2017 No.

MENTAL CAPACITY

The Mental Capacity (Suitably Qualified Person) Regulations (Northern Ireland) 2017

Made - - - - xx Month 2017
Laid before Parliament xx Month 2017
Coming into operation in accordance with regulation ***
To be laid before Parliament

The Department of Health, in exercise of the powers conferred by section 14(4) of the Mental Capacity Act (Northern Ireland) 2016 (a), makes the following Regulation:

Citation, commencement and interpretation

1. These Regulations may be cited as the Mental Capacity (Suitably Qualified Person) Regulations (Northern Ireland) 2017 and shall come into operation on [date].

(1) In these Regulations—

“the Act” means the Mental Capacity Act (Northern Ireland) 2016;
“approved social worker” means a person appointed under section 280 of the Act;
“Code of Practice” means one or more codes of practice made under section 288 of the Act;
“medical practitioner” means a fully registered person within the meaning of the Medical Act 1983 who holds a licence to practice under that Act;
“registered” in relation to nurses and midwives, means registered in the register maintained under article 5 of the Nurses and Midwives Order 2001 by virtue of qualifications in nursing or midwifery, as the case may be.
“practitioner psychologist” means a person who is registered as a practitioner psychologists;
“nominated person” has the same meaning as in Part 3 of the Act; and
“the Tribunal” has the same meaning as in the Act.

Persons suitably qualified to make formal capacity assessments

2.—(1) A person is suitably qualified to make a formal capacity assessment and provide a statement of incapacity if paragraph (2) and Regulation 3 are met.

(2) The person must be one of the following—

(a) a medical practitioner;
(b) a social worker;

(a) 2016 c 18.
(c) a registered nurse or midwife; or
(d) a practitioner psychologist.

Further requirements to be suitably qualified

3. In addition to Regulation 2 for a person to be eligible to make a formal capacity assessment and provide a statement of incapacity the person must—

(a) have knowledge of the Act and related Code of Practice;
(b) have successfully completed training that has been approved by the Department of Health;
(c) except in the 24 month period beginning with the date the person has successfully completed the training referred to in sub-paragraph (b), the person must, in the 24 months prior to the assessment, completed further training relevant to their role as a suitably qualified person to make a formal capacity assessment;
(d) have three years experience in a professional role working with persons who lack capacity; and
(e) have the skills necessary to obtain, evaluate and analyse complex evidence and differing views and to weigh them appropriately in decision making.

Sealed with the Official Seal of the *** on ***

Name

A senior officer of the
Department

Address

Date
The Department of Health, in exercise of the powers conferred by sections 21(2) and 63(3) of the Mental Capacity Act (Northern Ireland) 2016(a), makes the following Regulation:

**Citation, commencement and interpretation**

4.—(1) These Regulations may be cited as the Mental Capacity (Serious Interventions and Treatment with Serious Consequences) Regulations (Northern Ireland) 2017 and shall come into operation on [date].

(2) In these Regulations—

“the Act” means the Mental Capacity Act (Northern Ireland) 2016;

“serious intervention” has the same meaning as section 63 of the Act; and

“treatment with serious consequences” has the same meaning as section 21 of the Act.

**Serious interventions**

5. An intervention that does not cause serious and prolonged pain, serious and prolonged distress or serious and prolonged side-effects is not an intervention that falls within an intervention under section 63(1)(b) of the Act.

6. An intervention under section 63(1)(c) of the Act is not serious if it is not prolonged and demonstrable impact.

7. An intervention under section 63(1)(d) of the Act is not serious unless it will have serious consequences over a prolonged period and is not temporary.

(a) 2016 ch 18.
Treatment with serious consequences

8. An treatment that does not cause serious and prolonged pain, serious and prolonged distress or serious and prolonged side-effects is not a treatment that falls within a treatment under section 21(1)(a) of the Act.

9. A treatment under section 21(1)(c) of the Act is not serious if it is not prolonged and demonstrable impact.

10. An treatment under section 21(1)(d) of the Act is not serious unless it will have serious consequences over a prolonged period and is not temporary.

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Name
A senior officer of the Department

Address
Date

L.S.
The Department of Health, in exercise of the powers conferred by section 79 of the Mental Capacity Act (Northern Ireland) 2016 (a), makes the following Regulation:

Citation, commencement and interpretation

11.—(1) These Regulations may be cited as the Mental Capacity (Nominated Persons, Appropriate Person, Witnesses and Signatures) Regulations (Northern Ireland) 2017 and shall come into operation on [date].

(2) In these Regulations—

“the Act” means the Mental Capacity Act (Northern Ireland) 2016; and

“X” means a person making an appointment, revocation or declaration mentioned in section 79(1) of the Act.

Witnesses and persons unable to sign

12.—(1) A person can only be a witness in relation to the formalities under section 79 of the Act is he or she—

(a) is ordinary resident in Northern Ireland;
(b) has known X personally for at least two years;
(c) is not a relative to X; and
(d) is able to provide valid photo identification.

(2) A person is a relative if he or she is X’s—

(a) mother or father;
(b) brother or sister;
(c) son or daughter;
(d) grandparent or grandchild; or
(e) step child or step parent.
A person of half-blood is for the purpose of paragraph (2) to be treated as whole blood.

13.—(1) If X is physically unable to sign but has capacity to make such an appointment, revocation or declaration section 79(2)(a) is replaced by paragraph (2).

(2) An addition sheet is added to the document containing the appointment, revocation or declaration and the addition sheet must include—

(a) a signature in his or her own name by a person who is unconnected with X;

(b) a statement that the signature on the addition sheet is on behalf of X and that in his or her opinion X has capacity to make an appointment, revocation or declaration; and

(c) signed statements by two witnesses who must be unconnected with X stating that in their opinion X—

(i) understands the effect of the appointment, declaration or revocation; and

(ii) has not been subject to any undue pressure in relation to the appointment, declaration or revocation.

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Name

Address

Date

A senior officer of the

Department
The Mental Capacity (Independent Mental Capacity Advocates) Regulations (Northern Ireland) 2017

Citation, commencement and interpretation

14.—(1) These Regulations may be cited as the Mental Capacity (Independent Mental Capacity Advocates) Regulations (Northern Ireland) 2017 and shall come into operation on.

(2) In these Regulations—

“the Act” means the Mental Capacity Act (Northern Ireland) 2016;
“The Department” means the Department of Health;
“HSC trust” has the same meaning as under the Act;
“independent mental capacity advocate” means a person who has been appointed by an HSC trust under section 91 of the Act in accordance with the provisions in section 86(4) of the Act;
“P” has the same meaning as in section 86 of the Act; and
“unconnected with” has the same meaning as in section 304 of the Act.

