# Goldacre Review and Implications for the HRA

## Introduction

On 7 April 2022, the Department for Health and Social Care (DHSC) [announced](https://www.ons.gov.uk/aboutus/transparencyandgovernance/datastrategy/datapolicies/onsresearchanddataaccesspolicy) the publication of the report resulting from the review by Ben Goldacre[[1]](#footnote-1) (commissioned in February 2021) into the safe and effective use of health data for research. The full report can be found [here](https://www.nhsx.nhs.uk/ai-lab/ai-lab-programmes/regulating-the-ai-ecosystem/the-multi-agency-advice-service-maas/), along with a 2 page [executive summary](https://www.gov.uk/government/publications/better-broader-safer-using-health-data-for-research-and-analysis/better-broader-safer-using-health-data-for-research-and-analysis), and an 18 page [summary](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1067058/summary-goldacre-review-using-health-data-for-research-and-analysis.pdf) listing all 185 recommendations.

The report, titled "*Better, broader, safer: using health data for research and analysis*" is aimed primarily at policy makers in the NHS and government, research funders, and those who use NHS data for service planning, public health management, and medical research. The report – which has been informed by interviews, open sessions, and deep dives with stakeholders - focuses on identifying the barriers to making better use of NHS data and suggests how these should be overcome.

While the report acknowledges that progress has been made in recent years to improve the quality and accessibility of UK data assets for cutting edge, data-enabled research (particularly large-scale data analysis through interconnected NHS systems), it concludes that it has not yet been at the scale or speed needed.

## Overview of challenges and recommendation themes

The report breaks down the challenges to the complex landscape of data use, and potential solutions to improve the way health data are stored, accessed, and used, by investigating factors such as technical infrastructure, data quality/useability, transparency, privacy concerns, and cultural considerations related to the existing data governance ecosystem.

At present, it notes that data management systems and regulation are fragmented and siloed - resulting in duplication, and liable to foster monopolies over data - with slow moving and cautious governance systems for data-users. Consequently, researchers consistently cite difficulties in obtaining access to date as the primary blocker of researcher productivity.

To understand the underlying causes, the report refers to a “[culture of caution](https://www.gov.uk/government/publications/better-broader-safer-using-health-data-for-research-and-analysis/better-broader-safer-using-health-data-for-research-and-analysis#information-governance-ethics-and-participation:~:text=This%20culture%20of,range%20of%20factors.)” driven by a range of factors, as well as the diverse range of actors throughout the complex NHS ecosystem:

* an incorrect belief that patients are against data access for research;
* a lack of clarity in the rules, leaving individual decision-makers interpreting the rules feeling exposed by the privacy and ethical consequences of each individual access choice they make; and,
* current reliance by the NHS on less secure methods for data sharing (principally, transferring large volumes of pseudonymised but re-identifiable data to multiple destinations).

This combination means that each decision to grant access requires a very deep trust in every individual data user and organisation involved.

While the report acknowledges that “*new regulatory bodies and checks have been introduced with good intentions*” – together with various existing initiatives to address some of the complexity – it says more is needed to create a more coherent, connected system at scale.

The report therefore makes specific recommendations focused on the following broad objectives:

* Increasing data transparency while reducing the risk of data breaches by moving to the use of a small number of (‘[5 safe framework](https://blog.ons.gov.uk/2017/01/27/the-five-safes-data-privacy-at-ons/)’) secure, shared platforms for accessing sensitive and linked NHS data (Trusted Research Environments). This would be the default approach for de-identified analysis of NHS patient records by researchers without consent for wider forms of data sharing.
* Improving career opportunities for data analysts, including leadership roles, within the NHS.
* Encouraging open working for all NHS data analysis, including open and competitive funding to develop shared access systems, coding, standards, and practices for use across the NHS to improve transparency and cross-working.

Public trust is also recognised as a critical issue in relation to health data research, with an ongoing House of Commons Science and Technology Committee inquiry, [*The right to privacy: digital data*](https://www.gov.uk/government/publications/better-broader-safer-using-health-data-for-research-and-analysis/better-broader-safer-using-health-data-for-research-and-analysis), currently examining issues of concern arising from government ambitions to share personal health data across the health system. As Goldacre says, “*Overall, care.data shows the importance of clear communication, but also the need for clear rules around access, good mitigation for privacy risks, transparency around access, and due recognition of when a new programme is at a scale that pushes the limits the current “social license”.* The report proposes earning public trust through concrete action.

