The Human Body Commons

A Private Law Contribution for the Advancement of the Right to Health

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9.1 INTRODUCTION

For much of history, research results and scientific knowledge were considered a part of the public domain. Basic research, carried out by academic and other nonprofit institutions, was heavily financed by public funds and agencies, which generally required data deposit into public repositories.¹ However, around the 1980s, a push for privatization of research² led to what has been termed the "enclosure of the mind"³ and a resultant profit-driven culture around scientific research.⁴

Biomedical research has been particularly affected by this process of privatization. Broadly speaking, biomedical research is a field of science that aims to develop tools (e.g., medicines, tests, vaccines, medical devices) that prevent and treat diseases. This type of research relies heavily on three different but connected types of resources: human biological materials (HBM), health data, and previous scientific knowledge.

In biomedical research, the epistemological shift, from a public domain-oriented conception of science and knowledge to a profit-driven research culture, has limited the advancement of knowledge and, consequently, the human right to health.

Historically, private law – through patents, licenses, other intellectual property mechanisms, contracts, and property rights – has been instrumental to privatization

- ¹ See Sheldon Krimsky, The Profit of Scientific Discovery and Its Normative Implications, 75(1) Chi.-Kent L. Rev. 15, 17 (1999). ("(I)n the mid-1950s, the federal government provided about fifty-five percent of the support for university research, industrial firm supplied eight percent of the funds and the remaining thirty-seven percent came from foundations and state governments. By the late 1960's, the government share expanded to more than seventy rising budget deficits and the leveling of science funding in the 1980s.")
- ² Jerome H. Reichman & Paul F. Uhlir, A Contractually Reconstructed Research Commons for Scientific Data in a Highly Protectionist Intellectual Property Environment, 66 L. & Contemp. Probs. 315 (2003).
- ³ James Boyle, The Public Domain: Enclosing the Commons of the Mind (2008).
- ⁴ Krimsky, supra note 1.

and commodification. However, a political and legal struggle to subvert the privatization of resources in biomedical research has emerged, based largely on the argument that bringing back scientific knowledge to the public domain may cause positive spillovers (e.g., innovation, economic value, and protection of human rights). The "idea of the commons" plays a pivotal role in this argument.

Private law and the commons in biomedical research are typically regarded as opposing concepts. While the traditional understanding of private law elicits notions of ownership, patents, and privatization, the imagery of the commons in biomedical research evokes opposing notions of open access to HBM, data, information, and knowledge.

However, these two approaches are not always mutually exclusive. Scientific practice has demonstrated how private law rules can enhance and protect the commons, while at the same time, encouraging innovation. This chapter therefore explores how private law, via the establishment of property rights, intellectual property, licenses, and other contracts, can serve to advance the right to health by reinforcing biomedical research anchored in the commons. In particular, it explores how the interplay between private law and the commons is instrumental in protecting and promoting individual and collective human rights, with particular emphasis on the right to health and health care and the right to enjoy the benefits of science and scientific progress. More specifically, it explores whether the traditional functions of private law's institutional arrangements can be modeled, and if necessary, subverted, to develop commons on (health) data, HBM, and scientific knowledge (together "human body commons").

9.2 HUMAN BODY COMMONS ENTANGLED: UNRAVELING GENEALOGIES AND TYPOLOGIES

The terms "commons" or "communing" elicit different meanings and are used differently by different bodies of literature and disciplines.⁵ While the terminology may be similar, the normative foundations and objectives behind these strands of scholarship differ significantly. This difference has led to considerable confusion and misunderstanding of the concept of the commons. A clear disambiguation is therefore essential to understand the potential application of this concept to health data, HBM, and scientific knowledge.

This chapter focuses on two distinct, but intertwined, bodies of literature that have developed clear theories on the commons: (1) theories on open commons (OC) and the public domain;⁶ and (2) the works on the Institutional Analysis and

⁵ Tine de Moor, What Do We Have in Common? A Comparative Framework for Old and New Literature on the Commons 57(2) Int'l Rev. Soc. Hist. 269, 272 (2012).

⁶ See, e.g., Carol Rose, The Comedy of the Commons: Custom, Commerce, and Inherently Public Property, 53(3) Univ. Chi. L. Rev. 711 (1986), https://www.jstor.org/stable/1599583? seq = 1&cid = pdf; James Boyle, The Public Domain: Enclosing the Commons of the Mind

Development (IAD) framework for the governance of common pool resources (CPR),⁷ as proposed by Elinor Ostrom and further developed and adapted to account for different types of commons and institutions for collective action.⁸

The OC envisions an open commons with a symmetric freedom to operate. Nobody from an unidentified class of users can rely on the power of the State to restrict access to the resource (usually non-rival or partially congestible). In this sense, OC is conceptually located outside the property regime.⁹ Common pool resources are bottom-up arrangements with clear rules of membership and access to a resource (characterized by high rivalry and low excludability).¹⁰ From this perspective, CPR are commons inside, but property outside, as members can rely on the power of the State to prevent nonmembers from accessing the resources.

