

# Genomic Data Policy Resource List

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# Introduction

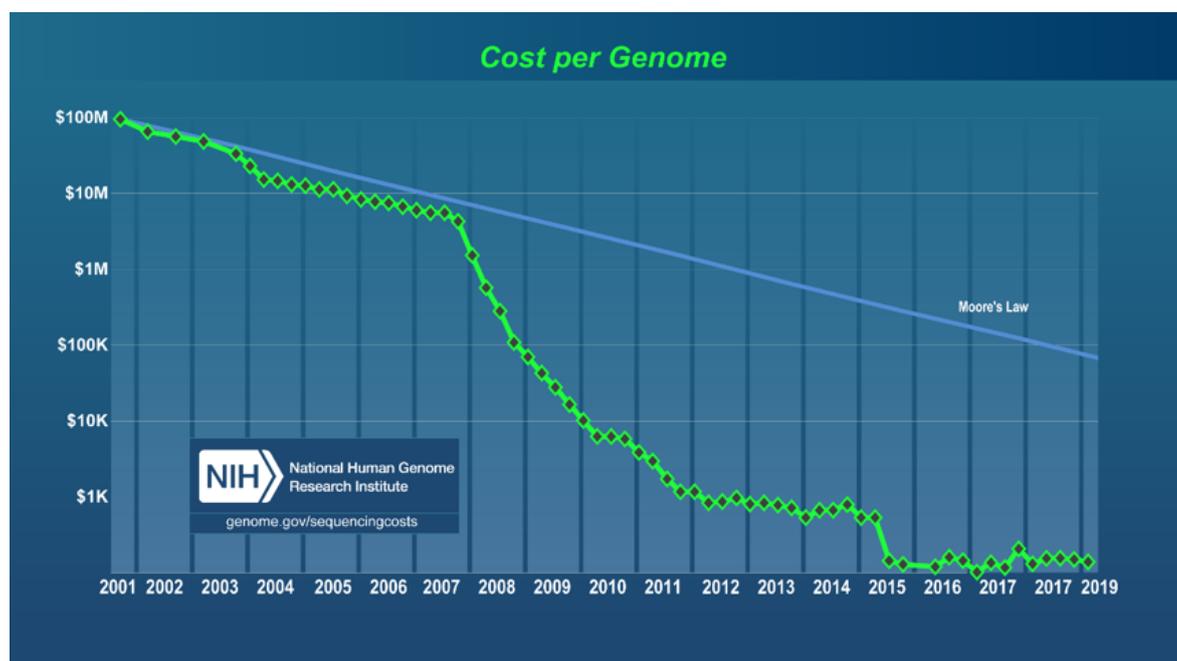
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On 14 April 2003, the International Human Genome Sequencing Consortium announced it had completed its task – the ~3 billion base pairs that make up the human genome had been mapped. The project took 13 years, involved six countries and cost more than \$3 billion. Four years later, James Watson became the first human to have his personal genome completely mapped – the project took two months and cost \$1 million. By 2016, several companies were advertising whole genome sequences for under \$1,000. Today, the price continues to plummet.

Even in an age when Moore's Law is the norm, this decline is remarkable. It is conceivable that in the very near future, personal genomic sequencing could be a routine part of our health data, and researchers could use unprecedented computing power to analyse millions of genomes, allowing the discovery of genetic correlates of diseases that were previously impossible to see.



This revolution in genomics, in tandem with our computing power, is accelerating the collection of genomic information around the world. The increased collection of genomic data, including in low- and middle- income countries (LMICS), will fill critical gaps in our understanding of populations in order to support scientific research, development and refinement of reference genomes, improved diagnostics and disease treatments that underscore precision medicine.

Science and science policy are rarely in sync with each other, and the exponential growth of the former has not been reciprocated by the latter. Structures to guide and govern the genomic revolution are lagging behind the science and, in their absence, existing country-level laws on health data are often applied to the ways genomic information will be collected and used.

With this in mind, the World Economic Forum's Precision Medicine Team has compiled the following resource list. This compendium is an attempt to map the current laws, regulations and guidelines predominantly affecting the conversation about genomic data at both the national and international level. The list is broken up into four sections – patient consent, privacy, data access and benefit sharing – that we believe must be addressed in a policy structure that wishes to leverage the genomic data revolution in a way that is just, ethical and dynamic. Within each section, the positions of important policies are described, along with a list of secondary references for further reading.

