



Llywodraeth Cynulliad Cymru
Welsh Assembly Government



Department
of Health

Mental Capacity Act 2005 and consent for research

What research does the Act cover?

1. The Mental Capacity Act Code of Practice (para 11.7) gives advice on the scope of the Act in relation to intrusive research. It summarises some cases where research will not require consent in order to be lawful. The following advice expands on the reference to section 251 of the National Health Service Act 2006 (NHS Act), formerly section 60 of the Health & Social Care Act 2001 and the role of the Patient Information Advisory Group (PIAG). It also addresses situations where consent is given to join a research project when it is possible that capacity will be lost before the end of the project.
2. Section 30 of the Mental Capacity Act 2005 (MCA) provides that intrusive research relating to people without capacity is unlawful unless the provisions of sections 31-33 are complied with.
3. 'Intrusive research' is defined as research of a kind which would be unlawful if carried out in relation to a person who could consent, where that person had not consented. Where the research is intrusive, a Research Ethics Committee (REC) must be satisfied it meets the requirements of section 31 and the consultation requirements set out in section 32 must be complied with. There are other detailed duties that must be complied with, such as the obligation to withdraw the person in question if he shows any sign of objection.
4. The question whether research is intrusive or not is a hypothetical or abstract one. One has to ask oneself: "if the person in question was able to consent for himself, would I need his consent to do this research lawfully?"

Does consent endure the loss of capacity?

5. A second hypothetical question about the scope of the Act is "has the consent needed already been obtained before the loss of capacity?" Where consent has been obtained prior to loss of capacity, the researcher needs to consider if this consent remains valid following the loss of capacity. There are only a very limited set of circumstances where an earlier consent at common law endures a loss of capacity. The following specific cases illustrate some of the limited circumstances where the research requirements in the Act will not apply to research on, or involving, a person who lacks capacity to consent.

Continued use of material to which express consent has previously been given will not generally constitute intrusive research.

6. Where consent to the use of data or tissue samples was given prior to the onset of incapacity, continued use of that material will generally not constitute "intrusive research" because no further consent to that use would be required from a person who had capacity. Researchers may rely upon properly informed and expressed consent that was given prior to the onset of incapacity to continue to use existing data and tissue samples after that time. The

precise nature of the consent will depend on the particulars of each project, but it will be necessary to address what is to be done with data and samples in the event of later loss of capacity. Data and samples collected in reliance on the original consent may therefore continue to be used for the purpose of the research, and sections 31 to 33 of the MCA will not apply. However, further consent from a patient, or, in cases where a patient no longer has capacity to give consent, compliance with sections 31 to 33, would be required in order to collect and use new data or samples because this would constitute “intrusive research”. New research uses of existing data would only be lawful if the use falls within the terms of the consent.

7. In the case of long-term research studies commenced before 1 October 2007, it may not be clear that consents given in the past were in fact expressed to survive a loss of capacity. Regulations¹ have therefore been made under section 34 of the Act allowing continued use of material obtained before loss of capacity in these circumstances, subject to certain safeguards.

Anonymised material

8. Where any data or tissue samples used have been anonymised so that the data subject or donor is not identifiable to the researcher, and as such are not confidential, the consent of a person with capacity is not required, and therefore the research will not be “intrusive research” for the purposes of the MCA.

What happens to research involving personal health information?

9. The common law duty of confidentiality, data protection and human rights legislation requirements need to be met alongside those of the MCA. Whilst the Data Protection Act 1998 (DPA) does not require consent for research purposes, the common law duty of confidentiality requires that data disclosed outside of the clinical care team should be processed with consent or another lawful basis. There are circumstances where patient identifiable information may be processed, pursuant to regulations made by the secretary of state under section 251 of the NHS Act 2006², notwithstanding the provisions of section 30 of the MCA (see summary at Annex A). Research undertaken with approval under section 251 would not be regarded as “intrusive” within the meaning of section 30(2) and the requirements of sections 31 to 33 would not apply because, if the person in question had capacity, his consent would not be a prerequisite for such research to be legally carried out.

10. Section 251 does not apply where consent is practicable. The principle of equity underpinning the provisions of the MCA means that those lacking capacity should not be treated less favourably than those with capacity. Consequently, lack of capacity is no longer an appropriate justification for why consent is not practicable under S251. The judgment that PIAG has to make in considering research applications relating to those lacking capacity is whether there are other reasons why consent is impracticable which would justify the use of powers under S251 and if the same reasons of impracticality would apply if the research were being conducted in those with capacity. This is straightforward where the research involves both those with and those lacking capacity but is less so, where the research is being conducted solely in relation to those lacking capacity. If the primary reason consent is impracticable is because the patient lacks capacity then Sections 30-33 of MCA will apply.

