Consent Policy

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1.0 Introduction

It is a general legal and ethical principle that valid consent must be obtained before starting treatment or physical investigation, or providing personal care, for a person. This principle reflects the right of patients to determine what happens to their own bodies and is a fundamental part of good practice. A healthcare professional (or other healthcare staff) who does not respect this principle may be liable both to legal action by the patient and to action by their professional body. Employing bodies may also be liable for the actions of their staff.

While there is no English statute setting out the general principles of consent, case law ('common law') has established that touching a patient without valid consent may constitute the civil or criminal offence of battery. Further, if healthcare professionals (or other healthcare staff) fail to obtain proper consent and the patient subsequently suffers harm as a result of treatment, this may be a factor in a claim of negligence against the healthcare professional involved. Poor handling of the consent process may also result in complaints from patients through the NHS complaints procedure or to professional bodies.

2.0 Purpose

To offer an up-to-date overview of contemporary guidance regarding consent. To detail procedures which will ensure that each person is consulted, listened to, and their wishes/instructions are respected and followed in the delivery of care.

To provide a clear work instruction for all staff with regards to how to handle all aspects of consent, including for medical treatment and other caring procedures provided.

To give clear details regarding responsibility and accountability.

To provide guidance regarding training, advice and support for staff in consent issues.

3.0 Scope

This policy is applicable to all interactions between healthcare professionals and their patients.

This policy is based on guidance issued by the Department of Health and applies to all Independent Health Group (IHG) staff involved in the physical examination of patients, or in providing any aspect of treatment and care, including for research purposes.

The policy does not include consent issues relating to:

- Participation in observational studies
- The use of personal information

These are dealt with under separate processes and policies.

The policy describes the circumstances in which consent should be sought. It does not prescribe whether written, verbal or non-verbal consent should be sought for particular procedures.

IHG does not currently treat persons under the age of 18 and therefore this policy only relates to gaining consent from adults.

4.0 Roles and Responsibilities

Every healthcare professional working with IHG is:	• Responsible personally and professionally for keeping themselves up to date with the current legal and ethical frameworks for obtaining consent, and for following relevant IHG policy and guidelines. • Has a duty to ensure that they work within the relevant legal and ethical frameworks. • Is individually accountable through external legal and professional regulatory processes; and • Is internally accountable through IHG's clinical governance and employment processes.
Chief Executive (Registered Manager)	• Responsible for the formulation and review of the policy in line with legislation and contemporary guidance. They are the Executive Lead for consent issues.
Medical Director	• Responsible for ensuring the correct implementation of the policy by clinical staff and that all clinicians are familiar with the policy and receive any necessary training, support and advice in applying the policy in their daily practice. Will hold the register of those authorised to take consent and which procedures.
Chief Nurse / Deputy Chief Nurse	• Responsible for ensuring the correct implementation of the policy and that all Healthcare staff are familiar with the policy and receive any necessary training, support and advice in applying the policy in their daily practice.
Lead for Safeguarding	• Will act as source of information and advice for staff, providing support and education as required, and arrange an application for Deprivation of Liberty (DoLS) if appropriate
Head of Quality and Governance	• Responsible for ensuring that compliance of this policy is maintained by regular audit of the processes which form part of this policy. The consenting process will be subject to audits of both quantitative and qualitative aspects on a regular basis.
Head of People	• Ensuring the necessary training on consent is provided to staff • Auditing that staff have received the necessary training in order to comply with the policy.
Clinical Staff	• Responsible personally and professionally for keeping themselves up to date with the current legal and ethical frameworks for obtaining consent, and for following relevant IHG policy and guidelines. They are also key decision makers, and provide leadership and guidance for their teams, in terms of Consent.

Individual Staff	• All health care professionals are responsible for seeking consent for any care or treatment they carry out themselves. Where responsibility for any aspect of the process is delegated to another person, overall responsibility remains with the person who actually carries out the procedure. It is a health professional's own responsibility: • To ensure that when they require colleagues to seek consent on their behalf, they are confident that the colleague is competent to do so. • To work within their own competence and not to agree to perform tasks which exceed that competence.

5.0 Related Legislation and Current Law

- Mental Capacity Act 2005
- Children Act 2004
- Human Tissue Act 2004
- Data Protection Act 1998
- Data Protection Act and General Data Protection Regulations 2018
- Montgomery v Lanarkshire Health Board [2015] UKSC 11
- A v East Kent Hospitals University NHS Foundation Trust [2015] EWHC 1038 (QB)
- Middleton v Ipswich Hospital NHS Trust [2015] EWHC 775 (QB)
- Spencer v Hillingdon Hospital NHS Trust [2015] EWHC 1058 (QB)
- Tracey v Cambridge University Hospital [2012] EWCA Civ 822

6.0 Procedures / Implementation

This section outlines the practical aspects of obtaining consent, based on the legal and ethical frameworks described in Appendix 2, and covers some specific and/or more complex situations. See also Appendix 1 which provides a flow chart for consent.

6.1 Who can Obtain Consent?

The process for gaining consent from the patient in order to carry out a surgical procedure or course of treatment should be:

- Gained by the person carrying out the procedure or;
- A person capable of carrying out the procedure independently or;
- A trainee capable of performing the procedure under supervision who has been authorised to take consent or;
- A person who has been trained in taking consent for that procedure.
- Clinical staff and senior trainees who have completed their final professional membership exams are assumed competent to take consent for all procedures in their specialty.

6.2 Underlying Principles

- All staff must take responsibility for the decision as to whether or not they can reasonably take consent. (this also applies to consent, whether implied, verbal or written for any action or treatment performed with the patient and not just “high risk” care or treatment actions i.e. surgical procedures.)
- Consent for the surgical procedure should ideally be taken by the clinician performing the procedure, but it is acceptable to delegate
- Senior medical staff delegating consent must be satisfied that the person taking consent is competent to do so.
- Where possible the person consenting should use a procedure specific consent form on which the risks and benefits are clearly outlined.
- IHG’s Medical Director will hold a simple register of authorisation to take consent (for delegated staff only). It is the responsibility of each member of staff delegated to take consent, to ensure that their authorisation to take consent for a procedure or group of procedures is recorded in the register. (See Appendix 3)
- At the point of surgery or planned treatment previous consent made by the patient should be confirmed as still valid by the clinician providing that surgery/treatment/care.

