Clinical Recordings for Academic Non-clinical Settings

CHERRI Project Report

Rachel Ellaway, Helen Cameron and Michael Ross
with contributions from Graeme Laurie, Margaret Maxwell and Rebekah Pratt

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Executive Summary

Introduction

Clinical recordings (such as images, videos and scans) have long been one of the mainstays of healthcare education. In recent years the subject matter of such images has remained largely constant but increasingly they are recorded digitally and viewed online. This new format and medium has so enabled duplication and onward transmission of recordings that processes and guidelines created to safeguard patients' interests and guide the practice of clinicians, teachers and technicians no longer fulfil their purpose.

This report is the result of a study on the practicalities of sharing and exchanging clinical recordings in support of teaching and research in the UK. This project, 'CHERRI' (Common Healthcare Educational Recordings Reusability Infrastructure - Practice, Interoperability and Ethics), has carried out surveys of existing practice, researched the medico-legal context and developed a consent and licensing model that it is anticipated will meet the needs of all those concerned.

Current Practice

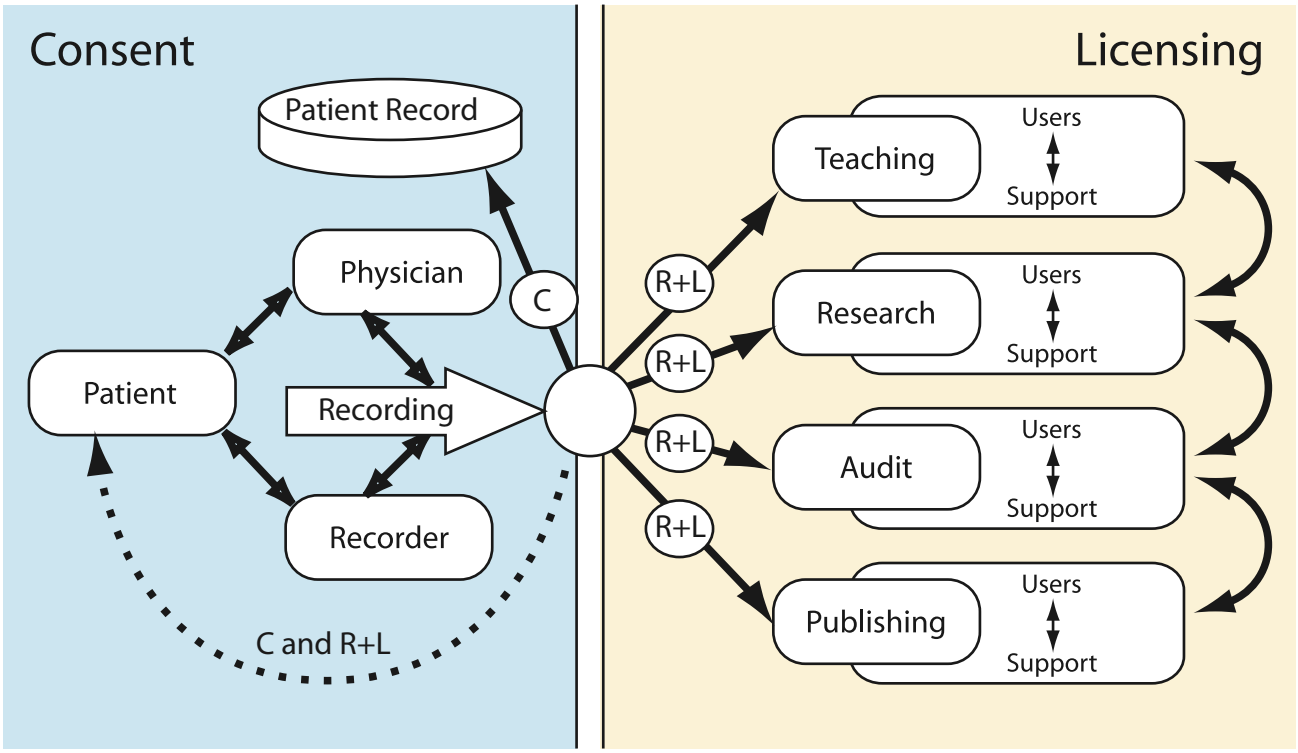
Despite UK-wide data protection and human rights legislation and guidance from bodies such as the GMC, current practice regarding the acquisition and use of clinical recordings for academic non-clinical settings (CRANCS) in the UK is highly varied. The project's survey and interviews revealed that most practitioners were aware of relevant legislation and national guidance relating to patient consent and confidentiality but did not know how to translate these into processes in the local context, where images would often be acquired in a clinical setting but used in an educational one. For some the process stops at acquiring informed consent and the recording, others try to log subsequent usage while many, faced with uncertainty and risk are turning away from the use of CRANCS altogether.

The uncertainty in practice did not only relate to consent; there were often conflicting or unclear issues of ownership and copyright. As an example, although the NHS asserts ownership of all recordings acquired in its clinical environments this has yet to be tested in law.

From the CHERRI project the following problems were identified: lack of common process and standards at a local level, lack of connection between terms of consent and subsequent use, unnecessary duplication in local contexts as a safety measure, and a pervading culture of risk and uncertainty that is leading to both individual and institutional anxiety and loss of utility.

CHERRI Consent and Licensing Model

The two principal issues are therefore ones of consent and ownership. Whatever solution is applied needs to accommodate both of these. CHERRI has developed a conceptual Consent and Licensing Model (or C+LM) that integrates the two to provide a solution that addresses both the uncertainty and the disconnectedness of current practice. C+LM licensing will need to be simple and easy to understand. As one way of achieving this it is recommended that it follows the same kind of model used by Creative Commons (see http://creativecommons.org) and provisional discussions have taken place regarding the creation of 'Clinical Commons' licences.



The CHERRI Consent and Licensing (C+L) Model. This illustrates a situation where a patient (possibly with their guardian or other family members) is seen by a physician who requests that a recording is taken. The consent is taken either by the physician or the recorder (who might be a medical photographer or the physician). A licence is drawn up and signed by a responsible staff member, regardless of the need for explicit consent and is made available along with the recording for non-clinical use. For images requiring explicit consent the licence is linked to the consent in perpetuity through use of a shared globally unique identifier (GUID) which encodes the identity of the patient and is maintained securely by the healthcare provider. The licence describes the copyright conditions along with either a declaration that consent is not required or a description of the conditions of consent. Within each use context there may be those who use the recording (such as teachers) or those who support users (such as technical staff). Because the recording and its licence (R+L) are not separated they can be passed from one use context to another with impunity as the conditions under which the recording can be used are known and expressed in a commonly understood format. In addition the consent (C), recording and/or licence can be entered into the patient record or made available to the patient.

Conclusions

The law and guidance on the use of CRANCS from professional and statutory bodies set out to protect the interests of patients, and generally practitioners are aware of these. However, local protocols do not take cognisance of the explosion in numbers and mobility of digitised images and thus current practice in the creation, use and reuse of CRANCS is generally non-standardised thereby creating risks and uncertainty for all concerned.

It's difficult to create complete safety in this area without sacrificing the utilitarian or 'greater good' aspects. Prohibiting the use of CRANCS for teaching and research would undermine the effectiveness of both and may impact on the competence of future healthcare professionals. Furthermore, seeking explicit consent for all images is impossible and would make the whole system unwieldy but current public opinion and the law lend most support to the rights of the individual patient in this area and standardised practice must take account of that.

Guidance on consent must continue to be updated to reflect changing societal opinion, the law and public concerns about the use of CRANCS. It must continue to clarify for practitioners the reasonable expectations that patients have to be kept informed about the use of their images and when explicit consent is required.

A common activity framework is required to support the current position regarding the storage and use of CRANCS. It is absolutely essential for any large-scale and dynamic exchange of these kinds of recordings. In its absence the continued use of CRANCS is creating risks and problems for both individuals and institutions and as a result their use may dwindle and utility is being lost. It is also essential that a robust, simple to use and commonly acknowledged mechanism for handling consent with respect to clinical recordings is adopted across the UK. The CHERRI common consent and licensing model (C+LM) is proposed to address the problems. Based on the simplicity of Creative Commons it seeks to accommodate specific clinical responsibilities and issues.

The challenge now is to disseminate this proposal and develop it in consultation with key stakeholders in Further and Higher Education, the NHS, GMC and other professional bodies towards the implementation of a practical and efficient UK-wide process. As the healthcare environment is subject to frequent change the framework will require review and updating over time. Undertaking the work is not currently within the JISC's remit although it may be of interest to a number of educational and healthcare organisations. Arrangements will need to be made to monitor the situation and action adjustments over time as and when they are required.

Recommendations

- That all creators and users of CRANCS should be better educated and supported in the use of such recordings, and that this training and support is normalised as much as possible both for quality assurance and economies of scale purposes.
    - This requires that we challenge complacency about current practices in obtaining and recording consent, and in the use of images without knowledge that consent has been obtained.
    - Further work must be undertaken in consultation with the DOH/NHS, GMC, BMA, IMI & Royal Colleges, patient group representatives and other interested parties to develop a consensus view on recommendations for practice and the production of common national (and preferably international) guidelines and documentation for gaining consent for clinical recordings.
    - A 3 tier consent model and organised databases should be adopted pending further guidance, along with clear procedures for gaining consent, storage, sharing and withdrawal of clinical recordings.
    - Once national procedures and guidance are adopted, these should be publicised as widely as possible to professionals involved with CRANCS and also to the lay public. This will require adequate investment in appropriate training and in promoting the use of these guidelines.
- That guidance from the GMC and other professional bodies, on use of patient recordings for teaching and research should continue to be regularly updated to take account of changing public and societal attitudes and concerns about use of CRANCS. The situations requiring explicit consent may change over time and even now further clarification is required around consent for 'non-identifiable images'.
- That a common consent and license model for CRANCS is developed and adopted UK-wide (preferably in other jurisdictions although this would need to be explored further as to how practical it is).
- That any model adopted in the UK adheres to UK/European law and encompasses both consent and IPR dimensions of a recording.
- That the licensing model is based on Creative Commons and that this Clinical Commons is set up and run either by CC or a qualified UK agency. There is an issue of jurisdiction here. The most useful model would be truly international with local rendering (as per Creative Commons) and as such a trans-national organisation such as Creative Commons would seem to be the logical home. However, it may be that medico-legal concerns would require management of a consent and licensing model to be at a national level and undertaken by a responsible NGO such as the NHS in the UK.

- That all CRANCS are tagged (potentially visibly) with a C+LM mark or icon to indicate its provenance and conditions of use. This icon should represent the different forms of use at a small enough resolution not to interfere with the recording.
- That practitioners refuse to use non-C+LM materials because they lack sufficient provenance and guarantee of patients' interests. This clearly illustrates the compliance rather than enforcement nature of the approach but the current environment and the availability of resources mean that an enforcement approach is impractical.
- That any central repository must adhere to the C+LM before any clinical materials are stored there. This combines issues of technical infrastructure, community-specific requirements and appropriate workflows. A national system like JORUM would need to accommodate the additional metadata, access controls and workflows associated with C+LM to safely store and supply access to CRANCS. This may indicate that separate systems will be required for CRANCS with access limited to healthcare education and its affiliates.
- That all relevant UK agencies (such as the GMC, NHS, legal groups etc) have input to and support the development of this common model and that steps are taken to develop the relationship between the NHS and the tertiary education sector (for instance by raising the profile of the NHS-HE Forum and making its work more transparent).

1: Introduction

1.1: Background

Although the use of clinical recordings (images, videos, audio recordings, scans, test results, patient notes etc) has been a fundamental part of healthcare education for centuries, the development of digital and Internet technologies has significantly altered the way these materials can be used, reused, transported, copied and stored. This has influenced the social and ethical dimensions of personal information, which has in turn led to developments in the law and professional guidance regulating the use of such recordings.

The same developments in technology that have contributed to a tightening of the law regarding them have also led to a rethinking of ownership, collaboration and access to information, both in clinical contexts and in general. In the last few years the reuse of digital content has been the focus of both European and UK investment as manifested in the development of repositories of digital educational content (such as JORUM or NLN) and standards and specifications for describing and managing it (see for instance CETIS). Shared digital materials for healthcare education have been the focus of a number of projects and services (such as HEAL and MedEdPortal in the US) but because of the clinical origin of much of these materials there remains a great deal of uncertainty about whether and how it might be shared.

1.2: Aim of Project

The Joint Information Systems Committee (JISC at www.jisc.ac.uk) provides the UK tertiary sector with a wide range of technology and associated services. The CHERRI Project was funded by JISC to perform a study of the issues regarding large-scale use and reuse of clinical recordings in academic non-clinical settings (CRANCS) in the UK. More specifically, CHERRI was tasked with making substantive recommendations to the JISC regarding whether, and if so then how, shared banks of CRANCS could be designed and implemented for the use of the JISC's constituencies.

Building on work already undertaken in the University of Edinburgh, the CHERRI Project has undertaken a review of confidentiality and consent issues, associated processes and other procedures relating to the secure deposit, sharing and reuse of clinical materials in teaching, research and other educational activities. Drawing on relevant literature, exemplar policies and procedures from the UK and beyond, and informed by consultation with medical and legal experts, the Project has sought to identify and develop best practice recommendations, workflows, and information and technical procedures to support the use of clinical recordings from clinical settings.

The Project has consulted with representatives from a wide variety of stakeholders concerned with human and veterinary healthcare delivery, education and research in HE and FE institutions, the NHS, professional and statutory bodies and current repositories for clinical recordings. The scope and boundaries of the work included human recordings made in the context of medical and dental care as provided by doctors, nurses and allied healthcare professions. It did not include recordings made in other contexts of treatment, for example alternative therapies outwith the NHS. The Project also covered issues regarding the use of recordings of animals and their owners in the context of veterinary care.

1.3: Intended Outcomes

The intended outcomes of the Project were that:

- patients, healthcare providers, educators, researchers and technical staff will be better able to understand their rights and responsibilities with respect to the use of recordings made in clinical settings and circumstances
- means will be found to normalise practice across the UK's education and research communities leading to a more transparent and regulated information environment for all concerned
- the risks associated with using CRANCS will be reduced
- there will be an increase in availability of CRANCS thereby improving their educational efficacy
- there will be improved sharing of best practice and debate to clarify difficulties in practice
- means will be found to improve the structuring of the required practices relating to use of UK patient recordings outwith the UK and use within the UK of recordings originating elsewhere

2: Exploring the Issues - Illustrative Scenarios

The use case scenarios below are theoretical illustrations of some of the potential problems to be addressed by the CHERRI project. We have made assumptions about practice, drawing on our experience to date to reveal issues that warrant further exploration and we have gone on to do this through our legal report, the questionnaire, interviews and information on institutional procedures.

The following basic use case scenarios illustrate the breadth of issues regarding the use of CRANCS:

Use of older technologies – carousels of slides: For several decades clinical lecturers and other academics have used banks of 35mm slides to support their teaching. Often stored in slide projector carousels in their offices, these slides were often accumulated over a number of years, from different institutions and they would be proudly transported from one job to the next as the essential property of the lecturer. This raises a number of concerns:

Uncertain consent for educational use: If they contained clinical material they were either originals (or duplicates of originals) taken by a medical photographer, or copies of other recordings, such as radiographs or ECG traces. Typically if a medical photography or illustration unit was involved, negatives or some other copy was also stored with the service provider, but it has been uncertain if informed consent for their use in teaching has been given. However in favour of security was the fact that very few copies were usually made and mass dissemination was not a possibility until recent technological advances have enabled conversion of 35mm slides to electronic formats.

Terms of consent quickly lost to the users: Provenance of such slides was very rarely recorded, hence details of the subject, location and date were quickly lost making simple queries on possible terms of consent and audit of consent procedures impossible.

Loss of rich resources: The lecturer assumed ownership of the images. When changing jobs these teaching resources were lost to the original institution. The individual academic would decide what happened to these slides at every stage and on retirement they were either kept, bequeathed to a colleague or destroyed.

Mine, mine, mine: The debate and confusion over ownership of recordings has the power to cripple initiatives to develop the use of clinical recordings. Take for instance a video made in an operating room of a surgical procedure. Almost everyone involved could make a claim for ownership including: the surgeon, other theatre staff, the university academics making use of the video, the camera team, the patient or their family, the hospital or clinic in which it was made, the university in which it was made and even the students who used it as part of their studies. Without clarity on ownership, it would be virtually impossible to use the video because of the need to canvass all stakeholders beforehand.

Identifiable recordings: A key question in the use of CRANCS is 'Can the patient be identified from the recording?', since much of the current guidance on seeking informed consent for use of recordings is based on a simple classification of recordings into the identifiable and the non-identifiable. But identified by whom: the patient, the immediate family, the responsible healthcare team? A face is easily identified by all who know that person but what about an ear, a single joint, a patch of skin on the forearm, an unusual abnormality on a chest x-ray or an idiosyncratic history of a recent illness. Is it ever reasonable to use such recordings without consent? And what about the retelling of a fairly standard clinical presentation supported by recordings? Each item may be very difficult to identify but when aggregated may together give several clues to the identity of the patient, so determining whether or not a recording will be identifiable is more complex than it might at first seem.

Anonymisation: This is related to the point above since altering a recording may render it unidentifiable. For example a photograph of a patient's wrist joint is very difficult to identify if it is cropped to remove the wristwatch and much of the hand. Alterations of recordings taken for clinical care are understandably prohibited but what of those used in the educational context? Would suitable alterations overcome the need for explicit consent? What is a reasonable or even required alteration to improve confidentiality even in the presence of consent for use?

Creativity: This refers to the creation of derivative works; that is the assimilation of recordings into a larger artefact such as a training package or virtual patient. Patient recordings from several sources may be used to support fictitious clinical scenarios. Such virtual patients, despite their obvious utility (Ellaway, 2004), create problems due to their associative nature; recordings are combined with the implicit message that they are all of the same individual, hence an identifiable patient is implied to have the condition or personality depicted in the virtual patient. Although patients may have given consent for their recordings to be used for teaching they may not expect to see images of themselves associated with other clinical scenarios, lifestyles or personalities. How can we protect patients while maximising the educational power of aggregated recordings and clinical stories?

Making the terms of consent transparent: Staff and students have some awareness of the impropriety of inappropriate use of clinical recordings without consent. Students especially may be particularly vulnerable to concerns and anxiety regarding the proper use of CRANCS and staff may overlook opportunities to enrich their teaching with materials because they are ignorant of the terms of consent for a recording. On the other hand it may seem reasonable to assume that if a recording is already being used for teaching it is acceptable to copy it for one's own teaching or an assignment. How can technology and codes of practice make the terms of consent for a recording transparent to all users and encourage the use of CRANCS within the limits of that consent?

Repositories and reusable learning objects: The development and spread of repositories of recordings (potentially CRANCS) and the associated concept of reusable learning objects (RLOs) has made the widespread use and reuse of educational materials a reality. The implication is that these materials will have a public currency that take them a long way from the context and culture in which they were created. The implication for CRANCS is that they can very quickly find their way into contexts where consent and clinical accountability have no relevance. The globalisation of educational activities has meant that the exchange of learning materials is increasingly taking place on an international basis, thereby exacerbating the problem by materials rapidly leaving the legal jurisdiction in which they were acquired. What technologies, international codes of practice and legal frameworks ca permit regulated use of reusable learning objects?

I changed my mind: Although a rare occurrence, the withdrawal of consent for a CRANCS means that all copies should be immediately withdrawn from use. However tracking use of recordings is rarely possible and copies can spread exponentially over the Internet. This represents a real and significant problem, not least due to the distress to patients and the substantial damage to public relations that would result if any institution were demonstrably unable to comply with a withdrawal request. Where and how would we look for the original recording and all its derivatives? How can we register, track and search for clinical recordings?

The issues raised here are addressed later in this report. However, there is one clear theme that runs through them all; that of the dialectic between utility and security. To be perfectly safe and secure regarding the use of CRANCS the simplest thing would be to stop acquiring and using them and for all existing ones to be destroyed. This would however be disastrous for the education and training of healthcare workers and presumably for the care of future patients.

From a legal perspective the rights of the individual are paramount and the concept of the greater good has far less standing. From a pragmatic point of view practitioners need help to abide by the law, protect the rights of patients and find ways to use CRANCS for the benefits of their teaching and future patients and practitioners. It is hoped that the proposals arising from the CHERRI Project will enable this to happen.

3: Legal Contexts

It is vitally important to separate out the central legal concepts that are invoked by this project. This is particularly true because differing legal regulatory regimes apply depending on which legal rights or interests are in play. It is also the case that potential legal liability will differ depending on which legal rights or interests are thought to be infringed; this, in turn, impacts on the sorts of remedies that an aggrieved party might be able to pursue. For example, an action for infringement of privacy under data protection law carries different legal remedies compared to a common law action for failing to respect a patient's consent to become involved in a teaching or research project. Finally, at various junctures in this project there is (considerable) potential for conflict between rights and interests of the various parties involved and it is important to appreciate how such tensions might arise and how they might be resolved.

The key legal concepts (and regimes) that are engaged are:

- Consent (requirements of which change depending on what is being proposed)
- Privacy (primarily, though not exclusively, through the data protection regime)
- Property (primarily, though not exclusively, in the form of copyright)

3.1: Consent

The reason we seek consent is to respect the individual, her wishes, her bodily integrity and her personal information. We often speak of the personal right to self-determination or the individual's autonomy. But consent manifests itself in many areas of life and in many different areas of medicine. What is meant by 'consent' can often change depending on the context. For example, what does it mean to consent to treatment as opposed to consent to involvement in a teaching or research project? Surely consent is consent. But it is not so simple. The difference in this example (and in this country) lies in what the patient needs to be told in order to give meaningful legally-relevant consent at common law (i.e. judge-made law as opposed to statute). When a patient is consenting to treatment they must be given as much information as the *prudent patient* would require in order to take an informed decision.[1] Things might be different, however, when the person is not being asked to consent qua patient but rather qua research subject or subject for teaching purposes. While this matter has not yet been addressed by the British courts, other jurisdictions have indicated that the standard of what the subject should be told will not be judged by reference to the prudent patient but rather by reference to the needs of the particular subject, i.e. it is a higher standard. Why? Because there is no prospect of personal benefit for the subject and the need for the protection of their interests is greater. When the project is a teaching or research endeavour, the questions of what the actual subject must be told, how much they should be told, how far the professional should seek the subject's understanding and what opportunities there are for subject questions must all be addressed. It should be noted, however, that the remedy available at common law is most likely to be a negligence action, and this would require the person to show that they had somehow suffered harm as a result of not being properly informed. Thus, in a research example that involves patient exposure to physical harm, it could be argued that inadequate explanation of the risks led a patient to run a risk they might not have accepted if they had known all the facts. If the risk of physical harm manifests itself, then damages might arise for negligent failure to inform; and the harm is the physical damage itself. But in the context of CRANCS, the risks to the participants are of a different nature. If there is mere upset at being involved when images are used in ways that were not properly

explained, then it is likely that a negligence action would fail since mere hurt to feelings is usually not accepted as a basis for damages.[2] Notwithstanding, if a person suffers psychiatric harm (as in psychiatric illness) as a result of negligent failure to disclose, then damages would be payable. This is, however, a high standard of harm to demonstrate and successful cases are rare.

Data protection is discussed below, but the relationship between data protection and consent is a very close one. Contrary to common believe, however, it is not always necessary to obtain consent to process personal data. This having been said, in the context of a teaching and research project such as this, it is almost certainly the case that consent should be sought, and that the uses and disclosures should be explained, including the fact that this use of personal data is optional (i.e. there is a right to object) and what kind of teaching will be involved (e.g. hospital, university, international etc.) For present purposes it is enough to note that the requirements of risk disclosure within the data protection legal regime will be satisfied if there is enough information made available to allow the individual to assess the risks for him/herself in providing the data, in consenting to further use and in not objecting to further processing of their data. It is specifically stated in official guidance, for example, that open-ended projects can be justified so long as this indefinite feature of the project is explained.[3] If these requirements are not respected, the remedy for the person would be one of damages and/or injunction under the Data Protection Act 1998.

Closely linked to both consent and data protection is the common law concept of confidentiality. It is axiomatic that a doctor owes her patient a duty of confidence, being a duty not to disclose patient details outside the confines of the doctor/patient relationship *without patient consent*. But duties of confidence arise whenever confidential information (i.e. not already made public) is received by someone in circumstances which imply that a duty would arise, objectively assessed. Thus, a photographer taking pictures of a patient during a private consultation would also come under a duty of confidence to the patient, even if they had never previously met. Consent to use of the information – the photo – should therefore be sought; consent elides future liability for breach of confidence. Here, however, it should be established clearly on what basis consent is being provided: is it to unrestricted use of the image which would allow the other party to place the image in the public domain as it is?, or is it a conditional consent, e.g. on the condition that anonymity be maintained? Failure to institute adequate measures to ensure the terms on which consent is given could, then, also lead to an action for breach of confidence. This having been said, the duty of confidence is not absolute; disclosures in the public interest can be justified. This begs the question, what can be justified *in the public interest*?

It is possible, of course, to argue that the involvement of patients in teaching and research projects furthers broader public and community interests. Indeed, this will undoubtedly be true when those projects are well-designed and ethically sound. Notwithstanding, the current legal climate - which is supported in many ethical quarters (although not in all) - places considerable store in the protection of individual rights and interests above other considerations. While instances do exist where this is not so clearly the case, including (a) using patient data without specific consent and in the public interest,[4] or (b) enrolling incapable adults in research even when they cannot consent,[5] these are very much exceptions to the general rule which requires that things should not be done to, or with, patients without their explicit assent. Moreover, further safeguards are always put in place in cases of departure from the general rule.[6] The idea of the *public interest* is an under-utilised and under-explored provision in many fields of law. Thus, whereas, as has been stated above, in the common law of confidentiality it is the case that a patient's right to respect for his/her confidential information can be overridden if a (greater) public interest is at stake, this has only been used to date in the context of physical harm or a threat of death to others, and the exact parameters of the exception remain largely unexplored. A similar provision appears in data protection law, where once again much research remains undone. It is unlikely that either this provision or the common law exception in the law of confidence could be pled in aid of the current project.

Despite the above, there has been specific acknowledgement of the public interest in research both in England and Wales & Scotland. As regards the former jurisdiction, section 60 of the Health and Social Care Act 2001 provides "…a power to ensure that patient identifiable information needed to support essential NHS activity can be used without the consent of patients. The power can only be used to support medical purposes that are in the

interests of patients or the wider public, where consent is not a practicable alternative and where anonymised information will not suffice. It is intended largely as a transitional measure whilst consent or anonymisation procedures are developed, and this is reinforced by the need to review each use of the power annually."[7] Applications are monitored through the Patient Information Advisory Group (PIAG) but the regime is intended to be temporary only and has been subject to some criticism. It is not clear whether the system has been, or would be, applied to the use of identifying images of patients, although on one view these are simply another form of "patient identifiable information". Closer scrutiny of the Register of Approved Applications and/or informal enquiries to PIAG Itself may be helpful.[8] The regime does not apply in Scotland, although there the Privacy Advisory Committee performs a similar function to PIAG.[9] It is similarly unclear whether this group has ever ruled on patient images, although it is highly unlikely.

In all circumstances where consent is or must be sought, it is only legally valid if properly informed (although the standards to be reached can vary, as indicated above), is free from coercion, and is done with adequate understanding from the person who purports to give consent. Written consent is not legally necessary, although it is practically prudent. It is telling to note, for example, that in over 90% of cases in the Bristol affair there was evidence of written parental consent. The problem was that the parents had not understood what consent to post mortem entailed. Ensuring proper levels of informedness and understanding is ethically and legally vital.

The legal relevance of withdrawal of consent can be unclear. Outside the data protection regime (which is described below), it is not obvious which legal interest is breached if a patient's withdrawal of consent is not respected and when there is no risk of physical harm (obviously, to continue to treat a patient without consent would be an assault). Most likely, an appeal could be made to the human right of respect for private life (see below).

