Good practice in consent implementation guide: consent to examination or treatment
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Introduction to this Implementation Guide

This Good practice in consent implementation guide contains a model consent policy and four consent forms, together with an accompanying information leaflet About the consent form. This model documentation has been developed in line with the Welsh Assembly Governments response to the Kennedy Report on Bristol Royal Infirmary, with the aim of assisting NHS organisations to promote good practice in the way patients are asked to give their consent to treatment, care or research. An electronic version of this documentation can be downloaded from:

http://www.wales.gov.uk/subihealth/toc-e.htm#Guid/Goodpracticeinconsentimplementationguide

The four forms are designed to meet the needs of different groups of patients at different times:

- consent form 1 for patients able to consent for themselves

- consent form 2 for those with parental responsibility, consenting on behalf of a child/young person

- consent form 3 both for patients able to consent for themselves and for those with parental responsibility consenting on behalf of a child/young person, where the procedure does not involve any impairment of consciousness. This form is shorter than the others, as the fact that the patient is expected to remain alert during the procedure makes some of the information covered in forms 1 and 2 unnecessary. The use of this form is optional.

- consent form 4 for adults who lack capacity to consent to a particular treatment. As no-one else can give consent on behalf of such a patient, they may only be treated if that treatment is believed to be in their ‘best interests’. This form requires health professionals to document both how they have come to the conclusion that the patient lacks the capacity to make this particular healthcare decision, and why the proposed treatment would be in the patient’s best interests. It also allows the involvement of those close to the patient in making this healthcare decision to be documented.

The development of these forms does not change the current position on when written, as opposed to oral, consent to treatment is necessary. It is a matter of local determination what form of consent is appropriate for individual procedures, within the broad guidelines set out in the model consent policy.

Further forms relating to post-mortems and the removal, retention and use of human organs and tissue following post-mortem will be added to this set in due course. A guide to their implementation will be published at the same time.
Customisation of model documentation

Circular WHC (2002) 42 makes clear that both consent forms and consent policy should be recognisable across the NHS and that the text included in this implementation guide should not be amended or removed. However, it may be appropriate to customise the documentation to reflect local needs, and the extent to which customisation is acceptable is set out below.

Consent Forms

Additional material relevant to local circumstances may be included in consent forms, as long as this does not result in forms becoming too unwieldy or in the font size being reduced inappropriately. NHS trusts who have developed the practice of documenting anaesthetic consent on the main consent form (as opposed to on the anaesthetic record) should feel free to include such a section within their new forms.

Relevant sections of the forms (such as those dealing with benefits and risks) may be pre-printed where high through-put specialities make this feasible and desirable. If this is done, it will, of course, always be necessary for health professionals to consider whether additional risk/benefit information should be added by hand, to reflect the particular needs of the individual patient. It is essential, however, to ensure that this does not lead to a ‘conveyor belt’ approach to consent in these circumstances.

While consent forms 1 and 2 have been designed in the form of 4 page booklets with the crucial information for patients on the facing inside pages, they may if desired be reduced to 2 sides of a single sheet by making the guidance notes on the back available to health professionals in another way. There must, however, be clear reference on the forms to the availability of those guidance notes, which must be readily accessible. As the guidance notes on consent form 2 (which explain the relatively complicated legal position regarding who may give consent on behalf of a child) may be less familiar to health professionals, it may generally be more appropriate to take this approach for consent form 1 than for consent form 2.

Whatever the format used, a copy of the page documenting the details of the treatment should be offered to the patient, for example through the use of ‘no carbon required’ (NCR) copies.

The text for patients ‘About the consent form’ should be made available to patients in advance of their being asked to sign a consent form, and may be published in any appropriate format. Text should only be omitted if it will never be relevant (for example the section on anaesthesia could be omitted if the organisation involved would never be seeking consent for anaesthesia).
Consent policy

The model policy has been designed to encourage the addition of local information where indicated. If it is felt to be helpful to extend the scope of the model policy, this should be done by means of a separate schedule so that it does not affect the existing layout of the rest of the policy. This will enable staff moving between NHS organisations to know exactly where to look for particular information in their new organisation’s policy.

