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04			

1. Introduction and Overview

Consent is a fundamental, legal, and ethical principle for all patients and constitutes one of the Care Quality Commissions fundamental standards (CQC April 2024) Regulation 11.

All patients have the right to be involved in decisions about their treatment and care and to make informed decisions if they can. The exchange of information between the health care professional and patient is essential to good decision making and should therefore be sufficient and balanced to support this. Serious harm can result if patients are not listened to, or if they are not given the information they need - and time and support to understand it - so they can make informed decisions about their care.

Healthcare staff must be satisfied that they have a or other valid authority before providing treatment or care.

Healthcare staff are expected to keep up to date with the law and follow their professional bodies guidance and other regulations that are relevant to their work.

2. Purpose

The purpose of this policy is to provide all Newmedica healthcare professionals with guidance on best practice for patient shared decision making and consent to examination and treatment. This is under pinned by current ethical, legal, regulatory, and professional standards in England.

3. Scope

Newmedical Systems Limited (NMSL) and associated OJV partnerships are committed to being an organisation that embraces diversity, equity and inclusion and the policy applies to all 'staff' that work within the organisation regardless of employment status.

This Policy sets out the principles and procedures that Newmedica has adopted, and will work to, in order to ensure fair and effective arrangements for maintaining appropriate standards throughout. It will apply to all staff.

4. Definitions

Consent	A patient's agreement for a health professional to provide care. Patients may indicate consent non-verbally (for example by presenting their arm for their pulse to be taken), orally, or in writing.

Valid Consent	Valid consent requires three elements: 1. The person has been provided with appropriate information about the care and treatment and any potential options or choices in a format they can understand. 2. The decision is made without duress/undue influence. 3. The decision maker has capacity to make and communicate the decision at that time.
Informed Consent	To give valid consent, the person needs to understand the nature and purpose of the procedure and be competent to consent to it. Any misrepresentation of these elements will invalidate consent. The individual should be informed of any 'material' or 'significant' risks or unavoidable risks, even if small, in the proposed treatment; any alternatives to it; and the risks incurred by doing nothing.
Standard consent	Consent for the procedure is taken by the healthcare professional who is competent to perform the procedure.
Delegated Consent	Consent is taken by a healthcare professional who is not competent to perform the procedure but has been trained to take consent for this procedure.
Mental Capacity	The ability to use and understand information to a make a decision and communicate any decision made. A person who lacks capacity is unable to make a decision for themselves because of an impairment or disturbance in the functioning of their mind or brain. It does not matter if the impairment or

	disturbance is permanent or temporary.
Acquiesce	Agreement, compliance, or silence without objection.
Best Interest	An act done or decision made under the Mental Capacity Act for or on behalf of a person who lacks capacity must be done or made in his/her best interests.

5. Roles and Responsibilities

5.1. Board of Directors

They are responsible for the strategic overview of this policy.

5.2. Medical Director / Clinical Quality and Governance Director

They are responsible for providing executive clinical leadership ensuring that there is an up-to-date policy that meets both legal and best practice guidance and that professional conduct relating to consent is maintained. They will ensure that the appropriate systems are in place for reporting compliance with this policy. They will provide updates to the Board of Directors and the Medical Advisory Committee and the Clinical Governance Committee on any issues or risks related to compliance with the consent policy.

5.3. The Quality and Patient Safety Team

They are responsible for ensuring there are clear processes and procedures in place for staff to obtain guidance and clarity on consent.

They will maintain oversight of quality in the application of consent, including incidents, complaints, and audit compliance. They will agree the standard elements for the quarterly consent documentation audit and liaise with OJVs and Managed services about completion of these. During any service mock CQC service inspection they carry out a small sample of observational audit on consent processes. They will support OJV staff with developing and reviewing any patient information for consent, ensuring that it complies with legal and regulatory standards.

5.4. Learning and Development

They are responsible for ensuring that both consent training and assessment of competence are available to healthcare professionals involved with standard and/or delegated consent.

5.5. OJV / Managed Services Directors and Clinical Directors

Hold local responsibility to ensure that staff in their service follow the principles outlined in the consent policy. They will ensure that all registered health professionals responsible for patient consent within their OJV/ managed service have been appropriately trained and training records maintained. They will also oversee the assurance for competencies to be assessed, signed off and recorded.

They will be responsible for ensuring that annual consent audits are completed, and action is taken as indicated by the consent audit results and appropriate action plans developed and monitored for assurance.

In conjunction with clinical staff, clearly identify those procedures where written consent is required, or verbal consent is obtained explicitly documented in the clinical records. They should ensure that all health professionals performing procedures are aware of these requirements and where written consent is indicated, the forms that should be used. Forms must comply with recommended best practice.

5.6. All registered health professionals seeking consent

Clinical, legal, and professional responsibility for ensuring that valid consent has been obtained before treatment is provided rests with the health professional carrying out the procedure.

All Registered professionals have a responsibility to maintain up to date evidence-based care; this includes maintaining a working knowledge of their responsibilities in relation to the consent process. They are also responsible for meeting any training requirements.

In some circumstances this may be delegated by a health professional to a colleague, (see below 6.7, Who should consent).

Health professionals who have been delegated responsibility for consent must complete the relevant consent training and specialty/ procedure specific training and have evidence of their competency being assessed.

They are responsible for confirming that they are on their OJV/ Managed Service approved list to seek such consent.

They must ensure that the patient is genuinely consenting to what is being done.

Recognise and understand their personal responsibility in safeguarding people who use the services.

Discharge their duties in accordance with their role, level of expertise and the requirements of their professional body where applicable.

Ensure their approach to care is interdisciplinary, involving all those needed in the management of the patient.

The health professional carrying out the procedure retains ultimate responsibility for seeking consent. If another member of the team with the appropriate skills and knowledge seeks consent, the health professional carrying out the procedure must ensure that consent has been taken properly.

All staff have a duty to ensure they know how to use the MCA, 2005 and apply the principles of the Act in their own professional practice.