In contrast, the matter is relatively clear under the Data Protection Act 1998, s.10 of which provides:

> *…an individual is entitled at any time by notice in writing to a data controller to require the data controller at the end of such period as is reasonable in the circumstances to cease, or not to begin, processing, or processing for a specified purpose or in a specified manner, any personal data in respect of which he is the data subject, on the ground that, for specified reasons-*
>
> *a. the processing of those data or their processing for that purpose or in that manner is causing or is likely to cause substantial damage or substantial distress to him or to another, and,*
>
> *b. that damage or distress is or would be unwarranted.*

So the strict legal position is that a data processor must receive a request in writing and the data subject must show actual substantial damage or distress, or likelihood thereof. This, then, is a high hurdle for the subject to clear; but it would be extremely imprudent in practice not to respect such requests. The realistic practical position is probably that while a data subject cannot object to past uses of images for which there is an original consent, they can do so to restrict future uses and that their objections should be respected.

3.2: Privacy

Privacy is a difficult concept to define. It concerns the interests that human beings have in being separate from others, and/or in being unobserved by others and/or in keeping information about themselves away from others. The law protects privacy interests in a number of ways, although it is interesting to note that there is no such thing as a right *to* privacy in the United Kingdom, as was recently confirmed by the House of Lords.[10] Rather, the protection of privacy interests falls into three main categories:

(a) the common law duty of confidentiality[11]

(b) the statutory protection afforded under data protection legislation[12]

(c) the human rights protection that mandates 'respect for private and family life'.[13]

The narrowest protection is that provided by the duty of confidentiality, which, as we have seen, can be elided by the consent of the subject to disclosure of personal information or when disclosure would be necessary to further a legitimate public interest.

Consent and privacy also overlap in the realm of data protection. Data protection refers to the statutory regime imposed throughout the European Union by a 1995 Directive. Data protection (DP) exists not only to protect the individual's privacy but also to regulate (and facilitate) the exchange of data. The consent of the 'data subject' can legitimise a number of practices under the regime but it cannot absolve a 'data controller' (i.e. someone who is processing personal data) from all of their obligations under the law. In this sense the protection under a data protection regime is broader than that given by the common law duty of confidentiality. The law protects 'personal data', being data from which an individual can be identified either from that piece of data alone or in combination with other data that the data controller has or is likely to come into possession of. Consent here can be implied or express, although the former is extremely limited. Implied consent to use of personal data for research purposes is probably not an arguable option. Moreover, because the consent relates to processing and use, the nature of the information to be conveyed to the person must involve a description of these activities. Specific guidance on consent and health data has been issued by the Information Commissioner's Office.[14]

Data protection only relates to protection of personal data as defined above, meaning that the focus of the legal regime is on *identifiability* of persons from data about them. The implication is that if someone is *not* identifiable from data being processed then those data fall *outside* the DP regime. Anonymisation therefore becomes a very important issue. The related legal issue, however, is how much, or what form, of anonymisation is required to remain within the law. The generally accepted answer seems to be that *relative anonymity* is acceptable, that is, it is not necessary to absolutely anonymise data such that a re-linkage between data and individual is never possible.

Further limits of the data protection regime are that it only applies to data about persons who are alive. The obligations fall away once a person is deceased. Note, however, that a common law duty of confidentiality may survive death.[15]

Interesting recent interpretations of European data protection laws reveal area of possible extension/limitation. In late 2003, the Supreme Court of Iceland adopted a purposive approach to the Icelandic data protection law (which is essentially an adoption of the 1995 EC Directive) in respect of its application to the ambitious Icelandic Health Sector Database (HSD) project. This project aims ultimately to link genetic data from the Icelandic people with other records, such as medical and genealogical records, so as to create a powerful genetic research resource. The HSD was enabled by legislation from the Icelandic parliament (the Althing) but it has proved to be controversial from the beginning, not least because of its adoption of an opt-out scheme - that is, that all Icelanders are to be included in the project unless they expressly refuse. The case in point arose as an action to prevent transfer to the HSD of a deceased man's medical records to which his daughter laid claim. The enabling legislation provided grounds for such a transfer but no opt-out was available to the relatives of deceased persons. Moreover, the provisions of the data protection law did not apply to deceased persons, as stated above. The Supreme Court, however, held that personal information relating to the daughter herself could be derived from that of the father because of their genetic connection. The implications of this ruling could be far-reaching through Europe in at least two respects, namely: (i) the meaning of 'personal data' under European data protection law - do all first generation family members, living or dead, have a say in the management of each other's data where this has some genetic basis? and (ii) the legality of human genetic databases - how far must researchers go in protecting personal privacy? The relevance of the decision in legal terms is that it is one of the first interpretation of the Europe-wide Directive on what is meant by personal data in a familial or 'group' context. As for medical images, the question arises whether there may be parallels to which this decision might apply. For example, would relatives have a say in the publication of images of a family member which revealed that an hereditary condition was present in the family?[16]

The Icelandic ruling is to be contrasted with the recent decision by the English Court of Appeal in *Durant v Financial Services Authority*.[17] While this is not a case dealing with medical information, it nonetheless lays down an important precedent about the meaning of 'personal data' in the UK. The court here preferred a narrower conception of the term 'personal data' than had previously been thought to apply: the law protects personal data 'relating to' a data subject and this could mean, broadly, information 'having some connection with…,' or, more narrowly, 'having reference to…' the subject. The court preferred the latter, stating:

The information should have as its focus the data subject rather than some other person with whom he may have been involved or some transaction or event in which he may have figured or had an interest…In short, it is information that affects his privacy…

This dictum certainly gives a court a way out if it wishes to avoid the uncertainty generated by the Icelandic ruling. It has been reported that Durant has filed papers with the European Commission alleging that the UK has improperly implemented the Data Protection Directive. Certainly, greater clarity in the area is required.

Finally, and as stated above, privacy is a wide-sweeping notion, and beyond confidentiality and data protection citizens also find that respect is due to their 'private and family life' by virtue of the Human Rights Act 1998, which incorporated the Articles of the European Convention on Human Rights (1950) into domestic law. This protection extends to the capture and re-use of personal images, consensual or otherwise. Thus in the case of *Peck v UK* [18] the capture of a man's image on CCTV with a knife in his hand suggesting that he was about to commit suicide invoked his right of to respect for private life. This right was breached when the images found their way into the hands of the media and were published. Importantly, the liability fell on the UK government which was found to be in breach of its obligations to its citizens for not providing this man with adequate protection of his privacy interests (requiring the law to be changed as a result). This reflects the fundamental nature of European human rights protection whereby the primary obligation to protect human rights falls on the state, and if the state itself interferes unduly with human rights or if it does not provide citizens with appropriate remedies against other citizens who interfere with their human rights, then the state will be held to account. The relevance of this ruling to the current project therefore extends beyond the fact that images were involved; it invokes the fact that the project will doubtless be run from within a public authority unit or other agency of the state.[19] Public authorities have an obligation – like the state – to protect human rights. The parallels should, therefore, be clear.

Most human rights are not absolute. For example, while Article 8(1) states that 'everyone is entitled to respect for his private and family life…', Article 8(2) provides that: '[t]here shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.' Once again, therefore, a form of public interest exception can apply to limit individual rights. But once again it is extremely unlikely that it would assist in the context of the present project because interference with the prima facie right must be *necessary* and *proportionate* to achieve the public interest aims and it is far from obvious that a teaching and research project would clear the high hurdle set by the law. It may be a highly desirable endeavour but it is not necessary to secure other public interests or human rights.

3.3: Property

This Project necessarily involves a role for intellectual property rights (IPRs). Certainly, any image resource that is established will attract a number of IPRs, and these are primarily in the realms of copyright and database rights. The resource itself will attract a database right – rights to control use/extractions from the database – and this right will be held by the 'maker' of the database. Moreover, any individual images that make up the database will also attract protection, this being copyright protection. Importantly: the owner of any copyright in an image or other element of the database goes to the 'author' of the image/work, i.e. the person who created it. The subject of the image – e.g. the patient – has no claim whatsoever in copyright over such images.

This raises very interesting issues about the interface between copyright, consent and privacy. What should happen, for example, if the copyright holder wishes to use a clinical image for purposes disapproved of by the patient? Should copyright yield to consent? Social and professional convention may say so, but there is no specific provision in statutory copyright law to address such a scenario. This requires far more research and closer consideration. It is a classic example of the potential clash of legal systems. The same issue arises if a patient feels their privacy is at stake by the use or publication of a copyright image. A short answer is that given that the regimes do not have provisions to deal with such clashes/interface issues, each would operate independently of the other; that is, while the copyright owner might have every right under copyright law to use/sell/license or otherwise dispose of their work, this does not preclude an action for infringement of privacy or under some other regime. The obvious analogy is with celebrities and the press. The photographer who snaps Naomi Campbell leaving a drug rehabilitation clinic undoubtedly has copyright in that photo, but the House of Lords will still hold (as it recently did for Ms Campbell) that the publication of the photo is a breach of her human right to respect for her private life.[20] Thus, in the terms of the current project, the copyright in an image taken of a patient's body would be held by the person who captured the image (or, most likely, her/his employer); but inappropriate public disclosure of such an image without the person's consent might lead to an action for infringement of privacy, albeit there is nothing the person could do to prevent disclosure from within the law of copyright.

This having been said, there is some judicial authority at common law to suggest that the copyright in works that are created in breach of a duty of confidence, or when their creation involves the invasion of 'legal or equitable rights',[21] the work will be held on constructive trust for the person who has been wronged. In short, this would not prevent copyright accruing in the work for the person who created it, but it would mean that they could only exercise rights over the work which furthered the interests of the wronged person. This is tentative and under-developed jurisprudence, the full implications of which would require far more research than the current report allows.

The situation is more complicated with the interface between copyright and consent. It is arguable, for example, that consent – properly informed – would legitimise subsequent use, but it depends how far future uses can be consented to. Also, what of unforeseen uses, such as the use of a personal image in an offensive or distasteful setting e.g. placing the image with text suggesting that the person in the image is violent or a paedophile or an alcoholic? While this is an extreme example, it goes to establish that a further area of law might be invoked, namely defamation, if images are put in a context where adverse inferences might be drawn about the person. The advice here is that if there is a possibility of any such adverse inference being drawn from the context in which an image will appear, then very clear and specific consent from the patient should be obtained and s/he should be fully apprised of the use to which her/his image with be put.

A final point worth mentioning concerns the lack of remedies within copyright law to protect the kinds of interests that might be at stake in this project. The closest copyright law comes to recognising the 'moral rights' of the subject of an image in s.85 of the Copyright, Designs and Patents Act 1998 which states:

> *A person who for private and domestic purposes commissions the taking of a photograph or the making of a film has, where copyright subsists in the resulting work, the right not to have-*
>
> *(a) copies of the work issued to the public,*
>
> *(b) the work exhibited or shown in public, or*
>
> *(c) the work broadcast or included in a cable programme service;*

and, except as mentioned in subsection earlier, a person who does or authorises the doing of any of those acts infringes that right.

This example merely serves to demonstrate that rights connected more to the 'moral' concerns of an individual are occasionally recognised in copyright, but clearly this right would not help a patient or subject involved in the current project since they would neither have commissioned the capturing of images nor would this be done for private or domestic purposes.[22]

On copyright and creative commons licences – the persons with authority to license will be those with the copyright or those to whom copyright has been assigned. The subject has no say whatsoever as of right.

It is moot whether it would be possible to include terms in such a licence to restrict use of the copyright works in an attempt to protect the moral rights of the subjects of the copyright-protected images. The matter has not been tested in the courts and we can only speculate as to the outcome. It would be an interesting test matter to explore further. Certainly, there is nothing explicit in law that would preclude such terms. If any such terms were not respected, the remedy would be in breach of contract.

Finally, depending on the institutional arrangements between organisations involved in the project – e.g. JISC and the NHS - especially in terms of creating or capturing images and related questions of ownership of those images, it would be extremely prudent to lay out clearly the respective terms of the collaboration in a Memorandum of Understanding or similar instrument.

Notes

1. The law is slowly changing in this field. Traditionally, patients need only be told what a responsible body of medical opinion would reveal, and if a responsible body of opinion would not have revealed a particular mater then it did not need to be disclosed as a matter of law. More recently, however, judicial attitudes have begun to change, albeit slowly, and the better, more prudent view is that we should ask, what would a reasonable patient in these circumstances need and want to know?

2. There is a difference here between Scotland and England & Wales; the latter jurisdiction would not award damages for mere hurt to feelings. In Scotland, this is a recognised basis for damages, although the sums involved are likely to be very small.

3. Information Commissioner's Office, Use and Disclosure of Health Data, 2002, p.7.

4. See the provisions of s.60 of the Health and Social Care Act 2001 which allow the Secretary of State for Health to authorises uses of identifiable patient data in the public interest without the need for explicit patient consent [N.B. – this does not apply to Scotland].

5. See, in Scotland, the Adults with Incapacity (Scotland) Act 2000 and, most recently in England and Wales, the Mental Capacity Act 2005.

6. For example, the 2001 Act established the Patient Information Advisory Group to vet applications to use patient data without consent, and the equivalent body in Scotland is the Privacy Advisory Committee. Similarly, under both the 2000 and the 2005 Acts a raft of additional safeguards are employed to protect the interests of incapacitated patients, including the need for specific ethical approval, the role of a proxy decision-maker and the need to demonstrate that the research to be undertaken could not otherwise proceed if this group of patients was not enrolled.

7. http://www.advisorybodies.doh.gov.uk/piag/About.htm.

8. Ibid.

9. http://www.isdscotland.org/isd/

10. Wainwright v Home Office [2003] UKHL 53.

11. For a full discussion, see W v Egdell [1990] 1 All ER 835.

12. Data Protection Act 1998.

13. Human Rights Act 1998, Schedule 1, Article 8(1).

14 .Information Commissioner's Office, Use and Disclosure of Health Data, 2002.

15. There is old legal authority to this effect (Morison v Moat (1951) 9 Hare 241) and this is certainly the current view of the General Medical Council (GMC), see GMC, Confidentiality: Protection and Providing Information, 2004, para 30.

16. On the data protection implications of genetic data see the paper by the European Commission's Article 29 Data Protection Working Group which is charged with monitoring and recommending necessary changes to European data protection law: Article 29 Working Group, Working Document on Genetic Data, (2004). The Group points out the following reality and options: 'To the extent that genetic data has a family dimension, it can be argued that it is "shared" information, with family members having a right to information that may have implications for their own health and future life...The precise legal consequences of this argument are not yet clear. At least two scenarios can be imagined. One is that other family members could also be considered "data subjects" with all the rights that flow from this. Another option is that other family members would have a right of information of a different character, based on the fact that their personal interests may be affected. However, in both scenarios further options and conditions would have to be considered to accommodate the various conflicts that are likely to arise between the different claims of family members, either to have access to information or to keep it confidential.", ibid, pp.8-9.

17. [2003] EWCA Civ 1746, [2004] IP & T 814.

18. (2003) 13 BHRC 669.

19. Section 6(3) of the Human Rights Act 1998 states: 'In this section "public authority" includes - (a) a court or tribunal, and (b) any person certain of whose functions are functions of a public nature...'.

20. Campbell v Mirror Group Newspapers Ltd [2004] 2 AC 457, [2004] 2 All ER 995.

21. Australian Broadcasting Corporation v. Lenah Game Meats Pty. Ltd. (2001) CLR 19; Attorney General v Guardian (No.2) [1990] AC 109, 263, 276.

22. In similar vein, there should be no implications for this project from the provisions of the new Human Tissue Act 2004, due to come into force in England and Wales in 2006. This is because its remit extends only to the regulation of storage and use of 'relevant material' which is defined as: '...material, other than gametes, which consists of or includes human cells.' , see s.53(1) of the Human Tissue Act 2004.

4: Current UK Guidance and Literature

This section summarises the national guidance and recommendations available to healthcare professionals. Where appropriate the legal framework is briefly mentioned but a fuller explanation of this complex area can be found in section 3.

The legal requirements of the Human Rights Act 1998 (particularly article 8 – right to respect for private and family life), the Data Protection Act 1998 (principle 8 of which states that patient-identifiable information should not leave the EEC) and the Freedom of Information Act 2000 are discussed in section 4 of this report. Various other acts also contribute to guidance in specific areas, such as the as the Mental Capacity Act 2005, the Age of Legal Capacity (Scotland) Act 1991 and the Access to Health Records Act 1990.

The Department of Health provides considerable guidance in this area. Duties of confidentiality in particular are often written into NHS contracts, breaches of which can result in disciplinary procedures (DOH 2003). The Caldicott committee reviewed all patient-identifiable information (including clinical recordings) passing out of NHS organisations for purposes other than direct care, with the purpose of minimising unnecessary information transfer. Their report (DOH 1997) recommended that clear guidelines and protocols for management of such information transfer should be developed which all NHS staff must adhere to, and that one nominated individual (subsequently called the "Caldicott Guardian") in each institution should be responsible for safeguarding patient-identifiable information. These principles are further developed in the department's general guidance on consent (DOH 2001a) and confidentiality (DOH 2003). The latter also details a 'confidentiality model' which requires NHS staff to a) protect patient's information, b) inform patients about how their information is used, c) provide choice about whether their information can be disclosed or used in particular ways and d) improve these systems on an ongoing basis wherever possible (DOH 2003). The Department of Health has issued model documentation on patient consent which includes a section on clinical photography and video recordings (DOH 2001b) which is now used in many NHS trusts (see section 5.3). The DOH is also in the process of revising the 'NHS Code of Practice for Records Management' which contains guidance on the management of clinical recordings (DOH 2005).

The most widely referenced current guidance document on the use of clinical recordings for non-clinical purposes is the GMC document "Making and Using Visual and Audio Recordings of Patients" (GMC 2002), which supplements the general guidance provided by the GMC on Consent (GMC 1998) and Confidentiality (2004) to which registered medical practitioners must adhere. The Institute of Medical Illustrators also produces excellent general guidance (IMI 1998), a model policy and procedure for clinical recordings (IMI 2002, which is an adaptation of Addenbrooke's NHS trust 2002), and guidance on areas of difficulty such as non-accidental injury (IMI 2004a) and mole-mapping (IMI 2004b). The British Medical Association has also produced excellent guidance on taking and using images of patients (BMA 2004) and some speciality colleges and other professional bodies have already adapted GMC guidance to reflect more specifically their own situation (such as Royal College of Psychiatrists 1998, LTSN-01 2004).

The are also increasing numbers of commentaries and editorials in the medical, allied health professional and clinical education literature which serve to illuminate controversial issues and highlight different perspectives (such as Hood et al 1998, and the cases reported in Smith 1998).

4.1: Scope of Current UK Guidance

The GMC guidelines relate to "originals or copies of video and audio recordings, photographs and other visual images of patients. A 'recording' does not include pathology slides containing human tissue (as opposed to an image of such a slide), or CCTV recordings of public areas in hospitals and surgeries, which are the subject of separate guidance from the Information Commissioner" (GMC 2002). The LTSN-01 guidelines go further stating *"recordings of patient materials in learning and teaching… includes everything from information about a patient (history, record, etc.) to tissues, images, video, sound recordings, images of family, clinical materials, etc."* (LTSN-01 2004). For the purposes of this review clinical histories, documented examination findings or qualitative data recordings used for research purposes have been excluded (those requiring further information on this area may be referred to Corti 1999).

4.2: Basic Principles

The GMC guidance starts with a number of over-arching principles which provide a context for the more detailed guidance in later sections, relating principally to respecting patients' autonomy and privacy.

- *"Seek permission to make the recording and get consent for any use or disclosure.*
- *Give patients adequate information about the purpose of the recording when seeking their permission.*
- *Ensure that patients are under no pressure to give their permission for the recording to be made.*
- *Stop the recording if the patient asks you to, or if it is having an adverse effect on the consultation or treatment.*
- *Do not participate in any recording made against a patient's wishes.*
- *Ensure that the recording does not compromise patients' privacy and dignity.*
- *Do not use recordings for purposes outside the scope of the original consent for use, without obtaining further consent.*
- *Make appropriate secure arrangements for storage of recordings." (GMC 2002).*

These principles are supported by the Human Rights Act 1998 Article 8 which states *"Everyone has the right to respect for his private and family life, his home and his correspondence"* (Human Rights Act 1998).

"Patient permission (or "consent" as it will be referred to here), is essential for the use of recordings of patient materials in learning and teaching." (LTSN-01 2004) and in order to obtain such consent, *"Patients must receive full information on the possible future uses of the recording, including the fact that it may not be possible to withdraw it once it is in the public domain."* (DOH 2001b).

The Data Protection Act 1998 requires that the minimum required sensitive information is passed to those that need to know. Thus extraneous information in a recording (or associated with recordings) should be removed, only those people covered by the consent should be allowed access, recordings should be stored securely, and recordings should not be kept for longer than is necessary. Although there may be clinical indications for whole body recordings (e.g. mole mapping – see IMI 2004b), when these recordings are used for non-clinical purposes *"Extraneous information should be removed, e.g. the image of a birthmark on the torso might not need the whole body to be shown in order t o get the point across."* (LTSN-01 2004), *"Patient-identifiable information should not be included unless it is essential for the specified purpose"* and *"The minimum amount of identifiable information is transferred or accessible as is necessary"* (DOH 1997, general principles 3&4). The BMA also states that *"when consent is withdrawn, as far as possible all copies and the master material should be destroyed and only material that is part of the patient's health record should be kept"* (BMA 2004). Therefore copies of recordings should be destroyed if consent is withdrawn or if the material is no longer required for teaching or other non-clinical purposes.

There is some concern that users legitimately viewing clinical images may pass these on to others who do not have a legitimate reason for viewing. *"Some bodies, including the BMA, have been concerned that doctors are not able to exercise adequate control over such visual teaching material, which could be illegally copied."* (BMA 2004). The BMA also stated that one should *"Avoid sending or recording identifiable images in ways that permit the recipient to forward it to others or use it for purposes beyond the original consent"* (BMA 2004) but many feel this is difficult or impossible to achieve, particularly with digital images. *"It is recognised that while digitally originated recordings are intrinsically no different to traditional recordings, they are easier to copy in electronic form and are therefore more at risk of both image manipulation and inappropriate distribution."* (IMI 2002).

"Clear guidance should be provided for those individuals/bodies responsible for approving uses of patient-identifiable information" and *"Protocols should be developed to protect the exchange of patient-identifiable information between NHS and non-NHS bodies".* It also recommends *"A senior person, preferably a health professional, should be nominated in each health organisation to act as a guardian, responsible for safeguarding the confidentiality of patient information"* (DOH 1997). These senior people have now become known as 'Caldicott Guardians'.

The NHS retains copyright for all recordings made on its premises or of its patients, and this is reiterated in most NHS trust guidance on clinical recordings; *"…NHS Trust holds the copyright of all recordings made of its patients… It is important that in any contract for publication the copyright in the recording remains with the Trust and does not pass automatically to the publishers on first publication."* (IMI 2002).

4.3: Apparently anonymous recordings of patients made for clinical purposes

The GMC guidance is quite clear that there are some classes of recordings which they feel do not require consent, even for publication. *"You do not need to seek separate permission to make the recordings listed below. Nor do you need consent to use them for any purpose, provided that, before use, the recordings are effectively anonymised by the removal of any identifying marks (writing in the margins of an x-ray, for example) images taken from pathology slides, X-rays, laparoscopic images, images of internal organs, ultrasound images. Such recordings are unlikely to raise issues about autonomy and will not identify the patient. It may nonetheless be appropriate to explain to the patient, as part of the process of obtaining consent to the treatment or assessment procedure, that a recording will be made."* (GMC 2002).

The GMC guidance also states that recordings other than those mentioned above may be used without consent if the patient is not identifiable, except for publication. *"If you are sure that the patient will not be identifiable from the content of the recording, and the recording is effectively anonymised by the removal of identifying marks, you may use the recording for teaching purposes without consent… When making a judgement about whether the patient may be identifiable, you should bear in mind that apparently insignificant features may still be capable of identifying the patient to others."* (GMC 2002).

This is supported by the BMA that states that *"as a general rule, any image that is truly anonymised may be used for teaching without consent"* (BMA 2004) and the DOH who state that *"anonymised information is not confidential and may be used with relatively few constraints"* (DOH 2003).

This is again supported by the most recent guidance on confidentiality from the GMC. However there appears to be a shift towards obtaining express consent regardless of whether or not the patient can be identified, though the GMC acknowledges that consent is not always practicable. ''*What about using case studies and photographs in teaching? You should obtain express consent, wherever that is practicable. If it is not practicable, you may use photographs and case studies in teaching and training, provided the material is not published or otherwise in the public domain. You must do your best to ensure that no patient is identifiable from such material."* (GMC 2004b Q12)

Some authors emphasise the imperative of gaining consent for all recordings - *"consent should be requested from patients for all medical photography and for the subsequent use of their images whether or not they can be identified by the picture"* (Hood et al 1988). LTSN-01 disagrees with the concept of anonymisation of recordings - *"there is no such thing as 'anonymising' a recording (image, movie, sound file, histology slide, DNA sample, liver, etc.). This is a shift in thinking from 'how much do we have to obscure before it is anonymous' to 'this belongs to the patient and must be treated as such'"* (LTSN-01 2004) and *"How anonymous is a photograph of a very rare condition? Is the photograph of a fingerprint, or physical representation of a strand of DNA, (with no name or demographic attached), anonymous? Will recordings and data, considered anonymous today, still be anonymous following the introduction of a new technology, or data re-combination technique, in the future?"* (LTSN-01 2004). IMI feel that professionals are not in a position to judge whether or not images would be identifiable; *"nor is it sufficient to rely on the photographer's or consultant's judgment that a particular patient is unlikely to be identified from a particular recording. … NHS trust has therefore adopted the policy that informed consent to recording is obtained from all patients and in all cases"* (IMI 2002).

The Caldicott report also highlights this issue of anonymisation and recommends a balanced approach; *"we concluded that all items of information which relate to an attribute of an individual ought to be treated as potentially capable of identifying patients, to a greater or lesser extent, and should be appropriately protected to safeguard confidentiality. Note should be taken of the degree of difficulty involved in actually identifying a specific individual, and this should be balanced against the purpose and usefulness of the specific items of information"* (DOH 1997 section 4.1.1).

4.4: Apparently identifiable patient recordings made for clinical purposes

If a patient is identifiable in a recording made for clinical purposes, their consent must be sought before using this for non-clinical purposes; *"information that can identify individual patients must not be used or disclosed for purposes other than healthcare without the individual's explicit consent, some other legal basis, or where there is a robust public interest or legal justification to do so"* (DOH 2003). *"Recordings made for clinical purposes form part of the medical record. As such, when considering disclosure of a recording, you should treat the recording in the same way as any other part of the medical record. In general, that means that you should seek consent for the disclosure"* GMC 2002. This is supported by the BMA; *"such images form part of the patient's medical record, and the same standards of confidentiality, and the same requirements for consent to disclosure apply"* (BMA 2004).

Difficulty arises with old collections of recordings (section 4.6) and those where the source is unknown or from places in the World where different standards apply, patients who have died (section 4.11), and regarding the distinction between 'identifiable' and 'non-identifiable' recordings (section 4.3).

The Royal College of Psychiatrists additionally recommends that, even for legitimate viewers of video material which has valid consent, "At a teaching event… audiences should be invited to declare personal acquaintance, in which case the presenter should then ask the participant to leave the room or decide not to use that piece of tape." (Royal College of Psychiatrists 1998).

One must also be aware of other people who may be included in the recording; *"accidental recording of patients who have not given appropriate consent must be avoided. Images of a patient that have inadvertently picked up the images of another patient or patients who have not consented should not be published under any circumstances… Members of staff who normally operate the equipment in a recording are deemed to have given their consent to the recording and its further use by appearing in the recording. If the member of staff does not normally work in that area, then a "model release" consent should be obtained"* (IMI 2002).

4.5: Recordings made for non-clinical purposes

"All recordings that illustrate a patient's condition or an aspect of the treatment are medical records, whether they were originally created specifically for this purpose or not" (IMI 2002).

