



# Genomics and Society:

Summaries of Research  
Findings and Results from the  
ESRC Genomics Network



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The ESRC Genomics Network (EGN) is a unique organisation involving probably the world's largest combination of researchers investigating the social aspects of contemporary life science. The EGN is composed of three research centres - Cesagen, Egenis and Innogen - and the Genomics Forum, a novel kind of organisation that acts as an intermediary between the social researchers and various audiences.

This booklet of EGN research summaries gives a very good indication both of the breadth of research that the Network carries out and of the kinds of conclusions that have been reached.

Many people are aware of the potential social importance of the contemporary life sciences. It is possible that current research in the life sciences will lead to new cures for degenerative diseases. Genetic screening of the population may allow people to anticipate the diseases that they and their family members could be exposed to later in life. Research on crop breeding and on the action of bacteria may enable technologists to develop new sources of energy, to allow trains and even planes to run on biological fuels. Eleven years ago Dolly the sheep became the first cloned mammal; in the future, companies may well offer to clone all sorts of farm animals and we may need to decide whether cloned steaks are as healthy and nutritious as conventional ones.

Each of these questions – and very many others as well – has a strong societal dimension. Does it make sense to put our health investment into genetics or into other forms of therapy? What role will transportation play in our lives? Which are the right institutions to make judgements about the safety of our food? These questions benefit from being investigated carefully and systematically by social scientists and, in the following pages, readers will find reports on a very wide range of these topics.

Researchers in the EGN recognise that there are additional issues to these questions about biology's impacts on society. For example, new thinking in the life sciences raises deep questions about our identity and individuality. Can we now be said to be responsible for our own genetic make-up or even of the make-up of our children? Things that were once thought of as part of fate now seem to be under our control. What are the consequences of this redistribution of responsibility and how do different actors – commercial testing companies, insurance firms and the legal system – respond to these new possibilities? These questions are partly philosophical, but they are also matters of psychology, economics and sociology and they have been skilfully examined by EGN researchers, too.

Finally, it is clear that the contemporary life sciences themselves are social organisations that are undergoing change even as they produce new knowledge. There are new sources of funding for biology and new pressures on scientific workers. The human genome was initially investigated by scientists working in public laboratories funded by government grants and awards from charities. But the genomic code was so important that other private institutions also became involved in a hard-fought race to complete the sequence. Now companies are seeking genomic information wherever they can, and are trying to use patent law to 'own' bits of the human and plant and animal genomes. Though these processes are within science they too have economic, psychological and cultural dimensions and so the EGN has studied the life sciences through the eyes of sociology.

All these strands make up the complex social relations of contemporary life science in its social contexts. I hope readers will enjoy the following accounts of the work that has been undertaken to try to figure out this intricate pattern.

Steve Yearley



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Foreword by Steve Yearley, Director ESRC Genomics Policy and Research Forum

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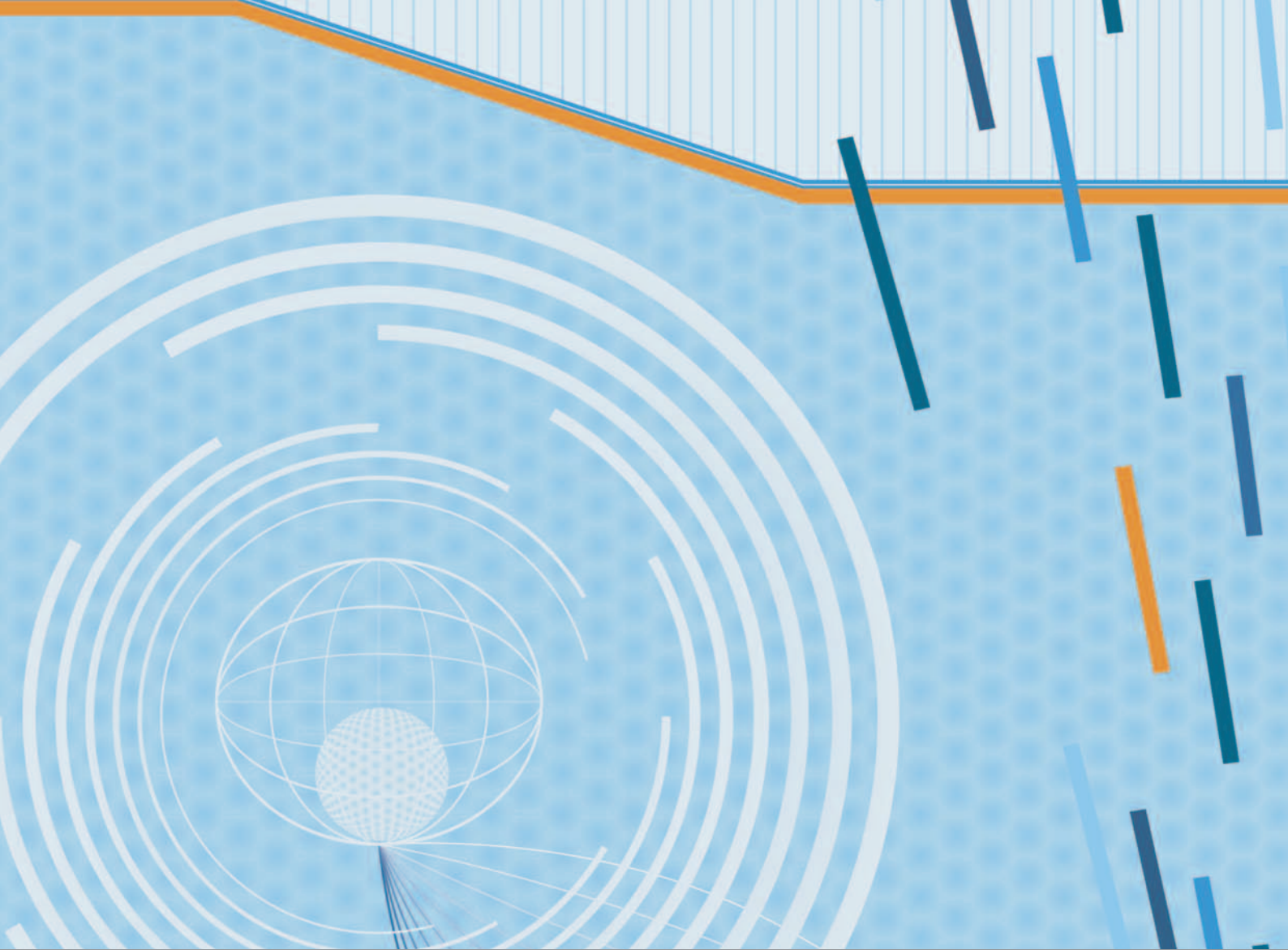
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### **ESRC Genomics Network Research Themes 2007-2012**



# Globalisation and Governance

The new life sciences operate internationally and can cross all manner of legal and commercial boundaries. Social scientists are concerned to trace global patterns in contemporary biology and to track the way new entities (such as human stem cells) are treated in different national contexts. The international mobility of the products of the new life sciences opens up fresh questions about the regulation and governance of these entities across and between countries.

# Animal cloning and genetic modification: a prospective study

<b>Research fellow:</b>	Ann Bruce (Innogen)
<b>Principal investigator:</b>	Joyce Tait/Ann Bruce (Innogen)
<b>Associated staff:</b>	Catherine Lyall (Innogen), Renate Gertz (AHRC Research Centre for Studies in Intellectual Property and Technology Law), Jonathan Suk (Genomics Forum)
<b>Project co-funder:</b>	European Science and Technology Observatory (ESTO)

## Background:

Innogen was invited to tender for this study by ESTO, based in the EC Institute for Prospective Technology Studies (IPTS) in Seville. Our ability to link with a team of eminent scientists based in Roslin Institute and the Genesis Faraday Partnership in Roslin, along with the legal expertise of our colleagues in the AHRC Research Centre for Studies in Intellectual Property and Technology Law, were instrumental in our being awarded the contract.

## Research aims:

- To provide a comprehensive picture of R&D and commercial activities involving animal cloning and/or genetic modification and their products, worldwide;
- To provide evidence on the pipeline of products for the next five years;
- To identify the potential socio-economic impacts (benefits and risks) and new policy implications of the development of these technologies and of the commercialisation of their products in the EU;
- To compare the regulatory frameworks and visions worldwide;

## Methods:

The study covered applications of the technology, including food production, molecular pharming, xeno-transplantation, the pet sector, sporting animals and endangered species.

We reviewed the main R&D actors and products in the market and in the pipeline worldwide in order to anticipate potential safety, trade and competitiveness implications.

## Key findings:

This project was confidential and only published findings related to cloned animals are indicated below.

- The widely held view among industry insiders is that meat and milk derived from the offspring of cloned cattle and pigs are likely to enter the food chain somewhere in the world before 2010. The emergence of food products derived from animal cloning raises numerous ethical and policy issues. One of the main barriers to commercial uptake of cloned elite animals is perceived as market acceptability and the pending regulatory assessment by the Food and Drugs Administration in the United States.
- The likely impact of existing legislation in the EU on products from cloned animals is unclear at the moment e.g. it is not clear if cloned animals will be classified as genetically modified organisms and therefore subject to Directives such as 2001/18/EC governing the commercial release of genetically modified organisms.
- There is currently no scientific method (and no obvious basis) for distinguishing between meat and milk from non-cloned and cloned animals (or from the offspring of cloned animals). Thus any labelling requirements related to the products of cloned animals would need to rely upon traceability regimes.
- No clear international agreements covering trade in semen and embryos from cloned livestock are in place, although some companies are actively working in this area.
- The lack of consistency poses a potential barrier to the animal biotech industry but may also increase the likelihood of public resistance.

## Publications:

IPTS will be publishing a report based on this work but the timescale is entirely within their gift. The work is considered confidential and publication by us is not permitted. An exception was made in the case of the publication below which was produced as a joint-publication with IPTS.

Suk, J., Bruce, A., Gertz, R., Warkup, C., Whitelaw, C.B.A., Braun, A., Oram, C., Rodríguez-Cerezo, E., Papatryfon, I. (2007) Dolly for dinner? Assessing commercial and regulatory trends in cloned livestock. *Nature Biotechnology* 25(1): pp 47-53

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# Co-operative management of intellectual property rights

<b>Principal investigator:</b>	Steve Hughes (Egenis), Xiaobai Shen (Innogen)
<b>Research fellow:</b>	Jane Calvert (Egenis)
<b>Associated staff:</b>	Robin Williams (Innogen), Joyce Tait (Innogen)
<b>Project funder:</b>	EU PRIME Network of Excellence

## Background:

During the last twenty years, intellectual property has been strengthened and extended to new technologies like software and biotechnology. Patents and copyrights have played a key role in the recent waves of innovation in these industries where numerous and scattered intellectual property rights (IPRs) may result in a tragedy of 'anti-commons' so that hold-ups and transaction costs impede innovation and competition. Furthermore, putting IPR at the core of innovative activities, as an economic target and a proxy for innovation performance, has modified the rationale for investing in research. Innogen is involved in this project with partners from France and Italy. We are working with colleagues in Egenis and contributing to a transverse analytical framework with Edinburgh staff with Open Source expertise.

## Research aims:

- To understand how collective institutions based on intellectual property rights (CIPR) develop in response to blocking IPRs on cumulative and/or complementary innovations
- To evaluate the performances of these institutions

## Methods:

This project applies a transversal approach to two different industries, Open Source Software and Patent Platforms in Agricultural Biotechnology, to develop a comparison between these two forms of CIPR.

## Key findings:

- The project analysed a diversity of tools for the collective management of IP rights (e.g. patent pools and clearing house mechanisms), and argued that these tools enable a decentralised yet coordinated management of R&D projects where cooperative R&D is commonplace.
- It showed that CIPRs vary widely in the details of their functioning and implementation. This reflects the variety of technological fields in which they can take place. Communities of IP users frequently find ways to avoid or reduce the anticommons situation, and the collective handling of IP rights allows the creation of original forms of organisation. However, although collective institutions are improving, nothing guarantees that they can perfectly compensate for all the deficiencies of the IP system, so IP proliferation remains a problem.

## Publications:

O'Malley, M, Bostanci, A and Calvert, J (2005) Whole genome patenting *Nature Reviews Genetics*, Vol. 6, No. 6, pp. 502-506.  
Shen, X (2005) A dilemma for developing countries in IP strategy? Lessons from a case study of software piracy and Microsoft in China, *Science and Public Policy*, Volume 32, Number 3, pp. 187-198.  
Calvert, J (2007) Patenting genomic objects: genes, genomes, function and information, *Science as Culture* Vol. 16, No. 2, pp. 207-223  
Hughes, S and Deibe, E, (2007), E Plant Breeders Rights, Room for Manoeuvre? *Tailoring Biotechnologies*, 2, pp. 77-86.

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# Detection and identification of infectious diseases foresight project: risk work package

**Principal investigator:** Joyce Tait (Innogen)  
**Research associates:** Catherine Lyall (Innogen), Jonathan Suk (Genomics Forum) and Laura Meagher (Technology Development Group)  
**Project funder:** Office of Science and Innovation

## Research aims:

The Innogen team undertook the risk analysis which underpinned the UK Foresight project on the projected risks from infectious diseases of humans, animals and plants over 10 and 25 year time horizons, comparing three geographical regions: the UK, sub-Saharan Africa and China. It drew on best available evidence to review and compare future risks using a common set of metrics to: identify the factors driving changes in risk; assess how the size and nature of risks are evolving; and indicate the range of plausible future patterns of risk, taking account of the needs and views of the wider stakeholder community.

## Methods:

Over 300 experts from over 30 countries were consulted during the full Foresight project. A qualitative framework enabled us to organise and prioritise factors influencing the spread of infectious disease.

There were two research phases:

- A preliminary scoping phase to develop an understanding of the most important issues and their interactions, to formulate the overall approach to the research and to plan the survey to be carried out in the second phase;
- A two-stage Delphi questionnaire-based survey of expert opinion on future risks in the UK and Africa, including a range of specially commissioned expert reviews.

## Key findings:

The challenge was to develop survey-based results that would be useful to decision-makers and would also be regarded as useful and valid by scientific peer reviewers. Results emphasised the importance of interactions among the drivers, sources and pathways of disease. Using data collected from these expert sources we developed an algorithm-based tool for considering future disease risks and decision-making on the need for and use of detection, identification and monitoring (DIM) technology. Decision-making in other areas may benefit from a similar modelling approach that allows a complex interdisciplinary risk situation to be broken down into more manageable elements. The innovative methodological approach developed for this project is thus of as much interest for future research in this area as are the outcomes of the survey itself. Results for all six survey samples, for 2015 and 2030 are available via [www.Foresight.gov.uk](http://www.Foresight.gov.uk).

The survey shed light on the differences in economic and political context in Africa and the UK.

Briefly, the highest perceived risks by 2030 related to:

- New pathogens or new strains of existing pathogens arising through natural genetic change
- Geographical extension of pathogens from within or outside the UK and Africa

In five of the six categories there was a perceived high risk of:

- New diseases from other species reservoirs, including wild species reservoirs
- Drug use leading to the emergence of drug-resistant disease organisms
- An increase in disease due to a mean temperature increase in the range 0.5 – 2 degrees Celsius
- Changes in disease sources were seen as important determinants of future risks in all six categories (plants, animals and humans; UK and Africa).
- Changes in pathways were seen as much less important generators of disease risks across all categories.
- For disease drivers many more were considered important in Africa than in UK.

## Publications:

Tait, J., Meagher, L., Lyall, C., and Suk, J. (2006), Foresight. Infectious Diseases: preparing for the future. T2: Risk Analysis. Report to Office of Science and Innovation, London

Lyall, C., Suk, J. and Tait J. (2006), Foresight. Infectious Diseases: preparing for the future. T3: Expert Survey of the UK and Africa. Report to Office of Science and Innovation, London.

Suk, J., Lyall, C. and Tait, J. (July 2007) Risk Analysis in the UK Foresight Programme on the Detection and Identification of Infectious Diseases, Innogen Working Paper

Suk, J., Lyall, C. and Tait, J. (submitted July 2007) Risk Analysis in the UK Foresight Programme on the Detection and Identification of Infectious Diseases, *Risk Analysis*

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## Genetic databases

**Principal investigator:** Ruth Chadwick (Cesagen)  
**Research associate:** Mina Bhardwaj (Cesagen)

### Research aims:

The Database project was developed under the theme of genomics, ethics and governance, focusing on ethical, legal and also scientific/statistical validity of creating large scale population based genomic databases. The project was divided into four strands to develop a bigger picture challenging ethics and law. Issues considered included:

- How biobanking is shaping ethics at personal and community level and the need to bring new ethical principles to accommodate changing trends in genomics.
- The publics' expectations of genetic databases and biobanks and how they might shape future choices for individuals and families.
- The typology of databases and the different governance mechanisms established in different countries for databases and the ethical underpinning of those frameworks.
- The global trends in biobanking and how it is influencing research priorities and ethical frameworks in poor countries.
- Statistical validity of databases and the ethics of healthcare advice based on figures.

### Key findings:

- The project included different strands around which individual projects were developed. The issues discovered and discussed in the project are relevant to the themes of public engagement with biosciences and health medicine and genomics with some reflections on economic issues.
- At the conceptual level there are parallel shifts in framing of the ethical questions as the focus of medicine is shifting from individuals to populations, and the role of 'individual' in medicine and ethics is contested. As genetic research has moved from Mendelian genetics to sequence maps to the study of human genetic variation at the level of the genome, there is an accompanying shift in emphasis in ethical framings of the issues - towards reciprocity, mutuality, solidarity, and citizenry. So far this substantial shift of ethical perspective has not been reflected in institutional practices and policies.
- The new emphasis on ethics in medicine in Asia corresponds with the global debate to include different cultural values, and since the role of the family is central in decision-making in Asia, new principles such as family based individual informed consent and collective confidentiality are being developed.
- Different countries have different models of governance of databases. From a policy-making point of view, biobanks with a firm legislative framework (model 1) enjoy a superior level of enforceability and greater certainty attached to governance frameworks. Biobanks created independently of legislation (model 2) enjoy a greater adaptability. In attempting to legislate for circumstances that are currently unpredictable it can be argued that model 1 biobanks are insufficiently flexible. It might be argued that both models suffer from the limitation of institutional policy practice indicated above.
- The empirical work showed that the requirement for individual informed consent does not address wider concerns over the type of society genetic applications could bring about, the commercialization and commodification of information and the privatization of public goods. Individual consent assigns control to other people. In order to be able to place their trust well, people need evidence of a relationship with obligations and expectations on both sides.
- Biobanks intend to focus on gene-environment association using genetic association studies models. However, definitions of environment are still unclear raising concerns over statistical validity of databases. The confounding factors that may affect results and the reliability and reproducibility of results need to be considered for such long-term large-scale population based studies. Whether governance arrangements adequately address this issue remains a question. Concerns are also raised over managing expectations in the healthcare system, the dangers of over enthusiasm and misreporting of the data.

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A link to this project website is at [www.lancs.ac.uk/fss/cesagen/gendata/](http://www.lancs.ac.uk/fss/cesagen/gendata/)

# Genomics and biosecurity

**Research fellow:** Jonathan Suk (Genomics Forum)

## Background:

International concern over the threat of naturally occurring infectious diseases as well as the potential malevolent use of biological knowledge, either through state-sponsored bioweapon development or through bioterrorism, has dramatically increased in recent years. The boundary between 'bioweapon' and 'biodefence' has blurred amidst a political environment in which traditional notions of national and global security have broadened.

Numerous actors have pursued initiatives designed to enhance global biosecurity by mitigating the potential misuse of biological knowledge. At the international level, several actors have called for a strengthening of the 1972 Biological and Toxin Weapons Convention (BTWC), which currently lacks a mechanism for confirming state adherence to the Convention. Meanwhile, a variety of additional measures have been explored. National governments and other relevant actors (e.g. Organisation for Economic Co-operation and Development (OECD), World Health Organisation (WHO), Non Government Organisations (NGOs), professional & scientific organisations) have pursued and debated mechanisms such as professional codes of conduct, export controls, biological resource centres and even the censorship of scientific articles with findings that could be applicable to the development biological weapons.

Each of these initiatives could significantly alter the trajectory of global biomedical and genomic research, and each initiative embodies a range of technological and political expectations and commitments.

## Research aims:

This work programme explored:

- How can the current governance landscape for bioweapons/biosecurity be contextualised?
- How is the threat to biosecurity from biowarfare/bioterrorism being perceived by key policy actors? Are advances in genomics altering this threat?
- How might governance tools designed to enhance biosecurity impact the trajectory of genomics research, and vice-versa?
- In exploring these and similar questions, what can this work programme contribute to broader debates on the relationship between science and its governance by global and national governments?

## Methods:

The key tool for this work programme was a 2-day expert workshop to explore the emergence of biosecurity controls and the possible impacts that these might have on the trajectory of genomics and biomedical research by encouraging sustained interaction between policy-makers, social scientists and scientists.

## Key findings:

- There is a need to clarify and contextualise the dimensions of any debate on biosecurity. What are the origins of governmental and non-governmental concerns over biosecurity? Do these relate to industrial research & development, state-sponsored 'biodefence' research, or covert terrorist activities? Each, if legitimate, requires a different set of responses; types and levels of intervention (international, national, regional) should vary depending on the nature and definition of the threat.
- Several attendees stressed the need for national and international governmental organizations to continue opening up policy spaces to a pluralist set of experts. In this field, there is the need to ensure the perspectives from biomedical, security, and intelligence disciplines as well as from NGOs. Representative, transparent and open debate over the nature of the threat in the first place is required so as to ensure that specific policy options, whether these be funding additional biodefence research, or foreclosing certain areas of biomedical research, are the product of a range of perspectives and not playing too the advantage of specific interest groups, whether security communities or pharmaceutical industries.
- One significant trend relates towards the desire of scientific communities to implement various codes of conduct and other forms of self-regulation. The social scientists and political scientists that participated in this workshop expressed concern that such communities, with strong general mandates to pursue biomedical research, have either the self-awareness or the impetus to be able to judiciously govern their own research.
- A more general but nonetheless important insight from the meeting is that in the absence of any 'hard' evidence about specific biosecurity threats, which are nearly impossible to quantify and predict, there is the possibility that over-attention to biosecurity diverts resources and expertise to the area at the expense of other pressing needs, such as infectious disease control in developing countries.
- The themes discussed in this workshop connect to broader theoretical debates that have been represented in other EGN research. How can actors at regional and national levels exert influence and collaborate with each other to decide how biomedical research and its products should be organized and regulated at the global level? How can a broader range of perspectives and expertise be effectively represented in emerging science governance systems? If there is a greater need for traditionally separate forms of government (security, trade and industry, environment, health) to interact, how can this be optimised?

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# Genomics and intellectual property

**Research fellow:** Nadja Kanellopoulou (Genomics Forum)

## Background:

This work stream was developed with the aim of identifying emerging issues for systematic public policy in genomics, intellectual property (IP) and health governance. The project forwards interdisciplinary academic research and policy collaborations to help discuss current problems in genomics, health and IP governance. These examine the advantages and limitations of IP regimes used in drug research and development, the role of international organisations in regulating IP and genomics, the impact of commercialisation on public trust, the implementation of social and ethical values and the need for equitable and collaborative models in genomics governance, the use of human tissue for research purposes, and property rights in the body.

## Research aims:

The project facilitates academic and policy synergies in dynamic, comparative research and policy context, with the aim to explore:

- The institutional nature of the IP system and its applications
- The impact of IP models on access to - and availability of - genomic technologies
- The influence of IP models on health governance mechanisms
- The relationship of IP models with international research ethics norms and values

## Methods:

Expert workshops and seminars in 2006-2007 brought together researchers including social scientists, natural scientists, economists, philosophers, lawyers, policy-makers, business and patient representatives as public and private stakeholders involved in the governance of genomics, IP and health. Project participants engaged in thinking about current problems and case studies on the social and economic impact of the implementation of IP systems in genomics, by focussing on issues of access, commercialisation and control of research processes and products.

## Key findings:

- The impact of new directions in the life sciences and the utility of IP in science and technology innovation:  
Global trends in genomics and bioinformatics (e.g. systems biology, whole-genome patenting) raise new scientific, social, legal and policy questions because of an informational shift as part of a broader shift towards intangible intellectual property rights in genomics. These questions relate to the nature of patenting research and its applications, with important implications for how research is financed and data are shared. They are of particular interest to social scientists in assessing how commercial interests shape the development of genomic science and how society might benefit from it in the future. They further our understanding of biological entities and the development of new conceptual approaches of genomes, their utility and classification.
- The role of IP systems in forwarding research and innovation:  
Evidence-based research now starts to emerge on the effect of IP systems in controlling access to data, stimulating research and managing innovation. This research follows global trends in patenting in the life sciences as affected by market-driven innovation; it examines the nature of academia-industry partnerships, open science and market-driven research, and emerging conflicts of interest. There is a plethora of research about the scale of difficulties that the current implementation of IP systems entails for a diversity of research users. These difficulties raise questions on what new governance mechanisms can help address problems of access to research knowledge, research tools and products efficiently.
- The nature of public and private research collaborations in funding research:  
There is arguably a contradiction between the exercise of exclusive IP rights and universal claims for access, inclusion and distributive justice. New interest emerges globally in the development of policy choices and public private partnership for models that promote innovation under a public welfare paradigm. These include public-private partnerships with a twin goal of fostering innovation while maintaining the public interest.
- The viability of collaborative mechanisms in economic, social, legal context:  
There is increasing interest in collaborative models that incorporate a variety of intellectual property strategies, such as patent pools, clearinghouse mechanisms and open source-style strategies, to facilitate access to patented genomic inventions in global and regional context. Not all areas of research or all forms of patents lend themselves to this kind of governance but such an approach might be particularly valuable for large, government-funded initiatives in controversial areas such as human embryonic stem cell research, where researchers may have to rely on multiple innovative steps and products (each of which may be covered by a patent) of other researchers, and would wish to avoid excessive royalty stacking and blocking patents.
- The need for implementation of social, ethical, cultural values in IP governance:  
As the focus of genomics research shifts from individuals to groups, there is also a shift in emphasis of the relevant ethical questions. This includes the need to incorporate new mechanisms that match a diversity of values in the governance of bio medical research. As an example from current interdisciplinary EGN work, there is a commitment to rethink notions of altruism, solidarity, responsibility and identity, together with the need for clarity of what research benefits are, whether framed in development terms, health terms or profit terms. These lead to questions as to whether these definitions depend on the needs, values, priorities and cultural expectations of research participants as volunteers or as partners in research. Do benefits transcend avoidance of harm in so far as they promote the welfare of individuals or groups? How closely are benefits associated with profits in the monetary or economic sense? What obligations arise from such considerations?

