

The Inquiry into Hyponatraemia-related Deaths

Chairman: Mr John O'Hara QC

Ms Wendy Beggs
Directorate of Legal Services
2 Franklin Street
BELFAST
BT2 8DQ

Your Ref: HYP B04/1

Our Ref: BC-0068-11

Date: 16 November 2011

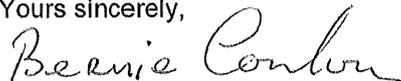
Dear Ms Beggs,

Re: Adam Strain

I acknowledge receipt of your letter dated 11 November 2011 in relation to my letter BC-0063-11.

I attach the document "Patient Consent to Examination or Treatment". It was provided to us by the Departmental Solicitors office. I realise that the document referred to at 1(H) does not refer to the admission policy. I may have caused confusion in the way my document was laid out. The reference to admission policy should have been on a separate line and does not relate to the document referred to. I would be grateful if you could send to me a copy of the admission policy.

Yours sincerely,



Bernie Conlon
Secretary to Inquiry

Secretary: Bernie Conlon
Arthur House, 41 Arthur Street, Belfast, BT1 4GB
Email: inquiry@ihrdni.org Website: www.ihrdni.org Tel: 028 9044 6340 Fax: 028 9044 6341



Management Executive
Office of the Chief Executive

Telephone: [REDACTED]

Fax: [REDACTED]

To the General Manager/Chief Executive,
Director of Public Health and
Chief Nursing Officer/Director of Nursing
of each Health and Social Services Board
Chief Executives of HSS Trusts
The General Manager of the Central Services Agency

6 October 1995

Dear Sir/Madam

PATIENT CONSENT TO EXAMINATION OR TREATMENT

SUMMARY

1. A patient has a fundamental right to grant or withhold consent prior to examination or treatment. This circular introduces a handbook of guidance about patients' rights in accepting treatment, advice to health professionals on advising the patient and obtaining consent to treatment and advice where patients are suffering from mental disorder.

BACKGROUND

2. The guidance in the handbook reflects the common law rights of patients. Doctors or health professionals and/or Health and Social Services Boards/HSS trusts may face an action for damages if a patient is treated without consent. Where treatment carries substantial risks the patient must be informed of this by a doctor so that consent may be well-informed, and the doctor's advice must be formally recorded.
3. The handbook and model forms are intended to replace existing arrangements. They are based on guidance and forms prepared by the Department of Health in London in consultation with professional organisations.

ACTION

4. Health and Social Services Boards/HSS trusts are asked to ensure that procedures are put in place to assure that consent is obtained along the lines set out in the handbook, and to introduce revised documentation (preferably based on the new model consent forms described in it), with adequate monitoring arrangements.

CH 89

Health and Personal Social Services Northern Ireland
Dunonald House, Upper Newtownards Road, Belfast BT4 3SF. Tel: [REDACTED] Fax: [REDACTED]



Management Executive Office of the Chief Executive

5. Boards/HSS Trusts are asked to confirm by 31 December 1995 that this has been done. Confirmation should be sent to Mr N Lunn, General Hospitals Policy Branch, Room 115, Dundonald House, to whom any enquiries about this circular should also be sent.
6. The Central Services Agency is asked to send a copy of this guidance to all General Practitioners and General Dental Practitioners.

CANCELLATION

7. My letter of 31 December 1990 which accompanied the booklet prepared by the Department of Health in England, distributed as an interim measure is now cancelled.

Yours faithfully

J HUNTER
Chief Executive

cc: All General Practitioners
All General Dental Practitioners
Unit General Managers
Dean of the Faculty of Medicine, QUB
Northern Ireland Council for Postgraduate Medical and Dental Education
Professors of Nursing, QUB and UOU
Health and Social Services Councils
The Secretary, British Medical Association (NI Branch)
The Secretary, British Dental Association (NI Branch)
The Secretary, Royal College of General Practitioners
The Secretary, Royal College of Nursing
The Secretary, Royal College of Midwives
The Secretary, Royal College of Obstetricians and Gynaecologists
Chief Executive Director, National Board for Nursing, Midwifery and Health Visiting for NI
The Secretary, Ulster Obstetric and Gynaecological Society
The Secretary, British Association of Social Workers
The Secretary, Chartered Society of Physiotherapy
The Secretary, National Association of Health Authorities and Trusts
Medical Defence Organisations
The Secretary, MENCAP
General Consumer Council for NI
Northern Ireland Association of Citizens Advice Bureaux

Health and Personal Social Services Northern Ireland

Dundonald House, Upper Newtownards Road, Belfast BT4 3SF. T: [REDACTED] Fax: [REDACTED]

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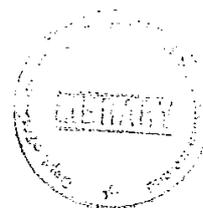
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A guide to consent for examination or treatment



