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ARTICLE

Reforming the Regulation of Health Research in England and Wales: New Challenges: New Pitfalls

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Abstract

The regulation of health research has developed apace over the last two decades. Guidance and specific legal regulation have proliferated, while the research community has expressed continuing disquiet regarding what it perceives to be a disproportionate regulatory burden. It is thus perhaps unsurprising that the government would look to review the situation. Rather than establishing a governmental review, however, it entrusted the task to the Academy of Medical Sciences, a body concerned with the promotion of advances in medicine and science. The Academy's report A New Pathway for the Regulation and Governance of Health Research (2011) has proved influential in informing the new reformed structure for the regulation of research. The government has now created a new regulatory body for research, the Health Research Authority. This article critically examines the proposals for reform set out in the report in the context of major subsequent developments which will change the nature of research regulation in the UK. These include the establishment of the Health Research Authority and the reform of the EU Clinical Trials Directive. The article explores the possible challenges and pitfalls of the reforms.

Introduction: The Backdrop

Health research has delivered some incredible advances over the last half century. From pharmaceuticals, to in vitro fertilisation, from 'bionic' limbs to artificial trachea coated with patients' own stem cells to prevent rejection, new technological interventions have enhanced and prolonged lives.[1]

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1 BBC News, 'Surgeons Carry Out the First Successful Synthetic Windpipe Transplant', www.bbc.co.uk/news/health-14047670, 7 July 2011.

However, clinical research and its regulation have had a somewhat checkered past.[2] From Nuremberg to the thalidomide tragedy and beyond,[3] there has been an uneasy relationship between the drive for scientific advancement and respect for individual rights and dignity.[4]

Over the last two decades the regulation of clinical research in England and Wales has come under increasing scrutiny. It has been suggested that the growth of regulation, both statutory and non-statutory, has constituted an inhibitor to research. The regulation and governance structures for research have been seen as both complex and limiting. Moreover, it has been suggested that formulaic 'box ticking' could work eventually against patient safety, as it could lead to issues being overlooked through focus on procedural minutiae.[5] This article examines the proposals to reform the system for the regulation of research in the UK published in the Academy of Medical Sciences 2011 report 'A New Pathway for the Regulation and Governance of Health Research' (Academy Report).[6] It discusses how these proposals are being taken forward by the government as part of the broader agenda of major legislative reform of health and social care,

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2 See generally the discussion in H. Biggs, *Healthcare Research Ethics and Law* (Routledge-Cavendish, 2009), ch. 2. For some notable international examples see J. Jones, *Bad Blood: The Tuskeegee Syphilis Experiment* (New York: The Free Press, 1981); 'Death of Research Volunteer at Johns Hopkins', S. Ramsey "John Hopkin's Takes Responsibility for Volunteer's Death" *Lancet* 358 (2001) 213.

3 On the thalidomide disaster see *Distillers v. Thompson* [1971] AC 458; H. Teff & C. Munro, *Thalidomide: The Legal Aftermath* (South Wales: Saxon House, reprinted 1979); P. Ferguson, *Drug Injuries and the Pursuit of Compensation* (London: Sweet and Maxwell, 1999); 'The Report of the Royal Liverpool Children's Inquiry' (2001), www.rlcinquiry.org.uk; The Bristol Royal Infirmary Inquiry, 'The Inquiry into the Management of Care of Children Receiving Complex Heart Surgery at The Bristol Royal Infirmary. Interim Report. Removal and Retention of Human Material' (2000), webarchive.nationalarchives.gov.uk/20090811143745/www.bristol-inquiry.org.uk/interim_report/index.htm. See also the resultant census undertaken by the Chief Medical Officer into the nature and extent of retained material in other hospitals, 'The Investigation into Retained Organs, Chief Medical Officer's Report on Organ Retention' (Department of Health, Social Services and Public Safety, 2001); also the report of the expert scientific group established by the secretary of state in the light of the Northwick Park incident, 'The Expert Group on Phase One Clinical Trials: Final Report' (2006), webarchive.nationalarchives.gov.uk/+/dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/dh_063117.

4 Adopted by the 18th World Medical Assembly, Helsinki, Finland 1964. Council of Europe Steering Committee on Bioethics, Draft Additional Protocol to the Convention on Human Rights and Biomedicine on Biomedical Research (Strasbourg 23 June 2003), CDBI/INF (2003) 6. Further recent guidance includes the Council for International Organizations of Medical Sciences, *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (CIOMS, 2002).

5 P.W. Stewart et al., 'Regulation, the Real Threat to Clinical Research', *BMJ* 337 (2008): 1732.

6 Academy of Medical Sciences, 'A New Pathway for the Regulation and Governance of Health Research' (London: Academy of Medical Sciences, 2011) (Academy Report), www.acmedsci.ac.uk/p99puid209.html.

and suggests that many of the proposed reforms and developments are not adequate to meet the challenges posed.

The article begins by examining the background to the Academy Report, looks at how formal regulation of clinical research in England has developed, and highlights the complexity of the structures and challenges that this poses for regulators, researchers and participants alike. Secondly, it considers the Academy's recommendations for the creation of a new health research regulator and the subsequent establishment by the government of a new UK Health Research Authority. It examines the extent to which this body will effectively align diverse issues and whether there is a risk of dilution of the prospect of effective scrutiny in certain areas. Thirdly, it focuses upon three major issues discussed in the Academy Report which relate to the question of reforming the current regulatory framework concerning research, namely the impact of the EU Clinical Trials Directive, the use of patients' records for research purposes, and compensation for injuries suffered during clinical research. The concluding section reflects on the changes being introduced and the pitfalls which may remain.

