

# **GUIDANCE FOR OBTAINING CONSENT FOR TREATMENT / PROCEDURE / INVESTIGATION**

**Healthcare professionals may provide emergency treatment to patients without consent provided that the treatment is necessary to preserve life or to prevent a serious deterioration in the patient's condition.**

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Author (s): Clinical policy advisor

Category/Level/Type: 1

Status: Approved

Date of Authorisation: Sept 24<sup>th</sup> 2014

Date added to Intranet: Nov 2014

Key Words: Consent

Version: 1.1

Authorised by: Clinical Policy Group

Review Date: Sept 2017

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## 1. INTRODUCTION

Patients have a fundamental right to:

- Receive sufficient verbal and written information to enable an informed decision to be made.
- Grant or withhold consent prior to any examination or treatment. However the ability to exercise this right may be limited where:
  - The patient has been assessed as lacking capacity (*see section 8*)
  - They are a child (*see section 9*)
  - The patient is detained under the Mental Health (Care and Treatment) (Scotland) Act 2003 and certain conditions apply regarding treatment related to his/her mental disorder. (*see section 10*)
  - The patient's understanding of English is limited

Consent is only legally valid if certain conditions are satisfied. This means that in any particular case a healthcare professional must satisfy him/herself that any consent obtained from a patient meets the following conditions:

- The patient is legally competent (i.e. capable of consenting)
- The consent is given freely (i.e. no coercion)
- The patient is adequately informed and has understood the information given. This may be supported through interpretation and communication support
- The patient is given sufficient time to reflect on the information provided before being asked to give consent
- If a significant period of time (3 months or more) has elapsed between consent and the procedure, consent will be reconfirmed by a member of the healthcare team
- If the treatment proposed has changed significantly, new consent will be required

An abbreviated summary guidance supports this document and can be found at Appendix 1.

## 2. WRITTEN CONSENT

Consent is often wrongly equated with a patient's signature on a consent form. A signature on a form is *evidence* that the patient has given consent, but is not *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. If a patient has given valid verbal consent, the fact that they are physically unable to sign the form is not a bar to treatment.

Patients may, if they wish, withdraw consent after they have signed a form. The signature is evidence of the process of consent giving; it is not a binding contract.

Healthcare professionals must seek written consent for procedures that carry a significant risk, for example:

- Any procedure to be carried out under general anaesthetic, sedation or regional anaesthesia
- Any procedure which could be considered new, novel or experimental (Please refer to NHS Lothian Clinical Policy on Introducing New Interventional Procedure and NICE Guidance on introduction of new or novel procedures)
- Any situation where there are implications for 'third parties' e.g. in relation to genetic studies
- Any treatment under the Human Fertilisation and Embryology Act 1990 (amended 2008) e.g. a person's gametes being used for the treatment of others, or to create an embryo *in vitro*.
- The storage of gametes
- Any treatment that is part of a project or programme of research approved by NHS Lothian

Completed consent forms must be kept with the patient's healthcare records. Alterations are not permitted after the patient has signed the consent form. If alterations are required then a new form must be completed. It will not usually be necessary to document a patient's consent to routine and low-risk procedures, such as providing personal care or taking a blood sample. However, if you have any reason to believe that the consent may be disputed later or if the procedure is of particular concern / of a personal nature to the patient e.g. if they have declined, or have become distressed when receiving similar care in the past, then this would be helpful to do so. It is considered best practice however, to ask: "is it all right if I...".

There will be occasions when the clinical presentation and subsequent management of a patient will be of interest to others in relation to training, education and research. Even when the information is to be anonymised it is best practice to seek the patient's consent to use their information as the basis for such presentations.

### **3. OBTAINING VALID CONSENT**

Obtaining valid consent requires provision of accurate and relevant information regarding the nature, consequences and alternatives to the treatment proposed in an understandable format. It is of particular importance that provision is made for patients who are not proficient in English or who have a communication support needs. Further guidance with regard to this is included within the NHS Lothian Policy for meeting the needs of people with limited English proficiency 2010.

Guidance on the production of patient information is also available to staff (NHS Lothian Policy for producing, reviewing and managing clinical information for patients 2010). There will be wide variations in the amount and complexity of information available and required by individual patients or that is relevant to particular procedures. As a minimum, the following information should be available:

#### **3.1 Diagnosis and prognosis**

Patients should be told the name and nature of the condition for which treatment or investigation is planned. If the diagnosis is unclear this should be stated and information as to the range of diagnoses and their likelihood provided.

Information as to prognosis and other consequences with and without treatment

may influence whether consent is granted and should be as accurate as reasonably possible.

### **3.2 Proposed investigation or treatment**

Clinicians should explain the purpose and nature of the proposed procedure so patients have a clear idea of what is involved and what will be experienced, inclusive of risks and alternatives. It is also necessary to include information as to adjunctive procedures including use of anaesthesia and analgesia. *A separate information leaflet ('You and your anaesthesia') is available (<http://www.rcoa.ac.uk/docs/yaya.pdf>)*

Where the extent or nature of a procedure may be influenced by operative findings, the range of possibilities should be explored with the patient. Clear documentation should be made in relation to the limitation of the procedure to which the patient has consented, emergency treatment being excepted.

For each option considered, the patient should understand the likely benefits and probabilities of success. It is important at this stage that attention is given to the patient's ability to understand and process the information given and to acknowledge their capacity for making informed decisions. Significant risks should be explained and clinicians must form their own view as to what it is appropriate to tell patients, guided by their knowledge of the patient and the knowledge of what other reasonable clinicians will do in the same situation. Serious, frequently occurring or individually relevant risks should be explained having considered the patient's beliefs, occupation and lifestyle.

### **3.3 Responsible healthcare professional**

The senior healthcare professional responsible for overall treatment / management should be clearly identified. It may also be relevant to specify other senior members of the team and whether or not and to what extent a healthcare professional in training will be involved in the patient's care.

### **3.4 Withdrawal of consent**

The patient should be reminded that at any stage up to and during the procedure, they can withdraw consent without prejudice to future treatment, although the patient should be advised of the consequences of doing so. Patients should also be reminded of their right to seek a second opinion.

### **3.5 Nature of information presented**

Individual healthcare professional and specialties should consider the following factors when presenting information:

- Use of additional written material or visual aids may be of particular relevance to patients with cognitive impairment. These should be kept up to date and be applicable and accurately reflect local practice. Wherever possible leaflets should be "easy read"

- Ensure language and other communication needs are met with access to interpreters, communication support, British Sign Language, Deaf Blind etc other patient representative or technical aids
- Ensure the use of plain English and that medical terminology is explained

### **3.6 Comprehension**

After providing such information, healthcare professionals should seek to ensure patients have understood what has been presented and whether they would like more information before making a decision. It is also important to ensure that patients have appropriate time in which to reflect and consider their decisions.

