Institution: University of York		
Unit of Assessment: 30 - Philosophy		
Title of case study: Changing the Governance and Culture of Information Gathering in Public Health England		
Period when the underpinning research was undertaken: 2007 - 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:**
Stephen Holland	Professor	Jul 1999 - present
Period when the claimed impact occurred: 2015 - 2020		
Is this case study continued from a case study submitted in 2014? No		

1. Summary of the impact (indicative maximum 100 words)

Research conducted by Prof Stephen Holland at the University of York underpinned the guiding principles and operating procedures of Public Health England's (PHE) first research ethics committee. PHE's Research Ethics and Governance Group (REGG) met for the first time in 2015, chaired by Holland. Prior to this, PHE did not have a body dedicated to the ethical oversight of its research activities. REGG thus changed PHE's information-gathering activities, including both public health research and non-research public health practice. In doing so, REGG transformed PHE's informational culture, requiring PHE staff to consider REGG review at the outset of their project planning, leading to a noticeable upskilling of staff in this area. In turn, this has impacted on wider society: REGG strictures protect participants from research related risks and harms, and change their experience of participating in PHE's information-gathering activities; and REGG has enabled and supported PHE's response to the current Covid crisis.

2. Underpinning research (indicative maximum 500 words)

The underpinning research is Holland's body of work in Public Health Ethics and Research Ethics. Regarding Public Health Ethics, **[3.1]** applies moral and political theory to public health dilemmas, and has been recognised internationally as a major contribution to the field since its first edition in 2007; **[3.2]** clarifies, and evaluates responses to, the central problem of liberty-limiting state intervention for public health purposes, and **[3.3]** analyses one such approach in depth, namely, 'nudges' to resolve public health dilemmas. Regarding Research Ethics, Holland has published on the role and remit of research ethics committees – including whether this should extend to judging the scientific merits of research studies **[3.4]** – and analysed the ethics of The National Institute for Health and Care Excellence (NICE's) restricting access to new health treatments and technologies by attaching research conditions **[3.5]**.

Holland's tenure as Chair of REGG coincided with research culminating in **[3.6]**. As a result, REGG's guiding principles and operating procedures were entirely informed by research findings published in the book, as explicitly stated in the Preface: "the research undertaken for this book has directly informed the work of REGG" [3.6, p. ix]. The book presents the following 'master argument': conceptually speaking, the book argues that the distinction between research and other information-gathering practices is defensible by appeal to Wittgenstein's 'family resemblance concepts'. Despite this conceptual distinction, research exceptionalism – i.e., the view that research is distinct from other information-gathering activities, in ways that justify particularly close scrutiny of the former – is false. This anti-exceptionalism about research implies that non-research information-gathering practices should be in the remit of research ethics committees, which threatens to inflate information governance beyond practicability. But such 'regulation inflation' is avoidable in two ways: first, by establishing that research is already overregulated; second, by devising measures such as ethical risk screening and proportionate review. Regarding the former, the claim that research is overregulated – which is persistently misconstrued in the literature – is clarified before being defended from objections. Regarding the latter, scepticism about proportionate review is met with evidence of effective systems of ethical risk screening aimed precisely at public health information gathering.

Throughout this body of work, Holland has consistently argued that public health data collection raises issues distinct from general research ethics [3.1]. Standard research axioms don't apply: e.g., individual voluntary informed consent to participate is impossible in public health contexts. The risks from public health data collection are also distinctive – e.g., stigmatising disadvantaged social groups is more of a potential hazard than direct physical or mental harm to

individuals – as are the benefits, e.g., reduced health inequalities. So, the way public health information gathering is ethically evaluated has to differ from traditional research ethics models. For example, the requirements on participant recruitment – including how participants are informed of, and consent to, studies – are different, as are the sorts of cost, benefits, and burdens of public health information gathering, and how to make appropriate trade-offs between individual privacy rights and mandatory data collection. This distinctive approach to public health data collection directly informed the way REGG operates: not as a standard ethics committee, but tailored to PHE's remit – i.e., public health information-gathering – in ways detailed below.

