

DIGITAL INNOVATION HUB PROGRAMME PROSPECTUS APPENDIX:

# **PRINCIPLES FOR PARTICIPATION**

**Updated January 2020**



## Overview

This document provides an overview of the principles that organisations and individuals must adhere to as part of their involvement in the Digital Innovation Hub (DIH) Programme.

The vision is to make the UK home to data-driven research, scientific advances and innovation in healthcare to improve patient outcomes. The UK has some of the richest healthcare datasets worldwide. However, NHS and health research data are not always accessible, and their potential uses for research and innovation are not being fully realised. The aim is to increase the access and use of health data in a trustworthy and ethical way in order to develop improvements in the UK's health technology and deliver benefits to patients and the population.

This document is for all organisations involved in the DIH programme (whether as a data user, Digital Innovation Hub or data custodian in the UK Health Data Research Alliance). The principles for participation draw on national and international best practice frameworks and recommendations. They will guide working practices and should be reinforced through specific agreements through which organisations will engage with each other and with the Programme. They are set out below followed by a summary of the existing frameworks, principles and recommendations that underpin the principles for participation.

*NB. The following changes have been made to the original principles for participation issued at the end of the Design and Dialogue phase of the Digital Innovation Hub Programme in May 2019 to reflect the feedback from the Participation and Sustainability Green Paper consultation during November/December 2019 following the launch of the health data research hubs:*

- *Addition of a principle (1) that makes explicit the need to demonstrate active and ongoing engagement with patients and the public (previously implied through other principles)*
- *Addition of “other health and care data” to principle 2 (encouraging the availability and use in the public interest) to acknowledge the importance of social care data and highlight the need for a broad definition of health-related data*
- *Addition of further explanation concerning ‘non-preferential access’ (principle 5) and incorporation of footnote to explain this refers to:*
  - *Uses that serve the public interest*

- *Ensuring that data remains available to, and accessible by, any organisation (concurrently or otherwise) provided the five "safes" criteria are met and the organisation meets the access requirements of the data custodian.*

## Principles for Participation

Every organisation involved in the Digital Innovation Hub Programme commits to:

1. **Demonstrate active and ongoing engagement with patients and the public** in the design, development and governance of their activities involving health data to provide assurance that these activities are in the public interest.
2. **Encourage the availability and use** of structured and unstructured health and care data, including clinical, administrative, imaging, genomic and other molecular data, for research and innovation that serves **public interest purposes**, while promoting the **protection of privacy and data security** in line with the OECD Recommendation of the Council on Health Data Governance<sup>1</sup>.
3. Make data Findable, Accessible, Interoperable and Reusable by adopting the **FAIR Guiding principles for scientific data management and stewardship**<sup>2</sup>.
4. Adhere to the **Foundation Principles and Core Elements for Responsible Data Sharing** set out in the Global Alliance for Genomics and Health Framework for Responsible Sharing of Genomic and Health-Related Data<sup>3</sup> and use a **proportionate approach to the governance** of data access based on the **five "safes"**<sup>4</sup>.
5. **Maximise the benefits of data for research and innovation through non-preferential access to data** for uses that serve the public interest, by ensuring that data remains available to, and accessible by, any organisation (concurrently or otherwise) provided the five "safes" criteria are met and the organisation meets the access requirements of the data custodian.
6. **Establish mutually beneficial ways of working in partnership** including contractual arrangements and Intellectual Property agreements in line with principles set out in the Life Sciences Sector Deal 2<sup>5</sup>
7. **Work collaboratively to increase harmonisation** and reduce the complexity of data sharing arrangements to improve the efficiency of accessing data for trustworthy and ethical research and innovation purposes. This includes making the terms of access clear, such as expected timescales and costs, and being transparent about the type and quality of data available.
8. Contribute to a **joined-up and UK-wide** offer for researchers in all sectors by collaborating with existing, relevant health research infrastructure.

## Summary of References

1. **OECD, *Recommendation of the Council on Health Data Governance***, OECD/LEGAL/0433  
<http://www.oecd.org/health/health-systems/Recommendation-of-OECD-Council-on-Health-Data-Governance-Booklet.pdf>
  1. Engagement and participation.
  2. Co-ordination within government and promotion of cooperation among organisations processing personal health data, whether in the public or private sector.
  3. Review of the capacity of public sector health data systems used to process personal health data to serve and protect the public interest.
  4. Clear provision of information to individuals
  5. Informed consent and appropriate alternatives
  6. Review and approval procedures, as appropriate, for the use of personal health data for research and other health-related public interest purposes
  7. Transparency, through public information mechanisms which do not compromise health data privacy and security protections or organisations' commercial or other legitimate interests.
  8. Maximising the potential and promoting the development of technology
  9. Monitoring and evaluation mechanisms
  10. Establishment of appropriate training and skills development in privacy and security measures for those processing personal health data.
  11. Implementation of controls and safeguards.
  12. Require organisations processing personal health data to demonstrate that they meet national expectations for health data governance.
  
2. Wilkinson, M. D. *et al.* **The FAIR Guiding Principles for scientific data management and stewardship**. *Sci. Data*3:160018 doi: 10.1038/sdata.2016.18 (2016).

