Table of terms commonly used in research involving adults with impaired capacity to consent

Advice

For intrusive research other than CTIMPs in England and Wales advice must be sought from a consultee on whether an adult lacking capacity to consent would wish to be included in the research study or not. Consultees are not asked to give consent on behalf of the adult, but rather to provide an opinion on the views and feelings of the potential participant. *

Assent

Agreement given by a child / young person (under 16 years) to participate in a research study. It is important to provide children / young people with information that matches their capacity when seeking assent. * If the child is able to give assent to decisions about participation in research, the investigator must obtain that assent in addition to the consent of the legally authorised representative. If the child does not assent, this should be respected^

Although sometimes used informally to refer to the process of involving adults who lack capacity in the decision-making process, or to the process of consulting consultees or seeking consent from legal representatives, the term 'assent' does not appear in UK legislation governing research involving adults lacking capacity.

Consent

Decision to participate given by someone who is competent, who has been adequately informed (and has adequate understanding), and who is free from undue influence enabling them to make a voluntary decision. The person can provide consent themselves (provided they are competent) otherwise someone else who is empowered by law can provide it. *

Consultee

In non-CTIMP research under the Mental Capacity Act (applicable in England, Wales and Northern Ireland), before an adult who lacks capacity to give consent can be included in research, the researcher must take reasonable steps to identify someone to consult (a consultee), to determine if participation in research is appropriate. This may be either a personal or nominated consultee. Consultees are not asked to give consent on behalf of the adult, but rather to provide an opinion on the views and feelings of the potential participant. *

- **Personal consultee**

  Someone who is involved in the person's care, interested in their welfare, and must be willing to help. They must not be a professional or paid care worker. They will probably be a family member but could be another person. *

- **Nominated consultee**

  If a personal consultee is not available, the researcher must consult a professional to act as a 'nominated consultee'. This person must have no connection with the project. [$]

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CTIMP

Clinical Trials of Investigational Medicinal Products governed by Medicines for Human Use (Clinical Trials) Regulations.

Deferred consent

Adults not able to consent for themselves can be recruited into CTIMPs in the UK without prior consent in emergency situations provided certain conditions are met. Consent is sought from a legal representative as soon as possible or from the adult if they regain their capacity to give consent.

In England and Wales, the law allows adults not able to consent for themselves to be recruited into other intrusive research (i.e. non-CTIMPs) without prior advice from a consultee, in emergency situations provided certain conditions are met. A consultee is consulted as soon as possible to seek advice on the participant's likely views and feelings or consent sought from the adult if they regain their capacity to give consent. *

See 'emergency research'

Emergency research

Emergency research is when: (i) treatment needs to be given urgently, and (ii) it is necessary to take urgent action for the purposes of the study. Obtaining consent from a legal representative or advice from a consultee may not be reasonably practicable. Where research participants do not have capacity to consent in emergency research, the law and associated requirements depend upon whether the research is a CTIMP and where in the UK your research will take place. *

See 'deferred consent'

Exception from informed consent (EFIC)

Predominantly a US term for the exception to the requirement that the investigator obtain informed consent from each subject, or the subject's legally authorized representative, prior to enrolment in emergency research provided certain conditions are met. ~

Legal representative

This is someone who can legally give consent on behalf of a child / young person or an adult unable by virtue of physical or mental incapacity to give informed consent themselves. This may be either a personal or professional legal representative. *

- **Personal legal representative**

  Under the Medicines for Human Use (Clinical Trials) Regulations in relation to CTIMPs the legal representative is a person who: (a) By virtue of their relationship with that adult / minor, is suitable to act as their legal representative for the purposes of that trial, and (b) Is available and willing to so act for those purposes.