Regulation Research, Processes and Procedures

For many years, health research concerning human participants in the UK in general and England in particular has been characterised by ad hoc piecemeal regulation. Despite the international drive to engage with research ethics post Nuremberg, it took many years for real engagement with such issues to permeate fully to national level.[7] It was not until 1991 that the Department of Health issued central guidelines governing the operation of research ethics committees in the form of the 'Red Book'.[8] These guidelines were not legislation and left ethical decisions to be made at local level. This allowed considerable potential for inconsistent decision-making, although attempts were made to address this over time by the National Research Ethics Service (NRES), which developed standards and operating procedures for research ethics committees. It took a supra-national regulatory driver in the form of the European Union (EU) Clinical Trials Directive, implemented in 2004, to place research ethics committees on a statutory basis.[9] The aim of the Directive was

7 See discussion in J.V. McHale, 'Medical Research: Some Ethical and Legal Dilemmas', *Medical Law Review* 1 (1993): 160.

8 Department of Health, Local Research Ethics Committees (Department of Health, 1991) (The Red Book), http://webarchive.nationalarchives.gov.uk.

9 Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (EU Clinical Trials Directive) (2001) OJ L121/34. See further

to provide an EU framework for the approval of trials on medicinal products. It applied to both commercial and non-commercial trials, requiring for the first time that such trials should be subject to research ethics committee approval. Driven by the need to facilitate the conduct of drug trials across the EU, it imposed clear guidelines directing research ethics committees to consider a range of specific criteria in determining the risk of new 'medicinal products' (drugs). In addition, those undertaking a trial were to be able to identify a 'sponsor' who would provide a backstop in relation to liability. Time limits were imposed regarding the conduct of such trials, and specific committees designated to approve them. Nonetheless, the question of consistency in ethical approval remained a national issue.[10] A National Research Ethics Advisors Panel was also established with the aim of assisting in strategy and service development of research ethics committees.

Although the institutional changes represented positive steps towards greater centralisation of oversight and heightened professionalism, the current system remained fragmented. In domestic law the regulation of research remains largely dependent upon related legal principles, such as criminal law and tort,[11] while a proliferation of different bodies increasingly concerned with the regulation of different research activities has emerged. Since the early 1990s embryo research has been regulated by the Human Fertilisation and Embryology Authority (HFEA), the regulatory body established under the Human Fertilisation and Embryology Act 1990.The legislation sets out procedures for the regulation and licensing of clinics undertaking such research[12] and criteria as to which forms of research will be approved.[13] The use and storage of other human tissue for research purposes is currently overseen by the Human Tissue Authority (HTA), established under the Human Tissue Act 2004, which follows a licensing model similar to that of the HFEA.[14] Research concerning adults lacking mental

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T.K. Hervey & J.V. McHale, *Health Law and the European Union* (Cambridge: Cambridge University Press, 2004), 248-259; A.J. Baeyens, 'Implementation of the Clinical Trials Directive: Pitfalls and Benefits', *European Journal of Health Law* 9 (2002): 31.

10 See further the Report of the Ad Hoc Advisory Group on the Operation of NHS Research Ethics Committees (London: Department of Health, 2005).

11 On the legal regulation of clinical research see generally M. Brazier & E. Cave, *Medicine, Patients and the Law* (London: Penguin, 2011); Biggs, *Healthcare Research* (note 2); E. Jackson, *Medical Law Text Cases and Materials*, 2nd ed. (Oxford: Oxford University Press, 2009), ch. 9; J.K. Mason & G. Laurie, *Law and Medical Ethics*, 8th ed. (Oxford University Press, 2010), chs 19 and 20; S. Pattinson, *Medical Law and Ethics*, 2nd ed. (London: Sweet & Maxwell, 2009), ch. 11; M. Fox, 'Clinical Research and Patients', in, *Nursing Law and Ethics*, 3rd ed., eds. J. Tingle & A. Cribb (Oxford: Blackwell Scientific, 2007); M. Brazier, 'Exploitation and Enrichment: The Paradox of Medical Experimentation', *Journal of Medical Ethics* 34 (2008): 180.

12 See further Human Fertilisation and Embryology Act 1990, Sch. 2, para. 3.

13 *Ibid.*, Sch. 2 para. 3.

14 See generally D. Price, 'The Human Tissue Act 2004', *Modern Law Review* 68 (2005): 798.

capacity must be approved by a specific designated research ethics committee under the Mental Capacity Act 2005 and related regulations.[15]

Perhaps inevitably, this proliferation of research mechanisms led to complexity and ultimately to calls to streamline the system. The concerns of the scientific community focused on what many saw as disproportionate and ineffective regulation. As a consequence, the then Secretary of State for Health asked the Academy of Medical Sciences to look at the regulation and governance of health research in 2010.[16] The terms of reference of its review into the regulation and governance of health research were to:

- review the regulatory and governance environment for medical research in the UK, with a particular focus on clinical trials
- identify key problems and their causes, including unnecessary process steps, delays, barriers, costs, complexity, reporting requirements and data collection
- make recommendations with respect to the regulatory and governance framework that will: increase the speed of decision-making; reduce complexity; and eliminate unnecessary bureaucracy and cost.[17]

It is of course important to define what constitutes research when examining how regulation is undertaken. The National Health Service (NHS) Patient Safety Authority definition is a useful starting point:

'The primary aim of research is to derive new knowledge: audit and service evaluation measure level of care. Research is to find out what we should be doing; audit is to find out if we are doing it'.[18]

Nonetheless, the distinction between research and audit has proved somewhat challenging over the years and labelling activities as audit may be a means of bypassing ethical review. Historically innovative therapies have been categorised differently from research itself. This is something which remains an issue and a regulatory challenge. The Academy Report stated that:

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15 The Mental Capacity Act applies to 'intrusive' research involving adults lacking mental capacity over the age of 16 in England and Wales. Research is regarded as intrusive research where it would be unlawful if it were carried out 'on or in relation to a person who had capacity to consent to it, but without their consent'. See further s. 30 of the Mental Capacity Act 2005 and Mental Capacity Act 2005 (Appropriate Body) (England) Regulations 2006 SI 2006/2810; P. Bartlett, *Blackstone's Guide to the Mental Capacity Act 2005* (Oxford: Oxford University Press, 2005), para. 2.125; J.V. McHale, 'Mental Health, Mental Capacity and Research', in *Principles of Mental Health Law and Policy*, ed. L. Gostin et al., (Oxford: Oxford University Press, 2010) 871-891.

