



# Annual Review 2011

**Centre for Health, Law and Emerging Technologies at Oxford (HeLEX)  
Department of Public Health  
University of Oxford**

This report covers the second year of operation of the Centre for Health, Law and Emerging Technologies (HeLEX) in the Department of Public Health. This research centre specialises in investigating the relationships between law, ethics, practice and governance in the area of emerging technologies in health. Its main research focus is on genomics and genetics, with the aim to develop interests in other areas including synthetic biology, nanomedicine, and stem cell research. Research at HeLEX will increase our understanding of how the use and impact of innovative technologies in health can be accommodated within existing legal and governance frameworks, and the extent to which such frameworks may need to evolve. Our current research in genomics has an emphasis on patient-centred initiatives, biobanks, privacy, data-sharing frameworks, global governance and translational research. This review covers the period from January 2011 until December 2011.

## **Vision:**

To be one of the leading research centres in the world focusing on the relationship between law, ethics and practice in the area of health by 2015, particularly in genomics and other emerging technologies, and to be well-known within the University of Oxford and internationally for the excellence of our research, expertise and knowledge.

## **Mission:**

To carry out interdisciplinary research drawing on tools from law, philosophy and the social sciences with the aim of improving or guiding evolving practice in the area of health. To ensure that this research is embedded in scientific practice and to use this research and knowledge to provide advice, support, teaching and a basis for input into policy deliberations to develop best practice and improved governance mechanisms.

## **Approach**

Our approach is to work alongside scientists to ensure that cutting-edge practice is developed in an ethical manner and in compliance with legal requirements. Within genomics we are involved in a number of high profile projects such as P<sup>3</sup>G,<sup>1</sup> the 1000 Genomes Project<sup>2</sup>, the newly funded UK10K and the Canadians for Tomorrow Project. Our aim is to develop best practice in the field of genomics based on high-quality research and to inform practice by providing advice and support, working on advisory boards, delivering training and helping to develop policy documents that have application at an international level.

Our research is interdisciplinary, using tools and methods of investigation and analysis from the disciplines of law, philosophy and the social sciences. The use of empirical research enables us to understand current and emerging practice in medical research and clinical care. Our analysis of legal requirements and regulatory environments provides a basis for understanding how emerging

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<sup>1</sup> (<http://www.p3g.org/secretariat/index.shtml>)

<sup>2</sup> (<http://www.1000genomes.org/page.php>)

technologies may be accommodated within these existing frameworks. It also identifies the areas where change is required in order to deal with the particular issues and circumstances raised by emerging technologies. A philosophical analysis enables us to carry out an analysis of the normative principles that exist, or need to be developed for emerging technologies. It is by combining the results of these investigations that it is possible to generate insights for more effective policy making. Any recommendations developed from our research are legally compliant, based on sound ethical principles and grounded in an understanding of current practice.

The key themes that run through our current research are:

- Understanding the relationship between regulation, law and practice
- Global research governance
- Protecting privacy and the interests of patients and research participants through IT and other governance mechanisms
- Improving governance frameworks for researchers to further enable research and improve practice
- Data sharing of samples and information
- Intellectual Property and translational research

## Key Achievements

The key achievements in the past year have been:-

- Consolidation of the administrative structures for a research centre, including website, Facebook and Twitter feeds
- Raising our profile within the University through Connections meetings and running “Talking Law and Ethics” and “Technological Innovations in Health” seminar series
- The publication of 13 articles
- A total of 21 presentations given by HeLEX staff
- Submission of 2 expert opinions to public calls for consultation
- Consolidation of funding

## The Future

Over the coming year we plan to build on these successes and increase our funding income and our impact. Over the next five years the core aims for our research programme are to:-

- Build on partnerships and the interdisciplinary approaches and insights that we have developed in past projects to develop a number of new research projects;
- Be responsive to changes in existing practice and emerging science within health by developing partnerships with those working in the field;
- Develop a comparative perspective on the relationship between practice, law and policy across different emerging areas in health to guide policy deliberations;
- Use a novel interdisciplinary approach of law, ethics and empirical research to understand the ELSI dimensions of new technologies;

Use these insights and knowledge to inform, influence and improve research practice both within Oxford and internationally.

# Funding Profile

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## Current Projects:

### 1. EnCoRe Project (2008-2012)

Principal Investigators - Dr. Pete Bramhall (Hewlett-Packard), Prof. Sadie Creese (Warwick), Dr. Edgar Whitley (LSE), Dr. Dave Lund (HW Communications) QinetiQ and Dr. Jane Kaye (Oxford).

This project is focussed on the development of software that will enable individuals to have greater control over the use of their personal information. One of our case studies is the Oxford Radcliffe Biobank. Development of this system will have implications for the way that research is currently governed as this system could facilitate re-contact for new research studies. <http://www.encore-project.info/> This project will finish in April 2012 but we are looking for continued funding to exploit the prototype that we have developed.

### 2. Administrative Data Liaison Service (ADLS) (2008-2012)

Principal Investigator – Dr. Chris Dibben (University of St Andrews), Co-applicants- Prof. Paul Boyle (formerly of St Andrews), Dr. Jane Kaye (Oxford), Prof. Michael Noble (Oxford) and Dr Mark Elliot (Manchester).