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A patient's rights in accepting treatment

1. A patient has the right under common law to give or withhold consent prior to examination or treatment (except in the circumstances outlined in Chapter 2 paragraph 17, Chapter 3 paragraph 2 and Chapter 4 paragraph 3). This is one of the basic principles of health care. Subject to certain exceptions, the doctor or other health professional and/or Health and Social Services Board/HSS Trust may face an action for damages if a patient is examined or treated without consent.
2. The patient is entitled to receive sufficient information about his or her medical condition, the proposed treatments, the possible alternatives and any substantial risks, in a way he or she can understand, so that he or she can make a balanced judgement. The patient must be allowed to decide whether he or she will agree to the treatment, and may refuse treatment or withdraw consent to treatment at any time. A patient who consents to treatment on the basis of inadequate information may allege that the treatment was negligently given and bring an action for damages alleging failure of duty or care.
3. Care should be taken to respect the patient's wishes. This is particularly important when the patient may be participating in the training of students and professionals in various disciplines. An explanation should be given of the need for the trainees to gain practical experience and the patient's agreement must be obtained before proceeding. It should be made clear to the patient that he or she may decline to be observed, examined or attended by those in training without this affecting in any way the care he or she receives.
4. When the patient gives information to doctors or other health professionals he or she is entitled to assume that the information will be kept confidential and will not be disclosed to anyone without the patient's consent other than for the provision of his or her health care. The only exceptions to this general rule are where disclosure is ordered by a Court; required by statute; or considered to be in the public health interest - for example, for some forms of specifically approved research. Where disclosure is made in the public health interest appropriate safeguards must be applied. Departmental guidance on the confidentiality, use, security, and disclosure of Health and Personal Social Services information and on Research Ethics Committees will be issued separately.

Doctor or other health professional's role in advising the patient and obtaining consent to treatment

Advising the patient

1. Where a choice of treatment might reasonably be offered, the doctor or other health professional should always advise the patient of his or her recommendations together with reasons for selecting a particular course of action. Enough information must normally be given to ensure that the patient understands the nature, consequences and any substantial risks of the treatment proposed so that he or she is able to take a decision based on that information. Though it should be assumed that most patients will wish to be well informed, account should be taken of those who may find this distressing.
2. The patient's ability to appreciate the significance of the information should be assessed. For example with patients who:
 - i. may be shocked, distressed or in pain;
 - ii. have difficulty in understanding English;
 - iii. have impaired sight, hearing, speech or understanding;
 - iv. are suffering from mental disorder but who nevertheless have the capacity to give consent to the proposed procedure (see also Chapter 4 - Consent by patients suffering from mental disorder);
 - v. are under the influence of alcohol or analgesics or other drugs.
3. Subject to the agreement of the patient, it may help if a close family member or a friend can be present at the discussion when consent is sought, or a member of staff may be able to assist the patient in understanding. Where there are language problems or hearing difficulties, it is important that the services of an interpreter should be provided. Agreement to treatment by anyone accompanying the patient is not a valid substitute for the competent patient's conscious informed consent.
4. A doctor will have to exercise his or her professional skill and judgement in deciding what risks the patient should be warned of and the terms in which the warning should be given. However, a doctor has a duty to warn the patient of substantial or unusual risk inherent in any proposed treatment. This is especially so with surgery but may apply to other procedures including drug therapy and radiation treatment. Guidance on the amount of information and warnings of risk to be given to a patient can be found in the judgement of the House of Lords in the case of *Sidaway V Gov of Bethlem Royal Hospital* [1985] AC 871 described below.

The Sidaway Case

5. In this case, Lord Bridge indicated that a decision on what degree of disclosure of risks is best calculated to assist a particular patient to make a rational choice as to whether or not to undergo a particular treatment must primarily be a matter of clinical judgement. He was of the further opinion that a judge might in certain

circumstances come to the conclusion that the disclosure of a particular risk was so obviously necessary to an informed choice that no reasonably prudent medical man would fail to make it. The kind of case which Lord Bridge had in mind would be an operation involving a substantial risk of grave adverse consequences. Lord Templeman stated that there was no doubt that a doctor ought to draw the attention of a patient to a danger which may be special in kind or magnitude or special to the patient. He further stated that it was the obligation of the doctor to have regard to the best interests of the patient but at the same time to make available to the patient sufficient information to enable the patient to reach a balanced judgement if he chooses to do so.