This list is neither exhaustive nor static. It should be viewed as a dynamic, living document to which contributions are welcome. Case studies of governments or organizations that represent the most effective techniques within the following four categories are particularly beneficial. Please feel free to send your contributions and thoughts to: [Elissa.Prichep@weforum.org](mailto:Elissa.Prichep@weforum.org).



## Consent

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### Common Rule

Part 46 of the Code of Federal Regulations, or the “Common Rule”, contains the United States’ rules and regulations surrounding research conducted on human subjects. The Common Rule stems from two of the most seminal documents in the history of bioethics: the [Nuremberg Code of 1947](#) and the [Belmont Report of 1979](#). As the Common Rule covers all human research, its definition of informed consent is extensive and nuanced. However, a 2019 [revision to the Common Rule](#), issued in response to concerns over secondary uses of data (especially genomic data), introduced the concept of *broad consent*, an attempt to reconcile subject autonomy with the perceived inefficiencies of specifically garnering consent each time data is reused. §46.116(d) explains that “broad consent for the storage, maintenance and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or non-research purposes) is permitted as an alternative to the informed consent requirements”.

### General Data Protection Regulation (GDPR)

Chapter I Article 4(11) of the General Data Protection Regulation defines consent as “any freely given, specific, informed and unambiguous indication of the data subject’s wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her”. This very general statement is clarified in [Chapter II Article 7](#) (Conditions for Consent) and in Recitals 32, 33, 42 and 43. A research participant has the “right to withdraw his or her consent at any time”, and it must be “as easy to withdraw as to give consent”. Consent cannot be given in situations in which power is disproportionate (e.g. employer-employee relationships) or in which other parts of a contractual agreement are contingent upon consent. It is important to note that though GDPR lays out stringent regulations for

consent and withdrawal thereof, [Article 6\(1\)](#) enumerates five other avenues by which personal data may be collected without consent, including “vital interests of the data subject”, “a task carried out in the public interest”, or “performance of a contract to which the data subject is party” *inter alia*. Furthermore, [Article 89](#) provides member states with the option of overriding many consent conditions with their own laws. Though they do not explicitly reference it, these articles will define the ways in which genomic data is collected from individuals.

### Global Alliance for Genomics and Health (GA4GH)

The [GA4GH Consent Policy \(2015\)](#) does not ascribe legal meaning but rather provides practical guidance on consent issues related to the sharing of genomic and health-related data in a way that respects autonomous decision-making while promoting international data access. The policy mostly applies to data that has been consented to by participants and/or approved by relevant authorities in compliance with national and international laws, ethical principles and methodologies that respect restrictions on downstream uses.

### Human Heredity and Health in Africa (H3Africa)

The [Model Framework for Governance of Genomic Research and Biobanking in Africa – A Content Description \(2018\)](#) provides a checklist of governance elements for genomics research studies or biobanking. The framework has 10 important elements, including consent. The framework promotes the use of broad consent that allows for “use of samples and data for unspecified future studies, but with specified conditions”. These conditions include: restriction on the types of studies or diseases that samples and data can be used for; a specified oversight and approval process for future use; if possible, ongoing consultation with participants about future use; and a process allowing participants to withdraw.

The [H3Africa Guideline for Informed Consent](#) (2017) also recommends the use of a broad consent model when enrolling participants in genomics studies or biobanks if accompanied by an arrangement (governance arrangement/framework) to ensure that data and specimens are shared only when consent is given by the participants. There is always a theoretical risk that participants could be identified if additional genetic information for the person is also available in the public domain. The guidelines provide examples on how to develop informed consent documents, based on H3Africa studies.

## Council for International Organizations of Medical Sciences (CIOMS) in Collaboration with World Health Organization (WHO)

The [International Ethical Guidelines for Health-Related Research Involving Humans](#) (2016) discuss informed consent under *Guideline 9* (Individuals capable of giving informed consent) as a “two-way communicative process that begins when initial contact is made with a potential participant and ends when consent is provided and documented, but can be revisited later during the conduct of the study”. The guidelines note that it is often not possible to use a specific informed consent (permission provided for a specific use) because the precise nature of the research is typically unknown. Broad consent is discussed as an acceptable alternative (permission provided for future research), but requires proper governance and management of the biobank. Other guidelines that discuss informed consent include *Guideline 10* (Modifications and waivers of informed consent), *Guideline 16* (Research involving adults incapable of giving informed consent) and *Guideline 17* (Research involving children and adolescents).

### Secondary sources

- Glimcher, L. (4 April 2016). [How Not to End Cancer in Our Lifetimes](#). *Wall Street Journal*.