- The impact of public perceptions in the governance of commercial genomics research and the need for shared governance *mechanisms*: Is there a realistic prospect for frameworks where medical research and development is free from commercial pressures and intellectual property rights? Is the challenge for patients and research participants to view their involvement with research as a lever to ensure that the commercialisation of genomics research meets their interests, and leads to novel products and services that benefit those who need them the most? Research emerges in support of models to support research participants and patients in shaping the direction of research as part of a broader understanding of a need for equitable and viable solutions in long-term research.

**Publications:**

Kanellopoulou, N.(2005), The Impact of Intellectual Property on Genomics Governance

Kanellopoulou, N.(Dec 2007), (ed.), Patents, Genomics and Commercialisation - Ethical, Legal and Social Concerns about Intellectual Property Governance in Genomics, forthcoming edited volume in *Genomics Society and Policy*

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Links to this project's website are at:

<http://www.genomicsforum.ac.uk/default.aspx?pagelD=91>

<http://www.genomicsforum.ac.uk/default.aspx?pagelD=113>

<http://www.genomicsforum.ac.uk/default.aspx?pagelD=164>

# Indigenous peoples and the globalization of genomics in Amazonia

**Principal investigator:** Paul Oldham (Cesagen)  
**PhD students:** Heather Walmsley (Cesagen), Jodie Chapell (Cesagen), Nina Moeller (Cesagen)

## Research aims:

This project is concerned with examining Amazonian peoples' perspectives and issues surrounding the globalisation of plant genomics. The project is situated within heavily contested debates surrounding the commercialisation of traditional knowledge and genetic resources that range across multiple scales from Amazonian communities to debates under the United Nations Convention on Biological Diversity.

## Methods:

The Amazon project has focused on both qualitative and quantitative methodological development in order to bridge the multiple scales and epistemologies involved and contribute constructively to international policy debates.

This has been achieved through a three stage approach:

- On the local and the national level, working in partnership with the Regional Organisation of Indigenous Peoples of Amazonas (ORPIA), field research was conducted with the Piaroa people of Amazonas State in Southern Venezuela. This consisted of establishing a small project with two indigenous researchers directed towards the exploration of Piaroa conceptions of human-nature relatedness that will ultimately feed into the development of the local school curriculum.
- On the state level, the project investigated the ethical and human rights dimensions of the Biozulua traditional knowledge database. This case exposed the difficulties confronting indigenous organisations and communities with managing research relationships in a context of a drive for commercialisation. In 2005 at the invitation of the Indigenous Peoples Commission, the Amazon project contributed to drafting a new national indigenous peoples' law with particular attention to research ethics and arbitration mechanisms. As part of a longer term commitment to working with indigenous peoples in Amazonas, future work will focus on research ethics and managing research relationships. On the regional level, in 2005 the Amazon project joined the Initiative for the Prevention of Biopiracy. This initiative is concerned with technical analysis of patent activity relating to biodiversity and traditional knowledge in Brazil, Colombia, Ecuador, Peru, Venezuela and Mexico. The Amazon project has developed working papers on research methods and international indicators for research on biodiversity, traditional knowledge and the patent system. Collaboration in this area is ongoing and in 2006 two PhD students commenced fieldwork with indigenous peoples organisations in the Brazilian and Ecuadorian Amazon. Additional funding has been secured from the UK Darwin Initiative to extend research collaboration to the Mapuche in Chile. A PhD student is also conducting field research on indigenous peoples and biobanks in Canada with a view to possible future expansion of work in this area to Latin America.
- On the international level the project has focused on providing independent professional research support to participants in the International Indigenous Forum on Biodiversity (IIFB) in debates surrounding traditional knowledge and access to genetic resources and benefit-sharing under the Convention on Biological Diversity. In particular the project has focused on developing evidence based approaches to the analysis of the heavily contested issue of intellectual property and "biopiracy". This has taken the form of a review of global status and trends in intellectual property claims across a spectrum from agriculture to pharmaceuticals, genomics and bionanotechnology. A series has been established for the purpose of disseminating the results. The first paper in the review was sponsored by the European Union as an independent contribution to debates under the Convention. The global patent dataset and related summary review have been made available in an open access journal and future project outputs will be made available in the same form.
- As the Amazon project enters its final phase the project is preparing publications for international peer review journals and exploring the theoretical utility of the concept of the bioeconomy in bridging multiple scales and epistemologies in the context of the globalization of genomics. Work will continue with indigenous peoples in Amazonia and beyond during Cesagen Phase 2 as part of an ongoing commitment to participatory research with indigenous peoples organisations.

## Key findings:

- Publicly funded researchers and public research organisations are increasingly seeking to commercialise biodiversity/traditional knowledge arising from research with indigenous peoples through intellectual property instruments.
- The global scale of intellectual property claims over biodiversity and traditional knowledge is much higher than has been thought and is accelerating.
- Limited consideration has been given to the externalities generated by the patenting of biodiversity and traditional knowledge and their impacts upon indigenous peoples' value systems and relationships with researchers.
- Indigenous peoples in Amazonia and elsewhere are confronted by the problem of managing research relationships with publicly and privately funded researchers directed towards commercial purposes. Debates under the Convention on Biological Diversity and within the World Intellectual Property Organisation (WIPO) suggest possible ways forward in creating constructive research relationships grounded in principles of participation, equity, trust and respect for human rights. Nevertheless, the challenges for indigenous peoples in navigating this complex terrain remain formidable.

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A link to the project website is at [www.lancs.ac.uk/fss/cesagen/indigenous/](http://www.lancs.ac.uk/fss/cesagen/indigenous/)

## Interests and values in risk-related stakeholder interactions

**Research fellow:** Ann Bruce (Innogen)  
**Principal investigator:** Joyce Tait (Innogen)  
**Associated staff:** Sarah Cunningham-Burley (Innogen), Graeme Laurie (Innogen) and Donald MacKenzie (Innogen)

### Background:

Distinctions between the 'interests' and 'values' of protagonists in risk debates are important for the understanding, prevention and resolution of conflicts. This project, which contributes to Innogen Centre's 'Risk, Governance and Regulation of Genomics' theme, aims to explore the way in which 'values' and 'interests' motivate responses in debates in the genomics area.

### Research aims:

- Can we identify 'interest'-based and 'value'-based arguments in a range of genomics applications?
- Are these framings critical in determining the acceptability or not of a genomics application?
- What methods can be used to explore the 'values' and 'interests' dimensions of biotechnology related controversies.
- How are these dimensions reflected in debates around different controversies in genomics, including genetic databases, stem cell therapies and GM animals?
- How are 'values' and 'interests' incorporated in the innovation and policy processes?

### Methods:

Case Study methodology, including in-depth interviews with key stakeholders. Focusing particularly on protagonists with different viewpoints on the issue.

Our research will improve decision making and dispute resolution by improving the level of understanding of the 'values' and 'interests' dimensions of disputes.

### Key findings:

- Presentation of preliminary thoughts on this subject to the Values in Decisions on Risk conference, Stockholm, Sweden in 2003, using the example of Genetically Modified crops.
- During 2004, we produced a paper analysing the 'values' and 'interests' dimensions of developments in population genetic databases, based on a literature review and informed by interviews with stakeholders which was presented at The XVIII European Conference on Philosophy of Medicine and Healthcare: Genetics and Healthcare, Iceland, August 2004.
- A 2-day public interest and ethical stakeholders workshop for policy makers, industry representatives, scientists and social scientists to engage with the issues of what values come into play when scientists and companies make innovations in bio sciences or when policy decisions are made, and how do these reflect or conflict with wider public concerns? This 'Chatham House' event provoked a rich discussion among the participants. A short report from this workshop was disseminated via the Innogen web site and a book chapter in collaboration with AHRC Research Centre for Studies in Intellectual Property and Technology Law. The theme was further developed at the 2005 Innogen international conference with a session on ethical and stakeholder pressures on the pharmaceutical industry and how the industry has responded to these pressures.
- Investigations have continued in the field of cloned and GM animals and also in stem cell research where 26 interviews have been carried out with key stakeholders, including research scientists, patient advocacy groups, policy makers, industrialists and antagonists of stem cell research. A typology of case studies is being developed.

### Publications:

Bruce, A. (2007) The public domain: ideology vs. interest, pp 200-210 in Waelde, C. and MacQueen, H. (eds) *The Many Faces of the Public Domain*, Edward Elgar, Cheltenham, UK & Northampton MA, USA.

Bruce, A and Tait, J (2004) Interests, values and genetic databases, in Arnason, G. Nordal, S and Arnason, V *Blood and Data: Ethical, legal and social aspects of human genetic databases*, International ELSAGEN Conference Proceedings, Reykjavik, pp 211-217

Bruce, A and Tait, J (2003) Interests, values and Biotechnological Risk, in Andersson, K (ed) *VALDOR 2003 Values in Decisions on Risk Proceedings*, pp. 109-118.

Haddow, G., Cunningham-Burley, S. Bruce, A. and Parry, S. (2007) Resolving public concerns: why population genetic databases require an early consultative ear and a strong legislative arm. *Critical Health Technology* (in press)

Bruce, A. (2007) How now cloned cow? submitted to special issue of *Genomics, Society and Policy*, Vol 3, No.2

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# Legal and bioethical regulatory mechanisms

**Principle investigator:** Graeme Laurie (Innogen)  
**Research fellow:** Shawn H.E. Harmon (Innogen)

## Research aims:

This project aims to consider the role of legal and ethical principles in guiding the regulation of genetic research and activities, and to examine the mechanisms by which these can take effect internationally, regionally and domestically. Questions include:

- How effectively do moral values influence legal instruments and policies in the genomics field at the various levels of governance?
- Which moral values do we rely on and why?
- How do these moral values translate into law and how well do these instruments work?

## Methods:

The methodology used has been case studies supported by documentary analysis (international and domestic legal instruments and policy papers), literature reviews (civil society submissions and academic articles), and interaction with civil society through conferences, workshops and public engagement exercises.

Outcomes include the identification and definition of key moral values relevant to genomics, the assessment of various legal instruments for their interaction with same, and the furtherance of the appreciation of the importance of moral values to the governance of human genetics and biotechnologies (as evidenced by personal contacts and requests received by academics and policymakers).

## Key findings:

The research programme supports a number of general findings, namely that:

- Although civil society appears quite concerned with the moral element of genomics and biotechnology, stakeholders are not as exercised
- The law (and policymakers and regulators) are not comfortable with engaging directly with the moral issues and legal instruments often do not effectively translate the moral values claimed; and
- Certain values are more embedded in our collective (legal) psyche (autonomy, dignity) than others (solidarity) and are represented in regulatory instruments much more effectively (and more often) than others; moral values can be indeterminate and, as a result, clear understandings and therefore applications of them are difficult (and rare)

## Publications:

Harmon, S., Law and Ethics: The Implications of Biotechnology Innovation for Practitioners of Medical Law – The Case of Advance Directives (with G. Pradella), (2007) submitted to *Osgoode Hall Law Journal*.

Harmon, S., Emerging Technologies and Developing Countries: Stem Cell Research Regulation and Argentina (2007) forthcoming in *Developing World Bioethics*.

Harmon, S., Biotechnology Innovation and Patenting in the Developing World: China – A Giant Among Nations? (2007) 12 *Journal of Intellectual Property Rights* 72-85.

Harmon, S., Solidarity: A (New) Ethic for Global Health Policy (2006) *Health Care Analysis* 14(4) 215-236.

Harmon, S., The Rules of Re-Engagement: The Use of Patent Proceedings To Influence the Regulation of Science ('What The Salmon Does When Comes Back Downstream') (2006) 4 *Intellectual Property Quarterly* 378-403.

Harmon, S., From Engagement to Re-Engagement: The Expression of Moral Values in Patenting Proceedings, Present and Future (2006) *European Law Review* 31(5) 642-666.

Harmon, S., A Penny For Your Thoughts, A Pound For Your Flesh: Implications of Recognizing Property in Human Body Parts (2006) *Medical Law International* 7(4) 329-354.

Harmon, S., The Significance of UNESCO's Universal Declaration on the Human Genome and Human Rights (2005) 2:1 SCRIPT-ed 18-47, at [www.law.ed.ac.uk/ahrb/script-ed/vol2-1/harmon.pdf](http://www.law.ed.ac.uk/ahrb/script-ed/vol2-1/harmon.pdf).

Harmon, S., Ethico-Legal Issues in Genetics (with R. Gertz and G. Pradella), in A. Wright & N. Hastie (eds.), *Genes and Common Disease – Genetics in Modern Medicine* (Cambridge: CUP, 2006) ch. 12.

Harmon, S., The Law and Ethics of Medical Research (2007) 4:3 SCRIPT-ed 237-240, at [www.law.ed.ac.uk/ahrc/script%2Ded/vol4-2/sh\\_review.asp](http://www.law.ed.ac.uk/ahrc/script%2Ded/vol4-2/sh_review.asp). (Book Review)

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# Local cells, global science: embryonic stem cell research in India

**Principal investigator:** Peter Glasner (Cesagen)  
**Research associate:** Aditya Bharadwaj (Cesagen)

## Background:

The potential for human exploitation, unfair trade practices, and morally contentious biogenetic research in the area of stem cell technology in nations of the global south is significant. This project, funded by a grant of £15,000.00 from Cesagen, examined, for the first time, the transnational movement of tissues, stem cells and scientific expertise in the context of nascent governance frameworks regulating research and development of biotechnology in India.

## Research aims:

To understand the extent to which the global advances of the new biotechnologies shape, and become shaped by, transnational collaborations it traced the journey of 'spare' human embryos from the point of conception in In-vitro Fertilisation (IVF) Clinics to public and private research laboratories engaged in isolating stem cells in India, to laboratories in India and elsewhere, developing potential therapeutic applications for local and global consumption.

## Methods:

To facilitate this, interviews were undertaken with donors and staff based in these clinics, and scientists in key public and private stem cell laboratories, in Delhi, Mumbai, Bangalore and Hyderabad. The field work was undertaken by Dr Adi Bharadwaj, who is a fluent Hindi speaker, and has the necessary ethnographic research experience in India to conduct, transcribe and translate any non-English interview material. Key questions included:

- In what way do the global demands for stem cell lines impact on the local production of stem cell technology in India?
- How are biogenic materials harvested and procured for research?
- What effect does this have on issues of privacy, confidentiality and discrimination?
- How are the resultant tissues and knowledge traded, consumed and exchanged in international arenas?

## Key findings:

The results provide a valuable ethnographic account of the production and use of embryos and stem cells within the global biotech industry, and will contribute to the understanding of largely ignored local and global ethical issues inherent in the regulatory practice of global science. They facilitate much needed, informed academic, policy and public debate within India on the issue of the globalisation of biotechnology research, particularly the trade in human gametes, stem cells and stem lines. They also set the stage for future research on burgeoning biotechnology trade links, particularly on the Indian sub-continent, between the countries of the developing south and prosperous north. Most importantly the results will impact the future shape of more robust regulatory and governance frames in India where the potential for human exploitation, unfair trade practices, and morally contentious biogenetic research remains significant.

We found:

- Stem cells effectively no longer have a history: they have only a future not a past, particularly in India where provenance issues are hidden
- Stem cells are geographically dissociated from their place of origin and presented as 'denatured' objects in later time through freezing.
- The locality in the site of production effectively disguises the globally dispersed forces that actually drive the production process
- Embedded in the transnational movement of tissues, stem cells and scientific expertise between North and South, there is a *technoscape* in motion facilitating the rapid growth of the 'supply chain' of stem cell technology within the Indian sub-continent
- The engine that keeps the supply chain on the move is a *moral economy* in stem cells driven by the global North

## Publications:

A book based on this research called *Local Cells, Global Science: Embryonic Stem Cell Research in India* by A Bharadwaj and P Glasner will be published in 2008 by Routledge.

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# Patenting and genomics

**Research fellow:** Jane Calvert (Egenis)  
**Associated staff:** Steve Hughes (Egenis), Adam Bostanci (Egenis), and Maureen O'Malley (Egenis)

## Background:

The question which initiated this project was: what difference does genomics make to patenting? Gene patenting is a familiar phenomenon, but do we see a difference from the perspective of genomics, which takes the whole genome into account instead of just the single gene?

## Research aims:

We pursued this question by investigating five different and interrelated topics:

- **Gene function from a genomic perspective**  
An assumption in patenting is that a gene is a chemical compound which has only one function. Genomics shows that gene function is more complex because many different genes can be involved in one biological function, and a single gene can have many different functions. This makes gene function a topic that is well suited to the study of patenting from a genomic perspective.
- **The patenting of genomic information**  
Genomic information is one of the most important outputs of genomics, so its patentability is an crucial issue. This relates to the study of gene function because in computational form, genomic information acquires new functions (for example, genomic databases can be compared).
- **The patenting of whole genomes**  
A third strand of investigation is the patenting of *genomes* as opposed to genes. Genome patenting has received relatively little attention (Venter's 2007 application being a recent exception). The study of genome patents overlaps with the study of informational patents, since in a patent a whole genome is represented in computational form. This topic raises questions about the importance of scientific concepts such as 'genome' in the day-to-day activities of patent examining.
- **Patenting in the emerging life sciences**  
Genomics shows that gene function is complex. Systems biology extends this further by drawing attention to the complexity of the interactions of different types of molecule in biological systems. We may well see attempts in the future to patent computer-embodied representations of complex biological systems.
- **Ownership regimes in the biosciences**  
How should Intellectual Property (IP) regimes should be organised in the context of new kinds of objects of study in the biosciences? Dynamic computational models in systems biology are perhaps suited to different ownership regimes from static objects. In *synthetic* biology, in contrast, interactive biological systems are divided up into parts which are substitutable. Life is made more machine-like, and more suited to patentability (although synthetic biology's modularity also fits well with open source principles).

These five different strands all focus on the interaction of IP law with the objects of study in genomics and the emerging biosciences, objects which are constantly being re-conceptualised in scientific practice.

## Key findings:

Gene function from a genomic perspective:

- Genomics shows that genes always work in a genomic context, so trying to patent an isolated function of a single gene becomes problematic.
- Scientific changes are leading to new understandings of the kinds of entity that can be patented, but law often lags behind these developments.

The patenting of genomic information:

- The simultaneously material and informational nature of DNA is exploited in patenting.  
There is a move in genomic patenting away from biochemical tools and products towards information resources.

The patenting of whole genomes:

- The notion of a 'genome', and the ways in which it may be different from a 'gene', plays no role in patent practice.  
Patent examiners do not object to the patenting of complete genome sequences *per se*, instead, their objections are based on classification, rules and procedure.

Patenting in the emerging life sciences:

- Patenting may bifurcate to cover the computer-based tools produced by systems biology and the material objects produced by synthetic biology.  
In synthetic biology scientists are re-building life in a way which fits with existing understandings of intellectual property.

Ownership regimes in the biosciences:

- Collaborative ownership regimes may be more practical in the context of interacting and dynamic biological systems.

### **Publications:**

Calvert, J. (2004). Genomic patenting and the utility requirement. *New Genetics and Society*, 23 (3), pp. 301-312.

O'Malley, M. A., Bostanci, A. and Calvert, J. (2005). Whole genome patenting. *Nature Reviews Genetics*, 6 (6), pp. 502-506.

Calvert, J. (2007). Patenting genomic objects: genes, genomes, function and information. *Science as Culture*, Vol. 16 , No. (2), pp. 207-223.

Hughes, S. and Deibel, E. (2007). Plant Breeders Rights, Room for Manoeuvre? *Tailoring Biotechnologies*, 2, pp. 77-86. Bostanci,

A. and Calvert, J. (in press). Invisible genomes: the genomics revolution and patenting practice. *Studies in History and Philosophy of the Biological and Biomedical Sciences*.

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A link to the project website is at [www.ex.ac.uk/egenis/research](http://www.ex.ac.uk/egenis/research)

# Stem cell research in context: a comparative study on the dynamic relationship between science, medicine & society

**Research team:** Christine Hauskeller (Egenis), Susanne Weber (Egenis), Dana Wilson-Kovacs (Egenis), and Katrin Gehring (Egenis)

## Background:

Britain and Germany currently represent opposite ends of a spectrum of restrictions applied to stem cell science in Europe. Different regimes of governing research on human embryos have been established since 1990. These facilitate embryonic stem cell research in the UK and largely restrict it in Germany. Consequently, Britain has invested substantially in embryonic stem cell research while Germany has strongly supported research using adult stem cells.

Using ethnographic methods, this project analyses the ways in which practices of public governance influence the conduct of stem cell research in both everyday laboratory activity and the configuration of stem cell research as a scientific field. It investigates how the infrastructure of stem cell science, its research questions, its objects and routines are shaped by national and international legal regulation, ethical discourses, science policies and professional backgrounds.

The project addresses the following questions:

- How do practices of public governance influence research questions and practices in stem cell science?
- How are different fields of stem cell science affected by legal and ethical regulation and science policies?
- Does 'stem cell science' represent a homogeneous field of scientific inquiry or is it an expression of a particular science policy agenda?

## Research aims:

- To map and compare research practices in different areas of stem cell science in British and German laboratories.
- To present case studies on the ways in which stem cell science is influenced by social factors such as legal regulation, ethical discourses and science policies.
- To analyse the relationship between international scientific achievements and the formulation of local and national research agendas.
- To evaluate how national and EU regulation, economics, ethics and local morality, shape science pathways and research practices.

## Methods:

- Ethnographic observations in laboratories involved in research on embryonic and adult stem cells, and in clinical trials using stem cells in heart repair in Britain and in Germany.
- In-depth interviews with team members and representatives from funding agencies and commercial research.
- Textual analysis of the scientific and governance literature.

Dimensions of analysis:

On both the national and the cross-national level we:

- Compare research practices on the basis of different types of stem cells used in laboratories.
- Analyse regulatory frameworks and disciplinary approaches to stem cell research, in relation to both applied and basic science.
- Critically examine practitioners' perceptions of and attitudes towards their science.

## Two PhD projects are carried out in association with the project:

### Translational space: stem cell treatment of the heart

Jean Harrington (Egenis)

Heart repair is one of the few areas in which stem cell applications are currently developing fast. Some options have entered into clinical trial phase. As the intersection between biology, physiology, established diagnostic and therapy practices, regulation and ethical issues is crucial for understanding social change, the objective of this study will be to produce a critical discussion of stem cell biotechnology and its practical and conceptual effects. This Ph.D. project will be presented through a detailed case study on the emerging science and its effect on established medical practices and concepts. It will also cover the mutual influence between the laboratory and the clinic and the impact of regulation.

## EU stem cells: a case study in scientific cooperation

Marco Liverani (Egenis)

In the last decade biomedicine has emerged as a crucial area for improving the performance and competitiveness of European scientific research. As a result the EU has promoted initiatives and networks in order to facilitate coordinated efforts across laboratories and institutes of member countries. However, striking differences between national profiles in regulation and resulting scientific practices appear to counteract the establishment of a homogeneous European platform for biomedical research. This project aims to explore the dynamics of co-operation and integration in stem cell science within the EU framework programme of research and development.

### Publications:

Hauskeller, C (2002) (ed.) *Humane Stammzellen - therapeutische Optionen, ökonomische Perspektiven, mediale Vermittlung*, Lengerich: Pabst Science Publishers.

Hauskeller, C (2004) How traditions of ethical reasoning and institutional processes shape stem cell research in the UK, *Journal of Medicine and Philosophy*, 29, 5: pp.509-532.

Hauskeller, C (2005) Überlegungen zur Institutionalisierung moralischer Entscheidungsprozesse in der Klinik, *Erwägen Wissen Ethik*, 16, 1 pp.33-35.

Hauskeller, C (2005) with Bender, Wolfgang and Manzei, Alexandra. (eds.) *Crossing Borders. Grenzüberschreitungen: Cultural Religious and Political Differences Concerning Stem Cell Research. A Global Approach*. Münster: Agenda Verlag.

Hauskeller, C (2006) Menschenwürde, Freiheit der Forschung und Missbrauchsgefahr, in Berlin-Brandenburgische Academy of the Sciences (eds.) *Stem Cell Supplement to the Gene Technology Report*, pp. 141-164.

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# The national and international policy environment for genomics

**Principal investigator:** Joyce Tait (Innogen)  
**Research staff:** Catherine Lyall (Innogen)  
**Associated staff:** David Wield (Innogen), Graeme Laurie (Innogen)

## Research aims:

This project sought greater understanding of some of the governance challenges posed by the life sciences. It explored whether new technologies (such as genomics) require new policy instruments and examined the links between governance and the creation of regulatory frameworks (including the extent to which the regulatory regime is being updated to take account of technological advances).

## Methods:

Themes around the multi-level, multi-actor governance of innovation were explored via a number of routes including an edited book, workshops and conference sessions. Methods included documentary analysis (academic journal articles, policy documents and press articles) and in-depth interviews with relevant actors.

