LONDON HEART CLINIC

CONSENT
POLICY AND PROCESS

Policy No	C005
Responsible Person	Anika Jivraj
Date Issued	Jan 2024
Next Review Date	Every two years
Authorised by	
Version No	01

Title	**Consent Policy & Process**
Author	
Responsible Person	Anika Jivraj
Authorised	Anika Jivraj
Issue Date	Jan 2024
Review Date	Every two years unless review required earlier
Policy No and Version	C005 Version 01
References	GMC Good Medical Practice 2013 CQC Fundamental Standards
Appendix	1 to 3
Scope	All individuals in the employ of this establishment *('employ' means any person who is employed, self-employed, volunteer, working under practising privileges or contract of service with this establishment)*

Aim:
The aim of this policy is to provide guidance for staff within LHC about the requirements and processes for obtaining informed consent. And ensure that patients undergoing procedures and treatments are provided with the information and opportunity to be able to give valid and informed consent.

Policy:
This policy is based on the Department of Health's model consent policy and has been updated following recent legislative changes, namely the Mental Capacity Act (2005)

1. Policy

1.1 Why consent is crucial

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 professionals and patients.

1.2 This policy

The Department of Health has issued a range of guidance documents on consent (see section 1.4), and these should be consulted for details of the law and good practice requirements on consent.

This policy sets out the standards and procedures in this establishment that 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.

1.3 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.

Consent is not valid if obtained by fraudulent means.

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.

In general, no-one else can give consent on someone else's behalf even where an adult patient lacks the mental capacity (either temporarily or permanently) to give or withhold consent for themselves However treatment may be given if it is in their best interests, as long as the requirements of the Mental Capacity Act 2005 are adhered to and it has not been refused in advance in a valid and applicable advance directive or advance decision (please see section **5.1** and **6** for more information).

1.4 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.

- **All doctors should refer to** current law on consent and the requirements of the General Medical Council.

- **12 key points on consent: the law in England** has been distributed widely to health professionals working in England. This summarises those aspects of the law on consent which arise on a daily basis and is available from www.dh.gov.uk/consent (see Appendix 1)

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 at www.dh.gov.uk /consent

2 Policy statements

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

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.

Doctors must now ensure that patients are aware of any "material risks" involved in a proposed treatment, and of reasonable alternatives, following the judgment in the case *Montgomery v Lanarkshire Health Board*.

This is a marked change to the previous "Bolam test", which asks whether a doctor's conduct would be supported by a responsible body of medical opinion. This test will no longer apply to the issue of consent, although it will continue to be used more widely in cases involving other alleged acts of negligence.

The new test

In a move away from the 'reasonable doctor' to the 'reasonable patient', the Supreme Court's ruling outlined the new test: "The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it."

It is notable that this decision enshrines in law principles that are already in the GMC's guidance on consent, *Consent: Patients and Doctors Making Decisions Together* (2008), and which are reflected in MPS's own advice materials on consent [read bespoke advice for doctors in England, Wales, Scotland and Northern Ireland].

Patient information leaflets/fact sheets are a useful means of providing information on the procedure and the risks, benefits, alternatives and sources of information, All patient information leaflets used must be developed as per the process for Writing and producing information for patients.

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'). Healthcare professionals **must follow** an advance decision if it is valid and applicable, even if it may result in the person's death. If they do not, they could face criminal prosecution or civil liability.

Each doctor and specialty wishing to delegate the responsibility for obtaining informed consent for specific procedures must:

- identify the procedures for which delegated consent is undertaken.

- develop a procedure specific training package for undertaking delegated consent for that particular procedure. The procedure specific fact sheets may form the basis of this competency-training package.
- identify the individual clinicians (including Specialist Nurses and AHPs) who are trained to obtain delegated consent.

The Registered Manager will maintain a record of those staff that are not capable of performing the procedure but are authorised to take consent. (see Appendix 4)

3 Duties and Responsibilities

All staff have a responsibility for ensuring that the principles outlined within this document are universally applied. This policy applies to all members of staff who are involved in taking consent.

Key duties are identified as follows:

- Registered manager and clinical leads should ensure that all members of staff involved in taking consent are fully conversant with the contents of the policy.
- Clinical Governance Committee is responsible for monitoring compliance and developing any necessary action plans.

4 When should Consent be sought?

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.

4.1 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 on-going 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.