16 www.acmedsci.ac.uk/p47prid80.html.

17 Academy Report (note 6).

18 NHS Patient Safety Authority (2008).

'Our review focuses on approaches to health research that are broadly labeled as 'experimental medicine', 'clinical trials' and 'epidemiology' and that involve human participants, their tissues or their data. The regulation and governance of research involving animals is outside the scope of this report.[19]'

It defines 'experimental medicine' as being a term which: 'is most often used to describe research that aims to identify the mechanisms (pathophysiology of disease)'.[20]

Clinical trials are defined as being 'research studies designed to assess the safety and efficacy of therapeutic interventions',[21] which would include such things as drugs and vaccines screening devices and surgical procedures. The Academy Report defines epidemiological research as being research which aims:

'to understand factors associated with disease. It includes investigating events such as causes of death, adverse consequences of certain behaviours such as smoking, reactions to preventative regimes, or the provision and use of health services.[22]'

What constitutes research is a major question which it is beyond the scope of this article to resolve. We simply follow the Academy's approach and analyse its proposals. Nonetheless it is submitted that the nature and scope of research itself as a precursor to regulation is something which should be examined by the new Health Research Authority.

The Academy Report recommends that regulation should be proportionate to the risks and benefits to society.[23] In particular, such regulation and governance should be underpinned by four principles. The first principle is that of safeguarding the well-being of research participants, which applies to both physical integrity and personal data.[24] The second is to facilitate high quality health research to the public benefit. The Report comments that research has a broad public benefit and that delaying it could be harmful.[25] The third is that research regulation should be proportionate efficient and coordinated. The fourth and

19 Academy Report (note 6), para. 1.4.
20 *Ibid.*, para. 1.4.2.
21 *Ibid.*, para. 1.4.2.
22 *Ibid.*, para. 1.4.4.
23 *Ibid.*, Box 2.B, page 26.
24 *Ibid.*, para. 2.3.
25 *Ibid.*, para. 2.3.

final principle is: 'To maintain and build confidence in the conduct and value of health research through independence, transparency and consistency'.[26]

The Academy Report rightly highlights the complex, piecemeal and ad hoc nature of the current system of research. It can be criticised by researchers for inhibiting research activity, by research participants who may feel that their rights are not being sufficiently safeguarded, and by the broader public regarding research choices and visibility. It suggests that while reform has improved the situation, there is still too much duplication and lack of proportionality.[27]

Health research today is frequently seen as 'good': something which is 'in the public interest' and generally in the broader national economic interest.[28] Research is regarded as something to be promoted across the NHS as a whole.[29] The Academy Report notes that there is broad support for health research as an activity, but that in relation to health services there is a need to embed research in NHS processes.[30] The Report identifies the need for a change in health care culture so that the importance of health research is properly valued.[31] These recommendations have subsequently been taken up by the UK government. Health research is regarded as a stated NHS priority and its perceived importance is now enshrined in legislation in an amendment made to the NHS Act 2006 by the Health and Social Care Act 2012. Section 1E of that Act now provides that:

'In exercising functions in relation to the health service, the Secretary of State must promote –

(a) research on matters relevant to the health service, and

(b) the use in the health service of evidence obtained from research'.

A similar duty is also imposed on the new NHS Commissioning Board.[32] Furthermore, under section 13, statutory powers are given to the secretary of state and bodies such as the NHS Commissioning Board and clinical commissioning groups to undertake, commission or promote research legal framework for research regulation.

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26 *Ibid.*, 6.

27 *Ibid.*, 6.

28 See further Academy of Medical Sciences, 'Biomedical Research: A Platform for Increasing Health and Wealth in the UK' (London: Academy of Medical Science, 2012).

29 *Ibid.*, 29.

30 Academy Report (note 6), para. 3.2.1.

31 *Ibid.*, 7.

32 NHS Act 2006, as amended by Health and Social Care Act 2012.

The extent to which a duty to promote research can or should be translated into a duty to participate in research is something which it is suggested requires far greater engagement by regulators and the public alike. The notion that there should be an obligation or indeed duty to participate in research has received the support of some biomedical ethicists.[33] Yet since Nuremberg the emphasis at international, Council of Europe and EU level has been upon individual participation in research being viewed through the prism of individual autonomy and human rights. Research participation internationally is regarded as a choice rather than an obligation upon individuals. Whether all health research can be seen as in the public good/public interest is also questionable. This may indeed be true of some research, but there can also be considerable differences between being in the public interest and being of commercial interest.

A New Health Regulator: An Ideal Solution?

The research ethics review system in England has for several years been criticised for lack of effective coordination at national level.[34] The government as part of its initial intentions in relation to health reform announced that it was intending to rationalise a number of health bodies, and proposed to establish a single research regulator.[35] So it is perhaps unsurprising that in its report the Academy of Medical Sciences considers the case for the establishment of a new health research regulator.[36] Such an approach has been adopted elsewhere; for example, a successful model of a single research regulator is the Central Committee for Research Involving Human Subjects (CCMO) in The Netherlands.[37] This works alongside local medical research ethics committees. The CCMO considers specialist studies such as vaccines and xenotransplantation. However, some of the responses to the call for evidence by the Academy criticised the move to a single regulator, on the grounds that this could lead to the risk of disruption to the existing system, including clinical trials authorisation. Moreover, it was suggested that a single body could lead to the perception that 'the researchers are regulating the researchers' and would lose the existing benefits of a broader regulatory structure.