¹ The Mental Capacity Act 2005 (Loss of Capacity during Research Project) (England) Regulations 2007 (SI2007/679) and The Mental Capacity Act 2005 (Loss of Capacity during Research Project) (Wales) Regulations 2007 (SI2007/837 (W.72))

² Health Service (Control of Patient Information) Regulations 2002 (S.I 2002/ 1438)

Research during elective surgery

11. During the passage of the MCA there was discussion of the situation relating to research that was undertaken as part of a routine surgical procedure. For example, a surgeon may wish to evaluate two different monitoring devices and seek consent from the patient to be randomised into one or other of the study groups. Although surgical research would be intrusive research within the meaning of section 30(2), it is not being carried out on "a person who lacks capacity" within the meaning of section 30(1). The research subject generally does have capacity at the time at which he or she consents to research to be done under anaesthesia, so section 30 of the Act does not apply at all. In this sense, the research is part of a single procedure (involving anaesthesia, standard surgery and experimental aspects) to which the person gives full consent. This does not affect the normal arrangements for clinical and research governance affecting research or experimental aspects of elective surgery.

Key messages

- Consent under common law cannot generally be said to endure the loss of capacity
- Research during general anaesthesia and elective surgery does not fall under the MCA research provisions.
- The MCA research provisions will not apply where:
 - there is properly informed and express consent to use existing data and tissue samples after loss of capacity,
 - where any data or tissue samples used have been anonymised,
 - where research is undertaken with approval under regulations made pursuant to section 251 of the NHS Act 2006.
- The MCA research provisions will apply where:
 - the consent did not expressly consider what would happen in the event of incapacity
 - there is a need to collect new samples or data from a person who has lost capacity or to use existing identifiable data or samples for new research purposes.

Annex A

Legislation affecting use of patient data in research

The common law duty of confidentiality

Common law or case law is that which has been established through precedents set in the courts. The common law duty of confidentiality requires that disclosure of personal health information i.e. identifiable information is only disclosed where there is a statutory basis for disclosure, where the consent of the individual has been obtained or where there is a clear over-riding public interest justification for disclosure. The only statutory basis applicable to research is section 251 of the National Health Service Act 2006 and the applicable Regulations(see below). The judgment with respect to the public interest is one to be made by the clinician or organisation owing the duty of confidentiality i.e. NHS organisations and clinical staff. This judgment requires balancing not only the public interest in disclosure against the private interests of the individual(s) concerned but the competing public interest in maintaining public trust in a confidential service.

Sections 251 and 252 of the National Health Service Act 2006 and the Health Service (Control of Patient Information) Regulations 2002

1. Section 251 of the National Health Service Act 2006 (“the 2006 Act”) (which re-enacts section 60 of the Health and Social Care Act 2001) enables the Secretary of State to make regulations enabling “prescribed patient information” to be processed (that is, used) for medical purposes, which includes medical research but not other forms of research. Such regulations must be in accordance with the provisions of the Data Protection Act 1998. Section 251 is envisaged as a course of last resort and is not to be used where anonymised information will suffice or where consent is practicable.

2. In addition to the specific support established by the Act, which requires regulations to be laid before Parliament, a class support mechanism was created under the Health Service (Control of Patient Information) Regulations 2002 (“the 2002 Regulations”). These regulations, which were made under section 60 of the 2001 Act, but continue to have effect under section 251 of the 2006 Act, provide for confidential patient information to be processed without breach of the common law duty of confidence in certain circumstances. It is the class support mechanism, which generally applies in the case of medical research.

3. The classes of support are:

- processing to anonymise or reduce the identifiability of data.
- Geographical analysis for research
- Identifying relevant patients in order to seek their consent either to participate in research or to permit their personal data or tissue to be used for research purposes.
- Linking information from two or more different sources, validating the quality or completeness of data or avoiding the impairment of data quality by incorrect linkage or unintentional duplication;

- Analysing provision made by the health service for patient care and treatment.

A requirement of the Act is that in addition to approval by the Secretary of State, research must also be approved by a Research Ethics Committee.

4. Section 252 of the 2006 Act (formerly section 61 of the 2001 Act) provides for the establishment of the Patient Information Advisory Group (“PIAG”) as an advisory body.

