Alder Hey Children's NHS
NHS Foundation Trust

Reference Number: FOIAH2324/316
From: Other

Date: 07 September 2023

Subject: Training in informed consent for doctors

Q1 Please can you disclose any policies and/or guidance and/or any other documentation you hold relating to training in informed consent for doctors working at your hospital. In particular, we are interested in any policies/guidance/documentation which address the following:

- Whether training in informed consent is mandatory for doctors working within your hospital
- Who provides/funds training in informed consent for doctors working at your hospital
- What a doctor must do to fulfil any training requirements relating to informed consent

A2 See attachment - *Informed Consent Policy - C7*

Alder Hey Children's
NHS Foundation Trust

C7 – INFORMED CONSENT POLICY

Version:	11.2
Name of ratifying committee:	Safety Quality Assurance Committee
Date ratified:	22/09/2021
Name of originator/author:	David Locke, Hill Dickinson Harriet Corbett, Consultant Urologist / Clinical Lead for Consent, Alder Hey
Name of approval committee:	Clinical Quality Steering Group
Date approved:	10/08/2021
Executive Sponsor:	Nicki Murdock, Medical Director
Key search words:	Consent, patient, information, competent, capacity, treatment, capacity, photography, PR, parental responsibility, procedure, C7
Date issued:	December 2022 (minor update)
Review date:	September 2024

Version Control, Review and Amendment Logs

Version Control Table				
Version	**Date**	**Author**	**Status**	**Comment**
11.2	December 2022	Consultant Paediatric Urologist	Current	Added reference to e-consent
11.1	April 2022	Trust Lawyer, Consultant Paediatric Urologist	Archived	Added reference to NG204
11	September 2021	Trust Lawyer, Consultant Paediatric Urologist	Archived	Minor amendments to be approved by the Surgical Division, with major amendments presented to SQAC as appropriate.
10.1	January 2020	Consultant Paediatric Urologist / Quality & Governance Manager	Archived	Extended pending publication of new GMC Guidance
10	October 2019	Consultant Paediatric Urologist / Quality & Governance Manager	Archived	Minor updates. Due to updated guidance from the GMC on Consent expected November 2019
9.1	January 2019	Consultant Paediatric Urologist / Quality & Governance Manager	Archived	6 month extension
9	October 2015	Consultant Paediatric Urologist / Quality & Governance Manager	Archived	Updated to add in Duty of Candour, new Mental Health Code of Practice and other process changes.
8	February 2012	Deputy Medical Director / Clinical Audit and Compliance Manager	Archived	Updated guidance added in relation to delegated consent, the Mental Capacity Act, Research and Post Mortem consent.
7	December 2009	Head of Integrated Clinical Governance and risk management medical director	Archived	The Alder Hey policy and the Department of Health model policy have been combined to provide best practice for the Trust
6	March 2009	Consultant Legal advisor/safety lead	Archived	
5	August 2006	Consultant Legal advisor/safety lead	Archived	
4	December 2005	Consultant Legal advisor/safety lead	Archived	
3	March 2004	Medical Director	Archived	
2	August 2003	Medical Director	Archived	
1	November 2002	Medical Director	Archived	

Record of changes made to Consent Policy – Version 11.2			
Section Number	**Page Number**	**Change/s made**	**Reason for change**
6	10	Addition of reference e-consent	To ensure that policy supports e-consent as the preferred modality for documenting written consent from the person with parental responsibility and patients (MIAA recommendation)

Record of changes made to Consent Policy – Version 11.1			
Section Number	**Page Number**	**Change/s made**	**Reason for change**
8	11	Addition of reference to NICE Guidance - Babies, Children and Young People's Experience of Healthcare (NG204)	Action as part of Baseline Assessment of NICE Guidance

Record of changes made to Consent Policy – Version 11			
Section Number	**Page Number**	**Change/s made**	**Reason for change**
All	All	Major revision, description of principles with addition of flow charts and links to podcast	In line with new GMC recommendations

Contents

Definition

"Consent" is a patient's agreement to a particular thing. Patients may indicate consent non-verbally (for example by presenting their arm for their pulse to be taken), orally, or in writing. For the consent to be valid, the patient must:

• have capacity to take the particular decision;
• have received sufficient information to take it; and
• not be acting under duress.

To note:

Throughout this policy reference to 'patients' should be read as referring to the child / young person if they are competent or the person / people with parental responsibility for the child or young person

1. Overriding Objective

The primary aim of healthcare professionals involved in the process of obtaining informed consent must be to protect the patient's freedom to make their own choices during the decision making process. Each step in any consenting process must be measured against this fundamental principle.

2. Background

Regulatory bodies have not made any substantial changes to what is required for an appropriate and ethical consent process, so this policy does not include new advice but what is given is presented in a new way.

Nonetheless, cases that have gone to court highlight that what happens in practice is not always done according to policy. Some cases have exposed complacency, where practitioners think they are taking consent appropriately when in fact they are not.