6. Policy Content

6.1. Key Principles Underpinning Consent

The General Medical Council and Royal College of Surgeons identify seven principles that should be considered regarding decision making and consent that can be applied by all health professionals seeking consent:

Principle 1	All patients have the right to be involved in decisions about their treatment and care and be supported to make informed decisions if they are able.
Principle 2	Decision making is an ongoing process focused on meaningful dialogue: the exchange of relevant information specific to the individual patient.
Principle 3	All patients have the right to be listened to, and to be given the information they need to make a decision and the time and support they need to understand what treatment or procedure (if any) they want.
Principle 4	Health Professionals must try to find out what matters to patients so they can share relevant information about the benefits, risks and harms of proposed options and reasonable alternatives, including the option to take no action. The discussion has to be tailored to the individual patient. This requires time to get to know the patient well enough to understand their views and values.
Principle 5	Health Professionals must start from the presumption that all adult patients have the capacity to make decisions about their treatment and care. A patient can only be judged to lack capacity to make a specific decision at a specific time, and only after assessment in line with legal requirements.

Principle 6	The choice of treatment or care for patients who lack capacity must be of overall benefit to them, and decisions should be made in consultation with those who are close to them or advocating for them.
Principle 7	Patients whose right to consent is affected by law should be supported to be involved in the decision-making process, and to exercise choice if possible.

6.2. When is it necessary to seek patient consent

Before any health professional examines, treats, or provides care for adult patients they must obtain their consent. The only exceptions to this are in emergencies where it is not possible to obtain consent, or when the law prescribes otherwise under mental health legislation.

Obtaining a patient's consent need not always be a formal, time-consuming process. A proportionate approach should be taken dependent on the specific circumstances of each decision. These include:

- The nature and severity of the patient's condition and how quickly the decision must be made.
- The complexity of the decision, the number of available options and the level of risk or degree of uncertainty associated with any of them.
- The impact of the potential outcome on the patient's individual circumstances.
- What you already know about the patient, and what they already know about their condition and the potential options for treating or managing it.
- The nature of the consultation.

Consent can be given in writing, verbally or even indicated non-verbally (for example by presenting an arm for a pulse to be taken). In all cases it is essential that an adequate record of the consent is maintained for future reference.

The context of consent can take many different forms, ranging from the active request by a patient for a particular treatment (which may or may not be appropriate or available) to the passive acceptance of advice from a healthcare professional. In some cases, the healthcare professional will suggest a particular form of treatment or investigation and after discussion the patient may agree to accept it. In others, there may be a number of ways of treating a condition, and the health professional will help the patient to decide between the available options.

Whilst it would be reasonable for health professionals to rely on a patient's non-verbal consent even for some routine, quick, minimally, or non-invasive interventions, they should still:

- Explain what is going to be done and why.
- Make clear the patient can say no and stop immediately if they do.
- Be alert for any sign that the patient may be confused or unhappy about what you are doing.
- Although a patient can give consent verbally (or non-verbally) this should be recorded in their notes.

6.3. What is valid consent

Proceeding with treatment without valid consent may put the patient at risk of harm. Obtaining valid consent should not be viewed as a "tick-box exercise" and reliance on generic consent forms without appropriate and documented discussions, potentially leaves the health professional who is carrying out the procedure and, where different, the health professional who sought consent, at risk of complaint and, potentially, legal, and/or professional regulatory sanctions.

For consent to be valid, the following four criteria must be met for the patient:

1. Capacity to make the decision.
2. Been offered sufficient information to make an informed decision.
3. Be acting voluntarily and free from undue pressure.
4. Be aware that they can refuse

6.3.1. Capacity to consent (Please refer POL-GOV 04 for Mental Capacity)

Under the Mental Capacity Act (2005), a person must be assumed to have capacity unless it is established that they lack capacity.

Patients should be treated as individuals, by all healthcare professionals and it must not be assumed that a patient lacks capacity to make a decision solely because of their age, physical frailty, disability, appearance, behaviour, medical condition (including mental illness), their beliefs, their apparent inability to communicate, or the fact that they make a decision which goes against professional advice.

Family members or carers do not have the legal authority to give consent on behalf of an adult patient with capacity unless they have been granted legal power of attorney.

Valid informed consent cannot be taken when the patient lacks the mental capacity for that decision at that time. The Mental Capacity Act (2005) provides a framework for the decision-making process and a lawful basis for acting where, because of a lack of capacity, there is no valid consent.

Capacity is time and decision specific. A person may have capacity for one decision but not for another or many decisions. All reasonable efforts to plan for changes in a patient's capacity to make decisions should be made to ensure that discussions about treatment are made at times and in situations where the patient is able to make decisions themselves or, where this is not possible, to maximally contribute to the decision process.

If there is any doubt about a patient's capacity, then the health professional should assess the capacity of the patient using the two-stage process set out in the POL-GOV 04 Policy for Mental Capacity - page 7.

Following a capacity assessment where a patient has been assessed as lacking capacity to give consent and if it is in the patient best interests to continue with treatment/ surgical procedure, providing the treatment has not been refused by a valid and applicable advance decision to refuse treatment (ADRT) or consent is refused by an attorney for health and welfare under a lasting power of attorney (LPA) or by a court appointed deputy for health and welfare, the assessment must be appropriately documented.

Consent Form 4 should be used to evidence the outcome of the assessment of capacity. Details should also be provided of the Best Interest decision taken by the health professional proposing the treatment in the patient's best interests. (See POL-GOV 04 Policy for Mental Capacity).

Details as to whether there is a valid and applicable ADRT, LPA or a court appointed deputy authorised to make the decision should also be recorded on the Consent Form 4 and where applicable signed by the appointed person.

Consent Form 4 should be signed and dated by the health professional seeking consent and where appropriate by anyone giving a second opinion.

6.3.2. Provision of Patient information for valid consent

The exchange of information between health professionals and patients is central to good decision making. During the consent process the patient centre discussion should focus on what is important to them and what information they will need before any decision is taken. It applies in whatever setting the interaction takes place.

The purpose of the dialogue is:

- To help the patient understand their role in the shared decision-making process, and their right to choose whether or not to have treatment or care.
- To make sure the patient has the opportunity to consider relevant information that might influence their choice between the available options.
- To try and reach a shared understanding of the expectations and limitations of the available options.

It is important that the person seeking consent is satisfied that the information they have given and that any decision the patient makes will be made independently and from an informed position. Any decisions involved choosing tests and treatments should be based both on current evidenced based guidance and on the person's individual preferences, beliefs, and values. It means making sure the person understands the risks, benefits, and consequences of different options through discussion and information sharing. This joint process empowers people to make decisions about the care that is right for them at that time (with the options of choosing to have no treatment or not changing what they are currently doing always included).

