Trust Policy	

Consent Policy

Department / Service:	Tetbury Hospital Trust
Originator:	Day Surgery Manager
Accountable Director:	Chief Executive Officer
Approved by:	Medical Advisory Committee
Date of approval:	November 2018
Revision Due:	November 2021
Target Organisation(s)	Tetbury Hospital Trust
Target Departments	All departments
Target staff categories	All clinical staff

Policy Overview:
This document is concerned that all patients who require an operation / treatment / procedure within the Trust have been given the correct and timely information so that consent can be given appropriately.

Key amendments to this Document:

Date	Amendment	By:
24th March 2015	Update of the policy	Matron
7th November 2018	Review and update of Equality Impact Assessment	Matron

Contents

1. Introduction

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 healthcare professionals and patients.

This policy sets out standards and procedures in Tetbury Hospital Trust, which aim to ensure that healthcare professionals are able to comply with the guidance.

This document is primarily concerned with gaining consent for examination or treatment – it should be considered that consent should be gained before providing certain forms of social care, such as those that involve touching the patient.

2. Scope of this document

This policy applies to all clinicians, including bank, agency who work with patients in the Trust who have to gain consent, prior to a procedure / treatment or operation.

3. Definitions

"Consent" is a patients' agreement for a health professional to provide care. Patients may indicate consent non-verbally – e.g. presenting their arm in order to take their blood pressure, orally, or in writing. For the consent to be valid it must be given voluntarily by the patient or an elected informed person who has the capacity to consent to the procedure. This could be:

- Someone with parental responsibility for a patient under18
- Someone authorised with a Lasting Power of Attorney or someone who has the authority to make treatment decisions as a court appointed deputy*.

In all cases the patient/elected person are required to:

- be competent to take a particular decision;
- have received sufficient information to take it; and
- not be acting under duress

Consent is not valid if obtained by fraudulent means.

The context of consent can take many different forms, ranging from the active request by a patient of a particular treatment (which may or may not be appropriate or available) to the passive acceptance of a health professional's advice. In some cases, the health professional will suggest a particular form of treatment or investigation and after discussion the patient may agree to accept it. In others, there may be a number of ways of treating a condition, and the health professional will help the patient to decide between them. Some patients, especially those with chronic conditions, become very well informed about their illness and may actively request particular treatments. In many cases, 'seeking consent' is

better described as 'joint decision-making': the patient and health professional need to come to an agreement on the best way forward, based on the patient's values and preferences and the health professional's clinical knowledge.

Where an adult 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 it has not been refused in advance in a valid and applicable advance directive.
(For further details on advance directives please refer to Department of Health's Reference Guide to Consent for examination or treatment second edition (P19 paragraph 47).

Healthcare professionals must be aware of guidance on consent issued by their own professional body in addition to the Department of Health's Guidance Document `Reference guide to consent for examination or treatment second edition 2009.

Healthcare professionals must also be aware of guidance on consent following changes in the law. I.e. Montgomery v Lanarkshire Health Board 2015

Common Law

Montgomery (Appellant) v Lanarkshire Health Board (Respondent) [2015]
The case of Montgomery clarifies the correct test to material risk in the consent process and repositions the focus of legal requirements regarding what information should be provided to patients prior to their making of a decision regarding healthcare.

Chester v Afshar [2004]

Have reinforced the importance of identifying serious risk to the patient even if that risk is relatively rare.

4. Responsibility and Duties

The people and/or committees/groups that have responsibilities and accountabilities to implement this policy and staff/others who have a responsibility to follow this policy

5. Policy detail

5.1 Documentation

For significant procedures, it is essential for healthcare professionals to document clearly both the patient's agreement to the intervention and the discussions, which led to the agreement. This may be in the form of a formal consent form – with additional details in the patient's Healthcare records or documentation in the patients' Healthcare records that they have given oral consent.

5.2 Written Consent

Consent is often wrongly equated with a patient's signature on a consent form. Signature on a form is evidence that the patient has given consent, but not proof of valid consent.

