Queen Victoria Hospital
NHS Foundation Trust

Policy for Consent to Examination or Treatment

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FORMS AND DOCUMENTS LINKED or ADDED AS APPENDIX IN THIS POLICY	Appendix A - List of Consent forms used in QVH Appendix B - QVH Consent Process Appendix C - Mental Capacity Act (MCA) Flowchart Appendix D - Delegation of consent taking
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AUTHOR	Chief Medical Officer, Tamara Everington
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Executive Summary

This policy aims to support patient's rights to make informed decisions about their healthcare.

Key principles include:

- Ensure the person has the mental capacity to give consent, provide evidence in the patient record when mental capacity assessment has been undertaken by completion of the Mental Capacity and Best Interest form. An incapacity statement must be made (and recorded on the form) when a patient lacks capacity to make the required decision.

- Valid consent requires a full and comprehensive explanation of the issues. A professional is under a legal duty to take reasonable care to ensure that the patient is aware of any material risk involved in the recommended treatment, and of any reasonable alternative or variant treatments.

- The test of material risk asks, whether, in the circumstances of the individual matter either:

    - A reasonable person in the patient's position would be likely to attach significance to the risk;
    - The professional is, or should reasonably be aware that the particular patient would be likely to attach significance to it.

- Consent must be given freely and voluntarily

- Additional procedures not covered by consent must not be undertaken on an elective basis.

- The health professional taking consent must be suitably trained and have sufficient knowledge of the procedure.

- Consent for the proposed elective surgery should be sought at the patient's outpatient appointment.

- The patient must sign the consent form and a copy be given to the patient. It is also imperative to ensure good contemporaneous record keeping of the discussions and issues of risk discussed with the patient both on the consent form and in the patient's records.

- A person with capacity can withdraw consent at any time, whatever the outcome.

- An advance decision must be followed, if valid and applicable.

- The Queen Victoria Hospital (QVH) requires written consent for all surgery/surgical procedures (see section 4.3) using the QVH paperwork.

- Under exceptional circumstances the role of the consent taker can be delegated to junior staff unable to undertake the procedure. It is the responsibility of the consultant delegating consent to satisfy himself/herself the person to whom the obtaining of consent is delegated has the knowledge detailed in the "Delegated Consent Training Assessment Form" (Appendix D).

- Where appropriate, information will be provided to patients by competent health professionals who will be involved in their care/treatment. For common procedures, information leaflets will be provided by the clinician involved in the patient's care or in the ward. Other information may be available via recognised websites. However the evidential value of information leaflets will be limited unless accompanied by a documented discussion with the patient to discuss any material risks involved with the treatment and any alternative

or variant treatment and this is then documented. In so far as any material risks, the professional must consider whether a reasonable person in the patient's position would be likely to attach significance to the risk, or whether the professional should reasonably be aware that this particular patient will attach significance to the risk.

- Where consent is withdrawn this must be clearly documented in the patient's health record and the person documenting must inform key relevant contacts both internal and external to the organisation where it is applicable to do so. A list of those informed should be documented within the patient's health record.

Version	**Date Ratified**	**Brief summary of significant changes/ amendments**	**Author/ contributor**
CL.3006.10	May 2025	Revision of MCA components, adjustment of titles and governance frameworks to reflect new structures.	Chief Medical Officer, Tamara Everington

Contents

1. Introduction

Why consent is crucial

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 rights of patients to determine what happens to their own bodies, and is a fundamental part of good practice. A healthcare professional who does not respect this principle may be liable to both legal action by the patient and to action by their professional body. Employing bodies may also be liable for actions of their staff.

Whilst there is no English statute setting out the general principles of consent, case law has established that touching a patient without valid consent may constitute the civil or criminal offence of battery. Further, if healthcare professionals 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 a complaint from patients through the NHS complaints procedure.

The Department of Health issued a range of guidance documents on consent in 2001, updated in 2009, and these should be consulted for details of the law and good practice requirements on consent. Since then further case law has been incorporated and this policy sets out the standards and processes at Queen Victoria Hospital NHS Foundation Trust, which aim to ensure that health professionals are able to comply with the guidance. While this document is primarily concerned with healthcare, social care colleagues should also be aware of their obligations to obtain consent before providing certain forms of social care, such as those that involve touching the patient or client.

1.1. Definitions

"**Consent":** is 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. For the consent to be valid, the patient must:

- be competent to make the particular decision;
- have received sufficient information to take it; and
- not be acting under duress.

The context of consent can take many different forms, ranging from the active request by a patient of a particular treatment (which may or may not be appropriate or available) to the passive acceptance of a health professional's advice. In some cases, the health 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 them, including the option of a second opinion or no treatment at all. Some patients, especially those with chronic conditions, become very well informed about their illness and may actively request particular treatments (although these may not be provided unless deemed clinically appropriate in all the circumstances). In many cases, 'seeking consent' is better described as 'joint decision-making': the patient and health professional need to come to an agreement on the best way forward, based on the patient's values and preferences and the health professional's clinical knowledge.

Where an adult patient lacks the mental capacity (either temporarily or permanently) to give or withhold consent for themselves, no-one else can give consent on their behalf unless the decision is one which can be taken by an individual appointed under a valid and applicable Lasting Power of Attorney for Health and Welfare, or Court Deputy (see separate Mental Capacity Act and DOLS Policy). A copy of which must be placed in the patient's record. However, treatment may be given if it is considered to be in that person's best interests, as long as it has not been refused in advance by way of a valid and applicable Advance Directive.

A mental capacity assessment must be evidenced by completion of the Mental Capacity and Best Interest form. Where a patient lacks mental capacity to consent to their care and treatment and they have a valid lasting power of attorney (LPA) for health and welfare or deputy the LPA or Deputy can consent on behalf of the patient. The assessment of their capacity will be recorded on the (orange) mental capacity form and the consent of the LPA or Deputy will be recorded on the (standard) Consent form. Where there is no LPA or Deputy and no valid Advanced Decision to Refuse Treatment then the Clinician proposing the treatment is the decision maker and will complete the Best Interest (part B) of the Mental Capacity and Best Interest form.

2. Scope

This policy applies to all permanent and non-permanent clinical staff seeking consent to examination or treatment.

3. Duties

Chief Medical Officer
The Chief Medical Officer is responsible for ensuring compliance with the policy.

Clinical Directors, Consultants and Heads of Nursing
Must ensure that appropriate healthcare professionals are suitably trained and qualified to take consentand ensure compliance with the policy by those within their directorate.

Executive Leadership Team
Responsible for ensuring consent processes are followed within the organisation.

Directorate General Manager
To maintain and update delegated consent records.

Patient Experience Manager
Respond to complaints and claims related to the consent process, supporting and advising as appropriate.

Safeguarding and MCA Team
Responsible for advising staff on how to manage consent and decision making for children in care (Looked after children) and adults who may lack capacity to make a decision. The clinicians remain responsible for the management of their patients care.

All Staff

Clinicians must hold in mind they are accountable for their decisions and are expected to work in line with hospital policy. To follow the consent processes detailed within this document.

4. Process for Obtaining Consent

4.1 Form of Consent

The validity of consent does not depend on the form in which it is given. Written consent merely serves as evidence of consent: if the elements of voluntariness, appropriate information and capacity have not been satisfied, a signature on a form will not make the consent valid.

Although completion of a consent form is in most cases not a legal requirement (exceptions include certain requirements of the Mental Health Act 1983 as amended by MHA 2007 and of the Human Fertilisation and Embryology Act 1990 as amended by the Human Fertilisation and Embryology Act 2008) the use of such forms is good practice where an intervention such as surgery is to be undertaken.

The Queen Victoria Hospital requires written consent for all surgery / surgical / interventional procedures. In addition the process of agreeing patient consent in any form must be documented in that patient's records and meet legal requirements as outlined in the MCA code of practice and the DH Reference guide to Consent to examination or treatment.

It is important, before the person is asked to sign any form, to establish both that they have the capacity to consent to the intervention and that they have received enough information to enable valid consent to be given.

Mental capacity is the ability to make a decision at a particular time. The MCA requires you to assume that every person aged 16 years or over has capacity to make their own decisions unless proved otherwise. The presumption of capacity does not go so far as to provide a defence for those who do not assess capacity when they should. If you believe that a patient may lack mental capacity to make a decision then you must assess their capacity.

Examples of people who MAY lack mental capacity and require an assessment includes those with the following conditions: dementia, learning disability, brain injury, certain mental health conditions, stroke, delirium, those displaying signs of confusion or disorientation and those intoxicated through alcohol or drugs

Consent may be expressed verbally or non-verbally: an example of non-verbal consent would be where a person, after receiving appropriate information, holds out an arm for their blood pressure to be taken. However, the person must have understood what examination or treatment is intended, and why, for such consent to be valid, and this is to be documented.

4.2 Valid Consent

Agreement where the person does not know what the intervention entails is not ‘consent’. For consent to be valid, it must be given voluntarily by:

- An appropriately informed person with the capacity to consent to the intervention in question,
- Someone with parental responsibility for a child under the age of 16 years,

- A child who has demonstrated they are Gillick competent and this has been documented

- For 16 and 17 years old young people who lack capacity, the mental capacity assessment and best interest decision must be evidenced in QVH's Mental Capacity and Best Interest form.

- Someone authorised to do so under a Lasting Power of Attorney for Health and Welfare (LPA) that is registered with the Office of the Public Guardian (the administrative arm of the Court of Protection). NB an Enduring Power of Attorney or LPA for Property and Financial Affairs is not a valid authority for granting consent for health care and treatment. Evidence of LPA for health and welfare must be seen and a copy placed in the patient's record, NB an LPA for health and welfare is only valid if the patient has been assessed as lacking mental capacity

- Someone who has the authority to make treatment decisions as a court appointed Deputy. Evidence must be seen and added to the patient record.

4.3 Written consent

For life or limb threatening situations which would be classed as emergency treatment the medical teams can proceed without written consent. However if the situation is urgent but not life or limb threatening then consent must be obtained using QVH processes laid out in this policy.