## Key findings:

- Through a study of a number of UK government - industry “task forces” and global developments in drug regulation, we identified two opposing trends in play which suggests that there are actually limits to the all pervasive notion of governance.
- This project extended the knowledge domain of multi-level governance studies, and developed theoretical links between the political studies and innovation studies approaches to the governance of science and technology.
- An international network of researchers working in fields related to the governance of science and innovation developed as a result of activities organised under the aegis of this project.
- The multi-faceted policy and regulatory situation that applies to the life sciences is leading to the existence of a government – governance continuum where different aspects of genomics and life science technologies sit at different points; contrasting the enduring role of the state in controlling and framing the context for the implementation of innovations in life sciences through the regulatory system with the more participative forms of policy-making being fostered to promote national competitiveness and encourage public acceptance of new technologies.
- This raises questions about how “joined up” it is reasonable to expect policies to be for quite distinct purposes (in the case of the life science industries, regulation vs. innovation and promotion).

This leads to tensions in the governance of the life sciences where policy-makers need simultaneously to:

- Engage with a wider range of stakeholders:
- Base decisions on evidence
- Reconcile conflicting views of that evidence in order to deliver greater transparency and understanding of new technology to wider publics and greater accountability of producers and users of that technology

## Publications:

Lyall, C. (2007), Governing Genomics: New Governance Tools for New Technologies? *Technology Analysis and Strategic Management*, 19/3, pp. 365-382.

Lyall, C. (2007), Changing boundaries: the role of policy networks in the multi-level governance of science and innovation, *Science and Public Policy*, 34/1, pp. 3-14.

Lyall C. and Tait J. (2004) Foresight in a Multi-level Governance Structure: Policy Integration and Communication, *Science and Public Policy*, 31/1, pp. 27-37.

Lyall C. and Tait J. (eds.) (2005), *New Modes of Governance: Developing an Integrated Policy Approach to Science, Technology, Risk and the Environment*, Aldershot: Ashgate.

Lyall C., Pappiannou, T. and Smith, J. (eds), *The Limits to Governance: The Challenge of Policy-making for the Life Sciences* (in preparation).

Tait J., Chataway J., Lyall C. and Wield D. (2006) Governance, policy and industry strategies: pharmaceuticals and agro-biotechnology in Dosi, G. and Mazzucato, M. (eds.) *Knowledge Accumulation and Industry Evolution: The Case of Pharma-Biotech*, Cambridge: Cambridge University Press, p. 24

Lyall C. and Tait J. (2005), Shifting policy debates and the implications for governance in Lyall C. and Tait J. (eds.) *New Modes of Governance: Developing an Integrated Policy Approach to Science, Technology, Risk and the Environment*, Aldershot: Ashgate, p.15

Tait J. and Lyall, C. (2005), A new mode of governance for science, technology and innovation? in Lyall C. and Tait J. (eds.) *New Modes of Governance: Developing an Integrated Policy Approach to Science, Technology, Risk and the Environment*, Aldershot: Ashgate, p. 12

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# Development and Sustainability

Contemporary life sciences hold a special interest for the developing world. In part, this is because they hold plausible promises of health and agricultural improvement, for example through novel vaccine programmes and through advances in crop development. But there are also worries that familiar stories of exploitation will arise again. For example, with the rise of global drug markets, fears circulate that new products may be tested in developing-country populations without all the safeguards expected in the west. At the same time, there is a danger that the attractive link between life-science innovations and socio-economic development could lead to the ecological consequences of these new technologies being overlooked.

# Exploring the power of knowledge and technology flows in developing countries

**Principal investigators:** Joanna Chataway (Innogen), James Smith (Innogen)  
**Research associates:** Aparna Joshi, Kalpana Chaturvedi, Matthew Harsh (Innogen), Norman Clark, David Wield (Innogen)

## Research aims:

The central focus of Innogen research in developing countries is on the role partnerships play in driving research, innovation, technology transfer and development embedded within crosscutting themes of governance and globalisation and public engagement with science.

## Methods:

Our methodology was fieldwork led. Methods include in-depth interviews with senior scientists, institutional managers, NGOs, policymakers, farmers and users. We have also used participant observation and other ethnographic techniques when working with scientists and smallholder farmers. Finally, we have worked as much as possible in collaboration with research, practitioners and policymakers engaged in science, technology and development

## Key findings:

- Our overriding concern has been to interrogate the conceptual apparatus of 'innovation systems' as a tool to analyse and to shape policy in developing countries. We have sought to move beyond an innovation systems approach and look more deeply into the politics and power of innovation itself. Our research has underlined that innovation systems approaches provide a sound framework for analysis and remedial policy action. Weaknesses are apparent, however, 'everything is important' and a lack of methodology highlights a lack of analytical precision. There is a further risk that innovation systems accrue 'normative weight' and become valued as a concept for their own sake.
- To this end we have sought to use our case studies to seek conceptual clarification of innovation systems. We have sought to interrelate key concerns from development studies, including 'power', 'knowledge' and 'participation' with innovation systems analyses. We have further sought to inject place, space and locality within innovation systems. A further concern has been to examine the dynamics between firm or initiative level actions/capacities and broader system.
- More specifically, projects 3 and 4 have enabled us to more precisely conceptualise North-South product-based R&D partnerships as complex, differentiated and context specific. The emergence of this new breed of partnerships operating with large degrees of autonomy from multilateral organisations, such as the United Nations, are the outcome of an interaction between local and international political and economic contexts.
- Second, these partnerships merge the public and the private in some important respects and force us to think about the ways in which we use those terms and what is conveyed by their use. The 'privatisation' of the public, with public sector organisations behaving in very similar ways to firms, and the emergence of organisations which have good claim to be serving the public interest but which behave as firms point to the need to develop new typologies and understandings of public and private.
- Third, the issue of access is key. Our work on agri-biotech demonstrates clearly that 'linear models' fail to deliver access to new technologies even when science and technological capabilities are improved. But the relationship between improved technological capacity and improved innovation in the South and access are poorly theorised. Hence, our research has focused on moving beyond innovation systems, away from understanding how things should work, towards understanding why things do not work. This will be the starting point for our work in Innogen phase two.

## Publications:

We have successfully fed into several important policymaking fora, advising government departments, NGOs and other policy-makers in Africa, North America and Europe and have had dealings with DFID, the World Bank, IDRC/CIDA and NEPAD amongst others institutions. We have also been active in disseminating our research at international conferences and workshops. See: [www.innogen.ac.uk](http://www.innogen.ac.uk) for details of policy documents and reports.

J. Smith, N. Clark and J. Mugabe (2005) *Governing Agricultural Biotechnology in Sub-Saharan Africa*, ACTS Press

J. Smith (2005) 'Globalising vulnerability: Impacts of subsidies and unfair trade on developing country agriculture', in R. Hester (ed.) *Modern Agricultural Practices: their environmental, social and public health impacts* Society of Chemistry Press, York

M. Mackintosh, J. Chataway and M Wuyts (2007) "Promoting innovation, productivity and industrial growth and reducing poverty: Bridging the Policy gap" *The European Journal of Development Research*, Vol. 19, No. 1 pp. 1-12

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J. Smith (2005) 'Context-bound knowledge production, capacity building and new product networks', *Journal of International Development*, Vol. 17(5)

J. Chataway, S. Brusoni, E. Cacciatori, R. Hanlin and L. Orsenigo (2007), 'The International AIDS Vaccine Initiative (IAVI) in a changing landscape of vaccine development: a public private partnership as knowledge broker and integrator', *European Journal of Development Research*, 19, 1, 100-117.

J. Chataway, K. Chaturvedi, R. Hanlin, J. Mugwagwa, J. Smith and J. Wield (2007), 'Building the Case for National Systems of Health Innovation', A Background Policy Paper prepared for NEPAD in advance of the AMCOST meeting and the African Summit January 2007.

J. C. Chataway and J. Smith (2006), 'The International AIDS Vaccine Initiative (IAVI): Is it Getting New Science and Technology to the World's Neglected Majority?' *World Development*, 34, 1, 16-30.

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# Institutional impacts of north-south partnerships in agricultural biotechnology

**Principal investigator:** Joanna Chataway (Innogen)  
**Co-investigator:** David Wield (Innogen)  
**Co-investigator and research fellow:** Seife Ayele (Innogen)  
**Project funder:** ESRC Science in Society programme

## Background:

The study investigated partnership projects formed between agricultural research institutions and non-profit and private sector participants from African countries (south), from developed countries (north) as well as multilateral organisations. It looked at several under-explored aspects of such partnerships: their characteristics, and the contributions they made to the development of scientific and technical capabilities, to policy development on agricultural biotechnology, and to processes in technology transfer and development.

## Research aims:

- How are north-south partnerships in agricultural biotechnology set up and what core technology transfer and development processes do they undertake?
- Do these partnerships contribute to the development of institutions, scientific and technical capabilities necessary for agricultural biotechnology?

The study highlighted three positive impacts:

- R&D capacity was created to some extent in all three case studies. Scientific staff were provided with the necessary cutting-edge research tools, and appropriate salaries. These provisions motivated staff to stay in their respective countries and mitigated the risk of 'brain drain'.
- These PPPs also helped the development of policy and institutions for biotechnology. For example, the IRMA project in Kenya catalysed the development of guidelines and regulation for biotechnology.
- The partnerships also assisted the creation of a variety of new products and companies. In Egypt, Biogro International was a new start up company supplying the biological pest control tool called Agerin, the exclusive right for the technology being obtained from AGERI.

## Methods:

The study comprised an in-depth investigation of three case studies: Millet and Sorghum Improvement Initiative in Mali, the Insect Resistant Maize for Africa project in Kenya, and the Agricultural Genetic Engineering Research Institute in Egypt.

## Key findings:

- A workshop on Technology Based Public Private Partnerships and Innovation Systems in African Agriculture was held on 19th November 2004 in London.
- Several presentations were given at international and national forums, including at the *Africa-Canada-UK Experience: Building Science and Technology Capacity with African Partners*, 30 Jan – 1 Feb 2005 in London (Wield, Chataway and Smith); at World Bank Workshop, Washington (Chataway); and in Cairo/Egypt and at CESAGEN International Conference, London (Ayele).
- New research ideas have emerged from this project. Chataway, Wield and Ayele have been awarded a £46K grant by the ESRC Science in Society Programme to undertake research on the 'regulatory practices and challenges of the African crop biotechnology sector'.
- This study contributed to the innovation systems analysis, a valuable conceptual tool to look at the way different organisations and institutions interact as part of the overall innovation process. Findings also challenge some of the more traditional frameworks for explaining the emergence of PPPs. Transaction cost analysis and resource based theories, commonly used to explain partnerships in industrially developed contexts do not adequately explain the emergence of this type of north-south PPP.
- Motivations and incentives require conceptualizing in ways that bring together analytical frameworks used to understand public sector agricultural R&D structures, international aid institutions and private sector incentives.

## Publications:

Ayele, S., Chataway, J. and Wield, D. (2006). Partnerships in African Crop Biotech, *Nature Biotechnology*, 24, pp. 619-621.  
Ayele, S. and Wield, D. (2005) Science and Technology Capacity Building and Partnership in the African Agriculture: Perspectives on Mali and Egypt in the *Journal of International Development*, Vol. 17 No 5.  
Chataway, J. (2005). Is it possible to create pro-poor agriculture-related biotechnology? *Journal of International Development*, 17, No 5, pp. 597-610.  
Ayele, S. (2005). Biotechnology generation, delivery and adoption: the case of Bt bio-pesticide in Egypt, *International Journal of Technology Management and Sustainable Development*, Vol. 4. No 2, pp.75-91.  
Ayele, S., Chataway, J., Hall, A., and Smith, J. (2005) (Editors). *Perspective on Institutions, Agricultural Biotechnologies and Development*. *Journal of International Development*, Vol. 17 No 5

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# Issues involved in diffusion of knowledge through migration of scientific labour in India

**Principal Investigator:** David Wield (Innogen)  
**Research Fellow:** Dinar Kale (Innogen)  
**Associated Staff:** Joanna Chataway (Innogen), Paul Quintas and Steve Little (Open University Business School)  
**Project funder:** ESRC Science in Society Programme

## Background:

In the past, 'brain drain' has proved to be a big curse for developing countries like India and China but in the emerging global competitive environment, the brain drain can provide crucial advantage to these formerly backward regions. Through successful diffusion of knowledge the communities of such scientists and engineers can provide the skill and know-how needed to help local firms shift higher value added activities. Such 'knowledge transfer' played an important role, for example, in the emergence of firms in South Korea and Taiwan to as global leaders in IT production.

## Research aims:

- This project explores the dynamics of scientific labour markets and its implications for international knowledge transfer.
- The project focuses on the reverse brain back to one country: India, and back into one industry, pharmaceuticals.
- Our previous research suggested that Indian firms are developing capabilities in innovative R&D by hiring Indian scientists working in multinational firms' R&D laboratories. Building on that this project explored process of knowledge transfer through interviews with scientists who have moved back from the US to work in innovative Indian pharmaceutical firms.

## Key findings:

### Brain circulation:

- India has suffered massive brain drain over the decades, mostly in the form of the migration of scientists and engineers to technologically advanced countries. These emigrants have often enjoyed impressive professional economic success. However, economic development and firms' strategies have played a key role in converting brain drain into brain circulation, with the success of the pharmaceutical industry resulting in the movement of non-resident Indians back to India.
- Firms are trying to fill knowledge gaps by hiring Indian scientists based in the United States and the UK, and working for major pharmaceutical firms. However, they are also realising that hiring scientists is not sufficient – such knowledge must also be assimilated, and made useful.

### Assimilation of the knowledge:

- Scientists from two generations are returning to work in Indian firms – junior scientists who have recently finished their doctoral or post-doctoral training, and senior scientists with extensive experience. The former, who are mostly concerned with learning news skills, find assimilation comparatively easy.
- There is also a mismatch between the broader requirements of Indian firms – for example, skills associated with 'whole drug discovery' – and the narrower sets of skills possessed by returning scientists, most of whom have specialised knowledge in particular disciplines or therapeutic areas.

### Working cultures:

- Differences in the working cultures of Indian and western firms are an important issue – especially in the case of returning senior scientists, used to professionally managed organisations. By contrast, most Indian firms are family-owned and controlled, and strong on 'process' research and development skills - the legacy of the 'generic market' mindset associated with the era of 'weak' patents.

### Social infrastructure:

- The research also shows the importance of social infrastructure on the decisions of scientists based in the United States to return to India, which suggests an important role for the government. Indian firms have responded to this issue by adopting global R&D practices, with firms introducing more open management structures, and offering junior scientists the chance to develop management and leadership experience. Firms provided support to returnees to adjust to their new environment by facilitating settling down in a new place of living. However the findings also suggest that firms require support from government policy in attracting returnees.

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# Plants and the bioeconomy

**Research fellow:** Emma Frow (Genomics Forum)

## Background:

Plants have a great effect on our livelihoods: from the food we eat to the air we breathe and the landscapes we admire, they are incorporated into the fabric of society in a number of quite different ways. Perhaps unsurprisingly, plants are also central to a number of social and policy challenges facing the world today, including climate change, food security, energy supplies, and human health and well-being. The ways in which humans choose to interact with plants and the natural environment will have a great bearing on our ability to meet these challenges.

From a scientific perspective, new technologies such as genomics are changing our understanding of how plants grow and develop in different environments — for example, how they respond to abiotic stresses such as drought, and how they interact with other plant, animal and microbial species to stabilize nutrient cycling processes. Such information has the potential to inform and influence our approach to issues including sustainable agriculture, environmental monitoring and biodiversity conservation. Consistent with this, terms such as the ‘bioeconomy’ are gaining increased visibility in policy circles: new technologies and the growing ability to harness natural, biological processes for practical applications are seen as key to providing sustainable options for sectors including health, industry, environment, agriculture and energy.

Moving towards a more sustainable, bio-based economy is predicted to involve the convergence of a number of research domains, technologies, infrastructures and government practices. In practice, areas of convergence among traditionally distinct sectors (e.g. agriculture and energy) may hinge on different or novel uses for plant material and biomass. How might improvements in our understanding of plant systems and our ability to manipulate plant material for different purposes influence the development of a sustainable bioeconomy? Can the development of a bio-based economy help to reconcile the tension between economic growth and environmental sustainability? This work programme run by the Genomics Forum aims to explore the relationship between cutting-edge research in plant genomics and the wider socio-political context of the bioeconomy.

## Research aims:

This work programme aims to map and synthesize research findings and policy developments relating to plant genomics and the bioeconomy from across a wide range of sources, providing overviews of:

- Ways in which new technologies such as genomics are changing our understanding of plant systems.
- Evolving concepts of sustainability, consumption and management of natural resources.
- Current UK/EU policy and regulatory frameworks relating to plant systems and plant materials in sectors central to the bioeconomy, including agriculture, energy, industry, natural resource management and the environment.

The two principal themes for this workstream are (1) conservation and biodiversity, and (2) farming and the bioeconomy. A number of specific case studies are being explored with respect to these themes (e.g. bioenergy, synthetic biology).

## Key preliminary findings:

This is an ongoing work programme, initiated in mid-2006 and due to finish in July 2009. Series of interdisciplinary workshops and expert meetings are designed to bring together researchers from across the natural and social sciences, as well as policy-makers and representatives from industry and NGOs.

The content and activities of this work programme are overseen by an external steering committee with the following members: David Ingram (*ESRC Genomics Forum Advisory Board*), Wayne Powell (*National Institute of Agricultural Botany*), Deryck Steer (*Joint Nature Conservation Committee*), Johannes Vogel (*Natural History Museum*) and Steve Yearley (*ESRC Genomics Forum*).

## Wider implications for policy:

A number of policy-relevant aims are associated with this work programme:

- To explore whether plants might offer a productive way of re-shaping the tension between economic growth and environmental sustainability.
- To identify research strategies, policies and planning considerations that might influence the development of a sustainable, bio-based economy.
- To identify specific examples where research findings from across the natural and social sciences can be integrated to promote informed decision-making.

## Publications:

Regularly updated working papers and meeting reports relating to this work programme are available to download from [www.genomicsforum.ac.uk/default.aspx?pagelid=116](http://www.genomicsforum.ac.uk/default.aspx?pagelid=116).

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# Plant genomics, commercialisation and environmental knowledge

**Principal investigators:** Brian Wynne (Cesagen), Claire Waterton (Cesagen), Jane Taylor (Cesagen),  
**Research associates:** Katrina Stengel (Cesagen), Mercy Kamara (Cesagen)

## Background:

Plant genetics research has always depended upon both private and public funding, intertwined. Historically, any boundary between basic and applied research in the plant sciences has always been blurred - as has the common distinction between 'public' and 'private' science. In the last few decades however, commercial visions in plant sciences research as elsewhere have intensified. The intensification of commercial relationships within the plant sciences can be understood in the light of wider structural changes affecting science generally. These have provoked controversy over the status and role of public research institutions, and they have also prompted questions particular to the UK plant sciences – asking in what ways might moves to privatise research laboratories also shape the kinds of scientific knowledge produced? The main UK biosciences funding body, the BBSRC, has thus looked to define 'public good science' in science policy. Against a historical background in which science was assumed to evolve purely according to its own objective logic, thus automatically a public good, this project was developed to explore these factors, and to help clarify any new dimensions impinging on the long-standing tension between the planning of science in reflection of social priorities, and the independence of science seen as an essential condition of its social value.

## Research aims and methods:

- To explore through in-depth semi-structured interview and participant observation methods, the ways that UK plant scientists experience, define and respond to these shifting broader cultures and policies of knowledge production;
- To chart the ways in which basic and applied, and private and public science, were distinguished if at all in scientific practice and reflection;
- To examine what working notions of 'public good science' are used by scientific practitioners, and to work out how to identify what implicit ideas of 'the public', 'public needs', and 'public capacities' inform these sciences today;
- To identify whether these changes of network relations and influences across the plant sciences might be subtly influencing the epistemic practical cultures of these disciplines.

## Key findings:

- Contrary to predominant understandings, the intensification of commercial cultures on scientific research is not only manifested by such 'obvious' processes as commercial contracts or academic start-up commercial companies. Research funded by public bodies may also be shaped less directly, by commercial pressures, imaginations and expectations.
- Scientists are continually aware of and wrestling with the tensions between the expectations of funders and policy networks, and their own felt need to defend a space for research independence and autonomy. There is a sense that such debates and discussions should be facilitated more as part of the internal 'public' currency of scientific research communities.
- It seems clear (though not yet quantified) that typical plant scientific researchers today spend more time in relation to commercial actors of various sorts as an integral part of their scientific research activities.
- One important concern typically expressed by scientists is a sense of erosion of freedom to pursue unconventional diverse questions and possible trajectories. This is not only due to direct commercial expectations alone, but also to standardisation around big high-output platform research technologies and model species. These views can be identified with the principles indicated in the next bullet-point.
- In terms of expressed policy concerns to develop 'public good' plant sciences, UK research policy has made commitments to diversify crop science research from the vertically-integrated and rather monopolistic global corporate-led genetic manipulation paradigm. This resonates well with deliberate diversity and versatility recognised in science policy research literature as a public good science principle.
- A substantive form of epistemic influence of commercial cultures on the intellectual shaping of UK plant genomics-related sciences (this is also being investigated internationally), is over the scientific imagination as to what is a viable pay-back period for a research question's investigation. Such practical scientific timescales seem to have shortened under more commercial imperatives. As these shorten, so too less adventurous projects appear more attractive.
- Like other fields of biosciences, plant sciences are undergoing transformations of their organisational and intellectual frames. Commercial cultures in science are a part of this, but not by any means the sole cause.

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A link to this project website is at [www.lancs.ac.uk/fss/cesagen/shiftingcultures/](http://www.lancs.ac.uk/fss/cesagen/shiftingcultures/)

# Regulatory practices and challenges of the African crop biotechnology sector

**Principal investigator:** Joanna Chataway (Innogen)  
**Research associates:** Seife Ayele (Co-investigator and Research Fellow, Innogen) and David Wield (Co-investigator, Innogen)  
**Project funder:** ESRC Science and Society programme

## Background:

This study examined the regulatory systems of crop biotechnology in Ethiopia, Kenya and South Africa. It identified and assessed the nature, and causes of regulatory progress and problems, in particular whether countries had sufficient capabilities and capacities to construct governance national and regional systems.

## Research aims:

The research questions were:

- What is the nature, and what is the extent, of regulatory problems?
- Do these emerge from an inadequacy or inconsistency within policy and guidelines and/or from structural bureaucracy?

## Methods:

The core methodology was an in-depth investigation of three national biosafety systems.

## Key findings:

Highlights of some of the key findings and conclusions were that:

- There is evidence of significant innovation in regulatory practices and routines, achieved through the concerted efforts of internal learning and a series of capacity-building initiatives.
- Institutionalising the structures and rules of GMO governance is contested. In each of the countries studied, a dominant protagonist has emerged but there is sufficient ground for decisions on GMO activities to be disputed. It is clear that different stakeholders perceive risk regulation from quite radically different perspectives and the notion of risk is related to different factors, for example, loss of biodiversity, control of national natural resources, threat to trade relations and investment in science and technology infrastructure.
- Facilitating intra-African trade in GM products is a key challenge. National differences over the scope of regulation and criteria for decision-making over GMOs and the lack of a single model for biosafety systems to converge are making the biosafety system harmonisation process at Africa level more difficult.

These findings echo the difficulties experienced in Europe and other parts of the world of constructing regionally harmonised biosafety regulatory systems. However, African countries face extreme constraints in scientific and technical resource. Thus, whilst there clearly are problems in implementing regional systems, there are also more pressures to succeed in this endeavour.

Seife Ayele presented papers entitled:

- *Biodiversity and Biosafety Systems Building in Africa*, at the African Studies Association 49<sup>th</sup> Annual Meeting, (Re) Thinking Africa and the World: Internal Reflections, External Responses, San Francisco, CA., November 16 – 19, 2006.
- *GMO Regulatory Practices: Experiences from Ethiopia, Kenya and South Africa* at the ESRC Innogen Centre Annual Conference 2006: Genomics for Development? The Life Sciences and Poverty Reduction, 5-6 September, London.
- *The Legitimation of GMO Governance in Africa* at the workshop *Governing Technology for Development: from theory to practice and back again*, London, 31 March – 01 April 2006.
- *Innovation in GM crop regulation in Africa* at the Development Studies Association Annual Conference 2005, 'Connecting People and Places: challenges and opportunities for development', Milton Keynes, UK, 7<sup>th</sup>-9<sup>th</sup> September.

Also:

- David Wield referred to the research in his presentation at the EU Presidency Invitee Conference for EU policy-makers 'The Future of Precaution for GM Crops' Vienna, April 16-17, 2006.
- An international workshop entitled: *Governing Technology for Development: from theory to practice and back again* (London, 31 March – 01 April 2006) was organised.
- A session on 'Agriculture and Innovation' was also organised at the *ESRC Innogen Centre Annual Conference 2006: Genomics for Development? The Life Sciences and Poverty Reduction*, 5-6 September, London.
- Chataway is currently supervising a PhD student whose work draws on analysis developed in this project.
- Chataway and Ayele are also supervising another PhD student looking at Kenyan biotechnology regulations.

## Publications:

Ayele, Seife (2007 forthcoming). Biotechnology and Biodiversity Debates and Policies in Africa, *International Journal of Biotechnology*.

Ayele, S. (2007) The Legitimation of GMO Governance in Africa, *Science and Public Policy*. Vol. 34, No. 4, pp.239-249.

Ayele, S. (2007) IRMA: a science and technology-based intervention to reduce hunger? Case study teaching material, TU870, *Capacities for Managing Development*, Open University.

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# The adoption and deployment of molecular marker-assisted breeding technologies

**Research fellow:** David Reece (Egenis)  
**Associated research staff:** Steve Hughes (Egenis)

## Research aims:

- In what ways will genomics affect the livelihoods of poor rural people in developing countries? How can it be used to help alleviate rural poverty?
- In what ways can indigenous knowledge contribute to advances in genomics?
- How easily can (public sector) Agricultural Science use such arrangements to gain access to genomic-based technologies?

## Key findings:

- It has been noted that while marker assisted selection has been available for fifteen years, the literature includes few or no reports of its use leading to released germplasm or varieties.
- A review of UK research relevant to crop science prepared for the Biotechnology and Biological Sciences Research Council states bluntly that 'there is little or no evidence to date that the high level of investment in plant science is having a significant impact on strategic and applied research in crop science.'