### **3.7 Withholding of consent**

A patient's decision not to consent and / or their reasons for refusal must be fully documented in the patient's healthcare records.

### **3.8 Patient has capacity but is unable to read or write**

If the person has capacity, but is unable to read or write, they may be able to make their mark on the form to indicate consent. It would be good practice for the mark to be witnessed by a person other than the healthcare professional seeking consent, and for the fact that the person has chosen to make their mark in this way to be recorded in the healthcare record. Similarly, if the person has capacity, and wishes to give consent, but is physically unable to mark the form, this fact should be recorded in the healthcare record. Or, the person can direct someone to sign the form on their behalf, but there is no legal requirement for them to do so. If consent has been given validly, the lack of a completed form is not a bar to treatment, but a form can be important evidence of such consent.

## **4. CONSENT FORMS**

NHS Lothian generic or procedure specific consent forms must be used. All newly developed forms must meet the NHS Lothian consent form standards and be approved by the relevant Clinical Management Team and ratified by NHS Lothian Clinical Documentation Group (Appendix 2).

All writing on the consent form must be:

- Legible
- Unambiguous
- Signed and dated by the patient and healthcare professional and
- Contain no abbreviations

If a change to previously agreed procedure and / or errors to original consent form are noted then a new consent form must be completed and previous form destroyed.

At the time of writing this document work continues on the development of an NHS Lothian suite of Consent Forms and these will be translated in to all relevant languages.



## 5. SCOPE OF CONSENT

Following the provision of appropriate information, a patient consents to a specific investigation, procedure or treatment. Additional or alternative procedures must only be carried out on anaesthetised or sedated patients where this is unequivocally in the patient's best interest. The desire to spare a patient a second anaesthetic is not sufficient justification in itself. Procedures unconnected with that for which consent has been obtained are very unlikely to be justifiable. The consent form provides an opportunity for the patient to note procedures that the healthcare professional may not carry out without discussing the matter further with the patient.

Discussing with patients the possibility of additional problems coming to light when they might not be in a position to make a decision is important. You should ask in advance what the patient would like to do if the situation arises and any procedure that they object to or if they want time to think about it. This discussion and any decision should be noted in the healthcare record.

## 6. TIMING OF CONSENT (SEE ALSO CONSENT FLOWCHART APPENDIX 3)

The timing of consent may depend on the urgency of the procedure. The minimum period which needs to elapse between giving information and obtaining consent and carrying out the procedure is not defined. There should be sufficient time for the patient to reflect on the information they have received. This is particularly important when the information is complex or the risks are significant, and more than one session may be necessary to inform the patient adequately.

For elective surgery, the process of consent should be initiated when the patient is placed on the waiting list. The operator should review the patient at the time of surgery and reaffirm the consent. If there has been a significant change in the patient's condition, or if an alternative form of treatment or investigation is required, or if more than 3 months has elapsed since the original consent was obtained, new consent should be obtained

*It is best practice not to obtain informed consent from a patient who has been pre-medicated with a sedative drug.*

**Consent must be verbally reaffirmed with the patient prior to the procedure to ensure that he or she has not had a change of mind.**

## 7. EMERGENCY TREATMENT WITHOUT CONSENT

Healthcare professionals may provide emergency treatment to patients without consent provided that the following criteria are met:

- The patient is assessed as being incapable of providing informed consent
- The treatment is necessary to preserve life or to prevent a serious deterioration in the patient's condition.

In these circumstances no certificate of incapacity is necessary. If a patient refuses emergency treatment and there is doubt about his / her capacity then the healthcare professional should take whatever steps are necessary to prevent deterioration in the patient's condition and then consider issues of capacity. These steps should also be taken if a proxy refuses consent but the healthcare professional judges that treatment would be in the patient's best interest.

## 8. COMPETENCE AND ADULTS WITH INCAPACITY

### 8.1 The Law

The law of Scotland generally presumes that adults (those aged 16 or over) are legally capable of making personal decisions for themselves and managing their own affairs. That presumption can **only** be overturned on evidence of impaired capacity. The Adults with Incapacity (Scotland) Act 2000 ('The 2000 Act') sets out a framework for regulating intervention in the affairs of adults who have impaired capacity, in the circumstances covered by the Act. Part 5 of the 2000 Act, and its associated Code of Practice, deals with medical treatment and research.

The common law doctrine of necessity allows medical practitioners to give life saving treatment to patients who cannot consent and in these circumstances there is no need to invoke the mechanisms in Part 5 of the 2000 Act. Part 5 of this Act covers non-emergency medical treatment and includes 'any procedure or treatment designed to safeguard or promote physical or mental health', including treatment for mental disorder. It does not authorise force unless immediately necessary and only for as long as necessary. Also it does not specifically authorise the transport of the adult to the place of treatment.

In the absence of consent, either from the adult patient, or from any proxy authorised under the 2000 Act to consent on his or her behalf, the 2000 Act confers a 'general authority to treat' on the medical practitioner primarily responsible for the medical treatment of the adult and to any other person authorised by him or her and acting on his behalf under instructions, or with his or her approval and agreement. This authority is certified by a 'section 47 certificate'; this authorises the treatment for the condition in question and can last for up to 3 years. From March 2006, Registered Nurses, Ophthalmic Opticians and Dentists who have undergone specialist training can authorise certain treatments without the need for a medical practitioner to issue a certificate of incapacity. Treatment cannot automatically proceed if a welfare attorney or guardian or a person authorised under an intervention order with relevant powers has been consulted and refuses consent. There is a mechanism for an independent opinion to resolve the disagreement. Further information is available from the [Patients detained under the mental health act \(2003\)](#) (2013).

### 8.2 Incapacity

For the purposes of the Act, 'incapable' means incapable of:

- acting **or**
- making decisions **or**
- communicating decisions **or**

- understanding decisions or
- retaining the memory of decisions

In relation to any particular matter, by reason of mental disorder or due to an inability to communicate because of physical disability, a person shall not fall within the definition by reason only of a lack or deficiency of communication if that can be made good by human or mechanical aid (whether of an interpretative nature or otherwise).

It is central to the 2000 Act that adults must not be labelled as incapable because of some circumstances or condition. The assessment of capacity must be made in relation to the particular matter or matters about which a decision or action is required. Incapacity is not an 'all or nothing' concept. A person may be legally capable of making some decisions and not of others. If you are unsure whether the person can give consent, you should talk to the relative/carer. They may know how much the person understands and if this changes from day to day. For further information please refer to Principles and procedure for care and management of vulnerable patients (16+) with a cognitive impairment.

The decision to intervene has to be taken by the medical practitioner primarily responsible for the proposed medical treatment. This may be the patient's consultant in a Medicine of the Elderly/Learning Disabilities or Psychiatric setting or the person's General Practitioner. In the case of an acute admission to hospital this may be a consultant who has never met the patient but who still must reach a view on whether or not the patient is capable of making a decision about the required treatment.

