Trust Policy	All Sites	Worcestershire Acute Hospitals NHS Trust

Policy for consent to examination or treatment

Department / Service:	Clinical Governance and Risk Department	
Originator:	Mr S Lake	Clinical Director Endoscopy
	Allan Bailey	Associate Director of Clinical Governance, Patient Safety and Risk
Accountable Director:	Chief Medical Officer	
Approved by:	Improving Safety Action Group/Fundamentals of Care Committee	
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Target Organisation(s):	Worcestershire Acute Hospitals NHS Trust	
Target Departments:	All	
Target staff categories:	All	

Policy Overview:

- 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.
- The Department of Health has issued a range of guidance documents on consent 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 Trust which aim to ensure that health professionals are able to comply with the guidance.
- Recent case law has confirmed that there must be sufficient discussion with patients regarding any issues of particular concern to them when seeking consent. This will be in addition to the information provided in the procedure-specific information given to the patient.

Key amendments to this policy

Date	Amendment	By
12th December 2023	Owners names	
5th January 2021	Document review date extended by 12 months in line with amendment to Key Documents Policy	Mr Lake
May 2020	Document extended for 6 months during COVID-19 period	

November 2019	Document extended for 6 months whilst review process takes place	Mr Lake
August 2019	Document extended for 6 months whilst review process takes place	Mr Lake
April 2019	Document extended for 3 months whilst review process takes place	Mr Lake
Sept 16	Document Approved at KDAG	Key Document Approval Group
Aug 16	Provision of face to face training for staff obtaining written informed consent Amendments to respond to case law (Montgomery) related to material risk to individuals Reference to advance decisions (living wills)	C. Rawlings S. Lake
Sept 2014	Training section – remove the exclusion of consultants from the training. Update provided for Mandatory Training Policy. Introduction of the consent training module available via ESR. Correction of hyperlinks to guidance documents	E. Duggan C. Rawlings
Sept 2013	Update monitoring section. Audit report findings no longer reported to Consent Committee now reported to Patient Safety Committee. Minor amendments approved by accountable director.	E. Duggan
May 12	Improved description of the e-consent process, archiving of information, amendment to responsible committees and duties in line with organisational changes, clarification of medical photography	C. Rawlings
July 10	Training – IX Training – competency assessment forms held within Clinical Governance. Formatting amendments	E. Duggan
Feb 09	Training - IX Training Section	E. Duggan
July 07	Mental Capacity Act 2005 – II Documentation section	J. Clavey E. Duggan
Sept 06	Postal consent for Endoscopic procedures	S. Lake E. Duggan
Jun 05	Use of tissue updated for Human Tissue Act compliance Medical Photography form included	T. Jones C. Rawlings
Dec 04	Addition of training details, local implementation of policy	C. Doherty
Sept 03	Reconfiguration to ensure that the Consent policy follows the DoH model consent policy with local additions where required.	P. Claridge C. Rawlings C. Ashton

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1. Introduction

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.

2. Scope of this document

The Department of Health has issued a range of guidance documents on consent 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 Trust which aim to ensure that health professionals are able to comply with the guidance. While this document is primarily concerned with healthcare, social care colleagues should also be aware of their obligations to obtain consent before providing certain forms of social care, such as those that involve touching the patient or client.

3. Definitions

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.

Appendix F Seeking Consent: remembering the patient's perspective, provides useful advice

<u>Mental Capacity</u>

All health care professionals should start from the presumption that adult patients have mental capacity to make decisions about their care. There must a reasonable and recorded decision by a healthcare worker to depart from this principle. A patient's mental capacity should be formally assessed if there is doubt, but it is important to remember that mental capacity assessments apply to a particular decision at a particular time. A temporary impairment in

mental capacity does not give indefinite 'carte blanche' for healthcare workers to provide treatment. Patients who lack mental capacity for some decisions may retain mental capacity for others – for example patients may not be able to weigh up the pros and cons of a proposition for surgery, but are able to give consent to receive medication for a painful condition.

Patients must be supported to regain mental capacity e.g. through the use of communication aids or providing treatment to restore mental function as quickly as possible.

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 decision. In this situation, major decisions should be made in consultation with those who are close to them or advocating for them wherever possible. Attempts to fulfil this duty should be recorded. 'Best interests' stretch beyond immediate medical care (although these are often the most pressing considerations) and may include consideration of other human rights such as the right to family life.

For further details on advance decisions see the Mental Capacity Act Code of Practice, Chapter 9 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/224660/Mental_Capacity_Act_code_of_practice.pdf

Consent to a particular treatment may be given by an attorney with a valid power of attorney or a deputy of the Court of Protection.

E-consent

This is the Trust's bespoke software that provides a tool to provide pre-populated procedure specific consent forms with accompanying information leaflets for clinicians to use when obtaining consent.

This tool is used alongside the process for discussing consent as set out in this policy.

4. Responsibility and Duties

4.1 Chief Medical Officer (CMO)

The CMO will have responsibility for:

- Ensuring that all medical staff follow this policy
- Monitoring progress to agreed action plans
- Reporting progress and exceptions to Clinical Governance Group.
- Notify the GMC of concerns about improper consent taking by trainee or experienced doctors where this is considered necessary

4.2 Trust Management Committee

This committee approves the Consent Policy

4.3 Health Professionals

It is a health professional's own responsibility:

- To obtain consent in line with this policy where they are authorised to do so and use the e-consent system wherever feasible
- To ensure that when they require colleagues to seek consent on their behalf they are confident that the colleague is competent to do so;
- To work within their own competence and not to agree to perform tasks which exceed that competence.

5. 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 e.g. GMC 'Decision making and consent guidance'.

- *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 may be accessed on the internet at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_103643

- *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.

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 from the Patient Safety Team on 33074 or 33444 and on the internet in the national archives at: http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4007005

Children: Information on Gillick competence and Fraser guidelines as well as obtaining parental consent for babies or small children is covered in Section 8 of this Policy and in Appendix B which contains a longer description and links to further information on both Gillick competence and the Fraser guidelines.

Case law and the explanation of risk

Recent case law (Montgomery v Lanarkshire Health Board) has demonstrated that good communication and documentation are essential in the process of agreeing consent. Patients must be made aware of the risks of the procedure and their implications. Effort must be made to find out what is important to the patient so that relevant information can be shared and discussed explicitly. The small risk of voice change after a general anaesthetic may affect a professional singer's decision making process more than someone else's for example.

Explanation should, in addition and as a routine, include common complications as well as any serious adverse outcomes, including rare complications, which may result in permanent disability or death. Patients must therefore be given the opportunity to weigh up the benefits and risks of medical interventions and the benefits and risks of not proceeding with treatment or any reasonable alternatives.

General Medical Counsel (2008), Consent: Patients and Doctors Making Decisions Together. This can be accessed from the following link:
http://www.gmc-uk.org/Consent English 0415.pdf 48903482.pdf

5.1 Documentation

For significant procedures, it is essential for health professionals to document clearly and fully both a patient's agreement to the intervention and the discussions which led up to that agreement, including the treatment offered and the opportunity to do nothing (if appropriate). 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.

5.2 Written consent

Consent is often incorrectly 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 and during a procedure: the signature is evidence of the process of consent-giving, not a binding contract.

It is rarely a legal requirement to seek written consent[1] 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 this Trust.

Completed forms should be kept with the patient's notes (a copy of the electronic form is stored within the e-consent system). 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 professionals.

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.

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

1. The Mental Health Act 1983 and the Human Fertilisation and Embryology Act 1990 require written consent in certain circumstances.

With reference to the Mental Capacity Act 2005 where an adult patient does not have the capacity to give or withhold consent to a significant intervention, this fact should be documented in 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. **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's notes. Refer to 'Mental Capacity Act 2005 – Summary and guidance for staff May 2007' - Appendices 1 and 2 for assessment guidance and checklist.

Also consider whether the patient has an advance decision in place. An Advance Decision enables someone aged 18 years and over, while still capable, to refuse specified medical treatment for a time in the future when they may lack the capacity to consent to or refuse that treatment. For further information, refer to the Policy for Advance Decisions (Living Wills) WAHT-CG-490

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, the use of interpreters, written formats, allowing extra time for consideration and other measures, 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. See Appendix E for details of how to do this.

5.4 Availability of forms

Standard consent forms and forms for adults who are unable to consent for themselves are reproduced in Appendix C and are available to order from Service point. 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 and

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.

form 4 is for adults who are unable to consent for investigation or treatment.