Reasons for limited impact of marker assisted selection:

- Inadequate links between pure science and applied science, in particular links between breeders and molecular biologists.
- Global decline in academic plant breeding, with resources being transferred to molecular genetics and transgenic technologies.
- The professionals who are needed to obtain practical benefit from advances in these technologies are no longer being trained in sufficient numbers. The shortage of plant breeders means that the potential contribution offered by molecular markers can only partially be realised.

Location of Research Institutes:

- The high cost of molecular marker discovery imposes an unavoidable pressure for centralisation (to capture economies of scale,) because the process requires expert scientific management and high cost equipment. Each such facility could serve breeding programmes throughout the world, so long as each 'client' breeding programme was equipped with the infrastructure necessary for electronic communication and for analysing and interpreting DNA sequence data.
- The diversity of circumstances and agro-environments cultivated by poor farmers means that they require a diverse and decentralised research and plant breeding system. The objectives of any breeding programme should be informed by the characteristics preferred by the farmers who are intended to grow the crop varieties that the programme will produce. Conversations between farmers and breeders can take place more easily if the breeding programme is based near to the farms of its clients.
- In view of the high cost of marker discovery, molecular marker researchers must maintain close links with plant breeders throughout the world, in order to ensure that the markers that they discover are for traits that are indeed of practical importance and are available in breeding lines that show good combining ability with elite cultivars.

Knowledge sharing & infrastructure:

- Professionals may be reluctant to share the knowledge that constitutes their most precious asset. Many professionals have little respect for those outside their field, even when all parties are supposedly seeking the same goal, and so are reluctant to learn from people outside their own profession.
- The discovery and use of valuable markers requires productive collaboration between scientists trained in molecular biology on the one hand, and applied sciences like plant breeding and genetics, pathology and entomology on the other. Since practitioners of each of these specialisms constitute distinct communities, deliberate efforts are required to integrate their work into a coherent whole. Effective leadership is required both to bridge the gap between the disciplines that are involved and to overcome the additional barriers created by scientists working in different institutions and cultures. Perhaps the primary task is that of building trust between the various researchers involved. Achieving this requires a commitment to spend a reasonable amount of time together.

## Publications:

Reece, JD and Haribabu, E, (2007) Genes to feed the world: The weakest link? *Food Policy* 32 pp. 459-479

Reece, JD, (2007) Does genomics empower resource-poor farmers? Some critical questions and experiences *Agricultural Systems* 94 pp. 553-565

Reece, JD, (2007) What enables innovation in the private sector? Lessons from the development of salt tolerant hybrid rice *Journal of International Development* 19, pp. 853-863

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A link to the project website is at [www.ex.ac.uk/egenis/research](http://www.ex.ac.uk/egenis/research)



# Understandings of Nature, Humanity and Society

Researchers in the EGN recognise that deep questions about our identity and individuality are raised by new thinking in the life sciences. Can we now be said to be responsible for our own genetic make-up or even of the make-up of our children? Things that were once thought of as part of fate now seem to be under our control. What are the consequences of this redistribution of responsibility and how do different actors – commercial testing companies, regulatory agencies and the legal system – respond to these new possibilities.

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## Animals and genomics

**Research fellow:** Matthew Harvey (Genomics Forum)

### Background:

This project began with the observation that little attention within the social sciences had been paid to the use of animals in genomics, yet animals are integral to many advances in the field. To stimulate and coordinate interest, this project sought to bring EGN researchers with an interest in animal genomics together with academics from other research centres and disciplines, and genomics scientists. The broad aim was to build capacity for thinking through and developing animal genomics both social scientifically and technically.

### Research aims:

The following substantive themes underscored discussion and outputs:

- To consider the context and shaping of the science of animal genomics, including direct research on animals (e.g. in agricultural applications) and other areas where animals are used (e.g. in human health research);
- Reflect on the implications of this work for the social position and cultural construction of animals and human-animal relationships; and
- Address policy issues for regulating/governing animal genomics and for exploiting animal genomic research.

### Methods:

An initial scoping meeting was held (December 2004) followed by a multi-disciplinary expert workshop (April 2006). A report of the scoping meeting and a lay report of the expert workshop can be accessed from the Genomics Forum website ([www.genomicsforum.ac.uk](http://www.genomicsforum.ac.uk)). Workshop papers contributed toward a special issue of the journal *Genomics, Society and Policy* (details below).

### Key findings:

- Social scientific study of animal genomics and biotechnology is now expanding. Initial work concentrated on certain cases – xenotransplantation, genetic modification, cloning – that had been opened up to public debate, or that seemed particularly problematic in terms of ethics or regulation, and usually concentrated on what these practices might mean for people. A broader research agenda that captures a wider range of genomic sciences and which considers the human, the animal, and the human-animal conceptual coupling is now under way.
- Social scientific attention often focuses on vertical (or within species) genomics, such as functional genomics and the performance of farm animals, or model organisms for human disease states. Less attention is paid to horizontal (or across species) genomics, yet this work has at least equal implications for understandings of the social position and construction of animals, and for regulatory and policy issues. For example, horizontal projects (e.g. DNA barcoding and comparative genomics) contribute to the recording and cataloguing of biodiversity, the classification of organisms, their conservation and regulatory status, and to debates on the continuity and difference between humans and other animals.
- The regulatory status of different creations within animal biotechnology is not yet fixed. This lack of clarity offers the prospect of creating socially robust policy and regulatory agendas.
- Other recurrent themes from discussions held through the project include: whether animal genomics merely updates and extends established debates about the use of animals in science and society, or whether it also raises novel issues; whether animal genomic science is reductive; the extent to which it aligns with narratives of instrumentalism; whether animal genomics alters both what we can and do know about an animal, and the animal that is known; and whether and in what ways animal genomics sits in tension with animal welfare.

### Publications:

Special issue: Animal Genomes, Bodies and Tissue in Science and Society, *Genomics, Society and Policy*, 2007, Vol. 3, No. 2.

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# A cultural history of heredity

**Research fellow:** Staffan Müller-Wille (Egenis)  
**Project funder:** Arts and Humanities Research Council (AHRC)

*The project is carried out in close collaboration with the Max-Planck-Institute for the History of Science.*

## Research aims:

- The project focuses on the cultural practices in which knowledge of heredity was generated and in which it unfolded its effects over the last four hundred years.
- We consider knowledge of heredity to be more than the science of genetics. Over the centuries a concept of heredity evolved in all areas of modern society, including medicine, jurisdiction and politics. The aim of the project is to explore the changing practices, standards, and architectures of this knowledge regime with a long term perspective.

## Key findings:

- As a biological concept, heredity only came into use in the early nineteenth century. Before, generation was understood as a singular act of procreation. Hereditary and environmental factors were not really distinguished.
- Heredity was a term that was originally used in legal contexts only, meaning “inheritance” or “succession”. Its use as a metaphor to describe phenomena connected with the reproduction of organisms dates from late eighteenth-century medical texts on familial diseases. It was subsequently adopted in a number of areas like breeding, natural history, anthropology, and public health. This development was fuelled by the transplantation of people and organisms that occurred in the context of urbanization, industrialization, and colonialism.
- By the mid-nineteenth century, heredity had moved into the centre of biological thought. The French psychiatrist Prosper Lucas, and the English naturalists Charles Darwin and Francis Galton were the most important “synthesisers” of current knowledge of heredity. Galton’s notion of “ancestral inheritance”, according to which the inheritance of a person was made of contributions from all its ancestors, proved widely influential among medical practitioners and breeders. The mechanism of inheritance became one of the main concerns of cytologists and developmental biologists at the end of the century.
- The rise of genetics in the early twentieth-century was connected to concerns with the standardization, recombination, and perpetuation of innovations in industrial and administrative contexts, especially agriculture and public health. Much research into heredity in the early twentieth century took place in applied contexts like seed production, breeding yeast and cereals for large-scale beer production, mass-production of vaccines, efforts to further public health, or administration of psychiatric hospitals. Increasing levels of division of labour and bureaucratic control in these areas led to the establishment of a culture of expertise and scientificity.
- An important property of this culture of expertise was its obsession with purity. Purity was an instrument of control, as results could be ‘checked’ against their inputs. It enabled practitioners to ‘fix’ characters and create identifiable and specifiable products. It created a set of discrete and stable life forms, rather than an uncontrolled continuum of variations. And it held a promise to divorce practices from the vagaries of historical tradition. In order to advertise, trade-mark, or patent agricultural or microbiological innovations, production methods had to be made transparent and reliable reproduction guaranteed. Heredity was commodified to become heritability, a marketable quality.
- Mendelism entailed conditions and costs that precluded many areas from adopting it. To do Mendelian experiments, organisms had to be first inbred, then cross-bred, and finally raised in large numbers. Asexual organisms and humans, but also many agriculturally significant animals, like cows, could not be subjected to such a practice. This is one of the main reasons, why animal breeding and clinical medicine became ‘geneticized’ only well after WWII, and why statistical approaches, developed by the so-called biometrical school long before the advent of Mendelism already, persisted in these areas to finally merge with population and quantitative genetics.

## Wider implications for policy:

- Heredity is not an evident phenomenon. It became visible to biology late in its history, as it depended on specialized institutions and practices. Many of the key concepts of modern genetics, like gene or heritability, are therefore difficult to intuit.
- Many of the older ways of thinking about reproduction persist alongside more technical, scientific notions of inheritance. Thinking in terms of generation or ancestral inheritance is still widespread, and also make sense in a lot of contexts, like assisted reproduction or animal breeding.

## Publications:

S. Müller-Wille, Early Mendelism and the subversion of taxonomy: Epistemological obstacles as institutions, *Studies in History and Philosophy of Biological and Biomedical Sciences* 36/3, pp. 465–487  
S. Müller-Wille, From Linnaean Species to Mendelian Factors: Elements of Hybridism, 1751-1870, *Annals of Science* 64/2 (2007), pp. 171–215  
S. Müller-Wille and H.-J. Rheinberger (eds.), *Heredity Produced: At the Crossroads of Biology, Politics, and Culture 1500-1870*, Cambridge, Mass.: MIT Press

## For further information contact:

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# 'Criminal' genes and public policy

**Principal investigator:** Mairi Levitt (Cesagen)  
**Research associate:** Elisa Pieri (Cesagen)

## Background:

Current research on behaviour tries to establish how violence and aggressiveness- that may lead to criminality - could have a genetic component. 'Criminal Genes' and Public Policy' was the first study to consider how genetic factors in aggressiveness and violence might impact on the justice system, public policy and professional practice. It did so by accessing the views of members of the legal profession, social workers and probation officers.

Research in behavioural genetics has traditionally involved the attempt to separate out nature and nurture in order to quantify the influence of one compared with the other. Caspi et al found a significant correlation between levels of MAOA activity and various measures of antisocial behaviour only among young men in the group who had suffered abuse as children. This study demonstrated that it is too simple to separate gene and environment since each constantly influences the other.

Research on the role of genes and environment in anti-social behaviour has highlighted the possibility of specific and personalised environmental interventions, targeting those individuals most 'at risk'.

## Research aims:

- To explore the implications of research into genetic factors in criminal behaviour for practice.
- To explore the implications of research into genetic factors in criminal behaviour for public policy.

## Methods:

This qualitative study has accessed the views of a variety of expert groups who work with those charged with, or 'at risk' of, engaging in criminal and anti-social behaviour. The views of professionals were accessed by running and analysing:

- 7 Focus groups between December 06 and May 07 with Probation Officers, Social Workers, Barristers, Solicitors (2 groups), Law students (2 groups)
- 15 Interviews between August 06 and May 07 with Probation Officers, Social Workers, Barristers, Solicitors, Judges, Criminologists, Geneticists, Clinical Psychiatrists.

The interview and focus group data was analysed using a Grounded Theory approach and the constant comparative method. This analysis is aided by Atlas.ti software for qualitative research.

## Key findings:

The findings were first presented to an invited audience at the project workshop 'Criminal Genes' and Public Policy (London on 17th September 2007). The study found that:

- The professionals' view was that violence and aggression are generated by a complex combination of factors - including social, cultural, and environmental.
- Intervention ought to target social factors that contribute to aggressiveness and violence even if these behaviours were shown to have a genetic component.
- Professionals did not see genetic research as impacting on their work. Some believed that the science had not progressed enough; some thought that genetics could never be a reliable predictor of behaviour, being only one factor among many; others saw the idea of a genetic predisposition as incompatible with the legal system (e.g. undermining the presumption of innocence). Despite its perceived lack of impact, practitioners did not object to funding genetic research into behaviour, but insisted research into other causes of aggressiveness and violence should be prioritised.
- The emphasis on aggressive and antisocial behaviour exacerbates the move towards further control and surveillance of citizens, particularly of those deemed 'risky' who are already over-patrolled. Genetic information relating to behaviour could be slotted into existing systems of profiling and collating information on individuals, including children.
- There was wide support for early intervention through schools to help all young people to manage their emotions more effectively (e.g. anger management classes). Including all children, rather than targeting specific 'at risk' groups, would prevent stigmatisation and labelling.
- Addressing inequalities and lack of opportunities was thought to be vital to tackle criminality, for example, through skills training and partnerships with employers, and by creating community facilities for young people. Participants recognised that the government has made moves in that direction but further funding is needed.
- Funding ought to be moved to early intervention, to prevent problems developing, and away from managing offenders.

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## Genomics and the politics of identity

**Research fellow:** Christine Hauskeller (Egenis)

### Project collaborations:

The Genomics Network's 3 research centres and the Genomics Forum are collaborating to organise a series of workshops between 2007 and 2009, which will focus on the diverse aspects of this overarching theme.

### Research aims:

The aim of this project is to analyze the role of genomics in society.

### Key findings:

- Announcements of what the Human Genome Sequencing Project would deliver claimed that it would tell us what is special about humans and what makes each of us unique. This self-understanding of genomic knowledge was followed in the ethical and social debates accompanying genetics since Asilomar and justified the exceptional treatment of genomic science in regulation and public discourse.
- The investigation of the self-representations of genomics in public declarations of aims and function identified the major role of genomics as the assurance of the identity of the species and of its members, including the marking of social status of individuals. The ethical discussions in amongst experts and public present a similar picture, where traits are often taken as markers for a person and the genome seems to define who and what one is.
- Mapping the actual social uses of genomic knowledge and technologies leads to findings supporting the above interpretation. Social practices involving genes or the genome as a word, a concept or an object are central to understanding its potential to establish what one is. Genomics is the currency in which the borders of what is considered to be human, and the traits of individual representatives of our kind, are negotiated and established.
- In a catch phrase: in its social reality, genomics is all about human identity.

### Publications:

The first findings of this analysis are published as:

Hauskeller, C., (2004) Genes, Genomes and Identity. *Projections on Matter, New Genetics and Society*, 23, 3: pp. 285-299.

Hauskeller, C., The promises of genomics: Only society makes them reality: work in progress.

This work was awarded the Young Scholar Award from the Centre for Ethics & Public Life at Cornell University, NY, in 2006.

The prize winning manuscript is part of the book in progress, 'Genomics and the Politics of Human Identity', which is available on request.

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A link to the project website is at [www.ex.ac.uk/egenis/research](http://www.ex.ac.uk/egenis/research)

## Media, culture and genomics

**Principal investigators:** Jenny Kitzinger (Cesagen), Maureen McNeil (Cesagen)

**Research associates:** Joan Haran (Cesagen), Kate O’Riordan (Cesagen)

### Research aims:

This project set out to develop an empirically grounded conceptual framework for examining the circuits of discourse through which genomics is constituted, by:

- Identifying multiple sites through which this mediation occurs, with a primary focus on the location of the UK’s media within global circuits of communication which also encompass two nation-states of secondary focus, the USA and South Korea;
- Providing a contextualisation of the different media forms under examination and their national and generic specificities;
- Focusing particularly on the discursive circuits of human cloning and stem cell research, as emerging applications of global genomic technoscience which occupy key symbolic terrains in local, national and international policy debates.

This has led to the production and substantiation of our thesis that genomic technoscience is the mediated science ‘par excellence’. That is, the meanings of this technoscience are made in and through the media – from news stories about discoveries, cures and clones, innovative speculative genres like docudramas supplemented with audience interaction, and spectacular Hollywood films about biotechnological futures - through to more intimate experiences of mediation including genetic screening and counselling. We explore this thesis through a number of interlocking case studies in our forthcoming monograph *Human Cloning in the Media* (Routledge: 2007).

### Key findings:

- Genomics in general, and human cloning and stem cell science in particular, are sciences made, contested, and remade in the media.
- Cloning science, in combination with or rigidly demarcated from embryonic stem cell science continues to arouse media controversy in the news, to provide a spectacular focus in Hollywood film and to exercise scientists and media producers over the most effective ways to communicate what is at stake.
- The intersecting (overlapping and competing) interests of media producers, scientists and national legislators operate flexibly and strategically in national and global circuits of genomic discourses.
- Cloning and embryonic stem cell scientists have become proactive and influential in setting media agendas in national and international arenas.
- Genomics and cloning are profoundly gendered in their mediation, privileging the male scientist and obscuring or fragmenting the female provider of ‘raw materials’.
- Audiences and publics perform sophisticated boundary management in the demarcation of science fact and fiction in their consumption and understanding of mediated genomics and cloning discourses.

Themes developed throughout the project outputs are:

- A focus on the temporal and geographical processes of mediation rather than a fixation on particular media platforms or events;
- Exploration of the strategic mobilization of the figure of the scientist, scientific knowledge and institutions by a range of interested parties;
- Critical evaluation of the representation of women’s bodies and interests, or its lack, in the production of particular representations of the terrain of genomics such as therapeutic and reproductive cloning, and stem cell research;
- Exploration of the relationships between media genres and truth claims, and the relative stability of the fact/fiction divide, despite fears to the contrary expressed by proponents of genomic science;
- The rhetorical and material constitution of publics and audiences;
- The use of imagined futures, characterized variously as rational hopes and possibilities or irrational fears.

Broader significance:

- This project has developed a critical analysis of the concept of mediation in relation to genomics that attends both to the persistence of conventional discourses and framing strategies and their strategic reworking in response to moments of innovation or crisis.
- Our critical reflection on the concepts of publics, engagement and communication provides an enriched understanding of the dynamics of science communication, public engagement and policy formulation in a media-saturated social environment.
- The project contributes to current debates and interest in science and society policies by providing an account of the circulation of scientific discourses that takes seriously their textual and visual composition, as well as the social processes of their production and consumption.

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# Reconfigurations of human-animal relations in genomics and beyond (ROAR)

**Principal investigator:** Richard Twine (Cesagen)

## Research aims:

This project has mapped out animal genomics in order to yield a better picture of the potential impacts in the short and long term. It has investigated the place of animals in bioethical discourse, and developed the idea of a 'critical bioethics' through the examination of the relationship between animal and human enhancement. By engaging with natural scientists it has considered how questions of social, economic and ethical context are framed and confronted by animal scientists themselves. Moreover it has appraised the regulatory apparatus in the UK in relation to farm animal genomics. Finally the project has also been a reflective interrogation of the capacities of social science itself conducted historically through an anthropocentric frame.

## Key findings:

- Generally the institutionalised discourse of bioethics provides insufficient space to fully represent views on animal ethics and the social, as opposed to instrumental, value of animals.
- Due to links between human, animal and ecological health there is a need for a closer relationship between bioethics and environmental ethics. In this respect the red/green distinction was found to be unjustifiable and unsustainable.
- Ethical frameworks should adapt to reflect how genomics and related knowledges break down and rationalize the efficiency of bodies across species boundaries.
- A high level of awareness and ethical literacy was found amongst animal scientists interviewed. Ethical debate was present in the 'canteen culture' of animal scientists. Although scientists often see their work as part of social progress narratives such as improving agriculture, their work was found to be uniquely commercially embedded vis-à-vis other areas of science.
- Significant points of conflict were found between animal geneticists and animal welfare scientists, which largely reflect broader debates on the future of agricultural paradigms and the moral value of agricultural animals.
- Animal genomics may encourage a geneticisation of the animal; specifically of animal health, animal behaviour and animal welfare.
- Animal geneticists tend to employ 'continuity' arguments in that prior or contemporary instrumental treatments of animals are seen to justify the application of new technologies.
- Significantly, interview data revealed that genomics does extend the degree of control, precision and manipulative capacities of animal science. QTL mapping may also make a future move to GM more likely.
- Genomics techniques are increasingly seen by commercial ventures as the safe option in light of continued opposition to GM.
- Regulatory foresight of farm animal genomics was found to be minimal.

## Wider implications for policy:

- Bioethical debate on the ethics of emergent technologies in livestock farming requires significant reinvigoration. Bioethics as a discipline requires greater cross-disciplinary input.
- The discontinuation of the AEBC, which was itself largely concerned with non-animal agriculture, has worsened the potential for public debate and contributed to the emergence of a regulatory gap. There is a danger that we now see the development of a lack of future preparedness for the regulation of emergent technologies in livestock farming. A broad body to look at these issues within the pressing context of sustainable farming is recommended. Ways to include diverse publics in such a body should be sought. The environments of animal genomics science which were found to foster internal debate already should be further encouraged in this endeavour. More dialogue between animal science, the sociology of science and the political economy of agriculture is strongly recommended. Animal welfare and nutritional science require an equal input into the commercialisation of animal genomics.

## Publications:

Twine, R (2007) Searching for the Win-Win? - Animals, Genomics and Welfare forthcoming in *International Journal of Sociology of Agriculture and Food*

Twine, R (2007) Animal Genomics and Ambivalence: A Sociology of Animal Bodies in Agricultural Biotechnology *Genomics, Society and Policy* Vol.3, No.2

Twine, R (2007) Thinking Across Species - A Critical Bioethics Approach to Enhancement forthcoming in *Theoretical Medicine and Bioethics*

Twine, R (2006) Agricultural Animals as Targets of Genetic Progress - Engaging with Animal Scientists about the Impact of Genomics in *Ethics and the Politics of Food* by Matthias Kaiser & Marianne Lien eds. Wageningen Academic Publishers

Twine, R (2005) Constructing a Critical Bioethics by Deconstructing Culture/Nature Dualism *Medicine, Health Care and Philosophy*. Vol.8, No.3, pp. 285-295.

## For further information contact:

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A link to the project website is at [www.cesagen.lancs.ac.uk/roar/](http://www.cesagen.lancs.ac.uk/roar/)

# Semantic drift in the dissemination of genomics

**Research fellow:** Christine Hauskeller (Egenis)

## Background:

Semantic studies are useful to analyze relationships between social spheres, because words as names, metaphors, analogies or concepts mediate between them. Central terms and their utilization by those engaged in the dialogues between science and the public, present valuable material for sociological and ethical analysis. Language and textual documentations conserve previous communication processes and in this sense language carries the history and presence of science-society interactions.

However, to describe the present evolution of biomedicine as the result of a negotiation between science and society presupposes that science can be separated from society. Although this may be conceptually possible on the basis of epistemology and the prominence of values such as truth and objectivity, science is a social activity and biomedical research even more so than sciences that are not about humans.

## Research aims:

- To capture, using case studies, the ways in which rhetoric displays both the particular perspectives of the many actors involved in the realization of modern bioscience and their moral intuitions and life-worldly interests.
- To give an account of key terms and concepts used in current genomics and stem cell science in order to reconstruct and understand better the discursive landscapes in which science policy and science-public interactions engage with each other.

## Key findings:

- Many disputed words in biomedical research such as cloning, embryo, gene, or life have no precise meaning. Their meanings change over time and depend on the social context in which they are used. Although this does not usually lead to communication problems within established discourse communities, it affects the wider social debate about biomedical research, where understandings and evaluations between communities often clash.
- Scientists often express a tension between their personal value orientations and their professional role and scientific curiosity. This conscious tension contrasts with the open attempt to rename biomedical practices that have become issues of public debate. Some scientists engage explicitly in the renaming of objects and technologies that feature as problematic in public discourse, and this strategy often fails (pre-embryo/embryo; cell nuclear replacement/cloning; chimera/cybrid). This failure may be due to the fact that biomedical science is insolubly intertwined with practices of human self-understanding. The charged words and the social debate are adequate expressions of the value-load of biomedical enquiry and its applications in medicine and everyday life.

Derived lines of inquiry:

- The ways in which genetic and genomic tests are used in society are all related to understandings of the identity of both the human species and any human individual. The investigation of the border regimes in which genomics is involved is still ongoing.
- A second line of research emerged with respect to testing out the ways in which science is shaped by regulation and social practice. The Egenis project Stem Cell Research in Context follows this line of inquiry, which aims to inform the role of science policy and the societal place of science.

## Publications:

Hauskeller, C (2004) Stammzellforschung und Menschenwürde, in M. Kettner (Ed.), *Politik und Menschenwürde*, Frankfurt am Main: Suhrkamp Verlag.

Hauskeller, C (2005) Science in Touch. Functions of biomedical terminology, *Biology and Philosophy*, 20, 4: 815-835.

Hauskeller, C (2005) The Language of Stem Cell Science in C. Hauskeller, W. Bender, and A. Manzei (Eds.) *Crossing Borders. Grenzüberschreitungen: Cultural Religious and Political Differences Concerning Stem Cell Research. A Global Approach*, Münster: Agenda Verlag, pp. 39-60.

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A link to the project website is at [www.ex.ac.uk/egenis/research](http://www.ex.ac.uk/egenis/research)

# The making of a syndrome: an examination of the clinical, laboratory and family classifications of Rett Syndrome (RTT)

**Investigators:** Angus Clarke (Cesagen), David Ravine, David Cooper, Paul Atkinson (Cesagen), Sharon Whatley, Daniela Pilz, Rachel Butler with Hayley Archer, Julie Evans and Katie Featherstone

**Project co-funder:** The Health Foundation

## Background:

This study provides an ethnography of the laboratory, clinical and family work in the classification of one genetic syndrome - Rett Syndrome. Our focus is to examine the way in which different technologies, clinical judgement, professional knowledge and family work are mobilised and interpreted to establish clinical entities and classifications.