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33 J. Harris, 'Scientific Research is a Moral Duty', *Journal of Medical Ethics* 31 (2005): 242; A. Kaplan, 'Is There an Obligation to Participate in Biomedical Research?', in *The Use of Human Beings in Research*, ed. S.F. Spicker et al., (Dordrecht: Kluwer, 1988).

34 M. Warnock, 'A National Research Ethics Committee', *BMJ* 297 (1988): 1626; M. Gilder, 'A National Committee for the Ethics of Research', *Journal of Medical Ethics* 16 (1990): 146.

35 See Department of Health, Liberating the NHS Report of the Arms Length Bodies Review (Department of Health, 2010); Cabinet Office, Public Bodies Reform: Proposals for Change (2010), http://download.cabinetoffice.gov.uk/ndpb/public-bodies-list.pdf.

36 As part of the review it issued a second call for evidence on this specific issue.

37 Academy Report (note 6), para. 9.2.2. and box 9.1.

Despite these concerns, the Academy supported the creation of a new single health research regulatory body, which would subsume a range of related bodies performing regulatory functions in this area. It recognised that a new body needed to build and maintain the confidence of stakeholders. Critically, it was seen as important that the new body was independent, that there was strong leadership and the expertise for this to be effective, that its operation should be transparent and accountable, and that it should have an effective dialogue with other organisations.

There are notable advantages in establishing some form of statutory research regulator. It may provide centralised oversight and independence. It is likely to ensure the clarity of procedures further. It is possible that having a central regulator may make it easier to demand resources to be channelled to support those involved in ethical review at local level, which is critically important to ensure that there is funding to provide local level administrative support and ethics review training. However, whether the establishment of such a regulator should be at the expense of the abolition of other statutory regulators remains very questionable. The analogies with the Care Quality Commission (CQC) are instructive. This body, which reviews standards concerning health and social care, was created in 2004, following radical proposals for the rationalisation of 'arms-length' bodies, by merging the Healthcare Commission, Care Standards Commission and Mental Health Act Commission, a merger which was vigorously resisted by all three.[38] Concerns were raised as to whether the proposed new body would have sufficient resources, focus and attendant expertise to undertake its huge and diverse range of tasks. Moreover, the CQC has come under very heavy criticism, not least for the adequacy of its investigations.[39]

Too broad a remit might result in dilution of review if a body is stretched too far across diverse areas. The government in its response to the Academy Report initially proposed to abolish the HTA and the HFEA and incorporate their research functions under the new research regulator. Both were established regulators governing research and also performing other regulatory functions. So for example, the HFEA regulates embryo research but also assisted reproductive technologies in general and the clinics providing such services.[40] It regulates questions of safety and practicality, while also engaging with complex ethical

38 See further J. McHale, 'Standards, Quality and Accountability – the NHS and Mental Health: A Case for Joined-up Thinking?', *Journal of Social Welfare and Family Law* 25, no. (2003): 369; J. McHale, 'Scrutiny of Standards', in *Principles of Mental Health Law*, ed. P. Bartlett et al., (Oxford: Oxford University Press, 2010).

39 'Care Quality Commission Head Resigns amid Widespread Criticism of the Watchdog', *Daily Telegraph*, 23 February 2012, www.telegraph.co.uk/health/healthnews/9100343/Head-of-Care-Quality-Commission-resigns-amid-widespread-criticism-of-watchdog.html.

40 HFEA s. 13(5) as amended.

questions which in the past have included the use of pre-implantation genetic diagnosis and sex selection.[41] The most recent reform of the HFEA came only after the Human Fertilisation and Embryology Act 2008 which amended the 1990 Act while substantially retaining the latter's structure.[42] The attempt to abolish the HFEA met with strong opposition.[43] This body is concerned with giving guidance in areas where there is still heated debate and fundamental ethical controversy. It can be argued that, given the sensitivity and complexity of such issues, it would be more appropriate for them to be dealt with by a specialist body. To abandon totally structures and procedures which were so recently the subject of careful re-evaluation and a considered decision to retain them was unwise, to say the least.[44] Similarly, the HTA came into existence in 2006. Its remit is far broader than research, covering issues from organ transplantation to the use of human material for medical education.[45] Again, whether abolishing this body and fragmenting its functions will provide effective oversight again remains very questionable.

Commenting on the responses to consultation, the Academy Report notes few responses were received in relation to the role of the HFEA, and speculates that this 'most likely reflects a broad view that the regulatory processes relating to research applications involving embryos work reasonably well'.[46] The report notes the proposals to abolish the HFEA but does not make specific recommendations, other than noting that the HFEA's role forms part of the pathway for regulation and governance of health research. In contrast, the operation of the Human Tissue Act is criticised by the Academy Report for its very broad scope.[47] It is claimed that it is costly and time-consuming to obtain licences. The legislation is criticised for introducing an unduly bureaucratic process. The Academy Report states that the Act does not provide a 'proportionate approach'.[48] The

41 See Consultation Document on Pre-Implantation Genetic Diagnosis (HFEA and the Advisory Committee on Genetic Testing: 1999); HFEA, Sex Selection: Choice and Responsibility in Human Reproduction (2002); HFEA, Sex Selection: Options for Regulation (2003), www.hfea.gov.uk; S. Sheldon & S. Wilkinson, 'Hashmi and Whittaker: An Unjustifiable and Misguided Distinction?', *Medical Law Review* 12 (2004): 137; R. Scott, *Choosing Between Possible Lives: Law and Ethics of Prenatal and Pre-implantation Genetic Diagnosis* (Oxford: Hart, 2007).

42 Department of Health, Review of the Human Fertilisation and Embryology Act 1990: Proposals for Revised Legislation, CM 6989 (London: Department of Health, 2006).

