PATIENT INFORMATION AND CONSENT POLICY

GENERAL POLICY No. GP2

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PATIENT INFORMATION AND CONSENT POLICY

1 INTRODUCTION

This policy is drawn directly from Department of Health guidance www.dh.gov.uk/consent . The policy creates the framework to set standards for gaining informed and understood patient consent across all services in the Trust. This includes providing sufficient information to enable patients, or a person acting on their behalf, to make informed choices and decisions about their care. The policy is based on the general legal and ethical principle that valid consent must be obtained before starting treatment or physical investigation, or providing personal care, for a patient. This principle reflects the rights of patients to determine what happens to their own bodies and to be active partners in their own healthcare. (DH 2009)

2 STATEMENT OF INTENT

The Trust is registered with the Care Quality Commission (CQC) which sets the standards of care expected of all NHS Trusts. The Trust is committed to ensuring that staff who are required to obtain patient consent comply with the Care Quality Commission’s Essential Standard of Care that outlines best practice guidance relating to consent:

- Outcome 2 : Consent to Care and Treatment
- Outcome 4 : Care and Welfare of People who use Services

This policy outlines the Trust’s standards for gaining patient consent and providing patient information as required by the Department of Health, CQC and the NHS Litigation Authority.

3 DEFINITIONS

Valid consent
For consent to be valid, it must be given voluntarily by an appropriately informed person who has the capacity to consent to the intervention in question

Mental Capacity
Mental capacity is the ability of a person to make decisions for himself/herself. This means that the person is able to:
- understand information given to him/her about particular issues
- retain that information long enough to be able to make a decision
- weigh up the information available to make a decision
- communicate that decision.
Mental Capacity Act 2005
The Act aims to protect people who do not have the mental capacity to make decisions for themselves. The Mental Capacity Act gives clear guidelines for carers and professionals about who can take decisions in these situations.

Best Interests
Under the MCA, anybody making a decision about the care or treatment of an individual, who has been assessed as lacking the capacity to make that decision for himself, will be required to take any statement of wishes and preferences into account when assessing that person’s best interests.
Part of assessing best interests should include making reasonable efforts to find out what a person’s wishes, preferences, values and beliefs might be. This is likely to involve contacting the person’s family or other care providers.

Advanced Decisions
An advance decision is intended to be a binding refusal of certain kinds of treatment as specified by the person making the advance decision. Advanced decisions state specific medical treatment that is to be refused in specific circumstances and cannot demand specific treatment be given. If the advanced decision refuses life sustaining treatment it must be in writing, signed and witnessed and clearly state that the decision applies even if life is at risk.

Lasting Power of Attorney
A lasting power of attorney (LPA) is a legal document where a patient can say who they want to make certain decisions for them if they cannot make them for themselves. A Lasting Power of Attorney cannot be used until it is registered with the Office of the Public Guardian. A health and welfare Lasting Power of Attorney can only be used once the donor (the person needing help) is unable to make their own decisions.

Independent Mental Capacity Advocate (IMCA)
An IMCA safeguards the rights of people who:
• are facing a decision about a long-term move or about serious medical treatment
• lack capacity to make a specified decision at the time it needs to be made; and
• have nobody else who is willing and able to represent them or be consulted in the process of working out their best interests, other than paid staff

Clinical Patient Information Leaflets
These leaflets are designed to enable patients to have sufficient information to understand clinical risks, benefits and alternative options if available to help the patient make informed decisions about their healthcare. This includes all internally produced information about treatments, conditions and procedures and care.

Service Patient Information Leaflets
All internally produced information about our services, what services they provide, opening times and contact details.
External Patient Information Leaflets
These are leaflets produced by external bodies. Staff should only recommend reputable sources such as NHS Choices and Diabetes U.K.

DUTIES

4.1 Duties within the Organisation

Chief Executive
The Chief Executive is responsible for the statutory duty of quality and clinical governance and takes overall responsibility for this policy.

Trust Board
The Trust Board have overall responsibility for ensuring that the Trust delivers high quality services that are efficient and effective.

The Trust Board is made up of the Chairman, Chief Executive, Executive Directors, Medical Director and Non-Executive Directors. The Board of Directors oversee the running of the Trust, make the decisions that shape future direction, monitor performance and ensure accountability

Quality and Governance Committee
The primary function of the Quality and Governance Committee is to provide assurance to the Board of overall compliance with all statutory and regulatory obligations and will ensure the effective management of Incidents, Complaints, Claims and Inquests and subsequent dissemination of lessons learnt, this includes compliance with the Trusts consent standards.

Quality, Patient Experience and Risk Group
This group provides information and assurance to the Quality and Governance Committee regarding how the Quality and Risk Strategies are being implemented and managed within the organisation.

In addition the group provides information and assurance to the Quality and Governance Committee regarding how risks are being managed within the organisation and escalates them when appropriate to the Quality and Governance Committee in accordance with the Incident Reporting Policy.

Incidents reported that related to the process of gaining consent would be subject to a root cause analysis and reported via this group and lessons learnt shared as appropriate

This group accepts the action plans of the Resuscitation Group to monitor compliance with all relevant standards and guidance.

