CP06

Consent to Treatment and Investigation Policy

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1.0 Policy Statement

1.1 Informed consent is fundamental to **all** clinical interventions, including prescribing medication (see the Cumberledge Report 2020), but especially invasive investigations, procedures and operations. This policy covers consent for treatment and investigation, post-mortem examinations and research; consent to information sharing and confidentiality are covered in OP13 Information Governance Policy.

1.2 Consent guidance is underpinned in common law and by statute such as the Human Rights Act and the Mental Capacity Act 2005. Breaches of the consent policy may lead to legal repercussions. Guidance from the General Medical Council (GMC) on decision making and consent was updated in November 2020 to provide a framework to practice "ethically and in line with the law" (see Attachment 1 Guide to Consent to Treatment and Investigation).

Local safety standards for invasive procedures (LocSSIPs) have been developed by departments and teams to compliment this guidance, outlining key steps for individual procedures which have given consideration to local conditions and circumstances.

All aspects of this document regarding potential Conflicts of Interest should refer first to the Conflicts of Interest Policy (OP109). In adhering to this Policy, all applicable aspects of the Conflicts of Interest Policy must be considered and addressed. In the case of any inconsistency, the Conflict of Interest Policy is to be considered the primary and overriding Policy.

2.0 Definitions

2.1 The Mental Capacity Act 2005 (MCA)

The MCA defines a standard assessment of capacity to give informed consent to clinical interventions and the processes that must be followed for individuals who lack capacity.

2.2 Two stage Consent

The process of consent for all significant elective interventions must consist of at least two stages: firstly, providing the patient with adequate information about an intervention for which the patient's consent is being sought, and then confirming that decision when the patient attends for the intervention at a later date. Two-stage consent is not applicable to emergency situations and is not always essential for minor elective treatments or invasive tests.

2.3 Coroner's Officer

Coroner's Officers work under the direction of Coroners to liaise with bereaved families, police, doctors and funeral directors.

2.4 Coroner's Post Mortem (PM)

A PM performed at the direction of a Coroner to determine the cause of death.

2.5 Hospital PM

A PM done to gain a fuller understanding of the deceased's illness or the cause of death, and to enhance future medical care.

2.6 Delegated Consent is consent obtained by a practitioner who has been trained and is competent to take consent for procedures that they have not been fully trained to perform.

3.0 Accountabilities

3.1 The Legal Services Manager will provide advice and guidance with regards to consent issues within the organization.

3.2 Consultant Medical Staff and Senior Dentists are responsible for training and assessing junior clinical staff to ensure that they are competent to seek consent from a patient. Consultant Clinical Supervisors are also responsible for following up any individual found to have taken inappropriate consent via audit results or the Trust's incident reporting method (See OP 10).

3.3 The person who obtains consent for any intervention must take full responsibility for the consenting process, but the ultimate responsibility for ensuring that the patient has given properly informed and valid consent is the practitioner who undertakes that procedure.

3.4 All staff must understand the need to seek consent for all healthcare interventions (including physical examination and providing personal care) and must act within their limits of competency with regards to seeking consent. All staff must ensure they are up to date with mandatory training on Consent.

3.5 Appropriately trained members of staff are responsible for seeking written consent for treatment, operations and invasive investigations from patients who have capacity, and they must follow this policy in so doing.

3.6 All staff engaged in obtaining consent must be able to assess the capacity of the patient to give consent, and they must follow this policy if they suspect the patient does not have capacity (see Attachments 1 and 3).

3.7 Appropriately trained members of staff are responsible for seeking written consent for hospital post mortem examinations and must follow this policy in so doing (see Attachment 2).

3.8 Clinical Directors must maintain up to date lists of all non-consultant staff who have been trained and are competent to obtain written consent from patients for treatment, interventions, investigations and operations (see Attachment 5). Delegated consent packs must be issued to all relevant staff at local induction.

4.0 Specific Detail

4.1 This policy applies to all procedures where consent is needed for treatment, interventions, investigations and operations. **Written consent must be obtained for all significant treatments, operations, procedures and invasive investigations that involve the use of sedation or general or regional anaesthesia, and for those that carry significant risks of death or adverse effects on a patient's social, sexual or professional functions. Written consent must also be taken if the provision of medical care is not the primary purpose of the procedure or if it is part of a research programme or if it is an innovative treatment** (see also OP95) Introduction of New Clinical Techniques and Interventional Procedures. **Finally, written consent must be obtained by law for the storage of or the use of a person's gametes to treat another person or to create an embryo in vitro.**

4.2 Discussions with the patient and, or their supporters must be documented in their medical record making clear the agreed treatment plan, the name(s) of the clinician(s), and the date and, for in-patients, the time of these discussions.

4.3 It is important that the identity of the clinician who will undertake the procedure is addressed during the consenting process. The standard consent forms include a disclaimer that the Trust cannot guarantee that a specific practitioner will do the procedure. Recent litigation found in favour of a claimant who averred that she would not have undergone an operation if she known that the surgeon of her choice was not going to be operating. You must highlight to the patient that the identity of the operator cannot be guaranteed. If the patient has been told or demands that a specific clinician undertake the procedure, this must be recorded in the notes and on the consent form and the disclaimer must be crossed out.

4.4 The policy details withdrawal and refusal of consent to treatments, investigations, the receipt blood products and post mortems.

4.5 Consent cannot be valid unless it is obtained by practitioners with the correct knowledge and skills: it is assumed that all Allied Health Professional, all consultant medical staff and all senior dentists can obtain consent for any procedures that they can perform. Medical trainees may or may not have the required skills to consent patients: each directorate must keep formal records of the specific procedures for which named trainees are suitably trained to obtain consent (see also 4.7). These records must be kept up to date, and copies must be given to the Governance Department to preserve an accurate audit trail. It must be stressed that Foundation Year 1 doctors must not take written consent for any procedure or treatment. Non-consultant non-training grade doctors (e.g. specialty doctors, staff grade doctors, associate specialists etc.) may be competent to perform and to take consent for some procedures: each directorate must keep formal, up to date records of the specific procedures that these doctors can perform and take consent for. Non-consultant non-training grade doctors may also take consent for procedures that they are not competent to perform: these procedures will be recorded by the directorates as Delegated Consent (see 4.8).

4.6 Many non-medical staff can obtain consent for treatments, interventions, procedures and operations (e.g. endoscopy) that they are trained and competent to perform: relevant directorates must keep up-to-date records naming them and the list of specific procedures that they can perform and for which they can obtain consent. Copies of these records must be given to the Governance Department to preserve an accurate audit trail.

4.7 Delegated Consent is consent obtained by a practitioner who has been trained and is competent to take consent for treatments, interventions, procedures and operations that they have not been fully trained to perform. This applies to non-consultant medical staff (see 4.3) and to some non-medical staff (although some may be competent to undertake and consent for specific procedures - see 4.6). All directorates must keep formal records of the specific procedures for which named non-medical staff members have been suitably trained to obtain consent. Each directorate must produce a Delegated Consent pack for each person who is authorized to undertake Delegated Consent. This pack must contain a list of the procedures for which Delegated Consent is authorized together with specific details of the procedures and their risks, benefits and alternative options (including the option of doing nothing) that the clinician must know to obtain properly informed

consent (see Attachment 5 Delegated Consent).

4.8 The clinician who is seeking consent must disclose all frequently-occurring and all material risks (side effects, complications and consequences) to the patient or the person with parental responsibility.

4.9 If a patient does not speak English adequately to give consent and the clinician taking consent is not sufficiently fluent in the patient's first language to proceed, an independent interpreter must be used and must, if present, sign the interpreter section of the consent form. If the consenting clinician is communicating to a non-English speaking patient in the patient's own language, he or she must also sign the interpreter section of the consent form. It is only appropriate to use telephonic or other forms of remote interpreting if the urgency of the situation or other circumstances prevent the interpreter being present, or if no suitable, face-to-face interpreter can be found in a reasonable time scale; the use of a family member would be a last resort (please see OP47 Interpreting Services Policy). If this situation arises it is vital that a careful note is made in the patient record to explain the circumstances and the action that has been taken. If a telephonic interpreting service is used, the consenting clinician must record the name and the Identity Number of the interpreter on the consent form in the section used for the interpreter's signature. If a face-to- face interpreter cannot be found, it is important that you report this to the Patient Advice and Liaison Service (PALS) office by telephone or e-mail so they can challenge the company that provides our interpreting service.

4.10 For written consent, all relevant sections of the consent form must be completed legibly in accordance with the Health Records Policy OP07. No abbreviations must be used for medical or technical terms on consent forms. Standard abbreviations that are in common use in English (such as e.g., i.e. and etc.) may be used.

4.11 Pre-printed procedure-specific forms can be used. The content of such documents must be agreed by the directorate which will use them, and they must be approved for use by the Trust Consent Lead or Chief Medical Officer prior to implementation (see Appendix 4 – Procedure-specific Consent Forms Process). They must all be in the standard Trust Consent Form format.

4.12 Please refer to the following attachments that form part of this policy:

Attachment 1 Guide to Consent to Treatment and Investigation

Attachment 2 Consent to Post Mortem

Attachment 3 Guidance for health Professionals on the Mental Capacity Act 2005

Attachment 4a Procedure for treatment of patients who refuse to consent to the use of blood and blood products

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5.0 Financial Risk Assessment

The screening checklist has been completed and no additional financial resources have been identified.

6.0 Equality and Diversity Risk Assessment

The screening checklist has been completed. Reasonable efforts have been made to eliminate any possible Equality and Diversity discrimination occurring.

7.0 Maintenance

7.1 The policy and associated procedures will be updated every year or when there is a change in legislation.

7.2 The policy and associated procedures will be reviewed by:

7.2.1 Legal Services Manager/Consent Lead (Consent to Treatment, Delegated Consent and Mental Capacity Act);

7.2.2 Hospital Transfusion Practitioner (Patients who refuse blood and blood products);

7.2.3 Head Biomedical Scientist - Histopathology (Consent to Post Mortem);

7.2.4 Research and Development Manager (Consent to Clinical Trials Procedure).

8.0 Communication and Training

8.1 All Executive Directors / Clinical Directors / Divisional Managers / Divisional Nurses and Directorate Managers are responsible for the communication of this Policy to their staff and for ensuring that they access and log their training sessions on the Trust's training database.

8.2 Delegated Consent training will be provided by consultant medical staff to those members of staff that are deemed capable of undertaking it.

8.3 Staff will receive mandatory consent training (see OP41 Induction and Mandatory Training – Appendix 4)

9.0 Monitoring and Audit Requirements

Criterion	Lead	Monitoring	Frequency	Committee / Group
• Are the right people obtaining consent?	Trust Consent Lead	Audit of consent forms against the lists of consultant and non-consultant consenting clinicians including those authorized to obtain delegated consent.	Annual	Clinical Audit Group
• Is the right information given to patients about the risks benefits and alternative to the procedure?	Trust Consent Lead and Clinical Directors	Consent Audit – patient case notes	Annual	Clinical Audit Group
• Is two-stage consent being done for all appropriate elective procedures?	Trust Consent Lead	Audit of consent forms.	Annual	Clinical Audit Group
• Has the Removal of Tissue box been signed appropriately?	Trust Consent Lead	Audit of consent forms.	Annual	Clinical Audit Group
• Has an independent interpreter been used where necessary?	Trust Consent Lead	Audit of consent forms.	Annual	Clinical Audit Group
• Are clinicians adequately trained to obtain consent and to obtain delegated consent.	Trust Consent Lead	Audit of mandatory training records and delegated consent packs.	Annual	Directorate Performance Meeting
• Consent to Post Mortem Procedure (Attachment 2)	Head Biomedical Scientist - Histopathology	Histopathology HTA horizontal Audit	Annual	Histopathology Departmental Governance Meeting

10.0 References

10.1 The Foetal and Infant Post Mortem: Brief notes for the professional. Confidential Enquiry into Stillbirths and Death in Infancy (CESDI) 1998.

10.2 Guidelines for the retention of tissues and organs at post mortem examination.

10.3 Royal College of Pathologists March 2000.

10.4 Tissue blocks and Slides. Retained Organs Commission. April 2001.Guidance on return of Organs, Tissue Blocks and Slides. Retained Organ Commission July 2001.

10.5 Human Tissue and Biological Samples used in research. Operational and Ethical Guidelines. Medical research Council (Ethics Series 2001).

10.6 *Reference guide to consent for examination or treatment (second edition) (Department of Health, July 2009)*

10.7 Gillick v West Norfolk and Wisbech Area Health Authority (1985) 3 All England Law Reports 402

10.8 McClelland DBL (2001) The Handbook of Transfusion Medicine

10.9 NHS Executive. Better Blood Transfusion: Appropriate Use of Blood. Department of Health, London 2002 (Health Service Circular 2002 / 009)

10.10 Shrewsbury and Telford Hospital NHS Trust Policy for patients who refuse to receive blood and blood products (2006)

10.11 University Hospitals Coventry and Warwickshire NHS Trust Policy for the treatment of patients who refuse consent to the use of blood and blood products (2006).

10.12 NHSLA standards

10.13 Fundamental Standards of Care – CQC Guidance for Providers Handbook

10.14 Health and Social Care Act 2008 (Regulated Activities) Regulated Activities Regulation 2014

10.15 Sokol DK Update on the UK law on consent British Medical Journal 2015;350:h1481

10.16 Decision making and consent. The General Medical Council September 2020

10.17 Baroness Cumberledge (July 2020) First Do No Harm. The report of the Independent Medicines and Medical Devices Safety Review

10.18 NG197 Shared decision making National Institute for Health and Care Excellence (June 2021) www.nice.org.uk/guidance/ng197.

Policy number and Policy version: **CP06 v11**	**Policy Title** **Consent to Treatment and Investigation Policy**	**Status:** Final	**Author: Trust Consent Lead** **Director Sponsor: Chief Medical Officer**

Version / Amendment History	Version	Date	Author	Reason
	V1	May 2003	Legal Services Manager	Introduction of policy
	V2	Nov 2008	Legal Services Manager	Review
	V3	March 2010	Legal Services Manager	Review
	V4	Nov 2011	Legal Services Manager / Divisional Medical Director	Review Minor amendments (Aug 12)
	V4.1	April 2014	Legal Services Manager / Divisional Medical Director	Minor amendments re attachment 4a Consent for blood transfusion
	V5	May 2015	Trust Consent Lead	Review of whole policy
	V6	May 2016	Trust Consent Lead	Annual Review
	V7	April 2017	Trust Consent Lead	Annual Review
	V8	April 2018	Trust Consent Lead	Annual Review
	V9	Mar 2019	Trust Consent Lead	Annual Review
	V10	Mar 2020	Trust Consent Lead	Annual Review

	V11	Aug 2021	Trust Consent Lead	Annual Review incorporating the 2020 GMC updated guidance on decision making and consent, the Cumberledge Report, and NICE guidance on shared decision making.

Intended Recipients: All clinicians who take informed consent.	
Consultation Group / Role Titles and Date: All Clinical Directors in Directorates where informed consent is obtained. Divisional Medical Directors February 2020.	
Name and date of Trust level group where reviewed	Policy Group – September 2021
Name and date of final approval committee	TMC – October 2021
Date of Policy issue	November 2021
Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated)	September 2022 - Annual
Training and Dissemination: Via CD's.	
To be read in conjunction with:	
Initial Equality Impact Assessment (all policies): **Completed Yes** **Full Equality Impact assessment (as required):** **Completed NA** If you require this document in an alternative format e.g., larger print please contact Policy Administrator8904	
Monitoring arrangements and Committee	Trust wide Consent Audits. QSIG.
Document summary/key issues covered. Minor policy updates from 2019.	
Key words for intranet searching purposes	

Part B **Ratification Assurance Statement**

Name of document:

Name of author: Ian Badger Job Title: Trust Consent Lead

I, the above named author confirm that:

- The Strategy/Policy/Procedure/Guidelines (please delete) presented for ratification meet all legislative, best practice and other guidance issued and known to me at the time of development of the said document.
- I am not aware of any omissions to the said document, and I will bring to the attention of the Executive Director any information which may affect the validity of the document presented as soon as this becomes known.
- The document meets the requirements as outlined in the document entitled Governance of Trust- wide Strategy/Policy/Procedure/Guidelines and Local Procedure and Guidelines(OP01).
- The document meets the requirements of the NHSLA Risk Management Standards to achieve as a minimum level 2 compliance, where applicable.
- I have undertaken appropriate and thorough consultation on this document and I have detailed the names of those individuals who responded as part of the consultation within the document. I have also fed back to responders to the consultation on the changes made to the document following consultation.
- I will send the document and signed ratification checklist to the Policy Administrator for publication at my earliest opportunity following ratification.
- I will keep this document under review and ensure that it is reviewed prior to the review date.

Signature of Author: 

Date: July 29th 2021

Name of Person Ratifying this document (Director or Nominee): Jonathan Odum
Job Title: Medical Director
Signature: 

- I, the named Director (or their nominee) am responsible for the overall good governance and management of this document including its timely review and updates and confirming a new author should the current post-holder/author change.

To the person approving this document:

Please ensure this page has been completed correctly, then print, sign and email this page only to: The Policy Administrator

IMPLEMENTATION PLAN

To be completed when submitted to the appropriate committee for consideration/approval

Policy number and policy version CP06 v11	**Policy Title Consent to Treatment and Investigation Policy**	
Reviewing Group	Policy Group	**Date reviewed:**
Implementation lead: Mr Ian Badger ibadger@nhs.net		

Implementation Issue to be considered (add additional issues where necessary)	**Action Summary**	**Action lead/s (Timescale for completion)**
1. Key communication messages from the policy / procedure, who to and how?	Dissemination by e-mail to CD's of directorates that require informed consent that the new policy will be on Trustnet	Consent lead

Attachment 1

Policy Reference:

CP 06

Protocol:

Guide to Consent to Treatment and Investigation

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1.0 The seven principles of consent

1.1 It is a fundamental principle that patients have the right to determine what happens to their bodies. Patients with capacity must be involved in all decisions about their investigations, treatment and care, and you need their consent for **any** intervention: e.g., drug treatments, invasive tests, major surgery, and helping them to dress - even touching them without consent could constitute the offence of battery. If there is not valid consent to an intervention from which the patient suffers harm, the clinician could face a claim of negligence and, or an investigation by their professional body. This guidance applies to every health and care decision including consent to treatments, procedures, operations, interventions, investigations, screening, examination etc. (for simplicity, summarized as treatment or investigation in the policy attachments). There is a particular emphasis on formal written consent for invasive treatment and investigations. In this guidance the terms 'you must' and 'you should' are used as in the GMC guidance: 'you must' is used for an overriding duty or principle; 'you should' is used to explain how to meet the overriding duty, or if the duty or principle will not apply in all situations, or if there are factors outside your control that affect whether or how you can meet that duty.

1.2 The General Medical Council (GMC) updated guidance, "*Decision making and consent*" (September 2020), defines seven key principles which apply to all clinicians involved in decision making and consent, not just doctors.

- **"Principle 1** All patients have the right to be involved in decisions about their treatment and care and be supported to make informed decisions if they are able.
- **"Principle 2** Decision making is an ongoing process focused on **meaningful dialogue**: the exchange of relevant information specific to the individual patient.
- **"Principle 3** All patients have a right to be listened to, and to be given the information they need to make a decision and the time and support they need to understand it.
- **"Principle 4** Doctors must try to find out what matters to patients so they can share relevant information about the benefits and harms of proposed options and reasonable alternatives, including the option to take no action.
- **"Principle 5** Doctors must start from the presumption that all adult patients have capacity to make decisions about their treatment and care. A patient can only be judged to lack capacity to make a specific decision at a specific time, and only after assessment in line with legal requirements.
- **"Principle 6** The choice of treatment or care for patients who lack capacity must be of overall benefit to them, and decisions should be made in

consultation with those who are close to them or advocating for them.
- **"Principle 7** Patients whose right to consent is affected by law should be supported to be involved in the decision-making process, and to exercise choice if possible."

1.3 The Care Quality Commission requires that the Trust complies with best practice in consent as reflected in this evidence-based policy.

1.4 NHS Resolution (formerly the NHS Litigation Authority) has clear standards as to how the Trust's compliance with this policy will be assessed. The Trust will need to show that that this policy is followed in all areas where written consent is taken.

1.5 For consent to be valid it must be given voluntarily by a properly informed person who has capacity to consent to the intervention (see section 13.0 *How do I assess capacity*? and attachment 3 *Guidance for Health Care Professionals on the Mental Capacity Act 2005*). Acquiescence, where the person does not know what the intervention entails, is not valid consent. Consent must be given without pressure or undue influence on the patient to accept or refuse treatment. Such pressure can come from partners, family members, healthcare practitioners or carers or from members of the police, prison or immigration services. If you suspect that any third party is preventing a patient with capacity from exercising their own free will in decision making, you must discuss the situation with the appropriate safeguarding team and, or Legal Services.

1.6 Getting consent for something straightforward, like taking a blood sample, is usually simple and quick, and does not need to be done in writing. Consent for more complex interventions, like surgery or a course of chemotherapy, is more involved because of the risks.

1.7 For any significant elective treatment or investigation, we use two-stage consent to comply with the GMC requirement that patients be given "…time and opportunity to consider before and after making a decision." In the first stage, the patient is given the information they need well beforehand so they can consider their options. The patient must signify their consent before the day of the treatment or investigation. In the second stage, the patient confirms their decision on the day, shortly before the treatment or investigation begins. The time intervals in this process are not fixed: some patients can signify consent when they are given the information about the treatment or investigation, but others need more time to think about it - they must, however, signify consent before the day of the procedure (so there may be more than two stages). There will always be a cooling-off period before the procedure is done; NHS Resolution recommend that this should be at least two weeks before the procedure. Two-stage consent is not feasible in most emergencies.

1.8 The Human Tissue Act 2004 makes consent a legal requirement for the removal, storage and use of human tissue or organs and sets out whose consent is needed in which circumstances.

1.9 Consent to an intervention remains valid indefinitely unless one or more of the following occurs:
- Consent is withdrawn by the patient;

- The patient's condition changes;
- There is new information that will affect the choice of procedure or the potential risks or benefits of the planned procedure.

2.0 What does consent allow me to do?

2.1 To get valid consent you must be explicit about the intervention you are offering, and you must not exceed the scope of the authority given by the patient (except in an emergency). For example, if the patient refused a mastectomy, a mastectomy must not done even if intraoperative assessment suggests that would be the best approach. This is straightforward for a single procedure done by the consenting clinician when the diagnosis is certain, but it is more difficult for staged treatments or if different people will do parts of the procedure. If the diagnosis is uncertain, the treatment may depend on what is found during the procedure when the patient cannot give valid consent. In these circumstances, you must agree in advance how to proceed – the patient may give you free rein to do what you think is best or they may allow only certain, specific interventions without further discussion. You must make a careful record of these discussions and decisions.

2.2 During an operation you may find a significant, unanticipated problem that needs a procedure that is not in the scope of the consent. If it would be unreasonable to defer the procedure until the patient can consent (e.g., if there is a threat to life), you might be justified in doing it in their best interest, but you must not do the additional procedure just because it is convenient. If you think you may find an unrelated problem during an operation, discuss it in advance and record what the patient would want you to do in that circumstance.

2.3 In an emergency, you can treat a patient without their consent if that treatment is immediately necessary to preserve life or to prevent a serious deterioration in their condition. The treatment you provide must be the least restrictive of the patient's future choices, and you must document clearly in the patient record and with Consent Form 4 what you have done and why. The legal principle of the *Doctrine of Emergency* allows and requires you to act in this way. You may continue to treat on this principle until the patient regains capacity, but then you must explain to them what you have done and why.

3.0 Can the patient withdraw consent?

3.1 You must tell patients that they can change any decision at any time, and they can withdraw consent at any stage, even during the procedure. If that happens, you must (if possible) stop and try to explain the consequences of not completing the procedure. It may be that the patient is in pain that needs to be treated. You must assess if they have capacity to withdraw consent. If it is dangerous to stop the procedure, you must continue until that risk no longer applies, but otherwise, if the patient has capacity, you must do as the patient directs.

