

# **Legal Framework for e-Research**

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### **Abstract**

This paper overviews the key legal issues that need to be addressed in building a sustainable e-Research framework. Very little work has been undertaken on this issue in Australia or overseas. The paper will build on the available material and explain why innovative approaches to legal issues relating to intellectual property, data management, privacy and contract will be needed to ensure that the full potential of e-Research is realised. This paper will be presented as part of the DEST funded SII Project on Legal Frameworks for e-Research.

### **Introduction**

The conduct of research and the dissemination of its outcomes are greatly enabled by recent and continuing development in communications networks, information and computing technologies. These new technologies not only improve productivity and quality of research, they also enable entirely different kinds of research, organisational models and collaborations across every discipline, and create new research domains that could not otherwise exist. Research in Australia, as elsewhere, still tends to be undertaken using more traditional methods, but with a gradual increase in the use of advanced ICT. Research still also tends to be undertaken within disciplines, with a gradual increase in a multi-disciplinary approach.

The term 'e-Research' encapsulates research activities that use a spectrum of advanced information and communications technologies (ICT) capabilities and embraces new research methodologies emerging from increasing access to:<sup>1</sup>

- Broadband communications networks, research instruments and facilities, sensor networks, data repositories and their associated data standards, management and curation tools, and high performance computing resources;
- Software and infrastructure services that enable secure connectivity and interoperability between researchers and the wide variety of data repositories, computers, systems and networks on which they depend;
- Application and discipline-specific tools such as graphics intensive visualisation and simulation software, and interaction tools that provide the human interface allowing

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<sup>1</sup> An E-research Strategic Framework: Interim Report of the E-research Coordinating Committee, 30 September 2005. <http://www.dest.gov.au/NR/rdonlyres/B6F765A7-DD2C-432B-9064-2F9CD4E17E66/10518/InterimReport2.doc>

researchers to interact with each other and with their instruments, computational tools and data resources.

These capabilities serve to advance and augment, rather than replace traditional research methodologies.

The Australian Federal government has implemented the National Collaborative Research Infrastructure Strategy (NCRIS) to provide greater focus and strategic direction for Australia's research infrastructure. The NCRIS Strategic Roadmap<sup>2</sup> identifies priorities for investment in research infrastructure. In addition to 15 specific areas of science and technology, "Platforms for Collaboration" are also designated as a priority capability area.<sup>3</sup> In addition to hardware and software elements, this priority area includes copyright and other legal considerations. Other developed countries have also seen initiatives in the development and coordination of e-Research capabilities, for example the Oxford e-Research Centre in the UK.<sup>4</sup>

In this article, we provide an overview of the main legal issues which are considered critical in undertaking e-Research. It is important to recognise that the issues are likely to extensively overlap with those encountered in traditional collaborative research scenarios. In illustrating various legal issues, we draw upon available information concerning conventional research collaboration. We then briefly review the approach taken by investigators in the UK to providing a legal framework to underpin development of e-Science. Finally, we describe our present activities which are directed towards recommendations to ultimately establish a legal framework to facilitate e-Research in Australia.

## **The Legal Issues**

Dr Michael Spence<sup>5</sup> has described the principal classes of legal problems which may arise in collaborative research as:

1. The legal relationship among the parties to collaboration, particularly where some of the parties are operating in different jurisdictions.
2. The information and materials that each party brings to collaboration.

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<sup>2</sup> National Collaborative Research Infrastructure Strategy (NCRIS)

[http://www.dest.gov.au/sectors/research\\_sector/policies\\_issues\\_reviews/key\\_issues/ncris/](http://www.dest.gov.au/sectors/research_sector/policies_issues_reviews/key_issues/ncris/)

<sup>3</sup> NCRIS Strategic Roadmap: Section 5.16 Platforms for collaboration.

[http://www.dest.gov.au/sectors/research\\_sector/policies\\_issues\\_reviews/key\\_issues/ncris/](http://www.dest.gov.au/sectors/research_sector/policies_issues_reviews/key_issues/ncris/) February 2006.