6.3 The Consenting Process

6.3.1 Capacity

Although it would be unusual for a patient without capacity to be referred for the services that IHG provides, due to the fluctuating nature of capacity for some patients it is still imperative to ask the question as to whether the patient has capacity to consent to the specific procedure or treatment being offered:

- If there is any doubt about this, advice should be sought.
- If appropriate, a formal assessment of capacity should be arranged and carefully documented as per advice and instructions in **Policy CL023** and **Guidance Document CL020**
- Consider whether the patient could be assisted to make a decision, by delaying the discussion, or extending the discussion over several sessions, or involving an interpreter or signer. Interpreters/signers can be arranged, and their use should be documented in the patient’s records. (see 6.3.4 below)

For any patient assessed as not having capacity it would be reasonable to assume, based on previous risk assessment profiles, that it would be unsafe for surgery under local anaesthetic as provided by IHG to continue. In this instance the patient would need to be referred to another provider. In the event that a less, interventional treatment plan of care could be provided to ensure the patients safety and comfort then the following would need to be assessed in line with best interests’ assessments (please also refer to CL023):

- Check whether the patient has made a valid and applicable Advance Decision.
- If the patient is assessed as lacking capacity to make the relevant decision, then the decision-maker should consult with the people close to the patient and other professionals and record the decision that is made in the patient’s best interests, with reasons.

- If the patient who lacks capacity is also “un-befriended” it may be necessary to arrange to appoint an IMCA to advocate on the patient’s behalf (If the patient appointed a Lasting Power of Attorney or the court has appointed a Deputy with authority to make decisions about healthcare (i.e. the power or authority is not limited to property and finances), then the LPA or Deputy must be consulted and asked to give consent on the patient’s behalf.
- If there is not consensus about what is in the patient’s best interests, or any concern that an LPA or Deputy may not be acting in the patient’s best interests, urgent advice should be sought from the Lead for Adult Safeguarding. In some cases, it will be necessary to apply to the Court of Protection for a declaration as to what is in the patient’s best interests and/or as to whether the LPA or Deputy is acting in the patient’s best interests.
- Urgent or emergency treatment should not be delayed for discussions to take place, but where treatment can be anticipated in advance then the necessary consultations should be arranged in sufficient time to allow for proper discussion to take place.
- Where it is necessary to restrain a patient, who lacks capacity in order to provide treatment safely, this will be lawful provided if the person using restraint reasonably believes it to be necessary to prevent harm and the proposed restraint is proportionate to the likelihood and potential severity of the harm. For further information on the lawful use of restraint, please refer to Policy CL023

6.4 Providing Information to Enable the Patient to Give Informed Consent

The provision of information is central to the consent process. Before patients can come to a decision about treatment, they need comprehensible information about their condition and about possible treatments/investigations and their risks and benefits (including the risks/benefits

They also need to know whether additional procedures are likely to be necessary as part of the overall treatment plan /procedure. Once a decision to have a particular treatment/ investigation has been made, patients need information about what will happen: where to go, how long they will be in clinic, how they will feel afterwards and so on.

Patients and those close to them will vary in how much information they want: from those who want as much detail as possible, including details of rare risks, to those who ask health professionals to make decisions for them. There will always be an element of clinical judgement in determining what information should be given. However, the presumption must be that the patient wishes to be well informed about the risks and benefits of the various options. It is important to ascertain what the patient wishes to know in terms of the “Material Risks”, this is deemed **"material" when a reasonable person**, in the patient's position would find that information important when making decisions about medical treatment. Where the patient makes clear (verbally or non-verbally) that they do not wish to be given this level of information, this should be documented. (see GMC(2008) Consent: Patients and Doctors making decisions together). The need to have a “meaningful, clear discussion” with the patient also follows the guidance which came out of the Montgomery Case (2015).

The following sources of patient information are available:

6.4.1 Patient Information Leaflets / Booklets

Procedure specific information leaflets are available in both paper-based format and on the IHG Website. Either on referral and booking of the first appointment or at the first appointment the patient will be provided the specific one for their intended procedure. These are produced and maintained regularly and include copies of the procedure specific consent form.

6.4.1 "Your Consent to Treatment" Information

General information about consent to treatment for patients is available on the NHS Choices website which patients can be signposted to at: https://www.nhs.uk/conditions/Consent-to-treatment/

6.4.2 Guidance on Production of New Written Information

All written information for patients, carers, relatives and other service users must be approved by the Integrated Governance & Business Committee.

6.4.3 Provision for Patients with Disabilities

IHG will provide information in different formats, as appropriate, to support people with sight or hearing disabilities, learning difficulties or low literacy skills, for whom existing resources may be unsuitable. Patients who require this can request it at their initial contact for an appointment, at the first appointment or by contacting the Patient Referral Centre line (03330 100362)

6.4.4 Provision for Patients Whose First Language is not English

IHG is committed to ensuring that patients whose first language is not English receive the information they need and are able to communicate effectively with healthcare professionals. IHG will use the Language Line Interpreter service as necessary.

Best practice guidance discourages the use of family and friends for interpretation and translation for a number of reasons, a good summary of this can be found in the NHS Scotland (2008) Now we are Talking Interpretation guidance (on page 22). However, this needs to be taken in context with the patient's own wishes. The GMC guidance (2008) states that: "You should accommodate a patient's wishes if they want another person, such as a relative, partner, friend, carer or advocate, to be involved in discussions or to help them make decisions." Therefore, it may be appropriate for other family members or friends to interpret for patients who do not speak English.

However, to ensure that coercion is avoided as per the Department of Health guidance (2010): "To be valid, consent must be given voluntarily and freely, without pressure or undue influence being exerted on the person either to accept or refuse treatment.

Such pressure can come from partners or family members, as well as health or care practitioners.

Practitioners should be alert to this possibility and where appropriate should arrange to see the person on their own in order to establish that the decision is truly their own." It is also advisable in this scenario to use a professional translator (i.e. Language Line) to confirm that the patient understands what they are consenting for or to. (see also 6.3.3 below). If the

patient insists that the family or friend remains for the whole of the consultation and consenting process a professional interpreter should be used to confirm that the consent process is valid.