New molecular techniques are being increasingly applied to a wide range of diagnostic classifications relevant to progressive and non-progressive intellectual disability in childhood. However, the use of these molecular technologies can lead to the breakdown of longstanding clinical categories and the generation of a large number of previously unknown anomalous categories of patient. For example, cases classified with the clinical disorder but without the mutation and cases with the mutation but who clinically do not have the disorder (or with an atypical form).

## Research aims:

This project is examining the following areas:

- The evolving laboratory and clinical diagnostic process to describe the complex interactions between laboratory technologies and diagnostic categories.
- The associated shifts in the diagnostic classification of RTT and its related disorders are being mapped.
- The process of clinical and laboratory collaboration are being traced, local, national and international collaborations in the 'making' of a syndrome are being mapped.
- The experience and impact of the process of diagnosis and the use of molecular testing for RTT on family members.
- The personal and practical significance for families in receiving (or not) a diagnostic label.

## Methods:

Our approach breaks new ground in providing empirical data examining professional and family perspectives on the production of new diagnostic materials, their subsequent interpretation in relation to the changing classification of a syndrome and the consequences for individuals and families. We have also gained valuable insights into how these diagnostic categories change in the face of scientific advances.

## Key findings:

- First, given that some clinically typical cases of RTT do not have a mutation in the *MECP2* gene identified, and that some individuals with a non-RTT clinical picture, or occasionally even healthy individuals, may carry a *MECP2* mutation, it can be seen that the addition of a molecular test to a field where diagnosis has previously been based purely on clinical grounds adds in an additional level of complexity. There are anomalous categories – those with classic RTT but no mutation and those with a mutation but a non-RTT clinical picture. Those families, where a child has the clinical picture but where no pathogenic mutation is found, can feel that the diagnostic label has been removed from them – and this can generate strong feelings, often of distress. When a mutation is found in a child, but where the clinical picture is not typical of RTT, feelings of puzzle ment and confusion can arise in the parents.
- Secondly, the new molecular diagnostics for RTT has consequences for the taxonomy of disorders of neurodevelopment. Clinicians working in this area have to refine their system for classifying disease and this becomes operationalised in terms of the circumstances in which a *MECP2* mutation test would be requested. As mutations in functionally related genes cause clinical problems that share some features, the clinician has to learn when to request the *MECP2* test and when to ask for *CDKL5* to be examined. The process of making a differential diagnosis becomes more elaborate.
- The scientists working on this in Cardiff have been accompanied to national and international events and their pattern of building collaborations with colleagues from other centres has been observed. This tracking of the progress of collaborations – shifting alliances in the search for publication in prestigious journals and for financial support from grant-giving bodies – demonstrates how researchers respond to the system within which they are required to operate.
- Overall, this project has had uniquely broad access to a range of family, clinical and scientific sites, allowing us to track developments in the delineation of a fascinating genetic disorder. We show how this has been achieved by interplay between the laboratory and the clinic, and how this in turn impacts upon the clinic and the family.

## For further information contact:

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# The relationship between theories of group membership and inter-group attitudes

**Research fellow:**  
**Associated staff:**

Thomas Morton (Egenis)  
Tom Postmes, Alex Haslam (Psychology, Exeter)

## Research aims:

The aim of this project is two fold. First, we aim to explore how people explain differences between social groups (e.g., based on race/ ethnicity, gender, sexuality) and the contexts within which particular forms of explanation are preferred to others (e.g., when do people see differences between groups as 'natural?'). Second, we aim to explore the consequences of promoting particular forms of explanation for people's behaviour towards others within their social world.

## Methods:

To answer the above questions, we draw on quantitative social-psychological research methods including both surveys and experiments. We have conducted our research using a variety of different populations, including students, members of the general public, school children, and members of specific minority groups in society.

For example:

- Surveys of the general public have examined relationships among beliefs about the causes of gender differences (biology, society), individual differences in prejudice (sexism), and perceptions of gender relations in society.
- Surveys within specific minority communities (e.g., amongst non-heterosexual people) have explored how they define their own identity, what they see the cause of their identity to be, and how the identity definitions and explanations they provide are related to perceived treatment by the mainstream (i.e., the heterosexual majority) and opportunities for social change.
- More controlled experiments have examined how manipulating individual perceptions of the social structure (e.g., perceptions of social inequality and social change) effects explanations for intergroup differences and, reciprocally, how exposure to specific explanations effects attitudes and actions toward others in society.

## Key findings:

- In relation to the question of *when* prejudice is expressed through essentialism, our research shows that this reliably occurs under conditions of social change. That is, when society is perceived to be changing, prejudiced members of the dominant group (e.g., men in the context of gender, whites in the context of race) are more likely to adopt a naturalized perspective on intergroup difference.
- Our research also shows that exposure to essentialist (naturalized) theories reinforces discriminatory attitudes intentions among members of the majority, and can undermine resistance amongst the majority.
- Together, these strands of research suggest a reciprocal relationship between essentialist beliefs and perceptions of the social structure: threats of change to positions of higher status produce essentialist thinking, and exposure to essentialist theories reinforces the social structure. Thus identity motives (e.g., desires to achieve and protect higher status) are likely to guide how people explain the differences they see between groups in society.
- Although this suggests that naturalized presentations of identity feed into social inequality, our research among minority groups suggests that they might also draw on essentialist ideas to challenge their treatment by the majority. For example, thinking about the ways in which their group is marginalized increased support for biological theories of sexuality among sexual minorities, and this in turn increased feelings of personal agency and control. Thus, although minorities might also endorse essentialist theories of difference, the motivations guiding this are likely to be different to the majority.
- Theoretically, this work contributes to recent social psychological work on essentialist beliefs about social categories by providing amore nuanced perspective on when and why people become motivated to see intergroup differences as natural.
- Specifically, our research suggest that essentialist beliefs are not simply a product of individual differences prejudice. Instead support for essentialist theories is also guided by identity concerns—specifically, desires to protect positions of status and dominance by the majority and desires to challenge social exclusion by the minority.
- Practically, this work highlights the political uses of scientific theories and suggests some causes and consequences for understanding human identity and intergroup differences in biological terms.

## Publications:

Morton, T. Hornsey, Blackwood, Louis, Fielding, Mavor, O'Brien, Paasonen, Smith, White (2007), Why do people engage in collective action? Revisiting the role of perceived effectiveness (2007), *Journal of Applied Social Psychology*.

Morton, T. Haslam, S. A., Postmes, T., & Ryan, M. K.(2007), We value what values us: The appeal of identity-affirming science, *Political Psychology*.

Morton, T. Postmes, T., & Jetten, J. (2007), Playing the game: When group success is more important than downgrading deviants., *European Journal of Social Psychology*.

Morton, T. Duck, J.M.(2006), Enlisting the influence of others: Alternative strategies for persuasive media campaigns, *Journal of Applied Social Psychology*, 36, 2, pp.269-296.

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# Economics, Ethics and Social Sciences in the Making of Public Policy

Social scientists have long been interested in the relationship between social research and the formation of public policy: how does research actually feed into policy-making and what are the best ways for policy actors and researchers to relate to each other? EGN researchers realise that these familiar questions are raised a new by genomics and contemporary life sciences where many different forms of expertise are needed to contribute to policy advising. EGN research has focused both on case studies and on issues of principle.

## 21st century genetic health (21CGH)

<b>Principal investigator:</b>	David Porteous (Innogen)
<b>Research fellow:</b>	Gill Haddow (Innogen)
<b>Associated staff:</b>	Sarah Cunningham-Burley (Innogen), Renate Gertz (AHRC Research Centre for Studies in Intellectual Property and Technology Law)
<b>Project funder:</b>	Scottish Funding Council

### Background:

This project arose from the *Generation Scotland* project funded in 2002-3. The aim is to investigate the interaction of genes and environment in the onset and progression of the serious diseases affecting the Scottish population. 21CGH brings together the parallel, yet different, projects of Generation Scotland and UK Biobank. SHEFC has funded the appointment of Dr Gill Haddow in Innogen and Dr Rena Gertz in the AHRB Research Centre for Studies in Intellectual Property and Technology Law as Research Fellows for 3 years to take forward the associated ethical, legal and social aspects (ELSA) programme within 21CGH. 21CGH is a multi-institution, cross-disciplinary collaboration led by the University of Edinburgh, embracing all of the Scottish Medical Schools, other important research institutes and the NHS in Scotland to create a novel consortium based approach to addressing important health priorities in Scotland. It has been funded by the Scottish Higher Education Funding Council (SHEFC) ([www.shefc.ac.uk](http://www.shefc.ac.uk)) through their Strategic Research Development Grant Initiative (Value and duration of award: £1.79 million, October 2003-2007).

21CGH will establish an enabling platform for translational application of the new genetic knowledge, backed by a multi-disciplinary and self-sustaining skill network in genetic epidemiology and health informatics. Our current role is specifically related to the public consultation on ethical, legal and social issues arising from the construction of DNA databases. Active and continuous public engagement is essential if we are to create and sustain a socially acceptable programme of genetic health research that addresses all of the attendant ethical and legal issues. 21CGH sought to engage with the people of Scotland, public interests groups, elected representatives and the media in order to articulate the objectives, solicit opinion and respond to concerns.

### Research aims:

- 21CGH addresses directly Scotland's three health priority areas - cancer, heart disease / stroke and mental health - and more.
- 21CGH provides the essential scientific infrastructure and social, ethical and legal framework on which multi-disciplinary research can build to identify, evaluate and utilise heritable (genetic) risk factors in early diagnosis, disease monitoring, treatment optimisation, avoidance of adverse drug reactions, healthcare planning and drug discovery.

### Methods:

Between April and July 2003, seventeen in-depth open-ended interviews were conducted with people broadly identified as 'specialists' in key fields with some relevance to genetic databases (i.e., geneticists, lawyers or theologians). Although we refer to them as 'specialists', their knowledge and experience varied according to discipline and also closeness to genetic related research. In January – March 2004, ten focus groups were undertaken, chosen to reflect a range of demographics (gender, ethnicity, and age), interests (patient, voluntary and civic groups), and localities (rural, semi-rural or urban).

### Key findings:

In both the public and specialist components of this preliminary consultation exercise we were keen to explore a range of issues.

- Although there was variation both within and between the two components, this was variation of degree and not of kind.
- We asked for opinions on participation, recruitment, withdrawal, access, consent, feedback (general/specific), public engagement, and confidentiality.
- We encouraged participants to raise issues themselves, to be candid about their concerns and to draw specifically on their own areas of interest as well as provide more general comment.
- The findings show public concern around consent, storage, access and use of genetic data.

### Publications:

Haddow, G., Cunningham-Burley, S., (forthcoming) Tokens of Trust or Token Trust?: Public consultation and 'Generation Scotland' in *Trust, Health and Illness* (eds) Alexandra Greene, Julie Brownlie and Alexandra Howson, Routledge.

Haddow, G., Laurie, G., Cunningham-Burley, S., & Hunter, K. (2007). Tackling Community Concerns about Commercialisation and Genetic Research: A Modest Interdisciplinary Proposal. *Social Science and Medicine*, 64, pp. 272-282.

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# Claims-making on nutrigenomics: a policy-driven analysis of marketing and media

**Principal investigator:** Paula Saukko (Egenis)  
**Research team:** Matt Reed (Egenis), Steve Hughes (Egenis), David Melzer, (Peninsular Medical School), Nicky Britten, (Peninsula Medical School)  
**Project co-funder:** Wellcome Trust, Biomedical Ethics Programme

## Background:

Nutrigenomics—the study of the interaction between nutrition and the genome—promises to give genotype based dietary advice. Some commercial companies are selling nutrigenetic tests online and in select retail outlets. Policy-makers and scientists have accused the companies of misleading the public about the validity of tests. It has been suggested that information provided to the public about nutrigenetic tests should be regulated.

## Research aims:

- To analyse marketing, media and scientific messages about commercial nutrigenetic tests and nutrigenomics more generally in order to assess what exactly is being claimed about these tests and the science more generally.
- To explore what cultural symbols around food, genes, medicine, science and lifestyle are associated with nutrigenomics.
- To examine broader social and political agendas, such as notions of individual responsibility and individuals' right to "choose" health-care and products they want, that are being supported in discourses on nutrigenomics.

## Methods:

In the first phase we have analysed the websites of seven commercial companies selling nutrigenetic tests online. We also analysed UK and US media coverage of nutrigenomics between 2001 and 2007.

The second phase of the study will involve interviews with key scientists and stakeholders in nutrigenomics.

The study will also involve attendance at select nutrigenomics conferences and policy events to contextualise the media, marketing and interview material.

## Key preliminary findings:

- On their websites commercial companies emphasise that they are testing for polygenic susceptibilities, merely indicating a risk of disease, not for single gene disorders that determine health and illness. Critics in the media accuse the companies of selling tests of poor validity and predictive power.
- Commercial companies frame the purchase of nutrigenetic tests as increasing consumers' power to decide about their own health. Critics charge the companies for misleading the public, arguing genetic information is too complex to be understood without the guidance of a qualified clinical professional.
- Many nutrigenetic companies recommend their customers to follow rather broad healthy eating guidelines, allegedly based on individuals' genotype, such as eating plenty of vegetables and avoiding saturated fats, some companies offer vitamin supplements, plant extracts or combinations of vitamins and over the counter drugs, for example, aspirin and folic acid. Critics have argued that the advice provided is too general to be meaningful and that companies are charging prices that are too high for vitamin supplements.
- In general, the marketing and media discourses indicate that nutrigenetic tests have become a struggle over the boundary between "medicine" and "lifestyle," which indicates its resonance with wider issues of contemporary health and health-care policy.

## Wider implications for policy:

The debates around nutrigenomics highlight a generally important political issues on preventive genomics.

- If the science produces tests, which can detect unspecific susceptibilities to heart disease and cancer with associated general advice about eating healthy foods, getting exercise and avoiding toxins these are seen as too "woolly." At the same time, unspecific tests are less likely to unduly worry people and may blend into general healthy lifestyle advice.
- If the science produces tests, which are specific and offer specific treatments, such as a particular preventive drug, this may seem more of an achievement. However, such test also carry the potential of medicalising people, leading to a situation where people are taking a variety of medications for diseases they would never develop.
- It is uncertain, whether research on genetic susceptibilities will produce predominantly "lifestyle" or "medical" tests. Selling lifestyle tests that merely recommend good eating habits are not the most problematic kind, and medical diagnostic tests for single gene disorders are currently largely regulated by clinical governance. Policy should, however, make sure that unspecific lifestyle genetic tests are not used to sell unnecessary drugs to people.
- It is an open question whether there should be special regulation on marketing of tests and medications under the umbrella term "genetic". The problem of selling tests and drugs is broader, as evidenced in the proliferation of whole body scans and online sales of Viagra and other drugs. . Policy-makers maybe should devise ways of regulating this widening market of quasi-medical products in general terms.

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A link to the project website is at [www.ex.ac.uk/egenis/research](http://www.ex.ac.uk/egenis/research)

# Complex risks and testing for genetic thrombophilia: a case study on genes and common disease

**Research fellow:** Paula Saukko (Egenis)  
**Research team:** Sian Ellard, John Campbell (both from Peninsular Medical school)

## Background:

It has been suggested that in the future genomics will help to identify individuals 'at risk' for common disease, such as cardiovascular disease, diabetes and cancer, and to offer them preventive advice and treatments. There are hardly any studies on how individuals' interpret and respond to being tested for a low risk genetic susceptibility to a disease. In this study we explored how individuals, who have undergone testing for a susceptibility to deep vein thrombosis (DVT), interpreted the test and what implications it had on their lives. Thrombophilia provided a good case for the study as it is one of the very few genetic susceptibility tests currently provided through the NHS. It is common (1:25 individuals have thrombophilia), it can be tested for in mainstream genetics (e.g. via a GP) and people, who have tested positive, can take preventive actions (avoidance of oral contraceptive Pill, hormone replacement therapy (HRT), precautions during flights, pregnancy and surgery and healthy lifestyle).

## Research aims:

- How do people, who have had a genetic test for a low risk susceptibility to deep vein thrombosis interpret the test?
- What did they do with the information?
- Do individuals from different backgrounds and in different situations interpret the test and its repercussions differently?

## Methods:

Qualitative interviews with 42 individuals in south west England, who had had a genetic test for thrombophilia. Analysis of six months of traffic on an internet support group for people with thrombophilia.

## Key findings:

- Individuals who had been tested did not consider the test to be 'special' or 'exceptional' even if it identified a genetic susceptibility. They thought it was similar to non-genetic tests for, for example, cholesterol or for diabetes. Participants considered the test to be far less serious than a genetic test for predisposition to breast cancer or a non-genetic test for HIV.
- Individuals, who had tested positive for thrombophilia, had stopped taking the oral contraceptive or HRT and taken precautions during flights but had not changed their lifestyle. Most were not unduly worried about thrombophilia and frequently estimated their risk to be low. This indicates an emerging way of interpreting genetic information not as providing "in depth" knowledge about one's health or identity but as occasionally relevant "surface" information, used to make specific health-care decisions.
- Particularly well-educated individuals had a good understanding of the test and its implications. They had often sought additional information on thrombophilia from relatives and the internet. Other participants, often from less privileged backgrounds, had a poor understanding of the test—seven participants were unaware of having had the genetic test.
- The exchanges in the online support group for people with thrombophilia were significantly different from the offline interviews. The most active participants on the online group had frequently experienced at least one DVT and the discussion revolved around the use of anticoagulant medications, which have potentially serious side-effects. Some exchanges in the group as well as comments by the interviewed people indicated that those people who merely had a risk of a DVT found the discussion on drugs alienating. This draws attention to how a genetic risk may be experienced differently in different contexts and calls for more research on internet communities and their role in constructing emerging "at risk" identities.

## Wider implications for policy:

Testing for genetic susceptibilities in mainstream medicine is a new or emerging phenomenon, and the practices and policy on testing is only just beginning to take shape. Based on our study we observed:

- People do not necessarily perceive genetic information as "exceptional" or vastly different from other medical information. Against this finding, it may not be advisable to devise special modes of delivering genetic susceptibility tests, as this may frame these tests as unusual and unduly serious. Still, the fact that some participants understood the test poorly indicates that mainstream medicine may not currently be prepared to manage genetic tests properly. There is a need to develop new modes of delivering genetic susceptibility testing that grounds them in ordinary healthcare but guarantees that all people, particularly those from less privileged background, obtain sufficient information about the tests and their implications.
- Our finding that people did not change their lifestyle dampens hopes that genetic susceptibility testing would motivate people to adopt healthier habits, and other research have pointed to similar direction.
- The fact that our participants had used the genetic test results to avoid specific medications may indicate that people may be prone to use genetic information to avoid or to take medications, which may lead to increasing trust in pharmaceutical solutions.

## **Publications:**

- Saukko, P, Ellard, S, Richards, M, Shepherd & J. Campbell (2007), 'Patients' understanding of genetic susceptibility testing in mainstream medicine: A qualitative study on thrombophilia', *BMC Health Services Research*, 7, 1.
- Saukko, P, Richards, S, Shepherd, M, Campbell, J. (2006) 'Are genetic tests exceptional? Lessons from a qualitative study on thrombophilia', *Social Science and Medicine*, 63, 7, pp. 1947-1959.
- Saukko, P (2004). 'Genomic susceptibility testing and pregnancy: something old, something new', *New Genetics and Society*, 23, 3, pp. 313-325.
- Saukko, P. (2004) 'The internet as a patient information tool', *Genomics Network*, 1, pp. 16-17.

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# Emerging politics of new genetic technologies

**Principal investigators:** Ian Welsh (Cesagen) and Robert Evans (Cesagen)  
**Research associate:** Alex Plows (Cesagen)

## Research aims:

To 'map' and sample UK public engagement with medical applications of new genetic technologies within civil society, and produce an anatomy of emerging networks. The project set out to identify both the underlying social dynamics of emerging public responses and key areas of engagement and concern. The project thus produced an anatomy of engagement in terms relevant to knowledge production within the bio-economy, policy making and citizen groups by revealing embedded frames, discourses and actions constitutive of a 'proto-politics'. To achieve this, the project provided overviews of:

- Producers of genomic techniques, including scientists, clinicians and administrators in both private and public sectors.
- Regulators of genomic techniques, at local, regional, national, European and global levels, but with a primary focus on UK and European institutions.
- Engagement with genomic techniques by Social Movement Organisations, emergent social movements, key 'prime movers' with the potential to influence the reception of medical genomics within the public sphere. Case study work and 'snapshots' of multiple publics formed the core ethnographic focus of the project.

## Key findings:

- The project identified a diverse range of publics engaging with both particular genomic techniques and the associated wider social stakes. These include disability rights and social justice activists, patients, and scientific workers, actively engaged in sense making efforts relating to the 'new genetics'. Prominent areas here include patenting, stem cell development, diagnostic and screening techniques.
- These multiple publics are engaged in such meaning construction in the face of a rapidly developing techno-scientific field, with multiple applications embodying a diverse range of technical, moral, ethical and social stakes.
- The crosscutting nature of genomic techniques makes boundary definition, and maintenance between types of genomic science (e.g. 'green' agricultural and 'red' medical'), and the allocation of specific techniques (e.g. 'reproductive', 'therapeutic' and 'enhancement'), to categories within such boundaries difficult.
- Blurred boundaries produce significant challenges to established Social Movement Organisations in terms of engagement.
- Specialised actors such as Genewatch become key resources and nodes within networks. Networked participants are diffusing information and perspectives, utilising a number of tactics including policy engagement, extending across Europe and beyond into global forums.
- These initial engagements are characterised by a high degree of ambivalence and are consistent with the identification of stakes associated with latency periods within which publics 'digest' complexity in a process of emergence.
- Beyond some clearly positioned actors (e.g. animal rights groups) there are currently few clearly defined 'pro' and 'anti' stances. The process of emergence is producing a number of counter-intuitive actor clusters. Examples of such 'strange bed fellow' clusters include those around patenting and egg donation.

## Wider implications for policy:

- The social forces coalescing around medical genomics are broad and diverse and contain multiple critical sub groups with significant bodies of situated knowledges.
- Thus the reflex to reduce social complexity via pro/anti dualisms should be resisted in favour of deep and diverse forms of public consultation which include 'up stream' concerns. A narrow focus upon ethics and public acceptability in terms of access to genetic resources and the licensing of specific techniques needs to be supplemented by such deep and diverse initiatives. These have the potential to yield social consensus on development trajectories, and a win-win outcome through commitment to meaningful deliberative democratic inclusion respecting the right to difference.
- Adequate public involvement cannot be secured through discussions between the usual suspects and requires attention to apparently 'queer folk'. This is an area where social science can play a key role in terms of translation between networks.
- Medical genomics raises counter-intuitive stakes within scientific, technical, commercial and public domains, which can confront established habits of mind. Established approaches to property rights, the importance of the positive freedom to say 'No' (e.g. to screening for certain conditions) and divisions between scientific and lay expertise are three prominent areas.
- Defining and focusing upon the crossovers emerging within numerous convergence spaces is a significant challenge for the social sciences, policy makers, techno-sciences and commercial interests.
- Medical genetics is developing in the context of a knowledge economy operating in a neo-liberal free market. Thus considering parallel public provision in key areas such as 'open-source' initiatives has the potential to address some of the concerns of key critical sub-groups. There are precedents for this in the area of vaccines.

## Publications:

Evans, R & Plows A. (2007) Listening Without Prejudice? Re-Discovering the Value of the Disinterested Citizen, *Social Studies of Science*, (forthcoming, December 2007).

Evans, R., Plows, A., Welsh, I., (2007). Towards an anatomy of public engagement with medical genetics in Atkinson P., Glasner, P. and Greenslade, H. Eds. *New Genetics, New Identities*, London, Routledge; 2007. pp. 139-156

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Welsh, I.,(2007) Participation, Innovation and Efficiency: Social Movements and the New Genetics in Germany and the UK, in Blüdhorn, I. and Jun, U. (eds) (2007) *Economic Efficiency – Democratic Empowerment: Contested Modernization in Britain and Germany*, Lanham, MD: Rowman & Littlefield/Lexington; pp. 275-295.  
Welsh, I., Evans, R., Plows, A. (2007) Human Rights & Genomics: Science, Genomics and Social Movements at the 2004 London Social Forum *New Genetics and Society*, Vol 26, No. 2, pp 1-13

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# Farmers' understandings of genetically modified crops within local communities

**Principal investigator:** Andy Lane (Innogen)  
**Research fellow:** Sue Oreszczyn (Innogen)  
**Associated staff:** Susan Carr (Innogen)  
**Project funder:** ESRC Science in Society Research Programme

## Research aims:

This research investigated the attitudes, intentions and practices of farmers regarding the new technology of genetically modified (GM) crops, in relation to their social setting. It:

- Explored how farmers construct their understandings of GM crops through their interactions with others, in particular family members, neighbouring farmers, seed companies, farming advisors and the local community.
- Ascertained the acceptability to farmers (both those with experience of GM crops and those without) of recommended management practices for GM crops used in the UK government Farm Scale Evaluations (FSEs).
- Is developing models of social learning systems appropriate to support individual farmers within informal social settings who decide to adopt contentious new technologies such as GM crops.

We investigated the following questions from the farmers' point of view:

- What do farmers see as the pros and cons of new technologies generally and what do farmers believe about GM crops?
- For farmers who were involved in the FSEs, what were their experiences of growing GM crops?
- Who or what are the influences on farmers concerning the introduction of new technologies to help run their farms as a business?
- To what extent do farmers engage in learning?

## Methods:

An interactive, relationship building methodology using mapping techniques was used through three linked phases. First, telephone interviews with farmers with and without experience of growing GM crops were used to create cognitive maps of the participants thinking about them. Second, face to face interviews with some of the same farmers employed a mapping technique to explore the influences on farmers' decisions concerning new technologies and their farming business. Third, an interactive workshop involving some of the same farmers and members of their community of influencers used a scenario planning tool to look at future developments.