Particular sub-themes are summarised under four headings below as most relevant to HRA responsibilities.

## Streamlining information governance (IG) and ethics

An overly complex combination of “*duplications, delays and contradictions of multiple legal, regulatory, professional, and ethical restrictions*” is said to be undermining UK health research activities. Navigating this complexity is said to be confusing researchers (and the public), as well as being disproportionately slow for lower-risk research projects. The report proposes some key changes to enhance usability for IG and ethics processes through simplification and streamlining the regulatory system, including notably the following suggestions:

1. [Recommendation IG 1. Create a single form for all ethics, IG, and other data access permissions](https://twitter.com/HRA_Latest/status/1499052887716122625/photo/1#information-governance-ethics-and-participation:~:text=IG%201.%20Create,data%20access%20permissions)
2. [Recommendation IG 2. Streamline the number of approvals meetings](https://www.gov.uk/government/publications/better-broader-safer-using-health-data-for-research-and-analysis/better-broader-safer-using-health-data-for-research-and-analysis#information-governance-ethics-and-participation:~:text=IG%202.%20Streamline,of%20approvals%20meetings)
3. [Recommendation IG 5. Create a single map of all approvals](https://ukhealthdata.org/#information-governance-ethics-and-participation:~:text=IG%205.%20Create,of%20all%20approvals)

|  |
| --- |
| **Comments on these recommendations from an HRA perspective:** |
| Many of the IG recommendations do not direct impact on the HRA where they concern non-identifiable data. Nonetheless, and as identifiability determinations are legally complex:  |
| * IG1 - A single form may or may not be appropriate. Much of the complexity related to the need for different forms flows from distinct remits of oversight associated with research data access (e.g., IG, ethics), which can reflect different interpretations (e.g. to oversight remit, purpose, and legal definitions). It is not something that could be built into IRAS now, but could be a long-term ambition.
 |
| * IG2 – A single review meeting where all relevant bodies can collectively review and discuss all aspects of data access on a project e.g., IG, ethics), is unlikely to work in practice where the types of oversight are different, unless the differences in remit are clearly distinguished. HRA are implementing changes to align CAG and REC review. There are already occasions where bodies discuss ‘behind the scenes’.
 |
| * IG5 – The creation of a single map of all required approvals related to data access is in hand. The MRC’s [Health Data Access toolkit](https://hda-toolkit.org/story_html5.html) does much of this already. It is a model that is being developed under the multi-agency advisory service ([MAAS](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1067057/executive-summary-goldacre-review-using-health-data-for-research-and-analysis.pdf)) programme for AI.
 |

Other recommendations under this sub-theme that could impact on the HRA include the following, although the report recognises that effecting cultural change may take longer:

* [Recommendation IG3 – Get researchers in the room](https://www.gov.uk/government/publications/national-data-strategy-open-call-for-evidence#information-governance-ethics-and-participation:~:text=IG%203.%20Get,in%20the%20room)
* [Recommendation IG 6 – Provide rapid unambiguous guidance when approval is not required](https://hda-toolkit.org/story_html5.html#information-governance-ethics-and-participation:~:text=IG%206.%20Provide,is%20not%20required)
* [Recommendation IG 7 – Establish 2 modest Centres for Regulatory Science](https://www.gov.uk/government/publications/better-broader-safer-using-health-data-for-research-and-analysis/better-broader-safer-using-health-data-for-research-and-analysis#information-governance-ethics-and-participation:~:text=IG%207.%20Establish,for%20Regulatory%20Science)
* [Recommendation IG 8 - Establish a clinic to help users who are blocked on data access](https://www.gov.uk/government/news/goldacre-recommendations-to-improve-care-through-use-of-data#information-governance-ethics-and-participation:~:text=IG%207.%20Establish,for%20Regulatory%20Science)
* [Recommendation IG 10 - Maintain excellent standards around governance issues not addressed by TREs](https://www.gov.uk/government/publications/better-broader-safer-using-health-data-for-research-and-analysis/better-broader-safer-using-health-data-for-research-and-analysis#information-governance-ethics-and-participation:~:text=IG%2010.%20Maintain,addressed%20by%20TREs)
* [Recommendation IG 17. Create a central repository of DPIAs, DSAs and related documents for local NHS data flows](https://www.gov.uk/government/publications/better-broader-safer-using-health-data-for-research-and-analysis#information-governance-ethics-and-participation:~:text=IG%2017.%20Create,NHS%20data%20flows)
* [Recommendation IG 18 - Produce boiler-plate templates for patient consent for data use and dissemination](https://www.gov.uk/government/publications/better-broader-safer-using-health-data-for-research-and-analysis/better-broader-safer-using-health-data-for-research-and-analysis#information-governance-ethics-and-participation:~:text=IG%2018.%20Produce,use%20and%20dissemination)
* [Recommendation IG 19. Simplify the rules governing use of posthumous data](https://www.gov.uk/government/publications/better-broader-safer-using-health-data-for-research-and-analysis/better-broader-safer-using-health-data-for-research-and-analysis#information-governance-ethics-and-participation:~:text=IG%2019.%20Simplify,of%20posthumous%20data)
* [Recommendation IG 20. Address the ‘multiple permissions’ problem](https://committees.parliament.uk/work/1733/the-right-to-privacy-digital-data/#information-governance-ethics-and-participation:~:text=IG%2020.%20Address,multiple%20permissions%E2%80%99%20problem)