4.2 Two or more stage process

In most cases where *written* consent is being sought, treatment options will

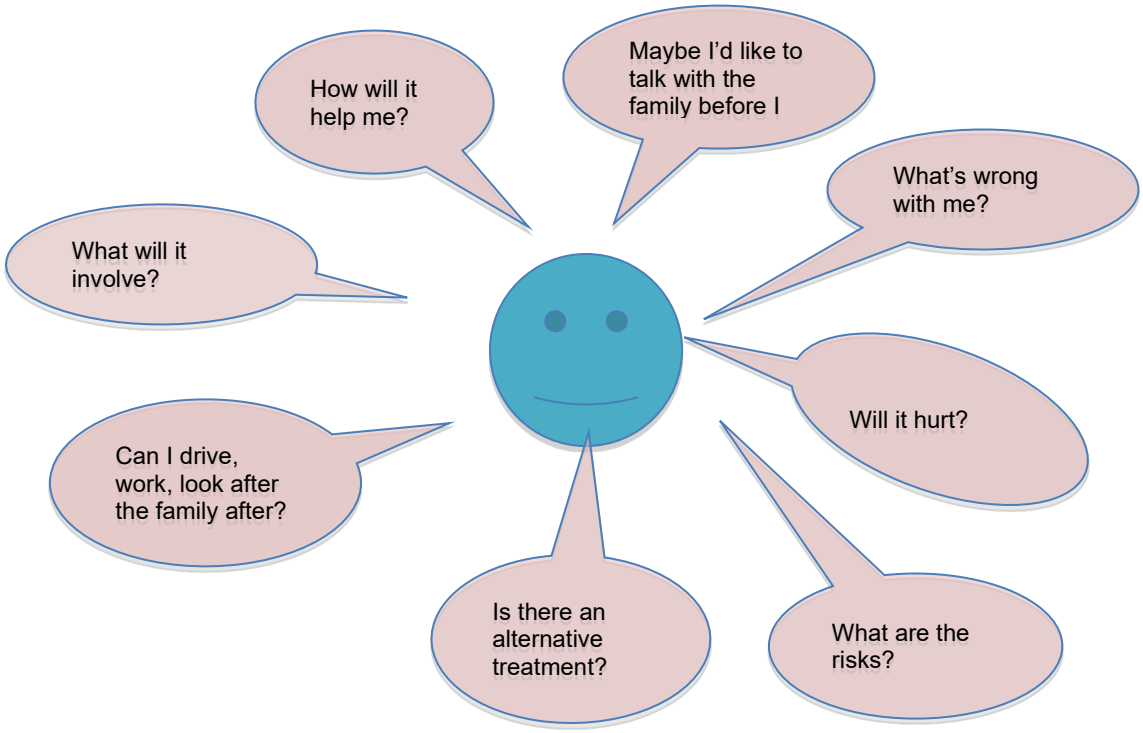
generally be discussed well in advance of the actual procedure being carried out. This may be on just one occasion (either within primary care or in a hospital out-patient clinic), or it might be over a whole series of consultations with a number of different health professionals. The consent process 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.

Seeking consent: remembering the patient's perspective



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:

When patients arrive for consultation / 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 hospital gown), unless this is unavoidable because of the urgency of the patient's condition.

4.3 Seeking consent for anaesthesia and sedation

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 that the patient has given consent to that procedure.**

4.4 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.

4.5 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. However, if new information becomes available regarding the proposed intervention (for example new evidence of risks or new

treatment options) between the time when consent was sought and when the intervention is undertaken, the General Medical Council (GMC) guidance states that a doctor or member of the healthcare team should inform the patient and reconfirm their consent.

The clinician should consider whether the new information should be drawn to the attention of the patient and the process of seeking consent repeated on the basis of this information. 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 risks of the intervention may also have changed.

If consent has been obtained a significant time before undertaking the intervention, it is good practice to confirm that the person who has given consent (assuming that they retain capacity) still wishes the intervention to proceed, even if no new information needs to be provided or further questions answered.

Further information on the law and consent can be found at Appendix 1.

5 Documentation

For clinical intervention 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.

5.1 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 form: the signature is evidence of the process of consent giving, <u>not a binding contract</u>.

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, *e.g. research trials, student observation*
- there may be significant consequences for the patient's employment, social or personal life, *e.g. HIV and Hepatitis B testing, pregnancy testing, stress testing.*

Attending for a procedure and proffering an arm or removing clothing implies consent for the

majority of the population. However, there are times when people may be directed or instructed what to do, without fully understanding why, or what is happening.

In the case of people with a learning disability, who present as inpatients, at out- patient clinics, the Emergency Department, community clinics and surgeries, they may not always arrive fully understanding why or what they are there for.

In these cases it is important to establish a person's preference regarding treatment and their capacity to consent. This should include their level of understanding, their ability to retain the information and their ability to express their choice. This is important even in the most common procedures, such as the taking of blood pressure, an injection, taking of blood and cytology.)

Completed consent forms should be kept with the patient's notes. 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.

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.

5.2 Availability of forms

Patient Consent forms and Consent Information forms are available within this establishment.