<sup>4</sup> <http://www.oerc.ox.ac.uk/>

<sup>5</sup> David PA and Spence M, *Towards Institutional Infrastructure for e-Science- the scope of the challenge*, Oxford Internet Institute, Research Report No 2, September 2003.

3. The products and resources, if any, to which the collaborative project will give rise.
4. The apportioning (among the parties) of liabilities for potential harm to participants and outside parties, arising from the collaborative project.<sup>i</sup>

The key legal issues facing collaborative innovation and e-Research which our DEST funded Legal Frameworks project proposes to consider are:

- the research contracting framework;
- intellectual property law;
- privacy law;
- private international law;
- jurisdiction; and
- liability (tort law).

In the present paper, we focus on the contractual framework, intellectual property and privacy law. We also consider issues relating to data management, which are inter-related with issues of intellectual property and privacy.

### *Contractual Framework*

Contract law is a vital part of the legal context of e-Research as it maps the framework for collaboration. The ability to be able to contract quickly and efficiently with large numbers of people from all over the country and world so as to enhance the serendipity and distributed nature of collaborative innovation and e-Research/Cyberinfrastructure is vital. This contracting framework also needs to be able to understand and integrate with collaborative software and hardware tools. Research contracts employed by funding bodies, universities, industry and governments will need to accommodate flexibility and efficiency in the establishment and progress of research communities.

In an ideal situation, prior to initiating R&D collaboration, the partnering entities could draw up a contract precisely defining each party's obligations, covering all possible eventualities. However, in practice, it is recognised that this will inevitably be impossible to accomplish.<sup>6</sup> It is recognised that uncertainties and risk relating to required resources and final outcomes are inherent attributes of R&D collaborations, and extremely detailed contracts could actually inhibit innovation and

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<sup>6</sup> Maskin E and Tirole J, "Unforeseen contingencies and incomplete contracts" (1999) 66 *Review on Economic Studies* 83.

knowledge creation.<sup>7</sup> Collaborative research ventures can run for many years and changes may be required as the work progresses.<sup>8</sup> This leads to the conclusion that, in addition to formal contracts, other, complimentary mechanisms are also critical success factors.<sup>9</sup> The importance of these informal governance factors has been found to particularly crucial in situations where there is significant asymmetry in the relative power and size of collaborating entities.<sup>10</sup> Blomqvist has identified trust as key factor which must be present operating in parallel with a well defined contract for successful R&D outcomes.<sup>11</sup>

In some instances, there has been guidance provided by national and international scientific organisations in setting up contractual frameworks for research collaborations. For example, the International Union of Pure and Applied Chemistry (IUPAC) set out elements which are commonly present in collaborative contracts.<sup>12</sup> The material was developed by considering such contracts from several different countries originating from firms in the USA and Europe. The result was not a standard form of contract, but rather a guide to the items which would normally need to be considered.

In their report, David and Spence point out a number of factors which potentially complicate any contractual arrangements between collaborating parties. The first relates to when and on what terms their relationship is formed, particularly when the collaboration is organised on an informal basis. The second is the problem of how to accommodate the inclusion of latecomers to the project, and the difficulties associated with the departure of key participants. Thirdly, difficulties can arise because of the unequal bargaining power of the collaborating parties. Fourthly, there are issues relating to the parties residing in different jurisdictions. Finally, there are perceived problems arising because of the expertise required to interpret contracts for scientific collaboration.

### *Intellectual Property*

Another significant legal issue facing collaborative innovation and e-Research concerns principles for sharing intellectual property in the form of patented material, copyright material, research data

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<sup>7</sup> Goel RK, "On Contracting for Uncertain R&D" (1999) 20(2) *Managerial and Decision Economics* 99; von Hippel E, "Cooperation between rivals: informal know-how trading" (1987) 16(6) *Research Policy* 291.

<sup>8</sup> Macneil I, *The New Social Contract*, Yale University Press, New Haven/London.

<sup>9</sup> Bruce, M, Leverick F, and Wilson D., "Success factors for collaborative product development: a study of supplier of information and communication technology" (1995) 25 *R&D Management* 1.