43 R. Deech, 'Abolishing the HFEA Makes No Sense At All', *The Times,* 25 August 2010.

44 See further J. McHale, 'The Bonfire of the Regulators: A Phoenix from the Ashes?', *British Journal of Nursing* 19, no. 16 (2010): 1058.

45 See further discussion in J.V. McHale, 'Legal Regulation of Human Material', in *Principles of Medical Law* 3rd ed., eds A. Grubb, J. Laing & J.V. McHale (Oxford: Oxford University Press, 2010).

46 Academy Report (note 6), para. 7.3.

47 *Ibid.*, para. 7.3.1.

48 *Ibid.*

government subsequently consulted in summer 2012 regarding the continued existence of both bodies.[49] In January 2013 it was announced that it had decided 'on balance' not to include either the HFEA or the HTA in the new Health Research Authority but to undertake a further consultation as to whether these bodies represent value for money.[50] The review will consider in yet another 'back to the future' type move whether both the HFEA and HTA should be combined, following the approach taken in earlier Department of Health proposals in 2004 to create a bespoke regulator for tissue and embryology Regulatory Authority for Tissue and Embryology – RATE).[51] These proposals were themselves at the time the subject of much controversy. It is submitted that such a move to combine such very different bodies would be wholly misguided – particularly if, as appears to be the case here, it is driven by cost considerations.

The Academy Report recommends that the new Health Research Authority develops a streamlined system for 'specialist approvals and licences'.[52] It proposes the establishment of a new National Research Governance Service within the Authority, with the task of aligning and streamline research governance checks with the aim of ensuring common standards.[53] The aim is to provide a 'single consistent efficient' process for obtaining NHS R&D permission.[54] Moreover, as part of the 'streamlining', a reduction in the number of research ethics committees themselves is envisaged. The National Research Ethics Service has introduced a pilot scheme to enable proportionate review of studies where these involve 'no material ethical issues'[55] so that such studies could be reviewed within 10 days. The suggestion is that if such a procedure continues then the number of research ethics committees could easily be reduced. The Academy Report suggests that there could be advantages in rolling this out to other forms of study. It also suggests extending the number of specialist 'flagged' research ethics committees, i.e. ethics committees designated to deal with certain specialist issues.[56] However, it also considers that there are some advantages in retaining a degree of flexibility in relation to localisation with new arrangements

49 Department of Health, Consultation on Proposals to Transfer Functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority (London: Department of Health, 2012).
50 Department of Health, Government Response to the Consultation on Proposals to Transfer Functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority(London: Department of Health, 2010).
51 Department of Health, Arms Length Review (note 37); see also Department of Health Review of the Human Fertilisation and Embryology Act 1990 (note 44).
52 *Ibid.*, para. 9.3, page 7.
53 *Ibid.*, para. 4.5.
54 *Ibid.*, page 41.
55 *Ibid.*, para. 8.4.1.
56 *Ibid.*, para. 8.4.3.

so that, for example, trusts could decide research feasibility within agreed local timelines.

Some of the practical recommendations for the operation of the new Health Research Regulatory Authority are praiseworthy. The National Research Governance Service would be well placed to build upon the strong recent foundations laid by existing bodies, such as the National Research Ethics Service, and learn some of the lessons from the past. It is clear that a proportionate and streamlined approach to research review may lead to more realistic solutions. Moreover, a lack of consistency in advice given at local level, in terms of interpretation of ethics review and even legal provisions such as the Data Protection Act, has been identified. A central regulator can be seen as important in providing not simply oversight but engagement and dissemination of information. The emphasis upon guidance, education and training is critical, as will be resourcing; this is a real concern, given that the initial 'arms-length review' aims were at least partly driven by concerns regarding cost. It is suggested that there is an equal need to be cautious in relation to the suggestion that the number of research ethics committees could themselves be reduced. Certainly a reduction in the workload of existing committees would be desirable to ensure that they have more time to focus on specific cases. Nonetheless, it remains questionable how many cuts in the system will necessarily facilitate better research ethics review in the long term.

Inhibitors and Challenges: The Academy's Response

In addition to identifying what it saw as a need for strong central regulation and the alignment of regulatory bodies, the Academy Report focused upon a number of areas of concern to researchers. Space precludes detailed consideration of all of these, and instead we focus upon three specific issues: the impact of the EU Clinical Trials Directive; the use of patient data in health research; and the issue of liability and indemnity for harm suffered.

In relation to trials of investigational medicinal products, as we saw above, the regulation of clinical research in the UK has been considerably impacted by the EU Clinical Trials Directive.[57] Although this was seen as having some positive impact in that it had improved standards in non-commercial trials, respondents to the Academy's review generally regarded its impact as negative, arguing that the Directive had led to greater administrative burdens without corresponding improvements in patient safety, and that there are concerns regarding its incon-

57 See note 9.

sistent application across EU Member States.[58] The Academy Report is critical of the operation of the Directive, suggesting that it has created bureaucracy without protecting patients.[59] In response to respondents' concerns regarding inconsistent application across the EU, it recommends that the scope of the Directive should be limited, its requirements in relation to approvals and monitoring should be seen as proportionate to risk and that requirements concerning the reporting of adverse events should be simplified.[60] The report also raises concerns regarding the definitions of the Directive and the dangers of 'over implementation', which could mean that where there are uncertainties sponsors might go beyond what is required. It is interesting that this is seen as a problem, while in fact such caution may be regarded as beneficial.

