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Report on the Management of Intellectual Property in Virtual Patients

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OJ L 79, 24.3.2005, p. 1.

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1 Abstract

Uncertainty surrounding intellectual property rights (IPRs), particularly copyright, is a major hurdle to academic institutions that wish to create and share digital content. This is particularly prominent in medicine due to the anonymity expected when the content includes patient-related clinical information. In addition, laws governing copyright and patient privacy differ from country to country, making the process of sharing even more complex. Although there will undoubtedly be disparities between countries, measures can be adopted to prepare and protect digital information intended to be shared. This document outlines a step-by-step process for preparing and protecting digital content in the medical and healthcare arena.

2 Background

The increasing use of the Internet for learning and teaching brings into question the traditional approaches for protecting digital content created with the intention of being shared. This is a persistent challenge in medical and healthcare education where, in addition to traditional ownership of the content and jurisdictional differences, there is the added complexity of ensuring patient anonymity. At the same time, the necessity for sharing is increasing, and in no area more so than in medical and healthcare education. Cost and time constraints are particularly high for those institutions wishing to create high quality content in this area.

2.1 Why do we need to share?

Opportunities for student-patient contact are critical for learning clinic competencies, yet these same opportunities are declining in most European Union (EU) Member States and most countries. Training is hampered by several important factors, including:

- The healthcare budget constraints that increasingly limit clinical teaching.
- The reduction in the time that patients stay in hospital.
- The increase in regulatory restrictions in the medical care.
- A greater level of expertise required before exposure to live patients; learning by trialand-error is simply not an option.

In response to this shortage, medical schools are increasingly turning to digital technology and developing more innovative methods for teaching and education. These approaches allow healthcare providers to practice procedures in an environment that poses no immediate risk to patients, where mistakes have no dire consequences, where animal use is unnecessary, and performance standards for specific procedures are raised.

2.2 Virtual Patients

The computer software that has been developed to create 'virtual patients', known simply as Virtual Patients (VPs), are now recognised by the medical education community as effective tools for addressing the lack of clinical training due to their ability to mimic real-life scenarios and empower students to make clinical decisions in a safe virtual environment.

A VP consists of many learning objects (e.g., text, images, animations, and videos) and can be defined as an interactive computer simulation of real-life clinical scenarios for the purposes of clinical training, education, or assessment². One limitation of VPs is that they are time-

² Ellaway R, Candler C, Greene P and Smothers V (2006), *An Architectural Model for MedBiquitous Virtual Patients*. Baltimore, MD, MedBiquitous

consuming and expensive to produce from 'scratch', and even leading e-learning institutions cannot produce a sufficient number to give full coverage of the medical or healthcare curricula³.

A possible solution is for e-learning institutions to share existing VPs, an option being explored by the Electronic Virtual Patient (eViP) project⁴. eViP consists of a European consortium of e-learning medical and healthcare institutions working with a number of well-respected international collaborators. The primary aim of the 3-Year project is to create a bank of repurposed and enriched multicultural VPs from across Europe.

This report explores some of the obstacles faced by the institutions and organisations involved with eViP project in their effort to share digital content for medical and healthcare education. This report will also propose a framework for a licensing model that will address some of the most challenging obstacles.

2.3 Intellectual Property Rights in Digital Content

Intellectual property (IP)⁵ is a legal field that refers to intellectual creations, such as those that are musical, literary, artistic works, inventions, symbols, names, images, and designs used in commerce⁶. Intellectual property rights (IPRs) are a bundle of such exclusive rights. The temporary monopoly granted to owners of these rights is intended to provide an incentive for the inventor to develop and share the creation rather than keep it secret. IPRs exist in the form of patents, copyrights, trademarks and related rights.

The IPR applicable to the VPs is copyright. Copyright protects the expressions of ideas or information and includes creative works such as books, movies, music, paintings, photographs, and software. For a work to gain copyright protection, it has to be original and should be expressed in a fixed material form, for example, in printed or electronic writing.

Once an original item is created and expressed in writing, copyright is automatically applied. In Europe one does not have to register the copyright in the work before it is protected. Copyright gives the copyright holder exclusive right to control reproduction or adaptation of such works for a certain period of time.

In addition, civil law jurisdictions, such as EU countries, recognise the creator's contribution in the form of certain 'moral rights'. Stemming from the origins of the copyright, the droit d'auteur system provides three moral rights, which due to their nature have had an impact on copyright of digital content⁷. The first is the right of the author of a work to be acknowledged as the author or creator (Right of Paternity). The second is the right to object to his or her name being attributed to something he or she did not create (Right of Attribution). The third is the right not to have his or her work subjected to 'derogatory' treatment that is to some amendment that impugns his or her integrity or reputation (Right of Integrity).

http://www.wipo.int/treaties/en/convention/trtdocs wo029.html. Accessed on 6th January 2009

http://www.opsi.gov.uk/acts/acts1988/UKpga 19880048 en 1.htm. Accessed on 20th December 2008.

http://www2.warwick.ac.uk/fac/soc/law/elj/jilt/1998 1/holderness/. Accessed on 20th December 2008.

³ Huang, G; Reynolds, R; Candler, C (2007), Virtual Patient Simulation at U.S. and Canadian Medical Schools, *Academic Medicine*

⁴ The eViP project website. Available online at: <u>www.virtualpatients.eu</u> Accessed on 5th January 2009

⁵ Art 2, para. Viii, WIPO Convention (1967). Available online at:

⁶ Copyright, Designs and Patents Act 1988. Available online at

⁷ Holderness M, 'Moral Rights and Authors' Rights: The Keys to the Information Age', 1998 (1) *The Journal of Information, Law and Technology (JILT)*. Available online at

The reciprocal recognition of rights of the creator of copyrighted works is obtained internationally through the Berne Convention for the Protection of Literary and Artistic Works agreement⁸. This treaty was devised in 1886 and applies to authors from any country that is a signatory. According to the treaty, these authors are awarded the same rights as other authors for a particular country as well as any rights granted by the Convention.

