

Ramsay Health Care UK

GROUP POLICIES AND PROCEDURES

Policy:Consent to treatment for competent adults and
children/young peopleCategory:Clinical/MedicalPolicy No:CN004

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulations 9, 11, 12, 13, 17, 18

Corporate Policy Cross References: CN024, CM003, CN043, CLM020, IS026

Reviewing Committee:	Clinical Governance Committee		
Responsible Person:	Director of Clinical Services		
Issue Date:	February 2003		
Last Review Date:	June 2016		
Next Review Date:	June 2019 (or in line with changes in guidelines)		

Name/Title	Signature	Date
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Am	Amendment Record				
Issue Status	Version	Date	Actioned By	Description	
Revised	v2.0	July 2010	Annette Shannon	Full revision of policy to include key principles of consent with supporting information within appendices.	
				Policy purpose amended to provide guidance of consent for competent adults and children	
Revised Final	v2.1	Jan 2013	Annette Shannon	4.1 Reinforcement of second stage process for all patients.	
				4.3 Clarification of use of consent form and consent process for bilateral procedures and recall procedures.	
				Addition of section 4.3.1 Receipt of consent forms by facsimile (fax)	
				1.6 Addition of reference to Ramsay Information Security policy 'Clinical Photography'	
				7. Addition of consent for Blood Transfusion and references	
Revised Final	v2.1	Feb 2013	Annette Shannon	Updated EQA added to policy – Appendix 5	
Final	v2.2	June 2016	Annette Hemming -Allen	Three year review 8.0 Supreme Court ruling and GMC guidance added to clarify communication of risk to patient.	
				9.0 Responsibility for consent / Nurse led	
				11.0 Consent forms – addition of clarification for use of pre-printed consent forms.	
				Clarification that labels, stickers and stamps will not be used on consent forms	
				Addition of 'consent forms will not be retrospectively altered.	
				11.1 Amendment to receipt of consent forms – Ramsay will not accept a faxed consent form.	
				15.0 Cosmetic procedures – section added	
				16.0 Consent training – section added	
				References updated	

Amendment Record



1.0 STATEMENT

It is a general legal and ethical principle that valid consent must be obtained before starting treatment or physical investigation, or providing personal care, for a person. This principle reflects the right of patients to determine what happens to their own bodies, and is a fundamental part of good practice. A healthcare professional (or other healthcare staff) who does not respect this principle may be liable both to legal action by the patient and to action by their professional body. As an employer, Ramsay may also be liable for the actions of their staff.

There is no English statute setting out the general principles of consent, case law ('common law') has established that touching a patient without valid consent may constitute the civil or criminal offence of battery. Further, if healthcare professionals (or other healthcare staff) fail to obtain proper consent and the patient subsequently suffers harm as a result of treatment, this may be a factor in a claim of negligence against the healthcare professional involved. Poor handling of the consent process may also result in complaints from patients through the complaints procedure or to an individual healthcare workers professional body.

Valid consent to treatment is absolutely central in all forms of healthcare, from providing personal care to giving medication or other forms of physical investigation to undertaking major surgery. Seeking consent is also a matter of common courtesy between health professionals and patients.

All healthcare workers must be aware of and take into account their own professional body/college guidance for consent.

This policy is based on providing informed consent to competent adults and children.

Further information is available in the appendices and referenced material for the provision of consent to those adults and children who are not considered competent to give consent.

2.0 PURPOSE

- To ensure patients are treated in accordance with recognised standards and guidelines.
- To ensure health professionals have clear guidance regarding their responsibilities for obtaining consent to treatment.
- To ensure that patients are recognised partners in decisions about their treatment.
- To ensure compliance with the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and the Care Quality Commission (Registration) Regulations 2009 and the 'Essential standards of quality and safety' (CQC) March 2010.
- To ensure patients are treated in accordance with the Mental Capacity Act 2005.



• To ensure compliance with the Human Rights Act 1998.

3.0 SCOPE

The operation of this policy applies to all Healthcare professionals providing treatment to patients within Ramsay Health Care UK hospitals and clinics including independent consultants and those on temporary contracts and/or employed as sub contractors to Ramsay Health Care UK.

4.0 EXCLUSIONS

Any staff member not involved in providing treatment to patients such as housekeeping, catering, maintenance or portering staff.

5.0 LOCATIONS

All areas in the hospital/unit where treatment is planned or delivered.

