyfeirio at Reoliadau Deddf Galluedd Meddyliol 2005 (Corff Priodol) (Cymru) 2007 2007/833 (Cy.71). 'Corff priodol' yw pwyllgor-

(i) a sefydlwyd i gynghori ar foeseg ymchwil ymwthiol ynglyn â phobl nad yw'r galluedd ganddynt i gydsynio iddo neu i gynghori ar faterion sy'n cynnwys y foeseg honno; a

(ii) a gydnabyddir at y dibenion hynny gan Gynulliad Cenedlaethol Cymru.

Mae i 'ymchwil ymwthiol' yr ystyr a roddir i '*intrusive research*' yn adran 30(2) o'r Ddeddf.

Mae Atodlen 2 yn gosod gofynion o ran ymgynghori ynghylch cyfranogiad P yn y prosiect, o ran parchu ei ddymuniad a'i wrthwynebiad ac o ran tybio bod ei fuddiannau'n gorbwyso buddiannau gwyddoniaeth a chymdeithas.

Mae Arfarniad Rheoliadol wedi'i baratoi ar gyfer Deddf Galluedd Meddyliol 2005 a gosodwyd copi ohono yn llyfrgell Cynulliad Cenedlaethol Cymru.

Schedule 1 provides that an appropriate body must have approved a protocol for the project with respects to research to be carried out in relation to a person who has consented to take part and then lost capacity. The appropriate body must also be satisfied that there are reasonable arrangements for ensuring that Schedule 2 will be complied with.

'Appropriate body' is defined in regulation 1 by reference to the Mental Capacity Act 2005 (Appropriate Body) (Wales) Regulations 2007 2007/833 (W.71). An 'appropriate body' is a committee which is-

(i) established to advise on, or on matters which include, the ethics of intrusive research in relation to people who lack capacity to consent to it, and

(ii) recognised for those purposes by the National Assembly for Wales.

'Intrusive research' is defined in section 30(2) of the Act.

Schedule 2 sets out requirements as to consultation about P's involvement in the project, as to respecting his or her wishes and objections and as to assuming that his or her interests outweigh those of science and society.

A Regulatory Appraisal has been prepared for the Mental Capacity Act 2005 and a copy has been placed in the library of the National Assembly for Wales.

2007 Rhif 837 (Cy.72)

GALLUEDD MEDDYLIOL, CYMRU

Rheoliadau Deddf Galluedd Meddyliol 2005 (Colli Galluedd yn ystod Prosiect Ymchwil) (Cymru) 2007

Wedi'u gwneud *13 Mawrth 2007*

Yn dod i rym

At y diben a grybwyllir yn rheoliad 1(1)(a) *1 Gorffennaf 2007*

At bob diben arall *1 Hydref 2007*

Mae Cynulliad Cenedlaethol Cymru yn gwneud y Rheoliadau canlynol drwy arfer y pwerau a roddwyd iddo gan adrannau 30(6), 34(1), (2) a (3), 64(1) a 65(1) o Ddeddf Galluedd Meddyliol 2005(**1**).

Enwi, cychwyn, cymhwyso a dehongli

1.-(1) Enw'r Rheoliadau hyn yw Rheoliadau Deddf Galluedd Meddyliol 2005 (Colli Galluedd yn ystod Prosiect Ymchwil) (Cymru) 2007 a deuant i rym -

(a) ar 1 Gorffennaf 2007 at ddibenion galluogi ceisiadau ar gyfer cymeradwyaeth at ddibenion Atodlen 1 i gael eu gwneud i gorff priodol ac i gael eu penderfynu ganddo,

(b) ar 1 Hydref 2007 at bob diben arall.

(2) Mae'r Rheoliadau hyn yn gymwys o ran Cymru.

(3) Yn y Rheoliadau hyn-

ystyr "y Ddeddf" ("*the Act*") yw Deddf Galluedd Meddyliol 2005;

mae i "corff priodol" yr ystyr a roddir i "appropriate body" gan adran 30(4) o'r Ddeddf a chan Reoliadau Deddf Galluedd Meddyliol 2005 (Corff Priodol) (Cymru) 2007(**2**).

(**1**) 2005 p.9. Enwir adran 64(1) oherwydd yr ystyr a roddir ynddi i "prescribed".

(**2**) O.S. 2007/833 (Cy.71).

2007 No. 837 (W.72)

MENTAL CAPACITY, WALES

The Mental Capacity Act 2005 (Loss of Capacity during Research Project) (Wales) Regulations 2007

Made *13 March 2007*

Coming into force

For the purpose mentioned in regulation 1(1)(a) *1 July 2007*

For all other purposes *1 October 2007*

The National Assembly for Wales makes the following Regulations in exercise of the power conferred upon it by sections 30(6), 34(1), (2) and (3), 64(1) and 65(1) of the Mental Capacity Act 2005(**1**).