Obtaining consent

6. Consent to treatment may be implied or express. In many cases a patient does not give express consent but his or her agreement may be implied by compliant actions, such as offering an arm for the taking of a blood sample. Express consent is given when the patient confirms his or her agreement to a procedure or treatment in clear and explicit terms, whether orally or in writing.
7. Oral consent will be sufficient for the vast majority of contacts with patients especially in general practice. Written consent should be obtained for any procedure or treatment carrying any substantial risk or risk of substantial side effect. If the patient is capable, written consent should always be obtained for general anaesthesia, surgery, certain forms of drug therapy, eg cytotoxic therapy and therapy involving the use of ionising radiation. Oral or written consent should be recorded in the patient's notes with relevant details of the doctor or other health professional's explanation. Where written consent is obtained it should be incorporated into the notes.
8. **Standard consent form.** The main purpose of written consent is to provide documentary evidence that an explanation of the proposed procedure or treatment was given and that consent was sought and obtained. The model consent forms (*see Appendices*) set out the requirements for obtaining valid consent to treatment in terms which will be readily understood by the patient. In the majority of cases these forms will be used by doctors or dentists but there may be occasions when other health professionals such as nurses, physiotherapists, or chiropodists will wish to record formally that consent has been obtained for a particular procedure. A separate form is available for their use.
9. It should be noted that the purpose of obtaining a signature on the consent form is not an end in itself. The most important element of a consent procedure is the duty to ensure that the patient understands the nature and purpose of the proposed treatment. Where a patient has not been given appropriate information then full consent may not always have been obtained despite the signature on the form.
10. Consent given for one procedure or episode of treatment does not give any automatic right to repeat that procedure or to undertake any other procedure. A doctor or other health professional may, however,

undertake further treatment if the circumstances are such that a patient's consent cannot reasonably be requested and provided the treatment is immediately necessary and the patient has not previously indicated that the further treatment would be unacceptable.

SPECIAL CIRCUMSTANCES

Treatment of Children and Young People

11. **Children under the age of 16 years.** Where a child under the age of 16 has a sufficient understanding of what is proposed, that child may consent to a doctor or other health professional making an examination and giving treatment. The doctor or other health professional must be satisfied that any such child has sufficient understanding of what is involved in the treatment which is proposed. A full note should be made of the factors taken into account by the doctor or other health professional in making his or her assessment of the child's capacity to give a valid consent. In the majority of cases children will be accompanied by their parents during consultations. Where, exceptionally, a child is seen alone, efforts should be made to persuade the child that his or her parents should be informed except in circumstances where it is clearly not in the child's best interests to do so. Parental consent should be obtained and will take precedence where a child does not have sufficient understanding and is under age 16 except in an emergency where there is not time to obtain it.
12. **Young people over the age of 16 years.** Section 4 of the Age of Majority Act (Northern Ireland) 1969 relates to "Consent by persons over 16 to surgical, medical, and dental treatment" and states that:-
 - "4.-(1) The consent of a minor who has attained the age of sixteen years to any surgical, medical or dental treatment which, in the absence of consent, would constitute a trespass to his person, shall be as effective as it would be if he were of full age; and where a minor has by virtue of this section given an effective consent to any treatment it shall not be necessary to obtain any consent for it from his parent or guardian.
 - (2) In this section "surgical, medical or dental treatment" includes any procedure undertaken for the purposes of diagnosis, and this section applies to any procedure (including, in particular, the administration of an anaesthetic) which is ancillary to any treatment as it applies to that treatment.
 - (3) Nothing in this section shall be construed as making ineffective any consent which would have been effective if this section had not been enacted".

This means that the consent of the young person who has attained 16 years to any surgical, medical, or dental treatment is sufficient in itself and it is not necessary to obtain a separate consent from the parent or guardian. In cases where a child is over age 16 but is not competent to give a valid consent, then the consent of the parent or guardian must be sought. However, such power only extends until that child is 18.

13. **Children in Care.** When parental consent is necessary for a child who is in care as a consequence of a Court Order (ie Fit Person Order or Parental Rights Order) irrespective of whether he or she is under or over the age of 16 years, account should be taken of the fact that the parental rights in respect of the child will have been transferred from the parents to the appropriate Health and Social Services Board or to a HSS trust acting on behalf of a Board. In the majority of cases, parents will have agreed to the Board or trust giving consent for the child to receive any necessary treatment. Nevertheless, consent should be sought from the parents as well as from the child's social worker. In the event of the parents refusing consent, legal advice should be sought. It should be noted that where a child is a ward of court, authority to give consent rests with the Court itself.
14. **Refusal of parental consent to urgent or life-saving treatment.** Where time permits, court action may be taken so that consent may be obtained from a judge. Otherwise hospital authorities should rely on the clinical judgement of the doctors concerned, normally the consultants, after a full discussion between the doctor and the parents. In such a case the doctor should obtain a written supporting opinion from a medical colleague that the patient's life is in danger if the treatment is withheld and should discuss the need to treat with the parents or guardian in the presence of a witness. The doctor should record the discussion in the clinical notes and ask the witness to countersign the record. In these circumstances and where practicable the doctor may wish to consult his or her defence organisation. If he or she has followed the procedure set out above and has then acted in the best interests of the patient and with due professional competence and according to his or her own professional conscience, he or she is unlikely to be criticised by a court or by his or her professional body.

