



UNIVERSITY OF
OXFORD

Annual Review 2010

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

The Centre for Health, Law and Emerging Technologies (HeLEX) was established in the Department of Public Health on the 1st of October 2009 under the directorship of Dr. Jane Kaye. This report covers the first year in the life of HeLEX. The centre specialises in investigating the relationships between law, ethics, and practice 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 focuses on genomics with an emphasis on biobanks, privacy, data-sharing frameworks, global governance and translational research. This review covers the period from October 2009 until December 2010.

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 help develop best practice.

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 P³G,¹ the 1000 Genomes Project², 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 technologies may be accommodated within these existing frameworks. It also identifies the areas where change is required in

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

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

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:-

- Establishment 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 two Talking Law and Ethics seminar series
- The publication of 18 articles
- A total of 51 presentations given by HeLEX staff around the world
- Hosting of the International Data Sharing Conference with 151 delegates from 20 countries with an Artist in Residence and Poets in Residence
- In excess of £250,000 income in new grants and over £600,000 in new applications
- Submission of expert opinions to 6 public calls for consultation
- Completion of 3 consultancies for external bodies

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

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/>

2. Administrative Data Liaison Service (ADLS) (2008-2011)

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 has set up an advice service for 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/>

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/>

Projects finished in 2010:

1. Provision of Ethics Training and Teaching at the University of Oxford, (2007 -2010)

Principal Investigator - Dr Jane Kaye with Profs. Savulescu, Hope, Parker and Dr. Mark Sheehan.

This project has funded the Oxford Bioethics Network that has provided training, support and teaching for people within the Medical Sciences Division. It also involved an empirical research to assess what ethical teaching, support and training were across the University. This project came to an end in November 2010. A strategic report will be distributed with recommendations.

2. Wellcome Trust Fellowship in Biomedical Ethics, Regulating Biobanks at an International Level (2007-2010)

Through this fellowship Dr Jane Kaye explored the role of law in the regulation of biobanks at an international level. She was involved in policy development at this level through P3G and the BMMRI project. This research has led to a number of articles and an international conference.

Successful Grants 2010:

1. BioSHARE F7 Project – (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/>

2. Aligning Current Practice– Biomedical Research Centre, University of Oxford

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.

3. READNA – F7 Project

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/>

4. SUMMIT – F7 Project

This is part of a large project that will pull together researchers who are aiming for translational research outcomes in diabetes. This consortium involves public as well as commercial partners. 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.

Impact

Consultancies:

1. Open Society Foundation: Medical genetic research: Key public interest concerns (May 2010)

This was a review of the current privacy issues that genetics present and an assessment of the advocacy groups that are working in this area to provide a basis for future funding in this area.

2. Wellcome Trust Study: GWAS Cohort studies and Biobanks - Access, Governance and Feedback (September 2009)

This study conducted interviews with 20 key people involved in GWAS, cohort studies in the UK and the US and it was used as a basis for the Trust to consider their current policy. The report from this study has not been released because of its ability to identify individuals but it will be published as a paper.

3. Wellcome Trust Literature Review: Ethical, Legal and Social Issues Arising From the Use of GWAS in Medical Research (March 2009)

This literature review, produced by researchers from HeLEX and Ethox, was commissioned by the Policy Unit in the Wellcome Trust to identify the key issues that have been raised by the use of genome-wide association studies (GWAS) in genomics research. This report was put on the Wellcome Trust website and published as a paper in European journal of Human Genetics.

Responses to Calls for Consultation:

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. Human Genetics Commission 'A Common Framework of Principles for direct-to-consumer genetic testing' (December 2009)
2. Ministry of Justice CP 22/09 'Knowing or reckless misuse of personal data - introducing custodial sentences' (December 2009)
3. Ministry of Justice CP 48/09 'Civil Monetary Penalties - setting the maximum penalty' (December 2009)
4. European Commission Consultation on the Legal Framework for the Fundamental Right to Protection of Personal Data (December 2009)
5. ICO Personal Information Online Code of Practice (March 2010)
6. 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. The account was also used extensively, and successfully, to keep a log of the presentations at the International Data Sharing Conference. As of 9 December 2010, the @HeLEXOxford Twitter account has 120 followers - none of which are spam accounts - made up of individuals and institutions from academia, industry, government, policymakers, and other areas.

