



# Virtual Physiological Human Network of Excellence

**Grant Agreement: 223920**

## **VPH ToolKit Guideline Document**

**Topic: Legal, Ethics and Provenance**

**Version 1.0**

**14-Mar-2011**

This page is intentionally blank

## Document Information

<b>IST Project Num</b>	FP7 – 2007 - ICT - 223920	<b>Acronym</b>	VPH NoE
<b>Full title</b>	Virtual Physiological Human Network of Excellence		
<b>Project URL</b>	http://www.vph-noe.eu		

<b>Document</b>	<b>Number</b>	G06	<b>Title</b>	Guidance (Ethics, Legal, Provenance)
-----------------	---------------	-----	--------------	--------------------------------------

<b>Status</b>	Version. 1.0	Final <input checked="" type="checkbox"/>
---------------	--------------	-------------------------------------------

<b>Dissemination Level</b>	Public <input checked="" type="checkbox"/> Consortium <input type="checkbox"/>
----------------------------	--------------------------------------------------------------------------------

<b>Authors (Partner)</b>	UCL	Coveney, Diaz, Mendes, Zasada, Haidar, Jacovella (QM)	
	UOXF	Cooper, Fletcher, Gavaghan, Kohl, McCormack	
	CNRS	Thomas, Friboulet, Cervenansky	
	INRIA	Sermesant, Bleuzé	
	UPF	Larrabide, Martelli, Omedas	
	UOA	Hunter, Britten, Christie, Lloyd, Brooks	
	EBI	de Bono	
	USFD	Fenner, Lawford, Wood	
	IMIM	De Fabritiis, Sanz, Villa-Freixa, Giorgino	

<b>Responsible Author</b>	John Fenner		<b>Email</b>	j.w.fenner@sheffield.ac.uk
	<b>Partner</b>	USFD	<b>Phone</b>	+44 (0) 114 271 2313

<b>Abstract (for dissemination)</b>	This document provides guidance on attributes required of VPH NoE ToolKit content.
-------------------------------------	------------------------------------------------------------------------------------

*The information in this document is provided as is and no guarantee or warranty is given that the information is fit for any particular purpose. The user thereof uses the information at its sole risk and liability. Its owner is not liable for damages resulting from the use of erroneous or incomplete confidential information.*

<b>Version Log</b>			
<b>Issue Date</b>	<b>Version</b>	<b>Author</b>	<b>Change</b>
31-Jul-10	0.1	WP3	Outline draft
21-Feb-11	0.5	WP3	First complete draft for comment
06-Mar-11	0.6b	WP3	Major restructuring following independent review
14-Mar-11	0.7	WP3	Minor alterations for improved readability
22-Mar-11	1.0	WP3	First public release

This page is intentionally blank

# Table of Contents

<b>EXECUTIVE SUMMARY .....</b>	<b>9</b>
<b>Introduction – the characteristics of this document .....</b>	<b>10</b>
<b>Setting the Scene: Legal, Ethics and Provenance.....</b>	<b>13</b>
<b>Interactions and Dependencies with Other Guideline Documents.....</b>	<b>14</b>
<b>The Legal Perspective – an introduction to legal, principles and their role in ToolKit content submission .....</b>	<b>17</b>
<i>Legal Aspects.....</i>	<i>17</i>
<i>Conclusion.....</i>	<i>18</i>
<b>Background – Legislative Aspects and Standards .....</b>	<b>19</b>
<i>Introduction.....</i>	<i>19</i>
<i>Copyright principles – originality, ownership, authorship.....</i>	<i>19</i>
<i>Data Protection.....</i>	<i>22</i>
<i>Liability.....</i>	<i>23</i>
<i>Conclusion.....</i>	<i>24</i>
<b>Legal Guidelines for ToolKit Content Delivery .....</b>	<b>25</b>
<i>Outline.....</i>	<i>25</i>
<i>Categorised ToolKit content – legal questions.....</i>	<i>26</i>
<i>Conclusion.....</i>	<i>28</i>
<b>The Ethics Perspective – an introduction to ethical principles and their role in ToolKit content submission .....</b>	<b>30</b>
<i>Ethical Aspects.....</i>	<i>30</i>
<i>Conclusion.....</i>	<i>31</i>
<b>Background – Ethical Aspects and Standards .....</b>	<b>33</b>
<i>Introduction.....</i>	<i>33</i>
<i>Implications – ethical analysis.....</i>	<i>33</i>

<i>The Medical/Clinical Perspective</i> .....	34
<i>Risk</i> .....	35
<i>References</i> .....	35
<b>Ethical Guidelines for ToolKit Content Delivery</b> .....	<b>37</b>
<i>Outline</i> .....	37
<i>Categorised ToolKit content – ethics questions</i> .....	38
<i>Conclusion</i> .....	39
<b>The Provenance Perspective – an introduction to provenance principles and their role in ToolKit content submission</b> .....	<b>42</b>
<i>Provenance</i> .....	42
<i>Conclusion</i> .....	42
<b>Background – Provenance and Standards</b> .....	<b>43</b>
<i>Introduction</i> .....	43
<i>Provenance and Formalisation</i> .....	43
<i>Conclusion</i> .....	45
<i>References</i> .....	45
<b>Provenance Guidelines for ToolKit Content Delivery</b> .....	<b>47</b>
<i>Outline</i> .....	47
<i>Categorised ToolKit content – provenance questions</i> .....	48
<i>Conclusion</i> .....	51
<b>APPENDICES</b> .....	<b>53</b>
<b>Appendix 1 – Case Studies</b> .....	<b>54</b>
<i>A UK Perspective</i> .....	54
<i>Case Studies – An Ethical Dilemma</i> .....	59
<i>Case Studies – Compliance, Ambiguity and Harmonization</i> .....	62
<b>Appendix 2</b> .....	<b>63</b>
<i>The Declaration of Helsinki</i> .....	63

<b>Appendix 3 - VPH and the Law: a wider perspective.....</b>	<b>68</b>
<i>Scope, Content and Limitations .....</i>	<i>69</i>
<i>Regulatory agencies .....</i>	<i>69</i>
<i>Copyright.....</i>	<i>69</i>
<i>Ownership .....</i>	<i>70</i>
<i>Databases and Copyright.....</i>	<i>71</i>
<i>Collective Works and Copyright .....</i>	<i>74</i>
<i>Data Protection.....</i>	<i>76</i>
<i>Identification, authentication and access.....</i>	<i>77</i>
<i>User Friendly Laws.....</i>	<i>77</i>
<i>Conclusion.....</i>	<i>78</i>

This page is intentionally blank

## EXECUTIVE SUMMARY

This Guideline is designed to support delivery of content to the ToolKit, by raising relevant legal, ethics and provenance issues with ToolKit contributors. In so doing it forms part of a wider framework, that helps to give meaning to concepts of 'acceptability' and 'quality' for material delivered to the ToolKit.

The 'take home message' of this guideline document is four-fold:

- Whether you are aware of it or not, as a provider of ToolKit content, you are operating in a territory regulated by law. Personal interaction with the ToolKit will result in you being classified as an author or user.
- Given the legal context, it is prudent to be aware of your legal responsibilities in respect of copyright, data protection, freedom of information and liability (see pages 17-28).
- The close association of the VPH with industry and the clinic requires that you operate in an ethically considerate manner. Ethical responsibilities are discussed on pages 30-40.
- The interaction of research, clinic and industry under the VPH umbrella implies a degree of interoperability that can only be effective in the context of robust provenance (software tools and data). Aspects of provenance are broached on pages 42-52.

This document is divided into three distinct sections (Legal, Ethics, Provenance), but all are underpinned by a common determination to promote delivery of high quality ToolKit content, driven by a desire to encourage its use within the clinical setting.

There are several such guideline documents in this series, covering the full range of issues affecting content providers. They are being developed over a period of time and, once finalised, may be bound together as a single VPH NoE resource.

## Introduction – the characteristics of this document

This document is not intended to be an exhaustive reference on ethics/legal/provenance matters relating to the VPH. Rather, it can be characterised as follows:

*SCOPE* – these ethics/legal/provenance guidelines are directed at VPH researchers that intend to contribute data/software to the VPH ToolKit. This particular document seeks to highlight a range of ethics, legal and provenance concerns that should be foremost in the minds of contributors seeking to expose their content to the wider VPH community. The recommendations issue from a generic European perspective only, since differences of interpretation at a National level add a degree of complexity that would unnecessarily compromise the clarity of this work. *This document does NOT provide a comprehensive perspective on the issues presented, rather it identifies a subset of topics deemed to be pertinent to, and require action from, VPH content providers.* For more detailed discussion of the topics addressed, the interested reader is referred to the bibliography and appendices attached to this document, noting that many of the principles presented, have their origins in the statutes of the key regulatory agencies listed below:

<u>Regulatory Agency</u>	<u>Regulation/Statute</u>
<b>Ethics:</b>	
• World Medical Association	- Declaration of Helsinki
• (Inter) National Law	- Nuremberg Code
<b>Legal:</b>	
• The World Trade Organisation	- TRIPs
• The World Intellectual Property Organisation	- WIPO Copyright treaty
• The OECD	
• The European Parliament	- Data Protection (Directive 95/46/EC)

*REVISION SCHEDULE* – future revisions of this document will be forthcoming. The ethics/legal/provenance landscape is dynamic, and significant changes and developments capable of influencing submission of ToolKit content can be expected in the (not-too-distant) future. Consequently, the revision cycle of this document will

be iterative, responding to the feedback, needs and dynamics of the VPH community and the changing environment in which it operates.

*ONE of a SERIES* - This document (along with several others) strives to encourage ToolKit contributors to consider some basic requirements that are pertinent to exposure of material to the VPH community. This guideline is one of a series that combine to form a complete guide to the ideal content and presentation of materials offered for distribution via the Virtual Physiological Human Network of Excellence ToolKit Portal. The full set of Guideline Documents is summarised below, and you are encouraged to consult these in advance of ToolKit content submission.

<b>Guidance Area</b>	<b>Description</b>
Tool characterisation	The attributes important for inclusion in the documentation of Tools, including performance validation
Model characterisation	The attributes important for inclusion in the documentation of Models, including performance validation
Data characterisation	The attributes important for inclusion in the documentation of Data
Ontological annotation	Methods of knowledge representation, in particular the significance, benefits and methods of ontological annotation of ToolKit content
Interoperability	Key attributes and methods for enabling ToolKit content to be utilised in concert within a multistage workflow
Ethico-legal issues, provenance	The inherited responsibilities that are attached to any item of ToolKit content – perhaps particularly data – including legal, ethical and territorial restrictions
Licensing	The conditions that apply to the legitimate use of the content from an intellectual property standpoint
Usability and training	The factors that are important for the easy use and ready acceptance of ToolKit content, taking into account the environment, the likely users and the need for interoperability. Additionally, the nature of training facilities of all types appropriate to particular content categories.

LICENSING - This document is licensed under the open [Creative Commons Attribution-ShareAlike 2.0 England & Wales licence](#).

## Setting the Scene: Legal, Ethics and Provenance

The ToolKit portal offers a unique integration of disparate biomedical resources and with it, the opportunity to cultivate an environment of tools/data exchange\*. The ToolKit provides links for VPH-related resources as well as services supporting the sharing of content. However, users of such services should be aware of vulnerabilities and responsibilities in the sharing of their material, particularly in respect of data protection, copyright protection, licensing, liability etc. all of which have legal implications and are designed to safeguard the rights of individuals and the interests of the wider population.

The sharing of clinical data presents particular challenges, the most immediate of which are those of ethics/consent, confidence and demonstrable best practice. At the very least, contributors should endeavour to ensure that those directly connected with clinically related content are satisfied that consent for data exposure has been obtained, and that the anonymisation and authorization processes of the infrastructure on which the material is exposed, are adequate and clearly specified.

The VPH/NoE ToolKit Portal is a work in progress and is not currently in a position to be considered a mature and robust platform, capable of supporting integration of clinical, industrial and research resources. Nonetheless this is its primary goal, and in an effort to accelerate and extend such capability, links to technologies around the globe that complement and support similar hosting activities are also accessible from the Portal. Users should be aware that these may invite separate, local ethical and legal consideration that is not applicable to its intended use elsewhere.

This document briefly considers the above challenges, partitioned according to three distinct sections:

- Legal (pages 17-28)
- Ethics (pages 30-40)
- Provenance (pages 42-52)

Appendices are attached at the end of this document, spanning a range of topics from the general to the technical, and including some case studies.