Consent is often wrongly equated with a patient's signature on a consent form. A signature on a form is *evidence* that the patient has given consent, but is not *proof* of valid consent. If a patient is rushed into signing a form, on the basis of too little information, the consent may not be valid, despite the signature. Similarly, if a patient has given valid verbal consent, the fact that they are physically unable to sign the form is no bar to treatment. Patients may, if they wish, withdraw consent after they have signed a form: the signature is evidence of the process of consent-giving, not a binding contract.

The Queen Victoria Hospital requires written consent for all surgery/surgical procedures.

- This includes treatment or procedure which is complex, or involves material risks (the term 'risk' is used throughout to refer to any adverse outcome, including those which some health professionals would describe as 'side-effects' or complications. In addition, the professional has a duty to ensure that a patient is aware of material risks of any reasonable alternative or variant treatment. The test of material risk asks whether (i) a reasonable person in the patient's position would be likely to attach significance to the risk, or (ii) the professional is or should reasonably be aware that the particular patient would be likely to attach significance to it.')

- the procedure involves general/regional anaesthesia or sedation;

- providing clinical care is not the primary purpose of the procedure;

- 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 QVH.

Completed consent forms must be kept with the patient's Health Records. Any changes to a form made after the form has been signed by the patient must be initialled and dated by both patient and health professional. It is imperative to ensure good contemporaneous record keeping of the discussions and issues of risk or options for treatment (including any alternatives) discussed with the individual patient on the consent form and in the patient records.

It is not always necessary to document a patient's consent to routine and very low-risk procedures, such as providing personal care or taking a blood pressure, although it is always good practice to do so and is encouraged. However, if you have any reason to believe that the consent may be disputed later or if the procedure is of particular concern to the patient (for example if they have declined, or become very distressed about similar care in the past), it must be documented. A record of this and any discussions with the patient is to be documented in the patient's health records.

If a patient with capacity agrees to proceed with a procedure but is unwilling to give written consent, the patient's agreement and all the issues discussed, including risks, complications, alternatives or any factors unique to that patient is to be recorded on the appropriate consent form and / or patient records, and be witnessed and signed by another clinical member of staff other than the clinician seeking consent. It would be unusual however for a patient to agree to a procedure and yet be unwilling to give written consent, and this should be explored to ensure that there are no other reasonable factors which may call into question the validity of the consent given.

If the person has capacity but cannot read or write, staff taking consent must make sure all information on the consent form is discussed with the patient and that this is documented in the records. The patient may be able to make their mark on the form to indicate consent. It is best practice for the mark to be witnessed by a person other than the clinician seeking consent, and for the fact that the person has chosen to make their mark in this way to be recorded in the patients' health records. If the person has capacity, and wishes to give consent, but is physically unable to mark the form, this must be recorded in the notes. If consent has been given validly, the lack of a signed form is no bar to treatment, but a recordof consent must be documented in the patient healthcare records.

4.4 Who is responsible for seeking consent?

The health professional carrying out the procedure, undertaking an investigation or providing treatment or care is ultimately accountable for ensuring that the patient is genuinely consenting to what is being done: they will be held responsible in law if this is challenged later. It is the responsibility of the person seeking consent to be satisfied that the patient has capacity and to demonstrate how this has been obtained is documented in the patient's record.

Where oral or non-verbal consent is being sought at the point the procedure will be carried out, this will naturally be done by the health professional responsible and documented as appropriate by that individual.

Team work is a crucial part of the way the NHS operates, and where written consent is being sought it may be appropriate for other members of the team to participate in the process of seeking consent

In certain circumstances, responsibility for taking consent may be delegated to a clinician who is *not* capable of performing the procedure. The GMC guidance states that the task of

seeking consent may be delegated to another person, as long as that person is suitably trained, qualified and are competent to do so; are able to work within their own competence and not to agree to perform tasks which exceed that competence. Clinical staff delegated to obtain consent must have sufficient knowledge of the proposed investigation or treatment, and understand the material risks involved in the recommended treatment and of any reasonable alternative or variant treatment, in order to be able to provide any information the patient may require. They must also be able to assess whether the particular patient would be likely to attach particular significance to the risks discussed.

It is the responsibility of the health professional authorising another clinical member of staff to obtain consent to satisfy himself/herself that the above criteria have all been met, before delegating consent to any member of staff who is not personally capable of undertaking the procedure (Appendix D).

When a patient formally gives their consent to a particular intervention, this is only the *endpoint* of the consent process. It is helpful to see the whole process of information provision, discussion and decision-making as part of 'seeking consent'. This process may take place at one time, or over a series of meetings and discussions, depending on the seriousness of what is proposed and the urgency of the patient's condition. The patient is to be given the option of seeking a second opinion where this is required. It must be remembered to record this information in the patient's record.

4.5 When should consent be sought?

The seeking and giving of consent is usually a process, rather than a one-off event. In most cases where consent is being sought, treatment options will generally be discussed well in advance of the actual procedure being carried out. This may be on just one occasion (at the patient's outpatient appointment or pre-assessment clinic), or it might be over a whole series of consultations with a number of different health professionals. This gives the patient time to properly consider their treatment options and for healthcare professionals to respond to questions and provide adequate information to patients. It also allows the medical professional in reasonable discussion with the patient to determine (i) whether a person in the patient's position would be likely to attach significance to the risks of the proposed treatment or any alternatives, or (ii) whether the particular patient is likely to attach significance to the risks associated with treatment options, in which case it will be deemed to be a material risk to be discussed with the patient fully.

The consent process will therefore have at least two stages: the 1st stage of consent being the provision of information, discussion of options or any reasonable alternative or variant treatment, as well as the discussion of any material risks involved and the patient's initial decision (taken at the patients out-patient appointment); and the 2nd stage of consent being confirmation that the patient still wants to go ahead. The consent form is to be used as a means of documenting the information stage(s), as well as the confirmation stage (see Appendix B). The patient record can also be used for or to supplement this process.

Patients receiving elective treatment or investigations for which written consent is appropriate should (following the 1st stage of consent) have received a copy of the page documenting their decision-making process and be familiar with the contents of their consent form before they arrive for the actual procedure. They may be invited to sign the consent form (completing the 2nd stage of consent), confirming that they wish treatment to go ahead, at any appropriate point before the procedure: in out-patients, at a pre-admission clinic, or (exceptionally) when they arrive for treatment.

If a form is signed before the patient arrives for treatment, a member of the healthcare team must check with the patient whether they have any further questions, concerns and whether their condition has changed. This is particularly important where there has been a significant lapse of time between the 1st stage of consent and the procedure. When confirming the patient's consent and understanding, it is advisable to use a form of words which requires more than a yes/no answer from the patient: for example beginning with "tell me what you're expecting to happen", rather than "is everything all right?" Any concerns regarding memory or patient behaviour will be brought to the attention of the treating doctor by nurses and therapists so that they can re-assess the situation.

It must always be remembered that for consent to be valid, the patient must feel that it would have been possible for them to refuse, or change their mind. It will rarely be appropriate to ask a patient to sign a consent form after they have begun to be prepared for treatment (for example, by changing into a hospital gown), unless this is unavoidable because of the urgency of the patient's condition.

4.6 Seeking consent for anaesthesia

Where an anaesthetist is involved in a patient's care, it is their responsibility (not that of a surgeon) to seek consent for anaesthesia, having discussed the benefits and material risks of that treatment as well as any potential alternatives (i.e. sedation). However, in elective treatment it is not acceptable for the patient to receive no information about anaesthesia until their pre-operative visit from the anaesthetist: at such a late stage the patient will not be in a position to genuinely make a decision about whether or not to undergo anaesthesia. Patients will therefore either receive a general leaflet about anaesthesia or any alternatives in out-patients (and then have the opportunity to discuss the benefits and material risks with the anaesthetist prior to surgery), or have the opportunity to discuss anaesthesia in a pre-assessment clinic (if patient is pre-assessed).

The anaesthetist will ensure that the discussion with the patient and their consent is documented in the anaesthetic record, in the patient's health records or on the consent form. Where the clinician providing the care is personally responsible for anaesthesia (e.g. where local anaesthesia or sedation is being used), then he or she will also be responsible for ensuring that the patient has given consent to that form of anaesthesia.

In addition, where general anaesthesia or sedation is being provided as part of dental treatment, the General Dental Council currently holds dentists responsible for ensuring that the patient has all the necessary information. In such cases, the anaesthetist and dentist will therefore share that responsibility.

4.7 Emergencies

In emergencies, discussion of options and confirmation that the patient wishes to go ahead should take place in so far as is reasonable in the circumstances of the individual case. The urgency of the patient's situation may limit the quantity of information that they can be given, but must not affect its quality. In the circumstance of a patient requiring emergency treatment, it is acceptable to complete only the 1st stage of consent (see Appendix B). For children consent from the person who holds parental responsibility (PR) must be given verbally at the very least, except if the person with PR is not available when replant of a digit or limb is required immediately.

In life threatening situations consent may not be possible and treatment may need to be taken without consent. In these situations doctors will jointly risk assess what is needed to save life or a limb.

4.8 Duration of consent

When a person gives valid consent to an intervention, in general that consent remains valid for an indefinite duration, unless it is withdrawn by the person or the circumstances for which the person provided consent changes. At QVH, good practice would be that where consent was taken more than six months prior to the surgery date it is to be re-confirmed by the surgical team. However, if new information becomes available regarding the proposed treatment / intervention (for example new evidence of material risks or new/variant treatment options) between the time when consent was sought and when the intervention is undertaken, GMC guidance states that a doctor or member of the healthcare team is expected to inform the patient and reconfirm their consent discussing all material risks and benefits with them.

A clinician is under a legal duty to take reasonable care to ensure that the patient is aware of any material risk involved in the recommended treatment, and of any reasonable alternative or variant treatments. Similarly, if the patient's condition has changed significantly in the intervening time it may be necessary to seek consent again, on the basis that the likely benefits and / or material risks of the intervention may also have changed. The test of material risk asks whether in the circumstances of the individual case (i) a reasonable person in the patient's position would be likely to attach significance to the risk, or (ii) the clinician should reasonably be aware that the particular patient would attach significance to it.

If consent has been obtained a significant time before undertaking the intervention, it is necessary to confirm that the person who has given consent wishes the intervention to proceed, even if no new information needs to be provided or further questions answered.