If the patient has not had all the relevant information to ensure an informed consent – then the consent may not be valid, despite the signature.

If the patient has had well-informed information regarding treatment / examination, the fact that they may be physically unable to sign the form is no bar to treatment.

Patients may if they wish withdraw consent after they have signed the form; the signature is evidence of the process of consent giving, not a binding contract.

It is rarely a legal requirement to seek written consent but it is good practice to do so if the following conditions apply:

- Treatment / procedure is complex, or involves "significant risk.
- The procedure involves general / regional anaesthesia or sedation.
- Providing clinical care is not the primary purpose of the procedure.eg research trials, student observation
- There may be significant consequences for the patient's employment, social or personal life.
- The treatment is part of a project or programme of research approved by the Trust.

In the case of people with a learning disability, who present at out-patient clinics, Day Surgery and MIU, they may not always arrive fully understanding why or what they are there for.

In these cases it is important to establish a person's preference regarding treatment and their capacity to consent. This should include their level of understanding, their ability to retain the information and their ability to express their choice. This is important even in the most common procedures, (such as the taking of blood pressure, an injection, taking of blood and cytology).
Completed forms should be kept with the patient's healthcare records. Any changes to a form, made after the patient has signed, should be initialled and dated by both patient and health professional.

For routine or low risk procedures, such as providing personal care or taking a blood sample are not usually necessary to document – however if there is any reason to believe that consent at a later stage be disputed it would be helpful to do so.

5.3 PROCEDURE TO FOLLOW IF A PATIENT LACKS THE CAPACITY TO GIVE OR WITHHOLDS CONSENT

Where an adult patient does not have the capacity to 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 an assessment of the patients capacity of why the health professional believes the treatment to be in the patients best interest, and the involvement of people close to the individual.

If mental capacity is required to be assessed then the Mental Capacity Assessment Form (Appendix of Safeguarding Adults Policy, March 2015) should be used to confirm capacity.

The standard consent form 1 should never be used for adults who are unable to consent for themselves.

For minor interventions – this information should be documented in the patient's notes.

Staff must be mindful of an apparent lack of capacity to give consent due to communication difficulties and be proactive in their approach to oversee this e.g. with the use of interpreters and non- verbal communication. These additional tools will enable patient to be informed, as much as possible and to be assessed by the multi-disciplinary team as having the `ability' to give consent.

Occasionally there will not be consensus on whether a particular treatment is in the incapacitated adult's best interest.

Tetbury Hospital does not routinely operate on patients who lack the capacity to consent to treatment, however nursing staff involved in the consent procedure must be aware of current practice on consent by referring to DOH reference guide second edition 2009 in the event that we are approached to make an informed decision for an individual's treatment.

Please see either the Hospital Matron or CEO in the event that a consent form 4 is requested by the surgical team to proceed with the treatment of a patient. Dependant upon ability, either the co-ordinator of the surgical list, the department lead, the Matron or the Hospital Manager would be responsible for assessing and organising peri and post-operative patient care.

Please see Appendix 1for a list of the consent forms currently in use.

5.4 WHEN SHOULD CONSENT BE SOUGHT?

When a patient gives their consent to a particular intervention, this is only the endpoint of the consent process.

This process may take place at one time or over a period of meetings and discussions.

Single stage process

In many cases it will be appropriate for a health professional to initiate a procedure immediately after discussing it with the patient. In many cases this type of consent is given verbally (for example for physiotherapy or fitting a cast).

For major interventions where the proposed procedure carries significant risks, it will be appropriate to obtain written consent and healthcare professionals must ensure patients

have sufficient time to absorb information necessary to make their decision. As long as it is clear that the patient understands and consents, the health professional may proceed.

Two or more stage process

In most cases where written consent is being sought, treatment options will be discussed well in advance of the actual procedure being carried out.