---

\* A perspective on many aspect of digital curation can be found at the Digital Curation Centre website. (<http://www.dcc.ac.uk>)

## Interactions and Dependencies with Other Guideline Documents

Data/software characterisation, the implications of licensing and due recognition of legal, ethics and provenance responsibilities are just some of the factors necessary for successful distribution of interoperable VPH resources. This interplay of technologies, ideas and data naturally ensures that a Guideline document such as this, interdigitates with others in the series. The topics addressed by the other Guideline documents (Tools, Models etc.) are wide-ranging in their coverage, reflecting the diversity of VPH research. Readers should be mindful of their existence for the following reasons<sup>†</sup>:

- **Data Characterisation Guidelines:** Exposure of software tools and data has legal implications (see this document), but such action invites additional responsibilities if interoperability is required. The use of particular software or data formats might be limited by legal constraints, and therefore the data characterisation document recommends strategies that can minimise conflicts and maximise interoperability.
- **Licensing Guidelines:** Licensing is a legal matter and the Licensing Guidelines are close to the heart of this ethico-legal guideline document. However, the topic is sufficiently complex that it merits a document of its own. In the Licensing Guidelines you will find recommendations relating to intellectual property, particularly data and software licensing. The VPH-NoE advocates the use of a business friendly, open source software license wherever possible. Similarly for data, an open license is encouraged, to promote sharing and re-use.
- **Tools Guidelines:** The function of tools is to manipulate data, taking inputs and transforming them into outputs. Characterisation of tools necessarily overlaps with descriptions of how files are generated, read, and restrictions concerning their distribution (ethico-legal implications). Matters of provenance are related to quality - what guarantees can be offered in order that tools/data can be trusted in their sphere of application?
- **Models Guidelines:** Publication of models involves a protocol and rigor that closely mirrors the exposure (ie. Publication) of data. Legal/ethics/provenance lessons can be learnt from both domains.

---

<sup>†</sup> See the following for a discussion of issues relating to sharing of software/data: Schofield PN, Bubela T, Weaver T, Portilla L, Brown SD et al. Post-publication sharing of data and tools. Nature 461, 171-173 (10 September 2009) | doi:10.1038/461171a; Published online 9 September 2009

- **Ontological Guidelines:** Ontologies have a close association with metadata. Not all meta-data can fit in a hierarchical construction, but the building of ontologies can assist with provenance in the realms of tools and data.
- **Interoperability Guidelines:** The guidelines presented under ‘interoperability’ govern what should appear in a good data definition and documentation. Overlap with this document is a requirement for robust interaction.
- **Usability and Training Guidelines:** Users need to be aware of advantages and drawbacks inherent to the use of tools and data. Documentation should include tutorials or other teaching tools to encourage uptake and interoperability. Details are defined more widely in the Usability and Training Guidelines document.

This page is intentionally blank

## **The Legal Perspective – an introduction to legal, principles and their role in ToolKit content submission**

The VPH ToolKit Portal offers the opportunity for cooperation across biomedical science on an international scale, but it also introduces some ethical dilemmas, and highlights the need for intelligent legislation. The ethical dimension necessarily includes the purpose of the VPH (ultimately, improved healthcare) and its suitability to fulfil that purpose. The legal component is necessary to safeguard the public (eg. copyright, privacy, freedom of information) and can provide guidance in anticipation of adverse outcomes resulting from inappropriate application of VPH Portal resources (eg. an error in a model or incorrectly interpreted data). Provenance is important because it introduces concepts of traceability and audit that can provide a perspective on data quality. The specifics of these influences and their implications for ToolKit content submission are addressed subsequently, but first the context of legal issues in respect of ToolKit content are presented below.

### ***Legal Aspects***

The ToolKit Portal is a repository of contributed health resources (applications, data, knowledgebases etc.) that may be used to influence patient management (either through clinical decision support or development of new devices by industry). The relevant, principal legislative aspects can be identified as:

- copyright – all contributions to the ToolKit should consider issues of ownership and clarify the terms of use of the contributed resource. (Licensing is one of the ‘Guidelines’ in the series, independently compiled as a separate ToolKit Guideline document).
- data protection and freedom of information – concerns the holding and processing of an individual’s personal data, particularly the safeguarding of their privacy.
- liability – relevant to responsibility for injury or mismanagement as a result of interaction with the VPH. Regulatory compliance might also be a feature of some cases.

The goal of VPH interoperability (tools and data) demands that copyright, IPR etc. must be given due consideration. This includes acknowledgement of originality, ownership and authorship, with particular care required in the context of data exposed from clinically related databases - data protection, ethics and provenance are acutely relevant in this domain.

Because of the potential of the VPH to influence healthcare, issues of liability must also be

given serious attention (eg. what happens if a VPH interaction adversely affects an individual?). There may be many reasons for an unforeseen adverse outcome such as patient variability, databases populated with incorrect data, inappropriate use of data or models, or a misunderstanding of the assumptions associated with a model. The attachment of adequate disclaimers to contributed ToolKit content is perhaps the simplest method of clarifying liability and the terms of use of the resource.

As with data protection, be aware that the laws (and their interpretation) covering such eventualities may differ between EU member States. In particular, content contributors and users should be aware of their own national obligations in respect of these issues (data protection etc).

### ***Conclusion***

Legal and ethical considerations pervade the domain of practical applied healthcare, and therefore it is both necessary and good practice for ToolKit resources to acknowledge these factors in delivered content. Additionally, provenance provides a complementary audit trail that can help to verify the quality, ethical and legal status of data/software provided.

The following pages justify the need for legislative aspects in more detail (p19-24) complemented by specific recommendations relating to delivery of VPH ToolKit content (p25-28).

## Background – Legislative Aspects and Standards

### ***Introduction***

Perhaps the law most pertinent to exposure of ToolKit content within the VPH is Copyright law, since it cuts across almost every topic with which the VPH is involved. However, this does not diminish the need for compliance with other laws; data protection, privacy, human rights. Contract law and international treaties also play a role in regulating interactions between researchers and end-users. The following section outlines responsibilities in terms of:

- Copyright
- Data protection
- Liability

### ***Copyright principles – originality, ownership, authorship***

Copyright, sui generis protection, neighbouring rights – these are terms relevant to many of the subject areas covered by VPH research, such as databases, software, publications etc. Several principles are so fundamental, that they cut horizontally across the body of Copyright law, particularly the principles of originality, ownership and authorship. A key characteristic of Copyright, is that such rights do not require a specific action (e.g. registration) since they are generated inductively by the creation of the material (ie. copyright automatically exists with the creation of its subject matter). This has important implications for VPH scientists. Whether they are aware of it or not, they are operating in a territory regulated by law, and will be classified as authors or users.

### **Ownership**

Historically, ownership and authorship were functions originally associated with an individual. The development of modern work structures, means that these are now identified as separate functions and carry separate rights. Moral rights belong to the author - the ‘first author’. This is the right to be identified as the author of the protected work, including the respect from others for the integrity of the work. However, authorship is not the same as ownership. For example, a researcher can be an ‘author’, but the employer can be the ‘first owner’ of the work (unless agreed otherwise, by contract). First ownership is important because:

- 1) it sets the limit of duration of the copyright
- 2) it separates transferable rights from the moral rights that remain with the first owner

*Joint ownership* applies to copyright works generated by the collaboration of two or more authors whose contribution cannot be separated from that of the other(s). It applies to copyright as well as to Intellectual Property Rights and other forms of protection. For a patent there might be many inventors, but only one can be identified as the First inventor and he/she is responsible for the maintenance of the patent. The concept of ownership can also accommodate scenarios in which an owner only owns a share or a proportion of the work.<sup>‡</sup> Such division is likely to be common within the VPH, due to the collaborative nature of many research projects. In respect of licensing, when copyright is jointly owned, each owner has a say on the granting of a license.

### **Authorship**

Copyright law has historically developed around the concept of a creator/author who dedicates time and effort to produce a literary creation. Copyright is a 'compromise right' that allows the author to make copies for distribution and profit in order to live off the fruits of his/her intellectual creation. It also allows the public to benefit from the work of the creator. In modern times, some of the rights associated with copyright have become the rights of the publisher who has an established ownership of the copyright (economic rights). Modern technologies have complicated the picture so that now, a copyright product can have many copyright owners, each of them owning copyright over one or more aspect or stage of production of the product.

*Joint authorship* - This is important in any work or project that requires multiple persons or organizations to work together. In general terms joint authorship applies to copyright works generated by the collaboration of two or more authors and which contribution cannot be separated from that of the other(s). The classic example is a publication that lists all the authors<sup>§</sup>. Note that joint authorship implies that each author owns and has rights over the entire work as if he/she was the sole owner (common property). Each author is entitled to his/her share that can be isolated. In summary, authorship is joined (joint authors), ownership is common (each owner owning a share).

These principles have relevance to exposure of VPH data/software, because its creation may

---

<sup>‡</sup> Consider the example of a cake as a metaphor for a work subject to IP rights. Each joint owner will own the cake and can eat it all, provided that the others are notified, can object and are compensated. The owner of a share can only eat a slice of the cake that is determined by its share of ownership.

<sup>§</sup> ...but the definitions of joint authorship and joint ownership vary under different national legislation.

have involved many contributors. Databases are a case in point, because a database may be a composite of many contributions. Clearly it is prudent to characterise the authorship of such content and establish agreed terms of exposure, prior to its release to the VPH community.

### **Databases and Copyright**

Databases are defined by the European Database Directive 1996: “database` shall mean a collection of independent works, data or other materials arranged in a systematic or methodical way and individually accessible by electronic or other means”. (Note that the Database Directive does not apply to software).

The definition of a database protectable by copyright requires four elements:

- 1) independence of the constituent elements
- 2) systematic or methodical arrangement of the elements
- 3) individual accessibility of the elements
- 4) intellectual creation in selection and arrangement of contents

A database is designed to facilitate storage of, and access to, a breadth of data. According to Copyright law, it is permissible to use the database or extract data for:

- (a) private purposes, in relation to the contents of a non-electronic database;
- (b) the purposes of illustration for teaching or scientific research, as long as the source is indicated and to the extent justified by the non-commercial purpose to be achieved;
- (c) public security or an administrative or judicial procedure.

Implied consent of the right holder is used in some cases to exempt certain uses from copyright protection (e.g. hyperlinks). Transient copies can be exempted from copyright for reproductions on Internet routers, web browsing or copies created in the Random Access Memory (RAM) of a computer, copies stored in local caches or copies created in proxy servers. Database protection lasts for a period of 15 years after completion of the database, or whenever subsequent modification has generated a new object of protection

*Originality* - A database can be eligible for protection when a degree of originality is present... “by reason of the selection or arrangement of their contents”... as a mark of the... “author’s own intellectual creation”. For example, if the authors only apply standard procedures, it cannot be eligible for protection. The test of originality is not a clear one and it

can be subject to different interpretation. In case of doubt, the test of labor and investment can assist with clarification.

*Authorship* – The presence of multiple authors of database content, and their associated rights is clarified within copyright law:

1. The author of a database shall be the natural person or group of natural persons who created the database or, where the legislation of the Member States so permits, the legal person designated as the right holder by that legislation.
2. Where collective works are recognized by the legislation of a Member State, the economic rights shall be owned by the person holding the copyright.
3. In respect of a database created by a group of natural persons jointly, the exclusive rights shall be owned jointly.

The compromise rights attributed to the authors includes authorization for :

- 1) the reproduction or copy of the database
- 2) any alteration including translation, adaptation, arrangement
- 3) distribution to the public
- 4) communication to the public
- 5) any reproduction, distribution and communication of the database resulting from its alteration, translation, etc.

### **Data Protection** \*\*

Within the terms of the European Data Protection Directive (Directive 95/46/EC), each member state is required to establish a supervisory authority to monitor and support the privacy of individuals,

\*\* See the VPH roadmap ‘Seeding the EuroPhysiome: A Roadmap to the Virtual Physiological Human’ ([www.europhysiome.org](http://www.europhysiome.org)), Chapter 9

#### Rules and Regulations Pertinent to Data Protection in Europe

- Article 8 of the European Convention on Human Rights and the judgements of the European Court of Human Rights
- Article 7 & 8 of the Charter of Fundamental Rights of the European Union
- OECD 1980 Guidelines on Privacy
- Council of Europe 1981 Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data
- Recommendation (97) 5 of the Council of Europe on the protection of medical data
- Recommendation (83) 10 of the Council of Europe on the protection of personal data used for scientific research and statistics
- Directive 95/46 on the protection of individuals with regard to the processing of personal data and on the free movement of such data
- Directive 2002/58 concerning the processing of personal data and the protection of privacy in the electronic communications sector
- Opinion no. 13 of the European Group on Ethics on Ethical Issues of Healthcare in the Information Society
- Declarations, Considerations and Guidelines from the World Medical Association on Patient’s Rights, Telemedicine, Health Databases, and Medical research involving Human subjects.

which includes the starting of legal proceedings when data protection regulation has been violated. (art. 28). For example in the UK, a public register is used to hold information about the data protection system, detailing the nature of the data held and its use, where the data comes from and where it may be passed on to. The compiler of the data must agree that all data is...

- obtained and processed fairly and lawfully
- held only for those lawful purposes described in the register
- disclosed only to those people in the register
- accurate and up to date
- held no longer than necessary
- accessible to the individual concerned
- properly secured

Individuals are permitted to make complaints to the supervisory authority or in a court of law.

