*Note: This is the authors’ 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* [*https://jme.bmj.com/content/early/2020/05/06/medethics-2020-106152*](https://jme.bmj.com/content/early/2020/05/06/medethics-2020-106152) *.*

**Public interest in health data research: laying out the conceptual groundwork**

**By Angela Ballantyne[[1]](#footnote-1) and G. Owen Schaefer1**

**Abstract**:

The future of health research will be characterised by three continuing trends: rising demand for health data; increasing impracticability of obtaining specific consent for secondary research; and decreasing capacity to effectively anonymise data.  In this context, governments, clinicians and the research community must demonstrate that they can be responsible stewards of health data.  IRBs and RECs sit at heart of this process because in many jurisdictions they have the capacity to grant consent waivers when research is judged to be of particular value. However, several different terms are used to refer to this value (including public interest, public benefit, public good, and social value), indicating a lack of conceptual clarity regarding the appropriate test for access to health data for research without consent.

In this paper we do three things. First we describe the current confusion and instability in terminology relating to public interest in the context of consent waivers. Second we argue for harmonisation of terminology on the grounds of clarity, transparency and consistency. Third we argue that the term ‘public interest’ best reflects the normative work required to justify consent waivers because is the broadest of the competing terms. ‘Public interest’ contains within its scope positive and negative implications of a study, as well as welfare, justice and rights considerations. In making this argument, we explain the normative basis for consent waivers, and provide a starting place for further discussion about the precise conditions in which a given study can be said to advance the public interest.

Ipsos MORI study found that:

. . . the public would be broadly happy with administrative data-linking for

research projects provided (i) those projects have social value, broadly defined

(ii) data is de-identified, (iii) data is kept secure, and (iv) businesses are not

able to access the data for profit.

**Introduction**

Routinely gathered patient health data have the potential to transform healthcare.[[2]](#footnote-2) Data is critical to precision medicine, understanding service utilisation, training artificial intelligence (AI) and improving diagnostic accuracy. The volume of health data and its potential value is increasing. In turn, demand for access to routine health data is growing, within and outside of the health sector and in both the public and private spheres.

Research ethics standards are undergoing revision in many jurisdictions as governments attempt to respond to advances in technology and demand for data. Options to effectively *anonymise* clinical or genomic data are dwindling rapidly.[1,2] Therefore, data sharing now involves either de-identified or identifiable data. De-identified data can be potentially re-indented and this risk varies depending on the nature of the data, the de-identification techniques used and environmental factors such as the possibilities for data linkage. Most countries still allow relatively liberal sharing, and even selling, of de-identified health data.

But for various reasons, researchers often require access, at least initially, to identifiable health records. [3–5] This can be due to the variable quality of the original clinical data, and the need to check, clean and remove errors or inconsistencies before the data is used for research. Alternatively, researchers might need identifiable data in order to link different datasets – e.g. data from mortality, birth, pharmaceutical, or condition-specific registries; or in the case of precision medicine, to link genomic, environmental and behavioural data.[6] In this paper we focus *only* on the ethics of using identifiable health data for research.

Researchers using potentially identifiable patient data typically will fall under research ethics regulation for observational research. Often the proposed secondary uses of the data will not be covered by the existing patient consent, and re-consenting all the patients in the dataset would be impractical.[[3]](#footnote-3) Therefore many jurisdictions allow Institutional Review Boards (IRBs) or Research Ethics Committees (RECs) to grant consent waivers, providing researchers access to identifiable health data for research in the absence of specific patient consent. National and international guidelines provide IRBs/RECs with criteria for judging when to allow researchers to use health data without patient consent.

Some jurisdictions with universal or public health systems, including Australia, New Zealand and Singapore[[4]](#footnote-4), require that the data use without consent must serve the public interest, or be likely to produce public benefit. This requirement is supported by global empirical research which consistently shows that the public is more willing to share their clinical data for research when that research offers public benefit.[9,10]

The notion of public interest does much of the normative justificatory work in the current biomedical data research ecosystem. [11,12] But the idea itself remains ambiguous, for two reasons. First, there are a remarkable number of different terms in play. Four common terms found in the bioethics literature and research regulations are: public interest, public benefit, public good, and social value. In addition, the following less common terms are also used: community benefit, common good, common interest, collective interests, collective good and social benefit. These terms seem to be used interchangeably, often within the same document. The number of different terms gives greater scope for divergent interpretations of their meaning. Second, for the most part these regulatory and guidance documents do not define the terms. This lack of clarity creates uncertainty about what the public interests criteria require, and provides for a wide scope of varying IRB/REC interpretation. Empirical research shows that RECs find interpreting public interest on behalf of a pluralistic community stressful and ambiguity regarding the scope and meaning of these terms contributes to this stress.[13]

The sustainability of biomedical research using identifiable health data relies upon earning public trust. The research community must demonstrate that data is being managed fairly and responsibly. Public trust is enhanced by clarity, transparency and consistency. These are important values for researchers applying for consent waivers, for IRBs and RECs trying to implement the guidelines, and the public who is called to trust IRBs/RECs to responsibly govern access to their health data and promote valuable research. We argue that the public interest criterion for data sharing currently lacks clarity and therefore IRBs’ and RECs’ judgements about public interest and benefit lack transparency and consistency. This is a significant risk to public trust and the future of health data-sharing for research.