Adult or competent young person refusing treatment

15. Some adult patients may wish to refuse some or all parts of their treatment. This may include those whose religious beliefs prevent them accepting a blood transfusion. Whatever the reason for the refusal such a patient should receive a detailed explanation of the nature of his or her illness and the need for the treatment or transfusion proposed. He or she should also be warned in clear terms that the doctor or other health professional may properly decline to modify the procedure and of the possible consequences if the procedure is not carried out. If the patient then refuses to agree, and he or she is competent, the refusal must be respected. The doctor or other health professional should record this in the clinical notes and where possible have it witnessed.

Teaching

16. Detailed guidance about medical students in hospital is given in circular HSS(TC8) 13/91 'Medical Students in Hospitals'. It should not be assumed, even in a teaching hospital, that a patient has consented to be available for teaching purposes.

Examination or Treatment without the patient's consent

17. The following are examples of occasions when examination or treatment may proceed without obtaining the patient's consent:
- i. For life-saving procedures where the patient is unconscious and cannot indicate his or her wishes. Exceptions to this may be:
 - a. Where the patient has previously indicated that he/she does not wish to have the particular treatment; or
 - b. This can be reliably deduced from the patient's immediate family.
 - ii. Where there is a statutory power requiring the examination of a patient, for example, under the Public Health Act (Northern Ireland) 1967. However an explanation should be offered and the patient's co-operation should nevertheless be sought.
 - iii. In certain cases where a minor is a ward of court and the court decides that a specific treatment is in the child's best interests.
 - iv. Treatment for mental disorder of a patient liable to be detained in hospital in circumstances permitted under the Mental Health (Northern Ireland) Order 1986 (see Chapter 4 below, and Chapter 5 of the Code of Practice, Mental Health (Northern Ireland) Order 1986).
 - v. Treatment for physical disorder where the patient is incapable of giving consent by reason of mental disorder, and the treatment is in the patient's best interests (see Chapter 4).

Examples of treatments which have raised concern

Maternity Services

1. Principles of consent are the same in maternity services as in other areas of medicine. It is important that the proposed care is discussed with the woman, preferably in the early antenatal period, when any special wishes she expresses should be recorded in the notes, but of course the woman has a right to change her mind about these issues at any stage, including during labour.
2. Decisions may have to be taken swiftly at a time when the woman's ability to give consent is impaired, eg as a result of medication, including analgesics. If the safety of the woman or child is at stake the obstetrician or midwife should take any reasonable action that is necessary. If, in the judgement of the relevant doctor or other health professional, the woman is temporarily unable to make a decision, it may be advisable for the position to be explained to her husband or partner if available, but his consent (or withholding of consent) cannot legally over-ride the clinical judgement of the doctor or other health professional, as guided by the previously expressed wishes of the woman herself.