### ***Liability***<sup>††</sup>

Liability is associated with Tort Law (<http://en.wikipedia.org/wiki/Tort>) of which ToolKit liability would be encompassed within the three major categories of torts - intentional torts, negligent torts, and strict liability torts. Disharmonies between national Tort Laws in Europe are acknowledged and these are discussed within the series 'PRINCIPLES OF EUROPEAN TORT LAW', edited by the European Centre of Tort and Insurance Law ([www.ectil.org](http://www.ectil.org)):

- Vol. 1: J. Spier (ed.), *The Limits of Liability: Keeping the Floodgates Shut* (1996);
- Vol. 2: J. Spier (ed.), *The Limits of Expanding Liability: Eight Fundamental Cases in a Comparative Perspective* (1998);
- Vol. 3: H. Koziol (ed.), *Unification of Tort Law: Wrongfulness* (1998);
- Vol. 4: J. Spier (ed.), *Unification of Tort Law: Causation* (2000);
- Vol. 5: U. Magnus (ed.), *Unification of Tort Law: Damages* (2001);
- Vol. 6: B.A. Koch/H. Koziol (eds.), *Unification of Tort Law: Strict Liability* (2002);

---

<sup>††</sup> See the VPH roadmap '*Seeding the EuroPhysiome: A Roadmap to the Virtual Physiological Human*' ([www.europhysiome.org](http://www.europhysiome.org)), Chapter 9

- Vol. 7: J. Spier (ed.), *Unification of Tort Law: Liability for Damage Caused by Others* (2003);
- Vol. 8: U. Magnus/M. Martín-Casals (eds.), *Unification of Tort Law: Contributory Negligence* (2004);
- Vol. 9: W.V.H. Rogers (ed.), *Unification of Tort Law: Multiple Tortfeasors* (2004).

### ***Conclusion***

The implications of these laws impose responsibilities on authors and users of ToolKit content. Specifically this includes recognition of copyright, data protection and liability.

## Legal Guidelines for ToolKit Content Delivery

This section is designed to raise practical issues relevant to delivery of content to the ToolKit, highlighting relevant legal, concerns that contributors may not have considered. In so doing it constructs a framework, that helps to give meaning to concepts of 'acceptability' and 'quality' for material delivered to the ToolKit. Perhaps ultimately, the degree of adherence to such concepts might be useful as a metric of 'quality'.

### **Outline**

ToolKit content can be characterised by many categories (Security, Simulation, Visualisation, Data, Protocol, Research and Innovation, Tools and techniques, Interoperability and workflow, Quality, Provenance) and in the context of its delivery, it is appropriate that each type of content should be reviewed in the light of legal/ethics/provenance factors. Common legal issues that are repeatedly raised by an analysis of these factors are:

- Licensing – is an appropriate license attached to your content?
- Copyright – has the involvement of all contributing parties been acknowledged?
- Copyright – are the conditions of use clearly stated?
- Disclaimer – has an adequate disclaimer been attached to your ToolKit content?

The following pages explore these legal issues categorised according to classes of ToolKit content. Individuals involved with submission of material to the VPH are challenged to consider such issues in the delivery of their content to the ToolKit.

## ***Categorised ToolKit content – legal questions***

### **Category: Simulation and Data**

- Are the legal constraints attached to the use of your simulation software defensible, transparent and clearly documented?
  - Under what license is it released?
  - Is there a demo version; is it time limited or otherwise restricted?
  - Are there scenarios in which it should not be used (eg.clinical)
  - Are appropriate disclaimers included?
- Are the ethico-legal constraints associated with the use of your data transparent, understood, clearly documented?
  - Might there be ethico-legal constraints related to the visualisation of your data (eg. adequate anonymisation, authorisation, ethics... some types of visualisation might be permitted and others not)<sup>††</sup>
  - Is data properly anonymised (data protection implications)? Where relevant is a de-anonymisation mechanism available?<sup>§§</sup>
  - Under what conditions are the data permitted to be used? When can it not be used? (eg the data may have a specified lifetime, and can be done with it beyond its 'expiry date' – issues relate to the public domain, removal etc?).
  - What are the constraints relating to the processing of your data (eg. visualisation of a face that might contain recognisable features)
  - Are authorisations/roles of the data user clearly stated?
  - Is an appropriate licence associated with the data?
  - Are appropriate acknowledgements included?
  - Are appropriate disclaimers included?

---

<sup>††</sup> Beware of private information displayed during the visualization. For example, some overlays can contain patient, practitioners names, etc...)

<sup>§§</sup> The DICOM committee has provided a long list of tags that shall be anonymized (supplement 142 : [ftp://medical.nema.org/medical/dicom/Supps/sup142\\_pc.pdf](ftp://medical.nema.org/medical/dicom/Supps/sup142_pc.pdf)). An article that compares different open-source anonymizers: An open source toolkit for medical imaging de-identification, Gonzales, Carpenter, Eur Radiol 2010.

### **Category: Security**

- Is an electronic/mechanical copyright protection mechanism a part of your ToolKit content? Is it robust and understood?
  - Is the copyright protection strategy clearly and fully documented?
  - Who should be contacted if the copyright protection fails and blocks user access?
- Are the authentication/authorisation hurdles associated with your ToolKit content, defensible, transparent and reliable?

### **Category: Research and Innovation**

- Have you clarified the legal implications of research outcomes that might emerge from research and otherwise innovative use of your ToolKit content?
  - Do you claim capabilities for the future that have not yet been realised in practice. Are you able to justify these claims?
  - Do you anticipate a next release – if so, when?
  - What level of user support are you willing to provide in order to ensure that future users of your ToolKit content can use it in their domain?

### **Category: Tools and Techniques**

- Have you clarified the applicability of the ToolKit content in the context of clinical, industrial and research scenarios?
  - Are the Tools and Techniques of your content copyrighted or limited by other restrictions? What are the consequences and liabilities of breaching these restrictions? – clarify.

### **Interoperability and Workflow**

- Have you clarified the extent to which this ToolKit content can be expected to interoperate with other applications. Are there guarantees associated with this claim, and who will support them?
  - What external restrictions might limit interoperability

- License incompatibility restrictions?
- Ethics interoperability restrictions?
- Data protection/freedom of information limits on interoperability?
- What level of user support are you willing to provide in order to ensure that other users of your ToolKit content can use it in their domain?

### **Sustainability: Standards**

- Are legal/ethics standards available that are relevant to your contribution...
  - Well defined, mature, temporally stable? Locally variable or internationally uniform?
  - Are the punitive measures for contravention of these standards...
    - Well defined, mature, temporally stable?
    - Locally variable or internationally uniform?
  - Is there legal precedent, as confirmation of the effectiveness of these measures?
  - Can you supply contact information for end users that might want to clarify the situation?
  - Are these standards currently accommodated within the VPH/NoE ToolKit?

### **Conclusion**

Here ends this analysis of legal issues relating to delivery of content to the ToolKit. The reader needs to be aware that whether he/she is aware of it or not, as a provider of ToolKit content, (s)he is operating in a territory regulated by law. Personal interaction with the ToolKit will result in his/her classification as an author or user; this imposes certain legal responsibilities. Given the legal context, it is prudent to be aware of legal responsibilities in respect of copyright, data protection, freedom of information and liability.

This page is intentionally blank

## **The Ethics Perspective – an introduction to ethical principles and their role in ToolKit content submission**

The VPH ToolKit Portal offers the opportunity for cooperation across biomedical science on an international scale, but it also introduces some ethical dilemmas, and highlights the need for intelligent legislation. The ethical dimension necessarily includes the purpose of the VPH (ultimately, improved healthcare) and its suitability to fulfil that purpose. The legal component is necessary to safeguard the public (eg. copyright, privacy, freedom of information) and can provide guidance in anticipation of adverse outcomes resulting from inappropriate application of VPH Portal resources (eg. an error in a model or incorrectly interpreted data). Provenance is important because it introduces concepts of traceability and audit that can provide a perspective on data quality. The specifics of these influences and their implications for ToolKit content submission are addressed subsequently (p36-38), but first the context for ethical issues in respect of ToolKit content are presented below.

### ***Ethical Aspects***<sup>\*\*\*</sup>

The presence of an ethical focus can help to promote best practice within the VPH and avoid abuse of ToolKit content for direct personal gain. The configuration of the Portal aims to sustain and support the rights of both contributors and users, encouraging the promotion of positive societal values, providing an environment that is consistent with the current ethico-legal environment. Respectful consideration of individuals and their protection through adherence to well-defined principles and legislation are key elements, creating a secure environment for resource exchange that does not compromise the ethically driven mores accepted by healthcare professionals. Significant attention to ethical considerations and ToolKit 'etiquette' is a prerequisite for the success of the VPH.

*Ethics and the VPH* - A ToolKit underpinned by sound ethical practice is a recipe for VPH longevity. Ethics mandates respect for the welfare, dignity and rights of all participants interacting with ToolKit content and the VPH. The ethical dimension acknowledges the value of the individual above the processes of biomedical research and requires that such research should be conducted with integrity, honesty, an absence of prejudice, cultural sensitivity, etc. The use of material exploited within the ToolKit for VPH purposes should therefore acknowledge the rights of those who have contributed data and content, including...

---

\*\*\* See the VPH roadmap '*Seeding the EuroPhysiome: A Roadmap to the Virtual Physiological Human*' ([www.europhysiome.org](http://www.europhysiome.org)), Chapter 9

- specific rights to publish
- the roles of all contributors
- compliance with relevant legal requirements.

*Ethics and Health Data* - Particular sensitivities are apparent in the context of processing/storing/curating health data since carelessness or abuse has the potential for significant individual harm. Ethics is important to the medical profession, which is very careful with personal data and wholeheartedly adheres to long established principles of patient confidentiality. The VPH must adopt similar standards if it seeks any credibility as a biomedical resource. This means that sources of health data contributing to VPH research should have consented to the use of that data, and ideally, should understand the manner in which the data might be exploited (ie. informed consent). Furthermore, ethical practice requires that such contributors can expect...

- to be able to withdraw or refuse the use of their data at any time
- that their data is treated with respect (ie. held for the consented purpose, with adequate measures to protect its integrity)
- that their data is treated confidentially (requires adequate anonymisation procedures, which ensures that inadvertent disclosure of information cannot be linked to an individual)
- that exploitation of their data will not expose them to unnecessary levels of risk.

*Ethics and Submission of ToolKit Content* - As a submitter of ToolKit content (noting that the submitted content may consist of contributions from many and varied contributors) it is prudent to consider your action from the perspective of all those involved with the submission of that content and any other people who may be affected by it. Certainly, all persons involved in material content exposed through the ToolKit should have given some consideration to the implications, responsibilities and limitations of data exposure and uptake within the VPH community. How can this be achieved? ... **at the very least read the guideline documents!** These are explicitly designed to inform, and assist researchers with submission of ToolKit content.

## **Conclusion**

Legal and ethical considerations pervade the domain of practical applied healthcare, and

therefore it is both necessary and good practice for ToolKit resources to acknowledge these factors in content that is delivered. Additionally, provenance provides a complementary audit trail that can help to verify the quality, ethical and legal status of data/software provided.

The following pages justify the need for a VPH ethical perspective in more detail (p33-36) complemented by specific recommendations relating to delivery of VPH ToolKit content (p37-40).

## Background – Ethical Aspects and Standards

### ***Introduction***

The word 'ethics' derives from a Greek root that refers to moral values, principles of right and good conduct in relation to others. At the very least, the VPH has to be consistent with the ethical standards of society, but really ought to operate according to principles of best practice if it is to have any credibility with the medical/clinical community. Therefore, ToolKit contributors should reflect on ethical issues raised by exposure of their work across the VPH. This includes both software and data. Contributors should feel comfortable about exposure of their material and its implications in terms of foreseen outcomes. The ethical dimension introduces concepts of responsibility that require acknowledgment of, and responsibility to:

- All contributors involved with the submitted content
- The employer(s) of those involved with submitted content
- Implicated research funders
- Professional organizations
- Other stakeholders
- Society in general

The individual submitting the content, should consider conflicts of interest at all levels, identifying and avoiding courses of action that may compromise honesty, integrity, openness and awareness.

### ***Implications – ethical analysis***

Although blatant breaches of ethical behaviour can be relatively easy to identify, unethical subtleties are more difficult, may be damaging and can prove awkward to manage. Honesty and openness are the watchwords that can help prevent ethical abuse. Hence this Guideline document recommends that each content contributor undertakes an ethical review, prior to ToolKit content submission. Depending on the circumstance, this needn't be an involved process, but all parties should be fully aware of possible implications, responsibilities and consequences of the submitted content. A short written document (bullet points) can be very helpful here and is an invaluable element of provenance. These structures are in place so that the VPH has no opportunity to be the weak ethical link in biomedical science; it is no place for subterfuge and 'cloak and dagger' politics.

Be aware that ethics needs to be responsive to the dynamics of the VPH environment. The situation in which content exposure was originally and perfectly ethical may change, and implies that the ethical scenario may need to be occasionally revisited. In the worst case, a subsequent reassessment might involve withdrawal of the originally submitted content. But beware... even though the content might be withdrawn from the ToolKit, its existence is likely to continue, stored (and used) on VPH research computers that have previously downloaded that content. Consider if this circumstance is likely to pose significant problems for all involved, and if so, perhaps there is a strong ethical argument that the content should never be released in the first place? Effective ethical analysis and forethought can identify possible adverse outcomes ahead of time, enabling strategies to be formulated that can be efficacious in dealing with such eventualities.

### ***The Medical/Clinical Perspective***

Medical ethics can trace its origins to sources such as the Hippocratic Oath, Muslim medicine (Conduct of a Physician by Ishaq bin Ali Rahawi), Thomas Aquinas etc [1,2,3]. More recently, organizations such as the World Medical Association espouse a medical ethics charter such as The Helsinki Declaration<sup>†††</sup>. Important principles that relate to ethics in 21<sup>st</sup> century medicine are:

- Autonomy – the right of the patient to choose or refuse treatment
- Beneficence – the importance of acting in the best interests of the patient
- Non-maleficence - the principle of “first, do no harm”
- Justice – relates to fairness and equality in the distribution of health resources
- Dignity – an expectation of both the person delivering treatment, and the person being treated.
- Truthfulness/honesty – the principle of informed consent. This not only requires that the patient has consented to the medical action, but implies that the patient is fully informed ie. he/she has an appreciation of outcomes and implications of treatment.

