

## **Genomics in the UK: Mapping the Social Science Landscape**

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### **Abstract**

This paper has been prepared from the perspective of the ESRC Genomics Policy & Research Forum, which has the particular mandate of linking social science research on genomics with ongoing public and policy debates. It is intended as a contribution to discussions about the future agenda for social scientific analyses of genomics. Given its scope, this paper is necessarily painted with a broad brush. It is presented in the hope that it can serve both as a useful reference for those less familiar with the themes and foci of UK-based social science research about genomics and, for those more engaged in the field, as a foundation for discussions about the future social sciences agenda in this area. This paper has four parts. The first identifies the boundaries of the topic. It is suggested that the boundaries of genomics are properly regarded by social scientists as soft rather than hard, and as encompassing far more than genomics as narrowly understood. In the second part, the UK context for social science research is briefly described before proceeding to part three, which offers a survey of the major areas and patterns of research. This is organised by reference to the themes of globalisation, governance and regulation, and refers to 129 current or recently completed projects (surveyed during the winter of 2005) that address these themes. Part four proposes some appropriate areas for future research, drawing on and advancing what has been achieved thus far. Social scientific analyses of the nature and consequences of genomic science, it is claimed, have been crucially framed by the institutionalising of non-scientific considerations under the heading of ELSA/ELSI (Ethical, Legal and Social Aspects/Implications). It is suggested that an understanding of the limitations and consequences of this framing provides a vital starting point in considering future research agendas.

### **Part I - The Boundaries of Genomics**

Whilst the much-celebrated completion of the sequencing of the human genome has given a certain familiarity in popular discourse to the word 'genome' (taken as signifying something to be understood as a sort of map or code of our genetic material), the word 'genomics' has gained much less currency and still less any depth of understanding. But even where there is a recognition of the term, there is often an uncertainty about its meaning and use. It was the experience of the Genomics Forum, in inviting a wide range of interested participants to meetings to discuss issues in human, animal and plant genomics, that even (perhaps especially) amongst interested parties, the use of the term 'genomics' is problematic.

Natural scientists understood the term, reasonably enough, to refer to a set of techniques or technologies specifically to do with the mapping or sequencing of genomes. In addition they associated genomics with 'post-genomic' disciplines (such as proteomics or metabolomics) and with developments of the quantitative and computational tools needed to exploit the vast amounts of data generated by sequencing technologies. Participants with different backgrounds and with different

interests (including policy-makers, members of civil society organisations, and social scientists) tended to use the term ‘genomics’ more loosely to signify something that might be called ‘genetic technologies’. In this latter usage, ‘genomics’ was not sharply distinguished from, for example, genetically modified (GM) crops, genetic modification more broadly, gene therapy, genetic testing, cloning, xeno-transplantation and even the use of stem cells. On occasions—and particularly, it seemed, where there was a fear that the controversy surrounding GM might somehow become attached to genomics unless the distinction were maintained—natural scientists found it necessary to try and maintain the more limited usage of the term ‘genomics’ and to complain of a risk of confusion. They pointed out, for example, that genomics and genetic modification are two distinct things, in the sense that the mapping and sequencing of genomes proceeds independently of genetic modification, and vice versa; there was plainly genetic modification before there was genomics, and there could be genomics whether or not there is genetic modification. This insistence on difference and discontinuity is, of course, also part of the wider presentation of the development of genomics as constituting a revolution in the biological sciences.

In understanding the scope of the social science of genomics (and thus the concern of this paper) it is important to recognise both the merit of the natural scientists’ rather precise usage, but also why the looser use of the term and the regular association of genomics with a range of other technologies points to something important about these scientific developments. The contrast between these two connotations of ‘genomics’ bears some elaboration.

If the genome is thought of as the totality of genetic material that provides the code which makes us what we are, then genomics is the science of this totality. By means of tools of mapping, sequencing and analysis of genetic material as a totality, genomics seeks an understanding of the functions and interactions of this genetic material and thus an understanding of the biology of organisms.

Understood in this way, the term ‘genomics’ refers us to the very specific scientific developments which led to and were advanced by the high-profile mapping projects which captured public attention. Even understood in this narrow sense, genomics opens up a rich field for social scientific reflection and analysis. The sequencing of the human genome was a major international programme of research and cooperation which involved huge effort and resources and which commanded considerable financial and political support, as well as significant media and public attention. The processes and institutions which shaped and were shaped by this scientific endeavour are quite properly the subject of investigation, as are the implications of genomics for understandings of what it is to be human, and a human individual.

If this, however, identifies the scope of genomics from a scientific viewpoint, those at the Forum’s meetings who understood genomics less precisely, or who immediately associated genomics with a wide range of other biotechnologies, should not simply be disregarded as mistaken. ‘Genomics’, understood in the narrow sense, is a range of techniques and technologies which enable us better to understand and hence to engage with living organisms. It is, if you like, a tool (or set of tools) which

increases our power to understand, and hence to affect, shape or manipulate the natural world. Thus, though it should not be confused with biotechnology in general, or genetic modification or stem cell research in particular, the tendency of popular discussions to link these separate activities indicates something of great importance—for the very sense of interest and high excitement around genomics is just that this tool increases the power of the other tools of biotechnology. Thus, though it is undeniable, for example, that there was genetic modification before there was genomics (and that one could pursue genomics while eschewing genetic modification), genomics enables scientists to make genetic modification more efficient and effective (although, arguably, it may also render GM otiose). Genomics is not genetic modification, but the linking of the two is not straightforwardly wrong. A hammer is not a chisel, and there may have been hammers before there were chisels, or vice versa; but the social significance of these two tools could hardly be comprehended were their study to be sharply differentiated.

When this is understood, it can be seen that the proper scope of the study of genomics for social science is much wider (and less easily bounded) than would be the study of genomics as understood by many natural scientists as an important but discrete field of contemporary science. Genomics is a tool, which has arisen from the advances in biology and genetics that span the fifty years from the discovery of the structure of DNA in 1953 to the sequencing of the human genome in 2003. It is a part of this story and intimately connected with the other elements of it, conceptually, practically and in popular thought and discourse. It is related to, and has implications for, all those things which are often connected with it, such as GM crops, genetic modification more broadly, gene therapy, genetic testing, cloning, xeno-transplantation, the use of stem cells and so on. Social science will be concerned to understand what is significant and important about genomic science narrowly construed; but it would be guilty of ignoring the wider context of meaning and significance in which genomics has been developed and which it has the power to affect and transform, if it concerned itself with the field as narrowly identified for the purpose of demarcating the specialisms of contemporary biology.

## **Part II - The UK Context**

A substantial amount of time, money and energy has been invested in the UK in social scientific research relating to genomics. This has been co-ordinated principally through Universities, associated think-tanks, and a wide range of funding bodies. The Economic and Social Research Council (ESRC) is a core UK funder of social scientific research and has sponsored a wide range of genomics-related activities. This commitment has been reviewed elsewhere.<sup>1</sup> For the purposes of this paper, most relevant is the ESRC Genomics Network (EGN), a £12.5 million investment which comprises the research centres Cesagen (Universities of Cardiff and Lancaster), Egenis (University of Exeter), and Innogen (University of Edinburgh and the Open University), as well as the ESRC Genomics Policy and Research Forum and ESRC Attitudes to Genomics Survey. The ESRC has also sponsored two research programmes, Science in Society and Innovative Health Technologies, which in turn have funded many projects relevant to analyses of genomics in society.<sup>2</sup> Other funding bodies which have invested heavily in research on genomics and society include the Wellcome Trust, the Leverhulme Trust and the European Commission.<sup>3</sup>

In addition to the centres of the EGN, several UK research institutes have run or are running programmes related to genomics and society. These include the Science and Technology Studies Unit (SATSU) at the University of York; The Institute for the Study of Genetics, Biorisks and Society (IGBiS) at the University of Nottingham; The Policy, Ethics and Life Sciences Research Centre (PEALS), a partnership between the Universities of Durham and Newcastle and the Centre for Life; The BIOS Centre of the London School of Economics; and the Science & Technology Research Unit (SPRU) at the University of Sussex. Further, the Nuffield Council on Bioethics, the Oxford Centre for Ethics and Communication in Health Care Practice (Ethox), sponsored by the Ethox foundation, and the University of Cambridge Centre for Medical Genetics and Policy (CMGP), associated with the Cambridge Genetics Knowledge Park, conduct research relevant to genomics and society.

Thus the UK is host to a wide range of research centres, funding bodies, and academic units focussed on the social and policy aspects of genomics research. Collectively, these centres have conducted an extensive amount of research seeking to understand how, and whether, the advent of genomics and post-genomics research is fundamentally altering society. The following section seeks to draw upon as much of this research as possible whilst remaining coherent and concise.

### **Part III - Genomics and Social Science: A Survey of Current Research in Genomics in the UK**

Our current epoch is often characterised as one of radical and transformative change in which boundaries—between state and society, global and local, even between the natural and unnatural—become increasingly blurred. Genomics has been developed and will continue to develop in this context of change, and will itself be shaped by, and contribute to, further transformations.