<sup>10</sup> Doz YL, "Technology partnerships between larger and smaller firms: some critical issues" (1998) XVII (4) *International Studies of Management and Organisation* 31; Cullen P-A "Contracting, co-operative relations and extended enterprises" (2000) 20(7) *Technovation* 363.

<sup>11</sup> Blomqvist K, Hurmelinna P and Seppänen R, "Playing the collaboration game right—balancing trust and contracting" (2005) 25 *Technovation* 497.

<sup>12</sup> Andrews PR, Borris R, Dagne E, Gupta MP, Mitscher LA, Monge A and DeSouza NJ, "General features of contracts for natural product collaborations" (1996) 68(12) *Pure and Applied Chemistry* 2333.

and confidential information.<sup>13</sup> Researchers need to know at the outset and during the project, the legal conditions and terms upon which they have access to intellectual property and data in order to legally collaborate with other researchers. Contractual licensing questions, and in particular how to facilitate the licensing of intellectual property rights to enable large scale collaboration among researchers, are of critical importance and need to be considered in light of this new research landscape. A failure to properly understand the intellectual property rights relating to collaborative innovation and e-Research will prove to be a major legal impediment in facilitating collaboration amongst researchers.

In its assessment of IP issues, the E-research Coordinating Committee<sup>14</sup> recognised that the line between pure and commercial research is being blurred as researchers increasingly interact across the public and private sectors, and as commercially and publicly funded research increasingly overlap. The Committee made the following recommendations:

- The results of publicly-funded research must remain, as far as possible, accessible to other researchers and reviewers, to stakeholders, to industry and to Government.
- Universities and PFRAs must assess the need for and the value of IP used by their researchers, including IP embodied in ICT resources, data, collaboration tools and applications software.
- As far as possible, the costs associated with making research outputs accessible, and of using commercial IP to conduct research should be recovered through appropriate capture and licensing of IP resulting from the research itself.
- Where research is conducted in collaboration with private organisations and companies, the legal agreements for sharing and licensing the resulting IP must be carefully negotiated in advance, so as to fairly distribute benefits between the taxpayer funding the research, institutional stakeholders and industry partners.

A recent article by Slowinski and Sagal<sup>15</sup> focussed on patent rights in collaborative research agreements. They point out that it is not uncommon for the technical employees of partners in a prospective R&D alliance to commence working together before an alliance agreement has been reached. The enthusiasm of the participants to collaborate without delay can lead to situations where projects are initiated without any clear understanding at all between the prospective partners

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<sup>13</sup> See J H Reichman and Paul F Uhlir, 'A Contractually Reconstructed Research Common for Scientific Data in a Highly Protectionist Intellectual Property Environment' *Law and Contemporary Problems* (2003) 66(1 & 2); Paul A David 'Can "Open Science" be Protected from the Evolving Regime of IPR Protections?' (July 2003) *Journal of Intuition and Theoretical Economics*; Henry R Hertzfeld 'Intellectual Property Mechanism in Research Partnerships' *Discussion Paper on Entrepreneurship, Growth and Public Policy*; Paul A David, *Can 'Open Science' be Protected from the Evolving Regime of IPR Protections*, (July 2003).

<sup>14</sup> An E-research Strategic Framework: Interim Report of the E-research Coordinating Committee, 30 September 2005. <http://www.dest.gov.au/NR/rdonlyres/B6F765A7-DD2C-432B-9064-2F9CD4E17E66/10518/InterimReport2.doc>

<sup>15</sup> Slowinski G and Sagal MW, "Allocating patent rights in collaborative research agreements: prospective partners can implement a legal structure that maximizes the value of their research collaboration" (2006) 49(1) *Research-Technology Management* 51.

of ownership of intellectual property. These authors believe that collaborative work prior to an unambiguous agreement on intellectual property rights is always a bad idea. Typical non-disclosure agreements or letter of intent are insufficient to adequately address the allocation of intellectual property rights based on exploratory joint work. They illustrate how collaboration without an agreement can have unintended consequences. For example, in a situation in which two firms create a patentable invention without an agreement, United States law defines the invention as jointly owned, and either partner can exploit the invention without the consent of the other joint owner. This includes licensing or selling their intellectual property interest to anyone they wish, including the partner's significant competitor.<sup>16</sup>