Clinical Policies and Procedures Group
This group oversees the development and the updates of clinical procedures and clinical patient information leaflets. The group co-ordinates the production of evidence based information for patients regarding the treatments, conditions and procedures for care as required.
4.2 Specific Duties of Staff

**Divisional Managers are responsible for ensuring:-**

- All relevant staff are compliant with this policy
- All relevant staff fulfill the standards expected by the Trust and use the Trust's consent forms
- Clinical services participate in clinical audits or a root cause analysis on consent standards as required
- Divisional managers oversee the completion of any consent related action plans at the Divisional Governance Group Meetings (DGGM)
- Divisional Managers oversee the production and update of Clinical Patient Information Leaflets for their services at DGGMs

**Service Leads are responsible for ensuring:-**

- All relevant staff are working within the standards of this policy and only use Trust Consent Forms
- Clinical services participate in clinical audits or a root cause analysis on consent standards as required
- There is a nominated author, when required, for the production and update of Clinical Patient Information Leaflets

**Team Leaders/Managers are responsible for ensuring:-**

- All clinical staff involved in gaining consent comply with this policy
- Ensure staff use appropriate Trust consent forms
- Ensure staff only use internally produced clinical patient information leaflets that have been approved by the Clinical Policy and Procedure Group

**Individual Clinical Staff are responsible for:-**

- Complying with the consent standards in this policy
- Supporting clinical audits being undertaken on behalf of the Trust
- Attending Essential Learning Training as per Trust Training Matrix
- Using Trust consent forms
- Only using internally produced clinical patient information leaflets that have been approved by the Clinical Policy and Procedure Group
- Being aware of what information is available to patients
- Actively sharing information with patients about services, treatment and care
- Documenting in the patients health records the discussion and provision of information to patients.
5. **PROVISION OF INFORMATION**

The provision of information is central to the consent process, depending on each individual patients needs, before patients can come to a decision about their treatment:

- they need comprehensible information about their condition
- information about possible treatments/investigations
- the risks and benefits of treatments/ investigations (including the risks/benefits of doing nothing)
- possible alternative treatments and their risks and benefits
- they also need to know whether additional procedures are likely to be necessary as part of the procedure, for example the removal of tissue samples

Once a decision to have a particular treatment/investigation has been made, patients need information about:

- what will happen
- where to go
- how long they will be in clinic
- how they will feel afterwards
- management of pain relief if appropriate

Clinical staff need to make the presumption that the patient wishes to be well informed about the risks and benefits of the various options. Where the patient makes clear, verbally or non-verbally, that they do not wish to be given this level of information, this should be documented in the health records.

Also see How Information is Provided to Patient Pathway. Appendix G

5.1 **How information is provided to patients to support their decision-making, including risks, benefits and alternatives where appropriate**

Clinical patient information leaflets contain information to support patients in their decision making, including risks and benefits and alternatives where appropriate

The Trust supports a range of methods for providing patient information, this will either be:

- Verbal information and the discussion recorded in the patients health records
- An internally produced patient information leaflet
- An externally produced patient information leaflet
- A completed Department of Health Consent Form, which specifies the treatment and the related risks, a copy of which is shared with the patient
Either be provided at the clinical contact or sent in advance e.g. with the Appointment

Internally produced Patient Information Leaflets will be placed on the Trust’s web site

5.2 How the discussion and provision of information to patients is recorded

Record Keeping:-
Clinical staff will record in the patient’s notes what type of information has been given to the patient by specifying:

- The name of the leaflet
- The name of the author/ producer
- The date it was produced (and the review date if included)
- Including summary of what information was explained to the patient, including risks, benefits and alternatives where appropriate

5.3 Provision for patients whose first language is not English

The Trust is committed to ensuring that patients whose first language is not English, and who cannot understand English, receive the information they need appropriately with healthcare staff. It is not appropriate to use children or other family members to interpret for family members who do not speak English.

The Trust uses ‘Language Line’ to reduce delay for the patient by resolving language difficulties immediately. Each service has an ID code which can be requested from your manager. The service will be used for the following circumstances:-

- When written consent is needed for new DH consent forms and there is limited time to arrange a face to face interpreter
- For Initial Health Contacts

Face to face interpreting is considered best practice and where possible should be implemented. Your line manager will advise on how to access Trust interpreter services.

5.4 Access to bespoke or specialist information

Patients may sometimes request more on line information about their condition or about a proposed treatment. The following sites provide arrange of reliable information:

- NHS Clinical Knowledge Summaries
- NHS Evidence
- NHS Choices
  - NHS Direct
  - Site specific – such as Diabetes UK, British Heart Foundation, Asthma UK
Some patients may need information in a format that meet their specific needs:

- Specific provision will be made for those with a learning disability to meet their specific communication needs e.g. all services will have an organisational leaflet in an easy to read format
- Specific provision should be made for other patient groups who would not find printed information particularly accessible (audio tapes, Braille etc) together with details of local independent advocacy groups where these exist

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

Clinical Patient Information Leaflets Developed Internally
The Trust will maintain a central record of clinical patient information leaflets developed within the Trust, co-ordinated by the Quality and Governance Service and have a record of those that either have been discontinued or are due to be updated.

