

EXPLANATORY MEMORANDUM TO
The Mental Capacity (Research) Regulations (Northern Ireland) 2019
2019 No 193

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

- 2.1. The purpose of the instrument is to provide details on who is deemed an appropriate body for approving research conducted under Part 8 of the Mental Capacity Act (Northern Ireland) 2016 (i.e. a person or body designated as an appropriate body by an HSC trust or a university).

3. Background

- 3.1. Part 8 of the Act provides when research can be done on, or in relation to, a person (“P”) who is 16 and over and lacks capacity to consent to the research.
- 3.2. Research that requires consent of the person involved in the research is not lawful unless the person has provided consent. 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 if the conditions outlined in the Act, these Regulations and the Code of Conduct are met.

4. Consultation

- 4.1. The Department publically consulted on the Mental Capacity Bill in summer 2014. This set the policy intent for the instrument. The outcome of the consultation saw overwhelming support for the legislation.
- 4.2. These Research provisions formed part of the draft Mental Capacity (Deprivation of Liberty) Regulations 2019 which were informally consulted on in spring/summer of 2019. The Department of Health also had a series of meetings on the regulations and other aspects of the deprivation of liberty safeguards. The meetings and consultation did not raise any significant issues that required changes to the overall approach.

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 Mental Capacity (Research) Regulations (Northern Ireland) 2019 have been screened for equality

impact and it is concluded that a full Equality Impact Assessment is not required.

6. Regulatory Impact

- 6.1. A Regulatory Impact Assessment (RIA) screening was carried out prior to consultation. 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 considers that a full RIA is not 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.

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.