4.0 Can students or trainees do procedures for which the patient has given consent?

4.1 You must tell a patient if a student or trainee will do the procedure to further their own education. There is no legal requirement to do so if the patient will benefit from the procedure, such as taking a blood sample, and the student is competent (but it is good practice to tell the patient).

5.0 Who must seek consent?

5.1 The health care professional who is undertaking the procedure is responsible for ensuring the patient gives valid consent. Decision making and consent can be delegated to anyone who knows enough about the benefits, risks and alternatives of the treatment or investigation and is suitably trained and qualified to obtain consent, but the operator remains responsible for the consenting process. If the consent is taken by someone who does not have the demonstrable knowledge or experience, the consent may be invalid. The delegatee must feel competent to do the task and agree to seek advice, information and support from an appropriate consultant. Part of the training of junior staff is to learn to perform invasive procedures and how to obtain consent for them. The consultant in charge of the patient's care remains responsible for ensuring that the patient has been given the information and the time and support that they need to make a decision and that they have given their consent before having the treatment or investigation.

5.2 If an operation is planned to be done under an anaesthetic that will be administered by an anaesthetist, it is the responsibility of the anaesthetist and not that of the surgeon to discuss it with the patient, their carers or the person with parental responsibility.

6.0 Who can give consent?

6.1 Mental capacity (often called "capacity") is the ability to understand, remember and weigh up information to make a decision that can be communicated to others (section 13.0 *How do I assess capacity?*). An adult who has capacity is the only person who can consent to undergo a treatment or investigation. Anyone over 16 years of age is presumed to have capacity, and many younger people (depending on their maturity) may have capacity to make decisions about healthcare.

6.2 Under English law, no-one can give consent on behalf of an adult who lacks capacity unless they have been authorized to do so as a court appointed deputy or under a Lasting Power of Attorney that includes authority for making healthcare decisions (see below).

7.0 Remote consent

7.1 The vast majority of decision making and consent discussions will be done face-to-face, which is the best option for optimal communication, both verbal and non-verbal. Remote consent is that obtained when the patient and clinician are in separate locations. It can be done by telephone or by video link, which is a better method of communication (albeit less good than face-to-face) because it should convey more non-verbal

communication than a telephone call. Not all patients will have access to the technology required for video consultations.

7.2 Remote consenting may be thwarted by technical problems or problems with hearing or diction that prevent a successful consultation.

7.3 The GMC has defined situations in which remote consultations may be appropriate:

- If the patient's clinical need is straight forward;
- If the clinician can convey all the information that the patient wants or needs by telephone, video link or the intranet;
- The clinician has access to the patient's records;
- The clinician does not need to examine the patient;
- The patient has capacity.

If these criteria are not met, face-to-face consultation should be done. The patient must consent to remote consultation, and clinicians must do everything possible to maintain confidentiality, however they must give an explicit warning that the privacy of a telephone or video link cannot be guaranteed.

7.4 Any directorate or specialty that wishes to use remote consenting must seek authorization to do so by submitting a formal proposal to the Trust Consent Group via the Trust Chief Medical Officer or the Trust Consent Lead. The proposal must include the following information:

- The justification for using remote consent;
- The specific procedures for which remote consent will be sought;
- How patients will be selected for remote consent;
- Who will have the decision-making and consent discussion with the patient (see Section 5), how they will document that discussion (see Section 21), and when that clinician will sign the consent form;
- How the decision making and consent discussion will be documented in the patient's record and how that will be communicated to the patient's GP;
- How the consent form will be sent to the patient;
- When the patient will sign the consent form (see Section 22);
- How the consent form will be returned to the Trust.

7.5 Postal consent is endorsed by the British Society of Gastroenterology for low-risk gastro-intestinal endoscopy (flexible sigmoidoscopy or gastroscopy). It is not authorized for use for any other procedures or by any other directorates in the Trust because the process is not fully consonant with the 2020 GMC guidelines or with the National Institute for Health and Care Excellence (NICE) guideline NG197 *Shared Decision Making*. Specific guidance about postal consent is being sought from the GMC.

8.0 Can I consent a patient for a number of interventions as a course of treatment rather than a single intervention (Serial Consent)?

8.1 It is legitimate to consent a patient for a specific course of treatment involving a series of interventions (sometimes called "serial consent") provided that you are offering a standard treatment programme and that the patient knows just what is going to be done throughout the treatment. The standard consent form does not have enough space to record that the patient agrees to have the intervention on each attendance for a series of interventions, so this fact must be recorded in the patient's clinical record. The patient must be reviewed frequently during the course of treatment to monitor the effects of treatment, to assess side effects and complications, and to determine if the treatment must continue. If the treatment needs to change in any way, a fresh consent process must be done.

9.0 Who can consent for treatment of a child or a young person?

9.1 A young person is aged between 16 and 18 years old; a child is younger than 16.

9.2 A young person with capacity (assessed as in adults – see section14.0 *Who can give consent if an adult patient lacks capacity?*) can consent to all healthcare interventions. It is good practice (if the young person agrees) to involve a person with parental responsibility in this process, but he or she cannot refuse a treatment to which the young person has consented. If a young person lacks capacity, consent for healthcare interventions can be given by whoever has parental responsibility provided they have capacity.

9.3 If a young person lacks capacity, the clinicians looking after the young person must make a formal best interests assessment of the needs of the patient (see paragraph 15 *what must happen if there is no-one to give consent for a patient who lacks capacity?*), which will include talking to those with parental responsibility amongst others. If there is disagreement within the clinical team or between them and the holders of parental responsibility, you must seek legal advice. Otherwise, consent should be documented on a consent form 4. It is imperative that all discussions and decisions are documented carefully and accurately in the clinical record.

9.4 Children can consent to healthcare interventions (including research and organ donation) if they have sufficient intelligence and maturity to understand fully what is involved (so-called 'Gillick-competent'). Some children can consent to minor treatments but not to more complex ones. Consent given by a Gillick-competent child to a treatment that you believe to be appropriate cannot be overridden by a person with parental responsibility, but it is good practice to encourage the child to involve that person. You must consider involving other members of the multi-disciplinary team, an independent advocate or a designated doctor for child protection if that would help children with capacity to make decisions.

9.5 Consent for children who lack capacity can be given by a person who has parental responsibility provided that person has capacity. For a child who lacks capacity, you only **need** consent from one parent, but it is best to seek consent from both parents, and if the parents cannot agree about consent, you must take legal advice unless a delay in treatment carries a risk of death or of a serious, preventable deterioration in condition.

9.6 It is good practice to discuss in advance with a person with parental responsibility any repeated interventions that may be necessary for their child, such as doing

observations or taking blood samples, to obtain their consent for them to be done.

10.0 What must I do if a young person or a child or a person with parental responsibility refuses consent?

10.1 These are difficult situations, and you must involve the multi-disciplinary team, an independent advocate or a named or designated doctor for child protection.

10.2 If a young person or a Gillick-competent child consents to a treatment but the person with parental responsibility refuses, you can proceed with treatment, but it would be wise to consult Legal Services (extension 85986 or 01902 695986 or via switchboard).

10.3 If a young person or a Gillick-competent child refuses treatment, the courts can override the decision if it is probable that the refusal will lead to death, severe permanent injury, or to grave and irreversible mental or physical harm. In theory, a person with parental responsibility could override the refusal, but it would be unsafe to rely on that course of action, so these issues must be put to the courts.

10.4 If a life-threatening emergency arises in a child or a young person and you cannot consult the person with parental responsibility or the courts, or if the person with parental responsibility refuses consent, you are legally empowered to treat to preserve life or prevent serious damage to health (the Doctrine of Emergency).

10.5 If a person with parental responsibility refuses a necessary treatment for a child who is not Gillick-competent, you must refer such cases to the courts unless the situation is an emergency as outlined above.

10.6 Some important decisions, such as sterilization of a child, must be referred to the courts for guidance, even if those with parental responsibility consent to the operation going ahead.

11.0 Who has parental responsibility?

11.1 A person with the rights and responsibilities that parents have in law for their child, up to the age of 18 in England, Wales and Northern Ireland and 16 in Scotland, has parental responsibility. The list below is set out in English law but the laws in different jurisdictions in the United Kingdom and in other countries are different. If the patient is in England, English law prevails regardless of their nationality or place of residence. In law, a young person with capacity has the right to consent for medical interventions. Case law now determines that a young person without capacity should be managed in the same way as an adult who lacks capacity (see 9.3 above).

11.2 The following have parental responsibility (but that responsibility can be restricted by court order).

- Mothers.
- Fathers who were married to the mother at the time of birth before 1 December 2003 (parents do not lose parental responsibility if they divorce).
- Since 1 December 2003, a father who was not married to the child's mother at the time of birth has parental responsibility if he is named on the birth certificate.

- A father who was not married to the mother of a child born before 1/12/03 or one who was not named on the birth certificate of a child born after 1/12/03 can make a Parental Responsibility Agreement with the child's mother or get a Parental Responsibility Order from the courts. Married step-parents and registered civil partners can acquire parental responsibility in the same ways.
- Same-sex partners will both have parental responsibility if they were civil partners at the time of treatment for conception (e.g. artificial insemination by donor).
- Same-sex partners who are not civil partners can gain parental responsibility for a child by Parental Responsibility Agreement or a court Parental Responsibility Order.
- The parents of a child who is in voluntary care of the Local Authority retain full parental responsibilities.
- The parents of a child who is subject to a compulsory supervision order or an order of the court retain full parental responsibilities unless they are limited by the children's hearing or the court.
- If the Local Authority has a permanence order for the child, the order will set out what parental responsibilities remain with the parents and what responsibilities reside with the Local Authority or the carer of the child, for example, a foster carer.
- Adoptive parents (parents lose parental responsibility if a child is adopted).
- A testamentary guardian, special guardian or those given a residence order.

11.3 Get legal advice if there is doubt about who has parental responsibility.

11.4 People without parental responsibility who have care of a child may do what is reasonable to safeguard or promote the child's welfare. This includes step-parents, grandparents and child-minders. You can rely on their consent if they are authorized by the parents, but you must be sure that their decisions are in line with those of the parents, particularly in relation to contentious or important decisions.

12.0 Contraception and sexual health advice for children

12.1 You can provide advice and treatment regarding contraception, abortion and sexually transmitted infections without the knowledge or consent of whoever has parental responsibility if:

- The child understands all aspects of the advice and its implications;
- The child rejects your advice to tell whoever has parental responsibility and will not allow you to do so;
- The child is likely to have sex with or without treatment;
- The child's physical or mental health is likely to suffer without such advice or treatment; and
- It is in the child's best interests to receive the advice and treatment without the knowledge or consent of a person with parental responsibility.

12.2 You must keep consultations confidential, even if you decide not to provide the

advice or treatment, unless there are exceptional circumstances:

- An overriding public interest in the disclosure;
- Disclosure is in the best interests of the child;
- The child does not have the maturity or understanding to decide disclosure; or
- Disclosure is required by law.

13.0 How do I assess capacity (see also Attachment 3 *Guidance for Health Practitioners on the Mental Capacity Act 2005*)?

13.1 Assessing capacity is a core skill. You must assume that a person has capacity unless you establish that they do not. You must not assume that a patient lacks capacity just because you think their decision is unwise, but you do need to establish why the patient has made that decision.

13.2 The Mental Capacity Act 2005 defines lack of capacity as the inability to make a specific decision because of impairment or disturbance in the function of the mind or the brain regardless of whether it is permanent or temporary. Capacity can be impaired due to the effects of injury, alcohol or drugs, and by confusion, panic, shock, fatigue or pain; however, the presence of such factors does not automatically mean that the person lacks capacity.

13.3 The capacity to consent is specific to each decision - some patients can make simple but not complex decisions; some patients can make decisions some but not all of the time if their impairment fluctuates. If in doubt, take advice from people who are close to the patient (bearing in mind your duty of confidentiality) and other healthcare staff.

13.4 Your assessment of and conclusions about incapacity must be recorded on the consent form and in the patient's notes (use the Mental Capacity Assessment and Best Interest Decision form on the *Safeguarding Adults at Risk* site on the Intranet if available).

13.5 If you are still unsure, seek advice from the Safeguarding Team or Legal Services about asking a court to determine capacity.

14.0 Who can give consent if an adult lacks capacity (see also Attachment 3)?

14.1 In most cases, no-one can give consent for someone who lacks capacity with three key exceptions.

- The Court of Protection can issue an order making a healthcare decision on behalf of a patient who lacks capacity.
- The Court of Protection can appoint a deputy to make decisions on behalf of the person who lacks capacity. The Court will define the scope of the deputy's authority, which is usually limited to a specific situation, but a deputy cannot refuse consent to life-sustaining treatment.
- Someone with a health and welfare Lasting Power of Attorney (LPA).

14.2 Where relevant, you must give the same information that you would ordinarily give to the patient to a Court of Protection appointed deputy or to a health and welfare attorney. They have the authority to sign a consent form 4 on the patient's behalf.

14.3 An LPA must be made in the correct form and be registered with the Office

of the Public Guardian before it can be used; it will specify exactly what decisions the attorney can make, which may or may not include decisions about life-sustaining treatment. You must read the LPA to understand the scope of the attorney's authority. If you are concerned that the attorney is not acting in the patient's best interest, take advice from Legal Services.

14.4 Consent form 4 must be used for all adults who lack capacity.

15.0 What must happen if there is no-one to give consent for a patient who lacks capacity (see also Attachment 3)?

15.1 If no third party is empowered to give consent for the patient, you must decide what to do. Any decision made for or on behalf of a person who lacks capacity must be taken in their best interests. The *Best Interest Principle* requires you to consult with "appropriately interested parties" (i.e. anyone close to the patient or engaged in caring for them or with an interest in their welfare). You do not need to make impracticable attempts to consult these individuals. You must decide on the basis of the patient's wishes, feelings, beliefs and values (as far as they can be determined) what the patient would have chosen if they had capacity rather than what clinicians or their family or friends would choose.

15.2 The urgency of the clinical situation may not leave enough time to consult with others. The *Doctrine of Emergency* puts a duty on us to take appropriate action if treatment is immediately necessary to preserve life or limb or to prevent a serious deterioration in the patient's physical or mental well-being. This doctrine covers the period of crisis. Some emergencies (e.g. percutaneous intervention to treat acute coronary syndrome) require such immediate action that there may be insufficient time to complete Consent Form 4 before the procedure: in these instances, the rationale for the clinical decision to proceed with treatment without consent must be detailed in the clinical record. Thereafter, if the patient does not regain capacity (when they can make their own decisions) you must proceed as described below.

15.3 The patient, those close to them and their carers may help to decide what the patient would want. Consider the following.

- All the options that would provide overall clinical benefit.
- The medical, emotional and welfare consequences of the treatment options.
- The option, including not to treat or investigate, that would be least restrictive of the patient's future choices.
- The views and opinions of anyone whom the patient asks you to consult.
- The views of other healthcare professionals involved in the patient's care.

15.4 If there is strong disagreement among appropriately interested parties, seek advice from Legal Services.

15.5 Record your decision and your rationale in the notes with a list of the people with whom you have discussed the issue.

16.0 Advance Decisions (ADs) (see Attachment 3)

16.1 An AD only applies to a patient who has lost capacity. It can only be made to refuse an intervention. It must be precise and specific as to what is being refused and in what circumstances the refusal applies: if the refusal includes life-sustaining

treatment, it must be made in writing, signed and witnessed, and it must state clearly that the decision applies even if life is at risk. A person with capacity can withdraw an AD at any time.

16.2 A valid and applicable AD has the same force as a contemporary refusal and failure to honour it may lead to prosecution or civil liability. Advances in medical science that came after the AD might render it inapplicable. In that circumstance, take advice from Legal Services.

16.3 A valid AD can be overridden by the Mental Health Act 1983 if the treatment is for a mental disorder or illness.

16.4 Advance Directives, Advance Statements or Living Wills made before the Mental Capacity Act 2005 are no longer valid, but they are evidence of a patient's wishes, so you must consider them when you assess the person's best interests (the same holds true for invalid AD's). If you have any doubt, consult Legal Services.

16.5 An AD made under the Mental Capacity Act 2005 cannot apply to actions that are needed to keep a person comfortable - the Act allows us to offer basic care such as warmth, shelter, measures to maintain cleanliness, relief from distress, and food and drink (but not artificial nutrition andhydration).

16.6 An individual with capacity has the right to refuse food and drink until death – if they lose capacity as their condition deteriorates, the decision to refuse food must be respected so you cannot force feed them or feed them artificially. If a patient with a mental disorder refuses to eat and drink, detention and treatment without consent may be a possibility under the Mental Health Act 1983.

17.0 Involvement of the Courts

17.1 You must apply to the Court of Protection in the following circumstances:

- Proposed organ, bone marrow or peripheral blood stem cell donation by an adult who lacks capacity;
- Proposed non-therapeutic sterilization of a person who lacks the capacity;
- All cases where there is a doubt or dispute about whether a particular treatment will be in a person's best interests;
- If there is doubt that the holder of an LPA is acting in the patient's best interest;
- If there is doubt about the validity of an AD;
- If there is doubt about the patient's capacity;
- If there are consent issues involving children (see above);
- Cases that raise ethical problems.

17.2 It is no longer mandatory to apply to the Court of Protection to withhold or withdraw Clinically Assisted Nutrition and Hydration from a patient who lacks capacity provided you have followed the Mental Capacity Act 2005 and have full agreement from those close to the patient (see CP10 Policy for Withdrawing or Withholding Clinically Assisted Nutrition and Hydration in Adult Patients Who Lack Capacity to Consent to Treatment).

18.0 Research involving people who lack capacity

18.1 The involvement of people who lack capacity in research must comply with the provisions set out in the Mental Capacity Act 2005 and the Medicines for Human Use (Clinical Trial Regulations) 2004. A family member or an unpaid carer must give formal agreement. If no such person is available, the researcher must nominate someone who is independent of the research to decide if the person would have agreed to participate if they did have capacity.

19.0 What information must I give when obtaining consent?

19.1 The exchange of information between patient and clinician is central to good decision making and consent. NICE and the GMC require that you must have “meaningful dialogue” with the patient.

19.2 You must discover what is important to the patient in terms of likely benefits and risks of any treatment or investigation so you can identify the information the patient needs to make a decision.

19.3 You must explore the patient’s needs, values and priorities that will influence their decision making and any concerns and preferences that they may have.

19.4 The information you give about potential benefits and the risks of harm of every appropriate option must be clear, accurate and up-to-date and based on the best available evidence.

19.5 Every patient must be told the following:

- What the treatment or investigation is – what it entails and what is its intended purpose (inaccuracy in this information might invalidate consent);
- If there is any uncertainty about the diagnosis or the options for treatment or investigation;
- The probability and magnitude of potential benefits (prognosis), including the likelihood of success, tailored to the individual patient’s circumstances;
- The risks of harm - you have a legal duty of care to tell the patient about **all** the frequently-occurring risks and **all** the material risks, especially any risk of serious harm (no matter how unlikely), including the risks of medication;
- What actions would be needed for common side effects;
- Specific benefits and risks that matter most to the individual patient based on your discussion with them;
- All the appropriate alternatives (including doing nothing) and their benefits and risks;
- If there is a time limit within which the patient must make their decision.

19.6 You must try to share this information at a time and in a place that maximizes the patient’s ability to understand and retain the information, and then give them time and opportunity to consider it before and after they make a decision. It is important not to share information in a time-pressured environment if possible, particularly if there is a potential for serious harm.

19.7 The patient may want to record the discussion, and clinicians have no right to refuse that request. That recording will belong to the patient and will not form part of the clinical record (if you want to record the discussion, you need to get

the patient's explicit consent to do so).

19.8 Risks include inevitable consequences (e.g., a scar), side effects and complications, which may be minor or have the potential to cause permanent disability or death. You must give this information to the patient in terms they will understand. A complication or side effect may have a greater impact on one person than another (e.g. the changes in the voice after a thyroidectomy may be a bigger problem for a singer than for a guitarist). Only the patient has the right to assess the importance of the risks. If you have any doubt about what information to give, take advice from Legal Services or your medical defense organization.

19.9 You must check if the patient has understood the information you have given and whether they want any more information.

19.10 Offer the patient any supporting information that is available and appropriate, but you cannot rely on written information because only around 60% of the population have enough "health literacy" to understand information leaflets. All documents used to support the decision making process (both those generated within the Trust and any produced by external organizations) must have been approved for use by the directorate(s) and ratified for use by the Trust Consent Group (see the *Existing and New Patient and Carer Information Leaflet SOP*).

19.11 You may recommend a particular option, but you must not pressurize the patient to accept your advice. The patient can accept or reject any option for any reason, even one that seems irrational. You must discuss the consequences of the patient's decision and offer further information or a second opinion if you think the patient has made the decision without a full understanding of the situation.

19.12 If the patient asks for a treatment or investigation that you think is inappropriate to their condition and they decline any alternatives, you are under no obligation to comply with their request, but you must offer a referral for a second opinion.

19.13 You must tell patients if a particular intervention is a new procedure or if it is part of a research programme, and that they have the right to refuse to take part in research or teaching. No experimental treatment can be given to a child or an adult who lacks capacity unless it would be in their best interests.

19.14 The patient may not want to know about their condition or the treatment or the risks of that treatment; you must respect their wishes, but you need to try to give them information about the aims of treatment, what it involves and if there are risks even if they do not want the details. You must tell them that their consent may be invalid if made without that knowledge. You must record that the patient has declined this information (in the notes or on the consent form) and tell them that you can give them this information at any time if they change their minds.

19.15 If the procedure is a unilateral procedure, the must put the side on the consent form. In unilateral ovarian disease, imaging results may not clarify which side is involved. In this situation, you must specify that a unilateral procedure will be done on the abnormal organ. You must tell the patient which ovary is thought to be affected but that the imaging can be misleading. You must include this information in the GP letter and send a copy of that letter to the patient.

19.16 If you do not have the time and resources to support patients' decision making, and you believe that this compromises patient safety, the GMC requires that you raise this as a formal concern (see HR16 *Raising Concerns at Work Policy* and *Raising and acting on concerns about patient safety*, GMC January 2012).

20.0 Can I withhold information from the patient?

20.1 You can only withhold information necessary for making decisions if you believe it will seriously harm the patient (not just because it may upset them or because it may sway them against a particular decision). If you decide to withhold any information, your justification must be recorded in the patient's notes.

21.0 How must I document the consent discussions?

21.1 Oral or non-verbal consent for simple procedures, such as taking blood, does not routinely need to be recorded formally unless there are unusual circumstances (e.g., a needle phobia) or your Professional Body mandates that oral or non-verbal consent is documented. Oral consent is adequate for minor invasive procedures with no significant risks, but you must record the discussion in the patient's notes. Written consent usually provides better evidence than oral consent, and written consent must be used for any procedure that involves the use of general or regional anaesthesia or sedation and for those that carry significant risks to the patient's life, social function, sexual functions or professional activities.

21.2 The consent form is designed to summarize the information given to the patient, including any specific requests made by the patient, and any recorded (written, visual or audio) matter given to them. You must also record in the patient's notes the risks, benefits and alternatives that have been discussed. A number of consent forms have been lost, so the case notes will provide evidence of the consent process. Better evidence is provided by including all this information in the letter to the GP and sending a copy to the patient. This has the additional benefit that, if the consent form has been lost, the responsible clinician can decide if the patient has given valid informed consent before the day of the procedure.

21.3 The Trust uses versions of standard Consent Forms1 (for patients with capacity to consent to investigation or treatment), 2 (agreement of a person who has parental responsibility) and 4 (for adults who lack capacity to consent). If patients are seen in outreach clinics, the clinician should take copies of our consent forms with them, but if consent is documented on a consent form of a different NHS organization, that form is valid if it conforms to the national standard and if all the essential information is documented (name of the procedure; intended benefits, risks, and alternative; the use of blood transfusion and other extra procedures that may be necessary; and the use of anaesthetic and, or sedation).

