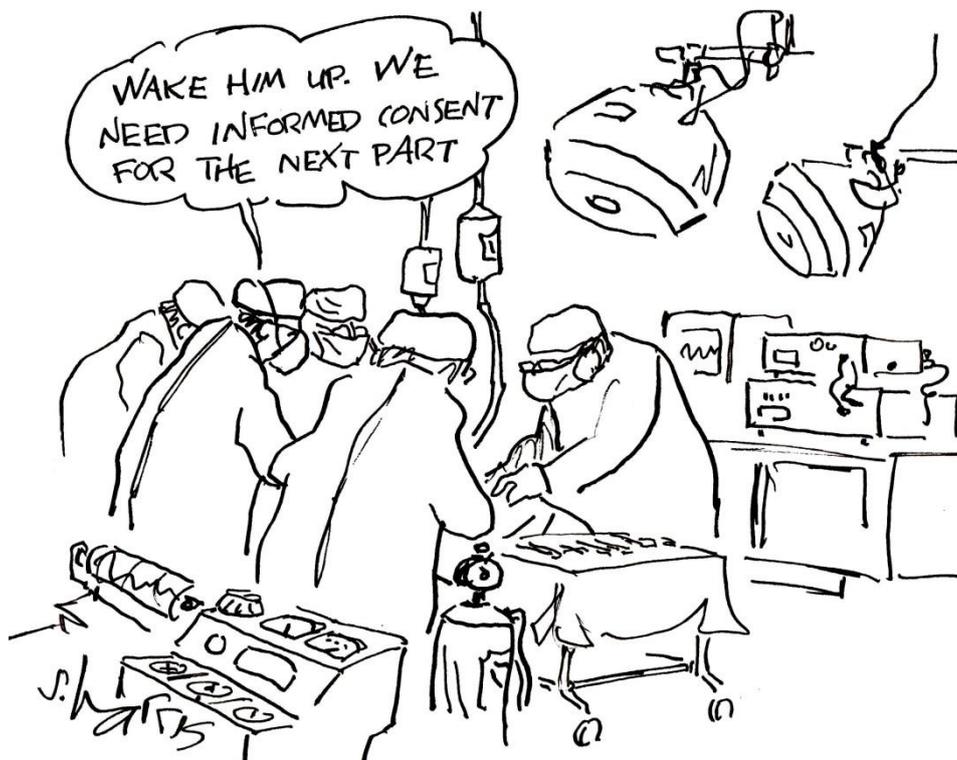




# Guide to Validating Consent:

## Dermatology Examinations or Treatments



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## Summary

The following guidance provides an overview on English law concerning consent to physical interventions on dermatology patients – from skin examinations, low to high risk surgery and the administration of prescription drugs to assistance with dressing – and is relevant to all healthcare practitioners (including students) who carry out dermatology interventions of this nature.

It describes the process of seeking consent, the importance of establishing whether the person has capacity to give consent, what constitutes valid consent, the form that consent might take and the duration of that consent. It highlights the need to ensure that the consent is given voluntarily and that sufficient information has been imparted to allow valid consent to be made.

A complete informed consent process consists of at least seven elements:

1. Discussing the patient's role in the decision-making process;
2. Describing the clinical issue and suggested treatment;
3. Discussing alternatives to the suggested treatment (including the option of no treatment);
4. Discussing risks and benefits of the suggested treatment (and comparing them to the risks and benefits of alternatives);
5. Discussing related uncertainties and answering their questions;
6. Assessing the patient's understanding of the information provided; and
7. Eliciting the patient's preference and understanding of the information provided (and thereby consent).<sup>1</sup> The patient must have the capacity to understand and retain this information, and weigh up the risks and benefits involved. The doctor should be aware that a patient would be likely to attach significance to the risk<sup>2</sup>.

Misrepresentation of any of this information will invalidate consent.

Consent may be given in writing or verbally. It may be expressed clearly or it may be implied. Implied consent is usually determined by the patient's acceptance of treatment given. Verbal or implied consent will be enough in most cases.

However, the patient's medical records or a consent form must be used to record the key elements of any clinical discussion with the patient. This should include the information discussed, any specific requests by the patient, any written, visual or audio information given to the patient, and details of any decisions that were made.

## 1.0 Introduction

It is a general legal and ethical principle that valid consent must be obtained **before** starting treatment or physical investigation, or providing personal care, for a person.