Clinical Patient Information Leaflets Developed Externally
Each division will have a central record of clinical patient information leaflets distributed in each service and have a copy of the information and a record of leaflets that have been discontinued.

Divisions will keep an archive record of any other formats they use to share clinical information e.g. audit tapes, DVD's

Divisions will forward a copy of their central record to the Clinical Procedures and Policies Group, annually.

Service Patient Information Leaflets Developed Internally
The Trust will have a central record of service information leaflets developed within the Trust, co-ordinated by the Communications Team, with a copy of the leaflet and a record of those that have either been discontinued or are due to be updated.

6 PROCESS FOR OBTAINING CONSENT

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.
6.1 Single stage process
In many cases, it will be appropriate for a health professional to initiate a procedure immediately after discussing it with the patient. For example, during an ongoing episode of care a physiotherapist may suggest a particular manipulative technique and explain how it might help the patient’s condition and whether there are any significant risks.

If the patient is willing for the technique to be used, they will then give their consent and the procedure can go ahead immediately. In many such cases, consent will be given orally.

If a proposed procedure carries significant risks, it will be appropriate to seek written consent, and health professionals must take into consideration whether the patient has had sufficient chance to absorb the information necessary for them to make their decision. As long as it is clear that the patient understands and consents, the health professional may then proceed.

6.2 Two or more stage process
In most cases where written 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, or it might be over a whole series of consultations with a number of different health professionals. The consent process will therefore have at least two stages: the first being the provision of information, discussion of options and initial (oral) decision, and the second being confirmation that the patient still wants to go ahead. The consent form should be used as a means of documenting the information stage(s), as well as the confirmation stage.

Patients receiving elective treatment or investigations for which written consent is appropriate should be familiar with the contents of their consent form before they arrive for the actual procedure, and

- should have received a copy of the page documenting the decision-making process.
- They may be invited to sign the form, confirming that they wish treatment to go ahead, at any appropriate point before the procedure: in out-patients, at a pre-admission clinic, or when they arrive for treatment.
- If a form is signed before patients arrive for treatment, however, a member of the healthcare team must check with the patient at this point whether they have any further concerns and whether their condition has changed.
- This is particularly important where there has been a significant lapse of time between the form being signed 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?”
While administrative arrangements will vary, it should 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 gown), unless this is unavoidable because of the urgency of the patient’s condition.

6.3 **Routine and Low Risk procedures**

It will not usually be necessary to document a patient’s consent to routine and low-risk procedures, such as providing personal care or taking a blood sample. 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 would be helpful to do so.

7 **PROCESS FOR RECORDING THAT CONSENT HAS BEEN GIVEN**

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 may be done either through the use of a consent form (with further detail in the patient’s notes if necessary), or through documenting in the patient’s notes that they have given oral consent.

7.1 **Completing consent forms**

The standard Department of Health Consent Forms provides space for a health professional to provide information to patients and to sign confirming that they have done so. The health professional providing the information must be competent to do so and to carry out the procedure.

If the patient signs the form in advance of the procedure (for example in out-patients or at a pre-assessment clinic), a health professional involved in their care on the day should sign the form to confirm that the patient still wishes to go ahead and has had any further questions answered.

7.2 **Availability of Forms**

Copies of standard consent forms and forms for adults who are unable to consent for themselves (Form 4) are listed in Appendix B and available on the Trust’s web site for printing. If printed stationery order forms are required they would need be ordered by the Service Manager.

There are three versions of the standard consent form:

- **Form 1** for adults or competent children,
- **Form 2** for parental consent for a child or young person
• **Form 3** for cases where it is envisaged that the patient will remain alert throughout the procedure and no anaesthetist will be involved in their care.

The use of form 3 is optional but may be thought more appropriate than form 1 in situations where patients do not need to be made aware of issues surrounding general or regional anaesthesia and do not need to make any advance decisions about additional procedures because they will be in a position to make any such decisions at the time if necessary.

### 7.3 Written Consent

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 consent form. The signature is evidence of the process of consent-giving, not a binding contract.

It is rarely a legal requirement to seek written consent, (The Mental Health Act 1983 and the Human Fertilisation and Embryology Act 1990 require written consent in certain circumstances) but it is good practice to do so if any of the following circumstances apply:

- The treatment or procedure is complex, or involves significant 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’)
- 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 Clinical Director of Quality and Governance on behalf of Wirral Community NHS Trust - as this would be an exception to the norm
- See Appendix F for when written consent is needed in Wirral Community NHS Trust

### 7.4 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 risks. 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 genuinely to make a decision about whether or not to undergo anaesthesia. Patients should therefore either receive a general leaflet about anaesthesia in out-patients, or have the opportunity to discuss anaesthesia in a pre-assessment clinic. The anaesthetist should ensure that the discussion with the patient and their consent is documented in the anaesthetic record, in the patient's notes 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 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. (see the Trust’s Clinical Protocols for Dental Services)

7.5 Filing of Completed Consent Forms

Completed forms should be kept with the patient's notes and follow the Trust’s Record Keeping Policy. Any changes to a form, made after the form has been signed by the patient, should be initialled and dated by both patient and health professional.

