

NUFFIELD
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BIOETHICS

BACKGROUND PAPER

Scientific Research Integrity

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**Forward Look
7-8 May 2013**

Note

The author was commissioned by the Nuffield Council on Bioethics to write this paper in order to inform the Council's discussions about possible future work on this topic. The paper is intended to provide an overview of key clinical, ethical, social, legal and policy issues, but is not intended to offer any conclusions or recommendations regarding future policy and practice. Any views expressed in the paper are the author's own and not those of the Nuffield Council on Bioethics.

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Summary

1. This paper outlines definitions of, and different scholarly and professional approaches to, 'scientific research integrity' (SRI). It introduces a number of debates and areas of contention in this field.

Introduction

2. In 2011 the House of Commons Science and Technology Committee published its report on the operation and effectiveness of the peer review of scientific findings prior to publication. It concluded that current approaches to research integrity are 'unsatisfactory.'² More than anything perhaps the Committee's Report showed how the inner workings of science have taken on a public relevance. In 2012 the UK Research Integrity Concordat discussed a proposal requiring all Higher Education Institutions receiving university funding to comply with the terms of forthcoming research integrity standards.
3. Just as the Nuffield Council of Bioethics is holding its 'Forward Look' meeting, the 3rd World Conference on Research Integrity (WCRI) is also taking place in Montreal, Canada (5-9 May 2013).

Brief historical background

4. Montgomery and Oliver have traced how institutions have mobilised to deal with deviance in science in the United States.³ They note that prior to 1975, discourse was about norms and counter-norms of the 'normal practice of science.'⁴ It then moved, between 1975 and 1990, to a focus

¹ The author would like to thank Susan Westwood for her assistance with editing and source-checking, and Tsachi Keren-Paz and Peter Mills for their helpful comments.

² House of Commons Science and Technology Committee (HoC STC) (2012) *Peer review in scientific publications: Government and Research Councils UK Responses to the Committee's Eighth Report of Session 2010-12. 10th Special Report of Session 2010-12.* London: HMSO.

³ Montgomery, Kathleen, and Oliver, Amalya L. (2009) 'Shifts in Guidelines for Ethical Scientific Conduct How Public and Private Organizations Create and Change Norms of Research Integrity.' *Social Studies of Science*, 39(1): 137-155.

⁴ These norms, proposed by sociologist Robert Merton, were: communalism, universalism, disinterestedness, originality and scepticism, and the counter norms were: solitariness,

on the prevention of scientific misconduct; and from 1990s to the present, to promoting research integrity.⁵ The British government public statement known as the 'Universal Ethical Code for Scientists' exemplifies this approach to SRI.⁶ Today, research misconduct and SRI are often dealt together in policy documents. This background paper only scopes the literature on SRI although is often difficult to disentangle the two.⁷

An issue of global concern

5. European and global efforts to engage the concept and practice of SRI include the European Science Foundation (ESF) Science Policy Briefing on Good Scientific Practice in Research and Scholarship (2000) and the All European Academies (ALLEA) Memorandum on Research Integrity (2003). The ESF and U.S. Office of Research Integrity initiated the first World Conference on Research Integrity (WCRI) in Lisbon (2007) and a second one in Singapore (2010). The globalisation of science, and the fact that scientists study, work and collaborate amongst each other across different jurisdictions, is arguably a critical reason for the setting of SRI standards having heightened currency at present.⁸
6. Given that research (especially biomedical research) can be relied upon in making decisions that affect individuals and populations, violations to the integrity of research have particular relevance to potential public harm.⁹

The idea of SRI

What is research?

7. Research is a methodical and critical investigation, a scientific enquiry. It is also professional activity,¹⁰ i.e. done by individuals who have been

particularism, interestedness, and dogmatism. See Merton, Robert (1979) *The Sociology of Science: Theoretical and Empirical Investigations*, Chicago: University of Chicago Press.

⁵ Montgomery and Oliver (2009), op cit; LaFollette, Marcel (1996) 'Paycheques on a Saturday night: a brief history and analysis of the politics of integrity in the United States' in S. Lock and F. Wells, eds, *Fraud and Misconduct in Medical Research*, 2nd ed., London: BMJ, pp.1-13.

⁶ Department of Innovation, Universities and Skills, Government Office for Science, *Rigour, Respect and Responsibility: A Universal Ethical Code for Scientists*, 2007.

⁷ The People Science & Policy Report prepared for Research Council UK in 2009 deals with them together, without reporting on how research integrity is defined: King, Suzanne and Dyball, Mark (2009) *Review of Current UK Arrangements for the Oversight of Good Research Conduct and Research Integrity. Final Report prepared for RCUK*, 20 November 2009, PSP/09/031. London: People Science & Policy Ltd.

⁸ Creutzberg, Tijset al. (2009) *The State of Research Integrity and Misconduct Policies in Canada. Prepared for Canadian Research Integrity Committee*. Ottawa, ON: Hickling Arthurs Low Corporation.

⁹ Coughlin, Steven, Barker, Amyre and Dawson, Angus (2012) 'Ethics and Scientific Integrity in Public Health, Epidemiological and Clinical Research.' *Public Health Reviews* 34(1): 1-13.

¹⁰ Dixon-Woods, Mary (2010) 'Regulating research, regulating professionals.' *Journal of the Royal Society of Medicine* 103(4): 125-126.

specially trained to do research.¹¹ Audit is a branch of quality assurance, along with other intelligence gathering activities, that is used to monitor service quality as compared to standards. Audits are increasingly sophisticated and published in peer-reviewed journals.¹²

8. Because these definitions can be manipulated by researchers who might wish to avoid regulatory oversight, it has been suggested that from an ethical point of view there is no clear division between research and audit, and that they differ in degree, not in kind.¹³

What is Integrity?