This project was funded for another year and Heather Gowns has a small number of hours per week to continue to provide the legal advice to researchers who wish to obtain access to administrative datasets held by government departments in the UK. We provide the legal support for this project and are carrying out research on the development of appropriate governance models for access. <http://www.adls.ac.uk/>. This research will directly feed into the Administrative Data Task Force that has been convened by the ESRC and will report at the end of this year. <http://www.esrc.ac.uk/funding-and-guidance/collaboration/collaborative-initiatives/Administrative-Data-Taskforce.aspx>

### 3. BioSHARE (2011-2016)

This is one of the first European scientific-led genomics projects that have an ELSI component in every work package. HeLEX will carry out the legal and regulatory analysis that will focus on the issues associated with the wide-scale sharing of data and tissues within Europe. <http://www.bioshare.eu/> Liam Curren completed the legal report for this project on the requirements for the sharing of data and samples between biobanks across Europe.

### 4. Aligning Excellence– Biomedical Research Centre, University of Oxford (2010–2011)

This project will provide the evidence base to help inform the way in which research structures should be developed between the University and the Oxford Radcliffe Trust to improve translational research and personalised medicine. The funding for this research finishes in April 2012 and Karen Melham who has been working on this project will start working as the Ethics Advisor to the biobanking platform of the Biomedical Research Centre.

### 5. READNA – F7 Project (2011-2012)

This is to complete a report of the ethical, legal and social implications of the new sequencing technologies being carried out in this project. <http://www.cng.fr/READNA/>. This report will be completed in May 2012.

### 6. SUMMIT – F7 Project (2011-2014)

This is part of a large project that will pull together researchers who are aiming for translational research outcomes in diabetes. We will carry out the ELSI research on this project with Dr Pascal Borry, Centre for Biomedical Ethics and Law, K.U.Leuven in Belgium. We will continue with a watching brief role in this project.

## Successful Grants 2011:

### **1. DIRECT Project – (2012-2017)**

This is an IMI project on stratified medicine in diabetes and builds on our involvement in the SUMMIT project. This consortium involves public as well as commercial partners. We are ensuring that the internal governance arrangements are ethically and legally compliant and that all of the consent and ethical approvals are in place for the project to progress. We will also set up a patient interface to enable difficult policy issues to be tested with diabetes patients and advocacy groups.

### **2. Biomedical Research Centre Funding for Ethical Support for the Biobanking Platform (2012-2014)**

This position that will be held by Dr Karen Melham, and she will provide ethics support to research groups in the BRC involved in the biobanking platform. This will incorporate her role as Chair of the Oxford Research Ethics Committee.

### **3. Wellcome Trust University Award Dr Jane Kaye (2011-2016)**

This award enables Jane Kaye to carry out research into the ethical and legal issues associated with embedding a biobank within healthcare so that it can be used for clinical and translational research purposes.

This research will focus on the BRC biobanking platform and the development of the dynamic consent approach. This is a five year fellowship funded by the Wellcome Trust and then will be funded as a tenured position by the Department of Public Health.

### **4. Administrative Data Liaison Service (ADLS) (2008-2012)**

This project was funded for another year.

### **5. Nuffield Foundation Grant, Development of materials to help families explain to their child about a sex chromosome abnormality**

Karen Melham provides the ethical advice on this project.

# Impact

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## Initiatives:

### 1. ELSI 2.0 (November 2011)

The aim of the ELSI 2.0 initiative is to develop an infrastructure to support global ELSI research and activity. This is being led by Jane Kaye, Eric Meslin (Indiana, USA), Bartha Maria Knoppers (McGill, Canada) and Eric Juengst (Chapel Hill, USA). In November 2011, we had a kick-off meeting that was supported by funding from the Wellcome Trust and was held at the Brocher Foundation in Geneva. A paper on the concept of the 'collaboratory' was submitted to Science in December 2011 and is currently being reviewed. A kick-off meeting will be held at the International Association of Bioethics conference in Rotterdam in June 2012. This is being supported by the P<sup>3</sup>G secretariat based in Montreal.

### 2. Making Connections

We are the initiators of this international network that focuses on the governance of biobanks. The meetings have been Oxford 2008, Banff 2009, Singapore 2010, Montreal 2011 and the next will be Edinburgh 2012.

### 3. Biobanking and Public Engagement Event, John Radcliffe Hospital, Oxford 9 December 2011

We organised this event in conjunction with the BRC which consisted of a one day workshop with Prof Mike Burgess (Vancouver, Canada), Prof Sarah Cunningham-Burley and members of the team from the SHIP project in Edinburgh. A paper is planned from this event and further interactions.

## Responses to Calls for Consultation 2011:

A number of bodies have a call for consultation when they are planning new strategy or policy and wish to include diverse points of view. The ones that we have responded to are:-

1. ICO Personal Information Online Code of Practice (March 2010)
2. Nuffield Council on Bioethics 'Give and Take? Human Bodies in Medicine and Research' (July 2010)

## Reaching Out:

HeLEX has used Twitter as a means of publicising events and publications, and keeping connected with news relevant to our research interests, since the first half of 2010. As of 20 February 2012, the @HeLEXOxford Twitter account has 316 followers (compared to 120 followers in 2010) - made up of individuals and institutions from academia, industry, government, policymakers, and other areas.