7.6 Emergencies

Clearly in emergencies, the two stages (discussion of options and confirmation that the patient wishes to go ahead) will follow straight on from each other, and it may often be appropriate to use the patient’s notes to document any discussion and the patient’s consent, rather than using a form. The urgency of the patient’s situation may limit the quantity of information that they can be given, but should not affect its quality.

7.7 Treatment of young children

Only people with ‘parental responsibility’ are entitled to give consent on behalf of their children. You must be aware that not all parents have parental responsibility for their children, for example, unmarried fathers prior to December 2003 do not automatically have such responsibility although they can acquire it (See consent form 2 on Trust web site).

Since December 2003, the father acquires parental responsibility if he jointly registers the child’s birth with the mother (even if not married).

If you are in any doubt about whether the person with the child has parental responsibility for that child, you must check.
7.8 Access to health professionals between formal appointments

After an appointment with a health professional, patients will often think of further questions which they would like answered before they 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).

All clinical services / practices need to inform patients when they are available for calls and the defined times to talk to a doctor or health professional.

7.9 Open access/drop in clinics

Where patients access clinics directly, it should not be assumed that their presence at the clinic implies consent to particular treatment. You should ensure that they have the information they need before proceeding with an investigation or treatment. This will be provided directly from the clinic and the practitioner providing the service.

7.10 Procedures to follow when patients lack capacity to give or withhold consent

Where an adult patient does not have the capacity to give or withhold consent to a significant intervention this fact should be documented in consent form 4 (form for adults who are unable to consent to investigation or treatment), along with the assessment of the patient’s capacity, why the health professional believes the treatment to be in the patient’s best interests and the involvement of people close to the patient e.g. family members, friends or from an attorney appointed under a Lasting Power of Attorney. The standard consent forms should never be used for adult patients unable to consent for themselves. For more minor interventions, this information should be entered in the patient notes. (see also Trust’s Clinical Protocol for Assessing Mental Capacity and Best Interests)

The Mental Capacity Act 2005 provides a statutory framework to empower and protect vulnerable people who may not be able to make their own decisions. It makes it clear who can take decisions in which situations and how they should go about doing this. It enables people to plan ahead for a time when they may lose capacity.

The whole Act is underpinned by a set of five key principles set out in Section 1 of the Act:

- A presumption of capacity – every adult has the right to make his or her own decisions and must be assumed to have capacity to do so unless it is proved otherwise.
  - Individuals being supported to make their own decisions – a person must be given all practicable help before anyone treats them as not
being able to make their own decisions.

- Unwise decisions – just because an individual makes what might be seen as an unwise decision, they should not be treated as lacking capacity to make that decision.

- Best interests – an act done or decision made under the Act for or on behalf of a person who lacks capacity must be done in their best interests.

- Least restrictive option – anything done for or on behalf of a person who lacks capacity should be the least restrictive of their basic rights and freedoms.

The Act also makes provision to create an Independent Mental Capacity Advocate (IMCA) who will represent and support patients with major, potentially life changing decisions who have no one else to do this on their behalf. An IMCA will not be the decision-maker but if you are the decision-maker, you will have a duty to take into account the information given by the IMCA.

An apparent lack of capacity to give or withhold consent may in fact be the result of communication difficulties rather than genuine incapacity. You should involve appropriate colleagues in making such assessments of incapacity such as specialist learning disability teams and speech and language therapists, unless the urgency of the patient’s situation prevents this. If at all possible, the patient should be assisted to make and communicate their own decision, for example by providing information in non-verbal ways where appropriate.

Occasionally, there will not be a consensus on whether a particular treatment is in an incapacitated adult’s best interests. Where the consequences of having, not having, the treatment are potentially serious, a court declaration may be sought. (Appendix D)

8 WHY GAINING CONSENT IS ESSENTIAL

Patients have a fundamental legal and ethical right to determine what happens to their own bodies. Valid consent to treatment is therefore absolutely central in all forms of healthcare, from providing personal care to undertaking major surgery. Seeking consent is also a matter of common courtesy between health professional and patients.

8.1 What consent is – and isn’t

“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 take 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. Some patients, especially those with chronic conditions, become very well informed about their illness and may actively request particular treatments. 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. However, treatment may be given if it is in their best interests, as long as it has not been refused in advance in a valid and applicable advance directive. For further details on advance directives see the Department of Health’s ‘Reference Guide to consent for Examination or Treatment’ (2009)

8.2 Guidance on Consent

The Department of Health has issued a number of guidance documents on consent, and these should be consulted for advice on the current law and good practice requirements in seeking consent. Health professionals must also be aware of any guidance on consent issued by their own regulatory bodies.