2.4 Issues arising from rights

Any project aimed at sharing work across several jurisdictions faces the challenge of having a mutually agreed upon system for this sharing. In addition to considering existing works, this system must also clarify how to share works that are jointly created or repurposed. These collaborations can only stem from transparency and a good understanding of differences between the partnering countries particularly around potential obstacles such as ownership and institutional/legal differences.

In the main e-learning arena of learning objects, Griffith⁹ has described the *chilling effects* that copyright law is having on efforts to reuse learning materials. An additional complication to shared information in the medical and healthcare sector is the plethora of regulations and legislations that need to be considered, including data protection, patient consent, and confidentiality as illustrated in the CHERRI project.¹⁰

3 The Model for eViP

The eViP project has adopted a common licensing framework that will permit sharing and repurposing of digital content, specifically VPs, for use in medical and healthcare education. In order to work out a solution to the previously outlined problems, the eViP project team carried out the following 5 steps and the outcomes each of which will be discussed in this report.

3.1 Step 1: Review IP and copyright status in eViP partnering countries

The first step was to conduct a detailed review of IP and copyright status with respect to medical digital content in all eViP partnering countries. Copyright is protected throughout Europe via a complex web of international conventions, treaties, agreements, and European Community (EC) Directives. A concerted move to harmonise the copyright laws of each Member State started in the 1970's, with the ultimate objective of removing obstacles to the establishment of a common market in Europe.

However, like other forms of IP, copyright is a creature of a country's national laws, which therefore places limits on the territorial extent of these rights. As there is no European copyright, harmonisation in Europe is achieved by a succession of international conventions, treaties and agreements, such as the Berne Convention, the Universal Copyright Convention, and EC Directives on copyright that attempt to establish a uniform framework for copyright protection. As signatories to these conventions, Member States are responsible for

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⁸ Berne Convention for the Protection of Literary and Artistic Works. Available online at http://www.wipo.int/treaties/en/ip/berne/trtdocs_wo001.html. Accessed on 16th December 2008

⁹ Griffiths, D (2005), Print to pixels: the implications for the development of learning resources, Vancouver, LORNET

¹⁰ Ellaway, R. et al (2005). "Clinical Recordings for Academic Non-clinical Settings" -the CHERRI Project (Common Healthcare Educational Recordings Reusability Infrastructure). Available online at http://www.cherri.mvm.ed.ac.uk/. Accessed on 16th December 2008.

implementation into national law. Over time, variation in interpretation and the level of implementation between countries has resulted in differences in copyright law throughout the EU.

Therefore, a detailed review of the IP and copyright status relating to different types of digital content was conducted by all partners with respect to their own national and institutional jurisdiction. The partners involved their respective institutional IP leads and consulted other legal experts to aide this step. In order to facilitate this process, a general template was developed and completed by the eViP project team. This template covered the following key areas to be addressed by each of the partners with respect to their national jurisdiction:

- What is copyright?
- What does copyright cover?
- What are 'original works'?
- How is copyright handled with computer programs?
- How is copyright ownership determined?
- Can copyright be transferred to someone else?
- What is the distinction between owning a possession and owning the copyright?
- How long does copyright last?
- Is material on the Internet protected by copyright?

3.2 Step 2: Compare copyright issues between eViP Partners

The next step was to identify the most important similarities and differences between eViP partners. Harmonisation of European copyright law has taken some steps forward, however there are still notable differences between many jurisdictions, often reflecting the cultural and historical differences underlying this form of protection. An example of this is the wide variation between the 27 countries of the EU regarding their respective copyright duration terms.

The eViP project includes partners from institutions based in Sweden, Germany, the Netherlands, Poland, Romania, and the UK. In order for eViP partners to share copyrighted work, any potentially impeding differences in copyright law need to be identified and accommodated. With this in mind, all eViP partners completed a questionnaire designed to identify and review the main aspects of national copyright law in their countries. The feedback can be found in Annex A.

The comparison of completed questionnaires identified conflicts relating to ownership of content protected by copyright and the duration of that copyright (summarised in table 1). High level academics of institutions in Sweden receive professorial rights, providing the creator, such as a professor, with greater control than other countries. The second difference was in the duration of protected works. In Sweden, most literary works are protected for the life of the author plus 70 years. Germany provides a limited duration of 25 years from publication for scientific articles in contrast to the Netherlands that provides perpetual rights for this type of work.

It was clear that the results from the limited number of countries involved with eViP would not be representative of jurisdictional differences of copyright laws throughout Europe. However, this process proved to be a very successful start to initiating and informing the discussions with other countries, not just in the EU but across the world.

Similarities	Differences
Types of work: Work protected by copyright includes literary, musical, and dramatic work.	Duration: The duration for which a work is protected under copyright varies by country. ¹
Application: Copyright is automatically generated once an original item is created and expressed in printed and/or electronic writing.	Ownership: The ownership of content under copyright protection varies by country and profession. ²
Criteria for protection: The item must be proven to be 'original' and an 'intellectual creation'.	
Moral rights: The 'droit d'auteur system' is recognised by all member countries, and moral rights cannot be transferred.	