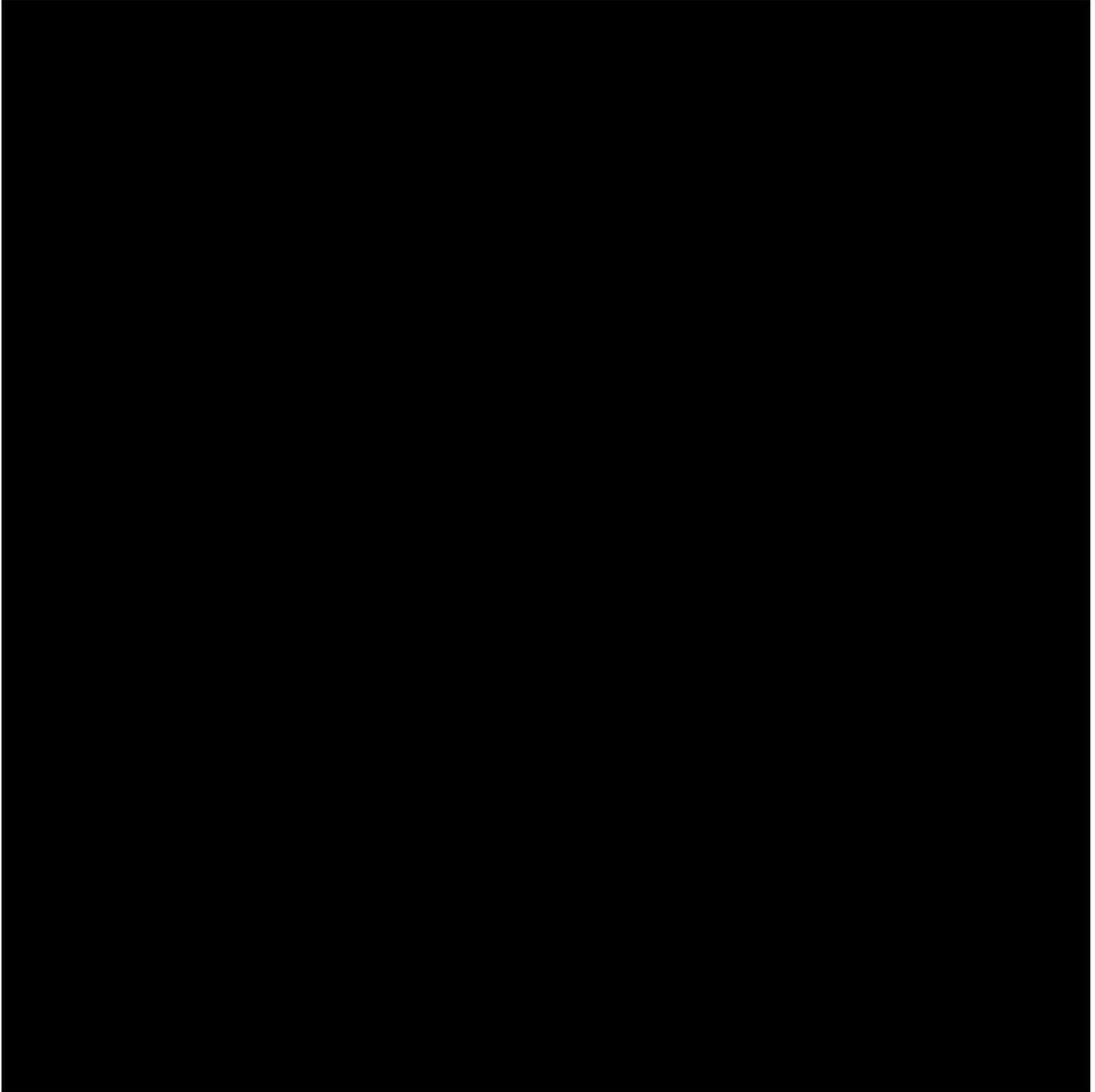
Breast Cancer

3. The usual principles of explaining proposed treatment and obtaining the patient's consent should be followed in treating cases of breast cancer. Breast cancer does not normally require emergency treatment. The patient needs reassurance that a mastectomy will not be performed without her consent, and that unless she has indicated otherwise the need for any further surgery will be fully discussed with her in the light of the biopsy and other results. This is a particular case of the principle, set out in para 10 of Chapter 2, that consent to an initial treatment or investigation does not imply consent to further treatment.

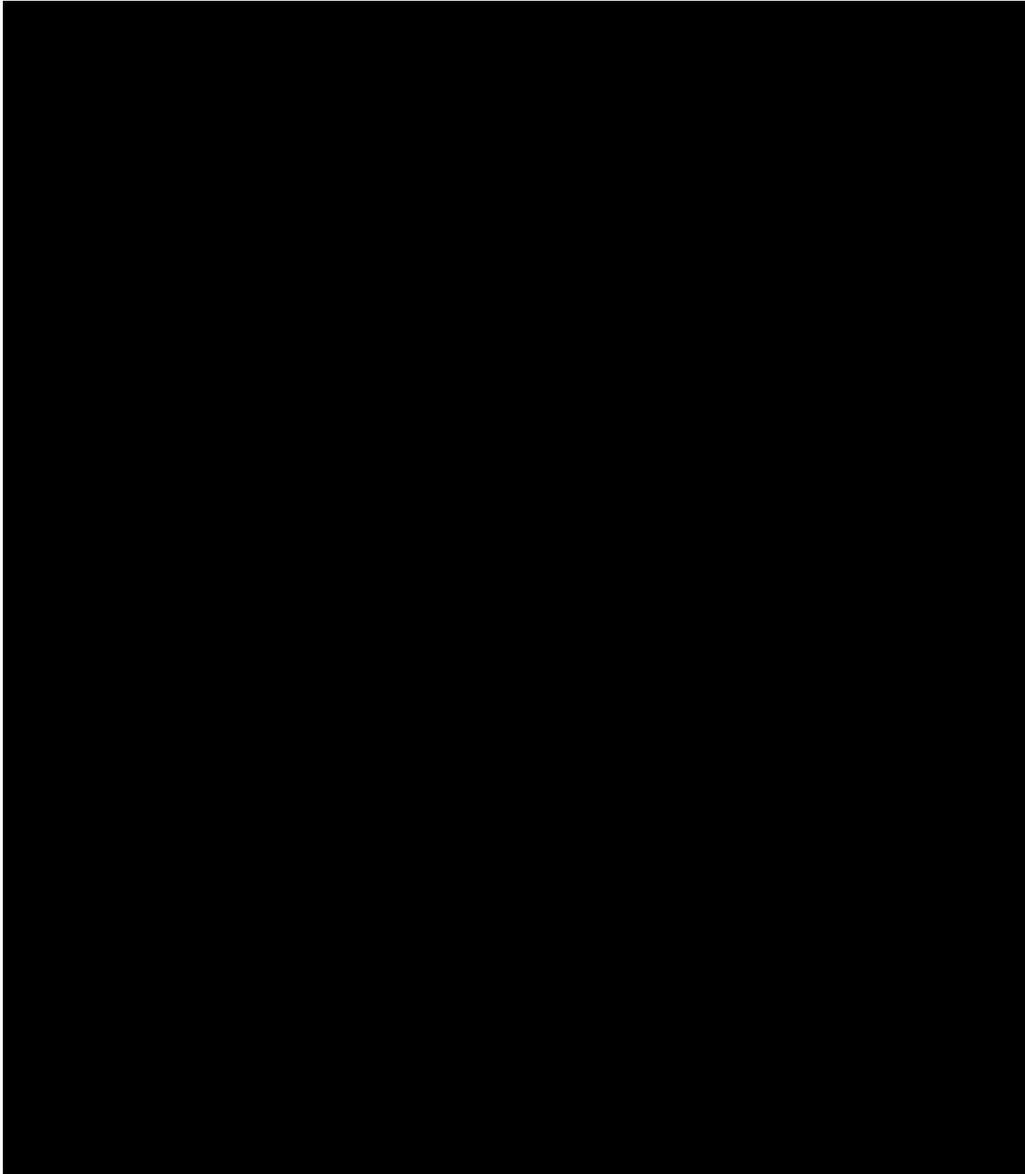
Tissue and Organ Donation: Risk of Transmitted Infection