6.0 RESPONSIBILITIES

The Registered Manager is responsible for the implementation of the policy and ensuring that medical and clinical staff are aware of the necessity of informed consent and the process of informed consent, and have the necessary skills and training to effect this.

Medical and Clinical staff are responsible for ensuring their practice incorporates the standards outlined within this Corporate policy.

7.0 General Principles

7.1 Valid consent

Consent is often equated with a patient's signature on a consent form. However, this is not proof positive. A signature on a form is one form of *evidence* that the patient has given consent, but is not necessarily *proof* of valid consent. If a patient is rushed into signing a form, on the basis of too little information, the consent may not be valid, despite the signature. Similarly, if a patient has given valid verbal consent, the fact that they are physically unable to sign the form is no bar to treatment. Patients may, if they wish, withdraw consent after they have signed a form: the signed form is evidence of the process of consent-giving, not a binding contract. In cases that involve higher risk, it is important that you get the patient's written consent. This is so that everyone involved understands what was explained and agreed.

For the consent to be valid, the patient must;

- be competent to take the particular decision i.e. capacity
- have received sufficient information to take it
- not be acting under duress i.e. given voluntarily and freely

7.2 Capacity

An assessment of a person's capacity must be based on their ability to make a specific decision at the time it needs to be made, and not their ability to make decisions in general. A person is unable to make a decision if they cannot do one or more of the following things;



- understand the information given to them that is relevant to the decision
- retain that information long enough to be able to make the decision
- use or weigh up the information as part of the decision-making process
- communicate their decision this could be by talking or using sign language and includes simple muscle movements such as blinking an eye or squeezing a hand.

People may have capacity to consent to some interventions but not to others, or may have capacity at some times but not others. Under the Mental Capacity Act 2005, a person must be assumed to have capacity unless it is established that they lack capacity.

A person's capacity to consent may be temporarily affected by factors such as confusion, panic, shock, fatigue, pain or medication. However, the existence of such factors should not lead to an automatic assumption that the person does not have the capacity to consent.

If there is any doubt, then the healthcare professional should assess the capacity of the patient to take the decision in question. This assessment and the conclusions drawn from it should be recorded in the patient's notes. Guidance on assessing capacity is given in Appendix 2 and also chapter 4 of the Mental Capacity Act (2005) Code of Practice and Ramsay policy CN024 Mental Capacity.

7.3 Informed consent

"Consent" is a patient's agreement for a health professional to provide care. Patients may indicate consent non-verbally (for example by presenting their arm for their pulse to be taken), orally, or in writing.

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

7.4 Additional procedures

During an operation it may become evident that the patient could benefit from an additional procedure that was not within the scope of the original consent. If it would be unreasonable to delay the procedure until the person regains consciousness (for example because there is a threat to the person's life) it may be justified to perform the procedure on the grounds that it is in the person's best interests. The procedure should not be performed merely because it is convenient. For example, a



hysterectomy should never be performed during an operation without explicit consent, unless it is necessary to do so to save life.

If a patient has refused certain additional procedures before the anaesthetic, this must be respected if the refusal is applicable to the circumstances. The General Medical Council (GMC) guidance states that it is good practice to seek the views of the patient on possible additional procedures when seeking consent for the original intervention.

7.5 Use of removed tissue

The Human Tissue Act 2004 makes consent the fundamental principle underpinning the lawful retention and use of body parts, organs and tissue from the living or the deceased for specified health-related purposes and public display.

The 2004 Act regulates removal, storage and use of human tissue. Patients may give or withhold the use of tissue removed during an operation for further research or training purposes.

7.6 Consent to photographs, filming or audio recordings

Photographic and video recordings made for clinical purposes form part of a patient's record. Although consent to certain recordings, such as x- rays, is implicit in the patient's consent to the procedure, health professionals should always ensure that they make clear in advance if any photographic or video recording will result from that procedure.

Photographic and video recordings which are made for treating or assessing a patient must not be used for any purpose other than the patient's care or the audit of that care, without the express consent of the patient or a person with parental responsibility for the patient. If you wish to use such a recording for education, publication or research purposes, you must seek consent in writing, ensuring that the person giving consent is fully aware of the possible uses of the material. In particular, the person must be made aware that you may not be able to control future use of the material once it has been placed in the public domain. If a child is not willing for a recording to be used, you must not use it, even if a person with parental responsibility consents.