21.4 Consent Form 1 is used regardless of the anaesthetic technique (local or general anaesthetic, sedation or no anaesthetic).

21.5 Consent Form 4, for adults who lack capacity to consent, requires health professionals to document both why they conclude that the patient lacks capacity to make this specific decision and why the proposed treatment would be in the patient's best interest. There is a section to record the involvement of those close to the patient in making this decision. There are sections on the form for use if there is someone with LPA to make healthcare decisions for the patient and if there is a court-appointed deputy who can make such decisions. There is also a section for use if an Independent Mental Capacity Adviser has been involved.

21.6 All relevant parts of the consent form must be completed legibly in black ink. Do not use abbreviations for technical terms; you may use common English abbreviations (such as e.g. etc.). Record if patient information leaflets have been given and identify them. Record if the patient has accepted their copy of the consent form; if the patient does accept it, you must ask them to bring it with them on the day of the procedure in case the hospital copy has been lost. If an interpreter is used, you must ask them to sign the consent form in the appropriate section. You must ask the patient to sign the *Removal of Tissue* box to signify that they agree to the retention of tissue and its use for research etc. if that is relevant. If the patient does not give consent for the retention of tissue, that information must be included on the Histopathology request form.

21.7 Directorates are encouraged to develop procedure-specific consent forms. All these forms must be approved by the Consent Lead or Chief Medical Officer before use, and all of them must be in the standard format of Consent forms 1, 2 and 4 (see Appendix 4 of the main policy - Procedure-specific Consent Forms Process).

22.0 When must consent be given?

22.1 For straightforward interventions, such as taking a blood pressure or a blood sample, the consent can be given immediately before the procedure.

22.2 Two-stage consent must be used for elective procedures done under general or regional anaesthesia or sedation and any that carry significant risks. This will give the patient time to reflect before and after they make a decision. You must seek consent for an elective procedure of this kind well before the date of the procedure, and the patient must signify consent **before** the day of the procedure (NHS Resolution, formerly NHS Litigation Authority, advises it should be at least two weeks before). The patient must confirm consent when they come for the procedure - ideally, the practitioner who is going to do it should seek this confirmation (particularly if someone else had the consent discussion with the patient), but anyone who can respond to any concerns or questions the patient may have can do it. The confirmation must be recorded on the consent form or in the notes. If there has been a long delay, you must check that there has been no significant change in the patient's condition or in the proposed procedure.

22.3 One-stage consent can be used for low-risk procedures, but it is good practice to give the patient with all the relevant information about the procedure as far in advance of the procedure as possible.

22.4 The Department of Health advises that patients should not sign the consent form on the day of the procedure, "If a person is not asked to signify their consent until just before the procedure is due to start…there may be real doubt as to its validity. In no circumstances must a person be given routine pre-operative medication before being asked for their consent to proceed with the treatment." (*Reference guide to consent for examination or treatment* (s*econd edition),* Department of Health, July 2009*).* The GMC requires that patients have time to reflect on any decision they make before they undergo the intervention. However, if a patient has signified consent before the day of the procedure but the form has been lost, detailed entries in the patient record (see 21.2) can be used to assure the clinician that valid consent exists and a duplicate consent form can be generated. If this action is taken, it must be recorded in the case notes.

22.5 Patients undergoing repeated interventions as part of a planned course of

treatments (such as dialysis, chemotherapy and radiotherapy) need only give consent once, and this can be recorded on one consent form.

23.0 How can consent be signified?

23.1 Patients can signify consent orally, non-verbally or in writing. Oral or implied consent is acceptable for minor or routine procedures provided the patient understands the procedure, the benefits, the risks and the alternatives. You must record the information that has been given the patient in the case notes if you are not using a written consent form.

23.2 You must seek written consent in the following circumstances: complex procedures; procedures with significant risks to the patient's life; procedures that may have significant consequences for the patient's employment, social life or personal life; procedures done under general or regional anaesthesia or sedation; if providing clinical care is not the primary purpose of the procedure or if it is part of a research programme or if it is an innovative treatment; and, under the terms of The Human Fertilisation and Embryology Act 1990 amended by the Human Fertilisation and Embryology Act 2008, to store a person's gametes or to use them for the treatment of others or to create an embryo *in vitro*.

23.3 By signing the consent form, the patient is agreeing to the procedure but they can still change their mind (N.B. no patient should be put on a waiting list until they have formally signified consent for the procedure – see OP39 Patient Access Policy). If you cannot get written consent for any reason, you can use witnessed oral or non-verbal consent; you must record this on the consent form identifying those who act as witnesses, who must also sign the consent form.

23.4 The original consent form (the white copy numbered pages 3 and 4) is the one that should be used when the patient undergoes the planned procedure. It is very important that this copy of the consent form is presented to the consultant's secretary or waiting list clerk to go to the appropriate treatment area to be put in the patient's "skinny file". Ask the patient to bring their yellow copy of the consent form (numbered pages 1 and 2) with them when they come in for the procedure (if the white copy is missing, we can use the yellow one – see below). Dictate a letter to the GP (and copy it to the patient) to confirm the treatment plan and include in the letter information about the planned intervention together with the specific risks, benefits and alternatives that you have discussed with the patient, and that the patient has signed a consent form.

23.5 If the original white copy of the consent form is lost, the following contingencies can be used.

- If the patient has the yellow copy, that can be used as the working document. After it has been signed to confirm consent it will be used in the checking in and WHO process. After the procedure, the form should be photocopied or scanned directly in to the portal and the yellow copy returned to the patient.
- If the patient does not have the yellow copy, but the clinical record documents an appropriate consent discussion with the patient (the procedure, risks, benefits and alternatives) **and** the patient knows what is to be done and wishes to proceed **and** the operator is satisfied that there is valid informed consent and is prepared to proceed with the procedure, it can be done. A new consent form will have to be written (unless there is a good-quality, scanned copy of the consent form in the portal, which can be printed

and used as the active document for confirmation of consent and the WHO checks). The clinician must make a careful record in the notes to explain why a consent form has been signed on the day. It is essential that the person doing the procedure is entirely happy that properly informed consent has been obtained – if not, it would be unwise to do the procedure. Remember that it is the clinician doing the procedure who is vulnerable if a complaint is made to the courts or their professional body.

- If the patient does not have their yellow copy and there is no adequate information in the notes to document the consent discussions (or the only evidence of consent is a poor quality scanned copy in the portal), then the procedure must be deferred and a proper consenting process must be undertaken and documented in the patient record.

- There is a specific issue about serial consent. The original white copy should be used for the first of the series and then scanned into portal in the standard way. That scanned copy can then be printed out and used as the working copy for subsequent procedures. At each attendance for a subsequent procedure, the treating clinician must record in the patient record that the intervention is still required and that the patient consents to undergo it.

23.6 The Human Tissue Act 2004 requires consent from the patient for the lawful retention and use for research (if the patient may be identifiable) of body parts removed surgically or during other procedures. This includes organs and tissue (any material from a human body that contains human cells except hair or nails or cultured cell lines; gametes and embryos are governed by another statute) from the living or the dead for specified health-related purposes (education and research) and public display. It also covers the **removal** of such material from the dead but not from the living. The standard consent forms have a specific section, *Removal of Tissue,* which covers consent for the use and retention of tissues for teaching, education, quality assurance, research, audit and diagnostic purposes. If the patient declines this consent, the clinician must indicate the absence of that consent on the Histopathology request form.

24.0 Does the patient need to consent to visual and audio recordings?

24.1 You must get specific written consent to make any visual or audio recording, including photographs or other visual images (see *CP18 – Clinical Photography, Video and Audio Recordings*) except for radiological images, images of pathology slides, images of internal organs or those taken during laparoscopy or endoscopy. You must explain the purpose and possible future use (e.g. clinical care, teaching, audit or research) of the recording before consent is sought. You must tell the patient that they can refuse without their care being compromised and that when required or appropriate the recording can be anonymized. Legally, the patient does not need to give specific consent for the use of this material in education or research if they cannot be recognized, but it would be good practice to seek consent. The patient can withdraw consent for the storage of recorded material at any time. The patient has the right to look at any recorded images or to hear audio recordings before they consent to it being retained. See also the GMC guidance *(Making and using visual and audio recordings of patients, March 2013*).

24.2 You will need specific written consent to publish any of these recordings.

25.0 What do I do if a patient refuses life-sustaining treatment?

25.1 This is only a consent issue if there are treatments that hold potential benefit for the patient's condition - you are under no obligation to provide futile treatment. Legally, there is no difference between withdrawing and withholding life-sustaining treatment.

25.2 An adult with capacity has the right to refuse any treatment, including life-sustaining treatments, and you must honour that refusal provided the patient is properly informed of the benefits, risks and alternatives and that the consequences of the decision is that they may die. Such a refusal can be made at the time the treatment is offered or in advance, by a valid and applicable Advance Decision. Artificial nutrition and hydration is a medical treatment, and can be refused by a properly informed patient with capacity.

25.3 If a person lacks capacity, a decision to withdraw or withhold life-sustaining treatment must be taken in their best interests and in a way that reflects their wishes as described in relation to consent for any procedure. You will need to consult with other parties as described above (14.0 *Who can give consent if the patient lacks capacity?*). Please note that the Mental Capacity Act 2005 requires that you must not be motivated by a desire to hasten the patient's death.

25.4 If there is doubt about providing life-sustaining treatment, you must assume that it **is** appropriate. Acute severe illness can impair capacity temporarily, so a patient's decision to refuse treatment may be invalid, and you would be acting in the patient's best interest to proceed with treatment.

25.5 Self-harm is a particular difficulty: if the person can communicate, assess their capacity urgently. If they lack capacity, you must give all necessary treatments until they regain capacity (as described above). If the patient is unconscious, you must treat them under the *Doctrine of Emergency* unless a specific and valid Advance Decision exists.

25.6 If a child with capacity refuses life-sustaining treatment, such a refusal will be overruled: the courts consider that decisions like this require a very high level of understanding, such that many children and young people would lack the capacity to make such a grave decision.

25.7 For a child who lacks capacity, the presumption will always be in favour of life-sustaining treatment that is indicated and holds potential benefit. If you disagree with the views and wishes of those with parental responsibility for the child, you must apply to the courts.

26.0 What treatment does the Mental Health Act cover?

26.1 Some patients detained under the Mental Health Act 1983 may be treated for their mental disorder without their consent, but they cannot be treated for physical disease unrelated to the mental disorder. The presence of a mental disorder requiring detention under the 1983 Act does not allow an assumption of incapacity, and the patient's capacity may fluctuate, so you must make a formal

assessment as described above. Community Treatment Orders only allow enforced hospitalization for treatment of the patient's mental health problem.

26.2 The 2007 amendments to the1983 Act specify that, except in an emergency (if the treatment is held to be life-sustaining or required to prevent severe deterioration), electro-convulsive therapy (ECT) may not be used on an adult patient with capacity without their consent, and that a valid Advanced Decision to refuse electro-convulsive therapy must be respected. There are specific provisions in the Act regarding the use of ECT in children and young people.

26.3 Neurosurgical treatment for mental disorders (psychosurgery) and the use of surgically implanted hormones to reduce male sex drive can only be administered with the patient's consent and subject to specific provisions of the 1983Act.

27.0 Can treatment be given without consent to people with notifiable infectious diseases?

27.1 The Public Health (Control of Disease) Act 1984 (amended by the Health and Social Care Act 2008) gives the power to a magistrate to order that people with certain notifiable infectious diseases can be medically examined and detained in a hospital without their consent, but it does not allow them to be treated without their consent.

28.0 Where can the patient or their supporters get further information?

The consultant in charge of their care via the secretary or the department in which they work.

PALS Office on the main Hospital Street or via 01902695362.

NHS Choices www.nhs.uk

29.0 Further Reading

Decision making and consent (General Medical Council, November 2020)

*First Do No Harm The report of the Independent Medicines and Medical Devices Safety Review (*Cumberledge et al July 2020)

Raising and acting on concerns about patient safety (GMC January 2012).

NG197 Shared decision making (NICE www.nice/org.uk/guidance/ng197).

Reference guide to consent for examination or treatment (s*econd edition)* (Department of Health, July 2009)

Principles of Patient Consent (General Dental Council, May 2005).

*Making and using visual and audio recordings of patients (*General Medical Council *March 2013*)

CANH and adults who lack the capacity to consent – guidance for decision-

*making in England and Wales (*British Medical Association and Royal College of Physicians 2018)

Consent in cardiac surgery. A good practice guide to agreeing and recording consent (The Society of Cardiothoracic Surgeons of Great Britain and Ireland & the Parliamentary Health Service Ombudsman May 2005)

The code: Standards of conduct, performance and ethics for nurses and midwives (Nursing and Midwifery Council, May 2008)

Raising the Standard: Information for Patients (Royal

College of Anaesthetists, February 2003)

Standards of Proficiency – Physiotherapists. Health and Care Professions Council (2013)

www.hcpcuk.org/assets/documents/10000DBCStandards_of_Proficiency_Physiothe rapist. pdf

The Chartered Society of Physiotherapy: Quality Assurance Standards (2012) www.csp.org.uk/standards.

A mismatch between population health literacy and the complexity of health information (Rowlands G et al British Journal of General Practice June 2015 e379-85)

Mental Capacity Act 2005 **www.legislation.gov.uk/ukpga/2005/9/contents** *Mental Capacity Act*

Code of Practice

www.direct.gov.uk/en/Governmentcitizensandrights/Mentalcapacity andthelaw/Makingdecisionsforsomeoneelse/DG_186479

Mental Health Act 1983 (as amended by the Mental Health Act 2007)

Montgomery v Lanarkshire Health Board 2015 UKSC 11

Human Tissue Act 2004

Human Fertilisation and Embryology Act 1990 (as amended by the *Human Fertilisation and Embryology Act 2008*) *The Human Rights Act 1998:*

- Article 2 (the right to life)
- Article 3 (the right to be free from inhuman or degrading treatment)
- Article 8 (the right to respect for privacy and family life)
- Article 10 (the right to freedom of expression, which includes the right to hold opinions and to receive information)
- Article 14 (the right to be free from discriminatory practice in respect of these rights).

www.justice.gov.uk/guidance/freedom-and-rights/human-rights.htm

Consent in cardiac surgery: a good practice guide to agreeing and recording consent (Parliamentary and Health Service Ombudsman, Society for Cardiothoracic Surgeons of Great Britain and Ireland, 2005)

Attachment 2

Policy Reference:	**CP 06**
Procedure Title:	**Obtaining Consent for Post Mortem (PM) Examination**
Author:	**Head Biomedical Scientist - Histopathology**

1.0 Introduction

1.1 The Human Tissue Act 2004 sets out a legal framework for the storage and use of tissue from the living and for the removal, storage and use of tissue and organs from the dead. This includes 'residual' tissue following clinical and diagnostic procedures.

1.2 The Act establishes the Human Tissue Authority as the regulatory body for all matters concerning the removal, storage, use and disposal of human tissue (excluding gametes and embryos) for scheduled purposes. This includes responsibility for living donor transplantation.

1.3 This policy sets out recommended practice for all those who communicate with relatives of children or adults who have to undergo a PM examination whether or not ordered by the Coroner.

2.0 Objectives

2.1 To ensure that those close to the deceased person are given the opportunity to understand the reason for a hospital or a Coroner's PM and to understand the processing part and their rights in the decision making process.

2.2 To ensure that the Trust Consent for Hospital PM Examination of an Adult form is completed correctly and appropriately.

2.3 To ensure that organs and tissue are not retained following PM examination without appropriate consent.

2.4 To ensure, where relevant, that the wishes of the deceased person are known and fully understood.

2.5 To ensure that the general information about PM examination is readily accessible.

2.6 This policy does not deal with body parts or organs held for the purpose of anatomical examination. Where the person who has died made an express wish that their body can be used for anatomical purposes, it will not be possible to carry out their wish if the body has been subject to PM examination or if any organs except the eyes have been removed for transplantation. However, carrying out a PM examination does not rule out organ donation for transplantation. However, the treating clinician may need to explain these exclusions to the deceased persons relative or relatives.

3.0 Responsibilities

3.1 Person obtaining Consent

The person obtaining consent for a PM must be fully trained and understand the procedure as detailed in this Policy.

The person obtaining consent must have completed the Trust Consent training for

hospital PMs, available via the following link:

Consent training for hospital PMs.

To assist Clinicians this process can be supported and undertaken by the Trust Medical Examiner or Bereavement Nurse who are fully trained.

The person must explain the PM process fully to the appropriate relative including details regarding obtaining, retaining and disposal of removed tissues.

3.2 Coroner's Officer

The Coroner's Officer will undertake all discussions pertaining to Coroner's PM examinations with the family.

Discussion relating to the retention or disposal of tissues and organs following a Coroner's PM examination will be undertaken by the Coroner's Officer.

3.3 Consultant Pathologist

The Consultant Pathologist must ensure that all the necessary documentation detailed within this Policy is fully completed prior to undertaking any PM examination.

4.0 Training

4.1 Key individuals within the Trust have been identified to undergo consent for PM training and have their competency assessed to ensure that they have the necessary skills to enable them to meet the requirements of this Policy. A register of these individuals' training record will be held by the Training Department and a copy is held in the Histopathology Department.

5.0 Policy Detail

5.1 Patients that are dying

5.1.1 This policy does not deal with the support and information that must be offered to dying patients.

5.1.2 The decision making at death is easier if patients have volunteered their wishes beforehand or have already made the relevant decisions. This is a very sensitive matter which will require clinical judgement in each individual case.

5.1.3 Where appropriate, the dying and their relatives must be offered help to understand what may happen immediately before and after death, while respecting the views of patients who indicate that they do not wish to discuss particular issues.

5.1.4 Clinicians must seek to ensure that:

- Staff are aware of any preferences expressed immediately before or after the patient's death, and are sensitive to culture-specific attitudes towards PMs and the use of tissue (each case and decision is an individual and personal one and must be treated as such);
- A dying person's decision in respect of organ and tissue donation is recorded and that the relevant procedures are understood, including PM examination;
- Discussions or preferences about the storage and use of organs and body parts for therapeutic purposes and for medical educational research are recorded;

- Wishes are recorded for the disposal of organs and tissue following PM examination, including those which may subsequently be used for medical educational research;
- Contact is made with a religious representative if required.

5.1.5 The points in 5.1.4 also apply to persons with parental responsibility for terminally ill children and babies dying in Neonatal Intensive Care. Raising these issues is highly sensitive; the persons with parental responsibility need to be prepared for what is likely to happen immediately before and after their child's death, as some would wish to discuss specific arrangements.

5.2 PM examinations

5.2.1 There are two reasons for a PM examination (autopsy). One is at the request of HM Coroner and the other is agreed upon by the deceased or their relative.

5.2.2 In any setting human tissue or organs may only be removed, stored, or used if the appropriate consent has been obtained. Before a PM begins, the person obtaining consent and the pathologist must check that the PM examination and any removal, storage or use of tissues has been properly authorised by a completed consent form or by the Coroner.

5.2.3 It must be explained to those giving consent that the storage of tissue blocks and slides may be essential to enable a diagnosis to be made and is valuable for review or audit purposes. Specific consent must be obtained to store or use tissue (including paraffin wax-processed tissue blocks and microscope slides) for any other scheduled purposes listed in the Act.

5.2.4 Relatives may agree to a hospital PM examination being undertaken however they may object to tissue being stored and, or used (including tissue blocks and slides). It must be explained to them that this may limit the usefulness of the PM; however, this must not prevent one from being undertaken, unless the pathologist believes that the examination would be uninformative.

5.2.5 It must be explained to relatives of the deceased person that medical students, doctors and other healthcare professionals may witness the PM examination or a demonstration of the findings for educational purposes and to develop their professional skills. Any one witnessing the PM examination must respect the confidentiality of any information relating to the deceased person.

5.3 Coroner's PM examination

5.3.1 A Coroner's PM examination is carried out according to the provisions of the Coroners Act 1988 and the Coroners Rules 1984 (amended 2005) in order to assist the Coroners with their functions.

5.3.2 Consent is not required for a Coroner's PM. This will need to be explained sensitively to any relatives. They must be given information about when and where the examination is to be performed and told of their right to be represented at the PM by a doctor if they wish.

5.3.3 The Coroner has a duty to inform the relatives or personal representatives of a deceased person about the retention of organs, tissue or material following a Coroner's PM examination under Coroners Rules 2005.

5.3.4 There is a legal provision for a copy of the Coroner's PM report to be provided to relatives for a fee. It may be necessary following a PM examination for the Coroner to hold an inquest into the death of the deceased. Where this occurs, the reasons for the inquest and its procedure must be fully and sensitively explained to relatives, usually by the Coroners officer.

5.4 Hospital PM examination

5.4.1 A hospital PM can only be carried out with the prior consent of the deceased person, their nominated representative or a person in a qualifying relationship. A list of qualifying relationships is given in **5.9** below.

5.4.2 The Human Tissues Act makes it unlawful to store or use the body of a deceased person, or to remove, store or use any material from a deceased person's body for scheduled purposes without appropriate consent.

5.4.3 The attached form (**Appendix 1** - *Consent for Hospital PM Examination for an Adult*) **must** be completed by trained and competent individuals. A register of such individuals is maintained by the Histopathology Department. Once this consent form has been fully completed, two copies are taken. The original form is then sent to the Histopathology Department with one copy being forwarded to Medical Records to be filed in the deceased patient notes and the other being given to the individual who has given consent for the PM examination to be carried out.

5.5 Who can give consent?

5.5.1 Consent must be obtained for a hospital PM and for the removal, storage and use of organs and tissue for scheduled purposes after a hospital PM, or after the functions of the Coroner have ended in relation to a Coroner's PM.

5.6 Appropriate consent – adults

5.6.1 For activities other than public display or anatomical examination the appropriate consent means:

- the consent of the deceased person, if they gave or refused consent immediately before death; or
- the consent of a nominated representative appointed by the deceased person to deal with this issue; or
- if there is no nominated representative, then the consent of someone who stood in a 'qualifying relationship' to the deceased person immediately before that person died.

5.6.2 If proper consent from a deceased person or their nominated representative is in force then there is no legal duty to obtain consent from the immediate family or others in a 'qualifying relationship'. If they object to the PM examination for whatever reason, clinicians must discuss the matter sensitively with them to encourage them to accept the deceased person's wishes. It must be made clear that they do not have the legal right to veto or overrule those wishes.

5.7 Appropriate consent – children

5.7.1 Under the Human Tissue Act a child is defined as being under 18 years old, and for activities other than public display or anatomical examination, appropriate consent means the child's consent if they are competent (Gillick-competent) to do so. If they did not give or refuse consent immediately before death consent can be given by:

- a person with parental responsibility (see CP06 attachment 1 section 9.0) for the child immediately before the child's death, or
- in the absence of a person with parental responsibility, a person in a 'qualifying relationship' to the child at that time.

5.7.2 Wherever practical, discussion must be with both parents and both must sign the consent form. If either parent is known to object to a PM examination, it

must not be carried out. Clinicians must discuss with the parents how they intend to proceed, when proper consent is obtained from the deceased child for a PM or the retention and, or use of organs and tissue for scheduled purposes for which it has been obtained. Where the parents of the deceased child or those close to the deceased child object to a PM examination being carried out when the child had expressly consented, clinicians must seek to discuss the matter sensitively with them. It must be made clear to the parents and those close to the child that they do not have a legal right to veto or overrule those wishes and to try and help them to accept the child's decision.

