INFORMED CONSENT POLICY

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Informed Consent Policy
Section 1: Board Statement

The Board recognises that a patient has 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.
  - Unless the patient is an adult with incapacity (see section 5)
  - Or a child (see section 6)

Section 2: Introduction

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

- the patient is legally competent (i.e. capable of consenting) (see section 5)
- the consent has been given freely (i.e. no coercion has taken place)
- the patient has been adequately informed and has understood the information given (see section 7)
- the patient has been given sufficient time to reflect on the information provided before giving consent
- if a significant period of time has elapsed between consent and the procedure, new consent will be obtained (see section 11)
- if the treatment proposed has changed significantly, new consent will be obtained

Section 3: Rationale

Successful relationships between clinicians and patients depend on trust. A patient must be properly informed about the risks, benefits and consequences of any proposed treatment and its possible alternative before signing a consent form. A fully informed patient is less likely to have cause to complain or to resort to litigation. Consent is a process rather than a one-off decision. The steps in the process include discussions with patients, the giving of verbal and written information and the explanation of risks and benefits. All these steps should be formally documented. Obtaining a signature on a consent form is normally the concluding part of the consent process. It is important to realise that if the patient has not been given appropriate information then consent may not be valid despite the signature on the form. Consent forms are evidence of a process not the process itself.
Section 4: Definition

Consent is the voluntary and continuing permission of the patient to:

receive a particular treatment or procedure based upon adequate knowledge and understanding of its

- purpose
- nature
- likely effects

and of the

- significant risks of that treatment including the likelihood of its success and outcomes
- consequences of either no treatment or alternative treatment

Permission given under unfair or undue pressure is not consent.

Consent is also required for the disclosure of information to safeguard patient confidentiality. Whilst this is discussed in detail within the Caldicott regulation, the basic principles of consent, as detailed in this document, will similarly apply.

Section 5: Capacity and Incapacity

The Adults with Incapacity (Scotland) Act 2000 (‘The Act’) covers issues relating to property, financial and personal welfare of adults incapable by reason of mental disorder or inability to communicate and has recently become law. Section 5 of this act covers issues relating to medical treatment. The clinician primarily responsible for the care of an adult is required to assess and document the adults’ capacity to consent to any proposed medical treatment.

Any planned intervention will be expected to adhere to the following core principles:

- Benefit to the Adult
- Minimum restriction to adults’ freedom to achieve desired benefit
- Account of adults’ wishes if these can be ascertained
- Consultation with relevant others e.g. carers (if reasonable and practicable to do so)
- Encouragement to the adult to exercise residual capacity

In the event of the adult being deemed incapable the clinician primarily responsible shall be expected to issue a certificate of incapacity. At present only the adult or a legally appointed proxy with welfare powers can consent to medical treatment. The Act will allow a clinician’s certificate of incapacity to stand in place of an incapable patient’s consent. In some cases a more formal intervention or guardianship order may be considered more appropriate.
Incapable is defined by The Act as incapable of –

- acting; or
- making decisions; or
- communicating decisions; or
- understanding decisions; or
- retaining memory of decisions

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

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

The Act accepts that no single measure of capacity exists at present. It is expected that relatives and carers as well as other professionals will be involved in decisions about incapacity.

The situation in an emergency is unchanged by The Act. Treatment necessary to save life or prevent serious harm to the patient should be given and consideration of matters of capacity and consent occurring later.

Section 6: Children

Before examining, treating or caring for a child, the clinician must also seek consent. Young people aged 16 and over are presumed to have the competence to give consent for themselves. Younger children who understand fully what is involved in the proposed procedure can also give consent (although their parents will ideally be involved). In other cases, some-one with parental responsibility must give consent on the child’s behalf, unless they cannot be reached in an emergency. If a competent child consents to treatment, a parent cannot over-ride that consent.

When a baby or a young child is admitted to Hospital, the clinician should discuss with the parents what routine procedures will be necessary and ensure that they have given their consent for these interventions in advance. If parents specify that they wish to be asked prior to particular procedures being initiated, this must be adhered to unless any delay involved in contacting them would put the child’s health at risk.

Only people with “parental responsibility” are entitled to give consent on behalf of their children. It is essential to establish who has responsibility for the child if the parents are not available, i.e. if the child is in the care of the local authority social services. It is important to remember that not all parents have parental responsibility for their children.
If a parent or parents refuse to give consent for treatment thought to be appropriate by clinical staff, consideration can be given to making the child a ward of court. In some circumstances, for instance in the case of objection to certain treatments on religious grounds, specialist support may be sought from other bodies.