The GMC states that *"you must obtain permission to make and consent to use any recording made for reasons other than the patient's treatment or assessment"* (GMC 2002). It goes on to say that before the recording is made, patients must *"understand the purpose of the recording, who will be allowed to see it - including names if they are known - the circumstances in which it will be shown, whether copies will be made, the arrangements for storage and how long the recording will be kept"*, understand that they can withdraw consent at any time and this will not affect their care, and are given time to read clear explanatory material and to consider the implications of giving their consent. Afterwards patients must be asked if they want to vary or withdraw their consent (leading to erasure), be given the chance to see the recording as it would be shown if they wish, and the recording should be *"given the same level of protection as medical records against improper disclosure"* and only used for the purposes for which patients have given consent (GMC 2002).

LTSN takes a similar view but with the additional requirement that patients are consulted every time a recording is to be used; *"consent should be obtained at the point of collection, again after the patient has had time to reflect and preferably at a time when they are no longer under treatment, and finally, every time that recording is going to be used, showing an example of how it will be used. Each consent agreement should be copied into the patient record"* (LTSN-01 2004).

The importance of treating such recordings as part of a patient's medical records is stressed in various different guidelines, including LTSN-01, although they do not indicate how this might best be achieved with larger items such as video cassettes. *"If you take a recording such as a photo of a patient for any purpose (including education and training) then it forms part of the patient record and a copy, plus a copy of the agreed consent form, must be stored in the patient record. If a patient makes a data request for their health record under Freedom of Information 2000 and you can't reproduce a recording taken for learning and teaching purposes and the appropriate consent (and say how that recording is used) then you may be in breach of the law"* (LTSN-01 2004).

These issues do not apply to images that are taken outwith a healthcare setting (i.e. not actually of a 'patient'), or where the subject is paid. *"If your recording is NOT part of health care promotion / treatment, is NOT taking during, before, after or because of treatment (which includes any recording taken, even of patients in a waiting room, for the purposes of education and training), then it is merely a recording and falls under copyright… rather than data protection. You don't need consent. … If you pay your subject then this changes the agreement to a 'contract' and again it shifts to contract law / copyright rather than data protection (but you should check your local circumstances)"* (LTSN-01 2004). Simulated patients, healthcare workers and other members of the public may need to complete a 'model release' consent, but the recordings fall outside this guidance and do not form part of their clinical records.

Patients should also not be exposed to unnecessary risks to obtain recordings for non-clinical purposes, such as additional X-rays exclusively for teaching purposes *"no investigation should be requested unless it can be clinically justified, and its result, normal or abnormal, is likely to influence management of the patient"* (Royal College of Radiologists 1998).

4.6: Historical collections of recordings, and those originating from outside the UK

The GMC states *"some doctors may have existing collections of recordings which they use solely for teaching purposes within a medical setting. Both this guidance, and the previous edition published in 1997, require permission to be obtained to make any recording which is not part of the patient's assessment or treatment,*

regardless of whether the patient may be identifiable. However, recordings may have been made for teaching purposes prior to 1997 without it being recorded whether or not permission had been obtained. Such collections may have a significant value for teaching purposes… You may continue to use recordings from which the patient is not identifiable, and which were made for teaching purposes prior to 1997. You should, however, seek to replace such recordings at the earliest opportunity with similar recordings for which permission can be shown to have been obtained. You may also continue to use effectively anonymised recordings that were originally made for treatment or assessment purposes, in line with … above. However, you should not use any recording, from which a patient may be identifiable, for teaching purposes if you cannot demonstrate that consent has been obtained for that use" (GMC 2002).

LTSN-01 also question the validity of consent to 'all future uses'; *"there is no such thing as universal consent to uses 'now' and 'in the future'. It is likely that the law would conclude that a patient can't agree in advance to a future use of recordings that they have no way of conceptualising, such as… the Internet for someone consenting to 'all future uses' over 30 years ago"* (LTSN-01 2004). Also in some instances time-limited consent is given, as in summative assessment videos of general practice registrars in which the guidance states that patients should be told the videos will be erased after a maximum of 3 years (Joint Committee for Postgraduate Training in General Practice 2002).

"These suggestions for best practice relate to the collection of new materials. Future guidelines may or may not be retrospectively applied (to existing collections), however there is a moral obligation for you to comply where possible. For example, it would be unreasonable to source recordings abroad (where laws on data protection might be different)" (LTSN-01 2004).

4.7: Recordings of Incapacitated Adults

"When a mental disability or mental or physical illness prevents patients giving their permission, you must get agreement to recording from a close relative or carer. In Scotland, you must seek agreement from any person, appointed under the Adults with Incapacity (Scotland) Act 2000, having an interest in the welfare of the patient" and people agreeing to recordings on behalf of others must be given the same rights and information as patients acting on their own behalf" (GMC 2002). *"In situations where the patient does not have the capacity to give informed consent, for example because of cognitive impairment, agreement must be sought from a close relative or carer"* (Royal College of Psychiatrists 1998*). "You must not make any use of the recording which might be against the interests of the patient. You should also not make, or use, any such recording if the purpose of the recording could equally well be met by recording patients who are able to give or withhold consent"* (DOH 2001b).

Incapacity must not be assumed however, but assessed in each case, e.g. *"persons detained for treatment under the Mental Health Act should not be assumed to have sacrificed their rights in respect of clinical illustration if they are still capable of making a judgement"* (IMI 1998).

Patients under general anaesthesia are also a special consideration. *"When no recording has been planned, but a record of an unexpected development would make a valuable educational tool, you may record patients undergoing treatment. If you cannot get permission at the time because, for example, the patient is anaesthetised, you must ensure the patient is later told about the recording and gives consent to its use… With recordings made in these circumstances, you must follow patients' instructions about erasure or storage. The only exception is if you think you need to disclose the recording because of the advice in the GMC booklet 'Confidentiality: Protecting and Providing Information', for example to protect the patient or others from risk of death or serious harm. Hospital policy on recording the treatment of unconscious patients should be adequately publicised"* (GMC 2002).

4.8: Recordings of Children

"Parents usually authorise recordings of their young children, while competent young people choose for themselves... Minors must be able to withdraw consent upon attaining maturity. Where the minor continues to be a patient, there should be opportunities to discuss permission as he or she becomes able to decide" (BMA 2004).

"Children under 16 who have the capacity and understanding to give permission for a recording may do so. You should make a note of the factors taken into account in assessing the child's capacity" (GMC 2002). In Scotland this relies on an assessment of 'Gillick competence' - for detailed guidance see Age of Legal Capacity (Scotland) Act 1991.

Although parents may consent for a child who lacks capacity, most authors agree that one should still seek the opinion of the child, and *"if a child is not wiling for a recording to be used, it must not be used, even if a person with parental responsibility consents"* (DOH 2001b).

Recordings of non-accidental injury are an area of particular concern in which valid consent may not be possible from either parents or child. The Institute of Medical Illustrators offers guidance on such recordings for clinical and legal purposes (IMI 2004a) but there is a lack of guidance on the use of such recordings for other purposes such as education and research. This issue exemplifies the potential conflict between protecting the rights of the individual (where no consent is available from parent or child) with the needs of society as a whole (in this case training medical staff to identify non-accidental injury).

4.9: Recordings of Telephone Calls

"Recordings of telephone conversations fall into a category of their own. Anyone using a telephone is subject to licence conditions under the Telecommunications Act 1984. They require you to make every reasonable effort to inform callers that their call may be recorded, and maintain a record of the means by which callers have been informed… Given the sensitive nature of calls to medical advice lines or similar services, you should pay particular attention to ensuring that callers are aware that their call may be recorded. You must not make intentionally secret recordings of calls from particular patients" (GMC 2002).

4.10: Recordings for use in Public and Broadcast Media

Regarding recordings made for clinical purposes, the GMC states *"since it is difficult to be absolutely certain that a patient will not be identifiable from a recording, no recording other than those mentioned… above should be published or used in any form to which the public may have access, without the consent of the patient"*. In addition *"You must not make recordings for use in publicly accessible media without written permission, whether or not you consider the patient to be identifiable. 'Publicly accessible media' includes medical journals. The only exceptions to this are outlined (above)"* (GMC 2002).

The advice above is reiterated by the GMC in its most recent guidance on confidentiality.*"I have some interesting case studies of patients which I would like to write up and publish. Do I need consent? It is very difficult to anonymise case studies fully, especially if they are of interest because they deal with a rare condition, or the detailed history of a patient with mental illness. Similar problems apply to many photographs. For this reason, you must obtain express consent from patients before publishing personal information about them as individuals in media to which the public has access, for example in journals or text books, whether or not you believe the patient can be identified. Express consent must therefore be sought to the publication of, for example, case-histories about, or photographs or, patients."* (GMC 2004b Q11)

It seems that few patients will not give consent to publications of their recordings if asked. *"Request for consent complicates the process of publishing medical papers, and some may not be published as a result. Most patients, however, will give consent, if asked"* (Smith 1998). *"85% of patients continue to give consent for publication of their image despite explicit discussion of the possibility of the image becoming available on the internet"* (Hood et al 1998).

"If you are involved in any way with recording patients for television or other public media, you should satisfy yourself that patients' permission has been properly obtained, even if you are not responsible for obtaining that permission or do not have control of the recording process… In addition, you should make sure that patients understand that, once they have agreed to the recording, they may not be able to withhold their consent for its subsequent use… If you believe that the recording is unduly intrusive or damaging to patients' interests, you should raise the issue with the programme makers. If you remain concerned, you should do your best to stop the recording, for example by halting a consultation, and withdraw your co-operation" (GMC 2002).

There are various reasons why one should always gain valid consent for recordings which are to be broadcast or published in the public domain. The main reason is that authors and broadcasters often think recordings are 'anonymised' when in-fact they are not. Smith 1998 reports on several real errors of this kind from the medical literature, and re-iterates guidance on this area provided by the 'Vancouver group' of medical journal editors. *"Identifying information should not be published in written description, photographs, and pedigrees unless the information is essential for scientific purposes and the patient, or parent, or guardian gives written informed consent for publication. Informed consent for this purpose requires that the patient should be shown the manuscript to be published. Identifying details should be omitted if they are not essential, but patient data should never be altered or falsified in an attempt to attain anonymity. …When informed consent has been obtained it should be indicated in the published article"* (International Committee of Medical Journal Editors 1995).

This is not the case when data becomes non-identifiable in a large pool however *"do we need to obtain the consent of every individual in an epidemiological study of 500 individuals, for example? The answer will always be no, when the data are presented in combined form and no one individual is readily identifiable"* (Smith 1998).

4.11: Recordings of Patients who have Subsequently Died

"When conducting a hospital post-mortem examination, you must seek permission from a close relative or carer before making any recording from which the deceased may be identifiable. If the death is the subject of a medico-legal investigation, the proposed recording should be discussed with the coroner or Procurator Fiscal (in Scotland) who has authorised the investigation" (GMC 2002).

The Royal Liverpool Children's Inquiry recommended that *"coroners shall be introduced, their function and procedures explained and the next of kin invited to express any specific concerns and requests"* and *"coroners shall ensure that all existing retained organs, tissue, blocks, slides, photographs and X-rays are specified within any preliminary and final post mortem reports"* (The Royal Liverpool Children's Inquiry 2001).

"Can I publish studies about patients who have died? You should follow the patient's wishes, if they are known to you. If not, you should consider whether publishing information which could be identified would cause distress to relatives or the patient's spouse or partner. If you are satisfied that the publication would not cause distress, and that you have no reason to think that the patient would have objected, you may use the case study or photo in published material. You should of course do your best to ensure that the patient is not identifiable from the material you publish" (GMC 2004b Q19).

The Institute of Medical Illustrators also offers guidance in this area. *"If a patient dies before a retrospective consent can be obtained, material by which the patient is identifiable should be retained until a relative can be approached. If the patient cannot be identified then the material can be released… It is preferable in all cases to obtain consent but it is unreasonable to stress relatives over this question. Unless the recordings have extraordinary teaching value, they are better destroyed"* (IMI 1998, section 9.4.6).

5: Current Practice

Surveying current practice with respect to the use of CRANCS was undertaken using three different approaches: an online questionnaire, telephone interviews and request to members of the Council of Heads of Medical Schools and Caldicott Guardians for current guidelines on acquisition and use CRANCS and consent forms.

5.1: Questionnaire

An online questionnaire was sent out to individuals in the NHS and the tertiary health education sector with a response of 38 returns. Although this is smaller than ideal, it is typical for this kind of survey in the time available. Authored and delivered using the commercial Survey Monkey system (www.surveymonkey.com) the questionnaire covered a number of key areas using a combination of selection and free-text responses.

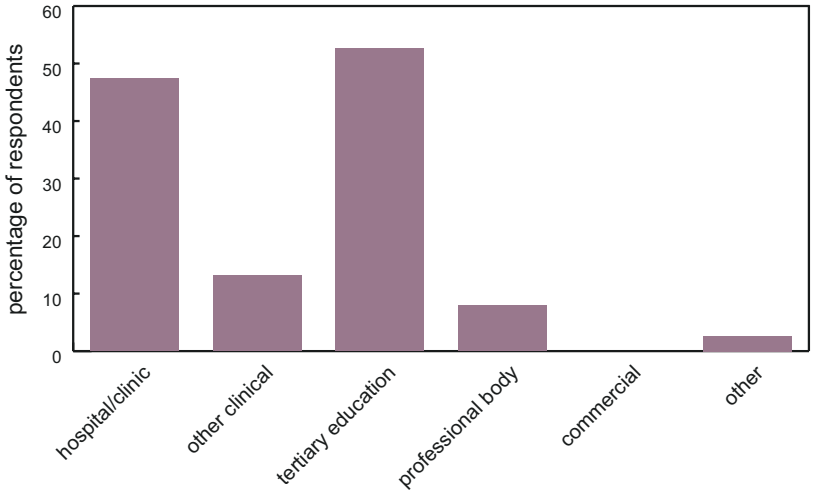


Figure 1: Working Contexts: spread of respondent working contexts: this indicates a reasonable split between health service and educational institutions.

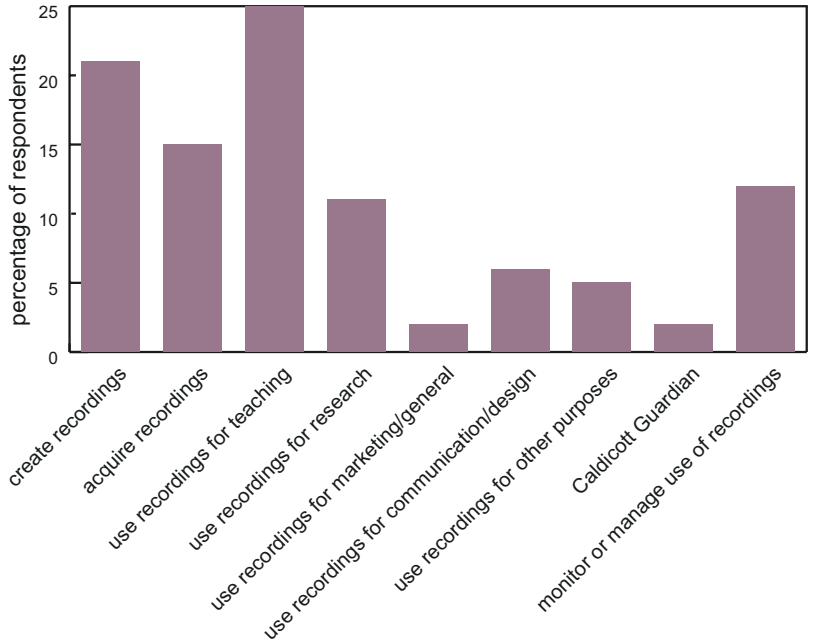


Figure 2: Engagement with Clinical Recordings: this indicates a reasonable spread of respondent involvement in all areas of CRANCS acquisition and use.

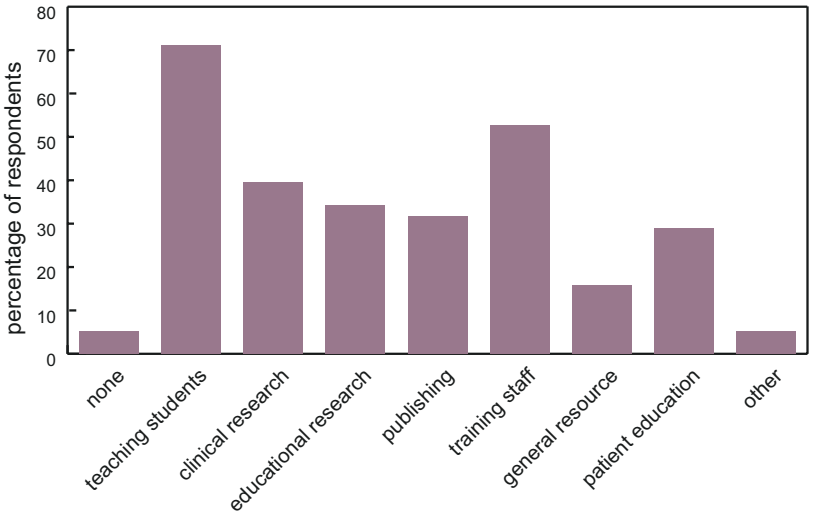


Figure 3: Use of Clinical Recordings: this clearly shows that teaching and training are the main focus for the use of CRANCS although research, publication and patient education are still important uses.

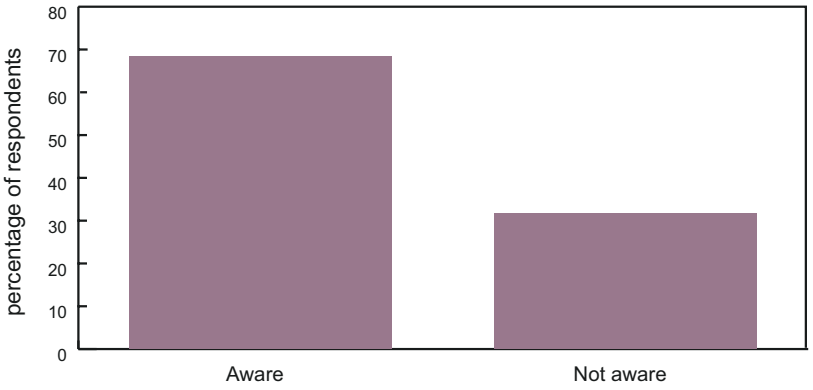


Figure 4: Awareness of Guidelines or Protocols: nearly a third of respondents reported that they were unaware of any general guidelines or protocols to support their use of CRANCS. This is worrying given the number of available guidelines.

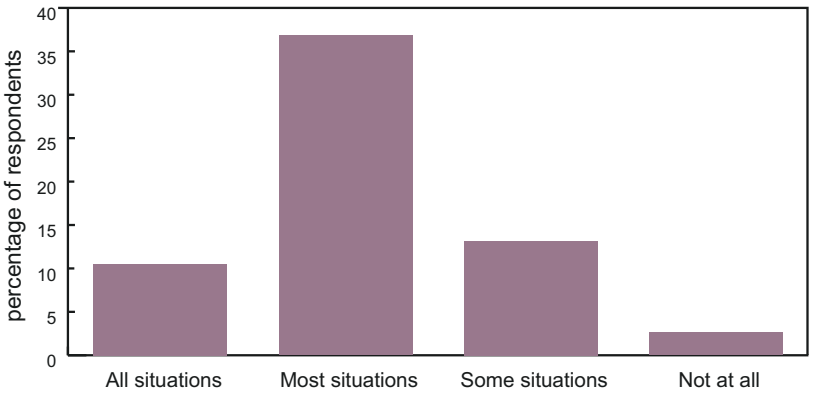


Figure 5: Utility of Guidelines and Protocols: even for those using guidelines it is clear that respondents do not consider them suitable for all circumstances.

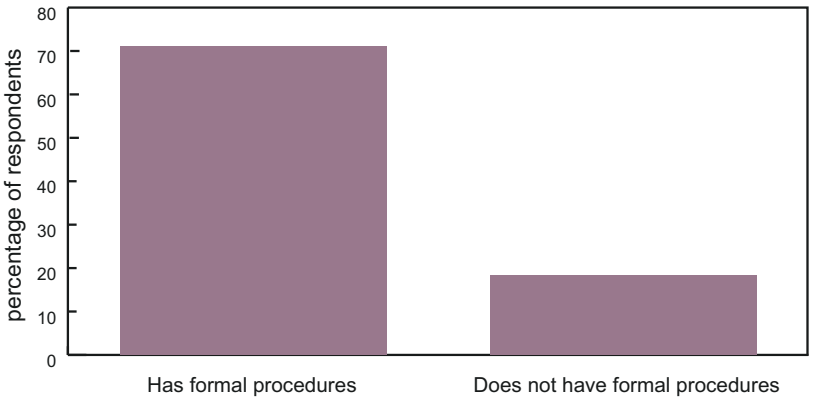


Figure 6: Formal Procedures for Obtaining Consent: nearly 20% of respondents indicated they had no formal procedures for gaining consent for the use of CRANCS.

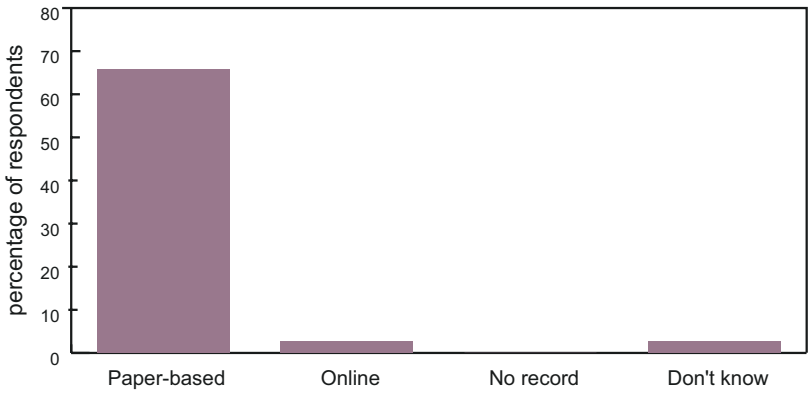


Figure 7: Consent Documentation: despite the omnipresence of online systems for storage of information the consent process and subsequent storage is still essentially paper-based.

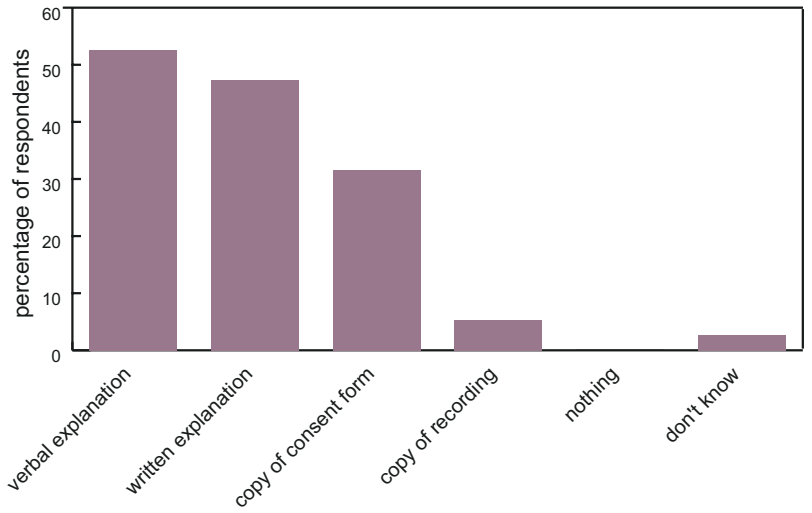


Figure 8: Information given to Patients: in a clear indication of the increasing attention paid to the needs of the patient nearly half the respondents reported patients receive a written explanation of what will happen to their recording and nearly a third received a copy of the consent form.

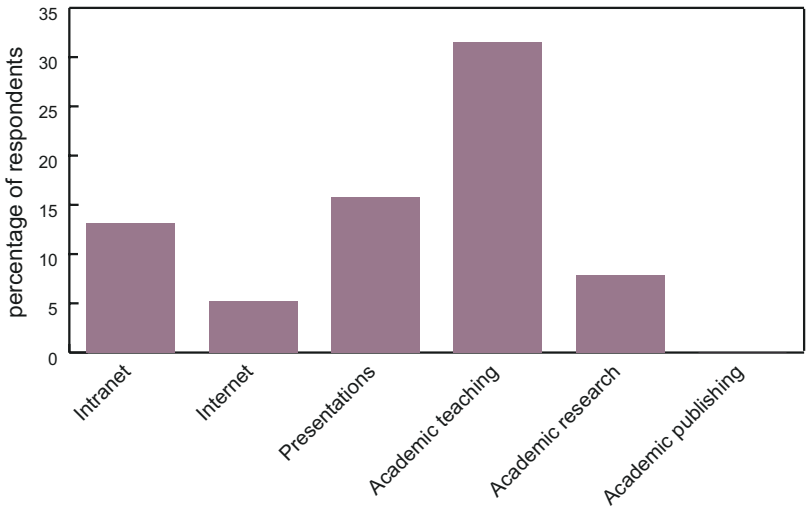


Figure 9: Terms of Consent – Types of Use: less than a quarter of respondents sought permission to put recordings online.

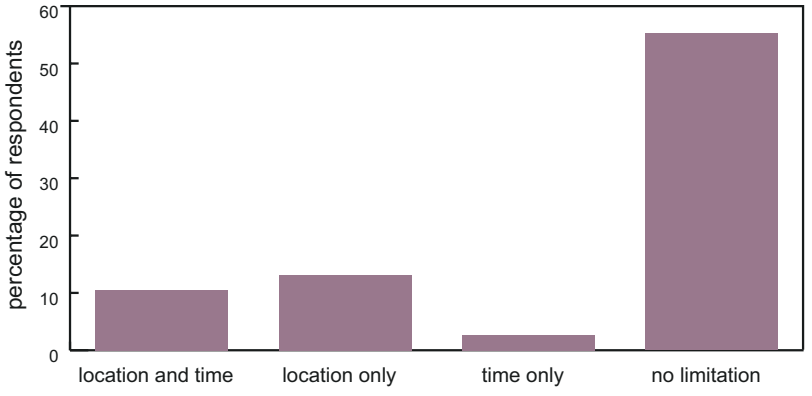


Figure 10: Terms of Consent – Limits on time and Location: there are seldom any limitations raised regarding consent on the location or length of time CRANCS can be used.

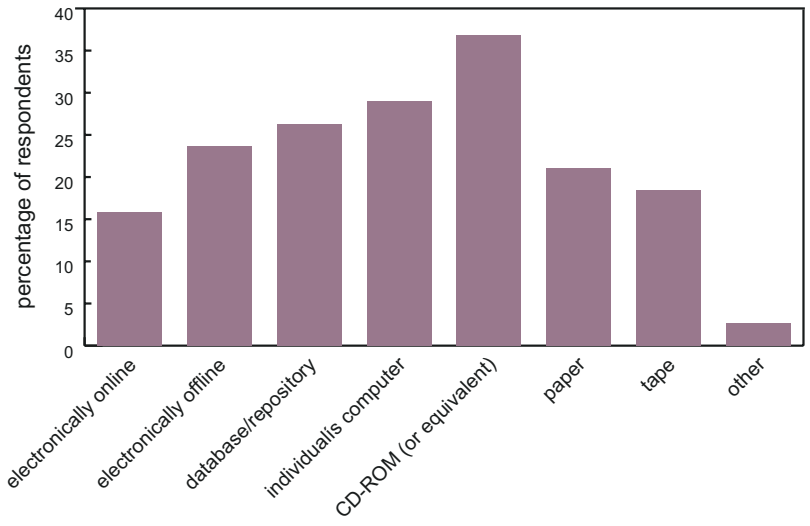


Figure 11: Storage of CRANCS: there are clearly a diverse range of forms of storage with no clear predominating form.