This section summarises some of the recent UK-based research that has devoted itself to elucidating and understanding such transformations. It is organised with reference to three broad themes: globalisation, development and genomics; governance, publics and genomics; and regulation, innovation and genomics. These themes were selected after the research projects reviewed for this paper (see Table 1 below<sup>4</sup>) were analysed according to their empirical and theoretical focus and principle research questions. The desire was to classify the projects with reference to a limited number of themes in order to appropriately represent individual projects whilst also encompassing the vast array of research surveyed in this paper. Thus the classification of projects according to the aforementioned themes is best viewed of as 'fluid': the themes provide a context for, and means of organising, this survey of current UK-based social science research engaging genomics and the broader range of biotechnologies from which it has arisen and with which it is associated.<sup>5</sup>

**Table 1. Ongoing and Recently Completed UK Research in the Social Science of Genomics**

Project	Institute	Project	Project Leader(s)
1	University of Dundee	A new geography of health: transforming heart disease in the new genetics era	E.C. Hall,
2	Wellcome Trust-KEMRI, Research Programme, Kenya	Action research to develop IEC materials that support informed consent processes for research in developing countries.	Catherine S. Molyneux
3	Cesagen	Indigenous Peoples	Brian Wynne
4	Innogen	Genomic and biotechnology partnerships in Africa	Joanna Chataway
5	Innogen	Genomics and biotechnology partnerships in less developed countries	Joanna Chataway
6	Innogen	Institutional Impacts of North-South partnerships in agricultural biotechnology	Jane Bower
7	Cesagen (In part of collaboration)	Genomics and Benefit Sharing with Developing Countries (BeSha)	Ruth Chadwick
8	Cesagen (In part of collaboration with Centre for Science, Society and Citizenship in Rome)	Bioethical Implications of Globalisation Processes (BIG)	Ruth Chadwick
9	Egenis	The impact of advanced genomics-based tools for agronomy, plant breeding and food production on local agricultural practices	Steve Hughes
10	University of East Anglia	The global politics of human embryonic stem cell regulation	Brian Salter
11	SPRU, University of Sussex	Report production on the latest trends of Life Science and Biotechnology in Europe	Nick von Tunzelmann
12	University of Cambridge: Centre for Business Research	Corporate responses to macroeconomic changes and shocks	M. Kitson
13	Cardiff University, Watt University, University of Wales College of Medicine	Genetic testing and insurance: the problem of adverse selection	Lindsay Prior
14	Cesagen	The economics of innovation in genomics	Phil Cooke
15	University of Leeds	Social And Ethnic Differences In Attitudes And Consent To Prenatal Testing	Jenny Hewison
16	University of Cambridge	Informed consent and genetic data	Dr Onora O'Neill
17	School of Nursing & Midwifery, King's College London	Facilitating choice, framing choice: the experience of staff working in preimplantation genetic diagnosis.	Clare Williams
18	IGBiS (Nottingham)	Genetic Counselling for Haemochromatosis	Melanie Pearce
19	Genetic Interest Group and University of Southampton	The Human Rights Act and genetics	Mr John Gillott

Project	Institute	Project	Project Leader(s)
20	University of Bristol	Ethical protection in epidemiological genetic research: participants' perspectives	Alastair Campbell
21	BIOS (LSE)	Genome-based Therapeutic Drugs for Depression (GENDEP)	Ilina Singh
22	London Metropolitan University, University of Birmingham, Imperial College, University of London	Ethical issues in the collection of pregnancy-related tissue samples	Naomi Pfeffer, Donna Dickenson
23	IGBiS (Nottingham)	Mothers' Responses to the Possibility of Pre-Implantation Genetic Modification of their Babies	Susan Johnson
24	Centre for Ethics in Medicine, University of Bristol; Institute of Ethics and Law in Medicine, University of Glasgow	Scoping Study: Ethical and practical concerns in changes to human tissue legislation.	Alastair Campbell and Sheila McLean
25	King's College, University of London	Informed consent in Sri Lanka: Current practices, quality of the information leaflets, consent forms and participants understanding process	Athula Sumathipala
26	Institute of Law & Ethics in Medicine, University of Glasgow	Ethico-legal governance in healthcare.	Sheila Mclean
27	University of Cambridge	From the corporeal to the informational: recent transformations in the constitution of collections of human biological materials and their implications for access and use	Bronwyn Parry
28	PEALS	Ordinary Ethics: moral evaluation of the new genetics by non-professionals	Tom Shakespeare
29	Cesagen (co-ordinating institution)	The Institutionalisation of Ethics in Science Policy: Practices and Impact (INES)	Ruth Chadwick
30	Department of Sociology, University of Exeter	Accountability and the governance of expertise: anticipating genetic bioweapons	Brian Rappert
31	Mountbatten Centre for International Studies, University of Southampton	Science, Security and Regulation: How effective are export controls?	Jez Littlewood
32	SPRU, University of Sussex	Dual use controls and genomic research	Paul Nightingale
33	IGBiS (Nottingham)	Representations of Complexity in Policy Networks	Ian Forbes
34	University of Leicester	Childhood cancer tissue donations: A gift relationship?	Mary Dixon-Woods

Project	Institute	Project	Project Leader(s)
35	Innogen (University of Edinburgh)	Legal and bioethical regulatory mechanisms	Graeme Laurie
36	Cesagen	Genetic Databases	Ruth Chadwick
37	Dept of Sociology & Social Policy, University of Durham	Forensic DNA databasing: A European perspective	Robin Williams
38	University of Cambridge and Anglia Polytechnic University	Policy issues in the evaluation of clinical genetic testing	David Melzer, Ron Zimmern, Simon Sanderson
39	University of East Anglia	Reforming the Governance Of Human Genetics: The Politics Of Public Trust	Brian Salter
40	Innogen (University of Edinburgh)	The national and international policy environment for genomics	Joyce Tait
41	IGBiS (Nottingham)	The Politics of Food	Brigitte Nerlich
42	Innogen	Interests and values in risk-related stakeholder interactions	Joyce Tait
43	SATSU, York University	Quality assured science: the role of standards in stabilising stem cell research	Andrew Webster
44	University of Durham and University of Nottingham	Genetic information and crime investigation: social, ethical and public policy aspects of the establishment, expansion and police use of the National DNA Database (NDNAD)	Robin Williams, Paul Martin
45	University of Lancaster (IEPPP)	Participation and the Dynamics of Social Positioning (PARADYS)	Bronislaw Szerszynski, Norman Fairclough (UK component of international programme)
46	Innogen (The Open University)	Trading up environmental standards? Trans-Atlantic governance of GM crops	D. Wield, Susan Carr
47	University of Birmingham	The politics of GM food	David Marsh
48	University of Cambridge	Information policy for pharmacogenetics	David Melzer
49	University of Oxford	Governing genetic databases	Michael Parker
50	Cardiff University	The clinical picture: the interaction of clinical medicine and genetic technology	J. Latimer
51	University of Oxford	Ideas, experts and the politics of eugenics: a comparative and historical analysis	Desmond King
52	University of Edinburgh / York University (SATSU)	Transformations in Genetic Subjecthood	Sarah Cunningham-Burley, Anne Kerr (now at University of Leeds)
53	IGBiS (Nottingham)	Exploring the implications of using race/ethnicity in applied population genetics	Paul Martin

Project	Institute	Project	Project Leader(s)
54	Cardiff University	Genetics, religion and identity : a study of Bangladeshi Muslims in Britain	S. Gilliat-Ray
55	Queen Mary: University of London	Genealogy and genetics : cultural geographies of relatedness	Catherine Nash
56	SPRU, University of Sussex	The Patenting of Human DNA: Global trends in commercial and public sector activity	Sandra Thomas
57	University of Warwick	The evolution of biomedical knowledge : interactive innovation in the UK and US	Jacky Swan
58	IGBiS (Nottingham)	Genetic Testing	Robert Frost, Paul Martin
59	Innogen	The public and private organisation of genetic information	David Wield
60	IGBiS (Nottingham) / SPRU	The Impact of Genomics on Innovation in the Pharmaceutical Industry	Paul Martin, Paul Nightingale
61	University of Cambridge: Centre for Business Research	Commercializing science : entrepreneurial UK genomics firms in comparative perspective	S. Casper
62	Cesagen	Transcending the genome: the paradigm shift to proteomics	Peter Glasner
63	Innogen	Genomics Innovation in Scotland	Jane Bower
64	Innogen	Innovation processes in genomics industry sectors	Joyce Tait
65	Centre for Economic Policy Research	GM foods: facts, mergers, business practices and intellectual property	P. Regibeau, K.E. Rockett
66	Cesagen	Plant Genomics, Commercialization and Environmental Knowledge: Shifting cultures of scientific research	Brian Wynne, Claire Waterton
67	SATSU, York University	Pharmacogenomics, diagnostic tests and clinician acceptance	Graham Lewis
68	IGBiS (Nottingham)/ SATSU	The clinical and commercial development of pharmacogenetics	Paul Martin, Andrew Webster, Graham Lewis
69	SATSU, York University/ SPRU	Pharmacogenetics and pharmacogenomics: State-of-the-art and potential socio-economic impact	Graham Lewis
70	Goldsmiths College, University of London and University of Wales College of Medicine	Ethical factors in psychiatric drug development: an archival study of the ethical factors that influenced the development and production of Prozac in Eli Lilly & Company Ltd	Mariam Fraser, Nikolas Rose, David Healy
71	Institute for the Study of Genetics, Biorisks and Society, University of Nottingham	Caught between science and society: food and mouth disease	Brigitte Nerlich
72	Cesagen	Definitions Of Genetic Knowledge & Pre-Implantation Genetic Diagnosis: An Ethnographic Study	Sarah Franklin (now at LSE)
73	Warwick University	Social Implications Of One Stop First Trimester Prenatal Screening	Gillian Lewando-Hundt