In practical terms, to demonstrate capacity, an adult should be able to:

- understand in simple language what the proposed medical treatment is, its purpose and nature and why it is being proposed;
- understand the principal risks, benefits and alternatives;
- understand in broad terms what the consequences will be of receiving the proposed treatment or not;
- retain the information;
- make the choice freely.

The 2000 Act accepts that no single measure of capacity exists at present. In determining if an intervention is to be made, it is expected that relatives and carers and other professionals will be consulted and involved in decisions about incapacity.

### **8.3 The General Authority to Treat and Core Principles of the 2000 Act**

The 2000 Act provides a general authority to treat an adult incapable of consenting to medical treatment. Medical treatment is defined in the Act to include: 'any procedure or treatment designed to safeguard or promote physical or mental health'.

There are however exceptions to the general authority to treat. Treatments dealt with under Part 16 of the Mental Health (Care and Treatment) (Scotland) Act 2003 are not covered by the general authority to treat.

The 2000 Act requires that any planned medical intervention should adhere to the following core principles:

- Provide a benefit to the person which cannot be reasonably achieved without the proposed medical intervention.
- Be the minimum intervention, consistent with the purpose of the intervention and the freedom of the individual.
- Should take account of the person's past and present wishes, so far as they can be determined.
- Include consultation with relevant others, so far as is reasonable, taking account of the views of the nearest relative, primary carer, any guardian or welfare attorney or any person nominated by a sheriff with powers relating to the proposed intervention, other persons with a legitimate interest in the welfare of the patient and who have made their views known.
- Encourage, as far as is reasonable, the person to exercise residual capacity.

#### **8.4 Certificate of Incapacity**

In the event that the person is deemed incapable of giving or withholding consent to medical treatment, a Certificate of Incapacity must be completed and signed by the medical practitioner primarily responsible for the patient's treatment, this being the medical practitioner who has undertaken the assessment of capacity.

A Certificate of Incapacity has to be in the prescribed form (Appendix 4) and must specify the period during which the authority remains valid, being a period which:

- The medical practitioner primarily responsible for the medical treatment considers appropriate to the condition or circumstances of the patient; but
- Does not exceed three years from the date of the examination and assessment on which the certificate is based.

A single Certificate of Incapacity is entirely appropriate when a person requires a single procedure, e.g. an operation, when the certificate, as designed, will provide authority to do what is reasonable in the circumstances, in relation to all aspects of care, to safeguard or promote the physical or mental health of the person. This could cover not only the operation, but also any post-operative care and pain relief required.

Careful completion of a Certificate of Incapacity is required for a person who needs multiple medical interventions and a possible way to complete the certificate in such circumstances would be by reference to a treatment plan. Patients incapable of giving or withholding consent who are being cared for in a continuing care setting will require a certificate of incapacity to authorise their general treatment and care provided by medical and other staff. Such a certificate requires to be regularly reviewed as the treatment plan requires and at least on an annual basis.

Specific guidance is available in the “Code of Practice for Persons Authorised to Carry out Medical Treatment or Research under Part 5 of the Act”. Also refer to [“Right to treat?” Mental Welfare Commission for Scotland \(July 2011\)](#) and [Consent to treatment Mental Welfare Commission for Scotland \(Nov 2006\)](#)

### **8.5 Proxy - Welfare Power of Attorney, Intervention Orders and Welfare Guardianship Orders**

Under the Act, an adult may at any time whilst having mental capacity appoint an attorney with powers over their personal welfare, (Welfare Attorney). This may include authority to consent to medical treatment or research. The powers of a Welfare Attorney only commence on the granter's incapacity. It is important to note that an adult has wide scope to grant to their Welfare Attorney whatever powers they choose, but unless powers are expressly in the written document, these cannot be implied. It is possible that a Welfare Attorney may have been appointed with powers over other matters of welfare, but without the authority to consent to medical treatment or research.

The role of a Welfare Attorney is not to be confused with that of a Continuing Attorney, who is appointed and granted powers over property and financial affairs. In circumstances arising when an adult is considered to lack capacity to make decisions regarding their personal welfare, and where, not exclusively, such incapacity is considered likely to be ongoing, a relative, carer or other individual with an interest in the welfare of the adult, or the Local Authority which has statutory obligations under the 2000 Act, may apply to the Sheriff to appoint someone with power to make decisions about medical treatment, to deal with a clearly-defined situation under an Intervention Order or an ongoing situation as a Welfare Guardian. Such powers are subject to the same exceptions as apply to Welfare Attorneys.

The Public Guardian, an office based on the Accountant of Court, registers powers of attorneys, intervention orders and guardianship orders and can be of assistance in dealing with queries which may arise regarding the existence of and terms of such appointments.

Procedures are laid down in the Act for handling situations where there is dispute between the medical practitioners primarily responsible for medical treatment, any appointed proxy, and anyone else having an interest. The advice and assistance of the Legal Department and NHS Lothian's nominated solicitors are available when required.

### **8.6 The Adult Support and Protection (Scotland) Act 2007 – Medical Examination**

Section 9 of the Adult Support and Protection Act (ASP) allows a clinician to conduct a medical examination of the adult at risk in private either during a visit under the ASP or elsewhere under an assessment order under section 11. The request for an examination would usually be made by the local authority social work department. Adults at risk have the right to refuse to be interviewed or

medically examined. Where the adult does not have capacity to consent, it would be expected that the healthcare professional would conduct an assessment or examination under other legislation e.g. adults with incapacity, mental health, emergency situations.

## **8.7 Advance Directives (Living Wills)**

A patient's past and present wishes must be taken into account in so far as they can reasonably be ascertained. An Advance Directive, sometimes colloquially referred to as a 'living will', made orally or in writing to a healthcare professional or solicitor would be a strong indication of a patient's previously expressed wishes about medical treatment, but should not be viewed in isolation from surrounding circumstances. The status of the statement should be judged in light of its age, its relevance to the clinical situation now presenting, medical developments since the time it was made, and the patient's current wishes and feelings. If possible, the patient should be asked directly whether they still maintain the position stated in relation to the proposed treatment.

Whilst there is no statutory legislation which determines legal rights in relation to Advance Directives, common law would suggest that an advance refusal of consent to treatment, properly given in contemplation of circumstances of which then arise, has the same standing as a contemporaneous refusal and would be binding. Advance Directives which seek to determine treatment which should be provided, whilst perhaps giving a helpful indication of the patient's wishes, are not necessarily legally binding. In any event, an Advance Directive cannot bind a clinician to provide treatment which is futile, unethical or illegal.

## **9. CHILDREN**

### **9.1 Obtaining consent for children**

**Young people of 16 years and over** have the right to consent or refuse to consent to medical, dental or surgical procedures or treatments.