The Clinical Trials Directive has now been the subject of review by the EU,[61] which has recognised the need for reform, given that costs and delays have increased in relation to multinational drug trials.[62] Proposals to replace the Directive with a Regulation have been published, with the aim of standardising processes across the EU so that it becomes a commercially much more attractive place to undertake research.[63] The introduction of a new EU regulation is likely to give the EU itself tighter control over the operation of clinical research, since far less discretion in implementation will be afforded to Member States. The proposed regulations include a much broader definition of what constitutes research. This applies to a new category of 'clinical study' of medicinal products, which is wider than the existing classification of 'clinical trial' under the Directive.[64]

The need to streamline research procedures has driven several reforms in the proposals. There is to be a central harmonised application/authorisation dossier and a single computer system for all applications for clinical trials which

58 Academy Report, para. 5.3.1.
59 *Ibid.*, para., 5.3.
60 *Ibid.*, 56.
61 Assessment of the Functioning of the Clinical Trials Directive 2001/20/EC (Brussels 9 October 2009), ec.europa.eu/health/files/clinicaltrials/docs/2009_10_09_public-consultation-paper.pdf; Assessment of the Functioning of the Clinical Trials Directive 2001/20/EC: Summary of Responses to the Public Consultation Paper (Brussels 30 March/2010), ec.europa.eu/health/files/clinicaltrials/2010_03_30_summary_responses.pdf.
62 Academy Report (note 6), para. 5.3.
63 Proposal for a Regulation of the European Parliament and of the Council on Clinical Trials on Medicinal Products for Human Use, and Repealing Directive 2001/20/EC (Brussels 17 July 2012), COM(2012) 369 final.
64 It is defined as: 'any investigation in relation to humans intended
a. to discover or verify the clinical, pharmacological or other pharmacodynamics effects of one or more medicinal products or
b. to identify any adverse reactions to one or more medicinal products or
c. to study the absorption, distribution, metabolism and excretion of one or more medicinal products; with the objective or ascertaining their safety or efficacy'.

will be linked to an EU database – an EU 'portal'.[65] It will therefore be much easier for the EU to overview the clinical trials application process in Member States and to determine patterns in clinical trials approval. This new computer system may also help alleviate the concerns regarding delay and disproportionate procedures highlighted in the Academy Report and elsewhere in the EU.

One major reform contained in the EU's proposals is that, instead of the requirement that a protocol be sent to a research ethics committee, EU Member States are to 'ensure that there must be a "reasonable number" of persons considering the application and they must "collectively have the necessary qualifications and experience'.[66] The Member State is then required to draw up an assessment report. As at present, time limits are set out with the aim of expediting consideration of the application. Specific provisions regulating the inclusion of children and adults lacking mental capacity will continue. The Commission is also to establish a public database, with the aim of ensuring the efficient flow of information between sponsors and Member States.[67] However, this will not contain personal information about trial participants. The role of the sponsor has been the subject of considerable debate. The Commission proposals allow for greater flexibility in relation to sponsorship, in recognition of the reality that a range of sponsors may be involved in the operation of a clinical trial.[68]

As at present there will be a database for reporting adverse events, and those involved in the clinical trials process will be obliged to report adverse reactions. Member States are to be required to establish an inspectorate to supervise compliance with the Regulation.[69] In addition, in a proposal which is likely to be exceedingly controversial in certain Member States, Article 76 of the Regulation provides that the Commission is to conduct controls to check whether Member States have correctly supervised compliance with the Regulation and whether the regulatory system applicable to trials outside the EU also complies with this regulation.[70] It also provides that the Commission is to be empowered to undertake inspections where necessary.[71] While these proposed EU reforms address to some extent the concerns raised in the Academy Report, they also pose what may be a considerable further challenge to national autonomy in terms of research regulation. They represent some streamlining, but at the same time give the EU greater 'reach' into domestic approvals through new

65 The Directive arts 5 and 77.
66 *Ibid.*, art. 9.
67 Proposal (note 66), 22, para. 52.
68 *Ibid.*, 21, para. 43.
69 The Directive art. 75.
70 *Ibid.*, art. 76(1).
71 *Ibid.*, art. 76(2).

central databases and provisions for spot checks. The proposed reforms are an interesting move away from the acceptance that research ethics committees should play a critical role in research regulation – which if taken forward is itself likely to prove extremely controversial.

A second major area considered in the Academy Report is the use of personal health information in research. One major concern for researchers is the availability of and effective access to information concerning individuals, not least because of the prospect of bias in research findings where datasets are incomplete.[72] As the Academy Report notes, patient data is used in a wide range of situations, which may range from population-based epidemiological research to the effectiveness of screening programmes and the identification of areas for improvement in the provision of NHS services.[73] Participant information used in clinical research may be derived from existing clinical information or obtained during the study itself. The Academy Report focuses upon two types of use of patient data. The first is the direct use of such data in relation to a study which can be undertaken without any direct contact with participants. The second is where data in the form of patient records is used to select individuals who may be invited to participate in such a study.

The use of an individual's personal data in research remains controversial.[74] There is no single statute safeguarding patient information; rather it is subject to safeguards under the law concerning patient confidentiality,[75] which is underpinned by the right to privacy under Article 8 of the European Convention of Human Rights which safeguards the right to privacy of home and family life.[76] Information is also protected through the Data Protection Act 1998, itself derived from the EU Data Protection Directive.[77] The perceived need to safeguard confidentiality and privacy of research participants' information is reflected in guidance regarding the use of information for clinical research purposes.[78]

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72 Academy Report (note 6), para. 6.1, box 6.1.

73 *Ibid*., para. 6.1.

74 See e.g. the discussion in I. Brown, L. Brown & D. Korff, 'Using NHS Patient Data for Research Without Consent', *Law, Innovation and Technology* 2, no. 2 (2010): 219.

75 See generally *X v. Y* [1988] 2 All ER 648; *W v. Egdell* [1990] 1 All ER 835; GMC, *Confidentiality* (London: GMC, 2009), www.gmc-uk.org/guidance/ethical_guidance/confidentiality.asp.