3. References to the research (indicative maximum of six references)

3.1 Holland, S. *Public Health Ethics (2nd Edn)*, Cambridge: Polity Press, pp. 276, 2014. (*1st Edn*, 2007).
3.2 Holland, S. "Public health ethics: what it is and how to do it,"' in Peckham, S. and Hann, A. (eds.) *Public Health Ethics and Practice*, Bristol: Policy Press, 2010, 33–48.
3.3 Holland, S. "Libertarian paternalism and public health nudges," in Freeman, M., Hawkes, S. and Bennett, B. (eds) *Law and Global Health – Current Legal Issues*, Volume 16, Oxford: Oxford University Press, 2014, 331–353.
3.4 Holland, S. and Belshaw, C. "Is it appropriate for research ethics committees to make judgements about the scientific quality of research proposals?" *Nursing Ethics*, 18 (1), 2011, 122–5. DOI
3.5 Holland, S. and Hope, T. "The ethics of attaching research conditions to access to new health technologies," *Journal of Medical Ethics*, 38 (6), 2012, 366–371. DOI [Submitted to REF 2014]
3.6 Holland, S. *Ethics and Governance of Public Health Information*, London: Rowman & Littlefield International, pp. 172, 2019. [Submitted to REF2021]
All publications above were peer reviewed.

4. Details of the impact (indicative maximum 750 words)

Holland's research, by informing the guiding principles of REGG, Public Health England's first research ethics committee, has changed practice and organisational culture at PHE, strengthened protection of large numbers of study participants, and contributed to PHE's response to the Covid-19 outbreak.

Overview. PHE is the executive agency of the Department of Health responsible for protecting and improving the nation's health and wellbeing, and reducing health inequalities. To fulfil this remit, PHE undertakes and sponsors a considerable amount of research. Prior to 2015, PHE research did not undergo ethical review because, being public health oriented, it fell outside the remit of the NHS Health Research Authority (HRA). But, as Holland has argued [3.1, 3.6], this research can be as ethically risky and potentially harmful as studies which do require standard research ethics approval (by the NHS HRA or an equivalent research governance body). In response, in 2015 PHE approached Holland, on the basis of his expertise in public health research ethics, to set up its first bespoke research ethics committee, the Research Ethics and Governance Group (REGG). Holland served in that role from 2015-19, during which REGG put into practice an approach to the ethics and governance of public health information underpinned by Holland's research.

4.1 How the Research Underpinned the Impact: Establishing the Guiding Principles for the Ethical Oversight of PHE's Information Gathering Activities

PHE identified Holland to Chair REGG "through his publications [and] research interests … [in particular] Stephen's 2014 book '*Public Health Ethics*' (2nd edition) provided a solid foundation to add value to PHE" [5.1]. REGG's guiding principles and operating procedures were underpinned by Holland's research insights. As outlined in Section 2 above, Holland has consistently argued that public health information requires a different sort of scrutiny to standard research ethics review. It was on this basis that PHE agreed to start REGG from scratch, including devising entirely new guiding principles and operating procedures [5.2].

These principles and procedures were founded on Holland's research. To refer back to the 'master argument' in Section 2, Holland's anti-exceptionalism [3.6] was the basis for expanding REGG's remit to include PHE information-gathering activities, which are routine public health practice, as well as 'research proper'. Such activities include collecting surveillance data and monitoring population health; population screening programmes; service evaluations and quality

improvement activities; information gathering in response to public health outbreaks and emergencies; and market research studies. By 2018 over half of the submissions to REGG were for such public health practice activities. That the decision to include such non-research PHE practice in REGG's remit was based on Holland's research is confirmed by PHE: "In line with Stephen's published insights, the REGG differs from [Research Ethics Committees] in considering and advising on non-research public health practice, for example surveillance, service evaluation and market research" [5.1].

To refer again to the 'master argument' in Section 2, Holland's views on the threat of 'regulation inflation' was the basis for devising REGG documentation. In particular, Holland "led discussion" [5.1] to devise and develop criteria for REGG review of PHE's information-gathering activities, based on his published views about proportional review, as detailed in Section 2 [3.6]. The upshot was a triage system of ethics and governance that included all PHE information-gathering activities, whilst avoiding 'regulation inflation' beyond practicability, by ensuring that submissions had proportionate review, as confirmed by PHE: "With Stephen as chairman, the initial tasks were to understand and define the scope of PHE's work relevant to the group, develop Terms of Reference, *devise proportionate ethics consideration and monitoring processes* and develop supporting documentation for guidance, to receive submissions and to engage with applicants" [5.1, emphasis added].