HeLEX also has a Facebook account with 49 followers on the HeLEX facebook page (compared to 28 followers in 2010) <http://www.facebook.com/helexoxford> and 319 followers on the OxBioNet facebook page (compared to 139 in 2010) <http://www.facebook.com/oxfordbioethicsnetwork>

## Advisory Boards:

Jane's advisory board appointments:

- 2011 Appointed as Member of the Ethics and Confidentiality Committee of the National Information Governance Board.
- 2010 International Scientific Advisory Board Canadians for Tomorrow Project; UK10K Ethics Advisory Group (Richard Durbin and others, Sanger Centre, Cambridge); READNA and SYBARIS (Prof. Ivo Gut and others, Barcelona, Spain).

- 2009 BASIC (F7 Consortium led by Prof. Mike Stratton, Sanger Centre, Cambridge, UK 2009-2014); SUMMIT (F7 Consortium led by Prof. Leif Groop and Prof. Mark McCarthy, University of Oxford, 2009-2014); DEAS (Dr. Mark Elliott, University of Manchester 2008-2010).
- 2008 EPSRC Research Cluster on Innovative Media for a Digital Economy (IMDE), (Dr. Marina Jirotko, University of Oxford 2008-2009); Synthetic Biology Project, (Dr. Antonis Papachristodoulou, University of Oxford 2008- 2012),CORTICAL Project (Prof. Jonathan Flint and others, University of Oxford 2008-2011).
- 2007 Chair of the CARTaGENE International Scientific Advisory Board, Canada (ongoing). Member of the International Samples and Ethics Committee of the 1000 Genomes Project (ongoing).
- 2004 Oxford Women in Politics, University of Oxford (on-going).

### Researchers

#### Dr Jane Kaye

The Centre is directed by Dr Jane Kaye, University Research Lecturer and Wellcome Trust University Award holder. Trained as a barrister/solicitor, she obtained her degrees from the Australian National University, University of Melbourne, and the University of Oxford (D.Phil). She is a member of the Faculty of Law, University of Oxford and has taught both Regulation and Medical Law and Ethics courses at the University of Oxford. She also directs the University of Oxford's Oxford Bioethics Network which brings together more than 42 researchers across the University of Oxford. She Co-Chairs with Alastair Kent the International Working Group on Ethics, Governance and Public Engagement for P<sup>3</sup>G, Public Population Project in Genomics, Canada. She is on a number of Advisory Boards for genomic projects, is Chair of the CARTaGENE International Scientific Advisory Board, Canada, a founding member of the International Samples and Ethics Committee of the 1000 Genomes Project and on the International Scientific Advisory Board Canadians for Tomorrow Project. Jane is on the Editorial Boards of the following journals:- *Law, Innovation and Technology*, Hart Publishing, UK; *Journal of Law and Information Science*, University of Tasmania, Australia; and the *Genomics, Policy and Society*, University of Cardiff, UK.

#### Dr Nadja Kanellopoulou

Dr Nadja Kanellopoulou is a Researcher in Law. Her research at HeLEX is focused on the legal, philosophical, and regulatory aspects of privacy and consent in the EnCoRe project, funded by EPSRC/ESRC/TSB. Her research in EnCoRe involves philosophical and legal investigations of privacy and personal identity; comparative legal and empirical studies of patient and researcher choices in research use of tissue samples and personal data; testing such choices in the EnCoRe/ORB pilot study; and, ways of implementing trustworthy governance mechanisms in research biobanking. Nadja became involved with EnCoRe because of her expertise in reciprocal models of research governance.

Nadja is a lawyer by training, with PhD and LLM (Edinburgh, UK), LLB (Athens, GR), Admission to Practice (Athens Bar). She specialises in Medical Jurisprudence with a particular interest in the governance of collective identities in biomedicine. She has expertise in comparative legal and social aspects of assisted reproductive technologies and human tissue research which include research biobanking, bio-gifting, benefit-sharing, property rights in the human body, public engagement with biomedical technologies. She completed her PhD on 'Group Rights in Biolaw – A Model Approach' at the AHRC/SCRIPT Research Centre for Studies in Intellectual Property and Technology Law, with Profs Graeme Laurie and Ken Mason. She was previously an ESRC Genomics Forum Research Fellow (Genomics and Intellectual Property), and an INNOGEN Research Associate (both in Edinburgh). Prior to entering UK academia, she practiced as a solicitor in Athens, where she specialised in public law and human rights jurisprudence. Nadja is interested in furthering her postdoctoral research in legal and comparative aspects of governing genomics and emerging technologies.

