VELINDRE NHS TRUST

Ref No: BLACK 92

Trust Policy

POLICY FOR CONSENT TO EXAMINATION OR TREATMENT

Policy Lead: Lisa Heydon, Clinical Governance Support Manager
Contents Page

<table>
<thead>
<tr>
<th></th>
<th>Purpose</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Objective</td>
<td>3</td>
</tr>
<tr>
<td>3</td>
<td>What Consent is – and is not</td>
<td>4</td>
</tr>
<tr>
<td>4</td>
<td>Context of Consent</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>The Consent</td>
<td>4</td>
</tr>
<tr>
<td>5.1</td>
<td>Types of Consent</td>
<td>5</td>
</tr>
<tr>
<td>6</td>
<td>When Should Consent be Sought?</td>
<td>7</td>
</tr>
<tr>
<td>6.1</td>
<td>Single Stage process</td>
<td>7</td>
</tr>
<tr>
<td>6.2</td>
<td>Two or more stage process</td>
<td>7</td>
</tr>
<tr>
<td>6.3</td>
<td>Elective or pre-arranged procedures or treatment</td>
<td>8</td>
</tr>
<tr>
<td>6.4</td>
<td>Seeking Consent for Anaesthesia</td>
<td>8</td>
</tr>
<tr>
<td>7</td>
<td>Information Provision</td>
<td>9</td>
</tr>
<tr>
<td>7.1</td>
<td>Sources of Service User Information</td>
<td>9</td>
</tr>
<tr>
<td>7.2</td>
<td>Communication</td>
<td>9</td>
</tr>
<tr>
<td>8</td>
<td>Obtaining Consent</td>
<td>10</td>
</tr>
<tr>
<td>8.1</td>
<td>Written Consent</td>
<td>10</td>
</tr>
<tr>
<td>8.2</td>
<td>Advising the Service User</td>
<td>11</td>
</tr>
<tr>
<td>8.3</td>
<td>Responding to Questions</td>
<td>11</td>
</tr>
<tr>
<td>8.4</td>
<td>Withholding Information</td>
<td>11</td>
</tr>
<tr>
<td>8.5</td>
<td>How long is consent valid?</td>
<td>11</td>
</tr>
<tr>
<td>8.6</td>
<td>Capacity to Consent</td>
<td>11</td>
</tr>
<tr>
<td>8.7</td>
<td>Determining Capacity to give Consent</td>
<td>12</td>
</tr>
<tr>
<td>8.8</td>
<td>Fluctuating Capacity</td>
<td>12</td>
</tr>
<tr>
<td>8.9</td>
<td>Can a competent service user refuse Treatment?</td>
<td>12</td>
</tr>
<tr>
<td>9</td>
<td>Cultural or Religious Issues</td>
<td>13</td>
</tr>
<tr>
<td>9.1</td>
<td>Jehovah’s Witnesses</td>
<td>13</td>
</tr>
<tr>
<td>10</td>
<td>Other Issues for which Consent must be Sought?</td>
<td>13</td>
</tr>
<tr>
<td>10.1</td>
<td>Tissue</td>
<td>13</td>
</tr>
<tr>
<td>10.2</td>
<td>Clinical Photography and Conventional or Digital Video Recording</td>
<td>13</td>
</tr>
<tr>
<td>10.3</td>
<td>Consent for Students/Teaching</td>
<td>14</td>
</tr>
<tr>
<td>10.4</td>
<td>Consent for HIV/AIDS Testing</td>
<td>14</td>
</tr>
<tr>
<td>10.5</td>
<td>Consent for Storage and Use of Human Gametes and Embryos</td>
<td>14</td>
</tr>
<tr>
<td>10.6</td>
<td>Consent to Post Mortem Examination and the Retention of Organs or Body Parts</td>
<td>15</td>
</tr>
<tr>
<td>10.7</td>
<td>Consent to Research</td>
<td>15</td>
</tr>
<tr>
<td>11</td>
<td>Advance Directives</td>
<td>16</td>
</tr>
<tr>
<td>12</td>
<td>Enduring Power of Attorney</td>
<td>16</td>
</tr>
</tbody>
</table>

Appendix 1 – 12 key points on consent – the law in England and Wales

Appendix 2 – Consent to Medical Treatment by a service user who refuses to have a blood transfusion.

