NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

Guidance on legally designated representatives

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An overview of the role of legally designated representatives in regulated health research

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

1. Overview

The term '*legally designated representative'* is routinely used in health research to describe a person who can represent a research participant lacking decision-making capacity. This person who understands their will and preference of the research participant, may consent on their behalf.

This guidance explains how the term is used for the purpose of health research that falls under relevant EU Regulations.

It further describes other terms for people that maybe similar or related to legally designated representative and their applicability in health research.

2. Legally designated representatives in regulated research

The term '*legally designated representative'* is referred to in the Clinical Trial Regulations (CTR) the Medical Devices Regulations (MDR) and In-vitro Diagnostic Regulations. (IVDR).

The Irish legislation[1] that brings these EU Regulations into effect, defines the *legally designated representative* as the person who can lawfully consent, on behalf of an individual that lacks-decision making capacity, to participate in research that research falls within the scope of these EU Regulations.

A *legally designated representative* can give informed consent to participate in a regulated study on behalf of a participant lacking decision making capacity. Such examples are:

- participants lacking decision making capacity,
- in an emergency situation where a participant may temporarily lack decision-making capacity due to a physical or mental impairment,
- or a minor (under the age of 16).

The Irish legislation specifies the following individuals that may be considered a *legally designated representative*, for a research study that falls under the scope of the EU Regulations:

- A family member, or someone with a personal relationship with the participant who because of their personal relationship can provide the best interpretation of the will and preferences of the individual.
- If no-one in the above category is available to provide consent, a medical practitioner who is primarily responsible for the medical treatment of the participant and not involved in the conduct of the clinical trial or investigation may act as the *legally designated representative*.
- In all cases, the person or medical practitioner acting as a *legally designated representative* should be able to provide the best interpretation of the will and preferences of the participant.
- For minors, the minor's parent or guardian can fulfil the role of the *legally designated representative*.

[1] The following Irish legislation for regulated research further defines 'legally designated representatives: SI 099/2022, SI 257/2022, and SI 671/2023

Where a minor is capable of forming their own opinion, they must also be given the opportunity to assent to participation in the research study.

The wishes of a prospective participant who refuses to participate, or a participant who requests to withdraw from a research study, should always be respected.

3. Related terms - not defined in legislation

Terms such as '*Next-of-Kin*' and *'Proxy Assent'* are not recognised under Irish law and should not be used in participant information leaflets, consent and assent documentation for Irish research participants.

The use of the term '*Impartial Witness*'[2] should be restricted to instances where a participant has full decision-making capacity to consent to research but is unable to provide a written signature. The Impartial Witness cannot consent on behalf of a research participant, and their role is strictly to witness the consent protocol and consent obtained.

The terms '*Legally Authorised Representative*' and '*Legally Appointed Representatives'* are often used in participant facing documents, but this terminology is not described in Irish legislation and should be avoided.

In instances where the NRECs note the use or misuse of these terms in the documentation, they may request further clarification.

4. Related terms - defined in Irish legislation

- *The Assisted Decision-Making (Capacity) Act 2015 (ADMA)*

The ADMA as amended in 2022 enables persons lacking decision-making capacity to participate in 'healthcare research and social care research' with the support of a 'decision-maker supporter'.

However, the ADMA does not apply to research that falls under the EU Regulations (CTR, IVDR, MDR).

Therefore, a registered '*decision-maker support'* (under the AMDA) is not interchangeable with '*legally designated representative'* and should only be used in the context of the applicable legislation.

However, where an individual is registered as a *decision-maker support* and also meets the criteria of being a *legally designated representative* for research that falls within the scope of the EU Regulations.

- *Health Research Regulations and consent for processing of personal data for health research purposes*

In Ireland, the legally designated representative can only consent to participation in the regulated study. The processing of personal data of participants lacking decision-making capacity, may require a consent declaration application to be made by the Health Research Consent Declaration Committee (HRCDC), as described in the Health Research Regulations 2018.

[2] Impartial Witness is defined in the ICH E6(R2) Good Clinical Practice