The use of children to interpret is not to be condoned as this is against all best practice guidance and should be discouraged except in exceptional emergency-based circumstances.

A good practice guide to interpreting published by BME in 2010, in a number of languages, provides patients information on why they should use professional services offered by healthcare providers and can be accessed on the Migrants Organise website: http://www.migrantsorganise.org/?p=21539

For Healthcare providers NHS England provides guidance on what good translation and interpretation services should look like and this can be found in: NHS England (2018) Guidance for commissioners: Interpreting and Translation Services in Primary Care, although this is for commissioners of primary care it is stated that it is appropriate and applicable to other health service providers. Language Line meets the standards set out in this guidance and so is the primary source for use by IHG staff when requiring translation or interpretation services. Details of arrangements for accessing Language Line will be available at all clinic and treatment sites as a prompt card. See Appendix 4.

Currently provision of printed health information in other languages can be arranged if sufficient notice is given. Referral Centre Staff will pass this information onto the Head of Nursing at the point of initial contact.

6.4.5 Access to More Detailed or Specialist Information

Patients may sometimes request more detailed information about their condition or about a proposed treatment than that provided in general leaflets. In the first instance such requests should be directed to the clinical staff, responsible for the procedure.

6.4.6 Access to Health Professionals Between Formal Appointments

After an appointment with a health professional, patients will often think of further questions which they would like answered before they make their decision. Written information provided to patients will include contact details to enable any further questions a patient may have to be answered by a member of the managing team either by telephone or in person.

After an outpatient clinic appointment, patients can contact the appropriate clinician via the Patient Referral Centre line (03330 100362), rather than waiting until the date of treatment.

7.0 Specific Consents

7.1 Consent for Anaesthetic

If a procedure or treatment is to be performed under local anaesthesia given by the clinician who will also carry out the procedure or treatment, then that clinician is responsible for obtaining informed consent for the local anaesthesia, as well as for the procedure or treatment itself. All the same general principles apply. Therefore, for a non-emergency procedure:

- it will not normally be acceptable for the first introduction/provision of information about anaesthetic options, and their risks and benefits, to take place immediately prior to surgery.
- Patients should be provided with advance information about anaesthesia by way of information leaflets and/or at a prior consultation and given time to consider any appropriate options.
- For patients taking up the option of a “one-stop” service the information sent prior to the procedure will include information about the anaesthetic as well as the procedure. This does not negate their right to request a delay or decline the surgery on the day. (see also 6.3.5 below)

7.2 Emergencies

In an emergency, where the patient lacks capacity, it will be necessary and appropriate to act in the patient’s best interests to save life or prevent serious harm. Once the patient regains capacity an explanation of what has happened should be given to the patient, and then the usual consenting discussions should resume.

Even if the patient has capacity, it is likely to be necessary to proceed quickly, without a full discussion with the patient, and without asking the patient (or someone else at the patient’s request if they have capacity but physically cannot sign) to sign a consent form.

In all such situations a full note should be made in the patient’s records as soon as possible afterwards describing the treatment provided and what was (or was not) discussed with the patient according to the circumstances.

7.3 Patients Whose First Language is not English

IHG is committed to ensuring that patients whose first language is not English receive the information they need and are able to communicate effectively with healthcare professionals. Effective communication is essential to the consent process, both in terms of providing patients with sufficient information to ensure that consent is valid and making sure that patients are not coerced into consenting to treatment. Due to the potential cultural conflicts for patients whose first language is not English, it is also advisable for the clinician who does speak the same language as the patient to make use of language line in the consenting process as a safeguard for their practice.

IHG will use the Language Line Interpreter service for this process and there is a Language Line User Information Prompt available at all IHG Sites. (See appendix 4)

7.4 Communication Disability Specialist Interpreters

As part of IHG’s ongoing commitment to continually develop and enhance our customer facing service, we partner with a number of organisations on mutually beneficial activities.

For those patients who have hearing and/or visual impairments, interpreters are used from the ASLI listings. (https://www.asli.org.uk/) and will need to be arranged prior to the first appointment. – See also Flow Charts in CL023.

7.5 Provision for Patients / Partners Undergoing Contraception / Sterilisation

For patients undergoing certain procedures (e.g. sterilisation / contraception procedures) counselling is preferred to be delivered to both the patient and their partner as part of the informed consent process, however it is accepted that couples often decide that only the patient will attend, and this is also acceptable. Information is provided in the patient information booklet and both the patient, and their partner are invited to an appointment which includes a counselling phase. If the patient wishes to take further time to consider their options prior to consenting to the procedure on the day ("one-stop" service), they can be deferred for treatment at a later date within the set time framework for the specific procedure.

7.6 Human Tissue

The Human Tissue Act 2004 came fully into force on 1 September 2006. It sets out the legal framework for the storage and use of tissue from the living and for the removal, storage and use of tissue and organs from the dead, including 'residual' tissue following clinical and diagnostic procedures. The Human Tissue Act makes consent a legal requirement for the removal, storage and use of human tissue or organs and sets out whose consent is needed in which circumstances. The Act also established the Human Tissue Authority (HTA). The HTA is also responsible for approving the transplantation of organs from living donors and bone marrow and peripheral blood stem cells from adults who lack the capacity to consent and children who lack the competence to consent. Further guidance on consent and codes of practice is available on the HTA's website.

7.7 Consent to Visual and Audio Recordings

Photographic and video recordings made for clinical purposes form part of the patient's healthcare record and must not be used for any purpose other than the patient's care or audit of that care without the express consent of the patient. Consent should be obtained for any visual or audio recording, including photographs or other visual images. The purpose and possible future use of the recording must be clearly explained to the person before their consent is sought for the recording to be made. If it is to be used for teaching, audit or research, the patient must be made aware that they can refuse without their care being compromised and that when required or appropriate it can be anonymised. The patient must also be made aware of the possible uses of the material and that its use may not be capable of being controlled once it is in the public domain. There is GMC guidance which gives more detailed advice, including situations when permission is not required and about obtaining consent to use recordings as part of the assessment or treatment of patients and for training or research. This can be accessed at:

General Medical Council's guidance: "Making and using visual and audio recordings of patients".