4.9 Responsibility of health professionals

Health professionals undertaking an investigation or providing treatment will ensure that there is a process for seeking advice from a colleague where the health professional 'confirming' the patient's consent are personally not able to answer any remaining questions or make a determination of the materiality of risk of the treatment or any alternatives arising from further discussion with the individual patient.

It is a health professional's own responsibility:

- to ensure that if and when they require colleagues to seek consent on their behalf they are confident that the colleague is competent to do so (see Appendix D); and
- is suitably trained and qualified
- has sufficient knowledge of the proposed investigation or treatment, and understands the material risks involved in the recommended treatment, and of any reasonable alternative or variant treatments.
- to work within their own competence and not to agree to perform tasks which exceed that competence.

If you feel that you are being pressurised to seek consent when you do not feel competent to do so you should seek the advice of the relevant Clinical Director.

4.10 When consent is refused

If an adult with **capacity** makes a voluntary and appropriately informed decision to refuse treatment (whether contemporaneously or in advance by way of an Advanced Decision (see QVH Mental Capacity Act and Deprivation of Liberty Safeguards Policy), this decision **must** be respected, except in certain circumstances as defined by the Mental Health Act 1983. This is the case even where this may result in the death of the person (and/or the death of an unborn child, whatever the stage of the pregnancy). The safety and well-being of the patient is to be reviewed with the safeguarding team and discussed with social care services (where the patient is known to them) to ensure the right decisions are being made for each patient.

Refusal of a patient with capacity to consent to a procedure or treatment must be written, fully documented and kept in the patient notes, discussed within a MDT and with the safeguarding team.

4.11 Withdrawal of Consent

A person with capacity is entitled to withdraw consent at any time, including during the performance of a procedure. Where a person does object during treatment, it is good practice for the practitioner, if at all possible, to stop the procedure, establish the person's concerns and explain the consequences of not completing the procedure. 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 person's consent. If stopping the procedure at that point would genuinely put the life of the person at risk, the practitioner may be entitled to continue until that risk no longer applies.

Where consent is withdrawn this must be clearly documented in the patient's health record and the person documenting must inform key relevant contacts both internal and external to the organisation where it is applicable to do so. A list of those informed is to be documented in the patient's health record.

Assessing capacity during a procedure may be difficult and, as noted above, factors such as pain, panic and shock may diminish capacity to consent. The practitioner must try to establish whether at that time the person has capacity to withdraw a previously given consent.

There must be comprehensive liaison with the patient's GP to allow adequate follow up and review of the patient's situation once they are back home.

4.12 Advance decisions to refuse treatment (Please also see QVH Mental Capacity Act and Deprivation of Liberty Safeguards Policy)

A person may have made an advance decision to refuse particular treatment in anticipation of future incapacity (sometimes previously referred to as a 'living will' or 'advance directive'). A valid and applicable advance decision to refuse treatment has the same force as a contemporaneous decision to refuse treatment. This is a well-established rule of common law, and the Mental Capacity Act 2005 now puts advance decisions on a statutory basis. The Act sets out the requirements that such a decision must meet to be valid and applicable. Further details are available in the QVH Mental Capacity Act and Deprivation of Liberty

Safeguards Policy as well as in chapter 9 of the Mental Capacity Act (2005) Code of Practice, but in summary these are:

- the person must be 18 or over to have made an advance decision
- the person must have the capacity to make such a decision at the time it was created
- the person must make clear which treatments they are refusing, and if necessary the circumstances when that refusal will apply
- if the advance decision refuses life-sustaining treatment, it must be in writing (it can be written by someone else or recorded in healthcare notes), it must be signed and witnessed (ideally not by the QVH own health professionals) and it must state clearly that the decision applies even if life is at risk
- a person with capacity can withdraw their advance decision at any time and this must be documented .

Healthcare professionals **must see a copy of the document and take a copy for the patient record to be able follow** an advance decision if it is valid and applicable in all the circumstances, even if it may result in the person's death. If they do not, they could face criminal prosecution or civil liability. The Mental Capacity Act 2005 protects a health professional from liability for treating or continuing to treat a person in the person's best interests if they are not satisfied that an advance decision exists which is valid and applicable. The Act also protects healthcare professionals from liability for the consequences of withholding or withdrawing a treatment if at the time they reasonably believe that there is a valid and applicable advance decision. If there is genuine doubt or disagreement about an advance decision's existence, validity or applicability, the case is to be referred to the Court of Protection for determination. While a decision is awaited from the courts, healthcare professionals can provide all necessary life-sustaining treatment or treatment to stop a serious deterioration in the patient's condition.

If an advance decision is not valid or applicable to current circumstances, healthcare professionals must still consider the advance decision as part of their assessment of the person's best interests.

Whilst some healthcare professionals may disagree in principle with a person's right to refuse life-sustaining treatment, the Mental Capacity Act does not change the current legal position. Healthcare professionals do not have to act in a way that goes against their beliefs; however, they must not simply abandon patients or cause their care to suffer. A patient is to be given the option of transferring their care to another healthcare professional or, if the patient lacks capacity, arrangements must be made for the management of the patient's care to be transferred to another healthcare professional.

Patients must always be offered measures that are essential to keeping them comfortable. This is sometimes referred to as 'basic' or 'essential' care, and includes warmth, shelter, actions to keep a person clean and free from distress and the offer of food and water by mouth. The British Medical Association's guidance advises that basic care will always be provided unless it is actively resisted by a patient, and that 'refusals of basic care by patients with capacity must be respected, although it will continued to be offered'. Advance decisions made under the Mental Capacity Act cannot refuse actions that are needed to keep a person comfortable. The Act allows healthcare professionals to carry out these actions in the best interests of a person who lacks capacity. An advance decision can refuse artificial nutrition and hydration.

However, although basic/essential care would include the offer of oral nutrition and hydration, it would **not** cover force feeding an individual or the use of artificial nutrition and hydration. The courts have recognised that an individual with capacity has the right to choose to refuse food and drink, although this may be qualified if the person has a mental disorder. Towards the end of such a period an individual is likely to lose capacity, and the courts have stated that if the individual has, while they have capacity, expressed the desire to refuse food until death supervenes, the person cannot be force fed or fed artificially when they lack capacity. If the person is refusing food as a result of mental disorder, then detention and treatment without consent may be a possibility under the Mental Health Act 1983, where different considerations may apply and more specialist guidance should be consulted.

4.13 Self-harm

Cases of self-harm present a difficulty for healthcare professionals. Where the person is able to communicate, an assessment of their mental capacity must be made as a matter of urgency. If the person is judged not to have capacity, then they may be treated on the basis of their best interests using QVH documentation and involving the relevant people. Similarly patients who have attempted suicide and are unconscious are to be given emergency treatment unless there is a valid Advance Decision specifically preventing the proposed treatment. If a patient has attempted suicide you may also wish to consider whether the person requires assessment under the Mental Health Act.

However patients with capacity **do** have the right to refuse life-sustaining treatment both at the time it is offered and in the future. The MHA 1983 is used for treatment of mental disorders and, in limited circumstances, related physical health needs. However, if a patient has capacity and is not subject to MHA or require physical health care not covered by MHA, their decision to accept or refuse treatment must be respected. Any such refusal must be clearly and fully documented in the patient's records. If the person is clearly suicidal, this may raise questions about their capacity to make the decision. If a patient with capacity has harmed themselves, a prompt psychosocial assessment of their needs is to be offered and consideration given to referring them for a MHA assessment.

4.14 Patients who lack capacity to give or withhold consent (Please also see QVH Mental Capacity Act and Deprivation of Liberty Safeguards Policy)

General principles

Mental disorder or detention and/or treatment under the Mental Health Act does not in itself denote incapacity to consent to other medical treatment. The law around this area is complex and if uncertain, practitioners are advised to seek advice from the QVH Safeguarding Named Nurse & MCA Lead or the Sussex Partnership Trust on matters involving psychiatric assessment and treatment.

The Mental Capacity Act 2005 applies in England and Wales to everyone who works in health and social care and is involved in the care, treatment or support of people over 16 years of age who may lack capacity to make decisions for themselves. Under the Mental Capacity Act, a person must be assumed to have capacity unless it is established that they lack capacity.

A person is unable to make a decision if they cannot do any one of the following:

- understand the information given to them that is relevant to their decision
- retain that information long enough to be able to make a decision
- use or weigh up the information as part of their decision-making process
- communicate their decision by any means – this could be by talking or using sign language and includes simple muscle movements such as blinking an eye or squeezing a hand.

They would be deemed to lack mental capacity to make that decision if:

- They have an impairment or disturbance in the functioning of the mind or brain causing an inability to make a decision.

People may have capacity to consent to some interventions but not to others, or may have capacity at some times but not others.If there is any doubt, an assessment of the capacity of the patient to take the decision in question must be carried out.

When to complete a capacity assessment

A person's capacity to consent may be temporarily affected by factors such as confusion, panic, shock, fatigue, pain or medication. However the existence of such factors would not lead to an automatic assumption that the person does not have the capacity to consent. The healthcare professional will decide whether, in the circumstances, it is possible to delay the decision making until such time as they may regain capacity.

Capacity must not be confused with a healthcare professional's assessment of the reasonableness of the person's decision. Under the Mental Capacity Act and the common law, a person is not to be treated as unable to make a decision merely because they make an unwise decision. A person is entitled to make a decision which may be perceived by others to be unwise or irrational, as long as they have the capacity to do so.

The QVH Mental Capacity and Best Interest form is available in all clinical areas printed on orange paper. Where a best interest decision is taken it is important to fully record this on the Mental Capacity and Best interest form (rather than elsewhere within records). The completed paperwork documenting the best interest decision once filed can be referred to prior to interventions. A best interest decision can be made in a face to face or virtual meeting or phone call. The QVH Safeguarding Named Nurse & MCA team can be contacted to support staff to manage these processes. MCA advice is recorded in the safeguarding file on EVOLVE. All information gathered relating to a best interest decision is be recorded on the Mental Capacity and Best Interest form.