Scope of section 251 and the 2002 Regulations and role of PIAG

5. Although PIAG’s role is advisory and does not have any statutory role in approving the processing of information under the 2002 Regulations, in practice it has delegated authority to approve applications under the class regulations on behalf of the Secretary of State. The purposes for which the Regulations can be used to allow processing of information without breaching confidentiality are limited to those mentioned above. In other words, the 2002 Regulations only enable information to be used, and only enable the Secretary of State to approve the use of information, for limited types of processing for research.

How section 251 operates

6. The PIAG established an application process for approval under s.251. This was to ensure that all applicants have a fair chance of approval and also because of the requirement to maintain a register of activities approved under s.251. Details of the application process can be found at www.advisorybodies.doh.gov.uk/PIAG.

Other legal restrictions on use of confidential patient information

7. In addition to the common law duty of confidentiality, addressed above, other legal restrictions apply to the use of confidential patient information for research:

- the requirements of the Data Protection Act 1998 (the Act does not necessarily require consent to the use of data for research but does require fair and lawful processing in all cases which means that the common law requirements above still apply, as well as imposing other obligations, for example relating to security of data);
- the requirements of section 30 of the MCA, once it is in force;
- Article 8 of the European Convention on Human Rights (“ECHR”). The law referred to in the previous three bullets must be interpreted as far as possible consistently with Article 8 and public authorities have an independent obligation to comply with Article 8.

8. As indicated, these legal restrictions or obligations are cumulative and do not cancel each other out, except where s251 approval is obtained in place of s30 of the MCA. In particular section 30 of the MCA says that research in relation to people without capacity is unlawful unless the terms of section 30 are complied with. It does not say that research is necessarily lawful if those terms are complied with (although if there is some illegality in the proposal then the REC approval required by section 30 should not be forthcoming).

Data Protection Act 1998

9. The Data Protection Act 1998 permits the processing of data without consent in certain circumstances set out in Schedule 2 to the Act. The one most relevant to processing for research is where the processing is necessary for the purposes of legitimate interests pursued by the data controller or third parties to whom the data are disclosed, except where the

processing is unwarranted by reason of prejudice to the rights and freedoms or legitimate interests of the data subject.

10. If the data in question is sensitive personal data (defined in the Act and including all data relating to a person's health) one of the conditions set out in Schedule 3 to the Act must additionally be met for the processing to be permitted. One of those conditions is that explicit consent is obtained. Where consent cannot be or is not obtained, processing for medical research may go ahead if it is done by someone with an obligation of confidentiality equivalent to that of a health professional. This is in addition to the common law requirements indicated above and not in substitution of them. Alternatively, secondary legislation made under Schedule 3 permits processing of sensitive data where that is necessary for research, provided that the processing is in the substantial public interest, that it does not support measures or decisions that affect individual's care or treatment and does not and is not likely to cause substantial damage or distress to the subject or anyone else.

11. In all cases there is a requirement that the processing be fair and lawful. This means that the common law duty of confidentiality, MCA and Human Rights Act provisions still need to be met.

12. The Data Protection Act imposes other requirements in relation to the processing of data, including requirements relating to data security, transfer abroad and information to be given to data subjects but these do not relate directly to the question of consent.

Article 8 of the ECHR

13. Article 8, entitled 'Right to respect for private and family life', provides:

- everyone has the right to respect for his private and family life, his home and his correspondence;
- there shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.

14. Use of confidential medical information for research would engage Article 8.

15. The required respect for privacy will be satisfied by obtaining proper consent to participation in research; where research is undertaken without such consent then the use without consent must be "necessary in a democratic society" for one of the purposes mentioned in Article 8(2).

16. Purposes of ethical medical research can fairly be regarded as "necessary in a democratic society in the interests of...the economic well-being of the country" or of "the protection of health", depending on the nature of the research. Ethical approval will be important in demonstrating that the research is "necessary" in this sense. Necessity in this sense includes a requirement for proportionality which the courts have judged equates to the 'public interest' test required by the common law of confidentiality (see eg *Campbell v MGN* [2004] 2 AC 457) – so that any invasion of privacy must be kept to the minimum necessary to achieve the legitimate objectives.

Further the use of data for research without consent must be "in accordance with the law" so must comply with domestic restrictions on such usage. The authority of section 251 of the 2006 Act is useful in that it constitutes a clear legal authority for lifting common law confidentiality restrictions. The requirements of the Data Protection Act 1998 and section 30 of the MCA must of course be complied with in addition as mandatory provisions of domestic law.