Principles such as these are reinforced and explicitly codified in national and European ethics documentation, across Europe and beyond [4,5], but arguably, this is not enough. The reader is reminded that the essence of the ethical mindset is one that asserts the true value of each individual, distinguishing itself by going beyond formulaic procedures, choosing to operate in accordance with nobler principles, such as honesty, integrity, openness,

---

<sup>†††</sup> See Appendix 1

sensitivity, awareness.

In the context of the VPH and its intended clinical sphere of action, best practice requires that these principles are given some consideration prior to submission of ToolKit content. ***This is particularly true of exposure of clinical data, even though it might be anonymised...***

- Consider if all participants (from whom the data is derived) have given informed consent. Have they consented to the release of their data; have they been informed of, and understood the nature of the data release (eg. data will be available across Europe, perhaps subject to specified constraints<sup>+++</sup>).
- The principle of autonomy implies that the data can be withdrawn, but does the participant appreciate that its withdrawal from the VPH server on which it was exposed is unlikely to prevent its continuing use from centres that have already downloaded it?
- Is the release of the data likely to compromise the dignity of the participant supplying it , or in any other way act against his/her best interests?

## ***Risk***

This process of ethics review is central to modern ethical practice, supported by medical ethical review panels whose duty it is to consider the risks posed by the research. In this context, a risk is an adverse outcome that would not have occurred, had the research not been undertaken. A broader perspective accepts that risks are not only present for the research subjects, but also the research investigators, and indeed, there may be risks to the success of the research programme itself. The ethical review process is not intent on avoiding risks, but seeks a strategy that can identify and manage any foreseen risks that might present themselves.

## ***References***

1. The Hippocratic Oath, [http://www.nlm.nih.gov/hmd/greek/greek\\_oath.html](http://www.nlm.nih.gov/hmd/greek/greek_oath.html)
2. J M Al Bareeq, Z Fedorowicz. The Impact of Abuse and Historical Perspective of Medical Ethics: A Moral Foundation for Human Research. Bahrain Medical Bulletin, Vol. 30, No. 3, September 2008
3. Ethics in the History of Western Philosophy. Ed. Cavalier, Gouinlock and Sterba

---

<sup>+++</sup> An individual might be comfortable with use of their anonymised data for research purpose by a third party, providing that it is not exploited by the Defence Industry.

(MacMillan/St. Martin's Press, 1990).

4. Directive 2001/20/EC of the European Union
5. *Research Ethics, Committees, Data Protection and Medical Research in European Countries* by Beyleveld D, Wright J, Townend D. Published by Aldershot : Ashgate 2005

## Ethical Guidelines for ToolKit Content Delivery

This section is designed to highlight practical issues relevant to delivery of content to the ToolKit, by raising ethics concerns that contributors may not have considered. In so doing it constructs a framework, that helps to give meaning to concepts of 'acceptability' and 'quality' for material delivered to the ToolKit. Perhaps ultimately, the degree of adherence to such concepts might be useful as a metric of 'quality'.

### **Outline**

Toolkit content can be characterised by many categories (eg. community, ontology, Infrastructure, standards, documentation, exploitation, interoperability and workflows) and in the context of its delivery, it is appropriate that each type of content should be reviewed in the light of ethics factors. Common themes that repeatedly emerge from an analysis of these factors are often most poignant in the context of sharing data:

- Consent – have all contributing parties consented to use of the content?
- Authorisation – have adequate authorisation hurdles been put in place (where necessary) to limit access to the submitted content?
- Anonymisation – Has the privacy of contributing individuals been safeguarded through adequate anonymisation procedures?

The following pages highlight relevant ethical issues characterised according to the categories outline above. Individuals involved with submission of material to the VPH are challenged to consider such issues in the delivery of their content to the ToolKit.

## ***Categorised ToolKit content – ethics questions***

### **Category: Software and Data**

- Are the ethico-legal constraints associated with the use of your data transparent, understood, clearly documented?
  - Has appropriate consent been obtained for submission as ToolKit content?
  - Authorisation/roles of the software/data user(s) are clearly stated?
  - Under what conditions is the content permitted to be used? When can it not be used? (eg Data may have a specified lifetime; what can be done with it beyond its 'expiry date' – issues relate to the public domain, removal etc?).
  - Is content properly anonymised (data protection implications)? Where relevant is a de-anonymisation mechanism available?<sup>§§§</sup>
  - What are the constraints relating to the processing of your data (eg. visualisation of a face that might contain recognisable features)
  - Can you cite the ethics codes/authorities that have sanctioned the exposure of this content? (In some cases it might be necessary to warn authorities if data is used<sup>\*\*\*\*</sup>)
    - Data protection/freedom of information limits on interoperability?
  - Are appropriate disclaimers included?

### **Community**

- Can you identify communities of legal/ethics/provenance expertise that are relevant to the content being delivered to the ToolKit? Are the following available?...
  - Informative documentation
  - Support forums and FAQs
  - Web addresses
  - Data protection/Freedom of Information/Licensing advice etc.

---

§§§ The DICOM committee has provided a long list of tags that shall be anonymized (supplement 142 : [ftp://medical.nema.org/medical/dicom/Supps/sup142\\_pc.pdf](ftp://medical.nema.org/medical/dicom/Supps/sup142_pc.pdf)). An article that compares different open-source anonymizers: An open source toolkit for medical imaging de-identification, Gonzales, Carpenter, Eur Radiol 2010.

\*\*\*\* For rexample, in France, the CNIL (Commission Nationale del'Informatique et des Libertés) is the reference organism.

- What level of user support are you willing to provide in order to ensure that other users of your ToolKit content can use it in their domain
- Are your disclaimers adequate

### **Sustainability: Infrastructure**

- What is the magnitude of supporting infrastructure relevant to the ethics issues of your content and its delivery to the ToolKit?
  - Recommended contact points?
  - To what extent does the NoE/VPH infrastructure directly support legal/ethics relating to your delivered content?<sup>\*\*\*\*</sup>

### **Exploitation**

- Does your ToolKit content raise issues that are not currently catered for within the current ethico-legal framework?
  - Document and discuss? Can you offer possible ways forward?
  - Are there ethico-legal loopholes that might be exploited to ease uptake of your ToolKit content? What risks might be associated with this strategy (eg. if the loophole is closed)?

### **Sustainability: Interoperability and Workflow**

- To what extent might your ToolKit content suffer restricted interoperability as a result of ethico-legal constraints?
  - Document and discuss? Can you offer possible ways forward?
  - Are you aware of forthcoming ethico-legal developments that might facilitate improved interoperability? Details/timescale?

### **Conclusion**

Here ends this analysis of ethics issues relating to delivery of content to the ToolKit. The reader needs to be aware that the close association of the VPH with industry and the clinic requires that individuals should operate in an ethically considerate manner. This is

---

<sup>\*\*\*\*</sup> The content might make use of other infrastructures (e.g. DEISA?). This may have security implications (e.g. patient-specific data being used in a simulation on HPC resources – could the HPC admin staff then get access to this data?)

particularly acute in the context of sharing data, and ethical behaviour should accommodate principles of consent, authorisation anonymisation. This is a matter of 'best practice', noting that appropriate consideration of ethical implications is a prerequisite for acceptance of the VPH (and its benefits) within society.

This page is intentionally blank

## **The Provenance Perspective – an introduction to provenance principles and their role in ToolKit content submission**

The VPH ToolKit Portal offers the opportunity for cooperation across biomedical science on an international scale, but it also introduces some ethical dilemmas, and highlights the need for intelligent legislation. The ethical dimension necessarily includes the purpose of the VPH (ultimately, improved healthcare) and its suitability to fulfil that purpose. The legal component is necessary to safeguard the public (eg. copyright, privacy, freedom of information) and can provide guidance in anticipation of adverse outcomes resulting from inappropriate application of VPH Portal resources (eg. an error in a model or incorrectly interpreted data). Provenance is important because it introduces concepts of traceability and audit that can provide a perspective on data quality. The specifics of these influences and their implications for ToolKit content submission are addressed subsequently (p46-50), but first the context of provenance in respect of ToolKit content is briefly presented below.

### ***Provenance***

The possibility of tracing data from the processed end result back to the examination or experiment that led to its creation provides a valuable audit trail by which to judge the context and quality of data. Furthermore, it permits repetition, evaluation of reproducibility, extension to other subjects, refinement of variables and so on. Such efforts are ideally placed to reap additional benefits through effective metadata annotation. Aspects of provenance are discussed forthwith, and the reader should refer to the *Ontological Annotation Guidelines* for more comprehensive information about metadata annotation.

### ***Conclusion***

Although legal and ethical considerations pervade the domain of practical applied healthcare, provenance provides a complementary audit trail that can help to verify the quality, ethical and legal status of data/software provided.

The following pages justify the need for provenance in the VPH in more detail (p43-46) complemented by specific recommendations relating to delivery of VPH ToolKit content (p47-52).

## Background – Provenance and Standards

### ***Introduction***

Provenance is an inherent feature of libraries, scientists' lab books etc. and has established itself as a necessary component of any digital curation exercise, from art to astronomy [1]. It has a close association with workflows, because in combination provenance and metadata promote interoperability across diverse interests. If metadata can be described as 'data about data' (ie. Information that gives meaning to data), provenance can be considered as information that describes how data was derived. In the context of the VPH, these definitions can be widened to include tools and software, the defining feature being that context can (and should) be associated with files/content delivered to the ToolKit. This has particular importance in cases with clinical implications. If the context of a delivered software tool includes associations with accepted standards, validation, quality assurance, revision history etc. then its sphere of application is defensible in much more demanding scenarios than in the absence of such assurances. The same argument is true of data. To some extent, metadata and provenance can be seen to overlap, but the latter is distinguished by its assertion of context in terms of history, audit, assurances. Consider a file of electrophysiology data. Metadata can facilitate its interpretation in terms of the number of data channels present, how they are interleaved, the bit depth of the data, sampling rates etc. This is essential context for interpretation, supporting re-use of that data by other groups and ideally would make reference to ontological terms. In contrast, provenance might include references to the age and make of the equipment that collected the data, the experience of the operator and any extenuating circumstances associated with data collection. In this example, metadata is seen to help with data interpretation, while provenance gives it context. Such supporting information can provide assurances that its use is appropriate for an anticipated scenario and can help with exploring reproducibility and identification of anomalies at a later date.

### ***Provenance and Formalisation***

The importance of metadata<sup>\*\*\*\*</sup> is widely recognized within the VPH and finds its formalisation in ontology development and deployment. An ontology captures consensual knowledge that provides a formalized structure of definitions and relationships between those definitions. Such a framework can facilitate discovery, re-use, interoperability and the

---

<sup>\*\*\*\*</sup> Described in [1] as "...structured data about an object that supports functions associated with the designated object".

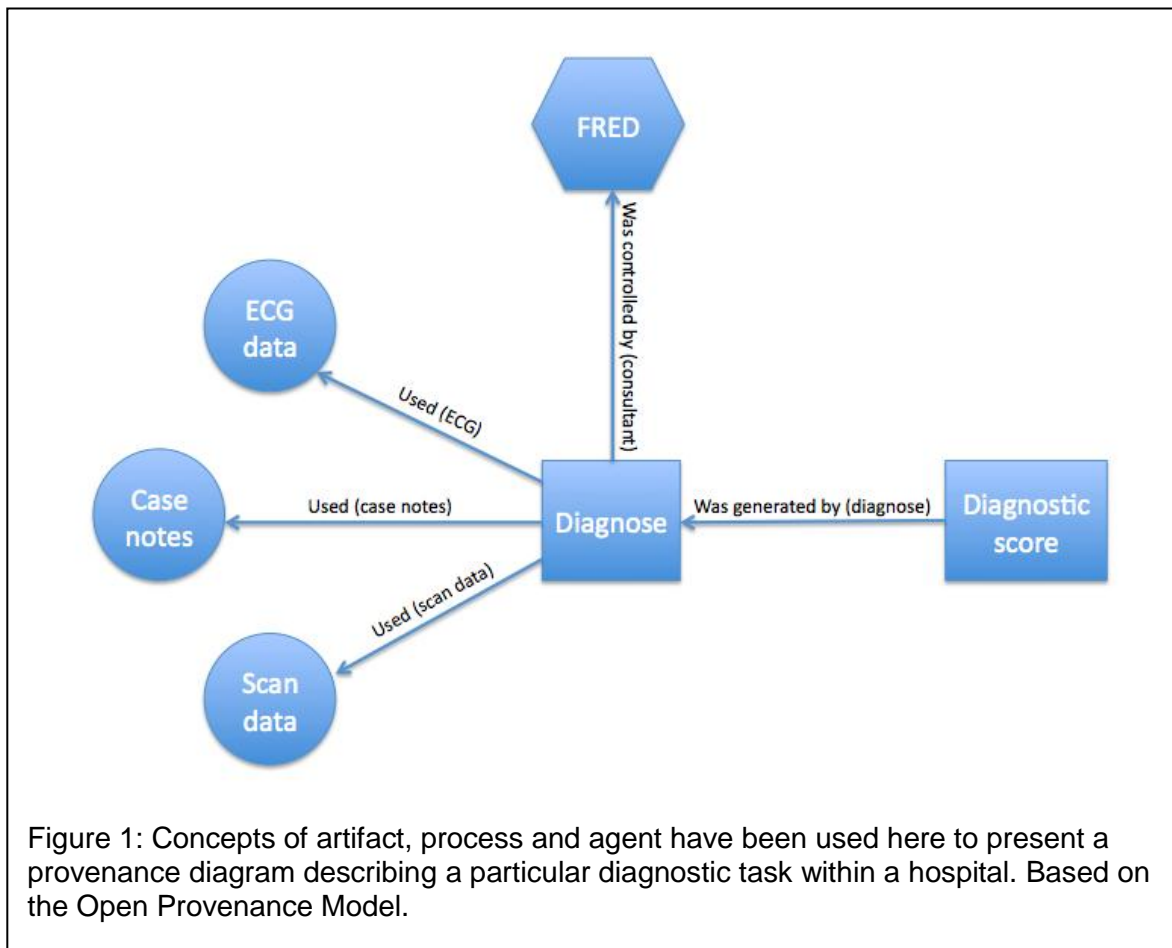
automation of scientific workflows. It is a topic of sufficient importance to the VPH that it has warranted production of a companion Guideline document (see *Ontological Annotation* in the series).

