Mental Capacity Act 2005
Guidance for Critical Care

By David K Menon & Doris Ann Chatfield
University of Cambridge
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Preface

These guidelines are aimed at those working in the critical care environment, where the overwhelming majority of admissions are of patients who lack capacity for a large proportion of their stay. The Mental Capacity Act 2005 has created a new statutory framework in England and Wales for decision-making on behalf of any individual aged 16 or over lacking capacity to make a decision for themselves.

This booklet will help to clarify issues raised within the critical care community in relation to the Act. However it should not be read in isolation from the Code of Practice for the Mental Capacity Act (MCA) which provides more detailed general information and guidance.

As far as possible the following chapters have been written in a similar format to the Mental Capacity Act Code of Practice as it is designed to work in conjunction with it. This document will provide guidance on areas specifically related to working in intensive care. Text written in italics are particularly pertinent to the Critical Care setting.
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Introduction.

The Mental Capacity Act 2005, covering England and Wales, provides a statutory framework for people who lack capacity to make decisions for themselves, or who have capacity and want to make preparations for a time when they may lack capacity in the future. It sets out who can take decisions, in which situations and how they should go about this. The Act came into force during 2007 and applies to everyone ‘habitually resident or present in England and Wales’.

Key Aspects

In practical terms, the major impact of the MCA on critical care practice will be incorporated within the following five major areas:

1. It is important to note that, in most areas, the MCA codifies what is currently best practice, rather than imposing completely new rules, and should therefore not be too onerous to comply with. Indeed, the documentation of these issues in statute and regulation will remove ambiguity and provide protection for clinicians dealing with incapacitated patients.

2. Detecting and defining capacity for healthcare decision-making. This will be most important at the time of admission, and during recovery from critical illness, and in Level 2 patients who are not sedated or incapacitated due to disease.

3. The majority of patients who are in level 3 beds will clearly have compromised capacity due to disease or drugs. In these patients the one major issue will be identifying and following procedures for consent that take account of any wishes or preferences they expressed when they still had capacity.

4. For clinical care we need to know who to approach and consult with as part of the best interests process and how to proceed if these are not known. It is important to recognise that such interactions should not unduly delay urgent or emergency care which could be conducted on the basis of best interests. Similar (but different) arrangements apply to research (see Chapter 9).

5. Finally, there will need to be much clearer documentation of these processes than has been the case thus far. At a strategic level, this will need to include evidence of formal Trust and Unit protocols and compliance with defined process and procedures. Units will also need to ensure that the application of these protocols is clearly documented in the clinical notes of individual patients.
Chapter 1. Principles of the Act. (Section 1 MCA 2005)

The MCA has five key principles which emphasise the fundamental concepts and core values of the MCA. These must always be considered when working with or providing care or treatment for people who lack capacity.

a) Every adult has the right to make his or her own decisions and must be assumed to have capacity to do so unless it is proved otherwise. This means you cannot assume that someone cannot make a decision for themselves just because they have a particular medical condition or disability.

b) People must be supported as much as possible to make a decision before anyone concludes that they cannot make their own decision. This means that you should make every effort to encourage and support the person to make the decision for themselves.

c) People have the right to make what others might regard as unwise or eccentric decisions. Everyone has their own values, beliefs and preferences which may not be the same as those of other people. You cannot treat them as lacking capacity for that reason.

d) Anything done for or on behalf of a person who lacks mental capacity must be done in their best interests.

e) Before the act is done, or the decision made, regard must be had to whether the purpose for which it is needed can be as effectively achieved in a way that is less restrictive of the person’s rights and freedom of action.

Most of these principles are pretty straightforward in their application to critically ill patients, but some important points need to be made.

- The support that can be provided for decision making in critically ill patients is clearly going to be different from that used in other settings. For example, some approaches, such as moving the patient to a more optimum environment for interaction may be impractical. Other approaches such as repeated interaction to allow for fluctuating capacity may be limited by the need for urgency.

- Many critically ill patients who do have capacity (e.g. when weaning from ventilation) may need special resources and professional skills to communicate their wishes (letter boards, light writers, etc) which may not be particularly common in other settings. We believe that additional work needs to be done to address this issue, and it should be seen as a subject for future work.

- While the MCA should inform all interactions with patients, it needs to be clearly stated that clinicians can only be expected to do what is reasonably achievable, allowing for the clinical context and urgency of the situation.
Chapter 2. People who lack capacity. (Section 2 MCA 2005)

‘A person must be assumed to have capacity unless it is established that he lacks capacity’. (MCA section 1(2))

This is always the starting point before any decision is made. Every effort must be made to establish whether a person has the capacity to make a decision or not. In the critical care setting it may be clear that a person lacks capacity to make a decision (e.g. a low Glasgow Coma Score (GCS) in severe head injury, or sedation and neuromuscular blockade to facilitate management of severe ventilatory failure). Even where a lack of capacity is obvious, this fact should be recorded in the notes and the clinicians should accept that, at that time, they are bound to act in the best interests of the patient.

However in circumstances where the issue of capacity is not as clear, an assessment of capacity must be undertaken and documented, even if the conclusion is that capacity is absent. Thus, the agitated patient who is recovering from head injury may have a higher GCS, but a careful assessment may still show that capacity for making critical decisions (such as further imaging) is still missing. On the other hand, the patient who is being weaned from ventilatory support may need little or no sedation, and will be able to communicate with a letter board or gestures regarding consent for a tracheostomy.

Many patients will have the capacity to make decisions at the time of ICU admission, or when they are receiving high dependency care. It is essential that all reasonable efforts are made to involve such individuals in both present and anticipated future decision making, and where an assessment shows that lack of capacity makes this impossible, the process of reaching this conclusion needs to be clinically documented.

Assessment of capacity

‘A person lacks capacity in relation to a matter if at the material time he is unable to make a decision for himself in relation to the matter because of an impairment of, or a disturbance in functioning of, the brain or mind’ (MCA section 1(2)) . This impairment may be permanent or temporary. Temporary impairment of the brain or mind may be caused by conditions such as acute renal failure or brain trauma as a result of a traffic accident.

Anyone assessing a person’s capacity to make a decision must use the two-stage test of capacity.

Box 1. Two stage assessment

Stage one.
Does the person have an impairment of the mind or brain, or is there some sort of disturbance affecting the way their mind or brain works? (It does not matter whether the impairment or disturbance is temporary or permanent)

Stage Two
If so, does that impairment or disturbance mean that the person is unable to make the decision in question at the time it needs to be made?
If after every effort and support has been given to help a person make a decision for themselves the answer to the above two stages is yes, then it can be determined that a person lacks capacity.

Most importantly, a person’s capacity must be assessed in terms of their capacity to make a particular decision, at the time it needs to be made. When assessing a person’s ability to make a given decision it might be useful to consider:

- what it is you are asking of them,
- what is it they need to understand,
- what do they need to be able to reason about,
- what is it they need to make a decision on, and then
- how would you expect them to communicate their decision.

It is important to underline the fact that assessment of capacity is decision specific. Thus, a patient in respiratory failure may be able to contribute to a decision regarding the question and timing of tracheostomy at a time when they are still unable to fully comprehend treatment options for the pulmonary malignancy that was the underlying cause of the respiratory failure.

Determining why a patient lacks capacity is important. Conditions such as electrolyte imbalance may seriously compromise conscious level and capacity. However, these may be correctable, and restore capacity to make subsequent decisions. Thus, in the elderly patient with hypercalcaemia or renal failure from a myeloma, it may be impossible to obtain meaningful consent for correction of electrolyte imbalance or haemofiltration, and these may need to be undertaken in the best interests of the patient (see chapter 4). However correction of metabolic abnormalities may now allow patients to make decisions about whether they wish to have the underlying malignancy treated.

Who should assess capacity?
Different people will be involved in assessing someone’s capacity to make different decisions at different times. The person who will be providing the treatment or care at the time the decision needs to be made has to assess capacity. Thus, in practical terms, each member of the team, be they nurse, physiotherapist, radiographer, dietician, or physician may need to make a judgement before carrying out an intervention as to whether a patient has the capacity to make a decision to consent to that intervention or not.

Where there is doubt about capacity, responsibility for making the assessment falls to the senior clinician in charge of the patient. Certain, possibly complex decisions may require an opinion from a psychiatrist. It would also be pertinent to involve psychiatrists or mental health professionals in situations such as when a patient has self harmed and may be refusing treatment such as stitches to wounds. But the ultimate assessment as to whether or not the person has capacity is the responsibility of the individual intensive care clinician who is proposing the intervention in question. There may be occasions where patients need to be detained under the Mental Health Act. The Mental Health Act is an entirely separate legal code which should not be confused with the issue of capacity. A patient who is detained under the Mental Health Act 1983 will often have capacity but the necessity to assess or treat the patient’s mental disorder may justify overriding their lack of consent to treatments for that mental health disorder.

Particularly in critically ill patients, assessing capacity should be a multi-disciplinary task. One-to-one nurse-patient ratios are common in such patients, and the continuing presence of the nurse at the
bedside provides an enormously useful resource to comprehend patients’ wishes. Discussions regarding capacity, should be an integral part of the ward rounds and team meetings, and be documented as such, in appropriate patients.

