University Hospitals Bristol NHS
NHS Foundation Trust

Policy for Consent to Examination or Treatment

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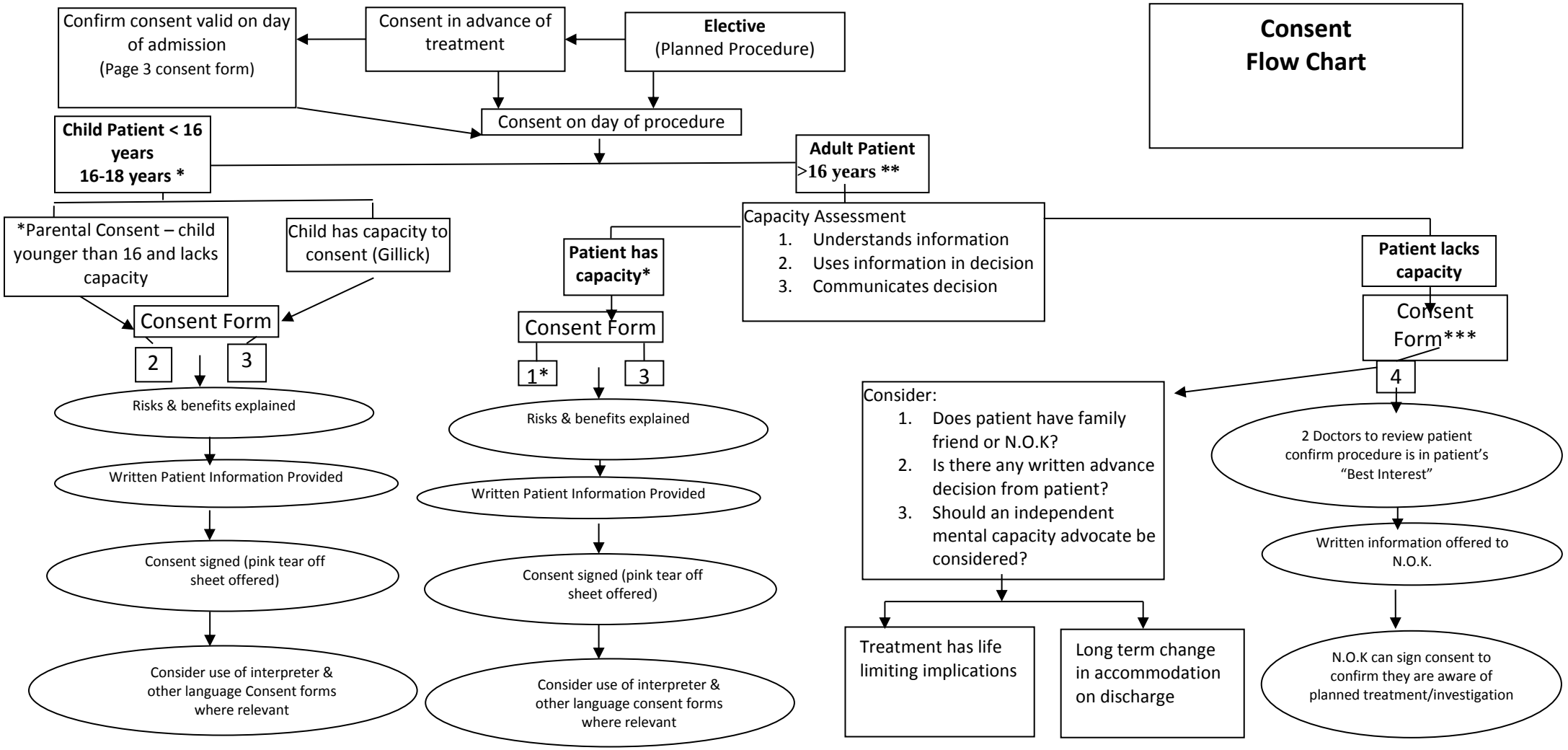
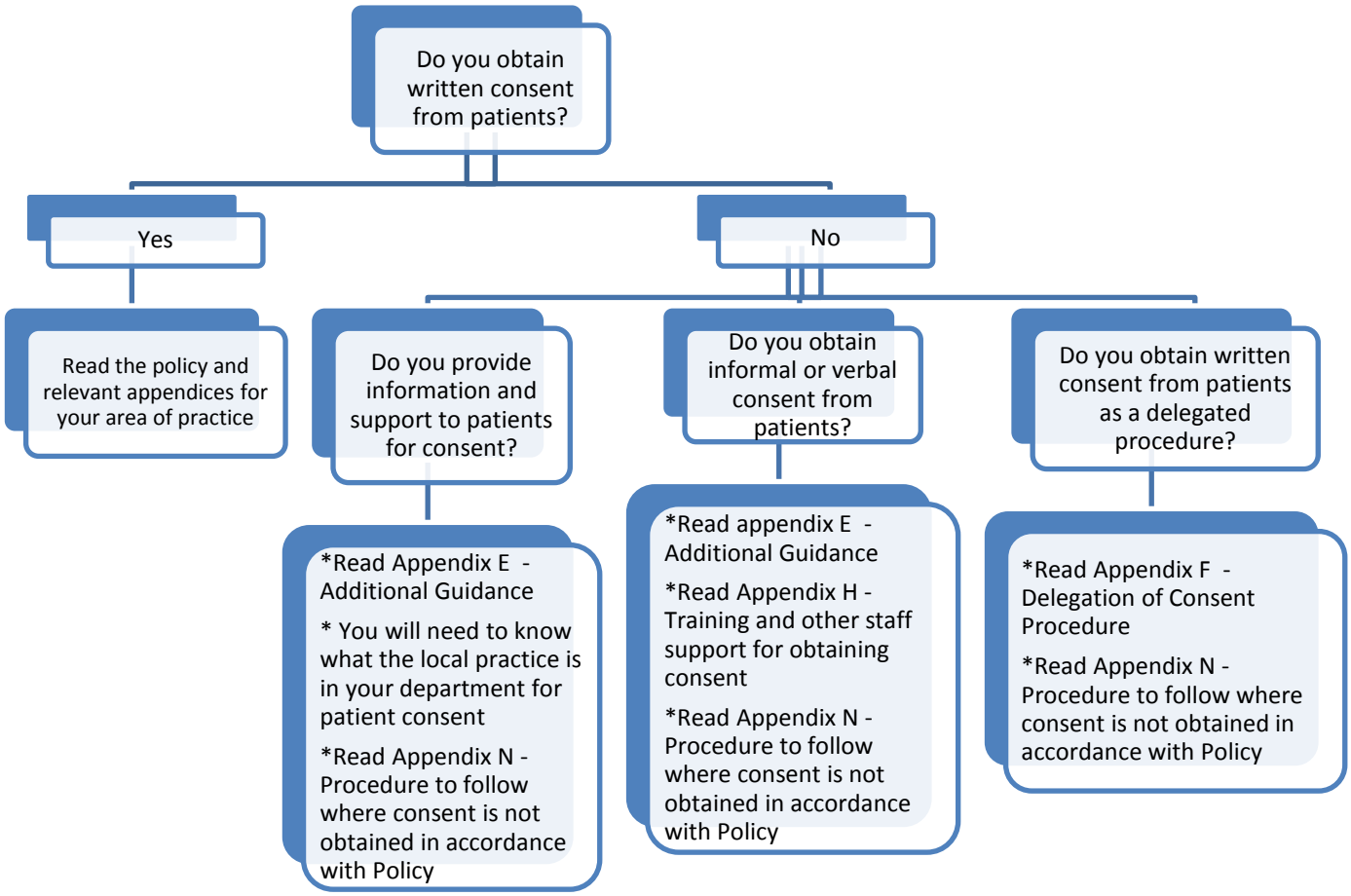
Introduction
This policy sets out the standards and procedures for staff to follow in University Hospitals NHS Foundation Trust (UHBristol) for patient consent in a range of settings. The policy reflects Department of Health, Professional Regulatory, External Accreditation Agency and Royal College expectations.



