Surrey and Sussex NHS
Healthcare NHS Trust

An Organisation-Wide Policy for use in Adults and Children on Consent to Healthcare Interventions

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Equality statement

This document demonstrates commitment to create a positive culture of respect for all individuals, including staff, patients, their families and carers as well as community partners**.** The intention is, as required by the Equality Act 2010, to identify, remove or minimise discriminatory practice in the nine named protected characteristics of age, disability, sex, gender reassignment, pregnancy and maternity, race, sexual orientation, religion or belief**,** and marriage and civil partnership. It is also intended to use the Human Rights Act 1998 to promote positive practice and value the diversity of all individuals and communities. This document is available in different languages and formats upon request to the Trust Procedural Documents Coordinator and the Equality and Diversity Lead.

Contents

1 Rationale

This policy sets out the standards and procedures at SASH to enable staff to comply with the relevant published guidance for obtaining valid consent before starting treatment, physical investigation or providing personal care for a patient. The policy was developed to protect the fundamental legal and ethical principle that patients have the right to determine what happens to their own bodies.

Consent can be defined as an agreement from a patient, a parent or person who has parental responsibility to receive health care interventions. For consent to be valid it must be based on the following criteria:

- Voluntariness. This describes the willingness of a patient or parent to agree to themselves or their child undergoing a health care intervention.
- Capacity. This term describes that the patient or parent is able to understand the nature of the proposed treatment.
- Knowledge. The patient or parent must have received sufficient information about the nature of the proposed treatment or intervention including risks and benefits.

Consent can be considered as having two major purposes:

Clinical purpose: the confidence, co-operation and critically, the agreement of the patient will contribute to a successful treatment and a satisfactory outcome for everyone.

Legal purpose: evidence that the clinician has been given permission to intervene and affect the physical integrity of the patient.

Surrey and Sussex Healthcare NHS Trust (SASH) is committed to ‘putting people first’ and ‘delivering excellent accessible care’. The vision is to ‘exceed patient and carers expectations for easy access to the delivery of safe, high quality care’ and to ‘come together as one team, respecting the choices of individuals and provide ever improving clinical excellence, levels of comfort and care’.

The Trust Board recognises that a key factor of delivering this vision and providing a quality patient experience is to ensure that partnership working between patients and those providing their care is embedded throughout the Trust.

All health care involves decisions being made by patients and those providing their care. This policy sets out the principles on which decision making is based

to deliver good care; from decisions about care through to decisions about significant interventions which have risk and / or side effects.

Patients will

- be listened to and have their views about their healthcare respected
- be informed what their diagnosis, prognosis, treatment and care involves
- have information shared with them as they want or need in order to ensure they can make decisions
- receive information in whatever way is necessary to enable them to maximise their opportunity and ability to make decisions and communicate them
- have their decisions respected by staff in line with legislation

This policy uses as its basis the **GMC guidance 2008 on Consent: patients and doctors making decisions together** and this comprehensive guidance should be used where additional clarification is needed.

2 Scope

This policy applies to all staff for the benefit of all patients (adults and children) and recognises that there is no single approach to discussions about treatment and care that suits all patients or fits all circumstances. It recognises that patients want varying amounts of information and involvement in decision making and that some patients will require additional support to make decisions.

It ultimately supports delivery of effective patient and healthcare worker relationships based on openness, trust and good communication whilst recognising that each person has a role to play in making decisions about treatment and care.

Whilst this policy is primarily concerned with healthcare, social care colleagues should also be aware of their obligations to obtain consent before providing certain forms of social care, such as those that involve touching the patient or client.

This policy applies to surgical, medical and therapeutic interventions. It does not specifically cover the use of unlicenced medicines, consent for which is covered it a separate policy. It applies to outpatient and inpatient care; elective and emergency.

3 Policy for Consent to operations and procedures

The consent process
(*This section applies to therapeutic treatments and procedures (those performed for the benefit of the patient. Special considerations apply where consent is sought for an intervention which is intended to benefit another e.g. research, transplants).*
It is helpful to see the whole process of information provision, discussion and decision making as part of seeking consent. This process may take place on one occasion or over a series of meetings and discussions, depending on the seriousness of what is proposed and the urgency of the patients condition. Treatment must never exceed that defined on the consent form, or accepted orally. Where there is a need to perform additional procedures beyond the scope of consent these must only be carried out if there is an immediate threat to the patient's life or well being.

3.1 Who is responsible for seeking consent?

The health professional carrying out the procedure is ultimately responsible for ensuring the patient is genuinely consented. *He/she may be held responsible in law if this is challenged later.*

However, teamwork is a crucial part of the way the NHS operates, and where written consent is sought it may be appropriate for other members of the team to participate in the process of seeking consent, subject to the following restriction that

- The healthcare professional is competent to obtain consent for the procedure / treatment proposed to the patient

Competency is established when either (1) the healthcare professional themselves carries out the procedure or is capable of carrying out the procedure **unsupervised** or (2) because they have received specialist training in advising patients about this procedure and have been assessed as competent to do so. This includes demonstrating that they are aware of the limits of their knowledge and that their practice is subject to audit (delegated consent).

Where the responsibility for seeking consent is delegated, procedure specific patient information must be available. The health professional taking consent must have access to the health professional carrying out the procedure. It is preferable that consent is only delegated for procedures where specific clinical guidelines are in place.

Details on consent training are at appendix 2

The Trust does not authorise any member of staff to obtain consent unless they fulfil the criteria set out above. Staff are required to report any breaches of compliance with this policy as an incident, in line with the trust policy. The incident will be fully investigated and appropriate follow up action will be taken. This may include HR actions with the staff member. *Staff are reminded of their duty to be open with patients about any incident which occurs in line with the Trust Being Open Policy.*

3.2 Information provision and confirmation

Before patients can come to a decision about treatment, they need comprehensible information about; their condition, possible treatments / investigations, risks and benefits including the risk / benefits of doing nothing. This must be documented in their healthcare record and appropriate information transferred to the consent form e.g. risks, additional procedures.

They should be informed of risks/ benefits no matter how small or remote **unless** they have expressly indicated they do not want all of the info.

They need to know whether additional procedures are likely to be necessary as part of the procedure e.g. blood transfusion.

Once they have made a decision to have a particular treatment / investigation they will need information about what will happen, where to go, how long they will be in hospital, how they will feel afterwards and any restrictions this may place on their life e.g. time off work, driving restrictions.

The healthcare professional is responsible for ensuring explanations are presented sensitively and in a way that the patient can understand. Unnecessary medical jargon should be avoided. Written information should be provided to support verbal explanations. Facilities provided by the Trust to support healthcare staff in difficult situations are set out in Appendix 1.

Patients have a right to know as much or as little as they wish to know to make their decisions. Some patients prefer to know very little. In these circumstances it is good practice to document in the healthcare record the information offered including the details of the written information provided and the patient's refusal.

NB Patient's wishes in relation to information may change over time – it is important to offer them opportunities to express this. The GMC and BMA guidance encourages doctors to explain to patients the importance of knowing their options whilst respecting their wish not to know. It states that basic information should be provided about what treatment aims to achieve and what it will involve.

There will always be an element of clinical judgement in determining what information should be given. However, the *presumption* must be that the patient wishes to be well informed. Where the patient indicates that they do not want this level of information this MUST be documented in their notes in case something goes wrong with the procedure.

Unless the patient has specifically refused such information, the health professional should discuss

- The nature and extent of the proposed procedure or intervention
- The expected outcome and benefits
- All risks, complications or side effects
- Alternatives available including no treatment
- The post procedure / follow up care likely to be needed
- Consider and provide relevant written information to support the discussion and decision making, where appropriate.

When discussing risk and possible side effects the health professional should use information from his/her own recent clinical experience, wherever this is available.

Written Patient Information provided must be agreed within departments and must conform to national specialty best practice.