|  |
| --- |
| **Comments on these recommendations from an HRA perspective:** |
| These are sensible recommendations, in particular:  |
| IG 3 – Getting researchers in the room at review meetings to address factual misunderstandings is something that RECs already do, and CAG is piloting.  |
| IG 10 – Maintaining excellent standards around governance issues not addressed by TREs is essential, as is establishing precisely which are those types of projects where analysis in TREs may not be appropriate. HRA needs to consider whether it should prevent or encourage specific projects using particular infrastructure. |
| * IG 18 – HRA already has standard text relating to GDPR for use in participant information and consent forms, and will be keen to collaborate on further developments. HRA has had public input into the development of its templates.
 |
| IG 20 – The ability for a single entity to review and approve data access requests would help streamline the system, as long as sponsors’ legal obligations would remain fulfilled. Getting data controllers to take assurance from a single body will require significant alignment across the community on areas that are currently interpreted variably. |

## PPIE

The report proposes detailed recommendations on how to ensure PPIE is high quality, informative, and proportionate, notably:

1. [Recommendation IG 26. Ensure PPIE expectations are proportionate to the sensitive and scale of the project](https://saildatabank.com/#information-governance-ethics-and-participation:~:text=IG%2026.%20Ensure,of%20the%20project.)
2. [Recommendation IG 27. Provide researchers with easy access to practical guidance, and examples of best-practice](https://www.gov.uk/government/publications/better-broader-safer-using-health-data-for-research-and-analysis/better-broader-safer-using-health-data-for-research-and-analysis#information-governance-ethics-and-participation:~:text=IG%2027.%20Provide,of%20best%2Dpractice)
3. [Recommendation IG 28. Resource and give a platform to experts in building public understanding](https://www.gov.uk/government/publications/better-broader-safer-using-health-data-for-research-and-analysis/better-broader-safer-using-health-data-for-research-and-analysis#information-governance-ethics-and-participation:~:text=IG%2028.%20Resource,building%20public%20understanding.)
4. [Recommendation IG 29. Consider centrally commissioning PPIE on common causes of concern](https://www.gov.uk/government/publications/better-broader-safer-using-health-data-for-research-and-analysis/better-broader-safer-using-health-data-for-research-and-analysis#information-governance-ethics-and-participation:~:text=IG%2029.%20Consider,causes%20of%20concern)

|  |
| --- |
| **Comments on these recommendations from an HRA perspective:** |
| These are sensible suggestions in line with HRA PPIE strategy.  |

## TREs

The report recommends the promotion of standardised Trusted Research Environments (TREs) to substantially reduce privacy risks involved in using NHS patient data. This would include a system of national TREs (2 or 3 only), and a few regional TREs, acting as data access platforms as standard across the NHS.

To effect this, a key recommendation is the creation of a single set of permissions processes, paperwork, and requirements for each TRE, and a single standard “recipe” for the “service wrapper” – i.e. the set of rules, regulations, governance and customer service that surrounds the technical components of a TRE. This should build on the excellent work by e.g. [ONS](https://www.gov.uk/government/publications/better-broader-safer-using-health-data-for-research-and-analysis/better-broader-safer-using-health-data-for-research-and-analysis) and [SAIL](https://www.gov.uk/government/publications/better-broader-safer-using-health-data-for-research-and-analysis/better-broader-safer-using-health-data-for-research-and-analysis) in pioneering centralised and streamlined approaches to the TRE governance field and providing tools for analysing linked data in a standardised way. All organisations that provide access to NHS data under a TRE will need to conform to these standards in an open and collaborative fashion. They will also need to be accredited. Accreditation will also be required for all those accessing TREs according to accreditation standards set by the TRE (see TRE 14 below)

Only data that has been agreed as necessary for a project will be made available to accredited researchers to analyse. Moreover, only summarised results will be available to export via an airlock system. At the same time, it is acknowledged that aspects of governance outside the proposed (‘one-stop shop’ review process for access to data) TRE model need to be maintained. That residual aspect would encompass ethics review and PPIE persisting for single analyses.