Further Reading/Contacts
1 Purpose

This Policy should be read in conjunction with the comprehensive Cancer Services Division - ‘Procedure and Guidance Notes for Consent to Examination or Treatment (Green 8)’ and the Welsh Blood Service Procedure – ‘Consenting Issues relevant to the WBS’.

For the purposes of this Policy the term service user encompasses patient, carer, donor, well-women or a member of the public.

The Velindre NHS Trust recognises the right of every rational, competent service user to be given suitable and sufficient information relevant to their condition, care and treatment, to enable them to make an informed decision about whether or not to consent to examination or treatment. It is the policy of the Trust that permission is obtained wherever possible, before such examination or treatment so that the service user can give reasonable consideration to the information, free of any duress.

Whilst there is no statute setting out the general principles of consent, case law has established that any treatment or investigation carried out without the appropriate consent may amount to battery. If insufficient appropriate information is not provided to a service user about risks and side-effects of treatment this could result in a claim for negligence. Successful claims by service users could give rise to an award of damages and a finding of serious professional misconduct.

This policy cannot answer the difficult questions of consent faced by healthcare professionals, eg “When do you have to mention a risk and when do you not mention a risk?” – “What percentage level of risk do you set as a limit?”. It can merely set out the good practice parameters and principles and the policy will adapt as the consent debate continues.

The term healthcare professional refers to professionally qualified personnel eg, doctors, dentists, nurses, midwives, clinical psychologists, professions allied to medicine and blood collection assistants as stipulated in the (Blood Safety & Quality Regulations 2005). Students may not under any circumstances, participate in the activity of obtaining consent to treatment (Medical Students in Hospitals, NHSME, April 1991).

2. Objective

The objective of this Policy is to:

• Affirm the rights of service users and their self autonomy without discrimination.
• Clarify the various ways in which consent may be given.
• Provide guidance on the form of consent that is appropriate in different situations.
• Establish the requirement for documentation of consent and its inclusion within the service users health record.
• Provide compliance with standards identified in the Welsh Risk Management Standards.
• Follow guidance in Welsh Health Circular (2002) 42 on Consent for Examination or Treatment.
3. **What Consent is – and is not.**

Service users may indicate consent non-verbally (for example by presenting their arm for their pulse to be taken), orally or in writing. Sufficient information should be provided to enable the individual to understand how their interests and confidentiality will be protected. For the consent to be valid, the service user must:

- Be competent to take the particular decision;
- Have received sufficient information to take it; and
- Not be acting under fraud, duress or misrepresentation.

4. **Context of Consent**

Consent can take many different forms, ranging from the active request by a service user for 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 service user 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 service users, 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’, and the role of the health professional is to advise and assist the service user. An agreement needs to be reached on the best way forward in the light of the person’s values and preferences and the health professional’s clinical knowledge.**

5. **The Consent**

The completion of a consent form and/or entry in the service users records may be evidence that the person has received an explanation of the proposed procedure and that they understand the nature of the procedure, the risks and the potential benefits. However, it is not conclusive evidence that all relevant risks and benefits have been explained.

The most important element of a consent procedure is to ensure that service users understand the nature and purpose of the proposed examination or treatment together with alternatives available and significant attendant risk. A signature on a form is not consent if the service user has not received and understood the relevant information.
5.1 Types of Consent

**Implied Consent**

Consent to minor procedures or investigations can be implied by compliant action for example rolling up a sleeve to receive an injection or offering up voluntarily an arm in the correct manner when asked to give a blood sample.

