

On the Importance of Intellectual Property Rights for eScience and the Integrated Health Record

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Introduction

- Use of data from primary health care
- eScience – new kinds of research
 - Use of medical data raising broader issues
- Integrated Health Record
- Legal frameworks that underpin these initiatives
 - Intellectual Property (IP)
 - How does IP relate to databases in IHR or eScience?

A Vision for Data

- eScience
 - New kinds of computational resources
 - New kinds of research collaborations
 - Building virtual organisations at a national or international level.
- Integrated Health Record
 - National accessibility
- Making access seamless
- Making data mobile

The Realities of Current Practice

- Data is shared for research
 - In mutually beneficial collaborations
- Trust & long term relationships
 - eg. with University depts, or specific researchers
- Commercial collaborations are also critical
 - Benefits for the participating clinic
- Data is a resource used to ensure maximum benefit for the health service
- *Ad hoc* local arrangements
- Current practice vs. eScience vision

Technology raises issues

- If data becomes accessible at a national level:
 - Who should be entitled to make deals with external researchers and organisations?
 - Who should benefit from such deals, and how?
 - What interest do external organisations acquire in shared data and do the rights of data custodians change?
- A lack of clarity on these issues could lead to:
 - An unwillingness to share data for research, or
 - costly litigation when conflicting claims arise

An eSocial Science Project

- IMaGE
 - Intellectual Property Rights in
 - Medical Data in
 - a
 - Grid
 - Environment
- Law, social science & computer science
- How future law should operate
- eDiaMoND

eDiaMoND Case Study

- Large interdisciplinary eScience project
 - £4.25m; 5 Universities; 4 NHS Trusts; 2 Commercial partners
- Focus on the UK National Breast Screening Programme
- Aim: “develop a next generation Grid enabled prototype to demonstrate the potential benefits of a national infrastructure to support digital mammography”
 - Expected shift from analogue to digital radiography
 - Manage digital images using eScience technology

The eDiaMoND Database

- Need significant quantity of patient data
 - 4 participating clinics; 4 participating universities; 1600 cases total
 - Data straight from patients and existing training archives
 - Digital and film-based equipment
 - scanning films, entering patient records; a significant task
 - Ethical clearance

Licensing of Data

- Most clinics contributed data freely to the project
- However, one requested formal IP terms & conditions
- Resulting 3-way negotiation took over a year to settle
 - Resulting in a complex pair of back-to-back collaboration agreements.
 - This uncertainty was highly problematic for the data collection effort.

