

BACKGROUND

Authors

Acknowledgements

Copyright

Disclaimer

The following guidance material is aimed primarily at students, teachers or doctors who wish to use a patient recording or patient data for learning and teaching. It will also be of interest and use to other clinical and healthcare workers as well as to university staff where patient recordings are being made available for learning and teaching.



Please note that this version is in draft form and hasn't been cleared for onward distribution

This guidance is based on a set of [ethical and professional principles >>](#)

The main objectives of the guidance are to

- Help you behave ethically and with consideration
- Introduce you to the special issues that arise when recordings are made in a clinical setting
- Provide practical guidance on how to make and use clinical recordings for learning and teaching
- Help you understand and meet the obligations that arise from doing this

[Enter guidance materials >>](#)

Principles

This guidance is based on the following ethical and professional principles:

[Provenance >>](#)

If you make, store, access, use and share recordings, you should at all times:

1. Acknowledge that patients' interests and rights are paramount.
 - a) Respect patients' privacy and dignity.
 - b) Wherever possible make use of existing recordings for which there is appropriate consent.
 - c) Ensure there is appropriate current patient consent for any new recordings.
 - d) Only access, store, use or share recordings with appropriate patient consent, or anonymise recordings before use.
2. Respect the rights to privacy and dignity of other people who are included in the recordings, such as family members and health care workers.
3. Respect the rights of those who own the recordings and any intellectual property rights associated with those recordings and check and comply with the licences for use.
4. Take professional responsibility for your making, use and sharing of recordings and alert colleagues to their own legal and ethical responsibilities where appropriate.
 - a) Wherever possible make use of existing recordings for which there is appropriate consent.

[Find out more about 1 >>](#)

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Principles - Provenance

Provenance of the principles

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The principles (and related guidance materials) were developed through a collaboration of cross-sector organisations to encourage shared understandings across clinical and educational settings around good practice for the creation and use of medical recordings for educational purposes. A British Medical Recordings Task Force was set up to oversee the work and this group developed the four main principles on which the guidance materials are based.

The principles cover consent to make and use recordings of patients and other people, ensuring ownership and licensed use of recordings are respected and professional responsibilities for the onward storage, use and sharing of those recordings are carried out.

The guidance material has been developed in consultation with the wider clinical and healthcare communities; please see the Acknowledgements section for a full list of individuals and organisations who have contributed to this material.

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Principle 1 - Patient consent

What are my obligations to the patient (patient consent)?

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- This all about the patient's permissions
- It covers the patient's rights of privacy and confidentiality, both personal and medical
- Consent can only be given by the patient. Patient Consent issues remain under control of the patient and cannot be given or passed on by anyone else on their behalf

You therefore need to seek a particular type of consent before making, and/or using, any recordings of medical patients.

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Principle 2 - Other people

What are my obligations to any other people included in the patient recording (other people's consent)?

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- This all about the permissions that need to be sought before making recordings of people in general
- It covers their personal rights of privacy and confidentiality
- Consent needs to be given by each person in the recording
- These permissions cannot be given or passed on by anyone else on their behalf

You therefore need to seek any person's consent before making, and/or using any recordings.

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Principle 3 - Copyright holders

What are my obligations to the copyright holder?

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Copyright

- Copyright is literally the right to copy and use the recordings for learning and teaching , or any other purposes, as opposed to the physical ownership of the actual recording
- The patient that gives their permission (consent) to make and use a recording of themselves, does not own the copyright of that recording. It is the individual or organisation who generates the material that owns the copyright
- Permissions to copy and use the recordings can only be given by the owner of the copyright, and cannot be given by the patient
- These permissions are usually given by way of a licence

You need to be clear who the copyright holder is and seek a licence for use if necessary

Moral rights

In addition to their rights of copyright, the copyright holder also has certain *moral rights* associated with their recordings.

These include:

- The right to be acknowledged as the copyright holder
- The right not to have the recording altered
- The right not to have the recording used in such a way as to bring the copyright holder into disrepute, for example by describing the contents of the recording inaccurately

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Principle 4 - Professional responsibilities

What are my ongoing obligations to my institution and my colleagues?

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- This is all about how you and your colleagues ensure recordings are used only for the purposes agreed with the patient and copyright holder (permissions)
- It covers storage, access, sharing and re-use by other users

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Guidance Materials

There are five steps that need to be considered. Although they are all related - in practice we need to address them in a particular order. We suggest that you look at these BEFORE going into the flowcharts.

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[Look at five steps >>](#)

Once you have decided exactly what patient recordings you need to make and/or to acquire, and what you and others might want to use these recordings for, follow the appropriate link to a flowchart which will take you through the issues.

Create new material

OR

Use pre-existing or archival material

[Find out what to do about patient consent >>](#)

[Find out what to do about patient consent >>](#)

[Find out what to do about copyright and licensing >>](#)

[Find out what to do about copyright and licensing >>](#)

[Find out what to do about storage, access, use and sharing >>](#)

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Guidelines

Steps in the process

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1. Decide exactly what patient recordings you need, either to make and/or acquire from other sources.
2. Decide what you want to use these images (recordings) for and who else might use them and for what sort of learning and teaching.
3. Ask for, and document, patient consent. You can only do this after carefully explaining to the patient, both what recordings you want to make, and how they will be used.
4. Request a licence for use. You can only do this after carefully explaining to the copyright holder both what recordings you want to use and how they will be used. The holder of the copyright cannot give permission for any use for which the patient hasn't first given their patient consent.
5. Be aware of your ongoing obligations during storage, use and sharing of recordings and make sure these obligations can be met.

Create new material

OR

Use pre-existing archival material

[Find out what to do about patient consent >>](#)

[Find out what to do about copyright and licensing >>](#)

[Find out what to do about storage, access, use and sharing >>](#)

[Find out what to do about patient consent >>](#)

[Find out what to do about copyright and licensing >>](#)

[Find out what to do about storage, access, use and sharing >>](#)

Creating New Material Patient Consent

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If your project involves the making of any of the following:

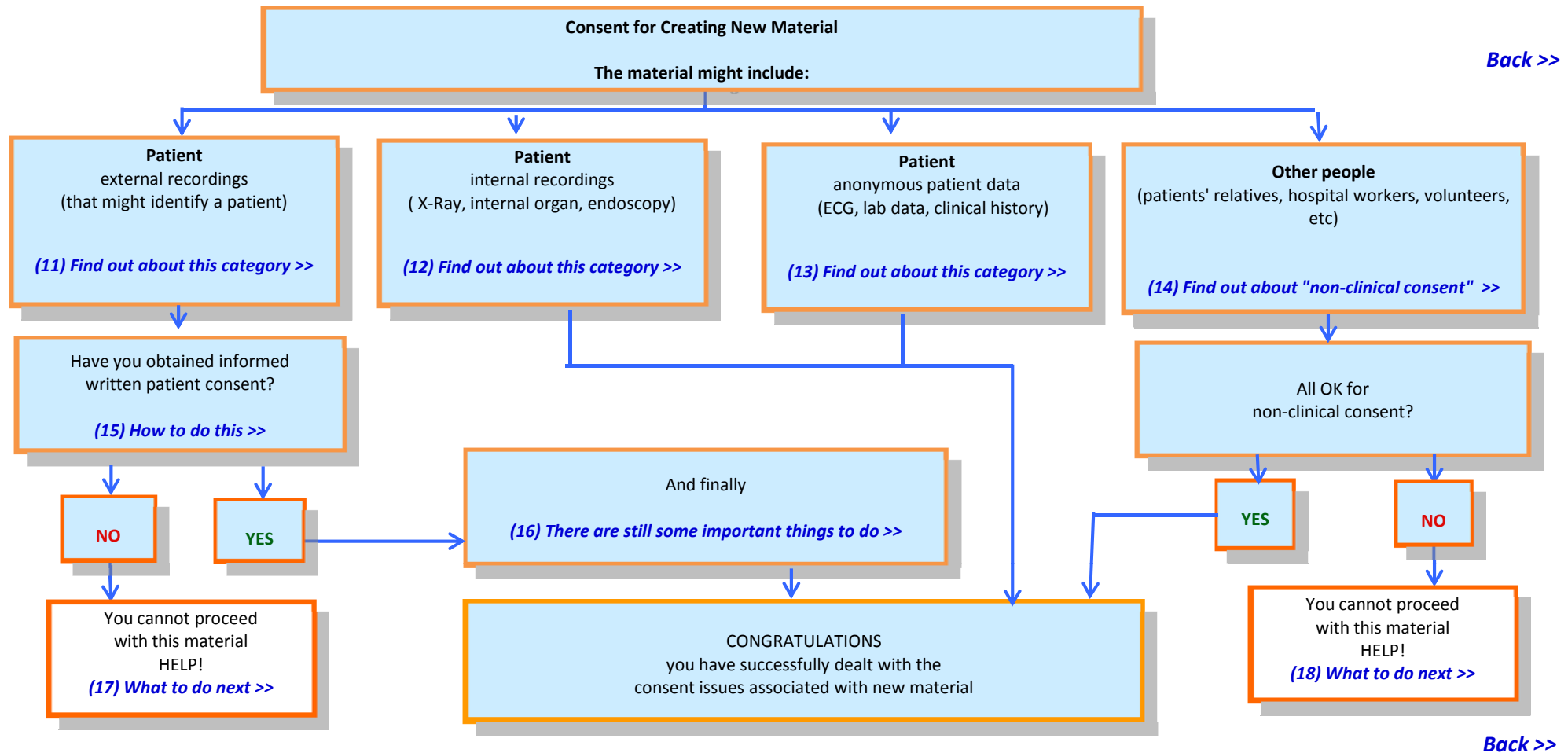
1. Recordings of patients (internal or external).
2. Patient data (patient notes, ECGs, lab data, etc).
3. Recordings of other people such as staff, relatives, teachers, students, members of the public.