9. Integrity is commonly understood as synonymous with high ethical standards. It has been recently reiterated that the integrity of the science is distinct from the integrity of individual scientists.¹⁴

Personal and intellectual integrity

10. Philosophers describe the person of integrity as 'committed to maintaining and acting on those of their commitments that they consider most important, but also to getting it right'¹⁵ that is, responding to the complete set of relevant factors. Integrity is also understood in relation to the self, and with acting morally.¹⁶
11. Anthropological accounts connect integrity with a very specific, rather than universal, understanding of the person. According to Blum, integrity is a product of the twentieth century preoccupation with authenticity, and at the source of academics' belief that 'ideally, original products derive from authentic beings, core selves unmediated by social demands.'¹⁷
12. Historians teach us that in earlier accounts of science there was no room to expect scientific expertise to translate into moral virtue.¹⁸ Within this account, we can distinguish between the scientists' 'internal scientific integrity' defined as 'the honesty that's needed to guard against finding

¹¹ Steneck, Nicholas H. (2006) 'Fostering integrity in research: Definitions, current knowledge, and future directions.' *Science and Engineering Ethics* 12(1): 53-74.

¹² Cave, E., and Nichols, C. (2007) 'Clinical audit and reform of the UK research ethics review system.' *Theoretical Medicine and Bioethics* 28(3): 181-203.

¹³ Cave and Nichols (2007) *ibid*, p.185.

¹⁴ House of Commons Science and Technology Committee (HoC STC) (2011) *The Reviews into the University of East Anglia's Climatic Research Unit's E-mails. First Report of Session 2010–11*. London: HMSO.

¹⁵ Rees, Clea and Webber, Jonathan (in press) 'Constancy, Fidelity and Integrity', in S. van Hooff and N. Saunders, eds., *The Handbook of Virtue Ethics*, Durham: Acumen Press.

¹⁶ Cox, Damien, La Caze, Marguerite and Levine, Michael (2005) 'Integrity', in E. N. Zalta, ed., *The Stanford Encyclopaedia of Philosophy* (Fall 2008 Edition). Stanford: Stanford University.

¹⁷ Blum, Susan (2009) *My Word! Plagiarism and College Culture*, Ithaca: Cornell University Press, p.89.

¹⁸ Shapin, Steven (2008) *The Scientific Life: A Moral History of a Late Modern Vocation*. Chicago: University of Chicago Press, p.13.

what you want to find,¹⁹ from the sort of integrity that is expected from individual scientists in their personal life.

The integrity of a system

13. The concept of integrity as ‘wholeness,’ is relevant for understanding the integrity of science as a system of work. Here, integrity does not presuppose something that is either complete or unified; rather “scientific inquiry, though fallible, is also capable of correcting earlier mistakes and refining earlier ideas as new information comes in, new concepts are devised.”²⁰ Whereas this seems to evoke a rather problematic notion of science (as the progressive conquest of ignorance), in the context of SRI it can be understood more modestly as the process of reconfiguring knowledge in more contemporarily stable forms. It is in this sense science is integrated, or at least *integratable*.²¹
14. Integrity also refers to how science as an institution is committed to the values of the scientific enterprise itself.²² The integrity of science as an institution is evidenced by how successfully it ‘ensures that everyone involved behaves as nearly as possible in accordance with epistemological values.’²³

Integrity of the work and record

15. Integrity can also be understood as being free of bias. Randomisation, blinding and other refinements of RCT were introduced to reduce research bias.²⁴ Bias by sponsors, for instance, is perceived as remediable so that integrity can be maintained.²⁵
16. It has been suggested that publishing negative as well as positive findings is essential to SRI, and even that refraining from doing so

¹⁹ Steven Shapin, *ibid*, p13, referring to Richard Feynman, (1998) *The Meaning of It All: Thoughts of a Citizen-Scientist*. Reading MA: Perseus.

²⁰ Haack, Susan, (2007) ‘The Integrity of Science: What It Means, Why It Matters’ *Etica e Investigacao nas Ciencias da Vida – Actas do 10 Seminario do CNEV, CNEV, Lisboa*, Portugal, pp. 9-28, 10.

²¹ Haack, Susan (2003) *Defending Science within Reason: Between Scientism and Cynicism*, Amherst: Prometheus.

²² Namely, ‘honesty and sharing with respect to evidence’: Haack, Susan (2007) ‘*op cit*’, 12.

²³ Haack (2007) *ibid*.

²⁴ Marks, Harry M. (2000) ‘Trust and mistrust in the marketplace: statistics and clinical research, 1945-1960.’ *History of Science* 38: 343-355; Helgesson, Claes-Fredrik (2010) ‘From Dirty Data to Credible Scientific Evidence: Some Practice to Clean Data in Large Randomised Clinical Trials’ in C.Will and T. Moreira, eds, *Medical Proofs, Social Experiments: Clinical Trials in Shifting Contexts*, Farnham: Ashgate, pp 49-66.

²⁵ By way of educating researchers, by the use of meta-analysis in systematic reviews, and by regulating the methods of reporting of standards with respect to methods, disclosure, and authorship: Will, Catherine (2010) ‘Addressing the Commercial Context: The Collective Critique of Clinical Trials’, in C.Will and T. Moreira, eds, *Medical Proofs, Social Experiments, Clinical Trials in Shifting Contexts*, Farnham: Ashgate, pp 67-83.

constitutes scientific misconduct.²⁶ Measures such as the clinical trials registry, supports the integrity of the research record, and enhances transparency in research (see paras. 40-4)²⁷

17. In recent years the field of science publishing has devoted considerable effort and resources to correcting literature. This derives from a shared preoccupation amongst editors, publishers and organisations that promote SRI²⁸, with the integrity of the scientific record for the benefit of readers: peers and the 'public.'
18. SRI includes specific aspects of the integrity of data, figures and images. Out of increasing concern over image manipulation, some scientific journals now have specific guidelines for authors that address 'image integrity and standards,' thus framing image processing as an SRI issue that is distinct from 'technical' aspects of manuscript preparation.²⁹

'Narrower' and 'broader' concepts of scientific integrity:

19. A narrow account relates the integrity of an individual scientist to his or her adherence to *epistemological* values of "evidence sharing and respect for evidence" and commitment to intellectual honesty.³⁰ Under this account, ethical considerations are neither necessary nor sufficient to good scientific work: someone may do innovative, important solid scientific work even though she is unkind to animals or ungenerous in giving collaborators credit. In turn someone may do poor science whilst behaving in a way that is morally impeccable.³¹
20. However, policy accounts tend to be broader and to list ethical values such as fairness and care as core values of SRI. The U.S. Institute of Medicine defends a broader understanding of scientific integrity involving 'a commitment to intellectual honesty and personal responsibility for one's actions as a researcher and to practices consistent with the responsible conduct of research and protection of the research participants.'³²

²⁶ Ian Chalmers, "Underreporting research is scientific misconduct" (9 March 1990) 263:10 JAMA 1405-8

²⁷ The World Health Organisation has established the International Clinical Trial Registry Platform: <http://www.who.int/ictip/en/>. Clinical trials registries include: ClinicalTrials.gov, a central repository for international research involving human subjects, and UKCRC Registered Clinical Trials Unit Network.