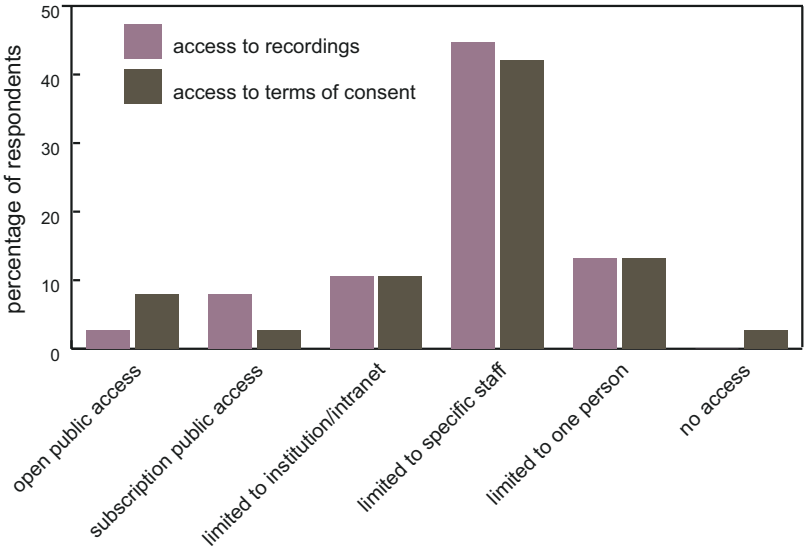


Figure 12: Access to CRANCS and Consent: Access to both materials and their terms of consent is usually limited to specific members of an institution's staff. The discrepancy between access to materials and terms of consent to the general public needs to be checked.

5.2: Local Policies, Protocols and Consent Forms

A request was made by e-mail to all heads of medical schools in the UK ("CHMS" members, 31 in total) and all current Caldicott Guardians in Scotland, England and Wales (620 in total). The body text of the e-mail request can be found in Appendix B. There were 35 responses to this request in total (response rate 5.4%).

Nineteen respondents reported that they did not have any guidelines, protocols or consent forms relating to clinical recordings used for non-clinical purposes. Seven were Strategic Health Authorities and reported that they did not require such guidance, 5 reported using outside sources of guidance (e.g. DOH guidelines, RCGP video guidelines, Data Protection Act, Caldicott principles and research ethics committees), 6 reported that they had no such guidance, and 1 questioned whether they should provide any information; *"whilst I am keen to share whatever information I can with you, I am uncertain regarding the status of this project which, on first perusal, appears to be research."* Of the 6 reporting no such guidance, sample e-mail responses included:

"I have to confess that we have no such protocols or consent forms",

"we are currently in the process of actively revising our documents, being very aware that this is an issue that needs addressing"

"there are no specific university guidelines or protocols. As all images are sourced through the hospital department of Medical Illustration, we follow their policies – if they exist."

Sixteen respondents forwarded guidance relating to these areas used in their own institutions, and 4 of the telephone interviewees also forwarded their guidance. Of these 20 collections of guidance some had varying degrees of commonality and have been grouped accordingly and are discussed in turn below. Some examples of good practice have been highlighted, and web-links to the guidelines (where available) or to the organisations who possess these are included in the references.

Six respondents sent a modified version of Good Practice in Consent Implementation Guide: Consent to examination or treatment (DOH 2001b). This document begins by stating that *"both consent forms and consent policy should be recognisable across the NHS and that the text included in this implementation guide should not be amended or removed. However, it may be appropriate to customise the documentation to reflect local needs"* and this consent guidance is increasingly becoming standard across NHS organisations in England and Wales. Section VIII relates to clinical photography and was reproduced verbatim in 4 of the guidance documents. In one, however, section VIII:3 was changed from *"photographic and video recordings, made for treating or assessing a patient and from which there is no possibility that the patient might be recognised, may be used within the clinical setting for education or research purposes without express consent from the patient…"* to *"the policy of [named] hospital is that photographic and video recording made for treating or assessing a patient should not be used for education or research purposes, even within the clinical setting and even when there is no possibility that the patient may be recognised without the express consent from the patient."* One of these respondents also sent a comprehensive clinical recording policy (Bedford Hospital NHS trust 2005) and one had appended a consent form for recording of 'visual, audio media information' into the guideline.

Two respondents sent their policy, protocol and consent forms which mirrored the IMI model documents (IMI 2002). One of them was Addenbrooke's itself, upon which the IMI guidance is based (Addenbrooke's NHS Trust 2002). The guidance and form allows for three levels of consent in clinical recordings – 1) medical records only; 2) medical record and teaching (of healthcare staff and students within the UK) and 3) the above plus one specified first publication or other purpose (which must be detailed on the form, and does not extend to any further publication). The procedures also detail how staff may take, store, track and use such recordings. These documents are much more detailed and specific than many of the others the authors have seen, and are highly recommended as examples of best practice. Extracts from, and references to, the IMI model were also found in many of the guidance documents below.

The remaining guidance received was much more individual, although most drew on material from the IMI model documents, GMC guidance and various other national sources. Gloucestershire Hospitals NHS Foundation Trust sent a draft of their updated 'Photography and video recordings of patients: confidentiality and consent, copyright and storage'. This is an excellent example of this type of local document but is currently only available in draft form (pending the revised DOH records guidance). One other respondent sent an adaptation of a previous version of Gloucestershire guidance which did not draw on some of the more recent literature. Great Ormond Street Hospital for Children NHS Trust has produced an excellent example of a local adaptation of national guidance developing it and relating it all specifically to recordings of children (reproduced in full in appendix D). Three other trusts sent guidance which cover similar areas but emphasise different aspects and so have been included in the references (University Hospital Birmingham NHS Foundation Trust 2003 - which contains some very practical flowcharts; Norfolk and Norwich University Hospital NHS Trust 2004; Cardiff and Vale NHS Trust / Cardiff University 2005). One respondent sent a policy which was based almost exclusively on the GMC guidance but gave no specimen consent forms or procedure.

One respondent sent web references to a two level consent form in which recordings could be used for clinical records, clinical teaching and research as standard, with the options of *"reproduction in textbooks or journals…"* and / or *"to illustrate and promote the work of … NHS Trust. For example leaflets, posters, brochures, reports or*

displays". This trust also had a 1-page section in their documentation on record keeping which outlined some of the basic concepts on the capture, use and safekeeping of clinical images.

Three respondents sent consent forms only. One PCT sent the RCGP/COGPED video consent form (JCPTGP 2002). The other two respondents had three levels of consent, one mirroring the IMI 2002 model consent form with third level consent being for a specified purpose only, whilst the second example of third level consent stated *"I consent to the use for the recordings to be shown to appropriate professional staff, used in educational publications, journals, textbooks and all forms of electronic publication, anywhere in the world."*

Our only guidance from outside the UK was sent by one of our telephone interviewees from the University of California: Los Angeles. It is quite different from most UK guidance and has been reproduced in the appendices below for information.

5.3: Interviews

Qualitative interviews were conducted to obtain an overview of expert opinion as to what they consider constitutes best practice, and to explore some of the practical, legal and ethical considerations arising from current practice, including what they might consider to be patient related concerns. Interviews also covered expert opinion of current guidelines and how these apply to current practice within their institution/organisation.

Interviews were conducted by telephone and digitally recorded and transcribed verbatim. To appeal to potential participants and increase participation rates, interviews were designed to take around 30 minutes to complete. However, this depended on an individual's role and remit in relation to clinical recordings. Interviews ranged from approx. 25 minutes to one hour. Additionally, some brief exploratory work was conducted among patient representative groups and 'patient advocate' representatives. These interviews explored what representatives perceived patient concerns might be around issues of consent, consent processes, and using and storing clinical images for non-clinical purposes.

A sampling frame was developed to ensure representation of different organisations, roles and professions from across different areas of the UK. Additional participants were identified by some interviewees as having a specific interest in the field. Twenty four telephone interviews were conducted and the sampling frame included interviews with a selected sample of leading experts from across a wide range of teaching institutions, healthcare organisations, image repositories and publishers, and patient representatives (e.g. patient and public involvement forums/patient councils/patient advocates).

The final sample included the following:

Role	Number of Participants
Medical Education	9
Medial Illustration	5
Publishing	4
Shared Resource	3
Vet Education	1
Patient Representative Group	2

Analyses of the interview data was facilitated by the use of the qualitative data package NVIVO. Analysis was conducted through the process of organising data according to 5 main themes: background of participants in using clinical images and recordings; guidelines; consent; data tracking, storage and access; future concerns in the field. A copy of the full report is available in Appendix C.

The main findings in relation to these themes are as follows:

- There is a great variety in the role of guidelines and policies to guide practice.
- The absence of internal policies was often justified through using common sense, consent forms and reference to external policies.
- Knowledge of external policies is variable, although GMC polices are perhaps the most influential.
- Most are satisfied with their own policy situation but many suggest that it is difficult to assess how well a policy is working when clinician practice can be challenging to influence or monitor.
- The consent form is the common element of the consent process across all participants.
- The consent forms are reflections of the wide variety of practices and range from broad general consent, to specific levels of consent relating to medical notes, education and publication.
- The level of consent for publication offers particular challenges with the rise of electronic publication
- Very few limits of time or geography exist
- Small informal data storage systems are common.
- The use of database management of images is growing in use.
- The more organised a system of storage is, the easier it is to manage access securely.
- The more organised a system of storage is, the more efficiently issues of withdrawing consent can be managed.
- Shared resources are appealing for many
- There would be a range of difficulties to overcome in relation to developing a successful shared resource
- National guidelines would be welcomed as a way to clarify practice and raise awareness about the issues around the non-clinical use of clinical images
- Future technologies are challenging the limits of policy and practice
- Future developments will need to address in rise of web based publishing, the increased transferability of information and the development of e-health.

5.4: Analysis of Current Practice

- The development of national guidelines would be welcomed but there is a need to strike a balance between facilitating practice and meeting professional needs, protecting patients' rights, and allowing local flexibility for specific local needs (particular patient groups or conditions).
- The development of shared resources are welcomed in principle, but the additional benefits of such a system would have to outweigh the concerns, and outweigh the appeal of local control over obtaining and using clinical recordings.
- Currently, the more removed an image/recording is from the original source (images being made available via an image repository), the less control or responsibility there is likely to be over consent procedures.
- There is a lack of critical reflection about the effectiveness or impact of local policies or guidelines: most people were generally satisfied with local procedures. However, utilising more stringent consent procedures placed more emphasis on protecting patient interests. Whereas, utilising blanket consent procedures more clearly benefited professional interests.

- Consent for publication is an area requiring further clarification and review. This should be informed by public/societal views.
- There is a lack of knowledge surrounding public/social attitudes to the use of clinical recordings. Therefore it is difficult to judge how well current practices address public/societal concerns.
- Despite guidelines practice is extremely varied, with blurred and individualistic interpretations of available regulations and guidelines the norm.
- Structured practice mostly stops at consent/acquisition. Subsequent tracking and regulation is infrequent and patchy.
- The GMC is the most often used reference point but cast as principles rather than steps for practice. Furthermore it is focused only on the responsibilities of doctors – whereas there are many people involved in the creation and use of CRANCS, many outside the clinical care context.
- Institutional guidance and information on procedures were very difficult to peruse both within the institution and as an external enquirer. Although this may in part be due to variations in practice across UK institutions, it is apparent that this is an area that is neglected by many institutions.
- Although there are some relatively common reference points there are no common frameworks or infrastructure for undertaking the appropriate steps to use and exchange CRANCS between settings.

6: CRANCS Lifecycle

Based on knowledge accumulated from our questionnaires and interviews it is possible to describe the variances in the processes associated with the acquisition and use of CRANCS in a lifecycle model comprising evaluation, acquisition, storage, usage, policy and community building, and maintenance and termination.

6.1: Evaluation of Recording Requirements

The first step is to assess whether explicit consent is required. The following abstracted scenario structures that process:

> *A [patient, animal] presents with an [interesting, typical] clinical case. Their [physician, dentist, other healthcare professional] decides that they wish to make one or more recordings. They also consider what they want to use the recording(s) for and what media will be employed. Based on the proposed recording(s), media and purposes they then evaluate whether explicit [written, verbal, other] consent is required against their local protocols. If consent is not required then they go ahead and acquire the recording. If it is required then the consent process is undertaken first.*

6.2: Acquisition

Having assessed the situation, the next step is to acquire the recording and consent if required:

> *The [physician, dentist, other healthcare professional] requests of the [patient, guardian, owner, other] that [images, video, audio, transcript of spoken words, other media] that are [used in the diagnostic process, made for educational/research purposes only, other, undefined] can be created for use in [limited, unlimited, undefined] [educational, research, both, other, undefined] purposes by [the physician, individual hospital staff, specific/generic students] and [limited to institution, state/region, country, international region, undefined] for [indefinitely, set period of time, undefined duration].*
>
> *Consent [is, is not] given [verbally, in writing, electronically, in another medium], which is recorded using [a paper pro forma, a letter, another form of paper-based record, an online system, audio/video recording, not recorded]. A copy [is, is not] [given to the patient, kept by the physician, kept in the patient's records, elsewhere in the institution, kept with the recordings].*
>
> *The recording is made [by the physician, by other clinical staff, by medical photographers, by third party individuals]. A copy [is, is not] [given to the patient, kept by the physician, kept in the patient's records, elsewhere in the institution, kept with the recordings].*

6.3: Storage

Having been created the recording and any associated metadata need to be stored:

> *The recordings are made and [retained locally in, transferred to] an [educational, research, audit, publishing] setting [physically, electronically, both]. The recordings are stored [physically, electronically offline, electronically online, admixture of these] [as single files, within a repository, within some other environment]. The consent conditions [are closely linked, loosely linked, unlinked] with the recordings [in the patient record, in an image archive, elsewhere].*

6.4: Usage

Having been acquired and stored the recordings may then be used:

> *The recording is made available to users [directly on their computer, on physical media (paper copy, CD-ROM), via a website or portal, via searching]. Accessing the recording [is, is not] recorded. Conditions of use [are, are not] made available with the recording. The recording is used for [teaching, research, website, VLE/LMS, individually or with others, other kinds of uses] and [is, is not] used within terms of use. This use [is, is not] recorded. The use is accessed by [just a few individuals, a body of users (such as a class of students), members of one or more professional communities, members of one or more institutions, subscribers to a service, anyone in the world]. The use [does, does not] result in the creation of a permanent artefact (such as a PowerPoint file).*

6.5: Policy and Community Building

The use of CRANCS is structured within community, institutional and sectoral policy frameworks:

> *[Personal, departmental, institutional, profession-specific, national] guidelines/frameworks [are, are not] available for use. [Personal, departmental, institutional, profession-specific, national] guidelines/frameworks [do, do not] meet [general, local, personal] needs. The acquisition and subsequent use of CRANCS [does, does not] follow [personal, departmental, institutional, profession-specific, national] guidelines/frameworks. Compliance with guidelines/frameworks [is, is not] policed and [is, is not] enforced.*

6.6: Maintenance and termination

> *The use and dissemination of CRANCS [is, is not] tracked. Freedom of information requests on the use of CRANCS [can, can not] be met. Withdrawal of consent requests [can, can not] be met. Match between actual use and terms of consent and copyright [can, can not] be monitored and enforced.*

7: Consent and Licensing Models

Having set out the issues and problems associated with using CRANCS, is it possible to develop a workable solution?

7.1: Consent

There are a number of factors regarding the use of CRANCS that need to be accommodated in any common framework:

- Informed consent needs to be acquired although further clarity is needed on the extent to which express consent is required for all recordings, either as a legal requirement or as a professional code of practice. What constitutes informed consent is unclear when the future uses and media are not specifically known, and changes in the use of a recording may require additional consent.
- The opportunity to acquire relevant images usually arises from patients' attendance at NHS services, predominantly a general practice surgery or hospital and the NHS also resources the acquisition of such images and claims copyright. With consent mages are transferred from the NHS to further or higher education institutions and seldom the other way. In the case of animals, it will usually be the veterinary surgeon providing care who arranges for images to be procured. Healthcare organisations are familiar with the legal framework and guidance around consent, confidentiality and use of health data. They currently not only have systems to obtain consent and file it in relevant patient records, they also undertake dissemination of information to explain to patients through booklets, posters and letters when and how data and images of them might be used.
- The terms of consent need to be provided with and attached to the recording so that they can be made available to any subsequent user.
- Without making available any personal information there needs to be a persistent and unique link between a recording and the identity of the patient who has given consent for the recording. This would provide an audit trail and a process for managing procedures such as withdrawal of consent.
- These procedures should be undertaken by all users of CRANCS to ensure a common basis for using and reusing them. As global implementation is unlikely in the short term, efforts should be made within specific communities to ensure adoption and use of common frameworks which could over time align to form a single framework.
- The acquisition of consent is not in itself sufficient as there are also aspects of ownership and conditions of use that are not found in the consent process and must be addressed in addition to it. It is nonetheless essential for any material that is identifiable and often advisable even when this is not the case.

7.2: Licensing

Licensing is in effect a form of contract between the provider and all subsequent users and it can encapsulate any conditions of use that the licensor wishes and the licensee agrees to. In this way both consent and copyrights can be managed together. While basic copyright is enshrined in national law (with variations between jurisdictions),

licensing, as a form of contract, can add or remove conditions from basic copyright and it can act as a common trans-jurisdictional rights framework.

Most published material is currently provided under specific licences, for instance the end-user licences (EULs) displayed when a software package is installed or a video played. The proliferation of licences with all their differences and potential contradictions has led in recent years to the creation of common licensing frameworks such as the Open Publication License (OPL) or the GNU Free Documentation License (GFDL). The GFDL was intended mainly as a license for software documentation, and the OPL is now largely defunct, and they have been superseded by Creative Commons (http://creativecommons.org). Creative Commons is based on just six basic CC licences, each of which is recast in the legal language of different jurisdictions worldwide. Although the wording of the full licenses is different in different jurisdictions the global conditions remain the same. This means that materials licensed under CC can be used under the same conditions anywhere in the world that has a CC licensing structure[23].

The CC system consists of the six licences, icons representing terms of use, metadata markers for online resource discovery and the many full jurisdiction-specific licences. These licenses all grant certain baseline rights, such as the right to distribute the copyrighted work on file sharing networks. The copyright holder has the option of specifying certain extra conditions[24]:

- Attribution (by): Permit others to copy, distribute, display, and perform the work and derivative works based upon it only if they give you credit.
- Non-commercial (nc): Permit others to copy, distribute, display, and perform the work and derivative works based upon it only for non-commercial purposes.
- No Derivative Works (nd): Permit others to copy, distribute, display and perform only verbatim copies of the work, but not derivative works based upon it.
- Share Alike (sa): Permit others to distribute derivative works only under a license identical to the license that governs your work.

The six CC licences are:

- Attribution Non-commercial No Derivatives (by-nc-nd)
- Attribution Non-commercial Share Alike (by-nc-sa)
- Attribution Non-commercial (by-nc)
- Attribution No Derivatives (by-nd)
- Attribution Share Alike (by-sa)
- Attribution (by)

Despite the growing popularity and evident simplicity of CC there are many critics of the system (Toth 2005). In addition there are many specific problems for its use with CRANCS:

- once granted, use is forever – this is contrary to data protection requiring use for no longer than necessary and is certainly contrary to any idea of withdrawal of consent and therefore use
- once granted, use is everywhere – this is potentially contrary to data protection which prohibits transfer of personal information outside the EU except where there are equivalent data protection regulations
- there is no concept of consent only copyright

There are few alternative frameworks to Creative Commons that can provide similar scope and simplicity (GFDL is for instance more limiting than CC) and other approaches, such as developing a standardised consent and licensing policy *de novo*, would be both more complex and run higher credibility risks.

Alternatives to a licensing model might be to improve practice through dissemination of current best practice and the principles of informed consent along with the promotion of a common consent form and process. The first two must certainly go hand in hand with longer term plans to create a common framework for the use of CRANCS and are to be supported for their simplicity and low-cost but they are unlikely to address many of the issues raised in this project.

As described above it is usually healthcare providers in an NHS setting who arrange for images to be recorded to support clinical management and/or for use in teaching and research and it is in the clinical setting that consent for future uses of images is sought, logged and stored in the patient record with a copy of the image. The patient's interests should best be served by keeping the consent process based with the healthcare provider. The NHS is expert at obtaining and safeguarding patient-identifiable data and images, is well-versed in the legal and professional requirements and has a duty and opportunity to explain to patients through personal and public information systems how their data and images might be used. The NHS also claims copyright of the images originating primarily for clinical care so for many reasons consent processes should not be moved outwith the NHS.

However when images are passed to institutions of Further and Higher Education, as they increasingly are to illustrate PowerPoint lecture slides and online teaching packages, there is a risk that the conditions of use are immediately lost. A paper copy of the consent form is likely to be the best source of information currently sent with an image but such practice is unwieldy with problems of storage and transfer and it risks making the image even more identifiable as the consent form is passed on to every system administrator. Institutions of education do not have a long tradition of storing such sensitive personal material amongst its learning resources and as seen in our interviews few staff could confidently explain where and how consent would be stored in their local education centre.

This simple model of consent travelling with the image fails to make apparent the conditions of consent to users so will do nothing to limit inappropriate copying, changing and use in other contexts. It also does little to improve recall of images. Without metadata, searching for a specific image recalled at a patient's request may be like looking for a needle in a haystack. The alternative would be complex logging of use attached to the education centre's copy of the consent form.

A simple system relying only on registered consent is less likely to be obvious to staff and students so risks being overlooked and not uniformly adopted; without protocol driven practice it will be very difficult to encourage all staff to safeguard patients' interests and without metadata there will be no obvious signal that teaching and assessment processes had been legitimately acquired and used.

The CHERRI Project has therefore developed the concept of 'Clinical Commons' to describe a licensing regime based on the simplicity and trans-jurisdictional nature of Creative Commons but accommodating the needs of the clinical community. Provisional discussions have taken place with Creative Commons and their affiliates in the UK but no definite decision or action has yet taken place. Despite this, there is precedent for adaptive models based on Creative Commons, for instance the 'Science Commons' that arose out of genetic research.

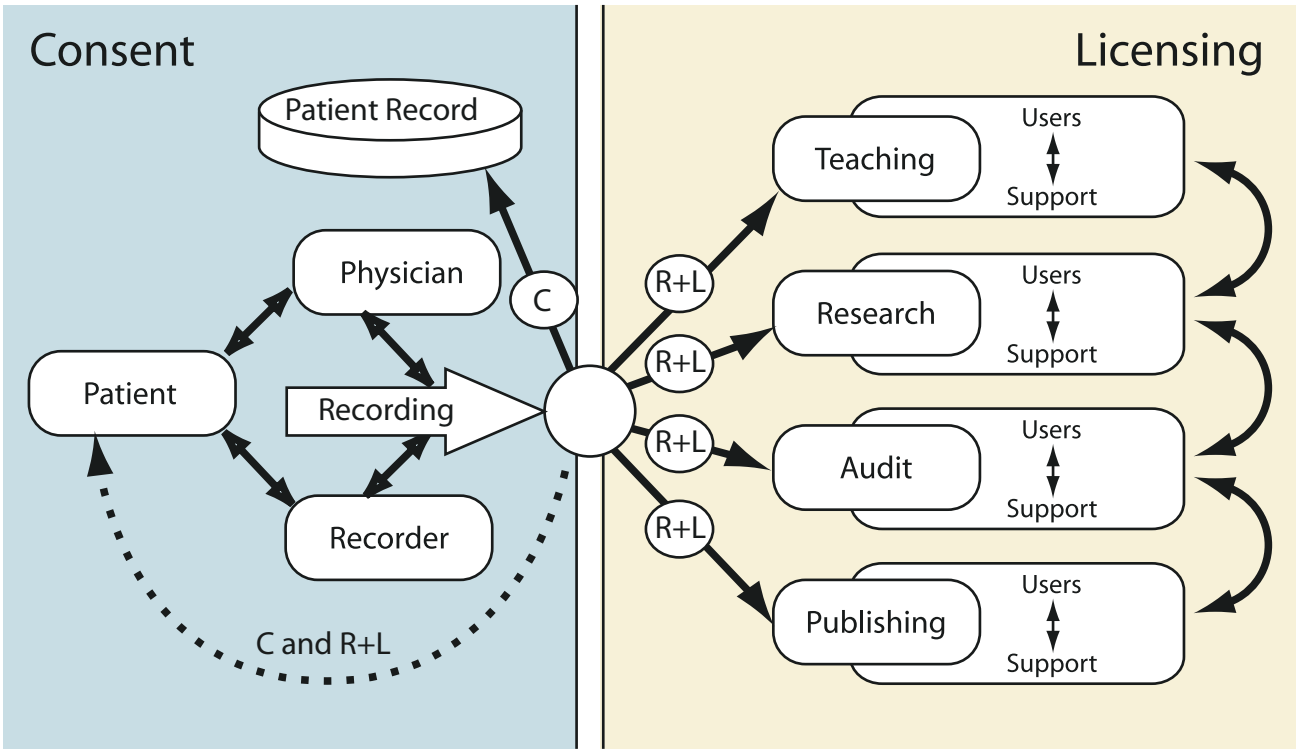


Figure 14: the CHERRI Consent and Licensing (C+L) Model. This illustrates a situation where a patient (possibly with their guardian or other family members) is seen by a physician who requests that a recording is taken. The consent is taken either by the physician or the recorder (who might be a medical photographer or the physician). A licence is drawn up and signed by a responsible staff member, regardless of the need for explicit consent and is made available along with the recording for non-clinical use. For images requiring explicit consent the licence is linked to the consent in perpetuity through use of a shared globally unique identifier (GUID) which encodes the identity of the patient and is maintained securely by the healthcare provider. The licence describes the copyright conditions along with either a declaration that consent is not required or a description of the conditions of consent. Within each use context there may be those who use the recording (such as teachers) or those who support users (such as technical staff). Because the recording and its licence (R+L) are not separated they can be passed from one use context to another with impunity as the conditions under which the recording can be used are known and expressed in a commonly understood format. In addition the consent (C), recording and/or licence can be entered into the patient record or made available to the patient.

8: CHERRI Consent and Licensing Model (C+LM)

The recommended procedure combines a consent and licensing step to create a properly consented resource that can then be released to the academic community and beyond with its conditions of use clearly described for all to see. This was in part a response to the way that the Health Education Assets Library (HEAL) works in the USA. Consent varies between states in the US but there is a single federal act that unifies all states with a set of procedures governing the transfer of personal patient information. This legislation is called HIPAA (Health Insurance Portability and Accountability Act of 1996 - www.hipaa.org) and HEAL requires all depositors to sign a HIPAA declaration that their materials have been properly consented. Thus the physician (or their proxy) undertakes the consent and takes responsibility for it by ensuring it follows HIPAA requirements. This effectively indemnifies HEAL against action regarding holding personal information in the form of clinical images.

This two-phase process encapsulates a number of steps:

- Consent evaluated, acquired and recorded along with recording
- Consent encoded in licence and the licence+recording is passed for use
- Licence stays with recording and outlines conditions under which it can be used (compliance dependent)
- Licence can be matched with original patient and their consent, thereby establishing an audit trail

Another way of looking at the C+LM is shown in figure 14:

The C+LM ensures that consent and the resulting documentation stays within the health service provider. Use of a persistent globally unique identifier (GUID) would be recorded on the licence and consent form so that they could be reconciled at a later date if required (for instance in support of withdrawal of consent).

The summative creation of such a licence would require a lot more effort and input than that available to CHERRI but the following factors should be considered:

- The four CC concepts of attribution, non-commercial, derivative works and share alike
- Limits on the duration of the licence (e.g. until 31 December 2015)
- Limits on the jurisdictions in which the license applies (e.g. Royal Infirmary of Newtown only or UK only)
- Limits on the scope of use (e.g. healthcare education only)
- Whether its scope included a recording's metadata (either created at the same time as the recording or subsequently added/augmented)

The CRANCS Lifecycle can be redrawn in the context of a common C+LM framework as follows:

- Evaluation: current guidelines on when consent is and is not required are commonly available to all healthcare practitioners, though further clarity on what constitutes 'non-identifiable' may be required.
- Acquisition: the acquisition of consent is structured to enable a common format for expression of the conditions of consent. The consent and copyright conditions are rendered in a commonly formatted

licence, which can be attached to the recording in different ways (depending on the form/medium of the recording). The licence and consent are given a common unique ID. The latter is stored in the patient record in a way that makes the licence ID subsequently searchable. The patient may also be given a copy of the recording, licence and/or consent.