Project	Institute	Project	Project Leader(s)
74	Cesagen	The emerging politics of new genetic technologies: the organisation, mobilisation and inclusion of public voices in the regulation of cutting edge science	Ian Welsh, Robert Evans
75	Centre for Environmental Risk, University of East Anglia	Public Perceptions of Risk, Science and Governance	Nick Pidgeon
76	The Open University	Farmers' Understandings of genetically modified crops within local communities	Andy Lane
77	University of Cardiff	Inside or outside the bioscience tent? The presentation of laboratory-self	A. Erkişon
78	University of Liverpool/ SATSU, York University	Variability in response to warfarin: a prospective analysis of pharmacogenetic and environmental factors	Munir Pirmohamed, Andrew Webster
79	Cesagen	Factors affecting preimplantation genetic diagnosis (PGD) patient's attitudes toward donation of embryos for stem cell research	Sarah Franklin (now at LSE)
80	Department of Anthropology, University of Sussex	Childhood vaccination: science and public engagement in international perspective	James Fairhead
81	SPRU, University of Sussex	Deliberative Mapping: Piloting an Innovative Public Consultation Process with the Case of Xenotransplantation and Organ Failure	Andy Stirling
82	Cardiff University	Collective learning in knowledge economies: milieu or market?	Philip Cooke
83	SPRU, University of Sussex	Public Perceptions of BSE and CJD Risk in Europe, their interplay with Media, Policy Initiatives and Surveillance Issues	Erik Millstone
84	IGBiS (Nottingham)	Decision-Making by Women At-Risk of Hereditary Breast And Ovarian Cancer	Emma Rowley
85	PEALS	Cumbria Genetics Database	Erica Haines
86	IGBiS (Nottingham)	The Regulation of DNA Databases	Paul Martin
87	University of Liverpool	How do users interpret probabilistic pregnancy screening information?	R. S. Bramwell,
88	IGBiS (Nottingham)	The Rhetoric of Genes	Craig Hamilton
89	Cesagen	Explanation in genetics: causality and accountability in complex disorders	Angus Clarke, Srikant Sarangi, Ruth Chadwick
90	University of Surrey	Attitudes to genomics (Genomics survey)	R. Shepherd
91	University of Surrey	Public understanding of genomics and the dynamics of attitude change	P. Sturgis
92	IGBiS (Nottingham)	The role of imagery and emotions in decisions concerning GM food	Ellen Townsend
93	PEALS	A comparative study of embryo donors' and non-donors' views on embryo experimentation for preimplantation genetic diagnosis and stem cell therapy	Erica Haines, Alison Murdoch
94	IGBiS (Nottingham)	New Social Movements, Popular Media and Policy-Making	Paul Martin

Project	Institute	Project	Project Leader(s)
95	IGBiS (Nottingham)	Patients' constructions of familial hypercholesterolaemia	Kate Weiner
96	Cesagen	Genetics, Health and Identity	Angus Clarke, Srikant Sarangi
97	Egenis	The relationships between theories of groups memberships and inter-group attitudes	Thomas Morton
98	Innogen	Talking about stem cells: The Social Dynamics of Public Engagement in Stem Cell Research	Sarah Cunningham-Burley, Sarah Parry, Wendy Faulkner, Austin Smith
99	Egenis	Complex Risks and Testing for Thrombophilia: A case study on genes and common disease	Paula Saukko
100	Goldsmith's College/SATSU	Xenotransplantation: Risk Identities and the Human / Non Human Interface	Mike Michael
101	SPRU, University of Sussex	Chemical / Biological Warfare	Julian Perry Robinson
102	IGBiS (Nottingham)	The Regulation of Small Biotech Start-Up Companies in Scotland and Norway	Robert Dingwall
103	SPRU, University of Sussex	Study on benchmarking of public biotechnology policy	Pari Patel
104	Cardiff University	The Construction Of Risk Estimates In A Cancer Genetics Clinic	Lindsay Prior
105	Cesagen	Genetic Screening For Susceptibility To Disease: The Case Of Haemochromatosis	Paul Atkinson
106	Brunel University	The impact of genetic risk information on families of Pakistani origin referred for genetic counselling	Alison Shaw, Jane Hurst
107	University of Sussex	The ethical and public policy implications of the new genetics and transgenics in the carcinogenic risk assessment of pharmaceuticals	John Abraham
108	King's College, University of London	Mapping stem cell innovation in action	Clare Williams
109	University of the West of England	Forgotten Fetuses - A Sociocultural analysis of the use of fetal stem cells	Julie Kent, Naomi Pfeffer
110	IgBis (Nottingham)/SATSU	Haematopoietic Stem Cells: The Dynamics of Expectations in Innovation	Paul Martin, Nik Brown
111	Cardiff University	Medical Device Governance: Regulation of Tissue Engineering in the UK and EU	Alex Faulkner
112	IGBiS (Nottingham)	The Regulation of Cloning	Paul Martin
113	University of Edinburgh	Health, life insurance and financial inclusion	P.G. Bennett
114	IGBiS (Nottingham)	Popular Media and the Production of News about Biorisk: 'Health risks, body risks and food presentation in women's general interest	Kathy Wilkinson

Project	Institute	Project	Project Leader(s)
		magazines'	
115	University of Plymouth	Nanotechnology and news production : scientists', journalists', and editors' views	A. Anderson
116	University of Nottingham	Implicit models of evolution in broadcast wildlife and nature programmes	M.E. Alridge, Robert Dingwall
117	Cesagen	Communicative frames in counselling for predictive testing	Srikant Sarangi, Angus Clarke
118	IGBiS (Nottingham)	The meaning of genetics - a project based on corpus linguistics	Craig Hamilton
119	IGBiS (Nottingham)	Genomics Discourse - Special Journal Edition of Discourse & Society	Brigitte Nerlich
120	University of Reading	The presentation of GM crop research to non specialists: a case study	G. Cook, P.T. Robbins
121	University of Reading	The discourse of the GM food debate: how language choices affect public trust	G. Cook, P.T. Robbins, E. Pieri
122	Egenis	Genomics as a Source of Status Markers	Barry Barnes
123	Egenis	The Cultural History of Heredity	Staffan Mueller-Wille
124	Egenis	Semantic Drift in the Dissemination of Genomics	Christine Hauskeller
125	Cesagen	Media, Culture and Genomics	Jenny Kitinger, Maureen McNeil
126	Egenis	Patenting and the utility of genomic knowledge	Jane Calvert
127	University of Exeter	Ambiguity and optimism	David Kelsey
128	University of York	Doing embryo ethics: safety and efficacy in research and practice	Anne Kerr (now at University of Leeds)
129	Cesagen	Reconfigurations of Human/Animal Relations in Genomics and Beyond (ROAR)	Richard Twine, Alan Holland

### (i) Globalisation, Development and Genomics

In the 1960's, Marshall McLuhan coined the term 'global village' when analysing the effects of the increased interconnectivity of global society through information technology.<sup>6</sup> Four decades later, globalisation has occurred not only through the compression of space and time by information technology but also via unprecedented levels of cross-border cultural and economic exchange.

Central to globalisation has been the reduced power of individual nation-states over global and domestic politics, economics and culture, as well as the rise of entities such as trans-national corporations, public-private partnerships, NGOs or the supra-governmental European Union. The rise of these organisations has profoundly influenced the way in which societies are governed (as will be further discussed in III (ii)). Some also argue that globalisation's 'new world disorder'<sup>7</sup> has lead to

greater disparity between rich and poor, northern and southern countries. As some feel increasingly empowered, others feel disempowered. Whether globalisation tends towards such polarisation is an open question; but disputes over the global commercialisation of genetically modified organisms (GMOs), for example, may be seen as indicative of the tensions created by globalisation:

*'Globalisation...connotes, at one extreme, confident utopian fantasies of omnipotence, and at the other, a sense of things falling apart, of centres that do not hold, and of a radically diminished sense that one's voice, one's actions, or even one's existence matters or makes a difference to the way things are. And perhaps nowhere is this more apparent than in contemporary responses to biotechnology.'*<sup>8</sup>

Thus studies of globalisation are aided by examining the social, political and economic issues surrounding biotechnology, and *vice versa*. This applies across the world, but arguably, the most urgent issues created by globalisation centre around the economic and health impacts on people in developing countries.<sup>9</sup> Studies of 'development', which suggest that technologies including biotechnologies have played a central but controversial role for the past half-century,<sup>10</sup> are thus highly relevant and properly address the present and future implications of genomic science.

Focal points for such studies include analyses of the capacity of developing nations to research, develop, apply and/or govern biotechnologies.<sup>11</sup> Moreover, building developing countries' capacities to assess for themselves the risks and benefits that biotechnologies pose is another important issue related to development. Of course not all such countries may be grouped together, as they have widely varying expertise in employing biotechnologies. However, in the context of development, biotechnologies remain highly controversial. Industrialised countries have, notoriously, had difficulties in establishing regulatory systems to govern the risks that biotechnologies may pose and in coming to consensus (nationally and internationally) on which biotechnologies should or should not be permissible; the challenges for more newly industrial countries, yet to develop biotechnology sectors, are likely to be more acute.