²⁸ For instance the Committee on Publication Ethics.

²⁹ Frow, Emma K. (2012) 'Drawing a line: Setting guidelines for digital image processing in scientific journal articles.' *Social Studies of Science*, 42(3): 369-392.

³⁰ Polanyi, Michael (1946) *Science Faith and Society* London: Cumberledge.

³¹ Haack (2007), op cit

³² Coughlin, Barker and Dawson (2012), op cit.

Policy Definitions

21. Research integrity has been defined as the 'researchers' commitment to intellectual honesty, as reflected in actual research practices.'³³ At other times research integrity is referred to as research behaviour viewed from the perspective of professional standards.³⁴ Sometimes 'white paper' types of documents propose guidelines and flowcharts to foster SRI without defining SRI itself.³⁵
22. Professional integrity can be defined as 'the quality of possessing and steadfastly adhering to high moral principles or professional standards.'³⁶

Values, principles and good practice

Values and Principles

23. Mnookin et al. describe the values that constitute 'necessary pieces of a well-functioning research culture in any discipline', namely: empiricism, transparency, and an ongoing critical perspective.³⁷ The Canadian Council of Academies describes SRI values as 'essential to encouraging and achieving excellence in the search for, and dissemination of, knowledge.' These values include: honesty, fairness, trust, accountability, and openness³⁸ The European Science Foundation suggests a similar list of 'values' referring to them as 'principles': 1) honesty in communication; 2) reliability in performing research; 3) objectivity; 4) impartiality and independence; 5) openness and accessibility; 6) duty of care; 7) fairness in providing references and giving credit; and 8) responsibility for the scientists and researchers of the future.³⁹

³³ Steneck, Nicholas (2003) 'The role of professional societies in promoting integrity in research.' *American Journal of Health Behavior* 27 (Supplement 3): S239-S247, p.S240.

³⁴ Steneck, Nicholas (2006) 'Fostering integrity in research: Definitions, current knowledge, and future directions.' *Science and Engineering Ethics* 12(1): 53-74, p.56.

³⁵ For example, Scott-Lichter, D and the Editorial Policy Committee (2012) *Council of Science Editors. CSE's White Paper on Promoting Integrity in Scientific Journal Publications*, 2012 Update. 3rd Revised Edition. Wheat Ridge, CO: <http://www.councilscienceeditors.org/i4a/pages/index.cfm?pageid=3331>

³⁶ Steneck (2006), op cit.

³⁷ Mnookin, Jennifer et al. (2011) 'The Need for a Research Culture in the Forensics Sciences.' *UCLA Law Review* 58: 725-780, p.740-2.

³⁸ The Expert Panel on Research Integrity (2010) *Honesty, Accountability and Trust: Fostering Research Integrity in Canada*. Ottawa: Council for Canadian Academies.

³⁹ European Science Foundation (ESF) (2010) *Fostering Research Integrity in Europe*. Strasbourg: ESF. These values have been endorsed by the Irish Council of Bioethics': Irish Council for Bioethics (ICB) (2010) *Recommendations for Promoting Research Integrity*, Dublin: ICB. For a similar list see Committee on Assessing Integrity in Research Environments, National Research Council, Institute of Medicine and National Academy of Sciences (2002) *Integrity in scientific research: Creating an environment that promotes responsible conduct*. National Academy Press, pp.34-5.

24. Principles of research integrity are expressed with action verbs, in order to implement values.⁴⁰ They include verbs like advise, assist, foster, promote, prevent (misconduct). Verbs like regulate or sanction are much rarer occurrences. They are expressed through 'clear policies and procedures, training and mentoring researchers, and robust management methods.'⁴¹ Management of research integrity involves ensuring awareness and application of high research standards, early detection and prevention of transgressions. Hence a robust culture of research integrity would include misconduct investigations that themselves satisfy the highest levels of integrity.⁴² Such investigations ought to be consistent with national law and natural justice, fair, speedy, and lead to appropriate sanctions.⁴³

Good research practice

25. Good research practice comprises standards of an even higher level of detail, including: 1) Data practices regarding storage, security and accessibility; 2) Procedures regarding research design and conduct (to avoid negligence, haste, carelessness and inattention); 3) Responsibility towards all research subjects, human, animal 'and non-living'; 4) Publication practices including openness, transparency and accuracy, dissemination 'at the earliest possible time unless IP considerations justify delay,' authorship issues, agreed criteria for establishing the sequence of authors, declaration of conflict of interest and financial or other support; and 5) editorial responsibility of editors and reviewers.⁴⁴
26. The UK Research Integrity Office has designed a *Code of Practice for Research*. Whilst not attempting 'to micro-manage research'⁴⁵, the Code includes detailed guidance on 'good research practice' (including organisational policies) to assist institutions and individuals involved in research.

'Questionable research practices'

27. Some cultural contexts may threaten the norms of respect for evidence and evidence-sharing e.g. emergencies and haste to ascertain the cause of a pandemic, certain political regimes, or theocracies.⁴⁶ The evaluation of scientific conduct is complex and it has been suggested we speak

⁴⁰ The Expert Panel on Research Integrity (2010), op cit.

⁴¹ ESF (2010), op cit, p6; Organisation For Economic Co-Operation And Development (OECD) Global Science Forum (2007) *Best Practices for Ensuring Scientific Integrity and Preventing Misconduct*, p11. Downloaded 25/3/13 from: <http://www.oecd.org/sti/sci-tech/40188303.pdf> .

⁴² OECD Global Science Forum (2007), op cit.