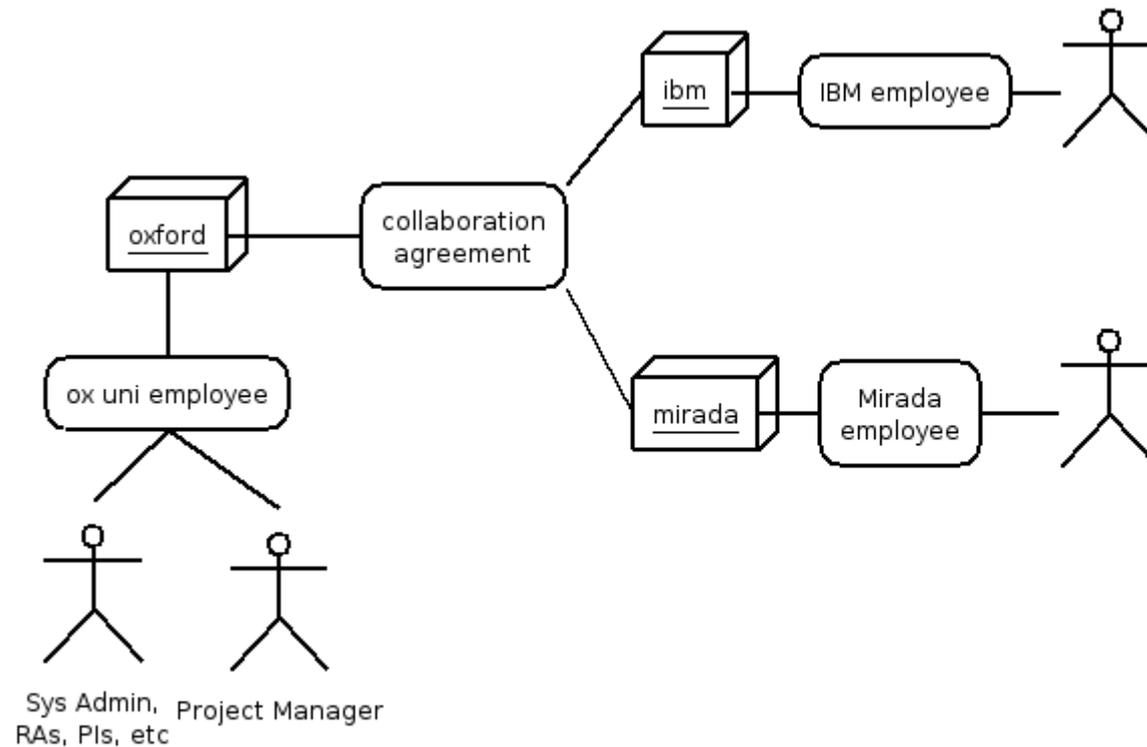
Legal Issues: Introduction

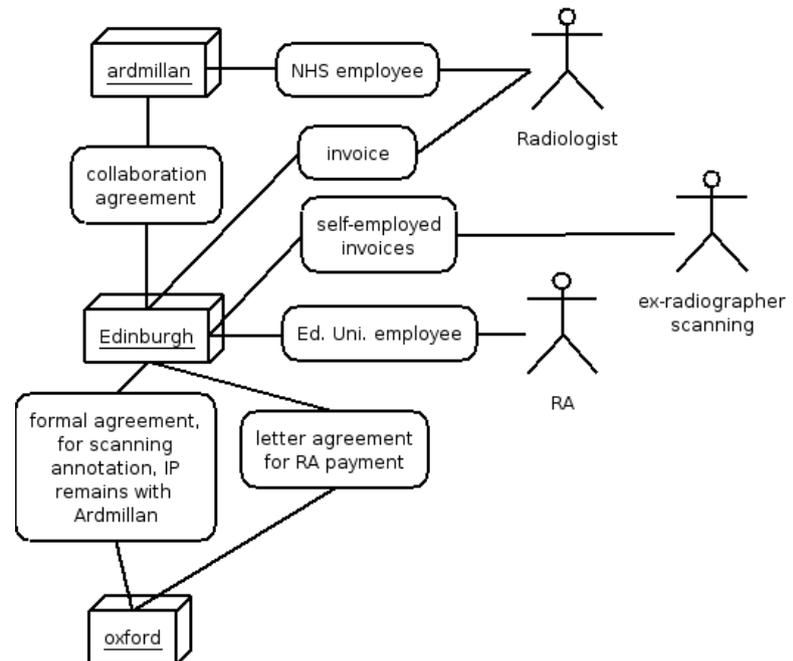
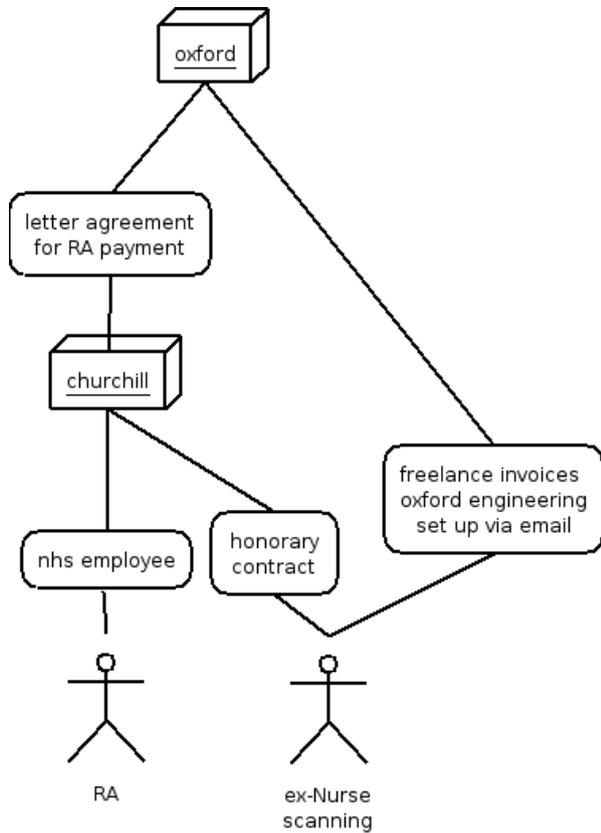
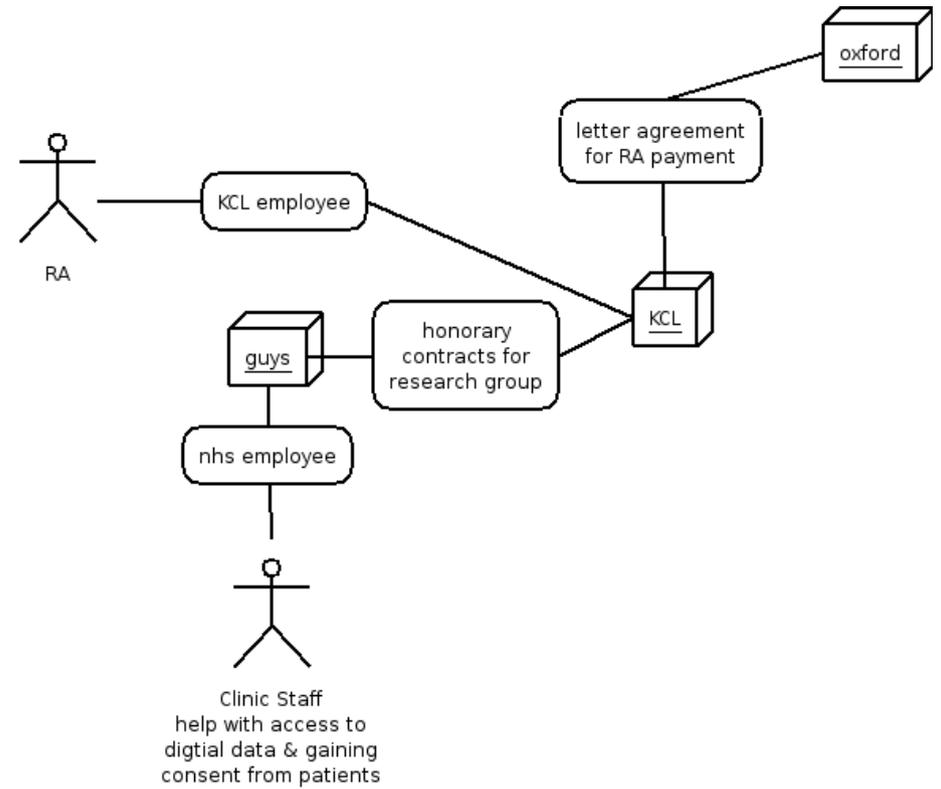
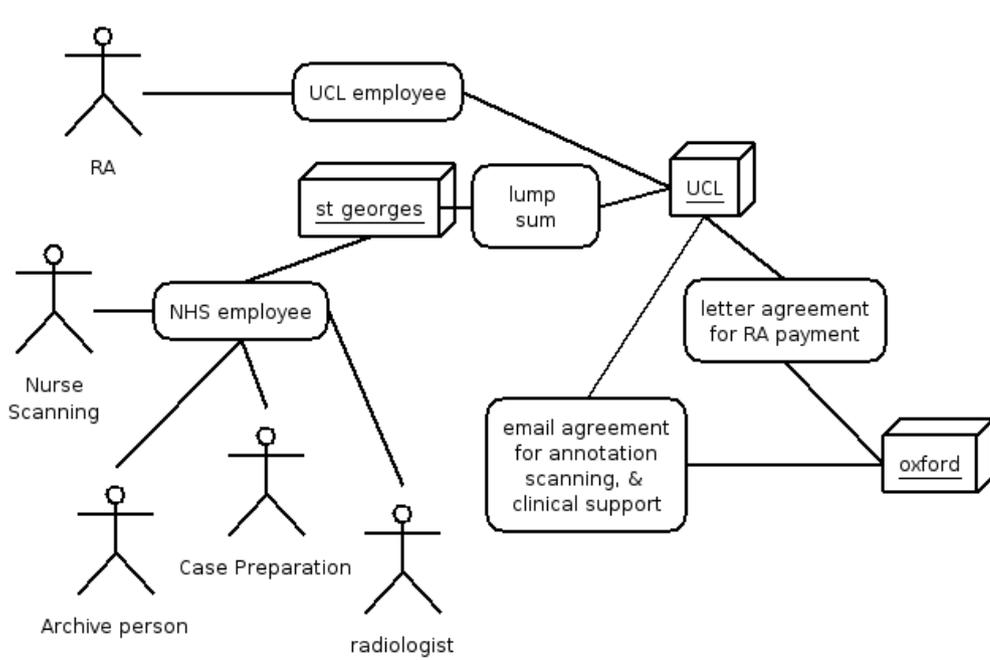
- The basics: IP and photography
 - Owning a photographic print
 - Owning the copyright in the image
- Digital data and IP
 - Computers copy data in order to function
 - Ownership without copyright = stultification
- IP ownership is controlled by:
 - Custom and practice
 - Shaped by contractual licenses (formal or implied)