Then, for each recording that you create, you will need to find out:

1. Whether there needs to be written consent.
2. If so, how to obtain this consent.
3. Whether there are any other obligations that you haven't thought of.

The following Flowchart will guide you through this sequence.

[Go to Flowchart >>](#)



Creating New Material
External recordings that might identify a patient

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Best practice would be to always get the patient's explicit written consent where it is practicable to do so.

What patient recordings fall into this category?

The following guidance is based on the GMC's [Making and using visual and audio recordings of patients - guidance for doctors](#) .

The GMC guidelines state that if the patient in the recording is either recognisable or the recording contains details that would allow the patient to be identified (including distinctive features, skin marks, jewellery etc), then that recording will require patient consent. If the patient is not recognisable in the recording (operations site or skin spots), then that recording will not require patient consent.

Practical tips

- Be aware that even apparently insignificant details may mean that the patient is identifiable. Please ensure that the patient is happy that the image will not be recognisable
- Iris recognition technology may preclude the use of images of a complete iris in material for wider distribution
- The previous black bar across the eyes is now not recognised as being adequate for anonymisation

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Creating New Material

Internal recordings e.g. X-ray, internal organ, endoscopy

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You will need to check each recording to ensure adequate anonymisation. Even apparently insignificant details may still be capable of identifying the patient. If adequate anonymisation is not possible then you need the patient's written consent for it to be used.

What patient recordings fall into this category?

The following guidance is based on the GMC's [Making and using visual and audio recordings of patients - guidance for doctors](#)

The GMC guidelines state that consent to make the recordings listed below will be implicit in the consent given to the investigation or treatment, and does not need to be obtained separately but where practicable you should explain that such a recording will be made and could be used in anonymised form for secondary purposes. These include:

- Images of internal organs or structures (such as laparoscopic images)
- Images of pathology slides (as opposed to actual pathology slides containing human tissue)
- Images taken inside body orifices (such as endoscopic images)
- X-rays, ultrasound and other scans
- Recordings of organ functions

Note

Adequate anonymisation involves removal of all the following:

- Patient's name and any other patient details
- Patient's identification number
- Doctor's name
- Name of the hospital
- Any Radiograph or Pathology number
- Any coding or writing in the margins of the recording

Practical tip

Be aware that there may be metadata (information about the recording) embedded with the recording itself which you will need to check and remove if appropriate.

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Creating New Material that Includes other People

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The main focus of these guidelines relates to recordings of patients. However, some of your material may have images of other people, either with the patient, or on their own. The general principles are exactly the same as those for patients, in that everyone has rights of privacy which need to be respected. The rules and guidelines are less well defined here than for patients' rights.

There is no equivalent of the GMC Guidelines relating to other people but Article 8 of the [European Convention of Human Rights](#) provides a right to respect for one's 'private and family life, his home and his correspondence.'

Schedule 2 of the [UK Data Protection Act of 1998](#) also sets out the conditions relevant for the processing of any personal data.

Changing cultures

Before the digital age most people were unconcerned if someone took a visual or audio recording. Now if someone takes a recording we generally like to know:

- Who they are
- Why they want to take the recording, and
- What they intend to do with it

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So what are the practical consequences of this?

For new projects that might show recognisable images of adults

You should get written consent wherever possible. What this means in practice will vary depending on who the people are. Here are some comments that might help.

- **For patients' relatives**
For new projects, it is sensible to obtain, and document, some sort of consent. Avoid images of children if possible. Although children or young people under 16 who have the capacity and understanding to give consent for a recording may do so, you should encourage them to involve their parents in the decision-making

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- **Hospital or other health-care workers**

On many NHS Hospital Trust premises, there are local guidelines and rules about this. Ask advice from the local Department of Medical Illustration or Caldicott Guardian

- **Volunteers such as students or teachers**

Most institutes of Higher and Further Education will have local guidelines and rules. You need to be aware of, and conform to these

- **Actors**

There will be a written contract which will deal with the details of such things but ensure the contract covers you for making and reusing the recordings

- **Public bystanders**

Try to keep out of recordings wherever possible

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Creating New Material

Anonymous patient data e.g. ECG, lab data, clinical history

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You will need to check each recording to ensure adequate anonymisation. Even apparently insignificant details may still be capable of identifying the patient. If adequate anonymisation is not possible then you need the patient's written consent for this part of their medical record to be used.

What patient information falls into this category?

The following guidance is based on the GMC's [Making and using visual and audio recordings of patients - guidance for doctors](#)

The GMC guidelines state that patient data, such as the following, will not require the patient's consent for their use for learning and teaching, provided they are adequately anonymised (see below):

- Investigatory traces such as ECGs, EEGs or blood pressure recordings
- Laboratory data such as Haematology, Chemistry or Microbiology results

Guidance about the confidentiality of written records such as clinical histories is provided in the GMC's [Confidentiality guidance](#)

As well as in [Confidentiality: disclosing information for education and training purposes](#)

This states that patient's personal information would not have required the patient's consent for their use for learning and teaching, provided they are adequately anonymised (see below). If the information cannot be anonymised then patient consent should always be sought.

Note

Adequate anonymisation involves removal of all the following:

- Patient's name and any other patient details
- Patient's identification number
- Doctor's name
- Name of the hospital
- Any Radiograph or Pathology number
- Any coding or writing in the margins of the recording

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Practical tip

Be aware that there may be metadata (information about the recording) embedded with the recording itself which you will need to check

Creating New Material Obtaining informed written patient consent

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Seeking and gaining consent takes skill and time and consideration. **It is very important that it is done properly.**

What is meant by properly informed patient consent?