Table 1. The summarized outcomes of the national copyright laws of eViP partnering countries. I. Germany allows for 25 years from publication for scientific articles, and the Netherlands grants perpetual rights. 2. Sweden's grants high level academics professorial rights

Comparison of the provisions of the copyright law in the eViP partner countries provided promising results. The nature of the differences, and the fact that more similarities were present than differences, indicated that obstacles faced to sharing copyright works are not insurmountable. To move forwards with a model, the next sensible step was to review existing patient consent forms and create a common consent form among eViP partnering countries. This step will ultimately enable the eViP partners to obtain the necessary permission for use (licence) from the owner for any existing VPs contributed to the project.

3.3 Step 3: Create a common consent form

The third step was to create a common consent form for recording patient information based on the similarities between the partnering countries. An important part of creating this consent form was having it reviewed by the legal department at each partner institution. A consent form is a document used to obtain permission from an individual to use their personal medical information for a certain purpose thus respecting the individual concerned and protecting their medical information. In the past two decades, a considerable volume of litigation in many countries focused on the issue of consent. As a consequence the doctrine of informed consent is assumed ¹¹. In the UK, standard practice for informed consent also ensures compliance with the Data Protection Act 1998 ¹² and the common law of confidentiality, as these pieces of legislation, although separate, are closely linked. These legislations and practices are mirrored in the eViP partnering countries.

A prerequisite to the success of the eViP project is the ability to actually share and reuse the digital content (i.e., the patient information) of the VPs contributed by each eViP partner.

¹¹ Madeleine Schachter and Joseph J. Fins. *Informed Consent Revisited: A Doctrine in the Service of Cancer Care*. The Oncologist, Vol. 13, No. 10, 1109-1113, October 2008

¹² Data Protection Act 1998. Available online at http://www.opsi.gov.uk/acts/acts1998/ukpga_19980029_en_1. Accessed on 16th December 2008

Even though the patient information is not considered intellectual property, the consent form, which is used to gather that information, is critical to the VP framework and thus an important piece to be considered within the discussion of copyright. In addition to understanding any differences in copyright law from partnering countries, the eViP project needed to identify the remit of any previously obtained permission to use patient information in existing VPs brought into the project. If necessary, the remit would need to be expanded to accommodate the project, as any previously obtained consent would have been for a limited purpose and for use only by the requesting institution.

Therefore, eViP emphasised the adoption of a common consent form that complies with national regulations and institutional policies across the EU and permits use by all eViP partners. More importantly, the design of a common consent form would also take into account the future plans of the project, considering both new, as well as old VPs. To that end, the comparison of standard practices and policies of eViP institutions (as detailed in Steps 1 and 2) were compiled to form a common consent form (see Annex B).

The eViP common consent form is a simple document establishing who will gain access to the information, the purpose of the study, an explanation of the uses and disclosures (e.g., giving the patients the right to object to the use of their personal information), and what kind of teaching will be involved (e.g., hospital, university, and all participants in the eViP project). All documents are also required to be written in plain and simple-to-understand language, and additional information and questions that any patient may request are addressed and presented in an information sheet that is annexed to this report (Annex C).

To ensure complete acceptance and avoid loss of any legal provisions in subsequent translations into languages of each partnering country, the consent form and information sheet was reviewed by the legal departments of partner institutions.

3.4 Step 4: Implement the common consent form

The fourth step was to implement the common consent form with both new and pre-existing VP content based on best practice. All eViP partners contributed previously created VPs to the eViP project for use and repurposing. In order to make them available to the public, a number of existing resources had to be cleared for use. Following review of individual practices, institutional policies, and jurisdictional legalities, the team came up with a model for how to tackle this issue. The devised clearance model is not just for signing off on existing VP content (Figure 1), it is also to inform others in the community on the best practices to clear new content for medicine and healthcare (Figure 2).

To illustrate the devised process, the eViP project team found the following common situation. A VP was contributed consisting of x-ray images obtained from a patient several decades ago through oral consent. Working through the flow chart, the project team found this VP to contain patient information obtained without consent, and therefore the primary objective would be to assess the risk of the eViP partners using this information within the eViP project

The most natural route would be to obtain a new consent from the patient for the required purpose. Limitations on time, resources, and often inability to obtain retrospective consent (e.g. death of the patient) poses the dilemma of either restricted use of the VP, stripping the relevant information and replacing it, or "signing off" on the information. The latter would require an internal risk assessment to enable an informed decision to be made. This provision

may not be suitable for all establishments as it does require acceptance by any institutional policy.

Based on the factors mentioned above, the eViP project team recommends as best practice that the clinician or responsible person in the establishment should consider the risk and decide whether to sign off on the information. The sign off would involve documenting all information available in the consent form and tagging the information with the selected licensing remit. The following best practice criteria should be considered during the evaluation:

- Type of consent and context in which it was obtained (e.g., given orally by patient in the clinician's office)
- Age of consent and value of information (e.g., 40 years old and a rare medical case)
- Status of patient and scope of consent (e.g., patient is now deceased but had given consent for all educational uses)
- Quality of consent (e.g., consent was loosely worded but there are not any underlying issues or problems)
- Existence of documentation (e.g. consent was orally given but never documented)

The advantage of this approach makes arriving at a decision on how to handle valuable and difficult information possible and less complex, where otherwise the issues might not be addressed or the information simply discarded. This approach would be applied to all preexisting VPs introduced to the eViP project. Furthermore, each resource used to create a new VP would be assessed using the process outlined at the end of Figure 1.