HeLEX also has a Facebook account with 28 followers on the HeLEX facebook page <http://www.facebook.com/helexoxford> and 139 followers on the OxBioNet facebook page <http://www.facebook.com/oxfordbioethicsnetwork>

HeLEX participated in two series of research podcasts, run by HeLEX and by the Oxford Bioethics Network, in the Open Spires project, University of Oxford (May-June 2010). <http://podcasts.ox.ac.uk/openspires.html>

Researchers

Dr Jane Kaye

The Centre is directed by Dr Jane Kaye, University Research Lecturer. 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 >42 researchers across the University of Oxford. She Co-Chairs with Alastair Kent the International Working Group on Ethics, Governance and Public Engagement for P³G, 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.

Liam Curren

Liam is a Researcher in Law at HeLEX, and a non-practising solicitor of the Senior Courts of England and Wales. His research focuses on the legal treatment of information utilised by existing and emerging technologies, particularly in the life sciences sector. Liam obtained a masters degree in biochemistry (MBiochem Oxon) before qualifying as a solicitor in 2005. He worked in private practice at leading firms in Oxford and London, where he specialised in intellectual property law in the life sciences and other high-tech sectors. He has worked on a number of intellectual property cases at the High Court, Court of Appeal and House of Lords, and has a diploma in intellectual property law and practice from the University of Bristol.

From 2009-2010 Liam worked with Jane Kaye and Nadja Kanellopoulou on the EnCoRe project –Liam's role on EnCoRe involved providing input and advice concerning data protection law, and other relevant legal matters, to the project partners responsible for designing bespoke EnCoRe technology. He continues to work with EnCoRe, on an occasional basis, in connection with the project's work with a local research tissue biobank. Liam begins work on the BioSHaRE Project (Biobank Standardisation and Harmonisation for Research Excellence in the European Union) in January 2011. His role on BioSHaRE will involve 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. Liam's current research interests focus on the relationship between legal and technological factors relevant to the adoption of more 'individual-centric' methods of processing personal data.

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 socio-legal 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.

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 three related areas:

- **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 CTRG 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.
- **Spring School** – 'Engaging Biomedicine' will be an intensive week, focussing on development of interdisciplinary skills for analysis and collaboration. It builds on the innovative formats and challenging material of the HeLEX International Data Sharing Conference. Karen is coordinating, working with Continuing Education and relying on administrative and academic resources of the HeLEX team.

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.

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 programming work. She works part-time on Mondays, Wednesdays and Fridays.

Research Associates

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.

Matthew Carlos

Matthew's work attends to the integration of Ethics with contemporary social fabrics, especially the ways in which information and knowledge are created and controlled (such as through the establishment and use of biobanks). Over the last fifteen years, he has examined the intersection of Ethics with political economy and corporate ontologies. Matthew's more recent research assimilates this prior work into an examination of how Ethics intersects with cultures of health, social technologies, as well as non-Western philosophies of law and medicine.

Matthew's general interest is Ethics in non-normative environments (such as biotechnology) where facts are uncertain, values in dispute, stakes high, and decisions urgent. Matthew Carlos holds advanced degrees in Philosophy and Cultural Studies. He advises and collaborates with governments, corporations and NGOs around the world.

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 recently 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 forthcoming 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 currently writing on body part ownership and recently 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's 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

2010

- 1. International Data Sharing Conference, St. Hughes College Oxford, 20th-22nd September.** This event involved 151 delegates from over 20 countries and featured an Artist in Residence and three Poets in Residence. Dr. Paula Boddington and Dr Jane Kaye are preparing a special journal issue on International Data Sharing for *Genome Medicine*, and the Oxford Statement on International Data Sharing is being drawn up based on the discussions at the conference.
- 2. Talking Law and Ethics, weekly seminar series, Medical Sciences Teaching Building, April – June.** This was a repeat of the early series described directly below, and it was organised ‘down the hill,’ in the Science Area.
- 3. Talking Law and Ethics, weekly seminar series, WTCHG, February – March.** 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. We will run another series in Trinity 2011.