4. Where tissues or organs are to be transplanted, the recipient should be informed, prior to consent to the operation being obtained, of the small but unavoidable risk of the transplant being infected. Further guidance is available in a CMO letter, "HIV Infection, tissue banks and organ donation" (HSS(MD)8/90).

Consent by patients suffering from mental disorder



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Appendices

Specimen consent forms

- A(1) - For medical or dental investigations, treatment or operation
- A(2) - For sterilisation or vasectomy
- A(3) - For treatment by a health professional other than doctors or dentists
- B - Medical or dental treatment of a patient who is unable to consent because of mental disorder

The wording of these forms has been agreed with professional associations and medical defence organisations.

However, these forms are models only and alternatives may be agreed locally. The responsibility for the form used rests with the health professional concerned.

CONSENT FORM

APPENDIX A(1)

For medical or dental investigation, treatment or operation

Board/HSS Trust Patient's Surname
Hospital Other Names
Unit Number Date of Birth
Sex: (please tick) Male Female

DOCTORS OR DENTISTS (This part to be completed by doctor or dentist. See notes on the reverse).

Type of operation, investigation or treatment for which written evidence of consent is considered appropriate

I confirm that I have explained the operation, investigation or treatment, and such appropriate options as are available and the type of anaesthetic, if any (general/local/sedation) proposed, to the patient in terms which in my judgement are suited to the understanding of the patient and/or to one of the parents or guardians of the patient.

Signature Date
Name of doctor or dentist

PATIENT/PARENT/GUARDIAN

- 1. Please read this form and the notes overleaf very carefully.
- 2. If there is anything that you don't understand about the explanation, or if you want more information, you should ask the doctor or dentist.
- 3. Please check that all the information on the form is correct. If it is, and you understand the explanation, then sign the form.

I am the patient/parent/guardian (delete as necessary)

I agree to what is proposed which has been explained to me by the doctor/dentist named on this form.
 to the use of the type of anaesthetic that I have been told about.

I understand that the procedure may not be done by the doctor/dentist who has been treating me so far.
 that any procedure in addition to the investigation or treatment described on this form will only be carried out if it is necessary and in my best interests and can be justified for medical reasons.

I have told the doctor or dentist about the procedures listed below I would not wish to be carried out without my having the opportunity to consider them first.

Signature
Name
Address
(if not the patient)