- *The adult consenting a child must have capacity to consent
- **If the patient is aged between 16 and 18 it is acceptable to utilise consent form 1 but it may also be appropriate to utilise consent form 2 which can be signed by the parent and patients between 16 and 18 years of age
- *** Ensure a mental capacity assessment is completed on appropriate trust form (to be included in consent form 4 fro 2016

Document Change Control				
Date of Version	**Version Number**	**Lead for Revisions**	**Type of Revision**	**Description of Revision**
2003	1	[redacted]	Major	Compliance with Department of Health policy requirements Actions from paediatric consent audit
August 2006	2	[redacted]	Minor	Routine review
September 2008	3	[redacted]	Minor	Routine review
March 2011	4	[redacted]	Major	Revised NHSLA standards issued
Nov 2015	5	[redacted]	Minor	Routine review revised governance structure Incorporation of Mental capacity Act Assessment form Consent 16-18 years olds
August 2016	6	[redacted]	Minor	Addition to section 3.3 regarding informing the patient/ parent about the people who will be mainly responsible for care and their roles including students and trainees
October 2016	7	[redacted]	Minor	To include recommendations from cardiac review relating to developments in the law in this area, emphasising the rights of patients to be treated as partners by doctors, and to be properly informed about material risks. Utilisation of % risk for major complications and mortality and capacity of adults consenting for children.

What is my role?



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1. Introduction

1.1 All healthcare provided involves decisions jointly made by clinicians in partnership with their patients. Central to the clinician patient relationship is a partnership, based on trust, openness and communication. In order to be effective clinicians must listen to and respect the views of patients about their health, discuss with patients their diagnosis , prognosis and treatment/ care options , share information that patients want or need in order to help them understand options and help them make a decision and respect the decisions made by patients .When discussing risks with a patient is it important to understand what matters or is likely to matter to the individual patient rather , what may be insignificant risk to one individual may be highly significant to another individual. The case of Montgomery v Lanarkshire health Board (March 2015) judgement describes the term 'materiality'. A material risk is one that a reasonable person in the patients' position is likely to attach significance to, or the doctor is or should reasonably be aware that their patient would be likely to attach significance to. A clinician should do their best to understand the patient's views and preferences and the adverse outcomes they are most concerned about. The percentage risk of major complications or mortality should be recorded on the consent form. This Policy and attached additional guidance document seeks to ensure that all clinical staff are aware of the expectations for this aspect of clinical care.

1.2 It is important when obtaining consent to ensure that the patient/ parent has understood the risks and benefits of all treatment options, clinicians may encourage patients to record such conversations as it is not easy to retain information, particularly under stressful circumstances

2. Purpose and Scope

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. It is relevant for all decisions including those of life limiting potential and following death.

If consent is undertaken in advance of an elective procedure it is essential to confirm consent with the patient or parent on the day of surgery

This Policy therefore applies to all staff involved in the consent process.

3. Definitions

3.1 Valid, Informed Consent

(a) Consent is a patient's (or proxy e.g. parent of a young child) agreement for a health professional to provide care. For the consent to be valid the patient must:

(b) be competent (have capacity) to take the particular decision

(c) have received sufficient information ,regarding the risks and benefits of the treatment and alternative treatment options , in order to make a decision

(d) not be acting under duress or undue inducement/reward to take a particular decision

3.2 Capacity

(a) Mental Capacity as defined in the Mental Capacity Act 2005 means the ability to make a decision. A person's capacity to make a decision can be affected by a range of factors such as a stroke, dementia, a learning disability or a mental illness. These conditions do not automatically mean a person lacks capacity for the particular decision. Mental capacity can also vary depending on the circumstances. (Mental Capacity Act 2005 Code of Practice)

(b) Should the patient be considered to lack capacity the trust mental capacity assessment form should be completed , from 2016 this will be part of Consent form 4

(c) Parents/ Guardians should also have capacity to consent for their child

3.3 Delegation of Consent

(a) UHBristol Trust advocates a closely governed use of delegation of consent to ensure that the information requirements of patients are not compromised. Trust Policy recommends that the person carrying out the procedure should obtain consent from the patient or parent of a child patient. Whoever takes consent must give the patients the information they want or need to know about the people who will be mainly responsible for and involved in their care, what their roles are, and to what extent students / trainees are involved.

(i) Where oral or non-verbal (gesture, blink etc.) consent is being sought at the point of the procedure this will be obtained by the health care professional carrying out the procedure as a matter of course.

(ii) Where written consent is sought in advance of a planned procedure e.g. in a pre-admission surgical setting, consent may be obtained by a different health care professional to the person who undertakes the procedure. Where the person seeking consent has the equivalent skills to carry out the procedure this is not viewed as delegation of consent. This will include clinicians in training if they have the appropriate knowledge to and skills to fully explain the risks and benefits to the patient/ parent with the permission of the consultant.

(iii) Where written consent for the procedure is sought by a health care professional who is not expected to carry out the procedure e.g. nurse specialist in a cardiac interventional procedure service, this is viewed as delegation of consent. The process to be followed when seeking to establish delegated consent for a procedure or service is detailed in Appendix F

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4. Duties, Roles and Responsibilities

4.1 Medical Director

(a) The Medical Director holds Executive responsibility for ensuring appropriate and valid patient consent is obtained for patients treated in UHBristol. The Medical Director Chairs the Quality Outcome Committee which receives reports from Patient Safety Group. This group has responsibility for ensuring effective governance is undertaken for patient consent. Operational responsibility for governance lies with the Patient Safety Manager who reports to the Medical Director and Patient Safety Group.

4.2 Consent lead

(a) Is responsible for updating the consent policy

(b) Prepares reports to the Quality Outcome Committee on CQC regulation 11 'Need for Consent'

(c) Liaises with Clinical Audit Team to ensure relevant consent audits are undertaken in accordance with annual audit plan. Disseminates relevant findings to clinical staff in divisions and presents the report to the patient Safety Group

(d) Provides consent training through e-learning in the essential training matrix and on request by clinical staff within specialties. Reviews content and delivery method annually.

4.3 Clinical Staff

(a) Medical and non-medical clinical staff have a responsibility to ensure that they follow the expectations of the Trust Policy and the relevant Professional Regulatory Body e.g. for medical staff, GMC Consent: patients and doctors making decisions together (2008).

(b) All staff should use Trust approved documentation for the recording of patient consent and information literature to support patient consent.

(c) Training is required for new staff and as an update as part of the http://connect/NewTeachingandLearning/EssentialTraining/Pages/HowdoIdeterminemytrainingrequirements.aspx

(d) Incident reporting and investigation should be used for examples of poor, absent or inadequate patient consent.

4.4 Other staff

(a) Non-clinical staff are expected to support clinical staff and patients in ensuring that valid informed consent is obtained.

4.5 Patient Information Service

(a) The Patient Information Service assist clinical staff in provision of robust document control for written and other format patient information to support patient consent. Details of specific procedures for preparation and review of leaflets are available in a separate policy and Connect site. Add link to Pat Information Policy and Connect site

4.6 Print Manager

(a) Has line management responsibility for the Patient Information Service and ensures any documentation which requires external printing is provided with appropriate scrutiny and governance.

4.7 Clinical Audit Manager

(a) Will assist the lead for consent to help ensure audits are undertaken in accordance with the monitoring requirements of this policy.

Policy Provisions

4.8 Policy Provisions are detailed in Appendices D to N.

4.9 Briefing paper from legal services on Montgomery v Lanarkshire Health Board [2015] UKSC 11, 2 WLR 76 Appendix O

5. Standards and Key Performance Indicators

5.1 Standards and Key Performance Indicators are included in the Monitoring Table. References/ Learning Resources

5.2 Internal

(a) UH BRISTOL Policies and Information on Document Management System

5.3 External

(a) The Department of Health website provides a number of documents relating to consent. Some have been superseded by legislative changes but remain relevant as guidance for practice:

(i) Consent what you have a right to expect: A guide for parents (2009)

(ii) Consent what you have a right to expect: A guide for adults (2001)

(iii) Consent what you have a right to expect: A guide for children and young adults (2001)

(iv) Consent what you have a right to expect: A guide for relatives and carers (2001)

(v) Good Practice in Consent Implementation Guide for healthcare Professionals: Consent to Examination or Treatment (2003)

(vi) Seeking Consent: Working with Children (2003)

(vii) Seeking Consent: Working with Older People (2003)

(viii) Seeking Consent: Working with People with learning Disabilities (2003)

(ix) Seeking Consent: Working with Prisoners and other Detainees (2006)

(x) Information to assist in amending consent form (2009)

(b) Reference guide to consent for examination or treatment (2009) provides a comprehensive summary of the current law on consent, and includes requirements of regulatory bodies such as the General Medical Council where these are more stringent. Copies are available on all wards and clinical areas and may also be accessed on the internet.