Presentations

Dr Jane Kaye

2010

1. Invited Presentation, 'Emerging Issues in International Forensic Bioinformation Exchange', King's College London, 10th and 11th December 2010.
2. Abstract Presentation, Data Sharing Panel with Prof Barbara Koenig, Dr Amy McGuire, Dr Maureen Smith, ASBH, San Diego, USA, 24th October 2010
3. 'Who Owns the Sample in Your Lab'? HeLEX Talking Law and Ethics Seminar Series, Oxford, 26th May 2010
4. Invited Speaker, Wellcome IAB2010 Satellite 'The Concept of Community in Bioethics' Singapore, 27th July 2010
5. Abstract Presentation, 10th World Congress of Bioethics, Singapore, July 2010
6. Invited Speaker, 'Returning Research Results to Participants in Large-Scale Genomics Studies' at the 2010 Biology of Genomes meeting, Cold Spring Harbor Laboratory, NY, 13th May 2010
7. Invited Speaker, 'Comparative Issues in the Comparative Governance of Biobanks', Trento Italy, 7-8th May 2010
8. Invited Speaker, 'Who Owns your Whole Genome?' Art and Social Controversy Workshop, Banff, Canada, 28th April 2010
9. Session Chair and Speaker, IWG Ethics and Governance Group, P3G Annual Meeting, Montreal, 25th-27th April 2009
10. Invited Speaker, 'Governance Structures and Professional Obligations' Workshop on Informed Consent and Data Sharing, Houston, Texas, 11th February 2010
11. Invited Speaker, 'Whole Genomes and Data Sharing' Human Genetics Commission Conference, Hinxton Campus, 9th February 2010
12. HeLEX Talking Law and Ethics Seminar Series, WTCHG, Oxford, 18th March 2010
13. Invited Speaker, 'Shaken, Not Stirred? The ELSI Challenges Raised by Changes in Scientific Practice', Sanger Centre Seminar Series, January 2010
14. Invited Speaker, 'Data Sharing in Genomics – 'What Are the Implications?'' EGENIS Workshop, Exeter, UK, January 2010

2009

15. Invited Speaker, 'From Biobanks to Expert Centres' Meeting, - Paris, France, 16th December 2009
16. Session Chair and Speaker, IWG Ethics and Governance Group, P3G Meeting, Luxembourg, 29th September 2009
17. Keynote Speaker, for the International Conference on the Foundation and Prospective of Life Science Governance Research Framework, at National Chiao Tung University in Hsinchu, Taiwan, 26th September 2009
18. Invited Speaker, 'Governance Challenges in Genomics', 5th International DNA Sampling Conference, The Age of Personalized Genomics, Banff, Canada, September 2009
19. 'Changes in Scientific Practice in Genomic Research', Mapping the Genomic Era: Measurements and Meanings, 3rd ESRC Network Genomics Conference, Cardiff, 7th-9th October 2009

Liam Curren

1. BBMRI Biobanking for Science Conference, Amsterdam - September 2010 - Poster Presentation: 'Individual Control of Information in Biomedical Research'.
2. International Data Sharing Conference, Oxford - September 2010 - 'Station' Presentation: 'Giving Individuals More Control Over Their Personal Information Using IT Mechanisms'.

3. Privacy Law Scholars Conference, Washington D.C. - June 2010 - Paper Presentation (with Nadja Kanellopoulou): '3-Dimensional Privacy, Consent, and Revocation of Consent: A Story of Two Tales'.
4. HeLEX Talking Law & Ethics series, University of Oxford - May 2010 - Seminar: 'Planning for Translational Research in Genomics'.
5. HeLEX Talking Law & Ethics series, University of Oxford - May 2010 - Seminar: 'What Researchers Should Know About Confidentiality and Privacy'.
6. HeLEX Connections series, University of Oxford - March 2010 - Seminar, 'Individual Control of Personal Information: What Is It, How Might It Work, and Why Might We Need It?'
7. HeLEX Talking Law & Ethics series, University of Oxford - February 2010 - Seminar: 'Why Should We Worry About Privacy and Confidentiality?'
8. DEMOS FYI People's Inquiry, London - October 2009 - Invited Speaker to discuss data protection and privacy issues with focus groups.