Refer to Ramsay Information Security policy IS026 Clinical Photography.

Further information is available from GMC guidance (2002) Making and Using Visual and Audio Recordings of Patients.

8.0 When verbal and written consent is used

It is not always a legal requirement to seek written consent, but it is good practice according to Department of Health guidance and Ramsay policy to do so if any of the following circumstances apply;

• The treatment or procedure involves physical intervention or is complex, or involves "significant risks" A patient should be informed if an investigation or treatment might result in a serious adverse outcome, even if the likelihood is very small. Questions are often raised



about the level of likelihood of an adverse outcome and discussion of that potential adverse outcome with a patient. In the recent case of Montgomery v Lanarkshire Health Board, the Supreme Court found that the assessment of whether a risk is material cannot be reduced to percentages. The significance of a given risk is likely to reflect a variety of factors besides its magnitude: for example, the nature of the risk, the effect which its occurrence would have upon the life of the patient, the importance to the patient of the benefits sought to be achieved by the treatment, the alternatives available, and the risks involved in those alternatives. The assessment is therefore fact-sensitive, and sensitive also to the characteristics of the patient.

The basic legal position is that a patient needs to be warned of all risks that a reasonably competent practitioner would consider it is important to warn a patient of.

Accordingly GMC Guidance draws attention to the case of Chester v Afshar where a failure to warn of a 1-2% risk was held to be negligent. In Chester, the court said that a doctor owes "a general duty to a patient to warn him or her in general terms of possible risks involved in the procedure. The only qualification is that there may be wholly exceptional cases where objectively in the best interests of the patient, the [doctor] may be excused from giving a warning."

An alternative course of action if it exists should be discussed with the patient should be evidenced in the stage one consent process.

Accordingly the GMC advises that:

- Patients should be told of any possible significant adverse outcomes of a proposed treatment;

- A small but well established risk of a serious adverse outcome has been considered by the House of Lords to be "significant".

Patients should be told about less serious side effects or complications if they occur frequently, and explain what the patient should do if they experience any of them. The term 'risk' is used to refer to any adverse outcome, including those which some health professionals would describe as 'side-effects' or 'complications. This applies to procedures/treatment undertaken in Outpatient departments and Ward areas as well as operating theatre areas.

- The procedure involves general/regional anaesthesia or sedation providing clinical care is not the primary purpose of the procedure.
- There may be significant consequences for the patient's employment, social or personal life.
- The treatment is part of a project or programme of research approved by Ramsay Health Care UK (refer to CM003 Research and Development policy).
- Should a patient provide a 'living will' or advance directive, written consent will also be obtained using the appropriate Ramsay form, refer to policy CN043 Advance Directives/Decisions/Statements.



• Should a patient not give consent for a blood transfusion, refer to CLM 020 Hospital Transfusion policy.

9.0 Responsibility for consent

The clinician providing the treatment or investigation is responsible for ensuring that the person has given valid consent before treatment begins, although the consultant responsible for the person's care will remain ultimately responsible for the quality of medical care provided. The GMC guidance states that the task of seeking consent may be delegated to another person, as long as they are suitably trained and gualified. In particular, they must have sufficient knowledge of the proposed investigation or treatment, and understand the risks involved, in order to be able to provide any information the patient may require. The practitioner who eventually carries out the investigation or treatment must also be able to determine whether the person has the capacity to make the decision in question and what steps need to be taken if the person lacks the capacity to make that decision. Inappropriate delegation (for example where the clinician seeking consent has inadequate knowledge of the procedure) may mean that the `consent' obtained is not valid. Clinicians are responsible for knowing the limits of their own competence, and should seek the advice of appropriate colleagues when necessary.

Nurse led consent – it is acknowledged that certain specialties that offer one stop services have nurse led consent. In Ramsay, nurse led consent is only acceptable for those nurses who hold a Clinical Nurse Specialist qualification within the specialty for which they are receiving patient consent, and have received specific training of, and have a current competency in this responsibility. The clinician with overall responsibility for delivering the procedure must have delegated this task explicitly and confirmed this in writing in line with the statements above.

Evidence of completion and certification of EIDO web based consent training 'be Informed' will fulfil this training requirement. See section 15.0.