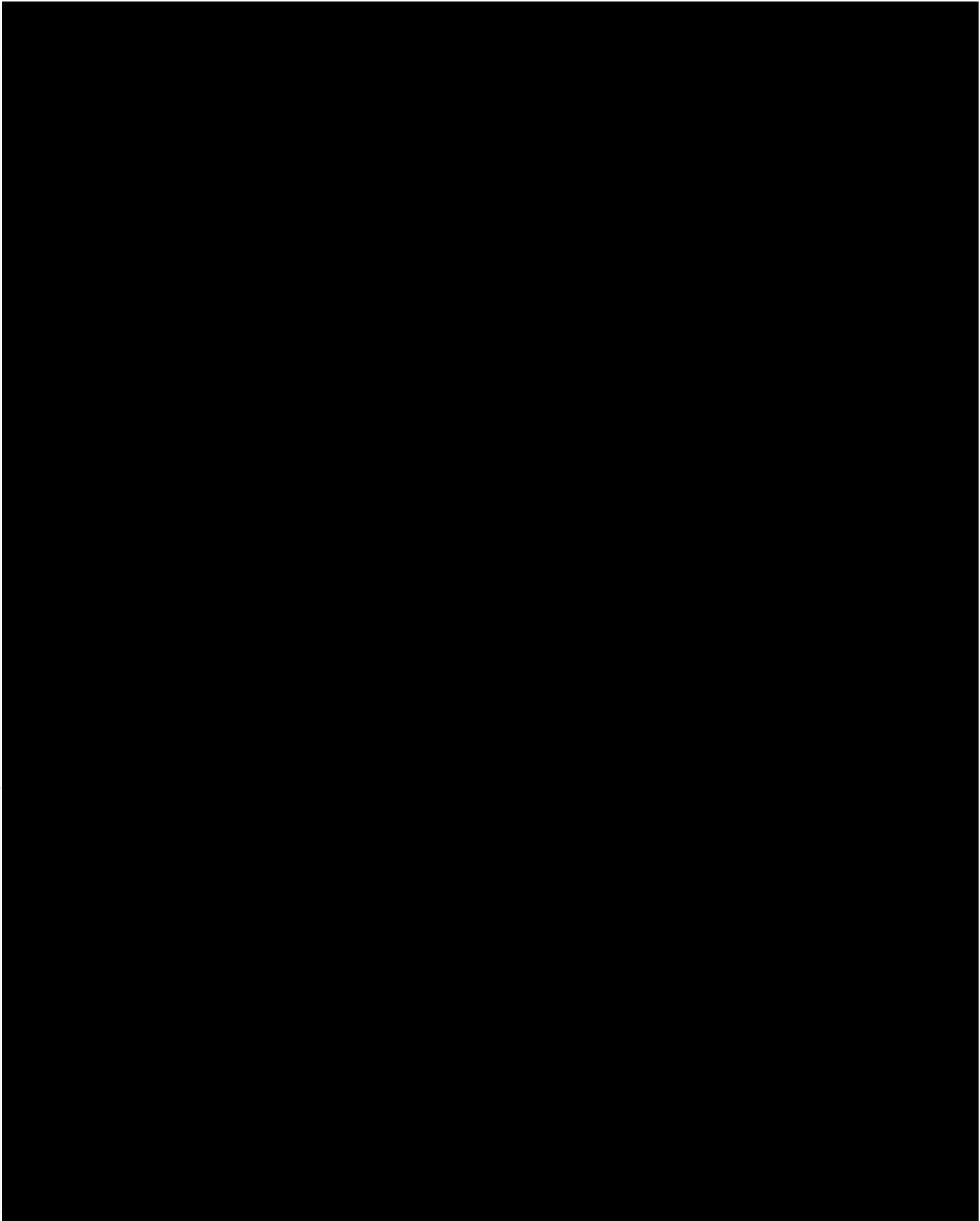
NOTES TO:

Doctors, Dentists

A patient has a legal right to grant or withhold consent prior to examination or treatment. Patients should be given sufficient information, in a way they can understand, about the proposed treatment and the possible alternatives. Patients must be allowed to decide whether they will agree to the treatment and they may refuse or withdraw consent to treatment at any time. The patient's consent to treatment should be recorded on this form (further guidance is given in HSS(GHS)2/95: A Guide to Consent for Examination or Treatment).

Patients

- The doctor or dentist is here to help you. He or she will explain the proposed treatment and what the alternatives are. You can ask any questions and seek further information. You can refuse the treatment.
- You may ask for a relative, or friend, or a nurse to be present.
- Training doctors and dentists and other health professionals is essential to the continuation of the health service and improving the quality of care. Your treatment may provide an important opportunity for such training where necessary under the careful supervision of a senior doctor or dentist.
- You may, however, decline to be involved in the formal training of medical, dental and other students without this adversely affecting your care and treatment.