The guidance is that this consent should ideally be written but can be gained retrospectively. If this is then not given visual and audio recording must be destroyed. This guidance includes all recordings including x-rays, endoscopy recording as well as photographs and videos of procedures for other non-clinical purposes. For clinical purposes it should be explained to the patient that as part of the clinical record they are subject to the same confidentiality

requirements as any other patient record and will only be shared or used for the patients care or treatment and further consent will be sought for any other future use for other purposes.

7.8 Completing Consent Forms

The standard consent form provides space for a health professional to provide information to patients and to sign confirming that they have done so. The health professional providing the information must be competent to do so: either because they themselves carry out the procedure, or because they have received specialist training in advising patients about this procedure, have been assessed, are aware of their own knowledge limitations and are subject to audit.

In many cases it will be appropriate for the healthcare professional to initiate a clinical procedure immediately after discussing it with the patient who has given oral consent. For example: where personal care, routine clinical assessment or physiotherapy is to be given. Where a procedure or treatment carries significant risks (such as surgery) it will be appropriate to seek confirmation of the patient's agreement in writing, having followed the principles described in Appendix 2. Unless it is an emergency, patients must be allowed sufficient time to consider and weigh up the options, the risks and benefits of each option, including the option of having no treatment.

Where the decision to be made is complex, it may be necessary to have more than one discussion with the patient, and/or to allow sufficient time for the patient to discuss the options with more than one healthcare professional. At the end of the process, the patient will be asked to sign a consent form confirming that they wish to proceed and acknowledging that they have considered the relevant risks that have been discussed with them.

If consent forms are provided to the patient as an outpatient and signed before admission for the procedure, (for example in out- patients or at a pre-assessment clinic), a health professional involved in their care on the day should sign the form to confirm that the patient still wishes to go ahead and has had any further questions answered.

Staff have access to the current approved consent forms along with IHG policies on the IHG SharePoint.

A final check that the patient still wishes to proceed should be made prior to carrying out the procedure because the clinical picture may have changed, and/or it may no longer be appropriate to proceed as planned, and/or because the patient has the right to change their mind or withdraw their consent at any time before the procedure takes place. It is not essential (unless the patient wants it) to repeat in the same level of detail all the previous discussions, but it may be appropriate to summarise what has previously been discussed, the progress that has been made or changes that have occurred, and what is to happen next. Each additional discussion should be documented, along with any new information or changes to the treatment plan.

In terms of the timing of the final check that the patient wishes to proceed with the procedure or treatment, it will rarely be appropriate to ask patients to sign a consent form once they are preparing for the procedure or treatment, for example by changing into a gown. This is because, to be valid, consent must be freely given and may be withdrawn at any time. It is

important that patients should feel able to withhold or withdraw their consent at any stage and not feel coerced into agreeing to something they may later regret and/or challenge.

7.9 Responsibility of Health Professionals

It is a health professional's own responsibility:

- To ensure that when they require colleagues to seek consent on their behalf they are confident that the colleague is competent to do so.
- To work within their own competence and not to agree to perform tasks which exceed that competence. If staff feel that they are being pressurised to seek consent when they do not feel competent to do so they should raise the matter in the first instance with their direct line manager. If staff are unable to raise the matter at this level or resolve the situation through this route they should seek advice from the Head of Nursing /Medical Director or Human Resources, as appropriate.
- If they have concerns about other health professionals and their competence in seeking consent, they should refer initially to the healthcare professional (e.g. consultant) managing the patient's care. If they are not satisfied with the response they should contact the Head of Nursing, Medical Director or Human Resources as per CP023 – Raising Concerns Policy.

7.10 Refusal of Treatment

If the process of seeking consent is to be a meaningful one, refusal must be one of the patient's options.

If an adult with capacity makes a voluntary and appropriately informed decision to refuse care/treatment, this decision must be respected, except in certain circumstances as defined in the MHA 1983 or in exceptional circumstances under common law.

If, after discussion of possible care/treatment options, a patient with capacity refuses any care and/or treatment this fact should be clearly documented on the patients record.

If the refusal of the care or treatment presents risk of serious harm to the patient staff should complete an Informed Consent Refusal Form to evidence that they have discussed the person`s condition with them and explained the proposed care and/or treatment with the patient.

The form should be signed and dated by the patient and witness/ staff member who has undertaken the discussion and held on the patient`s record.

Where a patient has refused a particular intervention staff must ensure that they continue to provide any other appropriate care to which the patient has consented. Staff should also ensure that the patient realises they are free to change their mind and accept treatment if they later wish to do so. Where delay may affect their treatment choices, they should be advised accordingly.

If a patient consents to a particular procedure but refuses certain aspects of the intervention, The staff member consenting the patient must explain the possible consequences of their

partial refusal. If the staff member genuinely believes that the procedure cannot be safely carried out under the patient's stipulated conditions, they are not obliged to perform it. They must, however, continue to provide any other appropriate care.

If consent is refused - where another health care professional believes that treatment can be safely carried out under the conditions specified by the patient, IHG will be prepared to transfer the patient's care to that health professional where possible.

7.11 When Patients do not Want to Know

If a patient does not want to know in detail about their condition or the care/treatment, staff should respect their wishes as far as possible, but must explain the importance of providing at least the basic information they need to give valid consent to the care and /or treatment being given.

The patient must be informed that they can change their mind and have more information at any time. This needs to be recorded in the patient`s record.

The health professional seeking consent must record the fact that the patient has declined relevant information to be able to give valid consent to the care/treatment.

The health professional will need to make a decision about proceeding with the treatment in this situation.

If the treatment involves significant risk the health professional should seek advice from the relevant clinical lead or Medical Director.

8.0 Documentation and Record Keeping

It is essential that each stage of the consenting process is documented whether by way of free text in the patient's records, by reference to standard patient information leaflets or other resources, or clinic letters to GP and/or the patient.

Completed consent forms are to be kept with the patients' notes. Any change to the form must be signed and dated by the patient and health professional. All consent forms should be attached to the patient's Integrated Care Pathway (ICP) on the electronic Patient Administration System (PAS).