#### *UK Research Addressing Globalisation, Development and Genomics*

Of the research programmes listed in Table 1, a relatively minor proportion are devoted to issues directly related to globalisation and development.<sup>12</sup> Most concentrated are a series of projects within the ESRC Genomics Network (Innogen, Cesagen, Egenis), which are broadly exploring how 'modern biotechnology can be translated into practice' given many constraints, such as lack of infrastructure, lack of 'capacity', and political and economic obstacles to technology transfer.<sup>13</sup> These projects comprise a critical analysis of the types, characteristics, operations and impacts of various development public and/or private initiatives.<sup>14</sup> The diffusion of knowledge/technology and its flow between various actors (e.g. scientists, farmers, businesspeople) is an important theme in this research. Another important theme is the rights of local populations, such as indigenous people in the Amazon, where one project is aimed at understanding the Amazonian perspective to inform policy

debates about issues such as indigenous peoples' rights, prior informed consent or benefit-sharing.<sup>15</sup>

Other research programmes, concerned with the dangers posed by the globalisation of biomedical R&D, focus on the potential exploitation of those used as subjects for research or as donors of biological materials. Whilst these projects are not focussed on issues arising solely from genomic research and medicine, the promise of genomic medicine and the globalisation of R&D makes these enquiries highly pertinent to this report. Research at Cesagen is seeking to identify and anticipate some of the key bioethical implications of globalisation processes.<sup>16</sup> Two projects sponsored by the Wellcome Trust are analysing current practices in specific developing countries aimed at seeking informed consent, and how these practices might be enhanced and supported.<sup>17</sup> This builds upon earlier research such as the 2002 report, *The Ethics of Research Related to Healthcare in Developing Countries*, published by the Nuffield Council on Bioethics, in drawing attention to the challenges in ensuring that globalisation of technology is sensitive to issues of justice as they occur in specific and local contexts.<sup>18</sup>

## (ii) Governance, Policy, Publics & Genomics

As discussed above, globalisation processes have arguably contributed to an alteration in the role and power of nation-states. This alteration has been so profound, it is suggested, that government (in the sense of the formal exercise of executive powers by regularly constituted political authorities) is no longer the determinant of public affairs. Where the state is hollowed out,<sup>19</sup> room has been created for more actors to emerge. The boundary between state and society has blurred:

*'...no single agency, public or private, has all the knowledge and information required to solve complex problems in a dynamic and diverse society, and no single actor has the power to control events in a complex and diverse field of actions and interactions.'*<sup>20</sup>

In this state of affairs:

*'...social-political governance and governing are not primarily looked upon as acts of governments, but as more or less continuous processes of interaction between social actors, groups and forces and public or semi-public organisations, institutions or authorities.'*<sup>21</sup>

The term 'governance' is used to mark this 'change in the meaning of government' and to refer 'to the new method by which society is governed.'<sup>22</sup>

In these circumstances, national governments no longer dictate policies so much as steer them. One of governments' key roles within governance becomes then, to create a forum in which policy-making can occur and decisions taken. Within this forum, transient and unforeseen alliances tend to mobilize around specific issues, creating loose and *ad hoc* policy networks.<sup>23</sup> But just as there is 'a multitude of autonomous actors who create patterns of structured cooperation despite the absence of a central organizing authority',<sup>24</sup> so there is, in fact, a multitude of fora in which

they act and engage. If ‘governance is about the ways and means in which the divergent preferences of citizens are translated into effective policy choices, about how the plurality of social interests are transformed into unitary action and the compliance of actors is achieved’,<sup>25</sup> then it must account for a transformation which emerges from numerous overlapping and competing fora, including regional and national governments, the European Commission, international agencies and authorities (e.g. OECD, UNESCO, GATT, the Cartagena Protocol on Biodiversity) and so on.

### *The Governance of Genomics*

The plurality of actors involved in governance has great significance for genomics. Biotechnologies, like other new bodies of knowledge, carry within them the ‘potential for new forms of power, regulation and surveillance. Professing to offer new ways to reproduce and “improve” our bodies, our minds and our environments, such techniques raise new questions about the nature of human existence and the type of social relationships we want to perpetuate.’<sup>26</sup> These questions are profoundly difficult, and their resolution is certainly rendered no easier by the wide range of actors or stakeholders who are implicated in contemporary patterns of governance, with its multiple fora. Consequently systems of governance—and within them, regulatory systems, which are often at the forefront of debates surrounding biotechnology<sup>27</sup> (as will be discussed in III (iii))—are placed under enormous strain as they confront these issues.

Salter and Jones have helpfully summarised some of the critical challenges related to the governance of the ‘new’ genetics:

*‘Civil society, science and industry all have a political interest in the creation of human genetics knowledge, its industrial application and its therapeutic potential. Sometimes those interests may overlap, on other occasions they may be completely incompatible. It is the political function of both the state and the supra-state regulation of human genetics to find a way of negotiating, and hopefully resolving, the tensions between the different interests. In so doing, the regulatory institutions concerned face an array of shifting political forces which place conflicting demands on the apparatuses of governance in terms not only of the outputs required but also the means by which these outputs are achieved. The legitimacy of the policy process itself – that is, the way in which policy is produced through agenda setting, formulation, implementation and evaluation – may be called into question.’<sup>28</sup>*

Thus as governments attempt to foster processes for resolving debates rather than issues, policy processes as well as policy outcomes are likely to be contested. As this happens, space is created for new policy networks/communities to arise and pursue particular agendas. One example that has been cited is the rise of bioethics in EU policy-making—as science-based governance (and risk assessments) has been increasingly challenged, a ‘new transnational policy network’ of bioethicists emerged, and groups such as the European Group on Ethics in Science and New Technologies (EGE) are now part of the institution of biotechnology policy making.<sup>29</sup>

There is, however, another layer of complexity to be added to the consideration of governance as it relates to the web of concerns raised by the advance and application of the new genetics. In the wake of scientific controversies surrounding topics such as BSE, GMOs or MMR vaccines, the scientific authority of 'expert' institutions has diminished, leading, so it has been argued, to crises of public trust in key institutions of governance.<sup>30</sup>

Previously, a common argument made by such governance institutions was that the public, if it properly understood science, would embrace rather than reject new technologies like GM crops. This viewpoint (resting on the so-called 'deficit model') has been rejected by those who insist that the public does not simply or typically misunderstand science, but rather assesses it by reference to a variety of different frames of meaning<sup>31</sup>—and not just by reference to the 'meaning of risk as defined by science'.<sup>32</sup> Against the deficit model, it is now commonly asserted that public ambivalence towards new technologies is neither necessarily nor typically the result of misunderstanding or wilful rejection, but of alternative concerns and modes of appraisal.

This perspective has been influential. Governments and social scientists alike have recently spent much energy arguing for and exploring means of 'opening-up' policy-making to the public.<sup>33</sup> A prominent example is the UK government's *GM Nation?* exercise, which was intended to provide one of three strands of evidence to contribute towards decisions on whether or not to commercialise GM crops—its stated objective was to 'improve the evidence-base, and to create a dialogue between all aspects of opinion on GM.'<sup>34</sup>

Importantly, despite its intentions, *GM Nation?* has been criticised for failing to achieve its objectives. According to one commentary, the debate did not so much engage the public, as attract a small and unrepresentative sample of campaigners.<sup>35</sup> It was, according to another appraisal, largely ignored by the wider population.<sup>36</sup>

The House of Commons' Select Committee on Environment, Food and Rural Affairs (EFRA) questioned the depth and seriousness of the good intentions which were said to have led to the exercise: 'the Government... must allay the suspicion that, having agreed to undertake a public debate, it did as little as it could to make it work.'<sup>37</sup> The Committee is not alone in harbouring this suspicion, and there has been a more general concern that although governments acknowledge the importance of understanding public attitudes to new research and fostering public discussion of the deployment of new technologies, in practice they continue to employ the deficit model.<sup>38</sup> Whether public engagement will emerge as a 'rhetorical concession'<sup>39</sup> or a significant transformation of biotechnology governance remains to be seen.

Consequently, core questions for the future application of genomics and genomic technologies are these: what system of governance will emerge to shape the development of this field? Which actors will be influential within this (undoubtedly complex) system? How will scientific expertise and public understandings be accommodated? And what particular challenges may genomics itself pose to emerging or established patterns of governance?

One particular challenge is likely to concern the boundaries, for example, between individual and public health, and the responsibilities for each. It is often noted that the new genetics may lead to the framing of what can be thought of as public health issues (such as heart disease) as individual problems (albeit that individuals may then be deemed to have a public duty to ascertain their genetic risks).<sup>40</sup> Yet, paradoxically, the identification and characterisation of individual risks may well depend on public screening programmes or on vast public projects of data gathering (such as UK Biobank). How will systems of governance manage the borders of public and private interest? If citizens are ambivalent towards scientific authorities, how likely are they to participate in or endorse genetic-based public health programmes, particularly when commercial interests are often perceived to be driving forces behind such programmes?<sup>41</sup> Are present practices of informed consent sufficiently robust to cope with the particular challenges of gathering and using genetic data, and to protect individuals against the state or corporations? And can such protection be achieved without loss to the public goods which are at stake in public health measures or programmes?