- Storage: the recording is stored with its licence. This may take the form of an XML file (for instance in a DREL[25]) or database entry in a repository or equivalent system that allows the licence conditions to be exposed as part of a search for resources. In-recording licence marks such as icons, by-lines or other marks are part of the recording itself but not necessarily discoverable in a search. Access to CRANCS can be limited to users with suitable qualifications or recorded at the point of access. Metadata may also record different applications or uses of the CRANCS. The pairing of the CRANCS with its licence is supported by different storage systems.
- Usage: the CRANCS are made available to users along with the terms of use. Practitioners will refuse to use CRANCS that do not have an attached licence as lacking sufficient provenance. Artefacts created using CRANCS will display the conditions of use of all constituent CRANCS and the use of the artefact will be governed by the combined conditions of use of all CRANCS along with any licensing or restrictions associated with the artefact as a whole.
- Policy and Community Building: by instituting a common model for the use of CRANCS, all associated activity in different institutions, professions and sectors can be normalised (to some extent) and both patients and practitioners better supported and protected from inadvertent risk.
- Maintenance and Termination: by exposing licence metadata and using a persistent and trackable unique licence ID that has been paired with the patient record withdrawal requests can be more easily met, conditions of use monitored and accountability more clearly established.

9: Options

It is acknowledged that a root and branch move to a common way of handling CRANCS is a huge undertaking, encompassing as it does every NHS and educational institution in the UK along with associated publishers and agencies. CHERRI has been tasked to observe, analyse and recommend. It is clear therefore that the development and implementation of the CHERRI C+LM in the UK will require substantial further funding and buy-in from the major stakeholders.

In the end the question must be asked, who is actually going to do this and why would they bother? Well, current practice appears to fall short of the requirements of data protection; C+LM would help to bring the healthcare education sector back in line with the law while maintaining the continued utility of clinical recordings. In the absence of any common end-to-end framework the risks associated with poor and varying practice must be borne by all concerned.

9.1: Non-human CRANCS

Note that consent only covers humans. For veterinarian scenarios basic data protection principles apply for humans only. Thus, a recording that included an owner and/or other recognisable individuals would be covered whilst one of an animal (or animals) would not and simple(r) issues of copyright and ownership would apply. Having said that, it might not be unreasonable for veterinary education to follow a C+LM framework to better prepare for any future changes in law or the academic environment.

9.2: Tagging Recordings

There are a number of ways recordings could be tagged:

- Visual marks (images and video): this is some form of visible mark applied to a recording so that all users may clearly see it. Analogous to a film classification or quality ‘kite mark’ this would follow the Creative Commons icons denoting conditions of use.
- Audio marks (audio and video): the linearity of audio and video means that any audio mark would most likely be at the start and/or end of a sequence. This could assert the conditions of use verbally.
- Embedded metadata: this is where conditions are embedded at the data level of the recording. This can either take the form of digital watermarking or embedded metadata fields.
- Encryption: a file can be encrypted so that it can only be opened with the suitable digital key. Although this does offer a high degree of security (certainly in comparison with the other options) it is hard to manage in practice given the amount of effort associated with identifying appropriate users and then providing them with unlock keys. However as a file needs to be unencrypted to be used then it becomes vulnerable again in its unencrypted form.
- Associated licence or metadata file: this is where the licence conditions are encoded in a separate metadata file that is associated with but not intrinsically part of the artefact they describe. This may take the form of a formatted (e.g. XML) or plain text file or a database entry. It would be important to see whether current digital rights expression languages such as ODRL were able to represent both consent and IPR conditions of a clinical recording.

However getting round these would not be particularly complicated:

- Screen capture: this involves taking a computer snapshot of all or part of the desktop as an image. Thus anything that is displayed onscreen can be grabbed.
- Video capture: this is similar to screen grabbing but it records the desktop or particular windows over time, creating a new video file in the process. Stills, video clips and audio clips can subsequently be extracted and edited for use.
- Audio capture: similar again to screen grabbing, this involves recording desktop audio, which can then be edited for subsequent reuse.
- Physical rerecording: this is when the RGB output is recorded (for instance on a video recorder) or a camera or microphone records the computer itself.
- Editing and masking: all captured media can be edited and data edited, removed, masked or otherwise tampered with – pixel integrity is also an issue for some clinical recordings where there is a condition of use that the image not be changed in any way.

The tagging of recordings with a C+LM mark and/or metadata is clearly neither simple nor perfect; it would not be hard to remove or forge a C+LM licence mark and whilst watermarking technologies for images are improving they do not yet provide a robust form of protection. The C+LM approach is one of compliance and communitarian support rather than one of absolute protection and could not be relied on for protecting the use of CRANCS in any absolute sense. However any such system that did have a much higher level of robustness would also require levels of investment and implementation that are far beyond any practical options available to the health service or education sector. In this respect C+LM is proposed as being ‘good enough’, fit for purpose and commensurate with the risks and utility it provides.

10: Recommendations

- That all creators and users of CRANCS should be better educated and supported in the use of such recordings, and that this training and support is normalised as much as possible both for quality assurance and economies of scale purposes.
    - This requires that we challenge complacency about current practices in obtaining and recording consent, and in the use of images without knowledge that consent has been obtained.
    - Further work must be undertaken in consultation with the DOH/NHS, GMC, BMA, IMI & Royal Colleges, patient group representatives and other interested parties to develop a consensus view on recommendations for practice and the production of common national (and preferably international) guidelines and documentation for gaining consent for clinical recordings.
    - A 3 tier consent model and organised databases should be adopted pending further guidance, along with clear procedures for gaining consent, storage, sharing and withdrawal of clinical recordings.
    - Once national procedures and guidance are adopted, these should be publicised as widely as possible to professionals involved with CRANCS and also to the lay public. This will require adequate investment in appropriate training and in promoting the use of these guidelines.
- That guidance from the GMC and other professional bodies, on use of patient recordings for teaching and research should continue to be regularly updated to take account of changing public and societal attitudes and concerns about use of CRANCS. The situations requiring explicit consent may change over time and even now further clarification is required around consent for 'non-identifiable images'.
- That a common consent and license model for CRANCS is developed and adopted UK-wide (preferably in other jurisdictions although this would need to be explored further as to how practical it is).
- That any model adopted in the UK adheres to UK/European law and encompasses both consent and IPR dimensions of a recording.
- That the licensing model is based on Creative Commons and that this Clinical Commons is set up and run either by CC or a qualified UK agency. There is an issue of jurisdiction here. The most useful model would be truly international with local rendering (as per Creative Commons) and as such a trans-national organisation such as Creative Commons would seem to be the logical home. However, it may be that medico-legal concerns would require management of a C+LM framework to be at a national level and undertaken by a responsible NGO such as the NHS in the UK.
- That all CRANCS are tagged (potentially visibly) with a C+LM mark or icon to indicate its provenance and conditions of use. This icon should represent the different forms of use at a small enough resolution not to interfere with the recording.
- That practitioners refuse to use non-C+LM materials because they lack sufficient provenance and guarantee of patients' interests. This clearly illustrates the compliance rather than enforcement nature of the approach but the current environment and the availability of resources mean that an enforcement approach is impractical.

- That any central repository must adhere to the C+LM framework before any clinical materials are stored there. This combines issues of technical infrastructure, community-specific requirements and appropriate workflows. A national system like JORUM would need to accommodate the additional metadata, access controls and workflows associated with C+LM to safely store and supply access to CRANCS. This may indicate that separate systems will be required for CRANCS with access limited to healthcare education and its affiliates.
- That all relevant UK agencies (such as the GMC, NHS, legal groups etc) have input to and support the development of this common model and that steps are taken to develop the relationship between the NHS and the tertiary education sector (for instance by raising the profile of the NHS-HE Forum and making its work more transparent).

11: Conclusions

- Current practice is generally non-standardised and partial and in some instances, poor, thus creating risks and uncertainty for all concerned in the creation, use and reuse of CRANCS.
- There can be absolute safety only when consent is given for all images or when no CRANCS are made or used at all. Despite being 'safe' neither of these extreme positions is perfect. It is not possible to obtain consent for every recording (for instance in the case of non-accidental injury) and prohibiting the use of CRANCS for education and research is likely to have a detrimental effect on the competence of tomorrow's healthcare professionals. The needs of current and future patients must be considered but today's public opinion and legal climate lends more support to individual rights than the 'common good' and recommendations for use of CRANCS must reflect this.
- Guidance on consent must continue to be updated to reflect changing societal opinion, the law and public concerns about the use of CRANCS. It must continue to clarify for practitioners the reasonable expectations that patients have to be kept informed about the use of their images and when explicit consent is required.
- A common activity framework is required to support our current position regarding the use of CRANCS and should include a robust, simple to use and commonly acknowledged mechanism for handling consent with respect to clinical recordings is adopted across the UK.. Standardised practice is essential for any large-scale and dynamic exchange of these kinds of recordings. In its absence the continued use of CRANCS is creating risks and problems for both individuals and institutions and as a result their use and impact in education, training and assessment may dwindle.
- The CHERRI common consent and licensing model (C+LM) addresses the issues explored in this project and is based on simplicity of Creative Commons but seeks to accommodate specific clinical responsibilities and issues.
- The challenge now is to disseminate the proposal of a consent and licensing model (C&LM) and to develop this idea in consultation with key stakeholders towards implementation of a practical and efficient UK-wide process.

Project members will work for dissemination of the framework as widely as possible through professional networks such as the Scottish Deans' Medical Curriculum Group and the HE Academy Subject Centres and through linked JISC projects and services such as JORUM. The website will remain active for at least 3 years after the end of the Project and Project members intend to pursue further journal and conference dissemination activities. There also needs to be targeted consultation with key stakeholders in Further and Higher Education, the NHS, GMC and other professional bodies on how the proposal may be developed into a practical process.

Attention should also be paid to the variability in relationships between the NHS and HE partners throughout the UK since this will impact on implementation. While one medical or nursing school may have many staff embedded in their local hospitals and may indeed undertake CRANCS-related duties such as medical photography on behalf of the NHS, others may have more segregated or removed relationships. The amount of transparency between clinical service and education providers has long been an issue for both parties and a precursor to a

successful C+LM implementation might be better (or at least more transparent). As an example the NHS-HE forum (who have already expressed considerable interest in this project) could take on a greater dissemination and transparency role for both communities.

The framework for handling clinical recordings is essentially structured around the social, legal and professional requirements within which healthcare, education and research are situated. As these are subject to frequent change the framework may also need updating and alteration over time to retain relevance and currency. Identifying these circumstances and undertaking the work is not currently within the JISC's remit although it would seem perhaps to fall in part within the remits of both the GMC and the HE Academy. Arrangements will need to be made to monitor the situation and action adjustments over time as and when they are required.

Glossary

BMA: the British Medical Association – the professional body for doctors in the UK - www.bma.org.uk/

C+LM: consent plus licence model as developed by CHERRI

CETIS: Centre for Educational Technology Interoperability Standards – www.cetis.ac.uk

CHERRI: Common Healthcare Educational Recordings Reusability Infrastructure - Practice, Interoperability and Ethics

CHMS: UK Council of Heads of Medical Schools - www.chms.ac.uk

CRANCS: clinical recordings in academic non-clinical settings

DOH: UK Department of Health - www.dh.gov.uk

DP: data protection

DREL: digital rights expression language

FE: further education – generally the part of the UK tertiary education sector that provides qualifications up to but rarely including first degrees

GMC: the General Medical Council, the statutory regulatory body for medicine and medical education in the UK - www.gmc-uk.org

HE: Higher Education – generally the part of the UK tertiary education sector that provides first degree qualifications and higher as well as academic research. In the UK most HE institutions are universities.

HEAL: the online Health Education Assets Library - www.healcentral.org

IMI: the UK Institution for Medical Illustrators - www.imi.org.uk

IPR: intellectual property rights

JISC: The Joint Information Systems Committee provides the UK tertiary sector with a wide range of technology and associated services - www.jisc.ac.uk)

JORUM: the JISC-funded national learning object repository service – www.jorum.ac.uk

LTSN: the UK Learning and Teaching Support Network, merged into the UK Higher Education Academy in 2004. The LTSN-01 became the HE Academy Subject Centre for Medicine, Dentistry and Veterinary Medicine - www.medev.ac.uk

MedEdPortal: an online clinical education resource bank set up and run for American Association of Medical College's members - www.aamc.org/meded/mededportal/

NHS: the UK's National Health Service – www.nhs.uk

NLN: UK-based 'National Learning Network' providing an extensive bank of learning resources for UK FE - www.nln.ac.ukColleges and related institutions

PCT: Primary Care Trust

RCGP: UK Royal College of General Practitioners (equivalent to family doctors in North America) - www.rcgp.org.uk

XML: extensible markup language - www.w3.org/XML

References

Age of Legal Capacity (Scotland) Act 1991 (c.50). HMSO. Available online http://www.hmso.gov.uk/acts/acts1991/Ukpga_19910050_en_1.htm

Access to Health Records Act 1990 (c.23). HMSO. Available online http://www.opsi.gov.uk/acts/acts1990/Ukpga_19900023_en_1.htm

Addenbrooke's NHS Trust 2002. Photography and video recordings of patients: confidentiality and consent, copyright and storage. Policy and Procedure. Available online http://www.addenbrookes.org.uk/advice/medethlaw/photog_consent.html

Adults with Incapacity (Scotland) Act 2000. HMSO. Available online http://www.opsi.gov.uk/legislation/scotland/acts2000/20000004.htm

Bedford Hospitals NHS Trust 2005: Visual and Audio Recording on Hospital Premises. Contact details on website http://www.bedfordhospital.org.uk/index.asp

BMA 2004. Taking and using visual and audio images of patients: Guidance from the medical ethics department. Available from http://www.bma.org.uk/ap.nsf/Content/AVrecordings/$file/AV.pdf

Cardiff and Vale NHS Trust/Cardiff University 2005. Policy for making and using illustrative clinical records. Further information and contact details on website http://www.cardiff.ac.uk/schoolsanddivisions/divisions/insrv/mediaresources/information/clinicalphotography.html

Corti L 1999. Text, sound and videotape: the future of qualitative data in the global network. IASSIST Quarterly 23:2 pp18-25. Available from http://iassistdata.org/publications/iq/iq23/iqvol232corti.pdf

Data Protection Act 1998. HMSO. . Available online http://www.hmso.gov.uk/acts/acts1998/19980029.htm

DOH 1997. The Caldicott Committee: Report on the review of patient-identifiable information. Available online http://www.dh.gov.uk/assetRoot/04/06/84/04/04068404.pdf

DOH 2001a. Reference guide to consent for examination or treatment. Available online http://www.dh.gov.uk/assetRoot/04/01/90/79/04019079.pdf

DOH 2001b. Good practice in consent implementation guide: consent to examination or treatment. Available online http://www.dh.gov.uk/assetRoot/04/01/90/61/04019061.pdf

DOH 2003. Confidentiality: NHS Code of Practice. Available online http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf

DOH 2005. Records management: NHS code of practice consultation. Available online (accessed 17/12/05) http://www.dh.gov.uk/Consultations/ClosedConsultations/ClosedConsultationsArticle/fs/en?CONTENT_ID=4119931&chk=D1y2nX

Ellaway, R. 2004. "Modeling Virtual Patients and Virtual Cases." MELD – online at http://meld.medbiq.org/primers/virtual_patients_cases_ellaway.htm

Freedom of Information Act; 2000. HMSO. Available online http://www.hmso.gov.uk/acts/acts2000/20000036.htm

Gloucestershire Hospitals NHS Foundation Trust 2005. Photography and video recordings of patients: confidentiality and consent, copyright and storage (draft). Contact details on http://www.gloshospitals.org.uk/default.htm

GMC 1998. Seeking patients' consent: the ethical considerations. Available online http://www.gmc-uk.org/standards/consent.htm

GMC 2002. Making and using visual and audio recordings of patients. Available online http://www.gmc-uk.org/standards/AUD_VID.HTM

GMC 2004a. Confidentiality: protecting and providing information. Available online http://www.gmc-uk.org/guidance/library/confidentiality.asp

GMC 2004b. Confidentiality: protecting and providing information - Frequently Asked Questions. Online http://www.gmc-uk.org/guidance/library/confidentiality_faq.asp accessed 15/12/05

Great Ormond Street Hospital NHS Trust. Policy for making and using illustrative clinical records of patients. Reproduced in full in appendix D (with kind permission of Jeremy Naylor, Director of Medical Illustration).

HMSO 1984. Telecommunications Act. Available online http://www.ofcom.org.uk/static/archive/acts/act_ownpages/about_acts.htm#Telecommunications%20Act%201984

Hood C, Hope T, Dove P; 1998. Videos, photographs, and patient consent. BMJ 316:1009-1011. Available online http://bmj.bmjjournals.com/cgi/content/full/316/7136/1009

Human Rights Act 1998. HMSO. Available online http://www.hmso.gov.uk/acts/acts1998/19980042.htm

Information Commissioner's Office 2002. Use and disclosure of health data (p7). HMSO

Institute of Medical Illustrators website http://www.imi.org.uk/

Institute of Medical Illustrators 1998. A code of responsible practice - protocols for ethical conduct and legal compliance for medical illustrators. IMI.

Institute of Medical Illustrators 2002. Photography and video recordings of patients: confidentiality and consent, copyright and storage. Model policy and procedure. Available online http://www.imi.org.uk/imidocs/Model%20Consent.pdf

Institute of Medical Illustrators 2004a. Photography of non-accidental injuries. Available online http://www.imi.org.uk/guidelines/IMINatGuide-NAI-Nov2004.pdf

Institute of Medical Illustrators 2004b. Mole mapping photography. Available online http://www.imi.org.uk/guidelines/IMINatGuide-MoleMapping-Nov2004.pdf

International Committee of Medical Journal Editors 1995. Protection of patients' rights to privacy. BMJ 311:1272. Further information available online http://www.icmje.org/#privacy

Joint Committee for Postgraduate Training in General Practice 2002. Guidelines for videotaping of consultations. Available online http://www.nosa.org.uk/information/video/cogped/code.htm

LTSN-01 FAQ information on AV materials and consent; FAQ 2004. Available online http://www.ltsn-01.ac.uk/resources/faq/index_html?my_num=66#66

Mental Capacity Act 2005. HMSO. Available online http://www.opsi.gov.uk/acts/acts2005/20050009.htm

Norfolk and Norwich University Hospital NHS Trust 2004. The management of digital clinical images and video recordings. Available online http://www.nnuh.nhs.uk/viewTrustDoc.asp?ID=108

Royal College of Psychiatrists 1998. Guidance for videotaping. Available online http://www.rcpsych.ac.uk/publications/cr/council/cr65.pdf

Royal College of Radiologists 1998. Making the best use of a department of clinical radiology: Guidelines for doctors. Fourth edition.

Smith R 1998. Patients' consent for publication of information about them. bmj.com COPE (Committee on Publication Ethics) Report 1998. Available online http://bmj.bmjjournals.com/misc/cope/tex7.shtml

The Royal Liverpool Children's Inquiry Full Report 2001. Available online http://www.rlcinquiry.org.uk/download/index.htm

Tóth P 2005, Creative Humbug INDICARE Monitor Vol. 2, No. 4, online at http://www.indicare.org/tiki-read_article.php?articleId=118

University Hospital Birmingham NHS Foundation Trust 2003. Photographic and video recording consent and confidentiality policy. Available online http://www.uhb.nhs.uk/about/policies/policies/all_policies/20030505%20Photographic%20%20Video%20Consent%20Policy.pdf

University of California- Los Angeles. Consent for and authorization for release of photographs, films, medical images, and other multimedia for educational purposes. Available from smcintyre@mednet.ucla.edu

UCS01: Acquisition of a C+LM CRANCS

ID	UCS01
Title	Acquisition of a C+LM CRANCS
Players	Patient, physician, medical photographer
Assumptions	The hospital has adopted the C+LM organisation-wide
Description	A patient is attending a hospital out patient surgery where they are seen by the physician. The patient has a particularly exemplary clinical condition manifesting in physical signs of which the physician would like to take a recording for teaching purposes. The physician decides that consent is required to take the recordings and, by using the C+LM guidelines available within the hospital she requests the patient's consent in writing on a standard C+LM form against the criteria she wishes to be associated with the recording. The patient asks for clarification of what some of the terms mean and the physician is able to use the supporting C+LM guidance notes to assist in this process. Once the terms of use have been agreed they are then recorded on the form and the patient and physician both sign it. A copy of the form is given to the patient and a copy entered into the patient's record. The physician gets the attending medical photographer to take a number of images and gives them a second copy of the C+LM consent form. The medical photographer later downloads the images to their image database and creates the C+LM licence from the information on the consent form which involves adding a C+LM entry in the hospital's database and visually tagging the images with the appropriate C+LM icons. The recordings and their C+LM licences are then transferred by the medical photographer to the associated University medical virtual learning environment for the physician to pick up and incorporate into their teaching.
Transactions	Physician assesses consent requirements, physician and patient negotiate terms of use, physician and patient sign form, copy of form is given to the patient, copy of the form entered in the patient record, copy of form given to medical photographer, medical photographer creates recordings according to instructions, medical photographer creates new C+LM licence in hospital C+LM system, medical photographer adds appropriate C+LM icons to the recordings, medical photographer transfers recordings with associated licences to the associated university medical VLE.
Exceptions	Recording is non-identifiable and/or doesn't need consent. Physician takes on some of the roles of the medical photographer. Recordings and licences are 'pulled' across from the hospital system by university staff rather than being 'pushed' across by hospital staff.
CHERRI notes	The C+LM licence should be able to be generated from the C+LM consent form. A hospital C+LM database should simultaneously record the creation of a CRANCS and generate the necessary licence information and metadata. The visual tagging of CRANCS should be minimal and no more than sufficient to identify the conditions of use of a recording.

UCS02: Reusing a C+LM CRANCS

ID	UCS02
Title	Reusing a C+LM CRANCS
Players	Clinical tutor, learning technologist, student, coursework marker
Assumptions	All players are working within institutions that use C+LM
Description	A clinical tutor wishes to include a number of CRANCS in an online teaching package they are writing. The learning technologist they are working with reminds them that they need to ensure that all such recordings have C+LM clearance and that online use needs to be enabled for every recording used. The clinical tutor finds that less than a half of the recordings they intended to use have sufficient clearance or licences. They create a number of new recordings under the C+LM scheme to fill the blanks and acquire one from another colleague that is C+LM enabled. The learning technologist ensures that the C+LM icons and conditions are appropriately displayed both within the teaching package and its accompanying metadata. A student user of the completed teaching package wishes to use one of the CRANCS to illustrate an essay they are writing. They see that the conditions of use associated with the CRANCS permits its use for personal study and unsure whether that permits the recording's use in their coursework they check the C+LM help website to get clarification. They find that this includes use for individual student coursework and so they include it in their essay along with an appropriate citation of both the source and the C+LM details. The latter is a requirement of the course they are on and is duly noted by the marker for the coursework.
Transactions	Clinical tutor provides recordings, learning technologist reminds tutor of C+LM requirements, recordings are checked and a number discarded as not having C+LM licensing or appropriate conditions of use, new and replacement C+LM recordings are sought and obtained, learning technologist ensures C+LM licences and icons are in place, student uses completed teaching package and having identified a recording they want to reuse they check the C+LM terms and online guidance, student reuses recording and includes C+LM citation, coursework marker checks for presence of C+LM markers and citation with the image
Exceptions	Equivalent permissions for use of CRANCS are available by a different route or they did not need to be consented. Any of the players fail to be strict about every recording having a licence. Alternatives to CRANCS are developed (3D models or other non-photographic illustrations)
CHERRI notes	Compliance is indicated throughout this scenario; any one of the players could have failed to follow C+LM procedure and made inappropriately licensed materials available to subsequent users.

UCS03: Withdrawing a C+LM CRANCS from Use

ID	UCS03
Title	Withdrawing a C+LM CRANCS from Use
Players	Patient, GP, university administrator, learning technologists, clinical tutors
Assumptions	All players are working within institutions that use C+LM
Description	A patient decides a number of years after having given consent for a CRANCS video to be created that he wants to withdraw it from use. The patient approaches his GP and makes the request. The GP checks the patient's clinical record and finds the copy of the C+LM consent form which indicates which university the recording was first passed to. The GP sends a written request to the university's medical school to have the recording withdrawn from use citing the C+LM licence ID and a brief description of the video. The medical school administrator passes this request to the local senior learning technologist. The learning technologist looks the recording up using the C+LM ID on the local resources database. The recording has logged as having been used in two PowerPoint presentations and a Flash movie for clinical skills training. The learning technologist contacts the relevant tutors for the PowerPoint uses and requests that the recording be deleted from their collections. The video is removed from the VLE copy of the presentations by the local learning technologist. The clinical skills Flash animation has been shared with a second medical school and the learning technologist from the original school contacts the learning technologist at the second school and tells them the recording must be withdrawn. A (C+LM enabled) replacement is sourced in the second medical school and supplied to the first and a new copy of the animation with the replacement video redistributed. The learning technologist writes to the GP to confirm that they have taken steps to remove the video from use. The GP passes this information on to the patient.
Transactions	The patient requests withdrawal of the recording from use, the GP contacts the university, the request is passed to the learning technologist, the learning technologist checks for use of the recording and contacts users, having taken steps to ensure the recording is withdrawn from use the learning technologist communicates this to the patient's GP, the GP passes the information on to the patient
Exceptions	Different roles within different institutions Some uses of the recording have not been logged The GP cannot find the C+LM documentation in the patient's notes and has to follow alternative routes to request the recording is withdrawn Some third-party users do not action the request to withdraw use and continue to make use of the recording
CHERRI notes	Again compliance and end-to-end documentation is required.

Appendix B: Freedom of Information request to Caldicott Guardians

Dear colleague,

Re: CHERRI PROJECT (Common Healthcare Educational Recordings Reusability Infrastructure - Practice, Interoperability and Ethics) at www.cherri.mvm.ed.ac.uk funded by JISC (Joint Information Systems Committee at www.jisc.ac.uk)

I'm writing to all Caldicott Guardians with requests for information and feedback on behalf of the CHERRI project, which has been commissioned and funded by JISC to investigate and advise on the use of clinical photographs, x-rays, images, videos and audio recordings etc for non-clinical academic purposes such as teaching and training, research, and academic publishing. The project investigators include university and NHS & clinical staff and at the end of the project we expect to be able to report on guiding principles, as well as current practices and difficulties. These findings will be reported back to JISC and other national bodies to inform development and policy, and will also be disseminated to all study participants in due course.

1) Firstly, we would like to gather two specific types of information:

1a) Can you please send any guidelines, protocols and consent forms that guide your staff members when acquiring clinical images and recordings (and associated consent) for non-clinical academic purposes?

1b) Can you also please send the guidelines, protocols and forms that guide staff members on how to store, track and use clinical recordings for non-clinical academic purposes?

I'd be grateful if you could send this information to Rachel Ellaway either by email to Rachel.Ellaway@ed.ac.uk or by post to her address given at the foot of this message.

2) Secondly, we would like to invite you or a senior colleague involved with (or responsible for) acquiring and using clinical images and recordings for teaching, research or publishing, to complete an online questionnaire to give us information on current practices and difficulties.

The questionnaire is at http://www.surveymonkey.com/s.asp?u=668801300775 login using the password 'cherri' (note lower case, and not including quote marks)

3) Finally I'd be grateful if you could disseminate the URL for the questionnaire to members of your clinical staff, teaching staff and those working in associated hospitals, general practices and teaching institutions who are in any way involved in acquiring or using clinical images for non-clinical academic purposes, asking that they complete it online at http://www.surveymonkey.com/s.asp?u=668801300775 along with the login password 'cherri' (note lower case, and not including quote marks)

yours etc

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Background

Participants were asked to provide a description of their role and their involvement in the use of clinical images for non-clinical purposes. During this description, participants also frequently offered information about the history of the area of regulating the use of clinical images for non-clinical purposes. Each of these areas will be discussed in turn below.

Role and Involvement with Clinical Images for Non-clinical Purposes

Overall, the key roles included in this study included medical educators, medical illustrators, publishers, shared resource representatives, veterinarian education and patient representatives. Participants had a variety of involvement with the collection of clinical images for non-clinical purposes. Medical illustrators tended to source most images internally for both internal and external use. Many of the participants involved in medical or veterinarian education sourced images internally and only used them internally, particularly when images were used in relation to course assessment. For publishers and those involved in shared resources, it was most likely images were sourced externally and used internally for publishers, but externally for those providing shared resources. Patient representative organisations collected images internally and used them internally.