In Line with good practice guidance and the GMC new consent guidance (available in draft and due for release later in 2019): "You must record the key elements of discussions about options, harms and benefits you have had with the patient, those close to them, anyone who has a legal role in the process

and other members of the healthcare team. You should take a proportionate approach to the level of detail you record. But you should usually include:

- a summary of the information you discussed
- any specific concerns or requests expressed during discussions

- any written, visual or audio information given to the patient, those close to them or those with a legal role in the process
- details of any decisions made."

The above should be recorded in the patients notes and/or on the PAS system. In addition, the patient should also be provided with a copy of any consent form that they have signed.

Capacity and Best Interest assessments and applications for DoLS under the Mental Capacity Act frameworks must be included, either as originals or copies, in the patients record.

IHG does not currently treat persons under the age of 18 and therefore does not carry the consent form for parental consent for a child or young person.

The current approved consent forms are available along with IHG policies on the IHG SharePoint.

9.0 Training Implications

Any record that there has been a discussion of issues surrounding consent can be interpreted as training. This would include:

- Formal training in a classroom setting or completion of a training module (e.g. E-Learning for Health (e-LfH) consent module or formal endoscopy nurse training module on consent)
- The completion of a Procedure Based Assessment (PBA) where there is a record that consent has formed part of the assessment.
- Informal point of care teaching on consent for a procedure is perfectly acceptable provided there is a record that this has taken place.

How much training required will depend on the level of experience of the consent taker. It may also be necessary to repeat training or include update training using an electronic learning platform (i.e. e-LfH). In determining whether training is adequate, senior staff should consider whether they could defend its adequacy in a court of law.

For those receiving training in obtaining consent for a procedure that they may not be personally undertaking competence must be assessed by a formal observed assessment by a clinician who is already competent in both consent and the procedure for which consent is being obtained.

10.0 Monitoring Arrangements and Audit

The Quality and Governance team are responsible for carrying out audits of consent.

The audit will be used to assess the quality of consent form completion by Clinicians and to identify potential areas of improvement. Where audit indicates that consent may have been obtained by someone not authorised to do so, it will be reported to the Head of Nursing / Medical Director and followed up through the Integrated Governance and Risk Management Committee as part of the actions arising from the audit. Follow up actions may include

requirements to produce evidence of competence and identification of training needs.

11.0 References

DOH (2009) Reference Guide to Consent for Examination or Treatment 2nd Edition

NHS (2016) Overview – Consent to Treatment

Austin J, (2015) CONSENT - The current law and implications for clinical practice, Salisbury NHS Trust

TSO (2005) Mental Capacity Act 2005 Code of Practice

TSO (2000) Code of Practice for persons authorised to carry out medical treatment or research under Part 5 of the Adults with Incapacity (Scotland) Act 2000

BMA (2007) The Mental Capacity Act 2005 Guidance for health professionals

BMA (2008) Mental Capacity Act Tool Kit

BMA (2018 Dec Update) Consent Toolkit Website

MDU (2019) Montgomery and informed consent. Webpage

NICE (2012) QS15 – Patient Experience in Adult NHS Services: Quality Statement 5 – Understanding Treatment Options.

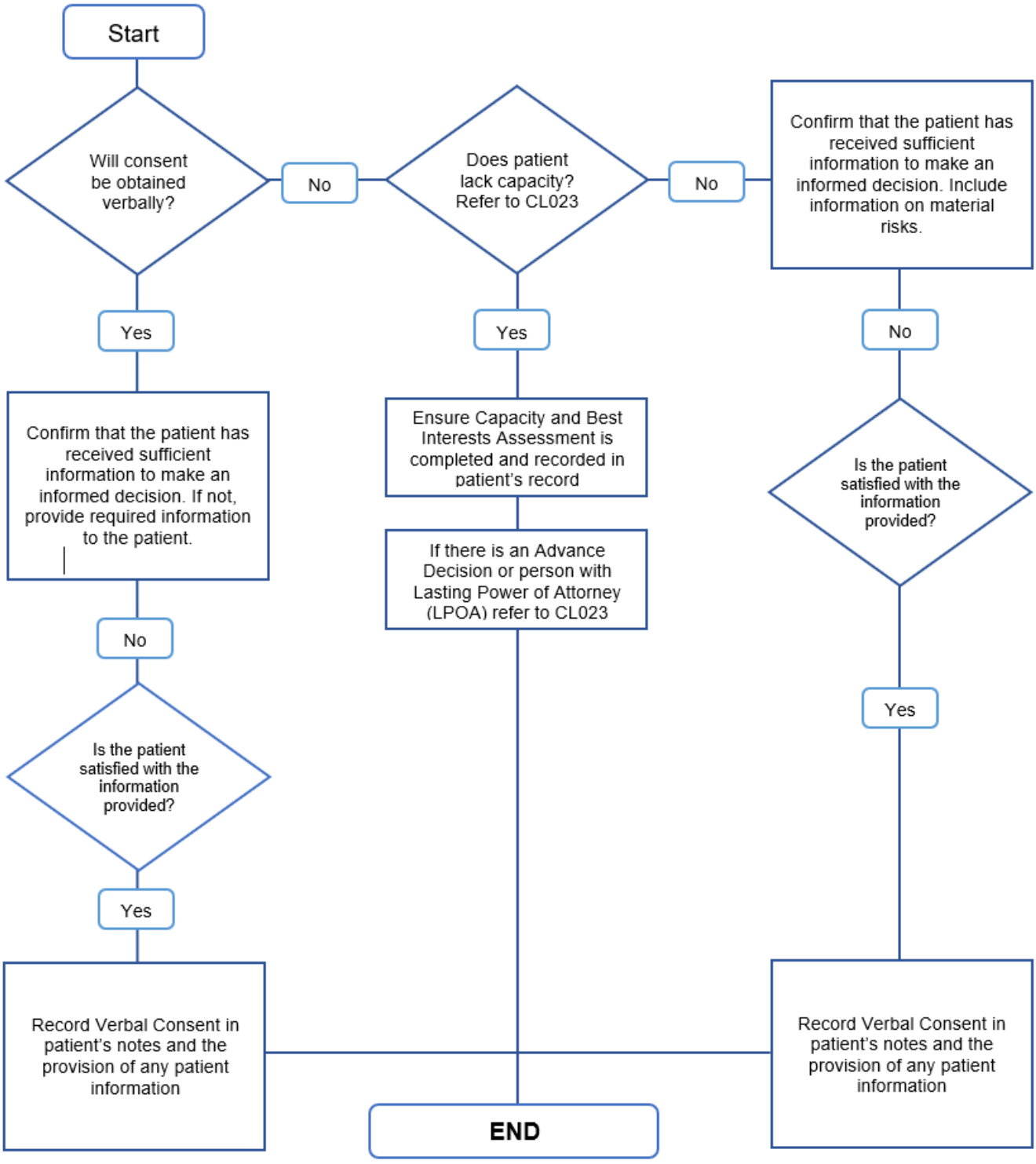
GMC (2020) https://www.gmc-uk.org/professional-standards/the-professional-standards/decision-making-and-consent