*Summary of UK-based Research Addressing Governance, Policy, Publics and Genomics*

The governance of existing and emerging genetic technologies, and the way in which (and degree to which) these technologies are forcing governance systems to adapt, is the focus of significant attention.<sup>42</sup> Some of these projects are focussed on describing, mapping and/or understanding the evolving governance systems relating to existing and new genetic technologies, such as stem cells, GMOs and pharmacogenomics.<sup>43</sup> This may involve focussing on changing patterns in networks of governance and how they might influence regulatory standards.<sup>44</sup>

As discussed earlier, public trust, engagement and understanding of science are critical to analysis of governance, genomics and public policy. The projects focussed on these issues<sup>45</sup> underscore this point in examining, for example, 'how far scientific, expert-driven risk assessment techniques can be reconciled with deliberative approaches to public consultation'.<sup>46</sup> Thus an appreciation of public understandings or perceptions of risk is important, and this has been the focus, from varying perspectives, of significant research.<sup>47</sup> Equally important are assessments of various public engagement techniques, a key element of research examining the social dynamics of stem cells.<sup>48</sup>

Public understandings of risk also tie-in with research into public understanding of, and attitudes towards, different aspects of genetic medical services and initiatives. One project argues that people's notions of citizenship, consumption and expertise will inform a fresh understanding of 'genetic subjecthood', and thus, it is hoped, contribute to more informed and sensitive policy-making.<sup>49</sup> Similarly, the views of different patient groups (e.g. people receiving pre-implantation genetic diagnosis or IVF treatments<sup>50</sup>) are expected to 'provide practical feedback to clinical scientists, practitioners, and policy-makers concerned with genetic and reproductive medicine'.<sup>51</sup> To this end, a few projects run through the ESRC Innovative Health Technologies programme have demonstrated that clinical/professional and 'lay' understandings of risk produce interpretations which may overlap but are also



divergent.<sup>52</sup> Such findings draw attention to, for example, the need for careful consideration of how genetic counselling is conducted.<sup>53</sup> Meanwhile, as it has been commonly argued, there may be benefits to ‘opening’ science to publics at earlier stages. Thus patient attitudes to genetic testing, for example, may usefully inform an algorithm to help physicians prescribe safe dosage of warfarin, which is the focus of social research studying pharmacogenetics.<sup>54</sup>

As previously mentioned, the emergence of bioethics is an influential aspect of contemporary governance of the ‘new genetics’ and thus as an important element in policy-making. Indeed, a Europe-wide project with its UK base at Cesagen is examining the institutionalisation of ethics in science policy.<sup>55</sup> Various other projects are specifically and varyingly focussed on ethical and governance issues arising from genetic research and services.<sup>56</sup>

A central norm of much recent bioethics has been that of ‘informed consent’, and the understanding and application of this norm is likely to be central to the future governance of medical interventions emerging from or advanced by genomics. Projects have explored social and ethnic differences to consent and the problems posed by practices of individual consent to procedures which yield information which may be of familial significance.<sup>57</sup> Views and preferences relating to the very specific problems around consent and other aspects of genetic research involving children in the UK are also being investigated.<sup>58</sup> Similarly the specific problems raised for procedures of consent outside the cultural context in which they have arisen are a concern.<sup>59</sup> An analysis of how non-professionals understand bioethics may help to address whether, and how much, significance the public places on consent as compared to the discipline of bioethics or current systems of clinical governance.<sup>60</sup>

### **(iii) Regulation, Innovation and Genomics**

Globalisation and governance (as against government), provide the context for both the regulation of genomics and its related technologies, and for further innovation in this field. Of course the choices that a society makes about governing new technologies are often manifested in the regulatory arena, and these choices are subject to myriad potential conflicts of objectives or interests, such as between ensuring consumer safety or promoting national economic competitiveness. The regulation of technologies, then, becomes a key area of controversy (and consequently of social science research): ‘Governance in its regulatory form is the political theatre where the pressures for change from the arenas of science and industry meet the inchoate needs, values and sensibilities of civil society.’<sup>61</sup>

Consumer groups, environmental groups, public health activists, patient advocacy organisations, industry and science all attempt to influence, shape or determine regulatory outcomes. Importantly, however, these groups influence more than regulation of new technologies; the socio-political environment they create also shapes the trajectory of new technologies:

*'Assessing the 'impact' of a new technology cannot...be simply separated from either the process of technical innovation or debates about public policy. The way in which social problems are anticipated and resolved influences the behaviour of actors, such as regulators and firms, and this in turn shapes the development of the technology.'*<sup>62</sup>

Regulation and innovation, therefore, are intrinsically linked. Understanding the processes influencing one will also contribute an understanding of the other. Both, from varying perspectives, have been the focus of substantial research.

### *Regulation & Genomics*

One thing regulatory regimes seek to regulate is risk. Biotechnologies in general (and those which may emerge from the further development of genomics) are centrally associated with the modern risk environment as Giddens characterised it, which is 'structured by humanly created risks.'<sup>63</sup> What is significant about these new risks from biotechnology, however, is that in a variety of ways they test and challenge existing regulatory regimes.

It is the case, of course, that these technologies may pose risks to the environment and risks to human health which are, in a manner of speaking, quite familiar to regulatory regimes. But this is not always the case. Some risks which may emerge from genotyping (e.g. the genetic risk of, or susceptibility to, breast cancer) are quite difficult to conceptualise, express and handle. Other risks may be introduced by biotechnologies (such as gene flow from GM crops) and not straightforwardly estimated or assessed. Such risks may not only create new uncertainties. They may also transcend the jurisdictions of existing regulatory institutions, creating the need for new forms of expertise as well as regulatory agencies.<sup>64</sup> All this occurs in the wider context described in III (ii), in which, so it is commonly argued, the public has lost trust in traditional institutions of governance, not least the scientific authorities. This web of uncertainty around risk has created what Brown & Michael have called 'meta-risks'—'the social and political risks that are incurred when decisions are made about how to go about assessing technical risks.'<sup>65</sup>

Jasanoff has argued that technical decision-making often incorporates socially or politically contingent judgements, such as those concerning appropriate levels of risk.<sup>66</sup> This is concealed, however, by the maintenance of a false boundary between 'science' and 'policy' with the result that there remains little room for accountability and public scrutiny.<sup>67</sup> The USA's Food & Drug Administration, as with other agencies, has maintained this boundary, so she argues, in order to 'harness the authority of science in support of its own policy preferences.'<sup>68</sup>

Insofar as the new biotechnologies have exposed the significance and depth of uncertainties surrounding risks and their assessment, there may be a new and robust awareness of the role of values and interests in shaping 'regulatory science'. However that may be, new and emerging biotechnologies will pose afresh the questions this section has introduced: How are regulatory issues framed? How is 'science' or 'evidence' used in regulatory decision-making? How are regulatory systems evolving to cope with new biotechnologies? How are stakeholders

organising in order to attempt to influence regulation and where are the boundaries between experts and non-experts drawn?

### *Innovation and Genomics*

As discussed earlier, regulatory policies, and the multitude of actors attempting to influence them, shape the trajectories of new technologies. More generally, it is essential to recognise that innovation does not happen in isolation. Rather, it occurs in so-called sociotechnical systems in which social actors both shape and are shaped by technologies,<sup>69</sup> and thus in the context of the issues of globalisation and governance.

Some actors promote the notion of a 'biotechnology revolution'<sup>70</sup> which is to be accepted and embraced. In the case of genomics and genomics-related technologies, potential social problems and risks which they may bring are reckoned by these advocates to be outweighed by the substantial potential benefits to society which they are said to offer. Government and industry have become strong advocates of biotechnology and link it to national wealth: agencies such as the UK Government's Department of Trade and Industry (DTI) emphasise the strategic importance of domestic biotechnology industries through funding publications such as '*Bioscience 2015: Improving National Health, Improving National Wealth*'.<sup>71</sup> In another report, '*Genome Valley: The Economic Potential and Strategic Importance of Biotechnology in the UK*', the DTI argues:

*'It will be important for Government to continue...to take action to ensure that entrepreneurial, fiscal and regulatory frameworks are set in a way which makes the UK the chosen location for major internationally mobile investments in biotechnology.'*<sup>72</sup>

This report stressed the necessity of a 'balanced regulatory regime'<sup>73</sup> but also addressed additional important factors influencing innovation, such as intellectual property rights, infrastructures fostering innovation (e.g. biotech clusters) and academic spin-out companies. These are all areas that have been the focus of policies to stimulate innovation in biotechnology.