Implementation

The required time-scales for implementing the model consent documentation are set out in circular WHC (2002) 42. The Welsh Risk Pool and the National Assembly for Wales will be revising its Welsh Risk Management Standard on “Consent to Treatment” to reflect the new requirements from the Welsh Assembly Government and will ensure that Trusts are aware of when they will be assessed against that new Standard.

Guidance on consent

The Department has published a range of guidance documents on consent, which are freely available in electronic format from NHS Quality: Clinical Standards Development Branch (029) 2082 5215 or from http://www.wales.gov.uk/subihealth/toc-e.htm

- Reference guide to consent for examination or treatment, April 2002
- 12 key points on consent: the law in England & Wales, April 2002
Model policy for consent to Examination or treatment
1. Introduction

Why consent is crucial

1. 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.

This policy

2. The Welsh Assembly Government has issued a range of guidance documents on consent (see overleaf), 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/LHG/practice] 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.

What consent is – and isn’t

3. “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.

4. 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.

5. Where an adult patient lacks the mental capacity (either temporarily or permanently) to give or withhold consent for themselves, no-one else can give consent on their behalf. However, treatment may be given if it is in their best
interests, as long as it has not been refused in advance in a valid and applicable advance directive. For further details on advance directives see the Welsh Assembly Government Reference guide to consent for examination or treatment (chapter 1, paragraph 19).

Guidance on consent

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

• Reference guide to consent for examination or treatment provides a comprehensive summary of the current law on consent, and includes requirements of regulatory bodies such as the General Medical Council where these are more stringent.

• 12 key points on consent: the law in England & Wales has been distributed widely to health professionals working in Wales. This one-page document summarises those aspects of the law on consent which arise on a daily basis and is attached at Appendix A. Further copies are available from http://www.wales.gov.uk/subihealth/toc-e.htm
II Documentation

1. For significant procedures, it is essential for health professionals to document clearly both a patient’s agreement to the intervention and the discussions which led up to that agreement. This may be done either through the use of a consent form (with further detail in the patient’s notes if necessary), or through documenting in the patient’s notes that they have given oral consent.

Written consent

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

3. It is rarely a legal requirement to seek written consent, 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/LHG]

[Individual Trusts/LHG may choose to list in an Annex whether written/oral/non-verbal consent is appropriate for specified procedures.]

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

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1 The Mental Health Act 1983 and the Human Fertilisation and Embryology Act 1990 require written consent in certain circumstances.
5. 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.

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

6. 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.

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

8. 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 D for details of how to do this.

**Availability of forms**

9. Standard consent forms and forms for adults who are unable to consent for themselves are reproduced in Appendix B and are available from [local details]. 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.
III When should consent be sought?

1. When a patient formally gives their consent to a particular intervention, this is only the endpoint of the consent process. It is helpful to see the whole process of information provision, discussion and decision-making as part of ‘seeking consent’. This process may take place at one time, or over a series of meetings and discussions, depending on the seriousness of what is proposed and the urgency of the patient’s condition.

Single stage process

2. 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.

3. 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.

Two or more stage process

4. 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.

5. 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?”

6. 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.

Seeking consent for anaesthesia

7. Where an anaesthetist is involved in a patient’s care, it is their responsibility (not that of a surgeon) to seek consent for anaesthesia, having discussed the benefits and risks. However, in elective treatment it is not acceptable for the patient to receive no information about anaesthesia until their pre-operative visit from the anaesthetist: at such a late stage the patient will not be in a position genuinely to make a decision about whether or not to undergo anaesthesia. Patients should therefore either receive a general leaflet about anaesthesia in out-patients, or have the opportunity to discuss anaesthesia in a pre-assessment clinic. The anaesthetist should ensure that the discussion with the patient and their consent is documented in the anaesthetic record, in the patient’s notes or on the consent form. Where the clinician providing the care is personally responsible for anaesthesia (eg 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.

8. 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.

Emergencies

9. 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.

Treatment of young children

10. 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.
11. 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.
IV Provision of information

1. 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.