5.8 Nominated representatives

5.8.1 Adults may appoint one or more persons to represent them after their death in decisions about PM examination and the retention of organs and tissue. Where the deceased person's wishes are not known, and a nominated representative has been appointed, consent must be obtained from that person. Where a person comes forward and presents themselves as a nominated representative, their authority to act on the deceased person's behalf must be verified, including what decisions they have the authority to make. The appointment of a nominated representative may be revoked at any time by the patient.

5.8.2 The appointment of a nominated representative may be:

- general or limited to consent in relation to one or more activities, and
- made orally (when it must be made in the presence of at least two witnesses present at the same time), or
- made in writing, when it must be:
  - signed in the presence of at least one witness who attests the signature, or
  - signed at the direction of the person making the appointment, in their presence and in the presence of at least one witness who attests the signature, or
  - contained in the deceased person's will.

Where there are two or more people appointed, unless the terms of the appointment make it clear that they must act jointly, it must be assumed that they can act individually. The nomination may be disregarded if no one is able to give consent under it, which includes where it is not reasonably practicable to communicate with the nominated representative within the time available if the consent is to be acted upon.

5.9 Qualifying relationships

5.9.1 Where the deceased person has not made a decision nor appointed a nominated representative, the Act ranks persons in a 'qualifying relationship' in order set out below. Consent must be obtained from the person ranked highest. Relationships listed together, for example 'brother or sister' are accorded equal ranking, in which case it is sufficient to obtain consent from just one of them.

5.9.2 The ranking system is intended to help those seeking consent to know whom to approach, and in what order (highest first):

1 spouse or partner (including civil or same sex partner);

2 parent or child;

3 brother or sister;

4 grandparent or grandchild;

5 niece or nephew;

6 stepfather or stepmother;

7 half-brother or half-sister;

8 friend of long standing.

5.9.3 There must be careful consideration given before proceeding on the basis of one person's consent where there are overwhelming objections to it. For example, if a spouse or partner has no objections to organs or tissue being used for research, but everyone else in the family strongly objects, going ahead may do more harm than good.

5.9.4 Where there are differences of opinion between people in qualifying relationships, decisions will need to be made on a case by case basis, taking into account:

- The views of the person in the highest ranking qualifying relationship take precedence over the views of other family members;.
- The views of other qualifying relatives: if for example a spouse consents to use of tissue for research but other family members strongly object, the benefits of carrying out the activity must be weighed against the distress and resentment that may be caused by proceeding;
- The potential benefit to other family members: if for example two siblings disagree on whether material must be retained, the potential benefits to family members of genetic information may be of value.

5.9.5 The law does not distinguish between foetal tissue and other tissue from the living; foetal tissue is regarded as the mother's tissue. Consequently, foetal tissue is subject to the same consent requirements under the Human Tissue Act as all other tissue from the living. Because of the sensitivity attached to this subject, it is good practice to always obtain consent for the examination of foetal tissue and for its storage or use for all scheduled purposes. It is also good practice to obtain consent for research on non-foetal products of conception (i.e. placenta, membranes, umbilical cord and amniotic fluid) even where the tissue is non-identifiable.

5.9.6 Obtaining consent for the removal, storage and use of the tissue of babies from stillbirths (babies born dead after 24 weeks gestation) and neonatal deaths (babies or foetuses of any gestational age which are born showing signs of life and die before the age of 28 days) must be handled in accordance with provisions for gaining consent for use of the tissue of the deceased. It is recommended that, where possible, the consent process for the examination of stillbirths and neonatal deaths involves the mother, and that, where appropriate, both parents are involved.

5.10 Discussing the PM with the family: who may seek consent?

5.10.1 Discussions with the deceased person's relatives must provide honest, clear objective information; an opportunity to talk to someone they feel they can trust, and of whom they feel able to ask questions; reasonable time to make decisions

about any donation of organs or tissue; privacy for discussion between family members; and support if they need and want it' including the possibility of further advice or bereavement counselling or psychological support. It is only after relatives have had the time to reach a decision that they must be invited to sign a consent form. If the deceased has registered on the NHS Organ Donor Register or carries an organ donor card, a discussion must take place and relatives may have to decide to donate if possible. All efforts must be made to allow those who wish to donate organs or tissue to do so and explanations must be given where it is not possible.

5.10.2 Discussions about the PM with relatives must be held in a suitable place, which must be comfortable and private, and preferably away from the clinical area. They must, wherever possible, be face to face, but if that is impossible consent to PM examination can be given by telephone or email. Any telephone conversation must be accurately documented and a copy of the consent form and other relevant documents sent to the relative. Pathologists will need to satisfy themselves that consent has appropriately been obtained before proceeding with a PM examination.

5.10.3 The discussion must give a full and clear understanding and information about the purpose of the PM, the procedure and the range of choices available to the relative(s), and they will need time to think this over.

5.10.4 A record of the discussion must be provided to the relatives, so they have factual information which will form a permanent record of the discussion and agreement reached; a copy must be kept in the patient's record. With an agreed time limit, relatives must be given the opportunity to change their minds.

5.10.5 Relatives must be provided with a name, telephone number and, or email address of the hospital's Designated Individual or person(s) with delegated responsibility that they can speak to and ask further questions of later.

5.10.6 The discussion must be conducted sensitively particularly around the detail of the examination. It must however, be a full and honest explanation that includes:

- A basic explanation of what happens (including the removal / retention and use of tissues for diagnosis);
- The benefits of PM examination and why the doctor thinks a PM might be valuable in this case, and, or the reasons for the Coroner's involvement;
- The possible outcome of the examination;
- Possible alternatives to a full examination (making clear the limitations to these, and the benefits of a full PM);
- Who will do the PM, where and when;
- If the PM is to be carried out at another hospital, and how and when the body will be transferred;
- When, to whom and how the results of the investigation will be available and explained;
- Options for retention of organs, tissue or slides after the examination, including specific consent;
- An explanation of the meaning of human tissue such as sizes of

samples (particularly relevant for babies and young children) (see also 5.10.7;

- Whether organs or tissue can be retained without limit of time for medical research, quality assurance or teaching purposes;
- The timing of the burial / cremation so that tissue removed can be reunited with the body, if the family wish. This timing will need to be done in consultation with the pathologist.

5.10.7 It must be made clear to relatives that consent to PM is separate from consent to the removal, storage and use of tissue and organs (including blocks and slides). The discussions must make clear to relatives that:

- The human tissue includes organs, parts of organs and tissue in various forms, such as frozen sections and samples fixed in paraffin wax;
- The various purposes for which tissue might be kept;
- Their options for giving or refusing consent to storage of any particular organ or tissue, and for any particular use.

5.11 Cultural traditions and language differences

5.11.1 Cultural attitudes to death, to PMs and the use of organs and tissues differ greatly, and the person providing bereavement support must be fully informed about the values and beliefs of a range of cultures and religions within their local community. Staff must be given the necessary training and support to identify possible range of needs and wishes within a range of cultures to be able to provide support to the bereaved.

5.11.2 Valid consent depends on proper communication. Independent, professional interpreters must be used to communicate with people who are not fluent in English, and suitable help and support must be available people with other communication problems.

5.12 Information to be given to relatives about the results of Coroner's and hospital PMs

5.12.1 A deceased person may have expressed a specific wish, before their death, that information must not be shared with relatives and this must be respected.

- The result of a Coroner's PM examination can only be given with the permission of the Coroner.
- Relatives must be told before the PM is carried out when the results will be available.
- Relatives must be offered an appointment to discuss the results of the PM with the clinician responsible for the deceased person's care and, or the pathologist, or other specialist clinician. Where there are delays in the results being available, the clinician and the pathologist must discuss the matter before information is given to bereaved relatives.
- The wishes of relatives who do not want to know the PM results or do not want to discuss them in detail must be respected, but they must be offered an opportunity to discuss them at a later date. Where a Coroner's PM is to identify the cause and circumstances of death, it must be explained to the relatives that this may be limited in scope. The Coroner must be consulted before the PM report or any information

about it is made available to anyone. Where the death is the subject of an inquest, any such discussions can only take place with the prior agreement of the Coroner.

- The discussion on a hospital PM can be as wide as the relatives want,

  but this must be treated in confidence and any information given must be met with proper care and sensitivity subject to any express wish of the deceased person.

- Parents, who have suffered pregnancy loss or the death of a baby, may wish to discuss the PM results as a couple. These discussions may need to include other professionals, e.g. a genetic specialist. They may feel unable to take up the offer immediately, but they must be given written contact details as to whom they can contact at a later date and be given details of the national and local support agencies.

- Parents of a deceased child, if they want one and, if relevant, the Coroner agrees, must be offered a copy of the full pathologist's report and access to a clinician to whom they can speak so that they can understand it. It may also be appropriate to do this for adult deaths. Subject to the agreement of the parents, the PM report must be given to the deceased child's GP and, or treating clinician or the mother's GP in the case of a neonatal death or a still birth.

5.13 Information about use of donated tissue and organs

5.13.1 If relatives have given consent to tissue and organs being stored and used after the PM, they must be asked if they wish to receive information about how they will be used.

5.14 Maintaining proper documentation

5.14.1 A system of maintaining proper records and documentation for all tissue and organs they acquire and, or pass on to others.

5.14.2 There must be a tracking system to establish what happens to organs and tissue for health and safety reasons.

5.14.3 The records system must have proper records of the following:

- Who gave consent;
- Exactly what the consent is related to and any restriction on use stipulated during the consent process;
- What processes are applied to the tissue;
- If tissue is transferred, when and to whom;
- If relevant, when and how disposal is undertaken.

5.14.4 When tissue is transferred from one place to another, an audit trail needs to be established for each establishment that handles the human organs or tissue so that a proper record is kept of the following:

- When the material was acquired and from where;
- The uses to which the material is put whilst under the responsibility of the establishment concerned and any processes applied to it;
- When the material is transferred elsewhere, and to whom.

5.15 Obtaining consent

For consent to be valid it must be given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question and it must be in writing.

Appendix 1

CONSENT FOR HOSPITAL POST MORTEM EXAMINATION OF AN ADULT

This form is <u>not</u> to be used in cases where the post mortem examination is to be performed on behalf of HM Coroner

Name of Deceased:

Date of Birth: Date of Death:

Sex: Male ☐ Female ☐

Consultant / General Practitioner (GP) Responsible for Patient:

Hospital / Unit Number and / or NHS Number:

This form enables you to consent to a post mortem examination of the body of the person named above. Please read it carefully with the person obtaining consent from you. For each section tick the relevant box to indicate your decisions and sign beneath each section.

☐ I confirm that I have had the opportunity to read and understand the ***Information for relatives about post mortem examination*** leaflet

☐ I confirm that my questions about the post-mortem examination have been answered to my satisfaction and understanding.

Signed by: …… Name: ……..

Part 1: Post Mortem Examination

A post mortem examination may be full or limited. The benefits and disadvantages of each will be explained to you. Please choose **<u>one</u>** of the following options.

Option 1: Consent to a full post mortem examination

☐ I consent to a **full** post-mortem examination of the body of the person named above. I am not aware that he / she objected to this. I understand that the reason for the examination is to further explain the cause of death and study the effects of disease and treatment.

Option 2: Consent to a limited post mortem examination

☐ I consent to a limited post-mortem examination of the body of the person named above. I am not aware that he / she objected to this. I understand that this may limit the information about the cause of death and effects of treatment.

I wish to limit the examination to:

☐ The head and mouth cavity, including the brain
☐ The chest and neck
☐ The abdomen and pelvis

☐ Other (please specify): ……..……

……

Option 3: Consent to a non-invasive post-mortem examination

☐ I consent to a non-invasive post mortem examination of the body of the person named above. I am not aware that he / she objected to this. I understand that this may limit the information about the cause of death and effects of treatment.

Signed by: …… Name: ……...

Part 2: Retention and Future Use of Tissue Samples

As part of a full or limited post mortem examination tissue samples and small amounts of bodily fluids may be taken and used to determine the diagnosis and extent of the disease. Bodily fluids will usually be disposed of following a diagnosis. However, the tissue samples removed during a post mortem examination are made into tissue blocks by the Histopathology laboratory which allow the production of slides for microscopic examination. These can be stored for use in the future. The storage of the tissue samples and their later use require your consent. These samples can be valuable for the education and training of healthcare professionals, research and other purposes. Please indicate whether you consent to this:

☐ I consent to the tissue samples being stored for future use, **and**

(Please tick all options that apply)

☐ I consent to the tissue samples being used for the purpose of evaluating the efficacy of any drug or treatment administered to the deceased, or for review on behalf of the family if a need arises

☐ I consent to tissue samples being used for education and training relating to human health, quality assurance, public health monitoring or clinical audit

☐ I consent to the tissue samples being used for research that has been approved by an appropriate ethics committee

If you decide tissue samples **must not** be kept after the post-mortem examination, further diagnosis will not be possible and the tissue samples will be disposed of. Please indicate **<u>one</u>** of the options below for the disposal of tissue samples:

☐ I wish the hospital to dispose of any retained tissue samples

or

☐ I will make my own arrangements for lawful disposal of any retained tissue samples

or

☐ I wish the tissue samples to be reunited with the body before it is released, even though this may delay the funeral. I understand that tissue blocks and microscope slides cannot be placed inside the body for the purpose of reuniting tissues with the deceased and will therefore be placed in a suitable container for transportation

Signed by: …… Name: ……...

Part 3: Retention of Organs for more Detailed Examination

As part of a full or limited post mortem examination, it may be necessary to retain some organs for more detailed examination. The person explaining about the post mortem examination will tell you what may be required. The retention of organs for more detailed examination requires your consent. Please indicate whether you consent to this:

☐ I do not object to any organs being taken for further examination if this is necessary to fully understand the cause of death and effects of treatment

or

☐ I object to **any** organs being taken for further examination

or

☐ I object to the following organ(s) being taken for further investigation (please list below):

……...

……...

After more detailed examination of organs removed during a post mortem examination, they must be either stored for specified uses or disposed of in a lawful manner. You have the option of donating retained organs for research or medical education. Please indicate your wishes by choosing **one** of the following options:

☐ I wish to donate retained organ(s) for research into related diseases, after which they will be disposed of lawfully

or

☐ I wish to donate retained organ(s) for education, after which they will be disposed of lawfully

or

☐ I wish the hospital to lawfully dispose of any retained organ(s), without them being used for research and / or education

or

☐ I will make my own arrangements for lawful disposal of any retained organ(s)

or

☐ I wish the organ(s) to be reunited with the body before it is released, even though this may delay the funeral

Signed by: …… Name: ……...

Other Requirements of the Post Mortem Examination

In some cases there may be further requirements of the post mortem examination, such as genetic testing of tissue samples. The person explaining about the post-mortem examination will explain these to you. Other requests or conditions which you would like to make:

……

……

Thank you for consenting to a post-mortem examination. You can change your mind about any of the decisions you have made, although there may be a short time limit for some of these. If you wish to make changes to anything you have consented to, or wish to withdraw your consent, please telephone the *Histopathology Department* on *(01902) 695289* as soon as possible and not later than 24 hours after completion of this form.

Please do not hesitate to contact the *Histopathology Department* at The Royal Wolverhampton Hospitals NHS Trust (New Cross Hospital) if you have any questions.

Signed by: …… Name: ……...

Address: ……

……

Telephone Number: ……

Relationship to the Deceased: …… Date ……

Details of person obtaining consent

Name: …… Job Title: ……..

Contact details……..

Notes for person(s) obtaining consent

- I confirm that the person consenting has a full understanding of the post-mortem examination procedure and has completed appropriate Trust training in post mortem consent.
- I confirm that I have checked that the person consenting is the appropriate person for the purposes of the Human Tissue Act 2004.

  Staff seeking consent must ensure that they have appropriate consent, in line with the Human Tissue Act 2004. Staff must ensure that consent is obtained from, **in this order:**

1. **The person concerned**- where an adult has, whilst alive, given valid consent for a post mortem examination to take place after their death, this consent is sufficient.

2. **Their nominated representative**- the Human Tissue Act 2004 sets out the terms for valid appointment of a nominated representative. See the code of practice on Consent for more information
www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm

or, in the absence of either of the above,

3. **A person in a qualifying relationship** with the deceased immediately before their death- consent must be obtained from the person ranked highest in the following order of closeness to the deceased. Consent is only needed from one person:

Order of qualifying relationships
Persons are ranked in the following descending order:
a) spouse or partner (including civil or same sex partner)
b) parent or child (in this context a child may be of any age)
c) brother or sister
d) grandparent or grandchild
e) niece or nephew
f) stepfather or stepmother
g) half-brother or half-sister
h) friend of long standing

- I have discussed the reason for requesting a Hospital consented Post Mortem.

- I have explained the consent process.

- I have explained what is involved in a post mortem examination.

- Types of Post Mortem:
  - Limited
  - Full
  - Non-Invasive

- I have explained about retention of organs and tissues.

- I have discussed options for what to do with the retained organ(s) or tissues once further examination is completed.

- Common questions have been discussed:
  - Will it disfigure?
  - Will it cause delay?
  - How will results be given?
  - What if I change my mind?

- I have discussed tissue samples being retained for future use and the potential uses for the tissue that is retained

- Consent is indicated by boxes which are ticked and signature of the person giving consent

- I have discussed any special requests or conditions concerning the post-mortem examination procedure
- I have offered a photocopy of this form to the person giving consent
- Where appropriate, I have discussed the requirements of the post-mortem examination with ..... ***(insert name of Consultant Pathologist)***

Signed: …… Date: ……...

Note: If **consent is subsequently withdrawn**, either for the entire post-mortem examination, or for specific sections of it, each page of each copy of the form (or the relevant section(s)) must be clearly struck through. The person taking the withdrawal must also sign and date the form clearly, and note action taken to inform the Mortuary (the date and time and member of Mortuary staff informed).

Important On completion of this form please ensure that two copies are taken:

Original Send to Histopathology Department
Copy 1 Forward to Medical Records to be filed in Deceased patient notes Copy 2 Give to the individual who has signed the consent form

Attachment 3

Policy Reference: **CP 06**

Procedure Title: **Guidance for Health Professionals on the Mental Capacity Act 2005**

1.0 Introduction

1.1 The Mental Capacity Act 2005 (MCA) provides a legal framework for protecting individuals who are unable to make decisions of their own. It sets out the criteria to be followed where an individual lacks capacity to make a decision, and this guidance is intended to help healthcare professionals, in line with the law, when dealing with patients who have lost their capacity to agree, or to refuse, care and treatment, examination or investigation.

1.2 Where there are particular issues of concern related to patients who lack capacity, advice must be sought from the Trust's Safeguarding Team and, or the Legal Service Department.

2.0 5 key principles of capacity

The Act introduces 5 key principles when dealing with individuals who may lack capacity.

2.1 Everyone is assumed to have capacity unless it is proved otherwise.

2.2 Everyone has the right to be supported to enable them to make their own decisions.

2.3 An individual has the right not to be treated as lacking capacity because they make their own decisions.

2.4 When a decision has to be made on behalf of someone who lacks capacity it must be in their best interests.

2.5 Where a decision is made on behalf of someone lacking capacity it must be the least restrictive intervention.

3.0 Inability to make a decision

Every adult and young person must be presumed to have capacity to make their own decisions. A patient must only be regarded as lacking capacity when it becomes clear, after being provided with help and support, that they are unable to do any one of the following:

- understand the information being provided which is relevant to the decision,
- retain the information long enough to make an effective decision,
- weigh up the information necessary in order to make a decision, or
- communicate their wishes, as to their care and treatment, whether by talking, using sign language or any other means.

4.0 The two-stage test of capacity

The Act sets out a two-stage test to be used when determining whether a patient lacks capacity.

4.1 Is there an impairment of, or disturbance in, the functioning of the person's mind or brain? It does not matter whether the impairment is permanent or temporary.

4.2 If so, is the impairment or disturbance sufficient that the person lacks the capacity to make that particular decision? A patient must not be considered as lacking capacity because of their age, appearance, or as a result of their condition, or because of an aspect of their behaviour that will lead others to come to an unjustified conclusion about their capacity to make a decision for themselves.

4.3 The two-stage test must be used and the outcome recorded in the patient's medical records. If available, a Mental Capacity Assessment and Best Interest Decision form (see *Safeguarding Adults at Risk* on the Intranet) must be completed to record the assessment of capacity, and it should then be filed in the patient's notes.

5.0 Assessment of Capacity

5.1 An assessment of a patient's capacity must appertain to a particularly decision that is to be made at a given time. It must not be assumed that because a patient lacks capacity to make a decision on one particular occasion that they will be unable to make a similar decision in the future, or that they will be unable to make any decision at all.

5.2 Where an assessment raises doubt about a patient's capacity to make a decision, the advice of other colleagues must be sought, e.g. nursing staff, or others involved in the patient's care, or those close to the patient who may know more about the patient's ability to consent or communicate their wishes; and also inform those with a specialist interest, such as, psychiatrists, speech and language therapists, neurologist, etc. If there is still doubt about a patient's capacity advice must be sought from the Trust's Legal Services Department.

6.0 Assisting a patient with decision making

6.1 The nature and severity of a patient's condition may affect their ability to make a decision about their care and treatment. Likewise, so can the complexity of information, or the need to consider a number of options, when being asked to make a decision.

6.2 Some patients may only be able to make simple decisions and have problems when given more difficult information. A patient's ability to make a decision may fluctuate because of their condition which affects their ability to understand, retain or weigh up the information, or communicate their wishes.

6.3 Additional support may have to be considered in cases where the patient suffers dementia or has learning difficulties. Such steps must include:

6.3.1 speak to the patient about their treatment options at the time when they are best able to understand and retain the information;

6.3.2 ask the patient if there is anything that you can do to help them retain information or to make the decision making process easier: bringing along their partner, relative, friend, carer or advocate; having information in written or audio format, detailing their condition and proposed treatment or investigation;

6.3.3 ascertain from those close to the patient and other care staff the best ways in which to communicate with the patient, but maintaining the awareness for the need for confidentiality;

6.3.4 offer a written record of your discussions with the patient, decision taken and the reason;

6.3.5 record all decisions made, wherever possible, when the patient has the ability to understand and retain the information, bearing in mind, any Advance Decision they may have made regarding refusal of treatment;

6.3.6 involve other health professionals e.g. Speech and Language Therapist, Learning Disability Nurse etc. as appropriate.

7.0 Best interests

7.1 Treatment would be in the best interests of the patient if it is done to save life or to ensure improvement or prevent deterioration in their physical or mental health.

7.2 The person making the decision in the patient's best interest must take all reasonable steps to deal with any unforeseen changes that might occur which will affect the patient's ability to make a decision.

7.3 To ascertain a patient's best interests, the person making the decision must consider all relevant circumstances, and in particular the following:

7.3.1 whether the incapacitated person will at some time in the future have capacity in relation to the matter in question, and if so, when;

7.3.2 as far as reasonably practicable, permit and encourage the incapacitated person to participate as fully as possible in the decision making process;

7.3.3 where the decision relates to life sustaining treatment, begin by assuming that it is in the person's best interests for his or her life to continue;

7.3.4 as far as is reasonably ascertainable have regard to the person's past and present wishes and feelings, past beliefs and values and any other relevant factors;

7.3.5 take into account the views of other parties interested in the person's welfare e.g. informal carers, family friends, professional and voluntary carers, anyone appointed under Lasting Power of Attorney, someone appointed by the Court, etc.

Independent Mental Capacity Advocates (IMCA)

7.4 An IMCA is someone appointed to support a person who lacks capacity and has no one to speak for them. The IMCA makes representations about the person's wishes, feelings, beliefs and values, at the same time as bringing the decision maker's attention to all factors that are relevant to the decision. The

IMCA can challenge the decision maker on behalf of the person lacking capacity if necessary.

8.0 Disagreements

8.1 A consensus must be reached as to the care and treatment to be provided to the patient in their best interests, by providing the time and opportunity to seek the views of those who have an interest in the patient's welfare. Where there is disagreement, the following options can be considered:

- involving an independent advocate or local mediation service;
- consulting a more experienced colleague, or an independent expert;
- a case conference;
- seek advice from the Trust Ethics Committee (referral process on the intranet).