#### **Age of Legal Capacity (Scotland) Act 1991**

A person under the age of 16 years shall have legal capacity to consent on his own behalf to any surgical, medical or dental procedure or treatment where, in the opinion of a qualified medical practitioner attending him, he is capable of understanding the nature and possible consequences of the procedure or treatment. (Available from: <http://www.legislation.gov.uk/ukpga/1991/50/section/2>) It may be referred to as [Gillick competent](#).

Good practice suggests that the child's parents/guardians should be involved when discussing consent and carrying treatment forward. However if a doctor, dentist or other clinician takes the view that the child has the capacity to consent then only the child can consent or not consent. The consent or refusal of someone else, such as the parent, is legally irrelevant.

If the child has the capacity he or she is entitled to patient confidentiality unless the clinician can justify disclosure on the grounds that they have reasonable cause to suspect that the child or other children are suffering, or are likely to suffer significant harm. In cases where confidentiality issues were to arise then the personnel involved must maintain their patient's trust but in most cases would look to resolve any dispute between the child and their parents so that a satisfactory agreement can be achieved.

**Assessing competence:** For young people to have the capacity (be competent) to take a particular decision they must be able to:

- Comprehend and retain information material to the decision, especially as to the consequences of having or not having the intervention in question and
- Use and weigh information in the decision making process.

**It should never be automatically assumed that a child with learning disabilities is not competent to take his or her own decisions:** many children will be competent if information is presented in an appropriate way and they are supported through the decision making process.

## 9.2 Who has the right to consent on behalf of a child?

If a doctor takes the view that the child does not have the capacity to understand the nature and consequences of treatment, then it is necessary to consider who has parental responsibility and rights to consent on the child's behalf. Legally, consent is only required from one person with parental responsibility.

The Children (Scotland) Act 1995 updated by the Family Law (Scotland) Act 2006 sets out who has parental responsibility and this includes:

- The child's mother whether married to the father or not.
- The child's natural father if married to the mother at the time of conception or subsequently.
- The child's natural father, even if divorced from the mother.
- Unmarried fathers whose child was born after 4 May 2006 and whose name is registered with the mother on the birth certificate
- Unmarried father, whose child's birth was registered before 4 May 2006, has a registered parental rights agreement with the mother or through a parental responsibility order from the Sheriff Court
- A married step parent or civil partner or grand-parent, aunt or uncle may also obtain parental responsibility in this way
- The child's legally appointed guardian (including Adoptive parents) – appointed either by a court or by parents with parental responsibility in the event of their own death.
- A person holding a Residence Order in relation to the child, or any other court order giving the right to consent on a child's behalf.
- Individuals who are normally the carers of a child may also consent to medical treatment in certain circumstances under section 5 of the 1995 Act. Where a person 16 years or over has control of a child under that age but no parental responsibility or rights they may consent to medical treatment if the child is incapable or they have no knowledge that a parent of the child would refuse.

- Where the parent of a child is under the age of 16 and they are entitled to consent to medical, surgical, dental procedures or treatment where, in the opinion of a qualified healthcare professional attending him/her, he or she is capable of understanding the nature and possible consequences of the procedure or treatment.
- Parents may also for example give authority for someone who cares for the child on a regular basis, such as grandparents, foster carer or child minder, to give consent for medical treatment under defined circumstances i.e. in emergencies or for routine treatments.

Consent given by one person with parental responsibility is valid, even if another person with parental responsibility withholds consent. However, the courts have stated that a 'small group of important decisions' should not be taken by one person with parental responsibility against the wishes of another, citing in particular non-therapeutic male circumcision and immunisation. Where persons with parental responsibility disagree as to whether these procedures are in the child's best interests, it is advisable to refer the decision to the courts.

### **9.3 Looked after children**

If a child is looked after this does not normally give the local authority the right to consent to treatment on behalf of a child. Regardless of whether the child is at home or away from home, parental responsibilities and rights remain with the parents.

The only clear exception is where a child is looked after because they are subject to a:

- Parental Rights Order (PRO) under section 86 of the 1995 Act. In that situation parental responsibilities and rights to consent to treatment are passed to the local authority.
- Exception to this would be the child is subject to a Child Protection Order, Child Assessment Order, a warrant or a supervision requirement which has a condition authorising medical treatment. In those situations it is presumed to be safe for the doctor to take that authority in place of the consent from the parent.

### **9.4 Child freed for adoption**

If a child has been freed for adoption in terms of section 18 of the Adoption (Scotland) Act 1978 then the local authority have all parental responsibilities and rights.

Where a person exercising parental responsibility is giving consent for a child's treatment or care, it is important that they have the necessary information about the proposed procedure in order to take a proper view as to the child's best interests.

### **9.5 Where no one is able to give consent**



Where there is no one available to give consent to treatment either because they are absent or are under the influence of drugs or alcohol and there is an urgent need to treat then it is lawful to provide immediate necessary treatment on the basis that it is in the child's best interests.

### **9.6 Where staff and those with parental responsibilities do not agree**

Parental responsibilities and rights are subject to a qualification that their exercise must be in the best interests of the child. Parents have no right to insist on treatment, which is clearly not going to benefit the child or to withhold treatment that would benefit the child.

Occasions will inevitably arise when healthcare professionals are confronted either with disputes over consent or purported refusals of consent which (in their view) are contrary to the best interest of the patient or child. At all times, healthcare professionals will principally be guided by their duty to act in the best interests of their patient or child. Most disputes can be resolved by negotiation and compromise, and the case that cannot is very much the exception.

### **9.7 Making sure children are involved in decision-making**

Even when children are not able to consent themselves, it is important to involve them as much as possible in decisions about their own health. Even very young children will have opinions about their health and care and methods should be used appropriate to their age and understanding to enable these views to be taken into account.

Decision making in older children is often a matter of negotiation between the child, those with parental responsibility and health care professionals.

## **10. OBTAINING CONSENT FROM PATIENTS DETAINED UNDER THE MENTAL HEALTH (CARE AND TREATMENT) (SCOTLAND) ACT 2003**

The Mental Health (Care and Treatment) (Scotland) Act 2003 (the 2003 Act) is concerned generally with the care and treatment of individuals with a mental disorder and specifically with the care and treatment of those who may be subject to compulsory admission and detention.

Mental disorder is defined in the 2003 Act as mental illness, personality disorder or learning disability, however caused or manifested. Mental disorder is not defined by any of the following alone:

- Sexual orientation
- Deviancy
- Acting as no prudent person would act
- Behaviour that causes or is likely to cause harassment, alarm or distress to any other person
- Dependence on alcohol and/or drugs,

Detention under the terms of the 2003 Act does not affect the fundamental right of an individual to receive sufficient verbal and written information to enable an informed decision to be made, nor does it interfere with the fundamental right to grant or withhold consent prior to any examination or treatment.