**Oral Consent**

There is no requirement for all consent to be written and oral consent may be sufficient. Any future allegation that consent was not given is, however, difficult to refute without written evidence. **ORAL CONSENT SHOULD BE DOCUMENTED WITH RELEVANT DETAILS OF THE HEALTHCARE PROFESSIONAL’S EXPLANATIONS. Wherever possible, such oral consent should be witnessed by another staff member.**

**Written Consent**

Written consent accompanied by a statement of explanations given, provides the clearest proof that the service user did in fact consent to the healthcare professional undertaking a procedure. It would be unreasonable to require such written consent for all invasive procedures.

The following are definitions of situations in which written consent is/maybe necessary.

(i) An **Invasive Clinical Procedure** (ICP) is defined as “a medical or surgical course of action that involves the permanent or temporary placement of an instrument or device into any part of the body of a person’s, or removal of same, as part of a therapeutic investigative or diagnostic act; or manipulation of a part of a body as part of a therapeutic act”. This obviously would include radiotherapy and chemotherapy treatments, but not a simple injection.

(ii) When undertaking any form of invasive clinical procedure the healthcare professional must be sure that information about the procedure is provided to the service user. This information must include:

- The nature of the condition
- Uncertainties in diagnosis
- Causes of the condition
- Options for treatment including the option not to treat
- The complexity of the procedure
- How long the procedure might take
- Who will be involved and the name of the healthcare professional with overall responsibility
- Whether or not the procedure is likely to be straightforward
- A realistic expectation of what the outcome out to be
- The risk benefit ratio of the treatment or procedure
• The fact that the patient may change his/her mind at any time
• Details of the way in which information concerning the service user may be used.
• The option for the service user to seek further information or clarification
• Details of any alternative procedures

In all cases, the information must be conveyed orally and should be offered in written form and/or other mediums most appropriate to the individual if available and appropriate.

The use of drawings, diagrams and models to explain procedures may be helpful in ensuring that service users understand prior to giving informed consent.

(iii) **Procedures that must have written consent**

Any invasive clinical procedure that requires the administration of a general, and, or, local anaesthetic and requires the performance of the procedure within the operating theatre environment by an appropriately qualified and experienced person(s).

(iv) **Procedures that may require written consent**

• Any invasive clinical procedure that usually requires the administration of a local anaesthetic and which is usually performed at the bedside by an appropriately qualified and experienced person(s).

• Written consent may also be required for treatments which do not constitute invasive clinical procedures but carry other significant or substantial risks or known side effects, eg radiotherapy, use of cytotoxic drugs or other medication, which has significant known side effects.

(v) **Any other procedure or treatment** which would be covered by the description of an invasive clinical procedure above, would require only implied or oral consent. However, informed oral consent should be documented in the notes.

(vi) **Consent Forms**

Further information or a copy of the consent form applicable to each Division is available from the following members of staff:

Cancer Centre – General Manager

Screening Services – Head of Administration

Welsh Blood Service – Department Head as appropriate e.g. Donor Services, WTAIL, Patient Diagnosis.

National Public Health Service – Nurse Consultant in Communicable Disease Control and Immunisation Co-ordinator
6. WHEN SHOULD CONSENT BE SOUGHT?

Appendix 1 shows the 12 key points of consent: the law for England and Wales

When a service user formally gives their consent to a particular intervention or course of treatment, this is 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 person’s condition. However, service users can change their minds and withdraw consent at any time. Consent is an on-going and continuous process.

6.1 Single Stage Process

In many cases, it will be appropriate for a health professional to initiate a procedure immediately after discussion with the service user. Consent should still be gained via the written form.

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

6.2 Two or more stage process

In most cases where written consent is being sought, treatment options will generally be discussed well in advance of the actual procedure being carried out. This may be on just one occasion or it might be over a whole series of consultations with a number of different healthcare 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 person 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.
6.3 Elective or pre-arranged procedures or treatment

Service users receiving elective treatment or investigations for which written consent is appropriate should be familiar with the 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. However, a member of the healthcare team MUST check with the person 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 person’s consent and understanding, it is advisable to use a form of words which requires more than a yes or no answer, for example, beginning with ‘tell me what you’re expecting to happen’, rather than ‘is everything all right?’.