- Reference guide to consent for examination or treatment provides a comprehensive summary of the current law on consent, and includes requirements of regulatory bodies such as the General Medical Council where these are more stringent. Copies are available from www.dh.gov.uk/consent

- 12 key points on consent: the law in England has been distributed widely to health professionals working in England. This one-page document summarises those aspects of the law on consent, which arise on a daily basis, and is attached at Appendix A. Further copies are available from www.dh.gov.uk/consent

- Specific guidance, incorporating both the law and good practice advice, is available for health professionals working with children, with people with learning disabilities and with older people. Copies of these booklets are available on the internet at www.dh.gov.uk/consent
9 WHO IS RESPONSIBLE FOR SEEKING CONSENT?

The health professional carrying out the procedure is ultimately responsible and accountable for ensuring that the patient is genuinely consenting to what is being done: it is they who will be held responsible in law if this is challenged later.

Where oral or non-verbal consent is being sought at the point the procedure will be carried out, this will naturally be done by the health professional responsible. However, team work is a crucial part of the way the NHS operates, and where written consent is being sought it maybe appropriate for other members of the team to participate in the process of seeking consent.

9.1 How the organisation identifies clinical staff who are not capable of performing the procedure, but who are authorised to obtain consent

The Trust does not authorise ‘delegated consent’ i.e. requesting that another clinician seeks consent who is not capable of carrying out the procedure themselves.

9.2 How the organisation follows up where an individual has obtained consent without the authorisation to do so

- Staff must complete incident forms if aware that consent is being obtained outside the standards set in this policy. The incident will be managed in line with GP8 Incident Reporting Policy
- If there is a complaint or a concern expressed by a patient or their representative there would be an investigation into the situation and any resulting action plan would be monitored at the Quality, Patient Experience and Risk Group. The complaint will managed in line with GP1 Complaints Policy
- Following the annual audit of consent processes, findings and action plans would be monitored by the Quality, Patient Experience and Risk Group

9.3 Responsibility of health professionals

It is a health professional’s own responsibility:

- To work within their own competencies 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 contact your line manager or contact the Director for Quality and Governance

10 REFUSAL TO TREATMENT

If a patient has already signed a consent form, but then changes their mind, you (and where possible the patient) should note this on the form.
Where a patient has refused a particular intervention, you must ensure that you continue to provide any other appropriate care to which they have consented. You should also ensure that the patient realises they are free to change their mind and accept treatment if they later wish to do so. Patients should be advised accordingly if there are any risks to them by withholding consent or where delay may affect their treatment choices. This advice should be recorded in the patient’s records.

If a patient consents to a particular procedure but refuses certain aspects of the intervention, you must explain to the patient the possible risks of their partial refusal. If you genuinely believe that the procedure cannot be safely carried out under the patient's requested conditions, you are not obliged to perform it. You must, however, continue to provide any other appropriate care.

Where another health professional believes that the treatment can be safely carried out under the conditions specified by the patient, you must on request be prepared to transfer the patient’s care to that health professional. All decisions must be documented in the patient’s health record.

11 TISSUE

The legal position regarding the use of human tissue (including blood samples and other bodily fluids provided for testing) raises some difficult issues (See the Human Tissue Act 2004). Such tissue can be very valuable in education and research and its use may lead to developments in medical knowledge and hence improvements in healthcare of all. The Human Tissue Authority (HTA) code of practice states that once tissue has been taken from patients for whatever purpose, it can be stored and used without consent for the following purposes:

- Clinical audit.
- Education or training relating to human health (including training for research into disorders or the functioning of the human body).
- Performance assessment
- Public health monitoring.
- Quality assurance.

At present, this Trust requires that patients should be given the opportunity to refuse permission for tissue taken from them during surgery or other procedure to be used for education or research purposes. Patients are asked for their consent or objection to the use of such tissue and for this to be notified to the laboratory. Patients must also be able to record any objections to particular uses or use of particular tissues.

If the patient refuses for tissue to be taken, this must be documented in the patient's records. Wherever possible, samples of tissue used in this way should be anonymised (i.e. no patient information can be identified) or pseudonymised (which means data can be tracked back to it origins).
Explicit consent is not necessary for public health surveillance using the unlinked anonymous method, but a well-publicised opt-out policy must apply.

12 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 should always ensure that they make clear in advance if any photographic or video recording will result from that procedure.

Photographic and video recordings which are made for treating or assessing a patient must not be used for any purpose other than the patient’s care or the audit of that care, without the express consent of the patient or a person with parental responsibility for the patient. Consent Form 6 must be completed.

Recordings for therapeutic intent are not permitted in this organisation.

If the patient is likely to be permanently unable to give or withhold consent you should seek the agreement of some-one close to the patient. e.g taking an essential photograph for monitoring wound healing rates.

In this organisation written consent must be sought for any form of publication of clinical photography or video recording for non clinical purposes and have prior approval of the Director of Quality and Governance, i.e. for academic publication or conferences, staff must also get approval from the Trust’s Communication Team and a specific Trust media consent form signed.

Ensuring that 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.