In some circumstances, subject to proper procedures in the Act being applied, a patient may be given compulsory treatment against their will. This relates only to treatment for their mental disorder or treatment for a physical disorder directly related to a mental disorder. The 2003 Act does not apply to treatments for physical conditions unrelated to the mental disorder. (Staff should also be familiar with the policy for Completion of Mental Health (Care and Treatment) (Scotland) Act 2003 – Consent to Treatment Certificates.)

Accordingly, in relation to treatment for physical or medical conditions a patient subject to compulsory detention under the 2003 Act would be dealt with as any other individual who has not been detained. In cases where the patient lacks capacity due to his/her mental disorder and requires treatment for a physical condition, then this should be dealt with under the Adults with Incapacity (Scotland) Act 2000 as described in section 8. Neither Act alters the underlying common law duty of care that impels medical practitioners to treat in certain circumstances. Emergency treatment can be given to any patient, who does not or cannot consent, to save life, to prevent harm or to alleviate serious suffering.

## **11. PHOTOGRAPHIC/AUDIO MATERIAL**

In order to ensure that the patient's right to confidentiality is preserved, NHS Lothian requires that **WRITTEN CONSENT** be obtained for photography and video recordings in **ALL** circumstances (NHS Lothian's Medical Photography Policy 2013).

### **11.1 Consent for photography, video or audio recordings**

- Photographic, digital, video, and audio recordings made for clinical purposes form part of a patient's healthcare record. Although consent to certain recordings, such as X-rays, is implicit in the patient's consent to the procedures, patients should be notified in advance if any photography, video or audio recording will form part of the procedure/consultation.
- Photographic, digital, video or audio recordings made for treating or assessing the patient must not be used for any purpose other than the patient's care, or audit of that care, without the express consent of the patient or person with parental responsibility for the patient (see also section 9).
- Photographic, video or audio recordings made for treating or assessing the patient and **even when there is no possibility that the patient might be recognised** must still have the consent of the patient for those images to be used in the clinical setting for educational or research purposes. Forms are available from the NHS Lothian Medical Photography Service.
- When consent is sought for any form of publication, the clinician must ensure that the person giving consent is fully aware of the possible uses for

the material. In particular, it must be made clear that there may not be any control over future use of the material once it is in the public domain.

- If a photographic, video or audio recording of a patient is being made specifically for education, publication or research purposes their written consent must be sought **both** to make the recording, **and**, to permit use of the recording. Patients must be informed that they are free to stop the recording at any time and that they are entitled to view/listen to the recording before deciding to give consent for its use. If the patient withdraws consent for the recording to be used then it must be destroyed.
- In cases where the patient is temporarily unable to give consent because they are, for example, unconscious, the health care professional may make the recording, but consent must be sought as soon as the patient is able to make a decision. The recording must not be used until consent has been obtained. If the patient does not give consent then the recording must be destroyed.
- If the patient is likely to be permanently unable to give or withhold consent then agreement should be sought from the next-of-kin. The recording should not be used in any way which might be against the interests of the patient.
- A separate consent form is available for babies that die and for those with abnormalities. Permission for the taking of these images, their storage and subsequent use are individually selected using this form.
- Further advice is available from the NHS Lothian Medical Photography Service.

## **11.2 Children and photographic image consent for long running treatment and / or assessment (see section 9)**

In the case of children where there is the requirement for photographic image recording for a whole course of treatment (such as orthodontics) the child may often be unaccompanied; Consent is required for each attendance for photographic images. If a child is not willing for a recording to be used, it must not be used, even if a person with parental responsibility consents.

## **12. NON SURGICAL INTERVENTIONS**

### **12.1 Medical interventions**

Many medical (drug therapy) interventions carry risks equal to or greater than surgical procedures yet consent to use such treatments is rarely sought. It is however expected that informed consent to receive medical therapy is obtained by the responsible healthcare professional. It is not necessary that a consent to treatment form is signed by a patient but it should be evident from the healthcare records that a process of informing the patient and obtaining consent has taken place. This also applies to patients receiving medical therapy in relation to diagnosis. Details of any treatment proposed should include information as to the type and duration of treatment and any serious or frequently occurring adverse effects. Alternatives to the proposed treatment and their relative risks and benefits should also be discussed.

The healthcare professional with overall responsibility should be identified and the ability of the patient to retract consent at any time emphasised, particularly where protracted or repeated treatments are required.

One example of this is specific consent forms for chemotherapy which have been developed and are available in the oncology unit. Important exceptions to the above include emergency treatment and treatments in the context of a clinical trial where separate consent procedures exist.

All forms developed must meet the Consent Form Standards (Appendix 5) and be approved by the relevant Clinical Management Team and ratified by the Clinical Documentation Group.

## **12.2 Immunisation**

Consent must be obtained before the administration of all vaccines.

The giving and obtaining of consent is viewed as a process, not a one-off event and must be sought on the occasion of each immunisation visit.

Consent must be given voluntarily and freely. The individual must be informed about the process, benefits and risks of immunisation and be able to communicate their decision. Information given should be relevant to the individual patient, properly explained and questions should be answered fully.

Consent remains valid unless the individual who gave it withdraws it. There is no legal requirement for consent to immunisation to be in writing. A signature on a consent form is not conclusive proof that consent has been given.

## **12.3 Interventions by Registered Health Care Professionals who are not Registered Medical Practitioners**

Guidance on obtaining informed consent is provided by individual professional bodies (e.g. General Medical Council, Nursing and Midwifery Council, College of Occupational Therapy, British Dietetic Association, Pharmacy and Health Professions Council etc) which follow the spirit of the recommendations laid out in the Department of Health guidance *'Good practice in consent implementation guide: consent to examination or treatment'*. In general it is considered adequate to obtain oral consent for most interventions which are considered not to involve 'risk' or 'substantial risk' (e.g. Spinal manipulation, Acupuncture, Vaginal Examination, Injection Therapy, Nail Surgery, Photography, Video or audio recording) – unless being used specifically for teaching purposes. For procedures which have been identified as involving 'risk' or 'substantial risk' written consent is required and the generic NHS Lothian Consent form should be used to record this (Appendix 2). If a healthcare professional is left with any doubt then written consent should be obtained.

## **13. TREATMENTS ACCEPTABLE/UNACCEPTABLE TO JEHOVAH'S WITNESSES**

Whenever possible, medical staff should discuss transfusion issues with a Jehovah's Witness patient in advance of any treatment and advise that their decision will remain confidential unless they themselves wish to disclose it. If the patient does elect to receive blood components or products, part of the discussion should entail whether the patient's next of kin is / or is not allowed to know this.

A patient who is one of Jehovah's Witnesses will generally not accept any of the following: whole blood or any of its four primary components, namely red and white cells, plasma or platelets.

On the basis of individual conscience, many Jehovah's Witnesses may accept the following treatment:

- use of dialysis, cell salvage and heart lung bypass (non-blood prime)
- Organ transplants.
- Certain blood products e.g. albumin, fibrinogen and factor concentrate.