The provision of written information is not in itself sufficient to ensure that the patient is able to make an informed decision. For example, the use of a pre-printed proforma outlining risks of a specific procedure, is not sufficiently, tailored to the individual patient. The healthcare professional consenting must be satisfied that the patient has understood the information received and can decide what decision to make.
As much of the consent process as possible should begin at the first consultation where a procedure is being considered and not on the day of surgery, to ensure that the patient has been given sufficient time between initial preoperative appointment and date for surgery or treatment to digest and consider the information that they have been given and ask any further questions. Consent is a continuous process rather than a one-off decision. It is important that patients are given continuing opportunities to ask further questions and to review decisions about their health care.

Patients in ophthalmology clinics may have greater requirements for support given the mainly older adults who are being treated and in particular many with poor vision. For consent to fulfil the law on accessibility standards, every effort must be made to ensure patients with disabilities including sensory loss must be asked and provided with information and communication materials in a format of the patient's choice such as audio, braille, easy read, or large print. The health professional should ensure within the consultation that all patients understand and can access the information required and read any written information provided, such as patient leaflets, decision aids, educational videos, and reliable websites such as patient charities. These information sources should ideally be recorded on the consent form and/or clinical notes. All Newmedica patients should receive a copy of the yellow patient information booklet in advance of any planned surgery.

Newmedica recognises that the diverse needs of different communities must be respected and met to ensure fair delivery of services to all. This includes the right of service users who experience language difficulties or literacy levels to have equal access to health services and to positive health outcomes. (Please *refer to Language Interpretation and translation policy POL-GOV 06)*, an interpreter must be used to ensure that the patient has the capacity to understand the full procedure planned. Details of the interpreter or service used must be documented on the consent form.

Newmedica is committed to ensuring that patients whose first language is not English receive the information they need and are able to communicate appropriately with healthcare staff. Except in time-critical circumstances it is not appropriate to use children, family members or relatives to interpret for family members who do not speak English. Newmedica has a contract for interpreting and translation services Details of the interpreter or service used must be documented on the consent form. The consent form should be signed as evidence that the discussion has taken place, it is acceptable to keep the signed copy in the notes. A copy of the consent form should be provided to the patient in advance of the day of surgery. The health professional should record in the notes that a copy of the form including any edits or changes for that patient made to the standard form and that the information was provided to the patient. For ophthalmology patients, particular care is needed around being able to review their consent form when vision is reduced by mydriasis following dilating drops so that they can be reviewed and thought about once dilating drops have worn off. This can also be aided by ensuring patients fully understand what is on the form in advance of the day of surgery.

Patients should also be given a way of contacting after consenting to have further questions answered and most consent forms have a space for this. It needs to be completed with a contact that will be accessible and reply.

6.3.3. Is consent given freely

Pressure to agree to a particular treatment can be intentionally or unintentionally applied by family, friends, or healthcare professionals. Health Professionals should be alert to this possibility, and where appropriate, arrange to review the patient on their own to establish that the decision is autonomous. If you suspect a patient's rights have been abused or denied, you must follow local safeguarding procedures see POL-GOV 08 Policy for Safeguarding Adults and consider raising a concern.

6.3.4. Withdrawing Consent

A patient is free and able to change their mind or withdraw their consent at any time. Patients may change their mind over time; it is for the healthcare professional to ensure that consent is still valid at the time of the intended procedure.

6.4. Material Risks

All reasonable treatment options (including alternatives and conservative management) and their implications should be explained.

This includes material risks tailored to the patient such as potential loss of eyesight and their specific needs discussed at the time and documented on the space provided on the consent form/OpenEyes.
Test of materiality is two-fold:

1. Whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk.

2. The doctor is or should reasonably be aware that the particular patient would likely attach significance to it.

6.5. Explaining the associated risks

These should be described in a manner that the patient understands and not simply as a list of terms or statistics. Patients like to understand which risks are likely to be temporary and which potentially permanent problems such as loss of sight and find giving a likelihood (e.g. up to 1 in 10, up to 1 in 100 etc) helpful. They prefer risks to be explained in clear lay terms avoiding medical jargon. The clinician should aim to support the patient in understanding how such risks could impact them as an individual and their approach to risk. Patients should be directed to read the yellow patient information booklet for all the risks/benefits.

Procedure specific prepopulated consent forms for common procedures can be helpful to ensure clear and comprehensive statement of risks and as an aide memoire for consenters to ensure they cover key points. However, they must allow for editing for individual patient circumstances, their personal and material risks, and questions.

The teach back method is a useful way to confirm that the information provided is being understood, by getting people to 'teach back' what has been discussed and what instruction has been given. This is more than saying 'do you understand?' and is a check of how well things have been explained and understood.

6.6. Other patient information about the procedure.

Patients may also wish to know the likely practicalities of the procedure, such as lens options and choices for cataract surgery, how long they will be on any waiting list, any preoperative assessments or actions required, and what the day itself and having the procedure will involve for them. They also need to understand what to expect after the operation and crucially any significant commitment to postoperative care for them such as frequent postop attendances after glaucoma drainage surgery or posturing after retinal surgery.

6.7. Cooling Off Period Time for Deliberation

Where relevant, surgeons should allow sufficient time for patients to deliberate on available options and to consider their goals and wishes in terms of their treatment. This may include reading further information or accessing online resources to provide them with more information on their condition and treatment options. There are no national timelines specified. The length of time, and amount of information needed will vary from patient to patient, and from procedure to procedure. It is important that the patient does not feel rushed into making a commitment and that they know they can change their mind at any time.

6.8. Who can seek consent

It is more likely that written consent is required for more complex procedures and treatments such as operations and invasive procedures. It usually requires a more structured approach, and consent might not be concluded in one consultation/visit.

Only health professionals who have undertaken the relevant consent training and specialty/ procedure specific training and have evidence of competency can seek such consent.

But unlike seeking verbal or non-verbal consent or consent by acquiescence, it is not always the health professional actually carrying out the intervention who will seek written consent for it from the patient.

Decision Making and Consent Principles

There are two mechanisms for taking valid informed consent:

Standard Consent - Consent for the procedure is taken by the healthcare professional who is competent to perform the procedure.

Delegated Consent - Consent is taken by a healthcare professional who is not competent to perform the procedure but has been trained to take consent for this procedure.