While there is no English statute setting out the general principles of consent, case law ('common law') has established that healthcare professionals must provide their patients with the necessary information required to reach a decision regarding their treatment; and that touching a patient without valid consent may constitute the civil or criminal offence of battery<sup>3</sup>. If healthcare professionals (or other healthcare staff) fail to obtain proper consent and the patient subsequently suffers harm as a result of treatment, this may be a factor in a claim of negligence against the healthcare professional involved. Poor handling of the consent process may also result in complaints from patients through the National Health Service's (NHS) complaints procedure or to professional bodies.

The legal position concerning consent and refusal of treatment by those under the age of 18 is different from the position for adults. By virtue of section 8 of the Family Law Reform Act 1969<sup>4</sup>, people aged 16 or 17 are presumed to be capable of consenting to their own medical treatment<sup>5</sup>. In order to establish whether a young person aged 16 or 17 has the requisite capacity to consent to the proposed intervention, the same criteria as for adults should be used<sup>6</sup>.

A child under 16 years who has sufficient understanding and intelligence to enable them to understand fully what is involved in a proposed intervention will also have the capacity to consent to a medical treatment, research, donation or any other activity that requires their consent.

Where a person lacks the capacity to make a decision for themselves, any decision must be made in that person's best interests<sup>7</sup>. The Mental Capacity Act<sup>7</sup> introduced a duty on NHS bodies to instruct an independent mental capacity advocate (IMCA) in serious medical treatment decisions when a person who lacks the capacity to make a decision has no one who can speak for them, other than paid staff. The Act allows people to plan ahead for a time when they may not have the capacity to make their own decisions: it allows them to appoint a personal welfare attorney to make health and social care decisions, including medical treatment, on their behalf or to make an advance decision to refuse medical treatment.

Case law on consent is evolving. All healthcare practitioners must remember their duty to keep themselves informed of legal developments that may have a bearing on their practice. British Medical Association (BMA) guidance advises that if in doubt about the amount of information to give a patient, doctors 'should contact their hospital lawyers or their medical defence organisation'.

The General Medical Council (GMC) makes it clear in its publication *Consent: doctors and patients making decisions together* (2008)<sup>5</sup> that it is the responsibility of the doctor undertaking the investigation or providing the treatment to discuss it with the patient.

Country-specific consent for examination or treatment guidance is available at the following websites:

- England Department of Health: [Gov.uk](https://www.gov.uk)
- Northern Ireland: [Department of Health, Social Services and Public Safety \(DHSSPSNI\)](https://www.dhsspsni.gov.uk) (please search for 'consent')
- Scotland: [NHS Scotland](https://www.nhs.uk)
- Wales: [Welsh Assembly Government](https://www.wales.gov.uk)

Clinicians should also refer to their employer's policies on patient consent.

## 2.0 Seeking and Validating Consent

The seeking and giving of consent is usually a process, rather than a one-off event. No single approach to discussions about treatment or care will suit every patient, or apply in all circumstances.

For consent to be valid:

- The person must be an appropriately informed person who has the capacity<sup>7,8</sup> to consent to the intervention in question. Acquiescence where the person does not know what the intervention entails is not 'consent'.
- It must be given voluntarily and freely, without pressure or undue influence being exerted on the person either to accept or refuse treatment. Such pressure can come from partners or family members, as well as health or care practitioners.
- Enough information must be provided to the person to make an informed judgement on whether to give or withhold consent.

Although informing people of the nature and purpose of procedures enables valid consent to be given as far as any claim of battery is concerned, this is not sufficient to fulfil the legal duty of care to the person. Failure to provide other relevant information may render the practitioner liable to an action for negligence if a person subsequently suffers harm as a result of the treatment received. **It is therefore advisable to inform the person of any 'material' or 'significant' risks or unavoidable risks, even if small, in the proposed treatment; any alternatives to it; and the risks incurred by doing nothing.**

The GMC guidance advises that discussions should focus on the patient's 'individual situation and risk to them' and sets out the importance of providing the information about the procedure and associated risks in a balanced way and checking that patients have understood the information given.

Some people may wish to know very little about the treatment that is being proposed. If information is offered and declined, it is good practice to record this fact in the notes.

### 2.1 Who should seek consent?

The clinician providing the treatment or investigation is responsible for ensuring that the person has given valid consent before treatment begins, although the consultant responsible for the person's care will remain ultimately responsible for the quality of medical care provided.

The GMC guidance<sup>5</sup> states that the task of seeking consent may be delegated to another person, as long as they are suitably trained and qualified. In particular, they must have sufficient knowledge of the proposed investigation or treatment, and understand the risks involved, in order to be able to provide any information the patient may require.

The practitioner who eventually carries out the investigation or treatment must also be able to determine whether the person has the capacity to make the decision in question and what steps need to be taken if the person lacks the capacity to make that decision.