Title, commencement, application and interpretation

1.-(1) The title of these Regulations is as the Mental Capacity Act 2005 (Loss of Capacity during Research Project) (Wales) Regulations 2007 and they come into force on -

(a) 1 July 2007 for the purpose of enabling applications for approval for the purposes of Schedule 1 to be made to, and determined by, an appropriate body,

(b) 1 October 2007 for all other purposes.

(2) These Regulations apply in relation to Wales.

(3) In these Regulations-

"the Act" ("*y Ddeddf*") means the Mental Capacity Act 2005;

"appropriate body" ("*corff priodol*") has the meaning given by section 30(4) of the Act and the Mental Capacity Act 2005 (Appropriate Body) (Wales) Regulations 2007(**2**).

(**1**) 2005 c.9. Section 64(1) is cited because of the meaning there given to "prescribed".

(**2**) S.I. 2007/833 (W.71).

mae i "P" yr ystyr a roddir iddo yn rheoliad 2;

mae i "R" yr ystyr a roddir iddo yn rheoliad 3.

Cymhwyso

2. Mae'r Rheoliadau hyn yn gymwys pan fo'r canlynol yn wir-

(a) bod person ("P") wedi cydsynio cyn 31 Mawrth 2008 i gymryd rhan mewn prosiect ymchwil ("y prosiect") a ddechreuodd cyn 1 Hydref 2007 ond

(b) cyn i'r prosiect ddod i ben, bod P yn colli galluedd i gydsynio i gymryd rhan ynddo, ac

(c) y byddai ymchwil at ddibenion y prosiect o ran P, heblaw am y Rheoliadau hyn, yn anghyfreithlon yn rhinwedd adran 30 o'r Ddeddf.

Ymchwil y caniateir ei gyflawni er bod cyfranogwr yn colli galluedd

3. Er i P golli galluedd, caniateir i ymchwil at ddibenion y prosiect gael ei gyflawni gan ddefnyddio gwybodaeth neu ddeunydd sy'n ymwneud â P -

(a) os yw'r prosiect yn bodloni'r gofynion a osodir yn Atodlen 1;

(b) os cafwyd yr holl wybodaeth neu'r deunydd sy'n ymwneud â P a ddefnyddir yn yr ymchwil cyn i P golli galluedd;

(c) os yw'r wybodaeth honno neu'r deunydd hwnnw naill ai-

(i) yn ddata o fewn ystyr adran 1 o Ddeddf Diogelu Data 1998, neu

(ii) yn ddeunydd sy'n gelloedd dynol neu'n DNA dynol a/neu yn eu cynnwys; ac

(ch) os yw'r person sy'n cynnal y prosiect ("R") yn cymryd y camau hynny sy'n ymwneud â P a osodir yn Atodlen 2.

"P" has the meaning given in regulation 2;

"R" has the meaning given in regulation 3.

Application

2. These Regulations apply where-

(a) a person ("P") has consented before 31 March 2008 to take part in a research project ("the project") begun before 1 October 2007; but

(b) before the conclusion of the project, P loses capacity to consent to continue to take part in it, and

(c) research for the purposes of the project in relation to P would, apart from these Regulations, be unlawful by virtue of section 30 of the Act.

Research which may be carried out despite a participant's loss of capacity

3. Despite P's loss of capacity, research for the purposes of the project may be carried out using information or material relating to P if-

(a) the project satisfies the requirements set out in Schedule 1;

(b) all the information or material relating to P which is used in the research was obtained before P's loss of capacity;

(c) that information or material is either-

(i) data within the meaning of section 1 of the Data Protection Act 1998, or

(ii) material which consists of and/or includes human cells or human DNA; and

(d) the person conducting the project ("R") takes in relation to P such steps as are set out in Schedule 2.

Llofnodwyd ar ran Cynulliad Cenedlaethol Cymru o dan adran 66(1) o Ddeddf Llywodraeth Cymru 1998(**1**).

Signed on behalf of the National Assembly for Wales under section 66(1) of the Government of Wales Act 1998(**1**).

13 Mawrth 2007

13 March 2007

D. Elis-Thomas

Llywydd y Cynulliad Cenedlaethol

The Presiding Officer of the National Assembly

(**1**) 1998 p.38.

(**1**) 1998 c.38.

ATODLEN 1

Rheoliad 3

Gofynion y mae'n rhaid i'r prosiect eu bodloni

1. Mae protocol a gymeradwywyd gan gorff priodol ac sy'n cael effaith mewn cysylltiad â'r prosiect yn darparu bod ymchwil yn cael ei gyflawni sy'n ymwneud â pherson sydd wedi cydsynio i gymryd rhan yn y prosiect ond sy'n colli galluedd i gydsynio i barhau i gymryd rhan ynddo.