2. Patients and those close to them will vary in how much information they want: from those who want as much detail as possible, including details of rare risks, to those who ask health professionals to make decisions for them. There will always be an element of clinical judgement in determining what information should be given. However, the presumption must be that the patient wishes to be well informed about the risks and benefits of the various options. Where the patient makes clear (verbally or non-verbally) that they do not wish to be given this level of information, this should be documented.

3. The following sources of patient information are available in this [Trust/LHG]:

   • [Insert local details, including advice on accessibility/readability for those developing such materials. Also include what specific provision is made for those who, for reasons of disability or otherwise, would not find printed information particularly accessible (tapes, pictorial materials etc) together with details of local independent advocacy groups where these exist. Some Trusts have developed ‘patient passports’ determining what information is needed at which points in a patient’s ‘journey’ through healthcare. Others have made provision for patients to receive tape-recordings of consultations so that they have a permanent record of what was discussed.]

Provision for patients whose first language is not English/Welsh

4. This [Trust/LHG] is committed to ensuring that patients whose first language is not English/Welsh receive the information they need and are able to communicate appropriately with healthcare staff. It is not appropriate to use children to interpret for family members who do not speak English/Welsh.

   • [Insert local details of how to access translation and interpreting service, what materials are available in which languages etc. Reference other relevant local policies or guidance eg on use of interpreting.]

Access to more detailed or specialist information

5. Patients may sometimes request more detailed information about their condition or about a proposed treatment than that provided in general leaflets. This [Trust/LHG] has made the following arrangements to assist patients to obtain such information:
• [Insert local details eg access on site to NHS Direct Online, links with local medical libraries. In hospitals, this policy can be adapted at Directorate level to include more specific information here.]

Access to health professionals between formal appointments

6. After an appointment with a health professional in primary care or in outpatients, 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). [Insert local details of what systems are in place at GP practice/ Directorate level eg GP surgeries which have a defined hour in the day for phone calls, space in consent form for contact number of appropriate health professional, such as specialist nurse.]

Open access clinics

7. 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. [Insert local details of relevant arrangements, such as provision of information through primary care.]
V Who is responsible for seeking consent?

1. 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.

2. 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.

Completing consent forms

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

4. 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.

[Insert local details, where appropriate at Directorate level, covering:

- what training is available for health professionals who do not themselves carry out specific procedures, but could potentially provide the information patients need in coming to a decision.

- what procedures are in place to ensure that the health professionals ‘confirming’ the patient’s consent have genuine access to appropriate colleagues where they are personally not able to answer any remaining questions.]

Responsibility of health professionals

5. It is a health professional’s own responsibility:

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

If you feel that you are being pressurised to seek consent when you do not feel competent to do so [insert local details of whom to contact, such as clinical governance lead.]
VI Refusal of treatment

1. If the process of seeking consent is to be a meaningful one, refusal must be one of the patient’s options. A competent adult patient is entitled to refuse any treatment, except in circumstances governed by the *Mental Health Act 1983*. The following paragraphs apply primarily to adults.

2. If, after discussion of possible treatment options, 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.

3. 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.

4. 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.
VII Tissue

1. The legal position regarding the use of human tissue (including blood samples and other bodily fluids provided for testing) raises some difficult issues and is currently under review. Such tissue can be very valuable in education and research, and its use may lead to developments in medical knowledge and hence improvements in healthcare for all. At present, this [Trust/LHG] 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. [Insert local details of how this should be done. The system must be well-publicised and transparent, making provision for patients to record their consent or objection to the use of such tissue and for this to be notified to the laboratory. Patients must also be able to record any objections to particular uses or use of particular tissues.]

2. Explicit consent is not necessary for public health surveillance using the unlinked anonymous method, but a well-publicised opt-out policy must apply. [Insert local details.]

3. Pending the outcome of the review of the law governing the use of human organs and tissue, the Welsh Assembly Government believes that tissue samples may be used for quality assurance purposes without requiring specific patient consent provided there is an active policy of informing patients of such use. This is essential to ensure the high quality of service which all patients have the right to expect. Wherever possible, samples of tissue used in this way should be anonymised or pseudonymised. [Insert local details of policy.]
VIII Clinical photography and conventional or digital video recordings

1. 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.