Arrangements of independent mental capacity advocates

15. Each HSC trust must make arrangements to ensure that they have appointed sufficient numbers of independent mental capacity advocates that one can be instructed under section 91 of the Act without delay.

16.—(1) A HSC trust may not make a direct financial arrangement with an independent mental capacity advocate but must make arrangements with a provider of independent mental capacity advocates.

(2) A provider of independent mental capacity advocates cannot enter into arrangements with a HSC trust for independent mental capacity advocates unless the provider has been approved by the Department as a provider for independent mental capacity advocates.

(3) When considering if a provider of independent mental capacity advocates should be approved as a provider the Department must consider—
(a) the provider’s ability to provide independent mental capacity advocates;
(b) the provider’s independence from the HSC trust;
(c) any other factors that would render the provider unsuitable as a provider.

Requirements on independent mental capacity advocates

17. A HSC trust can only appoint a person to be an independent mental capacity advocate if he or she—
   (a) has completed training approved by the Department;
   (b) has completed further training approved by the Department at intervals required by the Department;
   (c) has experience working with persons who lack capacity, or have other similar experience;
   (d) does not have any unspent criminal convictions.

18. If P is under the age of 18 a HSC trust can only instruct an independent mental capacity advocate who has experience in working with children.

19.—(1) When an independent mental capacity advocate has been instructed he or she must carry out the following steps when supporting and representing P—
   (a) ensuring that the act in relation to which the independent mental capacity advocate is instructed is one that requires an independent mental capacity advocate;
   (b) if practicable and appropriate interview the person;
   (c) examine any relevant records;
   (d) if practicable and appropriate consult persons who are in engage in the care, treatment or welfare of the person in a professional capacity or for remuneration;
   (e) if practicable and appropriate consult with other persons, including the nominated person if there is a nominated person;
   (f) taking all reasonable steps to obtain all relevant information about the person for understanding the person’s best interests;
   (g) evaluating all the information available to support the determination of the person’s best interests and consider what is the least restrictive option; and
   (h) provide a written report to the person determining best interests.

   (2) A written report under Regulation 6(1)(h) can be in any form but must contain:
       (a) who carried out the functions of the independent mental capacity advocate;
       (b) how the required steps in Regulation 6(1) have been carried out;
       (c) how the independent mental capacity advocate has supported and represented the person who lacks capacity’s best interests; and
       (d) any recommendations, if any, in relation to the best interests which it appears relevant to make.

   (3) A written report under Regulation 6(1)(h) must be signed by the independent mental capacity advocate.

Other provisions in relation to independent mental capacity advocates

20. An appropriate healthcare professional who can request a independent mental capacity advocate under section 88 is any person who is suitably qualified to make a statement of incapacity under section 14 of the Act.

21.—(1) Before an independent mental capacity advocate can be requested under section 88 of the Act P must be provided the following information—
(a) information about the role of an independent mental capacity advocate, including powers and requirements;
(b) notice that an independent mental capacity advocate will have access to P’s sensitive personal information if instructed;
(c) that an independent mental capacity advocate will be instructed unless refused;
(d) how to refuse an independent mental capacity advocate; and
(e) how to revoke an independent mental capacity advocate after one has been instructed.

(2) The information can be provided in any form and must not be personally tailored to P, although the information must be provided making it as accessible to P as practicable.

22. A person is able to act as a witness for the purpose of section 95(2)(b) if he or she is unconnected with the person making the declaration or revocation.

23.—(1) If P is physically unable to sign a declaration under section 90 or 93 but has capacity to make the declaration the requirements in section 95(2) is replaced by paragraph (2).

(2) For the purpose of section 90(3) or 93(4) of the Act, the conditions of section 95 of the Act are met if—
   (a) an addition sheet is added to the unsigned declaration or revocation;
   (b) the addition sheet include a statement that the signature on the addition sheet is on behalf of a person who cannot physically sign but has capacity to do so (“X”);
   (c) another person who is unconnected with X can sign the addition sheet in their own name on behalf of X; and
   (d) the signature in sub-paragraph (c) must be witnessed by two persons, both who must be unconnected with X, certifying that in their opinions X—
     (i) understands the effect of the declaration or revocation; and
     (ii) has not been subjected to any undue pressure in relation to the declaration or revocation.

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Name

Address

Date

A senior officer of the
Department
The Department of Health, in exercise of the powers conferred by sections 31 and 33 of the Mental Capacity Act (Northern Ireland) 2016(a), makes the following Regulation:

Citation, commencement and interpretation

24.—(1) These Regulations may be cited as the Mental Capacity (Community Residence Requirements) Regulations (Northern Ireland) 2017 and shall come into operation on [date].

(2) In these Regulations—

“the Act” means the Mental Capacity Act (Northern Ireland) 2017;
“community residence requirement” means a requirement imposed under section 30 of the Act; and
“P” has the same meaning as in section 31 of the Act.

Healthcare professional

25. A healthcare professional for the purpose of section 31 of the Act is a person who is—

(a) suitably qualified to make formal assessments of capacity under section 14 of the Act; and

(b) involved in the care and treatment of the person who lacks capacity.

Duties in relation to persons subject to community residence requirements

26. The HSC trust in which P is resident must arrange for every person subject to a community residence requirement to be visited at intervals of not more than 3 months by a person who is suitably qualified to make formal assessments of capacity under section 14 of the Act, and at least one such visit in any year shall be made by a medical practitioner that is suitably qualified to make formal assessments of capacity under section 14 of the Act.

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(a) 2016 ch. 18.
The Department of Health, in exercise of the powers conferred by sections 39, 42, 43 and 50 and Schedule 1 paragraphs 5, 6, 7, 8, 14 and 19, Schedule 2 paragraphs 1, 2, 3, 4, 7, 9, 11, 13 and 14 and Schedule 3 paragraphs 3, 4, 5, 6, 7, and 9 of the Mental Capacity Act (Northern Ireland) 2016(a), makes the following Regulation:

PART 1
General

Citation, commencement and interpretation

27.—(1) These regulations may be cited as the Mental Capacity (Authorisations and Extensions) Regulations (Northern Ireland) 2017 and shall come into operation on [date].