Patient information should be offered and available in the relevant language and/or appropriate format (e.g. large print, audio or Braille), and information should use language and images that reflect and promote equality. (see appendix 2)

3.3 Single stage consent

In many cases it is appropriate for the health professional to initiate a procedure immediately after discussing it with the patient during ongoing care e.g. a physiotherapist suggesting a specific manipulative technique and explain how it might help the patient and any risks. If the patient is willing for the technique to be used they will give consent and the technique can go ahead immediately. In many such cases consent will be given orally and recorded in the healthcare record, as a timed, dated and timed entry.

If a proposed procedure carries significant risks it would be appropriate to obtain a written record of the consent given by the patient. This will be documented on the appropriate consent form. The health professional needs to consider whether the patient has had enough time to absorb the information necessary to make the decision. As long as it is clear the patient understands and consents, the health professional can then proceed.

3.4 Consent as a two or more stage process

In most cases where written consent is being sought, treatment options will generally be discussed well in advance of the procedure(s) being carried out. The consent stage will have at least two stages; the first being the provision of information, discussion of options and initial decision and the second being confirmation that the patient **continues to consent.** The consent form should be used as a means of documenting the information stage(s) as well as the confirmation stage. (*Typical consent process for elective procedure shown at fig 1)*

3.5 Timing of consent for elective procedures

Patients receiving elective treatment/ investigations should have time to familiarise themselves with the contents of the consent form before they arrive for the procedure and should have received a copy of the page documenting the decision making process. They can be invited to sign the form confirming they wish to go ahead at any point before the procedure. However if the form is signed before the procedure / treatment a member of the healthcare team **must** check with the patient at the point of the procedure whether their condition has changed or whether they have any further concerns. This is particularly important if there has been a significant time lapse between the form being signed and the procedure. The consent should be re-taken if the original process was more than 6 months previously.

It should always be remembered that for consent to be valid, the patient must feel that it would have been possible to refuse, or change their mind. It is rarely appropriate for a patient to sign a consent form once they have begun to prepare for treatment e.g. changing into their gown, unless this is unavoidable because of the urgency of their condition.

Confirmation of consent should take place no more than 72 hours prior to the procedure being carried out. This needs to be balanced with allowing enough time for the health professional to answer any last minute questions that the patient may have, and to consult with colleagues where necessary.

On the **day of the procedure** a healthcare professional involved in the patient's care should sign the consent form to confirm that the patient still wishes to go ahead and has had any further questions answered. It will be appropriate for any member of the healthcare team to provide the confirmation signature as long as they have access to appropriate colleagues, who can answer any questions that they are not competent to answer themselves.

NB If an elective patient is taken for treatment and the first (information) stage of consent has not been completed then they must be returned to the ward. If the

procedure is urgent a senior member of the healthcare team, in consultation with colleagues, will need to decide whether to proceed. IN ALL SUCH CASES AN INCIDENT FORM MUST BE COMPLETED.

3.6 Seeking consent for Anaesthesia

Where an anaesthetist is involved in a patient's care, it is their responsibility (not that of the surgeon) to seek consent for anaesthesia having discussed the benefits and risks with the patient.

It is **not** acceptable, in elective treatment, for a patient to receive no information about anaesthesia until the pre-operative visit from the anaesthetist. At such a late stage the patient will not be in a position genuinely to make a decision about whether or not to undergo anaesthesia. Patients will therefore receive a general leaflet about anaesthesia in out patients or have the opportunity to discuss anaesthesia in a preassessment clinic. Leaflets can be obtained from http://www.aagbi.org/news/information-public

The anaesthetist should ensure that the discussion with the patient and the patient's consent is documented in the anaesthetic record, in the patient's notes or on the consent form.

Guidelines on best practice in consent for anaesthesia can be found in the publication from the Association of Anaesthetists of Great Britain & Ireland. http://www.aagbi.org/sites/default/files/consent06.pdf

Clear protocols should be followed to ensure that for each type of procedure appropriate consent to anaesthesia is always obtained. For some procedures, where the choice of anaesthetic is a key factor, it may be appropriate for the anaesthetist to discuss this with every patient and to provide them with appropriate written information.

Where the health professional undertaking the procedure is responsible for anaesthesia (e.g. where local anaesthesia or sedation is used) then he/she will also be responsible for ensuring that the patient has given consent to that form of anaesthesia.

Where general anaesthesia or sedation is being provided as part of dental treatment, the General Dental Council currently holds dentists responsible for ensuring that the patient has all the necessary information. In such cases, the anaesthetist and dentist will share responsibility.

3.7 Emergencies

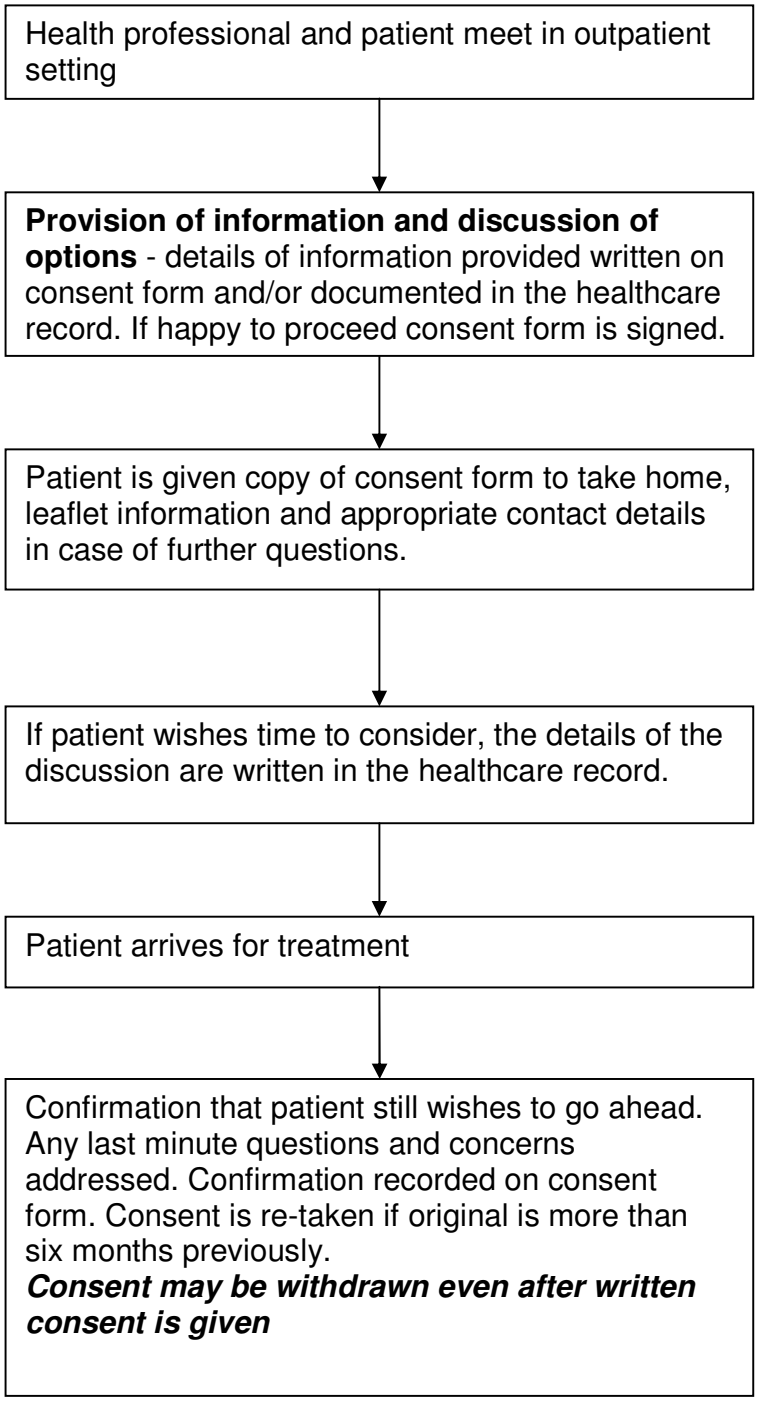
Clearly in an emergency the two stages of consent (information provision and confirmation) will follow straight on from one another. In these cases it may be

appropriate to use the patient's notes to document any discussion and the patient's consent rather than the consent form. The urgency of the patient's condition may limit the quantity of information that he/she receives but should not affect the quality.