10.0 Process of consent

The seeking and giving of consent is usually a process, rather than a one-off event. For major interventions, it is good practice where possible to seek the person's consent to the proposed procedure well in advance, when there is time to respond to the person's questions, provide adequate information and allow time for the patient to prepare for their hospitalisation and subsequent recovery. A healthcare professional should then check, before the procedure starts that the person still consents. If a person is not asked to signify their consent until just before the procedure is due to start, at a time when they may be feeling particularly vulnerable, there may be real doubt as to its validity.

10.1 Two stage process

For interventions requiring written consent (see section 8.0) it is Ramsay policy that consent will be initiated at the earliest stage and evidenced by the *first stage* of the consent form being completed and the patient confirming receipt of information to allow him/her to make an informed



choice of whether to proceed with the procedure and satisfactory period of time to ask further questions or be provided with further information.

The **second stage** will be on the day of procedure prior to the patient transfer to the procedure/operating suite. All patients will be asked by a healthcare professional if they have any further questions regarding the procedure and if there have been any changes in their medical condition since receiving the information regarding their procedure.

A positive response to either of these questions will prompt the healthcare professional to request the clinician performing the procedure to revisit the patient and reassess if the patient has been provided with appropriate information for the procedure to proceed.

The patient will also be asked at this stage if they have received information on risks, benefits and alternatives regarding their anaesthesia and opportunity to discuss this with the Anaesthetist and if they require further clarification/information.

When a confirmation response to the 3 questions stating no further clarification or input is required, this will allow the healthcare professional to sign off stage two of the consent form and for the patient to proceed with their procedure as planned.

10.2 Risks/benefits

Information on the description, risks and benefits of the major procedures carried out in Ramsay has been developed for use by patients in the form of patient information leaflets. These leaflets (EIDO) are revised annually, are version controlled and fully meet the Department of Health (DH) guidelines for informed consent and patient leaflets.

Any healthcare professional/Consultant wishing to provide their own or any other patient information leaflet to support the informed consent process must be written according to the DH guidelines and approved by the local Medical Advisory Committee and General Manager. A copy of the approved information leaflet must be dated; version controlled and have a review date, maximum of 3 years from date of issue. This will be held in the Consultants personnel file for future reference. A system must be in place to ensure all patient information leaflets provided are in date, referenced, version controlled, reviewed and available to be retrieved for future reference.

All information specific to the patient and procedure as discussed should be recorded contemporaneously in the patients' record. The hospital will hold a copy of this record within the patient record for future reference.

11.0 Consent forms

Ramsay has four consent forms printed for use when written consent is required.

Form 1 – is for use for adults and competent children.

Form 2 – for parental consent for a child or young person.

Form 3 – for cases where it is envisaged that the patient will remain alert throughout the procedure and no anaesthetist will be involved throughout their care. The use of this form is optional in place of using form 1; but may be considered more appropriate in situations where there are no issues



surrounding general or regional anaesthesia i.e. invasive radiological procedures, invasive procedures carried out in outpatient departments. *Form 4* – for adults who are unable to consent to investigation of treatment.

Should a Consultant wish to use a consent form that is not a Ramsay consent form to evidence the first stage of informed consent, this must first receive prior Medical Advisory Committee (MAC) approval and meet Ramsay consent form minimum standards and the Department of Health requirements for a consent record. Should a Consultant wish to use a pre-printed consent form to evidence first stage of informed consent, this must meet the standards and approvals as above. The Consultant must ensure patient specific risks and benefits are also recorded on the form.

Labels/stickers apart from the patient identifier will not be used on a consent form. Stamps will not be used. There is no evidence these have not been added at a later date.

A consent form must be completed for the procedure being undertaken. In the case of staged bilateral procedures being undertaken in two episodes of care, separate consent forms must be completed and the informed consent process must be evidenced for each procedure.

In some circumstances, it may be necessary to recall patients for further diagnostic investigation, e.g. endoscopy or MRI scan. A new consent form must also be completed for these recall procedures.

An evidenced consent process must be in place for each and every procedure.

A Ramsay consent form must be used to evidence stage two of the consent process should a non Ramsay consent form be used at stage one.

Consent forms **must not be** retrospectively altered.

11.1 Receipt of consent forms from a third party

Ramsay will not accept a faxed consent form.

It is Ramsay's best practice to ensure that consent forms received from a third party are scanned and emailed over a secure network to an appropriate person. Following receipt, the document should be printed and then placed in the patient's medical record and the email should be deleted.