76 *Z v. Finland* (1998) 25 EHRR 371; *MS v. Sweden* (1999) 28 EHRR 313; *Campbell v.Mirror Group Newspapers* [2004] 2 All ER 995.

77 Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (Data Protection Directive) (1995) OJ L281.

78 For example, Medical Research Council, 'Personal Information in Medical Research' (London: MRC, 2000), //www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002452; GMC *Confidentiality* (note 78). See generally discussion in Biggs, *Healthcare Research* (note 2), ch. 6.

The Data Protection Act 1998, which concerns personal data held in both computer and manual records, has for a number of years been regarded by certain parts of the medical and scientific community as effectively an inhibitor to research. To address such concerns, section 60 of the Health and Social Care Act 2001, which has now been re-enacted as section 251 of the National Health Service Act 2006, enables the secretary of state to make regulations which allow the processing of 'prescribed patient information for medical purposes as he considers necessary or expedient'.[79] Such regulations may be made in the interests of providing patient care or in the public interest. The Regulations provide for disclosure of patient information without consent, for example in relation to communicable diseases and for other public health purposes.[80] The Ethics and Confidentiality Committee of the National Information Governance Board gave advice to the secretary of state concerning applications under this section. This role will now be taken over by the Health Research Authority Confidentiality Advisory Group. Although these provisions have been welcomed by many in the scientific community as facilitating transfer of information for research purposes, in other respects they can be viewed as problematic. The regulations themselves enable the enactment of broad-brush exceptions to the equitable remedy of breach of confidence. While the emphasis on anonymity may be seen as addressing privacy concerns. While the emphasis on anonymity may be seen as addressing privacy concerns this remains controversial.[81]

Interestingly, despite the considerable statutory and non-statutory guidance exceptions already in place in relation to use of information for research purposes, respondents to the Academy Report indicated that they thought that access to data was a handicap to health research.[82] The report highlights the absence of clear mechanisms enabling researchers to search records to identify eligible participants. One option explored by the Academy was the use of 'safe havens'. Recommendations in relation to such havens followed the data sharing review undertaken by the Information Commissioner and the Director of the Wellcome Trust.[83] Such havens would create an environment where the risk of identifying

79 Health Services (Control of Patient Information) Regulations 2002 SI 2002/1438 reg. 4; see also P. Case, 'Confidence Matters: The Rise and Fall of Informational Autonomy in Medical Law', *Medical Law Review* 11 (2003): 208-236.

80 EU Regulation s. 3.

81 *R v. Department of Health ex parte Source Informatics* [2000] 1 All ER 786. See further D. Beyleveld & E. Histed, 'Betrayal of Confidence in the Court of Appeal', *Medical Law International* 4 (2000); 69.

82 J. Strobl, E. Cave & T. Walley, 'Data Protection Legislation: Interpretation and Barriers to Research', *BMJ* 321 (2000): 890.

83 R. Thomas & M. Walport, 'Data Sharing Review Report' (July 2008) discussed in note 6 at para 6.3.1 and box 6.3; see also Academy of Medical Sciences, 'Personal Data for Public Good: Using Health Information in Medical Research (London: Academy of Medical Sciences, 2006), www.acmedsci.ac.uk/p48prid5.html.

individuals would be minimised, and would include systems for approving researchers who are able to work within them. There are currently research portals which facilitate access to data; in England these take the form of the Health Research Support Service. The Academy Report recommends that the work to develop such havens should progress more rapidly and, if necessary, specific legislation should be introduced.[84] At one level such 'safe havens' can be seen as a means of respecting the privacy of participants' information. At the same time, it is submitted that this does not sufficiently address the broader issue of an individual's claim that this is personal information. A workshop undertaken by the Academy highlighted that patients wanted to be aware of research in order to be able to make choices and to have the right to choose.[85] Furthermore, the Academy Report states that: 'Many felt that currently the choice is not presented to patients and that others are making decision on their behalf'.[86] Nevertheless, the focus of the report seems to be upon the needs of the researchers rather than the rights of participants. For example, it highlights the perceived needs of researchers to access data regarding eligible patients. There is also a divergence between the findings of existing surveys as to whether individuals may be happy for anonymised data to be used for research purposes. Over the last few decades there has been growing recognition of the need to respect individual autonomy in relation to decision-making. One possible concern about the enhanced involvement of individuals in decision-making is the cost of contacting people. However, electronic forms of communication can drive costs down; for example, people today often retain the same mobile phone number even if they transfer to a different service provider and thus may be easier to track down. Moreover, while cost is often seen as a concern in relation to consent, it does not seem to be a problem when contacting individuals a second time to enroll them in a project or indeed ask for further information. Indeed, if cost is a major issue then perhaps the cost of contacting individuals should be built into the initial funding bid for research projects. The issue of data protection is currently under review by the EU in the context of the operation of the EU Data Protection Directive; the Academy Report notes this and suggests the need for government input into the process.[87]

There has been a gradual trend towards sanctioning disclosure of patient information for research purposes in the UK. If individuals consent to the use of their information or material this can generally be seen as unproblematic, and indeed such consent, if valid, would mean that subsequent use of information

84 Academy Report (note 6), para. 6.4.3.
85 *Ibid.*, para. 6.4.4.
86 *Ibid.*
87 *Ibid.*, 68.

depending upon the scope of the consent would not be subject to a successful action for breach of confidence. However, much depends here on what actually constitutes consent. Use of data in a one-off instance for a specific project is different to the intention to acquire and use information over a period of time and make it available to researchers undertaking a range of very different projects, as in relation to population databases.[88] Use of information and material without consent if anonymised may be seen as not infringing privacy, but in reality the situation is much more complex. Certain information and indeed samples are useless to researchers if totally anonymised. Anonymisation here in practice means non-identifiability. Access to information is coded but the information can be linked in some way. The Academy Report simply does not engage with the complexity of these issues. We need to step back and re-evaluate this approach and see if a more effective regulatory paradigm can be constructed to address this issue in the future.[89]