(2) In these Regulations—

“the Act” means the Mental Capacity Act (Northern Ireland) 2016;
“admission report” has the same meaning as in paragraph 11 of Schedule 2 of the Act;
“application” means an application under Schedule 1 of the Act;
“approved social worker” means a person appointed under section 280 of the Act;
“care or treatment” includes care and treatment;
“Department” means the Department of Health;
“exception certificate” has the same meaning as in paragraph 9 of Schedule 2 of the Act;
“extension authorisation” means a report under section 37 or 38 of the Act;
“further admission report” has the same meaning as in paragraph 13 of Schedule 2 of the Act;
“further report” has the same meaning as in paragraph 14 of Schedule 2 of the Act;
“HSC trust” has the same meaning as in the Act;
“independent mental capacity advocate” has the same meaning as in the Act;

(a) 2016 chapter 18.
“managing authority” has the same meaning as in the Act;
“measure” has the same meaning as in section 41 of the Act;
“medical practitioner” has the same meaning as in the Act;
“nominated person” has the same meaning as in the Act;
“P” means a person who lacks capacity and for whom a measure is proposed;
“practitioner psychologist” means a person who is registered as a practitioner psychologists;
“relevant trust” has the same meaning as in the Act;
“registered” in relation to nurses and midwives, means registered in the register maintained under article 5 of the Nurses and Midwives Order 2001 by virtue of qualifications in nursing or midwifery, as the case may be.
“responsible medical practitioner” has the same meaning as in paragraph 1 of Schedule 2 of the Act subject to the conditions in Regulation 8;
“responsible person” has the same meaning as in section 42 of the Act;
“RQIA” means the Health and Social Care Regulation and Quality Improvement Agency;
“short-term detention authorisation” means a report made under paragraph 2 of Schedule 2 of the Act;
“treatment” has the same meaning as in the Act;
“the Tribunal” means the Review Tribunal constituted under Article 70 of the Mental Health (Northern Ireland) Order 1986;
“trust panel” means a panel constituted under Schedule 1 of the Act in accordance with section 297 of the Act; and
“unconnected” has the same meaning as in the Act.

PART 2
Schedule 1 authorisations

Persons who can make a Schedule 1 application

28. A person can make an application under Schedule 1 of the Act if he or she is—
   (a) suitably qualified to make a formal capacity assessment and provide a statement of incapacity under section 14 of the Act;
   (b) involved in the care or treatment of P; and
   (c) not the same person making the medical report required in paragraph 6(1)(b) of Schedule 1.

Form of application

29. (1) An application for authorisation under Schedule 1 of the Act must include—
   (a) name and address of P, P’s Health and Social Care number (if available), and P’s current location;
   (b) name and address of the applicant, how the applicant has met the requirement in Regulation 2 and how the applicant is unconnected with P;
   (c) name and address of the person in charge of P’s care or treatment;
   (d) what measure is being applied for;
   (e) the length of authorisation required;
(f) a declaration by the applicant in the words “I confirm I am eligible to make this application. To the best of my knowledge all information in this application is correct and all required information is included.”;

(g) the following annexes:
   (i) Annex A detailing the measure subject to paragraph (2);
   (ii) Annex B including the statement of incapacity;
   (iii) Annex C including a best interests determination statement subject to paragraph (3);
   (iv) Annex D including a statement that the additional conditions are met subject to paragraph (4);
   (v) Annex E providing details on consultations with the nominated person subject to paragraph (5);
   (vi) Annex F containing a report, in the form required by regulations under section 87 of the Act, by the independent mental capacity advocate;
   (vii) Annex G containing a medical subject to Regulation 4;
   (viii) Annex H containing a care plan subject to Regulation 6; and
   (ix) if the measure is a deprivation of liberty or community residence requirement, Annex I including a statement whether P has capacity to apply to the Review Tribunal in respect of an authorisation by the trust panel subject to paragraph (6).

(2) The details about the measure must include—
   (a) any conditions in relation to the measure;
   (b) in the case of treatment with serious consequences, and the nominated person reasonably objects, the place where the treatment will take place;
   (c) in the case of an attendance requirement—
      (i) the place that has to be attended; or
      (ii) authorisation for a named HSC trust to specify the place; and
      (iii) the times and intervals of the attendance requirement; or
      (iv) authorisation for a named HSC trust to specify the times and intervals of the attendance requirement.
   (d) in the case of a community residence requirement—
      (i) the place, including which HSC trust it is in, of required residence; or
      (ii) authorisation for a named HSC trust to specify the place; and
      (iii) any conditions requiring P to allow healthcare professionals to access P at a place where P is living; and
      (iv) any conditions requiring P to attend particular places and times or intervals for the purpose of training, education, occupation or treatment with the following condition—
         (aa) either at a place specified in the application or an authorisation for a named HSC trust to specify the place; and
         (bb) either at times or intervals specified in the application or an authorisation for a named HSC trust to specify the times or intervals.
      (cc) and
   (e) in the case of a detention amounting to a deprivation of liberty the name of the place where care or treatment is available.

(3) A best interests determination must include—
   (a) details about the decision including—
      (i) details of the decision;
      (ii) why it has to be taken; and
(iii) when it has to be taken.
(b) details about the options including—
   (i) what the options are; and
   (ii) the least restrictive options.
(c) details of P’s views on the options, if any;
(d) details about the opinions of others that have been consulted where practicable and appropriate including—
   (i) who has been consulted;
   (ii) what are others’ views; and
   (iii) how have any disagreements been dealt with.
(e) details about the relevant circumstances, of which persons involved in the determination are aware of, including—
   (i) the social circumstances;
   (ii) views of carers and social workers, if involved with P, their involvement with P is relevant to the decision and it is practicable to establish their views.
(f) details about P’s past and present wishes and feelings and beliefs and values; and
(g) any further details which are relevant to the best interests determination.

(4) (a) The additional conditions are—
   (i) for treatment with serious consequences the prevention of serious harm condition in section 22 of the Act;
   (ii) for deprivation of liberty the prevention of serious harm condition in section 25(5) of the Act;
   (iii) for attendance requirement the receipt of treatment condition in section 28(5) of the Act; and
   (iv) for community residence requirement the prevention of harm condition in section 30(4) of the Act.
(b) A statement that the additional conditions are met must be made by the medical practitioner making the medical report and must include—
   (i) name of P;
   (ii) name and address of the person making the statement;
   (iii) how P meets the additional conditions;
   (iv) time and date the statement is made; and
   (v) signature by the person making the statement.

(5) Details on the consultation with the nominated person must include—
   (a) notification if the nominated person supports the application or not, or has no opinion as to whether the measure is in P’s best interests; and
   (b) how the nominated person has been consulted, the views of the nominated person and how any disagreements have been dealt with.