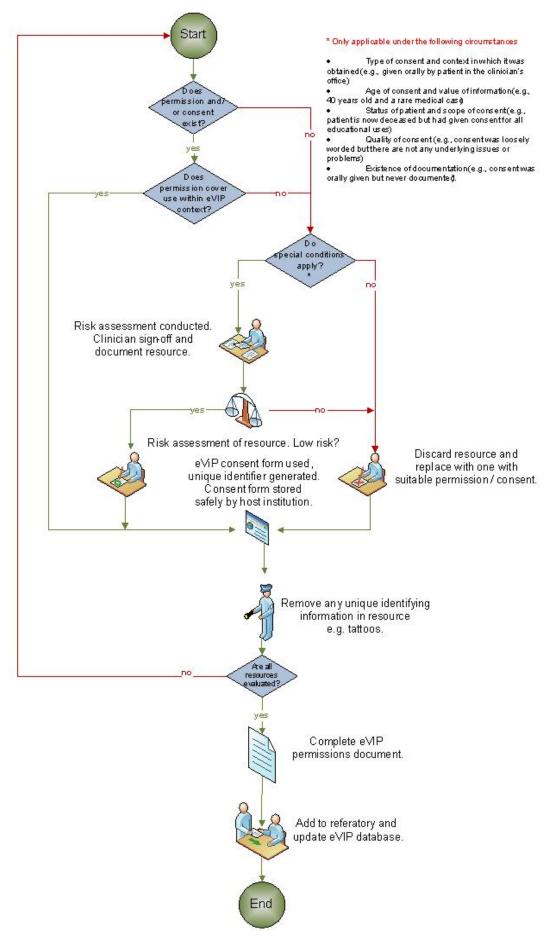


Figure 1. Best practice flow chart for the evaluation of pre-existing VPs introduced to the eViP project. Each resource used to create the VP is assessed until all resources are cleared. Where a resource has no consent, risk of using the resource will be evaluated, resulting in either sign off and use or replacement of the resource.

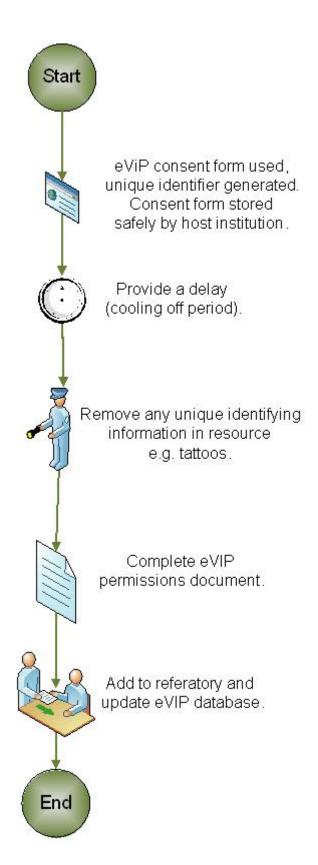


Figure 2. Best practice process flow for new VPs created in the eViP project.

3.5 Step 5: Adopt a simple and robust licensing model

The last step involves digital rights management (DRM) and the aim was to adopt a simple and robust licensing model for ensuring all new and repurposed digital content is appropriately used with copyright and IP acknowledgement to the source or repurposed source.

A licence is the permission to engage in a certain activity, for example, to use IPRs, such as trademarks, patents, or technology under defined conditions, granted by the appropriate authority ^{13,14}. Use without such permission would be unlawful.

By definition, patient consent is a type of licence. However, consent refers to use of patient information or material and accounts for the provisions of the data protection act and confidentiality.

A copyright licence is a contractual arrangement that defines the terms of use of the work protected by copyright. As a legal arrangement, it is the means of permitting use across jurisdictions and as such any licensing framework intended to share patient information in the medical and healthcare field would need to address this relationship: lack of adequate consent would limit the licensing terms of copyrighted work consisting of the consented information.

Due to the intricacies related to how the IP of digital content is managed in different European jurisdictions, the eViP partners agreed on a high level plan to adopt the Creative Commons (CC)¹⁵ as the licensing model of choice for all eViP repurposed and enriched VPs. The CC licensing platform is a widely recognised form of 'open' licensing for works generally protected by copyright. The CC builds upon traditional copyright practices to define possibilities that exist between the standard 'all rights reserved' full copyright and public domain 'no rights reserved'.

A CC licence lets individuals dictate how others may use their work. The Creative Commons licence allows individuals to keep their copyright but allows others to copy and distribute the work provided they give credit and only on the conditions the individual specifies. The intention being to avoid the problems current copyright laws create for the sharing of information⁵.

The type or version of CC licence is determined by a selection and combination of four main conditions that can be used to restrict how the licensee may use the licensed work, including:

- The licensee can change the licensed work, as long as they credit the creator of the original creation (Attribution);
- The licensee can exploit the licensed work (Non-commercial);
- The licensee can develop new work derived from the licensed product (No Derivative Works) and;
- The licensee may distribute derivative works only under a licence identical to the licence that governs the original work (Share Alike).

Using these conditions, the CC licensing model consists of six main licences that with the associated graphical icons are internationally recognised and used. In addition, the RDF/XML

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¹³ As defined at http://en.wikipedia.org/wiki/License

¹⁴ As defined at http://en.wikipedia.org/wiki/Software_license

¹⁵ Creative Commons. Available online at http://creativecommons.org/. Accessed 16th December 2008

metadata that describes the licence and the work enables licensed work to be automatically processed and located with ease

Despite its distinct advantages and overwhelming popularity, the CC is not ideal for all purposes. For sharing patient specific data in the form of digital content the CC does not address the following obstacles:

- Patient consent or withdrawal of consent
- Scope of permission (i.e., although the CC overcomes the issue of jurisdictional restrictions, the permission they grant is too wide and would contradict any gained consent)

A possible solution is to build on the current CC framework. Adaptive models of CC have been described for genetic research, such as the Science Commons' and the 'Clinical Commons' for the clinical community¹⁸. In collaboration with CCLearn¹⁹, the eViP project team are working to define a licensing model for the sharing and repurposing of VPs based on the CC licensing platform that accommodates the above listed obstacles. An overview of the eViP Commons licensing model is shown in Figure 3 and the remit of the agreed licensing terms agreed to by each eViP partner is outlined in Figure 4.



