

EXPLANATORY MEMORANDUM TO
The Mental Capacity (Research) (Amendment) Regulations (Northern Ireland)
2020

2020 No. 17

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 the 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.

3. Background

- 3.1. The Mental Capacity Act (Northern Ireland) 2016 makes provisions for research relating to persons that are over 16 and lack capacity to consent to participation in the research. For the protection of liability to apply, a researcher must have the 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.

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. The policy content, the list of persons, committees or other bodies that can act as an appropriate body, has been co-produced with the HSC Trusts, Universities, the HSC Board and the Public Health Agency. These are the key actors relating to the relevant research.

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 Regulations 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.
- 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.