(c) General Medical Council (2008) Consent: patients and doctors making decisions together

(d) General Medical Council (2007) 0-18 years guidance for doctors

(e) GMC Website

(f) Human Tissue Authority (2009) – http://www.hta.gov.uk/ Code of Practice 1 on Consent

(g) Institute of Medical Illustrators – http://www.imi.org.uk/

(h) Mental Capacity Act – http://www.publicguardian.gov.uk/mca/code-of-practice.htm

(i) SaBTO Advisory Committee on the Safety of Blood, Tissues and Organs http://www.transfusionguidelines.org.uk/index.aspx?pageid=7691&section=22&publication=BBT&Highlight=sabto

Consent : Supported Decision Making – a good practice guide https://www.rcseng.ac.uk/library-and-publications/college-publications/docs/consent-good-practice-guide/

6. Appendix A – Monitoring Table for this Policy

Detail	Policy Reference	What is evidence	Type of evidence and who reviews the evidence	Who: (i) prepares evidence (ii) frequency
Process for obtaining consent	Flow Chart Appendix E Appendix H	Annual consent audit National Inpatient survey	Minutes and agreed actions by: 1 Patient Safety Group (PSG) 2 Divisional Governance or Audit Committees	Divisional Clinical Audit Facilitator with Patient Safety Lead annually Div. Patient Safety Teams annually
Provision of information including risks and benefits	Appendix E	Audit of patient information leaflets Review of incidents and complaints	Audit report and action plan – Patient Information Team Annual Patient Consent Report to PSG	Every 2 years - Patient Information Team Patient Safety Manager – annually
Process for recording consent, documenting the discussion and provision of information to patients	Appendix E Appendix G	Audits 1.Health Records 2.Patient Information Leaflets 3. GTT[1] case note reviews	Audit reports: 1. Patient safety group 2. Patient Information Team. Content of patient information leaflets reflects min requirements 3.Patient Safety Group	1.As above annually 2.Patient Information Team bi annual audit 3.Monthly case note Reviews reported annually to Patient Safety Group
Archiving arrangements for any information given to patients			Details in Patient Information Policy	Patient Information Team
Identification of staff who are not capable of performing the procedure but are authorised to obtain consent **Actions when consent is obtained without authority** **Reports to General Medical Council for failure to follow policy**	Appendix F Appendix N	Annual Consent report Divisionally held list of individuals who have been trained to undertake delegated consent	1.Details of approved competencies and training attendance in last 12 months 2.Review of Risk Register for consent risks 3.Review of incidents, GMC referrals and complaints 4.Actions records audit	1 – Patient Safety Manager - annually 2. Chair of Patient Safety Group

[1] GTT Global Trigger Tool used for Adverse Event detection. IHI Model for Improvement

7. Appendix B – Dissemination, Implementation and Training Plan

7.1 The following table sets out the dissemination, implementation and training provisions associated with this Policy.

Plan Elements	Plan Details
The Dissemination Lead is:	Patient Safety Manager
This document replaces existing documentation:	Yes
Existing documentation will be replace by:	Rescinding of superseding document
This document is to be disseminated to:	Patient Safety Group
Training is required:	Yes
The Training Lead is:	Deputy Medical Director

Additional Comments
Not applicable

8. Appendix C – Document Checklist

8.1 The checklist set out in the following table confirms the status of 'diligence actions' required of the 'Document Owner' to meet the standards required of University Hospitals Bristol NHS Foundation Trust Procedural Documents. The 'Approval Authority' will refer to this checklist, and the Equality Impact Assessment, when considering the draft Procedural Document for approval. All criteria must be met.

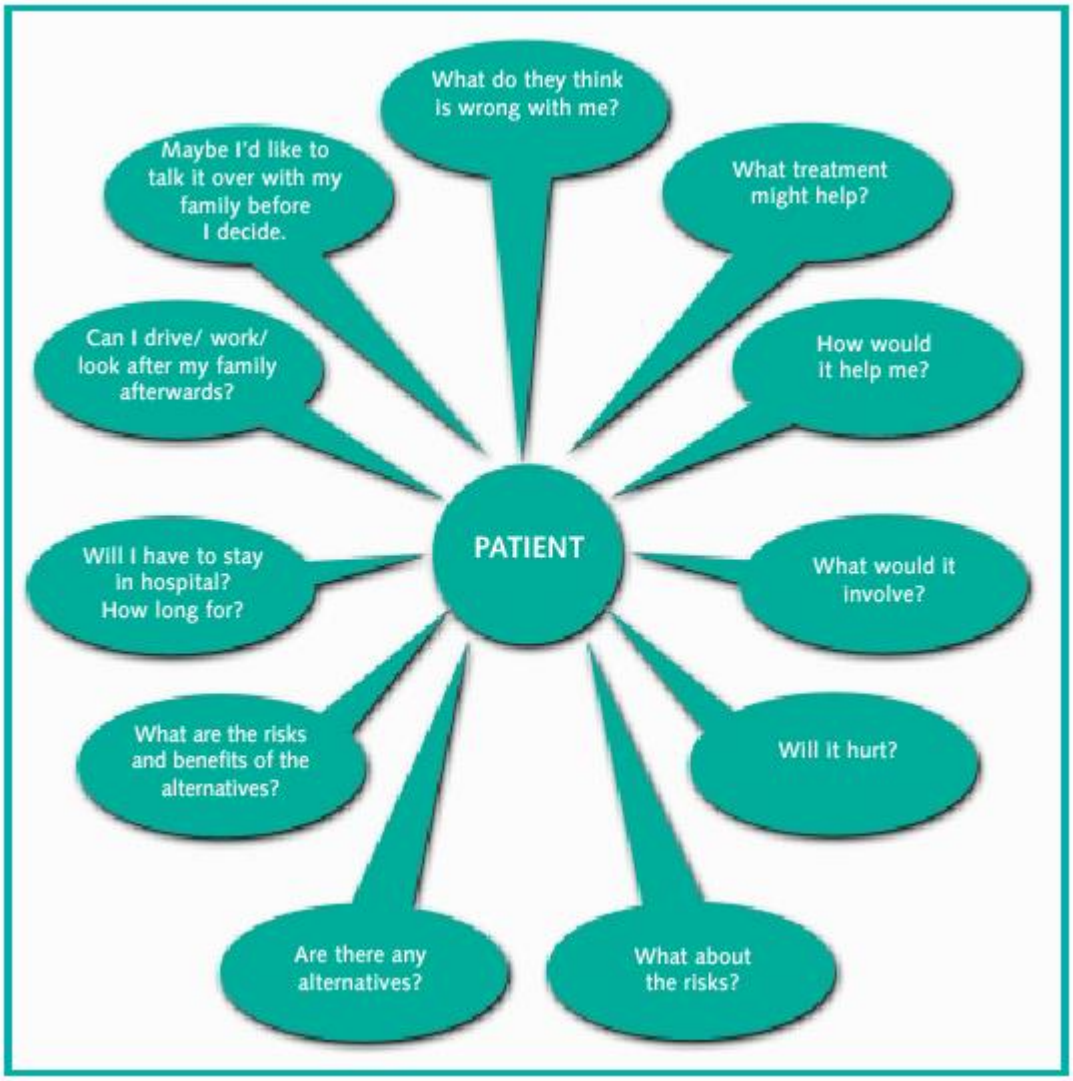
Checklist Subject	Checklist Requirement	Document Owner's Confirmation
Title	The title is clear and unambiguous:	Yes
	The document type is correct (i.e. Strategy, Policy, Protocol, Procedure, etc.):	Yes
Content	The document uses the approved template:	Yes
	The document contains data protected by any legislation (e.g. 'Personal Data' as defined in the Data Protection Act 2000):	Not Applicable
	All terms used are explained in the 'Definitions' section:	Yes
	Acronyms are kept to the minimum possible:	Yes
	The 'target group' is clear and unambiguous:	Yes
	The 'purpose and scope' of the document is clear:	Yes
Document Owner	The 'Document Owner' is identified:	Yes
Consultation	Consultation with stakeholders (including Staff-side) can be evidenced where appropriate:	Yes
	The following were consulted:	Pending
	Suitable 'expert advice' has been sought where necessary:	Yes
Evidence Base	References are cited:	Yes
Trust Objectives	The document relates to the following Strategic or Corporate Objectives:	Rescind previous document
Equality	The appropriate 'Equality Impact Assessment' or 'Equality Impact Screen' has been conducted for this document:	Yes
Monitoring	Monitoring provisions are defined:	Yes
	There is an audit plan to assess compliance with the provisions set out in this procedural document:	Yes
	The frequency of reviews, and the next review date are appropriate for this procedural document:	Yes

