

NUFFIELD  
COUNCIL ON  
BIOETHICS

# RESOURCE BANK

JANUARY 2024

# Resource Bank

This ‘resource bank’ accompanies our report ‘Towards a Gold Standard of Ethics Across Genomic Healthcare and Research: Where are we?’ report published in January 2024. This bank includes resources identified throughout this report and will be amendable over time at the request of external stakeholders who may have identified or developed missing or future resources. Similarly, resources can be removed on request if they are no longer relevant or appropriate. Requests can be made by emailing the Nuffield Council on Bioethics at: [bioethics@nuffieldbioethics.org](mailto:bioethics@nuffieldbioethics.org)

This resource bank supports the development of the UK Government commitment outlined in the [2020 Genome UK Strategy](#) to establish a ‘gold standard UK model’ for how to apply strong and consistent ethical standards in genomic healthcare and research.

The resources we included in our mapping included practical tools, guidelines, guidance, documentation, recommendations, ethics reviews and policy reports developed in the last 10 years. The resources also had to be genomic-specific, have a UK focus and be centred around ethics, or how to achieve practice that had considered ethics. These could be developed by any stakeholder across genomic healthcare and research.

# The Resources

## Consent and Confidentiality

Resource	Summary
<b>Health Research Authority (HRA) and the Medical Research Council (MRC) <a href="#">Consent and Participant Information Guidance</a> (2023)</b>	<p>This tool provides guidance for researchers and ethics committees on consenting participants for research, and how to prepare materials to support this process.</p> <p>The section '<i>Content: Participation Information Sheet – What's Involved</i>' includes a sub-section specific to 'Genetic Research'.</p>
<b>British Medical Association (BMA) <a href="#">Confidentiality Toolkit: A Toolkit for Doctors</a> (2021)</b>	<p>This toolkit provides answers to doctors (dealing with adult patients) on commonly asked questions about when confidential information can be disclosed to third parties.</p> <p>Sections 7 and 9 specifically reference genomics.</p> <ul style="list-style-type: none"><li>• Section 7 focuses on 'Public Interest Disclosures'</li><li>• Section 9 focuses on 'Requests from Third Parties'.</li></ul>

**Joint Committee on Genomics in Medicine (Royal College of Physicians, The Royal College of Pathologists and the British Society for Genomic Medicine)** [Consent and Confidentiality in Genomic Medicine – Guidance on the Use of Genetic and Genomic Information in the Clinic](#)  
3<sup>rd</sup> edition (2019)

This report provides guidance to enable healthcare professionals in all specialties to consider and understand how consent and confidentiality issues may arise in genomic medicine.

**General Medical Council (GMC)** [Confidentiality: Good Practice in Handling Patient Information](#) (2017)

This guidance sets out the principles of confidentiality and respect for patient's privacy that is expected to be understood and followed by healthcare professionals in the UK. This includes a framework for considering when to disclose patients' personal information and sets out responsibilities for all doctors managing and protecting patient information.

Sections 73-76 of this guidance refers to '*Disclosing Genetic and Other Shared Information*'.

# Data Use, Data Protection and Data Governance

Resource	Summary
<p><b>The British Society for Genetic Medicine</b> <a href="#">The Retention of Genetic Family Records: Guidance for Clinical Practice</a> (2023)</p>	<p>This report provides guidance and recommendations around the retention of genetic family information and genomic test data in health records in clinical practice.</p>
<p><b>Medical Research Council (MRC)</b> <a href="#">Guidance on Identifiability, Anonymisation and Pseudonymisation</a> (2019)</p>	<p>This guidance discusses the concept of identifiability and the controls that can be used to minimise the risk of identifiability of data within research.</p> <p>Section 5.3 specifically addresses ‘Genetic (Sequence) Information’.</p>
<p><b>PHG Foundation</b> <a href="#">The GDPR and Genomic Data</a> (2018)</p> <p>[Funded by the Information Commissioner’s Office]</p>	<p>This report explores how genomic data in healthcare and health research is impacted by the General Data Protection Regulation (GDPR) and the UK Data Protection Act 2018.</p> <p>The report includes challenges, potential mitigations and makes recommendations for genomics professionals, policymakers and regulators.</p>

**Nuffield Council on Bioethics**  
[The Collection, Linking and Use of Data in Biomedical Research and Health Care: Ethical Issues](#) (2015)

This report explores the ethical issues raised by the collection and use of data in biomedical research and healthcare.

The report includes principles for the design and governance of data initiatives and identifies examples of good practice relevant to anyone approaching a data initiative.