Despite their differences, both types of commons (OC and CPR) share the underlying assumption that state or market solutions for the governance of resources are not always sufficient, nor necessary.¹¹ Nonetheless, these two theories on the commons can offer a compelling normative underpinning for the de-privatized governance of science and knowledge.

Two related problems at the intersection of both types of commons make the case: (1) the problem of sharing and circulating the managed resources and (2) the problem of freeriding, reseeding the commons, and distributing its benefits.

These problems are particularly complex for the governance of the different resources within the human body commons. First, individual rights on informed consent, privacy, and data protection tend to limit the circulation and the repurposing (secondary uses) of data and HBM. This makes personal data and HBM highly excludable (i.e., the use of these resources by others without consent is very

- ⁷ Elinor Ostrom, Governing the Commons: The Evolution of Institutions for Collective Action (1990); Elinor Ostrom, Background on the Institutional Analysis and Development Framework, 39(1) Pol'y Stud. J. 7 (2011).
- ⁸ Tine de Moor, From Common Pastures to Global Commons: A Historical Perspective on Interdisciplinary Approaches to Commons, 19(4) Natures Sci. Societes 422, 422–31 (2011); De Moor, supra note 5.
- ⁹ Even if one may formally find different underlying titles of property, it is the case of some types of infrastructure falling under the public property regime.
- ¹⁰ Charlotte Hess & Elinor Ostrom, Understanding Knowledge as a Commons: From Theory to Practice 5 (2007); De Moor, supra note 5, at 426.
- ¹¹ David Bollier, The Growth of the Commons Paradigm, in Hess & Ostrom, supra note 10, at 27.

^{(2008);} Yochai Benkler, The Wealth of Networks: How Social Production Transforms Markets and Freedom (2006); Yochai Benkler, Between Spanish Huertas and the Open Road, in Governing Knowledge Commons 69–98 (Brett Frischmann et al. eds., 2014); Yochai Benkler, The Political Economy of Commons, IV(3) Upgrade Eur. J. Informatics Pro. 6, 6–9 (2003); Yochai Benkler, Open Access and Information Commons, in 2 The Oxford Handbook of Law and Economics: Private and Commercial Law 256, 256 (Francesco Parisi ed., 2017); Lawrence Lessig, Code and the Commons, Keynote Address at Fordham L. Sch. Conference on Media Convergence (Feb. 9, 1999), https://dash.harvard.edu/bitstream/handle/ 1/12942294/COMMONS?sequence = 1; Brett M. Frischmann, Infrastructure: The Social Value of Shared Resources (2012).

limited).¹² Second, HBM, (health) data, and scientific knowledge are different types of resources: While scientific knowledge and data are, in principle, non-rival intangible resources (i.e., many can use the same resource at the same time) provisioned in market, public, or social processes, HBM are naturally provisioned tangible rival resources (i.e., the use of HBM prevents simultaneous consumption by others).

Third, the material dimension of HBM makes them perishable, consumable, and prone to contamination. Human biological samples are often consumed after they have been analyzed and, if not, it is difficult to guarantee that the samples have not been altered after the first analysis, which would make them unsuitable for research. Fourth, these resources are circularly connected – HBM are necessary for the extraction of data, which in turn, together with other types of health and medical data, are the raw materials for the creation of scientific knowledge. The latter is an input for further innovation and a source of positive societal spillovers. The obvious consequence of this interdependence is that the enclosure and privatization of one of these resources negatively affects the existence of the other two, while opening them contributes to the growth of the value of the others.¹³

Against this backdrop, the question is: How can OC and CPR be applied to the governance of the human body commons? Several specific theories have been put forward to make use of these overarching frameworks to govern the resources included under the umbrella term "human body commons": knowledge, data, and HBM. These theories include medical knowledge commons,¹⁴ genome or genomic commons,¹⁵ and medical information commons.¹⁶

- ¹³ Bollier, supra note 11, at 34.
- ¹⁴ Governing Medical Knowledge Commons (Katherine J. Strandburg et al. eds., 2017).
- ¹⁵ Jorge L. Contreas & Bartha M. Knoppers, The Genomic Commons, 19 Ann. Rev. Genomics Hum. Genetics 429 (2018); Jorge L. Contreras, Constructing the Genome Commons, 99 Governing Knowledge Commons 112, 112–13 (Brett M. Frichmann et al. eds., 2014). Similar proposals for commons on the results on genetic tests have also been advanced, see, e.g., Barbara J. Evans, Genomic Data Commons, in Governing Medical Knowledge Commons 74, 74–101 (Katherine J. Strandburg et al. eds., 2017).
- ¹⁶ Robert Cook-Deegan & Amy L. McGuire, Moving beyond Bermuda: Sharing Data to Build a Medical Information Commons, 27(6) Genome Rsch. 897 (2017); Robert Cook-Deegan et al., Sharing Data to Build a Medical Information Commons: From Bermuda to the Global Alliance, 18 Ann. Rev. Genomics Hum. Genetics 389, 389–415 (2017); Patricia A. Deverka et al., Creating a Data Resource: What Will It Take to Build a Medical Information Commons?, 9(1) Genome Med. 1 (2017).

