*Note: This is the author’s post-print version of an article published in the Journal of Medical Ethics (Online First in 2018). The final publication is available via BMJ (which retains copyright) at* [*http://dx.doi.org/10.1136/medethics-2017-104550*](http://dx.doi.org/10.1136/medethics-2017-104550) *.*

**Consent and the ethical duty to participate in health data research**

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**Abstract**

The predominant view is that a study using health data is observational research and should require individual consent, unless it can be shown that gaining consent is impractical. But recent arguments have been made that citizens have an ethical obligation to share their health information for research purposes. In our view, this obligation is sufficient ground to expand the circumstances where secondary use research with identifiable health information is permitted without explicit subject consent. As such, for some studies the IRB/REC review process should not assess the practicality of gaining consent for data use. Instead the review process should focus on assessing the public good of the research, public engagement and transparency.

**Introduction**

Patients, communities and the public have interests in controlling access to and use of personal health information[[1]](#footnote-2). These interests relate to privacy, identity, stigma, inequality, and ‘the right to be forgotten’.[2–4] But patients, communities and the public also have an interest in the efficient use of resources, including health data, to drive innovation and more effective, safer, cheaper healthcare. Regulatory regimes must try to balance these competing interests. We do not dispute the legitimacy of any of these interests, but advocate for a shift in how these interests are weighed. One argument in favour of greater use of health data is based on citizens’ ethical obligations to participate in health data research. We argue that this obligation can ground waivers of informed consent for secondary research using public sector health data, even when obtaining such consent would be practicable.

**Obligation to participate in research**

Various authors have challenged the established view that research participation is voluntary and supererogatory and have instead proposed that citizens have a moral duty to participate in health research. [5–9] The literature identifies three potential grounds to support the obligation to participate: beneficence; fairness; and civic responsibility to support public goods. Beneficence, or more specifically the ‘rule of rescue’, demands that citizens participate in research where doing so results in minimal personal harm and offers the potential to save future lives or prevent serious suffering.[8]Fairness requires that we participate in research because have benefited substantially from the health knowledge derived from previous subjects. [8–11] Finally, health knowledge is a public good and citizens’ duty to preserve this public good entails volunteering as a research participant.[10–12]

We are neutral here on the specific grounds for supporting an obligation to participate but are generally convinced that such an obligation exists. We will not defend such an obligation, as these arguments are well developed in the existing literature. In this paper we want to explore a plausible implication of such an obligation in the growing field of health data research. The existence of a moral obligation to participate does not, on its own, necessarily license compulsory research. Context matters – how the obligation should apply depends on the nature of the research. Here we contribute to the existing literature by considering how an obligation to participate should apply to consent waivers in the context of data research.

Even among proponents of the duty to participate, few support conscription of competent adults into interventional research[[2]](#footnote-3), in the way that citizens are conscripted to jury service or compelled to pay taxes. Conscription into interventional research would breach legal and ethical norms regarding bodily integrity and autonomy, would risk significant harm to individuals, and would potentially damage public trust in health research. But could the obligation to participate in health research be binding in contexts where bodily integrity is maintained and the harms of participation are much lower? Consider the use of health data for secondary use research.

‘Secondary use research’ refers to the use of health data for research, where this research is outside the scope of the original data subjects’ consent. The use of health data from clinical records avoids many of the pitfalls of traditional highly-controlled health research in that it involves analysing interventions (often multiple interventions as once), provided to realistic patients (for example, with multiple co-morbidities), in representative clinical contexts (often under-resourced).[10] As such, it has some advantages over traditional research in producing meaningful health knowledge that is of public benefit.

Researchers can typically access a*nonymised* health data for research. But access to *identifiable* health data is often required for the purposes of data linkage or data hygiene (ensuring that data is complete and error-free). The default ethical position is that observational studies, even those that do not involve direct engagement with the subject, require subject consent.[11–13] Therefore data collected for health purposes cannot generally be used for a secondary purpose such as research without explicit consent. Many jurisdictions allow for an Institutional Review Board (IRB) or Research Ethics Committee (REC) to waive the consent requirement for secondary use research, where gaining consent would be impractical, or would impede the scientific validity of the study, and where the study addresses important health questions and poses minimal harm to participants.[14–18] Ethical exceptions have also been made for public health surveillance research. [19] Specific rules vary between jurisdictions. The expectation is that this waiver would be used rarely and the default position is that subject consent is required prior to accessing identifiable health data.