The Mental Capacity Act also requires that all practical and appropriate steps are taken to enable a person to make the decision themselves. These steps include the following:

- Communicating in an appropriate way. For example, could the information be explained or presented in a way that is easier for the person to understand?
- Making the person feel at ease. For example, are there particular times of the day when a person's understanding is better?
- Supporting the person. For example, can anyone else help or support the person to understand information and to make a choice. Is a Speech and Language Therapist or

Interpreter required? (NB where a patient's first language is not English and there are doubts regarding their ability to fully communicate a professional interpreter must be used. A family member or friend should not normally be used to interpret.

Guidance on how people should be helped to make their own decisions is given in QVH Mental Capacity Act and Deprivation of Liberty Safeguards Policy

4.15 Decision making where the patient does not have capacity

In law, no one is able to give consent to the examination or treatment of an adult who lacks the capacity to give consent for themselves, unless they have been authorised to do so in the circumstances under a valid Lasting Power of Attorney (LPA) for Health and Welfare or they have the authority to make treatment decisions in the circumstances as a Court of Protection appointed Deputy

Where there is no LPA or appointed Deputy, decisions can still be made about treatment, termed best interest decisions. The Mental Capacity Act (MCA) sets out the circumstances in which it will be lawful to carry out such examinations or treatment for a patient who lacks capacity, QVH Mental Capacity Act and Deprivation of Liberty Safeguards Policy details the processes to be followed and recorded.

The decision maker, in the absence of a LPOA or Deputy (and without a valid Advanced Decision to Refuse Treatment) is the clinician proposing the treatment.

4.16 Duration of lack of capacity

The provisions of the MCA apply to acts or decisions made on behalf of an individual aged 16 or over who lacks capacity – whether the lack of capacity is likely to be temporary or permanent. It is possible for capacity to fluctuate. In such cases, it is good practice to establish, while the person has capacity, their views about any clinical intervention that may be necessary during a period of anticipated incapacity, and to record these views. The person may wish to make an advance decision to refuse treatment or a statement of their preferences and wishes. If the person does not make a relevant, valid and applicable advance decision, decisions about that person's treatment if they lack capacity must be made in accordance with the Mental Capacity Act 2005 and that person's best interests in all the relevant circumstances. This would include considering whether the person is likely to regain capacity and, if so, whether the decision can wait, as well as the statutory principle that all practical steps must be taken to enable the person to make their own decision.

4.17 Lasting Power of Attorney (LPA)

The Mental Capacity Act enables a person aged 18 or over to appoint an attorney to make a wide range of decisions on their behalf, including health and welfare decisions, should they lack the capacity to make such decisions in the future. Under a health and welfare LPA, the attorney – if they have the authority to do so – can make decisions that are as valid as those made by the person themselves. The LPA must be checked as having been appropriately completed and registered with the Office of the Public Guardian before it can be used. The LPA might include instructions which the attorney is expected to follow it therefore needs to be read by the medical decision maker.

It will state whether the LPA can make decision regarding life sustaining treatment.

4.18 Court appointed Deputies

If a person already lacks capacity to make a decision relating to their personal welfare, then the Court of Protection can appoint a Deputy to make decisions on behalf of the person who lacks capacity. The court instructions will need to be read by the health professional who is the decision maker.

4.19 Independent mental capacity advocates (IMCA)

An IMCA is legally required when a patient has no family or friends to support them and serious medical treatment is proposed. The IMCA will consider what is being proposed and seek to represent the patients view. They will provide a report that must be considered as part of the best interest process. They are not the decision maker, Information on how to obtain one for a patient can be found on the MCA page on Qnet.

4.20 Children and Young People

The legal position concerning consent and refusal of treatment by those under the age of 18 is different from the position of adults. For the purpose of this policy, ‘children’ refers to people aged below 16 and ‘young people’ refers to people aged 16 or 17.

4.21 Young people aged 16 or 17

By virtue of section 8 of the Family Law Reform Act 1969, people aged 16 or 17 are presumed to have capacity to and capable of consenting to their own medical treatment, and any ancillary procedures involved in that treatment, such as an anaesthetic as if they were an adult. The Mental Capacity Act 2005 applies to anyone aged 16 or over. Whether an individual aged 16 or over is therefore able to consent to treatment will be dependent on whether they are deemed to have capacity to take that decision applying the Act. As like adults, consent will be valid only if it is given voluntarily by an appropriately informed young person capable of consenting to the particular intervention.

Young people aged 16 and 17 may sometimes not have capacity to consent to treatment for particular decisions. This could be for a variety of reasons – they are unconscious, suffering from the effects of medication and so on. You must consider whether that young adult may have fluctuating capacity, and it would be possible to wait to take any decision until that young person has regained capacity. Where a young adult does not have capacity to consent, QVH Mental Capacity Act and Deprivation of Liberty Safeguards Policy must be used.

Where a young person has capacity, their decision must be respected and you can rely on that young person's consent even if those with parental responsibility disagree. Equally a young person with capacity is entitled to refuse treatment. However, unlike adults, their refusal of treatment can, in some circumstances be overridden by a person with PR or a court. This is because we have an overriding duty to act in the best interests of a child. This would include circumstances where refusal would likely lead to death or severe permanent injury or irreversible mental or physical harm.

If the young person does not have capacity, and there is a disagreement between the clinician and those with parental responsibility with regard to decisions relating to serious

medical treatment, and this is unable to be resolved, then the matter is to be be referred to the Court of Protection.

4.22 Children under 16 – the concept of Gillick competence

In the case of *Gillick*, the court held that children who have sufficient understanding and intelligence to enable them to understand fully what is involved in a proposed intervention, what the material risks and benefits are, what alternative treatment options there are (including the consequences of no treatment) as well as the material risks and benefits of those alternative treatments; will also have the capacity to consent to that treatment or intervention. This is sometimes described as being 'Gillick competent'. A child under 16 may be Gillick competent to consent to medical treatment, research, donation or any other activity that requires consent.

The concept of Gillick competence is said to reflect a child's increasing development to maturity. The understanding required for different interventions will vary considerably and may also vary as between children. Thus a child under 16 may have the capacity to consent to some interventions but not to others. The child's capacity to consent must be assessed carefully in relation to each decision that needs to be made. Consideration is to be given to whether translation services are required to ensure that consent is clearly understood where a patient has English as an additional language.

If the child is Gillick competent and is able to give voluntary consent after receiving appropriate information, that consent will be valid and additional consent by a person with parental responsibility will not be required. It is, however, good practice to involve the child's family in the decision-making process, if the child consents to their information being shared. Where a competent child refuses to allow information to be shared with their parent, consideration of the risks of sharing information is to be documented in the health records. Clinicians must respect any request from an under 16 year old to keep their treatment confidential, unless disclosure to a particular individual or organisation is justified on the basis that you have reasonable cause to suspect that the child is suffering or is likely to suffer significant harm. Where it is the clinician's opinion that it is necessary to share information in the best interests of a child against their wishes, the Caldicott Guardian is to be consulted.

4.23 The requirement of voluntariness & a child with capacity providing consent

Although a child or young person may have the capacity to give consent, this is only valid if it is given voluntarily. This requirement must be considered carefully. Children and young people may be subject to undue influence by their parent(s), other carers or a sexual partner (current or potential), and it is important to establish that the decision is that of the individual him or herself.

Those with parental responsibility cannot override the consent of a competent child who agrees to treatment, although if this concerns serious medical treatment and cannot be resolved through discussion and mediation, very real consideration will need to be given about how best to proceed, and whether this matter will be referred to the Local Authority or to the Court.

4.24 Child with capacity refusing treatment

Where a child under 16 but Gillick competent, refuses treatment, it is possible that such a refusal could be overruled by those with parental responsibility if it would in all probability

lead to the death of the child or to severe or permanent injury. However this power to override a competent child's decision will be used rarely, particularly given the difficulties of forcing treatment on that child.

Where the treatment involved is for mental disorder, consideration is to be given to using mental health legislation.

A life-threatening emergency may arise when consultation with either a person with parental responsibility or the court is impossible, or the person with parental responsibility refuses consent despite such emergency treatment appearing to be in the best interests of the child. In such cases the courts have stated that doubt should be resolved in favour of the preservation of life, and it will be acceptable to undertake treatment to preserve life or prevent serious damage to health whilst the wider issues are resolved.

4.25 Children lacking capacity

Where a child under the age of 16 lacks capacity to consent (i.e. is not Gillick competent), consent can be given on their behalf by any one person with parental responsibility or by the court. In the face of parental disagreement, you can rely on one parent's consent provided they have parental responsibility. As is the case where patients are giving consent for themselves, those giving consent on behalf of child patients must have the capacity to consent to the intervention in question, be acting voluntarily and be appropriately informed. The power to consent must be exercised according to the 'welfare principle': that the child's 'welfare' or 'best interests' must be paramount. Even where a child lacks capacity to consent on their own behalf, it is good practice to involve the child as much as possible in the decision-making process.

If parents refuse treatment for their child, then treatment must not go ahead. If health professionals believe that the treatment is crucial, then the Courts can be asked to determine what is in the child's best interests. Where necessary, the courts can overrule a refusal by a person with parental responsibility. It is recommended that certain important decisions, such as sterilisation for contraceptive purposes, should be referred to the courts for guidance, even if those with parental responsibility consent to the operation going ahead. Similarly, parents cannot require professionals to provide treatment which they do not believe to be clinically appropriate, although it may be helpful to request a second opinion and attempt mediation.

The European Court of Human Rights judgment in a case where doctors treated a child contrary to his mother's wishes, without a court order (*Glass v United Kingdom*), made clear that the failure to refer such cases to the court is not only a breach of professional guidance but also potentially a breach of the European Convention on Human Rights. In situations where there is continuing disagreement or conflict between those with parental responsibility and doctors, and where the child is not competent to provide consent, the court should be involved to clarify whether a proposed treatment, or withholding of treatment, is in the child's best interests. Parental refusal can only be overridden in an emergency in favour of the preservation of life or to prevent serious harm.