This may be on one or over many occasions of consultation in a clinic or hospital environment and therefore the consent process will take place over at least two stages; the first being the provision of information and initial verbal decision and the second being confirmation that the patient still wishes to go ahead with the procedure.

The consent form should be used to document the information stage as well as the confirmation stage.

Before patients actually arrive for the procedure they should have received information regarding the procedure and a copy of the consent form documenting the decision process. This allows the patient time to `digest' the information given and to ask questions.

Patients listed for surgical procedures by Tetbury Hospital are sent consent information booklets in advance of either their consultation or day of surgery. The patient has the opportunity on the day of surgery to discuss the procedure again with a healthcare professional responsible for carrying out the surgery.
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If a consent form is signed prior to the day of the procedure, the healthcare professional providing the treatment **must** check with the patient at this point whether they have any further concerns and whether their condition has changed.

The health professional looking after patients must ensure that the potential vulnerability a patient may feel on the day of proposed treatment has not affected their decision.

It is appropriate to ask the patient "What are you expecting to happen".

For consents to be valid, the patient must feel that it would have been possible for them to refuse, or change their mind.

5.5 SEEKING CONSENT FOR ANAESTHESIA

Where an anaesthetist is involved in the patients care it is their responsibility to seek consent for anaesthesia, having discussed the benefits and risks.

In elective treatment it is not acceptable to receive no information about anaesthesia until their pre-operative visit from the anaesthetist, at such a late stage the patient would not be

in a position genuinely to make an informed decision about whether or not to undergo anaesthesia.

Patients should be given a patient information leaflet about anaesthesia in outpatients or have the opportunity to discuss anaesthesia in pre-operative assessment**.**

The anaesthetist should ensure the conversation regarding anaesthesia information is documented in the anaesthetic notes.

A surgeon administering local anaesthetic or sedation is responsible for ensuring that the patient has given consent to that form of anaesthesia.

5.6 Emergencies
Discussion of options and confirmation will follow straight on from each other and it may be appropriate to use the patient's healthcare records to document any discussion and the patient's consent rather than using a form.

The urgency of the situation may limit the quantity of information it should not affect its quality.

5.7 TREATMENT OF YOUNG CHILDREN
When children are seen at Tetbury Hospital it should be remembered that in law consent is required for **any** intervention, examination or treatment that is performed for the child (for example blood or urine tests or x-rays).

Only persons 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).

If you are in any doubt of parental responsibility you must check.

Tetbury Hospital does not offer elective day surgery for patients under the age of 18.

For the treatment of children in minor injuries, please see guidance notes for minor injuries consent form in appendix 3 of this document.

5.8 Duration of consent
When a person gives valid consent to an intervention, in general that consent remains valid for an indefinite duration, unless it is withdrawn by the person. However, if new information becomes available regarding the proposed intervention (for example new evidence of risks or new treatment options) between the time when consent was sought and when the intervention is undertaken, the General Medical Council (GMC) guidance states that a doctor or member of the healthcare team should inform the patient and reconfirm their consent.

The clinician should consider whether the new information should be drawn to the attention of the patient and the process of seeking consent repeated on the basis of this information.

5.9 PROVISION OF INFORMATION FOR THE CONSENT PROCESS

Patients and those close to them will vary in how much information they require.

There will always be an element of clinical judgement in determining what information should be given.

The presumption must be that the patient wishes to be well-informed about the risks and benefits of treatment. If the patient makes clear, verbally or non-verbally that they do not wish to be given a certain level of information this must be clearly documented in their health records.

There should be both patient consent information posters and a selection of patient information consent leaflets in all DSU, O/P, X-ray and MI waiting area.

The Trust is committed to ensuring that patients whose first language is not English receive the information they need and are able to communicate with healthcare staff effectively. It is not appropriate for children or relatives to interpret for family members.

The Trust is committed to ensuring that patients with hearing or sight loss receive the information they need and are able to communicate appropriately with healthcare staff. It is not appropriate to rely on children or family members to interpret or communicate to patients.