- Consent is given by patients, not taken by clinicians. Patients must be made aware that it's their choice whether or not to have treatment and that they can change their mind at any time. **Consent should start with shared decision making.**
- **Share:** Relevant information specific to the individual patient about the available options, including doing nothing, this should start at the time of diagnosis either in primary or secondary care.
- **Find out what matters to the patient:** So you can identify and share information that might influence their choice between available options.
- **Include risk assessment:** Discuss potential benefits, risks of harm, uncertainties about and likelihood of success for each option including the option to take no option. Including the impact of related co morbidities as well as what the patient could do to minimise the risk before the procedure.
- **Support the patient:** To understand and retain the information and to use it to make a decision. Check the patient understands the information they have been given. Try to reach a shared understanding of the expectations and limitations of the available options.
- **An ongoing process**: information exchange can take place over several appointments with different professionals. It should be tracked so that the person carrying out the procedure can be confident that the patient has had opportunity to consider all relevant information, has made an informed decision and is giving their informed consent.
- **No foregone conclusions:** You might usually recommend a particular option for someone in the patient's clinical position, but your discussion with the patient

could reveal wishes, fears, values or priorities that mean another option is preferable to them. When recommending an option explain your reasons, so you can unearth any incorrect assumptions.

- **Period of reflection:** Patients should be given the information they need as early as possible in the process, so that they have time to consider it and make an informed decision. There should be a period of reflection ('cooling off') purposefully built into the decision making and consent process. This could be between the provision of options (shared decision making) for minor procedures and between first and second stage consent for major procedures.
- **No surprises:** If new information is presented to the patient at a late stage (e.g. on the day of surgery) and this information tips the balance in favour of another option (including the option to do nothing) it must be made clear to the patient that they are free to change their mind.

Enablers:

1. All clinicians involved in the decision making and consent process should be skilled in shared decision making.
2. All clinicians involved in the decision making and consent process should be aware of the challenges patients can face in understanding health information and be skilled in health literate communication techniques.
3. Resources to support patients in making decisions should be provided to patients throughout the process and as early as possible. This should include decisions support tools where available.
4. All stages of the decision making, and consent process should be documented in such a way that allows other professionals to build on and complement what has already been discussed.
5. Written communications (e.g. clinic letters) should where possible include individualised risks and benefits and factors involved in the decisions to support deliberation in the 'cooling off' period.

Checklist:

1. Have all reasonable options been provided to the patient?
2. Is there documentation of a rationale for choosing a particular option based on what is important to the patient/ patient specific concerns?
3. Has a decisions support tool been used (where available)?
4. Is there evidence of a clearly delineated consent conversation once a decision has been reached?
5. Is there evidence of a period of reflection and a mechanism to answer patient queries during this time?
6. Was there a process of checking whether the patient has changed their mind (re- confirming the decision to proceed or withdrawing consent) after peri-operative risk assessment (where undertaken)?

The health professional carrying out the procedure is ultimately responsible for ensuring that the patient provides valid consent to what is being done; it is they who will be held responsible in law if this is challenged later.

Where oral or non-verbal consent is being sought shortly before the procedure will be carried out, this will naturally be done by the health care professional responsible.

Standard Consent.

In general, specialist trainees and surgeons are deemed capable of performing surgical procedures and therefore competent to seek patients' consent for those procedures.

For other non-surgical treatment provided by Newmedica it will be the registered professional who has the capability and competency who will be responsible for seeking consent.

Procedure for delegated consent.
GMC guidance states that the task of seeking consent may be delegated to another person, if they are suitably trained and qualified and competent to do so, that they have sufficient knowledge of the intervention and its associated harms and benefits. The guidance also states the individual should have the skills to have a dialogue with the patient in line with the guidance and that they will refer to the surgeon (or another appropriate colleague) for further information, advice, or support if necessary. The NMC, HCPC and College of Optometrist also have professional guidance which each health professional should refer to.

Teamwork is recognised as a crucial part of the way the Newmedica operates. Where written consent is being sought it may be appropriate for other members of the clinical team, who may not be competent or scheduled to complete the procedure to participate in the process of seeking consent, as long as they are in a position to provide all appropriate advice to the patient and answer any questions they may have about the procedure.

Notwithstanding the procedure of delegated consent, it remains the responsibility of the person undertaking the procedure/ treatment to ensure that the patient has given valid consent and that someone capable of performing the procedure has confirmed consent by the patient prior to the procedure / treatment.

For consent to be delegated appropriately there must be:

- Approved sources of patient information.
- Training/clinical guidance for each identified procedure.
- Assessment of a health professionals' competency to take consent.

General Exclusions

Consent taking must never be delegated when it is determined that the patient lacks the mental capacity to consent to the particular procedure / treatment. (Refer to POL-GOV-04 Policy for Mental Capacity).

Only agreed procedures, with approved patient information and training can be delegated.

Delegated consent must not proceed if the patient has expressed concerns regarding giving consent to the delegated health professional.

Delegated consent must not proceed if the consent taker has any queries regarding the appropriateness of the procedure for the patient. Where there are queries the consent taker must raise these with the referring clinician, the healthcare professional competent to undertake the procedure or the OJV Director.

STEP 1: Initial consultation/consent discussion with a healthcare professional

When the decision is made to refer a patient for treatment or investigation where delegated consent is taken, a trained delegated consent health professional will discuss the procedure and take consent in accordance with this policy for Consent.

Approved patient information leaflets for the procedure should be used to support the discussion.

Where the initial consultation is virtual the discussion with the patient in regard to the procedure, including potential harms, benefits of any treatment and any specific concerns the patient raises should be documented in the patient's clinical record and the patient's consent should then be undertaken on the day of surgery.

If the patient does not feel that they are able to make an informed decision on their treatment, based on the discussion with the trained health professional, they must be referred to a health professional that is competent to perform the procedure.

The patient must be advised that it is their legal right to make an informed decision.

Alternatively, the patient may have their initial discussion with a member of staff that is competent to carry out the procedure and step 2 below is carried out by a trained delegated consent healthcare professional.

STEP 2: Re-confirmation of consent

Consent must be re-confirmed by the healthcare professional undertaking the procedure prior to commencing treatment.

If a registered health professional takes consent for a procedure, they are not competent to perform and have not been formally assessed as being competent to take delegated consent for, an incident form must be completed, and the incident investigated.

Health care professionals who feel pressurised or asked inappropriately to seek consent should in the first instance speak to their line manager or OJV Director.