2. Photographic and video recordings which are made for treating or assessing a patient must not be used for any purpose other than the patient’s care or the audit of that care, without the express consent of the patient or a person with parental responsibility for the patient. The one exception to this principle is set out in paragraph 3 below. If you wish to use such a recording for education, publication or research purposes, you must seek consent in writing, ensuring that the person giving consent is fully aware of the possible uses of the material. In particular, the person must be made aware that you may not be able to control future use of the material once it has been placed in the public domain. If a child is not willing for a recording to be used, you must not use it, even if a person with parental responsibility consents.

3. 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.

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

5. 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.
6. 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.
IX  Training

[Insert details of training available on consent in this organisation, covering both basic training on the law of consent, and training on any specific procedures used in this organisation.]

Dated:
Person responsible for policy:
Policy approved by:
Policy to be reviewed by [date]:
Appendix A

12 key points on consent: the law in England & Wales

When do health professionals need consent from patients?

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

2. Adults are always assumed to be competent unless demonstrated otherwise. If you have doubts about their competence, the question to ask is: “can this patient understand and weigh up the information needed to make this decision?” Unexpected decisions do not prove the patient is incompetent, but may indicate a need for further information or explanation.

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

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

Can children give consent for themselves?

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

Who is the right person to seek consent?

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

What information should be provided?

7. Patients need sufficient information before they can decide whether to give their consent: for example information about the benefits and risks of the proposed treatment, and alternative treatments. If the patient is not offered as much information as they reasonably need to make their decision, and in a form they can understand, their consent may not be valid.
8. Consent must be given voluntarily: not under any form of duress or undue influence from health professionals, family or friends.

Does it matter how the patient gives consent?

9. No: consent can be written, oral or non-verbal. A signature on a consent form does not itself prove the consent is valid – the point of the form is to record the patient’s decision, and also increasingly the discussions that have taken place. 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 fetus.

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 in electronic format from NHS Quality: Clinical Standards Development Branch (029 2082 5215) or from http://www.wales.gov.uk/subihealth/toc-e.htm.
Appendix B

Current forms in use in this organisation
Appendix C

Useful contact details

[eg risk managers, training managers, clinical governance leads, clinical ethics committees]
Appendix D

How to seek a court declaration

[eg details of how to contact the organisation’s legal services, what information they will require etc]
Appendix E

Seeking consent: remembering the patient’s perspective

[Diagram showing patient's perspective with questions such as "What do they think is wrong with me?", "What treatment might help?", "Can I drive/ work/ look after my family afterwards?", etc.]
[NHS organisation name]

consent form 1

Patient agreement to investigation or treatment

Patient details (or pre-printed label)

Patient’s surname/family name______________________________________
Patient’s first names _____________________________________________
Date of birth ___________________________________________________
Responsible health professional ___________________________________
Job title________________________________________________________
NHS number (or other identifier)___________________________________
☐ Male           ☐ Female

Special requirements ____________________________________________

(eg other language/other communication method)

To be retained in patient’s notes
Patient identifier/label

Name of proposed procedure or course of treatment
(include brief explanation if medical term not clear)

___________________________________________________________________
___________________________________________________________________
___________________________________________________________________

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
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________
Serious or frequently occurring risks ______________________________________
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________
Any extra 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)__________________

Statement of interpreter (where appropriate)
I have interpreted the information above to the patient to the best of my ability and in
a way in which I believe s/he can understand.
Signed_____________________________ Date_____________________________
Name (PRINT)_______________________

Top copy accepted by patient: yes/no (please ring)
Statement of patient

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of page 2 which describes the benefits and risks of the proposed treatment. If not, you will be offered 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 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)_______________________________

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 notes).

Signed_____________________________________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 s/he has no further questions and wishes the procedure to go ahead.

Signed_____________________________________Date_____________________

Name (PRINT)______________________________Job title ___________________

Important notes: (tick if applicable)

☐ See also advance directive/living will (eg Jehovah’s Witness form)
☐ Patient has withdrawn consent (ask patient to sign/date here)________________
**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 Welsh Assembly Government’s *Reference guide to consent for examination or treatment* for a comprehensive summary of the law on consent (also available at [http://www.wales.gov.uk/subihealth/toc-e.htm](http://www.wales.gov.uk/subihealth/toc-e.htm)).