In this paper we do three things. First we describe and document the current confusion and instability in terminology relating to public interest in the context of consent waivers. Second we argue for harmonisation of terminology on the grounds of clarity, transparency and consistency. Third we argue that the term ‘public interest’ is the broadest of the competing terms as it includes within its scope positive and negative implications of a study, as well as welfare, justice and rights considerations. We argue that ‘public interest’ best reflects the normative work required to justify consent waivers. In so doing, we elucidate the normative basis for consent waivers, and provide a starting place for further discussion about the precise conditions in which a given study can be said to advance the public interest.

**Terminology**

In Table 1 we present some of the most commonly used terms referring to public interest and examples from key guidelines. [[5]](#footnote-5)

|  |  |  |  |
| --- | --- | --- | --- |
| **Table 1: Examples of terminology in regulation and guidance on identifiable health data access for research without consent** | | | |
| Country/Body | Quote | Document | Key term |
| UNESCO IBC | “Overriding **public interest** in this health research.” | Report of the IBC on Big Data and Health [15] | Public interest |
| Ireland | “**the public interest of the research significantly outweighs the public interest in requiring the explicit consent of the individual whose data is being processed.”** | **Health Research Regulations** [16] | Public interest |
| Australia | “…the **benefits** from the research justify any risks of harm associated with not seeking consent” | NHMRC Research ethics guidelines[17] | [public] Benefits |
| New Zealand | “**public interest** in the study outweighs public interest in privacy” (for collection without consent)  “the research has the potential to **benefit the public**” (for linkage without consent) | Guidelines for Observational Research [18] | Public benefit & public interest |
| Singapore | “the human biomedical research or health information research would reasonably be considered to contribute to the greater **public good**.” | Human Biomedical Research Act[19] | Public Good |
| India | “…the research has important **social** **and public health value**…” | ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants [20] | Social/public health value |
| CIOMS | “the research has important **social value**” | International Ethical Guidelines for Health-related Research Involving Humans, Fourth Edition[21] | Social Value |

*Why is the multitude of terms a problem?*

While the authors of the different regulations and guidelines listed in Table 1 may intend to mean something similar, each of these terms caries different connotation and lineages (as we describe below). Users of the guideline may in turn reasonably interpret the terms differently from the intended meaning. In addition, both the intended meaning and the users’ interpretation might differ from the most ethically appropriate meaning of the term. If the authors of the guidelines do intend to refer to the same core idea, it would be preferable to use a consistent term to capture this concept. The terms are very rarely defined or differentiated (we discuss exceptions below) and are sometimes used interchangeably within one document, suggesting that they are meant to capture the same concept. For example, a report from the Institute of Medicine (USA) roundtable on clinical data uses the terms ‘common good’, ‘public benefit’ and ‘public good’ seemingly interchangeably.[22] The Australia National Statement uses the terms ‘benefit’, ‘common good’, ‘public good’ and ‘public interest’ throughout, without a clear differentiation of the terms.[17] In our recent paper in this journal, we too are guilty of ambiguity by defining research as being in the *public good* when, (amongst other criteria) it has high *social value*. [23]

Alternatively, it is possible the authors do in fact mean something different when they refer to common good versus public interest versus public good versus public benefit. This is problematic in a different way. If the meanings of the key terms *do* differ, the guidance documents do not make this clear. This ambiguity will likely lead to confusion and inconsistency. Second, if the terms differ in meaning and multiple terms are used within one document, this amounts to multiple *different* tests that researchers must meet. This approach is not only confusing, but potentially overly burdensome and an unnecessary barrier to valuable research. Third, if the terms mean different things in different documents, this indicates variable standards between jurisdictions. Health data sharing is increasingly a global pursuit and different research ethics standards between jurisdictions can increase the cost, time and energy associated with getting consent waivers for researchers working across jurisdictions, for example on international public health data-sharing. We assume for the purposes of this paper that the despite the various terms employed, they are intended to capture the same central normative idea of an overarching common or public interest in research.

Consistency and speed of review are major challenges for IRBs/RECs and this is likely exacerbated by the use of multiple competing terms The ethics review process has been widely criticized by researchers for being opaque, [24,25] inconsistent, [26–29] and slow and unduly burdensome. [30–32] Slow, unpredictable and inconsistent processes can impede valuable science and frustrate researchers.[30,33] It is plausible that the use of inconsistent terminology and a lack definitions within guidelines generates uncertainty within IRBs/RECs and can slow review and increase variable interpretations. A systematic review of empirical literature evaluating IRBs found evidence of variation in multicentre review with inconsistent or ambiguous interpretation of the federal regulations. [34] Qualitative research with RECs in New Zealand found that the lack of clarity regarding terms such as public interest in the national regulations was a source of anxiety and stress for committee members: “We’re sort of operating in a little bit of the void.” Committee members described the process of approving consent waivers for data and tissue research as leaving “a bad taste in your mouth” and causing “my hairs to rise up on end”.[13] Empirical research in the UK found that the introduction of new regulation and specific guidance for RECs can provide clarity and authority and may facilitate the process of gaining ethical approval for tissue-based research.[35] This empirical literature suggests that the inconsistent use of terminology is problematic for IRBs/RECs trying to interpret and implement guidance and is plausibly slowing review and impeding approval of valuable research.

Note first that the multitude of different terms simultaneously in use is strikingly unusual. By comparison, other core concepts in research ethics do not have multiple synonyms. Concept such as *consent, risk, incidental benefit, autonomy* are referred to by a single consistent term, even where there is debate about the definition of that term. The marked plurality of terms referring to public interest in research ethics is perhaps indicative of conceptual confusion and the necessity for further work to unpack the normative role that the public interest criterion plays in justifying consent waivers. Below we explain the common normative force that underlies these related terms, and explain why this normative force can justify data research without consent.