#### **Policy Development**

1. Response to UK Biobank Public Consultation on 'Draft Access Procedures' (HeLEX)
2. 'Enhancing Consent and Effective Control of Personal Data' Response to the EU Commission 'Communication on a Comprehensive Approach on Personal Data Protection in the European Union' (EnCoRe Project)

#### **Papers Under Review**

- Kanellopoulou N, Curren L, Kaye J, '3D Privacy: An Analytical Framework to Assist Judicial Decision-Making'
- Kanellopoulou N, 'Privacy and The Maintenance of Personal Identity in Information Society'

## Teaching

- *Tutoring* (Michaelmas 2011). Medical & Biological Ethics; Pharmacological Revolution & Ethics of New Biotechnologies, St Catherine's College, Oxford
- *Developing Learning and Teaching (DLT)*, Training for Higher Education Academy Certificate (Medical Sciences Division)

## Dr Karen Melham

Karen is a Researcher in Ethics at HeLEX and is funded by the BRC. She obtained a PhD in Ethics from Emory University and has taught at Emory University, Candler School of Theology and Vancouver School of Theology before coordinating the Oxford Bioethics Network. She has experience in clinical ethics in Canada and the US and in research ethics in the UK. She is chair of Oxfordshire Research Ethics Committee A and is an ethics advisor for journals, FP7 projects, and the Institution of Civil Engineers' ethics committee. Her research interests include models of enactment for ethics and the formative moral pedagogy of governance procedures and mentoring.

Karen's current work focuses on the good practice of medical research and involves research, teaching, and ethics support. This comprises the following activities:

- **Aligning Excellence** – with Dr Jane Kaye; an initiative to identify, analyse, integrate and extend good practice in medical research and practice in Oxford. This involves collaborating with researchers and administrators of both the University of Oxford and the Oxford Radcliffe Trust to develop a shared strategic vision that incorporates a greater use of current expertise and embedded infrastructure to increase research capacity as well as improve patient care.
- **Cultivating Good Practice** – activities to maintain and extend work begun through the Oxford Bioethics Network. This includes drop-in ethics sessions for researchers held with R&D and CTGR representatives' participatory workshops; early advice and seminars. The position of REC chair affords possibilities to embed good practice with researchers, develop committee members, and influence national structure of research governance. She is Chair, NRES South Central Research Ethics Committee – Oxford A.
- **Advising the following projects:** Ethics and Governance Council, FP7 Project, ESPOIR: European clinical study for the application of regenerative heart valves; External Ethics Advisor, FP7 Project, CONTRACT: Consent in a Trial and Care Environment.
- **Acting in the following capacities:** Author and Reviewer, Epigeum Online Courses: *Research Ethics*; *Research Integrity*; Ethicist, Editorial Board, *Maturitas*, Elsevier Publishing; Ethicist/External Member, Ethics Committee, Institution of Civil Engineers, London.

## Dr Heather Gowans

Dr Heather Gowans is currently engaged as a part-time Researcher in Law. Heather has a D.Phil in social sciences/law from the University of Oxford. After graduation she practiced as a barrister, then had a career break, before returning to academic research at HeLEX. Heather is a member of the legal team on the Administrative Data Liaison Service (ADLS) project: this project is funded by the ESRC to support research in the UK which uses administrative data. The ADLS provides knowledge about the availability of administrative data, their suitability for specific research purposes, and the procedures required to gain access to, and to use such data. The ADLS is currently awaiting review by the ESRC to determine whether its funding will continue. The outcome of the review is expected in early 2011.

The ESRC Administrative Data Liaison Service (ADLS) supports administrative data research in the UK. The ADLS operates out of 3 centres: the Universities of St Andrews, Oxford (HeLEX) and Manchester. The following updates and developments for the service were introduced in October 2011:

1. Improvements to the ADLS website - [www.adls.ac.uk](http://www.adls.ac.uk).
  - i. Improved facility to search for administrative data.
  - ii. Improved guidance to help researchers apply for and use administrative data for research.

- iii. New section covering administrative data related studies and surveys.
- iv. New section on UK safe settings available for administrative data research.
- v. Quick links section to aid navigation around the site.

The legal aspects of the updates for the ADLS website were carried out at HeLEX, and include the following guidance notes and publication to date:

<http://www.adls.ac.uk/wp-content/uploads/2011/04/Section-33-of-the-DPA-a-practical-note-for-researchers.pdf>

<http://www.adls.ac.uk/wp-content/uploads/2012/01/DPA-legitimate-interests-guidance-note.pdf>

<http://www.adls.ac.uk/wp-content/uploads/2011/10/Interactive-Data-Protection-Guide.pdf>

<http://www.adls.ac.uk/wp-content/uploads/2012/01/ADLS-Data-Sharing-and-Security-paper.swf>

## 2. ADLS Trusted Third Party Service.

The ADLS TTP is a facility to enable the linkage or enhancement of administrative data for research purposes where there are privacy or security concerns. The ADLS is currently seeking a research project to help demonstrate the benefits of this service - more details about this available on the ADLS website. Legal guidance and advice has been given on various aspects of this project.

The legal work for the ADLS (updates and new guidance) will continue until the end of the project at the end of September 2012.

## Liam Curren

Liam left HeLEX on 3<sup>rd</sup> August 2011. In the time before he left the Centre, he began work on the BioSHaRE Project (Biobank Standardisation and Harmonisation for Research Excellence in the European Union) in January 2011. His role on BioSHaRE involved researching – and providing input to the scientific partners on the project – as regards the legal issues of developing harmonised measures and standardised computing infrastructures for the effective pooling of large amounts of sensitive personal data. Whilst with HeLEX, Liam was focussed on the relationship between legal and technological factors relevant to the adoption of more ‘individual-centric’ methods of processing personal data. We will be advertising this position in March 2012.