## Key findings:

Throughout the project the findings of each stage were shared with and validated by the participants and discussed with key stakeholders. The results of the final analyses will be used to inform discussions with stakeholders on the most appropriate ways to manage a new farming technology where the likely impacts are unclear or contested by different groups. They will also help identify the most important relationships to foster in such social learning systems.

- Farmers are responding to GM crops much as they would to any new technology.
- Farmers who have been involved in the FSEs, as well as those who have not, believe that GM crops offer both economic and environmental benefits.
- Farmers consider that agricultural research and policy are not well attuned to agricultural practice.
- Farmers learn a) by experimenting, that is they draw upon their tacit knowledge and experience in their own setting to develop new technologies in practice, and b) by engaging with their network of practice (mostly other farmers) and their community of influencers.
- There is a lack of boundary brokers between farmers' network of practice and other key communities of practice within a farmer's community of influencers.
- Work on extending the social learning models is continuing.

## Publications:

Oreszczyn, S & Lane A. (2005) 'Farmer responses to new agricultural technologies'. Paper presented at Flows & Spaces in a globalised world. RGS-IBG Annual International Conference, London.

Lane, A. & Oreszczyn, S. (2005) Should farmers be landscape planners too? In McCollin, D. & Jackson, J. I. (2005) Planning People and Practice: The landscape ecology of sustainable landscapes. Proceedings of the 13th Annual (UK) Conference, University of Northampton.

Oreszczyn SM and Lane AB (2006) Farmers communities of practice and high-tech futures <http://oro.open.ac.uk/5470/>

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# Genetic explanations: causality and accountability in complex disorders

**Principal investigators:** Ruth Chadwick (Cesagen), Angus Clarke (Cesagen), Jenny Kitzinger (Cesagen), Srikant Sarangi (Cesagen), Marie-Jet Bekkers (Cardiff), Ulla Raisanen (Cardiff), Paula Boddington (Cesagen).

**Project funder:** Wellcome Trust

## Background:

The starting point for this project has been an investigation into which causal explanations for common complex disorders are put forward in the scientific literature and, more particularly, by people who share a professional concern with the prevention and consequences of conditions like Type 2 Diabetes and Coronary Heart Disease.

The project has so far focused on an investigation of reasons for the downplaying of, or emphasis placed upon, different aspects of the causal origins of disease in policies on disease prevention. We have examined the links between various possible causes and other factors of cultural, social, economic and political importance, drawing comparisons across different countries and with different groups within countries.

We have attended to the impact of holistic, versus reductionist, accounts of disease causation, as well as different varieties of holism, upon causal attributions and the selection and highlighting of causal factors in policy documents.

We are investigating the implicit as well as explicit attribution of responsibility to individuals and to organisations with reference to complex diseases, and how these are related to understandings of disease causation and prevention. These understandings are displayed in policy documents and also in the thinking of scientists, clinicians and policy makers as demonstrated in interviews. We are especially interested in how causal explanations and attributions of responsibility are linked to notions of blame attributed to individuals and organisations.

We hope that the work from this project will have a direct effect of improving the quality of debate and argumentation about policies aimed at the prevention of complex diseases, especially in the context of disadvantaged indigenous communities.

## Methods:

Our approach has been qualitative, based upon the discourse and rhetorical analysis of (a) scientific publications, (b) policy documents and (c) interviews with representatives of key stakeholder communities (scientists, clinicians, patient organisation representatives, minority community representatives, policy makers). We are unable to cover all the groups and diseases we would like, but are focussing on type 2 diabetes and coronary artery disease in the UK and Australia, including the UK South Asian groups and the indigenous (aboriginal) groups within Australia.

## Key findings:

- Although scientific explanations for the causation of common complex disorders like Type 2 Diabetes and Coronary Heart Disease are wide-ranging, in terms of disease prevention current health policies both in the UK and in Australia (the two countries investigated so far in this project) focus primarily on promoting lifestyle changes.
- Thus the impetus for change is placed firmly with individuals and their immediate social environment. Our discourse analytic approach highlights how attributions of blame and responsibility can form part of the very fabric of causal explanations.
- Furthermore, our work exposes the diverse understandings of responsibility in this field and has consequent implications for how responsibility can most usefully be discussed.
- The frequent slippage between the various meanings of the word 'responsibility' is especially noteworthy and results in confusion in many debates and fruitless lines of argumentation.

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# Genetics, health and identity

**Principal investigators:** Angus Clarke (Cesagen) and Srikant Sarangi (Cesagen)  
**Research fellow:** Michael Arribas-Ayllon (Cesagen)

## Background:

This project was developed with the aim of understanding professional and familial decisions and explanations that have consequences for the genetic testing of children. In the first phase, we have investigated the reasoning of parents who have considered genetic testing and the attendant family processes of (not) disclosing genetic information to their children. In the second phase, the project has explored how professionals reconstruct retrospective cases as exemplars for prospective ethical reasoning and accounting for 'good practice'. Taking a discursive/rhetorical approach, we have focused on the moral work of parents and professionals who seek to endorse a balance between notions of autonomy and responsibility.

## Research aims:

- To understand how families manage and perform 'genetic responsibility' vis-à-vis decisions to test and/or disclose genetic risk;
- To examine how professionals account for parental responsibility and the autonomy of children;
- To understand how professionals interpret existing Codes of Practice and account for ethical/moral dilemmas when addressing a broad range of familial concerns.

## Key findings:

- Research interviews with parents who have requested or considered testing reveal evidence of three patterns wherein 'genetic responsibility' is transmitted to the child: aligned, deferred and misaligned responsibility. While 'aligned' and 'deferred' constitute the normative and default responsibility of consensual ethical disclosure, 'misaligned' responsibility emphasises how obstacles in open communication may not be in the best interests of the child – i.e. testing is potentially delayed into adolescence or adulthood.
- The same interviews also reveal differential strategies for managing genetic responsibility through other-oriented blame. Competing versions of genetic responsibility/understandings reveal subtle intergenerational problems of disclosure. For instance, reports of fatalism among other family members are cast as obstacles to communication and disclosure. Furthermore, while previous generations are blamed and exonerated for not understanding genetic information, there is less duty/obligation to exonerate present generations (e.g. siblings and spouses). Present generations are cast as more responsible and, therefore, more blameworthy for the management of genetic risk. Also, in accounts of disclosure, blaming others often entails claiming responsibility for being open.
- Professional codes of practice have been examined in relation to the genetic testing of children by Susan Hogben and Paula Boddington. Their work has shown that the 'official' codes are often elaborated from a chosen set of foundational principles. Practitioners are then faced with the difficulty of relating formal codes to the contingencies of everyday practice. More recent evidence suggests that professionals acquire their ethical reasoning via encounters with difficult cases. The introduction of codes of professional conduct, especially those that are based on certain disease exemplars, may lack applicability in situated practice. An alternative approach is to develop case-based discussion documents for clinical geneticists and genetic counsellors.
- Interviews with professionals indicate acute ambivalence regarding cases in which ethical guidelines are infringed. While there is strong evidence of ethical awareness, difficult/challenging cases involving persistent or anxious parents reveal tensions that are not easily resolved by consensual ethical discussion. Furthermore, our analysis of interview accounts suggests that 'good practice' is not a simple matter of implementing principles but managing the practical consequences of interactions with parents and children. An important device for facilitating ethical explanations is the use of case exemplars, which reconstruct good/bad cases as justifications of professional conduct. These findings suggest that more attention is needed to understand the way professional practitioners construct and share cases as powerful illustrations of ethical practice.
- We intend to connect this work with the Genethics Club nationally, a forum in which genetics professionals discuss difficult issues that have arisen in practice. We also hope to establish an international network as a way of comparing embodied professional practices against the existing codes of practice via European partners.
- The recent conference in London organised through the British Medical Association (July 2007) provided a broad range of opinions regarding present challenges for professionals and families. Advances in susceptibility and predisposition testing are thought to present future changes to current guidelines. A data set is being presently constructed from the event, which will complement our analysis of the interview material.

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A link to this project website is at [www.cesagen.lancs.ac.uk/research/projects/ghi.htm](http://www.cesagen.lancs.ac.uk/research/projects/ghi.htm)

# Genetic screening for susceptibility to disease: the case of haemochromatosis

**Investigators:** Paul Atkinson (Cesagen), Aditya Bharadwaj (Cesagen), Angus Clarke (Cesagen) and Mark Worwood (Cardiff)

**Project co-funder:** ESRC Innovative Health Technologies Programme

## Background:

This project was funded under the ESRC Innovative Health Technologies Programme, and was a research collaboration between social scientists and clinical scientists. It capitalised on the conduct of a research study of the genetic basis of haemochromatosis in South Wales by the Department of Haematology. Healthy blood donors (with their informed consent) had their blood tested for the 'susceptibility' gene for genetic haemochromatosis (GH). Individuals who are homozygous for this genetic mutation may develop the condition, which results from overload of abnormally high storage of iron. However, the development of clinical illness, its timing and severity are indeterminate. The condition is serious if not treated early, but is readily managed by regular depletion of the iron-store by bleeding. The research was conducted through interviews with individuals who were identified as having the susceptibility gene, and individuals who had developed clinical haemochromatosis (without any genetic screening). The research is an important case study that provides possible illumination informing future genetic screening programmes.

## Key findings:

- In the absence of genetic information, the clinical diagnosis of haemochromatosis is uncertain. We documented a high level of distress and anger on the part of patients with frank symptoms who had not received a diagnosis during early onset
- The identification of genetic risk among otherwise healthy individuals does not automatically give rise to high levels of expressed anxiety
- At-risk patients are, however, only reassured if they believe that they are being monitored and receiving follow-up care by medical services
- Consequently, future genetic screening may create a 'genetic iceberg' of anxious-well unless the NHS is able to cope with a greatly increased burden of counselling
- Better, early clinical diagnosis in primary health-care may be more cost-effective than screening programmes

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# Generation Scotland: The Scottish Family Health Study (SFHS)

**Research fellow:** Gill Haddow (Innogen)  
**Associated staff:** Sarah Cunningham-Burley (Innogen)  
**Project funder:** Scottish Executive

## Background:

Genetic databases are heralded as the way forward in improving the status of a population's health through the collection of DNA samples, lifestyle questionnaires and prospective medical health care. Following from the 21CGH project, this project is working on the issues of procurement, storage, access and use of bio-information, involving and engaging the public.

## Research aims:

- To engage a range of groups in discussions about the ethical, legal and social issues relating to family recruitment, consent, withdrawal, feedback, use, confidentiality, access, use, ownership and further public consultation (including responding to requests made by the multi-centre research ethics committee (MREC) about public discussion around feedback and commercialisation).
- To ascertain likely participation rates and assess acceptability of processes such as recruitment method, clinical feedback and information materials.
- To have input into the way that the DNA database is publicised in the media and elsewhere in the community from which participants will be drawn in a way that responds to local cultures and sensitivities.
- To document and understand how and in what circumstances the findings can be incorporated into, or influence, the development of Generation Scotland: The Scottish Family Health Study, particularly in relation to future use and further research.
- To research and evaluate the public consultation from a social scientific perspective which entails exploring the views and experiences of diverse groups, their connections to genetic research and the process of public engagement itself.

## Methods:

A multi-method approach was used that combined both quantitative and qualitative methods with participants and non-participants. However with this broad sampling umbrella we presumed there to be very different audiences (public/s, citizen groups, families and (social) scientists) who undoubtedly differ in their awareness, interest and experience of GS: SFHS.

The division of method was as follows:

Non-participants:

- Reconvened discussion groups: with publicly spirited citizens who can commit to an on-going forum for information and deliberation. We attempted to balance information and deliberation via a mixture of power-point presentations followed by spontaneous, unmoderated group work.
- The results of this work fed into a survey of 1,000 members of the general public conducted with Ipsos MORI Scotland and focussed upon participation, access, use and governance. Open and discrete choice questions were used.

Participants:

- 100 exit questionnaires were conducted with participants to give a broad snap-shot of recruitment and views about the clinic processes.
- Semi-structured interviews were conducted with individuals initially contacted about the study and the family members they were asked to recruit.

Non-participant observation of the GS: SFHS scientific committee group was also undertaken especially when the findings of the consultation were being discussed.

## Key findings:

- Empirically, this research will enrich our understanding of genetic databases and the public's views of, and attitudes to, them.
- This analysis will provide a solid empirical foundation for future ethical, legal and social debates about genetic databases and contribute further understanding to the concerns around procurement, access, storage and use. Moreover, it will contribute to the little that is known about family dynamics in relation to recruitment to such research. We will also incorporate a more critical approach to public engagement – both as an ideology and a method.
- The reconvened discussion groups, public survey, exit questionnaires and ethnography are complete and findings are currently being written up for publication.
- The interviews with families are continuing.

## Publications:

Smith, B., Campbell, H., Blackwood, D., Connell, J., Connor, M., Deary, I., Dominiczak, A.F., Fitzpatrick, B., Ford, I., Haddow, G., Jackson, C., Kerr, S., Lindsay, R., McGilchrist, M., Morton, R., Murray, G., Palmer, C., Pell, J., Ralston, S., St Clair, D., Sullivan, F., Watt, G., Wolf, R., Wright, A., Porteous, D., & Morris, A. (2006). Generation Scotland: the Scottish Family Health Study: A new resource for researching genes and heritability. *BMC Medical Genetics*, 7, pp 74

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# Patient interpretations of family history in evaluating the risk of heart disease in general practice

**Research fellow:** Paula Saukko (Egenis)  
**Researcher:** Ruth Hall  
**Research team:** Steve Humphries University College, London (UCL), Nadeem Qureshi, (University of Nottingham), Philip Evans (Peninsula Medical School)

## Background:

Coronary heart disease (CHD) is the leading cause of mortality in the developed world. Although epidemiological and genetic studies have indicated that CHD has a genetic component, there are no valid genetic tests for susceptibility for CHD. Assessing family history of CHD is suggested as a route for identifying 'at risk' individuals. However, little is known about how assessing family history works in clinical practice in terms of clinical communication and patient understanding and interpretation.

## Research aims:

- To analyse how doctors/nurses and patients communicate about family history of heart disease in the clinical consultation.
- How do participants conceptualise their 'family history of CHD' in relation to genes, lifestyle and environment?
- *What does it mean to patients to be 'at risk'?*

## Methods:

Video recording of 23 consultations between clinicians and patients, who were having their family history assessed, using a questionnaire, as part of the overall assessment of their risk of coronary heart disease. Interviews with patients two weeks afterwards.

## Key findings:

- In the consultations the clinicians tended to perceive family history to indicate "genetic" risk and focused on modifiable risk factors, such as diet and smoking. Patients understood their family history in the broader context of their families' behaviour and, for example, blood pressure that ran in the family, and often volunteered stories about their families' health in the consultation. Patients were left with concerns and unanswered questions when these broader questions about family history were bypassed in the consultation.
- In the interviews the patients related their family history to genes, behaviours as well as social circumstances, such as lack of good food and medications in the past, hard work in the mines, and the war, as well as chance. The patients held complex, multifactorial understandings of family history of heart disease that go beyond genes and individual behaviour.
- Reducing family history to genes misses its potential to capture the biological, behavioural, social-structural and historical dimensions of heart disease. The narrow understanding of family history caused problems in consultation, as it did not fit with patients' everyday experience of heart disease and family. Such a narrow understanding would also lead to a limited health-policy, solely focused on genes and lifestyle at the expense of the social and historical factors that play a role in common chronic diseases.

## Wider implications for policy:

- Currently clinicians lack a rhetoric to discuss family history of heart disease in terms of gene-environment interaction. If family history assessment is to become part of primary prevention of many common diseases, clinicians should be guided on how to communicate about family history as multifactorial. Otherwise this assessment ends up reproducing problematic genetic determinism and causes misunderstandings in the clinical encounter.
- Policy-makers in the US and the UK are planning to use family history of heart disease, diabetes and cancer to identify individuals at risk and to offer them preventive advice. However, family history captures not only genetic susceptibilities, but also lifestyle, social deprivation, ethnicity and regional differences, which all play an important role in the development of common diseases. If understood broadly family history could provide a tool and a heuristic to address the biological, behavioural, social and historical dimensions of health and bridge the differences between "personalised" and "social" medicine.

## Publications:

Hall, R, Saukko, P, Evans, P, Qureshi, N, Humphries (2007). Assessing family history of heart disease in primary care consultations: A qualitative study, *Family Practice*, 24.

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A link to the project website is at [www.ex.ac.uk/egenis/research](http://www.ex.ac.uk/egenis/research)

# Public engagement and personalised medicine: ethical, legal and social aspects of genetics

**Principal investigator:** Brian Wynne (Cesagen)  
**Research associate:** Elisa Pieri (Cesagen)  
**Project co-funder:** The North West Genetics Knowledge Park (Nowgen)

## Background:

Pharmacogenetics is the study of how genetic variations affect an individual response to a drug. Pharmacogenetics can also be defined as the use of genetic testing to prescribe and develop drugs, and as such it has been seen a technology that will accentuate the move towards the *individualisation* of healthcare. In a recent White Paper, the UK Department of Health (DOH) announced that 'genetics holds out the promise of more personalised healthcare with prevention and treatment tailored according to a person's individual genetic profile' and that 'pharmacogenetics will lead to prescribing which is more effectively tailored to the needs of the individual' (DoH White Paper *Our Inheritance Our Future*, 2003: 5 & 8).

This project was a two year qualitative study (2004-2006) on personalised medicine exploring the values and priorities of members of the public, particularly involving citizens from ethnic minority groups and hard to reach age groups in the North West of England.

This study was part of a larger Ethical, Social and Legal Aspects project carried out in collaboration with the North West Genetics Knowledge Park (Nowgen).

## Methods:

For this qualitative study 14 focus groups have been conducted with traditionally 'hard-to-reach' sections of the public – i.e. senior citizens, young people and parents of young children – as well as with members of some ethnic communities in the North West of England.

The data has been analysed using a Grounded Theory approach and the constant comparative method. This analysis has been aided by Atlas.ti software.

## Key findings:

- Members of the public reported strong concerns about *the increased (and often burdensome) levels of responsibility linked to the new asymptomatic/pre-symptomatic patient identities* that would come into being through the promises of personalised medicine, and through the necessary genetic testing it entails. Contrary to the discourse of personalisation, members of the public also highlighted how such concerns would impact and place *strains also on non-individual dimensions of their lives* (their families/relatives, as well as potentially leading to stigmatisation of groups that they identify with), and to limiting their access to key services, such as insurance, mortgages, some medical coverage, potentially even impacting their employment opportunities).
- Personalisation of information: was seen as *problematic* both in the sense of *acquiring 'trusted' health information* and advice (particularly in the context of commercialisation of the genetic testing and pharmacogenetic treatments, access to the internet, and in the absence of counselling), but also given that GPs' expertise was often deemed insufficient to deal with genetics advice. *Acting on genetic probabilistic information was also seen as problematic*, as it was recognised that other (often socioeconomic) factors would play a role in whether certain changes at individual level to people's lifestyles and treatments could be taken up.
- There was *great resistance* among participants in this study *towards* attempts to treat the political dimensions of personalised medicine (issues of equal access, treatment of data, social justice, trust and healthcare priorities) and their social impacts as requiring *individual solutions*.

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## Public-private collaboration in genomics and biotechnology

<b>Principal investigator:</b>	David Wield (Innogen)
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<b>Associated staff:</b>	Joyce Tait (Innogen), Joanna Chataway (Innogen)
<b>Project funder:</b>	ESRC Science in Society programme

### Background:

The shift from synthetic or fine chemistry to micro-biology and the subsequent revolution of genomics and biotechnology constitutes a possible major driver of change in health industries. The most important characteristic of this new paradigm of technological change and innovation in life sciences is the close collaboration between all public and private actors involved. This project began in August 2005 with the aim to explore the complex public-private relationships in genomics and biotechnology in the UK in order to reveal their role in building firm-based and policy-making capabilities. The focus is on regional innovation. The project examines the links between innovation policy bodies, life sciences research institutes, dedicated biotechnology firms and venture capital organisations from the standpoint of regional development.

### Research aims:

- What are the nature and characteristics of public-private collaboration in genomics and biotechnology in regions such as Scotland, Cambridge, Oxford and London?
- Whether specific types of public-private collaboration result in building specific firm-based and policy-making capabilities?
- What is the relationship between building innovative capabilities in genomics and biotechnology and regional development?

### Methods:

- Documentary analysis (academic journal articles, policy documents, company websites and press articles).
- In-depth interviews with a range of relevant public and private actors, including managers and industry stakeholders in dedicated biotechnology firms and policy makers in regional development agencies.
- Comparison of the Scottish situation, already being researched, with that in Cambridge i.e. a major UK regional agglomeration.

### Key findings:

- From August 2005 to September 2007, the project consistently explored the complex relationships between public policy, public research and private firms in genomics and biotechnology in the UK, revealing their role in building firm-based and policy-making capabilities. Additionally, research has been carried out in ethics and politics of Intellectual Property Rights with focus on human gene patents.

Highlights over the past two years include:

- Paper entitled Knowledge Ecology and Innovation System? The Case of Public-Private Interrelations of Biotech Innovation in Cambridge has reported research findings from the project in *The 6<sup>th</sup> International Triple Helix Conference on University-Government-Industry Relations* (Singapore 2007) and the *Regional Studies Association Conference* (Lisbon, 2007). The paper is currently under consideration at a peer reviewed international journal.
- Another paper has been prepared on 'Public-Private Collaboration in Genomics and Biotechnology' for publication in a peer reviewed international journal.
- 2 policy briefs on Regional Innovation and Public Policy and Building Innovative Capabilities through Public-Private Collaboration in Genomics and Biotechnology have been prepared for publication.
- 2 papers on Human Gene Patents presented at two DIME international conferences on *Intellectual Property Rights* at Birkbeck College, University of London.
- 2 working papers published in Innogen Website.
- 2 peer reviewed journal articles reporting related research published in *Science and Public Policy* and *Journal of Global Ethics*.
- Findings from the project and related research have been used in contribution to another paper on Governance and Justice: the Challenge of Genomics presented in the *8<sup>th</sup> Annual Conference of the European Sociological Association on Conflict, Citizenship and Civil Society* (Glasgow 2007).

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# Regulation of gene therapy in the UK

**Research fellow:** Graciela Nowenstein (Egenis)

## Background:

The aim of this research is to explore gene therapists' views in the United Kingdom about the institutions and/or structures that influence or have influenced developments in gene therapy. Special attention is given to the exceptional regulatory situation of the UK where gene therapy is submitted to the ethical scrutiny of a specially created body, the Gene Therapy Advisory Committee (GTAC). The influence of funding bodies and the media are also explored.

## Method:

Data has mainly been generated via semi-structured interviews with gene therapists. In order to complete and contextualise the data thus gathered observation has been conducted in a research unit, at GTAC and at different events such as education and information days and conferences.

## Key findings:

- What is gene therapy? Answers to this question help to delineate GTAC's sphere of legitimate competence according to interviewees. Gene therapy does not appear as a clearly defined area of biomedical research and practice. It is described as a diverse field that includes research on cancer, immunology, tissue regeneration, monogenic disorders, etc. In spite of this diversity, interviewees observe that there is enough commonality in the field to justify the existence of specific societies, journals, conferences and even a regulatory body.
- The most basic definition of gene therapy interviewees give is *the use of nucleic acids as drugs, or the introduction of some exogenous DNA with therapeutic aims*.
- The expected therapeutic effects should only concern the patient and not his or her progeny. The purposeful alteration of the germ line is thereby excluded.
- Most show a moral dislike for the idea of modifications of the germ line. They also agree that it is not realistic to think about it happening soon. Yet, if germ line manipulation ever becomes technically possible, most hypothesise that it will be used as therapeutic technique.
- What are the prospects of gene therapy? The promises that are made are less breath taking than in the early years. This view calls for a normalisation of the image of gene therapy: the basic knowledge is not yet there and time is needed to accumulate it; as in any other field of biomedical research, it is going to hurt and kill some of the subject-patients that will be submitted to it; is not going to be the *magic bullet* or the *holy grail* announced or expected; yet it is not an unnatural way of doing medicine.
- Is the existence of GTAC justified? Within the existing context interviewees agree that GTAC is exerting a control that responds to scientific, social and political needs. These are related to: (i) the novelty of gene therapy as a therapeutic approach; (ii) the social and political *sensitivity* vis-à-vis this approach; (iii) the excessive enthusiasm and optimism of the 1990s.
- Some interviewees note that GTAC is part of a more general phenomenon that concerns the entire biomedical sphere, namely the increasing amount of regulation to which biomedical research is submitted. This phenomenon has two important consequences for research: the bureaucratic burden on senior researchers has become greater and it is often necessary to find and fund regulatory expertise when it comes to submit clinical trial applications to ethical and technical approval.
- However, within this hyper-regulated and bureaucratized context, the action of GTAC is described in positive terms: GTAC's members have so far shown by their action an engagement in favour of gene therapy; they are well-informed and knowledgeable; GTAC has adopted a case-by-case strategy that is seen as *reasonable* when it comes to give acceptable levels of risks.
- The issue of regulation led interviewees to elaborate on their relationship to funding structures and the media, which is for many problematic. Some feel they *need to sell* their research to the media as well as to funding bodies to obtain money for research; this implies the risk of falling into communication traps, of being misinterpreted but also of producing non-realistic expectations in terms of future benefits and possible risks.

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A link to the project website is at [www.ex.ac.uk/egenis/research](http://www.ex.ac.uk/egenis/research)

# Risky relations: family and kinship in the era of new genetics

**Principal investigators:** Katie Featherstone (Cesagen), Paul Atkinson (Cesagen), Adi Bharadwaj (Cesagen) and Angus Clarke (Cesagen).

**Project co-funder:** The Wellcome Trust

## Background:

As more and more medical conditions are identified as having a genetic component, and as the use of genetic screening expands, there is increasingly urgent need to understand the cultural contexts within which individual social actors and their kin interpret and act upon the available information. This project provides a major new addition to the literature on the new genetics, on family and kinship in contemporary Britain, and the everyday practical ethical issues that arise for family members with an inherited medical condition. The project has involved original qualitative research with a series of family networks in South Wales (UK).