Interpreter service arrangements at Tetbury Hospital Trust are available. The use of an interpreter must be recorded by their statement on the Consent Form.

The production of procedure specific information must take into account the need for provision of that information in "easy read", Braille or in large print.

The Trust will coordinate an interpreter on site to explain the consent process and provide translated information when request for consent is required.

Patients may request more detailed information about their general condition or about their proposed treatment than that provided in the leaflets about the consent process and the proposed procedure. In the first instance, this will be managed by the department in which the proposed treatment is scheduled to take place.

5.10 RESPONSIBLE PEROSN/S FOR SEEKING CONSENT

The Health Care Professional providing the treatment is responsible for ensuring that valid consent has been given by the patient before treatment. However the Consultant responsible for the patients care will remain responsible for the quality of the medical treatment provided.

Seeking consent can be delegated to a suitably trained and qualified person (for example a surgical registrar) and must have sufficient knowledge of the proposed investigation or treatment and understand the risks involved, in order to be able to provide any information to the patient. This delegation is supported by GMC guidance.

Clinicians are responsible for knowing the limits of their own competence.

Inappropriate delegation to a clinician with inadequate knowledge may mean the consent obtained is not valid.

Where oral or non-verbal consent is being sought at the point of the procedure will be carried out, this will naturally be done by the health professional responsible.

Team work is an essential part of how Tetbury Hospital Trust operates and where written consent is being sought it may be appropriate for other members of the healthcare team involved in the care of the individual to participate in the process of consent.

5.11 COMPLETING CONSENT FORMS

The standard consent form provides space for a healthcare professional to provide information for patients and to sign confirming they have done so.

The healthcare professional providing the information must be competent to do so. Either by being able to carry out the procedure themselves or having received specialist training in advising patients about this procedure, they have been assessed, are aware of their own limitations and are subject to audit.

If a patient signs a form in advance of the day of the procedure, the Consultant or delegated health professional a health professional on the day should sign the form to confirm that the patient still wishes to go ahead and has had any further questions answered.

Tetbury Hospital ensures all visiting medical practitioners are granted “Practicing Privileges” to carry out medical practice and consultation to patients visiting the hospital. This includes evidence of specific training qualifications.

It is the health professional’s own responsibility:

- To ensure that when they require colleagues to seek consent on their behalf they are confident for that colleague to do so.

- To work within their own competence and not agree to perform tasks which exceed their competence.

5.12 REFUSAL OF TREATMENT

If the process of consent is to be meaningful, then refusal must be one of the options for the patient.

A competent adult patient is entitled to refuse any treatment, except in circumstances governed by the Mental Health Act 1983.

The situation for children is more complex and further information can be sought from the Department of Health – Seeking consent – Working with children on www.dh.gov.uk.

If after all discussions the patient refuses all treatment options this must be clearly documented in the notes.

If the patient has already signed consent form, but then changes their mind, the healthcare professional and where possible the patient should note this on the form.

Where a patient refuses a particular intervention, Tetbury Hospital will ensure that provision of any appropriate care to which they have consented continues.

Tetbury Hospital will ensure that the patient understands 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 of this accordingly.

If a patient consents to a particular procedure, but refuses certain aspects of the intervention, the health professional must explain the possible consequences of their partial refusal.

If the procedure cannot be carried out safely under the patient's stipulated conditions, the healthcare professional is not obliged to perform it. The healthcare professional must however continue to provide other appropriate care.

Where another healthcare professional believes the treatment can be safely carried out under the conditions specified by the patient, the healthcare professional must on request transfer the patient's care to the other healthcare professional.

It is important to note that a patient can withdraw consent during the procedure. It is good practice for the surgeon, if possible, to stop the procedure, establish the patients concerns and explain the consequences of not completing the procedure. Appropriate re-assurance may be sufficient to continue with the procedure with the patients consent. Refer to paragraph 43 p19 of DOH reference guide second edition 2009.