Dr Nadja Kanellopoulou

1. HeLEX Connections Seminar, 'The (Im)possibilities of Biobanking: A Discussion on Participants' Withdrawal from Human Research Biobanking', 17th Nov 2010
2. Invited Presentation, 'The (Im)possibilities of Biobanking: A Discussion on Participants' Withdrawal from Human Research Biobanking', at Workshop on 'Mission Creep in Biotechnologies', University of Lucern, 8th October 2010
3. Presentation on 'EnCoRe and E-Health: Building Novel Tools for Better Individual Control in the Management of Personal Data', at European Association for the Study of Science and Technology (EASST) Conference, Trento, 3rd September 2010
4. Presentation, 'Revoking the Research Gift: The Implications of Withdrawal from Human Genetic Databases for Biobanking Relationships' at 10th World Congress of Bioethics (WCB), Singapore, 28th July 2010
5. Presentation with Liam Curren, '3-Dimensional Privacy, Consent, and Revocation of Consent: A Story of Two Tales' at 3rd Annual Privacy Law Scholars Conference (PLSC), Washington DC, 4th June 2010
6. Presentation, 'Privacy and the Maintenance of Personal Identity in Information Society: A Preliminary Investigation' at Identity in Information Society (IDIS) Workshop 2010, Rome, 28th May 2010
7. HeLEX Connections Seminar, 'Privacy and Maintenance of Personal Identity in Information Society', 21st April 2010
8. Presentation, 'Patient-Driven Initiatives: "Privacy-Enabling" Platforms and Health Data' EnCoRe Project Meeting, London School of Economics, 24th March 2010
9. Talking Law & Ethics Series, 'Feeding Results Back to Research Participants' Repeat Seminar, February 2010 and May 2010
10. Poster Presentation, 'Reconsidering Altruism, Introducing Reciprocity in the Governance of Human Genomic Databases - Towards Model 'Empowered' Research Relationships', 5th International DNA Sampling Conference, The Age of Personalized Genomics, Banff, Canada, September 2009

Dr Karen Melham

1. Engaging with Research Ethics: Process and Content, "Bioethics Month at the WTCHG" (Wellcome Trust Centre for Human Genetics) University of Oxford, 18th November 2010
2. Research Integrity Maths and Physical Life Sciences (MPLS) Divisional Skills Training Seminar, University of Oxford, 16th November 2010
3. Ethics Review and Practice, FP7 Information Day for the Medical Sciences, European Office, University of Oxford, 29th September 2010

4. Facing the Ethics Committee, HeLEX 'Talking Law and Ethics' Repeat Seminar, University of Oxford, 4th March 2010 and 8th June 2010
5. Research, REC Applications and Ethical Review, Researcher Training Workshop, Medical Sciences Division, University of Oxford, 22nd January 2010 and 8th June 2010
6. Practice and Oversight: Ethical Considerations in E-Research, Oxford E-Research Centre, 23rd April 2010
7. NHS Research Ethics: Gaining Ethical Approval for Research, Oxford Doctoral Course in Clinical Psychology, Staff Seminar, University of Oxford, 20th April 2010
8. Research and Ethical Review, Oxford University Clinical Academic Graduate School (OUCAGS), with Dr Brian Shine, 20th January 2010
9. Research Integrity Maths and Physical Life Sciences (MPLS) Divisional Skills Training Seminar, University of Oxford, 9th November 2009

Dr Naomi Hawkins

1. Presentation, 'Law vs Practice: Gene Patents and Genetic Testing'. Intellectual Property Discussion Group, Faculty of Law, University of Oxford, 16th November 2010
2. Invited Presentation, 'Gene Patents and Genetic Testing in the UK', Childhood Cancer Research Group, 24th March 2010
3. Presentation, 'Data Sharing in GWAS: Views From Policy Makers', International Data Sharing Conference, Oxford, September 2010
4. Talking Law and Ethics Seminar, 'Planning for Translational Research in Genomics', June 2010
5. Presentation, 'Planning for Translational Research in Genomics', CESAGEN 3rd Annual Conference, Mapping the Genomic Era: Measurements and Meanings, Cardiff, October 2009