The need for multidisciplinary assessment of decision making capacity, in most instances will be implicit. However knowledge of the MCA should inform care provided to incapacitated patients, and it may become necessary, in some settings, to undertake (or repeat) the assessment of capacity in a formal fashion, record the result of such an assessment, and act on these results. Thus, a patient, lacking capacity, with multi-organ failure who is being treated on the best interests premise, may improve sufficiently to participate in decision making, and this recovery of capacity may become apparent to members of the multidisciplinary team. In this context, it would be important to involve the patient in subsequent management decisions wherever possible (e.g. tracheostomy, or even the continuation of organ support, where this decision is in question).

**Fluctuating capacity**

Often in the critical care setting patients will have fluctuations in their capacity to make decisions. It is important to note that this does not mean that they lack capacity for all decisions. As with all situations an assessment of a person’s capacity to make a decision must only be made when a particular decision needs to be made. It may be possible to delay a decision until a person has the capacity to make it.

**Box 2. Specific considerations in the critically ill patient – a conceptual framework**

*Is there a clear and incontrovertible cause for compromised capacity (e.g. severe TBI [traumatic brain injury] with low GCS/ metabolic coma/deep sedation)? If so, no further assessment of capacity is needed but the absence of capacity must be recorded.*

*If loss of capacity is not absolute, can the patient’s capacity, or his ability to communicate it be improved, so that he can participate in decision making (letter board etc; see Chapter 3 for details)?*

*If capacity is judged to be compromised despite every effort to involve the patient, can some or all of the decisions be made after an intervention that improves capacity (withdrawal of sedation, correction of metabolic abnormalities etc)? If so, make the minimum required intervention, and then reassess.*

*Does the urgency of the intervention permit reassessment of capacity later? If capacity is inadequate at the time of assessment, and the decision is urgent, the decision must be made as if the person was incapacitated.*

*With continuing care in the patient lacking capacity at the outset, it is essential to consider whether the clinical state of the patient changes in a way that might imply the need to reassess capacity. However, in a patient who is judged to be incapacitated, if the clinical context does not materially change, it is reasonable to continue care on the basis of the initial assessment.*
‘Reasonable belief’ of lack of capacity
To ensure protection from liability when providing care or treatment you must have ‘reasonable belief’
that a person lacks capacity to make decisions for themselves. This means that you have to take
reasonable steps to ascertain that a person lacks capacity to make a decision. They must also establish
that the act or decision made on behalf of a person is made in their best interests (see Chapter 5). There
is no formal process for making an assessment of capacity, but if challenged you must be able to describe
the steps taken during an assessment that bring you to the conclusion that a person lacks capacity. The
steps taken will be dependent on the individual and the urgency of the decision. Sections 4.45 and 4.49
of the Code of Practice provide helpful steps in the process of assessing capacity. However, in the context
of critical illness the decision making process needs to involve somewhat different mechanics before
proceeding to the considerations in the Code of Practice – these are listed in Box 2 (on the previous page).

Recording capacity
The Code of Practice notes that it is good practice to record assessments undertaken in the relevant
professional records. On a practical level assessment of capacity could be incorporated in the critical
care unit care plan. It is not practical to make a record each time a procedure is carried, however, it is
paramount that informal assessments be done on a decision by decision basis. Assessment of capacity
should be ongoing and reviewed regularly and may be a multi-disciplinary team decision following
discussion with all those involved in the care process.
Chapter 3. Inability to make a decision (Section 3 MCA 2005)

The Act states that a person is unable to make a decision if they cannot:

1. understand information about the decision to be made,
2. retain that information in their mind,
3. use or weigh that information as part of the decision-making process, or
4. communicate their decision.

Chapter 3 of the Code of Practice outlines the need to present information in a way that is appropriate to meet individual needs and circumstances, and stresses the importance of explaining information using the most appropriate form of communication for that person. The amount and type of information given will be dependent on the decision that needs to be made and the length of time they have to make it.

Providing information in emergency situations

In emergency medical situations urgent decisions may need to be made and action taken in a person’s best interests, in line with Part 1 Section 4 of the Act. This is discussed in greater detail later in Chapter 4. Clearly, in many settings, the urgent need to initiate treatment may limit the time that can be spent in maximising an individual’s ability to participate in the decision making process. In such circumstances the overwhelming decision in terms of best interests is to initiate emergency therapy using the best interests principle. (See checklist in Chapter 4).

Provision of information in non-urgent situations

When asking an individual to make a decision it is important to consider the gravity of the decision that needs to be made. Thus, information needs to be presented appropriately to the situation. In order to decide whether an individual has capacity, the clinician needs to assess the components of the decision making process, but he/she also needs to make sure that this process is facilitated as much as practicable. Thus, the patient needs to understand the nature of the decision and purpose of the decision. A person also needs to be aware of the consequences of deciding one way or another and of failing to make the decision. Within the stressful environment of a critical care unit, even individuals with capacity may need longer to take in information and understand it. It is also important to take into account cultural, ethnic or religious factors that shape a person’s way of decision making.

Providing information in an accessible format to aid decision making

The MCA Code of Practice outlines the ways in which this can be achieved. This includes the selection of the most appropriate environment, choosing the best time of day for someone with predictably fluctuating capacity, involving relatives or carers in the process, and the individualisation of information delivery. Such individualisation could include the use of simpler language, sign language, letter boards, etc.

However, many of these options may be impracticable in the critical care context, where there is often limited (or no) flexibility in the choice of site and timing when such discussions take place, relatives may be unavailable, and several of the options for improving information access are inappropriate. Despite this, it is important to keep these options in mind, since they may have a role. For example, the mildly demented individual who is presenting for major elective vascular or cancer surgery may wish to be involved in decisions about the extent of post-operative critical care, and this may be facilitated by using all of the options that are discussed in the previous paragraph. In the patient who is already receiving organ support, particularly with
mechanical ventilation, it is essential to ascertain what part of the patient’s apparent inability to participate in decision making is the consequence of communication difficulty, and what is truly due to lack of capacity. The use of particularly skilled professionals or of communication aids such as letter boards and pressure switches, clearly have a role in this area, but further development is required to make newer technology such as computer interfaces easily usable.

Some individuals may only be able to communicate by blinking or simply moving their little finger, for example. Communicating with patients in these circumstances can be difficult and may require the intervention of professionals with greater expertise and experience (e.g. physiotherapists, speech therapists, or occupational therapists) to intervene and provide information and ascertain a person’s decision. Emerging literature suggests that some patients who are clinically diagnosed to be in a vegetative state may be able to communicate through functional imaging that detects covert cognitive processing. However, this approach is still in its infancy, experience is very limited, and its role in the context of decision making in the apparently incapacitated patient is uncertain. The code of practice suggests that if no behavioural outputs are possible, the patient should be treated as though he lacks capacity.

Making unwise decisions
There may be many occasions in the critical care setting when a person may make what appears to be an unwise decision. The MCA provides the right of everyone with capacity to make decisions which to others may seem unwise. Strictly, this right applies only if the decision making process is not compromised by lack of capacity. Thus, a confused patient who is recovering from sedation or head injury may pull out a tracheostomy tube and indicate that he does not wish it replaced. However, a consideration of the circumstances may make it clear that the patient cannot comprehend the consequences of his actions, and hence the decision is not simply unwise, but based on an absence of capacity. Replacement of the tracheostomy tube in this context, even against the apparent wishes of the patient, is appropriate, because the patient lacks capacity and the action is in the patient’s best interests. It is thus a decision in accordance with the MCA.

However this needs to be contrasted with situations in critical care where a seemingly unwise decision is based on full comprehension. Consider the scenario of an adult patient with an isolated high spinal cord injury, who is thought to have a reasonable chance of significant neurological recovery. Most neurosurgeons and intensivists would choose to treat this aggressively, despite the small (but significant) risk of poor recovery and need for long term ventilation. However, if the patient was not otherwise confused or sedated, and was judged not to have clinically significant depression by a psychiatrist (which led to a lack of capacity or sectioning under the Mental Health Act), then it would be for the patient to decide whether to opt for continued ventilatory support and surgery. If the patient refused, he would be making an apparently unwise decision, but, as a person with capacity, this would be a decision the treating team would have to respect.

The presence of psychiatric illness does not automatically imply lack of capacity, even if the illness is severe. Thus, in a test case, the (apparently unwise) decision of a schizophrenic patient who chose not to have a gangrenous foot amputated was upheld by the Court, who determined that the schizophrenia did not impair his capacity to make such a decision. However where a patient is detained under the Mental Health Act and the refusal of treatment is a consequence of the underlying mental disorder, it is possible lawfully to override the patient’s lack of consent. Hence, for example, detained anorexic patients can be required to accept a feeding tube because their aversion to being fed is related to their mental disorder. Clearly, these two examples also highlight the need to obtain an expert psychiatric opinion and possibly legal advice.
Chapter 4. Best Interests (Section 4 MCA 2005).

One of the key principles of the Act is that any act done for, or any decision made on behalf of a person who lacks capacity must be done, or made, in that person’s best interests. This principle applies regardless of who is making the decision, and whether it involves a minor or a major issue, and covers all aspects of financial, personal welfare and healthcare decision-making and actions. One exception to this principle is where a person has made a valid advance decision (see Chapter Seven), in which case the person’s explicit wishes override any assessment of best interests. However, where such a decision involves the refusal of life sustaining treatment, it must be documented in writing, signed and witnessed, with specific and explicit recognition that the decision applies even if life is at risk. The Act and Code of Practice also exclude a consideration of best interests when decisions are being made regarding participation in research.

The Act does not explicitly define individual instructions that inform an assessment of best interests, simply because it would be too difficult to cover every type of decision and action in a variety of circumstances. However, Section 4 of the Act provides general guidelines for the rationale on which such assessments should be based. These reiterate the general principles of the Act and provide specific guidance in this setting (see checklist below).