Further advice and support can be obtained from:

- The Quality and Patient Safety team.
- The Head of Clinical Quality and Patient Safety Statutory- Named Lead for Adult Safeguarding.
- The Medical Director or Director of Clinical Quality and Governance.

6.9. Consent forms

Where written consent is required, i.e. patients aged 18 or over with **capacity,** the Newmedica approved consent form should be used.

Where a consent form 4 is required, i.e. Patients aged 18 or over **without capacity** to consent to care and or treatment should be used.

6.10. Consent for repeated treatments/procedures

Where patients are having a course of repeated treatments such as intravitreal injections, or having sequential cataract surgery- where this has been agreed with the OJVs local ICBs as acceptable practice, a single consent form can be used for repeated interventions as long as:

- The patient is aware they are agreeing to a course of treatments or sequential cataract surgery.
- Confirmation of consent is obtained prior to subsequently repeated interventions.
- The consent is retaken if the material risks change in any way due to changes in ocular or patient status.

6.11. What should be recorded in a patient's medical records?

Details of the discussions that have taken place with a patient, and any other relevant people, should be recorded in the patient's clinical record. This should usually include discussions about the treatment options, including potential harms and benefits of any treatment, any specific concerns the patient had and any other information that was given to them.

6.12. Making changes to the original consent form

After initial consent, if the patient has questions around initial risks or an item already discussed, the original consent form can be edited to highlight the concerns that have been discussed. These edits must be made at the time of the discussion In terms of an audit trail, at the moment there is limited information on Openeyes on specific edits, the system does record changes have taken place, although just the date and time stamp is visible. Version 10 of Openeyes will provide details these edits. All edits must be made at the time of discussion not at a later date.

6.13. New treatment plan / new risks discussed not included on the original consent form

If a new treatment plan is agreed with the patient following a discussion or if a new risk is discussed that is not on the original form, then a new consent form must be produced.

6.6. How long is consent valid for?

Patients can change their mind about treatment at any time. Before beginning any treatment, doctors and health professionals should check that the patient still consents.

This is particularly important if:

- A significant length of time has passed since the patient agreed to the treatment.
- There is new information available.
- There have been any significant changes to the patient's condition.

6.7. Consent on the day of a procedure

The Royal College of Ophthalmologist do not advocate consent being obtained on the day of an elective procedure, UKOA Consent for Ophthalmology Procedures (2020) Consent begins at the first consultation where a procedure is being considered or an option, and may occur in phases and over time, aiming to give the patient any information they need to make an informed decision about what treatment or procedure (if any) they want.

However, it is recognised there are some mitigating circumstances, and consent may be signed on the day of the procedure as part of an ongoing consent process that started with initial discussion and sharing of the patient information booklet beforehand.

Patients who have been identified as requiring a procedure for both eyes may be consented for both procedures during their initial preoperative appointment. Consent should always be confirmed on the day of the procedure to ensure the appropriate consent form is being used.

Same Day Surgery
In very rare circumstances, a patient may be seen and consented on the day of surgery, this type of consenting is not routine and is based on the clinical need of the patient (i.e. a patient with a life limiting illnesses), whereby coming back for surgery may increase the burden on the patient and their family/carers. If patients are seen and consented on the same day, in this type of scenario, the clinical justification for consenting on the same day, must be recorded in the clinical records.

Second Eye Surgery where consent wasn't obtained during the first eye consent process
Where a patient has undergone first eye surgery within a Newmedica service without complication and deemed to have had a good outcome it is acceptable for the patient to be consented on the day of surgery.

6.8. Confirmation of consent on day of surgery

If the consent has been obtained and signed before the day of an elective procedure, consent should be reconfirmed on the day of surgery by the surgeon carrying out the procedure/treatment and recorded on the consent form.

6.9. Consent for teaching purposes

All health professionals should seek a patient's consent for any health care students or other observers to be present during a consultation or treatment.

Patients should feel able to say no, knowing that it will not impact on their treatment in any way.

Wherever possible, patients should be given the option of considering the request before the arrival of the observers.

It is necessary to seek consent from patients for the use of visual and audio recordings of procedures, for teaching purposes. Health professionals must obtain consent from the patient prior to a recording being made and for its subsequent use for teaching purposes. Patients may withdraw their consent to the use of visual and audio recordings for teaching purposes at any time. If they do so, the recordings must be erased.

6.10. Doctors in Training Taking Consent

Newmedica are supporting the Royal College of Ophthalmologists (RCO), NHS England & Health Education England's ambition to train junior ophthalmologists to be proficient at undertaking Cataract surgery as set out in the RCO document Blueprint for Cataract training in the independent sector guidance for providers and trainees (2022).

For the purpose of consent taking the patient must be fully informed that a junior doctor may undertake their surgery under supervision.

Foundation trainees (F1 and F2) taking consent must:

- Have attended a course or session on consent, either undergraduate course or session within induction.
- Have been provided with training and guidance and have been observed on at least three occasions while taking consent for non-invasive procedures and have been deemed as competent by their trainer. A work-based assessment tool such as DOPS may evidence this process.
- Not take consent for an invasive procedure unless observed and trained by the doctor responsible for undertaking the procedure.

Foundation Year 1 (F1) Trainees

- F1 doctors should only take consent as part of a structured training opportunity. F1 doctors should not take consent for any invasive procedure without direct supervision.

Foundation Year 2 (F2) Trainees

- F2 doctors must understand the proposed intervention, its risks, and is prepared to answer associated questions the patient or carer may ask. If the foundation doctor is unable to do this, they should have access to a supervisor with the required knowledge.

Core and Specialty trainees:

Generic Standards for Specialty including GP training (GMC, 2010)

"Before seeking consent both trainee and supervisor must be satisfied that the trainee understands the proposed intervention and its risks and is prepared to answer associated questions the patient may ask. If they are unable to do so they should have access to a supervisor with the required knowledge. Trainees must act in accordance with the GMC's guidance Consent: patients and doctors making decisions together (2008)."

Core and Specialty trainees must:

i) be encouraged to be involved with the consenting process; and ii) have been formally delegated with the responsibility of taking consent by the senior operator for the procedure; and

iii) have demonstrated competence to take consent by having completed the tasks and experience set out above in points i, ii and iii for Foundation trainees, and be familiar with the operative procedure and its potential complications.

Correct site surgery (CSS):

CSS refers to operating on the correct side of the patient and/or the correct anatomical location or level (such as the correct finger on the correct hand).