  In relation to adults in Scotland, the legal representative can be: (i) Any guardian or welfare attorney who has power to consent to the adult's participation in research, or (ii) The adult's nearest relative. *

- **Professional legal representative**

  Under the Medicines for Human Use (Clinical Trials) Regulations in relation to CTIMPs a professional legal representative can be involved where no personal legal representative is available. This is someone other than a person connected with the conduct of the clinical trial who is: (a) The doctor primarily responsible for the medical treatment provided to that adult / minor, or (b) A person nominated by the relevant health care provider. *

Nearest relative

Nearest relative is a term used in Scotland in both the Adults with Incapacity (Scotland) Act and the Human Tissue (Scotland) Act. The Adults with Incapacity (Scotland) Act which covers non-CTIMP research uses the hierarchy of relationships defined in the Mental Health (Scotland) Act 1984 as the definition of nearest relative. The Human Tissue (Scotland) Act which covers the removal, retention and use of organs, tissue and tissue samples from the deceased, defines nearest relative with a list ordered from highest to lowest. *

Nominated representative/nominee

In England, Wales and Northern Ireland under the Human Tissue Act, an adult may appoint one or more persons to represent him after his death in relation to consent. The nominated representative's consent cannot be overridden by other individuals, including family members*

In Scotland under the Human Tissue (Scotland) Act, a person (aged 12 and over) can, before death, nominate a person or persons to represent them after their death. *

Power of Attorney

Under the Mental capacity Act in England and Wales, a personal welfare Lasting Power of Attorney can be appointed by the person to make decisions, including healthcare and medical treatment decisions, should they lose capacity. A person is not prevented from acting as consultee if they are an attorney authorised under a registered Lasting Power of Attorney or are a deputy appointed by the Court of Protection. But that person must not be acting in a professional or paid capacity (for example, the person's solicitor). &

Prospective or prior consent

A generic term for consent obtained prior to enrolment in research.

Proxy (or surrogate) consent

A generic term for consent provided by someone else (a proxy or surrogate) on behalf of a person who is unable to consent for themselves.

Retrospective consent

A generic term for consent sought following enrolment in research.

See also 'deferred consent'

Verbal or oral consent

For many studies, consent can be written, oral or non-verbal. A person's agreement with each statement contained in the consent form can be indicated by initialling or ticking boxes, or by providing the answers 'yes' or 'no' after each statement (verbal consent). The form itself is then signed by the parties involved in the consent conversation. However, in CTIMPs consent is not considered legal unless it is in writing, which can include electronic methods for documenting consent, including the use of electronic signatures. *

Waiver of informed consent (WIC)

Predominantly a US term for situations where an ethics board waives the requirement to obtain informed consent provided that certain conditions are met. #

Welfare attorney

In Scotland a power of attorney is an authority given by an individual (known as the Granter) to another person(s) (known as the Attorney/s) to deal with aspects of the Granter's affairs, under the Adult with Incapacity (Scotland) Act. In the case of Welfare Attorney, the Granter gives authority to deal with their personal welfare. Welfare powers cannot be exercised until such time as the Granter has lost the capacity to make these decisions. A Welfare Attorney can be anyone the granter trusts: a relative, a friend or a professional person. *

Welfare guardian

In Scotland a Welfare Guardian is a person who is appointed by court to take action and make decisions on behalf of an adult with incapacity, in relation to that adult's personal welfare; under the Adults with Incapacity (Scotland) Act. Guardianship is likely to be more suitable where the adult has long-term needs in relation to these matters. The standard term for a guardianship appointment is 3 years, although the Sheriff has the discretion to make the appointment for a longer or shorter period. Welfare Guardians are supervised by local authorities. *

Witnessed consent

An independent witness is not routinely required except in cases where potential participants are not able to read or write, or who are visually impaired etc. *

* Health Research Authority's online guidance http://www.hra-decisiontools.org.uk/consent/

^MRC Ethics Guide Medical Research involving children https://mrc.ukri.org/documents/pdf/medical-research-involving-children/

$ MRC Ethics Guide Medical Research involving adults who cannot consent https://mrc.ukri.org/documents/pdf/medical-research-involving-adults-who-cannot-consent/

~ FDA Guidance on Exception from Informed Consent Requirements for Emergency Research https://www.fda.gov/media/80554/download

FDA Guidance on IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects https://www.fda.gov/files/about%20fda/published/IRB-Waiver-or-Alteration-of-Informed-Consent-for-Clinical-Investigations-Involving-No-More-Than-Minimal-Risk-to-Human-Subjects---Printer-Friendly.pdf

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