Figure 3. Overview of the eViP licensing model. Consented information receives a unique identifier and is then introduced to the eViP central pool (referatory) with predefined licensing terms. The licensing terms of an eViP VP created from repurposed information (derivative VP) will be limited by the terms of the most limited resource.

⁹ CCLearn. Available online at http://learn.creativecommons.org/. Accessed on 20th December 2008

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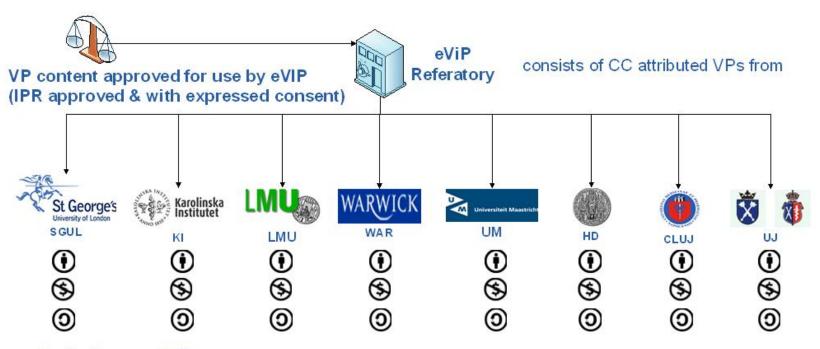
¹⁶ John Wilbanks and James Boyle (2006). *An Introduction Science Commons*. Available online at http://sciencecommons.org/wp-content/uploads/ScienceCommons_Concept_Paper.pdf. Accessed on 20th December 2008.

Science Commons. Available online at http://sciencecommons.org. Accessed on 20th December 2008.
 Ellaway, R. et al (2005). "Clinical Recordings for Academic Non-clinical Settings" -the CHERRI Project (Common Healthcare Educational Recordings Reusability Infrastructure). Available online at http://www.cherri.mvm.ed.ac.uk/. Accessed on 16th December 2008

4 The workflow for the eViP Model

The consent and licensing process involves the following steps based on best practice:

- 1. Clinician or healthcare specialist obtains consent using the eViP consent form and supplementary information sheet thus generating a unique identifier that will travel anonymously with the consented information.
- 2. Following a 'cooling-off' period (two weeks) to prevent unnecessary work in the event of the patient's change of mind, the information is evaluated to remove obvious identifiable information (e.g. distinctive birthmark, watch, tattoo etc.). Refer to figure 2 for more information.
- 3. Licensing terms associated with the consented information (any restrictions noted) are encoded digitally (tagged) and added to the eViP database. This is a form of digital rights management (DRM). The particular step has several purposes:
 - Effectively makes the information anonymous as the hard copy consent form with code is securely stored by the receiving institution. Only the metadata and information are submitted to the referatory of content
 - Creates an audit trail, a prerequisite is the ability to be retraced and withdraw consent if requested
 - Clearly identifies the remit of using the information
- 4. Listed and tagged information is placed within eViP referatory, ready for use by the team and the wider community of users wanting access to VPs.



Creative Commons KEY:

- Attribution. You let others copy, distribute, display, and perform your copyrighted work— and derivative works based upon it—but only if they give credit the way you request.
- Noncommercial. You let others copy, distribute, display, and perform your work—and derivative works based upon it—but for noncommercial purposes only
- Share Alike . You allow others to distribute derivative works only under a license identical to the license that governs your work
- No Derivative Works. You let others copy, distribute, display, and perform only verbatim copies of your work, not derivative works based upon it.

Figure 4. Remit of the licensing terms agreed by each eViP partners

5 Conclusion

Intellectual property in the form of copyright is not something to put on the 'back burner' any longer. It is a 'real' issue that threatens academic collaboration. However, provided the right steps are taken in preparation, such as the adoption of common consent forms and licensing models, it may still be possible to facilitate the sharing of digital content whilst protecting the liability of the respective institutions, regardless of geographic location.

The eViP project has demonstrated that by analysing the obstacles and devising common pathways that overcome these, it is possible to both manage and share digital content. Although there are many differences and obstacles to sharing digital content between medical institutions, a unified approach can be adopted. This approach will be used throughout this project. Further, this model can potentially be applied to any internationally developed/repurposed content that will be shared beyond the scope of this project.

6 Annex A – Completed copyright questionnaires from eViP partners

What is copyright?



Copyright arises automatically as soon as a literary, dramatic, musical or artistic work is put into a tangible form. Items which are protected by copyright include computer software, drawings, formulae, designs, text, letters, music and books. There is no requirement for registration (although registration can be useful in proving date of authorship) and protection currently lasts for the lifetime of the author plus 70 years. Copyright provides the owner with the rights to prevent others from copying the work without permission.



In Sweden, there is a special law regulating this in many aspects. It covers among other things: copying; adapting; distributing; communicating to the public by electric transmission (including by broadcasting and in an on demand service); renting or lending copies to the public; performing in public; and selling



In Germany the copyright is defined in the "Urheberrecht und verwandte Schutzrechte" (http://www.gesetze-im-internet.de/urhg/index.html) Works of literature, science and art are protected by Copyright. Precondition is that the work is an individual intellectual creation and one of the following: works of speech, like compositions, speeches, computer programs, pieces of music, pantomimic works, works of fine arts, photographic works, cinematic works, scientific or technical presentations like charts, tables, plans and drafts.