This policy has been written in a very simple way to make it easy to access and apply in day to day practice throughout the Trust.

There is now a separate policy dealing specifically with the assessment of mental capacity to provide or decline consent to medical treatment.

3. The Legal Test (the 'Test' used by Lawyers and Judges in Court)

In the past issues of poor consent-taking could be defended by the fact that the practice was 'how everyone does it' (common or established). This position changed some years ago, such that healthcare professionals are required to take into account that which is now considered to be reasonable when they are discussing consent with patients and families.

The current legal framework arises from the case of *Montgomery*. Following the Montgomery court case the law is such that healthcare professionals must discuss with the patient the 'material risks' of any proposed treatment, as well as any alternatives and the option of no treatment.

To clarify:

- A material risk is one which:
  - Would be considered significant by patients in general (the objective test); or
  - Would be considered significant by the specific patient bearing in mind their unique circumstances (the subjective test).
- To apply the subjective test properly you must have taken a very thorough patient history.
  - For example: think about a patient having an operation on their eye, the chance of losing their sight in the eye is extremely low (although there is a tiny chance that could happen) but if that patient has already

lost their sight in the other eye then that tiny chance is *very* important to this patient, compared to most people who have normal sight in the other eye]

- This 'subjective test' means that you should not rely simply on the percentage chance of a particular risk, you must think about the individual patient

- When discussing alternative treatments it is not necessary to deal with every theoretical approach. You should make sure the patient knows about all treatment options that a reasonable body of Healthcare Practitioners would consider to be suitable for the patient. This may include treatments which are only available at other treatment centres.

4. Exceptions

In common practice there is no exception to the obligations imposed by *Montgomery*.

In theory, if there were a situation where actually providing certain information would cause some clinical harm, then some information could be withheld. However, such circumstances are extremely rare and none have been reported to date.

If it were considered the exemption applied, a healthcare professional should seek support from their seniors, such as the divisional director or the consent lead.

5. A Moment of Reflection

At times the need to provide so much information and to ensure it has been understood may seem too difficult, and you may be tempted to write a list of situations when it might not be a good idea to tell a patient about a particular risk. Sometimes that might be because you think the patient might then decline the treatment.

It may be useful at this moment to pause and re-read the overriding objective of this policy. An adult patient is at liberty to refuse treatment, and withholding information which might influence their decision is directly contrary to the principle of protecting patient autonomy. Even though most of our patients are children who are not yet competent to make their own decisions, this principle is still important for the person(s) with parental responsibility who is making the decision on their behalf.

6. Obtaining Informed Consent in Practice

The remainder of the policy conveys the expectations of the Trust and its regulators, by addressing the various questions that are likely to arise in terms of putting the policy into everyday practice. The answers to the questions contain the key principles which need to be applied, wherever consent is required.

6.1 Is a proportionate approach to obtaining informed consent permissible?

Yes.

It is entirely appropriate for minor patient interactions – such as examinations - to take place without the need for detailed discussion or detailed documentation.

It is clear that as the importance of the treatment decision and the nature of the associated risks increase, so must the detail of the informed consent process. Where the risks have serious implications for a patient, written documentation of the information given to the patient is crucial, and a "cooling off" period may be required.

6.2 Should consent always be recorded in writing?

Not *necessarily*.

Principles of proportionality apply, but whenever a potential treatment carries with it a risk of any significant side-effects, there should be a written record of consent.

In addition to the standard Consent Forms, a separate note must be made in the medical records. Standard Consent Forms do not contain sufficient space to record the detail of any discussion.

Whilst it is not true to say "if it is not written down it did not happen", it is certainly true to say that if it is not written down it is much more difficult to prove that the discussion took place.

6.3 Who can obtain informed consent?

There is no specific rule about delegating the process of obtaining consent. However, there are certain requirements, which can be summarised as follows:

- The person taking consent must be appropriately experienced.
- If the person taking consent is not trained and qualified to provide the investigation or treatment in question, then the person delegating to them must ensure that they are trained to take consent.
- They must be able to apply the subjective test, recognising the individual characteristics of the patient. Accordingly they must either take or have access to a detailed history.
- They must have knowledge of the associated risks and complications and the reasonable alternative treatments (and potentially different techniques for delivering the same treatment), which will involve a process of ongoing education and keeping abreast of developing literature and guidance, in the usual way.

The healthcare professionals to whom responsibility for obtaining consent is delegated must ensure they are able to comply with the requirements set out above.

The health professionals who are delegating responsibility for obtaining consent are responsible for ensuring that the delegation is appropriate with regard to the requirements set out above.

6.4 Can literature be used to supplement or replace a discussion?

There is no substitute for discussion, but information leaflets or electronic equivalents can be very important by supplementing the consenting process.

However, healthcare professionals must be careful not to make assumptions, for example in relation to a patient's ability to read, or even that they have read information that has been provided.