Checklist Subject	Checklist Requirement	Document Owner's Confirmation
Approval	The correct 'Approval Authority' has been selected for this procedural document:	Yes

Additional Comments
No

9. Appendix D – Department of Health Patient Perspective and 12 Key Points for Consent

Seeking Consent: Remembering the patients perspective



12 Key Points on Consent: The Law in England

When do health professionals need consent from patients?

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

9.2 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.

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

9.4 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?

9.5 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, 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?

9.6 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?

9.7 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. Patients/ Parents should also be made aware as to who is likely to carry out any procedures.

Does it matter how the patient gives consent?

9.8 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.

9.9 Consent must be given voluntarily: not under any form of duress or undue influence from health professionals, family or friends.

Refusal of treatment

9.10 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 2007. 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

9.11 No-one can give consent on behalf of an incompetent adult - unless it has been previously organised for that person to have Lasting Power of Attorney (LPA) under the Mental Capacity Act 2005. However, you may still treat a patient without consent 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. If there are no relatives or LPA, then an Independent Mental Capacity Advocate should be involved in decisions regarding serious medical treatment and long-term accommodation.

9.12 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:
http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_103653.pdf

10. Appendix E - Additional Guidance for Patient Consent

10.1 General Principles

The Department of Health has issued a number of guidance documents on consent, and these should be consulted for advice on the current law and good practice requirements in seeking consent (Appendix D page15). Health professionals must also be aware of any guidance on consent issued by their own regulatory bodies.

(a) What consent involves

(i) The context of consent can take many different forms, ranging from the active request by a patient for a particular treatment (which may or may not be appropriate or available) to the passive acceptance of a health professional's advice.

(ii) In some cases, the health professionals 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.

(iii) 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.

(iv) The General Medical Council (GMC) explains the partnership approach in the following terms:

(A) Listen to patients and respect their views about their health

(B) Discuss with patients what their diagnosis, prognosis, treatment and care involve

(C) Share with patients the information they want or need in order to make decisions

(D) Maximise patients' opportunities, and their ability, to make decisions for themselves

(E) Respect patients' decisions (2008)

(b) Health care decisions without patient consent

(i) 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. The exception to this general rule applies when:

(A) Patients have given 'lasting power of attorney' to a friend or relative. [2] See UHBristol Safeguarding Adults Policy for further details.

(B) Patient has refused in advance the particular care decision in an advanced decision or statement (Appendix J).

(ii) For further details on advance decisions see Appendix J, Advance Decisions, Refusal of Treatment or the Department of Health's *Reference guide to consent for examination or treatment*.

10.2 When should consent be sought?

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

(a) Single stage process

(i) In many cases, it will be appropriate for a health professional to initiate a procedure immediately after discussing it with the patient. For example, during an on-going episode of care a physiotherapist may suggest a particular manipulative technique and explain how it might help the patient's condition and whether there are any significant risks. If the patient is willing for the technique to be used, they will then give their consent and the procedure can go ahead immediately. In many such cases, consent will be given orally.

(ii) 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.

(b) Two or more stage process

(i) 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. The process is detailed below:

(ii) Ideally patients receiving elective treatment or investigations for which written consent is appropriate should be familiar with the contents of their Consent Form

[2] Mental Capacity Act 2005

before they arrive for the actual procedure, and should have been offered a copy of the page documenting the decision-making process (page 2 tear-off sheet).

(iii) 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.

(iv) 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. It is good practice to obtain the patient/parent's signature alongside that of the member of staff. This acts as confirmation that this second check of consent has been carried out in situations where pre-admission consent is obtained.

(v) 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*?"

(c) Communication and Timing

(i) 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.

(ii) Patients requiring elective treatment/investigation should be given sufficient time to provide their consent. For example 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. It is important to avoid any suggestion of duress in obtaining patient's consent.

(d) Seeking consent for anaesthesia

(i) 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 immediately prior to the list commencing: 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.

(ii) Patients should therefore either receive a general leaflet about anaesthesia (available on the DMS) in out-patients, or have the opportunity to discuss anaesthesia in a pre-assessment clinic.

(iii) The anaesthetist should ensure that the discussion with the patient and their consent is documented in the anaesthetic record or in the patient's notes.

(iv) Where the clinician providing the care is personally responsible for anaesthesia (e.g. where local anaesthesia or sedation is being used), then he or she will also be

responsible for ensuring that the patient has given verbal or written consent to that form of anaesthesia as part of consent for the procedure.

(v) 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.

(e) Emergencies

(i) 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. Critically injured or ill patients should receive all the necessary treatment required in their best interests and it is not practical to seek consent. Once their condition has stabilised they may be able to provide consent to on-going treatment.

(f) Consent for intimate examinations

(i) Intimate examinations of patients are often required as part of assessment or treatment. It is important that patients are aware of the reason for the examination, provide consent and have the opportunity to request a chaperone. See the 'UHBristol' Chaperoning Policy.
http://nww.avon.nhs.uk/dms/download.aspx?did=9286

10.3 Provision Of Information

The provision of information is central to the consent process. Before patients can come to a decision about treatment, they need comprehensible information about their condition and about possible treatments/investigations and their risks and benefits (including the risks/benefits of doing nothing). They also need to know whether additional procedures are likely to be necessary as part of the procedure, for example a blood transfusion, or the removal of particular tissue. Once a decision to have a particular treatment/investigation has been made, patients need information about what will happen: where to go, how long they will be in hospital, how they will feel afterwards and so on. The clinician may encourage patients or parents to record conversations explaining treatment options and the risks and benefits associated with the treatments, to facilitate their retention of information given understanding

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.

(a) Information giving prior to admission

(i) 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 (Appendix F).

(b) Confirmation of consent provided prior to admission

(i) If the patient signs the form in advance of the procedure (for example in out-patient or pre-assessment clinic), an appropriate health professional involved in their care on the day of the procedure 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.

(c) Support offered by the Patient Information Services

(i) The UH BRISTOL Patient Information Service provides a production, creation, revision and archiving service of all UH BRISTOL patient information for all staff.

(ii) The Service creates information to a DoH Communication approved template which can be printed in-house without charge or sent to external printers at a cost born by Divisions. Alternatively, the leaflets can be downloaded and printed at source from the Document Management Service (DMS) at nww.avon.nhs.uk/pil

(iii) The service maintains a directory of patient information leaflets stored and archived on the DMS.

(d) Preparation of leaflets

(i) The service provides a range of self-help leaflets and one-to-one training sessions on writing leaflets - including leaflets containing risks and benefits - in plain English and format.

(e) Other formats

(i) The service can make arrangements to provide material in other formats, large print, Braille, tape etc. and in other languages. Contact: Patient Information Service.

(ii) Visit the Website for more information: http://connect/ClinicalCare/PatientInformation/Pages/default.aspx

(f) Provision for patients whose first language is not English

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

(ii) Written material can be made available in other languages through the Patient Information Service.

