

Responsible Research and Innovation in SynbiCITE

SynbiCITE and our partners across the UK and globally are committed to developing synthetic biology based technology through responsible research and innovation (RRI) which encompasses ethical, legal, societal and environmental considerations.

Background

From the landmark conference at Asilomar in 1975, where scientists debated the best approaches to regulating recombinant DNA and managing its potential dangers, through to the ethical, legal and social implications (ELSI) programme that was initiated alongside the Human Genome Project, a range of approaches have been developed for ensuring responsibility among scientific researchers working on new and emerging technologies. These initially emphasised the need for professional responsibility among the researchers themselves, and placed emphasis on the self-regulating capacities of the scientific community. A loosely defined and evolving approach to responsible innovation was developed to require scientists, technologists and all involved in innovation in new science and technologies to think about: what they are doing, why they are doing it and the implications before they proceed.

For an example of this approach, some years ago, Sir David King (Government Chief Scientific Adviser and Head of the Government Office for Science, 2007) proposed a number of guidelines on how the scientific and innovation community should approach these issues. He noted that those involved should employ rigour, respect and responsibility in all that is done and to follow the guidelines below:

- **Rigour:** involves principles of honest, integrity, prevention of professional misconduct, declaration of conflicts of interest and respect for the rights and reputations to others.
- **Respect:** involves attention to the implications of research for the lives of others and the public good, lawfulness, attention to potential adverse effects, respect for the rights and privacy of individuals.
- **Responsibility:** involves attention to all forms of communication, in work with students, colleagues, and the wider public, encouraging, and participating in, debate about the issues that research may raise for society, avoiding knowingly misleading others, or allow others to be misled, about research or about science

and intellectual inquiry more generally, honesty and accuracy in the presentation of research and review research data, theory or interpretation.

Today's researchers are trained in these principles and often contractually required to follow them. Imperial College, like many other public and private institutions, has formally encoded these principles into all aspects of its scientific research work: <http://www3.imperial.ac.uk/researchstrategy/researchintegrity> .

Research on incidents of scientific misconduct, such as the Hwang affair in South Korea (Gottweis and Triendl 2006) has shown that the professional responsibility of the scientist continues to be the key element in the process, and must operate in combination with peer review and declarations of conflicts of interest to ensure research integrity.

However, as is well known, claims concerning the professional responsibility of scientists and researchers have come to be seen as insufficient to ensure responsibility in research and development. The current emphasis on RRI should be seen as a supplement to, and not a replacement of, these crucial dimensions of scientific research and research integrity. Building on and developing this emphasis of professional responsibility and accountability, recognising that the trust those members of the general public place in scientific researchers cannot be taken for granted. Indeed it has been challenged by many current developments, including the pace of scientific innovation, the new powers of molecular biology to reshape living organisms at a fundamental level, and the increasing intertwining of scientific and technological development with the priorities of private corporations and their financial and economic drivers. Partly informed by the limited success of projects to enhance 'public understanding of science' – and the move from 'understanding' to 'engagement', the new models of responsible research and innovation that are being developed. These newer models, which are being employed at SynbiCITE, not only ensure that issues of responsibility are at the forefront of the thinking and practice of researchers, and routinely inform all that researchers do and why we do it, but also seek to open up the enclosed spaces of where research takes place to wider scrutiny and democratic debate (for some of the voluminous literature, see Callon, Lascoumes and Barthe 2009, Groves 2013, Guston et al. 2014, Owen, Macnaghten and Stilgoe 2012, Rose 2012, Von Schomberg 2013, von Schomberg 2014). Bringing practicing scientific researchers into regular contact with a range of stakeholder groups, including those who are wary and critical of these developments, not only enable and engender real and substantive communication (rather than bland reassurance of the public that they can trust

scientists) but also changes the very way in which the researchers conduct their work, frame their objectives and judge success. It is in this spirit that SynbiCITE and our partners are evolving a continually improving approach to RRI and put this into practice on a day-to-day basis.

Responsible Research and Innovation

In the face of perceived public concerns about technological innovations, and the desire to direct emerging technologies towards publicly desirable objectives, leading national and international bodies increasingly recognise the need for dialogue between policy makers, scientific researchers and civil society organizations and members of the public in order to shape the pathways of technology development to address the grand challenges facing society (as described, for example, in the Synthetic Biology Roadmap for the UK (Technology Strategy Board (UK) 2012) in a way that meets societal needs and gains public trust. Major funding bodies in the UK, Europe and elsewhere are addressing this issue by insisting on Responsible Research and Innovation (RRI) in the development of emerging technology. They are calling for comprehensive RRI frameworks to be developed for use in current and future initiatives - such as the Innovation and Knowledge Centres, Horizon 2020 projects and RCUK funded projects - to ensure that the research and development that is funded is ethically acceptable, sustainable and focused on delivering societal benefits.