The copyright gives the author the right to decide about right of use of his work freely and exclusively. The Copyright in Germany is not transferable, but inheritable. Transferable by the author are only rights of use and industrial property rights. The copyright owner has the right to decide that his name has to be mentioned when his work is used somewhere.



Copyright arises automatically as soon as a literary, scientific, dramatic, musical or artistic work is put into a tangible form. Items that are protected by copyright include computer software, drawings, formulae, designs, texts (except laws), letters, music, movies, pictures books, journalistic work (except news) and statues. Copyright arises from a creative action. There is no requirement for registration, no need for using the copyright sign © and the protection lasts for the lifetime of the author plus 70 years. Copyright provides the owner with the rights to prevent others from copying the work without permission. Violation of copyright is a penal offence.



Set of rights which protects interests of authors. Those rights permit the author to decide about using of his original work. We may distinguish:

- author's personal rights, author's moral rights ("autorskie prawa osobiste")— author's rights to associate his name (or alias) with his work; right to keep the content and form of his work unmodified; these rights never expire and are untransferable; it is not allowed to relinquish them and to transfer them to another person; The author may decide not to execute his personal right.
- *author's copyright ownership, author's economic rights* ("autorskie prawa majątkowe") monopoly of property rights which are given to the author or publisher/producer or owner of licence; only author's copyright owners are authorized to exploit it; authors may cease/sell their copyright ownership rights.

Copyright may regard a wide range of creative, intellectual, or artistic forms or works. These include: poems, theses, plays, and other literary works, movies, choreographic works (dances, ballets, etc.), musical compositions, audio recordings, paintings, drawings, sculptures, photographs, computer software, formulae, designs, radio and television broadcasts of live and other performances.



Copyright arises automatically as soon as a literary, scientific, dramatic, musical or artistic work is made public for the first time. The author is the person who creates the original work. Co-authors are the persons who collaborate to the creation of the original work. Copyright provides the owner with the rights to prevent others from copying the work without permission.

What does copyright cover?



- copying
- adapting
- distributing
- communicating to the public by electronic transmission (including by broadcasting and in an on demand service)
- renting or lending copies to the public
- performing in public



All types of "immaterial" material (Images, texts, photos, videos etc) that a single person, or legal entity, has developed. However this requires a certain "level of quality" ("verkshöjd" in Swedish) to be copyrighted.



- copying
- distributing
- exhibition/exposition
- presentation, publication, reproduction, communication and distribution

- editing, translating and reorganization
- communicating to the public by electronic transmission (including by broadcasting and in an on demand service)
- renting or lending copies to the public



- copying
- adapting
- distributing
- communicating to the public by electric transmission (including by broadcasting and in an on demand service)
- renting or lending copies to the public
- performing in public
- selling



- copying
- adapting
- distributing
- communicating to the public by electronic transmission (including by broadcasting and in an on demand service)
- renting or lending copies to the public
- performing in public
- elaborating of somebody's work
- translating
- recast

The name of the author and original title of work should be put on copies.



Items which are protected by copyright include computer software, drawings, formulae, designs, text, letters, music and books.

What are 'original works'?



A work can only be original if it is the result of independent creative effort. It will not be original if it has been copied from something that already exists. If it is similar to something that already exists but there has been no copying from the existing work either directly or indirectly, then it may be original.

The term "original" also involves a test of substantiality - literary, dramatic, musical and artistic works will not be original if there has not been sufficient skill and labour expended in their creation. But, sometimes significant investment of resources without significant intellectual input can still count as sufficient skill and labour.

Ultimately, only the courts can decide whether something is original.

There is much case law indicating, for example, that names and titles do not have sufficient substantiality to be original and that, where an existing work is widely known, it will be difficult to convince a court that there has been no copying if your work is very similar or identical

Copyright applies to computing and the internet in the same way as material in other media. For example, any photographs you place on the internet will be protected in the same way as other artistic works; any original written work will be protected as a literary work, and so on.



Anything that a person or legal entity creates



A work can only be original if it is the result of independent creative effort. It will not be original if it has been copied from something that already exists. E.g. answers to test questions are normally not regarded as original, but may be in case of inventive free text answers. Translation and adaption of a work is protected by copyright as an individual work.



A work can only be original "oorspronkelijk" if it is the result of independent creative effort. It will not be original if it has been copied from something that already exists. If it is similar to something that already exists but there has been no copying from the existing work either directly or indirectly, then it may be original.

The term "original" also involves a test of substantiality –literary, dramatic scientific, musical and artistic works will not be original if there has not been sufficient skill and labour expended in their creation.

Ultimately, only the courts can decide whether something is original.

There is law indicating, for example, that names and titles do not have sufficient substantiality to be original and that, where existing work is widely known, it will be difficult to convince a court that there has been no copying if your work is very similar or identical.

Copyright applies to computing and internet in the same way as material in other media. For example, any photographs you place on the internet will be protected as a literary work, and so on.



These are effects of human action which are characterized by creativity and individuality. In practice it is difficult to define these terms. Creative character means that work includes new values based on author's mental abilities. Individuality of work express oneself in its uniqueness; It could be understood as a mark of author's personality.



The first piece of work produced in a specific form / the result of a work process /creative activity.

How is copyright handled with computer programs?



Conversion of a program into or between computer languages and codes corresponds to adapting a work. Storing any work in a computer amounts to copying the work. In addition, running a computer program or displaying work on a video display unit (VDU) will usually involve copying and thus require the consent of the copyright owner.