Sometimes decisions will need to be made immediately (e.g. resuscitation after severe trauma). In such an emergency where there is doubt as to the appropriateness of treatment there should be a presumption in favour of providing life sustaining treatment.

When more time is available and the patient is an adult or child without capacity, all those concerned with the care of the patient – relatives, partners, friends, carers and the MDT – can potentially make a contribution to the assessment. The discussions and the basis for decisions should be recorded in the notes. If in doubt or disagreement, seek legal advice. (Legal Services x6840 office hours /via the on call general manager out of office hours).

Figure 1 Typical consent process for an elective procedure



3.8 Documenting consent

When consent is given the healthcare professional obtaining it must use the patient's medical records or a consent form to record the key elements of their discussion with the patient. This should include the information discussed, any specific requests by the patient, any written, visual or audio information given to the patient, and details of any decisions that were made.

By law written consent must be obtained for certain treatments, such as fertility treatment and organ donation. Separate policies cover the laws and codes of practice that govern these situations.

Written consent must also be obtained from a patient if:

- the investigation or treatment is complex or involves significant risks
- there may be significant consequences for the patient's employment, or social or personal life
- providing clinical care is not the primary purpose of the investigation or treatment
- the treatment is part of a research programme or is an innovative treatment designed specifically for their benefit.

Each Department must agree a list of procedures or investigations that require express consent and whether that is recorded in the notes or on a consent form.

If it is not possible to get written consent, for example, in an emergency or if the patient needs the treatment to relieve serious pain or distress, verbal consent can be sufficient. But the patient must still be given the information they want or need to make a decision. The discussion and decision must be recorded in the healthcare record.

However, consent is often implied by the patient's compliance, an obvious example being when a patient rolls up a sleeve so that a blood sample can be taken. Nevertheless, patients should be told about the nature and purpose of any examination, investigation or procedure beforehand

Standard NHS consent forms are in use in the Trust.

- Form 1: Patient agreement to investigation or treatment
- Form 2: Parental agreement to investigation or treatment for a child or young person

- Form 3: Patient/parental agreement to investigation or treatment where consciousness is not impaired
- Consent Form 4: form for adults who are unable to consent to investigation or treatment. This is used to record decisions made in a patient's best interests and to also to record the involvement of families and others close to the patient.

Specialty or operation specific consent forms can be used to provide the correct information regarding benefits and risks providing that

- They follow the general principles for the NHS Forms 1-3.
- They conform to specialty guidance eg from Colleges
- Have been agreed by the Department and Division

3.9 Refusal of Treatment

NB: the following applies primarily to adults with mental capacity. There is additional policy in relation to children and adults without capacity in sections 3.10 and 3.9 respectively.

General Principles

- Adult patients are entitled to refuse any treatment, even when that treatment would clearly benefit their health or when refusal of the treatment may result in their death as long as they have the appropriate level of mental capacity to make such a decision.
- The only exception to this rule is where treatment is for a mental disorder and the patient is detained under the Mental Health Act 1983.
- A patient may withdraw their consent after having signed a consent form (*the issue is always does the patient consent at the time of the treatment).* A patient's decision should always be respected (as long as they have capacity) even in life threatening situations or where the reasons seem irrational or where they do not give a reason at all.
- Where a patient has refused a particular treatment / intervention, the healthcare professional MUST ensure that they continue to provide any other appropriate care to which the patient gives / has consented.
- The healthcare professional must ensure the patient realises they are free to change their mind and accept treatment if they later wish to do so. Where a delay may affect the patient's treatment choices they should be advised accordingly.
- Any patient's agreement or refusal to consent to the removal, storage or use of tissue for purposes under the Human Tissue Act must not affect the investigation / treatment they receive.
- When a patient gives consent to any intervention, in general the consent remains valid for an indefinite duration, unless it is withdrawn by the person. However, if new information becomes available regarding the proposed

intervention between the times consent was sought and when the intervention is undertaken the GMC guidance states that the doctor or member of the healthcare team should inform the patient and reconfirm their consent. The healthcare professional must consider whether the new information or any changes in the patient's condition have significantly affected the validity of the consent in place and whether they need to seek consent again.

When a patient **refuses treatment of withdraws consent** the healthcare professional should see the patient with a witness (a relative where possible) and give a clear explanation of the consequences of not being treated. If the patient continues to refuse, after a full discussion of possible treatment options, this must be documented in the notes. If they have already signed a consent form but then changes their mind the healthcare professional (and where possible the patient) should also note this on the consent form.

The healthcare professional should document in the notes;
- Full details of the proposed treatment
- The explanation given to the patient of the consequences of rejecting the proposed treatment
- The entry MUST state explicitly that the patient understands this and continues to withhold consent. **The entry must be dated / timed and signed by the health professional, the patient and the witness**.

If a patient consents to a particular procedure but **refuses certain aspects (partial refusal) of the intervention** the healthcare professional must explain to the patient the possible consequences of this partial refusal. If the healthcare professional genuinely believes that the procedure cannot be safely carried out under the patient's stipulated conditions, they are not obliged to perform it. The healthcare professional must however, continue to provide any other appropriate care. Where another healthcare professional believes that the treatment can safely be carried out under the conditions specified by the patient, the healthcare professional must, on request, be prepared to transfer the care to that health professional.

Patients may decide in advance that a particular procedure must not be performed under any circumstances, as part of their treatment. The standard consent forms have a space reserved for patients to list any procedures which they would refuse in this way. The healthcare professional should document in the notes if a patient refuses a specific aspect of treatment If the consent form has already been signed then a note should be added to this affect (signed where possible by the patient as well as the health professional)

Patients with mental capacity, under the Mental Capacity Act 2005 prepare an 'Advanced Decision' or 'Living Will'. These are defined to clarify the patient's long term wishes with regard to treatments that may become necessary at a time in

the future when they have lost capacity to decide. In order to be valid, an Advance Decision must meet the following criteria

NB: It is crucial to remember that an Advance Decision is only applicable in a life threatening situation if it includes an explicit statement that it stands **'even if life is at risk'**. This clause must also be in writing, signed and witnessed.

- The patient had the capacity to give or withhold consent at the time of making the decision
- The decision is in writing, signed and witnessed
- Refusal of the specified treatment was intended to apply to the current circumstances
- The patient was aware of the likely consequence of the decision

If treatment is refused within the terms of a valid Advance Decision signed by the patient, then this fact must be documented in the patient's notes. If a patient's advance decision specifies that a certain procedure must not be performed as part of a treatment to which he/she does give consent (e.g. a blood transfusion for a Jehovah's Witness during a surgical procedure under general anaesthetic) then this should also be documented on the consent form.

If at any time after making the directive a patient with capacity indicates a change of mind the advance directive is over written. Any change of mind should be documented carefully, and the patient encouraged to confirm this in writing.

3.10 The Mental Capacity Act

General principles

- All adults are presumed to have the mental capacity to take decisions regarding their own healthcare unless it is proven otherwise.
- All decisions regarding mental capacity must be **time specific** and **decision specific.** No patient is to be declared wholly 'incapable' on the basis of a single assessment.
- Assessments should be repeated regularly whenever it is possible that the patient may regain their capacity to take any particular decision. Furthermore, whenever a new decision regarding the patient's health needs to be taken, the healthcare professional should always assess whether the patient is capable of taking that decision themselves even if they have failed other such assessments in the past.
- When a patient is proven to lack the capacity to take decisions, only a person who has special legal authorisation may give or withhold consent on their behalf. Family members, friends and partners **cannot** consent on behalf of the patient if they do not have such authorisation. However, it is always good practice to involve such persons in the patient's care, to keep them informed, and to treat them with sensitivity.