5.4.1 **e-consent system and archiving**

The electronic consent form has been developed to follow the best practice described in this policy and to enhance the process for written informed consent. It is the preferred method with which to record consent and its use will become mandatory at a time to be decided.

Printed copies of the electronic consent forms 1, 2 and 3 mimic the standard printed forms and comply with the DH model consent forms. Consent form 4 will remain a hand written form as two consultants are required to complete this form.

E-consent forms are printed for each individual patient. For areas not yet using e-consent, paper copies are available from Service Point.

The system is configured with the details of the clinician so that procedure specific consent forms can be pre-populated with risks and benefits and provided with supporting information for the patient for the procedures that the individual is authorised to obtain written consent.

The E-Consent system archives consent forms in a single document that includes the patient information documentation that was provided to the patient. This means that it is possible to retrieve the specific information leaflet associated with individual consent forms.

5.5 When should consent be sought?

When a patient formally gives their consent to a particular intervention through signing a form or giving an oral declaration, 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. Recent case law has confirmed that there must be sufficient discussion with patients regarding any issues of particular concern to them when seeking consent. This will be in addition to the information provided in the procedure-specific information given to the patient.

5.5.1 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, after a discussion with the patient about the procedure, its risks, benefits and whether doing nothing is an option.

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.

5.5.2 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.

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 hospital gown), unless this is unavoidable because of the urgency of the patient's condition.

5.6 Seeking consent for anaesthesia

Where an anaesthetist is involved in a patient's care, it is their responsibility (not that of a surgeon) to seek consent for anaesthesia, having discussed the benefits and risks and any concerns the patient may have. 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 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.

5.7 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.

5.8 Treatment of young children

Gillick competence is the principle we use to judge capacity in children to consent to medical treatment.

Fraser guidelines are used specifically for children requesting contraceptive or sexual health advice and treatment.

Where a person under the age of 16 is not Gillick competent and therefore is deemed to lack the capacity to consent, it can be given on their behalf by someone with parental responsibility or by the court. However, there is still a duty to keep the child's best interests at the heart of any decision, and the child or young person should be involved in the decision-making process as far as possible**.**

When babies or young children are being cared for in hospital, it will not usually seem practicable to seek their parents' consent on every occasion for every routine intervention such as blood or urine tests or X-rays. However, you should remember that, in law, such consent is required. Where a child is admitted, you should therefore discuss with their parent(s) what routine procedures will be necessary, and ensure that you have their consent for these interventions in advance. If parents specify that they wish to be asked before particular procedures are initiated, you must do so, unless the delay involved in contacting them would put the child's health at risk.

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 do not automatically have such responsibility although they can acquire it). If you are in any doubt about whether the person with the child has parental responsibility for that child, you must check.

Appendix B contains a longer description and links to further information on both Gillick competence and the Fraser guidelines.

5.9 Consent for research

Patients may undergo treatment and also participate in research. Patients need to be consented for both separately. The Research and Development department provide training for non-clinical staff obtaining consent for research or trials. Please refer to the Research Governance Policy for more information.

5.10 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. It is important to ensure that patients are given information that is helpful to them and that they are able to discuss their concerns with the clinician. 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.

The following sources of patient information are available in this Trust:

- Procedure specific information provided with the e-consent form to support the decision making process
- The Trust has a dedicated Patient Information Centre at the Worcestershire Royal Hospital, and at the Treatment Centre in Kidderminster.
- Information produced by the Trust on medical / surgical procedures is primarily available from the clinic or department the patient is visiting. Certain generic information is commonly available from the Patient Information Centres.
- The Trust holds a wealth of information from national patient support organisations. This is also available at the Patient Information Centres.
- The Trust produces both in and out-patient booklets to assist patients. The in-patient booklet is available on both audiocassette and CD.
- The Trust will make available letters from health professionals to other health professionals on request to patients.

5.10.1 Provision for patients whose first language is not English

This Trust 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. It is not appropriate to use children, family members or staff to interpret for patients who do not communicate in spoken English.

- The translating of written information is arranged on request. This service is currently provided through Word360. The latest information can be found on the Trust intranet “Interpreting and Translating”
- Professional interpreters are available for patients wishing to have an interpreter present at Hospital appointments. In the case of emergency admissions, there are two Interpreting on Demand machines in the Accident and Emergency Departments at Worcestershire Royal Hospital and The Alexandra Hospital to support with interpreting. Interpreters can also be booked for telephone, face to face and video appointments. through the links on the Intranet.
- Details of how to access interpreting and translating services are available on the Trust’s Intranet or via The Head of Patient, Carer and Public Engagement and the Patient Experience Lead Nurse.
- Advice on information to support verbal and nonverbal communication can be gained in the first instance from The Head of Patient, Carer and Public Engagement and the Patient Experience Lead Nurse.

5.10.2 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. This Trust has made the following arrangements to assist patients to obtain such information:

The Trust's Patient Advice and Liaison Services Team (PALS) is available to provide a wide range of information to patients. Where information is not readily available they will assist patients to obtain this from local (e.g. support groups) or national sources (such as NHS Choices, Macmillan Cancer Support) by reference to the Internet and by information already available from the Trust's Patient Information Centres. The PAL's Officer also has access to the Trust's Medical Library Services where more in

depth information may be found. Many Patient information leaflets also contain contact details for support groups and websites etc.

5.10.3 Access to health professionals between formal appointments

After an appointment with a health professional in primary care or in out-patients, patients will often think of further questions which they would like answered before they take their decision. Where possible, it will be much quicker and easier for the patient to contact the healthcare team by phone than to make another appointment or to wait until the date of an elective procedure (by which time it is too late for the information genuinely to affect the patient's choice). *Patients will be given details of whom they may contact for more information e.g. specialist nurses for the relevant specialty and/or the consultant team, at the time of the consultation. Contact details are normally contained within the patient information leaflets.*

5.11 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. As with other procedures, discussion regarding consent will take place prior to the procedure taking place and patients must be allowed sufficient time to consider whether or not they have all the information they require and whether they wish the procedure to go ahead.

In this Trust Patients are sent information and, in some cases, a consent form with their appointment letters e.g. Endoscopy, or the information is provided in advance to GPs and other Primary Care areas.

Specific guidance on postal consent is available for health professionals obtaining consent for endoscopic procedures. This can be found on the British Society of Gastroenterology website – www.bsg.org.uk - http://www.bsg.org.uk/attachments/217_consent.pdf

5.12 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 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 may be appropriate for other members of the team to participate in the process of seeking consent.

In this case the health professional carrying out the procedure will delegate junior staff, nursing or allied health professionals to obtain consent on their behalf, after ensuring and documenting that they have been trained to obtain consent and have suitable knowledge about the procedure to discuss the risks and benefits and answer any questions from the patient relevant to the procedure. Assessing competency and obtaining access to the e-consent system is described in Appendix H.

5.12.1 Completing consent forms

The standard printed and e-consent form provide space for a health professional to provide information to patients and a note of their discussions with the patient and any

questions answered 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.

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. 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.

- Training is available via the Trust's Training and Development Department for all members of staff involved in the consent process. During induction training junior medical complete e-learning on consent.
- The Directorates and consultant teams ensure that health professionals 'confirming' the patient's consent have access to appropriate colleagues where they are personally not able to answer any remaining questions. This may be within the clinic or via telephone.

  All clinical and nursing staff must follow their professional guidance on consent.

5.13 Refusal of treatment / withdrawal of consent

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 2007*. 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.

If, after discussion of possible treatment options, and exploring the reasons for refusal, a patient refuses all treatment, this fact should be clearly documented in their notes. If the patient has already signed a consent form, but then changes their mind, you (and where possible the patient) should note this on the form. Refusal of treatment should not automatically be taken as indicating a lack of mental capacity, but consideration should be given to if there is evidence of a mental condition developing that may have influenced the decision making process if this new decision goes against previous declarations.

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.

If a patient consents to a particular procedure but refuses certain aspects of the intervention, you must explain to the patient 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.

If a patient withdraws their consent during a procedure, e.g. during endoscopy under sedation, the procedure must be stopped and brought to a conclusion in the safest possible way.

A full record of discussions with the patient regarding their consent to/refusal of treatment must always be made in the patient's medical record.