Historical Context

The increased ability for clinicians to be able to record, store and use images, particularly in a digital format, has played an important role in how the area of the non-clinical use of clinical images has evolved. Addenbrookes Medical Illustrators, in particular Martin Johns, has had an influential role in the move towards better regulation of consent, storage and access of images. Participants referred to the long-standing role of medical illustrators as working alongside clinicians in creating and managing clinical images.

The first policies guiding consent of different uses of clinical images came in 1986, and was spurred on by the 1984 Health Service Commissioner annual report, where it was stated that hospitals should have a consent policy regarding the different uses in clinical images in place. This period is significant, as pre 1984 images may have no consent associated with them at all.

> *We don't limit that but one of the problems is that we have a huge collection of images which precede our current consent policy so we have a lot of pre 1984 images that haven't been consented at all. P02 (Medical Illustrator)*

Challenges have been particularly important for developing this area. One type of challenge is an increase in patient awareness of images being taken and used. It has also become more common that patients may request to see images taken of them and not being satisfied with the outcome, particularly when the images cannot be located.

> *I've heard of several instances where the patient has gone back and said "a photographer took a picture of me, I'd like to see them". When they've investigated it's not been the medical illustration department that's taken them, it's been a clinician or somebody else, and they no longer have the picture they've deleted them or they've done whatever else with them, and they've not been able to produce them. P13 (Medical Illustrator)*

Another strong influence to the development of policies around consent has been organ retention scandals, which not only highlighted issues around consent, but opened enquires into the use of collected images as well.

> *Certainly we went through lots of work and lots of agonising over the organ retention scandal in this trust, we got involved as well because we were unearthing… we had some very sad cases of people who were finding out, because they were checking up if the hospital had retained organs. I had one case where a mother found out that photographs had been taken of her child who didn't live past a few days, photographs were taken and she had never known. She had no photographs of the child, and she didn't know that we had taken any. That's horrendous, I think that's horrific. P13 (Medical Illustrator)*

Some participants felt the organ retention scandals provided an important illustration of how society has changed, and how issues of consent needed to change with society in order to be relevant and responsive to public attitudes.

> *I do think that because society's changing we have to constantly review these guidelines and a lot of the rules that we work by are changing and have changed over recent years so when the Data Protection Act came in there was a big change there. Incidents like the Bristol heart babies and Alder Hey scandals have changed society's attitude to images well to patients and how they see the people that treat them and I think we have to be sensitive to that and realise that it's a very dangerous world to be in if you're not very careful about what you do with patient information. P02 (Medical Illustrator)*

There was a strong sense that a crisis will facilitate changes and developments in this area in the future too.

> *Yes so it's one of those things that take a crisis to make change and unfortunately rather like you know the sort of national crisis we've had in the health sector but have made such huge changes in the way that, for example, patient tissues have been the policies and practices with regard to patient tissues have changed. P02 (Medical Illustrator)*

Some felt a keen sense of fear of legal consequences of getting it wrong in this area, and in particular future scandals could reflect situations of today's actions and activities being judged against new standards which may emerge in the future.

> *The whole scandal was about judging what happened then by today's standards. Standards are different now. P13 (Medical Illustrator)*

Guidelines

Participants were asked to describe the guidelines that were important to their practice, including internal and external guidelines. They also discussed areas of specific local need and gave their perception as to how well their current approach works for guiding the collection of clinical images for non-clinical purposes.

Internal Guidelines

There was a great level of variety in relation to the existence of internal policies to guide the collection of clinical images for non-clinical purposes. Some respondents reported that they had no internal guidelines for obtaining, storing or accessing images. Often these respondents indicated that their practice did pay attention to the principles of consent, but that this was not formally reflected in any policy or guideline form. These respondents did have consent forms to facilitate the process of obtaining consent, but these were developed independent of guidelines. One participant referred to knowing the 'unwritten rules of consent'. There was great variety of the type of consent sought in this situation; with general all use consent being one extreme, and a particular level of consent being the other.

> *Well there are no formal guidelines here as such. Obviously over the last 25-ish years we know what the "unwritten rules" are regarding patient consent. P15 (Medical Illustrator)*

In contrast other participants described comprehensive internal policies with a focus on informed consent and three main levels of consent. This seems particularly the case for the medical illustrators in the study. The three levels of consent related to firstly, consent for the use of images on clinical notes, secondly, the use of images for teaching and thirdly, the use of images for publication. The third level of consent, relating to publishing, often also required that the specific publication the picture would be included in would be named in the consent process.

> *Yes we do have a photographic consent policy and copyright policy and that's combined and it advises staff not only if they're doing their own or if they're commissioning from us the procedures to go through and the levels of consent. We have three levels of consent A, B and C and A is for everything publication including web etc., B is for restricted teaching use and C is for consent for case notes only and whether they're doing it themselves or whether we're doing it everybody should follow this policy. P14 (Medical Illustrator)*

As part of the commitment to the policy or guideline some institutions provided reinforcement to staff of the key principles and requirements through staff induction and fostering an institutional commitment to the principles of consent.

> *The main guidelines that are drilled into everybody, no matter how many times a week, no matter how many years you've worked there, is everybody must understand confidentiality and consent. That's the most important thing at the end of the day. And if somebody doesn't get that consent form signed, then you are in trouble, basically. P11 (Publishing)*

In some circumstances practice was guided by both a University policy and a local NHS Trust policy, i.e. when a clinician is also teaching. These policies are not always consistent and some felt it was a clinician's responsibility to negotiate this.

> *I think to be honest again it's pretty much based on an assumption of process, that we… clearly clinicians come and teach in the medical school all the time and they use images in those lectures, it would be entirely wrong to say that the University is in any way checking that those images are properly consented, we're not asking to see that documentation, we're assuming that those people as responsible clinicians and holding academic contracts with the University are conforming to policy. P05 (Medical Education)*

The case of shared resources required different types of policies, that consider the way in which images may have been gathered externally and how they will go on to be used. Whilst one participant had a clear policy requiring the contributor to clarify the way in which consent was obtained, others did not have this policy.

> *Because we're not producing the content ourselves, it's probably slightly different. As I say… to be honest it's raised a question for me, whether that is something that we need to add to our quality assessment guidelines, about when a website uses images do we need to check, do further checks around consent. P20 (Shared Resource)'*

External Policies

The external policies which participants drew on to help guide their practice were diverse. The GMC guidelines were referred to frequently, as was guidance from the British Medical Association.

The main ones, the main guidelines at the moment are the GMC's which… a few years ago at the medical education committee we tried to "encourage", shall we say, all our clinical colleagues are for the use of recording patient information in a clinical or a non-clinical setting. So that is the main one that we adhere to. There is also the BMA, we've had their guidelines out as well, but as I say they are not very specific on what you can and cannot use. P04 (Medical Education)

For one participant international guidance was the most relevant, with reference to federal law of the United States. Other guidance came in the form of the Caldecott Report and from fellow medical illustrators.

You'll find it's very similar to other one's around the country because it was developed using, I think the Cambridge original consent policy and then within the West Midlands all the heads of departments across the West Midlands across all the Trusts tweaked it so that we were confident and then we took it back to our individual Trusts really on the recommendation that if you have doctors that are rotating around the region that they will actually get you know they will come across exactly the same policy so nobody can say well actually I didn't know about that and generally 80% of Trusts around are all using a similar policy. P14 (Medical Illustrator)

Participants also referred to UK specific legislation, particularly the Data Protection Act, as being a key external guideline for practice.

And the reason for that in particular is the Data Protection Act which says that data subjects i.e. the patients have the right to disclosure of all records that you keep on them and there was a case where (our organisation) was threatened with litigation because the patient had asked for their records and they got everything that was officially there but not a photograph which they knew they had had taken. P03 (Medical Illustrator)

Some participants indicated they thought there weren't any external policies in relation to the using clinical images for non-clinical purposes.

Not in terms of actual images, I don't think the GMC supplies anything particularly, it never has to me but I'm assuming they have the same kind of source but then they don't do much in the way of publications so they probably don't or may well not realise there are commercial sources out there selling pictures. P06 (Publishing)

Specific Local Need

Participants did generally indicate that guidelines needed to be responsive to local requirements this was of particular importance for those participants that worked with children.

Well there are a number of conflicting guidelines most of the guidelines say it concurs but there are some subtle differences. We're also because we're a children's hospital we found out that that other people's guidelines don't always suit our needs. For example some Trusts see many fewer children than we do because we're a children's hospital and they have rules which we couldn't possibly operate by. P02 (Medical Illustrator)

Other participants indicating specific local needs were people involved in publishing. In particular there was concern that failing to understand the nature of publishing and reprinting existing materials would have a serious impact on the area of medical publishing.

And I mean it's a continual problem and I think what we need to feel is our authors take it seriously and use all means at their disposal to meet the guidelines, but there is just a little bit of room for things like when you're doing new editions for existing books. Yes because I mean if one took some of these things literally scientific publishing, medical publishing would literally halt. P07 (Publishing)

How well do the guidelines work?

Despite the variety in the policies used internally, or referred to externally, most participants felt their own practices were satisfactory and working well. Some felt they would not be able to assess how well their own policy was working due to the absence of systems capable of monitoring the process of obtaining consent and using images. However, due to the satisfaction with the current level of policy regulation of practice this was not seen as an issue by one participant.

But if you say to what extent are we monitoring that and how sure are we that everyone is aware and conforming to practice then to be honest I don't know where we would find that data. It's like a lot of things, I think, we assume that it's happening pretty much unless it goes wrong, if we're not actually receiving as it were complaints and if it's not obviously broken then we're not aggressively trying to fix it, if you see what I mean. P05 (Medical Education)

Some respondents commented that despite being pleased with their policy it was very difficult to enforce the policy with some clinicians. This made it challenging for some to estimate how well their policy was working.

I think it's the only problems with it are actually implementation we have a policy and everybody has to sign up to it when they have their generic induction into the Trust when they say they will abide by the Trust's policies, but we're finding its difficult to actually get people to adhere to it. P14 (Medical Illustrator)

There was a general sense that how well a policy might be working would be defined through being challenged in the future, making it difficult again to assess how well the policy was working.

Well I hope so I suppose one never knows until it's challenged but I hope it's as robust as it can be. P02 (Medical Illustrator)

Guidelines Summary Points

- There is a great variety in the role of guidelines and policies to guide practice.
- The absence of internal policies was often justified through using common sense, consent forms and reference to external policies.
- Knowledge of external policies is variable, although GMC polices are perhaps the most influential.
- Most are satisfied with their own policy situation but many suggest that it is difficult to assess how well a policy is working when clinician practice can be challenging to influence or monitor.

Consent

Different levels of usage

For many participants, and particularly in the case of medical illustrators, they used a model which allows for three different levels of consent, which cover consent for images to be used in medical records, in teaching and for publication. Patients would be asked to sign to each level of consent they were satisfied with.

> *We ask for, there are three levels. We ask for patient-treatment only, so that is as part of the medical record. Then the second level is that plus teaching. By teaching, we really mean teaching to a healthcare audience, that's how we would define. Now that may be internal, but we would also assume that that would be external as well. So if somebody is going to a conference in Germany or something, there is consent for that so long as it is a healthcare audience. The third level is publication. Now, we require for publication, we don't ask for blanket consent for publication. We used to do that, in fact, but we've stopped doing that now. If people want to use images for publication then they have to tell us what publication it will be in as far as they can. P13 (Medical Illustrator)'*

Some participants aimed to achieve level two consent to offer flexibility for using images for teaching.

> *So we say to people normally try and get consent up to level two which is teaching for everything because you never know when a picture is going to be useful for teaching. But consent don't worry about until you know what you're writing. So if you're in the middle of writing a text book and you know what you're doing then you can send the patient and get the consent sorted out at the time. P03 (Medical Illustrator)*

There was some variation on how the issue of consent for publication was managed. Some participants felt that the rise of electronic publication could mean an image could be more widely available than implied by giving consent for one specific publication.

> *And these days, to be honest, there's very little point in differentiating between print and electronic publication. With the vast majority of journals going to some form of electronic delivery, once something is agreed for publication then basically it could be available anywhere. P15 (Medical Illustrator)*

Some participants still sought a blanket, or all use, consent from patients.

> *I think it's usually a blanket consent that's used. There is a form that's provided by publishers that we can use if it's very specifically for a book or something like that and it is slightly different. But I think again the system would operate largely on the basis of assumed and fairly broad consent to educational use. P05 (Medical Education)*

Some participants felt that blanket consent was satisfactory, and to manage multi-level consent would be too challenging or require too much time.

> *I certainly don't think we go into, when seeking an image and the current Trust form wouldn't allow that as I recall, we don't go into immense detail on every single potential type or variation on educational use, I think that could take a long time to do that for one thing. P05 (Medical Education)*

For some medical education or publication participants, consent related to a specific project, publication or assessment activity. The use of an image would be limited to this activity only, and further consent would be used for additional use.

> *And if we've got consent for that specific project and we want to use that item or that piece of literature or that media piece or that research item or whatever for something else, then we will go back to the family and say "we know you've given consent before, but we would like to use it for something else that will involve X, Y and Z this time; are you happy about this?" So we always make sure that they don't come across the unexpected, that they suddenly see themselves on a website or on the television that they didn't give consent for. P11 (Publishing)*

Some participants felt there were difficulties when multiple consent requirements came into play, through NHS trust and University guidelines being different. A further difficulty perceived with gaining specific consent was when the image was wanted for a different use in the future that was not originally consented for. This particular situation was seen to create some frustration for clinicians.

> *And that is sometimes limiting because you can't always find the patient again and I do publish books and I have slides that I would love to use in the book but I don't feel I can use an image with identifiable patients just on the basis of the consent I've had already. P05 (Medical Education)*

Process

The process of obtaining consent varied between participants, and ranged from seeking verbal consent to obtaining written consent. The process of obtaining consent for many was facilitated by the use of a consent form. In the case of institutions where medical illustrators might obtain the image, the consent process happened twice in some settings.

> *Nine times out of ten the patient will be asked verbally if they would consent to any one of the three levels. Most of the time the clinician will ask the patient but not always, so the photographer has to be prepared to do that as well. P15 (Medical Illustrator)*

The consent forms were stored in a variety of ways, and when medical illustrators where involved they would ensure they had one copy of the consent, and the clinician may keep a further copy.

> *Well we have a consent form which covers anybody in the Trust and they're required to clinicians requesting photography or video are required to complete that form and even if they're taking their own photographs or using their own video they still use the same form they fill a different section of it. It's the requestors responsibility to get that consent and to get informed consent to give information to the families and the family get a copy of that consent, one goes into the patients notes and we store one here. P02 (Medical Illustrator)*

Those in publishing or shared resources are further away from the process of consent in that images may be obtained externally. In this case it is mostly assumed that the original consent obtained is adequate.

> *They usually tell you if they haven't but it has to be assumed, otherwise the actual activity of buying pictures would take a lot longer because you'd have to apply for permission every single time. P06 (Publishing)*

Some participants felt they might improve upon the process of reviewing the reliability of consent.

> *Perhaps it should be part of our quality controls, that where images are used we should check that consent has been obtained. P20 (Shared Resource)*

The process is important, as is links to the ability to withdraw consent.

Limits of time

Only three of the participants had a limit for the length of time clinical images were consented for non-clinical use. The remaining had no time limit in place.

> *I think that once somebody has given consent for their image to be used, it doesn't actually say but I think we assume that we can use forever, so to speak. It may be eventually that we stop using that question for whatever reason, but you know, while that question is useable and the image is usable, we'll continue to use it. So no, we don't have a time limit. P17 (Medical Education)*

There was some sense that images became dated over time and that this would be a factor that would limit the use of images. For some participants the older the image was, the less concern there was about the consent given to use the image.

> *In fact I think we tend to assume that the older the images are the less concern these kind of things cause. When one of my colleagues, when my predecessor retired, …she left in her office a filing cabinet which was full of photographs and slides and many of those I've had digitised and I have no idea who the patients are in some cases, I don't know their names or whatever, I know nothing about them other than that the slides, they're very small numbers, are occasionally useful. P05 (Medical Education)*

However for other participants, the use of historic images was seen as being potentially more problematic due to the concern that images collected prior to 1984 would have no consent at all.

> *We don't limit that but one of the problems is that we have a huge collection of images which precede our current consent policy so we have a lot of pre 1984 images that haven't been consented at all. P02 (Medical Illustrator)*

One of the exceptions to this related to two participant involved in medical education, where internally sourced images were used specifically for course assessment. In this case, the use of an image was time limited to the completion of training. The other time limited example was due to legal limits in place by local government.

> *Another problem is that it's a permission for a specific period, 50 years in (one state), after that it's not valid any more and consent is automatically withdrawn. P01 (Shared Resource)*

A limit that did exist for some was the withdrawal of images if the patient has died, although it was acknowledged that this could only be regulated by individual clinicians.

> *We can't possibly police them all, but if we are using material featuring a particular elderly person we do try and check that that person is still living because it can cause tremendous distress to a relative who suddenly sees their dead loved one on the screen at lunchtime or at the teatime news. P16 (Publishing)*

Geographical limits

Participants were asked to describe any geographical limits that would be applied to the non-clinical use of a clinical image. Generally there was no geographical limits applied. There was however some geographical restriction implied when an

institution had a consent policy that covered the three different levels of potential use, being for clinical use, teaching and publication. It was acknowledged that these different levels of consent would have geographical implications, although with teaching that might be very widespread:

> *That's an area we need to address … I think we are probably going to make it a worldwide thing in connection with teaching and medicine and allied subjects because it's unworkable, otherwise the doctors turn round and say oh well I've got to go and do a talk in Australia or whatever and I must take these pictures. So we've just got to somehow work in the wording that limits it to medical and related subject teaching rather than geographical. P03 (Medical Illustrator)*

The level of consent associated with publication was seen to have the greatest impact on the potential geographical use of images.

> *As far as our policy is concerned again if somebody signs for publication all in total then it can go anywhere you know we have to point that out to our patients that could even mean the internet and do they understand that. Restricted education again we will point out that could be just the local doctors here but it could be that somebody goes off to an international conference in Australia and they take that image and they do understand that but it's a medical audience. P14 (Medical Illustrator)*

Issues of regulating clinicians

One finding that emerged very clearly, particularly amongst the participants working in a medical illustrator context, was that a major challenge in implementing consent policies was the regulation of clinicians.

> *For example I was working in the operating theatre about six months ago and there were some visitors from (abroad) who suddenly produced cameras and said oh can we take pictures of that. And you wonder where those pictures are going to end up. P03 (Medical Illustrator).*

One way to encourage clinicians to comply was to design systems for obtaining, storing and accessing images that facilitates better use of images, convenience and access to a wider range of images across an institution. One participant described how his department provided camera in theatre to facilitate the ease of obtaining images, but that were then by default able to be monitored by the illustration department. In particular some participants used a system called iBase and this system was seen to have appeal for clinicians.

> *Our sort of long-term plan for this system is that it will support not only the images we take, but it will support all the images that are taken within the trust. People will be able to upload anybody with the right sort of security rights will be able to upload clinical images into the system, and that will then attach the right meta-data to the images so that, in one stroke, all those difficulties and obstacles to managing the images once you've got them will be taken out the individual's hands and there will be a trust-wide solution to that. P13 (Medical Illustrator)*

Some participants felt that clinicians can resent policies being in place.

> *I think it's extremely difficult. I know for a fact that images are published still without consent, without our knowledge, under either the title of academic freedom or the necessity to publish research material, or through stated ignorance. Certainly it is difficult if not completely impossible to police it. All one can do is put down guidelines and make sure that people are aware of them. P15 (Medical Illustrator)*

Some of those involved in medical education and also working as clinicians indicated that complying to more comprehensive consent requirements would be costly and a compromise of consultant independence.

> *Well very difficult indeed, I think that's the basic problem, and it applies to lots of other things, it actually includes things like consent for clinical teaching in the first place, how do you keep track of it? You would need a massive administrative machinery to actually systematically track all of this. And it's only one of the things that you could argue to be totally defensible that we ought to be monitoring and logging and keeping track of and storing data systematically, and there's a huge cost there if we were to do it, and it's funding that we don't currently have. P05 (Medical Education)'*

Some institutions had a system of taking action against clinicians who did not comply with the local consent requirements through monitoring use of images and being able to issue warnings to non-compliant clinicians.

> *What happens then is a letter should go out from the risk department just to say Dr so and so you were seen taking photographs of Joe Bloggs during their operation and we would like to remind you that you must store these images in line with our consent policy and that you must obtain patient consent retrospectively. That is their first warning and again in theory two months later we can pull the notes and we can see whether the patient's case notes have had it entered that the photographs were taken by this particular doctor on this particular time and then if it isn't recorded in there and therefore if there's an audit trail we have some comeback. I have to say that's the theory which is great but seeing it actually happen in reality we don't know whether it will work but that's in place. P14 (Medical Illustrator)*

Consent Summary Points

- The consent form is the common element of the consent process across all participants.

- The consent forms are reflections of the wide variety of practices and range from broad general consent, to specific levels of consent relating to medical notes, education and publication.
- The level of consent for publication offers particular challenges with the rise of electronic publication
- Very few limits of time of geography exist

Data Storage, Tracking and Access

The balance between restriction vs. access

Participants were asked to offer their perception of how well the balance between restricting access to images and facilitating access to images was struck. Many felt the balance was very good regardless of how restrictive their guidelines were.

> *I think generally we're not really restricted. Generally I think we do get access to what we need. Yeah. I would say that on the whole we do, I can't really think of any problems. P17 (Medical Education)*

Some felt the issue of balancing access or restriction was best articulated by considering how well the balance protects patients. The following participant felt the balance was on the side of the patient and was appropriately so.

> *As far as I'm concerned a lot of the guidelines are in place to protect the fact that the patient should know what's happening to their images. That's a good thing. …I think that the underlying case should always be that the patient should know what's happening to their image. I would be horrified if any image of me or anyone I knew was used in an inappropriate way or in a way that we didn't know about. I think generally the balance is now more towards the patient's rights, and I think that is correct. P15 (Medical Illustrator)*

Some publishing respondents were concerned about the limitation impacting the area of publishing, particularly in relation to text book reprints or reprinting historic images. Other participants felt that the current policy and guideline context had moved too far on the side of restriction. It was felt this would be potentially detrimental for the field of medicine.

> *I think it's difficult. I think… in many ways I feel that we have almost gone too far. In respect of… you know medicine wouldn't be where it is today if you didn't have access to images. And, you know, many of those images… up until maybe 15, 20 years ago, you know, we didn't get consent for photography at all. P13 (Medical Illustrator)*

There were some participants who felt that the current balance did not achieve the right mix, and that guidelines needed to go further to achieve that. The areas of concern related to the use of the internet and the transfer of images though digital media or on laptops. Some felt concerned that clinicians would reject more restrictive guidelines.

> *I would like to have a higher level of consent. I would like it to be even clearer and even harder but… we tried that, and quite frankly the clinicians just turned round and revolted. I think the academic world tends to be a little bit more conscious of these issues, whereas the health world doesn't want to be bothered. P08 (Medical Education)*

Storage of and Access to Images

A variety of storage options were used by participants, and some of these options reflected the scale and nature of the work participants were involved in. Some referred to the literal physical storage of material, mostly this was organised fairly local or informally: These participants tended to be dealing with small volumes of images and access to the images was limited although informally arranged.

> *The old slides are on hanging-type of draw in plastic little wallets. The CDs are just in a pile, really! They're in locked areas. It's on a mainframe but nobody has access to them apart from us. Me and the two people who work in the office with me, just three of us in this office. We're the only people who have access to that information. .P17 (Medical Education)*

Another feature of informally stored images was the extension of sharing or reciprocation of images across professional networks.

> *We took the decision that we would make available to others who we know teach in the same field. We can make available those copies on request provided that the application is in writing and we also when we're sending out any of those emphasise in the covering letter that the images have only been granted consent for use for teaching within (our profession). P19 (Medical Education)*

Others used different databases to organise and retrieve images, including iBase. Different participants were in different stages of making a transition to a database organised system.

> *When we photograph a patient we acquire those images as a raw file which is a format, a proprietary raw format that you can't save back to and we archive those images, we archive them on DVD at the moment. And then we acquire them and we then convert them into a standard format a tiff format and we in fact we keep them in a database, catalogue them in a database as jpeg images. P02 (Medical Illustrator)'*

One of the advantages to having a database is the ability to give different levels of access to the images based on areas of work and levels of consent.

Anybody with the right sort of security rights will be able to upload clinical images into the system, and that will then attach the right meta-data to the images so that, in one stroke, all those difficulties and obstacles to managing the images once you've got them will be taken out the individual's hands and there will be a trust-wide solution to that. P13 (Medical Illustrator)

Despite having a volume of data, some still relied on paper based systems, which was described as less secure and less accessible by appropriate parties.

So at the moment (we) are still dealing with printed records. Now these are produced within the photographic department and then taken off to medical records where they are meant to be put in to patient's notes. Access to those patient notes is variable. Obviously they are carried around from ward to ward or department to department as necessary, and anybody who flicks through those notes can see that visible records. P15 (Medical Illustrator)

Across system types, access was also defined by the type of activity the images were collected for. In the case of course assessment the image might only be accessed by people involved in the assessment procedure.

Withdrawing Consent

The storage of and access to images has clear implications for addressing the situation of withdrawing consent. A number of participants were unsure how they would remove an image from use if a patient withdrew their consent for it to be used. This uncertainty about how to do this seemed related to issues with being able to physically locate and retrieve the image.

Now if consent was to be withdrawn, if somebody wanted to withdraw consent for the use of that image is that possible? If so, how would that followed-up? That's quite a tricky question, I think… I don't keep people's names, we don't hold people's name with the images at all. I wouldn't have it on the database. The only way I could probably track down the person is if I asked the person who their doctor was and then tried to track it back. P17 (Medical Education)

For some, there was a sense that there had been no requests to withdraw consent historically and whilst it would be theoretically possible to do so, it would be practically difficult or time consuming. In particular when individual informal systems of storage were in place the ability to withdraw the consent appeared to rely on how efficient the individual storage system was.

They would have to contact me and assuming that too many years haven't gone by, they presumably would be able to contact me through the hospital and if they wanted to withdraw their consent then yes, I would know which images were relevant because, as I say, they're held by me and individually regulated and I could simply withdraw them. P05 (Medical Education)

Some participants indicated that withdrawing consent in relation to an image being used for publication or education means there may be no way to withdraw the image. There was a sense that once an image was integrated into presentation materials it was less controllable.

And depending on where it's being used if it's just being used as a stand-alone resource from wherever it's referenced, we could just vanish it off all those references. But if it's in a Power-Point then that is another problem. P04 (Medical Education)

One institution made it clear on their consent from that withdrawing consent may not completely prevent the use of the image, particularly if they had given consent to publication.

In our consent forms … we have a statement to the effect (and not verbatim) 'at any time you can withdraw consent but to the extent that others are relying on or using your material you will not be able to completely withdraw or prevent usage of your materials'. So it is recognised that once it's out there with permissions it will spread, the owner of the health information cannot entirely rescind everything. P01 (Shared Resource)

When consent was withdrawn in relation to a shared resource this required a two stage process, of the resource being contacted by the original contributor to inform them that the consent was withdrawn.

We would expect that if the consent was withdrawn, we would expect the contributor to contact us and tell us that this was the case, and we would expect to have to return that image and make sure that it was deleted from the website. P12 (Shared Resource)

In contrast to the difficulties in withdrawing consent on small and informal storage systems, the use of a database facilitated a comparatively easy process of withdrawing consent. In particular the way in which consent information is attached to the image, and effects access to the image meant withdrawing consent was only a matter of changing the information about the image on the relevant database.