4.2 Examples of Impact following from the Guiding Principles Established for REGG on the Basis of Holland's Research

4.2.1 Ethical Oversight of Market Research Studies

Before REGG was set up, PHE allowed market research companies to collect data in their name without any form of ethical oversight, despite the fact that market research studies "may collate, use and share personal information, including that provided by vulnerable people" [5.1]. Holland's research insights into anti-exceptionalism and proportionate review – as set out in the 'master argument' above – were central to REGG's response to this omission: "Stephen led discussion to establish and communicate expected standards of ethical practice and how the studies would be reviewed" [5.1]. The upshot was an innovative proportionate process for ensuring that market research now has ethical oversight, and meets industry standards of good governance, without overwhelming the committee [5.3]. From 2015, REGG reviewed and required changes to market research into a wide range of highly sensitive subjects, including a dementia awareness health check, school food standards, alcohol-related violence, and HIV-related attitudes and behaviour [5.4].

4.2.2 Embedding of Guiding Principles of REGG into PHE's organisational culture

The shift from allowing information-gathering activities sponsored by PHE to proceed without ethics committee scrutiny, to the current system of REGG review and approval, required a discernible change in PHE's informational culture. REGG's review of PHE projects in line with their guiding principles, and feedback given as a result of review, gradually made PHE researchers aware of ethical issues raised by their projects and the requirement to submit for ethical approval: "Colleagues developing research and public health practice studies appreciate the REGG feedback and increasingly are approaching the REGG to confirm study classification (research or non-research) and guide them through regulatory requirements, particularly the changes to data governance and sharing following the introduction of GDPR" [5.1]. The embedding of Holland's guiding principles of public health research ethics in the organisational culture of PHE is evidenced by, "an increasing percentage of applications approved by the REGG on initial review with a decreasing percentage requiring correction and resubmission. This is evidence of the improved quality of submissions" [5.1].

4.2.3 Bringing Ethical Oversight to a Range of Information Gathering Activities Affecting Large Numbers of Participants

The extent of REGG's impact on PHE's activities is captured in activity data [5.4] and illustrated as follows. The total number of applications to REGG increased from 10 in 2015, to 37 in 2016, 46 in 2017, and 54 in 2018 [5.1]. In addition to these submissions for full REGG review, as Chair, Holland was also instrumental in decisions affecting other information-gathering activities, including providing advice – informed by his body of research – to the PHE's Head of Research Governance, and taking Chair's Action on studies that did not require full review. In so doing,

Holland drew on his published views on the risks and benefits of public health information gathering, as outlined above [3.1, 3.6]. As the numbers grew, so too did the diversity of activities which came under scrutiny. REGG reviewed studies into the most pressing public health issues, ranging from the spread of the Zika virus and Ebola, coastal flooding and health protection, emergency preparedness, and responses to the Salisbury Novichok poisoning. REGG reviewed studies of the most sensitive and delicate kind, including particularly vulnerable participants – such as children, and prison populations – and highly contentious and politicised issues, such as sexual and reproductive health. The studies within REGG's remit involve huge numbers of participants, because public health research and practice require large quantities of data from a big pool of participants; this is one of the main reasons standard principles of research ethics do not apply well in public health (e.g., there are too many people in public health studies to get individual consent from each of them [3.1, 3.6]).

To illustrate the size of projects REGG reviewed. (1) A sentinel surveillance system for antimicrobial resistance among community acquired urinary tract infections was piloted throughout Greater Manchester in 2017 [5.5]; (2) a study to improve the enhanced surveillance of at-risk infants born to hepatitis B virus (HBV) infected mothers in 2018 required venous samples from ~3000/year HBV-infected mothers [5.5]; (3) a cross-sectional study in 2018 administered an electronic health outcome survey to all healthcare practitioners working throughout England - including General Practitioners, Medical Consultants, and Nurses and Allied Health Professionals - recruited through the Royal Colleges and member bodies for health care and allied health care professionals [5.5]; (4) in 2016, when REGG reviewed a study aimed at establishing a GP-based sentinel surveillance network to understand blood borne viruses (BBV) in migrants, including refugees and asylum seekers in England, the number of migrants registered with a GP in England for the first time – which was taken as an indication of how many new migrants would be affected by the study – came to 713,000 [5.5]. These four examples demonstrate how the total sum of participants involved in studies scrutinised by the REGG from 2015 easily numbers in the millions.

4.2.4 Protecting Study Participants

PHE studies which fall under REGG's remit - including both research and non-research activities, as informed by Holland's research - involve members of the general public. So, REGG review and approval ensures the public's safety, including minimising or avoiding risks and harms of participating in studies and providing data: "This is demonstrable among PHE staff in their improved expertise and confidence in managing ethical dimensions of research and other studies, thus benefitting the safety and well-being of study participants" [5.1]. Changes required by REGG altered the public's experience of PHE research and other information-gathering activities.