Healthcare professionals must ask patients if they have read the information provided about their treatment and give the patient an opportunity to ask questions. Healthcare professionals must document that the patient has had the chance to ask questions.

6.5 What if a patient says they do not wish to know the risks of a proposed treatment?

This situation is likely to occur from time to time. Healthcare professionals should endeavour to explain to patients why it is important that they are fully informed about the risks of proposed treatment. In the event that they still do not wish to have the advised discussion, the refusal should be clearly documented in the medical record.

The GMC have indicated that this is sufficient in their view. The Trust would encourage healthcare professionals to ask patients to counter-sign the relevant medical record.

6.6 How should written consent be documented?

The electronic 'e-consent' system should be used to document written consent for procedures, investigations where written consent is usually obtained (e.g. genetics blood tests) and medical photography. Paper consent forms should only be used when the e-consent system is unavailable and reasonable attempts have been made to access the system.

6.7 For how long is consent valid?

For a variety of reasons there may be a delay between obtaining written consent and undertaking a particular treatment. Healthcare professionals need to be aware that the patient's circumstances may have changed during that period. Where there has been a delay, there should be a follow up discussion with patients to make sure they are content to proceed, that their circumstances

are unchanged and that there are no new treatment options that ought to be considered. That conversation must be documented.

It is acceptable to consent a patient for a course of treatment, in such a way that it would not be necessary to re-consent them on each and every occasion. That intention should be clearly documented when consent is obtained.

6.8 Who can give consent?

People aged 16 or over are entitled to consent to their own treatment. This can only be overruled in exceptional circumstances.

Like adults, young people (aged 16 or 17) are presumed to have sufficient capacity to decide on their own medical treatment, unless there is significant evidence to suggest otherwise. If they do not have capacity then the reason(s) why they cannot make a decision for them self must be documented. Unlike adults (who can refuse treatment), if a young person aged 16-17 refuses treatment then you should seek advice as that could be overridden by a court of law in some situations.

Children under the age of 16 can consent to their own treatment if they are believed to have enough intelligence, competence and understanding to fully appreciate what is involved in their treatment. This is known as being Gillick competent. The GMC provides tools to use when assessing if a child is competent to make the treatment decision in question. A child may be competent to decide about one treatment but not about another, for example, if the consequences are profound. Any assessment of competence must be documented.

Otherwise, someone with parental responsibility can consent for them. This could be: the child's mother or father, the child's legally appointed guardian, a person with a residence order concerning the child, a local authority designated to care for the child, or a local authority or person with an emergency protection order for the child. In some specific situations such as surrogacy and same sex parents, the parents will know if they have parental responsibility or hold an appropriate court order that gives it.

There is a separate Trust policy on mental capacity.

7. Duties

The Medical Director is the Executive Lead for consent and is responsible for ensuring that the Trust’s systems for acquiring consent for examinations and treatment are fit-for-purpose and consistent with best practice.

The Divisional Directors, Associate Chief Operating Officers and Associate Chief Nurses should ensure this policy is disseminated and understood by clinical staff in the Division. They have oversight of consent training and must monitor how consent is done in practice through regular audit.

All healthcare professionals taking consent should ensure that consent processes used are consistent with Trust Policy and General Medical Council / other professional guidance and that recording of consent is of consistently high quality and content.

8. Further Information

Information resources:

Informed Consent Podcast Script (see DMS)

Decision making and consent - GMC (gmc-uk.org)

0-18 years - GMC (gmc-uk.org)

Policy on consent for post-mortem examination and tissue retention under the Human Tissue Act 2004 | Human Tissue Authority (hta.gov.uk)

A video of the patient information for General Anaesthesia consent is available on the Trust's YouTube account:
https://www.youtube.com/watch?v=ud92WdcFKGA

The Code - Professional standards of practice and behaviour for nurses, midwives and nursing associates – NMC (January 2015)

Reference guide to consent for examination or treatment (Second edition) – Department of Health (July 2009)

Babies, Children and Young People's Experience of Healthcare (NG204) NICE Guidance (Section 1.4 - Consent, privacy and confidentiality)

Policies: (see on DMS)