Assessing mental capacity is the responsibility of the most senior healthcare professional in the team proposing the treatment. If they are unsure a second opinion should be sought from another healthcare professional. In the event of continued uncertainty or if the patient has an active mental disorder a psychiatric opinion should be sought.

A patient is deemed to have a lack of capacity to make a particular decision if they are unable to do one or more of the following

- **Understand** the information relevant to the decision (including the consequences of deciding one way or the other, and of not making the decision)
- **Retain** that information
- **Use** or weigh the information as part of the process of making their decision
- **Communicate** their decision once reached (including non verbal methods of communication)

This test for assessing mental capacity is reproduced as a checklist and can be found on the Trust's Intranet on http://intranet.sash.nhs.uk/department-directory/clinical-support/adult-safeguarding/mental-capacity-act

It should be noted that an apparent lack of capacity may in fact be the result of a communication / language difficulty rather than a genuine lack of capacity. If in any doubt the healthcare professional must involve speech and language therapists, learning disabilities (safeguarding) nurses unless the urgency of the patient's clinical condition prevents this. The patient should be assisted to make and communicate their decision.

Incapacity and intoxication may be caused occasionally by medication, alcohol and other substances may affect a patient's capacity to give consent. Consent must not be obtained from a patient after they have been administered pre-medication. Consent taken under these circumstances will not be valid and should not be relied upon. Except under emergency circumstances, treatment should be deferred until the patient is judged to have regained sufficient capacity to make the decision.

Where an adult patient has been assessed as incapable of making a particular decision, no person, however closely related, can take that decision on their behalf unless that person is either

- A deputy appointed by the Court Or has been
- Granted **lasting powers of attorney (LPA)** by the patient before they lost the capacity to make their own decisions. Court appointed deputies are authorised to take a variety of healthcare decisions on behalf of incapacitated patients, but CANNOT refuse life saving treatments. Attorneys can be authorised to grant or withhold consent to ANY treatment, including life saving

treatments, depending on the terms of the agreement made with the patient. If an attorney comes forward claiming authority to make decisions on behalf of an incapacitated patient, the terms of this agreement should be requested urgently.

Where consent to treatment is given or withheld by a deputy of the court or an attorney authorised to act on the patient's behalf, this must be documented in the patient's case notes.

Treatment of a patient lacking mental capacity may proceed as long as it is deemed to be in the **patient's best interests**. In an emergency the healthcare professional must provide such treatment as is necessary to save the patient's life or to preserve health. Checklist available through the Safeguarding Adults intranet pages on http://intranet.sash.nhs.uk/department-directory/clinical-support/adult-safeguarding/mental-capacity-act/

The only exceptions to these rules are if (1) consent to the proposed treatment is withheld by a suitably authorised court deputy or attorney acting for the patient or (2) the patient rejected the proposed treatment in a valid and applicable Advance Decision (section 5.8.5)
In deciding the whether the treatment is in the patient's best interests it is important to consider the patient's wishes, beliefs and values. Under the terms of the Mental Capacity Act the healthcare professional should always chose the form of treatment that is ***least restrictive of the patient's basic rights and freedom***.

Where a patient (1) lacks capacity to give or withhold consent to a significant form of treatment and (2) has nobody close to them who is capable of making representations on their behalf, then the healthcare professional MUST refer to an Independent Mental Capacity Advocate (IMCA). Details on how to access an IMCA for Surrey and Sussex patients can be found in the Mental Capacity section of the Safeguarding Adults intranet page as above.
NB It is not necessary to delay life saving treatment in order to obtain the input of an IMCA.

Where an adult does not have the capacity to give or withhold consent to a significant intervention, and treatment is clearly in the patients best interests, this fact should be recorded on **consent form 4 (Consent Form for Adults who are unable to consent to investigation or treatment)** along with the results of the assessment of the patient's capacity, the reasons why the healthcare professional believes the treatment to be in the patient's best interests and the details of any involvement of people close to the patient. *No other consent form should ever be used for adult patients unable to consent for themselves.* For minor interventions the information should be recorded in the patient's case notes.

In a non emergency situation, two healthcare professionals must sign the consent form. One signature must be from the health professional, and the other ideally the patient's GP or a psychiatrist. However, if this is impractical the second health professional can be a senior health professional from another team.

Patients who have a mental disorder may or may not have the capacity to give valid consent. The first step should always be to obtain a psychiatric opinion. Whilst the Mental Health Act 1983 contains provisions for the detention of certain patients with a mental disorder, it gives no authority for treatment of physical disorders without consent, unless such physical disorders are a direct consequence of the mental and treatment is in the patient's best interests.

If legal advice is required the Legal Affairs Manager should be contacted on ext 6840 (office hours) and out of hours via the general manager on call.

3.11 Treatment of Children

When young children or babies are being cared for in hospital, it will not usually seem practicable to seek their parent's consent on every occasion for every routine intervention such as blood, urine tests, x rays etc. However, the healthcare professional should remember that, in law, such consent **is** required.

Where a child is admitted, the healthcare professional should therefore discuss with their parent (s) which routine procedures will be necessary and ensure they have parental consent for these interventions in advance. If parents specify that they wish to be asked before particular procedures are initiated, the healthcare professional must do so, unless the delay involved in contacting them would put the child's health at risk.

Persons with parental responsibilities

Only persons that have parental responsibility can consent on behalf of a child. This includes the following:

1. The natural mother

2. For children born prior to the following dates1st December 2003 (England and Wales)

Both parents have parental responsibility if they were married at the time of the child's conception or at some time subsequently. If the parents have never been married, only the mother automatically has parental responsibility. An unmarried father can acquire responsibility by, for example, a registered parental responsibility agreement with the mother, or via a parental responsibility order from a court.

3. For children born on or after those dates: both parents will have parental responsibility if they are registered on the child's birth certificate, irrespective of whether or not they are married.

4. Where a child has been formally adopted, the adoptive parents are the legal parents and have parental responsibility (It is good practice to seek written evidence of proof of adoption).

5. Where a child has been born as a consequence of some form of assisted reproduction, rules under the Human Fertilisation and Embryology Act 1990 set out the legal status of the child's parentage.

6. A person who is not the child's parent can assume parental responsibility by:

- Being appointed the child's legal guardian (for example, if a parent dies);
- Being granted a residence order in their favour.

7. Local authorities take on parental responsibility while a child is in care or the subject of a supervision order but this is shared with the parents who should be involved wherever possible.

8. Parental responsibility will rest with parents until a child is 18 years of age.

9. Parental responsibility is not lost if parents' divorce or separate (provided both parents had parental responsibility prior to the divorce or separation).

10. Parental responsibility continues to be held by the parents even if a child is in custody or care but it can be restricted by a court order and will be lost if the child is adopted.

11. The child's legally appointed guardian, appointed by a court or by a parent with parental responsibility in the event of their own death.

12. A person in whose favour a court has made a residence order concerning the child.

13. A local authority designated in a care order if the child (but not where the child is being looked after under section 20 of the Children Act)

14. A local authority or other authorised person who holds an emergency protection order in respect of that child

When no one with parental authority is available to consent e.g:

- Childs parents are deceased or
- Parents are overseas

In both cases there may be an informal living arrangement with extended family. The decision to proceed with treatment will depend on the circumstances of the assessment. You should seek advice from others including legal advice and involving the local authority and always act in the child best interest. Always document the decisions and reasons.

Young Persons' Ability to Consent

Young people aged 16 years and above, can consent to any surgical, medical or dental treatment without the consent of a parent/ guardian as defined in section 8 of the Family Reform Act (1969).