The mechanisms for implementing RRI remains largely unspecified; we have therefore sought collaborations with social scientists active in this area for guidance. Even at the onset of synthetic biology development in the UK, through the development of CSynBI and SynbiCITE, Imperial College has collaborated with social scientists. These researchers were initially based in the BIOS Centre at LSE, and now at the Foresight and Responsible Research and Innovation Lab (FRRIL) of the Department of Social Science, Health and Medicine at King's College London. FRRIL has worked extensively on emerging biotechnologies to ensure social responsibility in research and innovation, proposing novel ways in which these RRI principles can be translated into practical procedures for the governance of emerging technologies (Marris and Rose 2010, Marris and Rose 2012, Marris and Jefferson 2013, Rose 2012, Rose 2014, Singh, Sinnott-Armstrong and Savulecu 2013, Walsh et al. 2011, Zhang, Marris and Rose 2011).

FRRIL has a key role in the implementation of RRI in a number of projects, including the €1.3bn Human Brain Project where Professor Rose is a member of the Steering Committee of the Social and Ethical Division, and our group has the specific responsibility to establish and run the Foresight Lab: <http://www.kcl.ac.uk/sspp/departments/sshm/research/Research-Labs/Research->

Professor Iliana Singh has a key role in NERRI (Neuro-Enhancement: Responsible Research and Innovation), a three-year project supported by the European Commission under the 7th Framework Programme which aims to contribute to the introduction of Responsible Research and Innovation in neuro-enhancement in the Europe and to shape a normative framework underpinning the governance of neuro-enhancement technologies. The project will involve different stakeholders and will promote a broad societal dialogue about neuro-enhancement. This will be achieved through mobilization and mutual learning activities such as interviews and workshops engaging scientists, policy-makers, industry, civil society groups, patients and the wider public: <http://www.kcl.ac.uk/sspp/departments/sshm/research/Research-Groups/Biomedicine-Ethics-and-Social-Justice/BESJ-Projects/NERRI.aspx>

Other relevant activities of FRRIL include editorship of the PLOS Biology Series on Public Engagement; participation in workshops organised by leading scientific and regulatory bodies; through high quality peer-reviewed academic publications; and comments in popular science media outlets. Currently, seven people are associated with that Lab: Professor Nikolas Rose, Professor Iliana Singh, Dr. Claire Marris, Dr. Filippa Lentzos, Dr. Catherine Jefferson, Dr. Christine Aicardi, Dr. Michael Reinsborough and our Project Manager, Ms. Paola Bello. A further postdoctoral researcher, with specific responsibilities to work within the IKC, is currently being recruited.

The FRRIL group works within a large trans-disciplinary research centre comprising research students, research fellows, visiting researchers and visiting Professors as well as researchers working on funded projects. The Department of Social Science, Health and Medicine at King's College London is the leading interdisciplinary department in this area, established in 2012, and now with some 25 faculty, a large portfolio of externally funded interdisciplinary research, with funding from all the major research councils, dedicated high quality research facilities, and a very active programme of workshops, seminars, invited lectures, conferences and other interdisciplinary activities, working closely with researchers from the social sciences, the humanities, medicine, biomedicine and health from across King's, with partnerships in the US, Brazil, Chile, China, India as well as active networks across Europe. Further details are available here: <http://www.kcl.ac.uk/sspp/departments/sshm/index.aspx>

The view at FRRIL is that RRI work needs to be carried out on an interdisciplinary and trans disciplinary basis, and for that reason, our team is trans disciplinary and is associated with a large trans disciplinary research group in our Department which focuses on biotechnology, pharmaceuticals and public policy. The Biotechnologies, Pharmaceuticals and Public Policy research group comprises leading social scientists and policy analysts working on a number of new and sustained research programmes, including those funded by the ESRC, EPSRC, MRC and Wellcome Trust. Members of the group are experienced in advising UK Parliamentary Select Committees, UK Government Departments, the US Congress, the UK Medicines and Healthcare Products Regulatory Agency (MHRA), the French Ministry of Research and Higher Education, the ESRC, the Royal Society Science Policy Centre, the Biological Weapons Convention, and the Human Genetics Commission. The group's research is international in scope spanning Europe, North America, China, and beyond.

