Institution: University of Edinburgh

Unit of Assessment: 18 – Law

Title of case study:

Case Study 4: Protecting and Promoting Public Interest in the Regulation of Human Health Research

Period when the underpinning research was undertaken: 2008-2019

Details of staff conducting the underpinning research from the submitting unit:

Name(s):	Role(s) (e.g. job title):	Period(s) employed by submitting HEI:
Graeme Laurie	Professor of Medical Jurisprudence (until 31-Aug-2019); Professorial Fellow (01-Sep-2019 to present)	01-Sep-1995 to present
Edward Dove	Lecturer in Health Law and Regulation	12-Sep-2017 to present
Nayha Sethi	Chancellor's Fellow in Data Driven Innovation	01-Sep-2009 to present
Annie Sorbie	Lecturer in Medical Law and Ethics	01-Aug-2017 to present
Leslie Stevens	Research Fellow	16-Dec-2013 to 14-Jun-2017

Period when the claimed impact occurred: 2014-2020

Is this case study continued from a case study submitted in 2014? N

1. Summary of the impact

A work programme on health research regulation within the Mason Institute (2012-2020) – focussing on public benefits of regulation – resulted in multiple changes to practice in regulatory environments, both nationally and internationally. These include: (i) improving governance mechanisms for research on personal data across health and non-health sectors; (ii) promoting the responsible research use of human biomedical collections in the UK and Europe; and (iii) influencing UK law reform to better capture the role of public interest in research regulation. The main beneficiaries are researchers, funders and regulators faced with navigating the complexities governing contemporary human health research.

2. Underpinning research

A series of externally-funded projects was undertaken to improve the regulation of human health research. A common feature was to explore the role of public interest in justifying robust health research and in ways acceptable to the general public. Public interest is often a counterpoint in law to individualistic notions such as consent and privacy. However, its role in legitimating human health research was under-examined. Moreover, many biomedical

research initiatives cannot proceed on the basis of individual consent; for example, because some data and tissue collections span decades and it is impracticable to seek consent. This leaves many researchers and regulators confused about how to deliver research lawfully and in the public interest.

The role of public interest was examined in relation to (i) personal data; (ii) human tissue; and (iii) actors seeking to undertake or regulate health research.

i. **Personal data**: While interdisciplinary expertise was leveraged with colleagues at the Universities of Essex, Manchester, Oxford, Swansea and UCL to explore holistic models of good data governance, the Edinburgh team (Laurie, Sethi and Stevens) took the legal lead on designing novel solutions for cross-sectoral data linkage. Key research outputs addressed designing models of interoperable governance that can support health research within existing international legal structures (3.1); and demonstrating how research can be supported lawfully on a public interest mandate (3.2). The research built on work undertaken on the Scottish Informatics Programme (2009-2013; REF 2014 case study) and extended the reach internationally. For example, the involvement of Laurie and Dove in the Global Alliance for Genomics and Health revealed an unmet need for privacy and security toolkits for science stakeholders to feel confident in sharing data between countries (3.3).

ii. **Human tissue**: In 2008, the Scottish Government commissioned Laurie to undertake research on its Guthrie card collection – blood spots taken from newborns since the mid-1960s and now including approximately 2.5 million samples. While originally created for health-related reasons, the long-term storage of such collections raises questions about the lawfulness of their retention and use, especially for research. The report (2009; updated in 2014) confirmed lawful retention and made recommendations about the governance of the collection, advocating a public interest approach supporting research use (3.4). This work directly informed Laurie's participation in the Council of Europe's Working Party to revise its Recommendation on Biomedical Collections (2016).

iii. **Actors**: The concept of public interest is not well-defined, creating difficulties for institutions, research ethics committees and regulators trying to implement it. Nonetheless, international comparative research with colleagues at the National University of Singapore revealed that several jurisdictions have a public interest or public good criterion for granting waivers of consent in biomedical research (3.5). Furthermore, during the passing of the UK's Data Protection Act 2018, Sorbie's work on public interest and public engagement demonstrated how the application of a processual approach to regulation and law-making – involving multiple stakeholders in law and policy *at all stages* – can make public interest a viable and valuable tool in health research regulation (3.6).

3. References to the research

3.1: Laurie, G., Ainsworth, J., Cunningham J., Dobbs, C., Jones, K.H., Kalra, D., Lea, N.C. and Sethi, N. (2015) 'On Moving Targets and Magic Bullets: Can the UK Lead the Way with Responsible Data Linkage for Health Research?', *International Journal of Medical Informatics*, vol. 84, no. 11, pp. 933-940. https://doi.org/10.1016/j.ijmedinf.2015.08.011

3.2: Laurie, G. and Stevens, L. (2016) 'Developing a Public Interest Mandate for the Governance and Use of Administrative Data in the United Kingdom', *Journal of Law and Society*, vol. 43, no. 3, pp. 360-392. https://doi.org/10.1111/j.1467-6478.2016.00759.x

3.3: Dove, E.S., Laurie, G. and Knoppers, B.M. (2016), 'Data Sharing and Privacy', in Ginsburg, G. and Willard, H. (eds.), *Genomic and Personalized Medicine: Foundations,*

Translation, and Implementation, 3rd ed. (Waltham, MA: Elsevier), pp. 143-160. Can be supplied by HEI on request. https://doi.org/10.1016/B978-0-12-800681-8.00010-4

3.4: Laurie, G., Hunter, K. and Cunningham-Burley, S. (2014) 'Storage, Use and Access to the Scottish Guthrie Card Collection: Ethical, Legal and Social Issues'.* https://www.gov.scot/publications/guthrie-cards-scotland-ethical-legal-social-issues/

*This report was commissioned by the Scottish Government Social Research Unit and subjected twice to internal ScotGov review (once in 2009 and again in 2014 when the report was updated to take account of changes in ScotGov governance arrangements, including the establishment of NHS Research Scotland in the intervening period). The review process included input from the Central Legal Office of NHS National Services Scotland.

