EXPLANATORY MEMORANDUM TO

The Mental Capacity (Research) (Amendment) Regulations (Northern Ireland) 2022

S.R. 2022 No. 299

1. Introduction

1.1 This Explanatory Memorandum has been prepared by the Department of Health to accompany the Statutory Rule (details above) which is laid before the Northern Ireland Assembly.

1.2 The Statutory Rule is made under section 132 of the Mental Capacity Act (Northern Ireland) 2016 and is subject to the negative resolution procedure.

2. Purpose of the Regulations

2.1 The purpose of the rule is to amend the principal Regulations (the Mental Capacity (Research) Regulations (Northern Ireland) 2019) to provide specification for the person, committee or other body that can act as the appropriate body for the purpose of research under the Mental Capacity Act (Northern Ireland) 2016. This amendment updates this list of appropriate bodies in regulation 2 and maintains parity with other jurisdictions.

3. Background

3.1 Part 8 of the Mental Capacity Act (Northern Ireland) 2016 makes provisions for research relating to persons aged 16 and over and lack capacity to consent to participation in the research. For the protection of liability to apply, a researcher must have research authorised by an appropriate body.

3.2 The provisions relate only to intrusive research, which is defined as research that would normally require consent by the person but does not include clinical trials. If the person lacks capacity in relation to the research, he or she is unable to consent. In such circumstances the research can go ahead without the person's consent only in the conditions outlined in the Act, the principal Regulations and the Code of Conduct are met.

3.3 Maintaining parity with other jurisdictions is vital as often research is cross jurisdictional, and a failure to do so could have seen a number of research projects removed in Northern Ireland. As such, these amending Regulations are required to update the list of appropriate bodies noted in regulation 2.

4. Consultation

4.1 The Department publicly consulted on the Mental Capacity Bill in summer 2014. This set the policy intent for the rule. The outcome of the consultation saw

overwhelming support for the legislation.

4.2 The principal Regulations formed part of phase one implementation of the Mental Capacity Act (Northern Ireland) 2016 and were informally consulted on in spring/summer of 2019. These amending Regulations have been drafted in consultation with the Public Health Agency and HSC Research Governance Sub-Group. Membership of this group includes HSC Trust and Ambulance Service R&D Managers, Governance leads of QUB & Ulster Universities, the HSC R&D Clinical Research Networks and ORECNI.

5. Equality Impact

5.1 In accordance with guidance produced by the Equality Commission for Northern Ireland and in keeping with Regulation 75 of the Northern Ireland Act 1998, the proposals for the principal Mental Capacity (Research) Regulations (Northern Ireland) 2019 were screened for equality impact and it was concluded that a full Equality Impact Assessment was not required. This was also the case with SR 2020 No.17, the first amendment to these Regulations. With this being a technical amendment, no further screening for equality impact was required.

6. Regulatory Impact

6.1 A Regulatory Impact Assessment (RIA) screening was carried out prior to consultation of the principal Mental Capacity (Research) Regulations (Northern Ireland) 2019. The screening concluded that the Statutory Rule will have negligible cost impact on businesses, charities, social economy enterprises or the voluntary sector in Northern Ireland and will not otherwise adversely affect these groups. The Department considered that a full RIA was not required. No further impact would arise as a result of this technical amendment as and as result no further screening was required.

7. Financial implications

7.1 There will be negligible cost impact on businesses, charities, social economy enterprises or the voluntary sector in Northern Ireland.

7.2 There is no expected cost to the statutory sector.

8. Section 24 of the Northern Ireland Act 1998

8.1 The Statutory Rule is not deemed to breach Section 24 of the Northern Ireland Act 1998 as it is considered to be compatible with any of the Convention rights or community law and does not discriminate against a person on the grounds of religious belief or political opinion.

9. EU implications

9.1 Not applicable

10. Parity or Replicatory Measure

10.1 Not applicable.

11. **Additional information**

11.1 Not applicable.