13. HOW THE ORGANISATION TRAINS CLINICAL STAFF ON THE CONSENT PROCESS IN LINE WITH TRAINING NEEDS ANALYSIS

The Trust’s Learning and Development Policy outlines how the organisation monitors attendance at training and persistent non attendance.

An annual training needs analysis is overseen and co-ordinated by the Learning and Development Group (L&D) which leads to the development of a

- Trust Wide Mandatory Training Matrix
- Service Specific Mandatory Training Matrix

Consent and record keeping training is part of the Trust’s Mandatory Training Matrix
13.1 How the organisation provides procedure –specific training on consent for clinical staff who are not capable of performing the procedure, but who are authorised to obtain consent for that procedure

The organisation does not authorise the delegation of gaining consent to clinical staff who are not capable of performing the procedure.

14 HOW THE ORGANISATION MONITORS COMPLIANCE WITH THE STANDARDS

See Appendix I for Monitoring Tool for this Policy.

15 EQUALITY IMPACT STATEMENT

During the development of this policy the Trust has considered the needs of each protected characteristic as outlined in the Equality Act (2010) with the aim of minimising and if possible remove any disproportionate impact on employees for each of the protected characteristics, age, disability, gender, gender reassignment, pregnancy and maternity, race, religion or belief, sexual orientation.

If staff become aware of any clinical exclusions that impact on the delivery of care a Trust incident form would need to be completed and an appropriate action plan put in place.

16 REFERENCES


DH (2001) 12 Key Points on consent: the law in England

DH Mental Capacity Act 2005


17 ASSOCIATED DOCUMENTATION

The following list is a guide and is not exhaustive:

- Health Record Policy
- Safeguarding Adults Policy
- Do Not Attempt Resuscitation Policy
- Clinical Protocol for Assessing Mental Capacity and Best Interests
  - Clinical Protocol for Clarification of Parental Responsibility
  - GP1 Complaints Policy
- GP8 Incident Reporting Policy
12 key points on consent: the law in England

When do health professionals need consent from patients?

1. Before you examine, treat or care for competent adult patients you must obtain their consent.

2. Adults are always assumed to be competent unless demonstrated otherwise. If you have doubts about their competence, the question to ask is: "can this patient understand and weigh up the information needed to make this decision?" Unexpected decisions do not prove the patient is without competence, but may indicate a need for further information or explanation.

3. Patients may be competent to make some health care decisions, even if they are not competent to make others.

4. Giving and obtaining consent is usually a process, not a one-off event. Patients can change their minds and withdraw consent at any time. If there is any doubt, you should always check that the patient still consents to you caring for or treating them.

Can children consent for themselves?

5. Before examining, treating or caring for a child, you must also seek consent. Young people aged 16 and 17 are presumed to have the competence to give consent for themselves. Younger children who understand fully what is involved in the proposed procedure can also give consent (although their parents will ideally be involved). In other cases, some-one with parental responsibility must give consent on the child's behalf, unless they cannot be reached in an emergency. If a competent child consents to treatment, a parent cannot over-ride that consent. Legally, a parent can consent if a competent child refuses, but it is likely that taking such a serious step will be rare.

Who is the right person to seek consent?

6. It is always best for the person actually treating the patient to seek the patient's consent. However, you may seek consent on behalf of colleagues if you are capable of performing the procedure in question, or if you have been specially trained to seek consent for that procedure.
What information should be provided?

7. Patients need sufficient information before they can decide whether to give their consent: for example information about the benefits and risks of the proposed treatment, and alternative treatments. If a patient is not offered as much information as they reasonably need to make their decision, and in a form they can understand, their consent may not be valid.

Is the patient's consent voluntary?

8. Consent must be given voluntarily: not under any form of duress or undue influence from the health professionals, family or friends.

Does it matter how the patient gives consent?

9. No: consent can be written, oral or non-verbal. A signature on a consent form does not itself prove the consent is valid - the point of the form is to record the patient's decision, and also increasingly the discussions that have taken place. Your Trust or organisation may have a policy setting out when you need to obtain written consent.

Refusals of treatment

10. Competent adult patients are entitled to refuse treatment, even where it would clearly benefit their health. The only exception to this rule is where the treatment is for a mental disorder and the patient is detained under the Mental Health Act 1983. A competent pregnant woman may refuse any treatment, even if this would be detrimental to the foetus.

Adults who are not competent to give consent

11. No one can give consent on behalf of an adult without competence. However, you may still treat such a patient if the treatment would be in their best interests. 'Best interests' go wider than best medical interests, to include factors such as the wishes and beliefs of the patient when competent, their current wishes, their general well-being and their spiritual and religious welfare. People close to the patient may be able to give you information on some of these factors. Where the patient has never been competent, relatives, carers and friends may be best placed to advise on the patient's needs and preferences.

12. If patient without capacity has clearly indicated in the past, while competent, that they would refuse treatment in certain circumstances (an 'advance refusal'), and those circumstances arise, you must abide by that refusal.