6.4 Seeking Consent for Anaesthesia

Where an anaesthetist is involved, it is their responsibility to seek consent for anaesthesia, having discussed the benefits and risks. However, in pre-arranged treatments or procedures it is unacceptable for the patient to receive no information until the day of their anaesthetic and should therefore have received an information leaflet or the opportunity to discuss the anaesthesia beforehand.

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 consent has been obtained for that form of anaesthesia.
7. INFORMATION PROVISION

Service users have a right to information about their condition and the treatment options available to them. The amount of information healthcare professionals provide will vary according to factors such as the nature of the condition, the complexity of the treatment, the risks associated with the treatment or procedure, and the person’s own wishes.

The healthcare professional should take steps where possible to ascertain what a service user wishes to know, and ought to know about their condition and its treatment.

It is difficult in some cases, as experience has shown that some service users do not wish to know information about their disease. There is no easy answer to this, and each person will have to be assessed individually and the healthcare professional will make a judgement to the best of their ability.

When providing information the healthcare professionals must do their best to find out the persons’ individual needs and priorities; ask them their concerns about the treatment or the risks explained. They should always provide service users with appropriate information, which should include an explanation of any risks to which they may attach particular significance. Individuals should be asked whether they have understood the information and whether they would like more information or time before making a decision.

7.1 Sources of Service User Information

Many local sources of service user information are available. The Trust is committed to ensuring that service users whose first language is not English or Welsh receive the information in a form they understand and are able to communicate appropriately with healthcare staff. It is not appropriate to use children to interpret for family members whose first language is not English or Welsh.

If a person has hearing difficulties or is deaf, healthcare professionals must ensure that an appropriate interpreter is available for all contacts with the Trust.

7.2 Communication

The service user’s ability to appreciate the significance of the information given may be affected by, for example, shock, distress or pain, difficulty in understanding English, limited sight, hearing or speech or a mental disability or learning disability (not affecting capacity)

Occasionally and subject to the agreement of the service user, and where circumstances permit, it may help if a close family member or friend can be present at the discussion when consent is sought. If this is not possible another member of staff may be able to assist the service user in understanding.

The Trust is committed to ensuring that service users whose first language is not English or 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 or Welsh.
The Trust uses a facility called Language Line, which is a dual telephone interpretation service. Further information can be found by referring to the Trust Guidelines for Language Line (Black 20).

It is possible that some service users may not be able to provide signed consent because they are unable to read or write. In these circumstances the healthcare professional must read the contents of the Consent Form whilst another witness is present. Preferably this would be a relative and/or another healthcare professional. It must be recorded in the service users’ records that this has taken place and the reasons why this happened.

8. Obtaining Consent (Written and Oral)

8.1 Written Consent

Consent is often wrongly equated with a service user’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 service user is rushed into signing a consent form on the basis of too little information, the consent may not be valid, despite the signature. Similarly, if the service user has given oral consent, the fact that they are physically unable to sign the form is no bar to treatment.

Giving and obtaining consent is usually a process, not a one-off event. To enable the patient to give satisfactory informed consent they should be able to:

UNDERSTAND AND RETAIN the given information in regard to the reasons for, the nature, benefits, risks and discomforts of the proposed treatment; alternatives to and consequences of not accepting the proposed treatment and have an ability to WEIGH UP and DECIDE upon the information received.

- The patient has the right to GIVE, WITHHOLD or RETRACT consent prior to examination or treatment.
- Written and/or verbal information as described above must be given within a reasonable period prior to the procedure taking place. A reasonable period will obviously depend on the circumstance and whether an emergency situation exists.
- The location as well as the time is important.
- Information must be given in simplest language without the use of health service jargon or acronyms.
- Written and oral consent must be recorded in the service users records, including relevant details of the healthcare professional’s explanations. If an information sheet were given this may suffice. However, the more detailed information recorded in the patient’s medical records the better from a legal point of view.
- Whilst it is good practice to consult the next of kin (with the service user’s permission) about any proposed treatment (so that they may more effectively counsel and discuss options with their relative), any consent of the next of kin will have no standing in law (except in the case of children).
8.2 Advising the Service User

Where a choice of treatment might reasonably be offered the healthcare professional may always advise the service user of his/her recommendations together with reasons for selecting a particular course of action. Though it should be assumed that most service users would wish to be well informed, account should be taken of those who may find this distressing.