11.2 Evidence of process - audit

In order to assure Ramsay that all patients receive sufficient information of their procedure in a timely way to ensure full understanding and ability to request further information as required, audit will be carried out, at a minimum, every three months covering the key principles and requirements for those procedures requiring a written consent process.



12.0 Anaesthetic guidance

Where an anaesthetist is involved in a patient's care, it is their responsibility (not that of a surgeon) to seek consent for anaesthesia, having discussed the benefits and risks. It is understood in most cases the patient will not meet an anaesthetist until the day of their procedure. In elective treatment, it is not acceptable for the patient to receive information about anaesthesia until their pre-operative visit from the anaesthetist: at such a late stage the patient will not be in a position to make a decision about whether or not to undergo anaesthesia or to decide on the choices available.

Patients should therefore receive a general information leaflet about anaesthesia prior to their admission for treatment, and/or have the opportunity to discuss anaesthesia in a pre-assessment clinic.

The anaesthetist must ensure that the discussion with the patient and their consent is documented in the anaesthetic record or in the patient's notes. Where the clinician providing the care is personally responsible for anaesthesia (e.g. where local anaesthesia or sedation is being used), then he or she will also be responsible for ensuring that the patient has given consent to that form of anaesthesia.

If the anaesthetic procedure is the primary therapeutic intervention e.g. treatment of chronic pain or placement of a central line for chemotherapy, written consent should be gained from the patient.

Rectal Suppositories cannot be administered under anaesthetic without a patient's consent. The Anaesthetist is responsible for obtaining informed consent where the use of rectal analgesia is planned or likely and recorded on the anaesthetic record.

In no circumstances should a person be given routine pre-operative medication before being asked for their consent to proceed with the treatment. Preliminary medications must only be administered after stage two of the written consent process is obtained.

13.0 HIV Testing

The Department of Health letter, (PL/CMO (909) 2) states that explicit consent should be obtained before a person is tested for evidence of HIV infection. In such circumstances Consent Form 1 should be used.

14.0 Consent for Blood Transfusion

Routine blood transfusion does not require formal written consent. Verbal consent should be documented in the case notes following discussion of risks and benefits. Written consent using Form 3 should be obtained for long-term multi-transfused patients. See SaBTO Guidance for Clinical Staff.

15.0 Cosmetic Procedures

In addition to following all other areas of this policy, the General Medical Council (GMC) has stated consent for cosmetic procedures should not be delegated. *GMC June 2016*.

Ensure that consent is obtained in a two-stage process with a cooling-off period of at least two weeks between the stages to allow the patient to reflect on the decision. Should this not be possible, good reasons should be recorded in the patient's notes. Information on the procedure should be



received at a different time to the signing of the consent form. Royal College of Surgeons April 2016

16.0 Training

All health care professionals who perform significant risk or invasive procedures (see section 2) or complete second stage consent will undertake patient consent training every 5 years.

Training can be a certificated course/training day held by a reputable healthcare training company or by Ramsay's web based training.

Ramsay provides web based consent training by EIDO *be INFOrMED*. This training meets the level of knowledge required. Ramsay has agreed the competence level for this course to be a pass score of 85%.

Users can self-register to use *be INFOrMED*. To register they require web access, an email address and the unique organisation ID and hospital password. Each hospital will have a local administrator who has the unique organisation ID and hospital password. The local administrator will run reports and edit users. The user scores can be accessed by the local administrators. The user will be able to print off a certificate for their own portfolio.

Ramsay has made this consent training available to Consultants and RMO's. Access to the training is as above or via the local administrator.



References

Care Quality Commission: Guidance for providers on meeting the regulations, March 2015

Department of Health (2008) Code of Practice: Mental Health Act 1983

Department of Health (2001) Good Practice in Consent Implementation Guide

Department of Health Guidance (Nov 2001) Seeking Consent: Working with Children

Department of Health (2005) Mental Capacity Act

Department of Health (Oct 2002) Reference guide to consent for examination or treatment

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

Department of Health Chief Medical Officer letter (PL/CMO (909) 2)

General Medical Council (June 2008) Consent: patient and doctors making decisions together http://www.gmc-uk.org/static/documents/content/Consent_-_English_1015.pdf

General Medical Council (July 2010) Treatment and care towards the end of life: good practice in decision making http://www.gmc-uk.org/guidance/ethical_guidance/end_of_life_care.asp