5.13 REMOVAL OF TISSUE FOR EDUCATION/RESEARCH PROJECTS

The Human Tissue Act 2004 regulates the removal, storage and use of human tissue. It also lists the `scheduled purposes' and how appropriate consent should be sought.

Full details on the requirements of the Human Tissues Act 2004 and the HTA's codes of practice are on the HTA's website at www.hta.gov.uk . If Tetbury Hospital were to be involved in projects that required patient tissue samples, these should be consulted to ensure compliance.

At present Tetbury Hospital Trust requires that patients should be given the opportunity to refuse permission for any tissue taken from them during surgery or other procedure to be used for education or research purposes.

Tetbury Hospital at the time of this policy is not involved in any clinical research projects that requires the collection of human tissue.

5.14 CLINICAL PHOTOGRAPHY AND VIDEO RECORDINGS

Photographic and video recordings which are made for treating or assessing a patient must not be used for any other purpose than the patients care or audit of their care without the express consent of the patient.

If the healthcare professional wishes to use such a recording for education, research or publication consent must be sought in writing from the patient and hospital manager, ensuring the patient is aware of how this material will be used.

All clinical photography forms part of the patients healthcare records, patients must have a clear explanation of how these records may be used.

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 the consent of the patient as long as this policy is well publicised. However express consent must be sought for any form of publication.

The patient must be made aware that future use may be outside of Tetbury Hospitals control once it has been placed in the public domain.

In the event that Tetbury Hospital carries out any treatment which requires photographic evidence where the patient is recognisable, separate written consent must be sought. The storage of recognisable patient photography will be on site at Tetbury Hospital within the medical records storage area; this is kept locked at all times and has a limited access arrangement. All photography will be stored on a non-patient identifiable CD with the patient notes. Access to this photography will be through prior permission by the Hospital Manager. A register of CD's taken and returned from this store will be maintained. The storage details will be explained to patients as part of the consent process.
For more information please refer to; `Making and using visual audio recordings of patients –guidance for doctors GMC 2013

5.15 POST MORTEM CONSENT

By law a coroner can order a post mortem to be done, usually in cases where:

- A death has been sudden or unexpected
- A person has been ill but the doctor confirming death is not certain why it happened at that particular time.
- A death has been a result of an accident or unusual circumstances (including death following a medical procedure – such as surgery)

If a coroner has ordered post mortem consent is unnecessary.

The hospital can request that a post mortem examination is carried out, but this can only be done with the consent of the next of kin, or if the deceased gave permission to post mortem before they died. The deceased person's next of kin can also request a post mortem.

6. Implementation

6.1 Plan for implementation

This policy should be implemented on approval from MAC by all clinical staff.

6.2 Dissemination

This policy should be disseminated to all clinical areas of the hospital.

6.3 Training and awareness

Staff should be made aware of this policy and its contents. Training on consent is through an e-learning module and is mandatory for all trained clinical staff to complete.

7. Monitoring and compliance

Monitoring demonstrates whether or not the process for managing the risk, as described in the approved documentation, is working across the entire trust. Where failings have been identified, action plans must be drawn up and changes made to reduce the risks. Monitoring is through the annual clinical record keeping audits completed and also through the incident reporting process.

8. Policy Review

This policy will be reviewed every three year unless deemed unnecessary in which case it will remain in force. A review may take place earlier than three years if a change of legislation takes place that would impact upon the policy or if concerns about the policy's contents are highlighted that would deem a review necessary and appropriate.

9. References

References:	Code:
Good Practice in Consent: Implementation Guide. Department of Health, November 2001	
Hospital Communication Book -Helping to make sure people who have difficulties understanding and /or communicating get an equal service in hospital MENCAP	
Consent: patients and doctors making decisions together June 2008 (under review)	
Reference Guide to Consent for Examination or Treatment – Second edition DOH 2009	
Making and using visual audio recordings of patients –guidance for doctors May 2013 GMC	
Human Tissues Act (HTA) 2004 and the HTA's codes of practice www.hta.gov.uk	
Department of Health – Seeking consent – Working with children www.dh.gov.uk	
The Mental Capacity Act. The Mental Capacity Act Code of Practice 2005.	
Safeguarding Adults Policy, June 2017 – Mental Assessment Assessment Form	
Montgomery v Lanarkshire Health Board 2015	
Chester V Afshar (2004) UKHL 41	

10. Background

10.1 Consultation

No period of consultation is required for this document.