(iii) Language Line (a telephone translation service available 24/7) is available for all staff across the Trust. Contact Patient Information Manager for more information and to be set up with a Language Line Account and Pin Number. Contact:

(iv) The arrangements for using translators are detailed on the intranet http://connect/Governance/patientexperience/tandi/Pages/default.aspx

(v) Copies of the 4 standard consent forms are available on the Department of Health Website in several languages: http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/Consent/ConsentGeneralInformation/ConsentGeneralArticle/fs/en?CONTENT_ID=4001986&chk=eGd%2B7l

(g) Access to more detailed or specialist information

(i) Patients may sometimes request more detailed information about their condition or about a proposed treatment than that provided in general leaflets. This Trust has made the following arrangements to assist patients to obtain such information:

(ii) Patients and families may sometimes request further information about their condition or a proposed treatment or may require emotional support or someone to talk to on a confidential basis about any concerns or problems. The PALS Service are available for patients and/or their families to talk to and can be contacted either directly or via a member of staff:

(A) Phone: 0117 342 3604

(B) E-mail: PALS@UHBRISTOL.swest.nhs.uk

(C) Hours: 08.30 – 17.00 (Monday to Friday)

(h) Access to health professionals between formal appointments

(i) After an appointment with a health professional in primary care or in out-patients, patients will often think of further questions which they would like answered before they take their decision. Where possible, it will be much quicker and easier for the patient to contact the healthcare team by phone than to make another appointment or to wait until the date of an elective procedure (by which time it is too late for the information genuinely to affect the patient's choice). The contact arrangements should be provided at the time of the consent discussion. These vary between specialties.

(ii) Where a pre-admission assessment is used the details of who to contact before admission is given at the initial attendance. The specific arrangements vary depending on the proposed treatment and speciality. Information leaflets should contain contact numbers.

(i) Open access clinics/drop in centres

(i) 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.

10.4 Refusal Of Consent To Treatment Or Investigation

(a) If the process of seeking consent is to be a meaningful one, refusal must be one of the patient's options. A competent adult patient is entitled to refuse any treatment, except in circumstances governed by the *Mental Health Act 2007* [3]

(b) The following paragraphs apply primarily to adults who have been assessed as having capacity to make a treatment decision.(Appendix I Children and Consent)

(c) 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.

(d) 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. Where refusal has life limiting impact e.g. Do Not Attempt Resuscitation (Appendix J Advance Decisions and DNAR guidance.)
http://nww.avon.nhs.uk/dms/download.aspx?did=3934

(i) 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.

(ii) Those procedures or parts of a procedure for which a patient refuses consent (conditional consent) should be clearly documented on page 3 of both the adult and child consent forms (forms 1 and 2).

10.5 Consent Documentation

For significant procedures, it is essential for health professionals to document clearly both a patient's agreement to the intervention and the discussion which lead up to that agreement. This may be done either through the use of a Consent Form or through documentation within the health records (case notes). Trust Consent Forms are available in hard copy and supplies are ordered via the Trust Ordering system EROS. Clinical Departments are expected to hold sufficient supplies of relevant forms for their activity.

[3] MHA relates to certain treatments of mental illness only

The Approval protocol must be followed for all consent forms prepared with details of risks and benefits pre-printed (Appendix G).

Use of incorrect consent forms or lack of documentation of consent must be reported as a patient safety incident. Additional steps are required when medical staff are involved (Appendix N).

(a) Written Consent

(i) A signature on a consent form is evidence that the patient has given consent but is not proof of valid consent. Lack of time to make a reasoned choice, inadequate information to make an informed choice or lack of capacity to make a choice are all indications of invalid consent. In addition proceeding with treatment when the patient has withdrawn consent is also not acceptable.

(ii) It is rarely a legal requirement to seek written consent (exceptions include certain treatments for mental health care and fertilisation treatments). However UHBristol consider written consent is required in the following circumstances:

(A) The treatment or procedure is complex, or involves significant risk. The term risk is used throughout consent communication to refer to any adverse outcome. It includes some which clinical staff may consider to be side effects.

(B) The procedure involves general anaesthetic or regional anaesthesia

(C) The provision of clinical care is not the primary purpose of carrying out the procedure e.g. clinical research

(D) Rather than clinical risks, there may be significant consequences for the patient's employment, social or personal life as a consequence of the treatment.

(iii) Completed forms should be filed within the medical notes following discharge. Amendments to the form should follow Trust Policy for Clinical Records requirements i.e. score through sign and date the change. A new form should be offered to the patient if the amendment is significant.

(iv) It will not usually be necessary to document a patient's consent to routine and low risk procedures e.g. personal care, taking a blood sample. However in cases of uncertainty documentation of patient consent in the health records or on Consent Form 3 is recommended. Where patients are not required to provide written consent, it remains best practice to document in health records that the patient has agreed to the intervention and the main points of the explanation e.g. for transfusion of blood products.

(b) Patients who lack capacity to document their consent

(i) Consent Form 4 must be used for adult patients who do not have the capacity to provide and record their own consent (Appendix I for process for children). Documentation of capacity assessment is important along with details of why the clinician considers the intervention is in the patients' best interests. Minor interventions should include a note in the health records.

(ii) Capacity assessment will help to determine if the patient genuinely lacks capacity or whether additional/alternative forms of information may enable the patient to provide their own consent. Use of UHBristol Capacity Assessment Tool is recommended. http://nww.avon.nhs.uk/dms/download.aspx?did=9207

(iii) Additional forms of support for adults are available. Advice is available from the Safeguarding Adults and Learning Difficulties Teams.

(iv) In the event of dispute it may also be necessary to consult the Legal Services Team for advice.

(c) Consent Forms

(i) UHBristol Trust uses the model consent forms produced by the Department of Health with some minor modifications:

(ii) All forms are available for ordering on EROS.

(A) **Consent Form 1** for adults or older children where it is envisaged an anaesthetist will be involved in their care.

(B) **Consent Form 2** for parental consent for a child or young person where it is envisaged an anaesthetist will be involved in their care.

(C) **Consent 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

(D) **Consent Form 4** for adults who are unable to provide independent consent

Please see additional guidance on reverse of each consent form.

(iii) For some high volume or high risk procedures bespoke consent forms are available e.g. Cardiac interventional procedures, caesarean section, cataract removal

10.6 Useful Contact Details

(a) Patient Safety Team [redacted]

(b) Legal Services [redacted]

(c) Divisional Patient Safety Leads email or intranet patient safety site

(d) Ethics committee for clinical research – contact [redacted]

(e) Clinical Ethics Advisory Committee Connect Medical Director site

(f) **Other documents:** 'Consent and You' staff information leaflet on DMS

10.7 How To Seek A Court Order Or Declaration

(a) Contact Legal Service on [redacted] for advice in office hours or bleep via switchboard out of hours.

(b) The Courts have identified certain circumstances when healthcare professionals or others **must** make an application to the High Court.

(i) Where there is serious uncertainty about the patient's capacity to consent or their best interests

(ii) Where there is a serious unresolved disagreement between a patient's family and health professionals

(c) When seeking the authority of the Court for treatment in the face of parental or child refusal, the following will be necessary. A written statement or letter detailing the clinical issues and benefits of the proposed intervention will be required for an application to Court. For further advice contact Legal Services as above.

11. Appendix F – Delegation of Patient Consent Procedure

11.1 UH Bristol Trust advocates a restricted use of delegation of consent to ensure that patient's information needs are met. Trust Policy recommends that the person carrying out the procedure obtains consent from the patient or parent of child patient.

11.2 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, teamwork is a crucial element of health care, 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. Where a colleague obtains consent from a patient in advance of the procedure e.g. POAC[3] this is not delegated consent if they also have the necessary skills to carry out the procedure.

11.3 Approved delegation of consent[4] is permitted and has been found to be effective in ensuring patients are fully informed prior to providing consent.

The Patient Safety Group approves applications for delegation of consent. The practitioners need to demonstrate that this will not adversely affect patients and that the staff involved will receive the relevant training and competency assessment. They need to review the use of delegation in the form of a patient survey or audit within 18 months of approval. Procedure specific delegated consent preparation is provided by the Patient Safety Manager working with the clinical specialty.