If a significant disagreement persists, take advice from Legal Services.

9.0 Restraint

9.1 Section 5 of the Mental Capacity Act, provides statutory protection against civil or criminal liability for assault and trespass to person for actions done in connection with the care or treatment of another considered to be in the best interests of someone who lacks capacity, provided that if:

9.1.1 before doing the act, reasonable steps are taken to establish the lack of capacity in relation to the matter in question; and when doing the act it is reasonably believed that;

9.1.2 the person being cared for or treated lacks capacity in relation to the matter; and

9.1.3 it will be in the best interests of the person being cared for or treated, for the act to be done.

9.2 Restraint is defined by the Act as the use or threat of use of force where a person lacking capacity resists and any restriction of liberty or movement whether or not the person resists. However, the statutory defence will not arise if a person who is caring for or treating another, does an act intending to restrain that other person unless in addition to the requirements above where, the person using restraint reasonably believes it is necessary to prevent harm to the person lacking capacity; and the restraint used is proportionate to the likelihood and seriousness of the harm.

10.0 Treatment in an emergency

10.1 A patient can be treated in an emergency without their ability to consent where they require immediate, necessary treatment in order to sustain their life or prevent a serious deterioration of their condition.

The treatment must be the least restrictive on a patient's future choices and only last as long as the patient lacks the capacity to make a decision for themselves. As soon as the patient regains capacity and is able to

understand, they must be told of what treatment they have been given and why.

11.0 Lasting Powers of Attorney (LPA's)

11.1 The Act allows a person (donor) to appoint an Attorney to act on their behalf if they lose capacity in the future. This is similar to the existing Enduring Power of Attorney (EPA) but the Act also allows people to authorize an Attorney to make health and welfare decisions. Unlike EPAs, LPA's will have to be registered with the new Court of Protection once the person loses capacity, before they will be valid under the Act.

11.2 There are two types of Lasting Power of Attorney, these are:

11.2.1 Property and Affairs, which deals with an individual's finances, possessions and property, etc.;

11.2.2 Personal Welfare, which deals with an individual's health and welfare matters.

11.3 It must be noted that an Attorney acting under a registered LPA for Personal Welfare has no power to consent to, or refuse life-sustaining treatment, unless the LPA document expressly authorizes it.

12.0 Key Aspects of Lasting Powers of Attorney (LPA)

12.1 The donor must be aged over 18 and must have mental capacity at the time the power is executed.

12.2 The donor may at any time, when they have capacity, revoke an LPA.

12.3 An attorney must exercise their powers under the LPA subject to the "best interests" requirements in the Act and to any conditions or restrictions that the donor may choose to put in the LPA.

12.4 Where an LPA deals with decisions about welfare the Attorney will, subject to any donor restrictions, be able to give or refuse consent to treatment;

12.5 An LPA will not allow an Attorney to refuse consent to life – sustaining treatment unless authority is expressly given.

13.0 Advance Decision to Refuse Treatment

13.1 The Act replaces the existing common law relating to living wills or advance directives, which permits people to decide in advance to refuse treatment if they should lose capacity in the future.

13.2 An advance decision (AD) is a statement made in advance of a decision to refuse treatment or the continuation of treatment at a later date in specified circumstances should the person making the AD lack capacity at the time.

13.3 Such an AD will have no application to treatment which a doctor considers is necessary to sustain life unless strict formalities have been compiled with. These formalities are that the decision must be in writing, signed and witnessed by at least one person in the presence of the maker. All AD's that relate to life-sustaining treatment must also include a statement that is to

apply “even if life is at risk”.

14.0 To be Valid an AD must:

- be made by a person aged 18 or over who must have capacity at the time the AD is made;
- specify the treatment that is being refused, although this can be in lay terms;
- specify the circumstances in which the refusal will apply;
- not have been withdrawn by the person making it;
- not be overridden by a subsequent LPA; and

The person making the AD must not have acted in a way which is clearly inconsistent with the AD remaining their fixed decision.

15.0 An AD will not be applicable if:

- the person actually has capacity to make the decision when the treatment concerned is proposed;
- there are reasonable grounds for believing that the current circumstances were not anticipated by the person and, if they had been anticipated by them, this would have affected their decision;
- the circumstances specified in the AD are not present; or
- the treatment proposed is not that specified in the advanced decision

16.0 For further advice on the Mental Capacity Act, Advance Decisions, Lasting Powers of Attorney and Consent to Treatment, please contact the Trust’s Legal Services Office on extension 85956.

APPENDIX 1

Identifying who makes the decision when a patient lacks capacity

1. An Advance Decision to Refuse Treatment created when the patient had capacity must be followed provided that it is up to date with current medical opinion. If there is no advance decision:
2. The views and wishes of a person with a registered Lasting Power of Attorney for health and welfare issues, donated by the patient when they had capacity, must be implemented unless you believe they are not acting in the patient's best interests (when you should discuss with the Safeguarding team and, or Legal Services with a view to approaching the courts. If there is no Lasting Power of Attorney:
3. A Court appointed deputy or an order from The Court of Protection should be followed. If none is available:
4. The clinician responsible for carrying out the proposed intervention is The Decision Maker.

Attachment 4a

Policy Reference: **CP 06**

Procedure Title: **Procedure for treatment of patients who refuse consent to the use of blood and blood products**

1.0 Detail

1.1 Competent adult patients have a fundamental legal and ethical right to determine what happens to their own bodies. This right includes the right to decide what treatment to accept or refuse, including blood transfusions, notwithstanding the potential serious or even fatal consequences.

1.2 To administer blood to a competent adult in the absence of his or her consent or against their wishes is **unlawful** and ethically unacceptable and could lead to criminal, civil or disciplinary proceedings and, or action by your professional body.

1.3 Patients may refuse blood transfusions for many reasons, including: -

- Religion
- Safety concerns
- Antibodies
- Previous transfusion reactions to blood / blood components
- Previous bad experience

1.4 The main group of people who may refuse blood or blood products for religious reasons are Jehovah's Witnesses, who believe that the bible forbids the consumption of blood or blood products. Jehovah's Witnesses will therefore not accept a transfusion of whole blood or its measured derivatives. This includes fresh frozen plasma, packed red cells, white cells and platelets. Predeposit and storage of autologous blood is not acceptable. However absolute rules regarding other blood products do not exist and assumptions must never be made; some Jehovah's Witnesses may accept the use of plasma derivatives, with each Jehovah's Witness deciding individually which are acceptable to them.

1.5 In any case where a clinician needs further advice, please contact any of the following:

- Consultant Haematologist Lead for Transfusion Medicine (via switchboard)
- Legal Services Manager – ext. 5956
- Hospital Liaison Committee for Jehovah's Witnesses (Numbers below)

Out of Hours

- Consultant Haematologist on-call (via switchboard)
- On – call Trust Manager / Director (via switchboard)
- Hospital Liaison Committee for Jehovah's Witnesses:

Neil **Farmer** 01384 565308 / 07976 867421

Tom **Felton** 0121 354 3300 / 07973 669503

Roy **Jackson (Chair)** 0121 605 6613 / 07889 648508

Steven **Meah** 0121 240 9159 / 07958 546883

Paul **Millard** 0121 350 9108 / 07769 667723

Chris **Porter** 02476 317526 / 07970 072780

Gerald **Taylor** 01386 45639 / 07767 640447

Raphael **Waite** 0121 605 0567 / 07811 270511

2.0 Legal Position With Respect To Consent

2.1 The following is only a summary of part of the law, for further detailed information please refer to the Trust's Consent Policy.

Competent Adults

2.2 In law there is a presumption that an adult has capacity to consent to or refuse treatment. In order to be valid, consent must be informed and given freely by a competent person, without undue influence.

2.3 Capacity requires the patient to have the ability to:

- understand the information presented to them;
- retain the information;
- weigh the information in the balance as part of the decision making process; and
- communicate their decision.

2.4 Capacity can fluctuate over time and in relation to the nature or seriousness of the condition in question and should therefore be kept under review.

2.5 There is no legal requirement for consent to be given in writing. It is however, good practice that consent should be in writing. It is important that a clear and comprehensive entry is made in the medical records of the patient as well as the completion of the consent form, so that it can be produced as evidence of the action taken by the health professional staff.

2.6 A valid and applicable advance refusal of treatment is as valid as a contemporaneous decision and must be respected.

Adults who lack capacity

2.7 If a patient does not have capacity and there is no evidence of a valid and applicable advance refusal, then s / he can be treated in accordance with his / her best interests (see CP06 attachment 1 sections 14 to 17).

2.8 It is for the multi-disciplinary team to decide what treatment, if any, would be in the patient's best interests. The patient's views, in so far as the patient is able to express them or has previously expressed them, should be taken into consideration, as well as the views of the patient's family and friends, bearing in mind issues of patient confidentiality. In cases of dispute it may be necessary to seek a declaration from the Court and urgent advice should be

sought (see section 1.5). For patients who lack capacity to consent and have no one to whom staff can go to for advice, the Independent Mental Capacity Advocate (IMCA) should be contacted (Mental Capacity Act 2005). In an emergency situation staff should act in the patients best interests.

Minors

2.9 At the age of 16 a young person may consent to treatment, in the same way as if he / she were of adult age i.e. someone aged 18 and over. A decision to accept blood products would override any parental refusal. If the young person does not have capacity then a person with parental responsibility can consent on their behalf.

2.10 There is no presumed capacity in children under 16 years, however a Gillick-competent child (see CP06 attachment 1 sections 9 to 11), can make his or her own decision, which would override any parental refusal. Otherwise, a person with parental responsibility can consent on their behalf

2.11 Consent to proceed with a blood transfusion is only required from one person, namely from the competent minor patient or a person with parental responsibility, however as a matter of good practice those with parental responsibility should be involved in the decision making process wherever possible.

2.12 If a minor refuses to accept blood products, or a person with parental responsibility refuses to give consent on behalf of an incompetent minor, urgent advice should be sought (see section 1.5).

3.0 Clinical Management

3.1 In any procedure or situation where blood transfusion is anticipated or indicated the following procedure must be adopted:

- The possible need for a blood transfusion must be raised with the patient and his / her views ascertained as early as possible.
- The patient should be clearly informed of the indications for blood transfusion and the risks, benefits and consequences of refusing a transfusion.
- The consequences of refusing a transfusion must be clearly explained in a non-confrontational and non-judgemental manner.
- It must be made clear to the patient that in certain circumstances refusing to accept a transfusion can be fatal.
- A copy of the National Blood Service leaflet, *Will I Need a Blood Transfusion'* must be given to the patient.
- Wherever possible the patient should be seen on their own, without any family or friends present, as they may influence or impede the discussion and the patient's decision.
- If there is any doubt as to the patient's capacity, then a second clinical opinion must be obtained and the facts and decisions recorded in the medical records.

Competent adults who refuse blood transfusions

3.2 Every effort should be made to determine the reason for the patient's refusal in a non-confrontational and non-judgemental manner. Having identified the patient's reason, staff must consider whether the patient's reason is an issue that can be addressed and resolved, for example if the patient has safety concerns or had a previous bad experience, consider whether there is somebody else in the hospital able to talk to the patient and reassure them (e.g. Consultant, Transfusion Specialist etc.).

3.3 The patient must be informed of all available alternative forms of treatment, including techniques which are available to reduce intra-operative blood loss.

3.4 A clear record must be made of what treatment the patient will and / or will not accept. The patient's decision must be clearly communicated to all members of staff involved in the patient's care.

Elective surgery

3.5 Pre-operative patients must have their full blood count levels checked in keeping with NICE CG03 on preoperative testing. If abnormal, arrange appropriate investigation and treatment.

3.6 During pre-operative assessment, a discussion MUST take place between the patient and the Consultant responsible for the patient's care (Surgeon and / or Anaesthetist), and a meeting arranged with the patient to discuss the situation and alternative options (if any) such as pre-operative iron repletion, intra-operative cell salvage or erythropoietin.

3.7 It is essential that clinicians discuss treatment options and risks with the patient. During this process, the consultant in charge must balance the risks and benefits of carrying out the procedure with the patient. The patient and consultant in charge of the case must be allowed to have thinking time prior to surgery to assess perceived benefits and risks of the planned surgery.

3.8 Clinicians are not obliged to perform any procedure where they genuinely believe that the procedure cannot be safely performed under the patient's stipulated conditions. However, every effort should be made to refer the patient to a suitably qualified colleague who is prepared to perform the procedure. Where no such individual can be identified within the Trust, the patient should be referred back to his / her GP.

Adults who lack capacity who require blood transfusion

3.9 In the event of a trauma or emergency admission, a patient may not be able to communicate their wishes (for example an unconscious patient) or may not have capacity to consent to or refuse treatment.

3.10 Where there is a valid and applicable advance refusal in existence, this is as valid as a contemporaneous decision and must be respected. Practising Jehovah's Witnesses normally carry with them a document clearly refusing blood or blood products. A copy of this document may be within the patient's case notes, GP records and / or with family or friends. A specimen Advance decision is attached as Appendix 1.

3.11 Where there is no evidence of an advance refusal the patient should be treated in accordance with his / her best interests.

3.12 Where there is doubt as to the validity or applicability of an advance refusal,

urgent advice should be sought (see section 1.5). In an emergency the patient should be treated in accordance with his / her best interests, however alternatives to blood or blood products should be used if possible.

Children requiring blood transfusion

3.13 Remember that your duty of care is to the patient and not to anyone with parental responsibility. The well-being of the child is paramount.

3.14 In a non-emergency situation, where consent is withheld, it may be necessary to seek a declaration from the Court in advance of the procedure and advice should be sought (see section 1.5).

3.15 In a life threatening situation, clinicians are under a duty to act in the minor patient's best interests and should preserve life by providing clinically necessary treatment, including blood transfusions, notwithstanding any views to the contrary by a person(s) with parental responsibility. It is possible to obtain a declaration from the Court within a short timescale (i.e. 1 to 2 hours), however if there is insufficient time to seek a declaration, the Consultant should decide what treatment is to be given in the minor patient's best interests and, where time permits, this decision should be made in conjunction with another Consultant or other appropriate clinician. In an emergency, and in the absence of consent or a court declaration, blood and / or blood products must only be given in so far as they are necessary. Once the minor patient has been stabilised it may be necessary to seek a declaration, particularly if further treatment is likely to be required, and advice should be sought (see section 1.5).

Management of women during pregnancy, labour and post delivery

3.16 Women in pregnancy and during labour have the same rights as any other competent adult to determine what treatment they receive, notwithstanding the serious or even fatal consequences to them or the foetus.

3.17 Upon identification of a woman's absolute refusal of blood or blood products, the consultant Obstetrician MUST ensure discussion of the implications and alternatives. The agreed alternatives should be readily available at estimated time of delivery.

3.18 Specific delivery suite guidelines cover management of the patient during pregnancy, labour and post-partum and should be followed.

4.0 Documentation and record keeping

4.1 Clear, accurate and detailed record keeping is essential.

4.2 All discussions relating to the patient's care and decisions taken must be clearly and accurately recorded within the case notes and signed by the author, including the author's name in print.

4.3 Where a patient refuses blood and / or blood products, the agreed procedures, alternatives and non-acceptable treatments should be entered into the case notes. An Advance Decision, where appropriate should be included in all sets of notes.

4.4 The appropriate Consent Form must be completed, in accordance with the Trust's "Policy for Consent to Treatment and Examination". It must be noted on the consent form that certain aspects of treatment have been refused and,

where appropriate, reference made to the entries in the case notes for the relevant details.

4.5 Where an advance refusal is to be relied upon or rejected, a full explanation must be entered into the case notes and countersigned by the health professional author and, where possible, a second health professional of the same standing.

4.6 It is very important that the thought processes of staff are clearly evidenced in their entries in the medical records since they may come to rely on them at a later date.

Appendix 1

Advance Decision to Refuse Specified Medical Treatment

1. I,_____(print or type full name), born_____(date) complete this document to set forth my treatment instructions in case of my incapacity. **The refusal of specified treatment(s) contained herein continues to apply even if those medically responsible for my welfare and / or any other persons believe that such treatments are necessary to sustain my life.**

2. I am one of Jehovah's Witnesses with firm religious convictions. With full realization of the implications of this position I direct that **NO TRANSFUSIONS OF BLOOD or primary blood components (red cells, white cells, plasma or platelets)** be administered to me in any circumstances. I also refuse to pre-donate my blood for later infusion.

3. **Regarding minor fractions of blood,** for example: albumin, coagulation factors, immunoglobulin etc, (initial **one** of the three choices below):

   (a) _____I refuse all

   (b) _____I accept all

   (c) _____I want to qualify either (3a) or (3b) above and my treatment choices are as follows:

   _____

   _____

   _____

4. **Regarding autologous procedures** (involving my own blood, for example: haemodilution, heart bypass, dialysis, intra-operative and post-operative blood salvage):

   [Initial **one** of the three choices below.]

   (a) _____I refuse all such procedures or therapies

   (b) _____I am prepared to accept any such procedure

   (c) _____I accept only the following procedures:

   _____

   _____

   I am prepared to accept diagnostic procedures, such as blood samples for testing.

5. **Regarding other welfare instructions** (such as current medications, allergies, and medical problems):

   _____

   _____

   _____

   _____

   _____

6. I consent to my medical records and the details of my condition being shared with the Emergency Contact below and / or with member(s) of the Hospital Liaison Committee for Jehovah's Witnesses.

7.

Signature
Date

Address

8. **STATEMENT OF WITNESSES:** The person who signed this document did so in my presence. He or she appears to be of sound mind and free from duress, fraud, or undue influence. I am 18 years of age or older.

Signature of Witness		Signature of Witness	
Name	Occupation	Name	Occupation
Address		Address	
Telephone		Telephone	
Mobile		Mobile	

9. **EMERGENCY CONTACT:**

Name

Address

Telephone Mobile

10. **GENERAL PRACTITIONER CONTACT DETAILS:** A copy of this document is lodged with the Registered General Medical Practitioner whose details appear below.

Name

Address

Telephone Number(s)

NO BLOOD

(signed document inside)

Advance Decision to Refuse
Specified Medical Treatment

Advance Decision to Refuse
Specified Medical Treatment
(signed document inside)
NO BLOOD

Jehovah"s Witness Hospital Liaison Committee

Information and referral service

Main Office (London) **Tel: 020 8906 2211**

Local contact (Roy Jackson) **Tel: 0121 605 6613 & 07889 648508**

References

Gillick v West Norfolk and Wisbech Area Health Authority (1985) 3 All England Law Reports 402

McClelland DBL (2001) The Handbook of Transfusion Medicine

NHS Executive. Better Blood Transfusion: Appropriate Use of Blood. Department of Health, London 2002 (Health Service Circular 2002 / 009)

Shrewsbury and Telford Hospital NHS Trust Policy for patients who refuse to receive blood and blood products (2006)

University Hospitals Coventry and Warwickshire NHS Trust Policy for the treatment of patients who refuse consent to the use of blood and blood products (2006).

Attachment 4b

Policy Reference:	**CP 06**
Procedure Title:	**Procedure for obtaining consent for blood and or blood products transfusion**
Author:	**Hospital Transfusion Practitioner**
	Implemented April 2014
Implementation & monitoring:	**Hospital Transfusion Team**

Procedure for obtaining consent for blood and/or blood products transfusion

1.0 Procedure Statement

1.1 It is a general legal and ethical principle that valid consent must be obtained from a patient before they are treated. The Department of Health set up the Good Practice in Consent initiative and published a National guidance framework for consent. However, as blood transfusion is often an additional procedure during a course of treatment there is no specific guidance given for blood transfusion.

1.2 SaBTO (Safety for Blood, Tissues and Organs – an advisory committee to the Department of Health) have identified the following issues:

- Patients are not always given information on the risks, benefits and alternatives to transfusion, or the right to refuse transfusion.
- Patients are not always made aware that they have received a transfusion.
- Patients who are unaware that they have received a transfusion may go on to donate blood when they should not.
- There is inconsistent practice in the UK.

1.3 In March 2010 SaBTO initiated a public consultation on patient consent for blood transfusion through the Department of Health website resulting in a number of recommendations, the following of which are relevant to the organisation:

- Valid consent for blood transfusion should be obtained and documented in the patient's clinical record by the healthcare professional.
- There should be a modified form of consent for long term multi-transfused patients.
- Patients who have received a blood transfusion and who were not able to give valid consent prior to the transfusion should be provided with information retrospectively.

2.0 Accountabilities

2.1 The Hospital Transfusion Group is accountable for initial ratification of the procedure and responsible for ensuring the procedure is communicated to the relevant Healthcare Professions leaders and managers (Clinical Directors, Heads of Nursing, Head of Midwifery and Matrons).

2.2 The Healthcare Professions leaders and managers (Clinical Directors, Heads of Nursing, Head of Midwifery and Matrons) are responsible for distributing the procedure to all relevant staff within their spheres of responsibility.

2.3 The Hospital Transfusion Team is will actively promote implementation of the procedure, monitor compliance through clinical audit and report back to the Hospital Transfusion Committee.

2.4 All relevant healthcare staff are accountable for their own competence and must act within their limits of competency with regards to seeking valid consent for blood transfusion.

3.0 Procedure Detail / Actions

3.1 The decision to transfuse and consent to transfusion must, where possible, be made in advance with the patient (or for paediatric/neonatal patients those with parental responsibility).

3.2 Patients receiving a transfusion must be informed of the indication for the transfusion as well as an explanation of the risks, benefits and alternatives and also the right to refuse transfusion. This must be done in a timely manner and in a way they understand.

3.3 In an elective situation where the patient has not been consented, the practitioner must not proceed with the transfusion but escalate to the medical officer responsible for that patient's care, who must then consent the patient or assess the clinical risk of delay in transfusion and authorise the transfusion in the absence of consent if indicated.

3.4 Where consent is not possible, for example in emergency situations and/or the patient has no capacity to consent, in the absence of a valid "Advanced Directive", medical clinical judgement must be used as the patient may require transfusion in their best interest.

3.5 If a patient refuses consent for blood transfusion, please refer to CP06 Consent to Treatment Policy - Attachment 4a "Procedure for treatment of patients who refuse to consent to the use of blood and blood products"

3.6 The patient's medical record must contain evidence that the patient has either given valid consent, or was unable to. There are 3 ways of documenting that consent has been obtained, depending on the category of the patient group, which are as follows:

- Group 1

  The existing Trust Consent form (Consent form 1 "Patient agreement to investigation or treatment") has a section for blood transfusion which must be utilised for patients undergoing elective surgical procedures, interventions, or a planned episode of treatment where consent is required (e.g. chemotherapy) and there is a high probability the patient will require a transfusion of blood or blood components.

- Group 2

  The paediatric / neonatal Directorates utilise a "sticker" for transfusion which includes the requirement for verbal consent to be obtained for transfusion.

(Neonatal sticker - appendix 1)

(Paediatric sticker – appendix 2)

- Group 3

  A "Documentation of Informed Consent for Transfusion" sticker will be used for all other patients who do not fit into Group 1 or 2 categories. This will include long term "multi-transfused" patients' e.g. haematology patients, all "elective" transfusions and also emergency cases where retrospective information needs to be given because consent could not be obtained prior to transfusion due to urgency of situation e.g. trauma, emergency surgery, unexpected intra-operative bleed etc. (appendix 3).

3.7 Consent for transfusion must be obtained by one of the following healthcare professionals:

- The clinician responsible for obtaining consent in Group 1 (elective surgical procedures/interventions/planned care)
- The healthcare professional making the clinical decision to transfuse and / or "prescribing" the blood/blood components to be transfused.

3.8 There is no requirement to obtain a signature from the patient (or for paediatric / neonatal patients those with parental responsibility) for blood transfusion consent alone.

3.9 There must be a signature of the healthcare professional responsible for obtaining consent on the relevant document in the medical records.