6 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 and their risks and benefits (including the risks/benefits of doing nothing). 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.

Patients and those close to them will vary in how much information they want, from those who want as much detail as possible, including details of rare risks, to those who ask health professionals to make decisions for them. There will always be an element of clinical judgement in determining what information should be given. However, the *presumption* must be that the patient wishes to be well informed about the risks and benefits of the various options. 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 their health record. If a hazard that should have been mentioned is not mentioned, the law will impose an obligation to compensate if that hazard occurs. Recent court judgements (Chester vs Afshar) have reinforced the importance of identifying serious risk to the patient, even if that risk is relatively rare. This applies especially if the patient may choose an alternative treatment or no treatment at all if

made aware of the risk.

Patient information leaflets/fact sheets are a useful means of providing information on the procedure and the risks, benefits, alternatives and sources of information, All patient information leaflets used must be developed as per the process for writing and producing information for patients.

Guidance on the preparation of information leaflets is available at Appendix 2 and 3**.**

When providing patient information as part of the consent process, the use and provision of the relevant leaflet must be clearly documented in the patient's health record.

Information leaflets/fact sheets do not negate the clinician's responsibility to provide a verbal explanation of much of the same information. For example, the clinician will clearly need to explain why one procedure has been suggested over the alternatives in a particular client's specific case.

Patients will be asked whether they would like to have a friend or relative present for the discussion regarding their consent.

It is good practice to put a date on all patient information leaflets and schedule a review date in the same manner as you would policies and standard operating procedures.

6.1 Provision for patients whose first language is not English

This establishment is committed to ensuring that patients whose first language is not English receive the information they need and are able to communicate appropriately with healthcare staff.

Interpreter service arrangements are to be made locally if the patient is unable to bring an interpreter with them. It is not appropriate to use children to interpret for family members who do not speak English.

The use of an interpreter must be recorded by their statement on the Consent Form.

This establishment has consent forms and patient information leaflets in Arabic

6.2 Provision for patients with hearing or sight loss

This establishment is committed to ensuring that patients with hearing or sight loss receive the information they need and are able to communicate appropriately with healthcare staff. Interpreter service arrangements are to be made locally if the patient is unable to bring an interpreter with them. It is not appropriate to use a child to act as interpreter for a family member. The British Sign Language (BSL) for Deaf patients will be able to advise on support. The use of an interpreter must be recorded by their statement on the Consent Form. The production of procedure specific information must take into account the need for provision of that information in "easy read", Braille or in large print.

6.3 Access to more detailed or specialist information

Patients may sometimes request more detailed information about their condition or about

a proposed treatment than that provided in general leaflets. The treating clinician should be prepared to provide more detailed information on request.

6.4 Access to health professionals between formal appointments

After the appointment, 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). To ensure patients can easily follow up any queries, there is a section on the Patient Consent form for the health professional to fill in their contact details.

In compliance with cancer treatment guidelines, all patients are given contact details, including the number of the appropriate health professional, prior to treatment.

6.5 Open access 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.

6.6 Provision for patients with a learning disability

For patients with a learning disability, a referral to the patient's specialist learning disabilities team in the community may be needed to ensure information is adequate and appropriate.

7 Who is responsible for seeking Consent?

The health professional carrying out the procedure is ultimately responsible for ensuring that the patient is genuinely consenting to what is being done. It is health professional carrying out the procedure 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. Where written consent is being sought it may be appropriate for other members of the clinical team to participate in the process of seeking consent.

7.1 Delegated consent

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

Each consultant and specialty wishing to delegate the responsibility for obtaining informed consent for specific procedures must:

- identify the procedures for which delegated consent is undertaken (Appendix 4)
- develop a procedure specific training package for undertaking delegated

consent for that particular procedure. The procedure specific fact sheets may form the basis of this competency-training package.

- identify the individual clinicians (including Specialist Nurses and HCAs) who are trained to obtain delegated consent (Appendix 4).

The delegating clinician must remember that they retain accountability for the information provided to the patient at all times, even if they have not personally provided it.

Procedures are in place to ensure that the health professionals 'confirming' the patient's consent have access to appropriate colleagues where they are personally not able to answer any remaining questions.

Where the healthcare professional 'confirming' consent is unable to answer specific patient queries, they should contact the healthcare professional carrying out the procedure (or where not possible a colleague competent to undertake such a procedure) to ensure the information is provided in a timely manner.

7.2 Responsibility of health professionals

It is a health professional's own responsibility to:

- ensure that when they require colleagues to seek consent on their behalf they are confident that the colleague is competent and trained to do so; and
- work within their own competence and not to agree to perform tasks which exceed that competence.