**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, some-one 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.
[NHS organisation name]

consent form 2

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

Patient details (or pre-printed label)

Patient’s surname/family name___________________________________________
Patient’s first names _________________________________________________
Date of birth _______________________________________________________
Responsible health professional _______________________________________
Job title____________________________________________________________
NHS number (or other identifier)________________________________________

☐ Male  ☐ Female

Special requirements _________________________________________________

(eg other language/other communication method)

To be retained in patient’s notes
Name of proposed procedure or course of treatment
(include brief explanation if medical term not clear)

___________________________________________________________________
___________________________________________________________________
___________________________________________________________________

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 child and his or her parent(s). In particular, I have explained:
The intended benefits
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________
Serious or frequently occurring risks
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________
Any extra 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 and his or her parents.
☐ 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 child/parent wish to discuss options later)

Statement of interpreter (where appropriate)
I have interpreted the information above to the child and his or her parents to the best of my ability and in a way in which I believe they can understand.

Signed _________________________ Date _________________________
Name (PRINT) _____________________

Top copy accepted by patient/parent: yes/no (please ring)
Statement of parent

Please read this form carefully. If the procedure has been planned in advance, you should already have your own copy of page 2 which describes the benefits and risks of the proposed treatment. If not, you will be offered 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 and I confirm that I have ‘parental responsibility’ for this child.

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

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

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

___________________________________________________________________
___________________________________________________________________
___________________________________________________________________

Signed____________________________ Date______________________________
Name (PRINT) ___________________Relationship to child____________________

Child’s agreement to treatment (if child wishes to sign)

I agree to have the treatment I have been told about.
Name____________________________ Signed_____________________________
Date_________________________________________________________________

Confirmation of consent (to be completed by a health professional when the child is admitted for the procedure, if the parent/child have signed the form in advance)

On behalf of the team treating the patient, I have confirmed with the child and his or her parent(s) that they have no further questions and wish the procedure to go ahead.

Signed____________________________ Date______________________________
Name (PRINT) ___________________Job title______________________________

Important notes: (tick if applicable)
☐ See also advance directive/living will (eg Jehovah’s Witness form)
☐ Parent has withdrawn consent (ask parent to sign/date here)________________
Guidance to health professionals (to be read in conjunction with consent policy)

This form
This form should be used to document consent to a child’s treatment, where that 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 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, some-one 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. 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.

**Guidance on the law on consent**
See the Department of Health publications *Reference guide to consent for examination or treatment* for a comprehensive summary of the law on consent (also available at [http://www.wales.gov.uk/subihealth/toc-e.htm](http://www.wales.gov.uk/subihealth/toc-e.htm))
[NHS organisation name]
consent form 3

Form for Patient/Parental agreement to investigation or treatment
(procedures where consciousness not impaired)

Patient details (or pre-printed label)

Patient’s surname/family name_____________________________________
Patient’s first names _____________________________________________
Date of birth ___________________________________________________
Responsible health professional ____________________________________
Job title________________________________________________________
NHS number (or other identifier)____________________________________

☐  Male  ☐  Female

Special requirements _____________________________________________

(eg other language/other communication method)
Name of procedure
(include brief explanation if medical term not Clear)

___________________________________________________________________
___________________________________________________________________
___________________________________________________________________

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/parent. In particular, I have explained:
The intended benefits

___________________________________________________________________
___________________________________________________________________
___________________________________________________________________

Serious or frequently occurring risks

___________________________________________________________________
___________________________________________________________________
___________________________________________________________________

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 those involved.

☐ The following leaflet/tape has been provided)

Signed____________________________ Date______________________________

Name (PRINT) _____________________Job title____________________________

Statement of interpreter (where appropriate)
I have interpreted the information above to the patient/parent to the best of my ability and in a way in which I believe s/he/they can understand.

Signed__________________ Date______________ Name (PRINT)_____________

Statement of patient/person with parental responsibility for patient
I agree to the procedure described above.

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.