If the patient lets us know that they don't want their pictures to be used anymore then we will just change the consent level in the system and it would just automatically withdraw the pictures out. If someone has downloaded them that's too late we can't get them back and I don't know how we go about that but it's not a question that happens very often I have to say. P03 (Medical Illustrator)

Data Storage, Tracking and Access: Summary Points

- Small informal data storage systems are common.
- The use of database management of images is growing in use.
- The more organised a system of storage is, the easier it is to manage access securely.
- The more organised a system of storage is the more efficiently issues of withdrawing consent can be managed.

Looking Ahead

Shared resources

All of the participants in the study were aware of the existence of shared resources and had different experiences in relation to them, with some participants actually providing shared resources to others. Some had contact through either providing or sourcing images with a range of external sources. All were asked to reflect on the potential for developing a shared resource, including what types of concerns they would have with sharing images.

Many participants, particularly from medical education were positive about the potential of shared resources saving on replication, using resources effectively and enhancing teaching. Some referred to the use of resources through an international virtual medical school, including virtual patients, as offering huge benefit for medical education.

> *To me I can see no point in others having to reinvent the wheel and if there is a perfectly good teaching resource available I don't see any reason why it shouldn't be used rather than everybody having to make their own. Particularly given how much hard work it is to actually produce a decent recording of any treatment procedure. P19 (Medical Education)*

Many felt that to be successful, a common code of practice and guidelines (including around the issues of consent) would need to be agreed to facilitate consistent materials that people would feel comfortable to contribute and to access.

> *Say ten institutions wanted to do the sharing stuff it would mean drawing up some kind of code which would then be built into… it would get known, it would be built into part of any images taken and the releases in there. So I think it would just be a rewriting of the way it's done and it would be much better because everybody would know the same code exists including the patients. So I think it's a great idea. P06 (Publishing)*

Even some who supported the idea of having a shared resource were clear that it would only work for them if there was a clear sense of a reciprocation of images or materials.

> *The only major irritation or gripe I have is that I resent sharing images with people who aren't prepared to reciprocate. P19 (Medical Education)*

Some participants indicated that having a shared resource would be practically difficult, and one reason for this would be a sense of ownership of images amongst academics limiting sharing of images internally or externally.

> *One of the great things I've found out of my career … is there's a great thing called the not invented here syndrome and most doctors don't like teaching with cases that they don't know. And that's tended to be the dominant thinking that I've had as a result of that and knowing that, if you put stuff into (a shared resource it) is almost never going to go, I suspect, to other doctors to teach with. P03 (Medical Illustrator)*

Some participants reflected on the logistical difficulties that might arise from sharing resources. This included the different ways in which institutions may need to use resources in way that reflects different approaches to teaching.

> *The other thing is, it's amazing how each institution has a different slant, has a different want-list, a different wish-list. We are problem based learning, we do community practice from the very first week with our students, we do clinical skills and end-of-life sciences from the very first week with our students. Therefore our needs are quite different from the needs of, I don't know, (other institutions). P08 (Medical Education)*

There was sense of fear that emerged from many participants about getting consent in legally and ethnically appropriate ways. Some felt this sense of fear may negatively impact the potential for sharing resources.

> *Everyone is getting very twitchy about consent and confidentiality and with the Data Protection Act it's just frightening these days. And that may well be the killing thing for publicly shared stuff or widely academically shared stuff. P03 (Medical Illustrator)*

National guidelines

Many participants were enthusiastic about the idea of having national guidelines about the non-clinical use of clinical images. Some were concerned that guidelines would need to be easily workable in order to be successful.

> *I mean it would be sensible to have one common policy across the whole of the UK so that again people who are starting out trying to make these resources don't have to either try and write their own guideline or try and adapt something from somewhere else provided it doesn't impose undue restrictions on the ability to be able to make this sort of material. What I wouldn't want us to get into the same situation is the recent changes in ethical approval that make certain research trials almost impossible to establish. P19 (Medical Education)*

Some felt that national guidelines could help to clarify contradictions in current practice or guidelines. They may also have a positive impact in increasing the awareness of clinicians by providing a clear consistent message about best practice.

> *One additional benefit of national guidelines would that this could be used to educate and inform the clinicians, the people actually requesting pictures and using them. As you mentioned a few minutes ago, there is this concept or train of thought in some clinicians (although it is changing) that a picture that they've taken of a patient is their property and they can do whatever they want with it. That is changing but it is still around in some cases. This whole concept of thinking before use and making sure that things are properly regulated and national guidelines are adhered to is, I think, very important. I think that if national guidelines were drawn up … then that would be a great help. I know there are guidelines, but there is no one body or one group saying "there are now recognised national guidelines and you will adhere to these". It's too woolly still. P15 (Medical Illustrator)*

Participants expressed that there is an increasing need for practice to become more consistent across institutions and national guidelines might play a role in this happening. However some felt it would be very challenging to achieve consistency between institutions due to the variety of interests across institutions. One suggestion for making guidelines work well would be to provide illustrative examples of how the principle would apply across institutions and interests.

> *I think the principles need to be very clearly stated and then perhaps there needs to be some kind of appendix about common scenarios that happen, but covering all possible eventualities is really quite difficult. As I say I have a slide of a baby which is from about 30 years ago, a baby being treated for kidney failure, I've no idea who the baby is and I have no consent for using it, should I use that? There's all kinds of different scenarios that can crop up. P05 (Medical Education)*

There were a number of suggestions for making nation guidelines appealing, and these included building on the existing strengths of the guidelines that are currently available. A further point would be to ensure that guidelines would be able to have a local application, being responsive to local issues or needs.

> *If there were guidelines that people could adhere to and not bring in local issues, that would be the only drawback. But if there were guidelines where you could have a consent form, the letter of the law in layman's terms, that you could just download and distribute around your institution and then amend the consent forms to fit in with your local trust's requirements, for example. But if you had to stick to it as it was published online as a national requirement, that might cause a few problems. P04 (Medical Education)*

There was some level of concern that producing guidelines would potentially lead to over regulation which may become too restrictive.

> *I mean again speaking entirely personally I'm rather against over regulation in that it's right that there's a degree of sensitivity over all this and to really come up with a set of guidelines that cover all eventualities would be so complicated and potentially so restrictive that I think it would be very, very hard. P07 (Publishing)*

Some participants felt that the concept of copyright could also be useful, or might be integrated to the guidelines around use of clinical images for non-clinical purposes.

> *We do have, I do have a lot of requests for use of pictures that we've used because a lot of people who aren't in this business don't understand about copyright in the first place, and they think that if it's in the (our publication) it's ours and it's just not true, three-quarters of the stuff we have used is not our copyright anyway. P06 (Publishing)*

There was also some indication that the general principles of the guideline should aim to encourage empathy to patient perspectives in order to be effective, including making clear the consequences for patients if guidelines are not followed.

> *I believe that the people who are using those images need guidelines, but they also need digestible guidelines that they can work around rather than great screeds of contractual stuff. I think they need teaching; people need teaching about the possible ramifications. I think that if you work in a hospital all the time as a practitioner, it may be that you sort of perhaps… I don't know… have a different viewpoint from the patient who may be sort of deeply affected by any usage of the image if they knew it was happening. I mean, it's the same way as the whole body-part debate has developed, I think there is a connection' it's not quite the same, but there is a connection. P12 (Shared Resource)*

Future concerns

Overall there was a clear sense that technology makes the issues around non-clinical use of clinical images simultaneously harder and easier. Each aspect of technology that offered an advance in the field came with its own issues around increasing access and therefore increasing risk. One example of this was the ability for photo imaging to be associated to new devices, such as mobile phones.

> *There are all sorts of scenarios where distance communication with images may become necessary. You can't always either present that as a concept to the patient right at the beginning nor go back afterwards. I think there could be quite a number of scenarios where this would fall down and images could be seen in inappropriate circumstances quite easily. I suppose that's a very long way of saying "no". P15 (Medical Illustrator)*

There was a general sense that the field is unprepared for the impact of new technologies, and that with technology progressing at the rate it is, there will be new advancements to adapt policies and guidelines to come.

I think it's frightening, to be honest. The more technology progresses, and it's progressed an awful lot in the last 10 years and is progressing every day. Even such things as sending an email with an attachment of an image because that is how we send images to people, even internally to people within our organisation since email evolved. I think it's frightening that they could be intercepted and anything could be had from somewhere these days, digitally, electronically, technologically. And it's quite worrying, yes, what's going on out there and who's thinking up new ideas for getting information. P11 (Publishing)

There was also concern that there was change in society expectations of free information being available for the access for all, with a sense of a type of 'Google' mentality to the searching and retrieval of information. However on the other hand, some felt that the increased access offered by technology would also result in easier control and tracking of how images are accessed and used.

Well I only hope that emerging technologies will make it easier for us to control things, for us to track things. I'm not talking about Big Brother here, I'm just talking about people's usage being recorded so that people are aware that there are controls in place, automatic controls in place that are protecting the patient's rights and the copyright holder's rights, and at the same time helping people use those images for learning.P12 (Shared Resource)

The rise of e-health has lead to new technologies in telephone and electronic consultations, as illustrated by the forthcoming NPFIT NHS system. In some ways the concerns here relate to how clinical information is collected and accessed, however participants noted the potential for similar issues in non-clinical settings.

I think the idea that there have been patients being able to talk to doctors several miles away down these video links. Patients in remote areas having their images shared with a consultant in a hospital, I can see that they might be concerned how that image might then go on to be used, maybe for teaching purposes or whatever. … But I think there could be issues like that with more tele-consultations that are going on where you've given your image for a diagnosis but in fact it's going to be used down the other end to be fed into a research project or some lecture that the consultant's going to give a year later at a college of experts. P16 (Publishing)

One issue arising from the increased accessibility and transferability of images was the concern that national guidelines may not be enough, as the area will evolve to having more international concerns. One example of this is the offer of images for sale from countries where the process of consent may not be clear to people being offered images.

There was a gentleman who sent emails all round every hospital he could find not long ago from India saying I've got all these pictures you can have them for a dollar a time and you go to his website and there's all sorts of horrible head injuries and things with knives sticking out of them and all sorts of ghastly things. P03 (Medical Illustrator)

Looking Ahead Summary Points

- Shared resources are appealing for many
- There would be a range of difficulties to overcome in relation to developing a successful shared resource
- National guidelines would be welcomed as a way to clarify practice and raise awareness about the issues around the non-clinical use of clinical images
- Future technologies are challenging the limits of policy and practice
- Future developments will need to address the rise of web-based publishing, the increased transferability of information and the development of e-health.

Discussion

A historical context of crises and fear has influenced attitudes and practices

The area of the non-clinical use of clinical images has an interesting and dynamic history. At the core of this history is the role of crises, such as organ retention scandals, which have facilitated concentrated periods of activity and advancement in policy and practice. One implication of this history is that there is a sense of fear or anticipation of the next crisis or scandal that will play a formative role in future development in the area. This had led to a sense of concern about 'getting it right' in relation to how images are used for non-clinical purposes.

Social attitudes play a key role defining appropriate use of clinical images

A further consequence to the crises has been a rise in public awareness of how images or information might be used, as well as a change in social attitudes about what kinds of uses are acceptable. There was a sense that it was difficult to judge how well current practices were up to date with social attitudes.

Internal guidelines vary from the informal through to the comprehensive

There is great variety in the guidelines that were developed for internal use. At the very least, there was the use of 'common sense' and consent forms as the only guiding principles for practice. Given the historical context of the area it seems unlikely that common sense alone would be able to assess public attitudes with the accuracy required to prevent further crises. At the other extreme comprehensive internal policies were in place, and many of these were reported to be adaptations of the Addenbrookes policy and generally reflected the position of the medial illustrators. These polices typically reflected a three tier consent, with consent to use in medical records, for teaching and for named publications.

Inventive strategies are required to address clinical resistance to guidelines

Where comprehensive guidelines existed there was extensive reflection on the difficulties associated with achieving compliance with the policies. A range of inventive strategies were in place to support this, and included providing cameras, displaying posters, whistle blowing procedures, staff education. Policies did not always integrate well with other contexts, and clinicians working in one institution but teaching in another often found it difficult to know what the best practice was. It was also important that policies were able to be responsive to local needs, such as working with children. This has important implications for thinking about how the development of national guidelines can have relevance.

Issues of consent have not been well addressed by some shared resources

In the case of some of those representing shared resources there was an alarming lack of guidance about the consent processes relating to images provided to the resource. Some were clearly challenged by answering questions around consent and indicated they may include consent guidance in their future internal guidelines.

External guidelines were used and the GMC was particularly influential

External guidelines were particularly important for those who did not have internal policies, however a range of external policies were referred to by many in the study. The GMC guidelines were clearly the most well known policies and carried a clear sense of authority. Other guidelines such as the BMA were also seen as important. The concern for legal guidelines was also clear with frequent reference to the data protection act.

There is a lack of critical reflection about the effectiveness of guidelines

Despite the range of practice identified in this study, there was a general sense of satisfaction about how local policies were working. This suggests that the benefits offered by having limited or no local policy, were useful for participants. In some senses, blanket consent for all use works very well for the professionals involved in using images, however it illustrates that it is far more difficult to reflect on how well a policy works for those that are having their image taken. The three tier consent policies clearly work in the interests of patients more, and the institutions using this policy appeared more open to reflect on the short comings of their policies, such as, the ability to respond to issues of geographical use in relation to images published on the internet. This indicates that offering emphasis on patient rights in policies allows policy to be robust enough to facilitate critical review of ones own practices.

Guidelines shape consent practices

It is clear that guidelines had a significant impact on practice. The way in which consent was negotiated was clearly related to the guidelines of an institution. The more flexible the guideline, the more likely blanket consent was used. For the institutions using a three tier consent guideline, consent forms reflected this and in some cases may be discussed with a patient by a clinician and by a medical illustrator.

Consent for publication is an area requiring further clarification and review

Under the three-tier system consent for the third level, publication, was seen as an area of contention. Some felt having to name the publication was too restrictive, others felt that even naming the publication was not going far enough given how patients might be unaware of the potential distribution of electronic publishing. This area of consent could benefit from further review, and indeed taking time to become clear about patient and societal views on this issue could be informative.

The consent form facilitates consent and links patients to their images

Consent was sought usually through the introduction of a consent form. This consent data was not always kept with images, but was more likely to continue to be associated with the image where more formal systems of organising storage of and access to data existed. Additionally there may be little incentive for institutions obtaining blanket consent to keep consent forms attached to images as blanket usage has been assumed. Limits of time or geography of use were almost never given for any type of consent.

Inefficient storage systems compromise the ability to withdraw consent

Reflecting the variety of types of guidelines, the ways in which images were stored, tracked and accessed also varied tremendously. Systems were as informal as being a folder on a hard drive or a locked cabinet through to sophisticated database driven systems. The value of having an organised database was clear when considering the potential of an individual withdrawing consent for an image. A system that was searchable and maintained associated information regarding consent could easily respond to requests to withdraw consent. Where informal systems were in place dealing with a request to withdraw consent would be dealt with in terms of the limitations of such a system. The implications of this are that it would be theoretically possible but potentially unlikely to retrieve the appropriate image. This would appear to highlight an area in which much clearer guidance would be appropriate.

Formal systems can facilitate appropriate levels of access to images

The level of access to images again reflected the complexity of the system used to store images. Informal systems promoted informal, locally driven access. Formal systems such as databases could allow for restricted access on the grounds of level of consent obtained, the role, interests and departmental affiliation of the person accessing the image. This appeared superior in terms of regulating appropriate and secure access.

There is a lack of critical review of how images are stored and accessed

Most were very happy with the level of access to images, and felt the right balance was struck between access and restriction. Again, however, this may be a better indication of how well the system works for professionals rather than working to protect patients. Given the great variety in storage options it is surprising such a uniform satisfaction was present.

There is enthusiasm for shared resources, although practical challenges

There is an enthusiasm for developing shared resources, even though a number of issues were identified in relation to how successful this might be. If a shared resource was developed with stringent guidelines, along the three tier model, it is possible this system would need to offer significant benefits which overcome the appeal of small, informal and flexible systems currently in place. Whilst it may be logistically possible and theoretically appealing to share resources there were concerns about how this would suit the needs of institutions and individuals in teaching. In particular there was a sense that clinicians prefer to teach from cases they know and that institutions may have styles of learning which would limit sharing.

There is a genuine need for clear, illustrative, national guidelines

There appears to be a genuine need for national guidelines on the use of clinical recordings for non-clinical purposes. The range of relatively informal practices, including the use of ‘common sense’ and consent forms in the absence of guidance, indicates the need for clear guidelines. However guidelines would need to be locally relevant and responsive to specific needs, such as working with vulnerable populations. Some felt illustrative examples would be very helpful and would work towards increasing education and awareness of the issues involved.

Future technology offers benefits and challenges in combination

Technology offers future challenges to the area of non-clinical use of clinical images. In an area in which technology has had a great impact and has developed at pace there is concern about what the future holds. All technological advancements have offered improvements and challenges in combination. This highlights the need for regular review in order to maximise on the benefits technology brings, whilst minimizing the challenges each development brings.

Appendix C-A: Qualitative semi-structured interview schedule

Thank you for agreeing to take part in this study. Just to re-cap, we are particularly interested in how clinical recordings are used for non clinical purposes, such as for teaching, publishing, research etc. We are not hoping to capture right or wrong answers, but interested in finding out about different practices across different organisations, and exploring your thoughts and learning from your experience of this complex area.

Background Current role Current involvement with clinical recordings for non clinical purposes How clinical recordings are used i.e. are they used internally, externally…	Making sure we are talking to the right person Setting the scene for the interview
Theme: Guidelines What are the key guidelines you use to guide issues around consent and storage of clinical recordings? Internal/external If none, would they like some Are there any disadvantages or advantages of this current level of guidance	What do they currently say they do, and what guides that.
Theme: Consent What uses do you get consent for? Identifiable? Non-identifiable? And what else does consent cover? How do you get consent? Limits of time and/or geography How well do you feel current practices/guidelines strike a balance between restriction and access?	What happens between the guideline and the practice, are there specific issues in realising the requirements.
Theme: Data Storage, Tracking and Access How are they stored, who has access? Can the use of images be tracked? How are images accessed and under what restrictions? Can consent be withdrawn and how would this be followed through? What system would be ideal? How achievable is this?	Again, this is concerned with what happens between the guideline and the practice: are the requirements adhered to? What areas/issues are problematic in realising the requirements. How are recordings stored, accessed and tracked
Theme: Looking Ahead What do you think about sharing resources? (Resources meaning clinical recordings for non-clinical use). To what extent would you be willing to share resources? What might your concerns be? What might encourage this? What would you think about having a national/standard guideline? What would be the advantages/disadvantages of applying national guidelines in your local area? Any concerns for the future of this area? Do you think that current guidelines adequately cover situations which may arise through emerging technologies? Are we prepared for the future? Any comments in general?	Thinking ahead, how well will current guidelines stand with new developments.

Appendix C-B: Introduction Letter

Dear Colleague,

This letter is to inform you about the "Common Healthcare Educational Recordings Reusability Infrastructure – Practice, Interoperability and Ethics" (CHERRI) initiative being led by the University of Edinburgh on behalf of the Joint Information Systems Committee (JISC – www.jisc.ac.uk). This study is part of a review of consent issues and processes relating to the secure deposit, sharing and reuse of clinical recordings for non-clinical purposes such as teaching and research. It is hoped that the results of this study will inform the development of shared resources of such recordings, and for creating national and institutional guidelines and policy relating to patient recordings used for non-clinical purposes.

We are contacting you to ask if you would be interested in taking part in the research. You have been approached because you are seen as having a key role within your institution relating to the use of clinical recordings for non-clinical purposes. This study will involve taking part in one telephone interview lasting approximately 30 minutes at a time convenient to you.

Throughout the study the information given to the researchers will be treated in strictest confidence. Only the researchers will have direct access to the information, and your opinions and the expressed views of your institution will remain anonymous.

We have also provided the attached information sheet to provide further information about the study. Our researchers, Rebekah Pratt or Margaret Maxwell, will contact you shortly to answer any questions you may have and to ask if you would be willing to take part.

We would be most grateful for your help in this matter.

Yours sincerely,

Dr Michael Ross

Appendix C-C: Information Sheet

Information Sheet: CHERRI Research Project

Title: “Common Healthcare Educational Recordings Reusability Infrastructure – Practice, Interoperability and Ethics” (CHERRI). www.cherri.mvm.ed.ac.uk

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. If you would like to know more about the study before deciding whether or not to take part there is a contact number at the end of this document.

What is the purpose of the study?

Clinical photographs, images and other recordings are essential for authentic and effective healthcare education and these have long been used in this way within institutions. With the development of digitised picture archiving, communication systems and e-learning clinical recordings can now be copied and disseminated rapidly and thus there is potential for great harm unless the interests of patients are adequately safeguarded. This study is part of a review of consent issues and processes relating to the secure deposit, sharing and reuse of clinical recordings used for non-clinical purposes such as teaching, research and other educational activities. Drawing on exemplar policies and procedures and informed by further consultation the project will be seeking to deliver best practice recommendations, workflows, and information and technical procedures for managing these processes in a scalable fashion. This project will require consultation with representatives working in human and veterinary healthcare delivery, education and research in HE and FE institutions, the NHS, professional and statutory bodies and current repositories for electronic clinical recordings.

Why have I been chosen?

We are aiming to interview representatives from a wide range of stakeholders who are involved or responsible for guidance on the use of clinical recordings for non-clinical purposes (teaching and research) to gain an overview of current practice and guiding principles. You have been chosen because you are seen as having a key role within your institution in this area.

What will it involve?

Agreeing to take part in this study will involve taking part in a single telephone interview with one of our researchers. This telephone interview should last approximately 20-30 minutes and will be conducted at a time that is convenient to you. With your consent the interview would be tape recorded and transcribed. The full content of these tapes will only be available to the research team. We will use the information to produce a report for JISC who are funding the research. We will also produce a report for the GMC. Great care will be taken to ensure that no individual or institution could be identified in such reports or publication. Copies of these reports will be sent to all participants on request.

What will happen to the results of the research study?

JISC have commissioned this research study to help define a possible framework for the acquisition, deposit, storage and use of clinical recordings for non-clinical purposes. In addition, the findings of the research study will be very useful for individuals and institutions involved in the use of clinical recordings for non-clinical purposes (when creating national and institutional guidelines and policy, consenting patients to use recordings in this way, or when using recordings such as photographs or video clips in lectures, online tutorials and other resources).

Who is funding the research?

The Joint Information Systems Committee (JISC - www.jisc.ac.uk)

What do I have to do?

Please continue to read the rest of the documents and contact us if you require further information or if you think someone else in your institution would be better placed to take part in this research. Unless we hear from you a researcher will contact you shortly by telephone to answer any questions you may have and to ask if you would be willing to take part. If you agree to take part they will then arrange a suitable time to call you again to conduct the telephone interview.

There are a number of examples of good practice. For instance:

- Addenbrooke's NHS Trust. "Photography and video recordings of patients: confidentiality and consent, copyright and storage. Policy and Procedure" – this document is online at http://www.addenbrookes.org.uk/advice/medethlaw/photog_consent.html
- Institute of Medical Illustrators "Photography and video recordings of patients: confidentiality and consent, copyright and storage. Model policy and procedure". – this document is online at http://www.imi.org.uk/imidocs/Model%20Consent.pdf
- DOH "Good practice in consent implementation guide: consent to examination or treatment" – this document is online at http://www.dh.gov.uk/assetRoot/04/01/90/61/04019061.pdf
- Great Ormond Street Hospital NHS Trust. "Policy for making and using illustrative clinical records of patients. Reproduced in full below (with kind permission of Jeremy Naylor, Director of Medical Illustration).

POLICY FOR MAKING AND USING
ILLUSTRATIVE CLINICAL RECORDS OF PATIENTS

1. Introduction

1.1 It is common within Great Ormond Street Hospital for Children NHS Trust for visual and audio recordings to be made of patients, and sometimes also members of their families. Such recordings include photography, video, artwork, and audio recordings on either analogue or digital recording media. They may be made for the purpose of providing a clinical record, or for teaching, clinical audit, publication or research and development. Recordings may also be made for use as legal evidence.

2.2 A further use of recordings of patients may be for public relations and publicity purposes. Requests for such recordings are not covered by this policy and should be authorized by the Senior Press Officer, Public Relations and Fundraising Department.
2.3 Many of the issues covered by this policy also relate to radiographic and pathological images. The Trust policies Policy for using radiological images of patients for teaching, training, research or publication, Annex 1, Policy for making and using photographic images of histopathological material, Annex 2, and Policy for making and using photographic records at post-mortem examination, Annex 3, should be read in conjunction with this policy.
2.4 It is not the policy of GOS Trust to carry out covert recording of any kind. Video surveillance may be carried out for clinical purposes and will be subject to the same requirements for consent as any other clinical procedure or recording. This policy does not cover the use of security cameras (CCTV) for general security monitoring of Trust premises.
2.5 It is the duty of all staff in the Trust to act in the best interests of patients when making recordings of patients for the purposes of clinical assessment, teaching or publication, or when handling such recordings. Everyone working for the NHS is under a legal duty to keep patient records confidential. This policy outlines how staff should protect the confidentiality of patients and their families in relation to clinical recordings such as photography and video. It should be read in conjunction with the Trust policy on protecting patient information.
2.6 All recordings that illustrate a patient's condition or an aspect of their treatment form part of that patients' medical records and are subject to this policy, irrespective of who owns the equipment or materials with which they were produced. Any breach of this policy may lead to disciplinary action by the Trust and in serious cases could lead to dismissal.
2.7 All projects involving the recording of patients must be registered with the Trust's Data Protection Officer. A sample of the form to be used to register is at Appendix 1. Clinical images taken by Medical Illustration are already registered.
2.8 Full procedures are given in Appendix 2. When recordings are made by Trust personnel other than by staff of the Medical Photography & Illustration Department, the same procedures should be followed.

2. Professional liabilities

2.1 All NHS staff are bound by the Department of Health's standardised consent policies. Doctors are bound by the General Medical Council's guidance, May 2002: Making and Using Visual and Audio Recordings of Patients.

2.2 Medical Illustrators are bound by the Institute of Medical Illustrators' A Code of Responsible Practice, 1996, and the National Board of Registration of Medical Illustrators' Code of Conduct. From April 2005 Clinical Photographers will be bound by the rules and code of conduct of the Health Professions Council.

2.3 Other registered professionals should uphold the recommended good practice of their respective regulatory or professional body.

2.4 All staff, regardless of their professional position, should adhere to the principles set out in these documents.

3. Legislation

1.1 A number of Acts of Parliament pertain to the recording of patients (see list at Appendix 3). A detailed discussion is beyond the scope of this document. For a discussion of any particular issues you should contact the Department of Medical Illustration. Legal issues not covered by this policy should be referred to the Trust's Legal Department.

4. Confidentiality

4.1 Confidentiality is the patient's right and may usually only be waived by the patient or by someone legally entitled to do so on his behalf. You are reminded that breach of confidentiality may well amount to serious professional misconduct with inevitable disciplinary consequences and could result in substantial financial damages

4.2 In order to ensure that the patient's right to confidentiality is preserved, Great Ormond Street Hospital for Children NHS Trust requires Consultants to ensure:

4.2.1 That the patient's consent is obtained in writing for the original recording and for its use as a part of treatment or for teaching or further specified use, such as publication.

4.2.2 That prior to publication in journals, books or elsewhere or for any use other than as described in paragraph 4.2.1, the patient's (or Parent's/Carer's) permission for the specific use proposed is sought and written consent obtained. Informed consent in this context means that the patient should be shown the full manuscript of the relevant article or chapter.

5. Consent

5.1 Valid consent is necessary for all procedures, including any recording that involves patients. Such consent must be informed, given by a competent person including children if they are able to understand fully the nature and purpose of what is involved, and free from coercion. The Trust consent policy, *Guidelines on the procedure for obtaining valid consent to treatment* (Ops/C7/98), should be adhered to at all times. Trust policy complies with the Department of Health's Standardized Consent Policies; Section VIII: Clinical Photography and conventional or digital video recordings.