### Box 3. Best Interests Checklist

i. A person’s best interests can not be based on their age, appearance, condition or behaviour.

ii. All relevant circumstances should be considered when working out someone’s best interests.

iii. The decision-maker must consider whether the person is likely to regain capacity and if so whether the decision or act can wait until then.

iv. The decision-maker must involve the patient as much as possible in the decision that needs to be made. (This may not always be applicable in an emergency situation within the critical care setting)

v. If the decision concerns life-sustaining treatment the decision-maker must not be motivated by a desire to bring about the person’s death.

vi. As far as is reasonably ascertainable, the person’s past and present wishes, feelings, beliefs, values and other factors should be taken into account.

vii. If at all possible the decision-maker must consult other people if appropriate and take into account their views as to what would be in the best interests of the person lacking capacity, especially:

   a. Anyone named by the person as someone to be consulted
   b. Carers, close relatives, friends or anyone interested in the person’s welfare
   c. Any attorney appointed under Lasting Power of Attorney
   d. Any deputy appointed by the Court of Protection

For more detailed explanation of the above please refer to Chapter 5 of the Code of Practice.

The decision-maker must not make best interests decisions based on a person’s appearance, age, condition or behaviour. As far as possible, the decision-maker must encourage the person to participate in the
decision making process (using, where appropriate, the approaches described in Chapter 3). Where this is not possible, the decision maker must consult family members, caregivers and other relevant individuals, where it is reasonably possible to do so.

This consultation should include both an assessment of the patient’s expressed wishes and preferences, paying particular attention to any written expression of such preferences and wishes, and the existence of any documents or other evidence that detail an advance decision. The decision-maker must take into account a person’s past and present wishes, their beliefs and values and any other factor which may be relevant. When making life-sustaining decisions the decision-maker must not be motivated by a desire to bring about a person’s death.

In certain specific circumstances where a person who lacks capacity has no one to represent them you will need to involve the Independent Mental Capacity Advocate Service (see Chapter 8).

Who is the decision maker?
Many different people may be required to make decisions or act on behalf of someone who lacks capacity to make such decisions. The decision maker is therefore the person who is proposing to take an action in relation to the care or treatment of an adult who lacks capacity, or who is contemplating making a decision on behalf of that person. In the critical care setting this may often be a doctor; however, any member of the healthcare team may be involved in or initiate this process.

Making decisions about life-sustaining treatment
The Code of Practice makes it clear that all reasonable steps which are in the person’s best interests should be taken to prolong life. There will be circumstances where treatment is deemed to be futile and where there is no prospect of useful recovery. In such circumstance the decision-maker may come to the conclusion that it would be in their best interests to withdraw life-sustaining treatment. All the factors in the best interests checklist in Box 3 and which are provided in greater detail in Section 5 of the Act should be considered.

Specific rules apply if someone has made an advance decision to refuse life-sustaining treatment; these are discussed in more detail in Chapter 7.

Best interest in emergency situations
In circumstances where there is no time to go through the suggested checklist (e.g. following a head injury) decisions may need to be made quickly; in these settings the decision-maker will have to use professional judgement to determine the patient’s best interests, whether planned interventions can await the recovery of capacity, and assess the amount of time that can be spent in attempting to involve family members or other relevant individuals in the decision making process.

Who should be consulted when working out someone’s best interests?
Where a best interests test is being applied in an individual who lacks capacity, the Act requires the decision maker to consult other people close to a person, where such a process is reasonably practical and appropriate (with reference to the urgency of the decision). Such individuals may include:

i. anyone the person has named as someone they want to be consulted,
ii. anyone involved in caring for the person,
iii. anyone interested in their welfare, (e.g. family, friend),
iv. an attorney appointed by the person,
v. a deputy appointed by the Court of Protection, and
vi. an Independent Mental Capacity Advocate (IMCA) if there is no-one to speak about the person’s best interests.

The information and views of relatives or carers are important factors to be taken into consideration. Clinicians may wish to explore their knowledge of what the patient would have wanted as well as the personal views of the relatives or carers. It is important to structure these conversations in a sympathetic and careful way, avoiding the impression that, once the patient loses capacity, the relatives become the decision makers. Ultimate legal responsibility for making a best interests decision for a patient who lacks capacity in the clinical setting lies with the individual who carries out the intervention. If there is a disagreement about the way forward see below on “Resolving Disputes”.

Documentation
The Code of Practice recommends that records should be kept of the process used to work out what is in the person’s best interests, specifically setting out the following:

i. how the decision about the person’s best interests was reached,
ii. what the reasons for reaching the decision were,
iii. who was consulted to help determine best interests, and
iv. what particular factors were taken into account.

Resolving Disputes
There may be occasions when a patient’s family disagree with your proposed course of action as to what is in the patient’s best interests.

In this situation it would be worth considering the following:

i. delaying any proposed course of action pending resolution of the difference of opinion,
ii. informing the next of kin of avenues of support such as PALS (Patient Advocacy and Liaison Service),
iii. seeking an external second clinical opinion,
iv. involving an advocate who is independent of all the parties involved such as IMCA,
v. holding a formal or informal case conference.
vi. go to mediation.

If the matter involves a serious issue for the patient and it has been impossible to resolve these disagreements through discussion and dialogue as suggested above, it may be necessary to seek legal advice. Ultimately it may be necessary for the Court of Protection to make the final decision about the disputed decision.

These processes may involve a delay in decision making, and such delays may not always be in the patient’s best interests or be clinically acceptable in the setting of critical illness, where urgent intervention may be required. If decisions need to be made in the interim, whilst waiting on a decision from the Court of Protection, the lead clinician, as the person who is charged with making the decision on behalf of the patient, can be in a difficult position. A judgment needs to be made as to the extent to which it is important to take immediate decisions to protect the patient and promote his best interests with a delay to respect
the right of the family to refer the matter to the Court. However where a matter is important and urgent, a court hearing can be set up in a matter of hours with a telephone hearing for the Judge to reach a decision.

Where a matter is serious and the clinician feels that interim action is required despite the objections of the family, the clinician can proceed with interventions, providing that it can be demonstrated that the principles outlined in the Act were followed, and there were reasonable grounds for believing that the action was in the patient’s best interests. The interim action in such circumstances should be the minimal needed to protect the patient’s best interests whilst the dispute is resolved. In an emergency this can, in some circumstances, mean carrying out major medical interventions despite opposition from members of the patient’s family. However this should be avoided wherever it is possible to do so.

Conflict between religious beliefs and treatment
There may be circumstances where religious or other beliefs of family members may be substantially different from a professional assessment of the patient’s best interests. However, in reaching a view on the course of action which is in the best interests of an individual, it is important for the decision maker to take full account of “non-medical” factors including the beliefs and values of the patient. Where, even taking account of such factors, disagreements remain, these can be a source of conflict. The disagreement may involve a request by the family to withhold life-sustaining therapy, even in circumstances where such therapy is considered by the clinician to be clinically appropriate. Where there is reasonable doubt that the wishes of the person lacking capacity may have been different from those stated by family members, the conflict resolution measures outlined in the previous section may be useful.

Where there is such lack of clarity in an urgent situation, the clinician’s primary duty is to the patient. Hence clinicians should proceed to deliver appropriate emergency care on the basis of their professional judgement. It is important, however, to ensure that, if the clinician’s action is in conflict with the family’s wishes, he needs to provide and document reasonable grounds for having taken this course of action.

Where such disagreements occur in the face of clear evidence that the patient’s wishes, as clearly expressed at a time when the patient had capacity, are contrary to the clinician’s judgement of best interests, the patient’s views must prevail. If clinicians are professionally concerned about this it may be wise to seek a second professional opinion, or if the patient’s clear wishes conflict with the clinician’s conscience, hand over the responsibility for clinical care to a colleague who feels able to comply with the patient’s stated wishes.

Where there is a valid written advance decision, but the urgency of intervention means that a second opinion cannot be sought, the clinician will need to make a judgment about the degree of confidence he has in the validity of the patient’s wishes. If the clinician is confident about the patient’s wishes then these should be respected. The conditions that ensure the validity of an advance decision in these circumstances are detailed in Chapter 7. In other circumstances, family members may request continuation of therapy that is seen by decision makers to be futile and not in the individual’s best interests. Again, a second opinion and careful discussion may help resolve conflict. Such decisions are not usually urgent, and appropriate discussion should be possible.
Chapter 5: Providing care or treatment to people who lack capacity. (Section 5 MCA)

Section 5 of the Act allows carers, healthcare and social care staff to carry out certain tasks without fear of liability. The Act provides a legal framework for acts that need to be carried out in the best interests of persons who lack capacity to make a decision. It is important to note that section 5 of the Act does not provide defence in cases of negligence.

Protection for those working in health and social care

Protection from liability is given providing you have:

i. been compliant with the principles of the MCA as set out in the Act and the Code of Practice

ii. carried out an assessment of capacity, and reasonably believe that the person lacks capacity (chapter 2).

iii. a reasonable belief that the action you have taken is in the persons best interest (Chapter 4).

Box 4. Actions that might be covered by section 5 of the MCA

This is not an exhaustive list but is designed to give suggestions of care or treatment in the critical care unit which are covered by Section 5.

Personal care

i. personal hygiene,

ii. eating and drinking,

iii. helping with mobility.