11.4 It involves:

(a) Consent training for all relevant staff, medical nursing or AHP, to cover all aspects of the of the reference Guide to Consent for examination and treatment DoH 2009

(b) Identification of specific procedure/s where delegation is required and Patient Safety Group approval

(c) Observation of experienced practitioner (usually Consultant for Specialty)

(d) Agreed period of supervised practice and competency assessment with documentation to support

(e) Review within agreed timescale and inclusion in annual appraisal or equivalent Educational Supervision interview

11.5 Details of recommended documentation to be used are included in this procedure.

(a) Clinical staff should follow the consent flow charts to ensure that they are the appropriate person to obtain the particular patient's consent.

(b) It is a health professional's own responsibility:

(i) To ensure that when they require colleagues to seek consent on their behalf they are confident that the colleague is competent.

[3] POAC preoperative assessment clinic for elective surgery

[4] Delegated consent applies to those who do not carry out the procedure but provide information and seek written consent as an approved form of delegation by the Consultant in charge of the patient's care.

(ii) To work within their competence and not to agree to perform tasks which exceed that competence.

(iii) If you feel that you are being pressurised to seek consent when you do not feel competent to do so, please contact your Divisional Patient Safety Lead. The Royal College of Surgeons offers guidance on practice relating to consent[5].

(c) Use of inappropriate delegation of consent must be reported as a patient safety incident (Appendix N).

11.6 Recording and Procedure for Delegation of Consent

(a) Staff to whom the process of seeking written consent for examination or treatment is being delegated must have written evidence of their competence.

(b) This will provide both the staff member and the Trust with evidence that those staff expanding their role to undertake this task are competent to do so.

11.7 Clinical Staff expected to complete this documentation are:

(a) Registered Nurses/AHP's where a specialist role has been agreed with their Divisional Senior Nurse / Professional Manager and a Senior Clinician for that speciality.

(b) Trainee doctors who are not yet competent to carry out the clinical procedure but where prior approval of this delegation has been obtained from the Patient Safety Group.

11.8 The responsibility for ensuring appropriately informed consent is obtained remains with the delegating consultant /lead clinician. Annual audits of consent documentation will confirm compliance.

(a) Any Health Care Professional providing information to a patient and seeking consent to examination/treatment must be competent to do so: either because they themselves carry out the procedure, or because they have received training in advising patients about the procedure, have been assessed, and are aware of their own knowledge limitations and are subject to audit (Department of Health 2001).

(b) Inappropriate delegation (for example where the clinician seeking consent has inadequate knowledge of the procedure) may mean that the 'consent' obtained is not valid. Individual clinicians are personally accountable for their practice and as such are responsible for acknowledging the limits of their knowledge and competence, seeking the advice of appropriate colleagues when necessary

(c) The criteria below must be fulfilled to demonstrate:

(i) An understanding of the principles of informed consent

(ii) Knowledge of Consent Policy and practice at a national and local level

[5] Good Surgical Practice, 2014, RCS
https://www.rcseng.ac.uk/surgeons/surgical-standards/professionalism-surgery/gsp/domain-3/3.5.1-consent

(iii) In depth knowledge of the proposed procedure including, pre procedure investigations and care, risks, benefits, alternatives, aftercare

(iv) Effective communication skills

(v) Awareness of own limitations with regards to the consent process seeking appropriate help when necessary

Name:	Profession/Grade/Speciality:	Delegating Consultant:

Step 1 **Training session attended at as part of preparation for delegation 'Principles of consent'**	**(Date)**	**Step 2** **Accessed Trust Policy and Guidance for Consent to Examination or Treatment**	**(Date)**

Step 3 Assessor to sign competency for each procedure below:

Communication	**Practitioners Signature**	**Date**	**Assessors Signature**	**Date**
Uses language, pace, and volume which optimises patient understanding				
The Process (covered in 'Principles of Consent' session)	**Practitioners Signature**	**Date**	**Assessors Signature**	**Date**
Is aware of consent forms in use and completes appropriate form				
Is aware of sources of information a patient may wish to access				
Has understanding of who can give consent and what is meant by parental responsibility				
Can make an accurate assessment of a patient's capacity to give consent – will refer to senior colleagues if capacity is not certain.				
Understands procedure to follow if patient withdraws consent				
Understands procedure to follow if patient refuses blood or blood products				
Understands procedure to follow if patient refuses to allow use of surplus tissue for education/research				

Name:	Profession/Grade/Speciality:	Delegating Consultant:

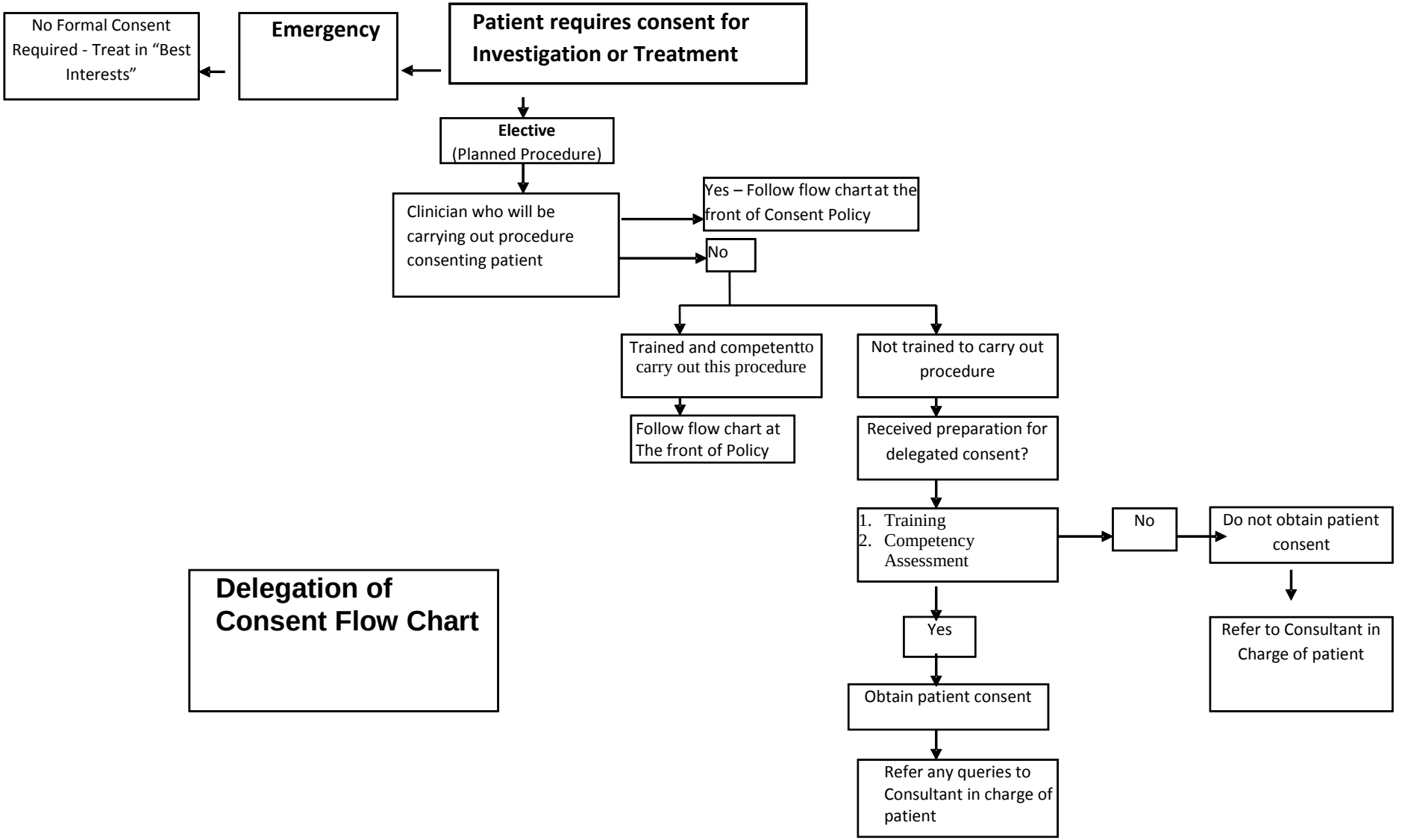
The Procedure	**Is able to explain the procedure and what it involves in clear and simple terms (including pre, peri, and post procedural care)**	**Is able to explain the intended benefits of the procedure**	**Is able to explain the risks associated with this procedure**	**Is able to explain alternative treatments to the procedure and their implications (including no treatment)**	**Is able to explain any further procedures which may become necessary e.g. blood transfusion**	Practitioners Signature and Date	Assessors Signature and Date

I am aware of my own limitations with regards to the consent process and will seek appropriate help when necessary.