BMA (2024) https://www.bma.org.uk/advice-and-support/ethics/seeking-consent/consent-and-refusal-by-adults-with-decision-making-capacity

12.0 Appendixes

12.1 Appendix 1 – Consent Flow Chart

NB: If you will not be carrying out the procedure and have not been trained to obtain consent for this procedure then you must not obtain consent.



12.2 Appendix 2 – Key Terms and Principles

12.2.1 Defining Consent

For consent to be valid, it must be voluntary and informed, and the patient who is consenting must have the capacity to make the decision.

These terms are explained below:

- **Voluntary** – the decision to either consent or not to consent to treatment must be made by the patient themselves, and must not be influenced by pressure from medical staff, friends or family
- **Informed** – the patient must be given all of the information in terms of what the treatment involves, including the benefits and risks, whether there are reasonable alternative treatments, and what will happen if treatment doesn't go ahead
- **Capacity** – the patient must be capable of giving consent, which means they understand the information given to them and they can use it to make an informed decision

If an adult has the capacity to make a voluntary and informed decision to consent to or refuse a particular treatment, their decision must be respected.

This is still the case even if refusing treatment would result in their death, or the death of their unborn child.

If a patient doesn't have the capacity to make a decision about their treatment, and they haven't appointed a lasting power of attorney (LPA), the healthcare professionals treating them can go ahead and give treatment if they believe it's in the patient's best interests.

But clinicians must take reasonable steps to seek advice from the patient's friends or relatives before making these decisions.

Please refer to the Mental Capacity Act and DoLS/LPS Policy CL023 and Adults with Disabilities Requiring Community Surgical Care - Guidance CL020

Gaining Consent

Consent can be given:

- **verbally** – for example, by saying they're happy to have an X-ray
- **in writing** – for example, by signing a consent form for surgery

Someone could also give non-verbal consent, as long as they understand the treatment or examination about to take place – for example, holding out an arm for a blood test.

Consent should be given to the healthcare professional directly responsible for the patient's current treatment, such as:

- a nurse arranging a blood test
- a GP prescribing new medication
- a surgeon planning an operation

If someone is going to have a major medical procedure, such as an operation, consent should be addressed well in advance, so the patient has plenty of time to obtain information about the procedure and ask questions, prior to the health professional securing the consent.

If they change their mind at any point before the procedure, the patient is entitled to withdraw their previous consent. Therefore, if a treatment plan has several stages or takes place over a period of time it will be necessary to check at each stage or after each interval of time that there are no changes to the patient's condition that might make it appropriate to modify the original treatment plan, and that the patient is still willing to continue with the treatment plan (as amended, if appropriate).

12.2.2 Exceptions / Contraindications

In an emergency appropriate care can be given without express consent to save life or prevent serious harm. Careful records should be made to explain why it was not possible to obtain consent and what was done. As soon as the patient regains capacity, the usual consent process should resume.

12.2.3 Recording Consent

A signed consent form is not "consent" but merely a record that the patient has agreed to proceed with the treatment offered. It is not proof that consent was validly obtained, or that the patient has made an informed decision. Obtaining consent is a process of discussion between patient and healthcare professional, with the patient making the final decision. Consent forms alone will often not reflect the full scope of the discussion, which will therefore need to be separately recorded in some way (for example, as free text in the records, or in a letter to the GP/patient, or by reference to an IHG approved information leaflet or checklist, or by a combination of these).

Written consent forms are only required by law in a few instances (Mental Health Act 1983 and Human Fertilisation & Embryology Act 1990) but it is good practice to obtain written consent when:

- The treatment or procedure is complex, or involves significant risk (i.e. any adverse outcome including side-effects or complications);
- The treatment or procedure involves general or regional anaesthesia or sedation;
- Providing clinical care which is not the primary purpose of the intervention;
- There may be significant consequences for the patient's employment, social or personal life;
- The treatment is part of a project or programme of research approved by the Organisation.

It may also be prudent to document consent for routine or low risk procedures or personal care if you have any reason to believe that it may later be questioned, or if the patient has in the past declined it. The current approved consent forms are available along with IHG policies on the IHG SharePoint. All consent forms are reviewed and updated regularly to reflect the current law and current clinical best practice.

12.2.4 Valid "Informed" Consent

For adult patients who have capacity to make their own decisions, their consent must be "informed". This means that the healthcare professional must ensure that the patient is told about:

- The proposed treatment and any alternative treatments, including no treatment; and
- The material risks and benefits of the proposed treatment, and of any alternatives, including no treatment

In the recent Supreme Court case of Montgomery the court said that:

- The information provided must be relevant and specific to the individual patient;
- Dialogue between healthcare professional and patient is essential;
- The so-called "therapeutic exception" must be used exceptionally; It should be noted that the term" Therapeutic Exception" here, is the legal term for withholding information about risks which the clinician feels will compromise the patient's decision because it will frighten or put the patient off unnecessarily. i.e. a paternalistic approach to provision of information or clinicians deciding what the patient should be told. In line with material risks this is no longer a viable option except in extreme or exceptional circumstances.
- Respect for the patient's views is paramount.

12.2.5 Material risks

"Material" risks are those that a reasonable person in the patient's position would be likely to consider significant (an objective test), or that this particular patient would be likely to consider significant (a subjective test).

In Spencer v Hillingdon Hospital, the court advised putting yourself into the patient's position: what would you want to know? A theoretical risk is not a material risk (A v East Kent) – it isn't necessary to list all possible outcomes if they are not objectively material or significant – but if asked about a particular risk or outcome you must discuss it.

