CONSULT

Key differences between provisions for adults lacking capacity under Mental Capacity Act 2005 (MCA), Adults with Incapacity (Scotland) Act 2000 (AWI), and Medicines for Human Use (Clinical Trials) Regulations 2004 (CTR)

	MCA	AWI	CTR
Who is involved in decisions about participation	***Personal consultee*** - a person who is engaged in caring for the person or is interested in their welfare, except as a professional or for remuneration – friend, relative, unpaid carer, attorney acting under LPA, court appointed deputy (s32(2)) ***Nominated consultee*** - a person who has no connection with the project - healthcare professional, nominated individual (s32(3))	***Guardian or welfare attorney*** - who has power to consent to the adult's participation in research, or where there is no such guardian or welfare attorney, from the adult's nearest relative (for both CTIMPs (AWI s51) and non-CTIMPs). Guardianship is granted by the sheriff's office upon application, can cover property and financial matters or personal welfare including health, or a combination of these. Power of attorney is appointed by the individual whilst they have capacity, and grants someone they trust powers to act as their continuing (financial) and/or welfare attorney ***Nearest relative*** - the AWI uses the hierarchy of relationships defined in the Mental Health (Scotland) Act 1984 as the definition of nearest relative	***Personal legal representative*** – a person who, by virtue of their relationship, is suitable to act as their legal representative and is available and willing to act. ***Professional legal representative*** – the doctor primarily responsible for their medical treatment or a person nominated by their health care provider. Must not be connected with the trial (Schedule 1 Part 5)
Basis for the decision	Consultee is asked for ***advice*** whether the participant should take part or would not have wished to participate (s32(4)). The responsibility whether to include the participant ***lies with the researcher***	Not stated - although general principle 3 is ***account must be taken*** of the present and past wishes and feelings of the person, as far as this may be ascertained	***Informed consent*** given by the legal representative represents their presumed will (Schedule 1 Part 5(12)). Representative to decide whether the participant would have wanted to participate had they capacity to do so.
Requirement for provision of information	MCA does not specify any provisions that the person has to be informed about the research once they have been assessed as lacking capacity	Does not specify any provisions that the person has to be informed about the research once they have been assessed as lacking capacity	Person lacking capacity must have received information about the trial, its risks and benefits, according to his or her capacity before they can be involved.
Weight of any dissent/objection	Weight is given to any refusal or dissent from the individual lacking capacity, even when the person has little or no ability to understand the situation. If the person indicates (in any way) that he wishes to be withdrawn from the project he ***must be withdrawn*** without delay (s33(4))	The research ***must not be carried out*** if the adult indicates unwillingness	The explicit wish of a subject who is capable of forming an opinion and assessing the information to refuse participation in, or to be withdrawn from, the clinical trial at any time ***must be considered*** by the investigator

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Level of risk permitted	Research must be connected with an impairing condition in the functioning of the mind or brain affecting the person, or its treatment. There must be reasonable grounds for believing that the risk to the person is ***negligible*** and that anything done in relation to the person will not interfere with their freedom of action or privacy in a significant way or be unduly invasive or restrictive (s31)	Purpose of research must be to gain knowledge of the causes, diagnosis, treatment and care of the adult's incapacity or the effect of any treatment or care given to the adult while he or she is incapable. Research must be of ***real and direct benefit to the adult involved,*** or where it is not likely to but ***likely to improve the scientific understanding*** of the adult's condition and in the long term contribute to the attainment of real and direct benefit to persons suffering from the same form of incapacity (s51(4)). The research involves ***no foreseeable risk or only minimal risk*** to the adult and should impose ***no or only minimal discomfort***. These conditions should be seen in the context of the adult's standard treatment, if that is appropriate.	The clinical trial must relate directly to a life-threatening or debilitating condition clinical condition from which the person suffers. There must be grounds for expecting that administering the product will ***produce a benefit to the person outweighing the risks or produce no risk at all*** (Schedule 1 Part 5(9))
Loss of capacity during research	Unless the research started before the MCA came into force (1st October 2007), when a person loses capacity during a research project, the study must have approval under s30 of the MCA. Consent given by a person with capacity is not considered to survive any loss of capacity during the study and the researcher must seek the views of a consultee (s34) (see also Mental Capacity Act 2005 (Loss of Capacity during Research Project) (England) Regulations 2007, and Wales equivalent)	There is no specific provision for adults who lose capacity while taking part in non-CTIMPs in Scotland. Researchers and RECs might expect that in most circumstances the original consent should be respected. However, a request by a legal representative to withdraw someone from a study after they have lost capacity, should be considered carefully to ensure that it reflects the wishes of the person before they lost capacity, and that their current situation is fully considered	If a capable adult gives informed consent to take part in a CTIMP and subsequently becomes unable to give informed consent by virtue of physical or mental capacity, the consent previously given when capable remains legally valid, provided the trial is not significantly altered. It is good practice in such cases to consult with carers and take note of any signs of objections or distress from the participant. The researcher should consider withdrawing a participant if any objections are raised. If a capable adult refuses informed consent, and subsequently becomes unable to give informed consent the refusal is legally binding. They cannot be entered into the trial by seeking consent from a legal representative.
Emergency situations	s32(8) of the Act allows exceptionally for a person lacking capacity to be entered into research prior to a consultee being consulted in emergency situations, if it is also necessary to take action for the purposes of the research as a matter of urgency, but it is not reasonably practicable to consult under the previous provisions of this section	No emergency research provisions relating to surgical, medical, nursing, dental or psychological research under AWI in Scotland, only CTIMPs under CTR	Inclusion without prior consent from the participant or a legal representative is possible under defined circumstances under the Medicines for Human Use (Clinical Trials) (Amendment No.2) Regulations 2006. This includes that the treatment to be given as part of the trial needs to be given urgently.