General Medical Council (April 2011) Making and using visual and audio recordings of patients

http://www.gmcuk.org/static/documents/content/Making_and_using_visual_and_audio_re cordings_of_patients.pdf

General Medical Council (June 2016) Guidance for doctors who offer cosmetic interventions

http://www.gmc-

uk.org/Guidance_for_doctors_who_offer_cosmetic_interventions_210316.pdf_65254111.p df

Royal College of Surgeons (April 2016) Professional Standards for Cosmetic Surgery

https://www.rcseng.ac.uk/publications/docs/professional-standards-for-cosmetic-surgery

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Part 3) as amended

NHS (2003) Toolkit for producing patient information version 2.0

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British Committee for Standards in Haematology (BCSH) Guideline on the Administration of Blood Components Addendum August 2011

SaBTO (Dec 2011) Guidance for Clinical Staff to support patient consent for blood transfusion v1.1

SaBTO (Oct 2011) Recommendations consent for patient transfusion

Chester v Afshar [2004] UKHL 41

http://www.publications.parliament.uk/pa/ld200304/ldjudgmt/jd041014/cheste-1.htm

Montgomery v Lanarkshire Health Board [2015] UKSC 11



APPENDIX 1

Children and young people

Refer to DH Reference guide to consent for examination or treatment 2nd edition, Section 3, pages 32 to 38.

The legal position concerning consent and refusal of treatment by those under the age of 18 is different from the position for adults. For the purposes of this guidance `children' refers to people aged below 16 and `young people' refers to people aged 16-17

Young People aged 16 to 17 years

By virtue of section 8 of the Family Law Reform Act 1969, people aged 16 or 17 are presumed to be capable of consenting to their own medical treatment, and any ancillary procedures involved in that treatment, such as an anaesthetic. As for adults, consent will be valid only if it is given voluntarily by an appropriately informed young person capable of consenting to the particular intervention. However, unlike adults, the refusal of a competent person aged 16-17 may in certain circumstances be overridden by either a person with parental responsibility or a court.

Section 8 of the Family Law Reform Act 1969 applies only to the young person's own treatment. It does not apply to an intervention that is not potentially of direct health benefit to the young person, such as blood donation or non-therapeutic research on the causes of a disorder. However, a young person may be able to consent to such an intervention under the standard of Gillick competence (see section 'the concept of Gillick competence).

In order to establish whether a young person aged 16 or 17 has the requisite capacity to consent to the proposed intervention, the same criteria as for adults should be used. If a young person lacks capacity to consent because of an impairment of, or a disturbance in the functioning of, the mind or brain then the Mental Capacity Act 2005 will apply in the same way as it does to those who are 18 and over. If however they are unable to make the decision for some other reason, for example because they are overwhelmed by the implications of the decision, then the Act will not apply to them and the legality of any treatment should be assessed under common law principles. It may be unclear whether a young person lacks capacity within the meaning of the Act. In those circumstances, it would be prudent to seek a declaration from the court. More information on how the Act applies to young people is given in chapter 12 of the Mental Capacity Act (2005) Code of Practice.

If the 16/17 year old is capable of giving valid consent then it is not legally necessary to obtain consent from a person with parental responsibility for the young person in addition to the consent of the young person. It is, however, good practice to involve the young person's family in the decision-



making process - unless the young person specifically wishes to exclude them - if the young person consents to their information being shared.

Children under the age of 16 years – the concept of Gillick competence

In the case of *Gillick*, the court held that children who have sufficient understanding and intelligence to enable them to understand fully what is involved in a proposed intervention will also have the capacity to consent to that intervention. This is sometimes described as being `Gillick competent'. A child under 16 may be Gillick competent to consent to medical treatment, research, donation or any other activity that requires their consent

The concept of Gillick competence is said to reflect a child's increasing development to maturity. The understanding required for different interventions will vary considerably. Thus a child under 16 may have the capacity to consent to some interventions but not to others. The child's capacity to consent should be assessed carefully in relation to each decision that needs to be made

In some cases, for example because of a mental disorder, a child's mental state may fluctuate significantly, so that on some occasions the child appears Gillick competent in respect of a particular decision and on other occasions does not. In cases such as these, careful consideration should be given as to whether the child is truly Gillick competent at the time that they need to take a relevant decision

If the child is Gillick competent and is able to give voluntary consent after receiving appropriate information, that consent will be valid and additional consent by a person with parental responsibility will not be required. It is, however, good practice to involve the child's family in the decision-making process, if the child consents to their information being shared

Where advice or treatment relates to contraception, or the child's sexual or reproductive health, the healthcare professional should try to persuade the child to inform his or her parent(s), or allow the medical professional to do so. If however the child cannot be persuaded, advice and/or treatment should still be given if the healthcare professional considers that the child is very likely to begin or continue to have sexual intercourse with or without advice or treatment, and that unless they receive the advice or treatment then the child's physical or mental health is likely to suffer.