If the patient signs the form in advance of the procedure (for example 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. It will be appropriate for any member of the healthcare team (for example a nurse admitting the patient for an elective procedure) to provide the second signature, as long as they have access to appropriate colleagues to answer questions they cannot handle themselves.

8 Refusal of Treatment

If the process of seeking consent is to be a meaningful one, refusal must be one of the patient's options. A competent adult patient is entitled to refuse any treatment, except in circumstances governed by the *Mental Health Act 1983*. The situation for children is more complex: see the Department of Health's *Seeking consent: working with children* for more detail. The following paragraphs apply primarily to adults. For the young patient who is not deemed to be Fraser competent, refer to the parent/carer. For further information on issues of refusal in a child, please refer to the document: Guidance on Clinical Ethics.

8.1 Advance decisions to refuse treatment

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 chapter 9 of the Mental Capacity Act (2005) Code of Practice.

Healthcare professionals **must follow** an advance decision if it is valid and applicable, 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 should be referred to the Court of Protection. The court does not have the power to overturn a valid and applicable advance decision. While a decision is awaited from the courts, healthcare professionals can provide 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 consider the advance decision as part of their assessment of the person's best interests. Advance decisions made before the Mental Capacity Act came into force may still be valid if they meet the provisions of the Act. There are transitional arrangements for advance decisions to refuse life-sustaining treatment made before 1 October 2007. Further information is available on the Department of Health website.

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 should have the option of transferring their care to another healthcare professional or, if the patient lacks capacity, arrangements should be made for the management of the patient's care to be transferred to another healthcare professional.

If, after discussion of possible treatment options, a patient refuses all treatment, this fact should be clearly documented in their health record. If the patient has already signed a consent form, but then changes their mind, you (and where possible the patient) should note this decision on the consent 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. Where delay may affect their treatment choices, they should be advised accordingly, and the discussion documented in their health record.

If a patient consents to a particular procedure but refuses certain aspects of the intervention, you must explain to the patient, and document in their health record, the possible consequences of their partial refusal. If you genuinely believe that the procedure cannot be safely carried out under the patient's stipulated 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.

9 Mental Capacity

A capable (or competent) person may not be given medical treatment to which he does not consent. The treating of an incapable person is governed by the Mental Capacity Act 2005. In some cases the Act permits medical treatment to be given without the patient's consent, as long as it is in their best interests and has not been refused in a valid and applicable advance directive (living will) or advance decision. Different rules apply in the case of children and in the case of patients detained under the Mental Health Act 1983, which take precedent.

Every adult is assumed to be capable. The default position, therefore, is that all adults have capacity until they are proven otherwise. This assumption will be displaced where:

The patient is unable to make a decision for themselves in relation to the matter because of an impairment of, or a disturbance in the functioning of, the mind or brain.

It does not matter if the impairment or disturbance is permanent or temporary. A person is unable to make a decision for himself if he is unable:

- to understand the information relevant to the decision
- to retain that information
- to use or weigh the information as part of the process of making the decision
- to communicate the decision

The assessment of capacity should be made by the practitioner in charge of the patient's medical treatment. Although a psychiatric opinion may be helpful, it should not in itself be regarded as conclusive.

Restraint will only be lawful to compel an incapable patient to receive treatment when the person using it reasonably believes that it is necessary in order to prevent harm to the patient and the restraint is proportionate to the likelihood and potential severity of that harm.

9.1 Third party consent and advanced decisions

As a general rule, one adult may not provide consent for the medical treatment of another adult. There are two exceptions under the Mental Capacity Act 2005:

- Lasting Power of Attorney (LPA): the person is instructed under an LPA, validly made by the patient while they were still capable and which relates to their health and social care.
- Court of Protection: the person is a Deputy appointed to make decisions

on behalf of the patient.

An advance decision (AD) is a refusal of healthcare treatment made when the person is capable. It will only apply when the person lacks capacity. If it is valid and applicable (i.e. it mentions the proposed treatment and circumstances), it will take precedence over consent given by an LPA appointed prior to the AD or Court of Protection Appointed Deputy. It need not be in writing unless it is refusing life-sustaining treatment, in which case it must be signed and witnessed. An AD that otherwise would be valid and applicable will not be so if:

- the patient has withdrawn the AD
- there are reasonable grounds for believing that circumstances exist that the person did not anticipate when the AD was made and that would have affected the decision.
- A LPA has been appointed since the AD
- Since making the AD, the patient has done something inconsistent with it.

Existing Advance Directives (from before the Mental Capacity Act 2005 came into force) are still valid unless they have subsequently been withdrawn.