Specific recommendations discussed under this sub-theme that could impact on the HRA include the following:

1. [Recommendation IG 9. Create a 2-track approval system to incentivise use of TREs](https://www.gov.uk/government/publications/better-broader-safer-using-health-data-for-research-and-analysis/better-broader-safer-using-health-data-for-research-and-analysis#information-governance-ethics-and-participation:~:text=IG%209.%20Create,use%20of%20TREs)
2. [TRE 14. Establish a standard scheme to accredit NHS TRE users](https://www.gov.uk/government/publications/better-broader-safer-using-health-data-for-research-and-analysis/better-broader-safer-using-health-data-for-research-and-analysis#information-governance-ethics-and-participation:~:text=TRE%2014.%20Establish,NHS%20TRE%20users)
*

|  |
| --- |
| **Comments on these recommendations from an HRA perspective:** |
| IG 9 – HRA is keen to explore opportunities for more light touch consideration of projects using TREs that meet robust accreditation standards. The value of independent scrutiny of public interest remains regardless of the security and governance of a TRE. |
| TRE 15 – A scheme of accreditation with transparent standards is essential to the success of TREs. It is unclear who would be tasked with accrediting those seeking access to TREs, as well as the TREs themselves. It may be that the HRA will be expected to have a role in this respect. Consultation with the HRA would be essential.  |

## Regulation and legislation

The report proposes some key changes to regulation and legislative provisions as follows:

1. [Recommendation IG 11. Review the National Data Opt Out Policy](https://www.gov.uk/government/publications/better-broader-safer-using-health-data-for-research-and-analysis/better-broader-safer-using-health-data-for-research-and-analysis#information-governance-ethics-and-participation:~:text=IG%2011.%20Review,TREs%20are%20established)
2. [Recommendation IG 13. Revise the definitions of ‘anonymous’, ‘identifiable’ and ‘linked’ data; add a new category of ‘pseudonymised but re-identifiable’](https://www.gov.uk/government/publications/better-broader-safer-using-health-data-for-research-and-analysis/better-broader-safer-using-health-data-for-research-and-analysis#information-governance-ethics-and-participation:~:text=IG%2013.%20Revise,but%20re%2Didentifiable%E2%80%99)
3. [Recommendation IG 14. Consider including health data in the Digital Economy Act](https://www.gov.uk/government/publications/better-broader-safer-using-health-data-for-research-and-analysis/better-broader-safer-using-health-data-for-research-and-analysis#information-governance-ethics-and-participation:~:text=IG%2014.%20Consider,Digital%20Economy%20Act)
4. [Recommendation IG 15. Appropriately sanction those who are caught deliberately and maliciously attempting to re-identify individuals in patient records](https://www.gov.uk/government/publications/better-broader-safer-using-health-data-for-research-and-analysis/better-broader-safer-using-health-data-for-research-and-analysis#information-governance-ethics-and-participation:~:text=IG%2015.%20Appropriately,in%20patient%20records)
5. [Recommendation IG 23. Start an overdue public discussion about commercial access](https://www.gov.uk/government/publications/better-broader-safer-using-health-data-for-research-and-analysis/better-broader-safer-using-health-data-for-research-and-analysis#information-governance-ethics-and-participation:~:text=IG%2023.%20Start,about%20commercial%20access)