The Academy Report highlights the question of liability and indemnity for research. This is another issue which has long been a matter of concern within the NHS research community and NHS research ethics committees.[90] There has never been specific statutory provision for compensation of those involved in health care research where things may go wrong. Health research inevitably involves risks and uncertainties, thus in practice proving that harm has been caused by negligence may be exceedingly problematic. Moreover, it can be argued that research is undertaken in the public interest, so a different approach to compensation should apply in this context. As long ago as the Pearson Commission in the 1970s it was argued that there should be provision for compensation for individuals injured in clinical research through the introduction of a no-fault scheme, but this still remains to be introduced.[91] In considering the whole area of compensation in the law of tort, the Pearson Commission, while rejecting generally the introduction of a no-fault compensation system in relation to the UK, nonetheless supported the introduction of a specific no-fault compensation system in relation to clinical trials.[92] This proposal was not taken up following the most recent recommendations on reforming the law of

88 See generally in relation to biobanks J. Kaye, 'Abandoning Informed Consent: The Case of Genetic Research in Population Collections', in *Genetic Databases: Socio-Ethical Issues in the Collection and Use of DNA* eds R. Tutton & O. Corrigan (London: Routledge, 2004); J.V. McHale, 'Regulating Genetic Databases: Some Legal and Ethical Issues', *Medical Law Review* 12, no. 1 (2004): 70.

89 See further M. Taylor, *Genetic Data and the Law* (Cambridge: Cambridge University Press, 2012).

90 See further J.V. McHale, 'Liability in the Law of Tort of Research Ethics Committees and their Members', *Research Ethics Review* 1, no. 2 (2005): 53.

91 Royal Commission on Civil Liability and Compensation for Personal Injury (Pearson Commission) (1978) Cmnd 7054.

92 Ibid., ch. 24 para. 1341.

clinical negligence contained in the Chief Medical Officer's report in 2003. These recommendations did pave the way for an attempt to resolve some clinical negligence actions outside the courtroom through the NHS Redress Act 2006, although the scheme has not been implemented to date.[93] The EU Clinical Trials Directive has now led to a reconsideration of the procedures for ensuring that research participants obtain compensation should something go wrong during a clinical trial. The role of the research sponsor has been enshrined in the Research Governance Framework for research ethics committees and, as noted above, research ethics committees should examine the availability of indemnity and compensation when considering the trial protocol. While this helps to delineate the boundaries of accountability and highlights the need for effective compensation systems, it only goes so far. It can be argued that if research is in the national interest, as has been claimed by the current government in its reform of health and social care, this is something which should be a matter for state responsibility.

The Academy of Medical Sciences very helpfully recognises and highlights these concerns. Nonetheless it also states that the NHS Litigation Authority, the body which as its name suggests manages claims against the NHS, has not received a claim in relation to research.[94] The Academy Report comments that there could be clarification on responsibility regarding research indemnity so that there is 'confidence' in relation to where responsibility falls.[95] However, the Academy Report does not engage with the broader question of compensation for personal injury in such a situation and whether, if this is something for the state to promote as a statutory duty, it should also be the state's responsibility to provide compensation if things go wrong. Critically, it leaves compensation to the vagaries of the law of tort rather than returning to the root of the issue, as highlighted by Pearson all those years ago.

Conclusions

The Academy Report provides a useful and considered insight into the regulatory and governance challenges regarding research in the UK. However, as highlighted in this article, many questions and challenges remain regarding the regulation of health research. In many ways, some of the problems

93 Making Amends: A Consultation Paper Setting Out the Proposals for Reforming the Approach to Clinical Negligence in the NHS (Department of Health, 2003); see further A.M. Farrell & S. Devaney, 'Making Amends or Making Things Worse? Clinical Negligence Reform and Patient Redress in England', *Legal Studies* 27, no. 4 (2007): 630.

94 Academy Report (note 6), para. 4.5.3.

95 Academy Report (note 6).

with the report and indeed the subsequent action taken by the UK government are related to the limited terms of reference which the Academy was given. As has been suggested previously, such a review would be better entrusted to an independent body divorced from competing interest groups – such as a royal commission.[96] Such a body would have been better able to consider the myriad of competing issues and to examine the hugely complex question of how should we regulate health and social care research. This requires a total re-evaluation of the engagement of health law and human rights in this area.

In the meantime, will the new reforms work? The UK Government has pressed ahead with its intention to reform research regulatory structures. The new Health Research Authority has now been established as a special health authority, chaired by Professor Jonathan Montgomery of University College London, with the aim of protecting and promoting the interests of patients and public in health research. In April 2013 the functions of the National Research Ethics service were transferred to it along with the roles of the former strategic health authorities in relation to research ethics committee. However as we have seen many research functions such as those performed by the HFEA and HTA still remain beyond its remit. Potentially the new Health Research Authority will have considerable advantages. Its very existence highlights the importance of engaging effectively with research regulation. It can raise the profile of research regulation outside the scientific and medical community, and the move towards enhanced centralisation could reduce duplication. Reducing unnecessary bureaucracy may assist in properly managing risk, building confidence and ensuring proportionality. But the new Health Research Authority is working against a backdrop of considerable legal complexity and indeed uncertainty, given the need to respond to and become compliant with not only domestic legal provisions but also, as we have seen in the context of the Clinical Trials Directive, research law and policy which is increasingly being driven from the EU. Overall, the Academy Report is likely to be seen over time as a pragmatic – if at times misguided – review of governance issues, which leaves many questions of law, ethics and policy for the new Health Research Authority to address in the future.

96 J.V. McHale, 'Law, Regulation and Public Health Research: A Case for Fundamental Reform?', *Current Legal Problems* 63, no. 1 (2010): 475-510.