(6) The statement required by paragraph 6(2) of Schedule 1 of the Act must include—
   (a) details that the assessment has been carried out, by whom it was carried out and when;
   (b) specification of which of the things in section 4(1)(a) to (d) in the Act that P is, in the assessor’s opinion, not able to do in relation to the measure because of an impairment of, or disturbance in the functioning of, the mind or brain;
   (c) a statement with the words “In my opinion the person in section 1 of the application lacks (or probably lacks) capacity to decide whether an application to Tribunal in relation to an authorisation granted by the trust panel should be made.”; and
   (d) signature by the person making the assessment.
For avoidance of any doubt details of a best interests determination as per paragraph (5) must always consider all steps in section 7 of the Act.

**Medical report**

30. The medical report must contain—
(a) name of the medical practitioner and how the medical practitioner is unconnected with P;
(b) name, address and Health and Social Care number (if available) of P; and
(c) how the nominated person has been consulted, the views of the nominated person and how any disagreements have been dealt with.

31.—(1) For avoidance of any doubt when a medical practitioner makes the statement in paragraph 7(2) of Schedule 1 of the Act or paragraph 5(1)(b) of Schedule 3 of the Act (the statement that in that person’s opinion the criteria for authorisation are met in relation to the measure for which the application requests authorisation) the medical practitioner can rely on information provided by others when forming an opinion, including information required for the application as found in Regulation 29.

(2) If the information relied upon is information required to be provided in the application under Regulation 29 it is sufficient to make reference to where that information is available (to avoid unnecessary duplication).

**Care plan**

32. The care plan must include—
(a) name and address of P and P’s current location;
(b) what treatment is to be provided to necessitate the application;
(c) how P’s care or treatment is to be managed during the duration of the authorisation period; and
(d) what actions are to be done to ensure the measure can be ended as soon as practicable.

**Information**

33.—(1) When an application is received by the relevant trust it must as soon as practicable provide the information in paragraph (2) to the persons in paragraph (3).

(3) The information that must be provided includes—
(a) the application, including all annexes;
(b) the procedure of the trust panel; and
(c) how to make representation to the trust panel.

(4) The information in paragraph (2) must be provided to the following persons—
(a) the nominated person; and
(b) any person P has asked the information to be given to.

34.—(1) As soon as practicable after granting or refusing an authorisation under paragraph 15 of Schedule 1 of the Act the panel must provide the information in paragraph (2) to the persons in paragraph (3)—

(2) The information that must be provided includes—
(a) the application including all annexes;
(b) the reason for the granting or refusing an application; and
(c) if the application is granted, how to apply to the Tribunal.

(3) The information in paragraph (2) must be provided to the following persons—
(a) the persons in Regulation 33(4)(a) and 33(4)(b);
the person who made the application;
the managing authority, or HSC trust in the case of a community residence requirement, where the measure will take place;
if the measure is within paragraph 2(2)(b) or (d) of Schedule 1 of the Act (deprivation of liberty or community residence requirement) and the application contains a statement mentioned in paragraph 6(2) of Schedule 1 of the Act (statement that P lacks, or probably lacks, capacity in relation to making an application to the Tribunal) the Attorney General; and
(a person employed by the RQIA who is designated by the RQIA as a person to be provided with information for the purposes of the Act.

PART 3

Schedule 2 authorisations

Responsible Medical Practitioner, alternative medical practitioner and medical practitioner

35. A medical practitioner can only carry out the functions of the responsible medical practitioner if he or she is—
(a) suitably qualified to make formal capacity assessment and provide a statement of incapacity under section 14 of the Act; and
(b) is approved by the RQIA for the purpose of being a responsible medical practitioner.

36. An alternative medical practitioner who may make a report under paragraphs 11, 13 or 14 in Schedule 2 of the Act is a person who meets the criteria for being a responsible medical practitioner but who is not in charge of P’s care.

37. A person is a medical practitioner who can make an exception certificate if they meet the requirements of a responsible medical practitioner in Regulation 35 or that of alternative medical practitioner in Regulation 36 or if he or she is the medical practitioner who made the initial medical report under paragraph 4 of Schedule 2 of the Act.

Persons who can make a report

38. A person is an appropriate healthcare professional for the purpose of making a report under paragraph 2 of Schedule 2 of the Act if he or she is—
(a) suitably qualified to make a formal capacity assessment and provide a statement of incapacity under section 14 of the Act;
(b) not the person who made the medical report under paragraph 4 of schedule 2;
(c) not the person who made the statement of incapacity relevant to the report; and
(d) unconnected with P.

Form of Schedule 2 reports and certificate

39.—(1) A short-term detention authorisation for examination or examination followed by treatment must include the following—
(a) name, health and social Care number (if applicable) and address of P;
(b) name of the person making the report, how that person has met the requirement in Regulation 38 and how that person is unconnected with P;
(c) name and address of the person in charge of P’s care;
(d) the hospital where P is to be detained;
(e) outline of what examination or examination followed by treatment that will be provided to P;

(f) the following annexes:
   (i) Annex A including the statement of incapacity;
   (ii) Annex B including a best interests determination statement subject to Regulation 29(3);
   (iii) Annex C including a prevention of serious harm condition statement which must include—
      (aa) name of P;
      (bb) name and address of the person making the statement;
      (cc) how the person making the statement is qualified to do so;
      (dd) how P meets the prevention of serious harm condition;
      (ee) time and date the statement is made; and
      (ff) signature by the person making the statement;
   (iv) Annex D outlining the details on consultation with the nominated person subject to Regulation 29(5);
   (v) Annex E containing a report, in the form required by regulations under section 87 of the Act, by the independent mental capacity advocate;
   (vi) if an approved social worker has been consulted as a result of paragraph 6 of Schedule 2 of the Act Annex F containing the views of the approved social worker;
   (vii) Annex G containing a medical report Schedule 2 paragraph 2(4)(a); and
   (viii) Annex H including a statement required by Schedule 2 paragraph 2(5) whether P has capacity to apply to the Review Tribunal in respect of the report under Schedule 2 paragraph 2 subject to paragraph (2).

(g) and
(h) date the report was made and signature by the person making the report.

2. The statement required by Schedule 2 paragraph 2(5) must include—
   (a) details that the assessment has been carried out, by whom it was carried out and when;
   (b) specification of which of the things in section 4(1)(a) to (d) in the Act that P is, in the assessor’s opinion, not able to do in relation to the measure because of an impairment of, or disturbance in the functioning of, the mind or brain;
   (c) a statement with the words “In my opinion the person in section 1 of the application lacks (or probably lacks) capacity to decide whether an application to Tribunal in relation to the short-term detention authorisation.”; and
   (d) signature by the person making the assessment.