8.3 Responding to Questions

Healthcare professionals must respond honestly to any questions the service user raises and, as far as possible, answer as fully as possible. In some cases, a service user may ask about other treatments that are unproven or ineffective. Healthcare professionals must answer such questions as fully, accurately and objectively as possible.

8.4 Withholding Information

- Decision making information should not be withheld unless in the view of the health professional there is clear evidence that disclosure of some relevant information would cause the service user serious harm. In this context serious harm does not mean the service user would become upset, or decide to refuse treatment.

- No-one may make decisions on behalf of a competent adult.

In any case where information is withheld from the service user this MUST be recorded in the service user’s records.

8.5 For how long is consent valid?

Consent should be perceived as a continuing process rather than a one-off decision. Where there has been a significant interval between the service user agreeing to a treatment option and its start, consent should be re-affirmed. In the intervening period, the service user may have changed his or her mind or there may have been clinical developments.

8.6 Capacity to Consent

Capacity is the ability to understand information relevant to a decision; to retain that information; to use or weigh that information as part of the process of making the decision; or to communicate his decision (whether by talking using sign language or any other means).
When an adult service user does not have the capacity to give or withhold consent to a significant intervention, this fact should be documented. If a service user lacks capacity, the health professional should always act in the persons best interest.

Adults

- It is important to note that in English Law that there is ‘no law of proxy’ – in that no adult may consent on behalf of another.
- A competent adult is a person who has reached 16 years of age and has the capacity to make treatment decisions on his/her behalf. The fact that a service user may be mentally ill, or have a learning disability, is not in itself sufficient grounds to determine that a person is not competent.

An individual is presumed to be competent until the contrary is proved

Children

In law consent is required from the parent or others with parental responsibility for every routine intervention such as blood, urine tests or x-rays prior to treatment. Where a child is receiving treatment as an inpatient or outpatient, discussions should have taken place with the parents to agree consent for routine procedures/interventions and treatment in advance.

8.7 Determining Capacity to give Consent

- Responsibility for determining capacity rests with the healthcare professional proposing the particular treatment and will primarily be assessed in conversation with the service user.
- Capacity must be routinely assessed in the process of obtaining consent and the result of the assessment must be recorded.
- Where the healthcare professional in charge of the case is unsure of the service user’s ability to provide valid consent, a second opinion should be sought. All advice must be carefully documented.
- Mental deterioration, eg confusion, may be attributed to the disease rather than a psychiatric condition.

8.8 Fluctuating Capacity

Once it has been proved that someone is incompetent this state of affairs is presumed to continue until the contrary is proved. However competence can fluctuate and an intermittent state of capacity is called a ‘lucid interval’. A document signed or decision made during a lucid interval may be valid. If treatment is not urgent, it may be possible to wait for the person’s full recovery to full competence before proceeding. When a service user has difficulty in retaining information or is only intermittently competent assistance must be provided to enable him/her to reach an informed decision.
8.9 **Can a competent service user refuse treatment?**

Competent adult service users are entitled to refuse consent to treatment even when doing so may result in permanent injury or death. Therefore, for example, a Jehovah’s Witness can refuse a blood transfusion even where this is essential for survival. Also in the case where a young adult between the age of 16-18 years refuses treatment, this can be overridden by parents or others with parental responsibility, although this may be a rare occurrence.

9. **Cultural or Religious Issues**

Assessment of capacity requires knowledge of the person, including his or her cultural values and social situation. In many cases, the service user’s general practitioner or other responsible doctor may be sufficiently qualified to make the necessary assessment but if the healthcare professional does not know the person, it may be necessary to seek the views of others with personal or professional knowledge of the person with regard to the decision in question.