Yet despite (or perhaps because of) the intensive emphasis placed on fostering innovation in biotechnology, an increasing number of observers are questioning the biotechnology 'revolution'—it seems clear that, to date, there have been far fewer new genomics-based products than originally expected.<sup>74</sup> The dearth of new products puts additional pressure on a pharmaceutical industry that had already been undergoing a significant transformation due to such factors as changing regulatory environments, negative publicity, and the patent expiration of many profitable products.<sup>75</sup>

With industry facing such pressures in the more lucrative markets, the question of how to stimulate innovation that will benefit developing countries remains critical. As WHO has argued, global research is determined by the markets of wealthy rather than developing countries.<sup>76</sup> If markets cannot be counted on to develop drugs sorely needed by developing nations, then other mechanisms may be necessary if innovation is to serve the needs of the developing world and prevent the further

exacerbation of inequalities. Among the possible mechanisms, the following are prominent: private-public partnerships, dedicated funds for research and development, tax incentives, differential drug pricing and more equitable usage of intellectual property rights.<sup>77</sup>

In summary: how and why new technologies are regulated closely relates to underlying beliefs about how societies should be organised.<sup>78</sup> As such, discussions about regulation often comprise the focal point for controversy and contestation amongst actors with competing and conflicting interests and objectives. Regulatory systems are also one of the forces shaping and being shaped by innovative new technologies. Since governments and industry have invested large sums to ensure that domestic biotechnology industries can contribute to national and international health and wealth, both regulatory systems and the way in which innovation is promoted have been, and will continue to be, key subjects for social science research.

### *UK Research Addressing Regulation, Innovation and Genomics*

Some of the UK-based projects studying risk governance, as one aspect of regulation, have already been described. In particular reference was made to projects focussed on examining the influence of various stakeholders in shaping regulatory systems relating to specific biotechnologies.<sup>79</sup> Other research seeks to understand the development of regulatory systems as they cope with issues thrown up by research informed by the new genetics, such as xenotransplantation or fetal stem cells.<sup>80</sup> Regulatory institutions themselves may play a role in 'stabilising' new technologies, and this is also the focus of research examining institutions like stem cell banks.<sup>81</sup>

The dynamic interrelationship between innovation and regulation has been the subject of work in the sociology of expectations.<sup>82</sup> Specifically in relation to stem cells, the project will consider how expectations of the application of technology—expectations held by academia, industry and government—shape not only the development of the technology, but also of perspectives and attitudes towards its regulation. Plainly, if expectations of the potential 'goods' of a technology are overstated, this might lead regulators to accept undue risks. Thus, study of the nature and character of risk assessment of, for example, pharmaceuticals is a key area of research contributing to a better understanding of unfolding patterns of regulation and innovation, and so to an understanding of how a medical technology may or may not diffuse from the 'bench to bedside'.<sup>83</sup> One such new technology or approach which is the subject of considerable expectation is pharmacogenomics, and the uptake of new diagnostic-based therapies based on pharmacogenomics is the focus of research that will look in particular at similarities and differences in regulatory assessment in the US, Europe and Japan.<sup>84</sup> Meanwhile, additional research is analysing the influence of regulatory agencies on the development of pharmaceutical products, and, more broadly, some research is considering whether public accountability and commercial success can be reconciled by regulatory systems.<sup>85</sup>

Finally, a wide range of research is studying the factors influencing innovation within industry, and the nature, direction and management of such innovation. Some<sup>86</sup> are focussed on the impact of genomic and post-genomic technologies on innovation within industry while others<sup>87</sup> are studying trends in patenting and how

they relate to public policy and innovation. Others yet are focussing on the influence of various factors on academic and industrial research and development, such as clustering, multidisciplinary interactions or the broader macroeconomic environment.<sup>88</sup>

#### **Part IV - Directions for Future Research**

As the social science research described in Part Three proceeds, the Genomics Forum has had the opportunity, as a newer part of the UK landscape, to take a step back and consider the overall direction of this research. In doing so, three broad and related areas are identified as providing important ground for future engagement.

- (i) The first area, taking note of the context in which much current social science research is located, involves a clarification of the nature of the contribution of social sciences to policy-making in genomics.
- (ii) The second area is related to issues which arise from the first, and involves social science in the further development of, and participation in, inter-disciplinary projects addressing central policy questions, working with, for example, law and economics.
- (iii) The third area, whilst noting the importance of policy questions, also notes the constraints which a focus on questions of immediate policy significance can place on social science, and involves the development of wider social scientific reflection on the meaning of genomics and post-genomic science for human self-understanding.

##### **(i) The Context or Framing of the Social Science of Genomics**

The contribution of social science to understanding the significance, implications and consequences of the rise of genomics is being made in intimate connection with the intellectual contribution of other disciplines, and chiefly in connection with the contributions of ethics and law. This connection was formalised in terms of funding by the decision of the Human Genome Project to devote a proportion of its vast resources to a stream of work on ethical, legal and social aspects of the sequencing of the genome. This formal linking of different disciplines and research interests is reflected in the acronyms ELSA (for ethical, legal and social aspects) or ELSI (ethical, legal and social implications), which are now accepted shorthand for referring to a range of non-scientific questions posed by science and technology.

That social science is operating in this context is highly significant in considering the framing of an agenda for future research. Whilst the linking of social science with ethics and law has been appropriate in certain ways, it is possible that this same linkage has threatened to conceal the particular contribution that social science properly makes to the field. There is a danger that the invention and institutionalising of work on ELSA/ELSI of genomics, has hidden rather than highlighted the contribution of the social sciences. Certainly, and at the very least, it is noticeable that bioethics has tended to dominate the framing of the ELSA/ELSI agenda.

It is important, therefore, for social science not simply to accept this situation as given, but to take steps to clarify its disciplinary integrity and its interdisciplinary relationships. In the context of the 'ELSA/ELSI-fication' of the critique of science, in the future, such steps will be a vital element in securing a proper hearing for the subject in the future in the policy arena. What is needed, therefore, is an attempt to

clearly state the nature of social science's contribution to the understanding and analysis of genomics and to clarify the particularity of this understanding by placing alongside it accounts from philosophy and law. But these discrete statements would not be enough. The framing of the contribution of social science in ELSA/ELSI programmes demands systematic thinking not only about the specific contribution of the social sciences, but also an attempt to describe how the social sciences complement (or challenge) the other elements which have become institutionalised partners in the policy debate.<sup>89</sup>

## **(ii) Social Science and Interdisciplinarity in Genomics**

The political reality of the ELSA/ELSI context currently demands that the social sciences work with and alongside other disciplines to ensure that the social sciences' particular insights and concerns are acknowledged. Two areas that seem worthy of further attention by social scientists, are those concerning intellectual property regimes and the evaluation of genetic services/interventions in the field of human health. These two areas are central to the development and application of genomic science and as such are deserving of continued critical attention from the social sciences.

It is a familiar point that different regimes for the protection of intellectual property will have crucially different consequences for the course of innovation, research and development—and not only 'development' in the R&D sense, but in the sense of 'international development'. But equally significant for the course of development of genomic science are choices relating to the recognition and protection of intellectual property, and both national and international budgetary decisions regarding which of the applications of genomic science to human health receive funding. As the previously cited WHO Report (*Genomics and World Health*) makes clear, critical questions will need to be addressed to the claims of genetic medicine for scarce health resources in developing economies; but the same evaluative questions will have to be asked by any system of health provision in which there are competing claims for health resources. Thus the NHS will have to ask what priority in funding should be given to the new possibilities opened up by genomics for Pre-implantation Genetic Diagnosis (PGD), or to so-called 'personalised medicine' based on pharmacogenomics, or to individual or population genetic screening or testing. The answers to these particular questions are in and of themselves highly significant, and like the answers to questions about the merits of different regimes of protection for intellectual property, have the added significance of shaping the equally socially important development path of a whole raft of new technologies.

If the framing of the larger ELSA/ELSI debate should be subject to critical questioning, so too should the detailed treatment of individual policy questions within the agenda. If the first requires that social science itself stand back from the entire debate and seek to clarify its disciplinary integrity and its interdisciplinary relationships in a theoretical way, the second circumstance requires that social science should seek to develop interdisciplinary work and relationships in key areas, such as in relation to the questions concerning the nature and form of regimes for the protection of intellectual property and the evaluation of genetic services or interventions.

### (iii) The Meaning of Genomics and Post-Genomic Science for Human Identity

Marc Quinn's portrait in the National Portrait Gallery of Sir John Sulston, Nobel laureate in Physiology or Medicine, posed starkly the issues of genetic or genomic essentialism. Quinn's portrait is simply the analysis of Sulston's DNA on jelly in a plate. Is John Sulston, so this portrait seemed to ask, this particular DNA sequence? Whilst in the rest of the Gallery we would scrutinise the faces of the subjects in an endeavour to fathom or understand the person depicted (something we might attempt even in the event of our knowing nothing else of a person's life or circumstances), this portrait seems to pose the question as to whether the person who is mysteriously and problematically present to us in his or her face, is properly present to us in his or her genome, once we have learnt to read it.

Of course the move beyond genomics to proteomics and metabolomics is already, in effect, a repudiation of this genomic essentialism—we need to understand much more than the functions and interactions of genetic material, even in the totality of the genome, if we are to understand the biology of organisms. However that may be, it is nonetheless the case that genomics has served to reinforce the view which predates it, namely that genetic information is peculiarly personal or fundamental information and somehow goes to the heart of who we are. As well as affecting understanding of, and attitudes to, individual responsibility, genomic science and technology (in the shape of DNA profiling, for example) is increasingly being used to create, inform and shape categories of identity (such as race, ethnicity, sexuality, criminality and health status). Social science's concern to contribute to the policy debate must be expressed, then, not only in its contribution to the discussion of questions of very immediate policy significance, but also in continuing to maintain a broader perspective of reflection on the meaning of genomics and post-genomic science for human identity and self-understanding.