40. An admission report must include the following—
   (a) name and address of P;
   (b) name of the person making the report, that the person has met the requirement in Regulations 35 or 36, or if not, that the person is a medical practitioner, and how that person is unconnected with P;
   (c) name and address of the responsible medical practitioner;
   (d) explanation how the examination requirement, prevention of serious harm condition, lack of capacity and best interests are met;
   (e) a declaration by the person making the report that the criteria for authorisation are met; and
   (f) date the report was made and signature by the person making the report.

41. A further admission report must include—
(a) the information in Regulation 40(a) and (c) to 40(f); and

(b) name of the person making the report, that the person has met the requirement in Regulations 35 or 36 and how that person is unconnected with P.

42. A further report must include—

(a) the information in Regulation 40(a) and (c) to 40(f); and

(b) the name of the person making the report, that the person has met the requirement in Regulations 35 or 36 and how that person is unconnected with P.

43. An exception certificate must include—

(a) name and address of P;

(b) name of person making the report and how that person has met the requirements in Regulation 37;

(c) how long the delay in admission is authorised to be;

(d) why a delay is necessary because of exceptional circumstances and what the exceptional circumstances are;

(e) certification that the delay in admission is necessary; and

(f) date the certificate was made and signature by the person making the certificate.

**Medical report**

44.——(1) The medical report must contain—

(a) name of the medical practitioner and how the medical practitioner is unconnected with P;

(b) name, address and Health and Social Care number (if available) of P; and

(c) how the nominated person has been consulted, the views of the nominated person and how any disagreements have been dealt with.

(2) For avoidance of any doubt when a medical practitioner makes the medical report the medical practitioner can rely on information provided by others when forming an opinion, including information required for the report as found in paragraph 2(4) of Schedule 2 of the Act and in Regulation 39.

(3) If the information relied upon is information required to be provided in the application under Regulation 39 it is sufficient to make reference where that information is available (to avoid unnecessary duplication).

**Information**

45.—(1) When a short-term detention authorisation is made the person making the short-term detention authorisation must as soon as practicable give the persons in paragraph (2) the information in paragraph (3).

(2) The persons are—

(a) P;

(b) the nominated person;

(c) any person P has asked the information to be given to;

(d) the managing authority of the hospital where P is to be detained;

(e) a person employed by the RQIA who is designated by the RQIA as a person to be provided with information for the purposes of the Act; and

(f) if the report contains a statement mentioned in paragraph 2(5) of Schedule 2 of the Act (statement that P lacks, or probably lacks, capacity in relation to making an application to the Tribunal) the Attorney General.

(3) The information that must be provided includes—
(a) a copy of the authorisation; and
(b) the procedure of the Review Tribunal and how to apply to the Review Tribunal.

PART 4

Extension by report

Extension authorisation

46.—(1) An extension authorisation must include—
   (a) name and address of P, P’s health and social Care number (if applicable) and P’s current location;
   (b) name, role and address of the person completing the extension report;
   (c) name and address of the person in charge of P’s care or treatment;
   (d) the specified measures;
   (e) the length of extension;
   (f) if it is the first extension or a subsequent extension;
   (g) the following annexes:
      (i) Annex A including any conditions in relation to the measure and details about the measure subject to paragraph (2);
      (ii) Annex B including the statement of incapacity;
      (iii) Annex C including a best interests determination statement subject to paragraph (3);
      (iv) Annex D including a statement that the additional conditions are met subject to paragraph (4);
      (v) Annex E outlining the details on consultation with the nominated person subject to paragraph (5);
      (vi) Annex F containing a report, in the form required by regulations under section 87 of the Act, by the independent mental capacity advocate;
      (vii) Annex G including a medical report made by the person making the extension authorisation including the statement in section 39(2)(c) of the Act;
      (viii) Annex H including a responsible person statement subject to paragraph (7); and
      (ix) Annex I including a statement whether P has capacity to apply to the Review Tribunal in respect of the extension authorisation subject to paragraph (6); and
(2) The details about the measure must must include—
   (a) any conditions in relation to the measure;
   (b) in the case of treatment with serious consequences, and the nominated person reasonably objects, the place where the treatment will take place;
   (c) in the case of an attendance requirement—
      (i) the place that has to be attended; or
      (ii) authorisation for a named HSC trust to specify the place; and
      (iii) the times and intervals of the attendance requirement; or
      (iv) authorisation for a named HSC trust to specify the times and intervals or the attendance requirement.
   (d) in the case of a community residence requirement—
      (i) the place, including which HSC trust it is in, of required residence; or
      (ii) authorisation for a named HSC trust to specify the place; and
(iii) any conditions requiring P to allow healthcare professionals to access P at a place where P is residing; and

(iv) any conditions requiring P to attend particular places and times or intervals for the purpose of training, education, occupation or treatment with the following condition—
   (aa) either at a place specified in the report or an authorisation for a named HSC trust to specify the place; and
   (bb) either at times or intervals specified in the report or an authorisation for a named HSC trust to specify the place.

(e) in the case of a detention amounting to a deprivation of liberty the name of the place where care or treatment is available.

(3) A best interests determination must include—

(a) details about the decision including—
   (i) details of the decision;
   (ii) why it has to be taken; and
   (iii) when it has to be taken.

(b) details about the options including—
   (i) what the options are; and
   (ii) the least restrictive options.

(c) details of P’s views on the options, if any;

(d) details about the opinions of others that have been consulted where practicable and appropriate including—
   (i) who has been consulted;
   (ii) what are others’ views; and
   (iii) how have any disagreements been dealt with.

(e) details about the relevant circumstances, of which persons involved in the determination are aware of, including—
   (i) the social circumstances;
   (ii) views of carers and social workers, if involved with P, their involvement with P is relevant to the decision and it is practicable to establish the views.

(f) details about P’s past and present wishes and feelings and beliefs and values; and

(g) any further details which are relevant to the best interests determination.

(4) (a) The additional conditions are—
   (i) for treatment with serious consequence the prevention of serious harm condition in section 22 of the Act;
   (ii) for deprivation of liberty the prevention of serious harm condition in section 25(5) of the Act;
   (iii) for attendance requirement the receipt of treatment condition in section 28(5) of the Act; and
   (iv) for community residence the requirement prevention of harm condition in section 30(4) of the Act.

(b) A statement that the additional conditions are met must be made by the person making the extension report and must include—
   (i) name of P;
   (ii) name and address of the person making the statement;
   (iii) how P meets the additional conditions;
(iv) time and date the statement is made; and
(v) signature by the person making the statement.

(5) Details on the consultation with the nominated person must include—
(a) notification if the nominated person supports the application or not, or has no opinion as to whether the measure is in P’s best interests; and
(b) how the nominated person has been consulted, the views of the nominated person and how any disagreements have been dealt with.