**Section 7: Who obtains consent**

It is the responsibility of the clinician providing the treatment, carrying out an investigation or performing a surgical operation or other procedure, to discuss it with the patient, provide information necessary for the patient’s understanding and to obtain consent. Signing of the consent form can only be delegated by the clinician to another person should he/she fulfil all of the following criteria:

- Possess suitable training and qualification
- Have sufficient knowledge of the proposed investigation or treatment (including knowledge of the risks involved)
- Act in full accordance with both this policy and their professional guidance.

This therefore precludes Pre-registration House Officers, very junior medical/surgical trainees and most other health professionals from obtaining patient consent for procedures that they themselves are not undertaking.

However there are situations in which it may be regarded as standard practice for one clinician to refer a patient to a colleague to carry out a particular procedure or investigation or aspect of treatment. An example could be referral of a patient by a surgeon for diagnostic or interventional radiology, or the request for anaesthetic services. In these circumstances the referring clinician should explain the general need for the proposed referral, possibly using information provided by the “receiving” clinician, and take consent on that basis. It would be for the “receiving” clinician to provide any further “specialist” information necessary to secure the patient’s full understanding and valid consent. Additionally it would be for the relevant specialist departments, under the guidance of their professional bodies where appropriate, to decide those situations when further written consent was necessary.

Regardless of who has provided the information and obtained consent, all discussions and consent should be recorded in the patient records. It remains the responsibility of the person performing the procedure to ensure:

- That the patient has been given sufficient time and information to make an informed decision
- That all the other requirements of this policy have been met.

**Section 8: Provision of Information**

The amount of information provided to each patient will vary according to factors such as the nature of the condition, the complexity of the treatment, the risks associated with the treatment or procedure and the patient’s own wishes.
All clinicians should take appropriate steps to find out what patients want to know and ought to know about their condition and its treatment. A careful balance needs to be struck between listening to what the patient wants and providing enough information in order that the patient’s decisions are informed.

The type of information the clinician should provide is:

- The purpose of the investigation or treatment
- Details and uncertainties of the diagnosis
- Options for treatment including the option not to treat
- Explanation of the likely benefits and probabilities of success for each option
- Known side effects and risks
- The name of the clinician who will have overall responsibility for the treatment proposed
- A reminder that the patient can change his or her mind at any time even after signing the consent form.

The clinician should also:

- Try to ascertain the patient’s individual needs and wishes
- Raise with patients the possibility of additional problems coming to light during the procedure and discuss the possible action in this event.
- Not exceed the scope of authority given by the patient (except in an emergency when the patient’s views are not known).

There is no agreed definition of what constitutes a “significant risk” and clinicians must form their own view on what it is appropriate to tell patients, guided by what other reasonable clinicians do in the same situation. Information must be given to the patient in a way that can be readily understood. The information may be given verbally, in writing or using audio-visual material. Written or audio-visual material may be departmental, Board-specific or externally produced. The clinician should record in the case records all information actually provided for each patient, including any key points of discussions held.

### Section 9: Consent Forms

Shetland NHS Board consent forms must be used

All writing on the consent form must be

- legible
- unambiguous
- contain no abbreviations
- signed and dated by the patient (or the patient’s legal representative) and the clinician

Alterations are not permitted after the patient has signed the consent form. If alterations are needed, a new form must be used.
Specific forms will be required for the following areas:

a. male sterilisation  
b. female sterilisation  
c. patients unable to consent*  
d. post-mortem examination*  
e. use of retained tissue*  
f. photography and video-recording*  
g. objection to transfusion of blood / blood products (Jehovah’s witness)*  
h. individual research projects  

* currently under development

Clinicians must get express (written) consent for:

- procedures that carry a significant risk  
- any procedure to be carried out under general anaesthesia, sedation or using local anaesthesia (other than topically* or by simple infiltration)  
- any procedure which could be considered new, novel or experimental  
- any situation where there are implications for “third parties” e.g. in relation to genetic studies or HIV testing

If the clinician is in any doubt about the need for written consent then it is preferable to obtain consent or at the very least record any discussion with the patient in the patient notes.

* Certain operations (e.g. phakoemulsification of cataract) can be carried out using topical local anaesthesia as an option. In these cases the use of this mode of anaesthesia does not remove the necessity for obtaining express written consent.