In our view, it is preferable to move towards greater international harmonisation of data research standards where possible. By harmonisation, we do not refer to formal regulatory alignment across jurisdictions. International regulatory harmonisation may be possible in some contexts such as financial markets [36] an trade,[37] but it is unlikely to be achievable in the area of research regulation, given the existing international regulatory divergences. [38,39] Instead, we are proposing a sort of conceptual harmonisation, where the way the relevant concept is deployed in ethical discourse as well as IRB/REC practice is made more consistent and defensible.[[6]](#footnote-6)

*Conceptual differences between different terms*

To demonstrate the potential for confusion and uncertainty arising from synonymous use of the terms, we take four very similar and commonly used terms and explain their different lineages outside of research ethics. This demonstrates the various connotations and implications the different terms carry.

**1. Public interest** Public interest is the broadest of the terms covered here. Douglass argues that the switch from the language of ‘common good’ to ‘public interest’ occurred in mid-seventeenth century England as part of a liberal and democratic revolt against the overbearing power and demands of royalty.[42] In modern usage, public interest refers to important freedoms and securities often called common goods: civic liberties, freedom of expression, privacy, proper administration of government, justice, national security, public health and safety and economic wellbeing. Common goods consist in “the interests that are the object of the civic relationship”. [43] Determining whether a specific action or policy is ‘in the public interest’ will require consideration of the trade-offs between competing common goods – for example freedom of speech may threaten national security in some cases. We tend to talk of ‘protecting’ the public interest, indicating that many common goods are things that already exist within the community.

**2. Public benefit** By contrast we tend to talk about ‘producing’ public benefit, suggesting that this is the additional benefit produced by research that would enhance the current knowledge or health status of a community. Public benefit might refer narrowly to health status or to wellbeing more generally. Net public benefit is typically assessed by weighing anticipated research harms against expected benefits. Laurie and Stevens define public benefit as one component of the public interest in data use: “the public interest lies in both the robust protection of individual privacy and uses of data that stand to result in wider public benefit.”[44] Public benefit is thus a narrower sub-component of public interest.

**3. Public good** The term public good may invoke (intentionally or unintentionally) the notion of economic public goods. In economic theory a public good is one that is both non-rivalrous (one person’s use of the good does not diminish the amount available for other users) and non-excludable (it is impracticable for one user to exclude others from using the good). A public good is thus one specific type of common good. The Nuremberg Code (arguably the first global research ethics guideline) argues that research should “yield fruitful results for the good of society”. [45] Legal scholar Jonathon Montgomery as argued that “The human genome can be seen as an example of …a public good.”[46]

**4. Social value**

The term ‘social value’ has been popular, especially in US bioethics discourse [47–51] since it was used in Emanuel et al’s influential 2000 paper on the necessary conditions for ethical research - the first of which was that the research have social and scientific value. [52] Council for International Organizations of Medical Sciences’ (CIOMS)uses social value as a core principle in their newly revised 2016 Guidelines, establishing this as a key term in international research ethics. Unlike many other guidelines, CIOMS provides an explicit definition. Social value is “…the importance of the information that a study islikelyto produce”, which can be determined by evaluating the direct relevance of the research for understanding a significant health problem, and whether the research is likely to promote individual or public health. [21]

Social value differs from the prior three terms because it is seen as a necessary basic requirement of all human research. Whereas the terms public interest, public good and public benefit are used more specifically in relation to justifying consent waivers. CIOMS does however use a subcategory of social value to justify research without consent. CIOMS applies a threshold concept of social value, where research conducted in the absence of consent must meet the higher threshold of *important* or *compelling* social value. In relation to human subjects research with participants who are not capable of giving consent (some adults, and children or adolescents[[7]](#footnote-7)) research must be minimal risk, unless there is *compelling* social value, in which case the IRB/REC can approve a minor increase over minimal risk. In relation to consent waivers for data research, the IRB/REC must determine (amongst other criteria) that the research has *important* social value before granting a consent waiver for the use of stored biological material or clinical data in research.[[8]](#footnote-8) CIOMS does not define the difference between important, compelling and ordinary social value.

*‘Public interest’ as the preferred term*

‘Public interest’, ‘public benefit’, ‘public good’ and ‘social value’ all have different meanings, implications and emphasis and should not be used interchangeably. Ongoing use of multiple terms impedes clarity, transparency and consistency – in the administration of research ethics guidelines, empirical research with the public and patients, and academic debate about the normative principles of good data sharing.

Of the above four terms, we propose ‘public interest’ be adopted more uniformly because it better captures the core normative force justifying consent waivers, whilst avoiding the baggage carried by some of the alternate terms. In the next section, we will elaborate on the role these norms play in justifying research without consent. Before turning to that role, we will briefly explain the relative deficiencies of alternative terms.

‘Public Good’, as noted, typically refers to the economic notion of non-rivalry and non-excludability. This may be an apt description of fully *open data*, where none can be excluded from access and use of the data by one party does not reduce the available supply for other researchers. But much health data research is, for good reason, controlled rather than open, and public good may be an ambiguous term to use in these contexts.

‘Social value’ is a problematic term for consent waivers because of its status as a necessary basic requirement of all human subjects’ research. Our present purpose is to explore the concept that offers normative justification for consent waivers in particular. Social value by contrast is used as a term that underpins \*all\* research, therefore using it in the context of consent waiver may lead to confusion and blurring of the line between general evaluations of a study’s contribution to social value, and the more specific question of whether data research without consent is on balance in the public interest.