In respect of provenance, formalisation is relatively recent [2], but the rationale for development is clear. Deelman et al [3] argue that the "...notion of provenance can be transposed to electronic data [4]. If the provenance of data produced by computer systems could be determined as it can for some works of art, then users would be able to understand how documents were assembled, how simulation results were determined, or how analyses were carried out. For scientists, provenance of scientific results would indicate how results were derived, what parameters influenced the derivation, what datasets were used as input to the experiment, etc. In other words, provenance of scientific results would help *reproducibility* [5], a fundamental tenet of the scientific method." Clearly provenance must be able to capture processes/workflows, relating to ToolKit content, even providing context that predates (ie. was a precursor to) the production of that content. The concept of provenance granularity is valuable here, ranging from lightweight contextual information at one end of the scale to substantial detail that could support comprehensive reproduction of a set of data bit-by-bit, at the other. Consideration of granularity can reduce the burden of provenance description by identifying an appropriate level of detail, whilst maximising benefit to the end-user (eg. is there sufficient detail to facilitate workflow debugging?). The use of recognised standards is also valuable since, by definition, every standard comes replete with its own extensive provenance trail.

The annotation of files with provenance information can call upon technologies such as SQL databases and RDF stores. Reviews from Bose and Frew [6], Simmhan [7] and exercises such as The Provenance Challenge [8] have identified the role of embedded provenance systems with facilities for comprehensive tracking of the diverse activities of the execution environment, and independent autonomous provenance stores. Within the VPH, the requirement for annotation is aligned with the goal of ontology metadata annotation and possibly a convergence of technologies will be a suitable solution. Currently, the VPH NoE recommends the Open Provenance Model [9,10] as the method of choice for provenance description. Its formalised approach permits description as an XML file, with exposition through informative provenance diagrams that employ concepts [9] such as:

- **Artifact:** Immutable piece of state, which may have a physical embodiment in a physical object, or a digital representation in a computer system.
- **Process:** Action or series of actions performed on or caused by artifacts, and resulting in new artifacts.

- Agent: Contextual entity acting as a catalyst of a process, enabling, facilitating, controlling, affecting its execution.



Complemented by a formalised description rooted in set theory and integrating notions of causality [11], this framework provides benefits that support discovery of relationships and derived inferences.

## Conclusion

The requirement of the VPH to support content discovery, re-use, interoperability and workflow automation is significantly assisted by the inclusion of relevant provenance information with ToolKit content. Electronic provenance description technologies provide a solution, but the use of the Open Provenance Model is recommended for provenance annotation across the VPH.

## References

- 1) Greenberg J. “Metadata and the World Wide Web”, *Encyclopedia of Library and*

*Information Science*, 2003

- 2) Governance of the Open Provenance Model. Luc Moreau, Juliana Freire, Joe Futrelle, Jim Myers, Patrick Paulson June 15, 2009. [twiki.ipaw.info/pub/OPM/WebHome/governance.pdf](http://twiki.ipaw.info/pub/OPM/WebHome/governance.pdf)
- 3) Ewa Deelman, G. Bruce Berriman, Ann Chervenak, Oscar Corcho, Paul Groth, Luc Moreau, Chapter 12: Metadata and Provenance Management. from Scientific Data Management: Challenges, Existing Technology, and Deployment. Editors: Arie Shoshani and Doron Rotem, Published by CRC Press/Taylor and Francis Books, 2010
- 4) Moreau L, Groth P, Miles S, Vazquez J, et al. "The Provenance of Electronic Data", Communications of the ACM, 2008
- 5) Gil Y, Deelman E, Ellisman M, Fahringer T et al. "Examining the Challenges of Scientific Workflows" IEEE Computer, vol 40, pp24-32, 2007
- 6) Bose R, Frew J. "Lineage retrieval for scientific data processing: a survey" ACM Computing Surveys, vol.37, pp1-28, 2005
- 7) Simmhan YL, Plale B, Gannon D. "A survey of data provenance in e-science" SIGMOD record, vol.34, pp31-36, 2005
- 8) Moreau L, Ludaescher B. Journal of Computation and Concurrency: Practice and Experience, Special Issue on the First Provenance Challenge, 2007
- 9) The Open Provenance Model (OPM). <http://openprovenance.org/>
- 10) Moreau L, Freire J, Futrelle J, McGrath RE, Myers J, Paulson P. "The Open Provenance Model" University of Southampton, 2007
- 11) Mile S, Groth P, Munroe S, Jiang T et al. "Extracting causal graphs from an open provenance data model". Concurrency and Computation: Practice and Experience, 2007

## Provenance Guidelines for ToolKit Content Delivery

This section is designed to highlight practical issues relevant to delivery of content to the ToolKit, raising provenance concerns that contributors may not have considered. In so doing it constructs a framework, that helps to give meaning to concepts of 'acceptability' and 'quality' for material delivered to the ToolKit. Perhaps ultimately, the degree of adherence to such concepts might be useful as a metric of 'quality'.

### ***Outline***

ToolKit content can be characterised by many categories (eg. community, ontology, Infrastructure, standards, documentation, exploitation, interoperability and workflows) and in the context of its delivery, it is appropriate that each type of content should be reviewed in the light of provenance factors. The most common theme that repeatedly emerges from an analysis of such factors relates to the importance of metadata, and the annotation of software and data if effective interoperability is to be assured. ToolKit users are encouraged to think beyond the immediate confines of their software/data usage and annotate with metadata in a manner that aids its wider exploitation if possible.

The following pages recognise the challenge that this presents by highlighting relevant provenance issues categorised according to classes of ToolKit content. Individuals involved with submission of material to the VPH are challenged to consider such issues in the delivery of their content to the ToolKit.

## ***Categorised ToolKit content – provenance questions***

### **Category: Protocol**

- Are necessary protocols for installation, uninstallation and other uses of your ToolKit content provided?
  - Have you clarified the protocol by which your ToolKit content was obtained?
  - If others wish to duplicate your protocol, is prior permission required?
  - Is the protocol by which the ToolKit content was obtained, underpinned by any guarantees? Clarify who will support those guarantees, and who is liable if the guarantees fail.
  - Are appropriate disclaimers included?

### **Category: Quality and Provenance**

#### General

- Have you attached any quality standards to the ToolKit content provided?
  - Can you verify that it is compliant with those standards?
  - Are there any quality guarantees associated with your content. Has it been quality assured with reference to a relevant traceable standard (eg. primary, secondary, tertiary etc.)?
  - Has the content been tested internally/externally, and if so, by whom?
  - Can you provide an audit trail that clarifies the provenance of the content?
  - Have appropriate details been entered in the provenance log?
  - Are appropriate disclaimers included?
    - To what extent are you prepared to guarantee that the provided content is as described. Are you prepared to underwrite losses that may result from errors, inappropriate use etc.?
  
- Data
  - Make sure you clarify the nature of your data...
    - synthetic/simulated

- measured
  - derived from a collection of supporting evidence
- How would you characterise the 'quality' of your data? How reproducible is the data you have provided? What confidence do you have in the data values you report? Can you quote confidence measures or error bars?
- What are the assumptions underpinning the data you have obtained? Are they listed (eg. as metadata, as bullet points in a readme file)?
- Have you provided a concise description of the data's creation and its journey to the ToolKit?
  - (Example: *"Data uploaded: carotid flow fields. Flow field computed from a fixed vessel geometry obtained from a contrast-enhanced CT image stack (Siemens Somatom Spirit, 512x512 matrix, patient condition unknown) using sinusoidal-flow/zero-pressure input/output boundary conditions. Newtonian flow assumption"*)
- Are appropriate units associated with your data?
- Software
  - Is a version history provided with your software, identifying...
    - relevant contact details; responsibilities
    - bug fixes
    - implementation of new features
    - removal of old features

## Security

- Is your provenance history secure? Is it liable to tampering and false editing? (perhaps you would only consider exposing it independently from a non-editable platform?).
- Does your ToolKit contribution have a proven, traceable and consistent license path throughout its development?
- Are appropriate authentication/authorisation hurdles in place?

## Simulation

- How is your provenance represented?
  - provenance log
  - free text document (eg. Word)

- flow chart
  - structured xml-type document
  - open provenance model
- Is it sufficiently detailed and complete to be traced to its origin?

### Provenance Protocol

- Are you working to a specified provenance protocol? If so, please specify.
- Is your provenance protocol consistent with a known standard (eg. open provenance model)?

### Research and Innovation

- Are workflows a feature of your ToolKit content? Have they been encapsulated in a provenance framework?

### Tools and Techniques

- Are particular tools or techniques recommended that can assist with the navigation of your provenance details?

### Interoperability and Workflows

- Is demonstrable interoperability an explicit feature of actions-past that have contributed to the provenance of your ToolKit contribution?
- Does your provenance imply sensitivities that the user should be aware of in respect of applying or using your ToolKit contribution? (eg. licensing, ethics constraints).

## **Category: Sustainability**

### Community

- Can you identify communities of provenance expertise that are relevant to the content being delivered to the ToolKit? Are the following available?...
- Informative documentation
- Support forums and FAQs

- Web addresses

### Ontology

- Is there an ontology associated with the provenance elements relevant to your ToolKit content? (The VPH-NoE recommends the use of an established, supported ontology in preference to inventing your own).
  - Is this an exercise that merits novel or additional effort; how might it be done?

### Documentation

- Is formal documentation available that can help to inform the user of provenance elements of your ToolKit content?
  - Can you supply details?

### Exploitation

- Does your ToolKit content raise issues that are not currently catered for within the current provenance framework?
  - Document and discuss? Can you offer possible ways forward?

### Interoperability and Workflow

- To what extent might your ToolKit content suffer restricted interoperability as a result of provenance constraints?
  - Document and discuss? Can you offer possible ways forward?

## **Conclusion**

Here ends this analysis of provenance relating to delivery of content to the ToolKit. The interaction of research, clinic and industry under the VPH umbrella implies a degree of interoperability that can only be effective in the context of robust provenance (software tools and data). In addition to simple text-based metadata annotation, a more comprehensive and formal approach is recommended through the Open Provenance Model.



# APPENDICES

## **Appendix 1 – Case Studies**

- A UK perspective
- An ethical dilemma
- Compliance, ambiguity and harmonization

## **Appendix 2 - The Declaration of Helsinki**

## **Appendix 3 – VPH and the Law: a wider perspective**

## Appendix 1 – Case Studies

### *A UK Perspective*

The VPH has a biomedical research/clinic/industry focus and this example provides a brief sketch of the ethics/legal environment for clinically related research in the UK<sup>§§§§</sup>. The UK is not atypical, and in many respects, a similar environment is apparent in many countries across Europe. Note that subtle differences between member states can present legal problems for trans-national interoperability of software and data.

#### **Introduction**

The National Health Service (NHS) in the UK is a rich source of personal information and legislation is in place to ensure that it is handled correctly. The UK Data Protection Act regulates how personal information is used and protects against misuse of personal details, whereas The Freedom of Information Act guarantees access to information held by public authorities. Particular responsibilities relevant to the NHS are clarified by an in-house publication – Confidentiality: NHS Code of Practice [1]. This mandates that patient identifiable information should be kept to a minimum, justification being required for transfer and exposure to other parties.

Research is acknowledged as a valuable practice within the NHS, but it has to be recognised as ethical before it is permitted to take place. Research has to be based on thorough scientific knowledge, should be beneficial to the population and requires informed consent if human participants are involved. The Integrated Research Application System (IRAS) is the mechanism by which permission and approval for research within the UK is granted [2]. An integral element of this process is referral to a Research Ethics Committee (REC), intended to safeguard the ethical conduct of research undertaken. This considers the safety, dignity, rights and well-being of those who participate and provides advice on ethical standards.