Signed____________________________ Date______________________________

Name (PRINT) _________________Relationship to patient____________________

Confirmation of consent (to be completed by a health professional when the patient is admitted for the procedure, if the patient/parent has signed the form in advance) I have confirmed that the patient/parent has no further questions and wishes the procedure to go ahead.
Signed __________________________ Date __________________________
Name (PRINT) ___________________ Job title _______________________

Top copy accepted by patient/parent: yes/no (please ring)
**Guidance to health professionals** (to be read in conjunction with consent policy)

**This form**
This form documents the patient’s agreement (or that of a person with parental responsibility for the patient) to go ahead with the investigation or treatment you have proposed. It is only designed for procedures where the patient is expected to remain alert throughout and where an anaesthetist is not involved in their care: for example for drug therapy where written consent is deemed appropriate. In other circumstances you should use either form 1 (for adults/competent children) or form 2 (parental consent for children/young people) as appropriate.

Consent forms are not legal waivers – 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 also have every right to change their mind after signing the form.

**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, if they wish. If the child is not able to give consent for himself or herself, some-one with parental responsibility may do so on their behalf. 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 (see also ‘This form’ above)**
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 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. 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 overleaf or in the patient’s notes.

The law on consent
See the Welsh Assembly Government’s Reference guide to consent for examination or treatment for a comprehensive summary of the law on consent (also available at www.wales.gov.uk/subihealth/toc-e.htm )
[NHS organisation name]
consent form 4

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

Patient details (or pre-printed label)

Patient’s surname/family name_________________________________________________
Patient’s first names _______________________________________________________
Date of birth _______________________________________________________________
Responsible health professional _____________________________________________
Job title_______________________________________________________________
NHS number (or other identifier)____________________________________________

☐ Male ☐ Female

Special requirements _______________________________________________________

(eg other language/other communication method)
Patient identifier/label

All sections to be completed by health professional proposing the procedure

A Details of procedure or course of treatment proposed

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

B Assessment of patient’s capacity

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

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

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

C Assessment of patient’s best interests

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

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

The treatment cannot wait until the patient recovers capacity because:
D Involvement of the patient’s family and others close to the patient

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

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

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

Any other comments (including any concerns about decision)
Name _____________________________ Relationship to patient
_________________________________________________
Address (if not the same as patient)_________________________________________________
___________________________________________________________________
___________________________________________________________________
Signature ___________________________________________________________________
Date ____________________________________________________________________

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

☐ Yes ☐ No
Details:

Signature of health professional proposing treatment

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

I have/have not sought a second opinion.
Signed____________________________ Date____________________________
Name (PRINT) _____________________Job title____________________________

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

Signed____________________________ Date____________________________
Name (PRINT) _____________________Job title____________________________
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 and respect any refusal. Where treatment is very urgent (for example if the patient is critically ill), it may not be feasible to fill in a form at the time, but you should document your clinical decisions appropriately afterwards. If treatment is being provided under the authority of Part IV of the Mental Health Act 1983, different legal provisions apply and you are required to fill in more specialised forms (although in some circumstances you may find it helpful to use this form as well). If the adult now lacks capacity, but has clearly refused particular treatment in advance of their loss of capacity (for example in an advance directive or ‘living will’), then you must abide by that refusal if it was validly made and is applicable to the circumstances. For further information on the law on consent, see the Welsh Assembly Government’s Reference guide to consent for examination or treatment (http://www.wales.gov.uk/subihealth/toc-e.htm).

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 patient’s best interests.

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

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

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

Best interests
A patient’s best interests are not limited to their best medical interests. Other factors which form part of the best interests decision include:
- the wishes and beliefs of the patient when competent
- their current wishes
- their general well-being
- their spiritual and religious welfare
Two incapacitated patients, whose *physical* condition is identical, may therefore have different best interests.

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

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

Before a doctor or other health professional examines or treats you, they need your consent. Sometimes you can simply tell them whether you agree with their suggestions. However, sometimes a written record of your decision is helpful – for example if your treatment involves sedation or general anaesthesia. You’ll then be asked to sign a consent form. If you later change your mind, you’re entitled to withdraw consent – even after signing.

What should I know before deciding?

Health professionals must ensure you know enough to enable you to decide about treatment. They’ll write information on the consent form and offer you a copy to keep as well as discussing the choices of treatment with you. Although they may well recommend a particular option, you’re free to choose another. People’s attitudes vary on things like the amount of risk or pain they’re prepared to accept. That goes for the amount of information, too. If you’d rather not know about certain aspects, discuss your worries with whoever is treating you.