## Key findings:

Our research has addressed and illuminated a number of related areas:

- Information imparted from genetic counselling and testing does not supplant or replace lay beliefs about inheritance and biological relatedness.
- Although genetic risks are formulated in the contexts of 'families', family membership is not determined by biological relations, practical kinship is more important than biological relatedness *per se*.
- Beliefs about the patterns and risks of inheritance are informed by beliefs about practical kinship, and their lay understandings and these are not necessarily congruent with biomedical ideas about equivalent phenomena.
- Families with genetically defined medical conditions and risks readily become sites of *surveillance*. Members of older generations can inspect younger family members in seeking to identify the emergence of symptoms of the family condition. Equally, younger members can inspect older family members in order to gauge the likely course of a genetic condition, should they develop it. The *geneticised family* is thus a potential site for mutual inspection.
- Our research consistently shows that we cannot talk sensibly about 'disclosure' within families. Rather, family members report very partial distribution of awareness. Rather than sharing parcels of 'information', families may have suspicions and hints. Such awareness that is shared is often tacit, embedded in normal family relations, rather than the topic of explicit discussion.
- The practical implications for training and practice include the suggestion that practitioners need more systematic training in anthropological and sociological perspectives on kinship and inheritance, in order to appreciate the social and cultural contexts within which genetic information is used by their clients and their families.
- Ethical judgements and decision-making are not the sole preserve of professional practitioners. We have identified *practical ethics* informing the sharing of knowledge among family members, to assess who should be informed of genetic conditions, under what circumstances, in what manner. They also assess who can *cope* with such information.

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# The clinical picture: the interaction of clinical medicine and genetic technology

**Investigators:** Katie Featherstone (University of Cardiff), Paul Atkinson (Cesagen), Joanne Latimer (University of Cardiff), Daniela Pilz, (University of Cardiff) and Angus Clarke (Cesagen)

**Project co-funder:** ESRC

## Background:

This project was a one-year, intensive case study of the everyday work of a speciality in clinical genetics. It focuses on the interaction of genetic technologies and clinical judgement within dysmorphology. The clinical work of dysmorphology displays the distinctive interactions of new medical technologies and more traditional forms of clinical perception. This ethnographic study documents the intersection of the 'clinic' and the gene. It provides an empirical corrective to premature assumptions that new genetic technologies automatically transform clinical practice.

## Key findings:

- We show that – in this crucial case at least - there is no one-way process of 'geneticisation' that automatically leads to a molecular reductionism in the clinic. Commentaries on the impact of new genetic technologies have too readily stressing the novelty of genetic testing and imply radical transformations in biological and medical paradigms We do not underplay the significance of genetic medicine, however, we emphasise the ways in which contemporary genetic medicine continues to incorporate and depend upon the long-standing mechanisms of clinical perception The 'clinical mentality' is not supplanted but supplemented by 'the gene'.
- Equally, our data from family-members strongly suggests, and supports other evidence, that the clients are not resistant of the labelling process of genetic medicine. Our data shows that the attribution of a genetic cause for dysmorphic conditions (where possible) can furnish ontological stability for the parents of affected children. Such a diagnosis can remove existential doubt as to aetiology and the moral agency of parents themselves. The diagnostic work of establishing diagnostic categories also accomplishes moral work in the clinic
- Our analysis of the performance of dysmorphology also illuminates the visual culture of the clinic. The inspection of patients' appearances and the uses of visual representations in assembling a clinical dysmorphic description highlights the spectacular display of clinical work. Dysmorphology thus furnishes a graphic exemplar of the visualisation of medical evidence in the construction of clinical entities.
- As a specialty, dysmorphology provides a rich and developing *nosography*. As we have indicated, the categorization of syndromes is not static. The classification and description of dysmorphic syndromes are subject to modification. This is, therefore, a nosography-in-the-making for some conditions at least. Dysmorphology has thus furnished us with a prime opportunity to document the processes of medical classification as it occurs.

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# The integrity of living beings as a normative concept in bioethics

**Principle investigator:** Michael Hauskeller (Egenis)  
**Project funder:** The Wellcome Trust

## Research aims:

The term integrity has been frequently used in moral debates about the genetic modification of animals. Usually it is claimed that an animal's integrity can be damaged even if its subjective well being is not affected. This may be thought to lend support to common intuitions about the intrinsic wrongness of all forms of animal genetic engineering. However it is not clear what integrity means, whether it is descriptive (and what it is supposed to describe) or prescriptive (and what it is supposed to prescribe) or both. Neither is it clear how integrity is related to other terms that were occasionally used in the debate, for instance an animal's 'basic nature', 'telos', 'dignity', or 'intrinsic value'. The project examined how the term is used, what moral concerns are addressed with it and whether those concerns can be philosophically justified.

## Key findings:

- Integrity was defined as an object's ideal condition and clarified by distinguishing between different kinds and modes of integrity, most importantly between hetero-integrity, which is dependent on an external reference point, and auto-integrity, which is determined by the nature of the object.
- It turned out that the only kind of integrity that can plausibly claim to be auto-integrity is biological integrity which is the ability to live according to one's own natural ends. That there are such natural ends present in individual animals and that they can plausibly be understood as establishing an objective good, was shown through a defence of Aristotelian biology and in particular his concept of final causes ('teloi').
- The project specified the relation between integrity and dignity by tracing them back to different traditions of thought: a *dignitas* tradition and a *bonitas* tradition. Integrity is rooted in the latter, which acknowledges the existence of an individual good in living creatures as a sufficient ground for objective intrinsic value which is the core of dignity. However, one can without logical contradiction grant the existence of such an objective value and yet deny that any moral obligations follow from it. This problem could not be solved but led to a discussion of the role of faith and emotions for morality which made it clear that all moral convictions ultimately rest on a quasi-religious intuition that what we do 'matters'.
- Once a moral stance is adopted, the biological integrity of animals should be respected. The reason for this is that animals exist as ends in themselves and not as means. It is argued that this fact is systematically concealed by the way genetically modified animals are conceptualized by those who create, use and sell them. Animals undergo a process of reification which eventually turns them into 'biofacts' with a seemingly diminished moral status. Yet although this is an illusion and biological integrity is still to be respected, there is no 'genetic integrity' as such so that the genetic modification of living beings cannot plausibly be held to be *intrinsically* wrong.
- The widespread belief among scientists and philosophers that medical research and medical practices can only be morally wrong if they increase the suffering of living beings has proved to be unjustified. Even when an action or a practice does not involve or produce suffering it is still possible and sometimes even reasonable to consider it morally wrong or at least dubious.
- Intrinsic concerns about the genetic modification of living beings and the use of biotechnology in general are to be taken seriously and can no longer be ignored on the grounds that they lack a rational basis and are at best merely aesthetic.
- The notion of harm has a wider application and covers more than just an impairment of subjective well being. 'Integrity' is a useful term that captures those concerns that go 'beyond well-being'.

## Wider implications for policy:

The arguments proposed in order to justify those widespread concerns should – provided they are valid and will be accepted – lend support to policy makers who are willing to take those concerns into account and save them from the awkward choice of either succumbing to the apparently irrational or pushing through decisions that a considerable part of the public find objectionable.

## Publications:

Hauskeller, M, (2005) Being Queasy about Reconstructing Animals, in *The Australian Journal for Professional and Applied Ethics* Telos.  
Hauskeller, M, The Revival of an Aristotelian Notion in Present Day Ethics, in *Inquiry* 48/1 (2004), pp 62-75.  
Hauskeller, M, Integrity and Dignity. Is there a difference?, in *Revista Romana de Bioetica* 1/3 (2003), pp 81-88.  
*Biotechnology and the Integrity of Life*, Ashgate, 2007

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# The social dynamics of public engagement in stem cell research

**Principal investigator:** Sarah Parry (Innogen)  
**Research fellow:** Fiona Harris, Stephen Bates, Nicola Marks  
**Associated staff:** S. Cunningham-Burley (Public Health Sciences & Centre for Research on Families and Relationships (CRFR);  
Dr W. Faulkner (Science Studies Unit); Prof A. Smith (ISCR).  
**Project funder:** ESRC

## Background:

This three year study aims to critically explore the scope for public engagement in stem cell research (SCR) and has two parallel aims. Firstly, to explore the social, cultural and ethical issues generated by stem cell research. Secondly to 'test' a range of public engagement techniques, for example, citizens' panels, focus groups, public meetings, education packs for schools, along with developing experimental approaches to this. Positive efforts will be made to engage the full spectrum of Scottish society, including hard-to-reach groups as well as scientists working in the field of stem cell research, potential users of therapies and other 'public' groups. It is intended that this project will critically engage with the issues relating to stem cell research and form an empirically based analysis of public engagement practices.

Specific objectives are:

- To examine how diverse groups of publics and scientists view a range of issues surrounding developments in SCR
- To 'situate' people's views in terms of their social identities and locations, and salient wider themes in contemporary culture
- To initiate a range of methods for promoting and researching public engagement in SCR, using the same social groups
- To analyse these efforts for insights into the social processes involved, and to explore practical ways of extending public participation in decision making about SCR.

## Research aims:

- To investigate views and concerns about Stem Cell Research, and
- To explore the scope for increasing public engagement in the developing field.

## Methods:

A literature review of the relevant literature will include: techniques of public engagement; critical approaches to the public understanding of science; the social implications of stem cell research and the new genetics. Two rounds of focus groups will be conducted with a range of stakeholder and non-stakeholder publics. These will include scientists, members of patient groups and other diverse publics ranging in age, social and geographic location. From these groups, members will be selected and invited to participate in further public engagement activities. These will be identified with assistance from participants. A range of different public engagement events and activities will be organised and analysed and also an educational intervention for teenage school pupils.

## Key interim findings:

- A recruitment matrix has been developed and a sample identified for the first round of focus groups.
- Collaboration with the Institute for Stem Cell Research to devise project information materials and develop the schools-based arm of the project with a newly recruited Science Communications Officer at ISCR.
- Significant progress with a wide-ranging literature review.

As the project is still in the early stages, the following is a list of anticipated areas of contribution:

- Contributions to sociology - the sociology of scientific knowledge; medical sociology.
- Sociology & social anthropology - conceptualising the body, emotion and personhood; constructions of the nature/culture boundary.
- Social anthropology - belief, the body and relatedness; anthropology of science; medical anthropology.
- Science & technology studies - theoretical debates around knowledge & expertise; critical approaches to the public understanding of science; development of innovative methods of public engagement in science.
- Public health - changing notions of health and illness; experiences of disability and health.

## Publications:

We anticipate submitting policy briefings and papers to a range of journals, which might include the following: *Science, Technology & Human Values*, *Social Studies of Science*, *Public Understanding of Science*, *Journal of the Royal Anthropological Institute*, *British Journal of Sociology*, *Social Science & Medicine*.

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# The transgenerational communication of genetic information

**Investigators:** Angus Clarke (Cesagen), Paul Atkinson (Cesagen), Peter Collins (University of Cardiff), Maggie Gregory (Cesagen), Paula Boddington (Cesagen), Rebecca Dimond (Cesagen)

**Project funder:** The Wellcome Trust

## Background:

The project aims to discover the ways in which genetic information is transmitted vertically between generations (between parents and children and, less commonly, from parent to grandparent) in four disease-related contexts which have different genetic bases. The communication of genetic information among family members raises many issues of principle. There may be good clinical reasons why a family member should pass on information to another about their genetic risk but communication may be hindered by other factors. Previous studies of the wider family (including siblings and cousins) have shown that there can be a number of barriers to the communication of information, including distance and estrangement. These are less likely to apply in parental-child relationships and other factors may come into play.

## Research aims:

The project aims to provide important background information for the development of policy on several contentious areas. Understanding family behaviour and motivational accounting will clarify the issues raised when family members make decisions about the genetic testing of children and more generally about the transmission of genetic information. This will be helpful in training current and future practitioners of genetic counselling.

## Key interim findings:

- To date the project has concentrated on families with haemophilia. This is a sex-linked recessive condition; while males have the condition, it is passed through the female line of the family as the genes for blood clotting are carried on the X chromosome. Interviews have been carried out with families where the father has haemophilia and thus his daughter/s are obligate carriers and with those where the mother carries the faulty gene. In the latter case a female child has a 50% chance of inheriting that gene and thus being a carrier. Genetic testing is needed to establish whether the daughter is a carrier.
- Preliminary analysis of the interview data shows that for families with a history of haemophilia, the existence of the condition is part of everyday life and generally there are few problems in the communication of information to daughters about their carrier, or potential carrier, status.

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# The use of family history in the risk assessment and primary prevention of heart disease

<b>Researcher:</b>	Hannah Farrimond (Egenis)
<b>Qualitative lead of the project:</b>	Paula Saukko (Egenis)
<b>Research team:</b>	Nadeem Qureshi (University of Nottingham), Steve Humphries (University College London), P Yoon (CDC), Joe Kai (University of Nottingham), Sarah Armstrong (University of Nottingham)
<b>Project co-funder:</b>	Department of Health, Genetics Based Health Services

## Research aims:

- What are the psychological, behavioural and economic impacts of including a family history of heart disease into routine coronary heart disease (CHD) risk assessments?
- What is the impact of being identified as 'high risk' of CHD over the short and longer term?
- How does family history of heart disease impact on the motivation both to seek treatment and engage in behaviour change?

## Methods:

- Quantitative randomised controlled trial with 24 practices in the South West and Nottingham. Twelve practices received risk calculations for patients without family history (controls) and six practices received risk calculations including family history (intervention). High risk participants are followed-up. Questionnaires assessing psychological and behavioural change are given at baseline, two weeks after results and six months later. Recruitment is still ongoing.
- Nested qualitative study. 'High risk' participants (n=38) are interviewed two weeks and six months later. Six focus groups are also being conducted with clinicians from the family history intervention practices.

## Key preliminary findings (from qualitative interviews):

- For many participants, being identified as 'high risk' came initially as a 'shock'. This was less the case for those with a positive family history. Making sense of being 'high risk' was an ongoing process. Participants often switched from feeling vulnerable to feeling not at risk within the same conversation, suggesting their identity as 'high risk' is neither stable nor established.
- Most 'high risk' participants were in older middle-age (55-65) years. As a consequence, many reported co-morbidity, ranging from a bad back to more serious illnesses such as cancer. This had two consequences. For some, it lessened the importance of being identified as at risk of CVD as being '*the least of my worries*'. It also meant that although many participants were keen to change as a consequence of the intervention, they were stopped by physical barriers, particularly in relation to exercise. On the other hand, many in this age group were very engaged with the notion of 'living a healthy lifestyle' and further dietary change is possible within this mind-set.
- Health is a 'joint project' for many couples in this social context. Participants talked about the 'we' rather than the 'I', particularly in relation to diet and potential changes.
- Family history was a orienting factor which motivated the initiation of risk assessments as much as subsequent behaviour changes.

## Wider implications for policy:

- CHD risk assessments and interventions need to take account of the distinct social context of 'high risk' participants, particularly in relation to their age, class and their understanding of health as a communal practice.
- There may be a case for targeting younger individuals who will be the 'high risk' patients of the future as the potential for change may be greater in this age group.
- Family history resonates with many individuals as a motivator to seek assessment and monitoring. It should therefore be included in health promotion materials encouraging people to have CVD risk assessments in primary care, as is the case with diabetes.
- If family history is to be included as an identifying 'marker' of risk in CVD primary prevention, as the current NICE preliminary guidelines are suggesting, further guidance will be needed on how to assess family history and utilise it effectively within clinical consultations, as well as on how to record family history systematically and consistently across the NHS.

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# Innovation and Evolution in the Life Science Industries

The life sciences have been part of every major country's innovation portfolio for at least the last twenty five years, yet the story has often been one of unfulfilled promise. EGN researchers have studied innovation systems and also regional and national economic policies to gain insights into the sources of success (and of failure) in the life science industries.

# Genetics, genomics and genetic modification in agriculture: emerging knowledge-practices in making and managing farm livestock

**Lead investigator:** Carol Morris (Egenis)

## **Background:**

Egenis supported the development of an ESRC grant proposal to investigate an aspect of the social dimensions of farm animal genomics. The application process was successful and the research itself will commence in autumn 2007, involving the Universities of Hull, Nottingham and Exeter. A summary of what the research will entail is provided below.

## **Research aims:**

According to the scientists involved, recent advances in genetic and genomic science herald a 'new era' - even a 'revolution' - in farm animal breeding. However, in spite of the considerable scientific activity and commercial interest in farm animal genetics and genomics, it is notable that these advances have stimulated very little social scientific inquiry. And yet, these techniques and technologies raise many important social questions. This research will focus on pedigree cattle and sheep breed societies and breeders, and on the ways in which they are engaging with the science that is trying to explain and improve livestock through genetic and genomic advances. These groups are particularly significant because of their direct involvement in selection and the production of future generations of breeding animals. The research will examine how livestock breeding knowledge-practices and geographies of livestock breeding are being reconfigured in relation to emerging genetic/genomic knowledge-practices (we understand *knowledge* as inseparable from *practice*, so we refer to *knowledge-practices* in acknowledgement of the co-constitutive relationship between them and of the different forms these can take). Three specific objectives follow:

- to examine the relationships between an emerging genetic/genomic science of livestock and lay livestock breeding knowledge-practices;
- to assess how breeder identities, farm businesses and human-animal relationships are being affected by genetic/genomic science;
- to examine the roles of different actors in emerging livestock breeding networks associated with genetic/genomic science and the circulation of genetic/genomic knowledge through these networks.

Using three specific genetic/genomic techniques in beef cattle and sheep breeding - genetic 'merit' assessments; genetic markers; and genetic modification - the research will adopt a multi-method approach to realising its objectives, including:

- Interviews and discussion groups with breed societies and livestock breeders involved in cattle and sheep breeding;
- Interviews with animal scientists working in farm animal genetics and genomics in both the public and private sectors;
- Interviews with the representatives of various 'intermediary' institutions such as agricultural colleges and research institutes, commercial breeding services, the National Beef Association and National Sheep Association;
- Textual analysis of various agricultural media reporting genetic and genomic advances;
- Use of a Consultation Panel of experts and interested individuals to guide the progress and development of the research.

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## Genomics innovation in Scotland

<b>Research fellow:</b>	Alessandro Rosiello (Innogen)
<b>Principal investigator:</b>	Joyce Tait (Innogen)
<b>Associated staff:</b>	Robin Williams (Innogen)
<b>Project funder:</b>	Scottish Enterprise (SE)

### Background:

Biotechnology is a classical example of a knowledge-based industry. Understanding the process of industrial and technological change requires concentrating on the interaction among a plurality of players and on the processes of knowledge 'exploration', 'examination' and 'exploitation'. This research has concentrated on the effect of knowledge exploration and exploitation dynamics and its interaction with institutional infrastructure, with collaboration networks and innovation policy on firms' locational choices.

### Research aims:

Empirical analysis has aimed to find out:

- Whether SE was able to encourage collaborative behaviour and the establishment of networks helping individual firms get access to and employ key assets?
- How important are the links outside Scotland?
- How significant and effective have the diverse activities of Scottish Enterprise been in support of companies' activities?
- What type of support have companies received from intermediaries such as lawyers and financial institutions?

### Methods:

Review of the literature on clusters and systems of innovation, including in-depth examination of theoretical and applied works on geographical agglomeration in high tech industries and of policy measures inspired by the doctrine of the 'triple-helix'. Dr Rosiello has collected evidence on the Scottish, Danish and Swedish systems of innovation and legislative/institutional frameworks. Interviews have been conducted in 18 core biotechnology companies based in Scotland and 14 based in Sweden and Denmark. The data were analysed in terms of: the impact of the policy framework on firms' location decisions; knowledge creation, use and transfer, the mechanisms of such process and how this affects firms' strategies and behaviour; and the inter-play and co-evolution between industrial and innovation trajectories and institutions.

### Key findings:

- The results are providing useful information on the influence of public policies on the development of effective corporate strategies, and the growth of a significant number of competitive firms in Scotland.
- Dr Rosiello has attended and presented papers at conferences and workshops in the UK, Italy, Holland, France and USA and expanded his network of connections with industrialists (CEOs of biotech companies), academics in the Copenhagen Business School, University of Toronto, the National Institute of Engineering, Technology and Innovation in Lisbon, and policy makers.
- Over the next few months, he will analyse the survey data from Scotland and Medicon Valley (Sweden and Denmark) in preparation for writing the final report and other publications.
- Recognised co-evolution of public policy, industrial structure and science/technology in different contexts;
- Factors affecting locational choices by dedicated biotechnology companies: more interested in learning and enhancing core competences than in stabilising relationships with suppliers and commercial partners, this includes:
  - Access to financial resources;
  - Facilitated access to knowledge in public research institutions;
  - Support in establishing international collaborations;
  - Availability of skilled labour force;
  - Local knowledge dynamics influence locational decisions but the biotech industry is truly affected by an early process of internationalisation.

### Publications:

- Rosiello, A (2004) At the Interfaces of Governance and Competence Perspectives presented at the *Proximity Economics: Proximity, Networks, and Co-operation* conference in Marseille, June 2004
- Rosiello, A (2004) Genomics Innovation in Scotland presented at the *20th EGOS Colloquium in The Organization as a Set of Dynamic Relationships* in Ljubljana, July 2004. This paper is under review by *Urban Studies*.
- Rosiello, A (2004) Discussing Organisational Choices in the Scottish Biotech Industry, presented at *Shifting Boundaries: Governance, Competence and Economic Organisation in the Knowledge Economy Conference* in Bristol. This paper is forthcoming in a special issue regarding the conference proceedings in *Technology Analysis and Strategic Management*.
- Rosiello, A (2004) On Knowledge Creation, Use and Transfer in the Scottish Biotech Cluster, presented at the *EUNIP* conference in Birmingham, December 2004.
- Rosiello, A (2005) The Institutional Foundations of the Scottish Life Sciences Sector, under review by the *Fraser of Allander's Quarterly Economic Commentary*.

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# Innovation processes in life science industries

**Principal investigator:** Joyce Tait (Innogen)  
**Research fellow:** James Mitra (Innogen)  
**Associated staff:** Donald MacKenzie (Innogen); David Wield (Innogen); Robin Williams (Innogen)

## Background:

Life science innovation is restructuring scientific research and its commercial applications in a variety of public and private sector organisations. In the pharmaceutical sector, new and complex re-alignments of companies and networks (through mergers, acquisitions, strategic alliances & licensing activities) are taking shape as companies attempt to extract value from new technologies and respond to internal and external pressures. This has the potential to fundamentally affect the existing processes of drug discovery, development and marketing. The promise of 'genomics' is that drug discovery and development will be expedited and the safety and efficacy of new therapies will be improved. There is deep uncertainty, however, about how best to extract value from genomics and what kinds of changes in firm strategy, innovation models, and regulatory processes may be needed.

## Research aims:

- Focusing on the science and industry side of these issues, this project investigated the changing nature, direction and management of life science-based innovations in the pharmaceutical industry.
- The key objectives were to investigate changing industry dynamics and structure in the context of the life sciences; assess the impact of changes in the knowledge and technology base on organisation and strategic management; and explore changing company relationships and interactions in the context of the global challenges facing drug R&D.

## Methods:

- Company-based case studies and in-depth interviews with senior scientists and managers within large pharmaceutical companies.
- Analysis of data from company websites, annual reports, press releases etc
- Analysis of commercial and therapeutic trends data from consultancy reports and external databases

## Key findings:

- New Technologies have radically changed aspects of early-stage R&D, but not yet revolutionised downstream drug development
- Failure of Big Pharma to fully exploit the life sciences reflect current strategic/commercial priorities and uncertainties in the operating environment
- Strategies to extract value from new technologies dependent on internal firm-specific factors.
- Diverse organisational models and strategies for improving the health innovation cycle have emerged; challenging the notion of a single Big Pharma model.
- Despite emphasis on distributed innovation systems and new therapeutic foci, the traditional 'blockbuster' approach persists
- Uncertainties of the external regulatory/policy environment, and growth of the biotech sector, continues to challenge traditional strategies

## Publications:

- Mitra, J. (2007) The Impact of Life Science Innovations on the Organisation and Strategic Management of Pharmaceutical R&D (Submitted to *Industry and Innovation*)
- Mitra, J., and Williams, R. (2007) Editorial: Evolution of the Life Science Industries, *Technology Analysis and Strategic Management*, Special Issue, 19 (3), pp. 251-255
- Mitra, J. (2007) Life Science Innovation and the Re-structuring of the Pharmaceutical Sector: Mergers, Acquisitions and Strategic Alliances, *Technology Analysis and Strategic Management*, 19 (3), pp. 279-301
- Tait, J. (2007) Systemic Interactions in Life Science Innovation, *Technology Analysis and Strategic Management*, 19 (3), pp.257-277
- Mitra, J. (2006) The Socio-Political Economy of Pharmaceutical Mergers: A Case study of Sanofi and Aventis, *Technology Analysis and Strategic Management*, 18 (5), pp. 473-496
- Mitra, J. and Tait, J. (2006) Public-Private Partnerships in Translational Medicine: Scotland's Translational Medicine Research Collaboration, Case study prepared for OECD Expert workshop on Emerging Research Models for the Delivery of Health Innovation (this case study will soon be published in an OECD report)
- Tait, J., and Mitra, J. (2006) 'Singing from the same Hymn Sheet: Can Genomics Harmonise with Chemistry?' *CHEManager*, August, 2006, p.14
- Tait, J. & Mitra, J. (2005) Big Pharma: Coping with Complexity, *ESRC Genomics Network Newsletter*, Issue 2, June 2005
- Mitra, J. (2005) Pharmaceutical Industries: Do They Prefer Treatment to Cure? *The Biochemist* 27 (3): pp. 32-34
- Tait, J. & Mitra, J. (2004) Industry Challenges, *Chemistry and Industry*, 6 December, 2004, No. 23, pp. 24
- Mitra, J., Suk, J & Tait, J. (2007) Risk Governance of Stem Cells as Therapeutic Products, RiskBridge essay, May 2007
- Mitra, J. (2007) Changing Strategies of Big Pharma, *Innogen Policy Brief*
- Tait, J. (2007) Creative Disruption in Life Science Industries, *Innogen Policy Brief*

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## New directions in genomics

This overarching field of research at Egenis covers the following areas:

**The philosophy of systems biology**

**The sociology of systems biology**

**Synthetic biology : philosophical considerations**

**Metagenomics and microbiology**

**Project co-funders:** ESRC and Arts and Humanities Research Council (AHRC)

### General Resources:

An annotated bibliographic database of key scientific papers in genomics, systems biology, synthetic biology, metagenomics, sociogenomics and sociomicrobiology is available on the Egenis website.