C1 - Blood and Blood Component Transfusion Policy

C16 - Interpreting, Translation & Accessible Information Policy

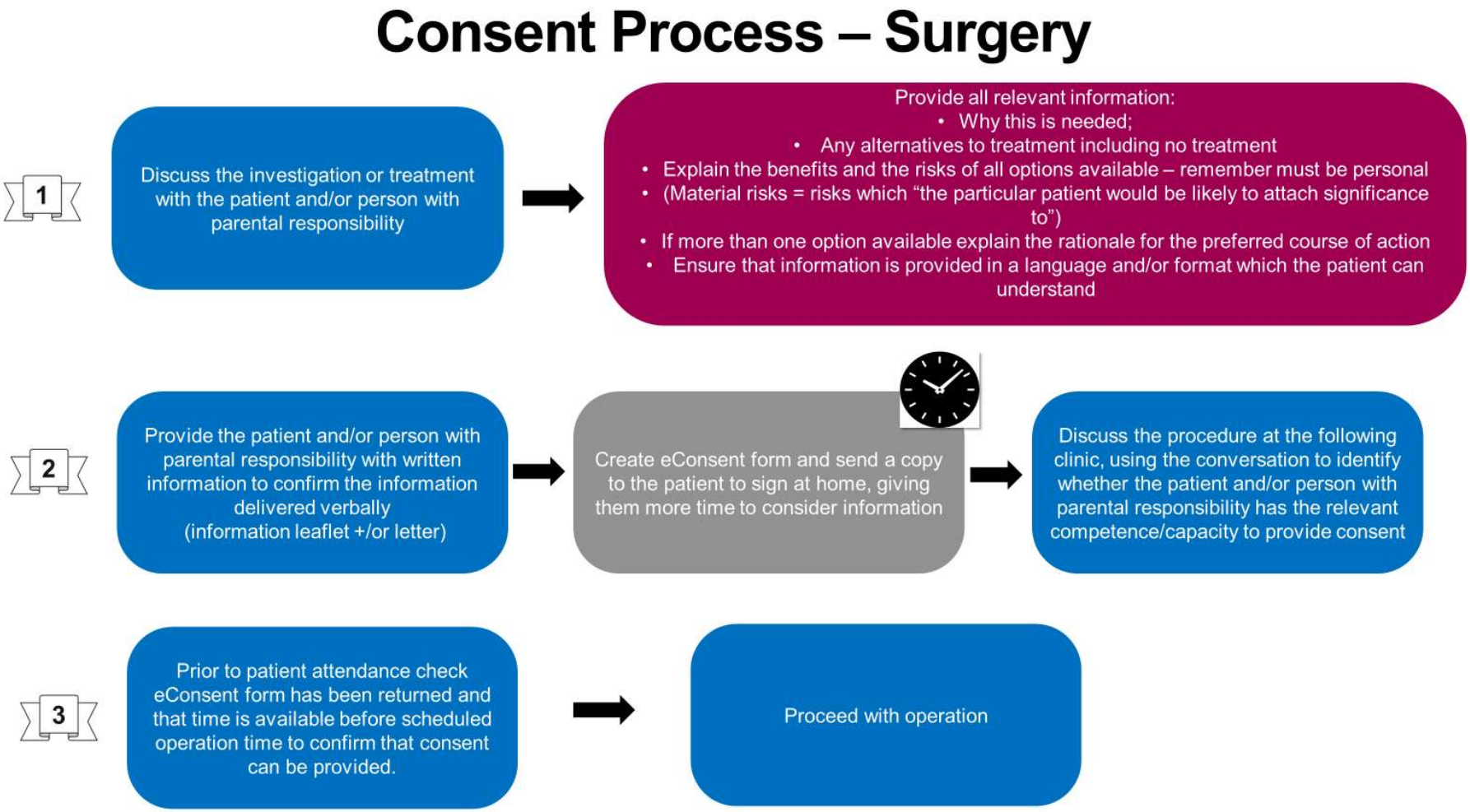
C47 - Privacy and Dignity Policy

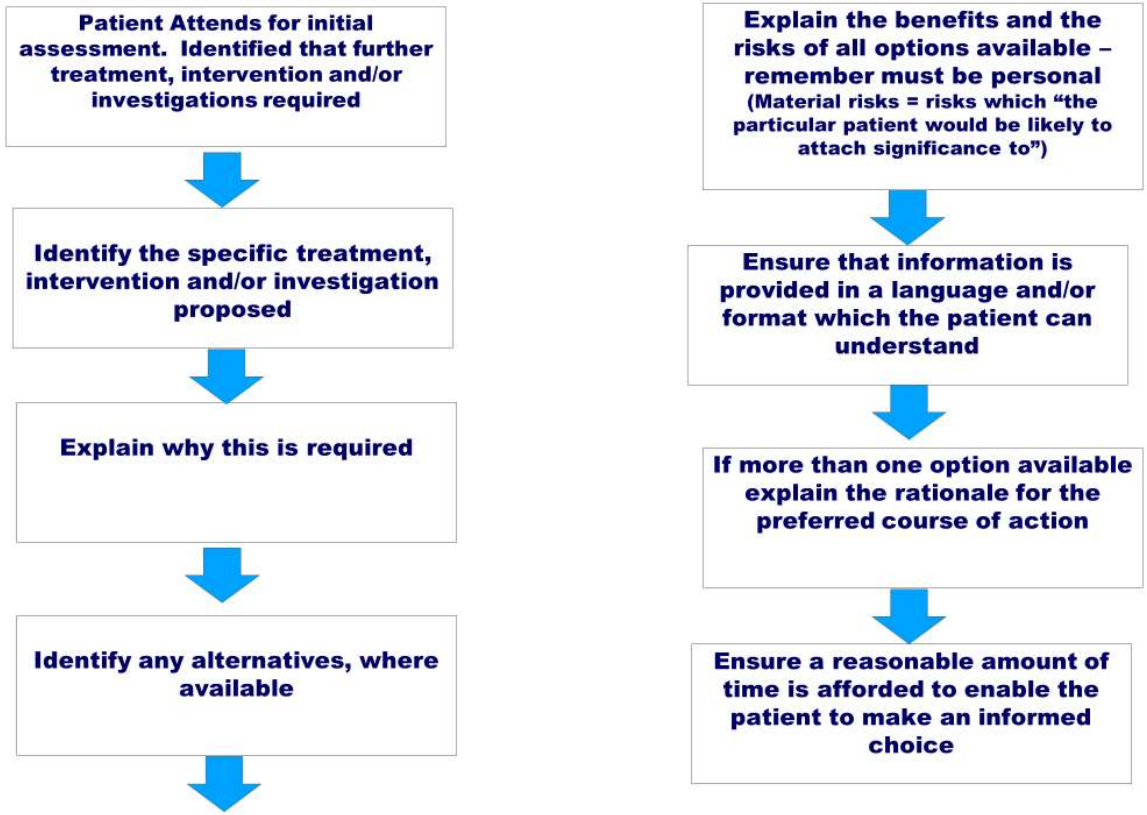
MH3 - Legal Aspects of Assessment and Treatment of Children and Young People with Mental Disorder Policy