10.2 Approval process

This policy should be submitted to MAC for ratification and acceptance.

10.3 Equality requirements

Detailed in Supporting Document 1

10.4 Financial risk assessment

Detailed in Supporting Document 2

10.5 Privacy Impact Assessment

Detailed in Supporting Document 3

Supporting Document 1 - Equality Impact Assessment Tool

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

		Yes/No	Comments
1.	**Does the policy/guidance affect one group less or more favourably than another on the basis of:**		
	• Age	Yes	Competency required and assessed by clinician
	• Disability	No	
	• Gender reassignment	No	
	• Gender	No	
	• Race	No	
	• Religion or belief	No	
	• Sexual orientation including lesbian, gay and bisexual people	No	
	• Marriage and Civil Partnership	No	
	• Pregnancy and Maternity	No	
2.	**Is there any evidence that some groups are affected differently?**	No	
3.	**If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?**	No	
4.	**Is the impact of the policy/guidance likely to be negative?**	No	
5.	**If so can the impact be avoided?**	No	
6.	**What alternatives are there to achieving the policy/guidance without the impact?**	None	
7.	**Can we reduce the impact by taking different action?**	No	

Supporting Document 2 – Financial Impact Assessment Tool

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

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

Supporting Document 3 – Privacy Impact Assessment Tool

Please review the question below: Answering ‘yes’ to any of these questions is an indication that a PIA is required

	Title of document:	Yes/No
1.	Will the project involve the collection of new information about individuals ?	No
2.	Will the project compel individuals to provide information about themselves ?	No
3.	Will information about individuals be disclosed to organisations or people who have not previously had routine access to the information?	No
4.	Are you using information about individuals for a purpose it is not currently used for, or in a way it is not currently used for?	No
5.	Does the project involve you using new technology which might be perceived as being privacy intrusive? For example, the use of biometrics or facial recognition	No
6.	Will the project result in you making decisions or taking action against individuals in ways which can have a significant impact on them?	No
7.	Is the information about individuals of a kind particularly likely to raise privacy concerns or expectations? For example, health records, criminal records or other information that people would consider to be particularly private?	Yes
8.	Will the project require you to contact individuals in ways which they may find intrusive?	No
	Comments:	

Appendix 1: Consent Forms in use at Tetbury Hospital

Table for consent forms to use in all departments. It is essential that the correct form be used in each case.

GHNHST Consent Form 1 (For use with a competent adult patient - aged 18 years & above)	GHNHST Consent Form 3 (For patient or parental consent where the patient is expected to be fully conscious)	GHNHST Consent Form 5 (For adult patients (to include Jehovah's Witnesses) refusing the use of blood transfusion or blood components)	THT Consent Form 1 (For use with a competent adult patient - aged 18 years & above)	THT MIU Consent Form 1 (For use in MIU ONLY - for patient or parental consent where patient is expected to be fully conscious)		Hereford Consent Form	

Appendix 2: Supporting Publications

Supporting publications required that need to be accessed by all patients. Relevant publications should be sent to patients with their appointment letters, given out at their initial clinic appointment or be available to the patients in the waiting areas of Tetbury Hospital.

Publications required:
Consent – What you have a right to expect. A guide for relatives and carers
Consent – What you have a right to expect. A guide for adults
Consent – A guide for people with learning difficulties
Consent – What you have a right to expect. A guide for children and young people
Consent – What you have a right to expect. A guide for parents
Seeking consent – Working with older people
Seeking consent – Working with children