Children under the age of 16 years can, in some circumstances, give consent if deemed "Gillick Competent". The decision as to whether a young person meets the criteria must be made by the person seeking to obtain consent and holds overall responsibility for implementing that particular heath care intervention. If there is any doubt to whether the child is Gillick Competent the procedure/ heath care intervention should not take place unless it is an emergency situation.

To establish Gillick competence the healthcare professional must ensure three conditions exist;

- The treatment is necessary in the best interests of the child
- The child does not want parental consent sought
- The child fully understands the implications of the treatment

When there is doubt, it is good practice to engage in discussions with other professionals who are involved for caring for the child so a mutual decision based on expert opinion can be made (Alderson 1992)

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 not able to make a 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.

Absence of persons with parental responsibility

If parents cannot be contacted, and waiting to secure parental consent would put the child's health at risk, then a senior member of the healthcare team must be consulted for a decision as to whether to proceed with the treatment. In some cases, it will be appropriate to seek legal advice.

A life threatening emergency may arise when consultation with either a person with parental responsibility or the court is impossible, or the person with parental responsibility refuses consent despite such emergency treatment appearing to be in the best interests of the child. In such cases courts have stated that doubt should be resolved in favour of the preservation of life, it will be acceptable to undertake treatment to preserve life or prevent serious damage to health.

If the only person with parental responsibility themselves are judged to be incompetent the healthcare professional should seek legal advice (ext 6840 in hours / via general manager out of hours). It may be necessary to take out an order under the Children's Act. In an emergency the healthcare professional should act in the best interests of the child.

Refusal of consent

If a patient or their parent refuses consent to a routine health care intervention and the child is not at significant risk then the clinician must clarify the exact reason for the refusal and offer a further explanation and information, clearly reiterating the risks, benefits and potential outcome of the procedure. If the patient or parent still refuses to consent, this must be clearly documented in the patient's healthcare records. All other treatment that the patient or parent consented to, should continue to be provided. If the patient or their parent refuse consent to treatment and the clinician has serious concerns about the potential or subsequent deterioration in the child's condition, they should discuss their concerns with a colleague. The need to continue treatment should be discussed with the parents/guardians in the presence of a witness. This must be recorded in the child's healthcare notes and countersigned by the witness.

If a Gillick Competent child refuses treatment then a person with parental responsibility may override this decision (Re K. W. and H 1993. 1FCR 240). However this practice should be discouraged as it contravenes the UN Convention (1989) on the Rights of the Child. The clinician should thoroughly investigate the reasons for the child's refusal and offer further written/verbal information, in order to alleviate any anxieties. If the child continues to refuse treatment then the clinician should seek legal advice. In exceptional circumstances when the child's health is at significant immediate risk, consent can be obtained from the parents. In the case of children who are deemed Gillick Competent and are under a supervision order, they can refuse an examination or medical assessment (Children Act 1989 section 38). Advise must be sought from the Legal Department (ext 6840 in hours / via general manager out of hours)

If parents withhold consent on religious or other grounds, then you may still administer such treatment as is required to save the child's life. If the child's condition is not life threatening, but treatment is required to prevent deterioration

of the child's health, then a court order may be required, and the healthcare professional must seek legal advice. Disagreements between the parents and the treating clinician may need to be resolved by referral to the Official Solicitor, who will make an application to the courts.

If a parent requests a treatment that is not considered to be in the child's interests and gives consent to its being administered, then the treatment should be refused unless ordered by the court. In extreme circumstances, consideration should be given to applying for a court to take responsibility for the child's welfare.
Legal advice can be obtained from the Legal Affairs Department on ext 6840 in hours or via the general manager out of hours.

3.12 Human Tissue

The Human Tissue Act 2004 (HTA), which came into force in 2006, sets out the new legal framework for the storage and use of tissue taken from the living and for the removal, storage and use of tissue taken from the dead: this includes residual tissue following clinical and diagnostic procedures. There is a separate policy for the removal of tissue from the deceased or for post mortem and this can be obtained from the Bereavement Office.

General principles

- The legal position regarding the use of human tissue (including blood samples and other bodily fluids provided for testing) raises some difficult issues.
- Explicit consent is not required for public health surveillance using the unlinked anonymous method, but a well publicised opt out policy must apply. This is applied to the universal HIV screening of women in the antenatal clinic
- The HTA applies to all 'relevant material' (material, other than gametes, which consists of or includes human cells). Currently this definition excludes
  - Embryos outside the human body
  - Hair and nail from a living person
  - Acellular material such a plasma and serum; and
  - Material 'created outside the human body' (e.g. cell lines)
- Consent under the Act relates to the purposes for which material might be stored or used. Anyone removing, storing or using material in the circumstances for which the Act requires consent, must be satisfied that the consent is in place. They do not need to have taken or recorded the consent personally, but must ensure that procedures are in place giving the necessary assurance.

Consent requirements of HTA are set out in the Code of Practice 1 (Consent) **http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code1consent.cfm** They vary depending on whether the patient is living or dead.

In **Living patients** the consent requirements for removal of tissue follow the same principles as consent for other procedures. Consent is required for storage and use of tissue (taken from the living) for the following purposes:

- Obtaining scientific or medical information which may be relevant to any other person now or in the future
- Research (if not ethically approved and anonymised / pseudoanonymised);
- Public display; and
- Transplantation.

Consent is not required for storage and use of tissue (taken from the living) for the following purposes:

- Any purpose which is integral to the general provision of clinical and diagnostic services to the living person from whom the tissue is taken;
- Clinical audit;
- Education or training related to human health (including training for research into disorders, or the functioning, of the human body);
- Performance assessment;
- Public health monitoring;
- Quality assurance;
- Research if the research project is approved by the Research Ethics Committee and the tissue is anonymised or pseudo-anonymised.

Tissue which is removed during surgery which is no longer needed for diagnostic or therapeutic purposes is considered to be “residual tissue” under the HTA. Such tissue may usefully be retained for future research projects in tissue banks; however, consent is required to store tissue for this. Patients must specifically consent to this to allow their tissue to be used in this way. If they have not consented their tissue must be disposed of following the appropriate waste route.

Only the patient from whom the tissue is being removed (if competent) may give consent for storage and use, as set out above. For children (who are not Gillick competent) and incompetent adults, consent may be provided as described elsewhere in this policy.

3.13 Consent for taking and usage of photographs / images, audio or video recordings and images for education and research

As a general rule, respect for the autonomy of patients requires that consent be obtained whenever recordings or photographs / images are taken, and that further consent be secured for any form of circulation or publication. Some specific expectations to this are outlined below

Making recordings

The healthcare professional must always obtain separate consent before photographing or recording a patient, whether for clinical or non clinical purposes with the following exceptions

- Images from pathology slides
- X-rays
- Laparoscopic images
- Images of internal organs
- Ultrasound images

Consent to these latter recordings is implicit in the patient's consent to the procedure and follows the **GMC guidance: Making and using visual and audio recordings of patients.**

However, healthcare professionals should always ensure that they make clear in advance if any photographs / image or audio / video recording will result from that procedure.

Using recordings

Photographic / Image and audio / video recordings which are made for treating or assessing a patient form part of the patient's confidential record, and must not be used for any purpose other than the patient's care of an audit of that care without the express consent of the patient or a person with parental responsibility for the patient. If the healthcare professional wishes to use photographs / images or recordings for education, publication or research purposes, they 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 they 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 the material to be used, the healthcare professional must not use it, even if a person with parental responsibility consents. The only exception to these principles is

- Photo/images and video recordings made for treating and assessing patients and from which there is NO possibility that the patient may be recognised, may be used within the clinical setting for education and research purposes without express consent as long as the policy is well publicised.

However, express consent must be sought for any form of publication.
If a healthcare professional wishes to make a photographic image or audio/video recording of the patient specifically for education, publication or research purposes they must first seek the patient's written consent (or that of the person with parental responsibility, as appropriate) to make the recording, and then seek consent to use it.