One might argue that this confusion could be allayed by generating a subclass of ‘social value’ relevant to consent waivers, as CIOMS does in explicating the higher ‘important’ social value threshold for consent waivers. [21] Given the lack of explanation differentiating ‘important’ from ‘ordinary’ social value, this term carries unnecessary ambiguity in relation to consent waivers. Additionally, CIOMS’ explication of social value is problematic because it distinguishes social value from other normative considerations that should be relevant when assessing the justification of a consent waiver. In particular, in Guideline 1 CIOMS explicitly differentiates promoting social value from protecting subjects’ rights. This distinction implies social value is relatively narrow in conceptual scope, not encompassing the *rights* of individuals. As we argue in detail below, consent waivers should take account of a broad range of considerations, including the potential for the research to breach data subjects’ or others’ rights. As rights seem to be excluded from an assessment of social value, this term is too narrow to capture the normative work necessary to justify consent waivers.[[9]](#footnote-9) Social value is therefore broad in its application across all clinical research; but its conceptual scope is narrower than public interest.

Similarly, ‘public benefit’ is problematic in this regard, insofar as it offers a relatively narrow account of what could justify consent waivers. Benefits relate to individuals or groups of individuals becoming better off – it is explicitly welfarist in this regard. Yet other values like distributional justice do not fall neatly into such a benefit rubric. Generating new knowledge that helps address health inequity without improving overall population-level benefit, should be reasonable grounds for a consent waiver. Justice and distributive concerns seem to fall outside the scope of ‘pubic benefit’ and this term is therefore too restrictive to reflect the full range of ethical considerations relevant to consent waivers.

**The role of the public interest criterion**

Our view is that the public interest criterion best captures the primary normative justificatory force for granting consent waivers. In order to better explicate the public interest criterion, we need to understand the purpose and function of the criterion in the context of waivers of consent.

Data research without consent needs some positive justification for the overriding of individuals’ privacy. By granting a waiver of consent to data access, there is an intrinsic privacy violation – sensitive information about individuals’ health is accessed or shared without their knowledge or permission. This poses some material risk to individuals, by increasing the possibility of a data breach due to dissemination of information beyond its original confines. But more importantly, it limits individuals’ autonomy by taking away their ability to control who has access to their health information. Because sharing identifiable data without consent carries some individual risk and impedes the rights of patients it must be justified.

Gelinas, Wertheimer and Miller argue that not all research without consent impedes individuals’ rights. In contexts where there are no rights violations, there would be no need for a public interest criterion to be used. That is to say, there would be no autonomy limitation in need of justification. One example they give is for quality improvement research, where institutions – not patients –presumably have a right of control. [12] One difficulty with this analysis is that it implies control is mutually exclusive, and if institutions maintain control of data patients are deemed to have no relevant interests or rights to control data. Yet insofar as patient health data is co-created by patients and institutions, both patients and institutions retain an interest in the collective governance of that data. [53] Additionally, even quality improvement studies using health data will generally require a certain form of justification with reference the interests of patients served by the institution. For research studies that aim to benefit a much wider array of the public by generating generalisable knowledge, there will need to be a commensurately broad justification that appeals to the public interest.

Importantly, public interest is only one of several criteria that must typically be met in the granting of consent waivers for data research. That is to say, public interest is a necessary but not sufficient condition for granting consent waivers. Other criteria will be familiar across many jurisdictions, particularly: 1) the research must be minimal risk; 2) obtaining consent is impracticable; and 3) identifiable data is needed to meet the study aims. But none of these criteria provide a positive reason for the research or allow for an assessment of the importance of the research relative to the risks. By contrast, the public interest criterion does the normative work of positively justifying the consent waiver. By formally requiring studies to meet this criterion, IRBs/RECs can better ensure that data research without consent is ethically justifiable.

**Scope of the public interest criterion**

We should conceptualize the criterion in a wide, rather than narrow manner, both in terms of its normative content as well as the sorts of populations it covers. ‘Public interest’ is broader than public goods, public benefits or social value.

Jurisdictions that have introduced a public interest criterion for consent waivers seek to ensure that IRBs/RECs consider the broad implications of allowing or preventing the research, both on the individual data subjects involved and the wider community. A broad focus is particularly important in relation to consent waivers because IRBs/RECs are assessing the acceptability and importance of the research on behalf of the public. When participants have the option to consent for themselves, they are able to make a judgment about whether the risks and benefits of the research are acceptable to them. This judgment is morally transformative, in that it makes permissible (in conjunction with other necessary criteria) what would otherwise be impermissible through the exercise of the participant’s agency. [54]

However, where consent is not sought, moral transformation falls exclusively on the shoulders of the IRB/REC. The transformation is no longer a reflection of the agency of the data or tissue subject, but instead reflects the judgments of a duly appointed body tasked with evaluating the public interest of a study (among other things). As such, their assessment of the interests, rights, risks and benefits involved must be broader and more substantial than what an individual participant might consider.