## Administrators

### Imogen Holbrook

Imogen is the Centre Administrator and has a Business Studies Degree and background in HR (IPD qualified). Imogen's role also involves taking minutes at the weekly Livewires meeting, organising ad-hoc meetings within the team and external visitors, stationery and equipment ordering and maintaining, room booking and car parking reservation and general centre administration. Another part of her role has been to support the visitors to HeLEX, both administratively and in setting them up within the office on their arrival. Imogen is also heavily involved in ad hoc, larger projects including for example, our office relocations, conference logistics and delegate registration and post conference expense processing and follow up. Imogen has the flexibility to help the team members with most of their administrative queries in a friendly and cooperative manner and is described as "the glue that keeps everything together!" She works with the HeLEX team on a part-time basis on Monday, Wednesday and Thursday between 9.30 – 2.30 and only during term time. This is one of the biggest challenges as she endeavors to meet her responsibilities with a high degree of accuracy within a tight timescale.

### Joanne Munt

Joanne is the Research Support Co-ordinator, providing administrative support for submitting grant applications and setting up the systems to identify new calls for potential new grants that may be applicable to HeLEX. In addition, Joanne performs a variety of IT work, with responsibility for maintaining the website and building our IT infrastructure, such as our Facebook and Twitter sites. She maintains a database of contacts and mailing lists, helps to run conferences and events, deals with enquiries, and books accommodation for visitors and delegates. Joanne's background is in law (LLM) and in IT work. She works part-time on Monday and Tuesday mornings, and Fridays all day.

## Research Associates

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### Dr Paula Boddington

Paula has a degree in philosophy and psychology from the University of Keele, a BPhil and DPhil in philosophy (with a thesis on self-deception) from the University of Oxford and an LLM in Legal Aspects of Medical Practice from Cardiff University. She has lectured in philosophy at Bristol University and the Australian National University. Prior to starting work at Ethox, Paula worked across various research projects on ethical and social aspects of genomics at Cardiff University, based in the Institute of Medical Genetics and working in collaboration with researchers at CESAGen (the ESRC Centre for Economic and Social Aspects of Genomics). Paula has worked on the Procardis project, a European consortium, co-ordinated at Oxford University, which aimed to identify novel susceptibility genes for early onset coronary artery disease and to provide more efficient tools for the diagnosis treatment and prevention of coronary artery disease. Paula was responsible for analyzing the ethical issues arising from this project.

### Dr Anne Davies

Anne Davies is Fellow and Tutor in Law at Brasenose College. She was awarded the title of Reader in Public Law in 2006. She studied at Oxford, completing the BA (winning the Gibbs and Martin Wronker Prizes) and the D.Phil. She was a Prize Fellow at All Souls College from 1995 to 2001, and a Visiting Scholar at the University of Michigan in 1999. Dr Davies is the author of three books and numerous articles in the fields of public law and labour law.

In public law, she has a particular interest in government contracts. Her D.Phil. thesis examined the phenomenon of contractualisation in the NHS from a public law perspective. She developed this research into a book entitled “Accountability: A Public Law Analysis of Government By Contract”, which was published by Oxford University Press in 2001. She has also written articles on the regulation of the medical profession and on accountability and autonomy issues in the NHS. She has also been working on a wider examination of government procurement and public/private partnership contracts from a public law perspective. Her book “The Public Law of Government Contracts” was published by OUP in September 2008.

### Prof Donna Dickenson

Donna Dickenson, BA, MSc, PhD, is Emeritus Professor of Medical Ethics and Humanities at the University of London and honorary senior research fellow at the Centre for Ethics in Medicine, University of Bristol. In 2006 she became the first woman to win the International Spinoza Lens Award for contribution to public debate on ethics; the first winner was Edward Said.

Her recent popular science book “Body Shopping”, an explanation of how gaps in the law have permitted the commodification of the body from BC (before conception) to AD (after death), was called 'essential reading for those who work in the medical profession' by The Lancet. The Financial Times termed it 'a thoughtful, intelligent, highly readable book written by someone with impeccable credentials,' and New Scientist noted that 'the book could not be more timely'. Professor Dickenson has also written or edited another twenty books and over sixty articles on topics ranging from death and dying to feminist medical ethics. She is a frequent contributor to radio and television and has been a member of ethics committees at the British Medical Association and the Royal College of Obstetricians and Gynaecologists. Her main research interests are: commodification of the human body, genetic patenting, reproductive ethics and law, personalised genetic testing and biobanks.

## **Charles Foster**

Charles is a barrister specialising in medical law but also writes extensively on many subjects. He trained originally as a vet at St. John's College, Cambridge and then was called to the Bar by the Inner Temple, and to the Bar of the Republic of Ireland.

## **Dr Susan Gibbons**

Sue's main research interests are in biomedical law (with a particular emphasis on law and genetics), governance (including regulatory theory, design, and implementation), civil procedure, and human rights. Her background is in civil litigation and private legal practice in New Zealand, where she worked as a barrister and senior solicitor before moving to the UK. She holds a BCL degree and a doctorate in civil procedure, and taught on that subject at postgraduate level at Oxford for many years. In addition to collaborating on a book of the 'Governing Genetic Databases' project, Sue's current research and writing projects include issues to do with defining biobanks, categorising biobanks effectively for governance purposes, consent (especially under the Human Tissue Act 2004), harmonising terminology, providing feedback to participants, rationalising legal and ethical frameworks, and re-appraising the subsisting data-tissue regulatory dichotomy.

