Guide to Management of Consent and Use Rights of Digital Content

Background

The increased desire to share and repurpose assets (images – still or moving, and audio) that may have associated restrictions regarding consent from individuals represented in the content and on use rights pose problems to all in keeping within ethical and legal boundaries. The increased concern in recent years over identity theft and product theft has resulted in more attention and legislation to protect the rights of individuals and of creative producers of content. Legal and technical remedies are being debated, proposed, and implemented. However, the speed and ease of dissemination of digital assets and products, especially with the Internet, surpasses the ability of society to manage the legal and ethical regulations and guidance. It has been demonstrated time and again that technological advances proceed more rapidly than do the corresponding regulations, policies, and ethical standards to accommodate those new changes.

The increased availability and access to digital content and the adoption of SCORM for the creation of education is expected to significantly increase options for the use and re-use of raw assets (e.g., photographs, film, video, audio recordings) Sharable Courseware Objects (SCOs) and aggregated content. For the purpose of this discussion assets, SCOs, and aggregated products of those components will be referred to throughout this document as 'content'. Problems with the permissions and restrictions associated with "the educational use of copyrighted material, as well as the business and institutional structures shaped by that law," have been identified as being "among the most important obstacles to realizing the potential of digital technology in education" (Fisher & McGeveran 2006, 6).

In the U.S., numerous legislative acts address issues related to determination of use rights and privacy issues (e.g., The U.S. Health Insurance Portability and Accountability Act of 1996 (HPPAA); the Technology, Education and Copyright Harmonization Act of 2002 (TEACH Act); Copyright Modernization Act of 2006). However, as the issue is an international one the conflicting perspectives of the many different jurisdictions need to be considered. The European Union, for instance, forbids personal data being passed outwith the EU without adequate safeguards being in place as part of its data protection principles. US legal frameworks will not be acceptable or appropriate for an international effort in this area.

Despite the establishment of legislation and data protection policies at national and international levels, current practices remain highly varied. However there are often conflicting or unclear issues of use rights and copyright. Practitioners don't know how to translate the legislation and policies into practical use and assure compliance beyond their relatively local geographic areas of focus.

Digital rights management is the management of intellectual property rights as applied to digital content and services. The characteristics of SCOs and aggregations are described in the learning object metadata and in the content packaging of the aggregate items. These methods can to a limited extent address licensing but not the issue of consent. Consent, which should always be informed and obtained with no aspect of duress, is the permission for use assigned by the subject represented in the content, not by the creator of the content. Digital rights management also has problems in comprehensively managing the licensing because the learning object metadata element of Rights Description includes sub elements of Cost, Copyright and Other Restrictions, and Description. These elements do not currently capture the level of detail required for both consent and use rights restrictions in a consistent way.

The following problems have been identified:

- Lack of common process and standards
- Lack of connection between terms of consent and subsequent use
- Unnecessary duplication in local contexts as a safety measure
- Pervading culture of risk and uncertainty leading to individual and intuitional anxiety and concern, and therefore reluctance to proceed with implementation and/or innovation

Approach

The need for attention to the use and management of consent and use restrictions for media components are clearly critical. This applies to all subject areas but probably none more than the healthcare domain. Developers and users of health sciences education learning objects must be particularly responsive to ethical and legal considerations in obtaining informed consent and adhering to permissions' restrictions of protected health information in photographs, films, and audio recordings . This also applies to adherence of use restrictions defined in copyright laws.

This document has been created to provide guidance to those acquiring, creating and using assets, SCOs, courses, and other materials in the healthcare setting. However, since consent and use rights issues apply to all subject matter domains, it is the intent that a broad management system be established that can be applied to all domains, not just healthcare.

These issues are being conjoined in the development of an international Clinical Commons which advocates a Consent And Licensing Management model (CALM) to:

- Provide guidance that can be used internationally to manage consent and licensing issues.
- Identify responsibilities for those acquiring and creating content and those using content that involves a consent dimension.
- Recommend standard practices and terminology for the description of consent and licensing restrictions and including that with its respective content.

Since change is constant, it is expected that this document must be revised as changes occur in technology, law, and practice. Readers are encouraged to notify MedBiquitous of changes in technology, law, policies, and practices that would affect the guidance provided here so that this document may remain a useful and current tool.

Consent

An asset may be used in various educational, communications, marketing, and entertainment products. When assets are incorporated into SCOs, and those in turn into products aggregating numerous SCOs, determining the corresponding user rights and consent becomes increasingly complex. It is necessary to review the use rights and consent for each component and its subcomponents in order to insure compliance with the original permissions allowed.

Permission can be granted in regard to several factors, each of which should be addressed in the asset description. These factors include:

- Purpose of the products in which the asset is used
- Audience to which the asset may be made available
- Duration during which the asset can be used
- Delivery method (media) of the products in which the asset is used
- Jurisdiction - geographic area covered by the permission
- Plus Creative Commons issues of attribution, derivatives, commercial use etc

A signed consent form must be maintained by the organization acquiring or creating the original asset so that it may be provided to verify the permissions received. It is recommended that the signed consent form be maintained for (insert length of time here).