So, while consent and the public interest criterion may perform overlapping ethical functions of moral transformation, they are different tests. When deciding whether to provide consent, the participant may dismiss claims of social benefit, reject without explanation certain considerations as relevant and give idiosyncratic weightage to specific considerations (for example, whether needles involved). The public interest test by comparison requires consideration of more general interests. Because it takes into consideration the interests of a range of affected individuals and groups with diverse values, commitments and circumstances, evaluation of the public interest must abide by procedural norms of publicity such as reasonableness and transparency. [55]

*Wide normative scope*

Ethical justifications may appeal to a wide variety of normative factors, such as welfare, distribution, human rights, respect, and so forth. Most health research, insofar as it aims to generate knowledge that may be used to improve health, will at least be seeking to advance well-being. But it may also attempt to alleviate unjust distributions by addressing neglected diseases, underserved or marginalised populations; or advance human rights by uncovering failures of states to live up to their obligations. Indeed, ‘public interest’ may be particularly consonant with the human rights considerations, given prominent accounts of human rights are grounded in our interests. [56] For example, analysis of health records has uncovered disparities in treatment according to race, ethnicity or gender. [57–60] This is not merely a problem in terms of maintaining the overall health of the population, but potentially an instance of unjust distribution of healthcare resources and/or unequal regard for patients on the part of practitioners.

The justificatory criterion for consent waivers should capture a wide range of these ethical considerations. Perhaps the information from a particular study would only marginally improve a population’s overall longevity, but substantially reduce longevity disparities within that population. The consideration of particular values such as distribution should not be ruled out ex ante by a concept that focuses too narrowly on another value such as welfare.

The concept of public interest is also broad enough to include consideration of the positive and negative elements of a study. In particular, any consent waiver will involve a prima facie setback to public interest, insofar as there is a public interest in respecting individuals’ autonomy by seeking their consent when identifiable data about them is used. As Laurie et al argue “the protection of privacy is itself in the public interest”.[61] The public interest criterion is met when the positive elements of the research, such as contributing to the prevention or treatment of disease, are sufficient to justify the negative elements. Public interest is therefore a fundamentally different type of assessment than public benefit, social value or public good. Public interest requires not just a tally of the positive aspects or research, but a weighing of the trade-offs between different elements of the common good.

This dual aspect of public interest is reflected in the language of the relevant New Zealand and Irish documents cited in Table 1. Both refer to ensuring that the public interest in a study (presumably, relating to the interests advanced by the knowledge generated such as improving healthcare) outweighs the public interest in keeping identifiable health data private.

*Wide population scope*

A narrow population scope might only take into account the interests of members of a particular group, such as those with a disease being studied or residents of a particular country where a study occurs. This might be justified by appeal to values like group solidarity. However, this narrow scope is inadequate because advancing the interest of anyone, no matter their group membership or characteristics, could potentially justify or prohibit a consent waiver. We should then adopt a wide population scope interpretation of public interest, such that the interests of humanity at large rather than particular subgroups can potentially be considered in weighing up whether a study sufficiently advances the public interest. [[10]](#footnote-10) It is important to make this point explicitly because IRBs/RECs are used to assessing the potential harm to a specific group of research subjects. Data research by contrast characterises groups of patients according to shared criteria (for example, disease status, age, smoking history, and genotype) and group harms resulting from the research may extend well beyond the specific data subjects. Stigma and discrimination in insurance, employment or access to health programs will affect future patients who share the relevant criteria, regardless of whether their personal data was used in the original research.

Though we should consider public interest wide in scope at the conceptual level, practical factors about individual studies may justify narrowing the scope in particular contexts. For example, the knowledge generated by a study on the impact of a particular country’s medical financing system may not be have implications beyond the country’s boarders, because its system is unique and insights relating to its implications cannot be generalized to other countries. Conversely, other studies will have more global relevance or impact, necessitating a more global approach to the public interest criterion. For instance, studies on health records relating to the 2015-16 Zika outbreak in countries like Brazil where it was endemic might have direct and pertinent relevance globally as the rest of the world seeks to understand the disease and mitigate potential future outbreaks.[63] IRB/RECs considering whether consent waivers for such studies are justified would do well to take such global interests into account.

The scope should also be ‘existential’ (relating to interests held by *anyone*) rather than ‘universal’ (relating to interests held by *everyone*). A universal quantification of ‘public’ would focus the criterion on those interests that all members of the public share, such as in the prevention of infectious disease. However, some relevant interests strong enough to justify a consent waiver might only be held by a subgroup of society, better captured by existential quantification than universal quantification. It is not, therefore, only population-level studies that could potentially advance the public interest sufficiently to justify a consent waiver. For example, a health records study on rare disease might require a reference dataset from the healthy population. The study would primarily be designed to advance the interests of individuals with rare diseases, rather than society as a whole, and the advancement of those subgroup interests could potentially be powerful enough to justify a consent waiver – something only captured by an existentially quantified version of public interest. This leaves open the question of whether the interests of such a small subgroup will in fact outweigh the interests in privacy of the larger group. But this is something to be settled by IRB/REC evaluation of particular studies, and not ruled out at the conceptual level.

**Implications**

We have argued that the justificatory role of the “public interest” criterion in relation to consent waivers is to provide the positive normative force for granting consent waivers for data use. We have advocated for public interest as the preferable term and concept, ahead of public good, public benefit or social value. Public interest is broader than these other terms in two regards. First it does not focus simply or even primarily on health. Public interest refers the overall assessment of the potential impact of the research of common goods such as privacy, trust, justice in addition to population health. Second, public interest considers both the negative and positive impacts of the research; whereas social value, public benefit and public good aim only to quantify the positive aspects of the study. We have argued that public interest is the right test for consent waivers because sharing health data without consent has broad implications beyond the data subjects.