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<sup>1</sup> I. Diamond & D. Woodgate. Genomics research in the UK – the social science agenda. *New Genetics & Society* 2005; 24(2): 239-252.

<sup>2</sup> The Innovative Health Technologies programme was also sponsored by the Medical Research Council. The Programme Director of the Innovative Health Technologies Programme was Andrew Webster, SATSU, University of York. The Programme Director for the Science in Society Programme is Steve Rayner, James Martin Centre for Science and Civilization, University of Oxford.

<sup>3</sup> The European Commission has funded research through, for example, the 6<sup>th</sup> Framework Funding Programme (FP6). One of the thematic priorities of FP6 is 'Life Sciences, Genomics and Biotechnology for Health'. Here, although many of the funding is for scientific projects, FP6 leaves significant scope for contribution from ethicists and social scientists: 'Ethical and regulatory issues should be taken into account, and experts, patients, and the public involved and consulted as appropriate, in an effort to promote socially responsible choices, public acceptance and an efficient exploitation of the new technologies being developed.' (See: <http://www.cordis.lu/lifescihealth/applications/home.htm>).

<sup>4</sup> The projects listed in Table 1 were reviewed during February, March and April, 2005. In order to reflect the current research landscape, only recent projects—those active or completed during or after 2002—were selected. The list of projects in Table 1 is neither fully comprehensive nor ordered according to any scale or prioritisation. Rather, the projects are a selection broadly representative of the current research landscape in the UK. Projects were selected from the websites of a wide range of centres and funding bodies' websites, many of which are described in Part I. Although every attempt was made to ensure that the table is accurate, projects may have evolved such that they are currently misrepresented. Apologies to any relevant projects that may have been omitted.

<sup>5</sup> Thus the text in Part III is organized according to themes but Table 1 is not—the authors would not wish to suggest that research projects could only be classified according to the themes we have prescribed them. The choice of, or basis for, any classification scheme is never unproblematic and most always contingent, and this is also the case for the classification of a diverse range of research projects according to a few cross-cutting themes.

<sup>6</sup> M. McLuhan & Q. Fiore. 1967. *The Medium is the Massage*. New York. Bantam.

<sup>7</sup> Z. Bauman. 1998. *Globalization: The Human Consequences*. Cambridge. Polity Press: 58-59; cited in M. Jackson. *Biotechnology and the Critique of Globalisation*. *Ethnos* 2002; 67(2): 141-154.

<sup>8</sup> M. Jackson. *Biotechnology and the Critique of Globalisation*. *Ethnos* 2002; 67(2): 141-154, 152.

<sup>9</sup> Whether or not the impacts of globalisation on people's health in developing countries have been negative, positive or neutral is debatable. For two differing perspectives, see, for example D. Dollar. *Is globalization good for your health?* *Bulletin of the World Health Organization* 2001; 79(9): 827-833; and G.A. Cornia. *Globalization and health: results and options*. *Bulletin of the World Health Organization* 2001; 79(9): 834-841.

<sup>10</sup> N. Clark, K. Stokes & J. Mugabe. *Biotechnology and development: threats and promises for the 21st century*. *Futures* 2002; 34: 785-806.

<sup>11</sup> Capacity in this sense refers not only to scientists but also to 'entrepreneurial capabilities, supportive institutions and associated networks needed to translate raw scientific data into economic production': Clark et al., op. cit. note 10, p. 791.

<sup>12</sup> See projects 2-8, Table 1.

<sup>13</sup> N. Clark & J. Smith. *Biotechnology and development: threats and promises for the 21st century*. *Futures* 2001; 34: 785-806.

<sup>14</sup> See especially Table 1, projects 3 ('Indigenous Peoples', Cesagen), 4 ('Genomics and biotechnology partnerships in Africa', Innogen), 5 ('Genomics and biotechnology partnerships in less developed countries', Innogen), 6 ('Institutional impacts of north-south partnerships in agricultural biotechnology', Innogen), & 9 ('The impact of advanced genomics-based tools for agronomy, plant breeding and food production on local agricultural practices', Egenis).

<sup>15</sup> Table 1, Project 3 ('Indigenous Peoples', Cesagen).

<sup>16</sup> Table 1, Project 8 ('Bioethical implications of globalisation processes (BIG)', Cesagen).

<sup>17</sup> Table 1, Project 2 ('Action research to develop IEC materials that support informed consent processes for research in developing countries', Wellcome Trust/ KEMRI).

<sup>18</sup> Nuffield Council on Bioethics. 2002. *The Ethics of Research Related to Healthcare in Developing Countries*. London. Nuffield Council on Bioethics. The Wellcome Trust cites the Nuffield Council on Bioethics report as well as others in its position statement on research in people living in developing countries (At [http://www.wellcome.ac.uk/doc\\_wtd015295.html](http://www.wellcome.ac.uk/doc_wtd015295.html)).

<sup>19</sup> Whether or not, or the extent to which, states have been or are being hollowed out is the matter of some debate. For more general discussions on governance, see, for example: R.A.W. Rhodes. *The Hollowing Out of the State: The Changing Nature of the Public Service in Britain*. *Political Quarterly* 1994; 65(2): 138-151; R. Rhodes. 1997. *Understanding Governance: Policy Networks, Governance, Reflexivity and Accountability*. Buckingham. Open University Press; J. Kooiman (ed.). 1993. *Modern Governance: New government-society interactions*. London. Sage.

<sup>20</sup> J. Newman. 2001. *Modernising Governance*. London. Sage: 15.

<sup>21</sup> J. Kooiman (ed.). 1993. *Modern Governance: New government-society interactions*. London. Sage: 3.

<sup>22</sup> R. Rhodes. 1997. *Understanding Governance: Policy Networks, Governance, Reflexivity and Accountability*. Buckingham. Open University Press: 46

<sup>23</sup> As a hypothetical example, the interests of industry and scientific communities could become aligned with patient advocacy groups in the case of stem cell research, whilst people within such patient advocacy groups might mobilize against industry on the commercialisation of GM crops.

<sup>24</sup> H. Gottweiss. *The governance of genomics*. *Critical Public Health* 2002; 12(3): 207-220, 208.

<sup>25</sup> *Ibid.*

<sup>26</sup> R. Bunton & A. Petersen. *Genetics, ethics and governance*. *Critical Public Health* 2002; 12(2): 95-102, 97.

<sup>27</sup> M. Jones & B. Salter. *The governance of human genetics: policy discourse and constructions of public trust*. *New Genetics & Society* 2003; 22(1): 21-41, 22.

<sup>28</sup> B. Salter & M. Jones. *Regulating human genetics: the changing politics of biotechnology governance in the European Union*. *Health, Risk & Society* 2002; 4(3): 325-340, 326.