Name of Practitioner: **……**Signature: **……**Date: **…….**

This practitioner successfully meets the above criteria and I am satisfied that he/she is able to obtain consent for the above procedure(s) as delegated

Name of Assessor: …… Signature:…… Date:……


Patient requires consent for Investigation or Treatment
Emergency
No Formal Consent Required - Treat in "Best Interests"
Elective (Planned Procedure)
Clinician who will be carrying out procedure consenting patient
Yes – Follow flow chart at the front of Consent Policy
No
Trained and competentto carry out this procedure
Follow flow chart at The front of Policy
Not trained to carry out procedure
Received preparation for delegated consent?
1. Training
2. Competency Assessment
No
Do not obtain patient consent
Refer to Consultant in Charge of patient
Yes
Obtain patient consent
Refer any queries to Consultant in charge of patient
Delegation of Consent Flow Chart

12. Appendix G – Pre Printed Risks

Clinical Record Keeping Group Approval of Consent Forms with pre-printed risks and benefits

Guidance for Clinical Teams Wishing to Develop These

12.1 Background

(a) The University Hospitals Bristol Trust Policy and Guidance Notes for Consent to Examination or Treatment has adopted the model Department of Health Consent Policy and standard Consent Forms.

(b) See DMS http://nww.avon.nhs.uk/dms/download.aspx?did=3910

(c) This was introduced in 2002 to facilitate consistency of practice when obtaining patient consent across the NHS in England. This is supported by the National Health Service Litigation Authority (NHSLA) Risk Management Standard on patient advice and consent www.nhsla.com. This is the benchmark against which acute hospital trusts are measured with regard to patient consent.

(d) At UHBristol the standard 4 consent forms are used where written (formal) consent is required. These are supported by the communication with the Clinician and additional information leaflets or similar resources.

(e) The consent form requires the Clinician to explain and record the specific risks, benefits and alternatives of the proposed intervention to the patient before seeking their agreement and signature.

12.2 Procedure specific consent

(a) For some procedures the recording of recognised risks and benefits takes a long time e.g.: cataract surgery.

(b) If a clinical team would like to devise a procedure specific consent form it will be necessary for the following process to be followed:

12.3 Process

(a) Step 1

(i) The format of the consent form used should reflect the standard consent forms 1 2 or 3 in layout

(ii) The customised aspects of the consent form should be limited to:

(A) The name of the procedure, investigation or operation

(B) The intended benefit

(C) The serious or frequently occurring risks subdivided into common, occasional and rare with an option to personalise for individual patients

(D) Any alternatives to the proposed intervention

(iii) A copy of this page of the consent form should be offered to the patient

(b) Step 2

(i) In addition any procedure specific consent forms must be submitted to the The Clinical Record Keeping Group for approval prior to use in clinical practice.

(ii) The Group will need to be assured that the implementation of these forms will enhance the ability of patients to provide informed consent. They cannot be used as a substitute to explanation and testing for understanding. Further the staff using these forms will still be assessing the individual patient to ensure that their particular risks are identified.

12.4 Benefits to patient and staff

(a) The primary saving will be of time used in hand-written recording of risks and benefits. This time can be utilised to confirm the patient is fully informed.

12.5 Who can use this consent documentation?

(a) The staff obtaining consent using this documentation will be either the Clinician carrying out the procedure or where delegated to a colleague, they will have sufficient understanding to meet the information needs of the patient. Where consent is delegated the Clinician will need to ensure that the member of staff has received appropriate training in the principles of informed consent and is assessed as competent to carry out the delegated task. See separate guidance in Consent Policy.

12.6 Long term storage

(a) Once approved the consent forms will be logged in an archive. The use of these forms should be reviewed periodically as part of the Clinical Divisions Governance activity. Further modifications to the consent forms e.g. to include a 'new' risk need to be submitted to Clinical Record Keeping Group to ensure that a central log of the documentation in use across the Trust is held.

13. Appendix H – Training and other Staff Preparation for Valid, Informed, Patient Consent

13.1 For staff involved in the consent process e-learning updates are available on the Education, learning and Development, Essential Training intranet site, and should be completed at least once every three years

13.2 Training

(a) The Trust Essential Training Matrix and Prospectus have details of all consent training and related risk training for clinical staff.
http://connect/TeachingAndLearning/EssentialTraining/Pages/default.aspx

13.3 Further Guidance

(a) See reference section of Policy)

13.4 Specific Staff Groups

(a) Medical Staff

(i) All medical staff are referred to the professional requirements detailed in 'Seeking patient's consent: the ethical considerations' GMC 2008.

(b) Existing Consultant Staff

(i) 2003 confirmed in writing that they were familiar with the requirements of UH BRISTOL Consent Policy.

(ii) April 2009 Medical Director correspondence to consultant colleagues confirming that delegated consent for specific procedures would require approval from Trust Clinical Risk Assurance Committee.

(c) Newly appointed Consultant staff

(d) All new medical and dental staff undertake the e-induction which includes scenarios on consent and mental capacity .Consent training is updated 3 yearly by undertaking an e-learning module.

(e) Junior Medical Staff

(f) Specialist Trainees (Single Training Grades and Clinical Fellows), F1 and F2 trainees receive consent training as part of e-induction. This includes information about the UHBristol Consent Policies and supporting record keeping. This specifies the Trust expectations re delegation of consent. The Trust Policy requirements for delegation of consent are provided to all new trainee medical staff at induction. (level 1)

(g) Nursing & Midwifery Staff and Allied Health Professionals

For staff involved in the consent process there are a number of levels of consent training offered:

Three Levels of Consent Training

Information Leaflet available on DMS for all staff http://nww.avon.nhs.uk/dms/download.aspx?did=11258 Presentation at induction and update.

(h) Research Nurses, Midwives and Allied Health Professionals (AHPs) currently obtaining written consent from patients for clinical trials receive individual training from their Project Supervisor.

(i) Clinical Nurses, AHPS and Midwives involved in obtaining written patient consent for procedures which they carrying out are offered e-learning or directed to appropriate courses

(j) Clinical Nurses, AHPs and Midwives providing information to patients and confirming consent with the patient on admission for the procedure attend patient safety update and induction training.

(k) Staff who obtain consent as a delegated responsibility are prepared for this role with training and competency assessment (Appendix F).

14. Appendix I – Consent and Children

14.1 Treatment of Young Children

(a) 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.

(b) Only people with 'parental responsibility' (see below) 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.

14.2 Parental Responsibility:

(a) Detailed guidance on the requirements for parental responsibility are provided to reflect the number of paediatric patients treated at UH Bristol and the tertiary referral status of Bristol Children's Hospital. Further case specific guidance may be obtained by referring to the Legal Services Team at Trust HQ.

(i) The mother always holds parental responsibility (PR) unless contrary arrangements have been made by court order.

(ii) Whether or not the father has PR is complicated and the law depends on where the child's birth was registered (see below). Once a father has qualified for PR, he will retain it even if the parents later divorce.

(iii) Adoptive parents have PR as soon as the child has been placed with them.

(iv) Step-parents and grandparents do not have PR unless it has been specifically arranged through a Parental Responsibility Agreement (this must be signed and witnessed by a justice's clerk or court officer, and filed at the Principal Registry of the Family Division to have legal recognition).