(6) The statement required by paragraph 6(2) of Schedule 1 of the Act must include—
(a) details that the assessment has been carried out, by whom it was carried out and when;
(b) specification of which of the things in section 4(1)(a) to (d) in the Act that P is, in the assessor’s opinion, not able to do in relation to the measure because of an impairment of, or disturbance in the functioning of, the mind or brain;
(c) A statement with the words “In my opinion the person in section 1 of the authorisation lacks (or probably lacks) capacity to decide whether an application to Tribunal in relation to the extension should be made.”; and
(d) signature by the person making the assessment.
(e) for avoidance of any doubt details of a best interests determination as per paragraph (5) must always consider all steps in section 7 of the Act.

(7) The statement by the responsible person must include the following—
(a) a statement using the words: “In my opinion, based on the balance of probabilities, the criteria for continuation of the specified measures are met.”;
(b) specifics on the measure;
(c) name, address and role of the responsible person;
(d) how the responsible person has met the requirements of section 42 of the Act;
(e) how, in the opinion of the responsible person, the criteria for continuation have been met;
(f) date when the statement was made; and
(g) signature by the responsible person.

Meaning of responsible person

47. If a social worker who is in charge of P’s case is involved in the care or treatment of P and the measure for which the extension report is sought is relevant to that care or treatment the social worker can be the responsible person, subject to the conditions in Regulation 50.

48. The managing authority in a hospital or care home where P is an in-patient or resident may designate anyone who is involved in the care or treatment of P as the responsible person, subject to the conditions in Regulation 50.

49. If P is subject to a community residence requirement or attendance requirement the HSC trust in which P is residing may designate anyone who is involved in the care or treatment of P as the responsible person, subject to the conditions in Regulation 50.

50. To be a responsible person the person must—
(a) be suitably qualified to carry out a formal assessment of capacity and meet the requirements set out in regulations under section 14(4) in the Act; and
(b) be unconnected with P.

Information when making an extension report

51.—(1) When an extension report is received by the relevant trust it must as soon as practicable provide the information in paragraph (2) to the persons in paragraph (3)—
The information that must be provided includes—
(a) a copy of the extension report including all annexes;
(b) the procedure of the Tribunal; and
(c) how to apply to the Tribunal.

(3) The information in paragraph (2) must be provided to the following persons—
(a) the nominated person;
(b) any person P has asked the information to be given to; and
(c) the managing authority, or trust in the case of a community residence requirement, where the measure will take place.

52. If the extension report includes a statement under section 39(3) of the Act (a statement that in the opinion of the appropriate medical practitioner P lacks (or probably lacks) the capacity whether an application to the Tribunal should be made in respect of the authorisation) the Attorney General must be notified of the extension report and provided all the information in Regulation 51(2).

PART 5
Extension by Schedule 3 authorisation

Schedule 3 application

53. A person can make an application for an extension of a measure under Schedule 3 of the Act if he or she meets the criteria in Regulation 2.

Form of application

54. (1) An application for authorisation under Schedule 3 of the Act must include—
(a) the information in Regulation 29(1)(a) to 29(1)(g)(vi)(viii); 
(b) if it is the first or a subsequent extension; and
(c) the following additional annexes—
(i) Annex I including the views of the responsible person subject to paragraph (2); and
(ii) if the measure is a deprivation of liberty or community residence requirement, Annex J including a statement whether P has capacity to apply to the Review Tribunal in respect of an authorisation by the trust panel subject to paragraph (3).

(2) The views of the responsible person must include the following—
(a) specifics on the measure;
(b) name, address and role of the responsible person;
(c) how the responsible person has met the requirements of section 42 of the Act;
(d) why the responsible person is not willing to provide a statement as per section 39(2)(d) of the Act; and
(e) signature by the responsible person.

(3) The statement required by paragraph 4(2) of Schedule 3 of the Act must include—
(a) details that the assessment has been carried out, by whom it was carried out and when;
(b) specification of which of the things in section 4(1)(a) to (d) in the Act that P is, in the assessor’s opinion, not able to do in relation to the measure because of an impairment of, or disturbance in the functioning of, the mind or brain;
a statement with the words “In my opinion the person in section 1 of the application lacks (or probably lacks) capacity to decide whether an application to Tribunal in relation to an authorisation granted by the trust panel should be made.”; and

(4) signature by the person making the assessment.

Medical report

55. The medical report must contain the same information as in Regulation 30(a) to (c).

Care plan

56. The care plan must include the same information as in Regulation 32(a) to 32(d).

Information

57.—(1) When an application is received by the relevant trust it must as soon as practicable
provide the information in paragraph (2) to the persons in paragraph (3).

(2) The information that must be provided includes—

(a) the application including all annexes;
(b) why the responsible person did not provide a statement as per section 39(2)(d) of the Act;
(c) the procedures of the trust panel; and
(d) how to make representation to the trust panel.

(3) The information in paragraph (2) must be provided to the following persons—

(a) the nominated person; and
(b) any person P has asked the information to be given to.

58.—(1) As soon as practicable after granting or refusing an authorisation under paragraph 9 of
Schedule 3 of the Act the panel must provide the information in paragraph (2) to the persons in
paragraph (3)(a) to (c)—

(2) The information that must be provided include—

(a) the application including all annexes;
(b) the reason for the granting or refusing an application; and
(c) how to apply to the Tribunal.

(3) The information in paragraph (2) must be provided to the following persons—

(a) the persons in Regulation 57(3)(a) and 57(3)(b);
(b) the person who made the application;
(c) the managing authority, or trust in the case of a community residence requirement, where
the measure will take place;
(d) if the measure is within section 41(2)(b) or (d) of the Act (deprivation of liberty or
community residence requirement) and the application contains a statement mentioned in
paragraph 4(2) of Schedule 3 of the Act (statement that P lacks, or probably lacks, capacity in relation to making an application to the Tribunal) the Attorney General; and
(e) a person employed by the RQIA who is designated by the RQIA as a person to be
provided with information for the purposes of the Act.

Sealed with the Official Seal of the Department of Health on ***

Name

Address

Date

A senior officer of the
Department
The Mental Capacity (Authorisation Panels) Regulations (Northern Ireland) 2017

Made - - - - xx Month 2017
Laid before Parliament xx Month 2017
Coming into operation in accordance with regulation 1.
To be laid before Assembly

The Department of Health, in exercise of the powers conferred by sections 297 of the Mental Capacity Act (Northern Ireland) 2016(a), makes the following Regulation:

Citation, commencement and interpretation

59.—(1) These regulations may be cited as the Mental Capacity (Authorisation Panels) Regulations (Northern Ireland) 2017 and shall come into operation on [date].