Patients must know that they are free to stop the recording at any time and that they are entitled to view it if they wish, before deciding whether to give consent to its use. If the patient decides they are unhappy for the recording to be used it must be destroyed. As with recordings made with therapeutic intent, patients must receive full information on the possible future uses of the recording, including the fact that it may not be possible to withdraw it once it is in the public domain.

Recording patients who lack capacity to consent

The situation may sometimes arise when a healthcare professional wishes to make a recording specifically for education, publication or research purposes, but the patient is temporarily unable to give or withhold consent because, for example, if they are unconscious. In such cases, the healthcare professional may make such a recording, but they must seek consent as soon as the patient regains capacity. The healthcare professional must not use the recording until they have received consent for its use, and if the patient does not consent to any form of use, the recording must be destroyed.

If the patient is likely to permanently lack capacity to give or withhold consent for a recording to be made, the healthcare professional should seek the agreement of their legal representative. The healthcare professional must not make or use any such recording which might be against the interests of the patient. The healthcare professional should also not make or use any such recording if the recording of patients who are capable of giving or withholding consent could equally well meet the purpose of the recording.

Documentation of the patient's consent both to the taking of photographs or video / audio recordings and to the use of that material for education is the same as that for consent to examination or treatment.

3.14 Research

Overview

It is legally and ethically unacceptable to perform clinical research on a person without first informing them, and obtaining consent.

The consent process for research will be carried out in accordance with the ethically and Trust Research & Development Management approved protocol and paperwork.

In the case of minors, consent should be obtained from a parent or personal legal representative. When the research subject is an adult who lacks mental capacity, consent should be obtained from a personal legal representative.
Consent for clinical trials involving medicines may be obtained from a 'Professional Legal Representative' if no suitable parent (for minors) or personal legal representative (for minors and adults lacking mental capacity) can be found.

A Professional Legal Representative cannot be a person who is connected with the conduct of the trial, and must be either

- the doctor primarily responsible for the minor or incapacitated adults medical treatment, or
- a person nominated by the relevant healthcare provider (e.g. Acute NHS Trust, Health Board)

Guidance on professional legal representatives and clinical trials with medicines is available from the National Research Ethics Service (NRES) part of the Health Research Authority (HRA) as well as the Trust research & Development department.

All Research projects requiring consent must have Clinical Divisional approval, R and D Management approval and NHS Research Ethics Committee (REC) approval.

Research tissue banks can be granted generic ethics approval for future research projects. REC approval is subject to formal mechanisms for reviewing applications to access tissue and data and that proposed studies meet defined ethics related conditions. R and D Management approval for each study must still be obtained. The requirements of the HTA set out the statutory framework governing the use of human tissue in research.

As part of the ethical review process the REC will review the research project's patient information sheet and consent form.

Clinical Trials involving medicines

Informed and valid consent in the context of clinical trials will be obtained in accordance with the Declaration of Helsinki (1964), the Principles of Good Medical Practice (2013), the Medicines for Human Use (Clinical Trials) 2004, Good Clinical Practice (ICH-GCP 1996) and the Informed Consent Standard Operating Practice (SOP) relevant to the individual trial protocol, or any amendment of the above or future relevant legislation or guidelines.

All clinical trials must be conducted to the principles of Good Medical Practice and Good Clinical Practice, and all staff involved in the conduct of a clinical trial must be trained and competent in the principles of GMP, ICH-GCP and UK trial legislation – the Medicines for Human Use (Clinical Trials).

Who may seek consent (all research)?

The Declaration of Helsinki (1964) states that obtaining consent is the responsibility of the physician. The Chief / Principal Investigator has the overall responsibility for the consent process on a research project but other suitably trained and competent medical and nursing staff may obtain informed consent. Management and responsibilities for the consent process should be considered on a trial by trial basis.

Once written informed consent has been obtained, one copy of the signed and dated consent form must be given to the patient, and a copy filed in the medical notes and research case record form.

4 Responsibilities

Chief Executive is accountable for the quality of services provided by the Trust. He/she is accountable to the Trust Board for the management of the Trust to maintain these standards including risk management, patient safety, clinical effectiveness and patient experience.

The **Medical Director** is the Executive Lead for consent within the Trust. He/she is accountable for ensuring the adequacy of systems related to consenting patients including training and documentation standards.

The **Head of Integrated Governance & Quality** is the senior manager responsible for the governance systems and supports that ensure the linkage of information related to consent including the Trust's ability to relate to external advice maintains best practice, minimises risk and promotes quality.

The **Patient Safety & Risk Manager** is responsible for the day to day delivery of the risk management systems in place including identifying any changes that are required to improve risk management from all sources of information. They are responsible for identifying with the **Head of Training & Education** the training needs of the organisation in relation to risk.

The **Clinical Governance Assurance Manager** is responsible for the day to day delivery of quality, external compliance and clinical effectiveness using all

sources of quality information. They are responsible for co-ordinating the Trust clinical audit programme annually and ensuring it includes all core audits in relation to patient safety, risk management, clinical effectiveness and patient experience.

The **Chiefs of Divisions and Divisional Chief Nurses** for each Division are responsible for ensuring there are systems and processes in place within their directorate to provide sufficient trained and competent staff in their clinical areas to consent patients in line with best practice. They will oversee the delivery of this policy and put systems in place to monitor compliance with the help of the audit facilitator. Annual audit of consent practice will be part of the annual audit programme for each specialty.

The **Clinical Lead and Matron** for each specialty shall ensure for their professional groups and spheres of responsibility that:

- Patients are appropriately consented in line with this policy
- Breaches of the policy will be reported through the Datix in line with the Trust Policy for the Reporting, Management and Investigation of Incidents (including SUI's)
- There are systems in place which ensure staff are trained and competent in the consent for any procedures they undertake.

Medical Staff taking consent will:

- Obtain consent in line with this policy and the standards set by the General Medical Council for procedures within their competence. They are only able to consent for procedures that they are competent to perform or those they have received specific consent training for.
- Check that there is appropriate consent in place prior to commencing the procedure.
- On discovering appropriate consent is not in place, ascertain the patient's mental capacity and check for the administration of premedication prior to gaining consent. If the patient has capacity they may consent the patient once the medical practitioner is satisfied that they have provided the patient the information they need to make an informed decision and that they are sure the patient is not under duress. If it cannot be established that the patient is not under duress or there is any doubt over their capacity the procedure **must not go ahead**.
- Ensure that any medical colleague who is asked to obtain consent on their behalf from the patient is either competent to perform the procedure they are consenting for or has been assessed as competent in consenting for that procedure through an assessment.
- Undertake a supervisory role for non medical practitioners who are training/ have trained in consenting for procedures.
- Ensure that where assessment has identified a lack of mental capacity they have followed all appropriate procedures and that all relevant information is recorded on consent form 4 (if the procedure would normally be one where a consent form is used) or in the healthcare record.

- Ensure they report any breach of this policy they observe or are involved in is reported on Datix.

In addition **Anaesthetists** are responsible for taking consent for all forms of anaesthesia in addition to the clinician taking consent for the procedure. They take the consent using the same principles outlined above from Medical Staff taking consent.

Dental Surgeons are responsible for consenting patients for both their dental treatment and the associated general anaesthesia or sedation required to perform the procedure. In these cases, both the anaesthetist and the Dental Surgeon share accountability.