5.2 It is not normally necessary to obtain consent for using the following types of images for teaching or publication, provided they can be effectively anonymised: images taken from pathology slides; X-rays; laparoscopic images; images of internal organs; ultrasound images. The health professional carrying out the procedure should, however, make clear at the time of obtaining consent to the treatment or procedure that a recording will be made. See also the policies for radiographic (annex 1) and post-mortem recordings (annex 3).

5.3 All patients who are to be recorded and their parents/ carers must be fully apprised of the reasons for the recording, its purpose and the uses that might be made of it. It should be made clear to all patients/ parents/ carers who are asked to sign a consent for recording that might be used for teaching or publication, that refusal to give consent will not affect their care.

5.4 Children under 16 who are competent to give consent should be encouraged to sign the consent in addition to the parent/ carer. If a child declines consent then no matter the opinion of the parent/carer, the records should not be made. A child must give their assent to recording even if they are not competent to give written consent.

5.5 All patients being recorded or their parents/carers must give valid prior informed consent and should receive detailed printed information about the uses to which they are asked to consent. Such consent may be given at one of three levels of permitted usage. Copies of the consent form are ordered from supplies and an example is included at Appendix 4.

5.6 The consent form provides the opportunity for the patients/parents/carers to consent to one further use at the time of the original recording: such extra use should be explicit and limited to one use. This form must be countersigned by the patient/ parent/carer and the member of staff obtaining the consent before the recording is carried out. Further consent is required prior to each additional use.

5.7 Patients'/ parents'/ carers' wishes concerning the uses made of their clinical recordings must be recorded on the consent form and respected. For example, consent to publication of a photograph in a scientific journal must be obtained before it is submitted to the journal.

5.8 A child, parent or carer's refusal to permit any level of recording should be respected. Such refusal in itself must not be allowed to prejudice a child's care. However, in some cases it may be judged that refusal of consent will adversely affect their clinical care. There may also be legal reasons for making recordings without consent. See section 11, 'Exceptions to consent rule' and the *Trust policy on protecting patient information*.

5.9 In the case of publication, consent may be withdrawn by the patient, or their parent/ carer at any time prior to publication of the image. Patients and their parents/ carers have the right to withdraw or alter the level of their consent at any time and this should be respected.

5.10 Care must be taken when making recordings, or obtaining consent, to respect the dignity, cultural and religious beliefs of the patient and their family.

6. Parental/ carer/ patient consent for clinical recording.

6.1 The 'consent to clinical photography' form is a three-part form set: the top copy is filed in the patient's casenotes. The second copy is given to the patient and the third copy sent to Medical Photography. The form must be completed each time a photographic or video recording is made of a patient.

6.2 If a patient dies before a retrospective consent can be obtained, recordings may only be released with the consent of the deceased's personal representatives. In addition, wherever possible the consent of the next of kin or near relatives should be obtained, particularly where the personal representatives are not relatives of the deceased. You are reminded that the duty of confidentiality survives the death of a patient and you and the Trust can be prosecuted under the Access to Health Records Act (1994).

6.3 If a consenting patient subsequently dies, permission should be sought for any new use outside the terms of the existing consent. In this instance the consent of either the next of kin or the personal representative is required.

6.4 In cases such as in paragraphs 6.2 and 6.3 any such recording should not be used if recordings of patients who are able to give or withhold consent could equally well meet the purpose of the recording.

7. Appropriateness of recordings

7.1 Records should only be taken if there are specific clinical features that need recording for purposes listed in Section 1.1.

7.2 Records should include only the areas of clinical interest.

7.3 A clear indication must be recorded on the consent form justifying records of genital areas, or of the chest in peri or post-pubescent girls.

8. Parents', carers' or patients' request for copies

8.1 Patients and their parents/ carers have the right to obtain copies of their clinical notes under the Access to Health Records Act (1990). Before copies of a patient's photographs are so released a request form should be completed (available in Medical Illustration), and signed by a parent or carer. A small charge is made for making such copies.

8.2 Following all requests by patients or their parents/ carers for access to their notes and other hospital-held information enquiry must be made of Medical Illustration to ascertain whether any data to which they are entitled are held there.

9. Consent for publication in a medical/ scientific journal or book

9.1 The practice of obtaining the patient's written consent only in the case of full length or facial recordings, from which the patient can easily be identified, is not sufficient. It is sometimes possible for people to be identified from other categories of recording, e.g. showing a tattoo or other distinguishing mark. Nor is it sufficient to rely on the photographer's or consultant's judgement that a particular patient is unlikely to be identified from a particular recording.

9.2 Where possible, efforts should be made to preserve anonymity in published images; for example, by excluding the face or other identifying features. However, such precautions do not preclude the need for consent. Altering the image in any way, including blacking out the eyes, is not an acceptable means of anonymising the image.

10. Clinical recordings made of the unconscious patient

10.1 Recordings of the unconscious patient may be made provided consent is obtained before the images are released. The patient or parent/carer must be told that the recordings have been made and if such a patient does not consent, the recordings must be destroyed

10.2 In the case of procedures in which recording is implicit, (e.g. endoscopy) consent for the procedure provides implicit consent to recordings made for the patient's case notes. Note that this does not include consent for making recordings for the primary purpose of teaching, publication or any other non-clinical use; specific consent should be obtained before undertaking such recordings. In either case, the health professional carrying out the procedure must ensure that they make clear at the time of consent for the procedure that photographic or video recordings might be made during the procedure.

11. Exceptions to consent rules

11.1 Recordings without parental consent may be necessary in certain circumstances such as suspected non-accidental injury to a child, where it might be unlikely that the parent or carer would give consent and the recording of injuries is clearly in the patient's best interests. However, it is essential that recording is authorised by the Consultant Clinician in charge with the involvement of the Social Worker. (see 1.4 above for note on Covert Video Surveillance). Refer also to section 7 of the *Trust policy on protecting patient information*: 'Disclosure of information against a patient's wishes'

11.2 There might be circumstances in which it is impossible to obtain prior parental consent and the recording needs to be obtained immediately. In this case the Consultant Clinician or Clinical Nurse Specialist in charge may request recordings to be made. Consent must then be requested as soon as possible and, if it is refused, the recordings must be destroyed. No material may be released until the appropriate consent is given.

12. Research and development

12.1 For recordings made solely for the purposes of research the consent form for parents or guardians of children participating in research studies (1997 NRO1) should be signed and the work must have Research Ethics Committee approval and must be officially registered with the Research and Development Office.

12.2 All research and development projects using illustrative clinical recordings must be registered with the Data Protection Officer.

13. Processing

13.1 Processing and reproduction of images should, wherever feasible, be kept within the direct control of Trust and Institute staff. Where external processing facilities are used staff must ensure that secure arrangements are made to prevent any misuse of recordings of patients. The Medical Illustration Department has secure arrangements with two professional processing laboratories, and can arrange processing of confidential images.

14. Copyright and making copies

14.1 Copyright in all recordings of patients made by staff is vested in the Trust.

14.2 Copyright in a clinical recording cannot be transferred, for example to a publisher, and it should be explicit in any publishing contract that copyright in the images remains with the Trust. It is not intended that this should restrict the use of images for educational purposes.

14.3 Copies of clinical recordings may only be made with the permission of the Consultant Clinician or Clinical Nurse Specialist in charge and within the constraints of clause 5 (consent).

14.4 In the case of staff that leave the Trust, recordings obtained during the course of their employment may continue to be used for teaching only if that level of consent has been obtained. No other use may be made of such images, regardless of the level of consent given, without the patient's further consent and written agreement of the Consultant Clinician. (see also Section 17.11).

14.5 A master copy of all recordings of patients must be stored securely on Trust premises.

15. Video recordings

15.1 The recording of patients of the Department of Psychological Medicine requires particular care and guidelines for these procedures have been published by the Institute of Medical Illustrators (see section 2.2).

15.2 Recordings made in the Department of Psychological Medicine are covered by the joint policy of Great Ormond Street and the London Borough of Camden: *Policy for the Making and Use of Videotapes*.

16. Diagnostic and post-mortem images

16.1 Radiographs, scans, and other diagnostic images that are used for any purpose other than patient diagnosis and treatment should be made anonymous by obscuring the patient's name and other personal details. See the *Policy for using radiological images of patients for teaching, training, research or publication* (Annex 1) and *Policy for making and using photographic records at post-mortem examination* (Annex 3)

17. Digital Images

17.1 It is recognised that while digitally originated recordings are intrinsically no different to traditional recordings, they are easier to copy in electronic form and are therefore more at risk of both manipulation and inappropriate distribution. Care must be taken to protect the image and maintain its integrity. Images should be stored in a secure place. The Trust's policies on data security and protecting patient information, and the Data Protection Acts apply. All computers, disk drives and other storage media should be kept in a secure location under lock and key when not in use.

17.2 Clinical recordings should only be made on equipment owned by the Trust, and not personally owned cameras or recording devices.

17.3 As for all other Trust data, clinical photographs for which consent for teaching or publication has not been obtained should not be stored on personally owned devices (e.g. laptop, palm or pocket PC, USB pen, hard disk, etc.). All such equipment used for storing clinical photographs or video must belong to the Trust or ICH.

17.4 Access to images should be password protected.

17.5 Computers should be located in such a way that the images of patients displayed on screen cannot be seen by passers-by.

17.6 Equipment used for storing images of patients must not be connected to public networks unless within the hospital's firewall and with the agreement of the Head of ICT.

17.7 No images of patients should be transmitted over a public network without further explicit permission of the patient and/ or parents/ carers. It must first be made clear that there is a possibility of such images being seen or downloaded by someone other than the intended recipient and that, once such images are in the public domain, there is no effective means of withdrawing consent. Transmission over a public network should be avoided wherever possible, and must never be done with pictures showing a face or genitalia, or of the chest in peri- or post-pubescent girls.

17.8 Original digital image files should be stored on disc with no manipulation or compression applied. Each image must be catalogued or assigned a file name by which the patient can be clearly identified, preferably incorporating hospital registration number and date of recording.

17.9 Where digital photography is to be used to record images of patients, due care must be taken before acquiring the images to ensure that their quality is adequate for their purpose.

17.10 In order to maintain the integrity of the image, manipulation may only be carried out to the whole image, and must be limited to simple sharpening, adjustment of contrast and brightness, and correction of colour balance.

17.11 Images of patients may only be transferred to personal computers for use in connection with research projects that have been approved by the Local Research Ethics Committee and registered with the Data Protection Officer, or for the preparation of teaching materials if the appropriate level of consent has been given.

17.12 Staff undertaking storage and retrieval of digital images must be trained in these procedures and have approved access via the ICT Department to the GOS network.

17.13 Before leaving the employment of the Trust, staff may seek specific permission to retain images for teaching purposes from the Director of Clinical Operations. GOS Trust may grant such permission subject to the retention of copyright and all reproduction rights. (see also section 14.4)

18. Recordings made principally for legal purposes

18.1 If the primary purpose of a recording is to provide evidence for use in court the recording must not be used for teaching or publication without the express permission of the court for which it was prepared. See also 'Disclosure of information against a patient's wishes': *Trust policy on protecting patient information*, section 7.

18.2 Recordings that have been made for teaching or publication should cease to be used for such purposes if legal action is taken against the Trust or if the images are used in a court case.

19. Non-clinical photography

19.1 In cases where the patient is incidental to the recording, e.g. where the picture is to illustrate a particular equipment set-up, consent to appear in the recording is still required from any patient or member of the public.

19.2 Accidental recording of patients who have not given appropriate consent must be avoided. Images of a patient that have inadvertently included the images of other patients who have not consented should not be published under any circumstances. Unless deleterious to the care of the subject patient, they should be destroyed.

19.3 Members of staff who normally operate the equipment in a recording are deemed to have given their consent to the recording and its further use by appearing in the recording. If the member of staff does not normally work in that area, then a 'model release' consent should be obtained and filed. (for sample see Appendix 5).

19.4 Freelance professional photographers are sometimes employed to make this sort of recording. They may only be introduced to Trust premises by arrangement with the Hospital Liaison Officer.

19.5 Contracts with 'outside' photographers must ensure that they waive ownership of copyright and moral rights in the recordings they prepare, although they may still be allowed to retain the right to reproduce the recording.

20. Logging and storage

20.1 Since any medical record has to be available for disclosure if required, it is essential that every photograph be properly logged in the case notes.

20.2 In the case of photographic negatives, these must be securely stored and logically catalogued in the originating department.

20.3 In the case of photographic transparencies, a second copy should be made at the time of photography to be used as a master transparency. This must be securely stored in the originating department. Where it is impossible to obtain a master as well as a show copy, the original photographs should be regarded as masters and duplicates made as necessary for further use.

20.4 All recordings of patients should be clearly labelled to indicate that copyright belongs to the Trust, as follows: Ó **Great Ormond Street Hospital for Children NHS Trust**. Master copies and copies that form part of the clinical case notes should be labelled with patient name, registration number and date of recording.

20.5 In accordance with Trust policy on clinical records, master copies of all recordings must be retained for a minimum period of twenty-one years. See 'Storage and disposal of data': *Trust policy on protecting patient information*, clauses 8.13-8.19.

21. Publications

21.1 Copies of the following Publications are held in Medical Illustration:

• General Medical Council. *Making and Using Visual and Audio Recordings of Patients:* GMC, May 2002.
• Institute of Medical Illustrators. *A Code of Responsible Practice protocols for ethical conduct and legal compliance for medical illustrators*; IMI, 1996.
• Royal College of General Practitioners. *RCGP Statement on the Use of Video-recording of General Practice Consultations for Teaching, Learning and Assessment: the importance of ethical considerations*; RCGP 1993.
• British Photographers' Liaison Committee. *The ABC of UK Photographic Copyright*; BPLC 1994.
• The Hospitals for Sick Children and London Borough of Camden *Policy for Making and Use of Videotapes*.
• NHS Executive. *Health Service Guidelines: The Protection and Use of Patient Information*. Department of Health document HSG(96)18; 1996.
• Committee for Accreditation of Medical Illustration Practitioners. *National Board of Registration Code of Conduct*.
• NHS Executive. *Caldicott Guardians*. Department of Health document HSC 1999/012.

Appendix 1: Registration form for recordings

GREAT ORMOND STREET HOSPITAL FOR CHILDREN NHS TRUST REGISTRATION FORM FOR PROJECTS INVOLVING PHOTOGRAPHY OR VIDEO RECORDING OF PATIENTS

1. Name of project/process: .....
2. Start and end dates of project/process: .....
3. Ethical Committee Approval received: YES NO Not Applicable
4. Department: .....
5. Lead Consultant: .....
6. Description of project (in particular outlining the photography and the proposed use of the photographs:
7. Proposed consent wording: .....

   .....

8. Data Protection Act requirements:
   a) Name of Data Custodian: .....
   b) Box number and address of Data Custodian: .....

      .....

   c) On what will images and data be held and processed? (*please specify model and serial number of computer(s), printer(s) etc)*

      .....

   d) Who is the legal owner of the equipment? .....
   e) Where is the equipment located? *(please specify and give room number if known)* .....
   f) What security measures are in place *(e.g. passwords, digital locks on office doors)*?
      (i) For equipment: .....
      (ii) For data and images: .....
   g) Which group(s) of people:
      (i) Have access to the data/images: .....
      (ii) Have use of cameras: .....
      (iii) Receive/use or are sent prints / hard copy / discs? .....
   h) Are you processing these images on behalf of anybody else? *(if yes, please specify):* .....

      .....

   i) Will you be copying these images to anyone else? .....

      .....

   i) Are there written policies and procedures in place to cover this project/new process? If not, when will they be written and by whom? .....

      .....

   k) Is the Data Custodian fully conversant with the Trust's policies for Data Protection, Security and Making and Using Illustrative Clinical Records of Patients? .....

      .....

9. If this is silver based photographic project, where will the films be processed? (if not by the Medical Illustration Department), a copy of the secure agreement with the processing laboratory must be attached). .....
10. Where will the recordings be stored and logged? (Remember they must not be stored off site): .....
11. If this is a digital photographic project, how has image storage been planned?

    .....

12. What are the budgetary implications for:
    a) Equipment purchase (including computers) .....
    b) Materials and processing: .....

c) Storage and retrieval: .....

13. What are your proposals for training in camera technique of the staff who will be taking the photographs:

14. If a digital project, what are your proposals for training in computer techniques of the staff who will be handling the images: .....

Signed: .....(Lead Consultant)

Countersigned: .....

Data Protection Officer: .....

Director of Medical Illustration: .....

Director of Clinical Operations:.....

Project Approved: YES / NO Date:.....

Appendix D-2

GREAT ORMOND STREET HOSPITAL FOR CHILDREN NHS TRUST

Photography and Video Recordings of Patients:

Confidentiality and Consent, Copyright and Storage

PROCEDURE

1. INTRODUCTION

1.1 In this Procedure, the term "recording" (or "recordings") is used to refer to photography and video recording (either conventional or digital).

1.2 All recordings that illustrate a patient's condition or an aspect of the treatment are medical records, whether they were originally created specifically for this purpose or not. They therefore have to be treated as rigorously as any other medical record.

1.3 The patient has a right to informed consent to recording and to any future use to which the recordings might be put. Recordings must be available for disclosure as required.

1.4 Copyright in all medical recordings of its patients is held by Great Ormond Street Hospital for Children NHS Trust and must be protected on further use of the pictures.

2. ROUTINE MEDICAL PHOTOGRAPHY FOR RECORD AND LOCAL TEACHING

2.1 Patients should be referred to the Medical Illustration Department for medical photographs or video recordings to be taken. A continuous "no appointment" service for outpatients is offered from 09.00 to 17.30 each weekday, and inpatients will be recorded either on the ward or in the department by arrangement, usually on the day of request. The contact number in the Medical Illustration Department is 5252.

2.2 All requests for clinical illustration should be made on the pink request form (GOS supplies No. WNU0205). Full patient details must be given, including a diagnosis (in brackets if provisional), and specifying the clinical features to be recorded.

2.3 Before referring a patient to the Medical Illustration Department, the 'Consent to Photography' form should be filled in and signed by the requesting doctor and countersigned by the patient. The top copy of this form should be filed in the casenotes, the second copy given to the patient and the third copy forwarded to Medical Illustration. A copy of the information leaflet, *Clinical recording of Patients – Family information* should be given to each patient/parent.

2.4 The 'Consent to Photography' form allows for three levels of consent: for medical record use only, for medical record and teaching or for **one specified other purpose** – for example to illustrate an article in a medical journal – to be obtained at the time of the original recording. This third level is a specifically limited additional consent to just one further use: it is not acceptable to describe such further use in an open ended way such as "publication as required".

2.5 In cases where it is impossible to obtain consent prior to the recording (e.g. photography of an unusual finding in the course of an operation where the patient is under anaesthetic), the Medical Illustration Department will carry out the recording but will hold the records in the Department until consent is subsequently obtained. If staff other than Medical Illustration staff take pictures in this context, consent must be obtained as soon as is practical after the patient becomes capable. If the patient declines to consent the record must be destroyed.

2.6 In certain circumstances medical photography may be prescribed without obtaining the consent of the patient. An example of this is a case of suspected non-accidental injury of a child where the parent or guardian is unlikely to give consent and the recording of the injuries is demonstrably to the patient's benefit. A consultant signature is required on the request card for prescribed and unconsented recording, and there must be involvement of a social worker.

3. MEDICAL PHOTOGRAPHY CARRIED OUT BY STAFF OUTSIDE THE MEDICAL PHOTOGRAPHY AND ILLUSTRATION SERVICE

3.1 Any recording that is to be carried out by staff other than members of the Medical Illustration Department must receive prior approval from the Director of Clinical Operations. This requirement is intended both to ensure the protection of both the patients' rights and the Trust, and is intended to be helpful rather than restrictive.

1.2 A copy of the registration form for recordings is attached as Appendix 1. This must be completed and approved by the Director of Clinical Operations prior to any recording being carried out.

1.3 The registration process requires that the Director of Clinical Operations is satisfied that:

- Necessary Ethical Committee approval has been obtained where applicable
- Consent procedures are appropriate
- Copyright and reproduction rights are suitably protected
- Storage of negatives, transparencies, original digital recording and videotapes is secure, and labelled with patient number and date of recording.
- The requirements of the Data Protection Act and the Caldicott Guardians are met
- Film processing is carried out by secure laboratories
- The equipment proposed to carry out the work is suitable for the purpose and approved by Medical Illustration
- That – where appropriate – the staff concerned are trained in using the online clinical image database to store digital images and are trained in the correct use of image manipulation software
- The budgetary implications are understood

1.4 All recording projects must therefore be discussed with the Trust's Data Protection Officer and Director of Medical Illustration prior to the submission of the Project Form.

PUBLICATION OF MEDICAL PHOTOGRAPHS

4.1 It is vital to ensure that copyright in any medical photograph that is published is retained by the Trust. Nearly all publishers' contracts require authors to sign away ownership of all copyrights associated with the publication.

Copyright is protected when the images are labelled with the words:

"This print is the copyright of Great Ormond Street Hospital for Children NHS Trust. Permission is granted for first publication in .....

(title of journal or book and date of publication)

All prints produced by the Medical Photography and Illustration Service carry a copyright label that prohibits reproduction. The wording in 4.2 above overrules the basic wording for the specified publication only.

It is the author's responsibility in all cases to obtain permission to publish from the patient. This must be filed in the patient's casenotes and a copy given to the patient.

DIGITAL STILL PHOTOGRAPHY

1.1 As in all photography, the choice of equipment to be used is usually predicated by a clear definition of the subject matter of the images and their eventual use. Particular questions that should be answered are:

- How "close-up" do you need to be to adequately record the lesion(s)?
- Are you planning to take measurements from the images?
- Is colour particularly important in the assessment of the images?
- Is repeatability of the image important in a long-term project?

1.2 The Trust requires that all original camera images are securely stored on a permanent recording medium, such as CD or DVD, prior to any image manipulation or compression. This is intended to protect both you and the Trust. A compressed (normally JPEG) copy of each image should be stored on a designated folder on Medical Illustration's server, or another restricted space on a designated Trust server. Stand-alone image storage systems are not allowed (by the Trust) to be set up or maintained by Specialities, Directorates or individual staff (other than staff of Medical Illustration) without the written permission of the Director of Clinical Operations.

1.3 The Medical Illustration Department will advise users about image manipulation software.

1.4 For images produced by departments other than Medical Illustration, collections of images will be established by Medical Illustration and all authorised users will be given password access to the image collection.
Accounts may be time limited and will normally be terminated when the account holder leaves the Trust. Specific privileges will vary accordingly to each individual's involvement in clinical care and teaching. They might include:

- Uploading: permission to upload images to the database, for projects approved by the Director of Clinical Operations.

- Viewing: ability to view images held in specified collection and up to a specified size, according to need.
- Lightbox: ability to save selections of images for further reference.
- Downloading: ability to download images for a specified purpose.
- Ordering: ability to order copies in digital or print form.
- Editing: ability to alter information held about images in specified collections.

Appendix D-3: Legislation

The Copyright, Designs and Patents Act, (1988).

The Protection of Children Act (1978).

The Criminal Justice and Public Order Act (1994).

The Children Act (1989).

The Access to Personal Files Act (1987).

The Access to Health Records Act (1990).

The Data Protection Acts (1984 and 1998).

The Obscene Publications Act (1959).

The Video Recordings Act (1984).

The Mental Health Act (1983).

Appendix D-4: The Great Ormond Street Hospital for Children NHS Trust Consent to Photography or Video recording form

GREAT ORMOND STREET HOSPITAL FOR CHILDREN NHS TRUST CONSENT TO PHOTOGRAPHY

Great Ormond Street Hospital for Children NHS Trust has adopted a policy in line with the Data Protection Act which gives you the right to control the future use of photographs (including video, slides and digital images) taken of you during the course of your treatment.

***a Referral to Medical Illustration:**

I wish to refer you to the Medical Illustration Department for medical photographs to be taken. These photographs will be part of your medical records and may be used for teaching of medical, paramedical and nursing staff as well as medical students, or for specific other use as detailed below.

***b Medical Photography in the Trust by other staff:**

I **.....** confirm that I have registered with Medical Illustration that the photography and the storage of the resulting images will take place in line with the Trust's Policy for making and using illustrative clinical records of patients, and I will take the appropriate photographs in a dignified manner, using equipment approved by Medical Illustration.

This consent limits their use to the purposes only specified by you and should it be desired to use your photograph(s) in any other way – for example, in a medical textbook or an on-line teaching resource – the Trust will seek your specific permission to do so.

Clinician's name**:** **.....***(print)* Speciality**:.....**

Clinician's signature

CONSENT

In view of the explanation given to me by Prof/Dr/Mr/Miss/Mrs**: .....**

- ❑ I consent to photographs being taken for my personal medical casenotes.
- ❑ I consent to photographs being made available for teaching in the Healthcare context as described above.
- ❑ I consent to my photographs being published for the specific purpose described below. This consent does not extend to any further publication(s).

.....

.....

Signature of patient/parent/guardian**: .....** Date**: .....**

Relationship if not patient**: .....**

Top copy to be retained in patient's Medical Records

Second copy to be given to the patient

Third copy to be forwarded to Medical Photography

Appendix D-5: Sample wording for model release.

This sample wording should be adapted as appropriate to the situation in hand: if it is possible to be more specific about the future use of recordings, it is advised that a more detailed explanation be given, although the broader form of consent is useful in developing the Trust's picture library for use at Open Days etc.

This consent should be filed in the medical records and a photocopy sent to Medical Photography prior to undertaking the recordings.

GREAT ORMOND STREET HOSPITAL FOR CHILDREN NHS TRUST GENERAL MODEL RELEASE

In view of the explanation given to me by

I agree to appear in photographs/video recordings to be taken for Great Ormond Street Hospital for Children NHS Trust/ Institute of Child Health publicity, information and exhibition purposes. I understand that they may be used in articles seen by the general public, in medical textbooks on public sale, or on websites managed by the Trust/ Institute.

Signed**: .....**

Date**: .....**

Appendix D-6

NOTICE IN DEPARTMENT

CONSENT TO PHOTOGRAPHY OR VIDEO RECORDING

Great Ormond Street Hospital for Children NHS Trust has adopted a policy to give you the right to control the future use of photographs or video recordings taken of you during the course of your treatment.

We would like you to have some medical photographs or video recordings taken for

- either your medical record
- or for teaching of medical, paramedical and nursing staff as well as medical students in Great Ormond Street Hospital for Children NHS Trust/Institute of Child Health and in other UK Hospitals or Medical Schools.
- or for some other specific and limited use as detailed on the consent form you will be asked to sign.

Should we wish to use these photograph(s) or video recordings in any other way in the future – for example, in a medical textbook – we will seek your specific permission to do so.

Appendix D-7

USE AND REPRODUCTION OF RADIOGRAPHS: Copyright and Storage

1. Introduction

1.1 Radiographs and related images (e.g. Ultrasound, MR etc.) are identifiable data under the terms of the Data Protection Act and form a part of the patient's confidential medical record. They are copyright material, which belongs ultimately to the Secretary of State for Health, although for practical purposes, custodianship of the copyright is vested in Great Ormond Street Hospital NHS Trust.

1.2 Because of the nature of the images, they are difficult to reproduce photographically and any reproduction requires **anonymised radiological images**.

1.3 Images issued by the Radiology Department are in digital format. It is the requirement of many journals that there is radiological input to papers, with the radiologists preparing the images for publication prior to their capture in photographic form.

1.4 In all cases of reproduction, Great Ormond Street Hospital NHS Trust retains both the right to approve the quality, relevance and accuracy of the images and their copyright.

2. Radiological Input

2.1 In all cases where radiological images are published, the case should be discussed with a consultant radiologist, who will advise on the quality, relevance and accuracy of the images.

2.2 Similar assistance is available with regard to images intended for use in slide or electronic presentations.

3. Data Protection

3.1 Images prepared for teaching and/or publication must be anonymised (this applies to both the images and their packaging/ mounts)

3.2 Copyright in the images must be protected on publication and under no circumstances passed on to the publisher. Advice on copyright protection is available from Medical Illustration.

Clinical Recordings for Academic Non-clinical Settings

CHERRI Project Report

Rachel Ellaway, Helen Cameron and Michael Ross
with contributions from Graeme Laurie, Margaret Maxwell and Rebekah Pratt

JISC PROJECT