In this respect it is crucial that REGG did not simply rubber stamp PHE research and practice; on the contrary, many of the studies REGG reviewed were shown by the committee's guiding principles to be ethically problematic. For example, 72% of research studies, and 58% of non-research public health practice studies, submitted to REGG in 2016 needed changes and a resubmission to REGG prior to approval [5.1]. Changes to studies required by REGG ranged from minor to substantial amendments. As an indication, the sorts of changes required by REGG to studies submitted in 2018 ranged from recruitment of participants (including acquiring appropriate consent), the content of participant-facing documents (such as information sheets and consent forms), data management (especially in light of GDPR and other recent data protection legislation), and dissemination of findings [5.4]. REGG also reviewed the scientific quality of studies, including research design (e.g., sample size) and method of statistical analysis, as grounded in Holland's published views [3.4].

To illustrate the ways in which REGG decisions impacted on study participants, a study to review dry blood spot testing in HMP Liverpool, and another into Bowel Screening in North West Prisons, both from 2018, required rewritten Information Sheets and Consent Forms to ensure that the prisoners were properly consented into the study; to provide appropriate access to support services if prisoners were upset by participation; to detail strategies in the event that the research revealed "incidental findings" such as poor practice in prisons; and to make improvements in data management [5.6]. Prior to the foundation of the REGG in 2015, whose

monitoring processes were underpinned by Holland's research, such oversight to protect the interests of participants in PHE studies did not exist. Rejecting some applications for ethical approval, and requiring full overhaul and resubmission of others [5.4], resulted in REGG "impacting positively on the quality of research and other public health studies led by PHE staff" [5.1].

4.2.5 Influencing the Ethical Governance of Public Health Research Globally

REGG's impact extends beyond the UK. To illustrate, during the Ebola outbreak in Sierra Leone in 2014/15, clinical specimens and accompanying data were collected from routine diagnostic testing, then transferred to PHE laboratories in the UK for curation. The biobank held approximately 9,955 samples of which 1,108 were positive for Ebola. The Ministry of Health and Sanitation in Sierra Leone (MOHS) retained ownership of the data and materials, and agreed to work with PHE and other collaborators on a series of research projects to inform future public health strategy relating to Ebola. The PHE-MOHS Ebola Biobank Governance Group (EBGG) was established in 2015 to coordinate access to the data and materials for researchers and to ensure effective use of the resource. The remit of the group and the arrangements for the group's oversight of the biobank were reviewed by REGG, which required changes to the way the EBGG was modelled, prior to REGG providing approval. The constitution of the REGG in line with its guiding principles – as informed by Holland's research – thus gave PHE a structure through which to ensure that the ethical implications of emergent situations could be dealt with effectively. This helped address press criticism regarding the removal of samples from West Africa at the end of the Ebola outbreak: "the arrangements that have been put in place at PHE are regarded as being a good model for transparency and for ensuring that all ethical and governance concerns are addressed when the samples are used for research" [5.7].

4.2.6 Continuing Impact: Covid-19

At the end of Holland's tenure, REGG was described by PHE's Chief Executive as "a high performing ethics committee providing an efficient and high-quality service" [5.8]. Subsequently, REGG has continued "in line with the Group's Terms of Reference" as established by Holland [5.1] and based on Holland's research. To illustrate, REGG has "played a vital role in the government's response to the Covid-19 outbreak" [5.1]. In particular, REGG has fast tracked twenty-eight PHE led studies into coronavirus since Covid-19 was first reported in the UK [5.1]. This process of expedited review is based on the triage system developed from Holland's research [3.6], and further demonstrates the wider impact of REGG: "these reviews have allowed investigations to proceed safely and quickly in a rapidly changing environment so that PHE could provide government, local government, the NHS, Parliament, industry and the public with evidence-based professional and scientific knowledge to manage and control the spread of this disease" [5.1].

5. Sources to corroborate the impact (indicative maximum of 10 references)

5.1 Testimonial letter from (jointly) Director, Research, Translation and Innovation at Public Health England, and Head of Research Governance, Research Translation & Innovation Division at Public Health England
5.2 REGG committee documents: Terms of Reference; Minutes of Annual Meetings of REGG 2015-2019
5.3 Process for the Approval of PHE Market Research Studies
5.4 REGG activity data 2014-2019
5.5 Official PHE documents relating to large-scale studies
5.6 REGG review forms relating to two prison studies
5.7 Email confirming REGG review and approval of the EBGG, from Head of Research Governance, Research Translation & Innovation Division at Public Health England
5.8 Valedictory letter from Chief Executive of Public Health England