Should I ask questions?

Always ask anything you want. As a reminder, you can write your questions in the space over the page. The person you ask should do his or her best to answer, but if they don’t know they should find someone else who is able to discuss your concerns. To support you and prompt questions, you might like to bring a friend or relative. Ask if you’d like someone independent to speak up for you.

Is there anything I should tell people?

If there’s any procedure you don’t want to happen, you should tell the people treating you. It’s also important for them to know about any illnesses or allergies which you may have or have suffered from in the past.

Who is treating me?

Amongst the health professionals treating you may be a “doctor in training” – medically qualified, but now doing more specialist training. They range from recently qualified doctors to doctors almost ready to be consultants. They will only carry out procedures for which they have been appropriately trained. Someone senior will supervise – either in person accompanying a less experienced doctor in training or available to advise someone more experienced.

What about anaesthesia?

If your treatment involves general or regional anaesthesia (where more than a small part of your body is being anaesthetised), you’ll be given general information about it in advance. You’ll also have an opportunity to talk with the anaesthetist when he or she assesses your state of health shortly before treatment. Hospitals sometimes have pre-assessment clinics which provide patients with the chance to discuss things a few weeks earlier.
Will samples be taken?

Some kinds of operation involve removing a part of the body (such as a gall bladder or a tooth). You would always be told about this in advance. Other operations may mean taking samples as part of your care. These samples may be of blood or small sections of tissue, for example of an unexplained lump. Such samples may be further checked by other health professionals to ensure the best possible standards. Again, you should be told in advance if samples are likely to be taken.

Sometimes samples taken during operations may also be used for teaching, research or public health monitoring in the future interests of all NHS patients. The NHS trust treating you will have a local system for checking whether you’re willing for this to happen.

Photographs and videos

As part of your treatment some kind of photographic record may be made – for example X-rays, clinical photographs or sometimes a video. You will always be told if this is going to happen. The photograph or recording will be kept with your notes and will be held in confidence as part of your medical record. This means that it will normally be seen only by those involved in providing you with care or those who need to check the quality of care you have received. The use of photographs and recordings is also extremely important for other NHS work, such as teaching or medical research. However, we will not use yours in a way that might allow you to be identified or recognised without your express permission.

What if things don’t go as expected?

Amongst the 25,000 operations taking place every day, sometimes things don’t go as they should. Although the doctor involved should inform you and your family, often the patient is the first to notice something amiss. If you’re worried – for example about the after-effects of an operation continuing much longer than you were told to expect – tell a health professional right away. Speak to your GP, or contact your clinic - the phone number should be on your appointment card, letter or consent form copy.
What are the key things to remember?

It’s your decision! It’s up to you to choose whether or not to consent to what’s being proposed. Ask as many questions as you like, and remember to tell the team about anything that concerns you or about any medication, allergies or past history which might affect your general health.
Questions to ask health professionals

As well as giving you information health professionals must listen and do their best to answer your questions. Before your next appointment, you can write some down in the space below.

Questions may be about the treatment itself, for example:

- What are the main treatment options?
- What are the benefits of each of the options?
- What are the risks, if any, of each option?
- What are the success rates for different options – nationally, for this unit or for you (the surgeon)?
- Why do you think an operation (if suggested) is necessary?
- What are the risks if I decide to do nothing for the time being?
- How can I expect to feel after the procedure?
- When am I likely to be able to get back to work?

Questions may also be about how the treatment might affect your future state of health or style of life, for example:

- Will I need long-term care?
- Will my mobility be affected?
- Will I still be able to drive?
- Will it affect the kind of work I do?
- Will it affect my personal/sexual relationships?
- Will I be able to take part in my favourite sport/exercises?
- Will I be able to follow my usual diet?

Health care professionals should welcome your views and discuss any issues so they can work in partnership with you for the best outcome.
If you require further electronic copies of this publication please contact:

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It is also available on our website at:
http://www.wales.gov.uk/subihealth/toc-e.htm

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First Published: April 2002