NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

# Guidance on age of consent for regulated research in Ireland

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An overview of the age of consent for participation in regulated research *and* associated data processing, aligning to 16 years

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| Document Type | Guidance |
| Owner | National Office for Research Ethics Committees |
| Version | V 1.0 |
| Publication date | July 2024 |

## 1. Legislative framework for consent

For the purposes of this guidance document and as per National legislation[1], a 'minor' participating in a regulated research study is deemed to be person under 16 years.

For reference purposes, an adult is deemed to be a person aged 18 years and over.

- In accordance with the Clinical Trial Regulations (CTR) [2] the Medical Devices Regulations (MDR) [3] and *In-vitro* Diagnostic Regulations (IVDR).[4], the age of consent to participate in;
  - clinical trials for medicinal product for human use,
  - clinical investigations of medical devices, and
  - performance studies of *in vitro* diagnostics

  is 16 years and over**.**
- In accordance with the Data Protection Commissioner, the age of consent for the processing of personal data for any purpose (outside of Digital Services) is considered to be when an individual **has capacity to do so,** in accordance with the Data Protection Commission's guidance on '*The Fundamentals for a Child-Oriented Approach to Data Processing*'.[5]
- The Data Protection Commission states that

  '*There is no national law in Ireland which specifies the age at which children have a legal right to exercise their rights as a data subject'* and ''*a child may exercise their own data protection rights at any time, as long as they have the capacity to do so and it is in their best interests.'*[6]

## 2. Age of consent for regulated research - 16 years

Taking into consideration the EU Regulations and the guidance issued by the Data Protection Commissioner, the following points are set out:

- where a participant is aged 16 years and older has capacity to consent to participate in a regulated study, this infers they have capacity to consent for their personal data to be processed for that study,

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[1] S.I. No. 99/2022 - European Union (Clinical Trials on Medicinal Products for Human Use) (Principal) Regulations 2022

[2] Regulation (EU) No 2014/536: clinical trials on medicinal products for human use

[3] Regulation (EU) 2017/745: Clinical investigations on medical devices

[4] Regulation (EU) 2017/746: Performance studies for *in vitro* diagnostic medical devices

[5] Children Front and Centre: Fundamentals for a child-orientated approach to data processing

[6] Children Front and Centre: Fundamentals for a child-orientated approach to data processing

- capacity to consent to participation and for data processing should not be treated separately, therefore
- a participant over the age of 16 years can consent to participation in a regulated study **and** consent for the processing of their data associated data with the study,

## 3. What this means for Sponsors

- For new regulated studies commencing:
  - A participant 16 years and older can consent to participation in a regulated study **and** consent to the processing of their data for the purpose of that study.
  - there is no requirement to seek consent from a parent/guardian for the processing of personal data for participants aged 16 years and17 years,
- For live/current studies that received ethics approval from a National Research Ethics Committee (NREC):
  - no action is required to reconsent all participants aged 16 and 17 years for the processing of their data.
- For substantial modifications to a regulated study:
  - where reconsent to the modification is required, it is recommended that the consent protocol is amended to reflect the age of consent to be 16 years and older
  - where reconsent is not required as part of the modification, no further action is required
- For a participant that reaches the age of 16 years:
  - They must be reconsented for the continued participation in the study, and for processing of their personal data and use of biological samples for secondary research.
  - Where personal data and/or biological samples are to be held beyond the age of 16years, there needs to be a clear indication that the participant's consent for ongoing use will be obtained.

Additional guidance on seeking consent from participants for health and social care research can be found in the HSE National Policy for Consent for Health and Social Care Research.[7]

[7] HSE National Policy for Consent in Health and Social Care Research