Pre-registration / Foundation Year 1 medical staff are not permitted to obtain consent for interventions

Non Medical Staff taking consent

- Will ensure they obtain consent in line with this policy for all interventions within their professional scope and training ensuring they adhere to their relevant professional standards and code of conduct.
- Ensure they have undertaken the Trust consent training programme and any additional procedure specific consent training in line with their role. Where this extends their scope of practice it must be managed in line with professional standards.
- Check that there is appropriate consent in place prior to commencing the procedure for which they have competence
- On discovering appropriate consent is not in place, ascertain the patient's mental capacity and check for the administration of premedication prior to gaining consent. If the patient has capacity they may consent the patient once the medical practitioner is satisfied that they have provided the patient the information they need to make an informed decision and that they are sure the patient is not under duress. If it cannot be established that the patient is not under duress or there is any doubt over their capacity the procedure **must not go ahead**.
- Will not do so for patients who have complex needs – patients requiring a medical consenting due to their mental, clinical needs or where the procedure lies outside the normal scope of practice for that profession.
- Report all breaches of this policy in line with the Trust policy for the reporting, management and investigation of incidents including SUI's.

5 Compliance Monitoring arrangements

Monitoring policy implementation

Consent training & practice is audited annually in each specialty as part of the departmental clinical governance framework. This includes a requirement to establish the grade and qualification of the person taking consent. For non medical and junior medical staff the clinical audit requires a check to be made against the delegated consent register to verify compliance with this policy. The audit results are presented at the specialty clinical governance meetings and actions to improve practice are identified.

During the ongoing monitoring processes where it is identified that a patient has been consented by an unauthorised person this will be reported as an incident and managed in line with the Trust Policy for the Reporting, Investigation and Management of Incidents (including SUI's). This is in addition to the ongoing staff requirement set out in section 4 of this policy for reporting incidents in real time.

Complaints, PALS, Claims, Incidents and patient surveys are reviewed 6 monthly to identify issues with consent from the service user's perspective. This information is used to update and review training programmes related to consent.

The training needs analysis is reviewed annually for centrally delivered training in consent.

Monitoring approval, amendments and document control

This policy and action plan has been approved and ratified by the Executive Board for Quality and Risk.

6 Training to ensure compliance with this policy

Training in consent & the Mental Capacity Act are essential for the work of all staff. For permanent staff training will be provided every 3 years as part of Mandatory & Statuary Training for doctors.

For trainees, departments will ensure that training is provided at induction and in specialty specific training days.

See Appendix 3

7 References and associated documents

References

GMC guidance 2008 Consent: patients and doctors making decisions together
Mental Capacity Act, 2005
Mental Capacity Act, Code of Practice
Mental Health Act, 1983
Human Tissue Act, 2004
Human Tissue Act, Code of Practice 1996
Good Clinical Practice
Children's Act, 1999
Human Rights Act, 1998
Declaration of Helsinki, 1964
Principles of Good Medical Practice 2013, GMC
Description of the Medicines for Human Use (Clinical Trials) Amended regulations,
MHRA 2006
Consent: Patients and Doctors making decisions together, 2008
Reference Guide to consent for examination or treatment, 2009

Associated Documents

Trust policy for Statutory and Mandatory Training
Trust policy for the reporting and investigation of incidents including serious untoward incidents
Trust's Risk Management Policy
Trust Policy for Diagnostic Testing
Trust Policy for Screening Procedures

8 Glossary/ explanation of terms used in this document

Type text here or use table below

Acronym/ Abbreviation/ Term	Meaning
Valid Consent	Consent given voluntarily by an appropriately informed person who has the capacity to consent to the intervention in question (this will be the patient or someone with parental responsibility for a patient under the age of 18, someone authorised to do so under a Lasting Power of Attorney (LPA) or someone who has authority to make treatment decisions as a court appointed deputy). Acquiescence where the patient does not know what the intervention entails is not 'consent'.
Express Consent	Consent that is specifically sought and documented in either the patient record or on a consent form or both
Implied consent	Where consent to a procedure is implied by the patient's actions (eg rolling up sleeve for blood test) or within a care pathway
Lack of Capacity	Where a person 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 this is permanent or temporary (Mental Capacity Act, 2005). 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
Independent Mental Capacity Advocate (IMCA)	Person who is instructed, under the duty placed on NHS bodies, to support and represent the interests of a person who lacks capacity and anyone to speak on their behalf when decisions needs to be made about serious medical treatment. IMCA' s are not decision makers for the person who lacks capacity they ensure that decision making is

	done appropriately and in accordance with the Mental Capacity Act. The duties of an IMCA are to; ▪ support the person who lacks capacity and represent their views and interests to the decision maker ▪ obtain and evaluate information, both through interviewing the person and through examining relevant records and documents ▪ obtain the views of professionals providing treatment for the person who lacks capacity ▪ identify alternative courses of action ▪ obtain a further medical opinion, if required, and ▪ prepare a report (that the decision maker must consider)
Court of Protection	Where a person lacks capacity to make a decision relating to their welfare, then the court of protection can make an order making a decision on their behalf. Alternatively, the Court of Protection can appoint a deputy to make decisions on the behalf of the person who lacks capacity.
Court appointed deputy	A person, judged by the Court of Protection to have the necessary skills and abilities and who is prepared to take on the duty and responsibility of the role, who can make decisions on behalf of the patient who lacks capacity. The principles of the Act must be followed and decisions must be made in the patient's best interests. Where a deputy has been appointed to make treatment decisions on behalf of a person who lacks capacity then it is the deputy rather than the health professional who makes the treatment decision. A deputy cannot go against a decision of an attorney under an LPA made before the person lacks capacity.
Lasting Power of Attorney (LPA)	The Mental Capacity Act enables a person aged 18 or over to appoint an attorney to look after their health and welfare decisions if they should lack capacity in the future. Under a personal welfare LPA, the attorney – if they have the authority to do so – can make

	decisions that are as valid as those made by the person themselves. The LPA must be made in the form, and meet the criteria, set out in the regulations and it must be registered with the Office of the Public Guardian before it can be used.
Best interests	The legal requirements of the Mental Capacity Act are underpinned by five statutory principles. One of the 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 healthcare professionals and to anyone working with or caring for a person who lacks capacity. By virtue of this the Act also creates a new offence of il l treatment or wilful neglect of someone who lacks capacity by someone with responsibility for their care or with decision making powers. The Mental Capacity Act provides healthcare professionals with protection from civil and criminal liability for acts or decisions made in the best interests of the person who lacks capacity. When determining what is in a persons best interests a healthcare professional MUST NOT make assumptions about someone's best interests merely on the person's age or appearance, condition or any aspect of their behaviour.

9 Document Control

Consultation record

Relevant service	Speciality, Sponsor or User Group name	Individual's name	Job title	Date consulted	Date feedback received
Legal Dept		Edwina Andersson	Legal Services Manager	6.6.12	
Nursing		Sally Brittain	Deputy Director of Nursing	March 2014	

Change History

Version	Date	Author/ Lead	Job title	Details of Change
1	Sep 2002		Medical Director	New Policy
2	Jan 2004		Medical Director	Revision and minor amendments
3	Jan 2005		Medical Director	Revision and minor Amendments
4	May 2006		Medical Director	Revision and minor Amendments
4.1	Dec 2007		Integrated Risk Lead	Revision and minor Amendments
4.2	Jan 2008		Deputy Director of Nursing	Revision and minor amendments
5	Feb 2008		Integrated Risk Lead	Revision and minor Amendments
5.1	Mar 2009		Head of Integrated Governance and Quality& Pathology Services Manager	Amendments to meet HTA requirements
6	Dec 2010		Head of Integrated Governance and Quality	Rewritten in-line with new DH guidance
6.1	May 2011		Head of Integrated Governance and Quality	Insertion of best interest checklist corrected
6.2	Jan 2012		Head of Integrated Governance and Quality	Minor amendments to reflect MBQR approved consent training
7	May 2014	B Bray	Chief of Surgery	New format, updating

Appendix 1 Equality Analysis (EqA)

By completing this document in full you will have gathered evidence to ensure, documentation, service design, delivery and organisational decisions have due regard for the Equality Act 2010. This will also provide evidence to support the Public Sector Equality Duty.