<http://www.kcl.ac.uk/sspp/departments/sshm/research/Research-Groups/BPPP/About-BPPP.aspx>

Collaboration between Imperial and King's College London on RRI

The collaboration of synthetic biologists at Imperial College (& SynbiCITE) and social scientist at FRRIL is at the centre of SynbiCITE's strategy of RRI implementation. Members of the FRRIL Lab have been embedded in the work of synthetic biologists at Imperial College, and their collaborators, since 2008, first within the BIOS centre at LSE and then from January 2013, with the Department of Social Science, Health and Medicine at King's College London. Initially in relation to the EPSRC funded CSynBI Consortium, then in the regular meetings of PI's and 'all hands' for the EPSCR funded Flowers Consortium. A Senior Research Officer and a Research Associate are funded from within these grants to work on RRI. Professor Rose, who directs them, is also a member of the management structure of both CSynBI and Flowers. The IKC bid grew out of CSynBI and Flowers and was extensively discussed in the management meetings that led up to the bid, and during an Awayday at Cumberland Lodge and these ensured that attention to RRI was built into the very fabric of SynbiCITE from its inception. Professor Rose was invited to have a formal role in the management structure of the IKC at the outset, but it was decided that given the dispersed nature of the activities that were to be funded by the IKC, it would be more appropriate for him to be involved at a later point if the bid was funded. After the funding of the IKC, and in the six months since the grant began, further discussions have taken place between Rose, Kitney and Freemont, about the most appropriate ways to build RRI into the activities of the IKC and a clear

way forward has been agreed. As part of this, King's is now in the process of formal incorporation as a full partner in the SynbiCITE project. Funding has been provided for a dedicated research officer specifically to work on the IKC, who will be part of the KCL team working on RRI within the FRRIL Lab. The need for further posts will be evaluated as the IKC moves to the next phase.

RRI Experience

Our approach to RRI is informed by our own previous work in the social and ethical dimensions of scientific and technological innovation, many years work within science and technology studies (Rose is the STS expert output assessor on the Sociology REF panel), extensive discussions with colleagues in the Social Science community over many years, a longstanding commitment to democracy in scientific and technological innovation and to the promotion of scientific citizenship, and a good knowledge of the work on RRI in the UK, continental Europe, and the work on Anticipatory Governance in the USA. Rose has been involved in developing approaches to RRI in the work of the Nuffield Council on Bioethics where he was a member of Council for six years, and helped initiate the large NCOB project on ethical issues in emerging biotechnologies; he is also a member of the Royal Society Science Policy Advisory group and has worked with the Academy of Medical Sciences and a number of other groups on these issues. Marris is involved in a number of governance committees including the Governance Committee of the Synthetic Biology Leadership Council and is involved in implementing RRI in a number of other projects in synthetic biology. Reinsborough was previously a postdoc in the Arizona State University group, which is the leading, group working in this way: <http://cns.asu.edu/about> (Professor Guston and Fisher from ASU have been keynote speakers at events organized by Imperial College).

The approach developed by FRRIL can be mapped onto the **AREA** framework set out by the EPSRC, and the four dimensions of RRI that are identified.

- **ANTICIPATION:** we work with synthetic biologists, regulators, civil society actors and other stakeholders to explore scenarios of potential developments and implications and feedback to the researchers to build capacity to adapt to differing uncertain futures. In particular we stress the importance of working with the envisaged 'end users' of any emerging technology at an early stage in the process, and throughout the pathway from bench to deployment, in order to understand their needs, priorities and concerns, and to shape the technology pathway itself so that it can meet these in the most effective manner.

- **REFLECTION:** we work closely with researchers, and with students in iGEM teams and elsewhere, to encourage reflection among researchers in synthetic biology to increase capacity of researchers to analyse societal implications of their R&D. In particular we stress the importance of incorporating RRI into the training of early career researchers, and into the regular reskilling of established researchers.
- **ENGAGEMENT:** we support, organize and participate in a range of public events to address key issues of acceptability and take up of the outputs from research in synthetic biology, and to discuss frankly any risks and uncertainties, explaining what these are and how they are being addressed. We stress the importance of researchers being able to explain clearly: what they are doing, why they are doing it, what the potential public benefits are, what the potential risks are, and how these are being addressed. We stress the need to avoid overstatements as to the benefits and timescale of their work.
- **ACTION:** through these activities we aim to enhance strategic pathways to social benefit, linking results back to the management and strategy of synthetic biology researchers themselves, to ensure that the research is directed towards achieving public benefits and meeting key societal challenges in a responsible and ethical manner.