Properly informed means the patient is in a suitable condition to understand and grant the consent. If the patient is not in a physical or mental state to understand the process - then they are legally unable to give proper consent. [\(15a\) Find out more >>](#)

Guidance on how to ask for patient consent

The following guidance is based on the GMC's [Making and using visual and audio recordings of patients - guidance for doctors](#)

In which the GMC emphasises the importance of:

- Complying with the laws, rules and guidelines (including local rules and guidelines) that apply to patient confidentiality, privacy and autonomy (the right to make their own decisions)
- Taking time to treat the patient well – they may be in a vulnerable position
- Being clear about the purpose of the recording
- Maximising the patient's opportunity to make decisions for themselves
- The patient understands their decision will not adversely affect their treatment
- Respecting the patient's decisions
- Ensuring that patient consent is a process that involves:
 - The provision of information in a way which is clear, simple and appropriate for their individual needs
 - Ensuring that the patient understands that you are seeking consent not just to make the recording, but also to store, use and share that recording in the future (you should ensure the widest consent possible if you want to share the recording in the future)
 - Listening and allowing time for discussion, reassurance and dialogue to ensure that you accommodate the

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Responsibilities

You need to:

- Maintain professional standards equivalent to those described in the GMC guidelines (see above)

- If in a clinical setting, comply with any local NHS trust's guidelines and requirements via that trust's department of Medical Illustration (if they have one) or the Caldicott Guardian [\(15b\) More about this>>](#)
- Ensure that the senior member of the patient's care team knows about your approach to their patient. If you are not a member of the senior team then consider having a member of the patient's care team present when you are seeking consent [\(15c\) More about this >>](#)
- If in a non-clinical setting such as a university , understand that patient consent is still vital, and comply with any local regulations [\(15d\) More about this >>](#)
- Have a well prepared, clear patient information sheet that spells out clearly that the teaching material may be made widely available for learning and teaching elsewhere (maybe including the internet) . If this is the case you need to clearly explain that a full withdrawal of the recordings may not be possible if they later change their mind [\(15e \) More about this >>](#)
- Have a well prepared, clear patient consent form [\(15f\) More about this >>](#)
- Ensure that the patient has an opportunity to fully read and understand both the patient information sheet and the patient consent form
- Ensure that there is a full record of the consent in the patient's notes (and keep a copy yourself) or in the department of Medical Illustration. (see next box on Flowchart)
- Be confident that there is a mechanism for fulfilling the expectations of the patient concerning safe storage and appropriate use. The signed consent form is a contract. (see next box on Flowchart)
- Understand that, if you have promised the patient that, if they change their mind at a later date, there needs to be a long-term mechanism for identifying the recordings and withdrawing them. Remember if you have asked the patient to make the recordings available to be shared that withdrawal may not be possible

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Who should ask for patient consent?

There is no consensus, but experience from the organ retention scandal of the 1990's tells us that it is very dangerous to delegate this delicate task. What are the options?

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- **You as the person who is organising the project**
If you are a clinician, this is entirely appropriate, but otherwise beware. It is something that needs care and attention. It is all too easy to do it badly
- **The doctor in charge of the patient**
For many projects, the clinician in charge of the patient is also the leader of the project to make the images. If not, doctors are very busy people and the clinician in charge of the patient may not be able to attend to this request
- **The nurse who knows the patient best**
Not so great as it sounds. As in practice, on that particular day the nurse on duty may not really know the patient well or may be very busy
- **A representative of the hospital's department of Medical Illustration**
The IMI recommend that members do not take on this responsibility, however they will be expected to check the validity of the consent by confirming that the patient has understood the purpose of the recording
- **If you are a student – your project supervisor**
A good safe bet, if you are worried. Your supervisor should be prepared to take on the responsibility for organising this. He/she is often the clinician in charge of the patient
- **University photographer- not usually recommended**
Some one has to assess whether the person has sufficient experience in dealing with patients

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Important footnote

If you are responsible for seeking consent, you must understand the research project, including what the project will involve and anticipated benefits and foreseeable risks.

If you delegate the responsibility to someone else, you must make sure they have sufficient understanding of the research project, and the appropriate skills and competence to seek consent. For whoever takes responsibility for asking for patient consent, two things are important:

- The doctor in charge of the patient needs to be informed that the pictures are to be taken and that appropriate consent has been sought and given
- Regardless of who actually does the explaining and organises the consent, both you and the patient need to be clear who is taking on responsibility for the ongoing safe storage and appropriate use of the images

What if the patient declines to give consent?

For the patient

- Remember the patient may be in a vulnerable position, so there must be absolutely no coercion
- Right at the outset you will have already reassured them, that the choice is entirely theirs, and - if they do decline - this will in no way affect their medical care or have any other knock-on effects

If the patient does decline:

- They will also need reassuring that they are not the first patient to decline
- It would be kind to reassure the patient that this decision will not jeopardise the whole project
- Remember to thank them for taking the request seriously

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For your project

- Have a re-think. It may be just as good to use volunteer non-patients or actors in role-play. However make sure you use the same due diligence and professional standards when using volunteers

Creating New Material Ability to give patient consent?

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You obviously need to be very careful if the recordings include such sensitive subjects as:

- Children as patients
- An unconscious patient
- A patient who is mentally incapable of giving meaningful consent

You need to make your best possible judgement, or you may need to get advice, as to whether the patient is fit and legally empowered both to understand the issues and to give proper consent.

As you can imagine, this is a complex and sensitive area of medical ethics. However, the principles and guidance are very clearly set out by the GMC. Here are two useful links from the Council:

[***Making and using visual and audio recordings of patients: guidance for doctors***](#)

[***Consent guidance: patients and doctors making decisions together***](#)

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Creating New Material

Taking recordings in clinical settings

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There are advantages to obtaining permission for the widest possible use for the recording as this will cover most likely onward uses for learning and teaching.

If in clinical settings

- Most NHS trusts or other clinical service providers will have spent months, through their ethical and governance committees, researching and agreeing their own patient consent forms for the taking and use of recordings of patients
- They will not take kindly to your turning up with your own patient consent form
- So your first task is to locate the NHS Trust's or clinical service providers' own patient consent form and see whether it covers your needs

Practical tips

- Go and introduce yourself to the department of Medical Illustration or Caldicott Guardian (where possible) and ask their advice
- It is difficult for most patients to envisage how recordings might be stored, displayed or accessed. Because of this many NHS trust's patient consent forms designate three possible levels to cover this. Here is some sample text from the United Bristol Healthcare Trust:

Consent level 1

I consent for these photographs/video recordings to be used for my **treatment, diagnosis** and **Medical Records** only.

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Consent level 2

I consent for these photographs/video recordings to be used for my **treatment, diagnosis**, **Medical Records**, for the **teaching of healthcare professionals** and **research purposes**.

Consent level 3

I consent for these photographs/video recordings to be used for publication in clinical journals and textbooks, etc including the **Internet**. (The images may be viewed by the general public as well as medical professionals).

Creating New Material
Your relationship with the patient's doctor in charge

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Most projects are planned by the senior clinician in charge of the patient. If you are not the senior clinician you should have planned the project in collaboration with them.

Beware, one of the recurrent complaints in healthcare is the lack of communication. So please ensure that the lead clinician knows in advance what you are doing with their patient.

And, if you are on NHS hospital trust premises, also make contact with the department of Medical Illustration in advance as you may need to register either yourself, or your project, before you can proceed. They will also be pleased to tell you about local guidelines and consent forms. They may even have a rule that they, rather than you, have to take any photos or recordings. If there is no department of Medical Illustration then seek out the hospital's Caldicott Guardian who is a senior person responsible for protecting the confidentiality of patient and service-user information and enabling appropriate information-sharing.

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Creating New Material

Taking recordings in non-clinical settings

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There are advantages to obtaining permission for the widest possible use for the recording as this will cover most likely onward uses for learning and teaching.

If in non-clinical settings such as a university lecture theatre or studio

- Few universities have rules and guidance about taking patient consent in their own setting
- Even fewer have their own guidance and patient consent forms for the taking and use of recordings of patients

Practical tips

- You need to find any rules and guidance in your own university or institution. Try the ethical and legal section of your institution's website or secretaries' office/legal team
- The patient is still a patient. Just because this person has volunteered outside the context of medical care does not mean that you can just abandon the responsibilities and protections that they would normally expect as a patient. Your standards of ethics and consideration must be the same as that of their healthcare team

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Creating New Material
Components of a good patient information sheet

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You may need to create your own patient information sheet, below suggests some of the components needed.