Here we challenge this default position based on the notion that citizens have an ethical obligation to share their health information for health research. In our view, this obligation is sufficient ground to expand the circumstances where secondary use research with identifiable health information is permitted without explicit consent.

If researchers can already apply for an IRB/REC waiver to use identifiable health information without consent, how does our model change the status quo? *Researchers would no longer be required to demonstrate that gaining consent is impracticable and/or that consent might introduce bias*. This would orient the review process away from consent, towards public good, transparency and data security.

Our account is limited to public sector health data. Public resources should be managed in a way that maximises public benefit. Our view is that health data generated in a public health system is a public resource for three reasons. First, the datasets will include data regarding many, if not all, citizens. Second, the data holds value for the public because it provides a platform for answering important questions about health and human flourishing. [20] The results of research using public sector health data can drive improvements in those very systems of public health care delivery, public health initiatives and other public enterprises. Third, there is some public claim on the data due to the public expenditures that were necessary for the data’s generation including training and employing health staff, as well as funding data collection and storage systems. Individuals rely on the health system to extract, interpret, process, classify and store their health information. Indeed, it has been suggested that public health research requires rethinking traditional research ethics frameworks. [21] Our proposal involves just such a rethinking.

Some of these arguments may also be applicable to private sector health data, and this will vary according to jurisdiction and the balance between public and private healthcare provision. For the purpose of this paper, we limit our arguments to public sector health data.

**Addressing criticisms**

While we accept that there is a general obligation to participate in research, this is a controversial position, both sides of which have been well developed in the literature. Here we explore three of the most powerful objections to enforcement of the obligation to contribute to research. Our intention is to show that these objections are not compelling in the case of data research; so that those who hold that the obligation to participate in research is not enforceable in *general*, could support enforcement in the *specific* case of data research.

Lack of access to the benefits

This critique is targeted at an obligation to participate in research grounded in fairness. Some have argued that access to, and benefit from, health knowledge is so unequal that an obligation to participate in research cannot be binding on all citizens. de Melo-Martin notes that “millions of people in the US have little or no access to the benefits of biomedical research.”[22]

We acknowledge huge, and in our view unjust, inequalities in access to health knowledge both within and between countries. But it is an overstatement to suggest that many people fail to benefit at all from health knowledge, or even benefit very little. Public health interventions such as sewerage, sanitation, clean water supplies,[23] fortification of food[24] and vaccinations[25] are largely responsible for the dramatic increase in life expectancy and decrease in childhood mortality in middle and high income countries. A large portion of these gains can be linked directly to research that established effective interventions.[26] And indeed, other civic duties such as jury service are not dependant on the degree to which a citizen has personally benefited from the justice system. Furthermore, if disadvantaged groups withhold their data from research, we risk further exacerbating health inequalities, insofar as data analysis and resultant health policies would be relatively insensitive to the needs and reality of those groups. [27] If fairness is a primary concern, an opt-in data research model that exacerbates inequalities within a community should be rejected.

In addition, in the case of secondary use research, the amount of health data generated by the individuals is likely to correspond to the amount of care received as patients. Patients who receive more clinical care generate comparatively more health information that is then available as a resource for future research. To be sure, utilisation of public health services does not necessarily entail benefitting from public health services, or reflect baseline health needs. However, if public sector healthcare delivery is not completely dysfunctional, the contribution of the patient to health research (via the use of health information) would be broadly *proportional* to the benefit of clinical care the patient receives.

Subject protection

Enforcing the obligation to participate means some individuals would become research participants who would prefer not to.[[3]](#footnote-4) Bypassing consent in this way could be seen as a failure of adequate subject protection, due to lack of respect for autonomy and exposure of subjects to risks they would otherwise avoid.

We can distinguish, however, between the severity of autonomy violations in *interventional* research and *observational* research. With interventional research, there may be a direct violation of bodily integrity. We agree that bloodily integrity trumps the goal of improving medical knowledge and therefore citizens should not be forced to participate in such research. And even enforcing the obligation for interventional research that does not involve bodily intervention is questionable, insofar as it amounts to actively and directly affecting some aspect of their lives without their consent.

But providing researchers access to health data does not involve an invasion of bodily integrity or other active intervention. There is still some loss of control, to be sure, over subjects’ personal data. This loss of control does not directly affect any individual’s personal experiences or life course; as such, it is much less central to our self-governance. By restricting our proposal to secondary data research, the violation of autonomy involved is kept relatively minimal and can plausibly be overcome by the strength of the obligation to participate.