We set out below some of the practical steps by which this will be achieved within SynbiCITE.

RRI in action in SynbiCITE

We can identify the activities that put RRI into action under the four headings of the AREA framework.

Anticipation

- RRI involvement at an early stage in planning the work of SynbiCITE, in collaboration with the PIs
- RRI representation in project proposal evaluation and selection process after proof of concept stage; satisfaction of RRI criteria is a key evaluation criterion for funding.
- RRI workshops with senior researchers in SynbiCITE
- Scenario planning, DELPHI exercises and stakeholder workshops with SynbiCITE members to discuss and analyse scenarios (for discussion of scnarion methodology in this context, see, for example, Aldrich, Newcomb and Carlson 2008, Calvert 2012, Frow and Calvert 2013)

- Analytics of translation programmes and practices with an RRI focus on social, legal, ethical and political conditions and implications.

Reflection

- RRI researchers will visit and work with partner projects and collaborative projects on a regular basis
- RRI presence at partners meetings
- RRI involvement in SynBio events and conferences
- RRI engagement in all training programmes of SynbiCITE
- RRI activities (workshops, conference participation, lab meeting participation) with researchers in the UK BioFAB and those involved in biosensor development

Engagement

- SynbiCITE researchers participate in multiple public events, and public workshops and debates will be held at various venues across London including the Royal Institution, Dana centre and Science museum. We have a good track record in a variety of public engagement activities e.g. PF curated an exhibition at the Dublin Science gallery called 'Living Machine' (Oct 2013 – Jan 2014) and PF and RIK contributed a 'pop-up' synthetic biology lab at the Synthetic Aesthetic late Friday Event at the Victoria and Albert museum in London (April 2014). RRI work in SynbiCITE will continue with such activities debating ongoing R&D in a variety of public platforms, interactive workshops and open debates around synthetic biology, which will also involve creation of a public website and the generation of material for public dissemination.
- The RRI team works closely and communicates regularly with other research groups engaged in RRI and cognate activities. E.g. those who work on Foresight, on Anticipatory Governance, Future Studies, Scenario Planning, DELPHI analysis, Social Responsibility Participatory Research etc.)
- The RRI team is integrated into leading international research in science and technology studies, and engage actively in debates over the democratisation of science and technology development.
- Researchers at FRRIL participate actively in deliberations of regulatory bodies and advisory organisations, such as the Nuffield Council on Bioethics, the Royal Society Science Policy Advisory Group, US National Academy of Sciences' Committee on Science, Technology, and Forum on Synthetic Biology, UK Synthetic Biology Roadmap Coordination Group and Synthetic Biology Leadership Council.
- SynbiCITE is working with the Society of Biology to extend outreach and development of RRI principles and practices and their dissemination to a wider audience. This activity has been developed alongside similar work in progress with the BioIndustry Association (BIA).

Actions

We will use a number of pathways to feedback the work on RRI research to the strategic direction of individual projects.

- RRI involvement at the early stages of project design, working with the PIs of the project.
- RRI representation on Steering & Governance committee. Given the composition of the S&G group it would also be able to provide access to how other industries and institutions approach RRI.
- RRI representation on Strategy Group.
- PIs and Co-Is of the project, together with other researchers, are involved in stakeholder workshops, discussion of scenarios, and other 'anticipatory governance' activities.
- Workshops and discussions are held with PIs and Co-Is on questions of translation pathways to public benefit

In these and other ways, we seek to ensure that RRI is not merely an external element in the research design, but an integral part of its strategic orientation and its day-to-day operation.