### The FAIR Guiding Principles

#### To be Findable:

- F1. (meta)data are assigned a globally unique and persistent identifier
- F2. data are described with rich metadata (defined by R1 below)
- F3. metadata clearly and explicitly include the identifier of the data it describes
- F4. (meta)data are registered or indexed in a searchable resource

#### To be Accessible:

- A1. (meta)data are retrievable by their identifier using a standardized communications protocol
  - A1.1 the protocol is open, free, and universally implementable
  - A1.2 the protocol allows for an authentication and authorization procedure, where necessary

- A2. metadata are accessible, even when the data are no longer available

To be Interoperable:

- I1. (meta)data use a formal, accessible, shared, and broadly applicable language for knowledge representation.
- I2. (meta)data use vocabularies that follow FAIR principles
- I3. (meta)data include qualified references to other (meta)data

To be Reusable:

- R1. meta(data) are richly described with a plurality of accurate and relevant attributes
  - R1.1. (meta)data are released with a clear and accessible data usage license
  - R1.2. (meta)data are associated with detailed provenance
  - R1.3. (meta)data meet domain-relevant community standards

3. **Foundation Principles and Core Elements for Responsible Data Sharing** set out in the Global Alliance for Genomics and Health Framework for Responsible Sharing of Genomic and Health-Related Data. <https://www.ga4gh.org/genomic-data-toolkit/regulatory-ethics-toolkit/framework-for-responsible-sharing-of-genomic-and-health-related-data/#fp>

### **Foundational Principles**

- Respect Individuals, Families and Communities
- Advance Research and Scientific Knowledge
- Promote Health, Wellbeing and the Fair Distribution of Benefits
- Foster Trust, Integrity and Reciprocity

### **Core Elements for Responsible Data Sharing**

It is good practice for those involved in genomic and health-related data sharing to have core elements of responsible data sharing in place. The following Core Elements of the Framework aid in the interpretation of the Foundational Principles to individuals and organizations involved in the sharing of genomic and health-related data. The Core Elements should be interpreted in a proportionate manner that acknowledges different levels of risk and community cultural practices. This Framework applies to use of data that have been consented to by donors (or their legal representatives) and/or approved for use by competent bodies or institutions in compliance with national and international laws, general ethical principles, and best practice standards that respect restrictions on downstream uses.

- Transparency
- Accountability
- Data Quality and Security
- Privacy, Data Protection and Confidentiality
- Risk-Benefit Analysis
- Recognition and Attribution

- Sustainability
- Education and Training
- Accessibility and Dissemination

4. **The Five Safes.** *Desai, Tanvi; Ritchie, Felix; Welpton, Richard (2016). "[Five Safes: designing data access for research](#)". Bristol Business School Working Papers in Economics*

Safe projects	Is this use of the data appropriate?
Safe people	Can the users be trusted to use it in an appropriate manner?
Safe settings	Does the access facility limit unauthorised use?
Safe data	Is there a disclosure risk in the data itself?
Safe outputs	Are the statistical results non-disclosive?

5. **Creating the right framework to realise benefits for patients and the NHS where data underpins innovation** – Guiding principles<sup>1</sup> set out in the Life Sciences Sector Deal 2  
<https://www.gov.uk/government/publications/creating-the-right-framework-to-realise-the-benefits-of-health-data/creating-the-right-framework-to-realise-the-benefits-for-patients-and-the-nhs-where-data-underpins-innovation>

- Principle 1: Any use of NHS data, including operational data, not available in the public domain must have an explicit aim to improve the health, welfare and/or care of patients in the NHS, or the operation of the NHS. This may include the discovery of new treatments, diagnostics, and other scientific breakthroughs, as well as additional wider benefits. Where possible, the terms of any arrangements should include quantifiable and explicit benefits for patients which will be realised as part of the arrangement.
- Principle 2: NHS data is an important resource and NHS organisations entering into arrangements involving their data, individually or as a consortium, should ensure they agree fair terms for their organisation and for the NHS as a whole. In particular, the boards of NHS organisations should consider themselves ultimately responsible for ensuring that any arrangements entered into by their organisation are fair, including recognising and safeguarding the value of the data that is shared and the resources which are generated as a result of the arrangement.

<sup>1</sup> Government is currently consulting on these guiding principles and will publish a revised version in due course.

- Principle 3: Any arrangements agreed by NHS organisations should not undermine, inhibit or impact the ability of the NHS, at national level, to maximise the value or use of NHS data. NHS organisations should not enter into exclusive arrangements for raw data held by the NHS, nor include conditions limiting any benefits from being applied at a national level, nor undermine the wider NHS digital architecture, including the free flow of data within health and care, open standards and interoperability.
- Principle 4: Any arrangements agreed by NHS organisations should be transparent and clearly communicated in order to support public trust and confidence in the NHS and wider government data policies.
- Principle 5: Any arrangements agreed by NHS organisations should fully adhere to all applicable national level legal, regulatory, privacy and security obligations, including in respect of the National Data Guardian’s Data Security Standards, the General Data Protection Regulation (GDPR) and the Common Law Duty of Confidentiality.