Relatedly, data research will pose significantly fewer risks to subjects than interventional research. The primary risks to individuals will involve data breaches. But these can be managed by a robust regulatory system – ensuring a reliable data security system, and an assessment that risks to data subjects are minimized and proportional to the benefits of the study. For this reason, enforcement of the obligation to participate must be accompanied by stringent measures to keep risks minimal; we discuss some of these measures in more detail below.

Public trust and the social licence

However, enforcing the obligation to contribute health data for research could significantly undermine public trust in researchers as well as health systems. Subjects could withdraw from health services that are contributing data, or be less willing to participate in voluntary studies due to a lack of confidence in researchers’ respect for their rights and autonomy. This can jeopardize citizens’ access to essential healthcare and threaten the health research enterprise. The most vivid example of this is the care.data debacle, where the UK government moved to allow greater access to clinical records for research on the grounds that the ‘social licence’ for the use of secondary use research was more permissive than the current UK regulatory environment allowed. There was significant and unexpected public backlash which led to the programme being shelved.[29]

We believe this is the most significant barrier to our proposal. The following regulatory model aims to minimise harm and promote transparency and public trust. This model must be introduced with care and a commitment to public understanding and engagement. Our proposal involves bypassing the consent of potential participants; in order to mitigate that lack of consent on the part of individuals, broad support on the part of society is necessary. Legislative action, rather than regulatory adjustment, is safest to ensure transparency and public acceptability. In addition, there should be robust public debate over the merits of the proposal; we hope this article will help prompt just such a debate.

**Regulatory changes**

Many jurisdictions permit a REC/IRB to provide a waiver of consent for the use of potentially identifiable health information if gaining consent is impossible or impractical (the ‘impracticality ’ test), sometimes with the additional requirement that the research is determined to be in the public good (synonyms for public good in different documents include common good, public benefit, public interest).[11,12,17]

Big data studies will meet the ‘impracticality’ test reasonably easily because of the size of the datasets and the number of data subjects involved. However, many smaller to medium size projects involving niche datasets may not meet the impracticality test and could be impeded, and/or required to spend considerable money and time in tracking patients and gaining consent for the secondary use of their health information. In response to the challenge that consent poses in the context of data research, several models have been proposed to make the consent process fit for purpose, including broad-consent, meta-consent and dynamic-consent [30] *How* to make consent work in the age of data, and *when* lack of consent is an appropriate ground for blocking research, are vexing ethical and policy questions.

We propose that the obligation to share health data for research justifies removing the ‘impracticality ’ test for obtaining a waiver to use health information for research without consent. The ‘impracticality ’ test is normally justified on the presumption that potential subjects have the right to decline to participate in research. But as we claim individuals have an obligation to share their public health sector data with researchers, it could be ethically acceptable for researchers not to seek consent from them even if obtaining consent were practicable.

An obligation to share data should only be enforced when the following regulatory measure are in place. These include requirements regarding data security, an obligation to de-identify data as much as possible, potential legal and/or financial ramifications for researchers who breach patient privacy or confidentiality provisions, review of the scientific integrity of the proposed data analysis, and obligations regarding transparency.

Transparency is especially important in the absence of consent because it facilitates accountability, public trust and debate about the uses of health data. Information about potential research use should be available at the point of enrolment with a health service, the point of data collection (posters in prominent public spaces), and centrally (government and organisational websites). In our view, minutes of IRB/REC review of applications for secondary use should be publicly available, including both applications that were approved and declined. A publicly accessible and easily searchable database of approved research studies is required. Regular audits, evaluation and analysis of research uses should be carried out and published. Breaches of data security should be recorded and published in a manner that protects the interests of victims. These transparency mechanisms would give citizens more information about how health data analytics are used to determine social policy that affects them.

Public good

If the ‘impartially test’ is dropped, a ‘public good’ test should be strengthened in jurisdictions that already require this (including Singapore, New Zealand, and Australia) and introduced in jurisdictions where this is not an existing requirement (e.g. the US and UK). An obligation to share health information for research is premised on the public good that will result from the research. Even where a public good test already exists, the concept remains under-defined. Here, we explore the components of public good relevant to granting a waiver of consent for research, in the absence of an impracticality criterion. (see Table 1)

Minimum requirements

Two factors are both relatively easy to define and directly relevant to whether a study should be said to fulfil the public good test: no restrictions on publications and lack of patents or other use-restricting copyrights on results.