An editorial from the *Wall Street Journal* that takes the opposite view on the new Common Rule additions. “The consents proposed by the administration are known as broad consent, which offer the patient little more than a generic menu of possible uses for the tissue. If patients are disconcerted by these broad consents or don’t understand them, they may well decline to sign them ... The new rules will curtail access to the biospecimens required to achieve the president’s ‘moon shot’ to cure cancer and other vital healthcare goals.”

- Pormeister, K. (2017). [Genetic Data and the Research Exemption: Is the GDPR Going Too Far?](#) *International Data Privacy Law*, 7(2).

According to Pormeister, while GDPR’s framing of consent might make sense for other forms of data, it fails to address the unique externalities and gravity of consenting to participate in research involving genetic information. This

brings with it the possibility of genetic research with no purpose limitation, no storage limitation and unconsented sharing between institutions if a person consents to *any* form of genetic testing at any point in time.

- Smith, J. D., Birkeland, A. C., Goldman, E. B., Brenner, J. C., Carey, T. E., Spector-Bagdady, K. and Shuman, A. G. (2017). [Immortal Life of the Common Rule: Ethics, Consent, and the Future of Cancer Research](#). *Journal of Clinical Oncology*, 35(17), 1879–1883.

The authors praise the new additions to the Common Rule, using their own cancer lab as a microcosm for how broad consent might be implemented. “The Common Rule agencies have thoughtfully addressed the public comments of a litany of stakeholders in their consideration and ultimate revision of the proposed Common Rule ... Of course, the process is imperfect; the final Common Rule is not a panacea ... But in essence, this is an illustration of the federal government doing its job.”

- De Vries et al. (2017). [Regulation of Genomic and Biobanking Research in Africa: A Content Analysis of Ethics Guidelines, Policies and Procedures from 22 African Countries](#). *BMC Medical Ethics*.
- Pormeister, K. (2018). [Genetic Research and Consent: On the Crossroads of Human and Data Research](#). *Bioethics*.
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- Tindana, P. and De Vries, J. (2016). [Broad Consent for Genomic Research and Biobanking: Perspectives from Low- and Middle-Income Countries](#). *Annual Review of Genomics and Human Genetics*.
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- [Guidelines on Human Biobanks and Genetic Research Databases](#) (2009). *Organisation for Economic Co-operation and Development*.
- [Universal Declaration on Bioethics and Human Rights](#) (19 October 2005). *United Nations Educational Scientific and Cultural Organization*.
- [Universal Declaration on the Human Genome and Human Rights](#) (22 January 1997). *United Nations Educational Scientific and Cultural Organization*.



## Privacy

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### Common Rule

The Common Rule's definition of privacy varies depending on the nature of the research being carried out. When seeking *informed consent*, the subject must be told of "the extent to which confidentiality of records identifying the subject will be maintained" (§46.116(b)(5)) and "a statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimen could be used for future research studies or distributed to another investigator for future studies without additional informed consent from the subject" (§46.116(b)(9)(i)). For *broad consent*, §46.116(d) (1-6) enumerates the elements researchers must divulge to participants prior to beginning a study: what private information will be used in research, whether and by whom sharing of private information will be permitted, the duration researchers will retain their information and a statement of whether the subject will receive details about the results of the study.

### General Data Protection Regulation (GDPR)

Chapter II, Article 9 of the GDPR (Processing of Special Categories of Personal Data) begins by explicitly prohibiting the processing of genetic data before listing caveats where such analysis is allowed. By opening with a whole-cloth ban, GDPR makes it clear that genetic data is among the most sensitive pieces of information a person can divulge. However, there are still several ways that genetic data may be obtained without running into legal issues, including "research purposes or statistical purposes ... which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject" (Article 9 ¶2(j)). Article 89 and Article 4 give context to this statement, as do Recitals 26, 34, 51, 52, 53 and 54.

### Genetic Information Nondiscrimination Act (GINA)

The GINA is divided into two sections, or titles. Title I concerns genetic nondiscrimination in health insurance, modifying several existing laws: the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Service Act (PHSA), the Internal Revenue Code (IRC) and the Social Security Act (SSA). It prohibits health insurers from using genetic information to adjust group plan premiums, requesting or requiring genetic testing, and requesting, requiring or purchasing genetic information for underwriting.

Title II deals with employment discrimination on the basis of genetic testing. It broadly prohibits employers from requesting, requiring or purchasing genetic information about their employees with limited exceptions (e.g. monitoring chromosomal damage due to exposure to toxic chemicals in the workplace).