As any other type of artistic material like a painting, photo or else. However, computer programs can normally not be patented.



Computer programs are all programs including draft material, copyright protection includes interfaces, ideas and concepts. Computer programs are protected like works of speech if they are a result of individual intellectual creation. Other criteria like quality or aesthetics are not relevant.

For a computer program designed by an employee (as part of his work) only the employer is authorized for copyright. Only the copyright owner may copy, translate, edit or distribute the program or allow others to do so.



Conversion of a program into or between computer languages and codes corresponds to adapting a work. Storing any work in a computer amounts to copying the work. In addition, running a computer program or displaying work on a video display unit will usually involve copying and thus require the consent of the copyright owner.



Legal protection given to computer programs includes every form of its expression. Ideas and rules, which are fundamental to every element of computer program, are not protected by

copyright. Property rights to computer program created by employees in result of doing their duty are given to employers, unless the contract has changed it.

Author's copyright ownership to computer programs include rights to:

- permanent or temporary multiplication of computer programs
- translating, adapting, different changes in computer programs
- distribution

It is not required to have permission to: do backups, test computer program's function (learn about their idea and rules), copy and translate code as far as it is required for the interoperability of the computer programs.

It is punishable to use legally protected computer programs without licence.



Copyright applies to computing and the internet in the same way as material in other media. The selling of the right to use a computer program doesn't imply the transfer of the copyright.

How to determine copyright ownership?



The general rule is that the author is the first owner of copyright in a literary, dramatic, musical or artistic work. In the case of films, the principal director and the film producer are joint authors and first owners of copyright. The main exception is where a work or film is made in the course of employment, in which case the employer owns the copyright.



A person that has created something claims the copyright But please note: 1. A person employed (a programmer for example) to create for example computer programs (or a VP), can usually NOT claim copyright. Thus, that copyright belongs to the employer. 2. A teacher at a Swedish university owns ALL rights of a inventions that are patentable. However, since a program cannot be patented, this does not apply here. So normally, the university claims copyright for teaching materials. 3. A teacher at a Swedish university might claim that he/she owns the commercial rights as well as the copyright to a computer program, if the construction of that system can be seen as not belonging to his/her normal duties at the university. However, that is hard to prove. Thus, normally, all Swedish university teachers share their rights in such a way that the university freely could use ANY type of systems the teacher has created, but the teacher can sell the system to another university or to a company.



The owner of the copyright is the creator of the work. If more than one author has contributed to the work and it is not possible to make use of the parts, all contributing authors are as well authors of the work. A contributing author can dispense with his exploitation rights.



The general rule is that the author is the first owner of copyright in a literary, dramatic, musical, scientific or artistic work. In the case of films, the principal director and the film producer are joint authors and first owners of copyright. The main exception is where a work is made in the course of employment, in which case the employer owns the copyright.



Author's personal rights are given exclusively to the work's author. It never expires and is untransferable. It is not allowed to relinquish them and to transfer them to another person; the author may decide not to execute his personal right. Author's copyright ownership belongs initially to the author or in some cases – to the publisher/producer. This right may be purchased by others.



The author is the first owner of copyright / the person who first make public a piece of work.

Can copyright be transferred to someone else?



Yes. Copyright is a form of intellectual property and, like physical property, can be bought and sold, inherited or otherwise transferred. A transfer of ownership may cover all or only some of the rights to which a copyright owner is entitled. First or subsequent copyright owners can choose to licence others to use their works whilst retaining ownership themselves



Yes.



The Copyright in Germany is not transferable, but inheritable. Transferable by the author are only rights of use and industrial property rights. The right of use can be transferred exclusively or limited (concerning time, content or area).

Maybe interesting in this context is the following about the communication to the public for teaching and science ($\S52a$): If someone has obtained the right of use from someone else and wants to use this for example to teach his students, there is a a duty to pay remuneration (this is in effect until the end of 2008, but may be extended). For universities the fee is $0.125 \in$ per page and user/member of staff. Communication to the public is prohibited if the copyright owner presents his work reasonably in digital form to the public.



Yes and no. Yes. Copyright is a form of intellectual property and, like physical property, can be bought and sold, inherited or otherwise transferred. A transfer of ownership may cover some of the rights to which a copyright owner is entitled. First or subsequent copyright

owners can choose to licence others to use their works whilst retaining ownership themselves. No. Not transferable is the 'droit moral' (the moral rights) as a part of the copyright.



Author's personal rights are un-transferable. It is not allowed to relinquish them and to transfer them to another person; the author may decide not to execute his personal rights. Author's copyright ownership can be transferred to others by inheritance or by a written contract.



The author can sell the copyright (patrimonial), can sell to an editor the reproduction and distribution rights or can rent a copy of the work (program) for a determinate period.

What is the distinction between owning a possession and owning the copyright?



Copyright exists independently of the medium on which a work is recorded. So if, say, you have bought or inherited a painting, you only own any copyright in it if that also has been transferred to you.



Unsure.



You cannot sell the copyright or give it away like something you own.



Copyright exists independently of the medium on which a work is recorded.



Copyright exists independently of the medium on which a work is recorded. To be owner of a copy doesn't mean to be owner of copyright.



The two are independent.

How long does copyright last?



Copyright in a literary, dramatic, musical or artistic work (including a photograph) lasts until 70 years after the death of the author. The duration of copyright in a film is 70 years after the death of the last to survive of the principal director, the authors of the screenplay and

dialogue, and the composer of any music specially created for the film. Sound recordings are generally protected for 50 years from the year of publication. Broadcasts are protected for 50 years and published editions are protected for 25 years.

For copyright works created outside the UK or another country of the European Economic Area, the term of protection may be shorter. There may also be differences for works created before 1 January 1996.