Healthcare and treatment

i. providing nursing care e.g. endotracheal suctioning,

ii. providing medical care e.g. mechanical ventilation,

iii. carrying out necessary medical procedures e.g. bronchoscopy,

iv. administering medication,

v. carrying out diagnostic examinations and tests,

vi. providing emergency care,

vii. major healthcare decisions e.g. withholding or withdrawing major medical interventions.

Decisions which must be made by the Court of Protection

There are some treatment decisions which are so serious that a decision on behalf of a person who lacks capacity can only be made by the Court of Protection (unless the person has made Lasting Power of Attorney or there is a valid written advance decision see Chapters 6 and 7).

It is not possible for a clinician lawfully to make a decision in this category because they have to be referred to the Court. These categories are:

i. Proposed withholding or withdrawal of artificial nutrition and hydration (ANH) from a person in permanent vegetative state,
ii. Cases where it is proposed that the person lacking capacity should donate an organ or bone marrow,

iii. Proposed non-therapeutic sterilisation,

iv. Cases where there is dispute about what particular treatment is in the person’s best interests,

v. Proposed use of untested or innovative treatment,

vi. Cases involving termination of pregnancy.

Limitations to Section 5 of the MCA

Restraint.
Section 6 of the MCA deals specifically with the issue of restraint. The decision to restrain a person who lacks capacity will only attract protection from liability if the following two conditions are satisfied.

i. The person taking action must reasonably believe that restraint is necessary to prevent harm to the person who lacks capacity; and

ii. The amount or type of restraint used and amount of time it lasts must be a proportionate response to the likelihood and seriousness of harm.

If the above two criteria are not satisfied then the clinician is likely to be acting unlawfully and may be sued for assault or reported to their relevant professional body for misconduct.

In the critical care setting, such intervention can take the form of either physical restraints, or more commonly, pharmacological interventions in response to challenging behaviour which represents a risk to the patient or other individuals. It is important to proceed from a starting point that appreciates that inappropriate limitation of an individual’s liberty is unlawful. There are times however when such restraint is clinically necessary in order to deliver the treatment which the clinicians have assessed to be in the best interests of the patient. In such circumstances restraint may be necessary to prevent harm to the patient (because without restraint the treatment cannot be given) and is proportionate (because in the balance between the options open to clinicians the benefits of treatment outweigh the dis-benefits of restraint).

Accordingly if the appropriate processes under the MCA have been followed and documented, the use of chemical or physical restraint is lawful under the MCA. However, it is important, before proceeding to the use of such restraint, that other options (such as discussion and persuasion) have been tried (or at least considered and dismissed as inappropriate based on reasonable and defensible criteria).

A further step is needed to ensure that restraint is lawful if, as will often be the case in a critical care setting, the level of restraint potentially amounts to a deprivation of liberty within the meaning of Article 5(1) of the European Convention on Human Rights Act.

Deprivation of Liberty Safeguards
The Mental Health Act (2007) included a provision to amend the Mental Capacity Act by introducing the Deprivation of Liberty Safeguards (DoLS), effective from April 2009. These amendments permit a deprivation of liberty within the defined new “rules”. The purpose of the DoLS is to protect vulnerable people lacking capacity from being arbitrarily deprived of their liberty and providing them with a range of safeguards. In the critical care setting this raises a number of issues which need to be considered to ensure that the health care team are working lawfully within the MCA. The healthcare team may therefore need to
address and document the following considerations.

1) Intent is important: It is not appropriate to apply the DoLS of the MCA where sedation or other medication is intended to facilitate treatment and not primarily to restrain patients. Thus, the use of sedation to facilitate ventilation in a patient with respiratory failure would not qualify as deprivation of liberty in this context.

2) However, the DoLS may apply (at least in theory), where physical or chemical restraint (with sedatives, tranquilisers, etc) are primarily or partly used to restrain patients.

3) Under these circumstances, the MCA requires that clinicians choose the least restrictive option that is compatible with ensuring the patients safety (e.g. using clinical supervision and persuasion rather than physical or chemical restraint, wherever possible).

4) In practice the choice of methods used to facilitate clinical care in these circumstances, may depend upon the local availability of potentially limited resources. Although this may provide a context for the decision to use physical or chemical restraint under-resourced healthcare is not a justifiable defence for excessive use of restraint.

5) Where measures are being partly or primarily being used for restraint, and a judgement has been made that the chosen method of restraint is most appropriate in the given clinical context, allowing for reasonable considerations of resource allocation it is appropriate that clinicians seek to work within the framework of the DoLS of the MCA.

6) These considerations suggest that the DoLS will need to be activated in contexts where sedative agents or major tranquilizers are used in confused and combative patients who are a risk to themselves, staff or other patients.

7) This is not an infrequent scenario in critical care units, but formal authorisation under the DoLS are rarely applied for. Given this, it could be argued that many clinicians, units and hospitals are acting illegally in these situations.

8) This is certainly true in terms of the letter of the law, but a reading of the DoLS Code of Practice and the examples of case law provided there, coupled with the continually emerging case law in this regard, suggest that a deprivation of liberty is not an issue in the majority of instances in which physical or pharmacological restraint is used in the critical care setting.

9) Consequently, where needed for clinical care the use of restraint is likely to be entirely justifiable under the best interests principle, and clinicians should not withhold such interventions where they are justifiable as being needed for safe care of patients.

10) However, even in a critical care setting, there will be instances where the DoLS will apply. In practice, this is far more likely to be the case where such interventions are aimed at managing the movement of patients and their access to individuals and places outside the hospital, rather than those targeted at enabling treatment. Clinicians need to be vigilant to such contexts, and where they exist, apply for authorisation under the DoLS.
11) It would be wise for ICU clinicians to have a discussion with their hospital management to explicitly decide how the organisation wished to deal with these circumstances.

12) In any case, as a minimum, ICU clinicians should consider applying for formal authorisation in cases where the use of physical or pharmacological restraint is not wholly being utilised to treat or manage symptoms, is likely to be prolonged and / or where there are social or interpersonal restrictions imposed even if they are in the person’s best interests, or where any member of the clinical team feels that a formal authorisation is merited.

13) Where a decision is made to apply for authorisation under the DoLS, the following considerations must apply:

   a) The patient must be over 18 years of age
   b) The treatment being initiated must not contravene a valid advance decision that is in place, or is contrary to the wishes of an authorised decision maker.
   c) The patient must lack mental capacity (following the capacity test set out in the MCA) in relation to the specific decision to be in the hospital or care home for the purpose of receiving proposed care and / or treatment.
   d) An important distinction needs to be made between patients who are deprived of their liberty because of a non-psychiatric illness (as discussed above) and those detained under the Mental Health Act 1983, as a result of psychiatric illness. The DoLS is not relevant to patients in the latter setting, where a psychiatric opinion is required to detain individuals under the Mental Health Act.

If the above apply to a patient, the clinician caring for that patient should document these and formally seek authorisation for the deprivation of liberty in this setting. The responsibility for providing such external authorisation rests with the Primary Care Trust (PCT) that is responsible for the patient’s care (which may not necessarily be the local PCT), and the hospital should apply to the PCT seeking such authorisation. In these circumstances, at the same time as external authorisation is sought, the hospital should give itself an urgent authorisation for a deprivation of liberty that can last for up to a week, and 14 days in exceptional circumstances, whilst external authorisation is sought. Application forms for standard authorisation are available at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_089772. Such external authorisation of deprivation of liberty can be for periods up to 12 months, but will be specified on a case by case basis.

Where measures are partly or primarily used for restraint, and a judgement has been made that the chosen method of restraint is the most appropriate in the given clinical context, allowing for reasonable considerations of resource allocation, it is fundamental that clinicians seek to work within the framework of the DoLS of the MCA.

It is important to note that the use of excessive restraint could leave clinicians open to a range of civil and criminal penalties or to a reference to the GMC or NMC. There is however an exception to the above rules where a person needs to be detained in hospital for treatment of a mental health disorder under the Mental Health Act 1983.

For more details please see: http://www.dh.gov.uk/en/SocialCare/Deliveringadultssocialcare/MentalCapacity/MentalCapacityActDeprivationofLibertySafeguards/index.htm
Chapter 6. Designated and authorised decision makers.

The MCA specifies three new arrangements or bodies that address decision making in individuals who may lack capacity.

Lasting Power of Attorney (LPA). Section 9 – 14 MCA 2005

The MCA introduces a new form of power of attorney known as the Lasting Power of Attorney. The process by which this occurs is known as “making an LPA”. An LPA is a person over the age of 18 who has been nominated by an individual (known as the donor) to make decisions on their behalf should they at a later point in time lack capacity. A donor may appoint one or more people to become their attorney (sometimes referred to as the “donee” in the Act and Code of Practice). The attorney is bound to make decisions in line with the principles of the MCA and must have regard to the Code of Practice.

There are two different types of LPAs.

i. A Personal Welfare LPA is appointed to make decisions about both health and personal welfare.

ii. A Property and Affairs LPA is appointed to make decisions about property and financial matters, but not health and personal welfare.

Important facts about LPAs

i. A donor can only make an LPA at a stage when they have capacity to understand the importance of the document and the level of power they are giving the appointed attorney.

ii. An LPA must also be registered with the Office of the Public Guardian discussed later in this chapter.

iii. A personal welfare attorney has no power to make decisions on any matter if the donor has the capacity to make a decision for themselves.

iv. A person directly involved in the care or treatment of a person who lacks capacity should not agree to act as their attorney.

v. All decisions made by an attorney must be made in the best interests of the donor.