The GINA's privacy restrictions are virtually unequivocal when it comes to health insurers or employers, but many commentators believe it does not go far enough; genetic information can still be used in several other contexts (e.g. life insurance, disability insurance, advertising).

### Global Alliance for Genomics and Health (GA4GH)

The *Privacy and Security Policy* (2015) distinguishes privacy from security. Privacy is treated as a fundamental value (but not an absolute right) that "establishes reasonable limits to the use of data, and protects all aspects of the lives of individuals and communities". Security is concerned with "organizational, technical and physical measures and standards to effectively manage risks to the sensitivity and integrity of data and the availability of resources and services".

## Human Heredity and Health in Africa (H3Africa)

The [H3Africa Consortium Data Access Release Policy](#) (2018) provides specific guidelines on data access and privacy, and distinguishes between internal and external data users with respect to access. The detailed process highlights terms and conditions of a Data Access Agreement (DAA) that aims to protect the privacy and interests of the research participants.

## Health Insurance Portability and Accountability Act (HIPAA)

The HIPAA was created with two goals in mind – to help people carry their insurance from one company to another by streamlining and digitizing medical records and to protect the privacy of individuals' health information. Its privacy rules are long and complex. However, genetic and genomic data were not mentioned anywhere in the document [Guidance Regarding Methods for De-identification of Protected Health Information](#) until the 2013 HIPAA Omnibus Rule changed the law to include genetic information on the list of [Protected Health Information](#). Even so, it is important to remember that the HIPAA is only applicable to “covered entities” (e.g. healthcare providers, health insurers etc.) or the “business associates” of covered entities (e.g. organizations that deal with electronic health records). Genetic data divulged to genetic testing companies or crowd-sourced genetic repositories are not covered by the HIPAA.

## Council for International Organizations of Medical Sciences (CIOMS) in Collaboration with World Health Organization (WHO)

The [International Ethical Guidelines for Health-related Research Involving Humans](#) (2016) discuss privacy protection in [Guideline 11](#) (Collection, storage and use of biological materials and related data), [Guideline 15](#) (Research involving vulnerable persons and groups) and [Guideline 22](#) (Use of data obtained from the online environment and digital tools in health-related research). The guidelines state that “privacy risks are not a simple function of the presence or absence of specific fields, attributes or keywords in a set of data. Much of the potential for privacy risks stems from what can be inferred about individuals from the data as a whole or when the data are linked with other available information.”

## Secondary sources

- Shabani, M. and Borry, P. (2017). [Rules for Processing Genetic Data for Research Purposes in View of the New EU General Data Protection Regulation](#). *European Journal of Human Genetics*, 26(2), 149–156.

Recognizing “pseudonymized” data (personal data with identifiers kept separately) as personal data could hamper research endeavours. Furthermore, the carve-out that allows EU member states to enact more stringent laws around pseudonymization vs. anonymization of genetic data might damage cross-border data protection. Other safeguards should be put in place to guard data while still encouraging scientific research and discovery.

- Areheart, B. and Roberts, J. (2019). [GINA, Big Data, and the Future of Employee Privacy](#). *Yale Law Journal*, 128(3).

Areheart and Roberts argue that, though the GINA has faced scrutiny for being “ill-conceived, unnecessary, and ineffective”, it has “unappreciated value as an employee-privacy statute”. Even if it does not go far enough in protecting individuals' genetic privacy, the law was surprisingly forward-thinking for 2008 and could serve as a foundation for more robust protections against genetic prying in future legislation.

- Chassang, G. (2017). [The Impact of the EU General Data Protection Regulation on Scientific Research](#). *Ecancermedicalscience*, 11.
- Lefebvre, K. (2015). [Genetic Discrimination Law in the United States: A Socioethical & Legal Analysis of the Genetic Information Nondiscrimination Act \(GINA\)](#). *School of Public Policy Capstones*, 39.
- Sarata, A. K. and Feder, J. (2015). [The Genetic Information Nondiscrimination Act of 2008 \(GINA\)](#). *Congressional Research Service*.
- Staunton, C., Slokenberga, S. and Mascalzoni, D. (2019). [The GDPR and the Research Exemption: Considerations on the Necessary Safeguards for Research Biobanks](#). *European Journal of Human Genetics*.
- Zhang, S. (13 March 2017). [The Loopholes in the Law Prohibiting Genetic Discrimination](#). *The Atlantic*.
- [OECD Privacy Framework \(2013\)](#). *Organisation for Economic Co-operation and Development*.
- [UK Biobank, Ethics and Governance Framework \(2007\)](#).