⁴³ ESF (2010), op cit, p.6.

⁴⁴ ESF (2010), op cit, p.7.

⁴⁵ UK Research Integrity Office Ltd, *Code of Practice for Research: Promoting and Preventing Misconduct*, September 2009, p. 4.

⁴⁶ Haack (2007), op cit, p.14.

about a spectrum of conduct⁴⁷ rather than simply focusing on research integrity as the antithesis of misconduct.⁴⁸

SRI as a practice and expertise

The professionalisation of SRI and of Misconduct Studies

28. Scholarship about research integrity is now seen as part of the new discipline of Research on Research Integrity (RRI), and research integrity has developed as the object of professional discourse.⁴⁹ Self-trained experts have 'originated' a new practical discipline to respond to institutions' concerns about misconduct by producing textbooks and course materials and training science students at avoiding and detecting misconduct. International networks of stakeholders⁵⁰ organise themselves to develop best practices in different countries, articulate definitions, promote dissemination, organise training workshops, offer research funding on RRI,⁵¹ post blogs, publish newsletters, etc. Scholars have used the concept of 'epistemic communities'⁵² in order to understand the organised working efforts of legal and ethical norm entrepreneurs.⁵³

Integrity verification technologies

29. The House of Commons Science and Technology committee, in its report on peer-review, whilst recommending continuing to rely 'on the vigilance of the people involved in the process' encouraged publishers to keep investing 'in new technology that helps to identify wrongdoings.'⁵⁴
30. Research integrity industries have developed electronic systems, algorithms, plagiarism software, and integrity detection technologies.

⁴⁷ Fanelli, Daniele (2011) 'The Black, the White and the Grey Areas: Towards an International and Interdisciplinary Definition of Scientific Misconduct' in N. Steneck and T. Meyer, eds, *Promoting Research Integrity in a Global Environment*, New Jersey: World Scientific, pp.77-87.

⁴⁸ The literature makes explicit reference to questionable research practices (QRP), which are actions that 'violate traditional values of the research enterprise and may be detrimental to the research process,' but which do not directly damage the integrity of the research process: National Academies of Science (1992) p.28, cited by Steneck (2006), op cit.

⁴⁹ Biagioli, Mario (2012) 'Recycling Texts or Stealing Time? Plagiarism, Authorship, and Credit in Science.' *International Journal of Cultural Property*, 19(3): 453-476.

⁵⁰ They include: the European Network of Research Integrity Offices' Council of Science Editors; World Association of Medical Editors; International Committee of Medical Journal Editors; the Committee on Publication Ethics; and the European Association of Science Editors.

⁵¹ Each year COPE offers grants of up to £5000 to fund research by its members on research integrity: <http://publicationethics.org/resources/research/grantscheme>

⁵² Adler, Emanuel, and Haas, Peter M (1992) 'Conclusion: epistemic communities, world order, and the creation of a reflective research program', *International Organization* 46(1): 367-390.

⁵³ Burris, Scott, Drahos, Peter and Shearing, Clifford (2005) 'Nodal Governance.' *Australian Journal of Legal Philosophy*, 30: 30-58.

⁵⁴ HoC STC (2011), op cit.

Two American medical researchers run a website called DEJAVU, which exposes highly similar and duplicated material in the Medline database of biomedical research.⁵⁵ The CrossRef technology ensures that the most up-to-date version of research output is out in the open. CrossMark, while not being involved in the process of correcting itself, communicates changes to readers. A logo next to article flags issues like erratum, corrigendum, updates, enhancements, withdrawals, retractions, new editions, protocols updates, expressions of concern. The idea behind engines like CrossRef is that there is no final version of scientific work:⁵⁶ the integrity of scientific research is maintained by an ongoing process of self-correction.

31. Textual similarity algorithms and statistical analyses of submissions, are now well integrated in the machinery of scientific publishing. Statistician Stephen Evans describes statistics as an 'omniscient adjudicator' of research integrity and misconduct, so convincing that "no corroboration is needed."⁵⁷

Legal and governance issues

Models and degrees of governance

32. Approaches to the governance of SRI include: 'self-regulation and peer-review; governance at institutional level; provision of oversight by research funding agencies, professional associations and learned societies; national oversight or more formal governance structures.'⁵⁸ More than one approach can be adopted across institutions and national bodies at the same time. A major challenge is to balance individual and local responsibilities and structures with national coordination or governance.
33. In the US for instance, work in regulation studies has discussed the possibility of extending the remit of IRBs (the US equivalent of the Research Ethics Committees) to include issues beyond the protection of research subjects, such as relations with graduate students in relation to publications, conflicts of interest, and scientific fraud.⁵⁹

⁵⁵ Tahir, Tariq (2008) 'Cleaning up the Act', *Times Higher Education*, 28 August: <http://www.timeshighereducation.co.uk/story.asp?sectioncode=26&storycode=403288>.

⁵⁶ Pentz, Ed (2012) 'Cross-Ref: There is no final version', presentation at the 2012 Committee on Publication Ethics Seminar on Correcting the Literature, London, 15 March.

⁵⁷ Evans, Stephen (2008) 'Can Statistical Analysis Reveal Research Misconduct?' in F. Wells and M. Farthing, eds, *Fraud and Misconduct in Biomedical Research*, London: Royal Society of Medicine, pp161-176, p161. For Mario Biagioli, integrity verification technologies computerise the detective role and discipline all scientists, whilst depersonalising and delocalising evidence of misconduct: Biagioli (2012), op cit, p468-8; Lewis, Jamie and Atkinson, Paul (2011) 'The Surveillance of Cellular Scientists Practice.' *BioSocieties* 6(4): 381-400.

⁵⁸ ESF (2010), op cit, p.9.

⁵⁹ Burris, Scott (2008) 'Regulatory Innovation in the Governance of Human Subjects Research: A Cautionary Tale and Some Modest Proposals.' *Regulation & Governance*, 2(1): 65-84, p.77; Bledsoe, Caroline et al. (2007) 'Regulating Creativity: Research and Survival in the IRB Iron Cage.' *Northwestern Law Review* 101(2): 593-642.