#### **Informed Consent**

Informed consent is the agreement by an individual to undergo treatment and procedures or participate in research after all the risks and benefits have been discussed and understood by all parties involved. In the hospital environment it is particularly relevant - it is a legal

---

<sup>§§§§</sup> See the JISC website ([www.jisclegal.ac.uk](http://www.jisclegal.ac.uk)) for a broader view of legal issues as pertaining to research in the UK.

requirement to gain informed consent before any invasive procedure can be undertaken.

### **Medical Data, Confidentiality and Ambiguity**

The healthcare system is awash with large quantities of personal information. Numerous regulations are in place to ensure that personal information is not shared without good reason and consent. Respect for patient confidentiality recognises that information pertinent to a patient should not be distributed without their informed consent. The Data Protection Act of 1998 [3] is the UK legislation that governs the protection of personal data; it provides a way for individuals to control information about themselves and complies with EC Directive 95/46/EC.

In the context of the NHS, data protection requires that...

- Data can only be collected and used for the purposes for which specific consent was given. Note that consent must be obtained if data is to be shared between different bodies. Conditions of data collection require that it be fair, lawful and accurate.
- An individual has the right to access any information held about himself/herself and has the right to alter any factually incorrect information.
- Personal information may not be kept for longer than necessary and may not leave the European Economic Area without consent or adequate protection.
- Entities holding personal information must have sufficient security measures in place; these include technical (e.g. computer security) and organisational (e.g. staff training).
- All bodies that process personal information must register with the Information Commissioner's Office.

The Freedom of Information Act 2000 [4] guarantees access to information held by the state. The Act creates, on request, a right to access information held by public authorities, although there are exemptions to this under certain circumstances (eg. issues of national security). Absolute exemptions cannot be obtained under any circumstance. Qualified exemptions are permissible and allow the public authority to decide if the public interest in disclosing the relevant information, overrides the public interest in maintaining the exemption. In the case of the Freedom of Information Act the definition of information is not limited to specific documents but encompasses any recorded information held by or on behalf of an authority; this includes emails, images, paper records etc. The office of the Information Commissioner oversees the operation of the Act. This is the same office that deals with matters relating to

the Data Protection Act enabling it to develop a more coherent structure for information handling and to provide a single point of contact for the public and public authorities.

### **Caldicott**

In pursuit of best practice, the UK healthcare system also operates within the recommendations of the Caldicott Report [5]. This supports confidentiality and protection of patient identifiable information through the following code of practice:

- The purpose for which information is needed has to be justified.
- Patient identifiable information must not be used unless absolutely necessary. Patient identifiable information must be kept to a minimum and if possible, numbers should be used to identify patients instead of names.
- Access to patient identifiable information should be on a strict 'need to know' basis only.
- Everyone who has access to patient identifiable information should be aware of their responsibilities to respect client confidentiality.
- Every use of patient identifiable information must be lawful
- Each NHS hospital trust benefits from a nominated Caldicott Guardian to safeguard and govern the uses of confidential patient information. He/she can assist with any queries that arise.
- These principles have been integrated into a document (*Confidentiality: NHS Code of Practice* [1]) which clarifies standards of practice concerning confidentiality and patient consent in respect of their health records.

### **Ethics**

The Declaration of Helsinki [6] - developed by the World Medical Association - is an internationally accepted statement of ethical principles regarding medical research on human subjects. The fundamental principle is respect for the individual under study, and their right to make decisions throughout the course of any research. The duty of the investigators is exclusively to the patient (or volunteer) and in the event of a conflict, the welfare of the subject should always take priority over the interests of science. Once the study is completed, the interests of the subject should not be forgotten and should be part of the overall ethical assessment. If the research subject is a minor, incompetent or physically or mentally incapable of giving consent then an individual acting in the subject's best interest

can give consent on their behalf.

Notably, the undertaking of research is expected to invoke an ethical assessment based on detailed knowledge of scientific background and careful assessment of risks and benefits. (A risk refers to an adverse outcome that would not have happened if the research had not been undertaken). There should also be an expectation that, the wider population can benefit from the research. The work has to be conducted by suitably trained investigators using approved methods. If information indicates that the original considerations are no longer satisfied the study should be discontinued. All information regarding the study should be made publicly available.

A formalised infrastructure supports medical ethical considerations in the UK. Research Ethics Committees (RECs) are committed to providing an efficient service to facilitate ethical research while protecting the safety, dignity, rights and well being of those who participate [7]. RECs provide independent advice to participants, sponsors, employers and professionals on whether the proposals of research studies comply with recognised ethical standards. Opportunities for bias are reduced by a strategy that seeks to secure their independence from political, institutional and professional influences. Such committees are responsible for the ongoing review of ethics policy (eg. see the NHS National Research Ethics Service) and also provide advice on its interpretation. It is in their interest to promote awareness and understanding of ethical issues in research and provide wider advice on ethical research matters. Their role is accommodated by the Integrated Research Application System (IRAS), which functions as a single system for ethical permissions and approvals required for research in the UK. This form-based process helps researchers meet regulations and governance requirements. Once data is entered, filters ensure that the data collected is appropriate to the type of study. This is intended to streamline the obtaining of necessary permissions and approvals.

JF/KH

## References

- 1) Confidentiality: NHS Code of Practice  
[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4069253](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4069253))
- 2) UK Integrated Research Application System – IRAS  
<https://www.myresearchproject.org.uk/>)

- 3) UK Data Protection Act 1998 (<http://www.legislation.gov.uk/ukpga/1998/29/contents>)
- 4) UK Freedom of Information Act 2000  
(<http://www.legislation.gov.uk/ukpga/2000/36/contents>)
- 5) Caldicott Report  
([http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4068403](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4068403))
- 6) The Declaration of Helsinki ([www.wma.net](http://www.wma.net))
- 7) UK (NHS) National Research Ethics Service (<http://www.nres.npsa.nhs.uk/>)

## ***Case Studies – An Ethical Dilemma***

The following is adapted from an exercise posed by an ethics workshop (Sheffield, UK; Jan 2011).

### Studying Vulnerable Individuals

Mark is a social worker who has worked for several years in a large group home for people with learning disabilities who function comparatively well in society. He is very good at his job and it shows, through the hugs and high-fives he receives while at work.

Mark has decided to pursue his doctorate degree in social work and has chosen a PhD program that specializes in learning disabilities research. Eager to make a name for himself, Mark proposes an ambitious dissertation to the director. Basing his study on previous research on persons with schizophrenia, he seeks to study tendencies towards violent/aggressive behaviour in people with learning disabilities. The study will include spatial mapping of their brain activity and correlation with abuse history.

His participants will need to agree to a closed MRI scan and a review of past physical, mental, and/or sexual abuse. Mark realizes that this is a lot to ask of any research participant, more so with a learning disabled individual. Recruitment could be difficult but he is confident that he can achieve sufficient power in his study, by drawing upon his client contacts at the group home. The clients are eager to please Mark, and most wouldn't dream of saying "no" to him. In cases where a legally authorized representative is necessary, Mark has agreed to meet with both the client and the surrogate decision maker to explain the details of the study. Most of the surrogate decision makers are parents of the clients or the group home administrators, who also like Mark as equally as the clients.

Mark and the university argue that although the participation is intensive, the benefits of the study are great, as psychopharmacological and counselling therapies could better treat violent behaviour in people with learning disabilities. A link with the VPH could permit exposure and sharing of data that would enhance the power of the study. Mark submits his proposal for ethics review, including a comprehensive informed consent form.

### Questions

Put yourself in the position of a member of the ethics committee reviewing this project. You learn of Mark's affiliation with the group home - do you approve the study? Why or why not?

What other ethical concerns are raised by this study?

### Ethical Analysis

- Risk to the research programme is evident because of the biasing influences introduced by the researcher's close association with the research participants.
- The participants suffer from learning disabilities and may not be capable of giving informed consent.
- If a participant is incapable of giving consent, who can be approached on their behalf?
- To what extent will parents be kept informed/consulted (they may be part of the abuse scenario)?
- The MRI scanner is typically a claustrophobic environment. Even if consent is obtained for a scan, the participant may react adversely to the claustrophobic conditions. Have adequate steps been taken to prepare the participants for the conditions and are suitable contingency plans in place?
- The MRI scan might reveal an unexpected pathology (possibly as a result of previous abuse). Are agreed protocols in place for informing the participant, his/her GP, legal authorities?
- Is it fair to subject this group of participants to the demands of this study?
- If the data were to be exposed via the VPH, how would such a concept be explained? Could consent be meaningfully obtained and are procedures in place for meaningful withdrawal of data if a participant requests it?
- Anonymisation of participants is important here. Are appropriate anonymisation procedures in place?
- Do the benefits of the study outweigh the costs/risks?
- Have the risks been prioritized (both in terms of likelihood and magnitude of adverse outcome)?
- Are responsibilities for managing the programme clearly delineated?
- Are the research aims clearly defined? Are they supported by an equally clear research plan with the potential to achieve those aims?

### Conclusion

By their very nature, ethical analyses are likely to raise unforeseen dilemmas. That is their purpose. The wise researcher comes to terms with such factors before research is undertaken.

## ***Case Studies – Compliance, Ambiguity and Harmonization***

The Data Protection Act of 1998 is the UK legislation that governs the protection of personal data; it provides a way for individuals to control information about themselves and complies with EC Directive 95/46/EC. Nonetheless, the presence of ambiguities within the directive opens opportunities for different interpretation/implementation across Europe. For example, although Directive 95/46/EC clarifies responsibilities for storing the personal data of an individual, it makes no assumptions about the health of that individual (eg. what if they were dead?). Article 2 of Directive 95/46/EC makes reference to every 'natural person', as a means of excluding 'legal' persons in its area of application. The extent to which a dead 'natural person' can be interpreted as a meaningful quantity and the extent to which it should qualify for protection under the law is clearly a matter for interpretation. It can be argued that the personal data of the deceased might have repercussions for those who are living and therefore merits (limited) protection of confidentiality.

Within the UK, the data of the deceased is not covered by the data protection act, but different interpretations are in evidence elsewhere across Europe and all are consistent with the directive. Legal inconsistencies such as this can be a danger for the unwary and may lead to legitimate prosecution in one country that is not possible elsewhere.

It is difficult to envisage a coherent legal environment in which the VPH can operate. A short-term solution is to establish codes of conduct specific to the VPH, but ideally a longer term solution should be sought, perhaps in the form of harmonization that identifies potential obstacles in each of the member states and proposes effective European solutions. In the meantime, content contributors and users should be aware of their own national obligations in respect of these issues (data protection etc). Clarification of trans-national inconsistencies despite widespread compliance with EU legal requirements is an area fraught with difficulties.

## Appendix 2

### ***The Declaration of Helsinki***

The [\*Declaration of Helsinki\*](#) (*DoH*) is a policy statement of the World Medical Association (WMA). Numerous amendments since its first incarnation in 1964 have led to the most recent version, adopted by the General Assembly in 2008. The following reproduces the text of the DoH, downloaded from the WMA website ([www.wma.net](http://www.wma.net)).

#### A. INTRODUCTION

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.  
The Declaration is intended to be read as a whole and each of its constituent paragraphs should not be applied without consideration of all other relevant paragraphs.
2. Although the Declaration is addressed primarily to physicians, the WMA encourages other participants in medical research involving human subjects to adopt these principles.
3. It is the duty of the physician to promote and safeguard the health of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.
4. The Declaration of Geneva of the WMA binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act in the patient's best interest when providing medical care."
5. Medical progress is based on research that ultimately must include studies involving human subjects. Populations that are underrepresented in medical research should be provided appropriate access to participation in research.
6. In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests.
7. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best current interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.
8. In medical practice and in medical research, most interventions involve risks and burdens.
9. Medical research is subject to ethical standards that promote respect for all human subjects and protect their health and rights. Some research populations are particularly vulnerable and need special protection. These include those who cannot give or refuse consent for themselves and those who may be vulnerable to coercion or undue

influence.

10. Physicians should consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.

## B. BASIC PRINCIPLES FOR ALL MEDICAL RESEARCH

11. It is the duty of physicians who participate in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects.
12. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected.
13. Appropriate caution must be exercised in the conduct of medical research that may harm the environment.
14. The design and performance of each research study involving human subjects must be clearly described in a research protocol. The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest, incentives for subjects and provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study. The protocol should describe arrangements for post-study access by study subjects to interventions identified as beneficial in the study or access to other appropriate care or benefits.
15. The research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the study begins. This committee must be independent of the researcher, the sponsor and any other undue influence. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration. The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No change to the protocol may be made without consideration and approval by the committee.
16. Medical research involving human subjects must be conducted only by individuals with the appropriate scientific training and qualifications.

- Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional. The responsibility for the protection of research subjects must always rest with the physician or other health care professional and never the research subjects, even though they have given consent.
17. Medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research.
  18. Every medical research study involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and communities involved in the research in comparison with foreseeable benefits to them and to other individuals or communities affected by the condition under investigation.
  19. Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject.
  20. Physicians may not participate in a research study involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians must immediately stop a study when the risks are found to outweigh the potential benefits or when there is conclusive proof of positive and beneficial results.
  21. Medical research involving human subjects may only be conducted if the importance of the objective outweighs the inherent risks and burdens to the research subjects.
  22. Participation by competent individuals as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no competent individual may be enrolled in a research study unless he or she freely agrees.
  23. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information and to minimize the impact of the study on their physical, mental and social integrity.
  24. In medical research involving competent human subjects, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information. After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.
  25. For medical research using identifiable human material or data,

physicians must normally seek consent for the collection, analysis, storage and/or reuse. There may be situations where consent would be impossible or impractical to obtain for such research or would pose a threat to the validity of the research. In such situations the research may be done only after consideration and approval of a research ethics committee.