We think it is 100 years.



Copyright lasts until 70 years after the death of the author or the last remaining author (if more than one are involved). For scientific articles the copyright lasts until 25 years after the publication of the article.



Copyright in a literary, scientific, drama, musical or artistic work (including a photograph) lasts until 70 years after the death of the author (post mortem auctoris). In The Netherlands also for authors who died between 1923 and 1995.

The duration of copyright in a film is 70 years after the death of the last to survive of the principal director, the authors of the screenplay and dialogue, and the composer of any music specially created for the film. For copyright works created outside The Netherlands or another country of the European Economic Area the term of protection may be shorter: i.e. the term of the Berner Convention: 50 years.



Author's personal rights never expire.

Author's copyright ownership lasts for all author's life and until 70 years after his death. If author is unknown – 70 years since the work had been published for the time. If author's property rights are transferred to another person (not the creator): 50-70 years since creation/distribution of work.



Copyright protection currently lasts for the lifetime of the author plus 70 years (including computer programs).

Is material on the Internet protected by copyright?



Yes. Under UK law (the position in other countries may differ) copyright material sent over the Internet or stored on web servers will generally be protected in the same way as material in other media. So anyone wishing to put copyright material on the Internet, or further distribute or download such material that others have placed on the Internet, should ensure that they have the permission of the owners of rights in the material.



Yes indeed.



Yes, WebPages can be seen as works of applied arts (but they are not listed explicitly in the law) and are therefore protected like any other material. Transient copying of content (like for example in a cache or Proxy) is allowed, but content change is not permitted.



Yes. Under Dutch law copyright material sent over the Internet or stored on Web servers will be protected in the same way as material in other media. So anyone wishing to put copyright materials on the Internet, or further distribute or download such material that others have placed on the Internet, should ensure that they have the permission of the owners of rights in the material.



Yes, lot of material on the Internet is acknowledged as original work and it is protected in the same way as material on other media. Illegal copy and publication of this content on internet pages is treated as a breach of author's rights.



Yes, they are.

7 Annex B- eViP Common consent form

This consent form is to be customised by each partner editing the 'green' areas of text to fit their own institution.

Unique identifier code: evip000001

e-Learning Unit

Centre for Medical and Healthcare Education St George's University of London 4th Floor Hunter Wing Cranmer Terrace London SW17 0RE United Kingdom

Project: eViP (Electronic Virtual Patients)

Performer Consent and Release Form for Virtual Patient Digital Content

Background:

- A. The aim of the eViP programme is to create a collection of multillingual and multicultural virtual patients to improve the quality and efficiency of medical and healthcare education across the world.
- B. [The e-Learning Unit at St George's Hospital Medical School (trading as St George's, University of London)], is working as part of this collaboration with other International medical and healthcare education establishments to repurpose and share existing virtual patients with the wider online community as part of the eViP programme.
- C. [St George's University of London] intends to allow other medical, healthcare and educational collaborative establishments to use, re-use, store and distribute the digital content, including x-rays, images, photographs, films, and recordings, for the purpose of developing digital teaching and educational tools in concordance with the Creative Commons licensing model.
- D. All personal information supplied will remain confidential and will not be made publically available.
- E. The undersigned have agreed to appear/perform on the digital content

Agreement:

- 1. The parent or guardian of any one or more of the undersigned who are 18 years of age or under, do assign to [St Georges, University of London] and the eViP programme all rights, whether or not known in and to all motion picture or still photographs of my or my child's likeness, poses, acts and appearances or the sound records made by [St George's, University of London] or my or my child's voice.
- The foregoing permission is given for the benefit of [St George's, University of London], the eViP consortium and any of its successors, assignees or corporations, to use, re-use, store, distribute present, assign and/or exploit any digital content involving the Undersigned, including photography, videos, recordings information and names.
- 3. I understand that my participation is voluntary and that I have the right to withdraw permission at anytime, by providing written notice to the address above, without any penalties. In the case of withdrawal it may not be possible to recall any multimedia items that have already been shared or disseminated.

 I have read this performer release and consent form carefully and fully understand its meaning and implications. I have had the opportunity to ask questions. 								
*If you are under 18 years of age, a parent or guardian must also sign.								
Name of Participant	Date	Signature						
*Name of Person giving consent (if different from participant, e.g. Parent)	Date	Signature						
Signed at the [e-Learning Unit at St George's, University of London]:								
Name of staff	Date	Signature						

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8 Annex C – Information sheet to accompany eViP consent form



eViP Consent Form Information Sheet

Study title: eViP (Electronic Virtual Patients)

You are being invited to take part in the eVIP programme. Before you decide whether or not to take part, 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

What is the purpose of the study?

The aim of the eViP programme is to create a collection of multilingual and multicultural virtual patients to be used across Europe to improve the quality and efficiency of medical education.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign the eVIP consent form. If you decide to take part you are still free to withdraw at any time and without giving reason. If you decide to withdraw attempts will be made to remove all information relating to you where possible however, this may not be possible for some material.

How will my information be used?

The information (digital content) provided will be used to create virtual patient scenarios that will be used as educational tools for improved medical and healthcare education. Generation of virtual patients will involve the use of provided information, digital content, including x-rays, images, photographs, films, and recordings, for the purpose of developing digital teaching and educational tools in concordance with the Creative Commons licensing model. This information will appear including photography, videos, recordings information and names.

Where possible any unique identifiable marks e.g tattoos will be removed.

Will my information be kept confidential?

All information provided will be kept confidential, at no point will personal information be distributed to others.

Contact for further information:

[Contact name, telephone number and email-to be inserted for the institution]