### **13.1 Health Care Advance Directive/Release from Liability Card**

Jehovah's Witnesses are encouraged to carry a Health Care Advance Directive /Release from Liability card at all times which details their wishes about medical care. A baptised Jehovah's Witness who has a signed Advance Medical Directive/Release Card directing that no blood be administered under any circumstances demonstrates a long and freely held view that the person does not want blood.

Jehovah's Witnesses accept full legal responsibility for any consequences resulting from the contents of the Advance Directive being respected. Staff must take all due cognisance of this directive.

Jehovah's Witnesses may accept any non-blood medical treatment on the basis of "informed patient choice". This includes non-blood replacement fluids and synthetic preparations.

Medical staff should discuss with the individual patient what they will accept as part of treatment.

### **13.2 Help & Advice**

Further help & advice on the non-blood management of Jehovah's Witnesses may be obtained from the Department of Transfusion Medicine, RIE.

## **14. RESEARCH**

### **14.1 Research Consent**

Informed consent should be requested for research which involves interventions, observations or interviews with patients or healthy volunteers (including NHS employees) and/or their tissue or data relating to them. Valid informed consent for participation in research must be given voluntarily, the patient having been given sufficient information by which to make a competent decision. Requests for informed consent for research should avoid any form of coercion. The process must be recorded in writing.

Further information may be obtained from:

<http://www.hra.nhs.uk/resources/before-you-apply/consent-and-participation/consent-and-participant-information/>

Or you could contact the R&D office:

[R&Doffice@luht.scot.nhs.uk](mailto:R&Doffice@luht.scot.nhs.uk)

Office address

NHS Lothian R&D, QMRI, 47 Little France Crescent, Edinburgh, EH16 4TJ

Office 0131 242 3330

Fax 0131 242 3343

## **14.2 Voluntary withdrawal**

Potential participants should understand that they are free to withhold consent and that doing so will not affect the standard of treatment they receive or upset the people responsible for their health care. Assurance should be given that once enrolled in a research study participants may withdraw at any time, without having to give a reason.

## **14.3 Information**

Potential participants must have a clear understanding that they are being asked to take part in research. Where one exists, the alternative standard treatment should also be explained. The purpose of the study together with actual and potential risks should be discussed. Arrangements for confidentiality and anonymity must be described, including who will have access to the participant's data. Investigators should disclose who is funding and/or sponsoring the research and that, participants will not be identifiable from publications. A patient information sheet outlining all these elements should be given to the patient prior to obtaining consent.

## **14.4 Competence**

Special requirements apply to research involving children and vulnerable groups. Please contact the South East Scotland Research Ethics Service for advice when planning research involving these groups.

The Adults with Incapacity (Scotland) Act 2000 (Part 5) and the Medicines for Human Use (Clinical Trials) Regulations (2004) *cover research matters relating to adults who lack the capacity to consent to participate in such*

*research. This research must be intended to obtain knowledge of the causes, diagnosis, treatment or care of/or relating to their incapacity*

This only applies to research carried out under The Adults with Incapacity (Scotland) Act 2000. The criteria for the Medicines for Human Use (Clinical Trials) Regulations (2004) are different. i.e. the research must relate to a condition or impairment that affects the individual or the treatment of this condition

*If proxy powers covering medical research have not been granted, then the question can be addressed by the medical practitioner responsible for treatment laid down under Part 5 (Section 51) of the Act.*

]

The Adults with Incapacity (Scotland) Act 2000 does not allow medical practitioners to provide proxy consent. If you can't get consent from a welfare guardian or nearest relative you can't recruit the participant. The Medicines for Human Use (Clinical Trials) Regulations (2004) does allow a legal representative to provide consent, this can be a medical practitioner but this usually applies to emergency situations only.

*The reasons for not obtaining informed consent for any research study must be documented and submitted to the Research Ethics Committee*

You can't undertake research without gaining informed consent from the participant unless you have approval from an appropriate Research Ethics Committee. The reasons for not obtaining informed consent would be part of the application and not reported to the committee after the fact.

#### **14.5 Written Consent to research participation**

A participant's signature on a consent form indicates that there has been full discussion of all relevant facts with time and opportunities for the potential subject to ask questions. Signed consent forms should be witnessed, dated and stored with the research data. Records should be retained for five years or longer if stipulated in the approval by Research Ethics Committee and the sponsor of the research. If in any doubt researchers should R&D or Ethics. All aspects of the research study are required to be audited and monitored to ensure compliance with research governance standards. This monitoring may be carried out by both the Sponsor and the appropriate Regulatory Authority. It is essential, therefore, that participants are made aware of this and indicate their willingness to consent to allow access to their records for this purpose. This must be documented on the consent form. A separate consent form should be used if tissue and/or blood are to be stored for future study.

The Principal Investigator may delegate another appropriately qualified person to obtain consent from prospective participants. However, the responsibility for ensuring the validity of the process remains with the Principal Investigator.

## **15 RETENTION OF TISSUE**

## **15.1 By Hospital**

The legal view is that once tissue / organs have been removed for pathology they become part of the healthcare record and therefore can be disposed of according to local procedure. Where it is known that tissue / organs are likely to be retained for diagnostic and / or research purposes this should be discussed with the patient and documented in their healthcare records.

## **15.2 By Patient**

Any request for the return of tissue e.g. a finger, gall stones should be refused. Removed tissue can be classed as a potential health hazard. Staff must follow infection control procedures when dealing with removed tissues at all times.

## **16. DISPOSAL OF PREGNANCY TISSUE FOLLOWING TERMINATION OF PREGNANCY**

NHS Lothian will ask for consent before concluding any arrangements relating to passed pregnancy tissue. Patients will have the opportunity to make their own arrangements via a funeral director. They will need to pay for this service. NHS Lothian is able to provide a sensitive disposal of the pregnancy tissue if the patients wished; there is no charge for this service.

NHS Lothian will keep the pregnancy tissue for 6 weeks. If there is no agreement in this time NHS Lothian will dispose of the products.

## **17. SEEKING AGREEMENT FOR A POST MORTEM**

The death of a patient can be a difficult time for the healthcare professionals involved as well as for relatives. Asking relatives to agree to a post mortem is a delicate and challenging task and the production of suitable guidance is out with the scope of this document. For further information please refer to the Human Tissue (Scotland) Act 2006

## **17. REFERENCES**

There is a wealth of information and guidance on taking consent and the following is not exhaustive.