26. When seeking informed consent for participation in a research study the physician should be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent should be sought by an appropriately qualified individual who is completely independent of this relationship.
27. For a potential research subject who is incompetent, the physician must seek informed consent from the legally authorized representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the population represented by the potential subject, the research cannot instead be performed with competent persons, and the research entails only minimal risk and minimal burden.
28. When a potential research subject who is deemed incompetent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorized representative. The potential subject's dissent should be respected.
29. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research population. In such circumstances the physician should seek informed consent from the legally authorized representative. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee. Consent to remain in the research should be obtained as soon as possible from the subject or a legally authorized representative.
30. Authors, editors and publishers all have ethical obligations with regard to the publication of the results of research. Authors have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. They should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results should be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest should be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

### C. ADDITIONAL PRINCIPLES FOR MEDICAL RESEARCH COMBINED WITH MEDICAL CARE

31. The physician may combine medical research with medical care only to the extent that the research is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects.
32. The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best current proven intervention, except in the following circumstances:
  - The use of placebo, or no treatment, is acceptable in studies where no current proven intervention exists; or
  - Where for compelling and scientifically sound methodological reasons the use of placebo is necessary to determine the efficacy or safety of an intervention and the patients who receive placebo or no treatment will not be subject to any risk of serious or irreversible harm. Extreme care must be taken to avoid abuse of this option.
33. At the conclusion of the study, patients entered into the study are entitled to be informed about the outcome of the study and to share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits.
34. The physician must fully inform the patient which aspects of the care are related to the research. The refusal of a patient to participate in a study or the patient's decision to withdraw from the study must never interfere with the patient-physician relationship.
35. In the treatment of a patient, where proven interventions do not exist or have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorized representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. Where possible, this intervention should be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information should be recorded and, where appropriate, made publicly available.

22.10.2008 – World Medical Association

## Appendix 3

### ***VPH and the Law: a wider perspective***

Science appears to proceed at a faster pace than the legislator. This dynamic landscape means that the VPH guidelines frequently cut across legal issues that are subject to continuous review and modification. Some of the aspects that the VPH guidelines consider are the subject of fierce debate at national, European and global levels. This appendix takes a wider look at legal issues relevant to the VPH and reinforces some of the elements already highlighted in the main text.

The topics examined in the following page are:

- Scope, Content and Limitations
- Regulatory agencies
- Legislation
  - Copyright
    - Authorship
    - Ownership
    - Joint Authorship/Ownership
    - Moral Rights vs Economic Rights
    - Attribution
    - Integrity
    - The Three Step Test
    - Exceptions
  - Databases and Copyright
    - Data and Databases
    - Originality
    - Database Authorship
    - Exceptions
    - Duration of the protection of databases
  - Collective Works and Copyright
    - Collective Works
    - Compilations
    - Published Editions
    - Computer Generated Works
    - Circuit diagrams
    - Anonymous Works
    - Orphan Works
    - Fair Use and Copyright
    - Public Domain
    - Digital Rights Management (DRM)
  - Data Protection
  - Identification, Authentication and Access
  - User Friendly Laws
    - Copyright and User Created Content (UCC)
    - Open Content Licences
    - Disability and Access
    - Personal Data Licensing
  - Conclusion

## Scope, Content and Limitations

Legislators and policy makers debate on the boundaries of legal intervention in an ever-changing territory. Consequently, a guideline appendix such as this is subject to numerous limitations:

1. Scope (the area of interest is large, as is the area of application and the landscape keeps changing; not many topics can be covered by a lightweight document such as this)
2. Level (a focus on European ‘consistency’ rather than national ‘inconsistencies’);
3. Time limit or expiry date (these guidelines can easily become out of date if they are not frequently revised; policies can change and technical advances can render past legal recommendations irrelevant).

(1) The present document is drafted under the assumption that the scope of these guidelines is to provide an indication of current legal issues affecting the VPH research field at regional (European) level. Where possible, some references to national laws or regulations have been added to clarify the meaning of European or international laws. Furthermore, these guidelines are addressed to ‘legally naïve’ researchers who would benefit from a general overview of possible legal influences affecting their work. The content is necessarily limited to an overview of a selection of major issues and makes no claim to cover the entire span of issues that affect the VPH. The most relevant law to VPH activity is probably Copyright law, since copyright cuts across almost any issue that the VPH debates. The VPH must also pay attention to laws regarding data protection, privacy and human rights. Contract law and international treaties may also play a role in regulating interactions between researchers and end-users.

It is beyond the scope and resources of this exercise to address national laws and regulations. This could and should be the topic of an extended European research action.

## Regulatory agencies

The regulatory agencies that are relevant to VPH’s activities are:

Organisation	Example of regulatory intervention	Status
The World Trade Organisation	TRIPs	Enforced at national level
The World Intellectual Property Organisation	WIPO Copyright treaty	
The OECD		Non-binding recommendations
The European Parliament	Directive 2001/29/EC on the harmonisation of certain aspects of copyright and related rights in the information society  Directive 96/9/EC on the legal protection of databases  Data Protection Directive (Directive 95/46/EC)	Subject to ratification

## Copyright

An important characteristic of Copyright, is that it confers rights that do not require a specific action (e.g. registration) since they generate automatically (copyright exists with the creation

of its subject matter). This has important implications for VPH scientists; they are operating in a territory regulated by law whether they are aware of it or not, whether they are authors themselves or users.

Some principles of copyright law cut horizontally across the corpus of Copyright law, particularly originality, authorship, ownership.

### **Authorship**

Copyright law has historically developed around the concept of a creator/author who dedicates time and effort to produce a literary creation. Copyright is developed under the assumption that knowledge is the product of the intellect, of the author's own genius and ingenuity. This justifies its possession, supported by the creation of law-made scarcity. Because knowledge possesses value, namely economic value, and its author has infused his/her energy and creativity to generate it, the legislator intervenes as a means of protecting the author's rights. By enforcing an artificial scarcity, the legislator guarantees the availability of the author's creativity to society.

Copyright is the compromise right that allows the author to make copies in order to sell it to others in order to live off the fruits of his/her intellectual creation and enables the public to benefit from the work of the creator. In modern times, some of the rights associated with copyright have become the rights of the publisher who owns the copyright (economic rights). The presence of modern technologies complicates matters further. A copyright product can have many copyright owners each of them owning copyright over one or more aspect or stage of production of the product. Moreover, the 'author's function' can be taken up, by groups of individuals, institutions or corporations, making the attribution to individual contributors more complex.

### **Ownership**

The concepts of property and ownership are intrinsic to intellectual property law. There is a clear distinction, however, between authorship and ownership. Property, copyright (or any other intangible property or IP right) can be alienated by the author who will only retain moral rights over his/her work. To complicate the matter authorship and ownership can be attributed to more than one individual so that it is possible to have co-authorship and joint-ownership.

### **Joint authorship/ownership**

This is extremely important in any work or project that requires more persons or organizations to work together. The definition of joint authorship and joint ownership vary under different national legislation.

In general terms joint authorship applies to copyright works generated by the collaboration of two or more authors and which contribution cannot be separated from that of the other(s). The classic example is publications that list all the authors.

Joint ownership however is a different matter and it applies to copyright as well as to other forms of Intellectual Property Rights protection. For a patent, although there might be many inventors, there is one who is indicated as First inventor and who is responsible for the maintenance of the patent.

It is important to note that joint authorship implies that each author owns and has rights over the entire work as if he/she was the sole owner (common property). Each author is entitled to his/her share that can be alienated. To clarify: authorship is joined (joint authors), ownership is common (each owner owning a share)

## Moral Rights v Economic Rights

Moral rights are rights that are inalienable by (ie.can't be separated from) the author. The legislator recognises the strong link between the author and his/her creation. This link cannot be severed. Therefore moral rights include the right of [attribution](#), the right to have a work published [anonymously](#) or [pseudonymously](#), and the right to the integrity of the work. The preserving of the integrity of the work bars the work from alteration, distortion, or mutilation. The right of attribution and the right of integrity of the author's work are particularly relevant to the VPH.

## Attribution

In defined communities, attribution is often part of unwritten norms that are applied without policing from a higher authority or the author. These communities share common objectives and present even a loose sense of identity. In academic settings this can also be norm. There are special licences that apply to software or copyright materials (e.g. open-software, Creative Commons licenses – see the Licensing Guideline document). The same approach can be used by scientists working for VPH.

## Integrity

The right to integrity does not mean that a work cannot be modified.

## The Three Step Test

Art 5(5) of Directive 2001/29/EC introduced a three step test for copyright exceptions and limitations without compromising the normal exploitation of the material. \*\*\*\*\*

## Exceptions

Under copyright law, libraries, educational establishments, archives and museums benefit from the following exceptions:

- An exception to the reproduction rights for specific act of reproduction for non-commercial purpose (Art 5(2)(c) of the Directive);
- An exception for the communication to the public and for the purpose of research or private study by means of dedicated terminals located on the premises of such establishments Art 5(3)(n)

## Databases and Copyright<sup>††††</sup>

Databases are defined by the European Database Directive 1996: "database` shall mean a collection of independent works, data or other materials arranged in a systematic or

---

\*\*\*\*\* For the three steps test see also: Art 9(2) of the Berne Convention and Art 13 of the TRIPs Agreement

†††† Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases. Official Journal L 077 , 27/03/1996 P. 0020 – 0028.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31996L0009:EN:HTML>.

Protection under this Directive shall not apply to computer programs used in the making or operation of databases accessible by electronic means.

Article 2

Limitations on the scope

This Directive shall apply without prejudice to Community provisions relating to:

(a) the legal protection of computer programs;  
 (b) rental right, lending right and certain rights related to copyright in the field of intellectual property;  
 (c) the term of protection of copyright and certain related rights.

methodical way and individually accessible by electronic or other means”.  
The definition of a database protectable by copyright requires four elements:

- 1) independence of the constituent elements
- 2) systematic or methodical arrangement of the elements
- 3) individual accessibility of the elements
- 4) intellectual creation in selection and arrangement of contents

The Database Directive does not apply to software.

## Originality

A database can be eligible for protection when: “by reason of the selection or arrangement of their contents, constitute the author's own intellectual creation”<sup>####</sup>. So, for example if the authors only apply standard procedures, it cannot be eligible for protection. The test for originality is not a clear one and it can be subject to different interpretation. In case of doubt, the test of labor and investment can help clarify.

## Database authorship

- The author of a database shall be the natural person or group of natural persons who created the database or, where the legislation of the Member States so permits, the legal person designated as the right holder by that legislation.
- Where collective works are recognized by the legislation of a Member State, the economic rights shall be owned by the person holding the copyright.
- In respect of a database created by a group of natural persons jointly, the exclusive rights shall be owned jointly.

---

### #### Article 5

#### Restricted acts

In respect of the expression of the database which is protectable by copyright, the author of a database shall have the exclusive right to carry out or to authorize:

- (a) temporary or permanent reproduction by any means and in any form, in whole or in part;
- (b) translation, adaptation, arrangement and any other alteration;
- (c) any form of distribution to the public of the database or of copies thereof. The first sale in the Community of a copy of the database by the rightholder or with his consent shall exhaust the right to control resale of that copy within the Community;
- (d) any communication, display or performance to the public;
- (e) any reproduction, distribution, communication, display or performance to the public of the results of the acts referred to in (b).

### Article 6

#### Exceptions to restricted acts

1. The performance by the lawful user of a database or of a copy thereof of any of the acts listed in Article 5 which is necessary for the purposes of access to the contents of the databases and normal use of the contents by the lawful user shall not require the authorization of the author of the database. Where the lawful user is authorized to use only part of the database, this provision shall apply only to that part.
2. Member States shall have the option of providing for limitations on the rights set out in Article 5 in the following cases:
  - (a) in the case of reproduction for private purposes of a non-electronic database;
  - (b) where there is use for the sole purpose of illustration for teaching or scientific research, as long as the source is indicated and to the extent justified by the non-commercial purpose to be achieved;
  - (c) where there is use for the purposes of public security or for the purposes of an administrative or judicial procedure;
  - (d) where other exceptions to copyright which are traditionally authorized under national law are involved, without prejudice to points (a), (b) and (c).
3. In accordance with the Berne Convention for the protection of Literary and Artistic Works, this Article may not be interpreted in such a way as to allow its application to be used in a manner which unreasonably prejudices the rightholder's legitimate interests or conflicts with normal exploitation of the database.

The author's function is expressed by the rights to authorise or carry out<sup>1</sup>:

- 1) the reproduction or copy of the database
- 2) any alteration including translation, adaptation, arrangement
- 3) the distribution to the public
- 4) the communication to the public
- 5) any reproduction, distribution and communication of the database resulting from its alteration, translation, etc.

### Exceptions<sup>§§§§§</sup>

It is possible to extract data or use the database for:

- (a) private purposes of the contents of a non-electronic database;
- (b) the purposes of illustration for teaching or scientific research, as long as the source is indicated and to the extent justified by the non-commercial purpose to be achieved;
- (c) public security or an administrative or judicial procedure.