Inappropriate delegation (for example where the clinician seeking consent has inadequate knowledge of the procedure) may mean that the 'consent' obtained is not valid. Clinicians are responsible for knowing the limits of their own competence, and should seek the advice of appropriate colleagues when necessary.

## 2.2 When should consent be sought?

When a patient formally gives their consent to a particular intervention, this is only the *endpoint* of the consent process. It is helpful to see the whole process of information provision, discussion and decision-making as part of 'seeking consent'. This process may take place at one time, or over a series of meetings and discussions, depending on the seriousness of what is proposed and the urgency of the patient's condition.

### *Single stage consent*

In many cases, it will be appropriate for a health professional to initiate a procedure immediately after discussing it with the patient. If a proposed procedure carries significant risks, it will be appropriate to seek written consent, and health professionals must take into consideration whether the patient has had sufficient chance to absorb the information necessary for them to make their decision. As long as it is clear that the patient understands and consents, the health professional may then proceed.

### *Two or more stages of consent*

In most cases where written consent is being sought, treatment options will generally be discussed well in advance of the actual procedure being carried out. This may be on just one occasion (either within primary care or in a hospital out-patient clinic), or it might be over a whole series of consultations with a number of different health professionals. The consent process will therefore have at least two stages: the first being the provision of information, discussion of options and initial (oral) decision, and the second being confirmation that the patient still wants to go ahead. The consent form should be used as a means of documenting the information stage(s), as well as the confirmation stage.

Patients receiving elective treatment or investigations for which written consent is appropriate should be familiar with the contents of their consent form **before** they arrive for the actual procedure, and should have received a copy of the page documenting the decision-making process. They may be invited to sign the form, confirming that they wish treatment to go ahead, at any appropriate point before the procedure: in out-patients, at a pre-admission clinic, or when they arrive for treatment. If a form is signed before patients arrive for treatment, however, a member of the healthcare team **must** check with the patient at this point whether they have any further concerns and whether their condition has changed. This is particularly important where there has been a significant lapse of time between the form being signed and the procedure. When confirming the patient's consent

and understanding, it is advisable to use a form of words which requires more than a yes/no answer from the patient: for example, beginning with “Tell me what you’re expecting to happen.”, rather than “Is everything all right?”.

### 2.3 Forms of consent

The validity of consent does not depend on the form in which it is given. Written consent merely serves as evidence of consent: if the elements of voluntariness, appropriate information and capacity have not been satisfied, a signature on a form will not make the consent valid.

Although completion of a consent form is in most cases not a legal requirement (exceptions include certain requirements of the Mental Health Act 1983<sup>8</sup>) the use of such forms is good practice where an intervention such as surgery is to be undertaken. Where there is any doubt about the person’s capacity, it is important, **before** the person is asked to sign the form, to establish both that they have the capacity to consent to the intervention and that they have received enough information to enable valid consent to be given. Details of the assessment of capacity, and the conclusion reached, should be recorded in the case notes.

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 clinician seeking consent, and for the fact that the person has chosen to make their mark in this way to be recorded in the case notes.

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 notes. 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 no bar to treatment, but a form can be important evidence of such consent.

Consent may be expressed verbally or non-verbally: an example of non-verbal consent would be where a person, after receiving appropriate information, holds out an arm for their blood pressure to be taken. However, the person must have understood what examination or treatment is intended, and why, for such consent to be valid. It is good practice to obtain written consent for any significant procedure, such as a surgical operation or when the person participates in a research project or a video recording (even if only minor procedures are involved).

The same legal principles apply when seeking consent from a person for research purposes as when seeking consent for investigations or treatment. GMC guidance advises that patients ‘should be told how the proposed treatment differs from the usual methods, why it is being offered, and if there are any additional risks or uncertainties’. Clinical trials are covered by the Medicines for Human Use (Clinical Trial Regulations) 2004<sup>9</sup>.

## 2.4 Duration of consent

When a person gives valid consent to an intervention, in general that consent remains valid for an indefinite duration, unless it is withdrawn by the person. However, if new information becomes available regarding the proposed intervention (for example new evidence of risks or new treatment options) between the time when consent was sought and when the intervention is undertaken, GMC guidance states that a doctor or member of the healthcare team should inform the patient and reconfirm their consent.

If consent has been obtained a significant time before undertaking the intervention, it is good practice to confirm that the person who has given consent (assuming that they retain capacity) still wishes the intervention to proceed, even if no new information needs to be provided or further questions answered.