**Section 10: Scope of Consent**

Following the provision of appropriate information, a patient consents to a specific investigation, procedure or treatment being carried out. Additional or alternative procedures must only be carried out on anaesthetised or sedated patients where this is unequivocally in the patient’s best interests and can be fully justified.

It is, however, difficult to cite examples of such additional or alternative procedures that would definitely satisfy a court as being unequivocally in the patient’s best interests. The desire to spare a patient a second anaesthetic is definitely 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 practitioner may not carry out without discussing the matter further with the patient. Patients may withdraw their consent at any time - including during a procedure, although they would need to be advised of the consequences of doing so.
Section 11: Timing of Consent

The timing of consent will depend on the degree of urgency of the procedure. Whilst there is no recognised absolute minimum period of time which should elapse between giving information/obtaining consent/carrying out the procedure, it is appropriate for there to be sufficient time for the patient to reflect. This is particularly necessary where the information provided is complex and/or the risks are significant. In such cases, more than one session may be necessary to inform the patient adequately.

For ‘elective’ surgery, consent should ideally be obtained at the time the patient’s name is placed on the waiting list. If a significant time has elapsed between obtaining the consent and the procedure, the consent should be reaffirmed. If there has been a significant change in the patient’s condition, new consent should be obtained.

It is good practice to confirm with the patient immediately prior to the procedure that he or she has not had a change of mind.

Section 12: Refusal to consent

A patient’s refusal to consent, with the reasons for refusal, must be fully documented in the patient’s notes. If there is no signed consent form available where one would be expected it should be presumed consent has not been given.

Section 13: Special Circumstances

The assessment of a patient’s capacity to make a decision about his or her own health care is a matter of clinical judgement, guided by current professional practice and subject to legal requirements. It is the personal responsibility of any clinician proposing treatment to determine whether the patient has the capacity to give valid consent and to proceed only if the treatment is in the best interests of the patient.

1. Consent may not be needed:
   - Where treatment is urgently required in order to save life, or alleviate pain and/or suffering
   - where the patient is unconscious and cannot indicate his or her wishes.

2. Advance Statements

A patient’s past and present wishes must be taken into account so far as they can be ascertained. An Advance Statement made orally or in writing to a clinician, solicitor or other professional would be a strong indication of a patient’s past wishes about medical treatment but should not be viewed in isolation from the surrounding circumstances.
The status of the advance statement should be judged in light of its age, its relevance to the patient’s current healthcare needs, medical progress since the time it was made which may change the patient’s attitude 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.

There has, as yet, been no direct legislation that covers Advance Statements. It is felt that advance refusal of certain kinds of treatment is likely to be considered binding. Whereas Advance Statements that indicate what care or intervention should be provided are unlikely to be binding but would give a clear indication of previous wishes.

An Advance Statement cannot bind a clinician to do anything illegal or unethical.

**Guidance**

*Proposals for treatment should as a matter of good practice be discussed with the multi-disciplinary team and where possible the nearest relative or other patient advocate. It may also be necessary to seek further specialist medical or legal advice. All decisions must be documented in the patient’s notes.*

**REFERENCES**

*Good practice in consent implementation guide: consent to examination or treatment*
Department of Health, London (2001)
http://www.doh.gov.uk/consent

*Seeking patient’s consent: the ethical consideration*
General Medical Council (1998)
http://www.gmc-uk.org/

*Consent tool kit*
British Medical Association 2001
http://www.bma.org.uk/

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

*Adults with Incapacity (Scotland) Act 2000.*
Scottish Executive
http://www.scotland.gov.uk/health

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Consent Flowchart

Is treatment required to save life or prevent serious decline? 

Yes → Proceed but only with lifesaving procedure

No

Is the patient capable of giving consent? 

Section 5
Section 13

Yes → Patient (and/or Parent) after receiving sufficient information consents to or declines treatment 

Sections 7-12

No

If a child: discuss with parent 

Section 4

Does the intervention clearly benefit the adult?

Is the treatment the least restrictive effective option? 

No → Reconsider procedure

Yes

Has account been taken of adults past and present wishes?

Has there been discussion with relevant others eg relatives if reasonable and practicable to contact?

Disagrees → Further discussion.

Agrees

Is there a Welfare Attorney with appropriate powers?

Disagrees

Opinion of 2nd Doctor

Agrees

Obtain Legal advice

If agrees

Issue Certificate of Incapacity and proceed