## Data access

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### Common Rule

The Common Rule has been updated several times since its adoption in 1991 to reflect the changing nature of human research. In 2017, the Office of Human Research Protection revised federal regulations through a [Final Rule](#) to reflect the growing prominence of aggregate genetic data and secondary uses of biospecimens in research. The rule went into effect this year and gives researchers much broader leeway to use subject data for purposes beyond their original intent. However, attempts to balance the individual and the aggregate are not lost in the rule: The addition of “identifiable information and biospecimens” under the definition of “human subject” provides greater data protection, and new rules make it more difficult for IRBs to waive re-consent. These changes fall under *broad consent* and attempt to balance individual privacy with the power that population-level health data can provide to elucidate connections between genes, environment and health outcomes.

### General Data Protection Regulation (GDPR)

[Chapter V](#) of the GDPR (Articles 44–50) describes the ways in which personal data may be transferred to a non-EU country or international organization. Approval for transfer can be obtained via an adequacy decision ([Article 45](#)), standard contractual clauses previously approved by the EU Commission ([Article 46\(2\)\(c\)-\(d\)](#)), binding corporate rules ([Article 47](#)) or via one of several derogations for specific situations (e.g. explicit consent, public interest, establishment of legal claims) set out in [Article 49](#). Lastly, [Article 50](#) gives the commission the authority to create an international code of conduct that could “promote the exchange and documentation of personal data”, thereby creating a new channel for multilateral agreements to expedite data access. Refer to [Recitals 101–116](#) and the 2015 [Schrems vs. Data Protection Commissioner](#) decision for further explanation of the legalities surrounding data transfers.

### Global Alliance for Genomics and Health (GA4GH)

The [Framework for Responsible Sharing of Genomic and Health-related Data](#) (2014) discusses data access that includes data transfer or exchange between data users, or where data is made available to secondary researchers, either openly or under specified access conditions. The framework is based on 10 core elements, which include transparency, accountability, engagement, data quality and security, risk-benefit analysis and sustainability.

### Human Heredity and Health in Africa (H3Africa)

The [H3Africa Consortium Data Access Release Policy](#) (2018) provides specific guidelines on data access for H3Africa internal and external data users. The policy describes H3Africa-generated data access through a controlled access process at European Genome-Phenome Archive (EGA). The requests for access are reviewed by a Data and Biospecimen Access Committee (DBAC), which determines whether the proposed use of the dataset is scientifically and ethically appropriate and does not conflict with constraints or informed consent limitations identified by the investigators who first submitted the dataset to the EGA.

### Health Insurance Portability and Accountability Act (HIPAA)

One half of the HIPAA (Health Insurance Portability and Accountability Act) deals with the complexities of moving health data from one system to another. The act, which became law in 1996, was partially a product of the increasing ubiquity of electronic health records. As such, the HIPAA has complex rules surrounding what information can and cannot be shared between health providers and patients. Pertinent to genetic information is the change the GINA made to the HIPAA: The GINA declared that

Americans have a right to see their genetic information and, in 2013, these changes were enshrined in the HIPAA. However, problems still remain – the HIPAA applies only to “covered entities” and their “business associates”, so direct-to-consumer genetic testing companies do not have to divulge data if they choose not to do so.

### Council for International Organizations of Medical Sciences (CIOMS) in Collaboration with World Health Organization (WHO)

The International Ethical Guidelines for Health-related Research Involving Humans (2016) discuss the conditions for data access in *Guideline 24* (Public accountability for health-related research) and briefly in *Guideline 22* (Use of data obtained from the online environment and digital tools in health-related research). The guidelines note that “the risks of data sharing may be mitigated by controlling with whom the data are shared and under what conditions, without compromising the scientific usefulness of the shared data”.

#### Secondary sources

- Fisher, C. B. and Layman, D. M. (2018). [Genomics, Big Data, and Broad Consent: A New Ethics Frontier for Prevention Science](#). *Prevention Science*, 19(7), 871–879. doi: 10.1007/s11121-018-0944-z.

Fisher and Layman describe the new idea of broad consent, focusing on the ethical implications of “collecting, storing, and engaging in secondary use of potentially identifiable information and biospecimens”. Their article is cautiously optimistic about the changes, saying that “broad consent increases transparency and provides greater opportunities for participants to decide if their ... information ... may be used by future researchers”.