5.14 Tissue

The Human Tissue Act 2004 regulates the storage and the use of human organs and tissue from the living, and the removal, storage and use of tissue and organs from deceased, for specific health-related purposes and public display. The Human Tissue Authority is the regulator and advice on compliance with the Act can be found at www.hta.gov.uk/ The Act came into force in 2006 and covers England, Wales and Northern Ireland.

Certain activities require CONSENT and may also require a LICENCE for the premises where they take place. Some activities are EXEMPT from the act. There are some differences between tissue obtained from the LIVING and from the DECEASED.

The HTA doesn't regulate all uses of human tissue.

- They do not regulate human tissue obtained from living patients for diagnostic testing. This is still covered by existing legislation and the usual rules on consent to treatment
- They do regulate tissue obtained from living patients for research and transplantation and all tissue obtained from the dead.

The Human Tissue Act impacts on several activities:

POST MORTEM SERVICES

- CONSENT is needed for all post-mortem examinations except for those ordered by the Coroner
- CONSENT is needed for all material removed after death and stored
- CONSENT is needed for any subsequent use of material removed after death
- All post-mortem examinations must only take place on LICENSED premises

The Mortuaries (Pathology Directorate) have department level policies for consent to post mortem that comply with the Act.

RESEARCH

- CONSENT must be obtained for any storage and use of tissue removed after death for research
- CONSENT is required for storage and use of tissue from the living unless:
    - The tissue will be released to the researcher in a non-identifiable form
    - the tissue will be used in a project that has approval by a recognised research ethics committee

STORAGE OF HUMAN TISSUE

- CONSENT is required for storage for living patients except for the exceptions on research material previously mentioned
- CONSENT is required for storage for the dead

- Storage from living individuals ONLY requires a LICENCE IF it is stored for:
  - Future research that has NOT been approved by an ethics committee (tissue banks)
  - More than 48 hours for transplantation

- Storage of tissue from the dead requires a LICENSE EXCEPT:
  - It is for use in a research project which has approval from an ethics committee
  - It is sent to unlicensed premises for the purpose of analysis (other than research) and is then returned to the licensed premises

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. Where we are informed that a patient does not want residual tissue following a procedure to be used for research or education, we will endeavor to ensure that their wishes are respected. Staff must record this information clearly on the consent form, the medical notes and the histopathology request form.

It is essential to ensure the high quality of service which all patients have the right to expect. Wherever possible, samples of tissue used for quality assurance purposes should be anonymised or pseudonymised.

Healthcare professionals seeking consent from patients are individually responsible for ensuring that the patient fully understands the reasons for taking tissue samples, having answered any questions from the patient clearly and fully and that they understand their right to refuse consent for this

Further advice is available for the Human Tissue Authority at www.hta.gov and from the Trust's Designated Individual for the HTA, Dr C. Allen.

5.15 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 Consent form contains a section on medical photography and will be used in most instances where medical photography will be included in the process of obtaining written consent. Where digital clinical photographs are taken by Trust clinical staff they must be published into the electronic patient record without delay and deleted from the recording device.

The one exception to this principle is 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 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.

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.

A separate form is available in Appendix G of this policy which should be used for procedures where written consent would not normally be sought but consent to make a photographic or video recording is required.

6. Implementation

6.1 Plan for Implementation

This policy has already been implemented

6.2 Dissemination

This policy will be made available on the Trust Intranet for all staff
A notice will be placed in the Trust weekly briefing that the policy has been amended and published

6.3 Training and awareness

The training needs of staff in relation to informed consent have been assessed as part of the training needs analysis. The population that requires training is described below:

All consultants and other healthcare staff who obtain written informed consent on their own behalf (i.e. are qualified to carry out or prescribe the procedure themselves) will be required to undertake training in the consent process and e-consent on joining the

Trust and receive refresher training at scheduled mandatory training. This will be provided through e-learning.

The medical staff in training who obtain written informed consent will be required to undertake training in the consent process.

Healthcare staff who obtain consent on behalf of someone else (usually their consultant) will require training to understand and explain the risk and benefits of and alternatives to the procedure to the patient. This is normally provided by their consultant who signs the system access form to confirm their competency has been assessed. These staff will also be required to undertake training in the consent process and the use of e-consent (if they will be using it) and at scheduled mandatory training.

Training and competency assessment of Health Care Professionals, in obtaining consent for specific procedures, is the responsibility of consultant medical staff within their respective specialties.

Training in consent theory and procedure is accessible through ESR, as an e-learning package.

The competency assessment process is described in Appendix H assessed and recorded on the (example) form attached as Appendix I, and specialty specific forms are available via the Trust's intranet site and consent pages. Health Care Professionals are only authorised to obtain consent for procedures where they are deemed to be competent.

Please refer to the Mandatory Training Policy - Training Needs Analysis for further information.

Assistance for any aspect of consent can be sought from the staff identified in Appendix D

7. Monitoring and compliance

The consent process is monitored through:

- Use of the e-consent system.
- Compliance with the training programme for staff obtaining informed written consent
- A consent documentation audit is carried out annually to monitor compliance with this policy. The findings will be reported to the Clinical Governance Group with recommendations and an action plan.
- The Clinical Governance Department will, at need, alert the CMO of any clinical issues raised through incident reporting.
- Monitoring of incident reports and audit results are the primary means to identify individuals who obtain consent without the authorisation to do so. These instances will be brought to the attention of the Chief Medical Officer for action and if necessary reporting to the GMC. The e-consent system builds in safeguards to ensure that only authorised staff have access to procedure specific forms.

8. Policy Review

This policy will be reviewed by the Clinical Governance Group 2 years from the approval date.

9. References

DH: Reference guide to consent for examination or treatment : 2009
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_103643

The Mental Health Act 1983
Consent: patients and doctors making decisions together – GMC 2008 http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_how_guidance_applies_to_you.asp
Human Fertilisation and Embryology Act 1990
Seeking consent: working with children – DoH http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4007005
Human Rights Act 1998 – Article 22
Human Tissue Act 2004, http://www.legislation.gov.uk/ukpga/2004/30/contents http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/legislation/humantissueact.cfm
Gillick v West Norfolk & Wisbech AHA & DHSS [1983] 3 WLR (QBD)
Wheeler R (2006) Gillick or Fraser? A plea for consistency over competence in children. BMJ 332(7545): 807
Policy on consent for post-mortem examination and tissue retention under the Human Tissue Act 2004 : http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/policyonconsentforpost-mortemexaminationandtissueretention.cfm
HTA – Code of Practice: Consent 2010: http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code1consent.cfm
Postal Consenting for Endoscopic procedures – British Society of Gastroenterology – www.bsg.org.uk
Mental Capacity Act 2005 and Code of Practice to the Mental Capacity Act 2005 - https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/224660/Mental_Capacity_Act_code_of_practice.pdf
Policy for Advance Decisions (Living Wills) WAHT-CG-490

10. Background

10.1 Consultation

This policy has been circulated for comment to staff as indicated below.

Key individuals involved in developing the document

Name	Designation
Chris Rawlings	Head of Clinical Governance and Risk
Stephen Lake	Consultant Surgeon
John Pick	Datix System Manager

Circulated to the following Teams for comments

Department / Team
Consultant Medical Staff
Infection Control Team
Professional Development
Divisional Management Teams
Divisional Quality Governance Teams
Pathology Quality Manager
Research & Development

Circulated to Chairs of the following Committees for comments

Committee / Group

Trust Infection Prevention and Control Committee
Medicines Safety Committee
Clinical Governance Group

10.2 Approval process
This policy will be reviewed at the Safe Patient Group and approved at the Trust Management Committee.

10.3 Equality requirements
The assessment conducted for this policy reveals no equality issues – see **Supporting Document 1**.

10.4 Financial Impact Assessment
The assessment conducted for this policy reveals no financial issues – see **Supporting Document 2**.

Appendix A
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 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. (Reference: Section 6 and Appendix B of this policy regarding Gillick Competence and Fraser guidelines)

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, alternative treatments and whether or not no treatment is a preferable option. 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. Your Trust or organisation may have a policy setting out when you need to obtain written consent.

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 foetus.

Adults who are not competent to give consent

11. **No-one** can give consent on behalf of an incompetent adult. 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 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,* available from the NHS Response Line 08701 555 455 and at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_103643

Appendix B

Consent for children – Gillick Competency and Fraser Guidelines

When consenting children to medical treatment, the terms 'Gillick competence' and 'Fraser guidelines' are frequently used interchangeably despite there being a clear distinction between them.