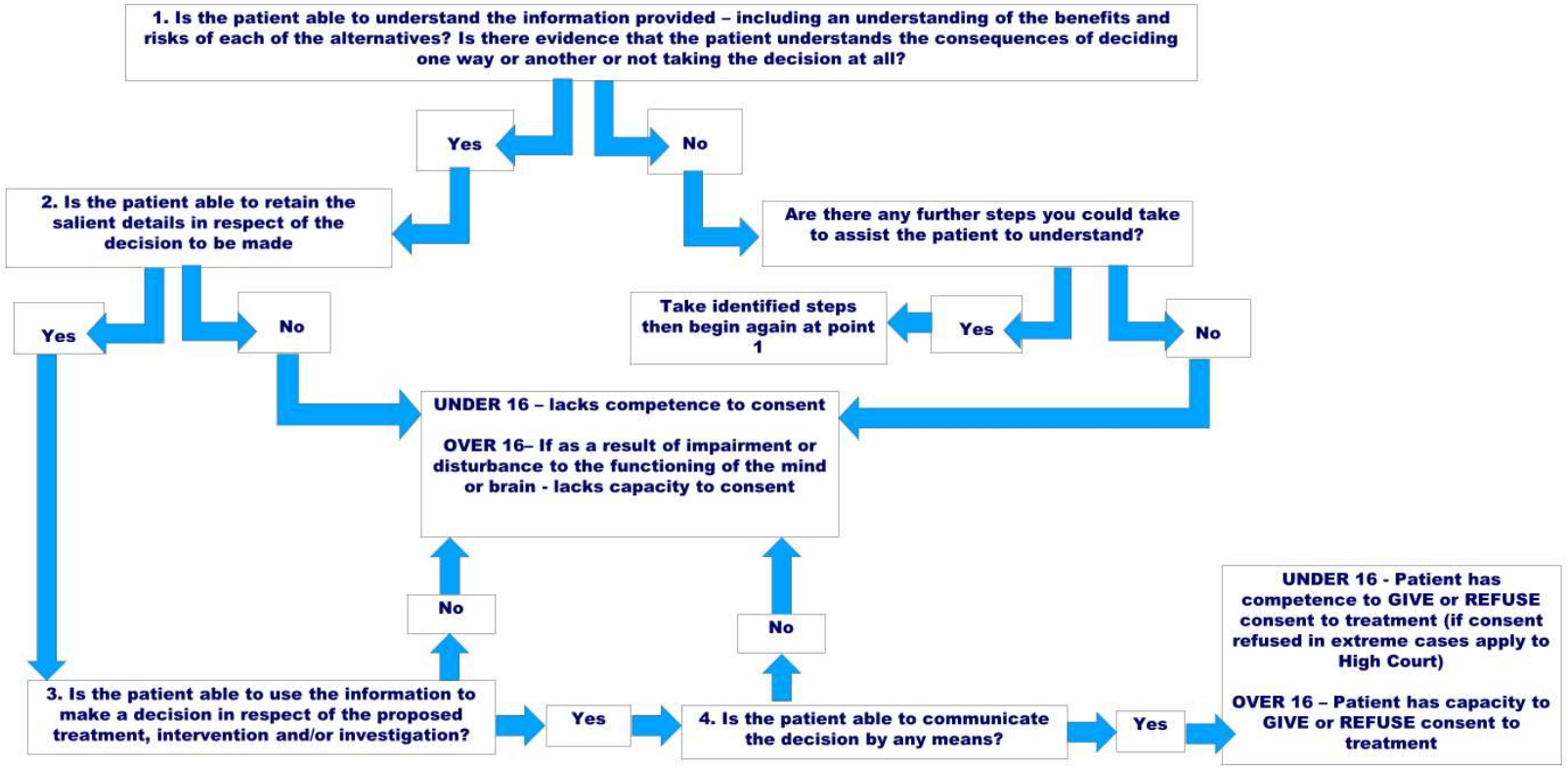
M13 - Policy for Producing Patient Information for Patients, Parents and Carers