Appendix 2 shows a copy of the consent form that must be signed by an individual who is consenting to medical treatment, but who refuses to undergo a blood transfusion.

9.1 **Jehovah’s Witnesses**

Jehovah’s Witnesses are opposed to the use of a blood transfusion. Discussions should take place early on in the service users’ care and a senior healthcare professional should review the medical alternatives and treat the person without using homologous blood. In a life threatening emergency, the service user’s views if known to the healthcare professionals should be honoured.

If a child is judged to be of sufficient age and maturity to fully understand the implications of their beliefs, they should be treated as above.

10. **Other Issues for which Consent must be Sought**

10.1 **Tissue**

The legal position regarding the use of human tissue raises some difficult issues. The Human Tissue Act 2004 clarifies that consent is needed for the removal, retention and use of tissues from people who have died, given either by the deceased in life or, if they died before expressing a wish or consent, given by someone nominated by them or close to them.

10.2 **Clinical Photography and Conventional or Digital Video Recordings**

Photographic and video recordings made for clinical purposes form part of a person’s record. Although consent to certain recordings, such as x-rays, is implicit in the individual’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 person must not be used for any purpose other than that individual’s care or the audit of the care, without the express consent of the individual or a person with parental responsibility for the person. This information should be held within the medical record.

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.

10.3 **Consent for Students/Teaching**

The healthcare professional carrying out the consultation should explain to the individual that an observer would like to sit in on the consultation, who that person is and why he or she wishes to observe. Service users are entitled to refuse, and be reassured that in no way will their decision affect their treatment. Wherever possible, service users should be given the option of considering this request prior to the arrival of the students, ideally before they attend the Trust.

10.4 **Consent for HIV/AIDS testing**

Staff must obtain consent from individuals before testing for HIV/AIDS except in the rare circumstances outlined below;

i. Where a child cannot give or withhold consent, consent can be sought from a person with parental responsibility if testing is deemed to be in the best interests of that child.

ii. Professional staff may test a deceased person for HIV/AIDS if they have a good reason to think that the individual may have been infected, and a healthcare worker has been exposed to the person’s blood or other body fluids. The permission of a relative should be sought before testing.

10.5 **Consent for Storage and Use of Human Gametes and Embryos**

The Human Fertilisation and Embryology Act 1990 states that human sperm and eggs or embryos cannot be stored or used without a licence from the Human Fertilisation and Embryology Agency.

Although not applicable to Velindre NHS Trust, a separate consent form for the consent for storage and use of sperm and embryos is available – reference HFEA (00) 6.
10.6 Consent to Research

Velindre NHS Trust recognises that research involving clinical trials of drugs and treatments, and research into the causes of, or possible treatment for, a particular condition is important in increasing health professionals’ ability to provide effective care. The research may not have direct benefits for the patients involved and for that reason particular care will be taken in seeking consent from patients.

The legal principles that apply to valid consent for investigations or treatment also apply when seeking consent from patients for research purposes. It should be ensured that research is not contrary to the individual’s interests.

All research involving adults or children must first be approved by the Research Risk Review Committee, a sub group of the Research and Development Committee of Velindre NHS Trust. Further advice on obtaining ethical approval should be sought from the Trust’s R&D office, 02920 316292.

Anyone asked to participate in research will be given the fullest possible information presented in a way that they can easily understand. Anyone asked to give consent for participation in research must:

- Be given information on the following:
  - The purpose of the research
  - The use of random allocation of treatment
  - Information about trial related procedures particularly invasive procedures
  - Arrangements for covering expenses
  - Compensation in the event of trial related injury

- Be given time to consider and reflect on the information that they are given
- Understand the potential risks and benefits of their participation in the research project.
- Be given information about confidentiality and possible access to records by third parties such as regulatory authorities, auditors or ethics committees.
- Be advised that they may withdraw from the study at any time without prejudice to their treatment in any way.

All consent for research must be obtained in writing and witnessed.

It is good practice to include a relative or significant other in the process, prior to consent being obtained for inclusion in research.