Components of a good patient information sheet (to accompany a patient consent form)

- Thank you for offering to help us in this project
- Who I am, and who I represent
- Why I am asking for your help
- Details of this recording and I why am making it
- The implications of this being a digital recording
- How confidentiality and privacy will be handled
- Reassurances about how and where the recordings will be stored
- Reassurances about how the recordings will be used
- Reassurances about who will see the recordings
- Position of not-for-profit
- Other important reassurances:
 - You do not have to give your consent
 - If you do not give your consent, it will not affect the quality of any care you will receive
 - The doctor in charge of your care has given us permission to approach you
- If you agree, what happens next
- What happens if you change your mind
- Who to contact

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Creating New Material
Components of a good patient consent form

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The clinical or non-clinical setting where you intend to make your patient recordings may have their own patient consent form (for the implications of this see the previous screen).

If you need to create your own patient consent form here is a list of the necessary components:

Components of a good patient consent form (to be accompanied by a patient information sheet)

- Title of project
- Details of recordings
- My details including on whose behalf I am making the recordings
- Patient's details
- Confirmation that:
 - The patient has read and understood the accompanying patient information sheet
 - The patient has been able to discuss the project, and has received satisfactory answers to all of their questions
- Patient's permission for the recordings to be made, stored and used in the ways described in the patient information sheet
- Patient's signature
- Date consent was given
- My signature

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Creating New Material
After you have obtained patient consent

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Who else needs to know?

- **Clinician in charge of the patient**
If the person who is seeking to make and use recordings of the patient is not the clinician in charge, then the project leader does need to discuss the project with this clinician.
- **NHS hospital trust**
Trusts are very nervous at the prospect of just anyone taking any sort of recordings on their premises, especially recordings of their patients. And rightly so. So, if you are making recordings of patients on NHS trust premises, you will already have set the project up via the trust's department of Medical Illustration or the Caldicott Guardian to ensure that you follow the local guidelines and rules that apply to that particular NHS trust. Before you leave that day, please ensure that what you have done is fully documented.
- **University**
If recordings of patients are to be made on university premises, such as in a lecture theatre or studio, then you need to make sure that someone knows what you are doing and that it is documented. 'Who' this someone is will vary greatly between different universities.

Document that recordings have been made

Most patient recordings that are to be used for learning and teaching are made on NHS Hospital trust premises. It is an absolute requirement that there is a record of the **patient's signed consent**. Who needs a copy? It is usually best practice to have three copies made:

- One copy for the patient
- One copy for the NHS trust (usually in the patient's notes with a copy of the patient consent)
- One copy for yourself (possibly on behalf of the university)

There also needs to be a record which shows:

- What recordings were taken. If the recordings were taken within the context of clinical care, then this information needs to be deposited either in the patient's notes or in the trust's department of Medical Illustration
- Where the recordings are stored. Not only as a reassurance that they are stored securely, but also in case the patient changes their mind and someone needs to delete the recordings.
- Who has taken responsibility for the safe storage and appropriate use of the recordings. This might be the trust, the doctor or the university

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What about safe Storage, and who can use the recordings and for what?

How can we accommodate our promise to the patient that if he/she changes their mind and wants to withdraw their permission, we will do our best to find and delete those recordings? [\(16 a\) Find out what to do >>](#)

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Creating New Material

Patient's right to withdraw consent

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Background

Prior to the extensive use of digital recordings, a patient could expect there to be a mechanism for the withdrawal of their images if they changed their mind later, even after many years.

Nowadays, the most useful recordings tend to be made available to as many healthcare workers as possible, which often requires the storage of more than one copy on different networks. In practical terms, it is no longer feasible to promise a patient that you will be able to trace every copy of the recording and delete it.

Here is some anecdotal evidence from a study in 2010

Where patients do change their mind, this usually occurs within a month of their giving consent.

The message from this is as follows

You should provide a one month 'cooling-off' period in which you agree not to use or distribute the recording. With increasing time since the giving of consent, there is less and less likelihood that the use of any recording being widely available for teaching and learning will be against the patient's original wishes.

So what should happen in practice?

The subject of withdrawal will have been covered at the time of patient consent including the fact that if the patient does at a later date change their mind and want the recordings withdrawn that this may not be possible in all cases.

This undertaking carries certain consequences:

- The patient needs to know with whom the patient consent agreement has been made, is it for instance with the NHS trust or with the University?
- There has to be an audit trail that can be used to link the recordings back to the individual patient
- There has to be a person or a team who can respond to the patient's request
- There has to be a mechanism for identifying and tracing the recordings so that they can be removed

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Note

- If a patient has granted consent for their recording to be used under very open licensing terms it will not be possible to revoke these terms and therefore it may not be possible to take down all copies of the recording. You need to ensure that the patient understands the implications of this when asking for consent. If you have any concerns that a patient might wish to withdraw consent it would be better not to use this recording or choose a more restrictive licence (see Licensing sections for more information).
- If consent was given more than six months previously, it would be reasonable to assume that continuing to store and use the recording for the purposes for which that consent was originally given, would not be against the patient's original wishes, but there may be situations where you need to use your judgement for example if the patient was very young when consent was given.

<<Add link to Take Down Policy example>>

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**Creating New Material
If patient consent is declined**

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For the patient

Empathise with the patient who may be in a vulnerable position and be very uncomfortable about declining. So:

1. Thank them for giving it such careful consideration, and
2. Re-assure them that:
 - This will in no way affect their medical care or have any other knock-on effects
 - They are not the first patient to decline
 - This decision will not jeopardise the whole project

For your project

Have a re-think about what you need

- It may be just as good to use a volunteer rather than a patient, or an actor (remember you will still need to get written consent). Take a look at the [JISC Model Consent Form](#)
- Find some other appropriately consented images

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**Creating New Material
If consent from other people is declined**

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This virtually never happens, other people in the recording are generally happy to support the patient in all things. However if the person has a problem, just accept that and take the recording without them in it.

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Using Pre-Existing Material Patient consent

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If the pre-existing material you want to use contains:

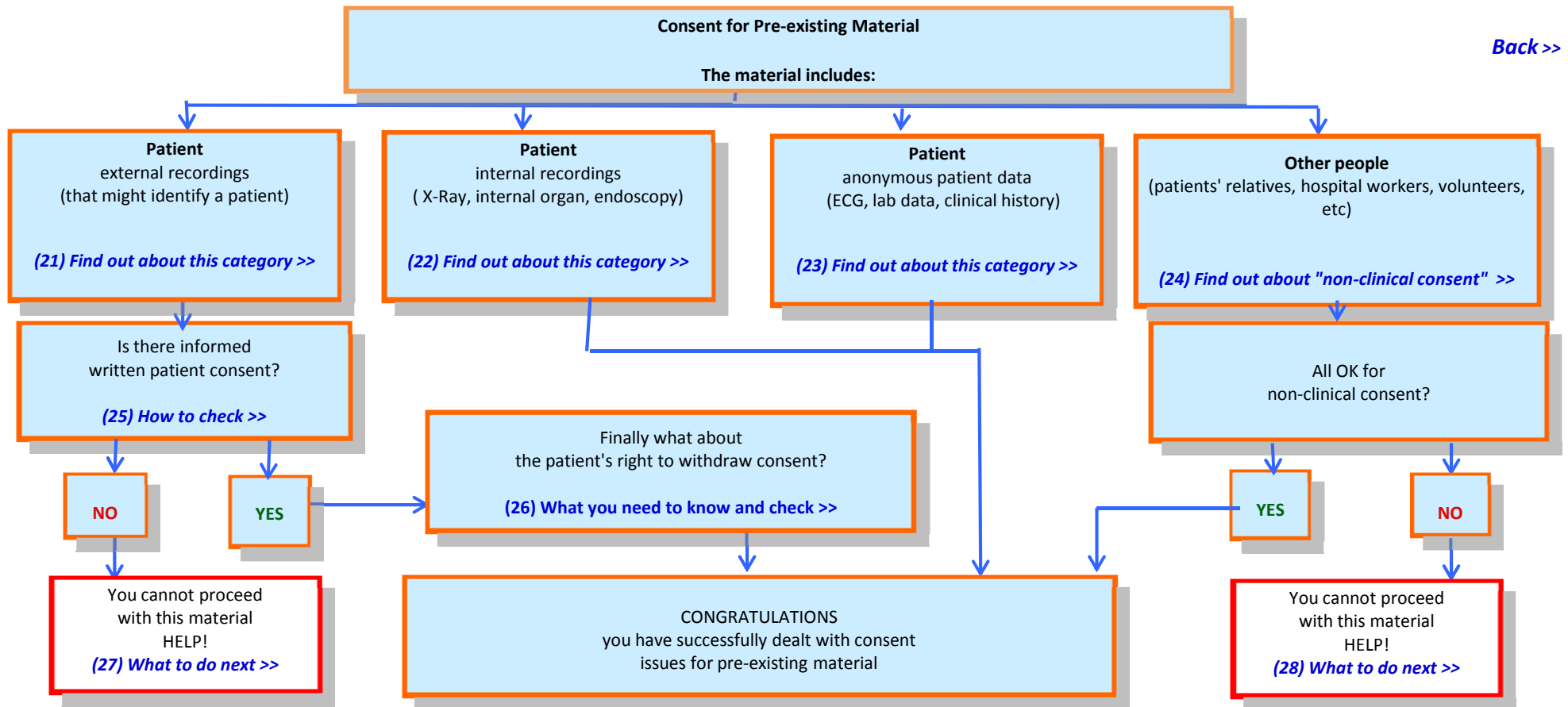
1. Recordings of patients (internal or external).
2. Patient data (e.g. patient notes, ECGs, lab data, etc).
3. Recordings of other people such as staff, relatives, teachers, students, public.

You need to check whether the consent taken at the time of making the recording is adequate for your intended purpose:

1. Whether there needs to be written consent if the recordings are used for learning and teaching.
2. If so, whether such consent exists.
3. If so, whether this consent covers permission for you to these recordings in the way that you intend.

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The following Flowchart will guide you through this process



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Using Pre-Existing Material
External recordings that might identify a patient

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Best practice would be to always get the patient's explicit written consent where it is practicable to do so.

What patient recordings fall into this category?

The following guidance is based on the GMC's [Making and using visual and audio recordings of patients - guidance for doctors](#)

The GMC guidelines state that if the patient in the recording is either recognisable or the recording contains details that would allow the patient to be identified (including distinctive features, skin marks, jewellery etc), then that recording would have required patient consent. If the patient is not recognisable in the recording (operations site or skin spots), then that recording would not have required patient consent.

Practical tips

- Be aware that even apparently insignificant details may mean that the patient is identifiable. Please ensure that the patient is happy that the image will not be recognisable
- Iris recognition technology may preclude the use of images of a complete iris in material for wider distribution
- The previous black bar across the eyes is now not recognised as being adequate for anonymisation

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Using Pre-Existing Material
Internal recordings e.g. X-ray, internal organ, endoscopy

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You will need to check each recording to ensure adequate anonymisation. Even apparently insignificant details may still be capable of identifying the patient. If adequate anonymisation is not possible then you need the patient's consent for the recording to be used.

What patient recordings fall into this category?

The following guidance is based on the GMC's [Making and using visual and audio recordings of patients - guidance for doctors](#)

The GMC guidelines state that consent to make the recordings listed below are implicit in the consent given to the investigation or treatment, and would not have needed to be obtained separately, but where practicable, consent should have been taken. These include:

- Images of internal organs or structures (such as laparoscopic images)
- Images of pathology slides (as opposed to actual pathology slides containing human tissue)
- Images taken inside body orifices (such as endoscopic images)
- X-rays, ultrasound and other scans
- Recordings of organ functions

Note

Adequate anonymisation involves removal of all the following:

- Patient's name and any other patient details
- Patient's hospital number
- Doctor's name
- Name of the hospital
- Any Radiograph or Pathology number
- Any coding or writing in the recording

Practical tip

Be aware that there may be metadata (information about the recording) embedded with the recording itself which you will need to check and remove if appropriate.

Reminder

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You will need to check each image to ensure adequate anonymisation. If adequate anonymisation is not possible then you need the

Using Pre-Existing Material
Patient data e.g. ECG, lab data, clinical history

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You will need to check each recording to ensure adequate anonymisation. Even apparently insignificant details may still be capable of identifying the patient. If adequate anonymisation is not possible then you will need the patient's consent for this part of their medical record to be used.

What patient information falls into this category?

The following guidance is based on the GMC's [Making and using visual and audio recordings of patients - guidance for doctors](#)

The GMC guidelines state that patient data, such as the following, would not have required the patient's consent for their use for learning and teaching, provided they are adequately anonymised (see below):

- Investigatory traces such as ECGs, EEGs or blood pressure recordings
- Laboratory data such as Haematology, Chemistry or Microbiology results

Guidance about the confidentiality of written records such as clinical histories is provided in the GMC's [Confidentiality guidance](#)

As well as in the GMC [Confidentiality: disclosing information for education and training purposes](#)

This also advises that patient's personal information would not have required the patient's consent for their use for learning and teaching, provided they are adequately anonymised (see below). If the information cannot be anonymised then patient consent should always be sought.

Note

Adequate anonymisation involves removal of all the following:

- Patient's name and any other patient details
- Patient's hospital number
- Doctor's name
- Name of the hospital
- Remove any Radiograph or Pathology number
- Any coding or writing in the margins of the recording

Practical tip

Be aware that there may be metadata (information about the recording) embedded with the recording itself which you will need to check and remove if appropriate.

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Using Pre-Existing Material Non patient consent

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The main focus of these guidelines relates to recordings of patients. However, some of your material may have images of other people, either with the patient, or on their own. The general principles are exactly the same as those for patients, in that everyone has rights of privacy which need to be respected. The rules and guidelines are less well defined here than for patients' rights.

There is no equivalent of the GMC Guidelines relating to patients but Article 8 of the [European Convention of Human Rights](#) provides a right to respect for one's 'private and family life, his home and his correspondence.'

Schedule 2 of the [UK Data Protection Act of 1998](#) also sets out the conditions relevant for the processing of any

Changing cultures

Before the digital age most people were unconcerned if someone took a visual or audio recording. Now if someone takes a recording we generally like to know:

- Who they are
- Why they want to take the recording, and
- What they intend to do with it.

Practical consequences

You will have to make your own judgement depending on the exact content and contexts. Here are some suggestions which may help, but beware, they are only suggestions:

- If it is possible, crop the bystanders' faces out of the material, especially children
- It is unlikely that materials created pre-1997 material (the year when the GMC guidance was created) would contravene what would have been the patient's wishes at the time. However you may wish to use your own judgement on certain cases, for example if the patient had been a child at the time.
- The more recent the material, the more circumspect you need to be, as contemporary culture is more protective of privacy

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Using Pre-Existing Material
Evidence of written patient consent?

Properly informed consent means the patient was in a suitable condition to understand and grant the consent. You will need to check whether there is written evidence that this consent exists.

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I have a recording in my personal collection

- You will need to check whether there is patient consent and whether this covers the use that you intend

A colleague has offered me just the recording I need

- You will need to check whether there is patient consent and whether this covers the use that you intend

I know there is a recording in the patient's hospital records

- Your best route is to contact the hospital's department of Medical Illustration or Caldicott Guardian

I have found a recording on the Internet

It is very unlikely that details of patient consent will be available direct on the internet itself. You will probably need to contact the creator of the recording and:

- Let him/her know who you are
- Let him/her know who you represent (university, etc.)
- Provide the link to where you found the recording
- Let him/her know what you wish to use it for
- Ask if there is patient consent and does this cover your use of the recording in the way that you have described

Practical tip

You will also need to enquire about copyright and licensing at the same time.