Gillick competence is concerned with determining a child's capacity to consent. Fraser guidelines, on the other hand, are used specifically to decide if a child can consent to contraceptive or sexual health advice and treatment. By confusing them, we lose crucial details necessary for obtaining consent. This myth buster clarifies the principles, laws and guidelines used when we assess children's ability to make decisions about their treatment, as well as the differences between Gillick competence and Fraser guidelines.

Age of consent

In UK law, a person's 18th birthday draws the line between childhood and adulthood (Children Act 1989 s105) - so in health care matters, an 18 year old enjoys as much autonomy as any other adult. To a more limited extent, 16 and 17 year-olds can also take medical decisions independently of their parents. The right of younger children to provide independent consent is proportionate to their competence - a child's age alone is clearly an unreliable predictor of his or her competence to make decisions.

Gillick competence

Victoria Gillick challenged Department of Health guidance which enabled doctors to provide contraceptive advice and treatment to girls under 16 without their parents knowing. In 1983 the judgement from this case laid out criteria for establishing whether a child under has the capacity to provide consent to treatment; the so-called 'Gillick test'. It was determined that children under 16 can consent if they have sufficient understanding and intelligence to fully understand what is involved in a proposed treatment, including its purpose, nature, likely effects and risks, chances of success and the availability of other options.

If a child passes the Gillick test, he or she is considered 'Gillick competent' to consent to that medical treatment or intervention. However, as with adults, this consent is only valid if given voluntarily and not under undue influence or pressure by anyone else. Additionally, a child may have the capacity to consent to some treatments but not others. The understanding required for different interventions will vary, and capacity can also fluctuate such as in certain mental health conditions. Therefore each individual decision requires assessment of Gillick competence.

If a child does not pass the Gillick test, then the consent of a person with parental responsibility (or sometimes the courts) is needed in order to proceed with treatment.

Fraser guidelines

The 'Fraser guidelines' specifically relate only to contraception and sexual health. They are named after one of the Lords responsible for the Gillick judgement but who went on to address the specific issue of giving contraceptive advice and treatment to those under 16

without parental consent. The House of Lords concluded that advice can be given in this situation as long as:

1. He/she has sufficient maturity and intelligence to understand the nature and implications of the proposed treatment
2. He/she cannot be persuaded to tell her parents or to allow the doctor to tell them
3. He/she is very likely to begin or continue having sexual intercourse with or without contraceptive treatment
4. His/her physical or mental health is likely to suffer unless he/she received the advice or treatment
5. The advice or treatment is in the young person's best interests.

Health professionals should still encourage the young person to inform his or her parent(s) or get permission to do so on their behalf, but if this permission is not given they can still give the child advice and treatment. If the conditions are not all met, however, or there is reason to believe that the child is under pressure to give consent or is being exploited, there would be grounds to break confidentiality.

Fraser guidelines originally just related to contraceptive advice and treatment but, following a case in 2006, they now apply to decisions about treatment for sexually transmitted infections and termination of pregnancy.

Under 13

There is no lower age limit for Gillick competence or Fraser guidelines to be applied. That said, it would rarely be appropriate or safe for a child less than 13 years of age to consent to treatment without a parent's involvement. When it comes to sexual health, those under 13 are not legally able to consent to any sexual activity, and therefore any information that such a person was sexually active would need to be acted on, regardless of the results of the Gillick test.

16-17 year olds

Young people aged 16 or 17 are presumed in UK law, like adults, to have the capacity to consent to medical treatment. However, unlike adults, their refusal of treatment can in some circumstances be overridden by a parent, someone with parental responsibility or a court. This is because we have an overriding duty to act in the best interests of a child. This would include circumstances where refusal would likely lead to death, severe permanent injury or irreversible mental or physical harm.

Summary

Gillick competence is the principle we use to judge capacity in children to consent to medical treatment. Fraser guidelines are used specifically for children requesting contraceptive or sexual health advice and treatment. Where a person under the age of 16 is not Gillick competent and therefore is deemed to lack the capacity to consent, it can be given on their behalf by someone with parental responsibility or by the court. However, there is still a duty to keep the child's best interests at the heart of any decision, and the child or young person should be involved in the decision-making process as far as possible.

Further information

- Wheeler R (2006) Gillick or Fraser? A plea for consistency over competence in children. BMJ **332**(7545): 807
- Gillick v West Norfolk & Wisbech AHA & DHSS [1983] 3 WLR (QBD)
- Axon, R (on the application of) v Secretary of State for Health [2006] EWHC 37 (Admin)
- Mental Capacity Act 2005

Appendix C

Current forms in use in this organisation

The written consent forms in use are provided on duplicating pads.

Electronic Consent Forms mimic these forms and are printed on an individual basis for each patient each time consent is sought.

Enclosed:

Printed consent forms
Consent Form 1
Consent Form 2
Consent Form 3
Consent Form 4

E-consent forms
Consent Form 1
Consent Form 2
Consent Form 3

Guidance to health professionals (to be read in conjunction with consent policy)

What a consent form is for
This form documents the patient's agreement to go ahead with the investigation or treatment you have proposed. It is not a legal waiver - if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoire to health professionals and patients, by providing a check-list of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way, however, should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent
See the Department of Health's *Reference guide to consent for examination or treatment* for a comprehensive summary of the law on consent (also available at www.dch.gov.uk/consent).

Who can give consent
Everyone aged 16 or more is presumed to be competent to give consent for themselves, unless the opposite is demonstrated. If a child under the age of 16 has "sufficient understanding and intelligence to enable him or her to understand fully what is proposed", then he or she will be competent to give consent for himself or herself. Young people aged 16 and 17, and legally 'competent' younger children, may therefore sign this form for themselves, but may like a parent to countersign as well. If the child is not able to give consent for himself or herself, someone with parental responsibility may do so on their behalf and a separate form is available for this purpose. Even where a child is able to give consent for himself or herself, you should always involve those with parental responsibility in the child's care, unless the child specifically asks you not to do so. If a patient is mentally competent to give consent but is physically unable to sign a form, you should complete this form as usual, and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form
If the patient is 18 or over and is not legally competent to give consent, you should use form 4 (form for adults who are unable to consent to investigation or treatment) instead of this form. A patient will not be legally competent to give consent if:-

- they are unable to comprehend and retain information material to the decision and/or
- they are unable to weigh and use this information in coming to a decision

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives **cannot** be asked to sign this form on behalf of an adult who is not legally competent to consent for himself or herself.

Information
Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and the alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'serious or frequently occurring' risks. In addition if patients make clear they have particular concerns about certain kinds of risk, you should make sure they are informed about these risks, even if they are very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on page 2 of the form or in the patient's notes.

WR1130

Worcestershire NHS
Acute Hospitals NHS Trust

CONSENT FORM 1

Patient agreement to investigation or treatment

Patient Details (attach sticker or record)

Name _____

NHS No ☐☐☐☐☐☐☐☐☐☐

Unit No ☐☐☐☐☐☐☐☐☐☐

Date of birth _____ Male ☐ Female ☐

Consultant _____ Ward _____

Responsible health professional _____

Job Title _____

Special requirements _____
(eg other language/other communication method)

To be retained in patient's notes

Patient Agreement to investigation or treatment.

Both sides of this sheet should be completed. Following confirmation of consent by patient's signature it should be retained in the patient's record.

1. Patient Details (or pre-printed label)

Surname/Family name ..... First Name(s) .....

Address .....

Date of Birth..... Patient record number..... Male ☐ Female ☐

NHS Number ☐☐☐☐ ☐☐☐☐☐☐

Special requirements (*eg other language/communication method*).....

2. Name of proposed procedure or course of treatment

(include brief explanation if medical term not clear)

.....

3. Statement of Health Professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in Consent Policy)

I have explained the procedure to the patient. In particular, I have explained:
THE INTENDED BENEFITS:

RISKS:

Any additional procedures which may become necessary during the procedure.
☐ Blood transfusion
☐ Other procedure (please specify)

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

The following leaflet/tape has been provided: ☐

This procedure will involve: ☐ General and/or regional anaesthesia ☐ Local anaesthesia ☐ Sedation

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

Name(print):..... Job Title:.....
Contact details (if patient wishes to discuss options later):

CONSENT FORM 1

Worcestershire NHS
Acute Hospitals NHS Trust

Statement of Interpreter (where appropriate)
I have interpreted the information overleaf to the patient to the best of my ability and in a way in which I believe she/he can understand.

Signed:..... Name(print):..... Date:..../..../....