The marking of an operating site should only be done by an operating surgeon who is deemed competent in the consent process for that particular operation. This may include a trainee surgeon providing they are guaranteed to be an active part of the operating team. Ideally, however this should be done by the most senior surgeon involved in the operation.

6.11.Consent for research

The same legal principles apply when seeking consent for research. The health professionals must ensure that patients asked to consider taking part in research are given clear information, presented in a way they can understand. Patients should be made aware that they are being asked to take part in a research project and that the results are not predictable. Adequate time must be given for reflection prior to the

patient giving consent. Where patients do not wish to receive full information about the research, this may affect the doctor's decision to involve them.

Information should preferably be provided in writing and should be approved in advance by a research ethics committee. It should include:

- The purpose of the research and what it involves.
- Information about research-related procedures particularly invasive procedures.
- The probability of random allocation to treatment, if appropriate.

The fact that patients can withdraw from the research at any time, without penalty or any adverse effect on the care they receive (but that once data or samples have been anonymised, it will no longer be possible to withdraw consent for their use).

Any financial arrangements in place, such as for covering patients' expenses and compensation in the event of trial-related injury.

Information about confidentiality and the possibility of access to confidential notes by third parties (such as regulatory authorities, auditors, or ethics committees).

What, if any, information they can expect to receive about the research findings and conclusions.

7. Training and Competency Assessments

All healthcare professionals must understand the core principles of consent. Healthcare professionals who are required to obtain consent must receive appropriate generic and specific training. Training content will include updates to the consent policy, relevant legal framework, and guidance. Specific training must cover the relevant scope of practice.

Training for mental capacity is included in mandatory training for all clinical staff (See MCA Policy).

Assessment for obtaining consent by healthcare professionals who are not capable of performing the clinical procedure or where obtaining consent is delegated.

Healthcare professionals where consent is delegated to them must be assessed against the specific procedure in order to be able to take consent from patients. Along with reference to this policy, assessment of competency in the procedure will be completed and signed for each procedure the healthcare professional has been trained to take delegated consent for. A copy of this will be held of the health professional's file.

8. Communication and Implementation

The policy will be published in the document library of policies on the Newmedica Vision intranet page and information disseminated to all Newmedica staff via communication channels.

9. Monitoring Compliance

How implementation and ongoing compliance is to be monitored, including standards and key indicators.

Aspects of compliance or effectiveness being monitored	Monitoring Method	Responsibility for Monitoring	Frequency of Monitoring	Group/Committee to review findings and monitor completion of action plan
Compliance with the consent policy	Audit of consent	OJVs Clinical Directors and clinical leads	Annual	OJV Governance Meetings Clinical Governance Committee
Breaches to consent policy	Incidents /Investigations	OJV Clinical Directors Divisional Governance Business Partners	Quarterly reporting	OJV Governance Meetings Clinical Governance Committee
Breaches to consent policy	Patient Complaints	OJV Clinical Directors Divisional Governance Business Partners	Quarterly reporting	OJV Governance Meetings Clinical Governance Committee
Compliance and competency assessment for delegated consent	Training and competency records	OJV Clinical Directors Divisional Governance Business Partners	Quarterly reporting	OJV Governance Meetings People Committee
Gaps in assurance	Risk register	OJV Clinical Leads	Monthly reporting	Medical Advisory Committee

10. Resources and References

Regulation and Guidance

- GMC Good Medical Practice. GMC, 2013.
- GMC Consent: Patients and Doctors Making Decisions Together 2008.
- GMC Confidentiality 2009.
- GMC Decision making and consent - ethical guidance - GMC (gmc-uk.org).

- GMC Guidance for Doctors decision making and consent 2020.
- GMC Good Medical Practice 2024.
- Royal College of Surgeons Good Surgical Practice 2019.
- Royal College of Ophthalmologist and UK Ophthalmology 2020: Standards of consent
- Reference guide to consent for examination or treatment (second edition) - GOV.UK (www.gov.uk).
- NMC The Code: Professional standards of practice and behaviour for nurses, midwives and nursing associates.
- Standards of conduct, performance and ethics | (hcpc-uk.org).
- NICE Guidance 197 Shared decision Making.
- Teach Back – The Health Literacy Place.

Legislation

- The Mental Capacity Act 2005 (England and Wales).
- Accessible Information Standard 2017. https://www.england.nhs.uk/ourwork/patients/accessibleinfo-2/
- CQC regulations Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 11.

Case Law

- Montgomery (Appellant) v Lanarkshire Health Board (Respondent) [2015] UKSC 11.
- Chester v Afshar [2004] UKHL 41 – The duty to warn patients about risk.
- Rogers v Whitaker (1992) 175 CLR 479 HC (Aus): This was an Australian ophthalmology case in which the patient developed sympathetic ophthalmitis (after the other eye was removed). The risk was estimated at 1 in 14,000. The patient was not informed. The court held that 'a risk is material if: a reasonable person... if warned of the risk would be likely to attach significance to it.'

Policies

- Mental Capacity Act Policy: POL-GOV 04.
- Supporting Patients with Dementia: POL-GOV 03.
- Patient Information and Translation: POL-GOV 06.
- Accessible Information: POL-GOV 12.
- Record Keeping; POL-GOV 18.
- Information Sharing: POL-IG -06.
- Records Management: POL-IG-09.
- Non-Medical Practitioner administering Yag Laser and intravitreal injections POL- CLI 20 &22
- *Consent for Cataract Surgery Underpinning Knowledge:* Consent for cataract surgery - underpinning knowledge.pdf (sharepoint.com).

11. Equality Impact Assessment

		Yes/No	Comments
1.	Does the policy/guidance affect one group less or more favourably than another on the basis of:	No	
a	Gender.	No	
b	Marital Status (including Civil Partnership),	No	
c	Gender Reassignment,	No	
d	Disability including Learning Disabilities, Physical Disabilities, Sensory Impairment, Mental Health Problems,	No	
e	Race, Nationality or Culture,	No	
f	Age,	No	
g	Sexual Orientation (including Lesbian Gay or Bisexual People),	No	
h	Religion or Belief,	No	
i	Trade Union Membership,	No	
j	Pregnancy or Maternity,	No	
2.	Is there any evidence that some groups are affected differently?	No	
3.	If you have identified potential discrimination, are any exceptions valid, legal, and/or justifiable?	N/A	
4.	Is the impact of the policy/guidance likely to be negative?	N/A	
5.	If so, can the impact be avoided?	N/A	
6.	What alternatives are there to achieving the policy/guidance without the impact?	N/A	
7.	Can we reduce the impact by taking different action?	N/A	

Appendix 1 Consent Form 4

Consent Form 4

Form for adults who are unable to consent to investigation or treatment

Patient details (or pre-printed label)

Patient's surname/family name.....