Personally identifiable data (e.g., name, Social Security Number) must be removed from assets intended to be used in any products other than patient records or other restricted and authorized uses.

It is advisable when creating SCOs and aggregated products that the consent and use requirements are defined at the most restrictive level based on the most stringent requirements of its subcomponents. If the consent and use restrictions are defined for each subcomponent, it will be easy to identify subcomponents that may be too restrictive for the purposes of the product in development, and those components may be replaced with those that will be in conformance with the restrictions pertinent to the intended use of the final product.

Use Restrictions

Intellectual property rights (IPR) in digital content are usually related to copyright or trademark law. IPR is not necessarily owned by the creator, but may be assigned to a different person or organization either voluntarily or by contract. The laws that apply to assignment of IPR vary according to geographic location.

(Insert overview points of copyright, TEACH Act, etc. just to present the range and granularity of what factors are considered in describing and using content.)

The Creative Commons (CC) (http://creativecommons.org/) is a widely adopted and simple model which allows authors to determine and communicate the terms of use for digital works. The license options articulate the concepts of attribution, non-commercial, derivative works, and share-alike. The CC licenses are also multilingual and address different copyright legislation in different jurisdictions. However although they have been applied to resources based on clinically obtained assets, once these licenses are assigned they are irrevocable, global, and lack any concept of patient consent. The CC site explains "One can stop offering a work under a Creative Commons license at any time; but this will not affect the rights with any copies of the work already in circulation under a Creative Commons license".

It should be noted that Creative Commons is attracting a lot of criticism for its particularly US take on rights and ownership.

The ability to withdraw permission is a key feature in many institutional policies regarding patient consent as is evidenced in forms reviewed by the LOWG (UCLA/HEAL consent for and Authorization for Release of Photographs, Films, Medical Images, and other Multimedia for Educational Purposes).

Technical Compliance

(insert in this section various methods to technically adjust content to make it permissible to use it based on consent and use restrictions)

Sometimes the image may be modified to prevent identification to a specific individual in order to be compliant with privacy requirements while still accomplishing the purposes of the image. Blurring faces, tattoos, scars, and other uniquely distinguishing characteristics and cropping images are options for eliminating the ability to associate an image to a specific person. Sound recording present a more difficult problem because often in the medical setting the sound recording' purpose is in the characteristics of the sound, not in the words spoken.

(insert guidance on when and how it would be possible to revise audio).

Management Recommendations

(Insert introduction to this section and include the cautions and limitations to the recommendations)

Ellaway, et al, recommended Consent and Licensing Model
Two-step process:

1. Consent evaluated, acquired and logged along with recording
2. Consent encoded in license along with copyrights and license+recording passed for use
   License stays with recording and outlines conditions under which it can be used (compliance dependent)
   License can be matched with original patient and consent = audit/provenance trail

Recommendations for defining consent and use rights for new assets
Consent

(Insert in this section tasks and responsibilities for those acquiring or creating content.)

1. Obtain consent for the broadest possible range within each factor (purpose, audience, duration, delivery method, jurisdiction)
2. Include the descriptions for each factor with your asset, SCO, and aggregate product

Recommendations for applying consent and use rights to assets, SCOs, and courses

(Insert in this section the responsibilities for those using content)

Notes to MedBiquitous Committee members

The following notes are meant to be included in this draft document only for convenience to the work group members for discussion of the contents of the guidance document.

1. Need to provide international guidance as much as possible, and to clearly indicate in the document the geographic limitations of certain guidance.
2. Obtain guidance from and document the official sources for the legal guidance pertaining to various national jurisdictions provided in this document.
3. Create a mechanism to receive comments on this guidance and to update the document as necessary according to changes in consent and use rights.
4. Create criteria that identify when it would be possible to incorporate elements in the MedBiq Healthcare LOM addressing consent and use rights.
5. Need guidance on when and how it would be possible to revise the sound so it could not be associated with a specific person but still would accomplish its purpose.
6. What experts do we need to consult with and/or add as ad hoc members of this committee to develop this guidance? You will need to speak to Lawyers and ethicists as well as techs, clinicians and teachers
7. What organization should have management responsibility of these guidelines and revisions to guidance of consent and use rights since this guide is broader than healthcare alone? Rachel Ellaway suggests that the consent/ use rights model be managed by an organization such as Creative Commons. Absolutely not CC – this needs to be managed by the Health Services as constructed in different jurisdictions eg AMA, NHS etc
8. Is the current rights expression language sufficient to describe all conditions of consent and use rights restrictions. - NO

1. Ellaway R, Cameron H, Ross M, Laurie G, Maxwell M, Pratt R. Clinical Recordings for Academic Non-clinical Settings: CHERRI Project Report. Edinburgh: JISC/University of Edinburgh; 2006 March 2006.