2. Rhaid bod y corff priodol wedi'i fodloni bod trefniadau rhesymol ar waith i sicrhau y bydd gofynion Atodlen 2 yn cael eu bodloni.

SCHEDULE 1

Regulation 3

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 must be satisfied that there are reasonable arrangements in place for ensuring that the requirements of Schedule 2 will be met.

ATODLEN 2

Rheoliad 3

Camau y mae'n rhaid i'r person sy'n cynnal y prosiect eu cymryd

1. Rhaid i R gymryd camau rhesymol i ddarganfod pwy yw person-

(a) heblaw rhywun sydd yn ei swydd broffesiynol neu er mwyn tâl, yn gofalu am P neu mae ganddo ddiddordeb yn lles P, a

(b) sy'n barod i R ymgynghori ag ef o dan yr Atodlen hon.

2. Os nad yw R yn gallu darganfod pwy yw person o'r fath rhaid i R, yn unol â chanllawiau a ddyroddir gan yr awdurdod priodol, enwebu person-

(a) sy'n barod i R ymgynghori ag ef o dan yr Atodlen hon, ond

(b) nad oes ganddo unrhyw gysylltiad â'r prosiect.

3. Rhaid i R roi i'r person a enwir o dan baragraff 1, neu a enwebir o dan baragraff 2, wybodaeth am y prosiect a rhaid iddo ofyn i'r person hwnnw-

(a) am gyngor a ddylid cyflawni ymchwil o'r fath a arfaethir mewn perthynas â P, a

(b) beth, ym marn y person hwnnw, fyddai dymuniadau a theimladau P yn debygol o fod wrth i ymchwil o'r fath gael ei gyflawni pe bai'r galluedd gan P ynglyn â'r mater.

4. Pe bai'r person yr ymgynghorir ag ef ar unrhyw adeg yn cynghori R y byddai dymuniadau a theimladau P ym marn y person hwnnw, yn debygol o arwain P i dynnu'n ôl oddi wrth y prosiect pe bai'r galluedd ganddo ynglyn â'r mater, rhaid i R sicrhau bod P yn cael ei dynnu oddi ar y prosiect.

SCHEDULE 2

Regulation 3

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 R must, in accordance with guidance issued by the appropriate authority, 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 that person-

(a) for advice as to whether research of the kind proposed should be carried out in relation to P, and

(b) what, in that person's 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, any time, the person consulted advises R that in his or her opinion P's wishes and feelings would be likely to lead P to wish to withdraw from the project if he or she had capacity in relation to the matter, R must ensure that P is withdrawn from it.

5. Nid yw'r ffaith bod person yn rhoddai i atwrneiaeth arhosol a roddwyd gan P, neu os yw'n ddirprwy i P, yn atal y person hwnnw rhag bod yn berson yr ymgynghorir ag ef o dan baragraffau 1 i 4.

6. Rhaid i R sicrhau na wneir dim byd i P yn ystod yr ymchwil a fyddai'n groes i-

(a) penderfyniad ymlaen llaw gan P sydd yn effeithiol, neu

(b) unrhyw ffurf arall ar ddatganiad a wnaed gan P ac na chafodd ei dynnu'n ôl wedyn,

y mae R yn ymwybodol ohonynt.

7. Rhaid tybio bod buddiannau P yn gorbwyso rhai gwyddoniaeth a chymdeithas.

8. Os bydd P yn dangos (mewn unrhyw fodd) ei fod yn dymuno bod yr ymchwil ynglyn ag ef yn dod i ben, rhaid dod ag ef i ben yn ddi-oed.

9. Rhaid dod â'r ymchwil i ben yn ddi-oed os bydd gan R ar unrhyw adeg sail resymol dros gredu nad yw un neu fwy o'r gofynion a osodir yn Atodlen 1 bellach yn cael ei fodloni neu eu bodloni ac nad oes bellach unrhyw drefniadau rhesymol ar waith i sicrhau bod gofynion yr Atodlen hon yn cael eu bodloni ynglyn â P.

10. Rhaid i R gynnal yr ymchwil yn unol â'r ddarpariaeth a wnaed yn y protocol y cyfeirir ato ym mharagraff 1 o Atodlen 1 ar gyfer ymchwil i gael ei gyflawni ynglŷn â pherson sydd wedi cydsynio i gymryd rhan yn y prosiect ond sy'n colli galluedd i gydsynio i gymryd rhan ynddo.

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 that person 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 P's which has effect, or

(b) any other form of statement made by P 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 or she wishes the research in relation to him or her to be discontinued, it must be discontinued without delay.

9. The research must be discontinued without delay if at any time R has reasonable grounds for believing that one or more of the requirements set out in Schedule 1 is no longer met or that there are no longer reasonable arrangements in place for ensuring that the requirements of this Schedule are being 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 take part in it.

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