M69 - Mental Capacity Act and Deprivation of Liberty Safeguards (DoLS)

Appendix A - Flowcharts to Support the Consent Process



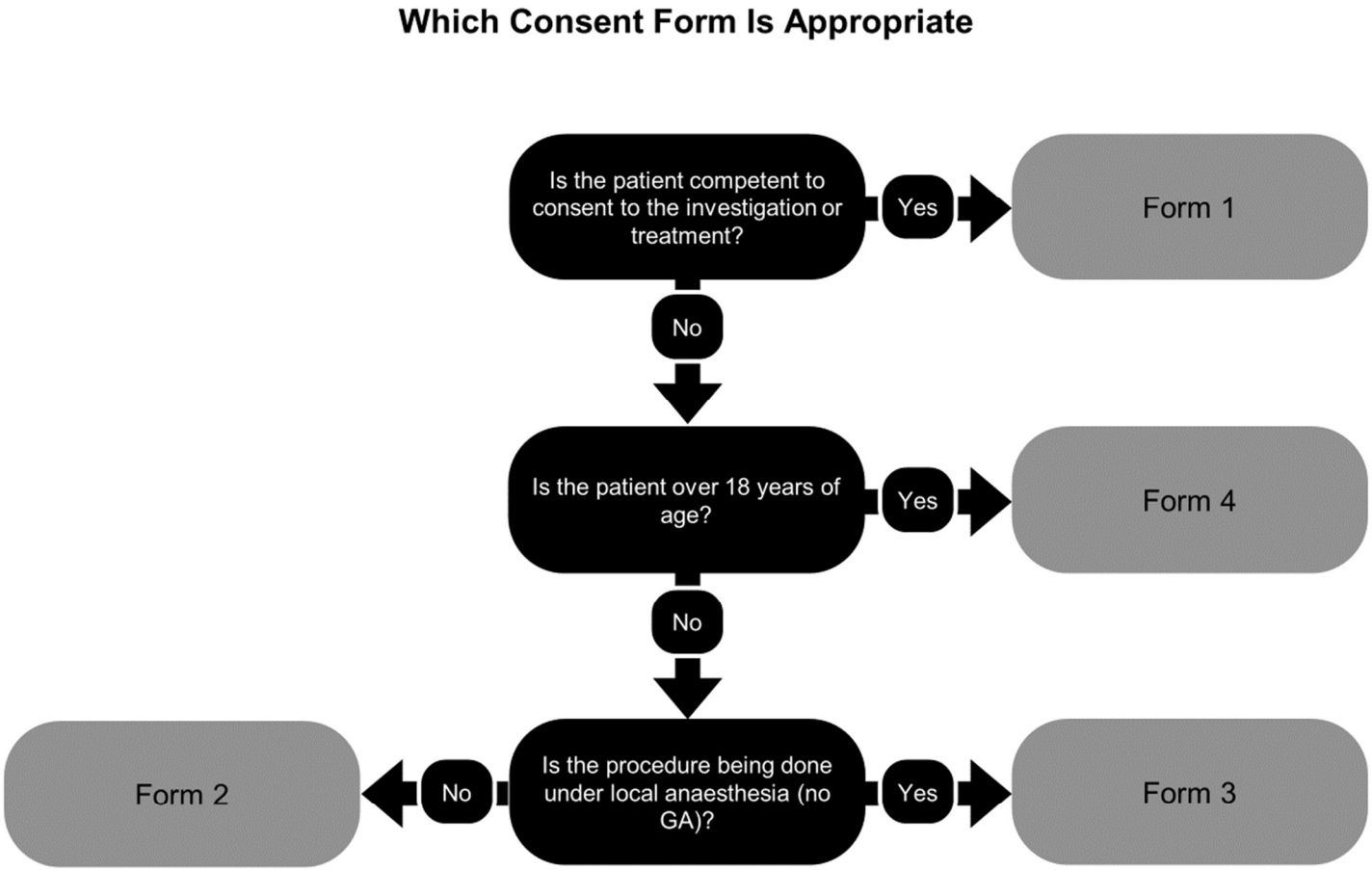

Patient Attends for initial assessment. Identified that further treatment, intervention and/or investigations required
Identify the specific treatment, intervention and/or investigation proposed
Explain why this is required
Identify any alternatives, where available
Explain the benefits and the risks of all options available – remember must be personal
(Material risks = risks which "the particular patient would be likely to attach significance to")
Ensure that information is provided in a language and/or format which the patient can understand
If more than one option available explain the rationale for the preferred course of action
Ensure a reasonable amount of time is afforded to enable the patient to make an informed choice