Clinical options which are not routinely offered may, in some circumstances, have to be offered in response to a patient's specific concerns (Middleton v Ipswich Hospital). In some circumstances it may be appropriate to offer a second opinion. In case of difficulty or uncertainty you should discuss matters with a senior colleague before proceeding.

In Montgomery the court also said that what is "material" is:

- Fact and patient sensitive, not merely about percentages;
- Dependent on the nature of the risk;
- Dependent on the effect of the occurrence of the risk on this particular patient's life; and
- Dependent on the importance to this particular patient of the benefits they seek from the treatment.

Therefore, in discussing the risks and benefits of each of the treatment options, the healthcare professional must find out and address what is important or significant to this particular patient so as to enable this patient to make an informed decision. What is significant to one patient

may not be significant to the next patient who has a different lifestyle and/or different beliefs or priorities. However, be careful not to make assumptions about what a particular patient is likely to consider significant as the subjective part of the discussion is about the patient raising their own questions or concerns, in addition to receiving information from the clinician about the objective risks and benefits.

12.2.6 Dialogue with the Patient

The healthcare professional has an advisory role which involves a dialogue with the patient, to ensure that the patient understands:

- The seriousness of their condition;
- The anticipated benefits and risks of each treatment option, or of no treatment; and
- The patient feels that they have sufficient information to make an informed decision.

This can be viewed as a three-part process:

1. Asking what is important to this patient and the outcome they hope for; and
2. Providing an explanation of relevant clinical information; and
3. Answering their questions and concerns.

Throughout the discussion it is implicit, and key to an informed decision, that the information provided by the healthcare professional should be comprehensible to the particular patient.

Patients are likely to want information about practical implications of the proposed treatment, such as how much pain they are likely to experience and how this will be managed; how mobile they will be after surgery and weight bearing; how long they may be in clinic; and whether they will be able to resume their previous level of activity/ hobbies/ playing sports/ employment. It is important that each patient is given the opportunity to raise and discuss these, and any other, issues that the patient feels is relevant to their decision.

The Supreme Court in Montgomery said that lack of time is not an acceptable reason for not having a discussion with the patient that allows them to make an informed decision. Therefore, it is suggested that basic information about common conditions and procedures is provided in advance of a discussion with the healthcare professional, either by way of information leaflets or reference to publicly available resources. If the options or the decision to be made are particularly complex, then several discussions over a period of time may be necessary to enable the patient to make an informed decision.

Patients vary in the amount of information they want or require before making a decision. To some extent how much information each individual needs to make an informed decision is a matter of clinical judgement, but the Supreme Court in Montgomery also said that it reserves the right to take a different view on how much information is enough information.

Therefore, taken together, both subjectively (what this patient wants to know) and objectively (what a reasonable person in the patient's position would want to know), the totality of the information provided has to be sufficient.

If a patient declines relevant information, then a careful note should be made in the patient's records in case it is needed later to justify the limited extent of the discussion that took place before proceeding with treatment.

12.2.7 Withholding information

The “therapeutic exception” means that a healthcare professional can withhold information about a risk only if its disclosure would be “seriously detrimental” to the patient’s health (Montgomery).

This will very rarely happen in practice. If it does, a very careful note of the information that was withheld and the reasons for withholding it will be essential in case of a later challenge. It may be sensible to consult a colleague and/or seek a second opinion and/or consult with the Medical Director / Head of Nursing, if this situation arises and treatment is not urgently needed.

The Supreme Court has warned that healthcare professionals must not use the therapeutic exception to subvert the patient’s right to make an informed decision, even if (or perhaps especially if) the patient’s decision is considered contrary to their clinical best interests. A patient with capacity has the right to make a decision which others (including their doctor or allied healthcare professional) may consider unwise, or even foolish.

12.2.8 Refusal of treatment

Refusing treatment may reflect an individual patient’s values and beliefs without calling into question whether they have capacity to make the relevant decision. Refusals may be formalised in writing as an Advance Decision – **Please refer to Mental Capacity Act and DoLS/LPS Policy CL023 and Adults with Disabilities Requiring Community Surgical Care - Guidance CL020**

Even if a patient has refused a particular intervention, all other appropriate treatment and care must be offered and provided if the patient consents to it. The patient should also be reassured that they can change their mind at any time. It should be noted that at times, an apparent objection may in fact be a cry of pain rather than withdrawal of consent, and appropriate reassurance may enable the practitioner to continue with the patient’s consent. If stopping the procedure at that point would genuinely put the life of the patient at risk, the practitioner may be entitled to continue until that risk no longer applies.