## **Dr Imogen Goold**

Imogen Goold is a Fellow and Tutor in Law at St Anne's College. She studied Law and Modern History at the University of Tasmania, Australia, receiving her PhD in 2005. Her doctoral research explored the use of property law to regulate human body parts. She also received a Masters degree in Bioethics from the University of Monash in 2005. From 1999, she was a research member of the Centre for Law and Genetics, where she published on surrogacy laws, legal constraints on access to infertility treatments and proprietary rights in human tissue. In 2002, she took up a position as a Legal Officer at the Australian Law Reform Commission, working on the inquiries into Genetic Information Privacy and Gene Patenting. After leaving the ALRC in 2004, she worked briefly at the World Health Organisation, researching the provision of genetic medical services in developing countries. She is writing on body part ownership and has published a collection of essays, co-edited with Catherine Kelly, on the historical interaction of legal regulation and medical practice.

## **Dr Naomi Hawkins**

Naomi Hawkins obtained her LLB and her BSc (Biomedical Science) from the University of Queensland in 2002 before being admitted as a legal practitioner in Australia. Following a period of legal practice in Australia clerking for a Supreme Court Judge, and working in a large commercial law firm, she completed her BCL at the University of Oxford in 2005. She completed her doctorate in law at the University of Oxford, as a member of HeLEX in 2009, supported by the Wellcome Trust. From 2009 to 2010 she was a researcher in law at HeLEX, and continues to be a research associate of the Centre. She is currently a lecturer in Law at the University of Exeter.

Naomi Hawkins' research focuses on the interaction of law and biomedical science, particularly around intellectual property rights. She uses traditional legal research and empirical methods to investigate the impact of human gene patents on the development of translational outcomes of genetics and genomics research. She is also interested in the ways in which data sharing practices intersect with intellectual property rights in science.

## **Jonathan Herring**

Jonathan Herring is a Fellow in Law at Exeter College, University of Oxford. He has written on Family Law, Medical Law and Criminal Law. His most recent books include *Older People in Law and Society* (OUP, 2009); *Medical Law and Ethics* (3rd ed, OUP, 2010); *Criminal Law* (3rd ed 2008); *Family Law* (4th ed, Pearson, 2008) and *The Woman who Tickled Too Much* (Pearson, 2009). Current projects include work on birth; carers; sexual offences; and issues surrounding dementia.

# Conferences and Seminars

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2011

## 1. Technological Innovations in Health - Seminar Series

Drawing together expertise from around the world and across the disciplines, the HeLEX 2011 Spring seminar series investigated how technologies can transform, investigate, and extend relationships of care - as well as harm. The aim of this series was to focus on new technologies and approaches that are being applied in healthcare and medical research. These technologies are in the fields of bioinformatics and research modelling, assisted living, biobanking, and enabling the research use of electronic medical records systems. This series gave a sense of the challenges that these applications raise for society and the implications for the future and ran from 01 May through 01 July at the Old Road Campus, Oxford. Co-ordinated by Matthew Steven Carlos and Joanne Munt of the Centre for Health, Law, and Emerging Technologies (HeLEX) in the Department of Public Health, University of Oxford.

John Finney - Building a Hospital Databank

Madeleine Cule - Understanding the Transmission of Clostridium difficile in Hospitals.

Prodromos Tsiavos - From Creative Commons to Consent Commons: Licensing Schemes and Technological Arrangements for Sharing Personal and Sensitive Data

Prof Hendrik Speck - How Social Technologies Change Personal Identity and Alter Care

Matthew Steven Carlos - How to Harm: Health, Technology, and Troublesome Ethics

Roy Nyberg - Emergence of Mobile Technology in Health Care

Fadhila Mazanderani - An 'Information Revolution'? Exploring internet use and patient autonomy in HIV treatment and care

Elisabeth Harding - Exploring the Concept of Informed Awareness

## 2. Talking Law and Ethics, weekly seminar series, WTCHG

This series was given by researchers in HeLEX and addressed some of the legal and ethical issues associated with research, such as property rights in laboratory samples, protecting privacy, feedback of individual findings, facing the ethics committee and intellectual property rights.

12 October

"Ethics in emerging forms of global health research collaboration"

Professor Mike Parker, Professor of Bioethics and Director of the Ethox Centre; and Dr Kirk Rockett, Research Manager MalariaGEN

19 October

"The structure of good collaboration: using governance mechanisms to your advantage"

Dr Jane Kaye, Director, HeLEX Centre for Health Law and Emerging Technologies

26 October

"Pre-nups: why they are important in research and how to get them in place"

Dr Richard Liwicki, Deputy Director Research Services, Head of the Medical Sciences Office, University of Oxford

9 November

"Making trials work in developing countries"

Dr Trudie Lang, Head of the Global Health Clinical Trial Research Programme

16 November

“How to survive your co-authors”

Tim Albert, author of “Winning the publications game”

23 November

“Taking care of business – relationships with industry”

Dr Maxine Allen, Manager, Business Development Office, Medical Sciences Division

## **Biobanking and Public Engagement**

9 December 2011

Lunchtime Seminar

“Deliberative public engagement: from biobanks to personalized medicine”

Michael M. Burgess, Professor and Chair in Biomedical Ethics at the W. Maurice Young Centre for Applied Ethics and the Department of Medical Genetics at the University of British Columbia.