For major interventions, it is good practice where possible to seek the person's consent to the proposed procedure well in advance, when there is time to respond to the person's questions and provide adequate information. Clinicians should then check, before the procedure starts; that the person still consents.

## 2.5 Recommendations for determining consent

- Take into account any views or preferences expressed by the patient and must follow the law on decision-making when a patient lacks capacity. If you are in doubt about your patient's capacity to make a decision about their treatment, a new GMC interactive online tool<sup>10</sup> will help you identify the steps you need to take.
- Check whether the patient has understood the information they have been given, and whether or not they would like more information before making a decision. Ask the patient to repeat back to you the information provided.
- Doctors must make it clear that their patient can change their mind about a decision at any time. This is more important than how the patient's consent is expressed or recorded.
- Listen and answer their questions (resist the urge to interrupt or pre-empt their questions). Repeat their question back to the patient along with your response.
- In the case of minor or routine investigations or treatments, if you are satisfied that the patient understands what you propose to do and why, it is usually enough to have oral or implied consent (recorded in the patient's notes).
- In cases that involve higher risk, it is important that you get the patient's written consent. This is so that everyone involved understands what was explained and agreed.
- Provide a contactable resource for the patient to answer any further questions in the interim to starting their treatment or procedure, when relevant.

It is sometimes difficult, because of pressures on clinical time or the limited resources available, to give patients as much information or support in making decisions as a doctor, or the patient would like. To help in this, doctors should consider the role that other members

of the healthcare team might play, and what other sources of information and support are available. These may be, for example, patient information leaflets (PILs), advocacy services, expert patient programmes, or patient support groups (PSGs) for people with specific conditions (see the British Association of Dermatologist's (BAD) PILs and list of PSGs or advise the patient to contact their local health watch team).

Note: If doctors delegate care, they are still responsible for making sure that the patient has been given enough time and information to make an informed decision, and has given their consent, before the start any investigation or treatment.

### 3.0 Cosmetic Interventions

The GMC issued new guidance which sets out the standards expected from doctors who provide cosmetic interventions<sup>11</sup>. The guidance came into force on 1 June 2016 and applies to all doctors who carry out both surgical (such as breast augmentation) and non-surgical procedures (such as dermal fillers)<sup>12</sup>.

If a patient requests an intervention, the doctor must follow the guidance on Consent, including consideration of the patient's medical history. They must ask the patient why they would like to have the intervention and the outcome they hope for, before assessing whether the intervention is appropriate and likely to meet their needs.

It is essential the patient is given the necessary time and information they need to reach a voluntary and informed decision about whether to go ahead with an intervention.

The amount of time patients need for reflection and the amount and type of information they will need depend on several factors. These include the invasiveness, complexity, permanence and risks of the intervention, how many intervention options the patient is considering and how much information they have already considered about a proposed intervention.

The doctor must tell the patient they can change their mind at any point.

They must consider whether it is necessary to consult the patient's General Practitioner (GP) to inform the discussion about benefits and risks. If so, they must seek the patient's permission and, if they refuse, discuss their reasons for doing so and encourage them to allow you to contact their GP. If the patient is determined not to involve their GP, they must record this in their notes and consider how this affects the balance of risk and benefit and whether they should go ahead with the intervention.

## Glossary of Abbreviations and Terms

<b>BAD</b>	British Association of Dermatologists
<b>BMA</b>	British Medical Association
<b>DHSSPSNI</b>	Department of Health, Social Service and Public Safety (Northern Ireland)
<b>GMC</b>	General Medical Council
<b>GP</b>	General Practitioner
<b>IMCA</b>	Independent Mental Capacity Advocate
<b>NHS</b>	National Health Service
<b>PILs</b>	Patient Information Leaflets
<b>PSGs</b>	Patient Support Groups