Slowinski and Sagal also stressed the importance of collaborating parties differentiating between “background” and “foreground” intellectual property. “Background intellectual property” is usually defined as relevant intellectual property that either partner created prior to the start of the alliance. “Foreground intellectual property” is defined as relevant intellectual property created during the alliance. These authors also stress the importance of defining boundaries of the alliance with a clear statement of the scope of the alliance. Inside the boundaries, the firms are allied. They will play by a set of rules defined by the alliance agreement. Outside the boundaries, the firms are not allied and a different set of rules will apply. They also strongly advocate linking patent rights to “marketplace alignment”. Parties should agree under what circumstances they will be working together in the marketplace. They will also agree on the circumstances under which they will not be working together in the marketplace, but rather proceeding independently of each other.

The importance of defining intellectual property rights in collaborative research has been recognised as a major factor in determining the viability of co-operative research centres (CRCs).<sup>17</sup> Australian CRCs have played a major role in fostering collaborative research during the past decade. Significant funding has been directed towards these research centres by the Federal government, and a primary objective has been to foster collaboration between universities, government agencies and the university sector.

Some of the specific pitfalls of collaborative research in the context of intellectual property rights are illustrated in an article by Bennett and Biswas.<sup>18</sup> These authors illustrate a hypothetical

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<sup>16</sup> United States patent law at 35 U.S.C. 262: "In the absence of any agreement to the contrary, each of the joint owners of a patent may make, use, offer to sell or sell the patented invention within the United States, or import the patented invention into the United States, without the consent of, and without accounting to the other owners."

<sup>17</sup> Liyange S and Mitchell H, “The Management of Intellectual Property Rights in Australian Cooperative Research Centres” (1995) 10(2-3) *International Journal of Technology Management* 343.

<sup>18</sup> Bennett VC and Biswas SJ, “Protecting the patentability of your collaborative research: Collaborations are great. But who gets the patent rights?” (1997) 15 *Nature Biotechnology* 472.

situation where two professors, A and B collaborate to identify a mutated form of a gene. Subsequently, they invite Dr C, an expert from a neighbouring medical centre to join the research. The three researchers confirm the association between the mutant allele and a particular cancer and develop a diagnostic test. A patent is then filed claiming both the DNA having the mutant sequence and the diagnostic test. The USPTO will probably view the isolated DNA mutant as invented by the entity (A+B). However, the diagnostic assays were invented by (A+B+C), a completely distinct inventive entity. Consequently, when examining the patent application, the USPTO may decide that the work of inventive entity (A+B+C) is obvious when considered against the work of inventive entity (A+B). This situation can arise even though (A+B) never published their findings and is viewed by the USPTO as “secret prior art”.<sup>19</sup> The scenario illustrates just a few of the types of problems that can be inadvertently encountered when researcher collaborations are initialised without guidance as to potential legal consequences.

### *Privacy*

In terms of privacy law, the key legal issue in relation to collaborative innovation and e-Research will be to what extent access to data sets containing personal or private/confidential information (trade secrets) will be allowed and upon what conditions. An allied privacy issue facing collaborative innovation and e-Research will be the extent to which personal and private information will be protected under privacy laws without the loss of the accuracy of the information.

Examples of situations where both privacy and data access issues are of paramount importance involve research using medical data. This was exemplified by the E-research Strategic Framework: Interim Report<sup>20</sup> with a case study on the InterRett Project. The understanding of causes and potential remedies for a rare debilitating disease, Rett Syndrome, which can lead to severe intellectual disabilities, requires a global perspective involving researchers and practitioners in multiple locations. The paucity of local data and clinical experience of this disease means that Australia cannot be self sufficient in this kind of epidemiological research. The InterRett Project aims to encourage international collaboration, identify genetic determinants, improve diagnosis and clinical understanding and identify suitable strategies to manage symptoms. Families and clinicians from around the globe enter data into the InterRett Database, making a potentially very large dataset available to researchers.

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<sup>19</sup> Note that patent law varies somewhat between jurisdictions.