Some study sponsors may, for financial or political reasons, seek to censor results that run contrary to their interests. Selective publication is inimical to the idea of public good. Preventing unfavourable results from being disseminated results in publication biases and unreliable information to inform health policy. Requiring sponsors to guarantee non-interference in publications should be a necessity for the sort of consent waiver we envisage here. And even if results are published, patents and other copyright restrictions can prevent the broader uptake of the results and inhibit its impact. While authors should have their intellectual contributions recognised, further restrictions on use and attempts to commercialise are contrary to the research’s status as a public good.

Further considerations

Meeting these minimum requirements is not sufficient for a study to pass the public good test. IRBs/RECs should also be guided to consider a wider array of factors that contribute to a study’s contribution to the public good. This primarily involves an assessment of the magnitude of the social value of the study. Social value can be achieved in a number of ways.

First, the research could offer significant potential benefit across the whole population by addressing conditions causing high morbidity or mortality.

Second, the research could address a source of health inequity between populations. Equity is a core public value and research that seeks to improve the health of vulnerable or disenfranchised groups contributes to the public good.

Third, the research could address the needs of populations traditionally excluded from research. Potential target populations include for example pregnant women, neonates, adults unable to consent, and patients with co-morbidities. Systematic exclusion from research is driven by a desire to control variables in research and assumptions about vulnerability. Research seeks to control variables, and patients with complex physiology (for example pregnant women and patients with co-morbidities) involve more variables that can affect the data analysis. In addition, some patient groups are deemed vulnerable and are excluded in order to protect them from the potential harms of research (for example pregnant women, neonates and adults unable to consent). But on the grounds of justice, all patients deserve access to evidence-based care that is safe and effective. Evidence-based care requires research. Attempts to protect patients by excluding them from research simply expose these same patient groups to the risk of untested treatments in the clinic. Often these complex or potentially vulnerable patients receive a significant amount of clinical care and therefore produce ample health data that can contribute to addressing gaps in the evidence-base. Addressing lacunae in existing research improves the social value of a study by mitigating concerns about the unjust distribution of benefits of research.

Fourth, the research could be made publicly available via open-access journals and/or repositories. One ethical justification for the use of health data isproviding evidence that can be used to formulate sound policy.Restricting access to publications will limit the results’ accessibility, particularly to those who lack institutional subscriptions to the relevant journals. Similar considerations should apply to datasets – publishing anonymized/aggregated datasets for use in future research serves to maximise the use and value of the data.

A final relevant consideration is the extent to which researchers have engaged with patient groups in terms of pre-research consultation, ongoing partnership and/or patient involvement with the research governance. This involvement helps ensure public buy-in, both bolstering claims about the research’s response to important group priorities and increasing the likelihood of acceptance and uptake of results. Public good claims will be more robust when researchers can cite the perspectives and engagement of external stakeholders.

**Conclusion**

We believe that on balance our model will facilitate more research that can improve healthcare delivery while still maintaining robust review of the ethical issues associated with health data use. In many ways our model is more demanding than existing criteria for secondary use; but it shifts the focus of ethics review away from consent, to the more substantive and relevant issue of public good. It is based on a sound duty to share data, and is a legitimate policy insofar as it enforces that duty without unduly burdening potential subjects of the data research.

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**Table 1: How to assess public good**

|  |  |
| --- | --- |
|  | Components of public good |
| Minimum requirements | Sponsors may not censor publications |
| Research results may not be patented or commercialised |
| Further factors for IRB/RECs to consider | The magnitude of the potential social value of the research relative to its risks and burdens |
| Whether the research addresses health inequities or the needs of disenfranchised or vulnerable patient groups |
| Whether the research addresses the needs of groups traditionally excluded from clinical research and therefore lacking in robust evidence to guide clinical care |
| Whether the research will be made publicly available and open-access |
| Whether the research has engaged with patient groups in terms of pre-research consultation, ongoing partnership and/or patient involvement with the research governance |

1. We define health information as health and biological data derived from: medical records, genome sequences, biomarkers, body and brain scans, data from clinical trials or observational studies, and lifestyle information collected directly by individuals. See the Nuffield Council of Bioethics. [1] [↑](#footnote-ref-2)
2. However some do support the enrolment of incompetent adults (unable to consent) into interventional research, such as comparative effectiveness research in ICUs. [11] [↑](#footnote-ref-3)
3. Some have argued that taxation alone may satisfy the duty to support research. See for example [28]. We would argue that funding is not commensurate with providing data for research. Biomedical research needs data about participants as well as financial support. See for example the arguments represented in [7]. [↑](#footnote-ref-4)