However there is a potential limitation of the broad approach. The arguments presented here demonstrate the complex and demanding job that IRBs/RECs are asked to perform when assessing requests for consent waivers. Members of IRBs/RECs are unlikely to have expertise or specific training to gauge many elements of the common good, for example the privacy impact or future economic benefit of research. A broader concept will be more challenging to apply in practice and IRBs/RECs will need specific tools to help them assess public interest. [64]

An advantage of our approach is that we make explicit the work required of IRBs/RECs in granting consent waivers and the critical role they are now playing in the new health data ecosystem. This can highlight the evidence committees may legitimately require to make their assessment. IRBs/RECs may ask researchers to commission a privacy impact assessment for their protocol; require researchers to further engage stakeholders to assess perceptions of value and risk; require greater patient and public involvement in the design or oversight of some research; or require a commitment to specific benefit sharing arrangements. Because of the breadth and complexity of the assessment required, IRBs/RECs may need to allocate more time to consider consent waivers.

A major challenge for governments, clinicians and the research community is how to demonstrate responsible stewardship of health and other personal data. IRBs and RECs sit at heart of this process. Future work must focus on aligning terminology and conceptual as well as normative standards for data sharing to ensure clarity, transparency and consistency. An important next step is to operationalise the concept of public interest and develop a workable framework for IRBs/RECs and other decisions making bodies to use when identifying, measuring and weighing different elements of the public interest.

**Works cited:**

1 Kaye J. The Tension Between Data Sharing and the Protection of Privacy in Genomics Research. *Annu Rev Genomics Hum Genet* 2012;**13**:415–31. doi:10.1146/annurev-genom-082410-101454

2 Tucker K, Branson J, Dilleen M, *et al.* Protecting patient privacy when sharing patient-level data from clinical trials. *BMC Med Res Methodol* 2016;**16**. doi:10.1186/s12874-016-0169-4

3 Black N. Secondary use of personal data for health and health services research: why identifiable data are essential. *J Health Serv Res Policy* 2003;**8**:36–40. doi:10.1258/135581903766468873

4 Faden R, Kass N, Whicher D, *et al.* Ethics and Informed Consent for Comparative Effectiveness Research With Prospective Electronic Clinical Data: *Med Care* 2013;**51**:S53–7. doi:10.1097/MLR.0b013e31829b1e4b

5 Federer LM, Lu Y-L, Joubert DJ, *et al.* Biomedical Data Sharing and Reuse: Attitudes and Practices of Clinical and Scientific Research Staff. *PLOS ONE* 2015;**10**:e0129506. doi:10.1371/journal.pone.0129506

6 Frizzo-Barker J, Chow-White PA, Charters A, *et al.* Genomic Big Data and Privacy: Challenges and Opportunities for Precision Medicine. *Comput Support Coop Work CSCW* 2016;**25**:115–36. doi:10.1007/s10606-016-9248-7

7 Ploug T, Holm S. Meta Consent - A Flexible Solution to the Problem of Secondary Use of Health Data: Meta Consent. *Bioethics* 2016;**30**:721–32. doi:10.1111/bioe.12286

8 Budin-Ljøsne I, Teare HJA, Kaye J, *et al.* Dynamic Consent: a potential solution to some of the challenges of modern biomedical research. *BMC Med Ethics* 2017;**18**. doi:10.1186/s12910-016-0162-9

9 Royal Statistical Society. New RSS research finds ‘data trust deficit’, with lessons for policymakers. 2014.https://www.statslife.org.uk/news/1672-new-rss-research-finds-data-trust-deficit-with-lessons-for-policymakers

10 Trinidad SB, Fullerton SM, Bares JM, *et al.* Informed Consent in Genome-Scale Research: What Do Prospective Participants Think? *AJOB Prim Res* 2012;**3**:3–11. doi:10.1080/21507716.2012.662575

11 Miller FG. Research on Medical Records without Informed Consent. *J Law Med Ethics* 2008;**36**:560–6. doi:10.1111/j.1748-720X.2008.304.x

12 Gelinas L, Wertheimer A, Miller FG. When and Why Is Research without Consent Permissible? *Hastings Cent Rep* 2016;**46**:35–43. doi:10.1002/hast.548

13 Ballantyne A, Moore A. Data and tissue research without patient consent: A qualitative study of the views of research ethics committees in New Zealand. *AJOB Empir Bioeth* 2018;**9**:143–53. doi:10.1080/23294515.2018.1518938

14 Dove ES, Chen J. Should consent for data processing be privileged in health research? A comparative legal analysis. *Int Data Priv Law* Published Online First: 25 February 2020. doi:10.1093/idpl/ipz023

15 UNESCO International Bioethics Committee. Report of the IBC on Big Data and Health. Paris, France: 2017. https://unesdoc.unesco.org/ark:/48223/pf0000248724

16 Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018. 2018. http://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf

17 National Health and Medical Research Council (Australia), Australian Research Council, Australian Vice-Chancellors’ Committee. *National statement on ethical conduct in human research*. Canberra: : National Health and Medical Research Council 2007.

18 National Ethics Advisory Committee. *Ethical Guidelines for Observational Studies: Observational research, audits and related activities*. Wellington: : Ministry of Health 2012.

19 Human Biomedical Research Act. 2015.

20 Indian Council of Medical Research. National Ethical Guidelines for Biomedical and Health Research Involving Human Participants. Bengaluru, India: 2017. https://www.icmr.nic.in/sites/default/files/guidelines/ICMR\_Ethical\_Guidelines\_2017.pdf

21 Council for International Organizations of Medical Sciences, World Health Organization. *International ethical guidelines for health-related research involving humans*. 2016.

22 IOM (Institute of Medicine). *Clinical data as the basic staple of health learning: Creating and protecting a public good: Workshop Summary*. Washington, DC: : The National Academies Press 2010.