Statement of Patient
Please read this form carefully. If your treatment has been planned in advance, you should already have see a copy of page 2 which describes the benefits and risks of the proposed treatment. If not, you can see a copy now. If you have any further questions, do ask - we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

I agree to the procedure or course of treatment described on this form.

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.

I understand that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia).

I understand that any tissue removed (including bodily fluid) will be treated, assessed, stored and disposed of as appropriate and in a manner regulated by appropriate, ethical, legal and professional standards.

I agree to the use of images for the purpose of diagnosis and treatment.

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

I have been told about additional procedures which may become necessary during my treatment. I have listed below any procedures **which I do not wish to be carried out** without further discussion.

.....

.....

Patient's Signature_____ Date_____

Name (PRINT) _____

Confirmation of consent *(to be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance)*

On behalf of the team treating the patient, I have confirmed with the patient that she/he has no further questions and wishes the procedure to go ahead.

Signed:..... Name(print):..... Date:..../..../....

Important notes: (tick if applicable)

☐ See also advance directive/living will

Patient has withdrawn consent (ask patient to sign below)

Signed:..... Name(print):..... Date:..../..../....

Guidance to health professionals (to be read in conjunction with consent policy)

What a consent form is for
This form should be used to document consent to a child's treatment, where the consent is being given by a person with parental responsibility for the child. The term 'parent' has been used in this form as a shorthand for 'person with parental responsibility'. Where children are legally competent to consent for themselves (see below), they may sign the standard 'adult' consent form (Form 1). There is a space on that form for a parent to countersign if a competent child wishes them to do so.

Who can give consent
Everyone aged 16 or more is presumed to be competent to give consent for themselves, unless the opposite is demonstrated. The courts have stated that if a child under the age of 16 has 'sufficient understanding and intelligence to enable him or her to understand fully what is proposed', then he or she will be competent to give consent for himself or herself. If children are not able to give consent for themselves, someone with parental responsibility may do so on their behalf.

Although children acquire rights to give consent for themselves as they grow older, people with 'parental responsibility' for a child retain the right to give consent on the child's behalf until the child reaches the age of 18. Therefore, for a number of years, both the child and a person with parental responsibility have the right to give consent to the child's treatment. In law, health professionals only need the consent of one appropriate person before providing treatment. This means that in theory it is lawful to provide treatment to a child under 18 which a person with parental responsibility has authorised, even if the child refuses. As a matter of good practice, however, you should always seek a competent child's consent before providing treatment unless any delay involved in doing so would put the child's life or health at risk. Younger children should also be as involved as possible in decisions about their healthcare. Further advice is given in the Department's guidance *Seeking consent: working with children*. Any differences of opinion between the child and their parents, or between parents, should be clearly documented in the patient's notes.

Parental responsibility
The person(s) with parental responsibility will usually, but not invariably be the child's birth parents. People with parental responsibility for a child include: the child's mother; the child's father if married to the mother at the child's conception, birth or later; a legally appointed guardian; the local authority if the child is on a care order; or a person named in a residence order in respect of the child. Fathers who have never been married to the child's mother will only have parental responsibility if they have acquired it through a court order or parental responsibility agreement (although this may change in the future).

Information
Information about what the treatment will involve, its benefits and risks (including side effects and complications) and the alternatives to the particular procedure proposed, is crucial for children and their parents when making up their minds about treatment. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'serious or frequently occurring' risks. In addition if patients make clear they have particular concerns about certain kinds of risk, you should make sure they are informed about these risks, even if they are very small or rare. You should always answer questions honestly.

The law on consent
See the Department of Health's *'Reference guide to consent for examination or treatment'* and *'Seeking consent: working with children'* for a comprehensive summary of the law on consent (also available at www.doh.gov.uk/consent).

WR1131

Worcestershire NHS
Acute Hospitals NHS Trust

CONSENT FORM 2

Parental agreement to investigation or treatment for a child or young person

Patient Details (attach sticker or record)

Name _____

NHS No ☐☐☐☐☐☐☐☐☐☐

Unit No ☐☐☐☐☐☐☐☐☐☐

Date of birth _____ Male ☐ Female ☐

Consultant _____ Ward _____

Responsible health professional _____

Job Title _____

Special requirements _____
(eg other language/other communication method)

To be retained in patient's notes

Parental Agreement to investigation or treatment for a child or young person.
Both sides of this sheet should be completed. Following confirmation of consent by patient's signature it should be retained in the patient's record.

1. Patient Details (or pre-printed label)

Surname/Family name . . . . . First Name(s) . . . . .

Address . . . . .

Date of Birth. . . . . Patient record number. . . . . Male ☐ Female ☐

NHS Number

Special requirements (*eg other language/communication method*). . . . . .

2. Name of proposed procedure or course of treatment

(include brief explanation if medical term not clear)

. . . . . .

3. Statement of Health Professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in Consent Policy)

I have explained the procedure to the patient. In particular, I have explained:
THE INTENDED BENEFITS:

RISKS:

Any additional procedures which may become necessary during the procedure.
☐ Blood transfusion
☐ Other procedure (please specify)

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

The following leaflet/tape has been provided: ☐

This procedure will involve: ☐ General and/or regional anaesthesia ☐ Local anaesthesia ☐ Sedation

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

Name(print): . . . . . Job Title: . . . . .
Contact details (if patient wishes to discuss options later):

CONSENT FORM 2

Worcestershire NHS
Acute Hospitals NHS Trust

Statement of Interpreter (where appropriate)
I have interpreted the information overleaf to the patient to the best of my ability and in a way in which I believe she/he can understand.

Signed: . . . . . Name(print): . . . . . Date: . . . . / . . . . / . . . .

Statement of Patient
Please read this form carefully. If your treatment has been planned in advance, you should already have seen a copy of page 2 which describes the benefits and risks of the proposed treatment. If not, you can see a copy now. If you have any further questions, do ask - we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

I agree to the procedure or course of treatment described on this form.

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.

I understand that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia).

I understand that any tissue removed (including bodily fluid) will be treated, assessed, stored and disposed of as appropriate and in a manner regulated by appropriate, ethical, legal and professional standards.

I agree to the use of images for the purpose of diagnosis and treatment.

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

I have been told about additional procedures which may become necessary during my treatment. I have listed below any procedures **which I do not wish to be carried out** without further discussion.

. . . . . .

. . . . . .

Signed: _____ Name(print): _____ Date: ____/____/____

Relationship to child _____

Child's agreement to treatment (if child wishes to sign)
I agree to have the treament I have been told about.

Signed: _____ Name(print): _____ Date: ____/____/____

Confirmation of consent *(to be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance)*

On behalf of the team treating the patient, I have confirmed with the patient that she/he has no further questions and wishes the procedure to go ahead.

Signed: . . . . . Name(print): . . . . . Date: . . . . / . . . . / . . . .

Important notes: (tick if applicable)
☐ See also advance directive/living will

Patient has withdrawn consent (ask patient to sign below)

Signed: . . . . . Name(print): . . . . . Date: . . . . / . . . . / . . . .

Guidance to health professionals (to be read in conjunction with consent policy)

What a consent form is for
This form should be used to document consent to a child's treatment, where the consent is being given by a person with parental responsibility for the child. The term 'parent' has been used in this form as a shorthand for 'person with parental responsibility'. Where children are legally competent to consent for themselves (see below), they may sign the standard 'adult' consent form (Form 1). There is a space on that form for a parent to countersign if a competent child wishes them to do so.

Who can give consent
Everyone aged 16 or more is presumed to be competent to give consent for themselves, unless the opposite is demonstrated. The courts have stated that if a child under the age of 16 has 'sufficient understanding and intelligence to enable him or her to understand fully what is proposed', then he or she will be competent to give consent for himself or herself. If children are not able to give consent for themselves, someone with parental responsibility may do so on their behalf.

Although children acquire rights to give consent for themselves as they grow older, people with 'parental responsibility' for a child retain the right to give consent on the child's behalf until the child reaches the age of 18. Therefore, for a number of years, both the child and a person with parental responsibility have the right to give consent to the child's treatment. In law, health professionals only need the consent of one appropriate person before providing treatment. This means that in theory it is lawful to provide treatment to a child under 18 which a person with parental responsibility has authorised, even if the child refuses. As a matter of good practice, however, you should always seek a competent child's consent before providing treatment unless any delay involved in doing so would put the child's life or health at risk. Younger children should also be as involved as possible in decisions about their healthcare. Further advice is given in the Department's guidance *Seeking consent: working with children*. Any differences of opinion between the child and their parents, or between parents, should be clearly documented in the patient's notes.