Embedding an RRI 'UK Code of Practice' into Commercial Synthetic Biology

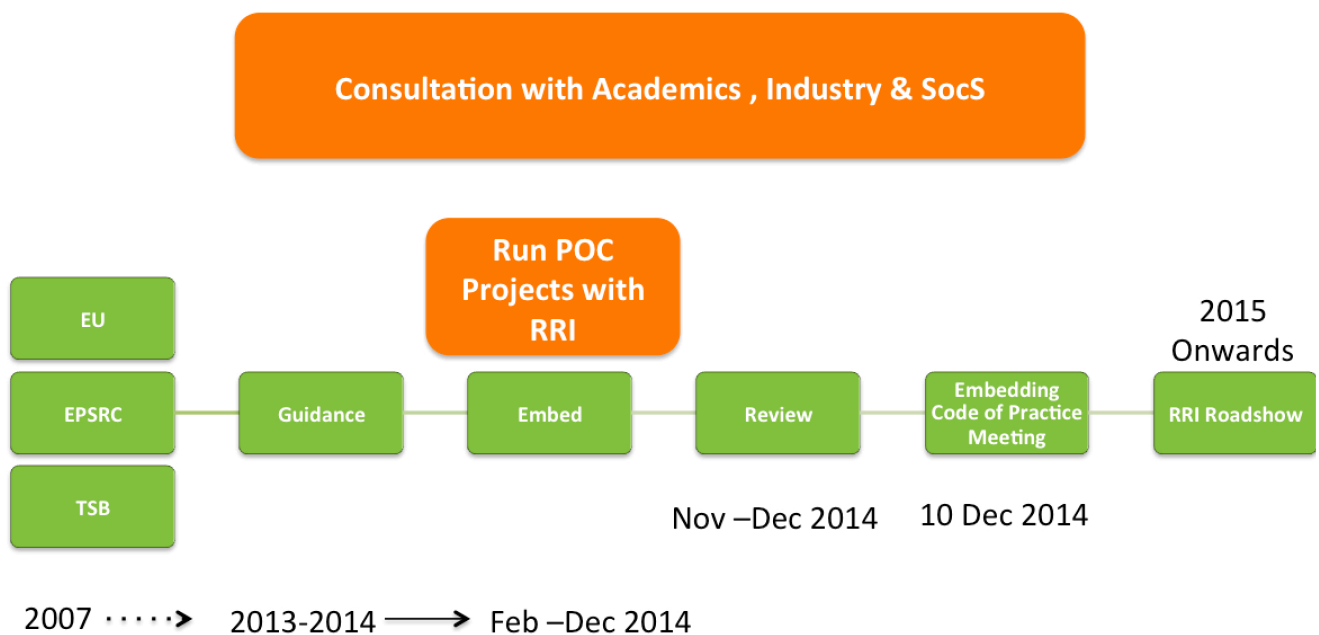
The process starts as collaboration between UK social scientists and SynbiCITE academic and industrial partners. A statement on SynbiCITE's commitment to RRI is published on its website and is included in all its forward-facing public pronouncements. These statements stress SynbiCITE's role in engaging in open and positive dialogue with the public and other stakeholders to promote RRI. Engagement with the partners on RRI starts with partnership agreement, which distils the guidance given in the EU, EPSRC and InnovateUK documentation on responsible innovation (such as presented by Technology Strategy Board in 2012 in "A Synthetic Biology Roadmap for the UK"; by Owen et al in "Responsible Research and Innovation: From Science in Society to Science for Society, with Society" in *Science and Public Policy*, 2012 and in René VonSchomberg's 2013 paper "A Vision of Responsible Research and Innovation" in *Responsible Innovation*).

This behaviour is reinforced through the actual running a project with the RRI embedded in the design and execution of the work performed. Subsequent review of the project and the process allows real events to dictate the discussions and the formation of a code of practise, which works for all parties.

SynbiCITE scheduled its first RRI Code of Practice Meeting for Wednesday, 10th Decembers 2014. The meeting marked the start of an evolving process of establishing a UK RRI Code of Practice specifically for industrial translation of synthetic biology R&D. The eventual Code of Practice established would identify best practices and ethical standards required when undertaking the commercialization of products of synthetic biology.

Prior to the meeting the discussion document ‘Responsible Research and Innovation in SynbiCITE’ was distributed to all partners for their comment and feedback. All our industrial and academic partners were invited to the RRI Code of Practice meeting. The meeting was held in conjunction with SynbiCITE’s partners meeting to ensure maximum participation of partners. This meeting was held at Imperial College and discussion facilitated by social scientists from King’s College London and University of Edinburgh. The topic on the agenda was: ‘What are the main challenges for implementing RRI in commercial organizations and what are the best strategies to address these challenges?’ Over the next months we will compile the output from the workshop and guided by Prof Nik Rose from King’s College London we will work closely with the UK’s experts in the field to produce a first draft for consultation with our SynbiCITE partners and the wider synthetic biology community across the UK.