If the child seeks advice or treatment in relation to abortion and cannot be persuaded to inform her parent(s), every effort should be made to help the child find another adult (such as another family member or a specialist youth worker) to provide support to the child.



APPENDIX 2

Adults without capacity

Refer to DH Reference guide to consent for examination or treatment 2nd edition, Section 2, pages 23 to 31.

Refer also to the Mental Capacity Act 2005 'Code of Practice'

General Principles

The Mental Capacity Act 2005 came fully into force in October 2007 and applies in England and Wales to everyone who works in health and social care and is involved in the care, treatment or support of people over 16 years of age who may lack capacity to make decisions for themselves. It is largely based on previous common law and creates a single, coherent framework for decision-making, including decisions about treatment. This chapter summarises the main provisions of the Mental Capacity Act. Detailed guidance is provided in the Code of Practice, which has statutory force. The Act imposes a duty on health professionals (and other healthcare staff) to have regard to the Code of Practice

Under English law, no one is able to give consent to the examination or treatment of an adult who lacks the capacity to give consent for themselves, unless they have been authorised to do so under a Lasting Power of Attorney or they have the authority to make treatment decisions as a court appointed deputy. Therefore, in most cases, parents, relatives or members of the healthcare team cannot consent on behalf of such an adult. However, the Mental Capacity Act sets out the circumstances in which it will be lawful to carry out such examinations or treatment

In general, the refusal to an intervention made by a person when they had capacity cannot be overridden if the advance decision is valid and applicable to the situation. There are certain statutory exceptions to this principle, including treatment for mental disorder under the Mental Health Act 1983.

The legal requirements in the Mental Capacity Act are underpinned by five statutory principles. One of these key principles is that any act done for, or any decision made on behalf of, a person who lacks capacity must be done, or made, in that person's best interests. This principle applies to health professionals as it does to anyone working with and caring for a person who lacks capacity. The Act also creates a new offence of ill treatment or willful neglect of someone who lacks capacity by someone with responsibility for their care or with decision-making powers.

Guidance on assessing a person's capacity (or lack of capacity) refers specifically to their capacity to make a particular decision at the time it needs to be made.

Clinical Medical Policy No. CN004 v.2.2 Date of last review: June 2016



The Mental Capacity Act 2005 defines a person who lacks capacity as a person who is unable to make a decision for themselves because of an impairment or disturbance in the functioning of their mind or brain. It does not matter if the impairment or disturbance is permanent or temporary. A person lacks capacity if:

- they have an impairment or disturbance (for example a disability, condition or trauma or the effect of drugs or alcohol) that affects the way their mind or brain works, and
- that impairment or disturbance means that they are unable to make a specific decision at the time it needs to be made.

The Mental Capacity Act provides healthcare professionals with protection from civil and criminal legal liability for acts or decisions made in the best interests of the person who lacks capacity. The Act makes it clear that when determining what is in a person's best interests a healthcare 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.

The Act requires that a healthcare professional **must** consider all the relevant circumstances relating to the decision in question. These are described as factors that the healthcare professional is aware of and which are reasonable to take into account.

In considering the relevant circumstances, the Act rules that the healthcare professionals **must** take the following steps;

- Consider whether the person is likely to regain capacity and if so whether the decision can wait.
- Involve the person as fully as possible in the decision that is being made on their behalf.
- As far as possible, consider:
 - the person's past and present wishes and feelings (in particular if they have been written down)
 - any beliefs and values (eg religious, cultural or moral) that would be likely to influence the decision in question, and any other relevant factors, and

 the other factors that the person would be likely to consider if they were able to do so.

 As far as possible, consult other people if it is appropriate to do so and take into account their views as to what would be in the Medical



best interests of the person lacking capacity, especially:

- anyone previously named by the person lacking capacity as someone to be consulted
- anyone engaging in caring for or interested in the person's welfare
- any attorney appointed under a Lasting Power of Attorney
- any deputy appointed by the Court of Protection to make decisions for the person
- for decisions about serious medical treatment, where there is no one appropriate other than paid staff, healthcare professionals have to instruct an Independent mental capacity advocate (IMCA).