<sup>29</sup> *Ibid.*



- <sup>30</sup> Numerous authors have discussed this. See, for example: N. Brown & M. Michael. From authority to authenticity: the changing governance of biotechnology. *Health, Risk & Society* 2002; 6(3): 259-272; A. Irwin. Constructing the scientific citizen: science and democracy in the biosciences. *Public Understanding of Science* 2001; 10(1): 1-18; B. Wynne. The Public Understanding of Science. In: *Handbook of Science and Technology Studies*. S. Jasanoff et al. (eds.). 1995. London. Sage.
- <sup>31</sup> e.g. Wynne, op. cit. note 30.
- <sup>32</sup> B. Wynne. Seasick on the Third Wave? Subverting the Hegemony of Propositionalism. *Social Studies of Science* 2003; 33(3): 401-417, 412.
- <sup>33</sup> e.g. Bunton & Petersen, op. cit. note 26; Jones & Salter, op. cit. note 27.
- <sup>34</sup> Prime Minister's Strategy Unit. 2003. *Fieldwork: Weighing up the costs and benefits of GM crops*. At <http://www.number-10.gov.uk/su/gm/index.htm>; quoted in R. Levitt. 2003. *GM Crops and Foods: Evidence, policy and practice in the UK: a case study*. London. Sage: 8.
- <sup>35</sup> S. Campbell & E. Townsend. Flaws undermine results of UK biotech debate. *Nature* 2003; 425: 559.
- <sup>36</sup> W. Poortinga & N. Pidgeon. Trust in Risk Regulation: Cause or Consequence of the Acceptability of GM Food? *Risk Analysis* 2005; 25(2): 199-209.
- <sup>37</sup> House of Commons Select Committee on Environment, Food and Rural Affairs. 2003 *Conduct of the GM public debate: eighteenth report*. London. Stationery Office: Para 41; quoted in Levitt, op. cit. note 34, p. 20.
- <sup>38</sup> E.g. Brown & Michael, op. cit. note 30; Bunton & Petersen, op. cit. note 26; Irwin, op. cit. note 30; Wynne, op. cit. note 30.
- <sup>39</sup> Jones & Salter, op. cit. note 40, p. 27.
- <sup>40</sup> e.g. Bunton & Petersen, op. cit. note 26.
- <sup>41</sup> The tensions related to the application of genomics for individual versus collective health benefit have been explored by, for example: E. Willis. Public health and the 'new' genetics: balancing individual and collective outcomes. *Critical Public Health* 2002; 12(2): 139-151.
- <sup>42</sup> Particularly, projects 10, 30-49 & 71-98 in Table 1.
- <sup>43</sup> See, for example, Table 1: Project 10 ('The global politics of human embryonic stem cell regulation', University of East Anglia), 30 ('Accountability and the governance of expertise: anticipating genetic bioweapons' University of Exeter), 33 ('Representations of complexity in policy networks', IGBiS), 43 ('Quality assured science: the role of standards in stabilising stem cell research', SATSU) & 111 ('Medical device governance: regulation of tissue engineering in the UK and EU', Cardiff University).
- <sup>44</sup> See, for example, table 1: Project 30 ('Accountability and the governance of expertise: anticipating genetic bioweapons' University of Exeter), 33 ('Representations of complexity in policy networks', IGBiS) & 46 ('Trading up environmental standards? Trans-atlantic governance of GM Crops', The Open University).
- <sup>45</sup> See Table 1: Projects 39 ('Reforming the governance of human genetics: The politics of public trust', University of East Anglia), 45 ('PARADYS: Participation and the dynamics of social positioning', University of Lancaster / IEPPP), 74 ('The emerging politics of new genetic technologies', Cesagen), 81 ('Deliberative Mapping', SPRU), 98 ('The social dynamics of public engagement in stem cell research', Innogen).
- <sup>46</sup> See Table 1, Project 81 ('Deliberative Mapping', SPRU).
- <sup>47</sup> e.g. Table 1, Projects 52 ('Transformations in genetic subjecthood', SATSU / University of Edinburgh), 75 ('Public perceptions of risk, science and governance', University of East Anglia), 80 ('Childhood vaccination: science and public engagement in international perspective', University of Sussex).
- <sup>48</sup> e.g. Table 1, Project 98 ('The social dynamics of public engagement in stem cell research', Innogen).
- <sup>49</sup> Table 1, Project 52 ('Transformations in genetic subjecthood', SATSU / University of Edinburgh).
- <sup>50</sup> Table 1, Projects 79 ('Factors affecting preimplantation genetic diagnosis (PGD): Patient's attitudes toward donation of embryos for stem cell research', Cesagen) & 93 ('A comparative study of embryo donors' views on embryo experimentation for preimplantation genetic diagnosis and stem cell therapy', PEALS).
- <sup>51</sup> Table 1, Project 93 ('A comparative study of embryo donors' views on embryo experimentation for preimplantation genetic diagnosis and stem cell therapy', PEALS).
- <sup>52</sup> Table 1, Projects 52 ('Transformations in genetic subjecthood', SATSU/University of Edinburgh), 72 ('Definitions of genetic knowledge & pre-implantation genetic diagnosis: an ethnographic study', Cesagen), & 105 ('Genetic screening for susceptibility to disease: the case of haemochromatosis', Cesagen).

- <sup>53</sup> Table 1, Project 72 ('Definitions of genetic knowledge & pre-implantation genetic diagnosis: an ethnographic study', Cesagen).
- <sup>54</sup> Table 1, Project 78 ('Variability in response to warfarin: a prospective analysis of pharmacogenetic and environmental factors', University of Liverpool / SATSU).
- <sup>55</sup> Table 1, Project 29 ('The institutionalisation of ethics in science policy: practices and impact', Cesagen).
- <sup>56</sup> See Projects 15-29, Table 1.
- <sup>57</sup> For example, Table 1, Projects 15 ('Social and ethnic differences in attitudes and consent to prenatal testing', University of Leeds) & 16 ('Informed consent and genetic data', University of Cambridge). The latter is also asking more broadly about the sort of information required for consent to be legitimate.
- <sup>58</sup> Table 1, Project 20 ('Ethical protection in epidemiological genetic research: participants' perspectives', University of Bristol).
- <sup>59</sup> For example, Table 1, Project 25 ('Informed consent in Sri Lanka', King's College, University of London).
- <sup>60</sup> Table 1, Project 28 ('Ordinary ethics: moral evaluation of the new genetics by non-professionals', PEALS).
- <sup>61</sup> Jones & Salter, *op. cit.* note 27, p. 22.
- <sup>62</sup> P. Martin and R. Frost. Regulating the commercial development of genetic testing in the UK: problems, possibilities and policy. *Critical Social Policy* 2003; 23(2): 186-207, 206.
- <sup>63</sup> A. Giddens. 1990. *The Consequences of Modernity*. Cambridge, UK. Polity: 111.
- <sup>64</sup> N. Brown & Michael. Risky Creatures: Institutional Species Boundary Change in Biotechnology Regulation. *Health, Risk and Society* 2004; 6(3): 207-222.
- <sup>65</sup> Brown & Michael, *op. cit.* note 30, p. 260.
- <sup>66</sup> e.g. S. Jasanoff. 1990. *The Fifth Branch: Science Advisers as Policymakers*. Cambridge, MA. Harvard University Press.
- <sup>67</sup> e.g. *Ibid.*; Irwin, *op. cit.* note 30.
- <sup>68</sup> Jasanoff *op. cit.* note 66, p. 178.
- <sup>69</sup> e.g. W. Bijker, T. Hughes & T. Pinch (eds.). 1987. *The Social Construction of Technological Systems*. Cambridge, MA. MIT Press; and D. MacKenzie & J. Wajcman. 1999. *The Social Shaping of Technology*, 2nd Edition. Buckingham. Open University Press.
- <sup>70</sup> This notion has also been challenged. See, for example: P. Nightingale & P. Martin. *The Myth of the Biotech Revolution*. *Trends in Biotechnology* 2004; 22(11): 564-569.
- <sup>71</sup> At <http://www.bioindustry.org/bigtreport/vision.html>
- <sup>72</sup> Department of Trade and Industry. 1999. *Genome Valley: The Economic and Strategic Importance of Biotechnology in the UK*. London. Department of Trade and Industry: 37.
- <sup>73</sup> *Ibid.*, p. 34
- <sup>74</sup> E.g. Nightingale & Martin, *op. cit.* note 70.
- <sup>75</sup> e.g. J. Tait & J. Mittra. 2004. *Complexity and Innovation in the Pharmaceutical Industry*. At <http://www.innogen.ac.uk>.
- <sup>76</sup> World Health Organization. 2002. *Genomics and World Health*. Geneva. World Health Organization: 127-133
- <sup>77</sup> *Ibid.*, pp. 132-133
- <sup>78</sup> For an extended discussion on this topic, see S. Jasanoff. 2005. *Designs on Nature: Science and Democracy in Europe and the United States*. Princeton, N.J. Princeton University Press.
- <sup>79</sup> For example, Table 1, project 46 ('Trading-up environmental standards? Transatlantic governance of GM crops', Innogen).
- <sup>80</sup> Table 1, Project 100 ('Xenotransplantation: risk identities and the human / non-human interface', Goldsmiths College, University of London / SATSU) & 109 ('Forgotten fetuses – a sociocultural analysis of the use of fetal stem cells', University of the West of England, Bristol).
- <sup>81</sup> Table 1, project 43 ('Quality assured science: the role of standards in stabilising stem cell research', SATSU).
- <sup>82</sup> e.g. Table 1, project 110 ('Haematopoietic stem cells: the dynamics of expectations in innovation', IGBiS / SATSU).
- <sup>83</sup> Table 1, Project 108 ('Mapping stem cell innovation in action', King's College, University of London). See also Table 1, Project 107 ('The ethical and public policy implications of the new genetics and transgenics in the carcinogenic risk assessment of pharmaceuticals', University of Sussex).
- <sup>84</sup> Table 1, Project 67 ('Pharmacogenomics, diagnostic tests and clinician acceptance', SATSU).

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<sup>85</sup> See Table 1, Projects 68 ('The clinical and commercial development of pharmacogenetics', IGBiS / SATSU) & 102 ('The regulation of small biotech start-up companies in Scotland and Norway', IGBiS).

<sup>86</sup> e.g. Table 1, Projects 60 ('The impact of genomics on innovation in the pharmaceutical industry', IGBiS / SPRU) & 62 ('Transcending the genome: the paradigm shift to proteomics', Cesagen).

<sup>87</sup> e.g. Table 1, Projects 59 ('The public and private organisation of genetic information', Innogen

<sup>88</sup> See Table 1, Projects 57 ('The evolution of biomedical knowledge: interactive innovation in the UK and US', University of Warwick) & 12 ('Corporate responses to macroeconomic changes and shocks', University of Cambridge).

<sup>89</sup> J.H. Evans' recent work, *Playing God?* (J.H. Evans. 2002. *Playing God? Human Genetic Engineering and the Rationalization of Public Bioethical Debate*. Chicago, University of Chicago Press), addresses the importance of this point. According to Evans, the very structuring of the debate about what he terms 'human genetic engineering' (HGE) has precluded the possibility of 'thick' as opposed to 'thin' debate about public policy. This contrast he explains by borrowing Weber's distinction (in *Economy and Society*) between formal and substantive rationality. Action is substantively rational if it applies criteria of ultimate ends or values to decision-making; action is formally rational if it is simply calculated to be the way to achieve predetermined or assumed ends. Debate about HGE is, he contends, increasingly of the formally rational kind and thus 'thin'.