9.2 Advocacy – Independent Mental Capacity Advocacy (IMCA)

In some circumstances, an advocate will have to be appointed for a patient who lacks capacity:

- The patient is to have 'serious medical treatment' (see below);
- The patient is to be in hospital for more than 28 days or in a care home for more than 8 weeks;
- The local authority is to arrange for the patient to be accommodated for more than 8 weeks.

A 'serious medical treatment' will involve providing, withdrawing, or withholding treatment in circumstances where:

- a single treatment is proposed and there is a fine balance between its benefits and burdens (and risks);
- there is a choice of treatments but a decision as to which one to use is finely balanced; or
- what is proposed would be likely to involve serious consequences for the patient.

9.3 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 the patient's records 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. The standard consent forms should never be used for adult patients unable to consent for themselves.

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, or not having, the treatment are potentially serious, a court declaration may be sought.

10 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. The one exception to this principle is set out in the next paragraph. If you wish to use such a recording for education, publication or research purposes, you must seek consent in writing, 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. If a child is not willing for a recording to be used, you must not use it, even if a person with parental responsibility consents.

Photographic and video recordings, made for treating or assessing a patient and from which there is no possibility that the patient might be recognised, may be used within the clinical setting for education or research purposes without express consent from the patient, as long as this policy is well publicised. However, express consent must be sought for any form of publication.

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 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 should seek the agreement of some-one close to the patient. You must not make any use of the recording which might be against the interests of the patient. You should also not make, or use, any such recording if the purpose of the recording could equally well be met by recording patients who are able to give or withhold consent.

11 Training

11.1 Generic consent training

Clinicians and all other healthcare professionals must be familiar with this policy and the establishments consent forms, specific training on consent as part of their induction. (Doctors will firstly follow the GMC guidance on Consent)

The principles of informed consent must be included as part of the best practice guidance of any clinical skills training. All mental capacity training will discuss issues of consent.

11.2 Procedure specific consent training

Clinicians seeking to delegate the role of procuring consent to junior staff have a responsibility to ensure that those to whom they wish to delegate are competent in the general principles of consent and in the specific details of the proposed procedure. The pro-forma in Appendix 4 is to be completed by the clinician seeking accreditation of competency and returned to the responsible person as directed.

Each consultant or specialty wishing to devolve the responsibility for obtaining informed consent for specific procedures must develop a procedure specific training package for consent to that particular procedure. The delegating clinician must remember that they retain accountability for the information provided to the patient at all times, even if they have not personally provided it. Procedure specific fact sheets may form the basis of this competency training package.

The primary responsibility for ensuring that the knowledge of consent principles and law is possessed by an individual clinician lies with the clinician themselves.

The registered manager is responsible for ensuring that all their staff receive appropriate training commensurate with their role.

11.3 Training records

Staff must keep a record of all training (including the taking of consent) in their portfolio. The establishment will keep a record of all training in a training matrix.

12 Monitoring Compliance

An annual audit of effectiveness and compliance with the consent process forms part of the clinical audit programme. The audit, Appendix 7, will include:

- Whether the correct consent forms are being used
- Whether the forms are being used correctly

- Whether the appropriate person obtained consent
- Whether training on delegated consent was undertaken

The findings of the audit will be provided to the Clinical Governance Committee (CGC). The CGC is responsible for addressing areas of non-compliance by the creation, monitoring and completion of an action plan to address the identified areas of risk.

If the audit identifies an individual taking consent who has not been trained to do so the circumstances will be reviewed by the lead clinician and governance lead (if different people). It is recognised that exceptional circumstances, such as emergency situations, can occur. In cases where the taking of consent was deemed inappropriate this will be discussed with the Medical Director prior to notification to the GMC.

13 References

Royal United Hospital Bath NHS Trust

Department of Health (2009) Reference guide to consent for examination or treatment: Second edition. London. www.dh.uk/publications

GMC (2008) Consent: patients and doctors making decisions together. London: GMC
GDC (2009) Standards Guidance: Principles of Patient Consent

BMA (2004) Medical Ethics Today: The BMA's Handbook of Ethics and Law (second edition). Update to chapter 2. London: BMJ Group. www.bma.org.uk/ethics/MET2007updates.jsp

GMC (2002) *Making and Using Visual and Audio Recordings of Patients*. London: GMC www.gmc-uk.org/guidance/current/library/making_audiovisual.asp

Re B (adult: refusal of medical treatment) [2002] EWHC 429 (Fam) at paragraph 100(viii); paragraph 9.61 of the 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 and www.publicguardian.gov.uk/forms/Making-an-LPA.htm

Appendix 1: page 1 of 2

12 Key Points on Consent: The Law

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 incompetent, 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 your caring for or treating them.

Can children give 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 the 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.

8. Consent must be given voluntarily: not under any form of duress or undue influence from 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. This establishment has a list of when written consent should be obtained.