NHS Lothian Principles and procedure for care and management of vulnerable patients (16+) with a cognitive impairment

NHS Lothian Policy and procedure for the management of patients with a learning disability

NHS Lothian Policy for producing, reviewing and managing clinical information for patients 2009

NHS Lothian Policy for meeting the needs of people with limited English proficiency 2010



NHS Lothian's Medical Photography Policy (2013)

NHS Lothian New Interventional Procedures Policy (2012)

Adults with Incapacity (Scotland) Act 2000, Scottish Executive

<http://www.scotland.gov.uk/health>

Mental Health (Care and Treatment) (Scotland) Act 2003, Scottish Executive

<http://www.scotland.gov.uk/Topics/Health/health/mental-health/mhlaw/home>

The Adult Support and Protection (Scotland) Act 2007 – Medical Examination

The Children (Scotland) Act 1995 updated by the Family Law (Scotland) Act 2006

Human Tissue (Scotland) Act 2006

Human Fertilisation and Embryology Act 1990 (Amended 2008)

Patient's Bill of Rights (2010)

Good Practice Guide on Consent for Health Professionals in Scotland (SEHD – HDL (34) 2006). ([http://www.sehd.scot.nhs.uk/mels/HDL2006\\_34.pdf](http://www.sehd.scot.nhs.uk/mels/HDL2006_34.pdf)) Last Accessed 17<sup>th</sup> July 2014

Good practice in consent implementation guide: consent to examination or treatment. Department of Health, London (2010) Available from:

[http://www.google.co.uk/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CCAQFjAA&url=http%3A%2F%2Fwww.health.wa.gov.au%2Fmhareview%2Fresources%2Fdocuments%2FUK\\_DOH\\_implementation\\_guide.pdf&ei=sn3HU5z0E6Kg0QWL-YGIAg&usq=AFQjCNHpVue6pu8e87zdajKhth7Ni24TEA&bvm=bv.71198958,d.d2k](http://www.google.co.uk/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CCAQFjAA&url=http%3A%2F%2Fwww.health.wa.gov.au%2Fmhareview%2Fresources%2Fdocuments%2FUK_DOH_implementation_guide.pdf&ei=sn3HU5z0E6Kg0QWL-YGIAg&usq=AFQjCNHpVue6pu8e87zdajKhth7Ni24TEA&bvm=bv.71198958,d.d2k)

Last Accessed 17<sup>th</sup> July 2014

Seeking patient's consent: the ethical considerations. General Medical Council (2008) available from [http://www.gmc-](http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp)

[uk.org/guidance/ethical\\_guidance/consent\\_guidance\\_index.asp](http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp) Last accessed: 17<sup>th</sup> July 2014

Consent tool kit. British Medical Association 2009 available from:

<http://bma.org.uk/practical-support-at-work/ethics/consent-tool-kit> Last Accessed: 17<sup>th</sup> July 2014

Consent to treatment Mental Welfare Commission for Scotland (Dec 2010) Available from <http://www.mwcscot.org.uk/media/51774/Consent%20to%20Treatment.pdf> last Accessed 17<sup>th</sup> July 2014

Consent ,rights and choices in health care for children and young people. British Medical Association (2001)

Treatment and care towards the end of life: good practice in decision making (July 2010) – replacement for the booklet Withholding and withdrawing life-prolonging treatments (2002)

“Right to treat?” Mental Welfare Commission for Scotland (July 2011) Available from <http://www.mwcscot.org.uk/media/51822/Right%20to%20Treat.pdf> Last Accessed 14<sup>th</sup> July 2014

‘Advocating for children’, The Royal College of Paediatrics and Child health 2000. [www.rcpch.ac.uk/publications/recent\\_publications/advocacy/advocating.pdf](http://www.rcpch.ac.uk/publications/recent_publications/advocacy/advocating.pdf)

Health Rights Information Scotland – Consent – it’s your decision: available from [http://www.hris.org.uk/mod\\_product/uploads/Consent.pdf](http://www.hris.org.uk/mod_product/uploads/Consent.pdf)

and for young people under 16:

[http://www.hris.org.uk/mod\\_product/uploads/ConsentU16s.pdf](http://www.hris.org.uk/mod_product/uploads/ConsentU16s.pdf)

Easy read version – <http://www.hris.org.uk/index.aspx?o=1304>

The HRIS leaflets above are also available in several languages

**Office of the Public Guardian – [www.publicguardian-scotland.gov.uk](http://www.publicguardian-scotland.gov.uk)**

[Reference guide to consent for examination or treatment, second edition 2009](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_103643)  
([http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_103643](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_103643))

Consent: patients and doctors making decisions together 2008

‘You and your anaesthesia’ is available (<http://www.rcoa.ac.uk/docs/yaya.pdf>)

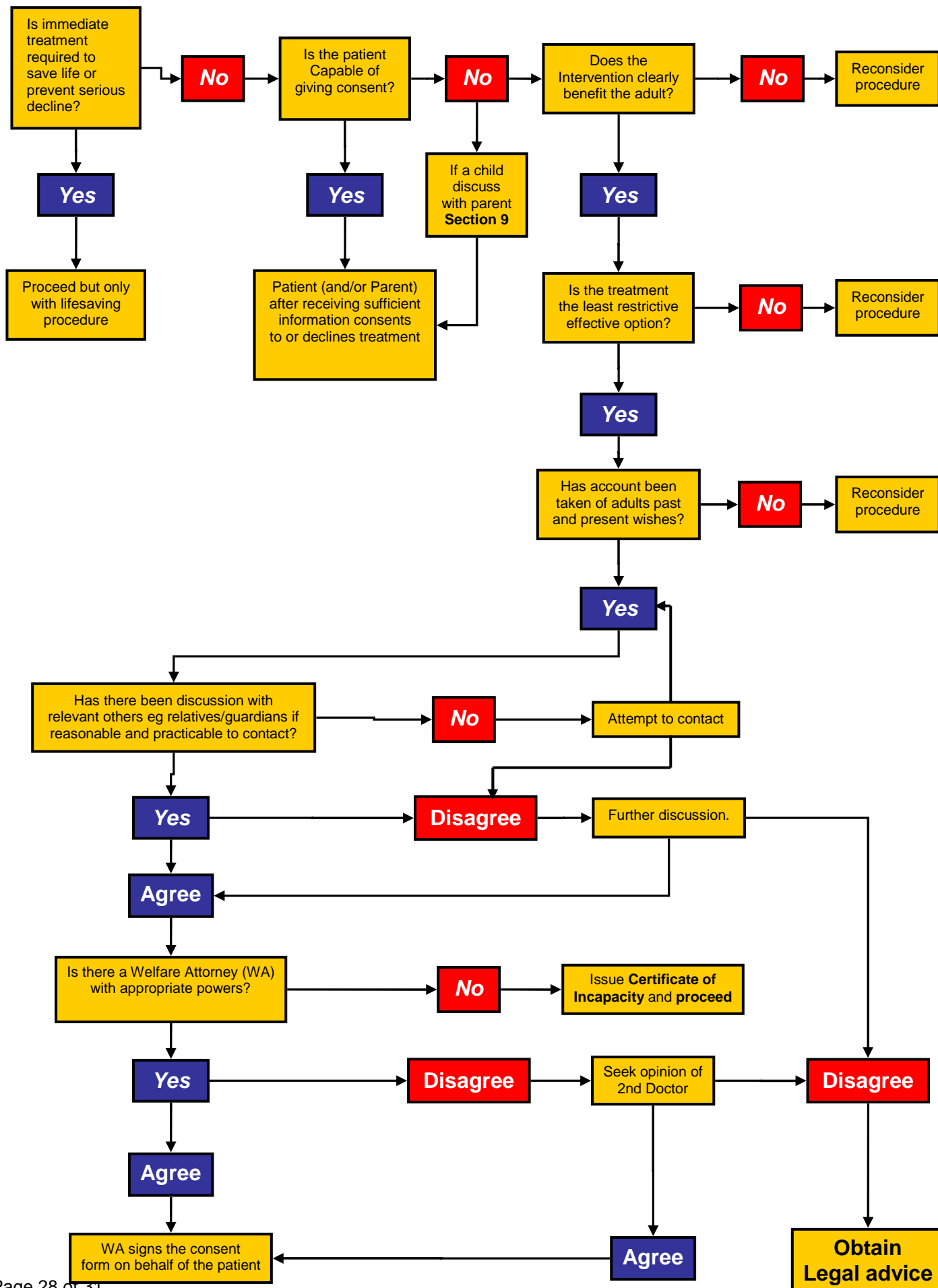
Research Governance Framework for Health and Community Care, second edition, 2006 available from