Implied consent<sup>\*\*\*\*\*</sup> of the right holder is used in some cases to exempt certain uses from copyright protection (e.g. hyperlinks).

Transient copies<sup>+++++</sup> can be exempted from copyright for reproductions on Internet routers, web browsing or copies created in the Random Access Memory (RAM) of a computer, copies stored in local caches or copies created in proxy servers.

### Duration of the protection of databases<sup>#####</sup>

The database protection lasts only 15 years after the completion of the database. Whenever the subsequent modification are such to generate a new object of protection

---

#### §§§§§ Article 9

Exceptions to the sui generis right

Member States may stipulate that lawful users of a database which is made available to the public in whatever manner may, without the authorization of its maker, extract or re-utilize a substantial part of its contents:

- (a) in the case of extraction for private purposes of the contents of a non-electronic database;
- (b) in the case of extraction for the purposes of illustration for teaching or scientific research, as long as the source is indicated and to the extent justified by the non-commercial purpose to be achieved;
- (c) in the case of extraction and/or re-utilization for the purposes of public security or an administrative or judicial procedure.

\*\*\*\*\* Commission of the European Communities. Commission Staff Working Document. Report to the Council, the European Parliament and the Economic and Social Committee on the application of Directive 2001/29/EC on the harmonization of certain aspects of copyright and related rights in the information society. SEC(2007) 1556  
[http://ec.europa.eu/internal\\_market/copyright/docs/copyright-info/application-report\\_en.pdf](http://ec.europa.eu/internal_market/copyright/docs/copyright-info/application-report_en.pdf)

+++++ **Directive 2001/29/EC of the European Parliament and of the Council** of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society. [http://eur-lex.europa.eu/pri/en/oj/dat/2001/l\\_167/l\\_16720010622en00100019.pdf](http://eur-lex.europa.eu/pri/en/oj/dat/2001/l_167/l_16720010622en00100019.pdf)

#### ##### Article 10

Term of protection

1. The right provided for in Article 7 shall run from the date of completion of the making of the database. It shall expire fifteen years from the first of January of the year following the date of completion.
2. In the case of a database which is made available to the public in whatever manner before expiry of the period provided for in paragraph 1, the term of protection by that right shall expire fifteen years from the first of January of the year following the date when the database was first made available to the public.
3. Any substantial change, evaluated qualitatively or quantitatively, to the contents of a database, including any substantial change resulting from the accumulation of successive additions, deletions or alterations, which would result in the database being considered to be a substantial new investment, evaluated qualitatively or quantitatively, shall qualify the database resulting from that investment for its own term of protection.

## **Collective Works and Copyright**

### **Collective works**

Collective works is applicable when the contribution of each collaborator can be separated. Each contributor has a separate ownership of his/her piece of work.

### **Compilations**

Compilations are subject to copyright and the compiler is an author even if the compilation is about different copyright works of different authors represented in the compilation.

### **Published editions**

The copyright of a published edition belongs to its publisher

### **Computer generated works**

Different levels of ownership are relevant to computer generated work. The author of the computer program is the first copyright owner of that program. (S)he will also be the owner of the work produced by the computer whose function is determined by the program. If however there is a software or program that enables the production of work (such as Microsoft Word) then the owner will be the person producing the literary work. Another case is that of computer-generated material, when there is no human author of the work. In this case the author is the person by whom the arrangement necessary for the creation of the work are undertaken. The distinction is therefore between computer-generated work and computer aided work, when the operator has a substantial input in generating the work. Because there are many gray areas, it is important to consider various tests: e.g. skills and labor; ownership of the machine, control of access, and degree of input in terms of programming and data.

### **Circuit Diagrams**

Electronic circuit diagrams are considered to be literary works by the interconnection of their components.

### **Anonymous works**

What happens when it is impossible to identify the author? §§§§§§ The copyright remains with the owner at the time of publication

### **Orphan works** \*\*\*\*\*

An orphan work is a work under copyright protection whose copyright owner is difficult or impossible to identify. The creator may be unknown, or where the creator is known it is unknown who represents them ††††††. The problem of orphan works is that it is

---

§§§§§§ Hector MacQueen, Charlotte Waelde, Graeme Laurie, Abbe Brown, 2011 . Contemporary Intellectual Property; Law and Policy. Oxford University Press

\*\*\*\*\* EC Commission 2008 Memorandum of Understanding on Orphan Works and diligent search guidelines

†††††† [http://ec.europa.eu/information\\_society/newsroom/cf/itemlongdetail.cfm?item\\_id=3366](http://ec.europa.eu/information_society/newsroom/cf/itemlongdetail.cfm?item_id=3366). See also i2010: Digital

impossible to exploit content without the prior authorization from the right holders. The use of orphan works remains a copyright infringement. The same apply to the digitalization<sup>+++++</sup> of copyright material (e.g. x-rays). If it is essential to use orphan works, it is important to show good faith and due diligence in trying to locate the right holders<sup>§§§§§§</sup>.

### Fair use and research

Examples of fair use include commentary, criticism, news reporting, research, teaching, library archiving and scholarship. It provides for the legal, non-licensed citation or incorporation of copyrighted material in another author's work under a four-factor [balancing test](#)

### Public domain

Works are in the public domain if their kind is not covered by [intellectual property](#) rights or if the intellectual property rights have expired, have been forfeited, or have never been claimed. Examples include the [English language](#), the formulae of [Newtonian physics](#), as well as the works of [Shakespeare](#) and the [patents](#) over [powered flight](#).<sup>\*\*\*\*\*</sup>

The concept of public domain is extremely important in research. Public domain must be distinguished from 'res nullius' or something that does not belong to anyone and therefore it is available for appropriation from 'res universitates'

### DRM

Digital rights management (DRM) is a term for [access control](#) technologies that can be used by hardware manufacturers, publishers, [copyright](#) holders and individuals to limit the usage of digital content and devices. The term is used to describe any technology that inhibits uses of digital content not desired or intended by the content provider. The term does not generally refer to other forms of [copy protection](#) which can be circumvented without modifying the file or device, such as [serial numbers](#) or [keyfiles](#). It can also refer to restrictions associated with specific instances of digital works or devices.

- DRM technologies attempt to control use of digital media by preventing access, copying or conversion to other formats by [end users](#)
- DRM technologies have enabled publishers to enforce access policies that not only disallow [copyright infringements](#), but also prevent lawful [fair use](#) of copyrighted works, or even implement use constraints on non-copyrighted works that they distribute; examples include the placement of DRM on certain [public-domain](#) or [open-licensed](#) e-books, or DRM included in consumer electronic devices that time-shift (and apply DRM to) both copyrighted and non-copyrighted works<sup>+++++</sup>.
- DRM are mainly used in the film industry, but can play a role in restricting access to patient information

---

Libraries. High Level Expert Group – Copyright Subgroup. Report on Digital Preservation, Orphan Works, and Out-of-Print Works. Selected Implementation Issues (adopted by the High Level Expert Group at its third meeting on 18.4.2007)

+++++ See Commission Recommendation 2006/585/EC on the Digitalisation and online accessibility of cultural material and digital preservation

§§§§§ See the Arrow (Accessible Registries of Rights Information and Orphan Works).

\*\*\*\*\* Source: Wikipedia

+++++ Source: Wikipedia

## Data Protection

### Data Protection Directive<sup>+++++</sup>

Directive 95/46/EC deals with the protection of individuals with regard to the processing of personal data and on the free movement of such data.

Origins:

- The [European Convention on Human Rights](#) (ECHR). Article 8 of the ECHR provides a right to respect for one's "private and family life, his home and his correspondence," subject to certain restrictions. The [European Court of Human Rights](#) has given this article a very broad interpretation in its jurisprudence.
- In 1980, in an effort to create a comprehensive data protection system throughout Europe, the [Organization for Economic Cooperation and Development](#) (OECD) issued its "Recommendations of the Council Concerning Guidelines Governing the Protection of Privacy and Trans-Border Flows of Personal Data." The seven principles governing the [OECD's](#) recommendations for protection of personal data were:
  1. Notice—data subjects should be given notice when their data is being collected;
  2. Purpose—data should only be used for the purpose stated and not for any other purposes;
  3. Consent—data should not be disclosed without the data subject's consent;
  4. Security—collected data should be kept secure from any potential abuses;
  5. Disclosure—data subjects should be informed as to who is collecting their data;
  6. Access—data subjects should be allowed to access their data and make corrections to any inaccurate data; and
  7. Accountability—data subjects should have a method available to them to hold data collectors accountable for following the above principles.

The [OECD](#) Guidelines, however, were nonbinding, and data privacy laws still varied widely across Europe. The US, meanwhile, while endorsing the [OECD's](#) recommendations, did nothing to implement them within the United States. However, all seven principles were incorporated into the EU Directive.

- In 1981 the [Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data](#) was negotiated within the [Council of Europe](#). This convention obliges the signatories to enact legislation concerning the automatic processing of personal data, which many duly did.
- The [European Commission](#) realised that diverging data protection legislation amongst EU member states impeded the free flow of data within the EU and accordingly proposed the Data Protection Directive.

### Privacy of Personal Data<sup>§§§§§§§§</sup>

Article 8 of the [European Convention on Human Rights](#), which was drafted and adopted by

---

<sup>+++++</sup> See also the UK The Data Protection Act 1998

<sup>§§§§§§§§</sup> Yuh-Jzer Joung, Shi-Cho Cha, 2008 . On-line Personal Data Licensing: Regulating Abuse of Personal Data in Cyberspace. Hideyasu Sasaki, 2008. Intellectual Property Protection for Multimedia Information Technology. Information Science Reference.

the [Council of Europe](#) in 1950 and meanwhile covers the whole European continent except for [Belarus](#) and [Kosovo](#), protects the right to respect for private life: "Everyone has the right to respect for his private and family life, his home and his correspondence." Through the huge case-law of the [European Court of Human Rights](#) in [Strasbourg](#), privacy has been defined and its protection has been established as a positive right of everyone.

Article 17 of the [International Covenant on Civil and Political Rights](#) of the [United Nations](#) of 1966 also protects privacy: "No one shall be subjected to arbitrary or unlawful interference with his privacy, family, home or correspondence, nor to unlawful attacks on his honour and reputation. Everyone has the right to the protection of the law against such interference or attacks."

### ***Identification, authentication and access***

The use of identification and authentication techniques, such as the use of biometrics, fingerprints or forms of visual recognition can have an impact on individual rights. Identification, authentication and access are often linked together because the identification of a user requires the authentication of her identity and often the access to his/her personal data. This might generate risks to the privacy of the individual concerned, but also expose the data to data and identity theft. Identification, authentication and access technologies are often based on an 'identifier' (e.g. a number), some attributes (e.g. date of birth, race, eye color, genetic pattern). Both are often the elements necessary for the identification of the subject. Authentication occurs when an attribute is validated and attributed to an individual. The access follows the decision to authorize the authenticated individual to access a set of data or information or a particular action.

### ***User Friendly Laws***

#### **Copyright and user-created content (UCC)**

The creation of copyright content by users poses various problems.

For example, users might create content using others' copyright material. In this case, the existing copyright exceptions for: quotation for criticism or review, incidental use and caricature, parody and pastiche might apply.

#### **Open content licenses**

- Open content describes a kind of [creative work](#), or [content](#), published under an open content license (OPL, pronounced like "opal") that explicitly allows copying and modifying of its information by anyone, not exclusively by a single organization, firm or individual.
- Open content is an alternative paradigm to the use of [copyright](#) to create [monopolies](#); rather than leading to monopoly, open content facilitates the [democratization of knowledge](#).
- The term *open content* has an ambiguity. It means that anyone can get copies of the content (e.g. source code) but it can also mean that it gives the user certain copyright freedoms.
- The largest open content project is [Wikipedia](#).

## Disability and access <sup>\*\*\*\*\*</sup>

The access to visually impaired people and people with other disabilities is a relevant issue for most web-based databases and content. Most EU countries have implemented copyright exception in their national legislation, but the measures are not uniform and the transfer from one country to another of copyright material can create some difficulties. TPM are often an additional impediment. <sup>††††††††</sup>

## Personal Data Licensing

On line Personal Data Licensing, is relevant to concerns about the privacy of personal data. In concept, any use of a person's data must be authorized by the person. By allowing people to issue licenses for the use of their data, they can control the way their data are to be used, and be more alert to the exposure of their personal data. In contrast, most Web services today adopt passive consent in which people generally are unaware of how their data have been, or will be used. Data licenses can be considered as a type of proxy consent but, with the support of a digital signature, they can provide the same power of evidence as written consent. Hence the use of data licenses can hopefully reduce the increasing dispute on privacy issues between users and service providers.

Further details relating to licensing can be found in the Licensing Guideline document.

## Conclusion

Ignorantia juris non excusat (the ignorance of the law is not an excuse) applies to the VPH. Technology is developing faster than the law. For scientists it is important to grasp the main principles behind the law, consciously operating in a manner that enables them to be compliant with developing laws and regulations.

---

\*\*\*\*\* UN Convention on the Rights of Persons with Disabilities

†††††††† For example on voluntary agreements or licenses see: Te federation of European Publishers, the UK Publisher Association, and the Copyright Licensing Agency