Publications

Publications 2009-2010

1. Kaye J and Spencer D, 2010 Developing Interdisciplinary Research on the Ground - Barriers and Opportunities, *In –Spires* Vol.5, No.1, 40-54
2. Curren L, Boddington P, Gowans H, Hawkins N, Kanellopoulou N, Kaye J, Melham K, 2010 Identifiability, Genomics and UK Data Protection Law, *European Journal of Health Law* Vol 17, 4: 329-344
3. Curren L & Kaye J, 2010 Revoking consent: a 'blind spot' in data protection law?, *Computer Law and Security Review* Vol 26, Issue 3, 273-283
4. Curren L, & Kaye J, 2010 Data subjects' rights — are they inadequate?, *Privacy & Data Protection Journal* Vol. 10 Issue 5.
5. Kaye J, 2010 Building a Foundation for Biobanking: The 2009 OECD Guidelines on Human Biobanks and Genetic Research Databases (HBGRDs), *European Journal of Health Law* 1: 187-190
6. Kaye J, Boddington P, de Vries J, Hawkins N, Melham K, 2010 Ethical Implications of the Use of Whole Genome Methods in Medical Research, *European Journal of Human Genetics* 18: 398-403
7. Heeney C, de Vries J, Hawkins N, Boddington P, Kaye J 2010 Assessing the Privacy Risks of Data Sharing in Genomics, *Public Health Genomics* (DOI:10.1159/000294150) Published Online: March 29, 2010
8. Kaye J & Stranger M, (Ed) *Principles and Practice in Biobank Governance* (Ashgate: 2009)
9. Kaye J, Biobanking Networks – What are the Governance Challenges?, in Kaye J & Stranger M, (Ed) *Principles and Practice in Biobank Governance* (Ashgate: 2009).
10. Kanellopoulou N 2009 Reconsidering Altruism, Introducing Reciprocity and Empowerment in the Governance of Biobanks in the UK. In: *Principles and Practice in Biobank Governance*, ed. by Kaye J, and Stranger M. Ashgate, chap. 2, pp. 33-52.
11. Kanellopoulou N 2009 Advocacy Groups as Research Organisations: Novel Approaches in Research Governance. In: *The Limits to Governance: The Challenge of Policy-making for the Life Sciences*, ed. by Cathie Lyall, James Smith and Theo Papaioannou. Ashgate, chap. 9, pp. 193-216.
12. Hawkins N, de Vries J, Boddington P, Kaye J, Heeney C, 2009 Planning for Translational Research in Genomics *Genome Med* 1:87doi:10.1186/gm87
13. P3G Consortium, Church G, Heeney C, Hawkins N, de Vries J, Boddington. P, Kaye J., Bobrow M., Weir B., 2009 Public Access to Genome-Wide Data: Five Views on Balancing Research with Privacy and Protection *PLoS Genet* 5(10): e1000665. doi:10.1371/journal.pgen.1000665
14. Caulfield T and Kaye J 2009 Broad consent in biobanking: reflections on seemingly insurmountable dilemmas. *Med Law Int* 10: 85–100
15. Kaye J, Parker M & Blair E. 'Predictive testing of adolescents for SCD' in *Disclosure Dilemmas: Ethical Issues of Information in Genetic Counselling* Ed. Christoph Rehmann-Sutter, C. & Müller, H. (Ashgate 2009)
16. Toronto International Data Release Workshop Authors, Prepublication data sharing *Nature* 461, 168-170 (10 September 2009) | doi:10.1038/461168a; Published online 9 September 2009 (Jane Kaye)
17. Kaye J, Heeney C, Hawkins N, de Vries J, Boddington P, 2009 Data-sharing in Genomics: changing Scientific Practice *Nature Reviews Genetics* 10:5, 331-335
18. Avard D, Bucci LM, Burgess MM, Kaye J, Heeney C, Farmer Y, Cambon-Thomsen A, 2009 Public Health Genomics (PHG) and Public Participation: Points to Consider *Journal of Public Deliberation* Vol. 5: No. 1, Article 7.