3.10 A single stage process for blood transfusion consent is acceptable. Two stage consent is not required.

4.0 Resources

Patient information leaflets:

Patient information leaflets produced by the UK Blood Services are available in all pre-operative assessment areas and all clinical areas where transfusions take place or alternatively are available from the Hospital Transfusion Practitioner (ext 6709 / bleep 7581). The relevant information should be given to the patient (or for paediatric/neonatal patients those with parental responsibility) prior to the transfusion where possible, or in an emergency situation the information should be given retrospectively.

The following patient information leaflets are available:

- Will I need a blood transfusion?
- Will I need a platelet transfusion?
- Information for patients needing irradiated blood
- Iron in your diet
- "Will your child need a blood transfusion"? [Pack]
- "Will your baby need a blood transfusion"?
- "Will your child need a plasma transfusion"?

- Information for patients who have received an unexpected blood transfusion

Trust consent forms – available in all relevant clinical areas

Neonatal / Paediatric stickers for transfusion – available in NNU / Paediatric departments

Consent for Transfusion stickers – to be distributed to all clinical areas / departments where consent for transfusion may be required.

5.0 Training

The requirement to obtain blood transfusion consent will be included in the mandatory training content, provided through the Trust mandatory training days, induction programmes, specialty in- service training and via the e-learning package.

6.0 References

SaBTO (2011) *Patient Consent for Blood Transfusion*

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216586/dh_130715.pdf

Neonatal Sticker

Appendix 1

BLOOD TRANSFUSION (Remember Pre-transfusion Blood Spot)

Date:_____
Birth Weight (kg):_____Current Weight (kg): _____
Product to be transfused (red cells/platelets/plasma_____
Indication for Tx:_____

Parent Information Leaflet given ☐ *(please tick)* Parent verbal consent – No/Yes

Volume:_____(mL/kg) =_____mls

Furosemide – No / Yes - Indications:_____

Dr/ANNP (sign & print):_____

Pre Hb (g/dl): _____

Time Tx commenced:_____

Observations:

	Pre Tx.	15 mins	30 mins	Post Tx.
HR				
B/P				
Temp				
Resp				

Time Tx stopped:_____ Batch number:_____

Actual volume infused:_____

Nurse (sign & stamp):_____

Post Hb (g/dl):_____8 hrs after transfusion

Paediatric Sticker

Appendix 2

BLOOD PRODUCT TRANSFUSION

Date:_____ Weight (kg):_____

Indication for Tx:_____Hb (g/dL):_____

Volume:_____(ml/kg) =_____mls / Units

(See guidelines on intranet; transfuse to nearest full bag if needed)

Product to be transfused (red cells/platelets/plasma)_____

Patient information given Y / N Verbal Consent obtained Y / N

Doctor (sign & print):_____

Time Tx commenced:_____

Observations:

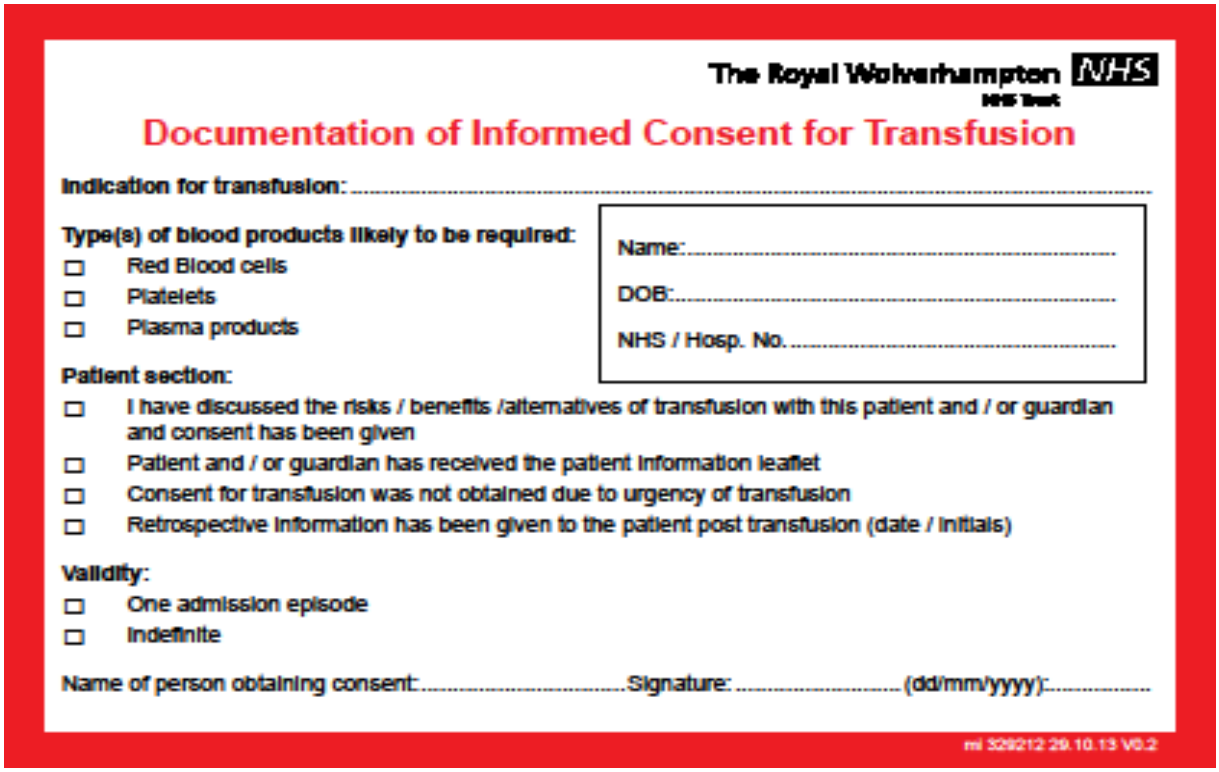
	P	1	3	P
H				
B				
T				
R				

Time Tx stopped:_____Batch Number_____

Volume infused:_____Nurse (sign & stamp):_____

Appendix 3

Consent Sticker



The Royal Wolverhampton NHS
NHS Trust

Documentation of Informed Consent for Transfusion

Indication for transfusion: .....

Type(s) of blood products likely to be required:

- ☐ Red Blood cells
- ☐ Platelets
- ☐ Plasma products

Name: .....

DOB: .....

NHS / Hosp. No. .....

Patient section:

- ☐ I have discussed the risks / benefits /alternatives of transfusion with this patient and / or guardian and consent has been given
- ☐ Patient and / or guardian has received the patient information leaflet
- ☐ Consent for transfusion was not obtained due to urgency of transfusion
- ☐ Retrospective information has been given to the patient post transfusion (date / initials)

Validity:

- ☐ One admission episode
- ☐ Indefinite

Name of person obtaining consent: ..... Signature: ..... (dd/mm/yyyy): .....

ml 328/212 29.10.13 V0.2

CP06 Attachment 5 - Delegated Consent

Policy Reference: **CP 06**

Procedure Title: **Consent to Examination or Treatment**

Specialty Specific Training Package for Healthcare Professionals Obtaining Consent

1.0 Introduction

Background

1.1 Informed consent is essential for all healthcare interactions.

1.2 It is assumed that all consultants, senior dentists, Allied Health Professionals and non-consultant career grade doctors are trained to take consent for any procedures that they are competent to perform. Also, there are also nurses who have been trained to undertake invasive procedures who can take consent for those procedures.

1.3 Consent may be taken by other doctors or health care practitioners who are trained and competent to take consent for specific procedures even though they are not capable of performing those procedures – this is delegated consent, because the person taking consent is doing so on behalf of the practitioner who will do the procedure and, or the consultant in charge of the patient's care. This includes all doctors in training except Foundation Year 1 doctors, because they are not permitted to take formal, written consent. The person taking consent will have full responsibility for the consenting process.

1.4 The enclosed pack contains information required to support delegated consent within Directorates.

2.0 What does the pack contain?

2.1 2.1.1 Details of Healthcare Professionals who are authorized to take delegated consent and evidence of competence.

- This will provide the directorate with an up to date list of which staff are competent to take delegated consent for which procedures.
- The list will require regular updating when staff start or leave.

2.1.2 Letter to person authorized to take delegated consent.

- This must be given to each person who is assessed as competent so that they understand the implications of what they are doing.

2.1.3 List of procedures for which delegated consent is authorized.

- The list will be specific to the individual person and will detail only the procedures for which the person can take delegated consent.

2.1.4 Procedure-specific details.

- The person taking consent must know, for each procedure, what is involved, the intended benefits, any alternative procedures, and the risks and benefits of the proposed procedure and the alternatives (including doing nothing).

2.1.5 GMC Guidance on the consent process

2.1.6 Evaluation

- In order to be able to take delegated consent, the person must be assessed by the responsible clinical lead.

2.2 A completed pack must be kept by the Directorate to provide evidence of each healthcare professional's competence to take consent.

2.3 Items 2.1.2 to 2.1.6 must be provided as an individual pack to each person who has been authorised to take delegated consent.

3.0 Process

3.1 Competence requires a demonstrable understanding of the consent process in general and the specific details of each procedure for which consent is to be sought. The person obtaining consent must know when to get advice from a more experienced colleague.

3.2 Each person's competence must be approved by the Clinical Lead for whom they are taking consent. If the person will be taking consent for procedures on behalf of a number of clinicians, only one Lead Clinician needs to sign-off their competence. The process of delegated consent will be audited and the results will be fed back to consultant leads for local action.

3.3 If there is concern over the person's competence to take consent, then their authority to do so must be suspended until the person has undergone further training and assessment. The concern must be communicated to the relevant Clinical Director and the Consultant in charge of the care of the patient.

3.4 If a clinician is required to obtain consent for a procedure and they do not think they have the necessary skills and knowledge to do, they must consider raising a formal concern (see HR16 *Raising Concerns at Work Policy* and *Raising and acting on concerns about patient safety*, GMC January 2012).

4.0 Review

4.1 This pack must be reviewed on a regular basis to ensure that the information held in it is up to date and relevant.

5.0 Details of Healthcare Professionals* who are authorized to take delegated consent and evidence of competence.

The Health Professionals listed below have been educated in the principles of and the Trust Policy on informed consent and understand the need to:

1. Give the patients the information they ask for or need about their condition, its treatment and prognosis
2. Have sufficient knowledge of the investigation / procedures and the benefits and risks involved
3. Know the alternatives to the proposed treatment, including the option not to have treatment
4. Be able to communicate the information to patients in a way that they understand
5. Refer to a senior colleague if unable to answer all of the patients questions

Health Professionals name	Grade	Procedure 1	Procedure 2	Procedure 3	Procedure 4	Procedure 5	Procedure 6	Procedure 7	Procedure 8	Procedure 9	Procedure 10	Procedure 11	Procedure 12	Procedure 13	Procedure 14	Procedure 15	Procedure 16	Procedure 17	Procedure 18	Procedure 19	Procedure 20	Signature Trainee	Signature of the Clinical Lead	Date

*** This applies to all training grade medical staff above PRHO and other relevant clinical professionals. Consultants who are undertaking consent for a procedure that they do not undertake must also be included on the list.**

6.0 Letter to person authorized to take delegated consent

Dear _____

This package has been designed to ensure that you can obtain informed consent for the specific procedures listed on the following page. The aim is to ensure that all patients are given consistent and adequate information. You must read the Trust Consent Policy CP06 including all the attachments to the policy (it is available on the Trust Intranet site), and you must have completed and be up-to-date with the Trust Mandatory Training for consent.

The Clinical Lead responsible for the patient's care is ultimately responsible for ensuring that properly informed consent has been obtained. To take properly informed consent you must have sufficient knowledge of the proposed procedure to provide any information that the patient wants, particularly:

- The nature of their condition
- The type and complexity of the proposed procedure
- The benefits and the anticipated outcome of the procedure
- The risks associated with the treatment or procedure and their severity
- Alternatives to the treatment (including the option not to treat)
- Consequences of the proposed treatment
- Consequences of not accepting the proposed treatment

It is important that you also give out any relevant Trust written information to reinforce what you have said.

The teaching that you have had is unlikely to cover every issue that a patient may raise. It is important that you are aware of your own knowledge limitations and that your work will be audited. If a patient asks any questions that you feel you are unable to answer, you must refer to a senior colleague.

Signed: _____

Clinical Lead

7.0 List of procedures for which consent is authorised

Name:_____ **Grade:**_____

NMC / BMA / HCIC Registration No.: _____

PROCEDURE	PAGE

Signature of Assessor_____ Date: _____

Signature of person
authorised to take consent:_____ Date:_____

8.0 Procedure Specific Details of Required Information (to be completed for each procedure)

Procedure:
Description of proposed procedure including type of anaesthesia
Intended Benefits and anticipated outcome of the treatment
Serious or frequently occurring risks
Available alternative treatments, including no treatment
Possible consequences of not accepting the proposed treatment

9.0 Refer to Consent Policy CP06 attachment 1 Guide to Consent to Treatment and Investigation

10.0 Competency Assessment: Health Professionals Obtaining Informed Patient Consent for Treatment or Investigation

Name:_____

Position: _____

I have assessed the knowledge of the generic requirements for taking informed consent and I have assessed the knowledge of the specific procedures list above, and I confirm that _____ is authorized to take delegated consent for these procedures.

Signature of Assessor:_____

Signature of Person Assessed:_____

Attachment 6

Policy Reference:	**CP 06**
Document Title:	**Obtaining Informed Consent from Subjects participating in Research Trials**

1.0 Policy Statement

The purpose of this policy is to set standards of practice for Trust staff who are involved in the informed consent process for Research.

Standards and governance have been built on many years of research practice and have led to the development of legal directives such as the Declaration of Helsinki, Medicines in Human Use (Clinical Trials) Regulations 2004 and Mental Capacity Act (2005).

The legal directives require that the process of seeking valid informed consent is well structured, transparent, properly documented and delivered in a way that protects the autonomy of the research participant and conforms to the Good Clinical Practice Standards.

2.0 Definitions

Chief investigator (CI): The lead researcher who has overall responsibility for the conduct of the research study across the Trust and any other sites the research is being conducted.

Principal Investigator: A person that has overall delegated duty for the conduct of the research study at each individual participating research site.

Clinical Trial of an Investigational Product (CTIMP): An investigational product or device is defined in the Medicines for Human Use (Clinical Trials) Regulations 2004 as any investigation in human subjects.

Non- CTIMP Clinical Trial: Evaluation of an intervention/treatment that does not involve investigational medicinal products.

Research Ethics Committee (REC)- Review applications for research and give an opinion about the proposed participant involvement and whether the research is ethical

MHRA – Medicines and Healthcare Products Regulatory Agency is a government body which was set up in 2003 to bring together the functions of the Medicines Control Agency (MCA) and the Medical Devices Agency (MDA).

3.0 Policy Details

3.1 Responsibilities

The Principal Investigator (PI) has overall responsibility for ensuring informed consent is obtained from all research participants on the study at the participating site. Delegation of informed consent to an appropriate, suitably qualified member of the research team should be considered on a study-by-study basis. If staff other than the Chief Investigator (CI) and Principal Investigator (PI) are to accept responsibility for the informed consent process, it is important the following criteria are met:

i. S/he is prepared to take on this additional responsibility **AND** feels confident to seek informed consent in line with The Royal Wolverhampton NHS Trust (RWT) Policies and Procedures.

ii. S/he works within their scope of professional practice and adheres to their relevant professional codes of conduct.

iii. S/he has full understanding of the study, potential risks and benefits and the associated disease area. They should be qualified by experience and/or should have received appropriate training for the trial. Training must be documented on the Trial Training Log.

iv. This delegation of responsibility should be documented on the study delegation log and authorised by the Principal Investigator (PI)/ Chief Investigator (CI).

v. The process has been approved by the relevant Research Ethics Committee (REC).

vi. An effective line of communication is maintained back to the Chief Investigator (CI)/ Principal Investigator (PI) who is the person ultimately responsible for the subjects care.

vii. S/he has undertaken NIHR Good Clinical Practice (GCP) training and NIHR Valid Informed Consent Training (where required) in accordance with R&D Directorate Standard Operating Procedure R&D/S12.

It is ultimately the responsibility of the Chief Investigator (CI)/ Principal Investigator (PI) to ensure that all subjects understand fully what they are consenting to. It is usual practice for the Chief Investigator CI/ Principal Investigator (PI) or co-investigator to countersign the consent form when non-medics are taking consent for Clinical Trial of Medicinal Products (CTIMP) trials.

3.2 Procedure(s)

The informed consent process can only commence when the following regulatory approvals are in place: Clinical Trial Authorisation (MHRA) (if a CTIMP trial), Health Research Authority (HRA) and Research Ethics Committee (REC) approvals and Trust approval confirmation of capacity and capability.

3.3 Subject Enrolment and

Consent Eligibility

Assessment

3.3.1 The Principal Investigator (PI)/Chief Investigator (CI) is responsible for ensuring the eligibility of subjects who potentially fulfil the inclusion/exclusion criteria for a study. For Clinical Trials of Investigational Medicinal Products (CTIMP), this task cannot be delegated to non-medically qualified members of the team, regardless of who obtains consent.

3.3.2 Confirmation of eligibility must be documented within the medical records and all subjects assessed for eligibility must be included on the Study Screening Log.

3.3.3 Consent of the potential subject must be obtained and documented prior to any study procedures being performed UNLESS otherwise approved by Research Ethics Committee (REC).

3.4Providing Information to Potential Subjects

3.4.1. The Patient information sheet and informed consent form should be printed on Trust Headed paper except for studies where all procedures are conducted outside the Trust by researchers from another organisation. In these cases an introductory letter should be provided on Trust Headed Paper but the main information sheet and consent form would be on headed paper for the other organisation.

3.4.2All information given to the potential subject must be approved by the Research Ethics Committee (REC).

3.4.3All individuals asked to consider taking part in research should be given full information about the research in verbal and written form, presented in non-technical language and in a form that they can understand. Whilst discussing the research the person seeking consenting must complete the Consent Verbal Checklist (R&D Template R&D/T03).

When describing the study the person seeking consent should explain (this is not an exhaustive list):

1. What the purpose of the study is and any background information that may be relevant.

2. Why the subject has been approached and confidentiality will be maintained throughout the study, should they decide to participate.

3. Details of the study design and details of any drugs used. If there is a placebo arm or randomisation involved then these procedures should be explained.

4. The number of people taking part in the study how many have been recruited to date.

5. The duration of the study and the number of study visits involved. It should be explained where the subject will be seen and by whom.

6. All procedures, such as blood tests etc. that are part of the study should be included and explained in lay language.

7. The potential benefits and risks of participation in the study, and any alternative treatments available to the subject should be discussed.

8. That the subject enters the study voluntarily and can withdraw at any time without any prejudice to them or their future care.

9. That a detailed discussion of the subjects medical history will be required should they agree to participate.

10. That giving informed consent does not necessarily mean the subject will be enrolled into the study if it is discovered they do not meet the inclusion/exclusion criteria.

3.4.4 The potential participant should be invited and encouraged to ask questions about the research, which should be answered to the best ability of the person obtaining consent. If additional information is needed in order to answer any questions to the potential participant's satisfaction, then this should be obtained prior to completion of the consent process.

3.4.5 Whilst there are no statutory requirements specifying how long potential subjects should be allowed to consider the trial, it is expected as best practice for patients to be given a minimum of 24 hours to consider participation. Exceptions to this are made whereby approval from Research Ethics Committee (REC) has been granted for consent to be taken outside of the 24 hour timescale. Where a timescale is not stipulated and been approved by Research Ethics Committee (REC), then a pragmatic approach should be taken to assess the requirements of the study, information provided and understanding of the patients to determine how long should be granted for considering participation.

3.4.6 If a potential participant is unsure about participation, extra consideration time will be given and they will be advised to speak to an independent person (perhaps a colleague); or their GP who will have been provided with information about the research.

3.4.7 The person obtaining informed consent must be confident that:

- The potential participant fully understands what he/she is agreeing to.
- The potential participant fully understands the implications of any decisions that may be made within the course of the research.

3.5Documenting Informed Consent

3.5.1 The informed consent form must be initialled in the allocated boxes against each statement, signed and personally dated by the subject and signed and dated as witnessed by the person who conducted the consent discussion. The subject and person obtaining consent should print their names in block capitals.

3.5.2 There must be one signed copy for the subject, one original for the investigator site file and one copy for the subject's medical records. The Consent Verbal Checklist must also be filed alongside the consent form in the subject's medical records. The informed consent form must not be stored in a way which could lead to linage of patient identity with case report forms or other study data.

3.5.3 The subjects medical records must include details of the study, to include title of study, sponsor contact details, research team contact details, date and time patient consented, version of patient information sheet provided, version of consent form completed and the length of time the patient was given to consider participation.

3.5.4 The medical records for the subject must be updated to document the consent process. It is essential to ensure dates are recorded correctly in the subject's notes, as the timings of consent and initiation of study procedures are subject to audit.

3.6. Re-Consenting

If there are changes to the trial design, the medication used or risks associated with trial participation, then the subject may be required to re-consent to the study. Re-consenting of subjects should be considered by both the Principal Investigator (PI)/ Chief Investigator (CI) and the Sponsor and a measured approach to determine which participants should be re-consented. Subjects should be re-consented in a timely manner. It is generally accepted that subjects are re-consented at their next visit but investigators and the Sponsor should also consider contacting subjects to arrange an unscheduled visit depending on the new information that has become available.

3.7Witnessed Consent

In situations where a subject is able to consent but is unable to write, consent may be given and recorded through alternative means (e.g. verbally or by telephone) in the presence of at least one impartial witness.

The witness shall also sign and date the informed consent form and the process described in 3.5 for documenting the consent process shall be followed.

3.8Translators

3.8.1 Potential subjects should not be denied the opportunity of taking part in a research study simply because they are unable to understand English.

3.8.2. Wherever practical, a professional translator should be used to provide information about the study and to assist with receiving consent. The use of family members and friends to translate must be avoided.

3.8.3 If it is likely that a significant number of people from specific language groups may be recruited into the study, then copies of the information sheets and consent forms should be provided in their languages. These arrangements should be set out in the application to the Research Ethics Committee (REC).

3.9Implied Consent

3.9.1 For some questionnaire-based studies, consent may be implied by virtue of completing questionnaires or other forms or documents, a separate consent form may not be required provided this has been approved by Regional Ethics Committee (REC). Implied consent should also be document in the subject's hospital records.

3.9.2 Data that could identify the subject must not be transferred outside of the Trust where consent is implied. Any such plans to transfer data must be ethically approved and the participant's consent for this must be documented.

4.0Consent in Vulnerable Groups

Providing certain criteria are met, approval may be granted for research studies that involve adults lacking capacity or minors (children under the age of 16 years). If the study is a CTIMP, the informed consent process described in the Medicines for Human Use (Clinical Trials) Regulations (as amended) must be followed. For all other types of studies in England and Wales the Mental Capacity Act (2005) will apply.

4.1 Adults Lacking Capacity

There is a legal presumption that persons aged 16 years or older have capacity to give consent unless it is established otherwise.

The relevant definitions are as follows:

'Unable to make decisions for him or herself in relation to the matter because of an impairment of, or disturbance in the functioning of, the mind or brain. It does not matter whether the impairment or disturbance is permanent or temporary' (Mental Capacity Act, 2005).

'Unable by virtue of physical or mental incapacity to give informed consent' (Medicines for Human Use (Clinical Trials Regulations) 2004.

4.2 Assessment of Capacity

Where it is suspected that a person may lack capacity, an assessment must be made to establish whether the individual can:

- Understand information relevant to the decision.
- Retain information relevant to the decision.
- Use or weigh up the information in order to arrive at a decision.
- Communicate his/her decision.

When the assessment is carried out within the context of a research study, it must be conducted by the Chief Investigator (CI)/ Principal Investigator (PI), or another appropriately experienced clinician. The assessment and its results must be recorded on the subject's medical notes.