Parental responsibility
The person(s) with parental responsibility will usually, but not invariably be the child's birth parents. People with parental responsibility for a child include: the child's mother; the child's father if married to the mother at the child's conception, birth or later; a legally appointed guardian; the local authority if the child is on a care order; or a person named in a residence order in respect of the child. Fathers who have never been married to the child's mother will only have parental responsibility if they have acquired it through a court order or parental responsibility agreement (although this may change in the future).

Information
Information about what the treatment will involve, its benefits and risks (including side effects and complications) and the alternatives to the particular procedure proposed, is crucial for children and their parents when making up their minds about treatment. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'serious or frequently occurring' risks. In addition if patients make clear they have particular concerns about certain kinds of risk, you should make sure they are informed about these risks, even if they are very small or rare. You should always answer questions honestly.

The law on consent
See the Department of Health's *'Reference guide to consent for examination or treatment'* and *'Seeking consent: working with children'* for a comprehensive summary of the law on consent (also available at www.doh.gov.uk/consent).

WR1131

Worcestershire NHS
Acute Hospitals NHS Trust

CONSENT FORM 3

Parental agreement to investigation or treatment for a child or young person

Patient Details (attach sticker or record)

Name _____

NHS No ☐☐☐☐☐☐☐☐☐☐

Unit No ☐☐☐☐☐☐☐☐☐☐

Date of birth _____ Male ☐ Female ☐

Consultant _____ Ward _____

Responsible health professional _____

Job Title _____

Special requirements _____
(eg other language/other communication method)

To be retained in patient's notes

CONSENT FORM 3

Patient/parental Agreement to investigation or treatment
(procedures where consciousness not impaired)
Both sides of this sheet should be completed. Following confirmation of consent by patient's signature it should be retained in the patient's record.

1. Patient Details (or pre-printed label)

Surname/Family name ..... First Name(s) .....

Address .....

Date of Birth..... Patient record number..... Male ☐ Female ☐

NHS Number ☐☐☐☐ ☐☐☐☐☐☐

Special requirements (*eg other language/communication method*).....

2. Name of proposed procedure or course of treatment

(include brief explanation if medical term not clear)

.....

3. Statement of Health Professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in Consent Policy)

I have explained the procedure to the patient. In particular, I have explained:
THE INTENDED BENEFITS:

RISKS:

Any additional procedures which may become necessary during the procedure.
☐ Blood transfusion
☐ Other procedure (please specify)

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

The following leaflet/tape has been provided: ☐

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

Name(print): ..... Job Title: .....

Contact details (if patient wishes to discuss options later):

CONSENT FORM 3

Worcestershire NHS
Acute Hospitals NHS Trust

Statement of Interpreter (where appropriate)
I have interpreted the information overleaf to the patient to the best of my ability and in a way in which I believe she/he can understand.

Signed: ..... Name(print): ..... Date: ..../..../....

Statement of Patient/Person with parental responsibility for patient

I agree to the procedure or course of treatment described on this form.

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.

I understand that the procedure will / will not involve local anaesthesia.

I understand that any tissue removed (including bodily fluid) will be treated, assessed, stored and disposed of as appropriate and in a manner regulated by appropriate, ethical, legal and professional standards.

I agree to the use of images for the purpose of diagnosis and treatment.

Signed:_____ Name(print):_____ Date:____/____/____

Relationship to child _____

Confirmation of consent *(to be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance)*

On behalf of the team treating the patient, I have confirmed with the patient that she/he has no further questions and wishes the procedure to go ahead.

Signed: ..... Name(print): ..... Date: ..../..../....

Guidance to health professionals (to be read in conjunction with consent policy)

This form should only be used where it would be usual to seek written consent but an adult patient (18 or over) lacks capacity to give or withhold consent to treatment. If an adult has capacity to accept or refuse treatment, you should use the standard consent form 1 and respect any refusal. Where treatment is very urgent (for example if the patient is critically ill), it may not be feasible to fill in a form at the time, but you should document your clinical decisions appropriately afterwards. If treatment is being provided under the authority of Part IV of the Mental Health Act 1983, different legal provisions apply and you are required to fill in more specialised forms (although in some circumstances you may find it helpful to use this form was well). If the adult now lacks capacity but has clearly refused particular treatment in advance of their loss of capacity (for example in an advance directive or 'living will'), then you must abide by that refusal if it was validly made and is applicable to the circumstances. For further information on the law on consent, see the Department of Health's *Reference guide to consent for examination or treatment* (www.doh.gov.uk/consent).

When treatment can be given to a patient who is unable to consent
For treatment to be given to a patient who is unable to consent, the following **must** apply:
- the patient must lack the capacity ('competence') to give or withhold consent to this procedure **AND**
- the procedure must be in the patients' best interests.

Capacity
A patient will lack capacity to consent to a particular intervention if he or she is:
- unable to comprehend and retain information material to the decision, especially as to the consequences of having, or not having, the intervention in question; and/or
- unable to use and weigh this information in the decision-making process.

Before making a judgement that a patient lacks capacity you must take all steps reasonable in the circumstances to assist the patient in taking their own decisions (this will clearly not apply if the patient is unconscious). This may involve explaining what is involved in very simple language, using pictures and communication and decision-aids as appropriate. People close to the patient (spouse/partner, family, friends and carers) may often be able to help, as may specialist colleagues such as speech and language therapists or learning disability teams, and independent advocates or supporters.

Capacity is 'decision-specific': a patient may lack capacity to take a particular complex decision, but be quite able to take other more straight-forward decisions or parts of decisions.

Best Interests
A patient's best interests are not limited to their best medical interests. Other factors which form part of the best interests decision include:
- the wishes and beliefs of the patient when competent
- their current wishes
- their general well-being
- their spiritual and religious welfare

Two incapacitated patients, whose *physical* condition is identical, may therefore have different best interests.

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

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

Worcestershire NHS
Acute Hospitals NHS Trust

CONSENT FORM 4

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

Patient Details (or pre-printed label)

Name _____

NHS No ☐☐☐☐☐☐☐☐☐☐

Unit No ☐☐☐☐☐☐☐☐☐☐

Date of birth _____ Male ☐ Female ☐

Consultant _____ Ward _____

Responsible health professional _____

Job Title _____

Special requirements _____
(eg other language/other communication method)

To be retained in patient's notes

Patient Identifier label

All sections to be completed by health professional proposing the procedure

A Details of procedure or course of treatment proposed

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

B Assessment of patient's capacity

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

☐ the patient is unable to comprehend and retain information material to the decision; and/or
☐ the patient is unable to use and weigh this information in the decision-making process; or
☐ the patient is unconscious

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

C Assessment of patient's best interests

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

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

The treatment cannot wait until the patient recovers capacity because:

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

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

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

I/We have been involved in a discussion with the relevant health professionals over the treatment of (patient's name). I/We understand that he/she is unable to give his/her own consent, based on the criteria set out in this form. I/We understand that treatment can lawfully be provided if it is in his/her best interests to receive it.

Any other comments (including any concerns about decision)

Name_____ Relationship to patient_____
Address (if not the same as patient)_____
_____
_____

Signature_____ Date_____

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

☐ Yes ☐ No

Details:

Signature of health professional proposed treatment

The above procedure is, in my clinical judgement, in the best interests of the patient, who lacks the capacity to consent for himself or herself. Where possible and appropriate I have discussed the patient's condition with those close to him or her, and taken their knowledge of the patient's views and beliefs into account in determining his or her best interests.

I have/have not sought a second opinion.

Signature_____ Date_____

Name (PRINT)_____ Job Title_____

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

Signature_____ Date_____

Name (PRINT)_____ Job Title_____

Consent Form 1

Patient agreement to investigation or treatment.

Both sides of this sheet should be completed. Following confirmation of consent by patient's signature it should be retained in the patient's record.

1. Patient details (or pre-printed label)

Surname/Family name …… First name(s) ……

Address ……

Date of Birth…… Patient record number …… Male ☐ Female ☐

NHS Number ……

Special requirements (*eg other language/communication method)* ……

2. Name of proposed procedure or course of treatment

(include brief explanation if medical term not clear)

……

3. Statement of health professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in Consent Policy)

I have explained the procedure to the patient. In particular, I have explained:

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

The following leaflet/tape has been provided: ☐

This procedure will involve: ☐ General and/or regional anaesthesia ☐ Local anaesthesia ☐ Sedation

4. Statement of interpreter (where appropriate)

I have interpreted the information overleaf to the patient to the best of my ability and in a way in which I believe she/he can understand.