34. Regimes of SRI are fragmented and enhanced by an array of guidelines and codes of conduct enacted by organisations, funding bodies, and charities and associations.⁶⁰

Comparative law approaches

35. Reports and white papers on research integrity widely use comparativist approaches to SRI, comparing the infrastructures of various jurisdictions, and then classifying them into families or clusters of systems, usually by qualifying them on a spectrum from the least to the most legalistic.⁶¹ Countries with established national research integrity procedures are: Germany, Canada, US Denmark, Norway, Finland, and Australia. These vary in size and authority, with the most developed being the U.S. and Nordic countries.⁶²
36. US commentators have criticised the UK model, arguing that expecting the promotion of good practices will solve the problem ‘flies in the face of the extensive and well documented experience in the USA where prolonged and energetic efforts, mandated by law, have been made for over 20 years to promote, advertise, and teach good scientific practices.’⁶³ In 2011 the UK House of Commons Science and Technology Committee recommended that there be an external regulator overseeing research integrity in the UK.⁶⁴ The resistance to a legalistic regulatory approach the domain of SRI stems from the belief that scientists can self-correct through self-regulation.⁶⁵

Harmonisation v. pluralism

37. The European and world-wide efforts, illustrated by the work of the European Science Foundation, the European Network of Research Integrity Offices, the World Conference on Research Integrity, and the Organisation for Economic and Co-operation Development, promote the unification, harmonisation and even universalisation of research integrity standards. However, scholars engaging in issues of research integrity, without calling specifically for a legal pluralist approach to research

⁶⁰ These include: the International Committee of Medical Journal Editors’ *Uniform Requirements for Manuscripts Submitted to Biomedical Journals*; the Committee on Publication Ethics’ flowcharts and code of conduct; the Council of Science Editors (CSE) *Policy Statement*; and the World Association of Medical Editors’ (WAME) various policy statements.

⁶¹ See for example: Irish Council of Bioethics (2010) *op cit*; Creutzberg et al. (2009), *op cit*.

⁶² ESF (2010), *op cit*, p.10.

⁶³ Drummond Rennie and Gonsky, C. Christina (2008) ‘What is Research Misconduct?’ in F. Wells and M. Farthing, eds, *Fraud and Misconduct in Biomedical Research*, London: Royal Society of Medicine, pp.29-54.

⁶⁴ HoC STC (2012), *op cit*.

⁶⁵ Interestingly similar arguments are made to resist regulation of the media in the UK, in the aftermath of the Leveson Report. This highlights the fact that SRI issues typify concerns over accountability and integrity that are endemic to most spheres of public life.

integrity, do debate the issue of the cultural specificity of research integrity norms, especially with regard to authorship.⁶⁶

38. Some attribute differences in research integrity standards to cultural norms. For example, some distinguish Western values of 'individual responsibility' and a tendency 'to give seniority more credit,' from values in other countries where an article could be regarded as a 'common piece of research and it does not matter much who takes credit for it.' Others point to generational differences, identifying the emergence, among younger generations of students (perhaps future generations of researchers) of a 'creative commons mentality,' where a collaborative model almost supplants authorship and authority, as exemplified by the overwhelmingly wide-spread use of Wikipedia as a source of information.⁶⁷
39. The European Science Foundation's stance is that 'beyond mutual respect for national diversity, there must be a common understanding of the demands of research integrity'.⁶⁸ Yet the ESF has clarified that although principles of integrity are universal, some rules for good practice "may be subject to cultural differences and should be part of a set of national or institutional guidelines.'⁶⁹ The challenge is to translate global principles into national policy and practice.⁷⁰

International Research Collaborations

40. National, regional (e.g. European) international differences amongst legal and normative environments of research, and across regulatory and publication oversight must be met by pan-European and international cooperation. This would address, for instance: doctorate and post-doctorate training of researchers, organisational and funding systems, and authorship.⁷¹ Because of the diversity of rules, and of the international reach of U.S. law with respect to research,⁷² collaborators in international research are advised to follow the guidance of the OECD Global Science Forum's Best Practices for the drafting of memoranda of agreement or protocols ahead of the commencement of their research project.⁷³

⁶⁶ The deliberations of the 1st World Conference on Research Integrity in Lisbon, 2007 are reported in: Christie Aschwanden (2007) 'Seeking an International Dialogue on Research Integrity.' *Cell* 131(1): 9-11, and reprinted in: *Final Report to ESF and ORI: First World Conference on Research Integrity: Fostering Responsible Research*, Lisbon, Portugal, 16-9 September 2007, Appendix 6.

⁶⁷ Blum (2009), op cit, p71.

⁶⁸ ESF (2010), op cit, p5.

⁶⁹ ESF (2010), op cit, p9.

⁷⁰ ESF (2010), op cit, p9.

⁷¹ Anderson, Melissa and Steneck, Nicholas, eds. (2011) *International Research Collaborations: Much to be Gained, Many Ways to Get into Trouble*, London: Routledge.

⁷² Capron, Alexander (2011), 'The Governance of Scientific Collaborations: The International Reach of U.S. Law', in M. Anderson and N. Steneck, eds., *International Research Collaborations: Much to be Gained, Many Ways to Get into Trouble*, London: Routledge, pp.97-104.

⁷³ ESF, Fostering xx

Research infrastructures and SRI: areas of ethical concern

Data-management, open access, and transparency

41. The information revolution has impacted the integrity of research as a form of labour. Notably new expectations about data management often require a more specialized data expertise than most researchers can deliver.⁷⁴ The open access movement embraces information technologies as ideal ways ‘to undermine excessive monopolies of publishers on the provision of information.’⁷⁵ The management and sharing of data raises new problems with respect to copyright law, privacy, quality control of data, public-private partnerships, the status of texts as key to scientific knowledge, and the economy of credit and authorship within science (see para.47).⁷⁶ The term e-science is understood to refer to ‘a shared view of computationally intensive research as a qualitatively novel way of doing research.’⁷⁷
42. Some scholars have tried to suggest that some features of science have not changed despite the information revolution, or have but not in ways expected and claimed. Others emphasise that e-science is not unified, and does not impact on science as much as the ways with which it is mediated via research institutions, infrastructures, and resources. To assess the impact of IT on the integrity of science, it is thus crucial to trace empirically the kinds of scientific work that the technologies ‘involve, enable, distribute, emphasize, and conceal.’⁷⁸
43. The Finch Report⁷⁹ has chronicled different ways to share research: repositories, e.g. ClinicalTrials.gov, a central repository for international research involving humans; open access journals, e.g. Public Library of Science (PLoS); and subscription-based publications, which limit the public accessibility of journals. The Finch report makes no explicit mention of SRI. However values associated with research integrity are mentioned as motivations, including: ‘enhanced transparency, openness

⁷⁴ The Virtual Knowledge Studio (2008) ‘Messy Shapes of Knowledge – STS Explores Informatization, New Media, and Academic Work’ in E.J. Hackett et al., eds., *The Handbook of Science and Technology Studies*, 3rd edition. Cambridge: MIT Press, pp.319-351.