If, as a result of the assessment, a subject is deemed to meet the above criteria then s/he should be regarded as capable of giving informed consent to take part in the study. However, when a person is deemed to lack capacity, special provision must be made with regard to consent.

4.3 Consent in Vulnerable Groups for CTIMPs

Legal representatives must be approached to obtain consent on behalf of the subject; legal representatives must not be involved in the conduct of the trial. A potential subject's legal representative should be suitable to act as legal representative by virtue of their relationship with the adult and should be approached first if willing.

In the absence of a personal legal representative, a professional legal representative may be approached. The professional legal representative should be either the doctor responsible for the medical treatment of the potential subject who is not involved in the clinical trial or another nominated independent member of staff.

If a capable adult gives informed consent and then subsequently loses the capacity with regards to decision making, then their previous consent remains valid.

If a capable adult refuses informed consent and then subsequently loses capacity with regards to decision making, then the refusal to consent previously remains valid and

consent cannot be sought from a legal representative.

4.4 Consent in Vulnerable groups Emergency Situation

Where trial treatment needs to be given to an incapacitated adult immediately, there may not be time to obtain consent from a legal representative. The Medicines for Human use (Clinical Trials Regulations 2006 amendment), made additional provision for adults lacking capacity to be entered into a trial before written informed consent is obtained provided that it is not reasonably practicable to obtain informed consent prior to trial treatment and that the action taken is in line with the procedure given a favourable opinion by the Research Ethics Committee (REC). Steps must be taken as soon as practicable to obtain consent from the subject (if capacity is regained) or the legal representative once the immediate emergency has passed. If consent is withdrawn, the subject must be withdrawn from the trial.

4.5 Consent in Vulnerable Groups Non-CTIMPS

Non-CTIMPs are governed by the Mental Capacity Act 2005. Those who lack capacity can be invited to participate in clinical trials if the research has been approved by the Research Ethics Committee (REC), the researcher considers the views of carers and other relevant people, the research treats the subjects interests as more important than those of science and society and the researcher respects any advance decisions or expressed preferences of a person who lacks capacity.

The opinion of a consultee, who is involved in the patients care or has an interest in the patient's welfare, should be sought for inclusion in the study. A personal consultee may be a family member or attorney acting under the Legal Power of Attorney. If a personal consultee cannot be consulted, the researcher must find someone not connected to the research who can fulfil the role of a nominated consultee.

In an emergency, if it is not possible to consult with a consultee in sufficient time, then the researcher must obtain agreement from an independent registered medical practitioner or comply with any other requirement of the Research Ethics Committee (REC).

4.6 Consent of Minors

A minor is defined as a person under the age of 16 years. The inclusion of minors is governed by the Medicines for Human Use (Clinical Trials) Regulation 2004. The minor's parent or person with parental responsibility should always be approached if available. If a parent or person with parental responsibility cannot be contacted before the proposed trial by reason of the emergency nature of the treatment provided, a personal legal representative can be approached. The professional legal representative should not be connected to the conduct of the trial and should either be the doctor responsible for the medical treatment of the minor or a doctor nominated by the Trust.

Children should receive information about the study that is appropriate to their age; the information must be given by a member of staff who has experience of working with children. The person receiving consent must consider the explicit wish of a child who is capable of assessing information and forming an opinion.

4.7 Consent of Minors in Emergency Situations

Where trial treatment needs to be given to a minor immediately, there may not be time to

obtain consent from the parent or legal representative. Minors can be entered into a trial before written informed consent is obtained provided that it is not reasonably practicable to obtain informed consent prior to trial treatment and that the action taken is in line with procedure with given favourable opinion by the Research Ethics Committee (REC). Steps must be taken as soon as is practicable to obtain consent from the parent/person with parental responsibility or legal representative once the immediate emergency has passed. If consent is withdrawn, the minor must be withdrawn from the trial.

4.8 Retention of Organs, Tissues or Body Fluids on Samples Obtained

The Human Tissue Act 2008 states that appropriate consent or authorisation must be obtained before taking or retaining organs, tissues or body fluids from patient or volunteers for research purposes. This applies whether the material is obtained solely for research purposes or retained following clinical or surgical treatment.

The trial subject must understand the amount and nature of the specimen being taken, how the sample will be used, where a sample is to be stored and if used in further research.

Any financial transactions associated with the use of research specimen should be discussed openly.

4.9 Assessing the Subjects Willingness to Continue

The informed consent process does not cease once the consent form has been signed and is an on-going process, particularly where there have been protocol amendments and availability of new information that may be relevant to the subjects willingness to continue.

The subjects willingness to continue in the study (whether CTIMP or Non CTIMP) must be assessed at each visit.

Willingness to proceed must be documented within the subject's medical records.

4.10 Withdrawal of Consent

Participants in research are free to withdraw consent at any time.

If a subject wishes to withdraw consent, this must be documented within the End of Study or Withdrawal forms.

The decision to withdraw consent may affect any previously collected information, samples and data. This decision must be discussed with the subject, documented and communicated with the Chief Investigator/Principal Investigator and Sponsor as directed by the Trial Protocol.

Patients who have capacity to consent to investigation or treatment

Consent Form 1

To be retained in patient's notes

Patient's details

Surname	Unit or NHS No.
Forename	
Address	DOB
	M ☐ F ☐
Postcode	(or affix patient label)

Responsible health professional

Name_____

Job title _____

Special requirements for patient _____

_____

eg other language/other communication method

Name of proposed procedure or course of treatment

(include brief explanation if medical term not clear. No abbreviations to be used) _____

_____

_____

Statement of health professional

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

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

The intended benefits_____

Significant, unavoidable or frequently occurring risks _____

_____

I have discussed what the procedure is likely to involve and any particular concerns of this patient. I have discussed the risks and benefits of the following available alternative procedures (including doing nothing)

_____

Any extra procedures which may become necessary during the procedure

☐ blood transfusion _____

☐ other procedure (please specify) _____

_____

Relevant leaflet given to patient Yes ☐ No ☐ N/A ☐

This procedure will involve:

☐ general and/or regional anaesthesia ☐ local anaesthesia ☐ sedation ☐ no anaesthesia

In taking consent for this procedure, I confirm that I am sufficiently qualified to perform the procedure and or, have been trained and assessed as competent to take consent for the procedure described

Signed:_____ Date_____

Name (PRINT) _____ Job title _____

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

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

Signed: _____ Date_____

Name (PRINT) _____

Copy accepted by patient: yes / no (please ring)

Statement of patient

Please read this form carefully.

If your treatment has been planned in advance, you should already have your own copy of page 3 which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

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

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

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

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

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

_____

_____

Patient's Signature _____

Name (PRINT) _____Date_____

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

Signature _____Name (PRINT) _____Date _____

Confirmation of preoperative marking

(to be completed by the operating surgeon or nominated deputy)

From reliable documentation and/or images, I have ascertained the intended surgical site and have marked the site with an arrow using an indelible pen.

Confirmation of consent

(to be completed by a competent health care professional when the patient is admitted for the procedure).

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

☐ Tick box if signing for both

Signed: _____

Name (PRINT) _____

Job title _____ Date _____

Signed: _____

Name (PRINT) _____

Job title _____ Date _____

Removal of Tissue

I understand that tissue removed as part of my treatment may be retained and used for teaching, education, quality assurance, audit, research and diagnostic purposes.

Signed: _____

Name (PRINT) _____

Important notes: (tick if applicable)

☐ See also advance directive / living will (eg Jehovah's Witness form)

☐ Patient has withdrawn consent (ask patient to sign /date here)

Signed _____

Name (PRINT) _____ Date _____

The Royal Wolverhampton NHS
NHS Trust

Consent Form 1

To be retained in patient's notes

Form for patients who have capacity to consent to investigation or treatment

Guidance to health professionals

(to be read in conjunction with consent policy)

What a consent form is for

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

The law on consent

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

Who can give consent

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

When NOT to use this form

If the patient is 18 or over and lacks capacity to give consent, you should use form 4 (Form for adults who lack the capacity to consent to investigation or treatment) instead of this form. A patient lacks capacity if they have an impairment of the mind or brain such that they are unable to do any one of these four things:

- understand information about the decision to be made,
- remember that information,
- use or weigh that information as part of the decision-making process, and
- communicate their decision (by talking, using sign language or any other means).

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so.

Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to so under a Lasting Power of Attorney or as a court appointed deputy.

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and the alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'serious or frequently occurring' risks. In addition if patients make clear they have particular concerns about certain kinds of risk, you should make sure they are informed about these risks, even if they are very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on page 3 of the form or in the patient's notes.

Patients who have capacity to consent to investigation or treatment

Consent Form 1

Patient's copy

Patient's details

Surname	Unit or NHS No.
Forename	
Address	DOB
	M ☐ F ☐
Postcode	(or affix patient label)

Responsible health professional

Name_____

Job title _____

Special requirements for patient _____

_____

eg other language/other communication method

Name of proposed procedure or course of treatment

(include brief explanation if medical term not clear. No abbreviations to be used) _____

_____

_____

Statement of health professional

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

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

The intended benefits_____

Significant, unavoidable or frequently occurring risks _____

_____

I have discussed what the procedure is likely to involve and any particular concerns of this patient. I have discussed the risks and benefits of the following available alternative procedures (including doing nothing)

_____

Any extra procedures which may become necessary during the procedure

☐ blood transfusion _____

☐ other procedure (please specify) _____

_____

Relevant leaflet given to patient Yes ☐ No ☐ N/A ☐

This procedure will involve:

☐ general and/or regional anaesthesia ☐ local anaesthesia ☐ sedation ☐ no anaesthesia

In taking consent for this procedure, I confirm that I am sufficiently qualified to perform the procedure and or, have been trained and assessed as competent to take consent for the procedure described

Signed:_____ Date_____

Name (PRINT) _____ Job title _____

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

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

Signed: _____ Date_____

Name (PRINT) _____

Copy accepted by patient: yes / no (please ring)

Statement of patient

Please read this form carefully.

If your treatment has been planned in advance, you should already have your own copy of page 3 which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

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

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

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

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

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

_____

_____

Patient's Signature _____

Name (PRINT) _____Date_____

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

Signature _____Name (PRINT) _____Date _____

Confirmation of preoperative marking

(to be completed by the operating surgeon or nominated deputy)

From reliable documentation and/or images, I have ascertained the intended surgical site and have marked the site with an arrow using an indelible pen.

Confirmation of consent

(to be completed by a competent health care professional when the patient is admitted for the procedure).

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

☐ Tick box if signing for both

Signed: _____

Name (PRINT) _____

Job title _____ Date _____

Signed: _____

Name (PRINT) _____

Job title _____ Date _____

Removal of Tissue

I understand that tissue removed as part of my treatment may be retained and used for teaching, education, quality assurance, audit, research and diagnostic purposes.

Signed: _____

Name (PRINT) _____

Important notes: (tick if applicable)

☐ See also advance directive / living will (eg Jehovah's Witness form)

☐ Patient has withdrawn consent (ask patient to sign /date here)

Signed _____

Name (PRINT) _____ Date _____

The Royal Wolverhampton NHS
NHS Trust

Consent Form 1

Copy to be given to patient

Form for patients who have capacity to consent to investigation or treatment

About the consent form

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

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

Should I ask questions?
Always ask anything you want. As a reminder, you can write your questions somewhere on this copy of your consent form. The person you ask should do his or her best to answer, but if they don't know they should find someone else who is able to discuss your concerns. To support you and prompt questions, you might like to bring a friend or relative. Ask if you'd like someone independent to speak up for you.

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

Can I find out more about giving consent?
The Department of Health leaflet Consent – what you have a right to expect is a detailed guide on consent in versions for adults, children, parents, carers/ relatives and people with learning disabilities. Ask for one from your clinic or hospital, order one from the NHS Responseline (08701 555 455) or read it on the web site www.dh.gov.uk/consent.

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

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

continued on page 2

About the consent form - continued

Will samples be taken?
Some kinds of operation involve removing a part of the body (such as a gall bladder or a tooth). You would always be told about this in advance. Other operations may mean taking samples as part of your care. These samples may be of blood or small sections of tissue, for example of an unexplained lump. Such samples may be further checked by other health professionals to ensure the best possible standards. Again, you should be told in advance if samples are likely to be taken. Sometimes samples taken during operations may also be used for teaching, research or public health monitoring in the future interests of all NHS patients. The NHS trust treating you will have a local system for checking whether you're willing for this to happen.

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

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

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

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

Questions may be about the treatment itself, for example:

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

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

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

Health care professionals should welcome your views and discuss any issues so they can work in partnership with you for the best outcome.

Consent Form 2

Agreement of a person who has parental responsibility to investigation or treatment

To be retained in patient's notes

Patient's details

Surname	Unit or NHS No.
Forename	
Address	DOB
	M ☐ F ☐
Postcode	(or affix patient label)

Responsible health professional

Name _____

Job title _____

Special requirements for patient _____

_____

eg other language / other communication method

Name of proposed procedure or course of treatment

(include brief explanation if medical term not clear. No abbreviations to be used) _____

_____

_____

Statement of health professional

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

I have explained the procedure to the child and/or person with parental responsibility. In particular, I have explained:

The intended benefits _____

Significant, unavoidable or frequently occurring risks: _____

_____

_____

I have discussed what the procedure is likely to involve and any particular concerns of this patient and/or person with parental responsibility. I have discussed the risks and benefits of the following available alternative procedures (including doing nothing) _____

_____

Any extra procedures which may become necessary during the procedure

☐ blood transfusion _____

☐ other procedure (please specify) _____

Relevant leaflet given to patient and/or person with parental responsibility. Yes ☐ No ☐ N/A ☐

This procedure will involve:

☐ general and/or regional anaesthesia ☐ local anaesthesia ☐ sedation ☐ No anaesthesia

In taking consent for this procedure, I confirm that I am sufficiently qualified to perform the procedure and or, have been trained and assessed as competent to take consent for the procedure described

Signed: _____ Date _____

Name (PRINT) _____ Job title _____

Contact details or person with parental responsibility (if patient wishes to discuss options later)

_____

Statement of interpreter (where appropriate)

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

Signed: _____ Name (PRINT): _____ Date: _____

Copy accepted by patient: yes / no (please ring)

Statement of parent or person with parental responsibility.

Please read this form carefully.
If the procedure has been planned in advance, you should already have your own copy of page 3 which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you and your child. You have the right to change your mind at any time, including after you have signed this form.

I agree to the procedure or course of treatment described on this form and I confirm that I have 'parental responsibility' for this child.

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

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

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

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

.....

.....

Person with parental responsibility.

Signature _____ Date _____

Name (PRINT) _____ Relationship to child _____

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

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

Signature _____ Name (PRINT) _____ Date _____

Confirmation of preoperative marking

(to be completed by the operating surgeon or nominated deputy)

From reliable documentation and/or images, I have ascertained the intended surgical site and have marked the site with an arrow using an indelible pen.

Signed: _____

Name (PRINT) _____

Job title _____ Date _____

Confirmation of consent

(to be completed by a competent health care professional when the child is admitted for the procedure).

On behalf of the team treating the child, I have confirmed with the child and who has parental responsibility that they have no further questions and wish the procedure to go ahead.

☐ Tick box if signing for both

Signed: _____

Name (PRINT) _____

Job title _____ Date _____

Removal of Tissue

I understand that tissue removed as part of my treatment may be retained and used for teaching, education, quality assurance, audit, research and diagnostic purposes.

Signed: _____

Name (PRINT) _____

Relationship to patient _____ Date _____

Important notes: (tick if applicable)

☐ Person with parental responsibility has withdrawn consent (ask to sign /date here)

Signed _____

Name (PRINT) _____ Date _____

The Royal Wolverhampton NHS Trust

Consent Form 2

To be retained in patient's notes

Agreement of a person who has parental responsibility to investigation or treatment

Guidance to health professionals

(to be read in conjunction with consent policy)

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

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

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

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

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

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

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

Consent Form 2

Agreement of a person who has parental responsibility to investigation or treatment

For the person with parental responsibility

Patient's details

Surname	Unit or NHS No.
Forename	
Address	DOB
	M ☐ F ☐
Postcode	(or affix patient label)

Responsible health professional

Name _____

Job title _____

Special requirements for patient _____

_____

eg other language / other communication method

Name of proposed procedure or course of treatment

(include brief explanation if medical term not clear. No abbreviations to be used) _____

_____

_____

Statement of health professional

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

I have explained the procedure to the child and/or person with parental responsibility. In particular, I have explained:

The intended benefits _____

Significant, unavoidable or frequently occurring risks: _____

_____

_____

I have discussed what the procedure is likely to involve and any particular concerns of this patient and/or person with parental responsibility. I have discussed the risks and benefits of the following available alternative procedures (including doing nothing) _____

_____

Any extra procedures which may become necessary during the procedure

☐ blood transfusion _____

☐ other procedure (please specify) _____

Relevant leaflet given to patient and/or person with parental responsibility. Yes ☐ No ☐ N/A ☐

This procedure will involve:

☐ general and/or regional anaesthesia ☐ local anaesthesia ☐ sedation ☐ No anaesthesia

In taking consent for this procedure, I confirm that I am sufficiently qualified to perform the procedure and or, have been trained and assessed as competent to take consent for the procedure described

Signed: _____ Date _____

Name (PRINT) _____ Job title _____

Contact details or person with parental responsibility (if patient wishes to discuss options later)

_____

Statement of interpreter (where appropriate)

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

Signed: _____ Name (PRINT): _____ Date: _____

Copy accepted by patient: yes / no (please ring)

Statement of parent or person with parental responsibility.

Please read this form carefully.
If the procedure has been planned in advance, you should already have your own copy of page 3 which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you and your child. You have the right to change your mind at any time, including after you have signed this form.

I agree to the procedure or course of treatment described on this form and I confirm that I have 'parental responsibility' for this child.

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

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

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

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

.....

.....

Person with parental responsibility.

Signature _____ Date _____

Name (PRINT) _____ Relationship to child _____

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

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

Signature _____ Name (PRINT) _____ Date _____

Confirmation of preoperative marking

(to be completed by the operating surgeon or nominated deputy)

From reliable documentation and/or images, I have ascertained the intended surgical site and have marked the site with an arrow using an indelible pen.

Confirmation of consent

(to be completed by a competent health care professional when the child is admitted for the procedure).

On behalf of the team treating the child, I have confirmed with the child and who has parental responsibility that they have no further questions and wish the procedure to go ahead.

☐ Tick box if signing for both

Signed: _____

Name (PRINT) _____

Job title _____ Date _____

Signed: _____

Name (PRINT) _____

Job title _____ Date _____

Removal of Tissue

I understand that tissue removed as part of my treatment may be retained and used for teaching, education, quality assurance, audit, research and diagnostic purposes.

Signed: _____

Name (PRINT) _____

Relationship to patient _____ Date _____

Important notes: (tick if applicable)

☐ Person with parental responsibility has withdrawn consent (ask to sign /date here)

Signed _____

Name (PRINT) _____ Date _____

The Royal Wolverhampton NHS
NHS Trust

Consent Form 2

For the person with parental responsibility

Agreement of a person who has parental responsibility to investigation or treatment

About the consent form

Giving consent for medical examination or treatment of your child
Before a doctor, nurse or therapist can examine or treat your child, they need consent or agreement. Sometimes children can give consent for themselves, depending on their age and how well they understand. Sometimes you will be asked to give consent for them as their parent.

How will your child or you be asked?
The way people providing health care (doctors, nurses or therapists) ask for consent partly depends on what they plan to do. It may be simple. For example, your GP might ask to have a look at your child's throat. You would then encourage a young child to open his or her mouth for the doctor. Older children will do so of their own accord. That shows you and they have given consent. For something more complicated, like an operation, you or they will be asked to sign a form agreeing to the treatment.

Who is responsible for giving consent?
You are entitled to agree to treatment on behalf of a child up to age 18 for whom you have what is called "parental responsibility".

However, children also gain rights to agree for themselves as they get older – as you'll see later.

Who can consent for treatment to a child or a young person?
Legal parental responsibility covers the rights and responsibilities that parents have in law for their child, including the right to consent to medical treatment for them, if that person has capacity to consent. The following have parental responsibility:

- The child's mother.
- The child's father but only if he was married to the mother at the time of the child's birth or subsequently – the father would not lose parental responsibility if they divorce.
- Unmarried fathers of children born since 1 December 2003 as long as his name is on the child's birth certificate.
- Unmarried fathers whose children were born before 1/12/03 and those who are not named on the birth certificate of a child born after 1/12/03 can acquire parental responsibility by a Parental Responsibility Agreement with the child's mother or by getting a Parental Responsibility Order from the courts. Married step-parents and registered civil partners can acquire parental responsibility in the same ways.
- The Local Authority shares parental authority with the parents of a child who has been taken into care by a care order, but not if the child is in voluntary care.
- Adoptive parents (the birth parents lose parental responsibility if a child is adopted).
- Local Authorities have parental responsibility while a child is subject to a care order.
- A testamentary guardian, special guardian or those given a residence order.

You may need to get legal advice if there is doubt about who has parental responsibility.

People without parental responsibility who have care of a child may do what is reasonable to safeguard or promote the child's welfare (e.g. step-parents, grandparents and child-minders). You can rely on their consent if they are authorised by the parents. But you should make sure that their decisions are in line with those of the parents, particularly in relation to contentious or important decisions.

A young person (i.e. 16 to 18 years of age) with capacity can give consent - it is good practise to involve a person with parental authority if the young person agrees, but that person cannot override the young person's consent. If a young person lacks capacity, consent can be given by whoever has parental responsibility.

Children can consent if they have sufficient intelligence and maturity to understand fully what is involved (see Consent Policy CP 06), but usually, consent is obtained from a person with parental responsibility.

How do you decide what's best?
Parents are expected to make health care decisions for their children, based on what they feel is in a child's "welfare" or "best interests". But it's still a good idea to involve children as much as possible. Even when they're not old enough to make decisions completely on their own, children can still play a part in decisions about their health care. The more they're involved, the more likely they are to feel positive about treatment.

What if you and people providing health care don't agree?
Sometimes health care professionals and parents may not agree on what is in the child's best interests. Usually the professionals cannot then go ahead and provide treatment.
It's always important to keep discussing things, so that eventually agreement can be reached. For example, it may help to ask for a second medical opinion, or talk to other people involved in caring for your child. But sometimes health care professionals may believe a particular treatment is crucial for the child, perhaps lifesaving. Then they can ask a court to decide. Equally, after seeking legal advice, it may be possible for you to go to court to request or prevent treatment, if you think it's in your child's best interests.

On the rare occasion when things go this far without agreement, the court has the power to grant or refuse the request of you or the practitioner if it thinks this is the right thing to do.

When can children give consent for themselves? 16-18 year olds
Once children reach the age of 16, they can agree to examination or treatment just like adults. People providing health care do not then have to ask you for consent as well.

Under 16's
The rules say that children under 16 may still be able to give consent for themselves, provided they are mature enough to understand fully what is involved.

So who gives consent – your child or you?
There is no hard and fast rule. A lot depends on the seriousness or difficulty of the proposed treatment. Although your child might be grown-up enough to consent to a meningitis vaccination, for instance, it might be too much to expect him or her to grasp all they need to know for consenting to a heart operation. Even if your child is grown-up enough to give consent independently, people providing treatment will still encourage them to involve you in their decision. However, if children refuse to share information with parents, health care professionals must normally respect their wishes.

What do you and your child need to know?
In order to make a decision, you and your child need to be provided with information about the treatment being offered. If you feel you haven't understood or don't have enough information, you should always ask questions. For example:

- What sort of things will the treatment involve?
- What benefits do they hope will result?
- How good are the chances of getting such benefits?
- Are there any alternatives?
- What are the risks, if any?
- If there are risks, are they minor or serious?
- What may happen if your child doesn't have treatment?

If the person who is asking you to agree to the treatment isn't able to answer your questions, ask them to find out or arrange for someone else to talk to you about your concerns. If your child or you want more time to think about the decision, say so. It is up to the two of you to decide whether or not to go ahead.