<sup>20</sup> An E-research Strategic Framework: Interim Report of the E-research Coordinating Committee, 30 September 2005. <http://www.dest.gov.au/NR/rdonlyres/B6F765A7-DD2C-432B-9064-2F9CD4E17E66/10518/InterimReport2.doc>

The following issues were identified as important with this type of collaboration:

- Patient privacy can be achieved, technically, through separation of identifying information from medical data and the use of existing web-based security methods.
- Formal guidelines and consensus are needed to define data submission, access and output processes;
- National guidelines would be useful to streamline interagency collaboration, especially in regard to establishing legal agreements or MOU's on data sharing, publication, security and privacy.

### *Data Management*

The e-research Coordinating Committee recognised that digital data lies at the core of modern research and knowledge generation in all fields.<sup>21</sup> The volume and importance of such data is increasing rapidly through conversion of existing information in other forms and generation of new information through research. In some research fields it is already becoming routine to handle terabytes and even petabytes of data. In general, the growth in data volume is driven by research facilities and major and distributed data holdings. These sources of data are geographically dispersed within Australia and internationally. The Committee emphasised that issues of access to data and the associated issues of intellectual property and privacy need to be addressed in the legal as well as technical context. It also acknowledged that in recent years, internationally, considerable activity and debate has centred on the merits or desirability of various open access and Creative Commons models for simplifying access to, and use of, data created or collected in the course of publicly funded research.

Issues of data management are particularly accentuated in fields of biological collaborative research during the past decade where vast amounts of data are produced by collaborating large research teams distributed internationally. Examples include the Human Genome Project,<sup>22</sup> the SNP Consortium<sup>23</sup> and the International HapMap<sup>24</sup> projects. The E-research Coordinating Committee

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<sup>21</sup> An E-research Strategic Framework: Interim Report of the E-research Coordinating Committee, 30 September 2005. <http://www.dest.gov.au/NR/rdonlyres/B6F765A7-DD2C-432B-9064-2F9CD4E17E66/10518/InterimReport2.doc>

<sup>22</sup> [Human Genome Project http://www.ornl.gov/sci/techresources/Human\\_Genome/home.shtml](http://www.ornl.gov/sci/techresources/Human_Genome/home.shtml)

<sup>23</sup> In April 1999, ten large pharmaceutical companies and the U.K. Wellcome Trust philanthropy announced the establishment of a consortium headed by Arthur L. Holden to find and map 300,000 common SNPs. The goal was to generate a widely accepted, high-quality, extensive, publicly available map using SNPs as markers. The international member companies, which together committed at least \$30 million, are APBiotech, AstraZeneca Group PLC, Aventis, Bayer Group AG, Bristol-Myers Squibb Co., F. Hoffmann-La Roche, Glaxo Wellcome PLC, IBM, Motorola, Novartis AG, Pfizer Inc., Searle, and SmithKline Beecham PLC.

cited the example of the Human Genome Project when discussing e-Research in the science and engineering domains under a case study titled “Mapping the blueprints of life”.

Some of the issues pertaining to data management in this type of collaborative project were recently considered by Chokski and co-workers<sup>25</sup> issues arising from the formation of an international research consortium known as MalariaGEN, whose aim is to identify molecular mechanisms of protective immunity against malaria. These authors considered issues of access within and outside the consortium as well as specific guidelines for intellectual property management.

### **Overview of DEST Funded Legal Framework Project**

It is apparent from the above discussion that the major legal issues pertaining to establishing successful e-Research collaborations can already be broadly identified. Many of these issues are similar to those encountered in collaborative research programs using more traditional communication modes. However, it is probably evident from the above discussion that the legal framework is potentially complex, even limiting our scope to traditional modes of collaboration. Collaborations by e-research will add further complexities, which need to be elucidated and understood to facilitate optimisation of returns to the research participants, funding agencies and to society in general.

