HRCDC
Health Research Consent Declaration Committee

Assisted Decision – Making (Capacity) Act 2015 and Amendment 2022. (ADMA)[1,2]

Introduction

The Assisted Decision-Making (Capacity) Act 2015 came into force on 26 April 2023. This document examines how the decision supports as defined in the Act link with the Health Research Regulations [3, 4] and the operation of the HRCDC.

The ADMA provides for the setup of the Decision Support Service, please also refer to their website for more support and information. https://www.decisionsupportservice.ie

Summary of the ADMA.

The ADMA provides for the reform of the law relating to persons who require or may require assistance in exercising their decision-making capacity, whether immediately or in the future. It details the types of decision supports, assisted decision making, co-decision making, the provision of a decision-making representative and the ability to plan ahead by way of an Enduring Power of Attorney or Advance Healthcare Directive.

One of the main guiding principles of the Act is that capacity of an adult must be presumed, unless proven otherwise. The Act also requires a functional approach to the assessment of capacity that is time specific and issue specific.

The amendment to the ADMA in 2022 includes, in the definition of personal welfare, decisions in relation to participation in healthcare research. However please note decisions in relation to participation in health research **exclude participation in research in relation to clinical trials of medicinal products for human use or clinical investigations undertaken to assess the safety or performance of medical devices.**

The guiding principles of the ADMA include the following: (note this is an extract only, for complete text please refer to the ADMA [1])

- It shall be presumed that a person has capacity unless the contrary is shown.
- A person shall not be considered as unable to make a decision in respect of the matter concerned unless all practicable steps have been taken, without success, to help him or her to do so.
- A person shall not be considered as unable to make a decision in respect of the matter concerned merely by reason of making, having made, or being likely to make, an unwise decision.
- The intervener, in making an intervention in respect of a relevant person, shall—
  (a) permit, encourage, and facilitate, in so far as is practicable, the relevant person to participate, or to improve his or her ability to participate, as fully as possible, in the intervention,

  (b) give effect, in so far as is practicable, to the past and present will and preferences of the relevant person, in so far as that will and those preferences are reasonably ascertainable,

The Act details the three types of decision making supports available.

- Decision making assistant – the relevant person still makes the decision.
- Co-decision-maker – the decision is made jointly with the relevant person.
- Decision making representative – the decision is made by the DMR on behalf of the relevant person if provided for within the court order.

For a person that wishes to plan ahead the following supports are available:

- Enduring Power of Attorney – the donor can specify which decisions the attorney can take in the event the donor loses their capacity to decide at a future date.

In summary:

- It shall be presumed that a person has capacity unless the contrary is shown.
- A decision-making assistant does not make decisions for the relevant person but explains the information to them and ensures the decision is implemented.
- If a co-decision- making agreement or decision-making representation order is in place and covers decisions about participation in research, then consent given jointly with a co-decision-maker or by a decision-making representative equates to explicit consent and an application to the HRCDC is not necessary for this cohort of participants.
- The agreements in place, as referenced above, must cover participation in health research for them to be considered valid in the context of participation in such research.
- Capacity to provide consent is a matter that should be determined on a case-by-case basis, it is important that researchers are still satisfied that the person has the decision-making capacity to provide explicit consent with regards the particular study at the time of assessing capacity.
- All other arrangements outside of the decision-making supports for example, where there is a legally appointed representative, cannot provide explicit consent for health research. However, non-decision-making representatives can provide proxy assent and may be used as a data protection safeguard.
- However please note decisions in relation to participation in health research, in the context of the ADMA, exclude participation in 'regulated' research; namely clinical trials of medicinal products for human use, or clinical investigations of medical devices and performance studies of invitro diagnostic of medical devices.

To check whether a particular agreement, as referenced above there is information about how to apply to search the DSS register on www.decisionsupportservice.ie.

Information in this document is not intended to and does not constitute legal advice. This information is for general informational purposes only.

Data controllers are advised to consult their DPO and, where required, seek legal advice related to their specific situation.

[1] https://www.irishstatutebook.ie/eli/2015/act/64/enacted/en/pdf

[2] https://www.irishstatutebook.ie/eli/2022/act/46/enacted/en/html?q=decision&years=2022

[3]https://www.irishstatutebook.ie/eli/2021/si/18/made/en/print?q=health+research+

[4]https://www.irishstatutebook.ie/eli/2019/si/188/made/en/print?q=health+research