Refusal of treatment

10. Competent adult patients are entitled to refuse treatment, even when 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 fetus.

Adults who are not competent to give consent

11. A capable (or competent) person may not be given medical treatment to which he does not consent. The treating of an incapable person is governed by the Mental Capacity Act 2005. In some cases the Act permits medical treatment to be given without the patient's consent, as long as it is in their best interests and has not been refused in a valid and applicable advance directive (living will) or advance decision. In some cases appointed advocates can make a decision on the patient's behalf.

12. If an incompetent patient 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,* at www.dh.gov.uk/consent .

Appendix 2:

Improving the achievement of informed consent for our patients

The following information provides a template for the development of information leaflets/fact sheets on any procedures that require informed consent to be gained from the patient or their guardian.

Such procedures may include:

- non-invasive investigations
- invasive examinations, with or without sedation
- surgical procedures
- medical photography
- inclusion in research

The list is not exhaustive

The consent forms require any clinician attempting to gain informed consent to explain the risks and benefits of the procedure to the patient and to record that interaction for medico legal reasons. It is anticipate that this information will be time consuming to deliver and document before every procedure, without some pre- planned information leaflet. The provision of a leaflet will also achieve consistency between clinicians.

Appendix 3: page 1 of 2

Patient Information Leaflet Development Template

To assist you in making an informed decision to undergo *xxxx procedure***.**

The Procedures Name: .....
Technical (and common name where it exists) for the procedure.

Normal function of the Organ involved:
Provide a description of the procedure that is framed in terms that will be easily understood by a layman. This will normally involve describing the organs involved and their function. (Provide illustrative diagrams wherever you believe that these will assist the patient in understanding anatomy, physiology or the disease in general.)

Reason for the procedure:
Describe, in lay terms, the most common reasons why this procedure is performed. These may include diagnostic or corrective or palliative etc. Include all the conditions that you may be looking for or confirming.

Preparation:
A brief explanation of preparations that may be required, e.g. enema, laxatives, nil by mouth, autologous blood collection cease warfarin, etc. This section need not be detailed if there is a separate patient information leaflet covering these issues. Also include any individual preparations that can be taken before the procedure to lower individual risk, like losing weight, smoking cessation

The Equipment
Describe the equipment used to achieve the procedure, in layman's terms, and in as much detail as you feel the average patient would wish to know. (Provide illustrative diagrams wherever you believe that these will assist the patient in understanding anatomy, physiology or the disease in general.)

The Procedure:
Include information on steps in procedure of which the patient will be aware and not aware. Detail will vary but should cover what you know to be of common concern to patients. Include steps that may be taken leading up to the procedure, such as weighing, removal of false teeth, pre-medication, shower, etc as well as the anticipated duration of the procedure and the recovery phase.

Results:
Explain the need for retention of any pathology specimens for diagnostic purposes and quality assurance purposes, stating clearly that they can opt out from the latter. Explain when the results will be available or when feedback on the success of the operative procedure should be available.

Alternatives: page 2 of 2

Explain the options that are available to this proposed procedure, and explain the limitations of those procedures.

Benefits:
Explain the benefits of this procedure over the alternatives, in general terms.

Side effects and Risks:
Describe the side effects and risks associated with this procedure. Please provide actuarial tables outlining the likelihood of each possible complication or side effect, where they are available on either national or local data. Where such detail is not possible, usually in more complicated/ multi-systems disease processes just provide a general level of risk as High, Medium, Low, or by using terms like often, seldom, rarely, occasionally.

Increased risk factors:
Provide information here related to reasons why this procedures inherent risks may be elevated by any particular factor in individual patients, like obesity, smoking, pregnancy.

Post-Procedural care:
Provide information here about the customary post-operative recovery period from the procedure and signs to watch out for and report to the medical or nursing staff.

Summary:
Provide a brief summary of the fact sheet for patients who do not wish to have as much detail as the main text provides.

External Sources for more information: Provide accredited sources such as doctoronline.com, your specialties professional organisations and any appropriate "self help" groups in the local area (along with contact details). Also include reference sources from which your material was taken.

If you have difficulty reading this information leaflet please ask the person who provided you with the leaflet to print it off in a larger font or to read it to you.

Last review date: _____ Next review date due: _____

Maintain copies of previous issues after any changes or review. These may be required to defend the establishment in any future litigation cases involving informed consent

Appendix 4:

Record of Delegated Consent

Delegation of Informed Consent for Interventional Procedures

It is a health professional's own responsibility to ensure that when they require colleagues to seek consent on their behalf they are confident that the colleague is competent to do so.