23 Ballantyne A, Schaefer GO. Consent and the ethical duty to participate in health data research. *J Med Ethics* 2018;**44**:392–6. doi:10.1136/medethics-2017-104550

24 Borgerson K. Redundant, Secretive, and Isolated: When Are Clinical Trials Scientifically Valid? *Kennedy Inst Ethics J* 2014;**24**:385–411. doi:10.1353/ken.2014.0029

25 Hammersley M. Creeping Ethical Regulation and the Strangling of Research. *Sociol Res Online* 2010;**15**:123–5. doi:10.5153/sro.2255

26 Caplan AL. Inconsistency, idiosyncrasy, and IRBs. *IRB* 1984;**6**:10–2.

27 Ahmed AH, Nicholson KG. Delays and diversity in the practice of local research ethics committees. *J Med Ethics* 1996;**22**:263–6. doi:10.1136/jme.22.5.263

28 Maskell NA, Jones EL, Davies, RJO. Variations in experience in obtaining local ethical approval for participation in a multi‐centre study. *QJM Int J Med* 2003;**96**:305–7. doi:10.1093/qjmed/hcg042

29 Goldman J, Katz M. Inconsistency and Institutional Review Boards. *JAMA J Am Med Assoc* 1982;**248**:197. doi:10.1001/jama.1982.03330020041027

30 Petrova M, Barclay S. Research approvals iceberg: how a ‘low-key’ study in England needed 89 professionals to approve it and how we can do better. *BMC Med Ethics* 2019;**20**. doi:10.1186/s12910-018-0339-5

31 Smith M, Doyle F, McGee H, *et al.* Ethical approval for national studies in Ireland: An illustration of current challenges. *Ir J Med Sci* 2004;**173**:72–4. doi:10.1007/BF02914559

32 Kotsis SV, Chung KC. Institutional Review Boards: What’s Old? What’s New? What Needs to Change? *Plast Reconstr Surg* 2014;**133**:439–45. doi:10.1097/01.prs.0000436846.00247.73

33 Richardson S, McMullan M. Research Ethics in the UK: What Can Sociology Learn from Health? *Sociology* 2007;**41**:1115–32. doi:10.1177/0038038507082318

34 Abbott L, Grady C. A Systematic Review of the Empirical Literature Evaluating IRBs: What We Know and What We Still Need to Learn. *J Empir Res Hum Res Ethics* 2011;**6**:3–19. doi:10.1525/jer.2011.6.1.3

35 Angell E, Tarrant C, Dixon-Woods M. Research involving storage and use of human tissue: how did the Human Tissue Act 2004 affect decisions by research ethics committees? *J Clin Pathol* 2009;**62**:825–9. doi:10.1136/jcp.2008.060699

36 Singer DA. Capital Rules: The Domestic Politics of International Regulatory Harmonization. *Int Organ* 2004;**58**. doi:10.1017/S0020818304583042

37 Sykes A. The (limited) role of regulatory harmonization in international goods and services markets. *J Int Econ Law* 1999;**2**:49–70. doi:10.1093/jiel/2.1.49

38 Lamas E, Ferrer M, Molina A, *et al.* A comparative analysis of biomedical research ethics regulation systems in Europe and Latin America with regard to the protection of human subjects. *J Med Ethics* 2010;**36**:750–3. doi:10.1136/jme.2009.035097

39 Alahmad G, Al-Jumah M, Dierickx K. Review of national research ethics regulations and guidelines in Middle Eastern Arab countries. *BMC Med Ethics* 2012;**13**. doi:10.1186/1472-6939-13-34

40 Beauchamp TL, Childress JF. *Principles of biomedical ethics*. 7th ed. New York: : Oxford University Press 2013.

41 Evans JH. A Sociological Account of the Growth of Principlism. *Hastings Cent Rep* 2000;**30**:31. doi:10.2307/3527886

42 Douglass B. The Common Good and the Public Interest. *Polit Theory* 1980;**8**:103–17. doi:10.1177/009059178000800108

43 Hussain W. The Common Good. In: Zalta EN, ed. *The Stanford Encyclopedia of Philosophy*. 2018. https://plato.stanford.edu/archives/spr2018/entries/common-good

44 Laurie G, Stevens L. Developing a Public Interest Mandate for the Governance and Use of Administrative Data in the United Kingdom. *J Law Soc* 2016;**43**:360–92. doi:10.1111/j.1467-6478.2016.00759.x

45 The Nuremberg Code. In: *Trials of War Criminals Before the Nuremberg Military Tribunals. Vol. 2*. Washington, DC: : US Government Printing Office 1949. http://ohsr.od.nih.gov/ guidelines/nuremberg.html

46 Montgomery J. Data Sharing and the Idea of Ownership. *New Bioeth* 2017;**23**:81–6. doi:10.1080/20502877.2017.1314893

47 Barsdorf N, Millum J. The Social Value of Health Research and the Worst Off: The Social Value of Health Research and the Worst Off. *Bioethics* 2017;**31**:105–15. doi:10.1111/bioe.12320

48 Wenner DM. The Social Value of Knowledge and the Responsiveness Requirement for International Research: The Social Value of Knowledge and Responsiveness. *Bioethics* 2017;**31**:97–104. doi:10.1111/bioe.12316

49 Ganguli-Mitra A, Dove ES, Laurie GT, *et al.* Reconfiguring Social Value in Health Research Through the Lens of Liminality: Reconfiguring Social Value in Health Research. *Bioethics* 2017;**31**:87–96. doi:10.1111/bioe.12324