Implications for Critical Care

The appointment of an LPA will have implications for healthcare workers in the critical care setting. If the LPA grants healthcare decision making to the holder of the LPA then clinicians must treat the holder of the LPA as standing in the shoes of the patient for the purpose of making treatment decisions, and must follow the decisions of the holder of the LPA unless they are concerned that the holder of the LPA is not acting in the best interests of the patient.

The most important changes produced by this process are highlighted by comparing the responsibilities of an LPA with those invested in an Enduring Power of Attorney (EPA), a designation that preceded the passage of the MCA. The law no longer permits the creation of EPAs, but clinicians may continue to encounter these for some time.

I. EPAs can only assume responsibility for property and affairs, whereas a Personal Welfare LPA can also act in matters of health and welfare

II. The procedural details and documentation for the two vary.

III. LPAs can be registered with the Office of the Public Guardian at any time – both before or after
the donor loses capacity; EPAs are only registered after loss of capacity.

IV. Both LPAs for property and affairs and EPAs can be used while the donor still has capacity to manage their own affairs (as long as the donor does not specify otherwise in the LPA). However, a Personal Welfare LPA can only be used after loss of capacity.

The checklist below highlights some points that may be useful when dealing with an attorney, and outlines the factors needed to be considered in order to assess the validity of an LPA.

Box 5. Lasting Power of Attorney.

i. The attorney must be 18 years old or over.
ii. The LPA must be written and set out in the statutory form prescribed by regulations.
iii. The document must be signed by the donor and the attorney.
iv. The document must include a certificate by an independent third party confirming that, in their opinion, the donor understands the LPA, that it is not fraudulent, was not compiled under pressure, and that there are no other factors that would invalidate the creation of an LPA.
v. The LPA must be registered with the Office of Public Guardian.
vi. In the case of personal welfare LPAs, it is important to check whether there are restrictions or conditions in areas where the donor does not wish the attorney to have power to act.
vii. The attorney must follow the principles of the Act and make decisions in the person’s best interests.
viii. The attorney can not demand certain treatments.
ix. A personal welfare attorney does not have the right to consent or refuse treatment in situation where:
   a. The donor has capacity to make decisions,
   b. The donor has an advance decision to refuse proposed treatment,
   c. A decision relates to life-sustaining treatment (unless the LPA document specifically authorises it), or
   d. A donor is detained under the Mental Health Act (section 28)

Court of Protection and Deputies. Section 15 – 23 MCA 2005

The MCA creates a new court and a new public official to protect people who lack capacity and to supervise and support those making decisions on their behalf.

Court of Protection

This new court is a specialist court that deals with all issues relating to capacity. It will be particularly useful in resolving complex cases and disputed cases. The court has the power to:
i. Make declarations about whether or not a person has capacity to make a particular decision.
ii. Make decisions on serious issues about healthcare and treatment.
iii. Make decisions about property and affairs of a person who lacks capacity.
iv. Appoint deputies to have ongoing authority to make decisions.
The Deputy could be an official of the Court or it could be a relative of the person without capacity.

**Public Guardian**
The Public Guardian is supported by the new Office of the Public Guardian and has many responsibilities including:

i. maintaining a register of and monitoring LPA’s,
ii. maintaining a register of orders appointing deputies,
iii. supervising deputies appointed by the courts, and
iv. providing reports to the courts.

_The referral mechanisms that are implied in these arrangements are still in their infancy. It may take the Office of the Public Guardian time to provide an opinion in the event of a dispute but a hearing before a Judge of the Court of Protection can be arranged at very short notice. Where there is a delay, clinicians will need to continue to rely on their professional judgement when it comes to urgent or emergency decisions in the clinical management of patients. In most cases it is better to err on the side of initiating rather than withholding therapy unless the therapy is not time critical. However, it is likely that these arrangements (and the requirement for referral to an Independent Mental Capacity Advocate – see Chapter 8) will have a substantial impact on decisions to withhold or withdraw life-sustaining medical treatment._
Chapter 7. Advance decisions to refuse treatment. (Section 24 – 26 MCA)

An advance decision allows a person aged 18 and over, while they still have capacity, to refuse specific medical treatment at a time in the future, when they may lack capacity to consent to or refuse that treatment. The MCA puts advance decisions on a statutory footing. An advance decision is effective at a time when the patient lacks capacity. However, since the decision was made at a time when capacity was present, it has the same force in law as refusal of treatment by an individual with capacity. Consequently, healthcare staff are obliged to abide by an advance decision, providing it is valid.

For an advance decision to be acted upon, there must be proof that the decision:

i. exists,
ii. is valid, and
iii. is applicable to the current circumstances

An advance decision can only apply to refusal of treatment; it cannot demand specific treatment. An advance decision does not oblige healthcare professionals to provide treatment that is judged to be clinically unnecessary, futile, or inappropriate. Importantly, the Act does not change the law on assisted death.

*It is probable that valid written advance decisions will have been made in advance of patients being considered for or receiving critical care. However, it is conceivable that some critically ill patients may wish to formally document their wishes regarding the extent of treatment they would be willing to accept, either when ICU admission is being considered, or at an early stage of their ICU stay while they still retain capacity, and will be able to sign a document that specifies their wishes, thus giving it the force of a written advance decision. If so, it is important that healthcare professionals enable the patient’s wishes to be recorded and followed, without pressurising them to make what at all times has to be their own advance decision. In many other patients however, preferences may be expressed verbally during the course of discussion with clinicians (see below).*

Verbal advance decisions

Advance decisions can be made verbally other than for life-saving treatment. There is no set format for verbal advance decisions. If there is sufficient proof of the advance decision then they have the same legal effect as a written decision. They key issues for the clinician are:

i. What is the quality of the evidence to show that an verbal advance decision was made (does it come from one source or more than one source)?
ii. Are the terms of the verbal advance decision clear?
iii. Is it an attempt to refuse life sustaining treatment? (in which case it would not be valid for such treatment).

Where possible healthcare professional should record a verbal advance decision to refuse treatment in a person’s healthcare records. The record should include:

I. A note that the decision should apply if the person lacks capacity to make treatment decisions in the future,
II. A clear note of the decision, the treatment to be refused and the circumstances in which the
III. Details of anyone who was present when the verbal advance decision was recorded and the role in which they were present, and

IV. Whether they heard the decision, took part in it or are just aware it exists.

Healthcare professionals must consider whether a verbal advance decision is valid and applicable in the same way as they would for a written advance decision.

**Box 6. What you need to know about advance decisions.**

i. When any patient who lacks capacity is admitted to a critical care unit, it is wise to check whether they have made an advance decision.

ii. If an advance decision does exist, it may be verbal or written, and the type of decision needs to be specified (see below).

iii. The validity of an advance decision must be confirmed. An advance decision is not valid if:
   a. The person withdrew the decision while they had capacity,
   b. The person made an LPA that included the authority to make treatment decisions in areas covered by the advance decision,
   c. The person has done something that is clearly contrary to the wishes expressed in the advance decisions, suggesting that they might have changed their mind.

iv. An advance decision must be applicable to the situation in question and current circumstance. The advance decision must also apply to the proposed treatment. It is not applicable to the treatment in question if:
   a. The proposed treatment is not the treatment specified in the advance decision,
   b. The circumstances are different from those that may have been set out in the advance decision, or
   c. There are reasonable grounds for believing that there have been changes in circumstance, which would have affected the decision had the person known about them at the time they had made the advance decision.

v. If the advance decision refuses life sustaining treatment there are additional safeguards in place
   a. It must be in writing,
   b. It must be signed by the person making the advance decision,
   c. It must be signed in the presence of a witness,
   d. It must include the specific written statement that the advance decision applies to the specific treatment even if life is at risk.

vi. Advance decisions refusing life-sustaining treatment can refuse artificial nutrition and hydration.

vii. Advance decisions refusing life-sustaining treatment cannot refuse actions needed to keep a person comfortable e.g. warmth, shelter, the offer of water by mouth. Section 5 of the Act allows healthcare professionals to carry out these procedures in the best interests of the person who lacks capacity.

Many individuals will express clear preferences regarding acceptance or refusal of specific therapies prior to becoming critically ill, especially if they suffer from a chronic disease (e.g. malignancy, progressive neurological disease, human immunodeficiency virus infection). In other patients, capacity may be
retained at the time of ICU admission, and the clinical team may be able, where appropriate, to discuss the treatment options available, and whether the patient would wish these to be used in the event that capacity was lost. In practice, critical care staff have always made enquiries about patient’s preferences that have been expressed in the past before making clinical decisions in difficult circumstances. The MCA formalises this process, and should lead to more consistent practice. In addition, it mandates that the process should be clearly documented.

If a verbal advance decision is made during a discussion between individuals and healthcare professionals (either before or during the patient’s stay on the ICU) a written record should be made to avoid future confusion. Such a record should include the following points;

i. A note that the decision applies if the person lacks capacity to make treatment decisions in the future.

ii. Clear notes of the decision, the specific treatment(s) to be refused, and the circumstance in which the decision should apply.

iii. Details of who else was present when the advance decision was made, and

iv. Whether they heard the decision, took part in it or are just aware it exists.