“The social dynamics of public engagement”

Sarah Cunningham-Burley, Professor of Medical and Family Sociology in the Division of Community Health Sciences at the University of Edinburgh. Co-Director, Centre for Research on Families and Relationships.

# Presentations

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## Dr Jane Kaye

1. "Research Governance, So... Last Century?" Exploring the ELSI Universe, Chapel Hill, USA, 12-14 April
2. "Protecting Participants in a Global Research Community" Nuffield Council, 20 May
3. "Research Governance, So... Last Century?" ESHG, 30 May
4. "Research Governance, So... Last Century?" and "Personalised Medicine", Workshop on Privacy Issues Arising from Whole Genome Sequencing, KoWi Brussels, 1 June
5. "Research Governance, So... Last Century?" Private– Gen Workshop, Nuremburg, 16 June
6. "Building Sustainability in Biobanking", BIOSHARE / BBMRI Workshop, Barcelona, 28 June
7. "Quo Vadis?" BIOSHARE/BBMRI Workshop, Barcelona, 28 June
8. "Incidental Findings in Research – the UK10K Management Pathway", ESRC Genomics Forum and HGC Workshop, The Royal College of Surgeons, London, 13 September
9. "Governance Challenges for Data Sharing", Epigenomics of Common Diseases, Hinxton, 15 September
10. "The Structure of Good Collaboration", Talking Law and Ethics, Oxford, 19 October
11. "A Significant Sea of Change", Patient-Centric Initiatives Conference, Rome 27-28 October
12. "Quo Vadis?" GLOBAL ELSI, Geneva, November
13. "Research Governance, So..... Last century?" 12th International Congress of Human Genetics, Montreal, November

## Dr Nadja Kanellopoulou

1. Conference Presentation on 'User Control in Biobanking: Researchers' Attitudes in the EnCoRe/ORB Pilot Study', 1st International Conference on Patient-Centricity, with Pre-Conference Workshop, Rome 27 October 2011.

## Dr Karen Melham

1. *Does the NHS Impede Commercial Research?* Oxford University Hospitals and University of Oxford Research Network Christmas Debate, University of Oxford, 7 December
2. *Research Integrity* Maths and Physical Life Sciences (MPLS) Divisional Skills Training Seminar, University of Oxford, 22 November
3. *Perspectives: the Ethics Committee* Experimental Therapeutics Module: How to do Research on Therapeutic Interventions: Protocol Preparation, Continuing Professional Development Centre, University of Oxford, 29 July
4. *Ethics 'Moral Maze'* 8<sup>th</sup> EASD Robert Turner Course in Clinical Research into Diabetes, University of Oxford, 8 April.
5. *Good Practice: Focus Groups and Interviews* Researcher Training for EnCoRe: Ensuring Consent and Revocation, University of Oxford, 1 March.
6. National Research Ethics Service *Nuts and Bolts of Running a REC* 2 November 2011.
7. European Science Foundation Forward Look Consultation: *Personalised Medicine for the European Citizen –Towards more precise medicine for the diagnosis, treatment, and prevention of disease.* 18–20 October 2011.

# Publications

## Publications 2011-2012

1. Kaye *et al* From Patients to Partnerships – Participant –Centred Initiatives (PCIs) in Research ( In press *Nature Reviews Genetics* )
2. Kaye J Tensions between Data Sharing and the Protection of Privacy in Genomics Research (Forthcoming *Annual Reviews of Genetics and Genomics* March 2012)
3. Whitley E, Kanellopoulou N, Kaye J, ‘Consent and Research Governance in Biobanks: Evidence from Focus Groups with Medical Researchers’ (Forthcoming, *Public Health Genomics* 2012)
4. Kaye J Embedding Biobanks as Tools for Translational Research ( Forthcoming *Norwegian Journal of Epidemiology* 2012)
5. Kaye J, Hawkins N, Kanellopoulou N, Curren L, Gowans H, Can I Access My Personal Genome (Submitted to *Medical law Review*)
6. Hawkins N, Kanellopoulou N, Kaye J, Melham K, Boddington P, Curren L, Gowans H, 'Ownership of Biomedical Information in Biobanks' in Macilotti M, Izzo U, Pascuzzi G (eds), *Comparative Issues in the Governance of Research Biobanks*, Springer (Forthcoming 2012)
7. Kaye J. From single biobanks to international networks: developing e-governance. *Human Genetics* 2011 (0340-6717):1-6.
8. Boddington P, Curren L, Kaye J, Kanellopoulou N, Melham K, Gowans H, Hawkins N, ‘Consent Forms in Genomics: The Difference Between Law and Practice’ *European Journal of Health Law* 18 (2011) 491-519.
9. Knoppers BM, Harris JR, Tassé AM, Budin-Ljøsne I, Kaye J, Deschênes M, Zawati MH. Towards a data sharing Code of Conduct for international genomic research. *Genome Med.* 2011 Jul 14;3(7):46.
10. Foster C, Herring J, Melham K, Hope T, ‘The Double Effect Effect.’ *Cambridge Quarterly of Healthcare Ethics*, (2011) 20: 56-72. doi: 10.1017/S0963180110000629 (Published online: 11 Jan 2011).
11. Kaye J, Whitley EA, Kanellopoulou N, Creese S, Lund D, Hughes, ‘Dynamic Consent – A Solution to Perennial Problems?’ *BMJ Rapid Letter Response*, published online, published online 8<sup>th</sup> November 2011, <http://www.bmj.com/content/343/bmj.d6900?tab=responses>
12. Kanellopoulou N, ‘Reciprocity, Trust and Public Interest in Research Biobanking’, in C. Lenk, Hoppe N, Beier K, Wiesemann C (eds), *Human Tissue Research*, Oxford University Press, 197-218
13. Kaye J, Gibbons SMC , Heeney C, Parker M and Smart A Governing Biobanks: Understanding the Interplay Between Law and Practice (Hart 2012)