## References

- 1 - Braddock CH 3rd, Fihn SD, Levinson W, et al. How doctors and patients discuss routine clinical decisions. Informed decision making in the outpatient setting. *J Gen Intern Med.* 1997;12(6):339–45. [PMC free article] [PubMed]
- 2 - Update on the UK Law on Consent: *Montgomery v. Lanarkshire Health Board.* *BMJ* 2015;350:h1481
- 3 - *Sidaway v. Bethlem Royal Hospital (1984)* All Engl Law Rep. Feb 23;[1984] 1:1018-36.
- 4 - Family Law Reform Act 1969 - <http://www.legislation.gov.uk/ukpga/1969/46>
- 5 - GMC Ethical Guidance 0-18 years: guidance for all doctors - [http://www.gmc-uk.org/guidance/ethical\\_guidance/children\\_guidance\\_contents.asp](http://www.gmc-uk.org/guidance/ethical_guidance/children_guidance_contents.asp)
- 6 - Royal College of Nursing: Consent: Advice Guides – <https://www.rcn.org.uk/get-help/rcn-advice/consent> - *“A child is anyone under the age of 16 years (or under 18 under the law of Northern Ireland, Scotland and Wales). A child is able to give valid consent to treatment if they have sufficient understanding and intelligence to fully comprehend what is being proposed. This is often referred to as “Gillick competence” as per Fraser guidelines.”*
- 7 - The Mental Capacity Act 2005 – <http://www.legislation.gov.uk/ukpga/2005/9/contents> - *“A person who lacks capacity: a person who is unable to make a decision for themselves because of an impairment or disturbance in the functioning of their mind or brain. It does not matter if the impairment or disturbance is permanent or temporary.”*
- 8 – Code of Practice: Mental Health Act 1983 - <https://www.gov.uk/government/publications/code-of-practice-mental-health-act-1983>
- 9 – Clinical Trial Regulations 2004 - [http://www.legislation.gov.uk/uksi/2004/1031/pdfs/uksi\\_20041031\\_en.pdf](http://www.legislation.gov.uk/uksi/2004/1031/pdfs/uksi_20041031_en.pdf)
- 10 – General Medical Council – Mental Capacity Flowchart - [http://www.gmc-uk.org/Mental\\_Capacity\\_flowchart/](http://www.gmc-uk.org/Mental_Capacity_flowchart/)
- 11 – Guidance for Doctors who offer Cosmetic Interventions - [http://www.gmc-uk.org/guidance/ethical\\_guidance/28687.asp](http://www.gmc-uk.org/guidance/ethical_guidance/28687.asp)
- 12 - Good Medical Practice Ethical Guidance in Cosmetic Surgery - [http://www.gmc-uk.org/guidance/ethical\\_guidance/28687.asp](http://www.gmc-uk.org/guidance/ethical_guidance/28687.asp)

## Appendix 1: Consent Form 3

Consent Form 3: Patient/parental agreement to investigation, treatment or procedure where consciousness not impaired

[NHS organisation name] consent form 3

### Patient identifier/label

Name of procedure (include brief explanation if medical term not clear)

.....

**Statement of health professional** (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)

I have explained the procedure to the patient/parent. In particular, I have explained:

The intended benefits .....

.....

Serious or frequently occurring risks: .....

.....

I have also 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 those involved.

The following leaflet/tape has been provided .....

Signed: ..... Date .....

Name (PRINT) ..... Job title.....

**Statement of interpreter** (where appropriate)

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

Signed ..... Date.....

Name (PRINT).....

**Statement of patient/person with parental responsibility for patient**

**I agree** to the procedure described above.

**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 the procedure will/will not involve local anaesthesia.

Signature ..... Date .....

Name (PRINT) ..... Relationship to patient .....

**Confirmation of consent** (to be completed by a health professional when the patient is admitted for the procedure, if the patient/parent has signed the form in advance)

I have confirmed that the patient/parent has no further questions and wishes the procedure to go ahead.

Signed: ..... Date .....

Name (PRINT) ..... Job title .....

Top copy accepted by patient: yes/no (please ring)

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

### This form

This form documents the patient's agreement (or that of a person with parental responsibility for the patient) to go ahead with the investigation or treatment you have proposed. **It is only designed for procedures where the patient is expected to remain alert throughout and where an anaesthetist is not involved in their care: for example, for drug therapy where written consent is deemed appropriate.** In other circumstances, you should use either form 1 (for adults/competent children) or form 2 (parental consent for children/young people) as appropriate.

Consent forms are not legal waivers – 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 also have every right to change their mind after signing the form.

### Who can give consent

Everyone aged 16 or more 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, if they wish. If the child is not able to give consent for himself or herself, some-one with parental responsibility may do so on their behalf. 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 (see also 'This form' above)

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 comprehend and retain information material to the decision and/or
- they are unable to weigh and use this information in coming to a decision.

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives **cannot** be asked to sign this form on behalf of an adult who is not legally competent to consent for himself or herself.

### 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, is crucial for patients when making up their minds about treatment. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'serious or frequently occurring' risks. In addition if patients make clear they have particular concerns about certain kinds of risk, you should make sure they are informed about these risks, even if they are very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this overleaf or in the patient's notes.

### The law on consent

See the Department of Health's *Reference guide to consent for examination or treatment* for a comprehensive summary of the law on consent (also available at [www.doh.gov.uk/consent](http://www.doh.gov.uk/consent)).