3.5: Schaefer, G.O., Laurie, G., Menon, S., Campbell, A.V. and Voo, T.C. (2020) 'Clarifying How to Deploy the Public Interest Criterion in Consent Waivers for Health Data and Tissue Research', *BMC Medical Ethics,* vol. 21, no. 23. https://doi.org/10.1186/s12910-020-00467-5

3.6: Sorbie, A. (2019) 'Sharing Confidential Health Data for Research Purposes in the UK: Where Are "Publics" in the Public Interest?', *Evidence & Policy*, vol. 15, no. 3, pp. 1-17. https://doi.org/10.1332/174426419X15578209726839

4. Details of the impact

Research by the Mason Institute had a major impact on the design and delivery of health research regulation in three overlapping fields of influence.

(i) Guiding responsible data use internationally

The Good Governance Framework for data sharing in Scotland – developed by Laurie and Sethi (REF 2014 impact case study) – has since been endorsed and applied internationally and beyond the health sector. This was achieved because research in the census period demonstrated that interoperable governance is possible irrespective of local laws.

In 2015, Laurie was appointed as the sole international member of the Expert Panel of the Council of Canadian Academies on 'Accessing Health and Health-Related Data in Canada'. The Chair of the Expert Group stated: *"One of the best practices endorsed by the Expert Panel in their report's key findings is Scotland's good governance framework…[t]he report has since been used widely by stakeholders across Canada. The leading sponsor of the assessment, the Canadian Institutes of Health Research, has used it as an important resource for a number of significant policy initiatives including its health research data framework and Canada's Tri-Agency Statement of Principles on Digital Management"* (5.1).

The Director of Research Strategy and Funding at the Irish Health Research Board also confirmed the influence of the framework in an important report, 'Proposals for an Enabling Data Environment for Health and Related Research in Ireland' (2016). Specifically: *"[i]t is cited at several points throughout the report to highlight that a principled, proportionate, risk-based approach to governance is required to support…safe national research infrastructures as extant legal frameworks are often inadequate and overly restrictive. This report has laid the foundation for a proof of concept project that is currently underway to trial the proposed infrastructure. Going forward with the plans to develop national infrastructure in Ireland to support data sharing and linkage of health and social care data, the good governance framework developed by Laurie and colleagues will continue to inform Irish best practice"* (5.2).

On behalf of the Global Alliance for Genomics and Health, the Chief Executive Officer stated: *"Laurie and Dove's work with the Global Alliance for Genomics and Health led directly to the development and implementation of a Data Privacy and Security Policy across*

its consortium of nearly 600 health research organisations in more than 50 countries. This Policy emphasized the importance of proportionate and harmonized privacy and security safeguards, and contributed to international alignment in this area" (5.3).

(ii) Justifying research on biomedical collections

The report on the Scottish Guthrie card collection (3.4) has had both national and international impact. For ScotGov's Chief Scientist Office, a Senior Research Manager confirmed: *"The report and subsequent input by the authors and colleagues from the Mason Institute into the supporting materials, deliberations and conclusions of a stakeholder workshop in 2019 underpins the Scottish Government's current approach. This is to more firmly establish the research utility of the Archive, and to establish a proposition for [its] use through public engagement including, but not limited to, formal public consultation. The conclusions of these reports are also helping to shape and provide important supporting evidence for public consultation/engagement documentation being prepared to explore the use of the Archive as a unique research resource of potential international interest"* (5.4). The influence of this report and Laurie's "*principal role*" in shaping the revised Council of Europe Recommendation on biomedical collections are verified by the Secretary of the Committee on Bioethics (5.5).

(iii) Promoting public interest in law reform

Sorbie worked with the funder (Wellcome) to influence the UK's Data Protection Act 2018. Previously, a narrow reading of the public interest in the proposed legislation threatened to impede data sharing to the detriment of responsible health research. Sorbie's advice, based on her deep understanding of public interest (3.6), was used directly by Wellcome in its parliamentary lobbying: *"Ms Sorbie's research very much contributed to a set of briefings on the Bill that I believe were compelling for Government to take our concerns seriously and engage with Wellcome as knowledgeable stakeholders. For example, we did succeed in getting Government to table an amendment to protect interventional research which was critically important for protecting clinical trials. In addition, there was a shift in the wording of the explanatory notes that accompanied the Bill in relation to the public interest clause (Section 8). Having originally made no reference to health research, these explanatory notes were subsequently amended to include wording that specifically referred to health research by universities"* (5.6).

5. Sources to corroborate the impact

5.1: Testimonial letter from the Chair of the Expert Group on for the Council of Canadian Academies.

5.2: Testimonial letter from the Director of Research Strategy and Funding, Irish Health Research Board.

5.3: Testimonial letter from the Chief Executive Officer of the Global Alliance for Genomics and Health (GA4GH).

5.4: Testimonial letter from the Senior Research Manager, Chief Scientist Office in Scottish Government.

5.5: Testimonial letter from the Secretary of the Committee on Bioethics (DH-BIO), Council of Europe.

5.6: Testimonial letter from the former Policy Advisor and now Understanding Patient Data Lead, Wellcome.