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Using Pre-Existing Material

Patient's right to withdraw consent

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Background

Prior to the extensive use of digital recordings, a patient could expect there to be a mechanism for the withdrawal of their recordings if they changed their mind later, even after many years.

Nowadays, the most useful teaching materials, including digital recordings of patients, tend to be made available to as many healthcare workers as possible, which often requires the storage of more than one copy on different networks.

For archival material, patient consent may well have been given either before the digital age made wide distribution of such recordings possible or, crucially, before such concepts could have been explained to, or understood by, the patient. So this aspect cannot have been explained to the patient.

If a patient has granted consent for their recording to be used under very open licensing terms it will not be possible to revoke these terms and therefore it may not be possible to take down all copies of the recording.

Here is some anecdotal evidence from a study in 2010

Where patients do change their mind, this usually occurs within a month of their giving consent.

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The message from this is as follows:

It is good practice to allow a 'cooling off' period of a month before the recording is distributed to allow the patient to change their mind. With increasing time since the giving of consent, there is less and less likelihood there is that the availability of any recording being widely available for learning and teaching will be against the patient's original wishes.

So what to do in practice?

- If you do know the patient details, then it would be good practice to make sure that a unique number is included with the metadata of all copies of the recording, so that if the patient did one day change their mind, there is an audit trail for tracking and withdrawal of the recording
- If not, and consent was given more than six months previously, it would be reasonable to assume that continuing to store and use the recording for the purposes for which that consent was originally given, would not be against the patient's original wishes

Using Pre-Existing Material
What if patient consent isn't available?

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Please don't give up there are lots of options:

1. Go back to donor of the recording

Recordings may have originated from a very wide range of possible sources such as your own archival collection, someone else's archival collection, or the internet. If you are able to contact the donor of the recording, make sure that:

1. You have a check-list of all that you need to ask.
2. Be clear that you are asking whether the owner has evidence of consent - not whether they will give consent (which of course they cannot).

Practical tip

You will probably need to enquire about ownership, copyright, and licence-to-use at the same time. However, they may or may not know the origin of the recording and may or may not have documented evidence of the patient consent.

2. Anonymise the recording

This may be possible but beware:

1. The old habit of just blacking out the eyes is no longer acceptable.
2. As cultural expectations change, so it becomes less and less likely that anonymisation will be acceptable.
3. The patient may be identifiable from apparently insignificant details.

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3. Go back and find the patient to ask for modified Patient Consent for your intended use (if possible)

4a. Replace with a new project

For guidance on these options, follow the *Patient Consent - Creating new material* pathway of this guidance.

or

4b. Use an actor or volunteer colleague to role-play the patient's role

This is increasingly a good option. Written consent is required even if you use a volunteer colleague. Either way, appropriate consent should be built into a written contract to suit your project.

Using Pre-Existing Material
What if consent from other people isn't available?

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Please don't give up there are other options:

1. Go back to donor of the recording

Recordings may have originated from a very wide range of possible sources such as your own archival collection, someone else's archival collection, or the internet. If you are able to contact the donor of the recording, make sure that:

1. You have a check-list of all that you need to ask.
2. Be clear that you are asking whether the owner has evidence of consent - not whether they will give consent (which of course they cannot).

Practical tip

You will probably need to enquire about ownership, copyright, and licence-to-use at the same time.

However, they may or may not know the origin of the recording and, particularly for non-patient consent, may well not have documented evidence of any consent.

2. Anonymise the recording

This may be possible but beware:

1. The old habit of just blacking out the eyes is no longer acceptable.
2. As cultural expectations change, so it becomes less and less likely that anonymisation will be acceptable.

3. Replace with a new project

For guidance on this, follow the ***Patient Consent - Creating new materials*** pathway of this guidance.

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Bottom line

Patient Consent is the biggest issue both for scope to upset the subject, or for any risk of complaint later. By comparison other people in the recording are likely to have co-operated willingly, and are much less likely to be sensitive to their images being included without written consent. However you will need to ensure that you have obtained appropriate permission from the copyright holder - see the ***Licensing Pre-Existing Materials*** pathway of this guidance.

Copyright and Licensing

New material

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Copyright

Copyright is literally the right to copy and use the recordings for learning and teaching, or any other purposes, as opposed to the physical ownership of the actual recording.

Moral rights

In addition to their rights of copyright, copyright holders also have certain **moral rights** associated with their recordings. These include:

- The right to be acknowledged as the copyright holder
- The right not to have the recording altered
- The right not to have the recording used in such a way as to bring the copyright holder into disrepute, for example by describing the contents of the recording inaccurately

Who becomes the copyright holder?

- The copyright of all images, video and other recordings is owned by someone
- Copyright is automatic and does not have to be registered
- The patient who gives their permission (consent) for you to make and use a recording of themselves, does not own the copyright of that recording

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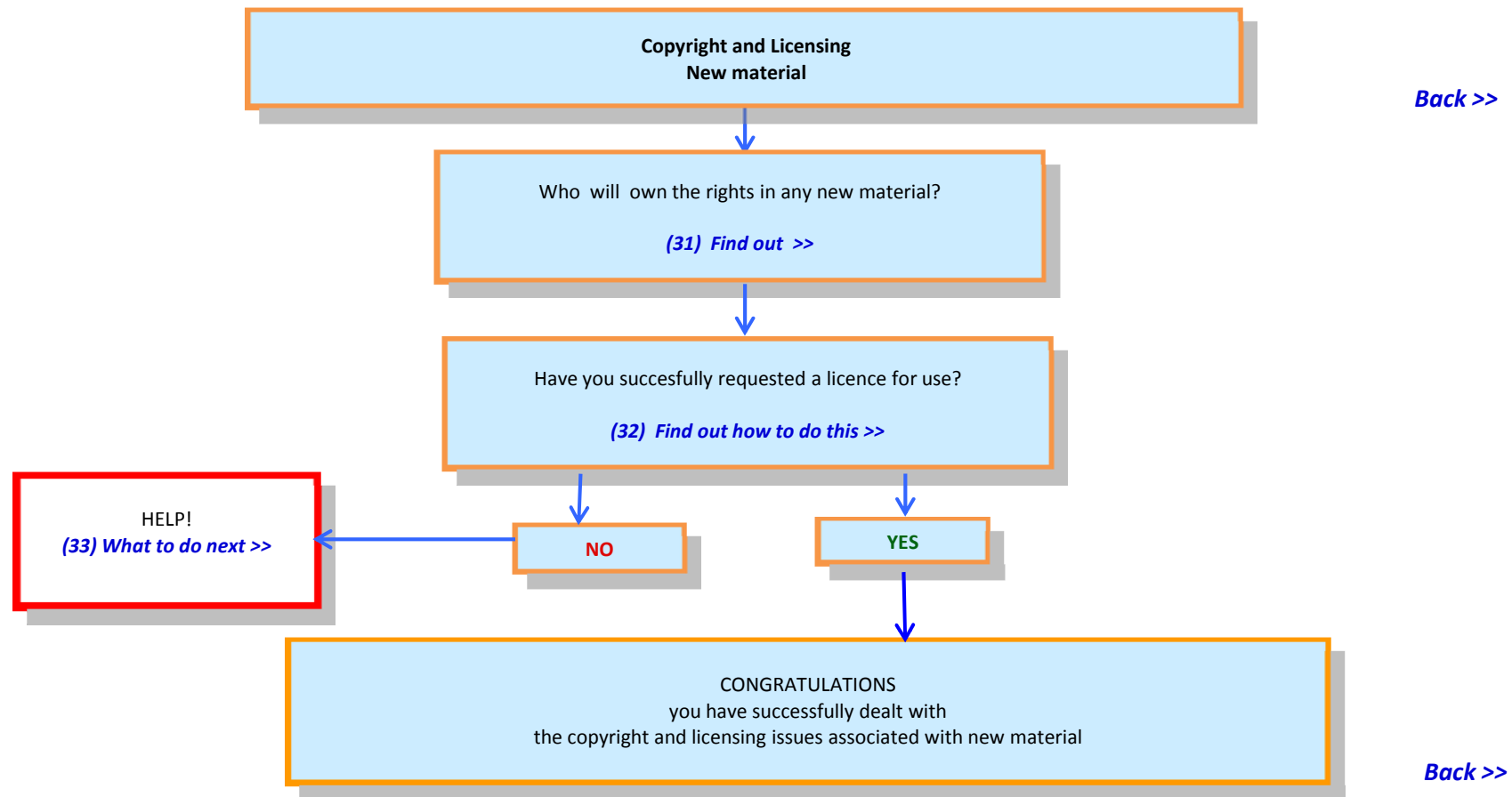
The copyright holder may be:

- The person who originates the material (e.g. took the recording), or
- If taken in the course of employment, the employer, regardless of who took the recording

Our flowchart shows you how to find out who will be the copyright holder of the recordings that you are about to make.