Parental Responsibility

It is important to confirm who holds Parental Responsibility (PR) for a child: A person with PR must have the capacity to give consent

The Children Act 1989 sets out persons who may have parental responsibility. These

include:

- the child's mother.
- the child's father, if he was married to the mother at the time of birth.
- unmarried fathers, if they are on the birth certificate or they can acquire parental responsibility.
- the child's legally appointed guardian.
- Where a child has been formally adopted, the adoptive parents are the legal parents and have PR- it is good practice to seek written evidence of adoption.
- a person in whose favour the court has made a residence order concerning the child; special guardianship order or residence order- a copy of the specific order is to be placed within the child's record.
- a local authority designated in a care order in respect of the child; Looked After Child or Child in Care- check with social care team the specifics of the order, parents may retain or share PR with the local authority.
- a local authority or other authorised person who holds an emergency protection order in respect of the child.
- a local authority designated in a care order in respect of the child.
- a local authority or other authorised person who holds an emergency protection order in respect of the child. Section 2(9) of the Children Act 1989 states that a person who has parental responsibility for a child 'may arrange for some or all of it to be met by one or more persons acting on his or her behalf'. Such a person might choose to do this, for example, if a childminder or the staff of a boarding school have regular care of their child. They will have written evidence of delegated responsibility. As only a person exercising parental responsibility can give valid consent, in the event of any doubt then specific enquiry should be made. Foster parents do not automatically have parental responsibility.

Consent given by one person with parental responsibility is valid, even if another person with parental responsibility withholds consent. However, the courts have stated that a 'small group of important decisions' is not be taken by one person with parental responsibility against the wishes of another, citing in particular non-therapeutic male circumcision and immunisation. Where persons with parental responsibility disagree as to whether these procedures are in the child's best interests, it is advisable to refer the decision to the courts. It is possible that major experimental treatment, where opinion is divided as to the benefits it may bring the child, might also fall into this category of important decisions.

Where there is doubt about whether a parent is acting in the interest of the child then the healthcare practitioner would be unwise to rely on the parent's consent. Seek guidance from the Safeguarding Team. Consideration is be given as to whether a safeguarding referral should be made to the child's local authority, or even to the Court. Follow Sussex child protection procedures if required.

In order to consent on behalf of a child, the person with parental responsibility must themselves have capacity. Where the person with parental responsibility for a child is themself under 18, they will only be able to give valid consent for the child's treatment if they themselves are aged under 16 but Gillick competent, or if aged 16-17, meet the test of capacity within the Mental Capacity Act (2005). Whether or not they have capacity may vary, depending on the seriousness of the decision to be taken.

Where a child is a ward of court, no important step may be taken in the life of the child without the prior consent of the Court. This is likely to include more significant medical interventions but not treatment for minor injuries or common diseases of childhood.

In an emergency, it is justifiable to treat a child who lacks capacity without the consent of a person with parental responsibility, if it is impossible to obtain consent in time and if the treatment is vital to the survival or to prevent a serious deterioration to the health of the child.

4.26 Withdrawing and withholding life-sustaining treatment

A person with capacity may decide either contemporaneously or by a valid and applicable Advance Decision that they have reached a stage where they no longer wish treatment to continue. Except in circumstances governed by the Mental Health Act 1983, if an adult with the capacity to make the decision refuses treatment, be it life-sustaining treatment or otherwise, or requests that it be withdrawn, practitioners **must** comply with the person's decision, even if it may result in the person's death. If a refusal is ignored, they will be treating the person unlawfully.

As with all decisions made under the Mental Capacity Act, before deciding to withdraw or withhold life-sustaining treatment, the healthcare professional must consider the range of treatment options available in order to work out what would be in the person's best interests (refer to MCA and DOLS Policy) and consider who must be part of the best interest meeting/consultation process. All of the factors set out in the Mental Capacity Act (2005) Code of Practice must be considered, and in particular the healthcare professional must consider any statements that the person has previously made about their wishes and feelings about life-sustaining treatment as well as consulting with key family and relevant professionals who can offer an opinion as to what may be in this individual's best interests in all the circumstances. If agreement cannot be reached between healthcare professionals and family members as to what may be in an individual's best interests, the Court of Protection must be asked to make this determination in the context of serious medical treatment. This is not required if there is consensus.

If a child with capacity makes such a request or refusal it is possible that such a refusal could be overruled if it would in all probability lead to the death of the child or to severe permanent injury. Moreover, the courts consider that to take a decision which may result in the individual's death requires a very high level of understanding, so that many children or young people who would have the capacity to take other decisions about their medical care may lack the capacity to make such a grave decision.

If a child lacks capacity, it is still good practice to involve the child as far as is possible and appropriate in the decision. The decision to withdraw or withhold life-sustaining treatment must be made in the best interests of the child. A person with parental responsibility for a child or young person is legally entitled to give or withhold consent to treatment. A person with parental responsibility cannot demand a particular treatment to be continued where the burdens of the treatment clearly outweigh the benefits for the child. If agreement cannot be reached between the parent(s) and the healthcare professionals, a court must be asked to make a declaration about whether the provision of life-sustaining treatment would benefit the child.

4.27 Requirements for living donation

The Human Tissue Authority is responsible for the regulation, through a system of

approvals, of the donation from living people of solid organs, bone marrow and peripheral blood stem cells for transplantation into others. Information on the legal requirements and how to proceed is available from the Human Tissue Authority at www.hta.gov.uk

4.28 Subsequent use of removed tissue

The Human Tissue Act 2004 repeals and replaces the Human Tissue Act 1961, the Anatomy Act 1984 and the Human Organ Transplant Act 1989 as they relate to England and Wales. It also repeals and replaces the Human Tissue Act (Northern Ireland) 1962, the Human Organ Transplants (Northern Ireland) Order 1989 and the Anatomy (Northern Ireland) Order 1992.

If an adult lacks capacity, and has not made a valid and applicable Advance Decision to refuse life-sustaining treatment, the provisions of the Mental Capacity Act will apply and the decision must be based on the best interests of the adult, again involving the person as far as this is possible

The 2004 Act regulates removal, storage and use of human tissue. This is referred to in the Act as 'relevant material' and is defined as material that has come from a human body and consists of, or includes, human cells. Cell lines are excluded, as are hair and nail from living people. Live gametes and embryos are excluded as they are already regulated under the Human fertilisation and Embryology Act 1990 as amended by the Human fertilisation and Embryology Act 2008.

The Human Tissue Act 2004 lists the purposes for which consent is required in Schedule 1, and they are referred to as 'scheduled purposes'. The consent required under the Act is called 'appropriate consent' which mean consent from the appropriate person, as identified in the Act. Where there has been a failure to obtain consent, or a misuse of consent, penalties of up to three years imprisonment or a fine, or both, are provided for in the Act.

Full details on the requirements of the Human Tissue Act and the HTA's codes of practice are on the HTA's website at www.hta.gov.uk. These are to be consulted to ensure full compliance with the legislation.

4.29 Research and innovative treatment

The same legal principles apply when seeking consent from a person for research purposes as when seeking consent for investigations or treatment. GMC guidance advises that patients 'should be told how the proposed treatment differs from the usual methods, why it is being offered, and if there are any additional risks or uncertainties'. Clinical trials are covered by the Medicines for Human Use (Clinical Trial Regulations) 2004 as amended by the 2008 Regulations (See further reading references or seek advice of the research department manager)

If the treatment being offered is of an experimental nature, but not actually part of a research trial, this fact must be clearly explained to a person with capacity before their consent is sought, along with information about reasonable standard alternatives or variant treatments. It is important to give a person information about the evidence to date of the effectiveness of the experimental treatment, both at national/international levels and in the practitioner's own experience, including information about known possible side-effects, or any material risks involved in the experimental treatment for the patient which are known.

Where the person is an adult who lacks capacity or a child, then the experimental treatment cannot be given, unless it is deemed to be in that person's best interests. Where there is perhaps no alternative treatment available and the disease is progressive and fatal, it will be reasonable to consider experimental treatment with unknown benefits and (material) risks but without significant risks of increased suffering to the patient, and where there is some chance of benefit to the patient. However in discussing this with relevant relatives, the doctor must ensure that there is a clear understanding of the potential consequences of the recommended experimental treatment, and any alternatives, including providing no treatment at all as an option for example.

4.30 Clinical photography and conventional or digital video recordings

Photographic and video recordings made for clinical purposes form part of a patient's record. Although consent to certain recordings, such as X-rays, is implicit in the patient's consent to the procedure, health professionals must always ensure that they make clear in advance if any photographic or video recording will result from that procedure.

Photographic and video recordings made for treating or assessing a patient must not be used for any purpose other than the patient's care or audit of that care, without the expressed consent of the patient or person with parental responsibility for the patient. If you wish to use such a recording for education, publication or research purposes, you must seek express consent in writing, ensuring the person giving consent is fully aware of the possible uses of the material. In particular, the person must be made aware that you may not be able to control future use of the material once it has been placed in the public domain. If a child/adult is not willing for a recording to be used, you must not use it, even if a person with parental responsibility/carer consents.

If you wish to make a photographic or video recording of a patient specifically for education, publication or research purposes, you must first seek their written consent (or where appropriate that of a person with parental responsibility) to make the recording, and then seek their consent to use it. Patients must know that they are free to stop the recording at any time and that they are entitled to view it if they wish, before deciding whether to give consent to its use. If the patient decides that they are not happy for any recording to be used, it must be destroyed. As with recordings made with therapeutic intent, patients must receive all necessary, relevant and full information on the possible future uses of the recording, including the fact that it may not be possible to withdraw it once it is in the public domain.

The situation may sometimes arise where you wish to make a recording specifically for education, publication or research purposes, but the patient is temporarily unable to give or withhold consent because, for example, they are unconscious. In such cases, you may make such a recording, but you must seek consent as soon as the patient regains capacity. You must not use the recording until you have received consent for its use, and if the patient does not consent to any form of use, the recording must be destroyed.

If the patient is likely to be permanently unable to give or withhold consent for a recording to be made, you must seek the agreement of the parent/family/IMCA. Such a recording can only be made if it is required to facilitate the care, treatment and support of the patient. You must not make any use of the recording that might be against the best interests of the patient. You must also not make, or use, any such recording if the purpose of the recording could equally well be met by assessing patients who are able to give or withhold consent.