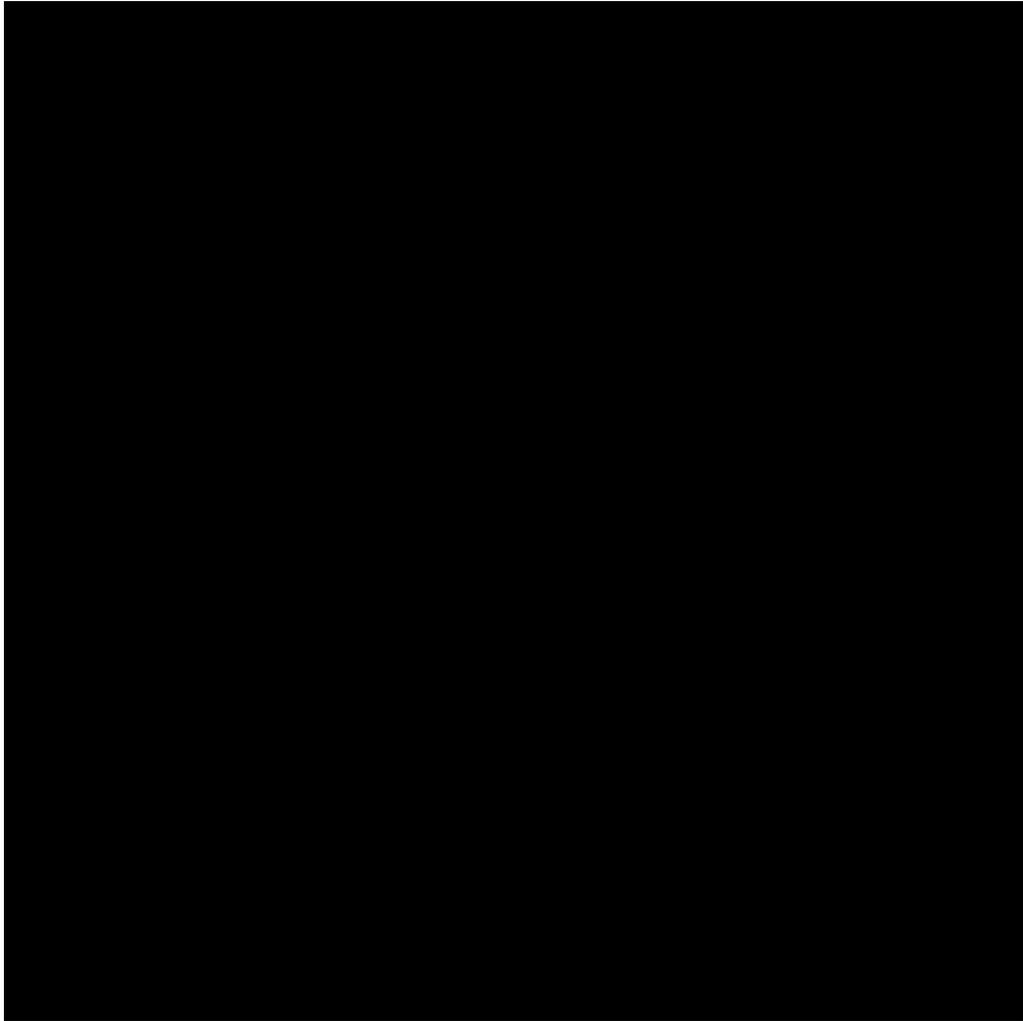


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CONSENT FORM

APPENDIX A(3)

For treatment by a health professional other than doctors or dentists

Board/HSS Trust..... Patient's Surname.....
Hospital..... Other Names.....
Unit Number..... Date of Birth.....
Sex: (please tick) Male Female

HEALTH PROFESSIONAL *(This part to be completed by health professionals. See notes on the reverse).*

Type of treatment proposed for which written evidence of consent is considered appropriate

Complete this part of the form

I confirm that I have explained the treatment proposed and such appropriate options as are available to the patient in terms which in my judgement are suited to the understanding of the patient and/or to one of the parents or guardians of the patient.

Signature..... Date

Name of doctor or dentist.....

Job Title of health professional

PATIENT/PARENT/GUARDIAN

1. Please read this form and the notes overleaf very carefully.
2. If there is anything that you don't understand about the explanation, or if you want more information, you should ask the health professional who has explained the treatment proposed.
3. Please check that all the information on the form is correct. If it is, and you understand the treatment proposed, then sign the form.

I am the patient/parent/guardian *(delete as necessary)*

I agree to what is proposed which has been explained to me by the health professional named on this form.

Signature

Name

Address

(if not the patient)

NOTES TO:

Health Professionals, other than doctors or dentists

A patient has a legal right to grant or withhold consent prior to examination or treatment. Patients should be given sufficient information, in a way they can understand, about the proposed treatment and the possible alternatives. Patients must be allowed to decide whether they will agree to the treatment and they may refuse or withdraw consent to treatment at any time. The patient's consent to treatment should be recorded on this form (further guidance is given in HSS(GHS)2/95: A Guide to Consent for Examination or Treatment.

Patients

- The health professional named on this form is here to help you. He or she will explain the proposed treatment and what the alternatives are. You can ask any questions and seek further information. You can refuse the treatment.
- You may ask for a relative, or friend, or another member of staff to be present.
- Training doctors, and dentists and other health professionals is essential to the continuation of the health service and improving the quality of care. Your treatment may provide an important opportunity for such training, where necessary under the careful supervision of a fully qualified health professional.
- You may however decline to be involved in the formal training of medical, dental and other students without this adversely affecting your care and treatment.