Name of the policy / function / service development being assessed	Consent for examination or treatment	
Date last reviewed or created & version number	Version 7 May 2014	
Briefly describe its aims and objectives:	This policy sets out the standards and procedures at SASH to enable staff to comply with the relevant published guidance for obtaining valid consent before starting treatment or physical investigation or providing personal care for a patient.	
Directorate lead	Surgery	
Target audience (including staff or patients affected)	Patients, Carers/Relatives, Staff, Trust	
Screening completed by (please include everyone's name)	**Organisation**	**Date**

Equality Group ***(Or protected characteristic):***	**What evidence has been used for this assessment?**	**What engagement and consultation has been used**	**Identify positive and negative impacts**	**How are you going to address issues identified?**	**Lead and Timeframe**
Age			Covered in the policy		
Disability			Some patients require use of translation and other communication services to ensure they reach the same levels of informed decision making.		
Gender reassignment			No impact		
Marriage & Civil partnership			No impact		
Pregnancy & maternity			No impact		
Race			No impact		
Religion & Belief			Covered in the policy		
Sex			No impact		
Sexual orientation			No impact		
Carers			Covered in the policy		

Appendix 2

Communication Facilities at Surrey & Sussex Healthcare Trust

Translation

Patient information should be offered and available in the relevant language and/or appropriate format (e.g. large print, audio or Braille), and information should use language and images that reflect and promote equality.
The PALS service will facilitate translation into alternative languages and formats and can be contacted in person at their Office situated in the Main Entrance at East Surrey
Hospital, or by telephone on 01737 231958 or email to pals@sash.nhs.uk

Interpretation and translation services

Telephone interpretation

The Trust has a contract with **Language Line** to provide the Trust with telephone interpretation services. Language Line can be used in two ways:
 Patient present - When the patient is present, this should be appropriate for most appointments.
 Patient not present – You may want to contact the patient by telephone (for instance to check that they are attending their appointment and to confirm that an interpreter will be present or that Language Line will be used).

To access Language Line you will need the language the patient speaks and the code for the site you are calling from. Language Line can be accessed from any telephone.
Accessing a telephone interpreter 0845 310 9900
(ID code for E. Surrey = L28200, ID Code for Crawley =L28199)
General enquiries 0800 169 2879
Face to Face Interpreters:
To book a face to face interpreter, British Sign Language interpreter, lip speaker or deafblind communicator:
A purchasing requisition, authorised by the Department Manager, should be raised and an order number requested from the Purchasing Department on ext 6539 before booking the appropriate service.

 Face to face interpreters are provided by either
Woking Interpreting and Translation Service (01483 750970) or
Croydon Translation Interpreting Services (0208 407 1369) and may be used when telephone interpretation is not appropriate. All these interpreting services can be provided during normal working hours and may be available at other times.

 British Sign Language Interpreters (BSL) and lip speakers
First Point: Hard of Hearing, Deaf and Interpreting services (01372 376558) and Silent Sounds UK Ltd (01494 796030) all provide qualified BSL interpreters and

lip-speakers for people with hearing and speech disabilities**.** All interpreters may be provided for work out of hours, but will need to be booked in advance.

Deafblind interpreters and communicators
Depending on their residual sight and hearing, people who are deafblind may use some form of tactile or other communication, including:
 Deafblind manual alphabet: also called fingerspelling, this involves spelling out words on someone's hand in BSL. (See appendix for finger spelling)

 Block alphabet: This is when a hearing person uses the tip of their forefinger to spell out each word in English in block capitals on the receiver's palm. This method is most often used when communicating with members of the public and others who are unlikely to be familiar with the deafblind manual alphabet.

 Hands-on signing: Some people who were born deaf and then experience sight loss as an adult continue to use sign language even when they can no longer follow visual signs. This is possible through the listener touching the hands of the person who is signing and following their movements.

 Visual frame signing: When a deafblind person has a limited field of vision, sign language can still be used if the signs are adapted according to their visual needs

First Point: Hard of Hearing, Deaf and Interpreting services (01372 376558) and Silent
Sounds UK Ltd (01494 796030) all provide deafblind interpreters and communicators.
All interpreters may be provided for work out of hours, but will need to be booked in advance

Document Translations can also be done by:
 Language Line (**0800 9176564**)
translations@languageline.co.uk
Please call/fax/email for free quotation
 0r **Language Shop – 0203 3732785**
Email: naheed.anwar@newham.gov.uk

Braille translation, audio and large print:
 RNIB Disability Access Services (**01733 37 53 70**) and
 Surrey Association for Visual Impairment (**01372 377701**)
A purchasing requisition, authorised by the Department Manager, must be raised and an order number requested from the Purchasing Department on ext
6539 before booking the service required.

Audio/ Easy Read:

Please contact PALS in person at their Office situated in the Main Entrance at East
Surrey Hospital, or by telephone on 01737 231958 or email to pals@sash.nhs.uk

Appendix 3

Consent Training

All staff receive training in the broad medico legal issues related to consent at their induction course.

All clinical staff receive training in Safeguarding Adults and Children, which includes specific training on Mental Capacity Act, 2005 and consent in relation to children via the e-learning consent training module or during Mandatory & Statutory Training.

The Consent training e-learning module can be found at http://esr.mhapp.nhs.uk

The Chiefs of Divisions have agreed that obtaining consent for treatment or examination is restricted only to those who

- Are competent and capable of carrying out the procedure unsupervised
- Have received specific training to consent for a procedure but are not competent to carry out the procedure unsupervised (delegated consent), have been assessed as competent to consent by the Lead Clinician for the specialty. (The Lead Clinician is responsible for ensuring the individuals are trained, assessed as competent and registered on the consent register via the clinical audit department)

In practice

- Consent for examination or treatment will be obtained by Consultants, SAS Drs and Specialist Registrars for the majority of procedures. Foundation year trainees will not take consent from patients unless they can perform the procedure unsupervised or have been assessed as competent to do so by their Lead Clinician and are registered on the Trust Consent Register.
- All staff carrying out any specific procedure will need to provide evidence of their training and competence to carry out the procedure to the Clinical Lead who will provide the assurance to the Chief of Division. Evidence of consent training / competence will need to be maintained by the Division using the Delegated Consent assessment form at appendix 4.
- It is the responsibility of the Chief and Divisional Chief Nurse to ensure that all staff attends the relevant consent and safeguarding training as set out in the mandatory and statutory training programme.
- Delegated consent competence is demonstrated through achievement by the individual of induction consent training, a relevant competency training package (e.g. Nurse Led Consent), observation of consenting by the Lead Clinician / Consultant on three occasions.

Appendix 4

Delegated Consent Assessment Template

Each Specialty is expected to identify the procedures for which delegated consent can take place and any limitations to the types of patients they can consent (e.g. complex medical patients).

Division		**Specific Procedure**	
Staff member		**Grade**	

	1st Assessment	**2nd Assessment**	**3rd Assessment**
Date			
Name of Assessor			
Grade of Assessor			
Outcome of Assessment			

Learning Outcomes:

- All staff within those staff groups who undertake delegated procedure specific consent **must** be trained and certified as competent prior to taking consent unsupervised.
- Only those staff that have received consent training, been fully assessed and authorized as competent will be deemed as authorized to consent patients for those procedures.

Assessment criteria	1st Assessment	2nd Assessment	3rd Assessment
Demonstrate that they understand the basic principles of the proposed procedure including its limitations and clinical relevance			
Demonstrate that they can communicate, clearly in a way the patient can understand the:			
1. The nature and extent of the procedure			
2. Expected outcomes and benefits			
3. ALL risks including complications and side effects			
4. Alternatives, including not having the proposed treatment			
5. Post procedure follow up and care, including impact on lifestyle.			
Demonstrate that they provide / offer appropriate written patient information and contact details for patients with any questions.			
Demonstrate that they can correctly document, in line with this policy, all stages of the consent process in the healthcare record and on the appropriate consent form.			
Demonstrate that they are aware of the limitations of their scope of knowledge and will seek appropriate senior clinical support in line with this policy.			