## Direct-To-Consumer Genetic Testing

Resource	Summary
<b>UK Parliament [Science and Technology Committee]</b> <a href="#">Direct to Consumer Genomic Testing</a> (2021)	<p>This report discusses the main opportunities and risks of direct-to-consumer genomic tests.</p> <p>The report includes recommendations directed at the government to address the identified risks.</p>
<b>Royal College of General Practitioners and the British Society for Genetic Medicine</b> <a href="#">Position Statement on Direct to Consumer Testing</a> (2019)	<p>This position statement provides recommendations for healthcare professionals who are asked to provide clinical expertise about the results of direct-to-consumer genomic or genetic testing.</p>

## Equitable Collaboration

Resource	Summary
<b>Wellcome Sanger Institute</b> Embedding Equity in International Research Collaboration (2023)	<p>This document is <b>internal policy</b> at the Wellcome Sanger Institute to support research teams to collaborate equitably with international partners based in low and middle income countries.</p> <p>This includes guidelines for collaboration and areas that require further exploration.</p>

## Gene Editing

Resource	Summary
<b>Nuffield Council on Bioethics</b> <a href="#">Genome Editing and Human Reproduction: Social and Ethical Issues</a> (2018)	<p>This report explores the range of ethical issues related to the prospect of genome editing becoming a reproductive option in the future.</p> <p>The report provides two overarching principles that must be met for 'heritable genome editing interventions' to be ethically acceptable.</p>
<b>Nuffield Council on Bioethics</b> <a href="#">Genome Editing: An Ethical Review</a> (2016)	<p>This review considers genome editing. This includes where it may have a use and the potential impact that future advances may have.</p>

## Genetic Relatedness

Resource	Summary
<b>British Medical Association (BMA)</b> <a href="#">Consent in Paternity Testing</a> (2020)	This guidance sets out doctors' legal and ethical responsibilities when asked to assist with paternity testing.

## Genomics and Artificial Intelligence

Resource	Summary
<b>PHG Foundation</b> <a href="#">Artificial Intelligence for Genomic Medicine</a> (2020)	<p>This report examines the intersection between AI and genomics. It investigates the limitations and challenges of realising its full potential for health.</p> <p>The report includes a practical set of recommendations for policymakers.</p>



## Genomic Research and Medicine

Resource	Summary
<b>The Association of Genetic Nurses and Counsellors</b> <a href="#">Code of Ethics</a> (2021)	This code provides guidance for the ethical and professional conduct of genetic counsellors working in the UK.
<b>Wellcome Sanger Institute</b> <a href="#">Good Research Practice Guidelines</a> (2021)	These guidelines are <b>internal policy</b> on good research practice at the Wellcome Sanger Institute, including ethics.
<b>Our Future Health</b> <a href="#">Ethics and Governance Framework</a> (2021)	This <b>internal framework</b> outlines the key principles for guiding programme decision-making and provides ethical and governance input on the major operational areas of the Our Future Health research programme.
<b>Health Education England</b> <a href="#">The Topol Review: Preparing the Healthcare Workforce to Deliver the Digital Future</a> (2019)	<p>This review explores the deployment of digital healthcare technologies, including genomics, throughout the NHS.</p> <p>Ethical considerations and recommendations to support for the citizen and the patient, healthcare professionals and the health system throughout this deployment are included.</p> <p>Chapter 4 focuses specifically on genomics, but genomics is also mentioned throughout.</p>

## Genetic Testing in Newborns, Babies and Children

Resource	Summary
<p><b>Royal College of Physicians, The Royal College of Pathologists and British Society of Genetic Medicine</b>  <a href="#">Genetic Testing in Childhood – Guidance for Clinical Practice</a> (2022)                      [Report of the Joint Committee on Genomics in Medicine]</p>	<p>This report provides guidance to healthcare professionals in the UK on best practice for genetic testing in childhood.</p>
<p><b>Nuffield Council on Bioethics</b>  <a href="#">Whole Genome Sequencing of Babies</a> (2018)</p>	<p>This briefing note explores the ethical issues raised by whole genome sequencing of babies.</p>

## Incidental Findings

Resource	Summary
<p><b>Medical Research Council (MRC) and Wellcome Trust</b>  <a href="#">Framework on the Feedback of Health-Related Findings in Research</a> (2014)</p>	<p>This framework aims to help researchers identify and consider the relevant issues when designing and implementing policy relating to the feedback of health-related findings.</p>

