These notes refer to the Mental Capacity Act (Northern Ireland) 2016 (c.18) which received Royal Assent on 9 May 2016

Mental Capacity Act (Northern Ireland) 2016

EXPLANATORY NOTES

COMMENTARY ON SECTIONS

Part 8 – Research

Section 132 - Research

This section allows intrusive research to be lawfully carried out on, or in relation to, a person who is 16 or over who lacks capacity to consent to taking part in that research ("P"), if the research is part of a research project approved by an appropriate body (to be prescribed) and it is carried out in accordance with the conditions set out in sections 134 to 137. Intrusive research is defined as research that would normally require consent if it involved a person aged 16 or over with capacity.

Section 133 – Section 132: exception for clinical trials

This section provides that clinical trials that are currently regulated by the Medicines for Human Use (Clinical Trials) Regulations 2004 (or regulations succeeding or amending them) are not to be treated as research for the purposes of section 132.

Section 134 – Approval of research projects

This section sets out the matters of which the appropriate body must satisfy itself before approving a research project involving a person who is 16 or over and lacks capacity. The research must be connected with an impairing condition (one that is, or may be, attributable to, or which causes or contributes to an impairment of, or disturbance in the functioning of, the mind or brain) that affects P, or with the treatment of his or her condition. There must also be reasonable grounds for believing that the research project cannot be carried out as effectively if it only involves people who have capacity to consent to taking part in it.

The research must have the potential to benefit P without imposing a disproportionate burden; or provide knowledge of the causes or treatment of P's condition, or of the care of people who have the same or similar condition. Where the latter applies, there must also be reasonable grounds for believing that the risk to P is negligible and the research must not interfere with P's freedom of action or privacy in a significant way, or be unduly invasive or restrictive.

Importantly the section also sets out that there must be a reasonable belief that no serious intervention will be carried out in respect of P as part of the research project unless the intervention could be lawfully carried out if it were not part of the project (for example, under Part 2). This in effect means that for a serious intervention, whether part of a research project or not, all the applicable safeguards in Part 2 must be met.

Section 135 – Requirement to consult nominated person, carer etc

Before a research project can be undertaken, this section requires the person conducting the research project ("R") to identify a person close to P who is prepared to be consulted about P's involvement. This could include an attorney appointed under a lasting power of attorney or enduring power of attorney, P's deputy or nominated person, but not someone acting in a professional capacity. If there is no such person, R must appoint a person independent of the research and who is prepared to be consulted, in accordance with Departmental guidance.

R must give the consultee information about the research and seek his or her advice as to whether P should take part and what, in his or her opinion, P's wishes and feelings would be about taking part if P had capacity in relation to it. If at any time the consultee advises that it is likely P would decline to take part, R must either ensure that P does not take part in the project, or if the research is already underway, that P is withdrawn from it. Where the latter applies, P may still receive treatment if it can be lawfully carried out despite no longer being part of the project.

Section 136 – Section 135: exception for urgent treatment

Treatment can still be provided urgently where it is not practical to undertake the consultation requirements in section 135, with the agreement of a medical practitioner unconnected to the organisation or the research project; or where it is not practicable in the time available to obtain that agreement, in accordance with a procedure previously agreed by the appropriate body.

Section 137 – Additional safeguards

The purpose of this section is to provide additional safeguards for P once the research has begun. It requires R to respect any signs of resistance from P (except where what is being done is intended to protect P from harm or to reduce or prevent pain or discomfort) and not involve P in research that would be contrary to an effective advance decision to refuse treatment, or any other form of statement made by P of which the R is aware. P's interests must also be assumed to outweigh those of science and society.

P must be withdrawn from the research without delay if he or she indicates that he or she wishes to be withdrawn from it, or if R has reasonable grounds for believing that any of the requirements for approval of the project are no longer met. However, in these circumstances, P may still receive treatment if it can be lawfully carried out despite no longer being part of the project.

Section 138 – *Loss of capacity during research project: transitional cases*

This section provides for a transitional regulation-making power to cover research started before section 132 comes into operation and which involves people who had capacity when enrolled but who lose capacity before the end of the project. The regulations will set out how such research should continue and any additional safeguards that are required.