5. Providing patients with sufficient information to support their decision making including material risks, benefits and alternatives

5.1 Provision of Information

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, material risks, benefits (including the risks/benefits of doing nothing) and any reasonable alternatives or variant treatments available to them. They also need to know whether additional procedures are likely to be necessary as part of the procedure, for example a blood transfusion, or the removal of particular tissue. 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 hospital, how they will feel afterwards and so on.

- The information provided to patients and those close to them will vary depending on how much information they require: 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 is to be given. However, the presumption must be that the patient wishes to be well informed about the risks, benefits and alternatives of the various options.

- In Montgomery v Lanarkshire Health Board (2015) it was held that the duty to warn about risks of a treatment would no longer be governed by a doctor sensitive test (ie what a responsible body of medical opinion would conclude are the risks that should be disclosed to the patient (as per Bolam) as this no longer reflects a modern doctor-patient relationship.

The new test is based on materiality of risk:

A doctor is under a legal duty to take reasonable care to ensure that the patient is aware of any material risk / benefits involved in the recommended treatment, as well as for any reasonable alternative or variant treatment.

Limited Exceptions

(i) A clinician is entitled to withhold information if he or she reasonably considers that its disclosure would be seriously detrimental to the patient's health;
(ii)A clinician is also excused from conferring with the patient in situations of necessity: where emergency treatment is required and the patient is unconscious for example.

It is of note, that if challenged, the clinician would need to be able to justify that his or her application of those exemptions was reasonable in all the circumstances.

Material Risk

The Montgomery test of material risk asks, whether in the circumstances of the individual case, either:

- A reasonable person in the patient's position would be likely to attach significance to the risk; or

- The clinician is, or should reasonably be aware that the **particular patient** would be likely to attach significance to it.

Additional

- Members of the medical profession have a duty of care to advise and inform patients of anything which the ordinary sensible patient would be justifiably aggrieved not to have been told when fully appraised of its significance.
- Medical professionals do not need to warn of risks which are theoretical and are not material. A patient cannot rely on Montgomery to state that they have an absolute right to know all risks, and in particular where evidence suggests that the risk would not, in fact, have been material to them.
- How the patient has communicated with clinicians and decisions taken during treatment are also relevant.
- A clinician should not take it upon themselves to decide not to inform a patient about a course of action they may themselves consider unwise, the patient if they wish to do so should make this decision themselves.
- Where the patient makes clear (verbally or non-verbally) that they do not wish to be given this level of information, this must be documented in the patient record.
- For further information on consent best practice please refer to the GMC guidance
- For further information on the case of Montgomery v Lanarkshire Health Board (2015) see references.

Where appropriate, information will be provided to patients by competent health professionals who will be involved in their care/treatment. For common procedures, information leaflets will be provided by the clinician involved in the patient's care or in the ward. Other information may be available via recognised websites. However the evidential value of information leaflets will be limited unless accompanied by a discussion with the patient to discuss the material risks/benefits involved with the treatment or any alternative/variant treatment, and this is then documented. In so far a material risks, the professional must consider whether a reasonable person in the patient's position would be likely to attach significance to the risk, or whether the professional should reasonably be aware that this particular patient will attach significance to the risk.

The information provided to patients including discussions on the risks, benefits and alternatives of the proposed procedure(s) (this could be a written leaflet and verbal) must be documented clearly within the patients' notes or on the consent form.

Some of the written information leaflets provided to patients here at QVH are produced internally and approved by the Patient Information Group. Other nationally approved information leaflets are ordered and distributed by various departments and directorates. However it is still imperative on light of Montgomery that an appropriate discussion with the patient also takes place as indicated.

The Patient Information Group ensures all patient information adheres to corporate and national guidelines, and are kept up to date. The group reviews all patient information to ensure that the language is clear and easily understood, with no jargon, and the information outlines risks, benefits and alternative options the patient may choose from.

5.2 Archiving arrangements for any information given to patients to support their decision making

Please refer to the Guidelines for Producing Patient Information for any information given to patients to support their decision making.

5.3 Provision of Information for patients who have communication difficulties

QVH is committed to ensuring that patients whose first language is not English or who have other communication difficulties receive the information they need and are able to communicate appropriately with healthcare staff. It is not appropriate to use a family member or friend to interpret for those who do not speak English. It is essential to use a professional interpreter.

Guidance on translation and interpretation services available can be found in the Trust Interpreting Policy (Provision of Translation and Interpreting Services for Non-English Speakers Policy) which is located on the Qnet.

5.4 Additional procedures

During an operation it may become evident that the person could benefit from an additional procedure that was not within the scope of the original consent. It would be unreasonable to delay the procedure until the person regains consciousness where, for example, there is a real and immediate threat to the person's life. In such circumstances it may be justified to perform the procedure on the grounds that it is in the person's best interests. ***However, the clinician must obtain further consent for any additional procedure*** unless the delay in doing so would genuinely put the patient's life at risk or cause serious harm to their health. The procedure must not be performed merely because it is convenient. The patient or carers/family involved in the consent process must be informed of any additional procedures undertaken at the earliest opportunity.

If a person has refused certain additional procedures before the anaesthetic, then this must be respected if the refusal is applicable to the circumstances. The General Medical Council guidance states that it is good practice to seek the views of the patient on possible additional procedures when seeking consent for the original intervention.

5.5 Access to health professionals between formal appointments

After an appointment with a health professional in out-patients, patients will often think of further questions which they would like answered before they take their decision. Where possible, it will be much quicker and easier for the patient to contact the healthcare team by phone than to make another appointment or to wait until the date of an elective procedure (by which time it is too late for the information genuinely to affect the patient's choice). Contact details can be provided on page 2 - the patient copy, of the consent form for a contact number of the appropriate health professional, or the QVH Patient Advice and Liaison Service.

6. Process for recording the discussion and provision of information to patients.

For significant procedures, it is essential for health professionals to document clearly both a patient's agreement to the intervention and the discussions which led up to that

agreement. This discussion must include amongst other things, (i) the risks of the procedure, (ii) the effect which the occurrence of the risk would have on the particular patient, (iii) the importance to the patient of the benefit of the proposed treatment, (iv) any alternatives or variants available and the material risks verses the benefits involved in those alternatives for the patient. Remember, in view of the Montgomery requirement for the clinician to ensure that the patient is aware of all material risks in so far as this is significant for them personally, it is imperative to ensure good contemporaneous record keeping of the discussions and issues discussed with the individual patient. This may be done either through the use of a consent form (with further detail in the patient's health records if necessary), or through documenting in the patient's health records, particularly where they have given oral consent.

Where a consent form is used, the clinician completing the consent form with the patient MUST provide the patient with a copy. This is to allow the patient time after consent to consider their options. Completed consent forms must be kept with the patients notes.

7. Process for recording that consent has been given

7.1 Availability of forms

Consent forms are produced externally and ordered via the Procurement and Purchasing department. There are two versions of the standard consent form which are available on all wards, outpatients departments and the Minor Injuries Unit:

- **Consent form 1** Patient agreement to investigation or treatment (for all patients)
- **Consent form 2** Parental agreement to investigation for a child under 16 [NB this is only for use for a child under 16.]
- **Mental Capacity Assessment and Best Interest form** orange form to be used for patients 16 years and over to record a mental capacity assessment and (where a patient is found to lack capacity) record a best interest decision where required.

Only the consent forms listed above and other procedure specific consent forms listed in Appendix A may be used within the QVH. Any new consent form introduced to the QVH must be approved by the ECQR Remember the evidential value of pro forma consent forms and information leaflets will be limited unless accompanied by a discussion with the patient to discuss the issues which are specifically relevant to the patient, in particular around material risks, and this is then documented.

In any event where a consent form cannot be used, the consent must be clearly documented within the patient's health records.

All consent forms listed above and in Appendix A are available on the wards and accessible to all healthcare professionals.

7.2 Completing consent forms for patients with capacity

The consent forms provide the space for health professionals to provide information to patients and to sign confirming that they have done so. The provision of information to the patient will incorporate the elements indicated within section 5 and is to be documented. A copy of the signed consent form is kept in the patient's notes and a copy given to the patient.

If the patient signs the form in advance of the procedure for example in outpatients or at a pre-assessment clinic, a health professional (for clarity this mean a registered health professional such as a nurse or operating department practitioner) involved in their care on the day of the procedure can sign the consent form to confirm that the patient still wishes to go ahead and has had any further questions answered. The section on page 4 of the consent form must be signed and dated by the health professional. If there are questions that fall outside of the health professionals sphere of competency these will be documented in the patients notes and the surgeon contacted.

Completed consent forms must be kept with the patient's health records. Any changes to a form made after the form has been signed by the patient must be initialled and dated by both patient and health professional.

Refusal to consent to a procedure or treatment must also be written and kept in the patient's notes.

For children under 16, where they are deemed Gillick competent Consent Form 1 is to be used. Where this is not the case, pink consent form 2 to be used. It is best practice that if the child wishes, they can sign alongside the parental responsibility signature. Parental responsibility must be confirmed prior to taking consent.

7.3 Completing consent forms for patients without capacity

Where treatment is provided to a person who lacks capacity following a best interests decision, a consent form cannot be signed unless someone has parental responsibility (in the case of children under 16 years of age), or has a LPA for health and welfare which authorises them, or they are a court appointed Deputy with similar authority. It must be noted within the orange best interest paperwork why the treatment was decided to be in the patient's best interests, and this information must be kept within the patient's records.

A LPA or Deputy has legal authority to consent for a patient who lacks capacity to do so. This must be recorded on consent form 1 .This is not formally a best interest decision. The Mental Capacity and Best Interest form must be used to establish capacity. However if the LPA/Deputy appears to not be acting in the best interest of the patient seek guidance from Safeguarding Team in the first instance. Legal advice and an application to the Court of Protection may be required.

8. Training

8.1 Process for identifying clinical staff who are not capable of performing the procedure, but who are authorised to obtain consent for that procedure

The process for identifying clinical staff who are not capable of performing the procedure, but who are authorised to obtain consent for that procedure is described in Appendix D.

8.2 Process for providing procedure specific training on consent for clinical staff who are not capable to perform the procedure, but who are authorised to obtain consent for that procedure

The process for providing procedure specific training on consent for clinical staff who are not capable to perform the procedure, but who are authorised to obtain consent for that procedure is described in Appendix D.