If treatment is innovative or experimental in nature but not part of a research trial this must be clearly explained to patients along with information about standard alternatives. It is good practice to give patients information about the evidence to date of the effectiveness of the new treatment both at national / international level and in the practitioners own experience.
11. **Advance Directives**

Service users may make a statement known as an advance directive or a living will, setting out how they wish to be treated if they are rendered incompetent and are suffering from specific conditions at some later date. Such a statement usually outlines treatment options, which the service user would wish to refuse, or set conditions upon treatment.

These statements will only be effective if:

- the refusal to treatment is specific to the circumstances of the service user
- the service user was competent at the time of the statement was made.
- the decision was a voluntary one
- the service user was fully informed so as to be able to make a choice
- the service user has not subsequently changed their mind.

12. **Enduring Power of Attorney**

Even if a relative had Enduring Power of Attorney they cannot consent to treatment on behalf of the service user. Enduring Power of Attorney only empowers an individual to oversee the service user's property and affairs.
Appendix 1

12 key points on consent: the law in England and 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 any doubts about their competence, the question to ask is: “can this patient understand, retain 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 consents to you 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. People over the age of 16 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, someone 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 treatments.

8. 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.
**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.

**Refusal of treatment**

10. Competent adult patients over the age of 18 years old 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 detailed 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. Further information on this issue is contained within the consent policy.
Appendix 2

Consent to Medical Treatment by a Patient who Refuses to have a Blood Transfusion

Velindre NHS Trust Headquarters
2 Charnwood Court
Parc Nantgarw
Cardiff CF 15 2 XL

I (name) ……………………………………………………………………………

Address: ………………………………………………………………………

acknowledge that I have been informed that I am or may be suffering from ………………………………………………………………………………………………..

and that I require or may require treatment, the nature and effect of which have been explained to me by Dr ………………………………………………………………….

I hereby give my consent to the administration of such medical treatment as the Doctor considers necessary, except that although it has been explained to me that in the course of the said treatment it may be necessary to give me a blood transfusion so as to enhance the effectiveness of any treatment, or even to preserve my life. I hereby expressly withhold my consent to and forbid the administration to me of a blood transfusion in any circumstances or for any reason whatsoever, and I accordingly absolve the Doctor, the hospital and every member of the medical staff concerned, from all responsibility, and from liability to me, or to my estate, or to my dependents, for any damage or injury which may be caused to me, or to my estate or to my departments in any way arising out of or connected with this refusal to consent to any such blood transfusion.

Signed: ……………………………………………………… (Patient)

Date: …………………

Witnesses to patient’s signature
…………………………………………………………………. (Doctor)

I confirm that I have explained to the patient the nature and effect of this treatment described above and/or overleaf and the possible risks attendant upon his/her refusal to accept a blood transfusion.

(Signed) ………………………………………… (Doctor)

Date: ………………………………
Guide to Further Reading

British Medical Association, *Consent Tool Kit*, March 2001


Department of Health, *The Removal, Retention and Use of Human Organs and Tissue from Post Mortem Examination: Advice from the Chief Medical Officer*, 2001


General Medical Council, *Seeking Patients Consent: the Ethical Considerations*, February 1999

HMSO (1994) Medicines for human use (marketing authorisations etc) Regulations 1994, Statutory Instruments No 3144

NHS Management Executive (1990) *A guide to consent for examination or treatment*, London HC (90) 22

Velindre NHS Trust, Child Protection Policy, Williamson K et al, 1999

Welsh Assembly Government WHC (2002) 02 *Good Practice in Consent Implementation Guide: consent to examination or treatment*

Internet Sites

[http://www.wales.gov.uk/subihealth/toc-e.htm](http://www.wales.gov.uk/subihealth/toc-e.htm) - Reference Guide to consent for examination or treatment, NHS Quality Standards Department, Welsh Assembly Government

[www.gmc-co.uk.org](http://www.gmc-co.uk.org)

[www.doh.gov.uk](http://www.doh.gov.uk)