# Patient and Participant Engagement

Resource	Summary
<p><b>Genomics England [Participant Panel]</b> <a href="#">Language and Terminology</a> (2022)</p>	<p>This guide has been developed by the Participant Panel at Genomics England to recommend how Genomics England and their partner organisations should talk about people participating in genomics research.</p> <p>This includes a set of general principles and advice about terminology relating to disability, genetics and genomics.</p>
<p><b>PHG Foundation</b> <a href="#">The Ethical and Legal Framework for a Genomics England and Sano Genetics Participant Engagement Platform</a> (2021)</p> <p>[Commissioned by Genomics England].</p>	<p>This report examines the legal and ethical implications of an online platform for patient engagement in precision medicine research.</p> <p>Overarching ethical and legal issues that apply to the development of any digital participant engagement platform - regardless of the features the application enabled – are included, as well as project specific considerations.</p> <p>Mitigation suggestions that could be adopted to address challenges are provided.</p>

# Polygenic Scores

Resource	Summary
<b>PHG Foundation</b> <a href="#">Evaluation of Polygenic Score Applications</a> (2023)	This report explores the application of medical test evaluation methods and their principles relating to polygenic score-based products.
<b>PHG Foundation</b> <a href="#">Implementing Polygenic Scores for Cardiovascular Disease into NHS Health Checks</a> (2021)	This report considers the implementation and delivery of polygenic score analysis for cardiovascular disease risk assessment as part of the NHS Health Check Programme.  It explores the implications arising from the implementation and delivery and the changes needed to implement and deliver polygenic score analysis within existing practice.

# Prenatal and Pre-Implantation Genetic Testing

Resource	Summary
<p><b>UK Cancer Genetics Group, Fetal Genomics Group and the British Society for Genomic Medicine</b> <a href="#">Prenatal Diagnosis and Pre-Implantation Genetic Testing for Germline Cancer Susceptibility Gene Variants: Guidance for Clinical Practice</a> (2023)</p>	<p>This report provides guidance to healthcare professionals to facilitate equitable access to prenatal diagnosis and preimplantation genetic testing for individuals and couples with a germline cancer susceptibility gene variant.</p>
<p><b>Royal College of Physicians, The Royal College of Pathologists and the British Society for Genetic Medicine</b> <a href="#">Ethical Issues in Prenatal Genetic Diagnosis – Guidance for Clinical Practice</a> (2022)</p> <p>[A report on the Joint Committee on Genomics in Medicine]</p>	<p>This report considers the ethical issues that can arise in prenatal genetic testing and provides guidance on decision-making processes for professionals and patients.</p>
<p><b>Nuffield Council on Bioethics</b> <a href="#">Non-Invasive Prenatal Testing: Ethical Issues</a> (2017)</p>	<p>This report considers the ethical issues Non-Invasive Prenatal Testing (NIPT) may pose and how we can address these through a series of recommendations.</p>

# Synthetic Data

Resource	Summary
<b>PHG Foundation</b> <a href="#">Are Synthetic Health Data ‘Personal Data’?</a> (2023)	This report analyses whether the use of synthetic data, such as synthetic human data, potentially mitigates some of the data processing challenges associated with the use of personal data.

Our report also mentions some relevant international resources that could be adapted or used to inform future UK resources, where we have identified gaps. These include:

- American College of Medical Genetics (2023) [The Clinical Application of Polygenic Risk Scores: A Points to Consider Statement of the American College of Medical Genetics and Genomics.](#)
- American College of Medical Genetics (2023) [Laboratory Perspectives in the Development of Polygenic Risk Scores for Disease: A Points to Consider Statement of the American College of Medical Genetics and Genomics.](#)
- EURORDIS Rare Disease Europe (2023) [Patient Partnership Framework for the European Reference Networks.](#)
- The National Academies of Sciences, Engineering and Medicine (2023) [Using Population Descriptors in Genetics and Genomics Research: A New Framework for an Evolving Field.](#)
- American College of Medical Genetics (2021) [Direct-to-Consumer Prenatal Testing for Multigenic or Polygenic Disorders: A Position Statement of the American College of Medical Genetics and Genomics.](#)
- Global Alliance for Genomics and Health (2021) [Framework for Involving and Engaging Participants, patients and Publics in Genomics Research and Health Implementation.](#)
- Global Alliance for Genomics and Health (2021) [Policy on Clinically Actionable Genomic Research Results.](#)
- World Health Organisation (2021) [Human Genome Editing: A Framework for Governance](#)

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