- Phillips, M. (2018). [International Data-Sharing Norms: From the OECD to the General Data Protection Regulation \(GDPR\)](#). *Human Genetics*, 137(8), 575–582. doi: 10.1007/s00439-018-1919-7.

According to Phillips, justifications stemming from consent are unsuitable for large-scale sharing, and binding corporate rules are unlikely to be applicable to genomic data. Though adequacy decisions have been the cornerstone of EU data-transfer justification for many years, the [Schrems](#) decision, mandating periodic review of adequacy status, puts this choice on shakier grounds, making standard contractual agreements more appealing. A general code of conduct “has the strong possibility of becoming the most attractive transfer mechanism for projects involving many countries”, though no such code presently exists.

- Slokenberga, S., Reichel, J., Niringiye, R., Croxton, T., Swanepoel, C. and Okal, J. (2018). [EU Data Transfer Rules and African Legal Realities: Is Data Exchange for Biobank Research Realistic?](#) *International Data Privacy Law*, 9(1), 30–48. doi: 10.1093/idpl/ipy010.
- Townend, D. (2018). [Conclusion: Harmonisation in Genomic and Health Data Sharing for Research: An impossible Dream?](#) *Human Genetics*, 137(8), 657–664. doi: 10.1007/s00439-018-1924-x.
- International Society for Biological and Environmental Repositories: [Best Practices for Repositories](#) (2012).
- [Data Storage and DNA Banking for Biomedical Research \(2003\)](#). *European Society of Human Genetics*.



## Benefit sharing

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### Common Rule

Though Common Rule regulations are light on discussions of benefit sharing, the newest [Final Rule](#) does tangentially address the issue of commercial usage, stating that consent documents must include “a statement that the subject’s biospecimens ... may be used for commercial profit and whether the subject will or will not share in this commercial profit” (§46.116(c)(7)).

### Human Heredity and Health in Africa (H3Africa)

The [Model Framework for Governance of Genomic Research and Biobanking in Africa – A Content Description](#) (2018) states that genomics research and biobanking may bring intangible benefits such as knowledge production and translation of relevant knowledge to healthcare practice. Capacity building described in the framework could be a tangible benefit: building a critical mass of researchers in genomics and biobanking. It can be done through training in genomics science and bioinformatics, but also in grants administration, contract negotiation, ethics and in transferable skills such as grant writing.

### Human Genome Organization (HUGO)

The [Statement on Benefit-sharing by the Human Genome Organization \(HUGO\)’s Ethics Committee](#) (2000) discusses issues around common heritage, benefit sharing and the principles of justice and solidarity. The recommendations made in the statement include the provision of immediate health benefits as determined by community needs, distribution of information about general research outcomes to all research participants, the allocation (by profit-making entities) of a specific percentage (e.g. 1–3%) of their annual net profit to healthcare infrastructure and/or to humanitarian efforts.

### Organisation for Economic Co-operation and Development (OECD)

The [Organisation for Economic Co-operation and Development \(OECD\) Guidelines on Human Biobanks and Genetic Research Databases](#) (2009) state that databases should encourage appropriate access to and use of human biological materials, data and information with a view to sharing benefits that may include building resource capacity or expertise. Further, the guidelines note that the benefit arising from research that uses a biobank or genetic research databases should be shared as broadly as possible, including by the sharing of information, licensing or transferring of technology or materials.

### United Nations

The UN has issued one declaration that explicitly discusses benefit sharing of genetic data in addition to several documents tangentially addressing the matter. The [2003 International Declaration on Human Genetic Data](#) states that benefits could be conferred using “special assistance to the persons or groups that have taken part in the research, access to medical care, or capacity-building facilities” *inter alia*. However, as the declaration is nearing 20 years old, many commentators have pointed to more recent, if less directly applicable, documents to guide their thinking. The [Nagoya Protocol](#), a 2011 document focusing on genetic resource use and benefits, emphasizes the rights of countries to maintain sovereignty over genetic resources. Article 14 established the [Access and Benefit-Sharing Clearing-House](#), a platform to “serve as a means for sharing of information related to access and benefit-sharing ... [and] provide access to information made available by each party relevant to the implementation of this protocol”. Articles 7, 11 and 12 address a particularly contentious problem in benefit sharing: the use of “traditional knowledge” held by indigenous peoples. To date, 118 countries are signatories to the Nagoya Protocol.

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- Sabatello, M. and Appelbaum, P. S. (2016). [Raising Genomic Citizens: Adolescents and the Return of Secondary Genomic Findings](#). *The Journal of Law, Medicine & Ethics*, 44(2), 292–308.
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