Name of Lead Clinician authorising delegation of consent: _____

I hereby certify that the following named practitioner has received training in obtaining fully informed consent in line with the establishments' consent policy, and is subject to regular audit of practice:

Name of Practitioner: _____

Role: _____

Procedures for which the above practitioner is authorised to take consent:

	Procedure	*Date of training*
1		
2		
3		
4		

Signed:_____
Lead clinician or Chair of Clinical Governance Committee

Date of signing: …….. Review date:……

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Capacity Assessment Form

Consent and Capacity Checklist

Valid consent (or dissent) requires that the individual has sufficient information to make the decision, has capacity to make it, and is not subject to undue coercion. This checklist is designed to help logical consideration of the validity of a person's consent to (or refusal of) a proposed treatment or management plan.

Individual details: (Title, First name, Surname)

Name: .....

DoB: _ _ / _ _ / _ _ _ _

Address: .....

.....

..... Post Code.....

Nature of decision to be made: .....

.....

.....

- Is there an impairment of, or disturbance in the functioning of the mind or brain?

  Yes / No
- Is this of a nature or degree, which might be sufficient to affect their capacity for this decision?

  Yes / No

Does the person have sufficient information to make a decision?

Yes / No

- Has the information been presented in ways which can enhance the person's likelihood of understanding and retaining the information?

  Yes / No
- Does the person understand the information?

  Yes / No
- Can the person retain the information for long enough to reach a decision?

Yes / No

- Can the person use or weigh the information as part of the process of reaching a decision?

  Yes / No

- Can the person communicate their decision?

  Yes / No

- Are they making the decision of their own free will?

  Yes / No

- Are they consistent in the decision they reach on this matter?

  Yes / No

Name of assessor ……
Assessor's relationship to individual
……

Date and time of assessment: _ _ /_ _ /_ _ _ _

Decision reached by assessor about individual's capacity:
……

……

……

This is only a checklist, an aide-memoire. Full details, as appropriate to the gravity of the decision to be made, must be entered in the patient's record.

Appendix 6:
Consent Audit – Part 1 Patient List

Speciality/Clinic*.....

Date audit started ..... Date audit completed……

Details of patients audited:

ID	Name of Patient (Title, First name, Surname)	Reference / DoB
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		
15		
16		
17		
18		
19		
20		

**audit may be a carried out on a specific clinic, speciality, doctor etc – this will depend on MAC or unplanned events.*

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Appendix 7:

Consent Audit - Part 2

Speciality:.....Week Commencing:.....

Please complete the table below for patients requiring consent (aim for 20% plus to be written consent)

ID	Procedure	Info leaflet given?	Were listed complications appropriate? (If no, state omissions)	Name of Person taking consent	Status of consent taker	Was name legible?	Were they trained appropriately?	Was consent form duly completed, signed and dated?	Was consent discussion noted in patient record?
1		**Y / N**	**Y / N**			**Y / N**	**Y / N**	**Y / N**	**Y / N**
2		**Y / N**	**Y / N**			**Y / N**	**Y / N**	**Y / N**	**Y / N**
3		**Y / N**	**Y / N**			**Y / N**	**Y / N**	**Y / N**	**Y / N**
4		**Y / N**	**Y / N**			**Y / N**	**Y / N**	**Y / N**	**Y / N**
5		**Y / N**	**Y / N**			**Y / N**	**Y / N**	**Y / N**	**Y / N**
6		**Y / N**	**Y / N**			**Y / N**	**Y / N**	**Y / N**	**Y / N**
7		**Y / N**	**Y / N**			**Y / N**	**Y / N**	**Y / N**	**Y / N**
8		**Y / N**	**Y / N**			**Y / N**	**Y / N**	**Y / N**	**Y / N**
9		**Y / N**	**Y / N**			**Y / N**	**Y / N**	**Y / N**	**Y / N**
10		**Y / N**	**Y / N**			**Y / N**	**Y / N**	**Y / N**	**Y / N**
11		**Y / N**	**Y / N**			**Y / N**	**Y / N**	**Y / N**	**Y / N**
12		**Y / N**	**Y / N**			**Y / N**	**Y / N**	**Y / N**	**Y / N**
13		**Y / N**	**Y / N**			**Y / N**	**Y / N**	**Y / N**	**Y / N**
14		**Y / N**	**Y / N**			**Y / N**	**Y / N**	**Y / N**	**Y / N**
15		**Y / N**	**Y / N**			**Y / N**	**Y / N**	**Y / N**	**Y / N**
16		**Y / N**	**Y / N**			**Y / N**	**Y / N**	**Y / N**	**Y / N**
17		**Y / N**	**Y / N**			**Y / N**	**Y / N**	**Y / N**	**Y / N**
18		**Y / N**	**Y/ N**			**Y / N**	**Y / N**	**Y / N**	**Y / N**
19		**Y / N**	**Y / N**			**Y / N**	**Y / N**	**Y / N**	**Y / N**
20		**Y / N**	**Y / N**			**Y / N**	**Y / N**	**Y / N**	**Y / N**

Any other comments? *(please state the id of the patient that the comments relate to – please continue of separate sheet)*

Audit carried out by …… Date……
Reviewed by…… Date……
Presented to Clinical Advisory Committee by …….
Date……

Appendix 8

Patient Consent Form

Please ensure that the patient receives a copy of this consent form, the original is to be filed in the patients record.