**Advance Decisions to refuse life-sustaining treatment**

The Act imposes particular safeguards on making advance decisions which refuse life-sustaining treatment. Such advance decisions MUST meet specific requirements which are set out below.

i. Such decisions must be in writing (but can be recorded by another person if individuals are unable to do so themselves).

ii. The document must include a clear, specific, written statement that the advance decision is to apply to the specific treatment even if life is at risk.

iii. The person must sign the advance decision, but if they are unable to do so, they can direct someone to sign on their behalf in their presence.

iv. The document must be signed in the presence of a witness.

v. The witness must sign the document in the presence of the person making the advance decision.

vi. Where the person making the decision is unable to sign the document personally, and directs another individual to do so on his/her behalf, this must be done in the presence of the witness, who must sign the document to indicate that they witnessed the signature by the individual who has been nominated to sign the document.

vii. An advance decision can legitimately specify the refusal of artificial nutrition and hydration.

viii. An advance decision can not refuse interventions that are needed to keep a person comfortable.

ix. It is recommended that an advance decision to refuse life sustaining treatment(s) should be discussed with a healthcare professional, but the absence of such a discussion does not invalidate the document.

Whether or not an intervention is life sustaining depends not just on the treatment, but also on the circumstances in which it is provided. For example, the use of antibiotics to treat infections may not be life sustaining in many circumstances, but should clearly be viewed as such in the patient with septic shock from a documented infection. Similarly, a patient with an intracranial malignancy may clearly document their decision to refuse intravenous fluids when clinical deterioration makes it impossible to deliver adequate hydration otherwise. However, if the patient suffers an upper gastrointestinal bleed (e.g. as a consequence of corticosteroid therapy, commonly used in such situations), it may be appropriate
to provide intravenous fluids and blood products for volume resuscitation, if this occurs at a stage when clinical deterioration has not otherwise resulted in the need for intravenous hydration.

**Advance decisions and emergency situations**
Where there is a clear indication that a valid and applicable advance decision exists and is available, it is important that healthcare professionals comply with the individual’s expressed preferences.

*However, where the existence of an advance decision is in doubt, or where there is no indication that one exists, healthcare professionals should not delay emergency treatment to look for one. In this setting the decision to initiate treatment must be taken in the patient’s best interests.*

*In other situations, it may be clear that an advance decision exists, but it may be unavailable when the individual presents for treatment. In such situations healthcare professionals should initiate emergency treatment as needed, and reassess clinical decisions once evidence of a valid and applicable advance decision becomes available. It is likely that clinicians will meet a range of circumstances of varying urgency in this situation, and professional judgement must be exercised to determine whether it is appropriate to wait until such documentation is available before treatment is initiated.*

**Disagreement with advance decisions**
It is ultimately the responsibility of the healthcare professional in charge of the person’s care when treatment is required to decide whether there is an advance decision, which is valid and applicable in the circumstances. If the clinician is not satisfied that an advance decision is valid and applicable, treatment must then be given in the person’s overall best interests (which may include taking account of views expressed by the patient which fall short of the level of proof required to constitute and advance decision).

However if there is an effective advance decision then the concept of best interests does not arise. The patient has, through the medium of the advance decision, given notice of their lack of consent to the proposed treatment. Hence to continue with the treatment in such circumstances would potentially constitute both the criminal offence assault and a civil legal wrong.

Where there is doubt as to whether a patient has made an effective advance decision, the clinicians should engage in dialogue with other multi-disciplinary team members, family and any others close to the person, so that everyone has an opportunity to express their views and the issue as to whether there was an effective advance decision can be clarified.

*Such discussions may be particularly relevant in critical care settings, where many clinical teams are involved in the patient’s care, and the overall responsibility for such care does not rest with a single individual. On occasion, such discussions may highlight disagreements between clinical teams about whether or not a given treatment should be initiated.*

Details of these discussions should be documented. Similarly, clear documentation should explain why an advance decision has not been followed. If it is impossible to resolve disagreements the case will then need to be taken to the Court of Protection.

If a clinician has a conscientious objection to the refusal of treatment set out in an advance decision, arrangements should be made as soon as possible to transfer the management of the patient to another healthcare professional.
Chapter 8: Independent Mental Capacity Advocate (IMCA) (Section 35 – 36 MCA)

Most individuals who lose capacity can have their views represented through the various mechanisms that have been discussed earlier in this document, such as the creation of an LPA, a written advance decision or verbally expressed advance decisions, communicated by family or close friends. However, some individuals lacking capacity may have made no provision to communicate their wishes at a time when they possessed capacity, and may have no family, friends or professional representative (e.g. a solicitor). Alternatively, a relative may be contactable, but may not wish to act as a representative for or supporter of the individual lacking capacity. Exceptionally, the clinician caring for a patient may feel that the patient’s relative or representative may not be acting in the patient’s best interests, and propose to take protective measures to safeguard the patient against abuse. The IMCA represents the interests of, and provides support for decision making in such individuals. The duty to instruct an IMCA in these circumstances lies with the staff of NHS organisations caring for the person lacking capacity. The IMCA service itself is independent of these organisations.

Individuals who act as IMCAs must have appropriate background, experience and/or training, and undergo enhanced checks with the Criminal Records Bureau. It is essential that the IMCA is independent of decision makers. An IMCA service is only available during office hours, and hence is not available out of hours, at weekends, or on public holidays.

There are four main elements to the IMCA work which can be broadly summarised as:

1. Ascertaining the views, feelings, wishes, beliefs and values of the person using whichever communication method is preferred by the client and ensuring that those views are communicated to, and considered by, the decision-maker.

2. Non-instructed advocacy. Asking questions on behalf of the person and representing them. Making sure that the person's rights are upheld and that they are kept involved and at the centre of the decision-making process.

3. Investigating the circumstances. Gathering and evaluating information from relevant professionals and people who know the person well. Carrying out any necessary research pertaining to the decision.

4. Auditing the decision-making process. Checking that the decision-maker is acting in accordance with the Act and that the decision is in the person's best interests. Challenging the decision if necessary.

The IMCA acquires and integrates all the available information about an individual lacking capacity, in order to best represent and support the person. This process could include direct interviews with the person lacking capacity (e.g. a patient with dementia) and discussions with individuals who are tasked with making decisions on their behalf. The IMCA is also empowered to acquire information from health and social care records. The MCA requires that an IMCA needs to be consulted when decisions are being made about serious medical treatment in a patient lacking capacity, whose wishes cannot be determined by other processes. In this context, serious medical treatment is defined as: “treatment which involves giving new treatment, stopping treatment that has already been started, or
withholding treatment that could be offered in circumstances where:

- If a single treatment is proposed, there is a fine balance between the likely benefits and the burdens to the patients and the risks involved
- A decision between a choice of treatments is finely balanced, or
- What is proposed is likely to have serious consequences for the patient.

Serious consequences are defined as those which have a serious impact on the patient, either directly or though wider implications. The list of “serious treatments” is not specified, but the interventions in Box 7 are specifically cited in the code of practice:

**Box 7. Some examples of medical treatments that might be considered serious include:**

- Chemotherapy and surgery for cancer
- Electro-convulsive therapy
- Therapeutic sterilisation
- Major surgery (such as open-heart or brain/neuro surgery)
- Major amputations (loss of an arm or leg)
- Treatments which will result in permanent loss of hearing or sight
- Withholding or stopping artificial nutrition and hydration
- Termination of pregnancy

In these situations, a “best interests” decision made on behalf of a patient must be made in consultation with the appointed advocate. It is important to note that advocates do not offer their own opinion or make the decision, but use the information available to judge what the patient’s wishes might be. Where they do not believe that a medical decision has been taken in someone’s best interests, IMCAs have the right (and indeed, the responsibility) to challenge them, and request a second opinion, where appropriate. In the event of disagreement between an IMCA and decision makers that is not resolved through discussion, the IMCA has the same right to appeal that a patient’s relative would have under these circumstances. It is also part of the IMCA’s formal duty to provide a report, usually written, to the decision maker, and to other relevant bodies.

*The IMCA process does not apply if a treatment is urgently required on clinical grounds. In these circumstances, it is inevitable that clinicians will have to make decisions in the best interests of the patient. This provision is clearly concordant with good clinical practice.*

*The IMCA’s duty is to act as the patient’s advocate, much as a relative or close friend would do in normal circumstances. There can be a tension between delaying treatment to involve an IMCA and acting in the best interests of a patient where this suggests early intervention. In clinical situations there may simply be no “right” decision because all treatment options have benefits and risks. There may be options that are not appropriate or there may one option which is the least worst alternative, but that may need to be delivered quickly to be clinically effective. The Mental Capacity Act and the Code of Practice recognise this dilemma. The Guidance from the Intensive Care Society is that no immediate clinical intervention which is time critical and important for an individual should be delayed whilst the views of an IMCA are sought.*
Where possible the IMCA should be engaged and their views sought but the delay caused by this process should not place the patient at any material risk.
The pragmatic position to be adopted can be summarised as:

1. Early identification of admissions when an IMCA may be required and initiation of referral.

2. Where an IMCA is unable to attend promptly and decisions on initiation, escalation or withdrawal of life-sustaining medical treatment are urgent, clinicians should:
   a. define the burdens of futile treatment for the patient, the time limits beyond which it would be unacceptable to continue such futile treatment, and the harmful impact of continuing futile treatment over a protracted period on any third party by denial of access to a critical care bed,
   b. ensure that there is documented multidisciplinary consensus on the above issues and the proposed course of action,
   c. consider the merit of an internal second opinion to consolidate the above decision,
   d. consider the merit of ethics committee opinion to consolidate the above,
   e. inform the IMCA service of these observation and the proposal to act in the patient’s best interests if attendance is not possible,
   f. inform the hospital’s risk management department of the proposed course of action,
   g. implement the proposed course of action and ensure full documentation of process.