Signed ……..….. **Name** (print) ……..……..… Date ……/……/…….

5. Statement of patient

Please read this form carefully. If your treatment has been planned in advance, you should already have seen side 1 which describes the benefits and risks of the proposed treatment. If not, you can see a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

- **I agree** to the procedure or course of treatment described on this form.
- **I understand** that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.
- **I understand** that where planned I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia).
- **I understand** that any tissue removed (including bodily fluid) will be treated, assessed, stored and disposed of as appropriate and in a manner regulated by appropriate, ethical, legal and professional standards.
- **I agree** to the use of images for the purpose of diagnosis and treatment.
- **I understand** that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.
- I have been told **about additional procedures which may become necessary during my treatment. I have listed below any procedures** which I do not wish to be carried out **without further discussion**.

  ……

A witness should sign below if the patient is unable to sign but has indicated his or her consent. Young people/children may also like a parent to sign here (see guidance notes).

Signature ……..…….. **Name** (print) ……..……. Date ……../……../……..

6. Confirmation of consent

(to be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed with the patient that she/he has no further questions and wishes the procedure to go ahead.

Signature ……. **Name** (print) ……..….. Date ……../……../……..

Important note: (tick if applicable)

See advance directive/living will

Consent Form 2

Parental agreement to investigation or treatment for a child or young person.

Both sides of this sheet should be completed. Following confirmation of consent by parent's signature it should be retained in the patient's record.

1. Patient details (or pre-printed label)

Surname/Family name …… First name(s) ……

Address ……

Date of Birth…… Patient record number …… Male ☐ Female ☐

NHS Number ……

Special requirements (*eg other language/communication method)* ……

2. Name of proposed procedure or course of treatment

(include brief explanation if medical term not clear)

……

3. Statement of health professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in Consent Policy)

I have explained the procedure to the patient. In particular, I have explained:

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

The following leaflet/tape has been provided: ☐

This procedure will involve: ☐ General and/or regional anaesthesia ☐ Local anaesthesia ☐ Sedation

4. Statement of interpreter (where appropriate)

I have interpreted the information overleaf to the patient to the best of my ability and in a way in which I believe she/he can understand.

Signed ……..….. **Name** (print) ……..……..… Date ……/……/…….

5. Statement of parent

Please read this form carefully. If your treatment has been planned in advance, you should already have seen side 1 which describes the benefits and risks of the proposed treatment. If not, you can see a copy now. If you have any further questions, do ask – we are here to help you and your child. You have the right to change your mind at any time, including after you have signed this form.

- **I agree** to the procedure or course of treatment described on this form.
- **I understand** that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.
- **I understand** that where planned I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia).
- **I understand** that any tissue removed (including bodily fluid) will be treated, assessed, stored and disposed of as appropriate and in a manner regulated by appropriate, ethical, legal and professional standards.
- **I agree** to the use of images for the purpose of diagnosis and treatment.
- **I understand** that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.
- I have been told **about additional procedures which may become necessary during my treatment. I have listed below any procedures** which I do not wish to be carried out **without further discussion**.

……

6. Child's agreement to treatment (if child wishes to sign)

I agree to have the treatment I have been told about.

Signature …….. **Name** (print) ……..….. Date ……../……../……..

7. Confirmation of consent

(to be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed with the patient that she/he has no further questions and wishes the procedure to go ahead.

Signature …….. **Name** (print) ……..….. Date ……../……../……..

Important note: (tick if applicable)

Consent Form 3

Patient/parental agreement to investigation or treatment (procedures where consciousness not impaired).

Both sides of this sheet should be completed. Following confirmation of consent by patient's signature it should be retained in the patient's record.

1. Patient details (or pre-printed label)

Surname/Family name …… First name(s) ……

Address ……

Date of Birth…… Patient record number …… Male ☐ Female ☐

NHS Number ……

Special requirements (*eg other language/communication method)* ……

2. Name of proposed procedure or course of treatment

(include brief explanation if medical term not clear)

……

3. Statement of health professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in Consent Policy)

I have explained the procedure to the patient. In particular, I have explained:

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

The following leaflet/tape has been provided: ☐

Signed …… Date ……

Name (print) …… Job Title ……

Contact details (if patient wishes to discuss options later): Please refer to patient information leaflet.

4. Statement of interpreter (where appropriate)

I have interpreted the information overleaf to the patient to the best of my ability and in a way in which I believe she/he can understand.

Signed ……..….. **Name** (print) ……..……..… Date ……./……./…….

5. Statement of patient/person with parental responsibility for patient

- **I agree** to the procedure described on this form.
- **I understand** that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.
- **I agree** to the use of images for the purpose of diagnosis and treatment.
- **I understand** that the procedure will/will not involve local anaesthesia.
- **I understand** that any tissue removed (including bodily fluid) will be treated, assessed, stored and disposed of as appropriate and in a manner regulated by appropriate, ethical, legal and professional standards.

Signature ……..…….. **Name** (print) ……..… Date ……../……/…...

Relationship to child …….

6. Confirmation of consent

(to be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed with the patient that she/he has no further questions and wishes the procedure to go ahead.

Signature …….. **Name** (print) ……..….. Date ……../……../……..

Appendix D

Useful contact details

Chief Medical Officer	Mark Wake	or via mobile / switch
Clinical Director for Endoscopy	Mr Stephen Lake	30810 or via mobile / switch
Senior Patient Safety Adviser	Liane Binns	38718
Head of Clinical Governance and Risk Management	Chris Rawlings	38640
Assistant Director of HR (Training & Development)	Sandra Berry	33731
Head of Legal Services	Jane Clavey	44600 or via Alex switch out of hours
Assistant Legal Services Manager	Louise Barratt	43867 or via Alex switch out of hours
Patient Relations Manager	Pauline Spenceley	0300 123 1732

Appendix E

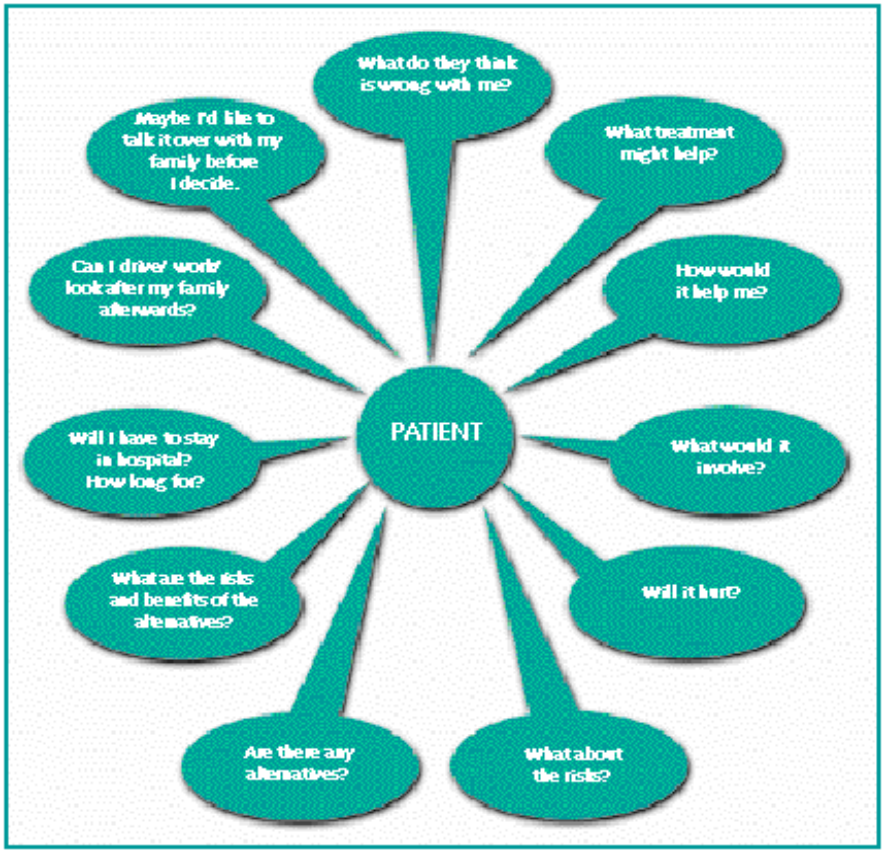
How to seek a court declaration

In the event that a Declaration by the Court is required to authorise treatment for an adult patient who is incapable of consenting, the Consultant in charge should contact the Legal Services Department on ext. 43867.