Timeline and Rollout of RRI through SynbiCITE into Partners and Beyond



Conclusion

RRI activities in SynbiCITE are still developing as the research and translation activities themselves develop. The near term plan is to pilot these various activities forward with the goal of developing a RRI code of practise for the industrial translation of synthetic biology research. Long-term collaborations have convinced all parties that the commitment to RRI is genuine and tangible, and we look forward to working together on this landmark project over future years, following the commitment of the Synthetic Biology Roadmap to “responsible innovation, incorporating the views of a range of stakeholders and addressing global societal and environmental challenges within an effective, appropriate and responsive regulatory framework.... engagement’ means genuinely giving power to a wide range of diverse social groups, including those who will be the end users or presumed beneficiaries of the technologies. This will include on-going stakeholder engagement and dialogue with wider social groups” (Technology Strategy Board (UK) 2012). Road-mapping is not a one off event, it should be a process, and it is our intention that the work of RRI within SynbiCITE, together with that of other RRI researchers in the field, will help ensure that roadmaps to the future in synthetic biology will be dynamic and evolving as the technology and its social implications develop in tandem.

References

- Aldrich, Stephen, James Newcomb and Robert Carlson. 2008. "Scenarios for the Future of Synthetic Biology." *Industrial Biotechnology* 4(1):39-49.
- Callon, M., P. Lascoumes and Y. Barthe. 2009. *Acting in an Uncertain World: An Essay on Technical Democracy*: The MIT Press.
- Calvert, Jane. 2012. "Governing and Imagining the Future: Reflections on the Uk Synthetic Biology Roadmap."
- Frow, Emma and Jane Calvert. 2013. "Opening up the Future (S) of Synthetic Biology." *Futures* 48:32-43.
- Gottweis, H. and R. Triendl. 2006. "South Korean Policy Failure and the Hwang Debacle." *Nature Biotechnology* 24(2):141-43.
- Groves, Christopher. 2013. "Horizons of Care: From Future Imaginaries to Responsible Research and Innovation." *Shaping Emerging Technologies: Governance, Innovation, Discourse*:185-202.

- Guston, David H, Erik Fisher, Armin Grunwald, Richard Owen, Tsjalling Swierstra and Simone van der Burg. 2014. "Responsible Innovation: Motivations for a New Journal." *Journal of Responsible Innovation* 1(1):1-8.
- Marris, Claire and Nikolas Rose. 2010. "Open Engagement: Exploring Public Participation in the Biosciences." *Plos Biology* 8(11):e1000549.
- Marris, Claire and Nikolas Rose. 2012. "Let's Get Real on Synthetic Biology." *New Scientist* 214(2868):28-29.
- Marris, Claire and Catherine Jefferson. 2013. "Scoping Report."
- Owen, Richard, Phil Macnaghten and Jack Stilgoe. 2012. "Responsible Research and Innovation: From Science in Society to Science for Society, with Society." *Science and Public Policy* 39(6):751-60.
- Rose, Nikolas. 2012. "Democracy in the Contemporary Life Sciences." *Biosocieties* 7(4):459-72.
- Rose, Nikolas. 2014. "The Human Brain Project: Social and Ethical Challenges." *Neuron* 82(6):1212-15.
- Singh, Iliana, Walter P Sinnott-Armstrong and Julian Savulecu. 2013. *Bioprediction, Biomarkers, and Bad Behavior: Scientific, Legal, and Ethical Challenges*: Oxford University Press.
- Technology Strategy Board (UK). 2012. "A Synthetic Biology Roadmap for the UK." Vol. London: Technology Strategy Board.
- Von Schomberg, René. 2013. "A Vision of Responsible Research and Innovation." *Responsible Innovation*:51-74.
- von Schomberg, René. 2014. "The Quest for the 'Right' impacts of Science and Technology: A Framework for Responsible Research and Innovation." Pp. 33-50 in *Responsible Innovation 1*: Springer.
- Walsh, Pat, Mayada Elsabbagh, Patrick Bolton and Iliana Singh. 2011. "In Search of Biomarkers for Autism: Scientific, Social and Ethical Challenges." *Nature Reviews Neuroscience* 12(10):603-12.
- Zhang, Joy Yueyue, Claire Marris and Nikolas Rose. 2011. "The Transnational Governance of Synthetic Biology: Scientific Uncertainty, Cross-Borderness and the 'Art' of Governance. For the Royal Society Science Policy Centre (Uk)." *The Royal Society*.