<http://www.cso.scot.nhs.uk/Publications/ResGov/Framework/RGFEdTwo.pdf> Last Accessed 7/8/2014

**Example of generic consent form**

**Under Review**

Consent Flow Chart



## Adults with Incapacity (Scotland) Act 2000 – Certificate of Incapacity

ADULTS WITH INCAPACITY  
(SCOTLAND) ACT 2000Certificate of Incapacity under Section 47 of the  
Adults with Incapacity (Scotland) Act 2000

I [redacted] (name)  
of [redacted] (address)

\*am the medical practitioner primarily responsible for the medical treatment of; or

\*am a person who is \*a dental practitioner/an ophthalmic optician/a registered nurse and who satisfies such requirements as are prescribed by the Adults with Incapacity (Requirements for Signing Medical Treatment Certificates) (Scotland) Regulations 2007 and who is primarily responsible for treatment of the kind in question of:

[redacted] (name)  
of [redacted] (address) [D][D][M][M][Y][Y] (date of birth)  
for whom the \*guardian/welfare attorney/person appointed by intervention order/nearest relative/carer

is [redacted]

I have examined the patient named above on [D][D][M][M][Y][Y] (date). I am of the opinion that \*he/she is incapable within the meaning of the Adults with Incapacity (Scotland) Act 2000 ("the 2000 Act") in relation to a decision about the following medical treatment:

[redacted]  
because of (nature of incapacity) [redacted]  
[redacted]  
[redacted]

This incapacity is likely to continue for [redacted] months.

\*I therefore consider it appropriate for the authority conferred by section 47(2) of the 2000 Act to subsist from:

[D][D][M][M][Y][Y] (date of examination) until [D][D][M][M][Y][Y], being a period which does not exceed one year from the \*date of the examination on which this certificate is based/date of revocation of the certificate issued previously by me; or

\*I am of the opinion that (a) \*he/she is suffering from \*a severe or profound learning disability/dementia/a severe neurological disorder; and (b) \*what he/she is suffering from is unlikely to improve within the meaning of the Adults with Incapacity (Conditions and Circumstances Applicable to Three Year Medical Certificates) (Scotland) Regulations 2007/ [Y][Y] and therefore consider it appropriate for the authority conferred by section 47(2) of the 2000 Act to subsist until:

[D][D][M][M][Y][Y] being a period which does not exceed three years from the \*date of the examination on which this certificate is based/date of revocation of the certificate issued previously by me.

The authority conferred by section 47(2) of the 2000 Act shall subsist for the period specified above or until such earlier date as this certificate is revoked.

In assessing the capacity of the patient, I have observed the principles set out in section 1 of the 2000 Act.

Signed [redacted] Date [D][D][M][M][Y][Y]

\*delete as appropriate

## NHS Lothian Standard for Consent Form Content

Within NHS Lothian there are two generic consent forms namely Consent Form 1 and Consent Form 2. If these consent forms are not being used for proposed procedures or courses of treatment it is essential that the consent form being used has the following:

### 1. Patient and Hospital Details

- Hospital/Location where proposed procedure will take place
- Patient's Surname
- Patient's First Name(s)
- Date of Birth
- CHI Number
- Hospital Number

The above details can be in label format.

### 2. Proposed Procedure or Course of Treatment

- The name of proposed procedure or course of treatment. This should include a brief explanation if medical term is not clear.

### 3. Statement of Clinician

- The intended reasons for or benefits of the procedure or course of treatment
- The serious or frequently occurring risks
- A section on extra procedures that may be necessary during the procedure. There should be adequate space to detail the other procedures.
- A section on providing a leaflet or tape on the proposed procedure.
- A section for the healthcare professional to sign. This section should include signature, printed name, job title and date.

### 4. Statement of Interpreter

- A section for an interpreter to sign. This section should include signature, printed name and date.

### 5. Statement of Patient/Parent/Guardian

- This should include statements as to whether the patient agrees or understands the following:
- The proposed procedure/treatment
- The use of photography for the purpose of diagnosis and treatment
- Permission for a healthcare professional student to examine under anaesthesia but to only involve parts of the body relevant to current medical condition
- That a particular person cannot be guaranteed to carry out the procedure
- Opportunity to discuss details of anaesthesia with an anaesthetist
- That any other procedure will only be carried out if it is necessary to save the patient's life or prevent serious harm to their health
- That the patient has been informed of additional procedures and has listed procedures that they do not wish to be carried out
- That the patient has been informed that they can change their mind at any time even after signing the consent form
- A section for the patient/parent/guardian to sign/mark.

- A section for a witness to sign if a patient is unable to sign/mark or young people/children want a parent to sign.

#### 6. **Confirmation of Consent**

- A section for confirmation of consent. This should include signature, name, job title and date.

#### 7. **Other**

- A section on advance directive/living will
- A section for the patient to sign and date if they have withdrawn consent

#### 8. **Completion of Consent Forms**

- **No abbreviations** should be used on any part of the consent form.
- If the consent form has two or more pages the CHI number should be on all pages. Where no CHI exists a unique patient identifier should be used.
- Clinicians completing the consent form **must** print their name.

The above sections should be included on all consent forms. Additional information may be added for specialist procedures. All specific procedure consent forms have to be approved by the NHS Lothian Clinical Documentation Group having first been ratified by the relevant Clinical Management Team.

A footer to include the originator of the consent form, version, and date of issue, review date and page numbers and totality of pages must also be evident. See NHS Lothian Clinical Documentation Standards 2009.