This summary cannot cover all situations. For more detail, consult the Reference guide to consent for examination or treatment, available at www.dh.gov.uk/consent
Appendix B

Department of Health Consent Forms Used in the Trust

All current forms are available on the Trust’s web site, with the logo of the Trust added.

**Consent form 1**
Patient agreement to investigation or treatment

**Consent Form 2**
Patient agreement to investigation or Treatment for a child or young person

**Consent Form 3**
Patient / Parental agreement to Investigation or treatment
(Procedures where consciousness not impaired)

**Consent Form 4**
Form for adults who are unable to Consent to investigation or treatment

This form should only be used where it would be usual to seek written consent but an adult patient (18 or over) lacks capacity to give or withhold consent to treatment.

**Consent Form 5**
For clinical photography of wounds to monitor healing progress

**Consent Form 6**
For clinical photography or digital video recordings for clinical reasons

Communications Team have an additional consent form for use of images in the media and within the organisation

Any other consent form for clinical treatment/intervention must be formally approved via the Risk and Governance Group. Staff are working outside the scope of this policy if using any other forms.
## Appendix C

### Useful Contact Details

Contact switchboard on 0151 651 0011:

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lisa Cooper</td>
<td>Director of Quality and Governance</td>
</tr>
<tr>
<td>Ewen Sim</td>
<td>Medical Director</td>
</tr>
<tr>
<td>Sandra Christie</td>
<td>Head of Nursing, Quality and Governance</td>
</tr>
<tr>
<td>Ann Marie Nobes</td>
<td>Head of Safeguarding</td>
</tr>
<tr>
<td>Cindy Freeman</td>
<td>Quality Manager</td>
</tr>
<tr>
<td>Claire Wedge</td>
<td>Patient Safety Advisor</td>
</tr>
</tbody>
</table>
How to seek a court declaration

Clinical staff who are unsure of their position with issues relating to consent for the non emergency treatment of adults who lack capacity should seek the advice firstly from the Service Lead who will liaise with the Clinical Director for Quality and Governance if needed.

Further advice may also be sought from the Safeguarding Team if relevant.

The Director for Quality and Governance would contact the Trust’s legal advisors if needed.

Out of Hours: staff must contact the ‘on call’ duty manager who will decide upon the appropriate action to take.
Appendix E

Seeking consent – remembering the patients perspective

PATIENT

What do they think is wrong with me?

Will it hurt?

What treatment might help?

What are the risks and benefits of the alternatives?

Can I drive / work / look after my family afterwards?

How would it help me?

What would it involve?

Maybe I’d like to talk it over with my family before I decide

What about the risks?

Are there any alternatives?

Will I have to stay in hospital? How long for?
Appendix F

**Guidance for procedures which need a written consent form**

It would not be practicable to anticipate all new areas of service development that require written consent. The list below is not exhaustive but includes a range of services that must use formal Trust consent forms for the following interventions:–

<table>
<thead>
<tr>
<th>Service</th>
<th>Intervention</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Podiatry</td>
<td>Nail Surgery</td>
<td>Risk of post operative infections, risk of poor re growth of nail tissue</td>
</tr>
<tr>
<td>Heart Support Services</td>
<td>Diagnosis Exercise Tolerance Testing</td>
<td>Death or myocardial infarction occurs in about 1 in 10,000 tests Ventricular tachycardia or ventricular fibrillation may occur in about 1 in 5,000 (Hill J, Timmis A 2002)</td>
</tr>
<tr>
<td>Physiotherapy</td>
<td>Acupuncture</td>
<td>Procedure identifies a range of potential risks Potential risk of joint infection following procedure</td>
</tr>
<tr>
<td></td>
<td>Joint and soft tissue injections</td>
<td></td>
</tr>
<tr>
<td>Dental Services</td>
<td>Dental Extractions</td>
<td>Risk of infection or bleeding</td>
</tr>
<tr>
<td>GP Practice</td>
<td>Surgical Interventions</td>
<td>Risk of anaphylaxis from the local anaesthetic and risk of post operative infections Potential risk of joint infection following procedure</td>
</tr>
<tr>
<td></td>
<td>Joint and soft tissue injections</td>
<td></td>
</tr>
<tr>
<td>Minor Injuries Walk in Centre</td>
<td>Wound closure (with or without local anaesthetic)</td>
<td>Risk of infection , scarring, tissue or nerve damage and failure to granulate</td>
</tr>
</tbody>
</table>
Appendix G

How Information is Provided to Patient Pathway

Healthcare professional advises the patient that they require investigation / treatment / operation

Discussion with the patient / carer regarding:
- Investigation
- Benefits / risks
- What to expect
- Recovery

Provision of written information and alternatives if appropriate, this is recorded in the healthcare records and as directed on the appropriate consent form

Process at Assessment Clinic (if using the two stages method)
Discussion with the patient / carer to reiterate:
- Planned investigation / procedure / operation
- What to expect
- Provision of written information
- Opportunity to ask questions / request to seek further information

Provision of written information is documented on patient assessment documentation within the healthcare record or is included as appropriate on the relevant consent form.