Connections Meetings 2010

Speakers List

Hilary

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|------------------------|---|
| 31 st March | Dr. Jane Kaye – HeLEX, University of Oxford |
| 13 th April | Dr. Mark Sheehan- Ethox, University of Oxford |
| 21 st April | Dr. Nadja Kanellopoulou - HeLEX, University of Oxford |

Trinity

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|-----------------------|--|
| 5 th May | Mr. John William Devine - HeLEX, University of Oxford |
| 12 th May | Mr. Charles Foster – Outer Temple Chambers and Research Associate, HeLEX, University of Oxford |
| 19 th May | Dr. Jane Kaye - HeLEX, University of Oxford |
| 26 th May | Prof. Jonathan Herring – Exeter College, University of Oxford |
| 2 nd June | Dr. Teresa Finlay – Oxford Brookes |
| 9 th June | Mr. Jesse Wall – Faculty of Law, University of Oxford |
| 23 rd June | Ms. Laura Feldman – Intern, HeLEX, University of Oxford |
| 30 th June | Prof. Donna Dickenson – Research Associate, HeLEX, University of Oxford |
| 7 th July | Dr. David Erdos – CSLS, University of Oxford |
| 14 th July | Ms. Kathryn Bunch – Childhood Cancer Registry |
| 21 st July | Dr Simone Penasa – University of Trento, Italy |

Michaelmas

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|---------------------------|---|
| 27 th October | Dr. Katerina Sideri - CSLS, University of Oxford |
| 3 rd November | Dr. Eric Meyer and Dr. Ralph Shroeder - OII, University of Oxford |
| 10 th November | Prof. Luciano Floridi – University of Hertfordshire |
| 17 th November | Dr. Nadja Kanellopoulou - HeLEX, University of Oxford |
| 24 th November | Prof. Sigrid Sterckx, Ghent University, Belgium |
| 1 st December | Dr. Matteo Macilotti – University of Trento, Italy |

Visitors 2010-2011

Dr Simone Penasa (30/06/2010 – 30/08/2010) University of Trento, Italy

Simone Penasa is Research Fellow in comparative constitutional law at the University of Trento, Italy. Simone received his Ph.D. in Comparative and European Legal Studies, at the Department of Legal Sciences of the University of Trento, after having submitted the thesis "Verso una costituzione scientificamente intesa? Progetto costituzionale e progresso scientifico in Italia e Spagna" ("Towards a Scientifically Intended Constitution? Constitutional Project and Scientific Progress in Italy and Spain") in 2007. He is also part of the Progetto Biodiritto (Biolaw Project), within the Department of Legal Science of the University of Trento. His main research interests are in ARTs and embryonic stem cell research regulation, decision-making process in regulating biomedical issues and the legal treatment of genetic data.

Dr Nils Hoppe (30/04/2010 – 01/01/2011) Health Law & Ethics Research Group, Gottfried Leibniz Universitaet Hannover

Nils read law at Nottingham Trent University, Erlangen-Nürnberg and Göttingen, specialising in medical law and human rights law, and graduated in 2000 with honours. He worked as a legal assistant in England and then as legal counsel to a large German teaching hospital before becoming a research associate and project officer at the Dept. of Ethics and History of Medicine in Göttingen. He was a lecturer in English for Law at the University of Hannover from 2004 to 2008 and now leads the Medical Law and Bioethics Group (AGMB) at the Center for Philosophy and Ethics of Science (ZEWW).

His research focus is currently on the issue of the 'Europeanisation' of health law and policy. He is also working on a number of book projects and is co-coordinator of the EU-funded project TISS.EU on ethical and legal issues in relation to human tissue and cells. Nils is the author of "Bioequity - Property in the Human Body" (Ashgate, Aldershot) and, together with colleagues from Göttingen and Zurich, the editor of "Ethics and Law of Intellectual Property" (Ashgate, Aldershot) and "Human Tissue Research" (Oxford University Press, Oxford).

Prof Natalia Alvarez Lata & Prof Jose Seoane (23/08/2010 – 6/09/2010) Department of Civil Law, Faculty of Law, University of A Coruña, Espana

Whilst Prof Alvarez Lata and Prof Jose Seoane were visiting HeLEX they continued their research on the requirements and consequences of the United Nations Convention on the Rights of Persons with Disabilities (New York, 13th December, 2006), especially in the process of decision-making and the scope of autonomy and competence of persons with disabilities.

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.