If the decision concerns the provision or withdrawal of life-sustaining treatment, the person making the best interests decision must not be motivated by a desire to bring about the person's death.

The Mental Capacity Act (2005) Code of Practice makes it clear that the steps set out in the Act should form the starting point for considering all the relevant circumstances of each case, and often other factors will be important. Further guidance on interpreting best interests is provided in chapter 5 of the Code of Practice.

Healthcare professionals should demonstrate in their record-keeping that the decision has been based on all available evidence and has taken into account any conflicting views. What is in a person's best interests may well change over time. This means that even where similar actions need to be taken repeatedly in connection with the person's care or treatment, the person's best interests should be reviewed regularly

In cases of serious doubt or dispute about an individual's mental capacity or best interests, an application can be made to the Court of Protection for a ruling. The duty officer of the Official Solicitor can advise on the appropriate procedure if necessary. See also chapter 8 of the Mental Capacity Act (2005) Code of Practice for further information.



APPENDIX 3

Treatment and care towards the end of life

A healthcare professional's legal duty is to care for a patient and to take reasonable steps to prolong their life. Although there is a strong presumption in favour of providing life-sustaining treatment, there are circumstances when continuing or providing life-sustaining treatment stops providing a benefit to a patient and is not clinically indicated. There is no legal distinction between withdrawing and withholding life-sustaining treatment. A person with capacity may decide either contemporaneously or by a valid and applicable advance decision that they have reached a stage where they no longer wish treatment to continue. If a person lacks capacity, this decision must be taken in their best interests and in a way that reflects their wishes (if these are known)

Treatment and care towards the end of life: good practice in decision making, GMC (July 2010) http://www.gmc-uk.org/guidance/ethical guidance/end of life care.asp

Refer also to DH Reference guide to consent for examination or treatment 2nd edition, Section 4 pages 39 to 41



Appendix 4

Information leaflets for patients about consent

Ramsay Health Care UK provides a range of information leaflets for patients based on DH guidance explaining the consent process

These leaflets are titled;

- About the consent form
- Consent, what you have a right to expect a guide for adults
- Consent, what you have a right to expect a guide for children and young persons
- Use of pathology specimens

Provision for patients whose first language is not English

Ramsay Health Care UK is committed to ensuring that patients whose first language is not English receive the information they need and are able to communicate appropriately with healthcare staff. It is not appropriate to use family members to interpret for patients who do not speak English.

The Matron/Clinical Services Manager shall ensure the provision of interpreter services for patients who do not understand the English language.

Provision for patients with visual impairment

In the case of the visually impaired the priority is to provide information about the procedure that the patient can understand, this will depend on their use of Braille etc. The consultant/s will need to document how and what information was shared very carefully, as will any other HCP'S who have contributed to the preparation. In terms of documented consent the consultant could seek verbal consent in outpatients and ensure this is witnessed by a family member/ nurse. It is highly likely that despite visual impairment, the patient is able to sign a consent form, it would then only need a supporting witness to sign that the contents of the consent form were read to the patient accurately.



Appendix 5

Initial Equality Impact Assessment Template

		Yes/No	Comments
1.	Does the document/project affect any group less or more favourably than another on the basis of:		
	Race	No	
	Ethnic Origins	No	
	Nationality	No	
	Gender	No	
	 Gender Reassignment 	No	
	Culture	No	
	 Pregnancy & Maternity 	No	
	Religion or Belief	No	
	Sexual Orientation	No	
	Marriage or Civil Partnership	No	
	Age	No	
	 Disability – learning disabilities, physical disabilities, sensory impairment and mental health problems 	No	
2.	Is there any evidence that some groups are affected differently?	No	
3.	If you have identified potential discrimination, are there exceptions valid, legal and/or justifiable?	N/A	
4.	Is the impact of the document/project likely to be negative?	No	
5.	If so can the impact be avoided?	N/A	
6.	What alternative is there to achieving the document/project without impact?	N/A	
7.	Can we reduce the impact by taking different action?	N/A	

Completed by:

Name	Signature	Position	Date Completed:
Annette	AHemming-Allen	Clinical Risk Manager	30 th March 2016
Hemming-Allen			