
Executive Summary of the 2024 Amendment of the HSE National Policy for Consent in Health and Social Care Research

HSE Research & Development

Requestor:	HSE National Policy for Consent in Research and Social Care Steering Group
Date:	30 th January 2024
Topic:	Amendment to the HSE National Policy for Consent in Health and Social Care Research (V1.1, 2023) concerning the age of consent of minors

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1. Purpose

The purpose of this document is to provide a rationale for the 2024 amendments of the HSE National Policy for Consent in Health and Social Care Research, V1.1, 2023, concerning the age of consent of minors for health and social care research.

2. Scope

This document refers exclusively to amendments to the age of consent for research in health and social care and the data protection rights of children and young people in this context¹. Any other considerations are outside the scope of this paper.

3. Issues identified

In 2022, the HSE published the HSE National Policy for Consent in Health and Social Care Research (hereinafter "the Policy"). The Policy was developed with the collaboration of key experts and stakeholders, along with Public and Patient Involvement (PPI). The Policy has been widely welcomed for providing clarity on many aspects of consent in health and social care research.

However, one aspect of the Policy was challenged by the Data Protection Commissioner (DPC) in 2023. Specifically, the Policy position is that 18 years old is the age at which individuals can consent to the processing of their data for research purposes, as it marks the age of adulthood.

The concern raised by the DPC specifically referred to the position set out in Section 5.1 of the Policy, which cites Section 29 of the Data Protection Act, 2018, stating that,

"Once they have reached the age of 18 years, a prospective research participant can provide consent in their own right for both their participation in health research and for the processing of their personal data...a parent or other legally appointed guardian must provide consent on behalf of their child to participate in research."

was a misinterpretation of Section 29 of the Data Protection Act 2018.²

Section 29 of the 2018 Act, titled 'Child for the purposes of the application of Data Protection Regulation,' which is part of the interpretation provisions, states that:

"for the purposes of the application of the Data Protection Regulations in the State, a reference to "child" in the Regulation shall be taken to be a reference to a person under the age of 18 years".

The DPC holds the view that data protection law does not specify an age of consent for such processing purposes. Consequently, neither the General Data Protection Regulation

¹ Although Irish law sometimes refers to a 'child' as someone under the age of 18 years, there are legal distinctions between someone under the age of 16 years and someone aged 16 or 17 years. For this reason, this policy uses the term 'child' to refer to someone under the age of 16 years and 'young person' to refer to someone aged 16 or 17 years (please see the HSE, National Consent Policy, V1.2, 2022 (2024), <https://www.hse.ie/eng/about/who/national-office-human-rights-equality-policy/consent/>)

² Data Protection Act (2018) Section 29, <https://www.irishstatutebook.ie/eli/2018/act/7/enacted/en/html>

(GDPR) nor the 2018 Act establishes a minimum age of consent for the processing of personal data.³

The current position under the Clinical Trial Regulations⁴, as interpreted in the context of Irish law, is that for children under 16 years of age, consent must be obtained from a holder of parental responsibility for participation in clinical trials. However, individuals aged 16 and 17 years have the legal capacity to provide their own consent to participate in clinical trials under Irish law in accordance with the provisions of Regulation (EU) No 536/2014

4. Summary of amendment to address identified issues.

Taking into consideration the position of the DPC and the context of the Clinical Trial Regulations, the Policy has been amended to introduce the term “*young person/people*”, which the policy defines as a person aged 16 or 17 years old. The Policy takes the position that a “young person” can consent to participate in health and social care research and can consent to the processing of their data in association with such health and social care research.

5. Justification

Clarification and compliance with GDPR and Data Protection law

The introduction of the term “young person” clarifies the ambiguity highlighted by the DPC regarding the age of consent for processing personal data in health research. By allowing young people aged 16 or 17 years old to consent, the amended Policy acknowledges the DPC’s view that there is no specific minimum age of consent for data processing in research under GDPR and the Data Protection Act 2018. This ensures the Policy is in line with legal standards and avoids potential misinterpretation that could otherwise result in non-compliance with data protection regulations.

Furthermore, the amendments incorporate the view that the age of consent for processing one’s own data shall be assessed in an individual capacity.

Alignment with the evolving legal landscape and the National Office for Research Ethics Committees (NREC)

The amendment reflects the evolving understanding of “young persons” autonomy in legal and medical contexts. In other areas of law, including EU-regulated research, young people aged 16 and 17 years old can make informed decisions about their own participation in clinical trials and consent to the use of their personal data. This revision is now aligned with the NREC position. This Policy change brings consistency with these existing regulations, ensuring coherence in the legal treatment of consent across different health-related contexts.

Respect for the autonomy of young people:

Young people aged 16 and 17 years old generally have reached a level of maturity that allows them to understand the nature of health research and the implications of processing their personal data. Many jurisdictions and regulatory frameworks recognise the importance of respecting the autonomy of the “young person” making decisions

³ Article 8 of the GDPR specifies that the minimum age for a child to consent to the processing of their personal data in relation to information society services is 16 years.

⁴ Regulation (EU) No 536/2014, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0536>

related to their own health and well-being. This amendment recognises that young people in this age group are capable of providing informed consent independently rather than relying on parental consent. However, the Policy still incorporates provisions for parental and/or guardian support, along with the option to involve independent persons. This allows young people to include these individuals in the consent process if they choose, providing flexibility and support for those who prefer or require additional guidance.

Practical considerations in health and social care research

Health and social care research often involves sensitive and personal topics, and young people are the ultimate beneficiaries of such research. This amendment ensures that their voices and experiences are adequately considered in research without unnecessary barriers, enhancing the validity of research outcomes. Furthermore, having a clearer framework for young people's consent promotes smoother interactions between researchers and participants and prevents potential ethical dilemmas or delays in the consent process.

6. Summary of the decision-making process for the amendment

The process for this Policy amendment has been as follows:

1. Two meetings with the HSE Research and Development (R&D) PPI Reference Group have taken place, one for consultation and one for final approval of proposed amendment (minutes of such meetings are available).
2. Four meetings with the HSE National Policy for Consent in Health and Social Care, Research Steering Group, have taken place, two for consultation and to discuss the best approach and two for approval of proposed amendment (minutes of such meetings are available).
3. This paper was prepared outlining the process and matters considered herein and circulated to the HSE R&D PPI Reference Group and Policy Steering Group members with the final version of the revised Policy.
4. The new amendment Policy will be published on the HSE website.
5. The Department of Health representatives on the Policy Steering Group will bring to the attention of the Minister for Health that there is a legislative gap regarding the age of consent for research and that new legislation is needed to provide clarity and certainty.

7. Conclusion

In conclusion, the amendment to Section 5.1 of the Policy was made in response to the DPC's concerns. The term "young person," defined as individuals aged 16 or 17 years old, was introduced, allowing them to consent to participate in health and social care research and consent to the processing of their data in relation to such research, aligning the Policy with the DPC's interpretation of data protection law.

VERSION	DATE	AUTHOR
V0.1	22/01/2024	RB
V0.2	30/01/2024	TC / AH / BC
V0.3	11/10/2014	AH/BC
V0.4	15/10/2024	AT
V0.5	07/11/2024	Steering Group