Licensing

- When the copyright holder of a recording (such as an NHS trust) grants their permission to another person (such as yourself) to use their material, they usually do this in the form of written permission or a **licence** outlining the specific ways that their material can be used
- Permissions to copy and use the recordings can only be given by the owner of the copyright, and cannot be given by the patient
- The holder of the copyright cannot give permission for any use for which the patient hasn't first given their patient consent
- The licence may be granted to an individual or an institution



Licensing New Material
Who will own the rights in any new material?

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The majority of recordings of patients that are created for learning and teaching are made on NHS premises, usually within an NHS trust hospital.

For the protection of their patients, the guidelines of most NHS hospital trusts state that:

- No recordings of patients, relatives or staff may be made without permission of the trust

Practical note

In practice a blind eye is usually turned to relatives, for instance, taking pictures of a proud mum with her newborn baby.

- For any recordings that are made on trust premises, the trust claims ownership of the copyright

Legal note

In law however this is not actually correct, in that ownership of copyright is determined by the status of the person making the recording, not where the recording is made.

What are the practical implications for you?

- You will need the trust's permission to make any recordings on their premises. This is usually via the department of Medical illustration who will have a standard procedure
- At the same time, they should be able to advise you about copyright. The most straightforward plan is to have the recordings made by an employee of the trust such as a member of the department of Medical Illustration, or a clinician, because the copyright will then be owned by the trust and you can request a licence for use (see next box on flowchart)

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Note

If you are a university-based clinical academic with an honorary clinical contract, you are working within your employment contract with the trust when working in the hospital and so the trust will own the recording.

Beware

If you make the recording in the role of a university employee many trusts may not recognise that you are the copyright holder and the last thing you need is any conflict which might scupper the success of your project. Hence the suggestion you work through the department of Medical Illustration.

Other scenarios

If you are a university member of staff without an honorary clinical contract with the Trust, and are making the recording on university or other premises as part of your job, then:

- Your university (as your employer) will own the copyright
- You will need a licence for any use outside of the university

If you are a student, then:

- You will own the copyright of the recording
- Your university will normally ask you to grant a licence for use

If you are a freelancer, such as a professional actor, then:

- You will own the copyright of the recording
- The university will normally ask you to grant a licence for use
- This is usually written into the contract

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Licensing New Material Requesting a licence for use

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If you are clear that you or your institution is the copyright holder then you can proceed to the next section.

How do I request a licence?

If you are working within a university then various research committees or research ethical committees will have had to prepare all sorts of licences of this type. There may be a pre-prepared model licence on your university web site.

You can find a [model licence](#) from the excellent JISC Strategic Content Alliance's IPR Toolkit

You might suggest the copyright holder uses a common licensing framework such as [Creative Commons](#), although some rights holders may prefer to use their own contracts.

The licence holder will need to know:

- Who you are
- Who you represent
- Details of the project and its context
- Details of the images or recordings that you have just made or are about to make
- Details of your intended use (see below)

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Here is a checklist for your description of intended use:

- Where? e.g. Limited to a geographical region
- Who? e.g. Who will have access
- For how long? e.g. Limited to a specific range of dates
- Via what medium? e.g. Print, video, film, digital, website, portable media etc
- For what use? e.g. Non commercial or private study
- Any payment? e.g. This can be a one-off payment, a fee per use (royalty) or no fee

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Comment

As a general principle you will want to request the widest possible conditions of use to allow you to share the recordings in the future.

Practical tips

- Plan ahead by contacting the appropriate person in advance
- You will need to show the copyright holder the patient's consent as the copyright holder cannot give permission for uses beyond those for which the patient has given consent
- Ask for written confirmation that warrants that they are the copyright holder as verbal confirmation won't hold up if there were any problems down the line

Note

In addition, the patient's consent is a powerful argument in favour of granting you the licence that you are seeking:

- Request permission to make minor alterations such as labelling or highlighting, with the re-assurance that any alterations would not place the copyright holder in a poor light or to change the recording in such a way that it no longer conformed to the original description
- Ask what the acknowledgement statement should be, there may be implications for naming a doctor or hospital if the recording is anonymised
- Because most NHS hospital trusts do not have a pre-written licensing agreement available, and will be wary of having to suddenly produce one in response to your request, it is a good idea to take one with you, pre-prepared

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Licensing New Material
You cannot obtain a licence - what are your options?

Please don't be disheartened - it's very unlikely that you will draw a blank.

Most hospital trusts are entirely sympathetic to the need for patient images for clinical learning and teaching, particularly if the patient has already given their consent.

If you do draw a blank

- You may want to consider using volunteers or actors in role-play for your project (remember you still need to get their consent)
- There may be suitable material available which you missed on your first search

Tip

Take a look at the JISC Digital Media Tutorial on the [Internet for Image Searching](#)

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Copyright and Licensing

Pre-existing material

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Copyright

Copyright is literally the right to copy and use the recordings for learning and teaching, or any other purposes, as opposed to the physical ownership of the actual recording.

Moral rights

In addition to their rights of copyright, copyright holders also have certain **moral rights** associated with their recordings. These include:

- The right to be acknowledged as the copyright holder
- The right not to have the recording altered
- The right not to have the recording used in such a way as to bring the copyright holder into disrepute, for example by describing the contents of the recording inaccurately

Who is the copyright holder?

- The copyright of all images, video and other recordings is owned by someone
- Copyright is automatic and does not have to be registered
- The patient who gives their permission (consent) to make and use a recording of themselves, does not own the copyright of that recording

The copyright holder may be:

- The person who originated the material (e.g. took the recording), or
- If taken in the course of employment, the employer, regardless of who took the recording

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Licensing

- When the copyright holder of a recording (such as an NHS trust) grants their permission to another person (such as yourself) to use their material, they usually do this in the form of written permission or a **licence** outlining the specific ways that their material can be used
- Permissions to copy and use the recordings can only be given by the owner of the copyright, and cannot be given by the patient
- The holder of the copyright cannot give permission for any use for which the patient hasn't first given their patient consent
- The licence may be granted to an individual or an institution

[Proceed to Flowchart >>](#)