The report by David and Spence<sup>26</sup> at the Oxford Internet Institute highlights many of the legal issues relevant to development of e-Research, and proposals to accommodate these through a structured framework. They contend that perceived difficulties with e-Research collaborative agreements are not as easily overcome by standard form contracts as public research administrators and some members of the scientific community would appear to believe. They suggest that the most obvious problem is that the structure of different types of collaborative agreement will vary widely, making it virtually impossible to effectively use standard form agreements. They advocate

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<sup>24</sup> The International HapMap Project is a multi-country effort to identify and catalogue genetic similarities and differences in human beings. Using the information in the HapMap, researchers will be able to find genes that affect health, disease, and individual responses to medications and environmental factors. The Project is a collaboration among scientists and funding agencies from Japan, the United Kingdom, Canada, China, Nigeria, and the United States. The goal of the International HapMap Project is to compare the genetic sequences of different individuals to identify chromosomal regions where genetic variants are shared. <http://www.hapmap.org/thehapmap.html.en>

<sup>25</sup> Chokski DA, Parker M and Kwiatkowski DP, “Data sharing and intellectual property in a genomic epidemiology network: policies for large scale research collaboration” (2006) 84(5) *Bulletin of the World Health Organisation* 382.

<sup>26</sup> David PA and Spence M, *Towards Institutional Infrastructure for e-Science- the scope of the challenge*, Oxford Internet Institute, Research Report No 2, September 2003.

a balance between formal and informal governance mechanisms, together with the development of standard form clauses and principles for their implementation.

They also support the creation of coordinating and facilitating mechanism through establishment of a new public agency. This would take the form of an independent body called the Advisory Board on Collaboration Agreements (ABCA). Its function would be to guide and oversee the legal framework in regard to “Grid-enabled” collaborations in science and engineering research through producing, maintaining, evaluating and updating sets of standard contractual clauses.

David and Spence suggest that more information is required about current practices in planning the institutional structures of e-Science collaborations. From their work they concluded that there was a comparative paucity of concrete empirical knowledge concerning the specifics of current individual researchers’ experiences with informal governance arrangements for research collaborations. There is also a parallel lack of systematic information regarding the ways formal legal rules are being used by cooperating institutions. In particular, they suggest that it is important to know the extent to which working scientists themselves have an input into planning the structures and mechanisms of collaborations, rather than simply specifying requirements at a technical level. Other situations to consider are where disputes arise between collaborators, and these authors pose the question – when do collaborators invoke the traditional informal norms of the scientific community, and when do they resort to formal legal rules?

To achieve its overall goals the DEST funded Legal Framework project will examine the way in which model agreements can be employed across the research sector to deal with the key legal issues in a uniform, easy to understand and efficient way. This will include an examination of existing agreements and processes for putting in place legal relationships. As part of our research we will survey Australian researchers about their use of an e-Research methodology and the legal issues they have experienced.

We also propose to consider the institutional arrangements needed for best practice e-Research contracting/team building and in doing so examine the benefits of establishing a national institution or clearing house, which would be responsible for removing the legal impediments in order to facilitate the most effective and efficient model for collaborative innovation and e-Research. Paul David argues that ‘it is important that institutional arrangements are made so as to minimise the extent to which the law becomes an impediment to cooperation among researchers, whether directly or indirectly by undermining informal mechanisms of trust and dispute resolution.’<sup>27</sup>

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<sup>27</sup> Paul A David *Towards a cyberinfrastructure for enhanced scientific collaboration*, Research Report No 4, Oxford Internet Institute, August 2004.

In addition to these issues, other issues relating to areas of general law may also arise including private international law/jurisdiction and tort law. Due to the international and transnational nature of the technologically enhanced world we live in, jurisdictional issues will inevitably arise and need to be considered as part of this research, especially those relating to the contracting framework. Principles for apportioning responsibility for loss and liability also need to be considered. There is also the issue of the owners of the computing systems and networks, who may want some share in any 'product' of the research. Many of these systems are using innovative, and expensive to develop, maintain and run, software and hardware platforms that may be offered on a 'sharing results' basis.

\*\* This research has been undertaken as part of the DEST funded *Legal Framework for e- Research Project* – a Systemic Infrastructure Initiative (SII) funded project and part of the Commonwealth Government's *Backing Australia's Ability – An Innovation Action Plan for the Future*

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