What if my child refuses treatment?
Sometimes children who are able to take their own decisions refuse treatment which their parents wish them to accept. In spite of that, health care professionals can legally overrule them and go ahead with the treatment if a parent has given consent. But young people may resent treatment given to them against their will. So it's better for everyone to avoid this happening. If your child is refusing treatment, try to find out what's worrying them before considering going against their wishes. So long as the child's condition is not life-threatening, it may be possible to delay treatment until the child is willing for it to go ahead.

Suppose I don't want my child to have treatment?
You may not want your child to have a particular treatment or intervention – contraception, for example. But if your child has the maturity to understand what's involved and asks for it, the law does allow health care professionals to provide treatment or care they believe is appropriate. Although they will always try to persuade children to keep parents informed, they must respect the wishes of a child who refuses to share information with you.

What if children are asked to take part in research?
This may be as part of their treatment, for example to compare two different kinds of treatment; or it may be quite separate, for example being asked to provide extra blood samples for a research project. In any case, a research project will always be approved by a Research Ethics Committee before your child is asked to take part in it. You and your child should usually be given an information sheet about the research project, and you should both ask as many questions as you want before coming to a decision, for instance about:

For all kinds of research
- the purpose of the research;
- any possible risks;
- how great or small the risks might be;
- any possible benefits;

And if the research is a new or different treatment
- what the standard treatment would be;
- any possible alternatives.

Only you and your child can decide whether any risks are worth taking for possible benefits to them or future patients. The older children are, the more you should involve them in decisions about whether to take part. If children are mature enough, they can decide for themselves. If you or your child decide they do not wish to take part, this ought not to affect the rest of their care. Having agreed to take part, if either of you change your mind, your child is free to withdraw at any time.

Is there any advantage or disadvantage to taking part in research?
Sometimes your child may only be able to get a certain treatment as part of a research trial. This is because it is new or experimental and cannot be made generally available until properly tested. There is a type of research in which neither you, your child or doctor knows whether the proposed treatment is new, standard or even no treatment. (You and your child will always be told what options are being used in the research project, even though you will not know which option your child will receive.) If you or your child is not happy about being involved in this kind of trial, either of you should feel free to say no. Your child will always be able to have the available standard treatment. All treatments, even established ones, have risks and these have to be weighed up when making your decision.

Suppose we're not happy about how we've been approached about consent?
You can tell the health care professionals concerned that you're worried. But if you're still not satisfied, you are entitled to complain. You can find out how to go about it from Your Guide to the NHS or from NHS Direct on 0845 4647. NHS Direct can also give you details of a new service called PALS (Patient Advocacy and Liaison Service) designed to help sort out problems simply and quickly.

Would you like more help with giving consent?
The Patients Association: 0845 6084455
Website: www.patients-association.com

Patient Concern: 020 7373 0794
Website: www.patientconcern.org.uk

Action for Sick Children: 0800 0744519
Website: www.actionforsickchildren.org.uk

CERES (Consumers for Ethics in Research)
Website: www.ceres.org.uk

Consent Form 4

Form for adults and young people who lack capacity to consent to investigation or treatment

To be retained in patient's notes

Patient's details (or pre-printed label)

Surname	Unit or NHS No.
Forename	
Address	DOB
	M ☐ F ☐
Postcode	(or affix patient label)

Responsible health professional

Name _____

Job title _____

Special requirements for patient _____

_____

e.g., other language/other communication method

All sections to be completed by health professional proposing the procedure.

A Details of procedure or course of treatment proposed

_____

_____

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

B Assessment of patient's capacity (in accordance with the Mental Capacity Act)

I confirm that the patient lacks capacity to give or withhold consent to this procedure or course of treatment because of impairment of the mind or brain which renders them unable to do one or more of the following:

- ☐ Understand information about the procedure or course of treatment
- ☐ Remember that information
- ☐ Use or weigh that information as part of the decision-making process, or
- ☐ Communicate their decision (by talking, using sign language or any other means)

Give, where relevant, further details about how you reached this judgement; which colleagues you consulted; what attempts you made to assist the patient make his or her own decision and why these were not successful.

C Assessment of patient's best interests

I am satisfied that the patient has not refused this procedure in a valid advance decision to refuse treatment. As far as is reasonably possible, I have considered the person's past and present wishes and feelings and their beliefs and values that might influence this decision. As far as is reasonably possible, I have consulted other people (e.g., carers for the patient, people who are interested in the patient's welfare and those whom the patient has said should be consulted) as appropriate. I have considered the patient's best interests in accordance with the requirements of the Mental Capacity Act and believe the procedure to be in their best interests because:

_____

If the lack of capacity is likely to be temporary, the treatment cannot wait until the patient recovers capacity because:_____

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

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

Independent Mental Capacity Advocate (IMCA)

For decisions about serious medical treatment where there is no one appropriate to consult other than paid staff, has an Independent Mental Capacity Advocate (IMCA) been instructed? ☐ Yes ☐ No

IMCA No _____ Name _____ Signature _____ Date _____

E The patient has an attorney or deputy

If the patient has authorised an attorney to make decisions about the procedure in question under a Lasting Power of Attorney or if a Court Appointed Deputy has been authorised to make decisions about the procedure in question, the attorney or deputy will have the final responsibility for determining whether a procedure is in the patient's best interests.

Signature of attorney or deputy

I have been authorised to make decisions about the procedure in question under a Lasting Power of Attorney / as a Court Appointed Deputy (delete as appropriate). I have considered the relevant circumstances relating to the decision in question (see Section C) and believe the procedure to be in the patient's best interests.

Name _____ Signature _____ Date _____

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

Removal of Tissue

I/We understand from our discussion with the relevant professional that tissue removed as part of the patient's treatment may be retained and used for teaching, education, quality assurance, audit, research and diagnostic purposes.

Any other comments (including any concerns about decisions): _____

_____

Name _____ Relationship to patient _____

Address (if not the same as patient) _____

_____

Signature _____ Date _____

If a person close to the patient was not available in person, has this matter been discussed in any other way (e.g., over the telephone)? ☐ Yes ☐ No

Details: _____

_____

Signature of health professional proposing treatment

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

I have / have not sought a second opinion.

In taking consent for this procedure, I confirm that I am sufficiently qualified to perform the procedure and or, have been trained and assessed as competent to take consent for the procedure described.

Signature _____ Date _____

Name (PRINT) _____ Job Title _____

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

Signature _____ Date _____

(PRINT) _____ Job Title _____

Confirmation of preoperative marking

(To be completed by the operating surgeon or nominated deputy.)

From reliable documentation and/or images, I have ascertained the intended surgical site and have marked the site with an arrow using an indelible pen.

Signed _____

Name (PRINT) _____

Job title _____ Date _____

Important notes: (tick if applicable)

☐ See also advance directive / living will (e.g., Jehovah's Witness form)

☐ Health Professional confirms that Attorney / Court Appointed Deputy has withdrawn consent (ask Health Professional to sign/date here)

Signed _____

Name (PRINT) _____

Date _____

NHS
The Royal Wolverhampton
NHS Trust

Consent Form 4

To be retained in patient's notes

Form for adults and young people who lack capacity to consent to investigation or treatment

Guidance to health professionals

(to be read in conjunction with consent policy)

This form should only be used where it would be usual to seek written consent but an adult or young person (16 or over) lacks capacity to give or withhold consent to treatment. If an adult or young person has capacity to accept or refuse treatment, you should use the standard consent form and respect any refusal. Where treatment is very urgent (for example if the patient is critically ill), it may not be feasible to fill in a form at the time, but you should document your clinical decisions appropriately afterwards. If treatment is being provided under the authority of Part IV of the Mental Health Act 1983, different legal provisions apply and you are required to fill in more specialised forms (although in some circumstances you may find it helpful to use this form as well). If the adult or young person now lacks capacity, but has clearly refused particular treatment in advance of their loss of capacity (for example in an advance directive or 'living will'), then you must abide by that refusal if it was validly made and is applicable to the circumstances. For further information on the law on consent, see the Department of Health's Reference guide to consent for examination or treatment (www.dh.gov.uk/consent).

When treatment can be given to a patient who is unable to consent

For treatment to be given to a patient who is unable to consent, the following must apply all decisions made on their behalf must be made in the patient's best interests in accordance with the Mental Capacity Act 2005.

Capacity

A patient lacks capacity to give or withhold consent to a procedure or course of treatment if they have an impairment of the mind or brain which renders them unable to do one or more of the following: understand information about the procedure or course of treatment; remember that information; use or weigh that information as part of the decision-making process; or communicate their decision (by talking, using sign language or any other means)

Best interests

The Mental Capacity Act requires that a health professional must consider all the relevant circumstances relating to the decision in question, including, as far as possible considering:

- The person's past and present wishes and feelings (in particular if they have been written down)
- Any beliefs and values (e.g., religious, cultural or moral) that would be likely to influence the decision in question and any other relevant factors
- The other factors that the person would be likely to consider if they were able to do so.

When determining what is in a person's best interests a health professional must not make assumptions about someone's best interests merely on the basis of the person's age or appearance, condition or any aspect of their behaviour. If the decision concerns the provision or withdrawal of life-sustaining treatment the health professional must not be motivated by a desire to bring about the person's death. The Act also requires that, as far as possible, health professionals must consult other people, if it is appropriate to do so, and take into account of their views as to what would be in the best interests of the person lacking capacity, especially anyone previously named by the person lacking capacity as someone to be consulted and anyone engaging in caring for patient and their family and friends.

Independent Mental Capacity Advocate (IMCA)

The Mental Capacity Act introduced a duty on the NHS to instruct an independent mental capacity advocate (IMCA) in serious medical treatment decisions when a person who lacks capacity to make a decision has no one who can speak for them, other than paid staff. IMCAs are not decision makers for the person who lacks capacity. They are there to support and represent that person and to ensure that decision making for people who lack capacity is done appropriately and in accordance with the Act.

Lasting Power of Attorney and Court Appointed Deputy

A person over the age of 18 can appoint an attorney to look after their health and welfare decisions, if they lack the capacity to make such decisions in the future. Under a Lasting Power of Attorney (LPA) the attorney can make decisions that are as valid as those made by the person themselves. The LPA may specify limits to the attorney's authority and the LPA must specify whether or not the attorney has the authority to make decisions about life-sustaining treatment. The attorney can only, therefore, make decisions as authorised in the LPA and must make decisions in the person's best interests.

Second opinions and court involvement

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

Consent Form 4

Form for adults and young people who lack capacity to consent to investigation or treatment

Friend / family /carer's copy

Patient's details (or pre-printed label)

Surname	Unit or NHS No.
Forename	
Address	DOB
	M ☐ F ☐
Postcode	(or affix patient label)

Responsible health professional

Name _____

Job title _____

Special requirements for patient _____

_____

e.g., other language/other communication method

All sections to be completed by health professional proposing the procedure.

A Details of procedure or course of treatment proposed

_____

_____

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

B Assessment of patient's capacity (in accordance with the Mental Capacity Act)

I confirm that the patient lacks capacity to give or withhold consent to this procedure or course of treatment because of impairment of the mind or brain which renders them unable to do one or more of the following:

- ☐ Understand information about the procedure or course of treatment
- ☐ Remember that information
- ☐ Use or weigh that information as part of the decision-making process, or
- ☐ Communicate their decision (by talking, using sign language or any other means)

Give, where relevant, further details about how you reached this judgement; which colleagues you consulted; what attempts you made to assist the patient make his or her own decision and why these were not successful.

C Assessment of patient's best interests

I am satisfied that the patient has not refused this procedure in a valid advance decision to refuse treatment. As far as is reasonably possible, I have considered the person's past and present wishes and feelings and their beliefs and values that might influence this decision. As far as is reasonably possible, I have consulted other people (e.g., carers for the patient, people who are interested in the patient's welfare and those whom the patient has said should be consulted) as appropriate. I have considered the patient's best interests in accordance with the requirements of the Mental Capacity Act and believe the procedure to be in their best interests because:

_____

If the lack of capacity is likely to be temporary, the treatment cannot wait until the patient recovers capacity because:_____

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

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

Independent Mental Capacity Advocate (IMCA)

For decisions about serious medical treatment where there is no one appropriate to consult other than paid staff, has an Independent Mental Capacity Advocate (IMCA) been instructed? ☐ Yes ☐ No

IMCA No _____ Name _____ Signature _____ Date _____

E The patient has an attorney or deputy

If the patient has authorised an attorney to make decisions about the procedure in question under a Lasting Power of Attorney or if a Court Appointed Deputy has been authorised to make decisions about the procedure in question, the attorney or deputy will have the final responsibility for determining whether a procedure is in the patient's best interests.

Signature of attorney or deputy

I have been authorised to make decisions about the procedure in question under a Lasting Power of Attorney / as a Court Appointed Deputy (delete as appropriate). I have considered the relevant circumstances relating to the decision in question (see Section C) and believe the procedure to be in the patient's best interests.

Name _____ Signature _____ Date _____

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

Removal of Tissue

I/We understand from our discussion with the relevant professional that tissue removed as part of the patient's treatment may be retained and used for teaching, education, quality assurance, audit, research and diagnostic purposes.

Any other comments (including any concerns about decisions): _____

_____

Name _____ Relationship to patient _____

Address (if not the same as patient) _____

_____

Signature _____ Date _____

If a person close to the patient was not available in person, has this matter been discussed in any other way (e.g., over the telephone)? ☐ Yes ☐ No

Details: _____

_____

Signature of health professional proposing treatment

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

I have / have not sought a second opinion.

In taking consent for this procedure, I confirm that I am sufficiently qualified to perform the procedure and or, have been trained and assessed as competent to take consent for the procedure described.

Signature _____ Date _____

Name (PRINT) _____ Job Title _____

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

Signature _____ Date _____

(PRINT) _____ Job Title _____

Confirmation of preoperative marking

(To be completed by the operating surgeon or nominated deputy.)

From reliable documentation and/or images, I have ascertained the intended surgical site and have marked the site with an arrow using an indelible pen.

Signed _____

Name (PRINT) _____

Job title _____ Date _____

Important notes: (tick if applicable)

☐ See also advance directive / living will (e.g., Jehovah's Witness form)

☐ Health Professional confirms that Attorney / Court Appointed Deputy has withdrawn consent (ask Health Professional to sign/date here)

Signed _____

Name (PRINT) _____

Date _____

NHS
The Royal Wolverhampton
NHS Trust

Consent Form 4

Copy to be given to friend / family / carer

Form for adults and young people who lack capacity to consent to investigation or treatment

Consent –
What you have a right to expect: A guide for relatives and carers

Before a doctor, nurse or therapist can examine or treat a patient, they usually need his or her consent or agreement. As long as the person you care for can understand what's involved in the treatment, like anyone else over 16 he or she is the only person who can give consent. (For advice see our leaflet Consent: A guide for adults.) But what happens about consent if they have problems in understanding?

Big problems
Suppose someone is unconscious after an accident, cannot communicate at all after a severe stroke, or is too bewildered to make decisions because of advanced dementia – then they're not usually in a position to give consent. Then who is?

Some problems
Sometimes people can understand enough to make everyday decisions about health care, such as pain relief. But when it comes to a major operation, perhaps because of a learning disability, they have too much of a problem in understanding to give consent. Or do they? Where do you stand as a relative or carer in situations like these? This guide is designed to help you.

How far is the person you care for able to decide for themselves?
A patient might seem unable to understand enough to consent to, or refuse, proposed medical treatment. Or they might seem unable to communicate their wishes. But no one should assume (neither carers nor health care professionals) that a patient with for example a learning disability or dementia is not capable of consenting. No one knows better than you that if time is spent explaining the options simply, they may be able to reach a decision.

Making the most of people's abilities
If individuals have some ability to understand and think things over, they should always be encouraged to decide for themselves. It may not be a decision you agree with, but that's not the key test. What you and the people providing the health care need to ask yourselves is: can the patient understand and weigh up the information provided?

What if a person is totally unable to decide for themselves?
Under English law, no-one (not even husbands or wives, partners, close relatives or carers) can give consent to treatment on behalf of another person unless they hold a specific lasting power of attorney power for health and welfare decisions. This obviously causes a problem if patients are not in a condition to give consent for themselves.

How can they be treated?
Doctors, nurses and therapists are generally allowed to provide treatment which they believe is in their patient's "best interests". This doesn't just mean what might be best for the patient's physical health. It takes into account their general well-being and what they're known to believe in.

You can help
It's true that friends and relatives cannot make decisions on behalf of patients who can't decide for themselves. Even so, they may be able to tell health care professionals about the person's opinions and beliefs – for example whether they've ever accepted or refused certain kinds of treatment, or if they have strong views about particular health conditions or treatments. This will help health care professionals make a better decision about what will be in the patient's best interests.

People close to the patient should be involved in this way, unless the patient has made clear in the past that he or she would not want a particular person involved.

So – who does decide?
Whose opinion counts on whether or not the person you care for understands enough to decide about consent? And if they cannot decide, who is to judge what's in their best interests? On the one hand, health care professionals may feel the need to take urgent action; but this should not lead them to assume a patient isn't capable of deciding. On the other, no one is in a better position than you to stand up for the patient, but you need to take on board medical opinion. It's a difficult area and requires give and take all round. In the end, everyone usually agrees what's best. Occasionally they don't. If this is about a serious matter, either you or the person providing health care can ask a Court to intervene and decide what is in the patient's best interests. You should never be asked to sign a consent form on behalf of the person you are looking after. However you may be asked to sign a form to say that you have been consulted.

Refusing treatment in advance
Sometimes people may decide that they would not want a particular treatment if something happened to them in the future and they were no longer capable of refusing consent. This is sometimes called an Advance Decision. What if this situation actually comes about?

- If you know that the person you care for has taken such a decision in the past, you should tell the health care professionals caring for them.
- If the patient has signed a document in which they refuse treatment, you should, if possible, give a copy to the health care professionals.
- Health care professionals are bound by that earlier decision, even if you disagree with it.

Suppose I or the person I care for is not happy about how we've been approached about consent?
You can tell the health care professionals concerned that you're worried. But if you're still not satisfied, you are entitled to complain. You can find out how to go about it from Your Guide to the NHS or from NHS 111 They can also give you details of a new service called PALS (Patient Advocacy and Liaison Service) designed to help sort out problems simply and quickly.

Want more help with consent?
Here's a list of useful organisations you can ask for more help or support about giving consent to treatment. Further information about these organisations and other aspects of consent for treatment is available on the website http://www. dh.gov.uk/consent.

The Patients Association
0845 608 4455
www.patients-association.org.uk

Patient Concern
020 7373 0794
www.patientconcern.org.uk

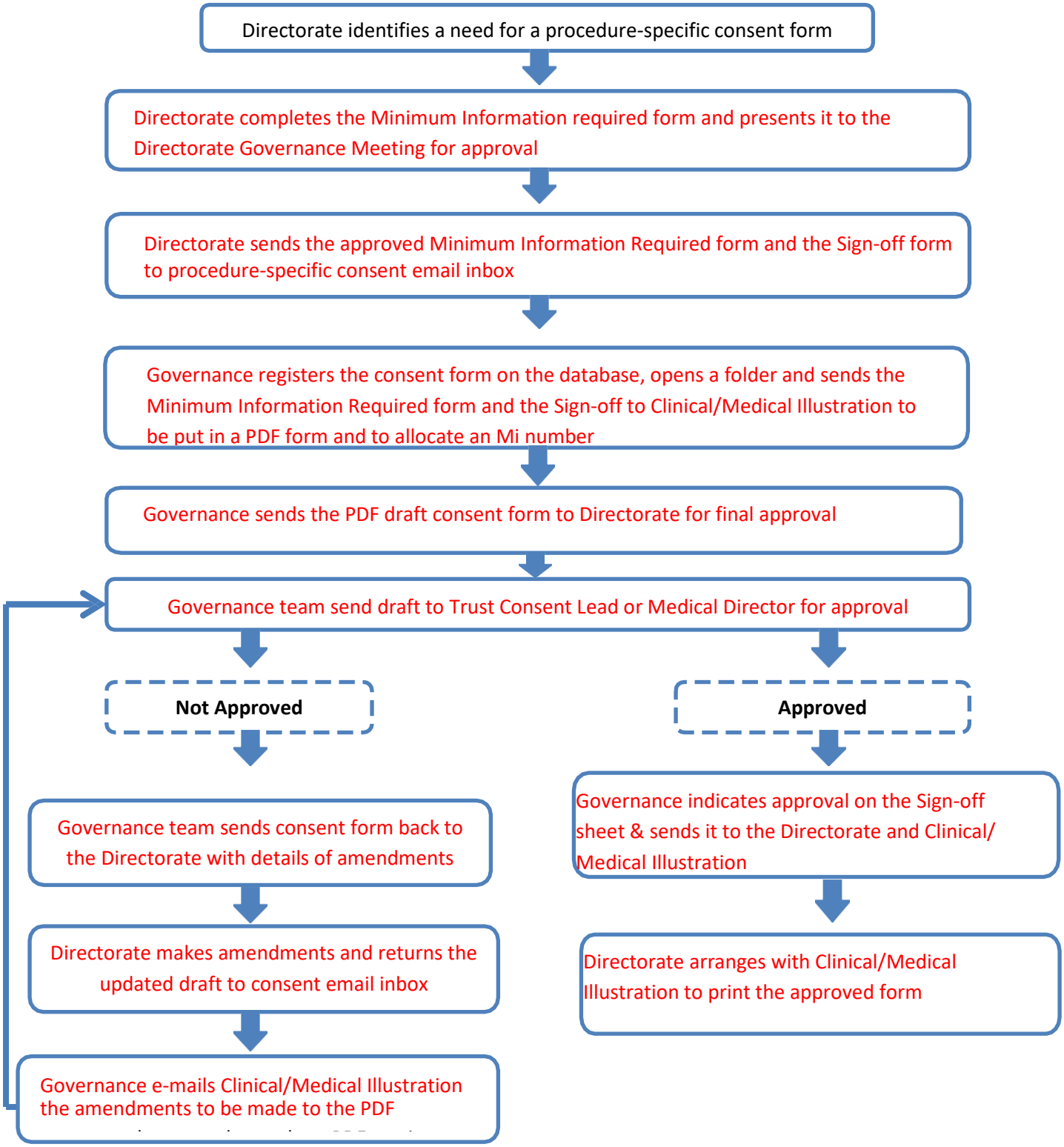
Mencap
020 7454 0454
www.mencap.org.uk

Alzheimer's Society
020 7306 0606
www.alzheimers.org.uk

Carers UK
020 7490 8818
www.carersuk.org

UKAN: UK Advocacy Network
01142 728171
www.u-kan.co.uk

Appendix 4- Procedure Specific Consent Forms Process



Procedure Specific Consent Forms – Minimum Information Required

Indicate which consent form template is to be used

☐ Form 1 for patients who have capacity to consent to investigation or treatment

☐ Form 2 for agreement of a person who has parental responsibility to investigation or treatment

Name of proposed procedure or course of treatment (please include brief explanation if medical term not clear. No abbreviations to be used)

List all intended benefits:

List all significant, unavoidable or frequently occurring risks:

List alternative procedures (including doing nothing):

Any extra procedures which may become necessary during the procedure:

1. Blood Transfusion: ☐
2. Other procedure (please specify):

This procedure will involve:

☐ General and/or regional anaesthesia ☐ Local anaesthesia

☐ Sedation ☐ No anaesthesia

The Royal Wolverhampton NHS
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Procedure Specific Consent Form Sign-Off Sheet

1. Approval by Directorate

Title of Procedure	
Directorate	
Author/ Lead	
Date of Governance meeting where review undertaken	
Outcome of review, e.g. what (if any) issues arose and have they been addressed	

2. Ratification by Trust Consent Lead/ Chief Medical Officer (For Governance use only)

Mi Number	
Version	
Date of ratification	
Date Directorate and Clinical Illustration notified	