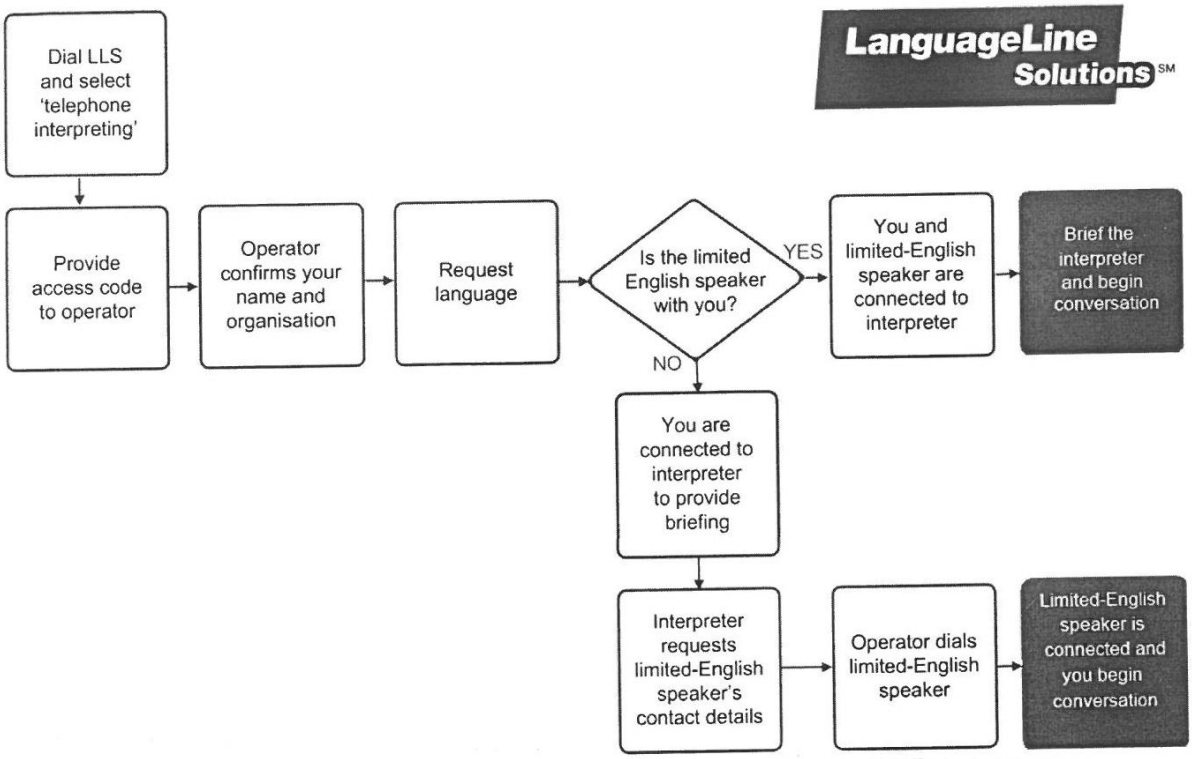
If a patient refuses some aspects of an intervention, then an explanation of the (additional) risks attached to their conditional consent or partial refusal must be provided. If the procedure genuinely cannot be carried out safely under the patient’s stipulated conditions, then the healthcare professional is not obliged to perform it. However, all other appropriate care and treatment must be provided. If another healthcare professional would be willing to carry out the intervention under the patient’s stipulated conditions, then the patient’s care must be transferred on request.

12.3 Appendix 3 – Consenter Register Exemplar

Register of Approved Consenters

Name of Consenter	Professional Registration	Procedure they can consent for	Procedure they have delegated consent status for	Date approved	Date of most recent training	Date due for update

12.4 Appendix 4 - Language Line Prompt Sheet



LanguageLine Solutions℠

Accessing a Telephone Interpreter

When your client is with you

If you have a LanguageLine Dual Handset Phone please skip step 1.

1. Phone 0845 310 9900
2. The operator will ask you for:
   - Your ID Code (_____) L53881
     (Please note: this code is **confidential** to your organisation or dept.)
   - Your organisation name (and department where appropriate)
   - Your initial and surname
   - The language you require (say if you need a specific interpreter*)
   - Your client's location, i.e. **with you**
3. Stay on line while the operator connects you to a trained interpreter (about 30 seconds).
4. Note the interpreter's ID code, introduce yourself and brief the interpreter saying what phone you are using, e.g. single/ dual handset, speaker phone or mobile.
5. Ask the interpreter to introduce you and themselves to your client and give the interpreter the first question or statement. Give the interpreter time to interpret between you and your client. Continue the conversation.
6. Let your client and the interpreter know when you have finished.

*whenever possible we meet specific requests, e.g. for a female interpreter

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Making outgoing client calls

The operator will connect you to an interpreter, then conference your client into the call.

1. Have your client's name and telephone number ready.
2. Follow steps 1 and 2 for **'When your client is with you'**, but advise the operator your client is **NOT with you**.
3. Give the operator your client's name and telephone number.
4. Stay on line while the operator connects you to a trained interpreter (about 30 seconds).
5. Note the interpreter's ID code. Introduce yourself and brief the interpreter: explain the operator is phoning your client. Ask the interpreter to introduce you and themselves to your client and give the interpreter the first question or statement.
6. The operator introduces your client into the call. The interpreter proceeds as you directed above.
7. Give the interpreter time to interpret between you and your client.

   Continue the conversation.
8. Let your client and the interpreter know when you have finished.

Handling incoming client calls

If you have conferencing facilities

1. Put your client on hold using your organisation's conference call facilities (try to obtain your client's telephone number in case they hang up while on hold).
2. Follow steps 1 and 2 for **'When your client is with you'**, but advise the operator your client is **ON HOLD**.
3. Brief the interpreter, then conference your client into the call.

If you do not have conferencing facilities

1. Note your client's telephone number, language and, ideally, name.
2. Assure your client that you will call back shortly with an interpreter.
3. Follow the procedures for **'making outgoing client calls'**.

Useful Numbers

1. General enquiries, feedback and materials
   Tel: 0800 169 2879
   Fax: 0800 783 2443
   Email: enquiries@languageline.co.uk
   Website: www.languageline.co.uk
   Post: 25th Floor
   40 Bank Street, Canary Wharf,
   London, E14 5NR
2. Document Translations
   Tel: 0800 917 6564
   Fax: 0800 783 2443
   Email: translations@languageline.co.uk

12.5 Appendix 5 - Addendum to CL002 - Consent Policy v3.2

This addendum has been prepared to align the CL002 - Consent Policy v3.2 with the updated Care Quality Commission (CQC) guidance issued in May 2025 on Regulation 11: Need for Consent.

12.5.1 Summary of Alignment with CQC Regulation 11 (May 2025)

The CL002 - Consent Policy v3.2 demonstrates substantial compliance with the CQC's May 2025 guidance on Regulation 11. The following key areas of alignment have been identified:

1. Informed Consent - The policy provides comprehensive guidance on delivering informed consent, including the communication of material risks as per Montgomery v Lanarkshire.
2. Capacity Assessment - Section 6.2.1 outlines procedures for assessing capacity in accordance with the Mental Capacity Act 2005, including best interest decisions and IMCA involvement.
3. Voluntary Consent - The policy addresses the need for voluntary consent and the avoidance of coercion, particularly for patients with language or communication barriers.
4. Documentation - Section 7 and Appendix 2.4 provide detailed standards for documenting consent, including verbal, written, and non-verbal consent.
5. Training and Competency - The policy includes clear responsibilities for staff training and maintaining a register of authorised consenters.
6. Respect for Autonomy - The policy supports patients' rights to refuse treatment and change their minds, in line with CQC expectations.