IP: Copyright

- Copyright Designs and Patents act 1988
 - Grants various exploitation rights to 'author' who 'creates' a work.
 - Originality, skill, judgement & effort are all important
 - Copyright usually granted to original author
 - True for independent contractors
 - But not for full employees
 - CPDA also governs copyright transfer and licensing
 - Licence form: written, oral, or implied by conduct
 - Licence type: exclusive or non-exclusive; full or partial.

eDiaMoND Contractual Structure





eDiaMoND Copyright Analysis

- Copyright in: mammograms, annotations, patient records.
 - Skill & judgement by clinical staff required in each
- Less clear if second layer of copyright exists in the scanned images & typed patient data
 - some skill required for reclassification of data.
- NHS Trusts (broadly) retain copyright
 - Explicit licence in one case (for specific purpose)
 - Implied licences elsewhere
 - But scope & duration of licence is hence unclear.
 - Ambiguity remains wrt independent contractors

IP: Database Law

- UK Copyright and Rights in Databases Regulations 1997:
 - Database: a collection of independent works, that are arranged in a methodical way, while remaining individually accessible.
- 3 tiers of legal protection for databases:
 - Copyright in their contents (described previously)
 - Copyright in the database design
 - Requires high standard of originality
 - Investment in gathering the data guarded by separate 'database right'
 - In recognition of risk & initiative therein

eDiaMoND Databases Analysis

- Overall eDiaMoND database
 - Claim to copyright in database
 - Claim to database right
 - However, in this mixed public / private partnership, it is less clear is who actually holds this right (likely shared).
- Existing training databases contributed by NHS Trusts
 - Could also claim copyright in database
 - And a database right
- Data taken 'straight from waiting room'
 - copyright & database right: seem weak or unlikely

The Current Situation

- eDiaMoND has finished
 - Ethical clearance has ended
 - Data has been archived
- What if ethical clearance was granted for further research?
 - Who has authority to control eDiaMoND data?
 - Implied licences are ambiguous.
 - Prudent to request permission again from every Trust?
 - Would this approach scale to a national level?
 - eScience vision of seamless sharing

Alternative Models for IP Ownership

- Vest ownership with NHS Trusts (*status quo*)
 - Tighten honorary contracts for ind. contractors
 - 'Grid Contract,' to achieve uniform policy?
 - Short term solution for eScience
- Vest ownership with Patients
 - Contrary to current law, and to current NHS policy on the exploitation of IP
- Vest ownership in a national organisation
 - Single body for the control & exploitation of data
 - But how to balance against local control and benefits?
 - Long term implementation through legislation

Conclusions

- Confusion over 'who owned the data' resulted in
 - Time consuming negotiations
 - Disagreement over who controls future use of data
- Our aim: to develop models of ownership that maximise the benefits to all parties involved whilst protecting patient's rights.
- In sum, we believe a clear IP framework is vital to eScience and IHR.

And finally...

- If you, or people you know, are affected by the issues raised in this programme, or even if you'd just like to find out more...
- **...please do attend our symposium!**
- Wednesday 12th April, 2006
- London / Oxford
- chris.hinds@comlab.ox.ac.uk