3. Ensure that the overall Unit policy incorporates the above proposals, and that this has been explicitly endorsed by the risk management department.
Chapter 9: Research. (Section 30 – 34 MCA).

The Act recognises the importance of research in general, and the role of research in advancing the clinical care of patients who suffer from diseases that result in mental incapacity (referred to in some parts of this section as an “impairing condition”). The Act covers research that:

I. is intrusive (intrusive research is defined as that which would require consent in an individual with capacity).
II. involves patients with an impairment of, or disturbance in, the functioning of their brain or mind, which makes them unable to consent for themselves.
III. is not research that involves clinical trials of medicines, as this is covered by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031).
IV. Consent is not a legal requirement – and so MCA does not apply - where research involves only non-identifiable data, “Existing holdings” of tissue (prior to 1 September 2006; see Human Tissue Act); data with approval of National Information Governance Board for Health and Social Care (previously known as Patient Information Advisory Group), non-identifiable tissue from the living, processing of identifiable data with approval of National Information Governance Board for Health and Social Care.

Responsibility of ensuring the research meets the Act’s requirements lies with:

i. the researcher,
ii. the ‘appropriate’ body which is an organisation that can approve research projects.

Obtaining approval for research
Since participants in this context are unable to provide consent, the Act provides a series of safeguards that need to be satisfied to legitimise their involvement in research studies. However, the Act also recognises the difficulties involved in research in emergency and critical care medicine, and provides processes that allow such research to be undertaken. The following requirements need to be addressed in order to allow such research to take place:

1. The research must be approved by the “appropriate body”, which,
   - in England is a research ethics committee recognised by the Secretary of State
   - in Wales is a research ethics committee recognised by the Welsh Assembly government.

2. The research must follow the requirements of the Act:
   - the views of carers and other relevant people must be considered,
   - the participant’s interests must be treated as more important than those of science or society,
   - the researcher must respect any objections that the participant makes during research.

3. The project must focus on a disease that causes impairment of capacity, since it would be unethical to enrol incapacitated subjects into projects that had no relevance or bearing on the disease that affects them. Consequently a study cannot be approved unless;
   - it is linked to an impairing condition,
   - it is linked to the treatment of an impairing condition, and
- there are reasonable grounds for believing that research of comparable effectiveness could not be carried out if the project were confined to persons who have capacity to consent to participate.

Many critically ill patients may have impaired capacity not due to the underlying disease (e.g. severe community acquired pneumonia) or to its direct treatment (e.g. antibiotics or ventilatory support). However, such patients often lack capacity as a consequence of the need to use sedatives to facilitate mechanical ventilation. While not explicitly stated either in the Act or Code of Practice, the implicit assumption is that that if sedation can be justified as essential therapy, research into the underlying condition or treatment is permissible under the Act. However, there could be concern that unscrupulous researchers may sedate subjects in order to impair capacity and avoid having to obtain consent. It is imperative that submissions for permission to conduct research in this context clearly demonstrate that this is not the case.

4. Such research must meet one of two requirements in balancing benefit against the risks and burdens of research:

- It must have some chance of benefiting the person who lacks capacity; such benefit must be in proportion to any burden caused by taking part. Such benefit may be direct (e.g. an imaging study might provide additional information about the nature or severity of their disease or help refine its therapy). While the Code of Practice recognises that such benefit may be indirect, it is important to note that, for research to qualify under this section, the benefit must apply to the participating individual. One example in the Code of Practice is a change in protocols that improve patient care when the subject presents for continuing clinical management; however, this example is unlikely to be relevant in most critically ill patients, who usually have a single episode of treatment.

- Alternatively, where the research does not benefit the participant, the aim of the research must be to provide knowledge about the cause of, or treatment or care of people with the same impairing condition, or similar conditions. In this setting, the benefit is not to the individual, but to society at large, and more specifically, to future patients who suffer from the same (or similar) illnesses. While the Act and the Code of Practice accept the case for such societal benefit, the lack of benefit to the individual must be balanced by a more rigorous reduction of risk in this context. The Act therefore states that if research is legitimised on these terms:
  - The risk to the individual from participation in the study must be negligible, and
  - The research must not affect the patient’s freedom of action or privacy in a significant way, or be unduly invasive or restrictive.

These requirements must be carefully interpreted in the context of critically ill patients who may be sedated and will not be able to make their objections known. Given that this is the case, researchers must be particularly sensitive to the wishes of carers and their views on what the individual might wish. Conversely, research procedures that present considerable risks to other patients may, in critically ill patients, be undertaken with little additional risk simply because of the presence of vascular access devices and other monitoring equipment that are part of routine clinical care in this setting. Thus, placement of a pulmonary artery catheter, jugular bulb catheter or ventricular drain for selective sampling involves significant risks in healthy volunteers or in patients who do not have these monitoring
devices in place. However, the additional risk of drawing blood or CSF samples from these catheters is negligible, when they are already in place as an essential part of clinical management.

5. Researchers need to be aware of their responsibilities when undertaking studies in patients lacking capacity. These responsibilities include:

   Ethical Approval: The need to obtain approval for research from the appropriate body (usually Research Ethics Committee approval)

   Consulting carers or other individuals who inform decisions on research enrolment: Since the potential participant’s wishes cannot be directly determined, the researcher must take into account previous wishes and feelings that the individual may have expressed in order to determine whether or not they would wish to participate in the proposed research. In this context it is important to consult other individuals who will be able to provide a judgement on whether the potential participant would have wished to be involved in the study. It is essential that any person who is consulted is provided with the appropriate amount of information regarding the purpose, risks, and benefits of the proposed research, so that they can make an informed decision about whether the individual lacking capacity would wish to participate in the research study. Where the person being consulted is not a carer, he/she must be provided with as much information as is reasonably practicable in order to make an informed decision about what the individual lacking capacity would have wished to do. The Act and Code of Practice prescribe the following approaches:

   a. Where a personal carer is available and is willing to be consulted on the matter, the researcher must consult them on whether the individual lacking capacity would have been willing to participate in the research project; this person is referred to as a personal consultee.

   b. The use of the phrase “personal carer” is relevant in the context of chronic disease, which impairs capacity where such relationships are common, but rarely apply when acute critical illness impairs capacity. In this context the alternative phrase: “an individual interested in the welfare of a person lacking capacity” is more appropriate. In most instances, this phrase will apply to a family member who would be willing to be consulted about the patient’s participation in research studies.

   c. Ideally, such an individual should be someone who knows the potential participant and has knowledge of his or her wishes (e.g. a family member), but this role cannot be fulfilled by a paid or professional care worker.

   d. An individual who is authorised under a Lasting Power of Attorney or is a Deputy appointed by the Court of Protection is not disqualified from acting as a consultee, unless they are acting in a paid or professional capacity (e.g. an individual’s solicitor).

   e. Where a carer is unavailable, or unwilling to be consulted regarding research participation, the researcher must nominate a person who has no connection with the project and who is willing to be consulted about the participation of a person...

f. Where the urgency of the research intervention makes it impossible to put arrangements in place to contact a nominated consultee, it is permissible to consult an independent registered medical practitioner, providing he/she is unconnected with the research study. It is permissible for such a professional consultee to be responsible for the clinical care of the patient, but it is essential that they have no connection with the research study.

g. In special circumstances the research intervention may be of such urgency (e.g. studies in cardiac arrest or acute head injury) that it is impossible to undertake any consultation prior to enrolling subjects in a study. Initial inclusion of subjects lacking capacity in such a study is permissible without any consultation, providing the protocol to do so has been approved in advance by an Approved Authority (a Research Ethics Committee). However, the researcher must obtain permission, using one of the processes listed above, for continued participation of the individual lacking capacity in the study at the earliest reasonably practicable opportunity.

h. Regardless of the process by which consultation takes place, no action should be taken (or if the study has begun, continue to be taken) as part of a research project, if
   i. the individual lacking capacity appears to object to such action (unless the action is essential to reduce harm, pain or distress),
   ii. the action is contrary to an advance decision or other statement made by the individual and subsequently withdrawn, and which is known to the researcher, or
   iii. the patient indicates (in any way) that he wishes to be withdrawn from the study. In these circumstances it is the duty of the researcher and the consultee to stop the specific procedure(s) and/or withdraw the subject from the study.

The provisions in the section above are difficult to interpret in the context of a sedated patient in a critical care scenario. In these circumstances it may be difficult for researchers to determine when subjects are unwilling to continue with the research, and researchers need to be especially vigilant. Neither the Act or the Code of Practice provide specific guidance in this area, but it would seem reasonable to continue with research providing the subject’s clinical care is not compromised and they do not show signs of distress. It remains clear however, that participation in the research should cease if the consultee who had initially provided permission feels that continuing participation would be against the wishes of the individual lacking capacity, providing that such withdrawal does not entail a risk to the subject’s health (see next section).

i. Despite the comments in the previous section, there is no requirement to withdraw the subject from the research study, or to withhold study interventions, if doing so would result in a significant risk to the subject’s health.
One example might be the enrolment of a patient in a trial of high frequency ventilation for severe respiratory failure. It is possible that permission for participation in the study may be initially given by the personal consultee, and following initiation of the study protocol, this permission is subsequently withdrawn. If the patient was randomised to the conventional ventilation arm of the study, withdrawal would be easy, and data collection for the study would stop. However, if the patient was randomised to the high frequency ventilation arm of the study, the responsible clinician might make the judgement that attempting to alter ventilation modes in an unstable patient would be dangerous. In this circumstance, the patient may be withdrawn from the study itself (i.e. no further data collection would continue for research purposes). However, the study intervention (i.e. high frequency ventilation) could continue, as this was felt to be in the clinical interests of the patient. Note that since this hypothetical study involves a randomised trial of a CE marked device, it is governed by the MCA rather than the Clinical Trials Regulations. (Non-CE marked medical devices require approval for use in research from the UK Competent Authority which is the Medicines and Healthcare Regulatory Authority -MHRA)

Appendix 1 and 2 includes algorithms which aim to guide the researcher through the process of determining which pieces of legislation apply when conducting research and also an algorithm detailing the consenting process.