50 Nurmi S-M, Halkoaho A, Kangasniemi M, *et al.* Collaborative partnership and the social value of clinical research: a qualitative secondary analysis. *BMC Med Ethics* 2017;**18**. doi:10.1186/s12910-017-0217-6

51 Wertheimer A. The Social Value Requirement Reconsidered: The Social Value Requirement Reconsidered. *Bioethics* 2015;**29**:301–8. doi:10.1111/bioe.12128

52 Emanuel EJ, Wendler D, Grady C. What Makes Clinical Research Ethical? *JAMA* 2000;**283**:2701. doi:10.1001/jama.283.20.2701

53 Ballantyne A. How should we think about clinical data ownership? *J Med Ethics* 2020;:medethics-2018-105340. doi:10.1136/medethics-2018-105340

54 Hurd HM. The Moral Magic of Consent. *Leg Theory* 1996;**2**:121–46. doi:10.1017/S1352325200000434

55 Daniels N. Accountability for reasonableness. *BMJ* 2000;**321**:1300–1. doi:10.1136/bmj.321.7272.1300

56 Finnis J. *Natural law and natural rights*. 2nd ed. Oxford ; New York: : Oxford University Press 2011.

57 Tammemagi CM. Comorbidity and Survival Disparities Among Black and White Patients With Breast Cancer. *JAMA* 2005;**294**:1765. doi:10.1001/jama.294.14.1765

58 Goel MS, Brown TL, Williams A, *et al.* Disparities in Enrollment and Use of an Electronic Patient Portal. *J Gen Intern Med* 2011;**26**:1112–6. doi:10.1007/s11606-011-1728-3

59 Johnson EK, Daignault S, Zhang Y, *et al.* Patterns of Hematuria Referral to Urologists: Does a Gender Disparity Exist? *Urology* 2008;**72**:498–502. doi:10.1016/j.urology.2008.01.086

60 Lin RY, Lee GB. The Gender Disparity in Adult Asthma Hospitalizations Dynamically Relates to Age. *J Asthma* 2008;**45**:931–5. doi:10.1080/02770900802395504

61 Laurie G, Mallia P, Frenkel DA, *et al.* Managing Access to Biobanks: How Can We Reconcile Individual Privacy and Public Interests in Genetic Research? *Med Law Int* 2010;**10**:315–37. doi:10.1177/096853321001000404

62 Lederman Z, Capps B. Expanding a Shared Benefit Approach in One Health Research. *Am J Bioeth* 2018;**18**:47–9. doi:10.1080/15265161.2018.1513604

63 de Paula Guimarães C, Macedo MS, Barbosa MA, *et al.* Clinical findings in congenital infection by Zika virus: a retrospective study in a reference hospital in Central-West Brazil. *BMC Pediatr* 2019;**19**. doi:10.1186/s12887-019-1762-6

64 Schaefer GO, Laurie G, Menon S, *et al.* Clarifying how to deploy the public interest criterion in consent waivers for health data and tissue research. *BMC Med Ethics* 2020;**21**:23. doi:10.1186/s12910-020-00467-5

1. Centre for Biomedical Ethics, Yong Loo Lin School of Medicine, National University of Singapore [↑](#footnote-ref-1)
2. For this paper ‘health’ includes interventions and systems designed to maintain or restore health including clinical medicine, epidemiology and public health. [↑](#footnote-ref-2)
3. This is true for much research, even given innovative models of consent recently proposed such as broad -, meta- or dynamic- consent.[7,8] [↑](#footnote-ref-3)
4. Notably, however, the latest version of the Common Rule, regulating federally-funded research in the US, does not include a public benefit test (instead it requires that use of health information not infringe participants’ rights and that research be minimal risk). (45 CFR 46.116(f)(3)) [↑](#footnote-ref-4)
5. For reference, the UK and South Africa also have public interest criterion for research consent waivers in respective data privacy laws. However, in those contexts, the assessment of public interest falls on the data controller rather than on an IRB/REC or equivalent as is the case for all the documents listed here. [14] Since we are focused primarily on the concepts as they may be deployed in the ethics review process, we set aside the UK and South African regulations. It is, though, notable that both used the term ‘public interest’, which as we argue below is the most preferable terminology. [↑](#footnote-ref-5)
6. A much more ambitious historical example of such conceptual harmonisation would be the generation and promulgation of the four principles of biomedical ethics. [40] While principlism has attracted considerable criticism, it has become a standard framework and *lingua franca* for conceptualising biomedical ethics issues. [41] [↑](#footnote-ref-6)
7. Guideline 16 – Research involving adults incapable of giving informed consent, and Guideline 17 – Research involving children and adolescents [↑](#footnote-ref-7)
8. Guideline 10 - Modifications and waivers of informed consent; Guideline 11: collection, storage and use of biological materials and related data; Guideline 12: collection, storage and use of data in health-related research [↑](#footnote-ref-8)
9. This is not a criticism of social value and role the term currently plays in ensuring that all clinical research addresses questions are non-trivial, non-redundant and relevant to the health of local populations. However, the conceptual narrowness of social value means it is not well suited to performing the normative work of justifying consent waivers. [↑](#footnote-ref-9)
10. We may further ask whether the scope of the public interest criterion would reasonably be restricted to human interests. Such a restriction could be justified based on the explicit focus of human subjects research. However, an equivalent criterion might be defensible for research projects in other domains, particularly in the area of One Health where the interests of non-humans and environment are explicitly taken into account. [62] [↑](#footnote-ref-10)