

Surname:
First names:
Date of birth:
Hospital no:
(Use Hospital Identification label)

Consent form 1
Patient agreement to investigation or treatment



Special patient requirements
(e.g. other language/other communications method)

Responsible Healthcare Professional.....

Job Title:

Name of procedure or course of treatment

Side/site
(as appropriate)

(include brief explanation if medical term not clear)

Statement of Health Professional

(To be filled in by a health professional with an appropriate knowledge of the proposed procedure, as specified in the Trust's Consent Policy)

I have explained the procedure to the patient. In particular I have explained:

- The intended benefits of the procedure
- Any significant, unavoidable or frequently occurring risks, or risks patient thinks important

This procedure will involve: General and/or regional anaesthesia local anaesthesia sedation

- Any extra procedures which may become necessary during the procedure
 Blood product transfusion Radiological procedure Other procedure (please specify)

- Information leaflet provided (name)
 I have offered the patient information about the procedure but s/he has refused information.

I have discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.
I have checked that the patient has no outstanding queries and all their questions have been answered to their satisfaction. I have given them the information sheet(s) as detailed above.

Health Professional's signature Date:.....

Name (PRINT): Job Title:

Contact details (if patient wishes to discuss options later)

Statement of the Interpreter (if appropriate)

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe s/he can understand.

Interpreter's signature Date

Name (PRINT)

Copy accepted by patient: yes/no (please ring)

TOP COPY: CASE NOTES BOTTOM COPY: PATIENT

Statement of Patient

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy, which describes the benefits & risks of the proposed treatment. If not, you will be offered a copy now. Do ask if you have any further questions - we are here to help you. Please read this form carefully. **You have the right to change your mind at any time before the procedure is undertaken, including after you have signed this form.** You may ask for a relative, or friend, or a nurse to be present whilst the procedure is being explained and consent is obtained.

The training of doctors 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. You may, however, decline to be involved in the formal training of medical and other students without this adversely affecting your care and treatment.

Please initial the boxes to indicate you have understood and agree to the statements below.

- I agree to the procedure (or course of treatment) described on this form.
- I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.
- I understand that any tissue removed as part of the procedure or treatment may be used for diagnostic and therapeutic purposes as part of my care and may subsequently be stored as part of my Medical Records and may be of benefit to my subsequent care management.
- I understand that any surplus tissue may also be used for quality control/monitoring and/or public health surveillance purposes, where at the point of use my identity would not be known. The disposal of any surplus tissue would be done in a manner regulated by appropriate, ethical, legal and professional standards.
- I agree that any tissue removed as part of the procedure or treatment, which is then surplus to my own care, may be used for audit, teaching, and/or research. Any sample used for such purposes would be done in an anonymous way so that my identity at the point of use would not be known. All research studies would be subject to Research Ethics Approval and would be subject to national standards of practice. (See notes over re Tissue Samples)
- I agree to the use of photographs/video for the purpose of diagnosis and treatment.
- I understand that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia.)

Female Patients only (when applicable); I understand my care may involve X-rays and that radiation should be limited during pregnancy. There is a chance I may be pregnant. Yes No

- I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.
- I have been told about additional procedures, which may become necessary during my treatment. I have listed below any procedures that I do not wish to be carried out, without discussion with me.

.....

Patient's own signature Date

Name (PRINT)

If the patient is unable to sign but has indicated his/her consent, a witness should sign below.

Signature: Date

Name (PRINT)

Confirmation of Consent: to be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance.

On behalf of the team treating the patient, I have confirmed with the patient that s/he has no further questions and wishes the procedure to go ahead.

Signed: Date:

Name (PRINT) Job title:

Important notes: (tick if applicable)

- The patient has withdrawn consent (ask patient to sign/date here)
- See also Advance Directive/Living Will (eg Jehovah's Witness Form)

Guidance to Patients

Tissue samples

Consent is obtained in accordance with the requirements of the Human Tissue Act (2004), the Human Tissue Regulations (2007), and the Human Tissue Authority Codes of Practice.

Tissues may be removed during your procedure for diagnostic examination by a histopathologist (a specialist doctor who looks at tissue from patients). Tissue samples needed for diagnosis are stored by the laboratory for several years. The stored tissue may be anonymously used for laboratory quality control, audit and education. These are essential activities for maintaining high quality diagnostic pathology services. Any remaining excess tissue removed is incinerated.

The specimen may be digitally photographed and the images temporarily stored in the laboratory as part of the diagnostic process. Other completely anonymised images may also be used for quality assurance, audit and education purposes.

Occasionally stored tissues and photographs might be used for research projects. Any such research will have been approved by a research ethics committee (REC). Usually any pathology specimens used for research are anonymised, so that individual patients cannot be identified in any way. If this is not possible, the REC will require the researcher to contact you and ask permission to use your stored tissue or photographs. You would then be free to decide whether or not to allow the use of the material. Your decision would not in any way affect your medical care.

Guidance to health professionals (to be read in conjunction with consent policy)

What a consent form is for

This form documents the patient's agreement to go ahead with the investigation or treatment you have proposed. It is not a legal waiver - if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoire to health professionals and patients, by providing a check-list of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way, however, should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent

See the BMA's guidance on consent (available at <https://www.bma.org.uk/advice/employment/ethics/consent>)

Who can give consent

Everyone aged 16 or over is presumed to be competent to give consent for themselves, unless the opposite is demonstrated. If a child under the age of 16 has "sufficient understanding and intelligence to enable him or her to understand fully what is proposed", then he or she will be competent to give consent for himself or herself. Young people aged 16 and 17, and legally 'competent' younger children, may therefore sign this form for themselves, but may like a parent to countersign as well. If the child is not able to give consent for himself or herself, someone with parental responsibility may do so on their behalf and a separate form is available for this purpose. Even where a child is able to give consent for himself or herself, you should always involve those with parental responsibility in the child's care, unless the child specifically asks you not to do so. If a patient is mentally competent to give consent but is physically unable to sign a form, you should complete this form as usual, and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this Form

If the patient is 18 or over and is not legally competent to give consent, you should use Form 4 (form for adults who are unable to consent to investigation or treatment) instead of this form. A patient will not be legally competent to give consent if:

- They are unable to understand and retain information material to the decision and/or
- They are unable to weigh the information and communicate their decision.

You must always take all reasonable steps (for example involving more specialist colleagues or using alternative methods of communication) to support a patient in making their own decision, before concluding that they are unable to do so.

No one else can be asked to sign this form on behalf of an adult who is not legally competent to consent for himself or herself. (see MCA/Best interest policy on ICD)

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and the alternatives to the particular procedure proposed (including no treatment), is crucial for patients when making an informed decision. The GMC requires doctors to tell patients about 'serious or frequently occurring' risks. The courts state that patients should be told about 'material risks' which means 'risks to which a reasonable person in the patient's position would be likely to attach significance'. Therefore, patients should be asked if they have concerns about any specific kind of risk, and you should make sure they are informed about these risks, even if they are very small or very rare. You should always answer questions honestly and as fully as the patient wishes. Sometimes, if patients say they don't want any information about the options but want you to decide on their behalf, you should do your best to ensure that the patient receives at least basic information about what is proposed. Where information is refused, you should document this carefully on the consent form and/or in the patient's records.

Pregnancy disclaimer

If the patient has answered **yes** the advice of a radiation professional should be taken before proceeding with treatment involving X-rays between nipples and knees.

Photographs and video recordings of patients

You must tell the patient wherever possible if this is going to happen and seek written consent. If you are requiring consent to use photographs/video recording/video conferencing for teaching/research and/or publication a specific consent form is available on ICD.