Patients with capacity can consent to have tissue removed from their body for diagnostic or other procedures as part of their clinical management. If patients lacking capacity require removal of tissue from their body to aid clinical management, this is permitted under the Act, providing the decision to do so is taken in the best interests of the patient. Such action is legitimised under Section 5 of the Act and listed in Box 4 of this Guidance.

Where tissue is stored or used for research purposes, patients with capacity must give explicit permission for tissue to be used in this way. (Similar explicit permission is required when individuals with capacity donate tissues or organs for transplantation; this is discussed in the next Chapter).

However, permission to use tissue for research is not required if:
- The tissue samples are anonymised and the research has ethical approval (as described in Section 1(9) of the Human Tissue Act)
- The tissue is being used for
  - clinical audit
  - education or training in relation to human health
  - performance assessment
  - public health monitoring, or
  - quality assurance

This background in individuals with capacity provides a framework against which the research involving tissue from individuals lacking capacity can be legitimately conducted.

If an adult lacks capacity, the Human Tissue Act (2004) says that tissue can be stored or used without permission if the storage or use is:
1. to get information that is relevant to the health of another individual (e.g. for transplantation), providing the action was thought to be in the best interests of the incapacitated individual,
2. part of a clinical trial approved and carried out under the Clinical Trials Regulations (2004), or part of intrusive research undertaken after the MCA comes into force, providing it meets the Act’s requirements, and has ethical approval.

It is important to emphasise that these considerations apply to the storage or use of tissue that has already been removed. Clearly, if a procedure is required to remove tissue for research purposes, the researcher must seek specific permission to undertake the procedure, as with any other intrusive research activity.

**Loss of capacity during the course of research**

It is possible that patients with capacity, who have consented to participate in a research project, may lose capacity during the course of the project. Current research ethics application processes specifically deal with this and further information is available at [http://www.nres.npsa.nhs.uk/](http://www.nres.npsa.nhs.uk/).

Importantly, there is no blanket prohibition on continuing to collect data, or to use data or samples collected while they still had capacity. Providing the research can be justified, and appropriate approval is obtained, it may be possible for patients who now lack capacity to continue to participate in research.

**Transitional arrangements**

When the MCA was initially introduced, there were transitional arrangements in place that legitimised research that had been authorised before the Act came into force. This involved making supplementary applications of approval prior to the 1st October 2008. Further information is available in the ‘Mental Capacity Act 2005 - questions and answers v3.0’ document published in June 2009 [http://www.nres.npsa.nhs.uk/applications/guidance/#Adultsunabletoconsent](http://www.nres.npsa.nhs.uk/applications/guidance/#Adultsunabletoconsent)

However, the transitional period is now over, and all research in incapacitated individuals is expected to fully comply with requirements of the MCA otherwise they are breaking the law.

**Patients who regain capacity during research**

While the issues discussed in the previous section may be relevant to research in critically ill patients, this will apply only to a tiny minority of studies. A far more common (and probably universal) consideration in such studies is the fact that patients who lacked capacity at the onset of the studies will regain capacity as their clinical condition improves. The MCA provides no explicit guidance on the processes that need to be followed, but it is important to conform to the general principles of the Act in this setting. It is also important to ensure that any approach is compliant with the Data Protection Act (2000).

Given this background, the following course of action is advised. Permission for participation in research should be obtained from a consultee, as detailed in this chapter. Once the patient regains capacity, and as soon as is reasonably practicable, the patient should be directly consulted about participation in the study. If consent is confirmed, the study proceeds as planned. If the patient withdraws consent, it is reasonable to offer a range of options, including:

1. withdrawal from study procedures, but continued collection of data obtained as part of clinical
management

2. withdrawal from the study, no continued data collection of any sort, but permission to use data already collected

3. withdrawal from the study and removal of previously collected data from the study database

These arrangements fulfil the requirements of the Data Protection Act ensuring fair processing of information, providing that such processing is essential for the purpose of research, and that such research could not be undertaken with non-identifiable personal data.
Chapter 10: Organ Donation.

Organ donation is governed by the Human Tissue (HT) Act 2004 for England, Wales and Northern Ireland. There is a separate law for Scotland, the HT (Scotland) Act 2006. In addition persons who are deemed to lack capacity are further protected by the statutory instrument The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006. Subsequently this piece of legislation should be used alongside the Mental Capacity Act and its Code of Practice. As with the MCA the HT Act should not be read in isolation from the Codes of Practice. The HT Authority published their Codes of Practice in September 2009 and for the purposes of these guidelines we shall be referring to Code of Practice 2 – Donation of solid organs for transplantation and Code of Practice 9 – Research.

Consent

Before organs can be removed, stored or used for transplantation, appropriate consent must be obtained. The HT Act makes it lawful for donation from the deceased to take place provided that consent was given by the person prior to their death. Trained staff should determine whether consent was given by checking relevant sources, such as Organ Donor Register. In the case of non heart beating organ donation, legal guidance from the Department of Health in November 2009 states that if it has been established that the person wished to donate, successful donation may be seen in the person’s wider best interests by maximising the chance of fulfilling the donor’s wishes about what happens to them after death. Taking of blood samples and maintenance of life-sustaining treatment may be considered in the best interest of someone who wanted to be a donor if it facilitates donation and does not cause the person harm or distress. In the absence of their wishes being known, consent may be obtained from a person nominated by the deceased person, from a family member or a person close to them. Consent in this situation must be obtained by a person who is in a ‘qualifying relationship’ with the deceased. Those in a ‘qualifying relationship is stated in the HT Act in the following order:

i  Spouse or partner (including civil or same sex partner),
ii  parent of child,
iii  brother or sister,
iv  grandparent or grandchild,
v  niece or nephew,
vi  stepfather or stepmother,
vii  half-brother or half-sister,
viii  friend of long standing.

Consent is needed from only one person in the hierarchy of qualifying relationships and should be obtained by the person ranked highest. If the person ranked highest refuses to give consent it is not possible to act on consent given by someone else further down the list.

If a person cannot be located in a reasonable time for the activity in question to be addressed, or does not wish to accept the responsibility, or are unable to do so because they are a child or lack capacity as per the MCA then the next person in the hierarchy would become the appropriate person to give consent.

Nominated representatives

Under the HT Act adults may appoint one or more people to represent them after death and provide a
decision on consent on their behalf. This appointment can be made verbally or in writing which differs from the appointment of an LPA under the MCA which has to be done in writing and following the correct procedures. It is important to note the consent of a nominated representative cannot be overridden by other individuals, including family members. It is advisable however, to ensure that appropriate consultation and discussion takes place between all those involved.

**Research**

The HT Act does not contain a definition of research but research does fall within the HT Authority’s statutory remit. The accompanying Code of Practice 9 (Research) provides professionals with practical guidance and should be read prior to undertaking any research involving the removal of any human tissue. Guidance on the definition of relevant material for research can be found on the HT Authority website. [http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/definitionofrelevantmaterial.cfm](http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/definitionofrelevantmaterial.cfm)

It is important to note that consent is always required for the removal and storage of human tissue from the living and deceased other than in exceptional circumstances as follows:

- tissue was obtained before 1 September 2006 or
- it is from the living and is non-identifiable to the researcher and is for a specific project approved by a recognised research ethics committee.
Appendix 3. Electronic Resources

British Association of Critical Care Nursing  
www.baccn.org.uk/

Data Protection Act  

Department of Health  

General Medical Council Guidance  
www.gmc-uk.org/guidance/ethical_guidance/index.asp

Human Tissue Act  
www.opsi.gov.uk/acts/acts2004/ukpga_20040030_en_1

Human Tissue Act Codes of Practice  
www.hta.gov.uk/policiesandcodesofpractice/codesofpractice.cfm

Independent Mental Capacity Advocate (IMCA) service  
www.dh.gov.uk/en/SocialCare/Deliveringadultsocialcare/MentalCapacity/IMCA/DH_6599

Intensive Care Society  
www.ics.ac.uk/

Legal issues relevant to non-heart beating organ donation  

Medical Research Council  
www.mrc.ac.uk/index.htm

Mental Capacity Act 2005  
www.opsi.gov.uk/acts/acts2005/ukpga_20050009_en_1

Mental Capacity Act booklets  
www.publicguardian.gov.uk/forms/additional-publicationsa-newsletters.htm#mcab

Mental Capacity Act Code of Practice  

Mental Capacity Act 2005 Deprivation of Liberty Safeguards Code of Practice  

Mental Health Act 2007  
www.opsi.gov.uk/acts/acts2007/ukpga_20070012_en_1

National Information Governance Board for Health and Social Care  
www.nigb.nhs.uk/

National Research Ethics Service  
www.nres.npsa.nhs.uk/applications/guidance/

Office of the Public Guardian  
www.publicguardian.gov.uk/index.htm
Intensive Care Society
Churchill House, 35 Red Lion Square
WC1R 4SG
T: 020 7280 4350, F: 0207 280 4369
www.ics.ac.uk

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