### Speakers List

31 <sup>st</sup> March	Biobanking Case Law Update - Liam Curren, HeLEX
20 <sup>th</sup> July	From physical integrity to the free use of the body: reconstructing a Basic Human Right -Brunello Stancioli
27 <sup>th</sup> July	Mapping Legal Barriers to Open Sharing - Diane Cabell
3 <sup>rd</sup> August	Person, Body, Samples... Bioethical Considerations - by Mária Šuleková
10 <sup>th</sup> August	Adequacy of Data Protection in Total Hospital Information System (THIS); The Malaysian Story Noriswadi Ismail

## Visitors 2011-2012

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### **Matteo Macilotti (1/11/2010 – 31/12/2011) University of Trento, Italy**

Matteo Macilotti is a postdoctoral researcher in Comparative Private Law, at the University of Trento and a non-practicing barrister. His research is focused on IP and Biotechnology Law and, in particular, on the legal aspects of human tissue research. His current work focuses on legal issues related to biobanks and on legal instruments for the facilitation of data sharing in biobanking activities. He is legal advisor to the Trentino Biobank, and he is involved in numerous research and policy projects on the regulation of biobanking in Italy. His visit at HeLEX is funded by a Marie Curie Fellowship.

### **Teresa Finlay**

Teresa Finlay is a Registered Nurse and Lecturer with experience in cancer and critical care nursing, and postgraduate education in healthcare. Her interest in cancer screening and genetics prompted development of a research proposal to explore UK Users' and Clinicians' experiences of direct-to-consumer genetic testing for disease risk, and its potential impact on the NHS. Teresa is undertaking this project as an ESRC-funded doctoral study at Cardiff University in the School of Social Sciences.

This first year of the three-year study is being spent gaining various ethics committee and NHS R & D approval, undertaking research training, completing the literature review and commencing participant recruitment. A poster outlining the study has been presented at the School of Social Sciences Doctoral Student conference and at HeLEX. Teresa is concurrently based with the HeLEX team in the Department of Public Health as an academic visitor to share expertise and findings related to genomics and ethics specifically, and clinical and education experience more generally.

## Students 2011

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### **Firdaus Aziz (DPhil Public Health)**

Firdaus is currently in his first year as DPhil candidate at the Department of Public Health, which is sponsored by the Malaysia Ministry of Higher Education. His study is under the supervision of Dr. Jane Kaye. His area of interest is the interdisciplinary development of human embryo research. He is looking at the progress of the research, the ethical issues involved and its governance in different jurisdictions. Firdaus is particularly interested in the legislation pattern in the UK. The expected outcome of his study, among others, is to come out with recommendations for the future legislation approach in Malaysia, his home country.

Firdaus graduated with MA in Biotechnological Law and Ethics from the University of Sheffield after successfully procuring the National Science Fellowship awarded by the Ministry of Science, Technology and Innovation, Malaysia. His first degree is in Genetics and Molecular Biology, which he obtained from the University of Malaya, Malaysia.

### **Andelka Phillips**

Andelka Phillips has just begun her time at HeLEX in 2011 and is currently reading for the degree of Doctor of Philosophy in Law. Dr Jane Kaye is supervising her research. Andelka is investigating genetic privacy law, specifically focussing on issues relating to the privacy of an individual's genetic and genomic sequence information in the context of Direct-to-Consumer genetic testing. Prior to embarking on her doctoral studies, Andelka completed BA/LLB, BA(hons), and LLM(First Class Honours) degrees at the University of Auckland in New Zealand. She received the Spencer Mason Travelling Scholarship in Law in 2011 and is tremendously excited about furthering her studies at Oxford. She has worked as a tutor in the Law Faculty at Auckland for 3 years and has also worked as a notetaker and amanuensis for examinations.

## Colin Mitchell

Colin is reading for a Master of Studies (MSt) in Legal Research focusing on the role of law in the prevention of non-communicable disease. This work aims to analyse law that impacts on health promotion proposals, to determine whether or not existing laws enable healthier environments and lifestyles. He is currently researching the regulation of food and drink marketing in the UK. This builds on his previous work in the department of public health on legal powers and limits affecting local government obesity prevention.

Colin graduated from the University of Cambridge with a degree in Law and joined the department of public health in Oxford in 2009 as a researcher at the BHF-Health Promotion Research Group (BHF-HPRG). He is also working with National Heart Forum (NHF) in London to develop a 'healthy places' web-resource that explains legal issues for local government and community health groups.