(v) Under the Children's Act 1999, a court may grant PR to other individuals or to Social Services. This can be through a Parental Responsibility Order, or one of several other orders (e.g. an Emergency Protection Order, or Care Order).

(vi) It is important to ensure that the parent has the capacity to consent

(b) For children born abroad, the law of the country of residence applies.

14.3 England & Wales:

(a) The father has PR if he was married to the mother at the time of the child's birth. Marrying the child's mother afterwards does not confer PR.

(b) A father who was not married to the mother at the time of the child's birth does not have PR unless he is registered on the birth certificate – this only applies to births registered on or after 1.12.2003. If the birth was registered before this, then the presence of his name on the birth certificate does not confer PR. Births can be re-registered to take advantage of this change in the law.

(c) A mother can agree to share PR with a father (who otherwise wouldn't have it) through a Parental Responsibility Agreement (see above).

14.4 Scotland:

(a) The father has PR if he was married to the mother at the time of conception or at any point since then.

(b) A father who has not been married to the mother at any point since conception does not have parental responsibility unless he is registered on the birth certificate – this only applies to births registered on or after 4.5.2006 (if the birth was registered before this, then the presence of his name on the birth certificate does not confer PR).

14.5 Northern Ireland:

(a) A father has PR if he was married to the mother at the time of the child's birth. Marrying the child's mother afterwards does confer PR (unlike in England & Wales) provided he was living in Northern Ireland at the time.

(b) A father who was not married to the mother at the time of the child's birth does not have PR unless he is registered on the birth certificate – this only applies to births registered on or after 15.4.2002. If the birth was registered before this, then the presence of his name on the birth certificate does not confer PR.

14.6 Some examples of determining parental responsibility

(a) If a child has been placed in care voluntarily, the birth mother or parents retain the power of consent.

(b) If a child has been placed in care, then Social Services adopt this responsibility. The Senior Team Leader usually deals with consent issues.

(c) If a child is with Foster Parents, short or long term, they do not have the authority to provide consent without the necessary written order.

(d) Same sex partners may obtain Parental Responsibility Orders allowing them to provide consent.

For more information, see: http://www.direct.gov.uk/en/Parents/ParentsRights/DG_4002954

14.7 Treatment of older children under the age of 16

(a) Older children may provide their own consent to treatment/investigations in limited circumstances:

(i) They need to show they have 'sufficient maturity and understanding' of the proposed treatment to provide valid consent (known as Gillick competence),

(ii) In addition access to the parents is denied by circumstances or explicitly by the child and

(A) Harm will occur if the treatment is not carried out

(B) The treatment should not be delayed

14.8 Treatment of children between the ages of 16 and 18

(a) Teenagers of 16 to 18 are able to provide their own consent to investigations or treatments unless there is an impairment of their ability to make decisions about their own care. Their parents do not have to be involved in the consent process however it is usually helpful for them to be so involved. See Appendix 2 refusal of consent.

14.9 Refusal by a child

(a) Whilst patients of 16 years or older can provide consent to treatment (Appendix F) they are more restricted in refusing treatment, and the law does not always recognise their refusal as binding.

(b) The refusal of consent by a child of 16 or 17 (or the competent refusal by a child under 16) can be over-ruled by a court if that refusal is likely to lead to the child's death or to serious permanent injury. In the past, courts have also upheld the parents' right to over-rule the refusal of consent by competent minors (e.g. *Re W [1992] All ER 627*), however these cases pre-date the enactment of the Human Rights Act 1998, and it is unclear whether or not courts would still do this.

(c) It is advisable to seek advice from the Trust Legal Services Team unless the treatment is necessary on the grounds of emergency. In this case the minimum treatment necessary to stabilise the patient's condition should be given before seeking consent once more.

(d) For more information see the Department of Health *Reference guide to examination or treatment* (2009). http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_103653.pdf

14.10 Refusal by a parent or those with equivalent parental responsibility

(a) If the child is able to provide valid consent to treatment (over 16 or viewed as Gillick competent[4]) then the treatment can proceed on this basis despite the refusal of the parent.

(b) For children who are not able to provide their own consent, the test is whether the proposed treatment is in the best interests of the child. Both the medical staff and parents are allowed to seek confirmation of the proposed decision through the courts (Appendix I).

14.11 Conscientious objection by parents or child

(a) In the situation where a child under 16 and their parents refuse a treatment which medical staff consider is necessary but not an emergency e.g.: child of Jehovah's Witness parents requiring transfusion as part of an elective procedure, it may be necessary to apply via the Courts for a 'Specific Issue Order'.

4 Definition of Gillick competence from case law. "As a matter of law the parental right to determine whether or not their minor child below the age of 16 will have medical treatment terminates if and when the child achieves sufficient understanding and intelligence to enable him or her to understand fully what is proposed' (Lord Scarman in Gillick v West Norfolk)

(b) Further details are obtainable from the Legal Services Department on x23612. Once this has been obtained, it is important that 2 doctors of Consultant status should make an unambiguous, clear and signed entry in the clinical record that blood transfusion is essential, or likely to become so, to save life or prevent serious permanent harm.

15. Appendix J – Advance Decisions Protocol

http://nww.avon.nhs.uk/dms/download.aspx?did=3908

There is also a patient information leaflet for patients and families

http://nww.avon.nhs.uk/dms/download.aspx?did=9526

16. Appendix K – Consent and Human Tissue

16.1 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 covered by the licensing schemes of the Human Tissue Act 2004. 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.

16.2 Explicit consent is not necessary for public health surveillance using the unlinked anonymous method, but a well-publicised opt-out policy must apply. Information is available in Patient Information Leaflets 'What We Do With Your Personal Information'

16.3 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.[6] 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.

16.4 Explanation of the purpose of clinical audit and quality assurance is given in the Research Activity at UH BRISTOL leaflet, details of which are sent out with patient admission letters and available in bedside patient information packs.

16.5 Staff obtaining consent from relatives for post mortem examination should be aware of the Post Mortem Policy and Procedure on DMS and use the appropriate consent form and relative information booklet (Appendix G)

16.6 Staff obtaining consent from parents for cell cultures used in diagnostic assays for inherited metabolic disorders must ensure parents understand the reason for the retention of these samples for both their child and as future controls. Please see information leaflet 'Testing for inherited metabolic diseases using skin biopsies'. DMS

16.7 Unlicensed use of human tissue may be subject to a criminal penalty.

6 Human Tissue Act 2004 Consent Code of Practice section 18 http://www.hta.gov.uk/_db/_documents/2006-07-04_Approved_by_Parliament_-_Code_of_Practice_1_-_Consent.pdf

17. Appendix L – Consent for images 2012

Clinical Photography and Video Recordings

Full details of the policy requirements are provided in the Clinical Photography Policy
http://nww.avon.nhs.uk/dms/download.aspx?did=3980

For further advice contact Medical Illustration and see patient information leaflet 'Medical photography and video recordings' on DMS
http://nww.avon.nhs.uk/dms/download.aspx?did=1341 .

18. Appendix M – Post Mortem Consent Policy and Procedure

Policy is held on Document Management System.
http://nww.avon.nhs.uk/dms/download.aspx?did=3909

19. Appendix N – Failure to Follow Patient Consent Policy

19.1 Where an example of failure to follow any aspect of the requirements for valid consent is noted, this should be reported internally as a patient safety incident via the Ulysses Incident Reporting Online Incident Report. The relevant cause group would be Failure to Receive Valid Consent.
http://ubhnt122/Safeguard/

19.2 Incidents will be reviewed and graded in accordance with Trust Policy
http://nww.avon.nhs.uk/dms/download.aspx?did=10881

19.3 This will determine the level of investigation and review of the completed investigation at Division or Corporately.

19.4 Delegation of consent and patient safety incidents

(a) Where patient consent failures involve medical staff the GMC reporting process should also be followed in addition to internal incident reporting.

(b) This is specifically required if the failure relates to incidences of an individual obtaining patient consent without the authorisation to do so. (NHSLA Risk Management Standards for Acute Trusts 2012) http://www.gmc-uk.org/education/nhsla_pmetb_supervision_levels_guidance.asp

End Of Policy