Out of hours Jane Clavey, Head of Legal Services or Louise Cherry, Assistant Legal Services Manager can be contacted via switchboard at the Alexandra Hospital.

Appendix F

Seeking consent: remembering the patient's perspective



Appendix G

Consent Form

Patient/parental agreement to clinical photographs or video recordings.

Following confirmation of consent by patient's signature it should be retained in the patient's record.

1. Patient details (or pre-printed label)

Surname/Family name ..... First name(s) .....

Address .....

Date of Birth..... Patient record number ..... Male ☐ Female ☐

NHS Number .....

Special requirements *(eg other language/communication method)* .....

2. Name of proposed record

.....

Details:

3. Statement of health professional

We would like you to have some clinical photographs or video recordings taken of you for:

- Teaching of medical, paramedical and nursing staff as well as medical students at Worcestershire Acute Hospitals NHS Trust or other health care professionals outside of this Trust.
- For a one-time use in a print or electronic scientific/medical publication or public display.

Signed ..... Date .....

Name (print) ..... Job Title .....

Contact details (if patient wishes to discuss options later): .....

4. Statement of patient/person with parental responsibility for patient

Under the Data Protection Act you have the right to obtain copies of the stored recordings. You may also withdraw consent for use of the recordings at a later date.

- I agree to have recordings taken for teaching purposes. Yes ☐ No ☐
- I agree to the recordings being used for scientific/medical publication (not for commercial marketing or gain). Further consent will be obtained for additional publishing. Yes ☐ No ☐

Signature ..... Name (print) ..... Date ...../...../.....

Relationship to child

.....

Appendix H

Worcestershire Acute Hospitals NHS Trust

Process for Assessment of Competency in Consent / System Access Form

1. Competency can be assessed by consultant medical staff, and designated nurses who have experience in and are themselves competent to obtain consent for procedures that they perform

2. The competency assessment is intended to focus on the attainment of clinical skills, attitude and behaviour together with confirmation that the health care professional has an understanding of the practical aspects of informed consent. Theory training as described in this policy should be undertaken as part of this process of assessing competence.

3. There is no expectation that competency requires to be assessed on a predetermined number of occasions. Instead it is expected that assessors will become confident, through their knowledge of junior colleagues, that the individual concerned has acquired sufficient confidence and competence to be signed off

4. If competence is not achieved the reasons why must be identified, documented and advice given to the individual concerned. Another assessment should be undertaken at a later date

5. Once the competency assessment has been completed the person being assessed must receive a copy of the system access form and another copy must be sent to John Pick, Clinical Governance Systems Manager, Clinical Governance Department, Kings Court, WRH

Appendix I

Consent to treatment - system access form ***Complete form and return to John Pick, Datix Manager, Clinical Governance Department, 3 Kings Court, WRH***			
Directorate		**Specialty**	
Name of health professional		**Signature**	
Grade of health professional		**Start date**	

Statement of assessor (educational supervisor)	The Health Professional has completed the required training on Informed Consent and has been educated in the Department of Health principles of Consent. He/she fully understands the need to: • have sufficient knowledge of the investigations or procedures and has an understanding of the risks involved. • give patients / parents the information they ask for or need about their condition, its treatment and prognosis including effect on patient's lifestyle. • know alternatives to the proposed treatment, frequency of adverse effects, their seriousness and performance. • be able to communicate satisfactorily to patients / parents in a way they understand. • ensure that the patient / parent is satisfied and has understood what is proposed and consents to it. **See procedures indicated below delegated by Consultant that the health professional can seek consent**		
Name of assessor (educational supervisor)		**Signature of assessor (educational supervisor)**	

Name of procedure	**Competent (tick as appropriate)**

Supporting Document 1 - Equality Impact Assessment Tool –

To be completed by the key document author and included as an appendix to key document when submitted to the appropriate committee for consideration and approval.

Please complete assessment form on next page;

NHS Worcestershire Acute Hospitals NHS Trust

Herefordshire & Worcestershire STP - Equality Impact Assessment (EIA) Form
Please read EIA guidelines when completing this form

Section 1 - Name of Organisation (please tick)

Herefordshire & Worcestershire STP		Herefordshire Council		Herefordshire CCG	
Worcestershire Acute Hospitals NHS Trust	x	Worcestershire County Council		Worcestershire CCGs	
Worcestershire Health and Care NHS Trust		Wye Valley NHS Trust		Other (please state)	

Name of Lead for Activity	**Policy for Consent to Examination or Treatment**

Details of individuals completing this assessment	**Name**	**Job title**	**e-mail contact**
	Allan Bailey	Associate Director of Clinical Governance, Patient Safety and Risk	allan.bailey6@nhs.net
Date assessment completed			

Section 2

Activity being assessed (e.g. policy/procedure, document, service redesign, policy, strategy etc.)	**Title:** Policy for the consent to examination or Treatment			
What is the aim, purpose and/or intended outcomes of this Activity?				
Who will be affected by the development & implementation of this activity?	❑	Service User	x	Staff
	x	Patient	❑	Communities
	❑	Carers	❑	Other _____
	❑	Visitors	❑	
Is this:	X Review of an existing activity			

	❑ New activity ❑ Planning to withdraw or reduce a service, activity or presence?
What information and evidence have you reviewed to help inform this assessment? (Please name sources, eg demographic information for patients / services / staff groups affected, complaints etc.	
Summary of engagement or consultation undertaken (e.g. who and how have you engaged with, or why do you believe this is not required)	
Summary of relevant findings	

Section 3

Please consider the potential impact of this activity (during development & implementation) on each of the equality groups outlined below. **Please tick one or more impact box below for each Equality Group and explain your rationale**. Please note it is possible for the potential impact to be both positive and negative within the same equality group and this should be recorded. Remember to consider the impact on e.g. staff, public, patients, carers etc. in these equality groups.

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Age		X		
Disability		X		
Gender Reassignment		X		
Marriage & Civil Partnerships		X		
Pregnancy & Maternity		X		
Race including Traveling Communities		X		
Religion & Belief		X		
Sex		X		

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Sexual Orientation		X		
Other Vulnerable and Disadvantaged Groups (e.g. carers; care leavers; homeless; Social/Economic deprivation, travelling communities etc.)		X		
Health Inequalities (any preventable, unfair & unjust differences in health status between groups, populations or individuals that arise from the unequal distribution of social, environmental & economic conditions within societies)		X		

Section 4

What actions will you take to mitigate any potential negative impacts?	Risk identified	Actions required to reduce / eliminate negative impact	Who will lead on the action?	Timeframe
		.		
How will you monitor these actions?				
When will you review this EIA? (e.g in a service redesign, this EIA should be revisited regularly throughout the design & implementation)				

Section 5 - Please read and agree to the following Equality Statement

1. Equality Statement

1.1. All public bodies have a statutory duty under the Equality Act 2010 to set out arrangements to assess and consult on how their policies and functions impact on the 9

protected characteristics: Age; Disability; Gender Reassignment; Marriage & Civil Partnership; Pregnancy & Maternity; Race; Religion & Belief; Sex; Sexual Orientation

1.2. Our Organisations will challenge discrimination, promote equality, respect human rights, and aims to design and implement services, policies and measures that meet the diverse needs of our service, and population, ensuring that none are placed at a disadvantage over others.

1.3. All staff are expected to deliver services and provide services and care in a manner which respects the individuality of service users, patients, carer's etc, and as such treat them and members of the workforce respectfully, paying due regard to the 9 protected characteristics.

Signature of person completing EIA	
Date signed	6/08/2024
Comments:	
Signature of person the Leader Person for this activity	Allan Bailey
Date signed	
Comments:	

Supporting Document 2 – Financial Impact Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document:	Yes/No
1.	Does the implementation of this document require any additional Capital resources	No
2.	Does the implementation of this document require additional revenue?	No
3.	Does the implementation of this document require additional manpower?	No
4.	Does the implementation of this document release any manpower costs through a change in practice	No
5.	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff?	No
	Other comments:	

If the response to any of the above is yes, please complete a business case and which is signed by your Finance Manager and Directorate Manager for consideration by the Accountable Director before progressing to the relevant committee for approval