⁷⁵ Ibid p.320.

⁷⁶ Biagioli, Mario (2006) ‘Documents of Documents’ in M. Biagioli and A. Riles, eds, *Documents: Artefacts of Modern Knowledge*, Ann Arbor: University of Michigan Press, pp. 127-157; Corynne McSherry (2002) ‘Uncommon Controversies: Legal Medications of Gift and Market Models of Authorship’, in M. Biagioli, and P. Galison, eds, *Scientific Authorship, Credit and Intellectual Property in Science*, London: Routledge, pp. 225-250.

⁷⁷ The Virtual Knowledge Studio (2008), op cit. See also UK Research Council’s e-Science Programme: <http://www.rcuk.ac.uk/research/xrcprogrammes/prevprogs/Pages/e-Science.aspx>

⁷⁸ The Virtual Knowledge Studio (2008), op cit, p.331.

⁷⁹ National Working Group on Expanding Access to Published Research Findings (‘The Finch Report’) (2012) *Accessibility, sustainability, excellence: how to expand access to research publications*, London: Research Information Group.

and accountability, and public engagement with research.’⁸⁰ Other motivations are thought to include: ‘returns on investments in research, efficiency in the research process, benefits for policy and economic growth.’⁸¹ The latter raise issues pertaining to impact agendas of research (see para.48ff).

44. Open-access proposals that include transferring the publishing costs from readers to authors have implications for SRI. Universities, as employers of authors, are likely to prioritise the type of publications they will support, for instance by privileging high impact prestigious journals over small specialist journals. In order to get published, scientists may have to align their research with their institutions’ priorities.⁸²
45. Openness of data is a crucial tenet for science. Unfortunately however, advocates of transparency often assume that what is transparent is also necessarily “intelligible, relevant, accurate and honest.”⁸³ Sole focus on transparent dissemination risks losing sight of epistemic and ethical standards of good communication of science.⁸⁴

Publication ethics

46. Silbey and Ewick claim that publications have become the new public space of science, in and through which it establishes itself openly.⁸⁵ New libel law proposals address an important publication ethics aspect SRI, by protecting scientists’ freedom of expression through the defences of ‘qualified privilege’ and ‘fair comment’.⁸⁶ Publication ethics covers a number of other areas, including: authorship; plagiarism; text-recycling or self-plagiarism; self-citation; duplicate publication; disclosure of competing financial interests; confidentiality, and issues of guest/honorary/ gift and ghost authorship.⁸⁷

Authorship

47. In addition to the above practices of honorary /gift/ guest authorship and ghost authorship, conceptual discussions on the very notion of authorship have occupied a lot of space in discussions on the meaning

⁸⁰ The Finch Report, *ibid*, p.5.

⁸¹ The Finch Report, *ibid*.

⁸² See: Hunter, Rosemary et al. (2012) ‘Open Access: What Future for Academic Publishing?’, *Socio-Legal Newsletter* 68: 6-9.

⁸³ Boulton, Geoffrey et al. (2012) *Science as an Open Enterprise*, London: The Royal Society UK, p.38.

⁸⁴ O’Neill, Onora (2006) ‘Transparency and the ethics of communication’, in C. Hood & D. Heald, eds., *Transparency – The key to better governance*, Proceedings of the British Academy Vol 135, Oxford: Oxford University Press, pp. 75-90.

⁸⁵ Silbey, Susan and Ewick, Patricia (2003) ‘The Architecture of Authority: The Place of Law in the Space of Science’, in A. Sarat, L. Douglas and M. Umphrey, eds., *The Place of Law*, Ann Arbor: University of Michigan Press, pp. 75-108.

⁸⁶ Editorial (2012) ‘Honest opinions.’ *Nature* 480: 285 (17 May 2012).

⁸⁷ Stern, Simon and Lemmens, Trudo (2011) ‘Legal Remedies for Medical Ghostwriting: Imposing Fraud Liability on Guest Authors of Ghostwritten Articles’, *PLoS Med* 8(8): e1001070.

of science, and more recently in the context of SRI. The definition of authorship, and the complex ways with which credit gets allocated for various types of labour, have been discussed by bioethicists, lawyers, and sociologists and historians of science. In addition, particular groups of scientists (e.g. particle physicists in the United States in the 1990s,⁸⁸ and French mathematicians in the 1930s⁸⁹) have challenged not only regulatory frameworks of authorship such as those of the International Committee of medical Journal Editors (ICJME, also known as the Vancouver Group)⁹⁰ but also the values of prestige, creativity, originality and responsibility that have been associated with authorship. (see also para. 40)⁹¹

Peer-review

48. An essential component of research and self-regulation of professions,⁹² peer-review has been described as, just like democracy, a 'system full of problems but the least worst we have.'⁹³ The House of Commons Science and Technology Committee has concluded that 'the integrity of the peer-review process can only ever be as robust as the integrity of the people involved.'⁹⁴
49. According to Biagioli, the integrity of peer-review is a key and under-examined area for SRI, as violations occurring during this process (when a reviewer rejects a paper or grant application and 'runs with the idea' of the original author) are more damaging to individual scientists than other areas of misconduct such as plagiarism.⁹⁵ Conscious of the key role peer-review plays for SRI, the Committee on Publication Ethics recently published detailed guidelines for peer-reviewers.⁹⁶

⁸⁸ Mario Biagioli (2003) Rights or Rewards? Changing Frameworks of Scientific Authorship in M Biagioli and P Galison eds., *Scientific Authorship: Credit and Intellectual Property in Science*, New York: Routledge, pp.254-79.