Consultant or other responsible health professional

Name and job title……

Any special needs of the patient *(e.g. help with communication)*? ….……

……

Name of proposed procedure ……

……

(include brief explanation if medical term not clear)

Statement of health professional (details of treatment, risks and benefits)

I confirm I am a health professional with an appropriate knowledge of the proposed procedure, as specified in the consent policy. I have explained the procedure to the patient. In particular, I have explained:

a) the intended benefits of the procedure *(please state)* ……

……

b) the possible risks involved *(all precautions are take to ensure any risks are minimised, however all procedures carry some risk and I have set out below any significant, unavoidable or frequently occurring risks including those specific to the patient)*

……

……

c) what the procedure is likely to involve, the benefits and risks of any available alternative procedure (including no procedure) and any particular concerns of this patient:

……

……

The following information leaflet has been provided: ……

……

Signed……Date: ……/……/…… Time *(24hr):* ……
(Health professional)

Name……Designation:……
(PRINT)

Contact information

If you have any questions or concerns during your treatment of following it please contact us:
Name:…… Designation:……

Telephone: …… Available from: …… am/pm to: …… am/pm

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Consent of patient / person with parental responsibility
I confirm that the risks, benefits and alternatives of this procedure have been discussed with me and my questions have been answered to my satisfaction and understanding.

I have read and understood the Patient Information entitled *Patient Information about Consent* and the above additional information. I agree to the procedure.

Signed (Patient):..... Date:...../..... /.....

Name of patient (PRINT): .....

Please see over

Please complete any of the following if appropriate, if not applicable patient to strike through them.

a) *If signing for a child or young person; delete if not applicable.*
I confirm I am a person with parental responsibility for the patient named on this form.

Signed: ..... Date: ...../...../.....

Relationship to patient: .....

Address: .....

.....

b) *If the patient is unable to sign but has indicated his/her consent, a witness should sign below.*
Signed *(Witness):* ..... Date: ...../...../.....

Name of witness *(PRINT)* : .....

Address: .....

.....

c) Interpreter's statement *(if appropriate)*
I have interpreted the information to the best of my ability, and in a way in which I believe the patient can understand:

Signed *(Interpreter):* .....Date: ...../...../.....

Name of interpreter*(PRINT):* .....

Address: .....

.....

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Patient information about consent

What is consent?
Consent is the process by which you give permission to a health professional to provide your care and treatment. It may be implied (offering your arm for a blood pressure reading) or formal (signing a formal consent form for an operation).

In either case your consent must be given voluntarily and you must have all the information you need to make a decision. This includes what the procedure or treatment involves, the benefits and risks, the details of any alternative treatments and what may happen if the procedure or treatment does not go ahead.

How do I give consent?
Consent is a two way process between you and your health professional. It is a chance for you to ask any questions, and for the health professional to explain what your procedure will involve.

It is this establishments policy that consent will be recorded on a consent form. The form enables the health professional to record the different aspects involved in consent and allows you to sign to show you agree. The form alone does not prove consent but it does confirm your joint discussion.

Where a child or young person cannot give consent for themselves, someone with parental responsibility must sign the form on their behalf. Please ask your health professional for advice and for further information.

Explaining the consent form
The procedure: benefits, risks and alternatives
Your health professional will explain the procedure to you, in particular the intended benefits of the process, any risks involved, any available alternatives and the alternative of not having the procedure.

You may be offered an information leaflet about your procedure. Where applicable, we will also give you a copy of the consent form to read in advance of your treatment. If you have not had a copy, please ask us.

Important things you need to know
Patient choice is an important part of your care. You have the right to change your mind at any time, even after giving consent, and even if the procedure has started (as long as it is safe and practical to do so). However, there may be procedures you do not wish us to carry out and these can be recorded on the consent form.

We are unable to guarantee that a particular person will perform the procedure. However, the person undertaking the procedure will have the relevant experience.

All information we hold about you is stored under the provisions of the Data Protection Act 1998

The Consent Form
Signed consent forms are kept with your medical records. If you would like a copy, please ask your health professional.

Privacy and Dignity
We are committed to treating all patients with privacy and dignity in a safe, clean and comfortable environment.