(2) In these regulations—
“the Act” means the Mental Capacity Act (Northern Ireland) 2016;
“care or treatment” has the same meaning as the Act;
“the Department” means the Department of Health (Northern Ireland);
“HSC trust” has the same meaning as the Act;
“interim period” means the period in Schedule 1 paragraph 20(5)(a).
“managing authority” has the same meaning as the Act and any limitations imposed in regulations under section 306(6);
“measure” has the same meaning as in section 41 of the Act;
“P” means the person who is the subject of the application to the Panel requesting authorisation of a proposed intervention or treatment with serious consequences;
“panel” means a panel constituted under Schedule 1 or Schedule 3 of the Act;
“permitted period” has the same meaning as Schedule 1 paragraph 19 or Schedule 3 paragraph 9 of the Act;
“relevant HSC trust” has the same meaning as Schedule 1 paragraph 2 or Schedule 3 paragraph 2 of the Act;
“treatment” has the same meaning as the Act; and
“unconnected with” has the same meaning as section 304 of the Act.

Panel membership

60.—(1) A panel must have:
   (a) three members, all of whom must be appointed by the relevant HSC trust;
   (b) a chair who is—
       (i) appointed by the relevant HSC Trust as a panel chair; and
       (ii) unconnected with P.
   (c) membership which includes a minimum of a majority of health and social care
       professionals who—
       (i) have relevant expertise and knowledge in relation to the proposed measure(s)
           detailed within the application to the trust; and
       (ii) are unconnected from P.

   (2) All members of the panel must have completed training approved by the Department
       regarding the Act within 12 months of their first occurrence as a member of a panel.

   (3) A health and social care professional means a person who is qualified to make formal
       assessments of capacity under section 14 of the Act.

Remuneration or allowances of auditor panel members

61. The relevant HSC Trust may pay members of the panel such remuneration or allowances as
the trust may determine necessary to facilitate the member’s participation on the panel.

Opportunity to make representations to the panel

62.—(1) The panel must give the following people the opportunity to make representations in
writing to the panel where practicable—
   (a) P;
   (b) the person who made the application;
   (c) the nominated person;
   (d) any attorney with authority to act on behalf of P and who’s authority is relevant to the
       application;
   (e) any deputy appointed for P by the court; and
   (f) any person consulted as part of the best interest consideration.

   (2) Invitations to make representations must be issued as soon as is practicable following the
       receipt of an application.

   (3) Representations must be received by the panel no later than 2 working days after receipt of
       invitation to make representation.

   (4) The panel have discretion in exceptional circumstances to allow representation to be made in
       other forms than in writing.

   (5) The panel may make arrangements as appropriate to accommodate representations being
       made including, but not limited to, visiting those who may make representations.

Power to call for evidence

63.—(1) The panel may request anyone it considers relevant to provide information in writing to
the panel or attend before the panel to give oral evidence in relation to application being
considered.
(2) Information or oral evidence must be provided to the panel within the permitted period or interim period as relevant to the application.

**Duty to record and retain information and records**

64.—(1) Any information or evidence provided under Regulations 4 or 5 must be recorded by the panel.

(2) All information and records received by, and produced by the panel must be retained by the relevant HSC trust.

**Assessment of the best interests**

65.—(1) When determining if a proposed measure would be in P’s best interest panel members must—

(a) be satisfied that the determination is not based merely on a P’s age, appearance, or any other characteristic of P that would lead to unjustified assumptions being made regarding P’s best interests;

(b) be satisfied that all relevant circumstances have been considered;

(c) be satisfied that waiting for a time in the future when P may regain capacity, if at all possible, to make the decision for themselves would not be in P’s best interest;

(d) be satisfied that as far as practicable P has been encouraged and supported to participate in the best interest determination;

(e) be satisfied that P’s past and present wishes and feelings, beliefs and values and any other factors or written statements have been given special regard when reaching the determination;

(f) be satisfied that relevant people have been consulted, so far as practicable, and that the views of those people have been taken into account;

(g) be satisfied that the proposed measure is the least restrictive appropriate option;

(h) be satisfied that regard has been given to whether failure to do the act is likely to result in harm to other persons with resulting harm to P; and

(i) be satisfied that any determination relating to life sustaining treatment is not motivated by a desire to bring about P’s death.

(2) Panel members may base their assessment of the requirements set out in paragraph (1) solely on the information provided within the application.

**Decisions of the panel**

66.—(1) Where a decision by the panel is not unanimous, an authorisation can only be granted with the approval of a majority and the chair.

Sealed with the Official Seal of the *** on ***

Name

Address

Date

A senior officer of the Department

[Signature]
The Department of Health, in exercise of the powers conferred by sections 61(1) of the Mental Capacity Act (Northern Ireland) 2016(a), makes the following Regulations:

**Citation, commencement and interpretation**

67.—(1) These regulations may be cited as the Mental Capacity (Transitional Arrangements for 15 Year Olds) Regulations (Northern Ireland) 2017 and shall come into operation on [date].

(2) In these Regulations—

“the Act” means the Mental Capacity Act (Northern Ireland) 2016.

**Transitional Arrangements when an act is proposed before a person is 16**

68.—(1) Subject to paragraph 2 and Regulation 4, Part 2 the Act apply to a person who is within one month of reaching the age of 16 as it would to a person who is over 16 if—

(a) an act is proposed to be done in respect of a person after that person has reached the age of 16, but

(b) the time the act is proposed, the person is under 16.

(2) The following provisions of Part 2 of the Act do not apply to anyone under the age of 16—

(a) sections 9 to 12; and

(b) sections 37 to 44.

69. Regulation 2 applies in particular to—

(a) a formal assessment of capacity under section 13 of the Act;

(b) the requirement to ensure a nominated person is in place under section 15 of the Act;

(c) the provisions of a second opinion under section 16 of the Act;

(d) the extra requirements required as a result of an objection from a nominated person under section 19 of the Act;

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(a) 2016 ch. 18.
(e) the requirements for a—
   (i) deprivation of liberty under section 24 of the Act subject to Regulation 4;
   (ii) attendance requirement under section 28 of the Act; and
   (iii) community residence requirement under section 30 of the Act; and
(f) the need to have in place and consult an independent mental capacity advocate under section 35 of the Act.

70. A report under Paragraph 2 of Schedule 2 (report authorising detention in hospital for examination etc) cannot be made before the person has reached the age of 16.