⁸⁹ Carl Djerassi (1994), *The Bourbaki Gambit*, New York: Penguin, as discussed in: Hugh Gusterson (2003), The Death of the Authors of Death: Prestige and Creativity amongst Nuclear Weapons Scientists, in M Biagioli and P. Galison, *Scientific Authorship: Credit and Intellectual Property in Science*, New York: Routledge, pp. 282-307.

⁹⁰ International Committee of Medical Journal Editors (the Vancouver Group), Uniform Requirements for Manuscripts Submitted to Biomedical Journals,

⁹¹ See, for example, references in note 73. See also: Resnik, D. (1997) 'A proposal for a new system of credit allocation in science'. *Science and Engineering Ethics* 3(3): 237– 243. Resnik, D. B., and Z. Master. 2011. Criteria for authorship in bioethics. *American Journal of Bioethics* 11(10): 17– 21. M-A Jacob (2011) 'But What Does Authorship Mean, Indeed? Open-Peer Commentary' *American Journal of Bioethics* 11:10, 28-30.

⁹² Irish Council of Bioethics, 2010, op cit, p.14.

⁹³ Smith, Richard (2011) *The Trouble with Medical Journals*, London: Royal Society of Medicine, p83. See also: Horton, Richard (2010) 'Understanding Uncertainty: A brief history of peer-review' in R. Muir et al., *The Independent Climate Change Emails Review*, July 2010, Appendix 5.

⁹⁴ HoC SCT (2011), op cit.

⁹⁵ Biagioli (2012), op cit.

⁹⁶ Irene Hames (on behalf of COPE Council) (2013), *COPE Ethical Guidelines for Peer-reviewers*, March 2013, v.1: http://publicationethics.org/files/Ethical_guidelines_for_peer_reviewers_0.pdf

Research with ‘impact’

A new context for scientific research

50. Under current conditions of knowledge production, scientists not only need to accommodate societal demands for accountability and transparency, they also ought to be aware and responsive to ‘priority setting’ and to additional criteria for assessing the quality and relevance of their scientific work.⁹⁷ Research councils, advisory committees and other bodies set standards that reconcile ‘standards of scientific quality’ as well as ‘new demands that transcend them.’⁹⁸ The questions of whether science should speak to society and whether society can speak back to science, raise the issue of the integrity of scientific research.
51. Today the need for ‘impact’ has encouraged goal-driven research intending to guide future action or policy (as contrasted with ‘blue sky’, curiosity-driven research). This impact agenda can affect the integrity of research and the responsibilities of researchers. Impact can be intended (see paras.52-4) or unintended (see paras.55-6).

Impact and conflicts of interests:

52. The impact agenda raises questions that are relevant to SRI to the extent that in some cases a researcher’s scientific work must cohabit with his or her ‘commitment,’⁹⁹ beliefs, or activism. Rather than expecting researchers not to hold any commitments, SRI would demand transparency regarding the commitment and activism of researchers, as indicated in the reports on the email leaks at the Climate Research Unit at the University of East Anglia.¹⁰⁰ The GMC Fitness to Practice Panel classed as misconduct the fact that Andrew Wakefield’s research on MMR vaccine was sponsored by a litigation team trying to build a case against MMR vaccine manufacturers, and that this had not been disclosed.

⁹⁷ Gibbons et al. (1994), *The New Production of Knowledge: The Dynamics of Science and Research in Contemporary Societies*, London: Sage, p8.

⁹⁸ Nowotny, Helga, Scott, Peter and Gibbons, Michael (2001) *Re-thinking Science: Knowledge and the Public in an Age of Uncertainty*, Cambridge: Polity Press, p.47. Mode-2 knowledge production can be defined as follows: ‘Mode 2 implies an enlargement of the number of participants in research and the widening of what is defined as research. It also implies a multiplication and social diffusion of the sites at which knowledge is produced Finally, Mode 2 implies an extension of quality control mechanisms to include new criteria and new constituencies, without denying that demarcations between ‘good’ and ‘bad’ research can, and indeed must, still be established’.

⁹⁹ Irish Council of Bioethics, 2010, op cit, p.15.

¹⁰⁰ Oxburgh, Ron, et al. (2012) *Report of the International Panel set up by the University of East Anglia to examine the research of the Climate Research Unit*, Climatic Research Unit of East Anglia: <http://www.uea.ac.uk/mac/comm/media/press/CRUstatements/SAP>; Muir, Russell et al. (2010) *The Independent Climate Change E-mails Review*, <http://www.cce-review.org/pdf/FINAL%20REPORT.pdf> . Note in that these reports the rigour of the CRU scientists was not in doubt.

Science-based policymaking

53. Science is an open-ended enquiry, and in the context of science-based policy making, its integrity can be challenged by the need of policy makers for certainty. Under conditions where specific impact is sought, scientists can be over-enthusiastic about their findings, and present their advice with unjustified certainty.¹⁰¹
54. The fact that scientific research informs policy-makers activates new demands for accountability. For instance, the NIH strongly supports appropriate degrees of transparency in the preparation and identification of the scientific and technological information that it uses for policymaking.¹⁰²

Dual-use technology

55. The issue of non-intended impact must also be considered. Today the ease with which research is disseminated via information technologies means that sometimes research that was not intended to have 'impact' can 'last forever and be receivable in all places' and can remain, whether the scientists wish it or not, an 'indelible if insignificant, contribution to knowledge or ignorance and to public affairs.'¹⁰³
56. Regulatory or advisory oversight over the dissemination of research about technologies capable of beneficial and harmful effects, raise issues of SRI. For example, because of concerns that scientific papers could become a 'blueprint for bioterrorism,' the US National Science Advisory Board for Biosecurity (NSABB) has recommended scientific journals suppress parts of scientific papers describing technology assisting in the transmissibility of H5N1 strain of the avian influenza virus.¹⁰⁴ But the idea that free access to knowledge can present a risk for society raises broader philosophical questions about the scope and limits of scientific freedom.