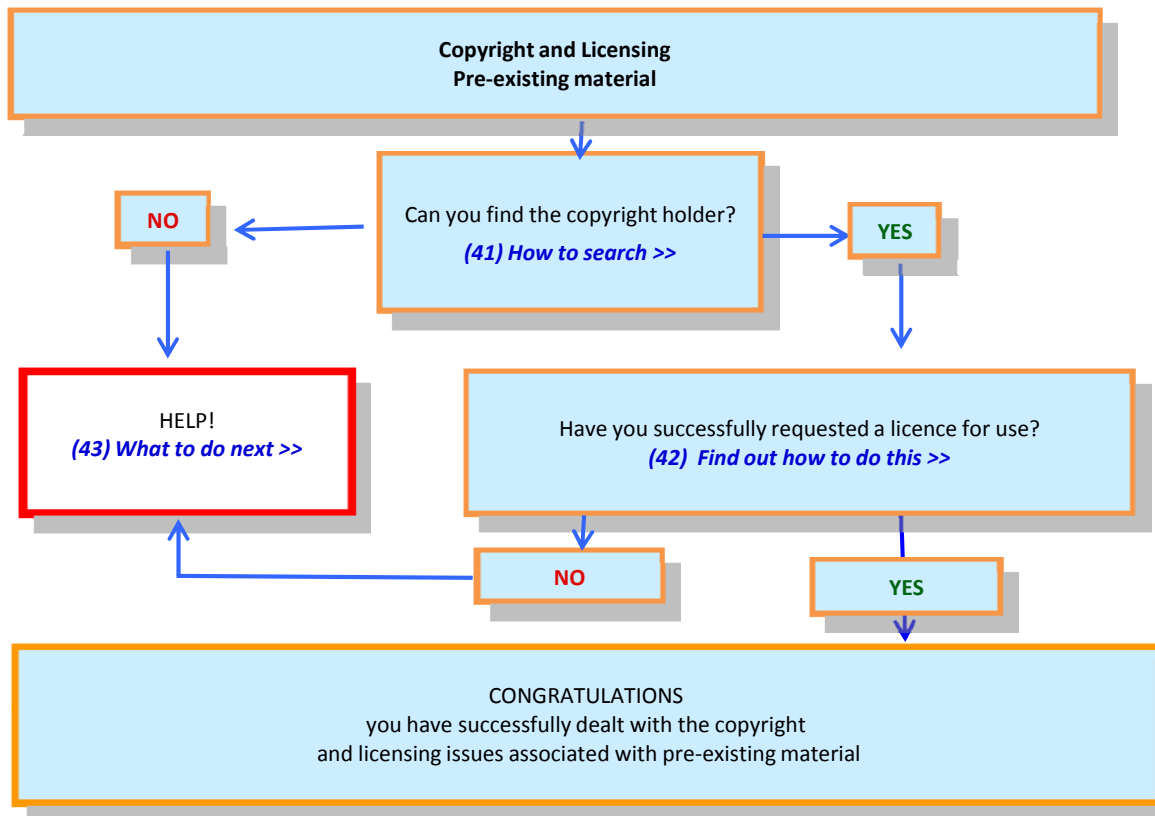
Practicalities

The first step is to find out whether there is an existing licence that clearly allows you to use the material for the purpose you intend. If not, you need to search out the holder of the copyright, so that you can request a licence that fits your intended uses.

Our flowchart helps you:

- Find the original copyright holder

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Licensing Pre-Existing Material
How to find the holder of the copyright

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Your plan has two stages:

1. Find out who is the holder of the copyright (remember there may be joint copyright holders)
2. Request a licence for the uses that you want.

1. Find the copyright holder

Patient recording was originally recorded on NHS trust premises

This is the most likely scenario. Most NHS trusts claim that they are the copyright holders of any patient recordings produced on their premises. Whilst this is probably not strictly accurate in law:

- It will be true if it was one of their employees (such as a member of their department of Medical Illustration or a doctor) made the recording as part of their employment. Their own guidelines will also usually state that you will need their authority to make any such recordings of their patients
- Your best first stop is the department of Medical Illustration as they will be familiar with the local practices and guidelines
- Many NHS hospital trusts do not have their own pre-written licensing agreements, so it is wise pre-prepare your own and take it with you.

From the Internet

- Copyright information is sometimes available for internet recordings, to specify what you are allowed to do with any downloaded copies that you might make. Take a look at the terms and conditions of the website to find out the copyright status of the recordings are and what they can be used for.
- JISC Digital Media have produced a very useful tutorial on finding existing materials: [Internet for Image Searching](#)

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In my own collection or someone else's collection

- Most recordings in people's archival collections do not have any accompanying information about ownership of copyright
- Beware, there was (and still is) a popular misconception amongst doctors that any recording they take of a patient belongs to them (the doctor). In most instances this is not true
- You may well have to go back to the NHS trust (likely – see above) or the university (less likely).

In a publication

This is much more straightforward. The publisher will know about the copyright status of all recordings in their publications.

2. Request a licence for the uses that you want

To find out how to do this, return to the Flowchart and go to the next box.

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Licensing Pre-Existing Material

How to request a licence for use

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If you are not the copyright holder then you need to undertake the following process.

How do I request a licence?

If you are working within a university then various research committees or research ethical committees will have had to prepare all sorts of licences of this type. There may be a pre-prepared model licence on your university web site.

You can find a sample [model licence](#) from the excellent JISC Strategic Content Alliance's IPR Toolkit

If a licence doesn't already exist then an agreement might be specifically created, or you might suggest the copyright holder uses a common licensing framework such as [Creative Commons](#).

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The licence holder will need to know:

- Who you are
- Who you represent
- Details of the project and its context
- Details of the recordings that you want to use
- Details of your intended use (see below)

The licence agreement will need to describe your intended uses. Here is a checklist:

- Where? e.g. Limited to a geographical region
- Who? e.g. Who will have access
- For how long? e.g. Limited to a specific range of dates.
- Via what medium? e.g. Print, video, film, digital, website, portable media etc
- For what use? e.g. Non-commercial use or private study
- Any payment? e.g. This can be a one-off payment, a fee per use (royalty) or no fee

Comment

As a general principle you will want to request the widest possible conditions of use to allow you to share the recordings in the future.

Practical tips

- Plan ahead by contacting the appropriate person in advance
- You will need to show the copyright holder the patient's consent as the copyright holder cannot give permission for uses beyond those for which the patient has given consent. Take a look at the advice under ***Patient consent for pre-existing materials***

Note

The patient's consent is a powerful argument in favour of granting you the licence that you are seeking. If you do have to also negotiate a new patient consent with the patient, remember to do this first before you approach the copyright holder to request the licence. See the advice under ***Patient consent for pre-existing materials***

- Request permission to make minor alterations such as labelling or highlighting, with the re-assurance that any alterations would do not place the copyright holder in a poor light or to change the recording in such a way that it no longer conformed to the original description
- Ask what the acknowledgement statement should be, there may be implications for naming a doctor or hospital if the recording is anonymised
- Because most NHS hospital trusts do not have a pre-written licensing agreement available and will be wary of having to suddenly produce one in response to your request, it is a good idea to take a pre-prepared one with you
- Make sure that you get their written confirmation that they are the legal copyright holder

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Licensing Pre -Existing Material
You cannot proceed with this material - what are your options?

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Orphan works

Material for which copyright cannot be traced are sometime referred to as **orphan works**. It is estimated that there are over 50 million items across UK public sector organisations that can be classed as orphan works.

If you have been unsuccessful in identifying the copyright holder of a recording that you wish to use you may wish to carry out a risk assessment regarding the use of that material in your project. See the [SCA Briefing Paper on Risk Assessments](#) for more information on how to go about this.

If you feel that the risk is low enough and you decide to go ahead with the use of that material then:

- Include a disclaimer and ensure it has high visibility within the learning materials
- Instigate a rapid take down policy and associated procedures. <<Link to Naomi's adapted version of the SCA take down policy>>
- Ensure that your organisation has an agreed approach for liaising with rights holders if they come forward

You may decide it is safer and easier to replace the image or recording with a new one. For guidance on this, follow the Ownership, Copyright and Licensing **Creating New Material** pathway of this guidance.

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Note

If you do have to replace the image or recording with a new one, it is likely to fit your particular purpose better than an archival image.

Storage, Access, Use and Sharing

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Congratulations - you now have your recordings complete with patient consent and appropriate licence to use for learning and teaching purposes.

This section is still under development but likely to contain guidance in areas such as:

- Access and safety of consent sheets and recordings
- Encryption
- Storage of recordings
- Responsibilities of the individual and the organisation
- Reuse of recordings in other organisations

How to ensure the trust from the patient and obligations of the licence are

1. safe in your hands
2. only entrusted to other people if they are also equally aware of their ethical and legal responsibilities

If you have any specific issues you would like to see raised here please specify in the feedback form