71. For avoidance of doubt the protection of liability under section 9 of the Act does not apply to any act done on behalf of a person who has not reached the age of 16.
The Department of Health, in exercise of the powers conferred by section 276 of the Mental Capacity Act (Northern Ireland) 2016(a), makes the following Regulation:

Citation, commencement and interpretation

72.—(1) These regulations may be cited as the Mental Capacity (Money and Valuables) Regulations (Northern Ireland) 2017 and shall come into operation on [date]

(2) In these Regulations—
   “the Act” means the Mental Capacity Act (Northern Ireland) 2016;
   “Department” means the Department of Health;
   “P” has the same meaning as in section 276(1) of the Act.
   “property or affairs” also means property and affairs;
   “relevant authority” has the same meaning as in section 276(6) of the Act;
   “relevant decision” has the same meaning as in section 276(6) of the Act;
   “relevant person” means a person who is no P but is authorised under the Act, or under any other lawful measure, to hold and manage the money or valuables for P; and
   “RQIA” means

Money and valuables

73. If it appears to a relevant authority that a person who is an in-patient or resident in the hospital or care home lacks capacity in relation to managing their property or affairs the relevant authority may receive and hold money and valuables on behalf of that person.

74.—(1) The relevant authority must not receive or hold on behalf of any one person money or valuables exceeding the amount in section 276(3)(a) of the Act without the consent of RQIA.
If the total combined value of money or valuables in relation to one person exceeds the value in paragraph (1) the RQIA must consent to the relevant authority receiving or holding the money or valuables.

(3) When RQIA is considering whether consent under paragraph (2) should be provided RQIA must have consideration to the best interests of the person and whether the money and valuables can be stored safely in the hospital or care home.

75. A receipt or discharge given by a relevant authority for such money or valuables should be treated as a valid receipt or discharge given by P.

76.—(1) Where a relevant authority holds money or valuables it may expend that money or dispose of those valuables for the benefit of P subject to paragraph (2).

(2) When a relevant authority expend money or dispose of valuables for the benefit of P the relevant authority must—

(a) have regard to the sentimental value any article may have for P, if P had capacity;
(b) consult P’s nominated person (if one is appointed and if it reasonable and practicable to do so) regarding the expenditure or disposal;
(c) ensure that the expenditure or disposal is not of such nature that P’s future options will be limited, unless necessary due to a contractual commitment or to ensure P’s best interests.

77.—(1) A relevant authority must hold the money and valuables in a safe and secure manner.

(2) Any loss of money and valuables, where the money is not expended or valuables disposed under these Regulations and is not returned to P (if P has regained capacity) or relevant person, are the responsibility of the relevant authority who has the obligation to replace lost money at full value and lost valuables at full monetary value.

78.—(1) A relevant authority must keep records of money and valuables kept for P.

(2) The records must include—

(a) who the money or valuables are kept for;
(b) the value of money or description of valuables;
(c) where the money or valuables are kept;
(d) date and time the money or valuables were received, or when new money or valuables are received when they were received;
(e) who received the money and valuables;
(f) date and time money is expended or valuables disposed;
(g) the value of money or description, including value and monetary equivalent received, of valuables, expended or disposed of;
(h) the reason for expenditure of money or disposal of valuables;
(i) how the conditions in Regulation 5(1) have been met;
(j) who expended money or disposed of valuables;
(k) signature of person doing anything in sub-paragraph (a) to (j); and
(l) countersignature of another person witnessing the signature in sub-paragraph (k).

79.—(1) A relevant authority must furnish annual returns to the RQIA.

(2) The returns must include information in relation to all persons money or valuables were held for and contain the information in Regulation 7(2).

80.—(1) For avoidance of doubt any decision to expend money or dispose of valuables under these Regulations—

(2) are not acts to which section 9 (protection from liability) of the Act applies;
(3) cannot be contrary to a relevant decision; and
(4) must—
(a) not be made if P has capacity to make the decision;
(b) be in the best interest of P; and
(c) not be contrary any aspect of Part I of the Act.

Sealed with the Official Seal of the Department of Health on ***

Name

A senior officer of the Department

Address

Date

L.S.
The Department of Health, in exercise of the powers conferred by sections 132(4) and 138(2) of the Mental Capacity Act (Northern Ireland) 2016(a), makes the following Regulation:

Citation, commencement and interpretation

81.—(1) These regulations may be cited as the Mental Capacity (Research) Regulations (Northern Ireland) 2017 and shall come into operation on [date].

(2) In these Regulations—

“the Act” means the Mental Capacity Act (Northern Ireland) 2016;
“appropriate body” has the same meaning as in section 132 of the Act;
“Department” means the Department of Health;
“human tissue” has the meaning of “relevant material” in section 53 of the Human Tissue Act 2004; and
“intrusive research” has the same meaning as in section 132 of the Act.

Appropriate body

82. In relation to a research project referred to in Part 8 of the Act the appropriate body is a committee—

(a) established to advise on, or on matters which include, the ethics of intrusive research in relation to persons who lack capacity to consent to it; and
(b) recognised for that purpose by the Department.

Lack of capacity during research project –transitional cases

83. Regulation 3 to 6 apply where—

(a) a person (“P”)—

(i) has consented to take part in a research project (“the project”);
(ii) before the conclusion of the project loses capacity to consent to continue to take part in it; and

(iii) research in relation to P would be unlawful by virtue of Part 8 of the Act.

84. Despite P’s loss of capacity, research for the purposes of the project may be carried out in relation to treatment or using information or material relating to him if—

(a) the treatment is treatment that can be provided to P under Part 2 of the Act (including any additional safeguards which that Part requires);

(b) the information or material is either—

(i) data within the meaning given in section 1(1) of the Data Protection Act 1998; or

(ii) material which consists of human tissue or DNA;

(c) the project satisfies the requirements that—

(i) a protocol approved by an appropriate body and having effect in relation to the project makes provisions for research to be carried out in relation to a person who has consented to participation in the project but loses capacity to consent to continue to take part in it; and

(ii) the appropriate body is satisfied that there are arrangements to ensure that the conditions in Regulation 5 will be met;

(d) the person conducting the project (“R”) takes such steps as set out in Regulation 5.

85.—(1) Immediately when R is of a reasonable belief that P no longer has capacity to consent to continue to take part in the project R must—

(a) carry out the requirements in section 135 (Requirements to consult nominated person, carer etc) of the Act;

(b) comply with the conditions in section 137 (Additional safeguards) of the Act.

(2) For avoidance of doubt section 136 (Section 135: exception for urgent treatment) of the Act applies to Regulation 5(1)(a) as it would to section 135 of the Act.

86. For avoidance of doubt when Regulations 3 to 6 apply section 134(2) to (5) does not apply.

Sealed with the Official Seal of the Department of Health on ***

Name

Address

Date

A senior officer of the Department

L.S.