|  |
| --- |
| **Comments on these recommendations from an HRA perspective:** |
| Agree that many of these changes should only be tackled once the TRE ecosystem has been put in place, so that the ethical or public preference aspects of data use are not confused with privacy challenges.  |
| * IG 11 – Agree that any changes to the national data opt-only should be carefully considered with meaningful input from patient and public representatives, following adequate research into the motivations of opt-out usage. Retrospective changes to current opt-outs should be handled with great caution.
 |
| IG 13 – HRA is currently feeding into the ICO consultation on new draft guidance on anonymisation, pseudonymisation, and privacy enhancing technologies.  |
| * IG 14 – Recommendation to include health data under the Digital Economy Act, to enable its linkage with other administrative datasets under the same legal framework needs to be thought through carefully. In particular, consultation would be necessary around the extra protections required for health data, and the role of HRA/CAG under this framework regarding determinations of medical purpose research (and the impact on increased workload).
 |
| * IG15 – The proposal to include HRA as one of the coordinating regulators - to develop and implement appropriate fines and sanctions for those caught deliberately breaching patient privacy - needs careful consideration in terms of the statutory remit of HRA powers. Section 171 of the Data Protection Act 2018 already makes it an offence “for a person knowingly or recklessly to re-identify information that is de-identified personal data without the consent of the controller responsible for de-identifying the personal data”, which is enforceable by the Information Commissioner’s Office.
 |
| * IG 23 - Agree to the need for a frank public discussion about commercial use of NHS data executed through citizens’ juries alongside other forms of public consultation, along with NDG and HRA input.
 |

## Conclusion

The Government will include its response to the report in the final version of the Health and Social Care Data Strategy (currently in draft form) for publication later this year, setting out its vision to make better use of data to save lives.[[2]](#footnote-2) Some of this response is already underway, including the following milestones, at each stage of which it is said there will also be wider public engagement and stakeholder consultation:

* **March** - the government [announced up to £200 million](https://www.gov.uk/government/news/260-million-to-boost-healthcare-research-and-manufacturing#:~:text=Of%20the%20funding%20announced%20today,the%20highest%20levels%20of%20privacy.) to boost data-driven clinical trials and support the development of TREs, and more widely interoperable Secure Data Environments (SDEs) where other types of NHS data analytics can take place, e.g. to enable better use of data to support Population Health Management decisions. (HRA provided social media [support](https://www.gov.uk/government/publications/better-broader-safer-using-health-data-for-research-and-analysis/better-broader-safer-using-health-data-for-research-and-analysis)).
* **Spring/Summer** - draft (10 high-level) policy principles to guide approach to SDEs/TREs will be published within the final data strategy. This will propose PPIE in SDE/TRE governance mechanisms and decision-making, although further input will be sought on what form this should take.
* **Late Summer** - blogs will be published on the technical specifications expected of SDEs/TREs (and how adherence will be assessed/monitored), plus the accreditation framework development.
* **Autumn** - final policy principles, technical specification and accreditation framework will be published, along with draft implementation roadmap with timelines and digital maturity models.

Notable areas where input will be sought are highlighted as

* Whether there are justifiable exemptions to data access as default through a TRE (e.g. consented clinical trials).
* How to take an appropriate 4-nations approach, while recognising many commonalities for standards modelling, even if variations are justifiable. Also, how to delineate those circumstances where local TREs may remain justifiable and provide agility (e.g. for local datasets, or ‘in vicinity’ interventions for patients).

Separate but related, [a pan-UK Data Governance Steering Group](https://committees.parliament.uk/writtenevidence/43419/html/#:~:text=pan%2DUK%20Data,Governance%20Steering%20Group) has been formed by HDR UK. It had its first meeting on 21 April (attended by e.g. NHSD, ONS, the existing national TREs, the MRC RSC, along with an HRA representative), and the next meeting is in July. HDR UK set out an ambitious statement of intent to work in partnership to build a robust and streamlined governance approach to data access based around the ‘5 safes’ framework. Four key pillars of work were proposed to build on existing work of the [UK Health Data Research Alliance](https://www.gov.uk/government/publications/better-broader-safer-using-health-data-for-research-and-analysis/better-broader-safer-using-health-data-for-research-and-analysis) (with this Group proposed to form a sub-group of the Alliance):

* 1. developing researcher accreditation (building on the researcher passport schemes developed under the Digital Economy Act);
	2. training;
	3. aligning legal terms/agreements; and,
	4. creating a ‘fast track’ data access application form and standardised approval criteria (using a UK-wide review panel with PPIE).

**Author**: Dr Alison Knight (HRA Data and Privacy Specialist)

**Date:** 28 April 2022

1. Bennett Professor of Evidence Based Medicine at the University of Oxford and Director of the Bennett Institute for Applied Data Science. [↑](#footnote-ref-1)
2. The strategy includes commitments to simplify information governance, building on the work started by the [Information Governance Portal](https://www.nhsx.nhs.uk/information-governance/guidance/), and to introduce legislation which will create a statutory duty for organisations within the health and care system to share anonymous data for the benefit of the system as a whole. [↑](#footnote-ref-2)