1. Is the patient able to understand the information provided – including an understanding of the benefits and risks of each of the alternatives? Is there evidence that the patient understands the consequences of deciding one way or another or not taking the decision at all?
Yes
No
2. Is the patient able to retain the salient details in respect of the decision to be made
Are there any further steps you could take to assist the patient to understand?
Yes
No
Take identified steps then begin again at point 1
Yes
No
UNDER 16 – lacks competence to consent
OVER 16– If as a result of impairment or disturbance to the functioning of the mind or brain - lacks capacity to consent
No
No
3. Is the patient able to use the information to make a decision in respect of the proposed treatment, intervention and/or investigation?
Yes
4. Is the patient able to communicate the decision by any means?
Yes
UNDER 16 - Patient has competence to GIVE or REFUSE consent to treatment (if consent refused in extreme cases apply to High Court)
OVER 16 – Patient has capacity to GIVE or REFUSE consent to treatment

CIRCUMSTANCE	PARENTAL CONSENT REQUIRED	TREATMENT CAN BE GIVEN	TREATMENT CANNOT BE GIVEN	COURT APPLICATION REQUIRED
Patient under 16 – Competent and Consents	✖	✔	✖	✖
Patient under 16 – Competent and refuses consent	✖	✖	✔	✔ Court Authorisation would be required before providing treatment – Court would only us intervene in respect of serious/life threatening cases
Patient under 16 – Not competent but compliant	✔ Case Law indicates that medical treatment falls within the 'zone of parental control' but be careful – the older the child the less clear this is	✔ If it is considered to be in the patient's best interests to receive the treatment and there is no dispute	✖	✖
Patient under 16 – Not competent and non-compliant	Case Law indicates that medical treatment falls within the 'zone of parental control' but be careful – the older the child the less clear this is	If it is considered to be in the patient's best interests to receive the treatment and there is no dispute	✖	✔ Although case law indicates that medical treatment falls within the 'zone of parental con given the lack of clarity in this area where the patient is non-compliant and may require restraint sensible to seek authority from the Court. Depends on age of the child and the nature of the treatment – seek advice
Patient 16/17 – Capacitous and Consents	✖	✔	✖	✖
Patient 16/17 – Capacitous and refuses consent	✖	✖	✔	Court authorisation would be needed before treatment could be given. Very unlikely to authoris treatment where patient has capacity - Court would only usually intervene in respect of serious/l threatening cases
Patient 16/17– Lacks Capacity but compliant	✖ If the patient lacks capacity best practice would be to provide treatment under s.5 and 6 MCA in the patient's best interests (s.4 MCA)	✔ Treatment can be provided under s.5 and s.6 MCA in the patient's best interests (s.4 MCA) if there is no dispute	✖	✔ If providing treatment would involve DoLand under 18. If there is a dispute as to patient's best interests and/or decision is finely balanced seek advice i respect of referring the matter to the Court ✖ If the treatment being provided is the same as that which would be provided to an indiv without a mental disorder then may not be considered to amount to a deprivation of liberty. The automatic requirement to refer to the Court in cases where there is no dispute that the treatment in the patient's best interests
Patient 16/17 – Lacks Capacity and non-compliant	✖	✔ Treatment can be provided under s.5 and s.6 MCA in the patient's best interests (s.4 MCA) if there is no dispute	✖	✔ If providing treatment would involve DoLand under 18. This is usually where there is the requirement to use sedation and/or restraint, which would not otherwise be used to deliver the t care and treatment to a patient who did not have a mental disorder. If there is a dispute as to patient's best interests and/or considered to be finely balanced seek a respect of referring the matter to the Court.

The information and any commentary contained in this presentation are for general information purposes only and do not constitute legal or any other type of professional advice. We do not accept and, to the extent permitted by law, exclude liability to any person for any loss which may arise fro relying upon or otherwise using the information contained in this presentation. Whilst every effort has been made when preparing this presentation, no liability is accepted for any error or omission. If you have any particular query or issue, we would strongly recommend you contact a member of Legal Team who would be happy to provide specific advice.

Appendix B - Which Consent Form to Use



Equality Analysis (EA) for Policies		
The Public Sector Equality Duty (section 149 of the Equality Act 2010) requires public authorities to have due regard for the for need to achieve the following objectives in carrying out their functions: a) Eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010. b) Advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it c) Foster good relations between persons who share a relevant protected characteristic and persons who do not share it. Please refer to Equality Analysis Step-Wise Guide for Policies when completing this form		
Policy Name	Consent Policy	
Policy Overview	The overriding objective of this policy is to ensure that healthcare professionals involved in the process of obtaining informed consent protect the patient's freedom to make their own choices during the decision making process. Each step in any consenting process must be measured against this fundamental principle. Regulatory bodies have not made any substantial changes to what is required for an appropriate and ethical consent process, so this policy does not include new advice, but what is given is presented in a new way. This policy has been written in a very simple way to make it easy to access and apply in day to day practice throughout the Trust. There is now a separate policy dealing specifically with the assessment of mental capacity to provide or decline consent to medical treatment.	
Relevant Changes (if any)	The policy has been completely rewritten such that there are principles given that can be applied across many consent situations.	
Equality Relevance Select LOW, MEDIUM or HIGH	HIGH	
If the policy is LOW relevance, you **MUST** state the reasons here.	Click here to enter text.	
Form completed on:	Date: 11/12/2022	
Form completed by:	Name: Harriet Corbett	Job Title: Consultant Urologist / Clinical Lead for Consent