Powell, A., O'Malley, M.A., Mueller-Wille, S., Calvert, J. and Dupré, J. (forthcoming, 2007). Disciplinary baptisms: A comparison of the naming stories of genetics, molecular biology, genomics and systems biology. *History and Philosophy of the Life Sciences*.

## Systems biology

**Research team:** Jane Calvert (Egenis), Jonathan Davies (Egenis), John Dupré (Egenis),  
Dan Nicholson (Egenis), Maureen O'Malley (Egenis) and Alexander Powell (Egenis)

### Background:

Systems biology is a new approach to biology which makes use of computational tools and mathematical modelling to analyse the vast amounts of data that have been generated by genome sequencing and other 'omic' projects. It requires the collaboration of scientists from many different disciplines, including physicists, mathematicians, computer scientists, engineers and biologists. Because of its potential to transform biology and healthcare, systems biology has been heralded as the future of genomics and has received high levels of investment around the globe.

Systems biology raises numerous interesting philosophical and social issues, from system conceptualization and the evaluation of modelling techniques to the social achievement of interdisciplinarity. Our work on systems biology in Egenis falls into two interacting categories: the philosophy of systems biology and the sociology of systems biology.

# The philosophy of systems biology

## Research team:

Jane Calvert (Egenis), Jonathan Davies (Egenis), John Dupré (Egenis),  
Dan Nicholson (Egenis), Maureen O'Malley (Egenis) and Alexander Powell (Egenis)

## Background:

Our project is based on a distinction between two overlapping modes of practising and thinking about systems biology. One we call *pragmatic systems biology* and the other *systems-theoretic biology*. Pragmatic systems biologists see a system as an interacting collection of molecules and other components. More theoretically driven systems biologists see systems as special levels of biological organization. This distinction has implications for modelling practice. Pragmatic systems biologists normally model the interaction of molecules from the bottom-up. Systems-theoretic biologists, on the other hand, tend to model systems from the top-down. For both systems biologies, the simple diagrammatic models that are routinely encountered in biology are insufficient for modelling systems. Both groups believe that systems modelling has to be mathematical in order to capture the complexities of higher-level biological organization. We are investigating a number of philosophical questions in relation to each form of systems biology.

- The nature and properties of systems. Are systems merely collections of molecules, or entities with novel emergent properties? What are those properties? Which biological entities can be conceived of as systems?
- Reductionism. Reductionism is classically the attribution of ultimate reality to components, with higher-level entities considered to be no more than the sum of those components. Is pragmatic systems biology still reductionist?
- Emergence. What does emergence mean for systems biologists and how do they put this philosophical concept to practical use?
- Downward causation: system effects on components. The most robust form of anti-reductionism accords reality to systems and attributes causal powers to them. How is downward causation understood in systems biology? And how should causation more generally be thought of in relation to systems?

## Key findings:

- Our early analysis of systems biology uncovered two main epistemological trends in how systems biology was being practised: systems-theoretic biology and pragmatic systems biology. This analysis also raised some fundamental philosophical questions for systems biology to address. Further work has looked at the historical context of systems biology's development, with a particular focus on how it was named, in relation to the older disciplines of genetics, molecular biology and genomics.
- The combination of top-down and bottom up models in systems biology can be interpreted as the attempted reconciliation of two hitherto antagonistic modes of explanation: local and distributed causal explanation.

## Publications:

O'Malley, M. A., Calvert, J., and Dupré, J. (2007). The socioethical study of systems biology. *American Journal of Bioethics*, 7 (4): pp 67-78.

O'Malley, M. A., Calvert, J., and Dupré, J. (2007). Response to our commentators. *American Journal of Bioethics*, 7 (4): W7-W9.

O'Malley, M. A., and Dupré, J. (2005). Fundamental issues in systems biology. *BioEssays*, 27: pp 1270-76.

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# The sociology of systems biology

**Research fellow:** Jane Calvert (Egenis)

*This work has raised additional funding from the US Social Sciences Research Council (SSRC) for an ESRC/SSRC visiting fellowship.*

## Research aims:

The institutionalization of systems biology:

- What constitutes a systems biological approach? How is systems biology establishing itself as a new field? To what extent is systems biology continuous with previous biological research?

The organization of interdisciplinarity:

- What mechanisms are put in place to bring scientists together from very different disciplines? What implications does the interdisciplinarity of systems biology have for the allocation of expertise and for individual disciplinary identities?

Epistemic aspirations:

- What epistemic aspirations drive systems biology? Is it possible for biology to become an exact quantitative science with the facility for prediction and control?

The commercialization of systems biology:

- What implications does systems biology have for existing intellectual property regimes? How are guidelines being developed for the ownership of complex biological models and for standards for data sharing?

Socioethical discussion:

- What new social and ethical issues does systems biology raise? How will systems biology and its potentially contentious applications be perceived across society?

## Key findings:

The institutionalization of systems biology:

- Integration is a key feature of systems biology, at the level of data, technologies and disciplines, and at a meta-level of the integration of all of these within the field. Integration is an important metaphor for systems biology as a whole.

The organization of interdisciplinarity:

- It is often necessary for systems biologists to step outside of established organisational structures and disciplinary 'silos', and develop their own novel organisational forms.
- Expertise in systems biology is distributed, and all the necessary skills are rarely found in one person.
- Even in centres which specialise in systems biology not many scientists call themselves a 'systems biologist', although senior founders of the field and younger researchers are happier to adopt this identity.

Epistemic aspirations:

- In systems biology ideas about science and what it is to do science are articulated and discussed.
- Some systems biologists think that their field will make biology more rigorous and law-like. Others argue that the inherent complexity of biology mitigates against this.
- Some scientists doubt that true biological understanding will be achieved through systems biology, and advocate more traditional experimental approaches.

The commercialization of systems biology:

- Because biological systems are interconnected, dynamic and networked, intellectual property regimes which are based on the understanding of a gene as a static entity will not easily be applied to systems biology.

Socioethical discussion:

- The interactive and dynamic nature of systems biology means that ethical analyses which are based on critiques of genetic reductionism or determinism may have to be re-thought in a systems context.
- Systems biology's interdisciplinary approach, which purports to override conventional disciplinary distinctions, could potentially challenge the way we conceive of the relationship between natural scientists and those who study them.

## Publications:

O'Malley, M. A., Calvert, J., and Dupré, J. (2007). The socioethical study of systems biology. *American Journal of Bioethics*, 7 (4) pp. 67-78.

O'Malley, M. A., Calvert, J., and Dupré, J. (2007). Response to our commentators. *American Journal of Bioethics*, 7 (4): W7-W9.

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# Synthetic biology: philosophical considerations

**Research team:** Jane Calvert (Egenis), Jonathan Davies (Egenis), John Dupré (Egenis), Christine Hauskeller (Egenis), Dan Nicholson (Egenis), Maureen O'Malley, (Egenis) and Alexander Powell (Egenis)

## Background:

Synthetic biology is a rapidly growing scientific field with an increasingly high profile. Already synthetic biologists have succeeded in constructing a number of novel entities with a range of functions, some of which are just beginning to attract wider social attention.

## Research aims:

We are interested in two distinct aspects of synthetic biology: its epistemological basis and characteristics, and its relationship with definitions of life. Concerning the former we seek to conceptualize different approaches to synthetic biology in terms of their methods, aims and assumptions, and relate the approaches to each other and to other disciplines. In relation to the latter, our aim is to understand the ways in which biological definitions of life evolve with and within research directed at the synthesis of cellular components and protocells.

## Key findings:

We propose a categorization that identifies three inter-related and interacting approaches to the synthesis of biological entities. As well as having different aims and approaches they differ in terms of their commitments to genetic determinism, their attitude towards cellular context, and their handling of complexity and emergence.

- DNA-based device construction emphasizes the engineering principles of standardization, decoupling and abstraction, and aims at the construction of biological components that can be combined in a modular fashion ('BioBricks').
- Genome-driven cell engineering works at the whole-genome level, using top-down and bottom-up strategies to conduct minimal genome analysis, whole genome synthesis and the transplantation of modified genomes into cells.
- Protocell creation attempts to construct minimal cellular systems by synthesizing their basic molecular constituents or by a 'semi-synthetic' strategy in which extant genes and enzymes are inserted into vesicles.

Synthetic biology and related disciplines:

- Genetic, protein and metabolic engineering and synthetic biology share the common aim of creating novel functions by engineering biological material. Although synthetic biologists claim that greater use of design principles (rather than hit-and-miss approaches) and more engagement with context and system-wide properties (rather than specific genes and proteins) differentiates their work from related approaches, we find considerable continuity between synthetic biology and more established bioengineering approaches.
- Both systems biology and synthetic biology emphasize system-level behaviour, its dependence on networks of interacting components, and the quantitative modelling of function. With the exception of the protocell school, however, the attitude towards complexity of synthetic biologists differs from that of systems biologists.

Tensions in synthetic biology:

- Synthesis versus analysis: synthetic biology relies upon both synthetic and analytic approaches.
- Biology versus engineering: engineering approaches run the risk of sacrificing the ability to address the context dependence, non-linearity and evolvability of biological systems.
- Complexity versus simplicity: what are the implications of the removal of complexity from biological systems for the possibility of understanding them as living systems?

If synthetic biology is to extend biological understanding, ways will have to be found to incorporate, rather than reduce, the inherent complexity of biological systems. This may require reformulation or extension of the engineering principles that currently dominate the field, as well as continued interaction between the different approaches it subsumes and engagement with wider biological interests.

## Publications:

Hauskeller, C. (2007, in press) Towards a critical evaluation of proto cell research, in Bedau, M. and Parke, E. (eds), *Our Future with Protocells*, Boston, Mass.: MIT Press.

O'Malley, MA., Powell, A., Davies, JF., and Calvert, J. (forthcoming, December 2007). Knowledge-making distinctions in synthetic biology. *BioEssays*, 29 (12).

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# Metagenomics and microbiology

**Research team:** John Dupré (Egenis), Maureen O'Malley (Egenis)

## Background:

Metagenomics is the large-scale study of the DNA of naturally existing microbial communities rather than 'artificial' lab cultures. It can involve the shotgun sequencing of all the genomes in these communities, but is most likely to be about screening and sequencing large segments of DNA extracted from wide-ranging environmental samples.

Metagenomics does more, however, than merely provide microbiologists with lots of interesting DNA sequence data. It takes a non-traditional focus on the genomic resource of a dynamic microbial community, rather than individual strains of microbes or individual genes and their functions. A community genomics perspective is interested in how horizontal transfer allows otherwise distantly related organisms to share these resources.

Moreover, metagenomics analyses microbial communities as systems that have functional properties that go beyond those of individual genes or individual microbes (or even single-taxon populations). Metabolic cascades, for example, can be distributed over different members of multi-taxon communities. We could say, therefore, that metagenomics studies something like a metaorganism, and that understanding such an entity also requires a systems-biologic approach. We examine all these aspects of metagenomics in the philosophical strand of our investigation.

One of the major success stories in metagenomics involves the discovery in marine bacteria of totally unexpected genes and proteins called proteorhodopsins, which are involved in previously undetected processes of photobiology. The torrent of research (biophysical, biochemical, physiological, phylogenetic) this finding has initiated provides a remarkable illustration of the power of a metagenomic approach. This case study has been a focus of our 2007 work on metagenomics.

## Key findings:

- As well as identifying a microbiological gap in the philosophy of biology, we launched a discussion about the ontological implications of metagenomics for philosophical questions in biology to do with units of investigation, evolution and selection.
- Follow-up research has investigated the historical roots of the debate about biogeography in contemporary molecular microbiology, as well as the nature of experimentation in the discovery of proteorhodopsin made via metagenomic analysis.

## Publications:

O'Malley, M. A., and Dupré, J. (2007). Size doesn't matter: towards a more inclusive philosophy of biology. *Biology and Philosophy*, 22 (2): pp155-191.

Dupré, J., and O'Malley, M. A. (in press). Metagenomics and biological ontology. *Studies in History and Philosophy of Biological and Biomedical Sciences*.

O'Malley, M. A., and Dupré, J. (in press). Introduction: Towards a philosophy of microbiology. *Studies in History and Philosophy of Biological and Biomedical Sciences*.

O'Malley, M. A. (2007). The nineteenth-century roots of *Everything is everywhere*. *Nature Reviews Microbiology*, 5: 647-651.

O'Malley, M. A., and Boucher, Y. (2005). Paradigm change in evolutionary microbiology. *Studies in History and Philosophy of Biological & Biomedical Sciences*, 36: pp183-208.

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# The economics of innovation in the biotechnology sector

**Principal investigator:** Phil Cooke (Cesagen)  
**Research associate:** David Knight (Cesagen)

## Research aims:

This flagship project has the key aim of understanding the dynamics of pharmaceuticals biotechnology in the post-genomic era. The research is set within a 'systems of innovation' perspective and is interested in national, regional and technological dimensions of post-genomic biotechnology's innovation systems. Thus the research, which focuses upon post-genomic biotechnology dynamics in the UK, identifies the economic geography, industry organisation and structural dynamics of the sector.

## Key findings:

- First, it is a heavily clustered industry in that most of the UK's incumbents are found within commuting distance of Cambridge, Oxford and to a lesser extent, Central Scotland. Incipient clusters exist in Cardiff, Manchester and York. In every case proximity to RAE5\* or 6 bioscience research causes this. Proximity to sources of tacit knowledge is extremely important for businesses at the early establishment phase, and later, attracted by an emerging market, business services firms move to such locations, accordingly embedding mature firms.
- Second, in industry organisation, the sector is a pioneer of 'open innovation' and influential on industry organisation in other sectors accordingly. 'Open innovation' characterises research conducted by smaller knowledge-intensive biotechnology laboratories and firms at the behest of large multinational pharmaceuticals companies. R&D outsourcing has thus grown – dramatically in the 1990s – as internal R&D capabilities of 'big pharma' have diminished.
- Third, the structural dynamics of post-genomic biotechnology reveal small businesses and laboratories being the repository of 'exploration' knowledge, concentrated in regional innovation systems as specialised biotechnology clusters. Meanwhile, 'examination' knowledge firms specialising in clinical research, combinatorial chemistry and for 'exploitation' knowledge (commercialisation), industry financing, are found in close proximity within clusters or in easy reach of them from regional innovation systems. But the industry is also highly globalised and the technological system extends accordingly.

## Wider implications for policy:

Policy makers have found these results interesting and important because of three main concerns the research addresses:

- In the UK and Europe, to what extent will commercial biopharmaceuticals research continue to be viable if, as our evidence shows, the R&D headquarters of European firms have largely relocated to North America? The logic of this is a further weakening of UK and European knowledge exploitation unless models that exploit, especially, US commercial know-how are evolved.
- To what extent will this translocation of research clients affect basic research in universities and research institutes in the UK? There is evidence that UK and European basic research remains competitive (on smaller budgets), and that late stage pipeline candidate biotechnologically derived drugs are marginally greater in number in Europe than the US.
- What are the scientometric characteristics of successful UK and European research teams. Leading UK and European researchers co-publish significantly with each other and North Americans. Similarly, leading institutes and firms engage in significant transatlantic co-patenting.

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A link to the project website is at: [www.cesagen.lancs.ac.uk/research/projects/economics.htm](http://www.cesagen.lancs.ac.uk/research/projects/economics.htm)

# The role of venture capital in promoting high tech and science-based growth: a new rationale for European policy making

**Principal investigator:** Joyce Tait (Innogen)  
**Associated staff:** Julian Sulej (University of Dundee/Innogen) and Alessandro Rosiello (Innogen)  
Shefaly Yogendra (The Policy Analyst)  
**Project funder:** PRIME Network of Excellence

## Background:

Changes in the organisation of science-based industries is increasingly based on the entry and development of new high tech firms. Venture capital (VC) is considered here as a specific industry whose purpose is to contribute to the technological and financial choices of innovating firms. It is seen as a component of an innovation system whose interactions go beyond financial support so that venture capitalists are part of the selection environment that allow economic systems to change with regard to innovation and growth. This selection function is termed intermediation. Innogen is a partner in this project along with researchers from France, Finland, Italy and Israel.

## Research aims:

- Are there institutional characteristics of the respective national innovation systems that influence the development of the VC industry in each country?
- To what extent is the development of VC industry sector-specific: the lessons from two industrial areas (ICT and biotechnology)
- Are some forms of VC intermediation more prone than others to internationalise? Can we speak of the competitiveness of VC industries?

## Methods:

- Desk based research on 'grey' literature and published papers; analysis of existing databases on the VC industry.
- Quantitative data collection: a comprehensive data set has been gathered comprising information on any deal in the pharmaceutical and biotechnology sectors for the 1996-2006 period.
- Qualitative data collection: 20 in-depth interviews have been conducted with venture capitalists and the directors of dedicated biotechnology companies in Cambridge and Scotland.
- Design of a framework for identifying policy implications and developing policy lessons for the countries participating in the project.
- Development of a further proposal for EC funding through the PRIME Network.

## Key findings:

- Description of VC investment patterns in terms of incentives, targets, and value-added provided to investees
- Quantitative evidence as regards the concentration of VC investments in knowledge intensive areas in the UK
- Qualitative and Quantitative data have been coupled to explain the relationship between the provision of added-value and the regionalisation of VC investment.

## Publications:

Rosiello, A, Parris, S, and Massimiliano, C., Venture Capital as a New Form of Intermediation: Implication for the Emergence of Bio-Clusters in the UK. This paper will be presented at the final *PRIME VC FUN* dissemination workshop in Rome, December 2007.

Rosiello, A, Teubal, M, and Avnimelech, G., Towards the Framing of Venture Capital Policies in Europe. The paper will be presented at the *Atlanta Conference on Science, Technology, and Innovation Policy 2007*.

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# Transcending the genome: the paradigm shift to proteomics

**Principal investigator:** Peter Glasner (Cesagen)  
**Senior research associate:** Ruth McNally (Cesagen)  
**PhD students:** Andrew Bartlett (Cesagen), Jamie Lewis (Cesagen)

## Background:

For most of the 20<sup>th</sup> century, the gene occupied a privileged position in Western culture, reaching its ultimate expression in the Human Genome Project (HGP) and other genome initiatives. Whilst the resultant genomic DNA sequences are widely acknowledged to be invaluable resources, these initiatives highlighted complexities in biological systems which transcend the explanatory power of genomic DNA. Rather than marking the pinnacle, the HGP has been re-cast as the foundation and blueprint for a new era of research in the biosciences. This project critically examines claims for a paradigm shift in the 21<sup>st</sup> century biosciences through the lens of the emergent field of proteomics.

## Research aims:

- To explore whether, and in what ways, knowledge production in the biosciences is undergoing a transformation
- To experiment with research methods commensurate with 21<sup>st</sup> century 'laboratory life'
- To reflect upon the relationships between trajectories of knowledge production in the biosciences and the social sciences that study them

## Methods:

- IssueCrawler software to locate, map and monitor proteomics on the Web.
- Qualitative analysis of proteomics publications and communications.
- Interviews with leading local, national and international figures.
- Participant / observation (Ruth) as Secretary to the Human Proteome Organisation's (HUPO) Proteomics Standards Initiative Mass Spectrometry Working Group.
- Participant / observation at face-to-face meetings including presentation at HUPO and invited speaker in Brazil.

## Key findings:

- Proteomics, the protein counterpart of genomics, was the first of the new 'omic' 'discovery sciences' to mimic genomics. It is a growing, global phenomenon. There are at least 35 proteomics societies (most in Europe, none in India or Africa). Since 2002 HUPO has co-ordinated the Human Proteome Project comprising 8 international Initiatives, the largest single sponsor of which is the government of China.
- The proteomics community comprises a heterogeneous network of organisations, including specialist journals, research centres and initiatives, instrument and software vendors, and online research tools and databases (McNally 2005).
- Compared to protein *Laboratory Life* in the mid 1970s (Latour and Woolgar), proteomics knowledge production is:  
Bigger – 'Big science'  
On-line and digital – 'E-science'  
More multidisciplinary – but less of a bioscience?
- The extent to which these transformations constitute a radical change is contested. Whilst discourses of paradigm shifts and revolutionary changes are dominant, they co-exist with informal and local resistances and assertions that 'paradigm talk' is just 'marketing talk', an 'obligatory passage point' to the acquisition of resources.
- Definitions of 'proteome' and 'proteomics' remain in a state of flux amidst a broader, ongoing 'turf war' over the naming and definition of research fields, features of 'boundary work' which is allied to competition for resources.
- Regarding the future, two distinct trends can be identified (McNally and Glasner 2007). One is 'de-geneticisation', apparent in the emergence of research fields with 'de-geneticised' names, such as transcriptomics, proteomics, metabolomics, systems biology and even synthetic biology, which could signal the gene's demise and herald the dawn of a 'post-genomic era'.
- The other trend is the expansion of genomics through 'functional genomics', which extends the molecular repertoire of genomics to encompass proteins and other biomolecules as well as DNA, a manoeuvre which not only enables genomics to claim resources for research on proteins, but also treats proteomics as a toolbox rather than a discipline.
- 'Systems biology' also treats the 'omics' not as ends in themselves but as infrastructures, whose role is to populate community databases with standardised, digital datasets which collectively constitute a comprehensive catalogue (parts list) of biomolecules and their functions. The goal of the 'new biologies' is to take 20<sup>th</sup> century molecular biology and genetic engineering to another level.
- However, current proteomics platforms only capture the so-called 'low hanging fruits' which constitute just a fraction of the protein types in a sample. This means that whilst protein biologists may feel they are drowning in a sea of data, systems biologists waiting at the end of the proteomics data pipeline are more likely to complain of thirst.
- Moreover, there are also pressures on/within proteomics to temper the pure "discovery science" approach with research that (also) targets biomarker-discovery.

## Sociomics: Opening the Omic Black Box and finding ourselves inside

- Sociomics is a word we have coined to capture convergences and entanglements between knowledge production in omics and the social sciences. Sociomics is also a manifesto for a 'third wave' of science studies, that rises to the unique opportunities and responsibilities of studying knowledge production in the omics and the new 21<sup>st</sup> century biologies.

**Publications:**

- McNally (2005). Sociomics! Using the IssueCrawler to map, monitor & engage with the global proteomics research network. *Proteomics* 5(12): pp.3010-3016
- McNally and Glasner (2007) Survival of the gene? Twenty-first century visions from genomics, proteomics and the new biology. *New Genetics, New Social Formations*. Glasner, Atkinson and Greenslade (eds). London, Routledge, pp.253-278
- Glasner, P. (2002) Beyond the genome: Reconstituting the new genetics, *New Genetics and Society* 21(3): 267-277

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A link to the project website is at:

<http://www.lancs.ac.uk/fss/centres/cesagenflag/proteomics/>

October 2007 marks the start of a new era for the ESRC Genomics Network with the transition to the second phase of ESRC support that will fund activities until 2012.

The Network's Phase II research themes and projects are listed below.

For further information on this work, please visit: [www.genomicsnetwork.ac.uk](http://www.genomicsnetwork.ac.uk)

Science, Technology and Innovation	
<b>cesagen</b>	<b>Bioknowledge economies and sustainable Innovations</b> <i>Projects:</i> Knowledge economies; Globalisation; Sustainable innovation
<b>egenis</b>	<b>New directions in genomics</b> <i>Projects:</i> Systems biology; Metagenomics; Synthetic biology
<b>innogen</b>	<b>The new life science economy</b> <i>Projects:</i> Company strategies; Public/private sector applications; Convergence/divergences of life-science industries; Globalisation; Public/private partnerships; New techno-scientific models (Systems biology; Translational research)

Governance, Regulation and Public Interest	
<b>cesagen</b>	<b>Publics and the media*</b> <i>Projects:</i> Public engagement; Media and cultural representations
<b>egenis</b>	<b>Co-production of life sciences</b> <i>Projects:</i> Intellectual property and property regimes
<b>innogen</b>	<b>Governance of innovation in life sciences</b> <i>Projects:</i> Multi-level governance; Evolution of regulatory regimes; Compressed foresight and new approaches to engagement; Values, interests and styles of engagements

\* A cross-cutting theme through all Cesagen projects.

Biomedicine, Health and Identity	
<b>cesagen</b>	<b>Biomedicine, identity and behaviour</b> <i>Projects:</i> Susceptibility genes; Behavioural genetics and psychiatry;
<b>egenis</b>	<b>Preventive medicine and genomics of common disease</b> <i>Projects:</i> Genomics and coronary heart disease; Nutrigenomics; Genomics of ageing
<b>innogen</b>	<b>Access, inclusion and genetic technologies</b> <i>Projects:</i> Belief systems, religious and ideological differences in approaches to genetic technologies; Genetic databases and genetic citizenship; Delivering better services to citizens in developed and developing countries

Transforming Nature	
<b>cesagen</b>	<b>Therapies and enhancements</b> <i>Projects:</i> Stem cells; Tissue engineering; Enhancement; Chimeras; Mitochondrial genetics
<b>egenis</b>	<b>Breeding strategies informed by genomics and co-production of the life sciences</b> <i>Projects:</i> Apomixis; Molecular marker associated breeding; Stem cells; Gene therapy; Life sciences and identity
<b>innogen</b>	<b>Implementation of genomics-related transformations</b> <i>Projects:</i> Comparative analysis of transformations and implementation pathways; Translational issues in nano-biotechnology, synthetic biology and stem cells; Animal cloning and plant genetic modification

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