¹⁰¹ Science and Trust Expert Group, Report and Action Plan: Starting a National Conversation about Good Science, March 2010:

<http://scienceandsociety.bis.gov.uk/trust/files/2010/03/Accessible-BIS-R9201-URN10-699-FAW.pdf>, as cited in: Nuffield Council of Bioethics (2012) *Emerging biotechnologies: technology, choice and the public good*. London: Nuffield Council of Bioethics, p. 6. See also:

Everson, Michelle and Vos, Ellen (2009) 'The scientification of politics and the politicisation of science' in M. Everson and E.Vos, eds., *Uncertain Risks Regulated*, London: Routledge, pp.1-17.

¹⁰² *NIH Policies and Procedures to Promote Scientific Integrity*, NIH, 2012, accessed at: <http://www.nih.gov/about/director/sci-int-nov2012.pdf>

¹⁰³ Harris, John (2013) 'In Search of Blue Skies: Science, Ethics, and Advances in Technology.' *Medical Law Review* 21(1): 131-145.

¹⁰⁴ Harris (2013) *ibid*.

Rankings and the Research Excellence Framework

Threats to SRI

57. The managerial focus on efficiency, performance, targets, outcomes, markets, and rankings is perceived as a threat to creativity and the integrity academic work.¹⁰⁵ The Research Excellence Framework (REF) prompts preoccupations amongst scientists about impact and citations rankings. Self-citation and citation manipulation, where a journal editor or other person associated with a journal puts pressure on an author to cite a particular journal), pose challenges for SRI values. More than the REF or rankings, it is this particular system of rewards that is most often identified as a critical factor eroding SRI.¹⁰⁶
58. The system of rewards is associated with the building of 'academic capital' i.e. membership of editorial boards and in research council review colleges, which has more subtle and pervasive influence on SRI than the financial rewards that have been blamed for the corruption of scientists.¹⁰⁷ Seen in this light, the line between pure academic- and industrial scientists cannot be so clearly drawn, and issues of SRI become inherent, rather than a pathology, of the complex system of rewards. Competition amongst scientists (over publication records, citation rates) and the complex private-public relationships that characterise the funding environment of research, can have a corrosive effect on SRI.¹⁰⁸

Opportunities for SRI

59. The REF however could sustain SRI in surprising ways. The national assessment of research, as a relatively flexible infrastructure, can offer opportunities for scientifically-coherent recognition of the skills, rigour, and creativity of scientists. For instance, the REF system could credit researchers for currently undervalued scientific work of integrity, such as the useful communication of data (on the same scale as journal articles) and innovative forms of collaboration.¹⁰⁹

¹⁰⁵ Deem, Rosemary (2008) 'Unravelling the fabric of academe: the managerialist university and its implications for the integrity of academic work', in J. Turk, ed., *Universities at Risk: How Politics, Special Interests and Corporatization Threaten Academic Integrity*, Toronto: Lorimer, pp.256-281. See also: Marilyn Strathern, ed., (2000) *Audit Cultures: Anthropological Studies in Accountability, Ethics and the Academy* (European Association of Social Anthropologists), London: Routledge.

¹⁰⁶ Casadevall, Arturo, and Fang, Ferric C. (2012) 'Reforming Science: Methodological and Cultural Reforms.' *Infection and Immunity* 80(3): 891-896; Dingwall, Robert (2001) 'Scientific misconduct as organisational deviance.' *Zeitschrift für Rechtssoziologie* 22(2): 245-258.

¹⁰⁷ Rabinow, Paul (1996) 'American Moderns: On Science and Scientists', in P. Rabinow, *Essays on the Anthropology of Reason*, New Jersey: Princeton University Press, p.181.

¹⁰⁸ Jon Thompson (2008) 'Academic Integrity and the Public Interest' in J. Turk, ed., *Universities at Risk*, Lorimer: Toronto pp.306-348.

¹⁰⁹ Boulton Geoffrey et al. (2012) *Science as an Open Enterprise*, The Royal Society Science Policy Centre Report 02/12. London: The Royal Society, p.73.

60. This last example illustrates the fact that whilst current research infrastructures are in flux, the recent and forthcoming changes are not in themselves corrosive to SRI. In fact the flexibility of research infrastructures may provide opportunities to better sustain a robust culture of SRI.

Questions for consideration

61. The following questions suggest directions of possible further inquiry for the Council.

- How shall we demarcate 'research' from other knowledge-gathering activities, in the context of SRI?
- Can various, multidisciplinary definitions of 'integrity' contribute to a workable account of SRI?
- What do we lose, and what do we gain, by treating SRI in the language of 'good practice' instead of 'misconduct'?
- What is the connection between SRI and public good? Would a broader or narrower concept of SRI best serve the public good?
- How should we better reiterate, implement, and sanction current principles of SRI? Which legal and regulatory approaches should be taken to foster SRI and sanction deviance?
- Should we re-evaluate these dominant principles? How can this be done tactfully, without immediately jeopardizing good practice?
- Who should decide what SRI means and how it should be implemented and sanctioned?
- How should responsibility for SRI (and liability for misconduct) be allocated? To systems, institutions, or individuals?
- What does the professionalization of the field of SRI mean for the ongoing theoretical and critical evaluation of SRI principles and practices?
- Does open access to science entail richer SRI? In turn, how can SRI help negotiate confidentiality with open-access to science with other legitimate values such as confidentiality and privacy?
- What model/s of authorship best reflect and implement SRI? Can SRI help reconsider what authorship is constituted of?

- Does peer-review preserve or threaten SRI? What is the gap between the normative definition of peer-review and the practices of peer-reviewers (of articles and grant applications) and editors?
- How we do define 'impact' of research? What is the 'impact of impact' in the context of SRI?
- Do esteem indicators and rankings in science stimulate scientists or erode their integrity? Could different forms of ranking bring about different (more or less positive) effects on SRI?
- Is the distinction between industrial/for profit science and 'pure' academic work tenable? Is it a helpful distinction to maintain for the sake of SRI?
- How should all the above issues of SRI be considered in the context of internationalisation of research?
- Should cultural and disciplinary differences inform SRI, and should we foster a diversity of norms/practices of SRI, or strive for universalisation?