If LOW relevance, proceed to Approval and Ratification Section. No further information required

If MEDIUM or HIGH Equality Relevance, complete all sections		
Equality Indicators Identify the equality indicators which will or could potentially be impacted by the policy and	Protected Characteristic	Mitigation
	Age ☑ How: Click here to enter text.	See section 6.7
	Disability ☑ How: Click here to enter text.	See section 6.7 and Trust policy on mental capacity

include details of how they may be impacted. (use **Equality Relevance** to assess the impact on each protected characteristic)	Gender reassignment ☑ How: Click here to enter text.	Considered – but there would be no change to the consenting process. Any issues relating to disagreement between parents and child – See section 6.7 and Trust policy on mental capacity
	Marriage & Civil Partnership ☑ How: Click here to enter text.	Relates to rules on parental responsibility.
	Pregnancy or Maternity ☐ How: Click here to enter text.	Click here to enter text.
	Race ☑ How: Click here to enter text.	There is potential for language barriers – see Trust Interpreting and Translation policy
	Religion or Belief ☑ How: Click here to enter text.	A person's religion / belief may be relevant to their treatment preference and should be considered when discussing treatment options. In addition, see Trust policy on blood transfusion (Appendix D – Jehovah's Witness – Complex Consent Situations) and Trust policy on mental capacity
	Sex ☐ How: Click here to enter text.	Click here to enter text.
	Sexual Orientation ☐ How: Click here to enter text.	Click here to enter text.
	Human Rights (FREDA principles) ☑ How: Click here to enter text.	Article 5: The right to liberty – See Trust policy on deprivation of liberty (DoLS).
Equality Information & Gaps What equality information is available for protected groups affected by the policy? If none available, include steps to be taken to fill gaps.	The policy is based on General Medical Council Decision Making and Consent recommendations incorporating the current legal framework arising from the case of Montgomery. Following the Montgomery court case the law is such that healthcare professionals must discuss with the patient the 'material risks' of any proposed treatment, as well as any alternatives and the option of no treatment. This policy should be used in combination with the Trust mental capacity policy for complex consent situations.	
Stakeholder Engagement What stakeholders are engaged to help understand the potential effects on protected groups? See **Gunning Principles** for public consultation requirements.	The policy has been co-authored with the Trust Lawyers	

How has consultation influenced the policy?		
Interdependency How will this affect other policies, projects, schemes from an equality perspective?	Links to: C1 - Blood and Blood Component Transfusion Policy C16 - Interpreting, Translation & Accessible Information Policy C47 – Privacy and Dignity Policy MH3 – Legal Aspects of Assessment and Treatment of Children and Young People with Mental Disorder Policy M13 - Patient Information Leaflets Policy M69 – Mental Capacity Act and Deprivation of Liberty Safeguards (DoLS)	
Public Sector Equality Duty Include a summary of how each of the PSED requirements have been considered in order to demonstrate compliance with the Act.	a) Eliminate discrimination, harassment, victimisation etc Healthcare professionals applying the principles in this policy should be compliant with this PSED requirement.	
	b) Advance equality of opportunity Healthcare professionals applying the principles in this policy should be compliant with this PSED requirement.	
	c) Foster good relations Healthcare professionals applying the principles in this policy should be compliant with this PSED requirement.	
	Has the Public Sector Equality Duty been met? Yes ☒ No ☐ The policy addresses potential negative impact for protected characteristics.	
Monitoring Include details of how the equality impact will be monitored.	Trust processes of monitoring complaints and incidents.	
Review of Equality Analysis (if indicated)	Rationale for review: Click here to enter text.	
	Changes made: Click here to enter text.	Reason for change: Click here to enter text.

If **MEDIUM** or **HIGH r**elevance, the EA should be reviewed annually. Complete Approval and Ratification Section.

Approval & Ratification of Equality Analysis		
Policy Author:	Name: Harriet Corbett	Job title: Consultant Urologist / Clinical Lead for Consent
Approval Committee:	Clinical Quality Steering Group	Date approved: 10/08/2021
Ratification Committee:	Safety and Quality Assurance Committee	Date ratified: 22/09/2021
Person to Review Equality Analysis:	Name: Harriet Corbett	Review Date: 22/09/2024
Comments:	Click here to enter text.	