8.3 Process for following up where an individual has obtained consent without the authorisation to do so

In the event of someone obtaining consent for a procedure without being authorised to do so, this will be reported immediately as an incident on the QVH Datix system and to the Chief Medical Officer for appropriate action. These incidents will be investigated and managed in accordance with the QVH Incident Reporting and Investigation Policy.

Unauthorised consent would also be identified via the health records audit and any cases escalated to the Chief Medical Officer, reported on the QVH Datix system and investigated.

8.4 Process for notifying the GMC of any individual who has obtained consent without the authorisation to do so.

Once it has been identified that any individual has obtained consent without authorisation to do so, this will be reported to the GMC as soon as possible in writing via practise@gmc-uk.org by the QVH Chief Medical Officer.

9. Equality

This policy and protocol has been equality due regard assessed in accordance with the Trust's Equality Due Regard Assessment Guidance. Completed assessments are available upon request from qvh.edra@nhs.net.

10. Review

This policy will be reviewed in three years' time. Earlier review may be required in response to exceptional circumstances, organisational change or relevant changes in legislation or guidance.

11. Monitoring

Monitoring of this policy will be through reviewing documentation, auditing practices, and assessing patient feedback to ensure compliance and continuous improvement. These will be reported into the Clinical Outcomes and Effectiveness Committee.

12. References

- Family Law Reform Act 1969
- Mental Health Act Commission (1979) *Guidance Note 3: Guidance on the treatment of anorexia nervosa under the Mental Health Act 1983* (updated March 1999)
- Gillick v West Norfolk and Wisbech AHA [1986] AC
- https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors---decision-making-and-consent-english_pdf-84191055.pdf?la=en&hash=BE327A1C584627D12BC51F66E790443F0E0651DA
- Children Act 1989
- Human Fertilisation and Embryology Act 1990 as amended by the 2008 Regulations
- Human Tissue Act 2004
- National Collaborating Centre for Mental Health, commissioned by the National Institute for Clinical Excellence (2004) National Clinical Guideline 16: *Self-harm.*
- Mental Capacity Act (2005) Code of Practice
- *Mental Capacity Act 2005 (lasting Powers of Attorney, Enduring Powers of Attorney and Public Guardian) Regulations 2007,* SI 2007,2161
- *QVH Mental Capacity Act and DOLS Policy*
- *Mental Health Act 1983 as amended by the Mental Health Act 2007*
- HM Government (March 2015) *Working Together to Safeguard Children: A guide to inter-agency working to safeguard and promote the welfare of children.*
- BMA (2007) *Withholding and Withdrawing Life-prolonging Medical Treatment: Guidance for decision making (third edition)* (Part 2.11). London BMJ Group
- Human Fertilisation and Embryology Act 2008
- www.nice.org.uk/nicemedia/pdf/CG16FullGuideline.pdf
- *NHS Trust A v M, NHS Trust B v H* [2002] Fam 348 Fam Div
- http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_087073.pdf
- Glass v The United Kingdom – 61827-00[2004}ECHR 103
- Montgomery v Lanarkshire Health Board (2015) UKSC 11
- Reference guide to consent for examination or treatment (DH, 2001)
- Good practice in consent: achieving the NHS plan commitment to patient centred consent practice (Health Service Circular HSC 2001/023)

- Seeking Consent: working with children (DH, 2001)

- Relevant guidance and codes of conduct relating to consent published by professional registration councils such as the General Medical Council, Nursing & Midwifery Council, General Social Care Council and the Health Professions Council

- Mental Health Act Code of Practice (2007) and (2008) –

- https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/139565/dh_4122427.pdf

- http://www.legislation.gov.uk/ukpga/2005/9/contents

Appendix A

Current forms in use in this organisation:

Consent Form 1 (QVH39)

Patient agreement to investigation or treatment

Consent Form 2 (QVH40)

Parental agreement to investigation or treatment for a child

Cataract Consent Form (SP 24)

Patient agreement to investigation or treatment for Right/Left Cataract Extraction or Intraocular Lens Insertion

Consent Form for Nipple and Areola Micro-Pigmentation (available from Breast Care Nurses)

Patient agreement to the application of semi-permanent pigmentation to nipple and areola

Major Head and Neck Consent Form

Orthognathic Consent Form

Dental Extraction Consent Form

Skin Lesion Consent Form (in development 2018)

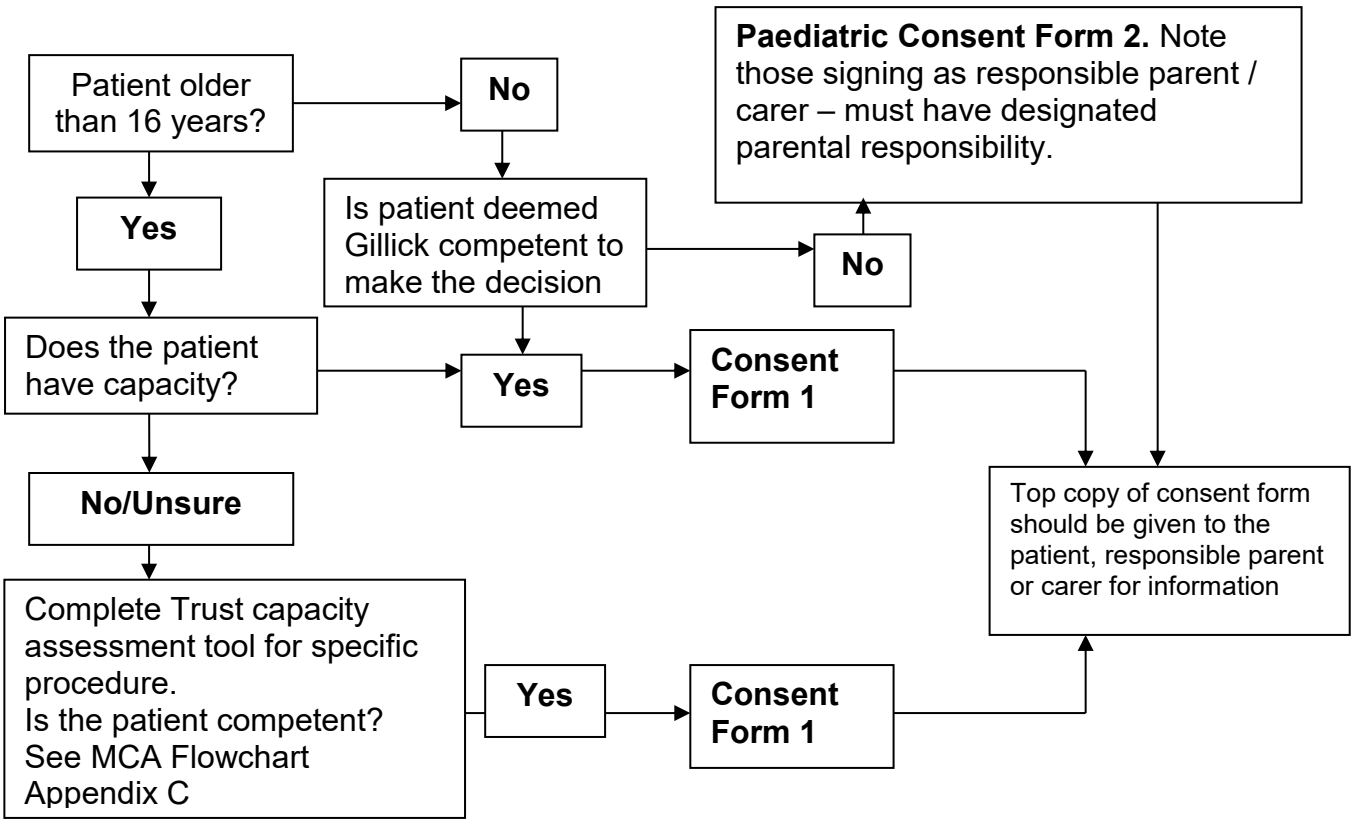
Mental Capacity Assessment and Best Interest Form (orange)

Appendix B

QVH Consent Process

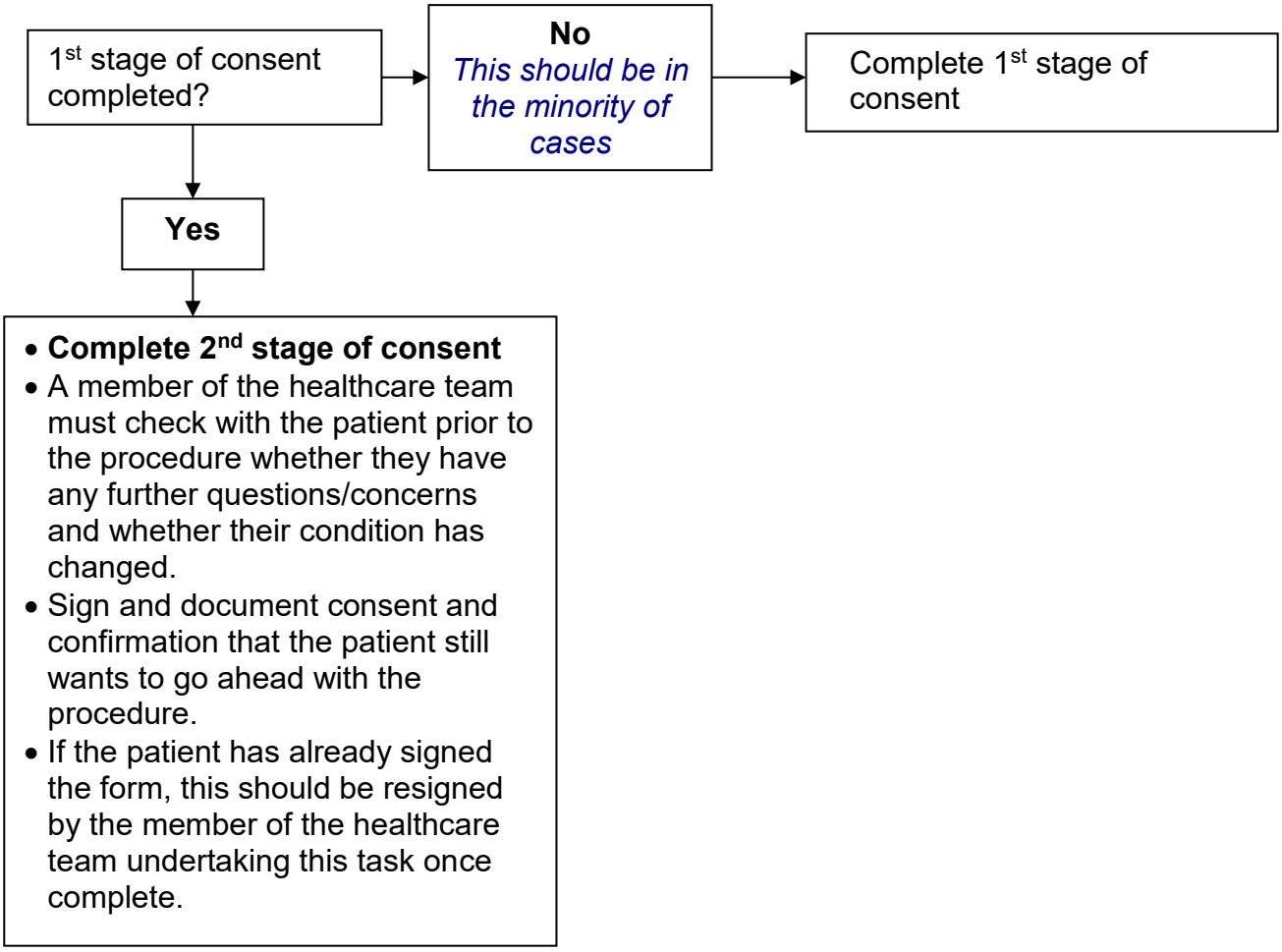
1st stage of Consent:

It is expected QVH practice that consent should be taken in advance of the patients proposed procedure (e.g at their outpatient appointment or pre-assessment clinic) where there is time for the patient to properly consider the options they have, for a meaningful discussion to take place with the patient, for the provision of information in line with this Policy and for healthcare professionals to respond to questions. In the circumstance of the patient requiring emergency treatment however, it is acceptable to complete only the 1st stage of consent so far as possible.

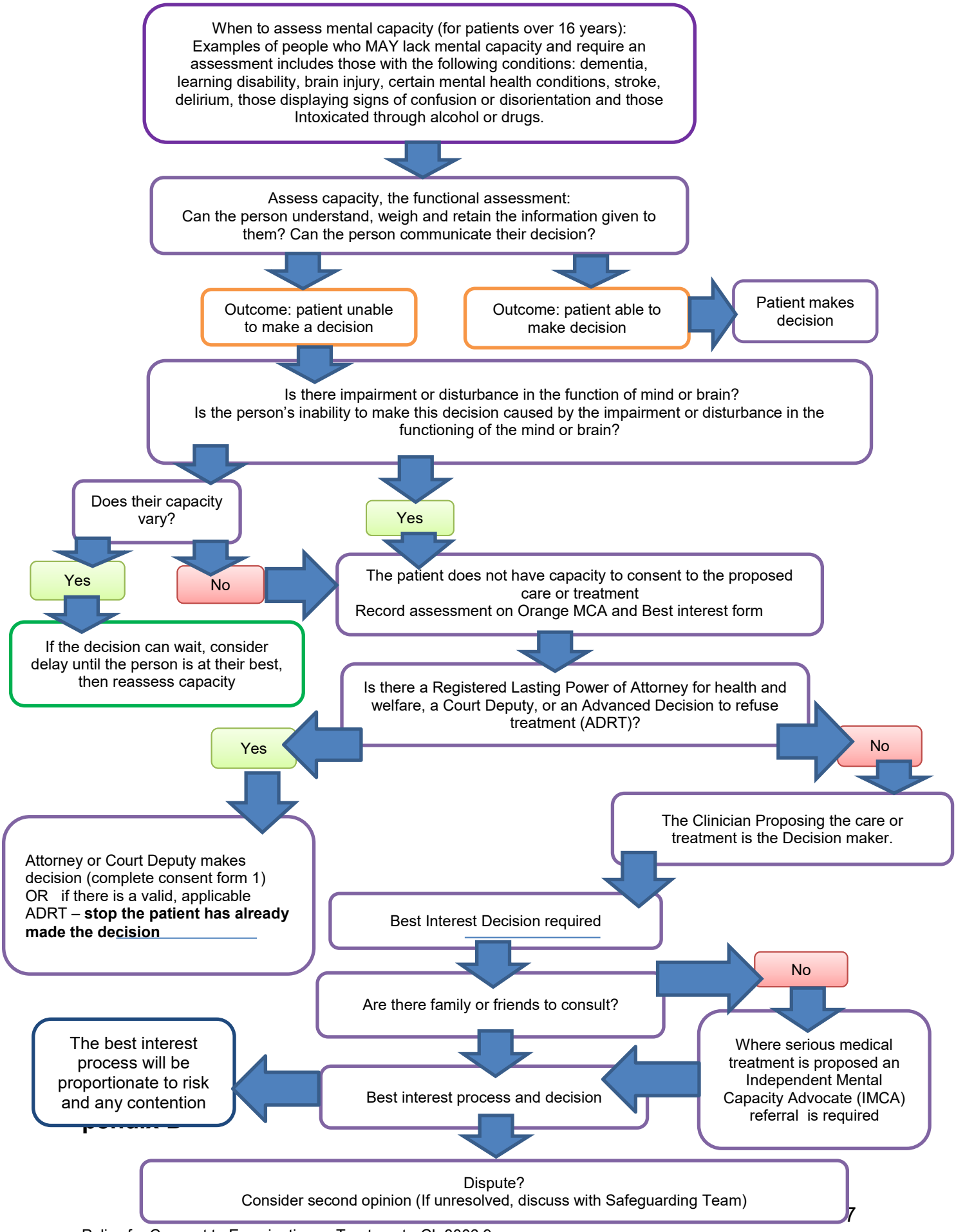


2nd Stage of Consent:

A member of the healthcare team must check and re-confirm before the procedure, that the patient or responsible parent still consents and agrees to undergo the procedure and that they have had an opportunity for any further questions to be answered or information provided.



Appendix C: Mental Capacity Act (MCA) Flowchart



Delegation of consent taking

This Appendix relates only to **1st Stage consent** taking. Subsequent **2nd stage of consent** prior to the procedure can be undertaken by any appropriate healthcare professional without recourse to this procedure in so far as they are able to answer any additional questions of the patient, or seek input from a senior colleague where this is necessary.

Introduction

The most appropriate person to take consent for treatment is normally the clinician undertaking the procedure, or another clinician who is also competent to undertake the procedure and aware of any clinical or other factors which may be relevant to that patient.

Consent is taken by senior staff within QVH who have the knowledge and skills to perform the procedure due to the experience and level of training already received. These grades can include the following:

- Consultant
- Associate Specialist
- Staff Grade
- Specialty Trainee (ST3 and above) or Trust Registrar
- Senior Fellow
- Locum consultant

All newly employed resident doctors (specialty trainees, trust registrars and senior fellows) should have a conversation with the consultant prior to gaining consent for a procedure for the first time at QVH, to ensure that they are comfortable to do so.

Identifying Staff who are not capable of performing the procedure but are authorised to obtain consent

Under exceptional circumstances the role of the consent taker can be delegated to a member of junior staff who is unable to undertake the procedure. It is the responsibility of the consultant delegating consent to satisfy himself/herself that the person to whom consent is delegated to has the knowledge detailed in the “Delegated Consent Training Assessment Form” detailed below and that the delegated consent taker is able to ensure that the patient is aware of any material risk / benefit involved in the recommended treatment, and of any reasonable alternative or variant treatments so far as they relate to that individual patient.

The junior staff within QVH who will require training prior to obtaining consent are the following:

- Core Surgical Trainee (CT2) or Junior Clinical Fellow
- Core Dental Trainee (DCT1/2) or Junior Dental Fellow
- Speciality Trainee (ST1 and 2)
- Foundation doctor (FY1/2)
- Ophthalmic nurses Band 6 via specific guidelines
- Optometrist via specific guidelines

- Clinical Specialist/Extended Scope Practitioner, Occupational Therapist or Physiotherapist
- Advanced Clinical Practitioner

The Service Manager for each Directorate will retain and review annually a list of the general procedures that clinical staff are required to obtain consent for and send to the Chief Medical Officer. This list should be minimal as delegated consent is for exceptional circumstances only.

Process for the delivery of procedure specific training

In circumstances where a junior member of staff is required to obtain consent training by the accountable Consultant or qualified clinician, it must be carried out before the staff member is authorised to obtain consent for that procedure. This training may be delivered in a group as part of local induction / doctors training session or individually. In order to demonstrate the individual has attended training the "Delegated Training Assessment Form" must be completed and sent to the relevant Directorate Service Manager who will retain the training records for delegated consent.

Delegated Consent Training Assessment Form

For use for those that are NOT capable of performing the procedure but may take procedure specific consent

Name / type of procedure (s):	
Has the person (s) familiarised themselves with QVH Policy on Consent?	Yes ☐ No ☐
Has the person (s) familiarised themselves with the different Consent Forms	Yes ☐ No ☐
Can the person (s) being assessed list the benefits of the procedure?	Yes ☐ No ☐
Can they list the serious and frequently occurring and material risks of the procedure?	Yes ☐ No ☐
Do they know where to locate the relevant patient information?	Yes ☐ No ☐
Do they know what to do if they are asked a question to which they do not know the answer?	Yes ☐ No ☐
Do they know any extra procedures that may be involved?	Yes ☐ No ☐
Do they know whether the procedure requires anaesthesia?	Yes ☐ No ☐
Do they know how to contact an interpreter/ translator?	Yes ☐ No ☐

Declaration

I confirm that the staff name (s) listed below have/has been trained to obtain consent for the procedure listed above.

Name	Signature
Name	Signature

Name	Signature
Name	Signature
Name	Signature
Name	Signature
Name	Signature
Signed…….. Job Title…… Date……	
Please send this completed form to the Directorate Service Manager	