Process when patient has the investigation / procedure / operation
Discussion with the patient / carer to reiterate:
- Planned investigation / procedure / operation
- What to expect
- Consent form reviewed / completed and shared with patient

Provision of written information is documented on patient assessment documentation within the healthcare record or is included as appropriate on the relevant consent form.

(Written information detailing any specific aftercare would be expected if needed)
PARENTAL RESPONSIBILITY

Birth mothers automatically have parental responsibility (PR)

Married fathers automatically have PR and do not lose it, even on divorce. Unmarried fathers have automatic PR for their children if they are named on the birth certificate and the birth was registered after 1st December 2003. If this is not the case, unmarried fathers don’t have automatic PR, but may obtain it by:

- Marrying the mother
- Having the name re-registered on the birth certificate
- Making a Parental Responsibility Agreement with the mother
- Obtaining a Parental Responsibility Order from the court
- Obtaining a Residence Order from the court, or
- Becoming the child’s guardian

A step-parent, even if married to a parent of the child, does not automatically have PR for a child. Step-parents can acquire PR through:

- A Court order, or
- A formal agreement to obtain Parental Responsibility

Other people (including step-parents) can also obtain PR

- If appointed as the child guardian
- By way of a residence order from the court
- By having an Adoption Order made in their favour

The local authority can acquire PR through an Emergency Protection Order or Care Order

Always check with foster parents what PR they have assigned to them.

Source: Sections 2-4 of the Children Act as amended by section 111 of the Adoption and Children Act 2002
### APPENDIX I

#### PATIENT INFORMATION AND CONSENT POLICY MONITORING TOOL

<table>
<thead>
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<tbody>
<tr>
<td>Patient Information and Consent Standard 5: 5.2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. Process for obtaining consent</td>
<td>Consent Audit</td>
<td>Clinical Audit Team</td>
<td>Once in calendar year</td>
<td>Divisional Managers</td>
<td>Quality, Patient Experience and Risk (QPER) Group</td>
</tr>
<tr>
<td>b. How information is provided to patients to support their decision making, including risks, benefits and alternatives where appropriate</td>
<td>Consent Audit</td>
<td>Clinical Audit Team</td>
<td>Once in calendar year</td>
<td>Divisional Managers</td>
<td>QPER Group</td>
</tr>
<tr>
<td>c. How the discussion and provision of information is recorded</td>
<td>Consent Audit</td>
<td>Clinical Audit Team</td>
<td>Once in calendar year</td>
<td>Divisional Managers</td>
<td>QPER Group</td>
</tr>
<tr>
<td>d. Process for recording that consent has been given</td>
<td>Consent Audit</td>
<td>Clinical Audit Team</td>
<td>Once in calendar year</td>
<td>Divisional Managers</td>
<td>QPER Group</td>
</tr>
<tr>
<td>e. Archiving arrangements for any information given to patients to support their decision making</td>
<td>Compliance Audit of:- • Quality and Governance Service for Clinical leaflets • Communications Team for Service Leaflets • Divisions for any other information given to patients</td>
<td>Clinical Audit Team and nominated leads in Divisions</td>
<td>Once in calendar year</td>
<td>Divisional Managers</td>
<td>Quality, Patient Experience and Risk Group</td>
</tr>
<tr>
<td>Consent Training Standard 5: 5.3</td>
<td></td>
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</tr>
<tr>
<td>f. How the organisation trains staff on the consent process in line with the training needs analysis</td>
<td>Reports on attendance</td>
<td>Learning and Development Lead</td>
<td>A minimum of twice in the financial year</td>
<td>Divisional Managers</td>
<td>Learning and Development Group</td>
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<tr>
<td>g. How the organisation identifies clinical staff who are not capable of performing the procedure, but who are authorised to obtain consent for that procedure</td>
<td>This is not an approved process in the Trust</td>
<td></td>
<td></td>
<td></td>
<td>Not applicable</td>
</tr>
<tr>
<td>h. How the organisation provides procedure–specific training on consent for clinical staff who are not capable of performing the procedure, but who are authorised to obtain consent</td>
<td>This is not an approved process in the Trust</td>
<td></td>
<td></td>
<td></td>
<td>Not applicable</td>
</tr>
<tr>
<td>i. How the organisation follows up where an individual has obtained consent without the authorisation to do</td>
<td>Via Incident and complaints reports</td>
<td>Head of Quality and Governance Service</td>
<td>As the incident occurs it would be reported in the Monthly Quality Report</td>
<td>Divisional Managers</td>
<td>Quality, Patient Experience and Risk Group</td>
</tr>
<tr>
<td>i. How the organisation monitors compliance with all of the above</td>
<td>1. Consent audit report  2. Compliance Audit of How Patient Information is Archived  3. L&amp;D Attendance Reports</td>
<td>Clinical Audit Team</td>
<td>Once in financial year for audits A minimum of twice in the financial year for L&amp;D reports</td>
<td>Divisional Managers</td>
<td>Quality, Patient Experience and Risk Group and by exception to Quality and Governance Committee</td>
</tr>
</tbody>
</table>