Patient's first names .....

Date of birth .....

Responsible health professional.....

Job title .....

D Male D Female

Special requirements .....

(eg other language/other communication method)

To be retained in patient's notes

Affix patient identifier/label

All sections to be completed by health professional proposing the procedure

A Details of procedure or course of treatment proposed

(NB see guidance to health professionals overleaf for details of situations where court approval must first be sought)

B Assessment of patient's capacity

I confirm that the patient lacks capacity to give or withhold consent to this procedure or course of treatment because:

☐ the patient is unable to comprehend and retain information material to the decision; and/or

☐ the patient is unable to use and weigh this information in the decision-making process; or

☐ the patient is unconscious

Further details (excluding where patient unconscious): for example, how above judgements reached; which colleagues consulted; what attempts made to assist the patient make his or her own decision and why these were not successful.

C Assessment of patient's best interests

To the best of my knowledge, the patient has not refused this procedure in a valid advance directive. Where possible and appropriate, I have consulted with colleagues and those close to the patient, and I believe the procedure to be in the patient's best interests because:

(Where incapacity is likely to be temporary, for example if patient unconscious, or where patient has fluctuating capacity)

The treatment cannot wait until the patient recovers capacity because:

D Involvement of the patient's family and others close to the patient

The final responsibility for determining whether a procedure is in an incapacitated patient's best interests lies with the health professional performing the procedure. However, it is good practice to consult with those close to the patient (eg spouse/partner, family and friends, carer, supporter or advocate) unless you have good reason to believe that the patient would not have wished particular individuals to be consulted, or unless the urgency of their situation prevents this. "Best interests" go far wider than "best medical interests" and include factors such as the patient's wishes and beliefs when competent, their current wishes, their general well-being and their spiritual and religious welfare.

(to be signed by a person or persons close to the patient, if they wish)

I/We have been involved in a discussion with the relevant health professionals over the treatment of

…… (patient's name).

I/We understand that he/she is unable to give his/her own consent, based on the criteria set out in this form.

I/We also understand that treatment can lawfully be provided if it is in his/her best interests to receive it.

Any other comments please list here (including any concerns about decision)

Name ……Relationship to patient……

Address (if not the same as patient……

……..

……..

Signature ……. Date…….

If a person close to the patient was not available in person, has this matter been discussed in any other way (eg over the telephone?)

□ Yes □ No

Details:

Signature of health professional proposing treatment

The above procedure is, in my clinical judgement, in the best interests of the patient, who lacks capacity to consent for himself or herself.

Where possible and appropriate I have discussed the patient's condition with those close to him or her and taken their knowledge of the patient's views and beliefs into account in determining his or her best interests.

I have/have not sought a second opinion.

Signature:…… Date ..
…… Name (PRINT) ……. …… Job title ……..
……

Where second opinion sought, s/he should sign below to confirm agreement:

Signature:…… Date ...
…… Name (PRINT) ……. …… Job title …….
……

Guidance to health professionals

This form should only be used where it would be usual to seek written consent but an adult patient (18 or over) lacks capacity to give or withhold consent to treatment. If an adult **has** capacity to accept or refuse treatment, you should use the standard consent form and respect any refusal. Where treatment is very urgent (for example if the patient is critically ill), it may not be feasible to fill in a form at the time, but you should document your clinical decisions appropriately afterwards. If treatment is being provided under the authority of Part IV of the *Mental Health Act 1983*, different legal provisions apply, and you are required to fill in more specialised forms (although in some circumstances you may find it helpful to use this form as well). If the adult now lacks capacity but has clearly refused particular treatment in advance of their loss of capacity (for example in an advance directive or 'living will'), then you must abide by that refusal if it was validly made and is applicable to the circumstances. For further information on the law on consent, see the Department of Health's *Reference guide to consent for examination or treatment* (www.doh.gov.uk/consent).

When treatment can be given to a patient who is unable to consent

For treatment to be given to a patient who is unable to consent, the following **mus**t apply:

- the patient must lack the capacity ('competence') to give or withhold consent to this procedure AND
- the procedure must be in the patient's best interests.

Capacity

A patient will lack capacity to consent to a particular intervention if he or she is:

- unable to comprehend and retain information material to the decision, especially as to the consequences of having, or not having, the intervention in question; and/or
- unable to use and weigh this information in the decision-making process.

Before making a judgement that a patient lacks capacity you must take all steps reasonable in the circumstances to assist the patient in taking their own decisions (this will clearly not apply if the patient is unconscious). This may involve explaining what is involved in very simple language, using pictures and

communication and decision-aids as appropriate. People close to the patient (spouse/partner, family, friends and carers) may often be able to help, as may specialist colleagues such as speech and language therapists or learning disability teams, and independent advocates or supporters.
Capacity is 'decision-specific': a patient may lack capacity to take a particular complex decision but be quite able to take other more straight-forward decisions or parts of decisions.

Best interests

A patient's best interests are not limited to their best medical interests. Other factors which form part of the best interests decision include:

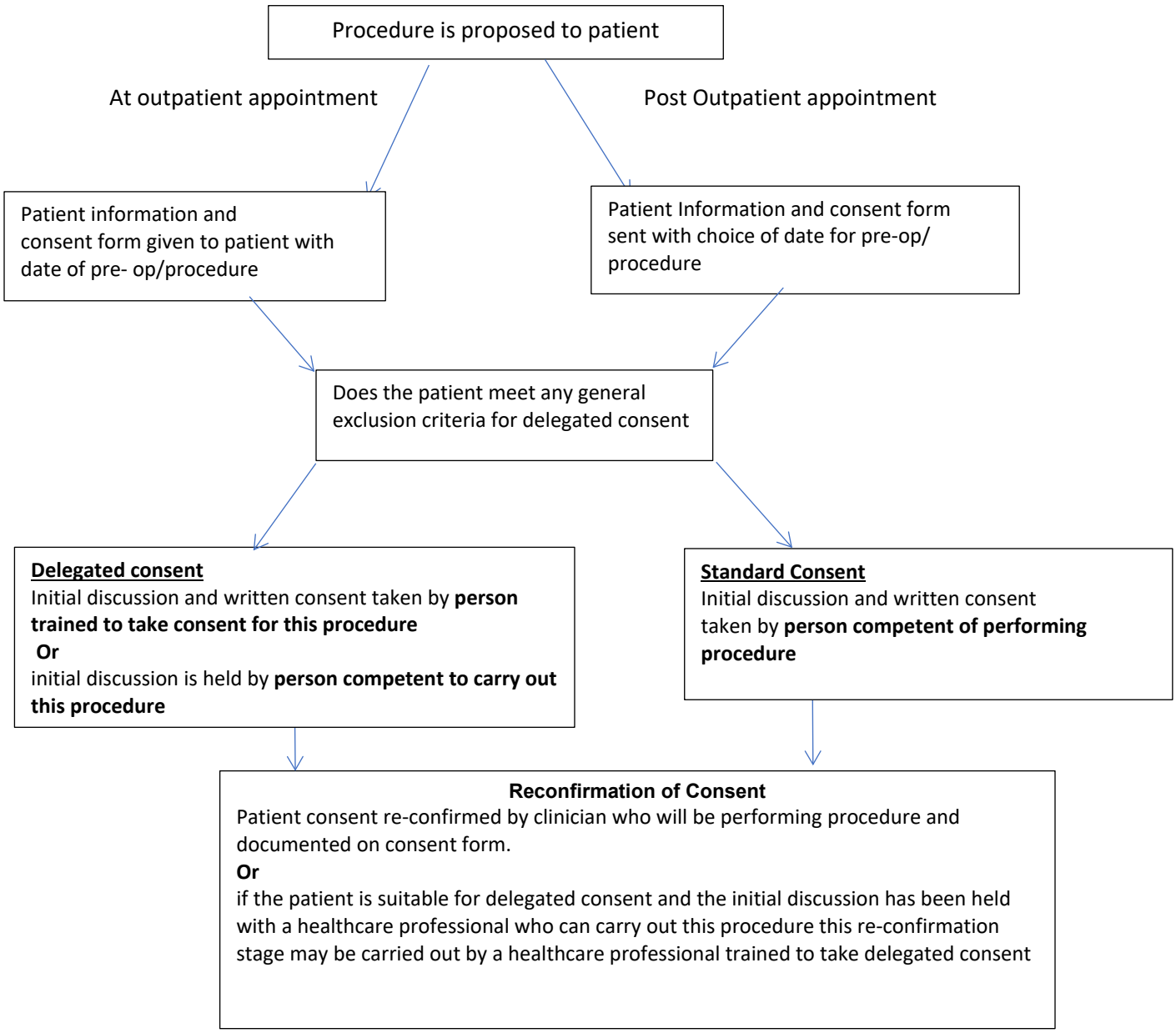
- the wishes and beliefs of the patient when competent
- their current wishes
- their general well-being
- their spiritual and religious welfare

Two incapacitated patients, whose *physical* condition is identical, may therefore have different best interests. Unless the patient has clearly indicated that particular individuals should not be involved in their care, or unless the urgency of their situation prevents it, you should attempt to involve people close to the patient (spouse/partner, family and friends, carer, supporter or advocate) in the decision-making process. Those close to the patient cannot require you to provide particular treatment which you do not believe to be clinically appropriate. However, they will know the patient much better than you do, and therefore are likely to be able to provide valuable information about the patient's wishes and values.

Second opinions and court involvement

Where treatment is complex and/or people close to the patient express doubts about the proposed treatment, a second opinion should be sought, unless the urgency of the patient's condition prevents this. Donation of regenerative tissue such as bone marrow, sterilisation for contraceptive purposes and withdrawal of artificial nutrition or hydration from a patient in PVS must never be undertaken without prior Hight Court approval. High Court approval can also be sought where there are doubts about the patient's capacity or best interest.

Appendix 2 Delegated Consent Procedure Flowchart



Appendix 3 – Consent and Capacity

CONSENT AND CAPACITY. FUNDAMENTAL PRINCIPALS TO CONSENT

Staff must be trained and competent regarding consent and mental capacity prior to gaining consent (verbal, non-verbal or written) for undertaking an examination, treatment or care for a patient.

Provide information about the examination, treatment or care that is proposed

Document the information provided and any special measures taken to provide information

Do you have reason to believe that the patient has not:
- Understood some or all of the information you gave them? OR
- Retained the information for long enough to make a decision? OR
- Weighed up the risks/ benefits of having/not having the care or treatment or the various alternatives? OR
- Been able to communicate the outcome of their decision-making by any means?

Yes

Document that in your opinion the patient does not have the mental capacity to make the decision regarding the particular examination, care or treatment that is proposed, as they are unable to: understand/ retain/ weigh-up/ communicate. This should be documented on the Part A&B forms – "Mental Capacity Two Stage Test" MCA Policy

Ascertain if there is any evidence of a Court of Protection appointed Deputy or a Lasting Power of Attorney for Health and Welfare with the authority to consent/refuse on behalf of the patient for the care or treatment proposed. If so, they will be the decision-maker

Ascertain if there is any evidence of a valid and applicable Advance Decision to Refuse Treatment which relates to the care or treatment proposed. If so, the care or treatment cannot be undertaken, and alternatives should be

Use / consider the information in – "Best Interests Checklist" MCA Policy to establish what you believe would be in the patient's best interests (medically, emotionally, socially and psychologically) to help plan the patient's treatment/ procedure, referring to an IMCA for an independent opinion where the patient has no appropriate family to consult and it is a residence or serious medical treatment decision.

Document the process of determining best interests either using "Best Interests Checklist" or documenting in the clinical notes and proceed with examination, treatment or procedure where you believe this to be in the patient's best interests.

No

Ask the patient if they are happy to proceed with the examination, treatment, or procedure that is proposed.

Yes

The valid, informed consent (verbal, non-verbal or written) that a patient provides is sufficient lawful authority for proceeding with the examination, care or treatment. NB: For consent to be valid it must also not be given under duress. If you have concerns about this consider

Document that consent obtained

Proceed with examination, treatment or procedure

No

Where a patient refuses examination, care or treatment this must be respected unless certain provisions of the Mental Health Act apply

Document that patient refused and offer appropriate alternatives.

Document care given and any associated observations or anomalies.

Appendix 4: Amending Consent