¹² The European Data Protection Regulation (GDPR), for example, prohibits as a rule the processing data without the consent of the data subject. However, the GDPR also established a series of exceptions, among which the use of sensitive data for scientific research. See Enrique Santamaría, Governing Health Data for Research, Development and Innovation: The Missteps of the European Health Data Space Proposal, Bill of Health (Mar. 23, 2023), https://blog.petrieflom.law.harvard.edu/2023/03/23/governing-health-data-for-research-develop ment-and-innovation-the-missteps-of-the-european-health-data-space-proposal/ (with further references).

Although these theories reach different conclusions,¹⁷ their importance lies in their theorization of knowledge (and data) as a resource: (1) The fact that knowledge is cumulative makes sharing and creation inextricably related processes; (2) the intellectual products of the past are inputs for future products; (3) the non-rivalry and non-excludability of knowledge in abstracto lead its boundaries to be either artificially built (e.g., through patents) or derived from the embodiment of the knowledge resource (e.g., HBM containing data); and (4) the creation of knowledge depends on rivalrous inputs (e.g., time and money).

Through the analysis of commons-based initiatives of different scales and purposes, the next section examines how private law, by accounting for the aforementioned characteristics, can contribute to the further construction of the human body commons.

9.3 PRIVATE LAW AND HUMAN BODY COMMONS: BETWEEN OPEN COMMONS AND CPR

Commons may be the result of a top-down regulatory approach or, on the contrary, may arise as a response to a legal system establishing a proprietary regime for the governance of a given resource. In the latter case, the commons are carved out of the background law, by using or subverting the legal tools disposed by that very same legal regime.

Contract law and contracts constitute a relevant legal tool for the construction of human body commons. Jerome Reichman and Paul Uhlir were perhaps the first ones to explore the idea of a contractually reconstructed scientific commons.¹⁸ Their advancement constitutes, yet again, a response to the phenomenon of privatization of science and data taking place in the last two decades of the twentieth century in the United States. Precisely because of the cumulative and circular nature of knowledge, their analysis focused primarily on the deposit of data in publicly accessible databases. However, it did not include the sharing of HBM.

But building on their work, a combination of theory and practice may show how contracts can contribute to the construction of commons on HBM. Material transfer agreements, the Structural Genomics Consortium Open Trust Agreement, and data cooperatives serve as examples.

¹⁷ The point of departure of these theories is either: (1) Hess and Ostrom's variation of IAD framework for data and information which – together with other intelligible ideas and scientific knowledge – are covered under the umbrella term "knowledge commons," and/or (2) the Governing Knowledge Commons framework (GKC) developed by Katherine J. Strandburg, Brett M. Frischmann, and Michael J. Madison. See, e.g., Hess & Ostrom, supra note 10, at 7; Governing Knowledge Commons (Brett M. Frischmann et al. eds., 2014).

¹⁸ See Reichman & Uhlir, supra note 2 (providing information on contractual models for scientific data commons); Arti Rai & James Boyle, Synthetic Biology: Caught between Property Rights, the Public Domain, and the Commons, 5(3) PLOS Biology 389 (2007) (providing a specific analysis in the field of synthetic biology).

A material transfer agreement (MTA)¹⁹ is a contract in which a provider and a recipient agree to the transfer of tangible research materials, including HBM, for the recipient's use.²⁰ Beyond their importance in determining the intellectual property rights for provider and recipient, MTAs are also central to one of the core institutions in the collection, processing, and sharing of HBM: the biobank. Despite the many differences in types and purposes, from population to disease-specific, a biobank is essentially an organized collection of human biological samples and associated data for the purposes of present and future research.²¹ Biobanks may rely on tailor-made MTAs or can adopt a standardized MTA to share the samples in their collection to researchers and institutions. However, depending on the type of MTA, the recipient of the materials may not be allowed to further share original or derived materials.

For this reason, several standardized MTA models have been developed to facilitate the transfer and sharing of biological materials beyond the first recipient. These models include the Uniform Biological MTA (hereafter UBMTA),²² the Science Commons MTA,²³ and the Open MTA.²⁴

The first of these models, the UBMTA, was developed in the United States by the National Institutes of Health (NIH) in collaboration with other repositories.²⁵ Although it facilitated sharing materials by eliminating the need for lengthy or impractical negotiations between institutions, it was also limited to academic or nonprofit institutions and precluded both commercial uses and the further distribution of materials and derivatives.²⁶

- ¹⁹ See Victor Rodriguez, Material Transfer Agreements: Open Science vs. Proprietary Claims, 23
 (4) Nature Biotech. 489, 489–91 (2005) (an overview of the notion of material transfer agreement and the debate around open science on human materials).
- ²⁰ Int'l Soc'y for Biological and Env't Repositories (ISBER), Best Practices for Repositories: Collection, Storage, Retrieval and Distribution of Biological Materials for Research 88 (3rd ed. 2001).
- ²¹ Lisa Dive et al., Public Trust and Global Biobank Networks, 21 BMC Med. Ethics 1 (2020).
- ²² Uniform Biological Material Transfer Agreement, dated March 8, 1995, for the Transfer of Materials between Non-Profit Institutions and an Implementing Letter for the Transfer of Biological Material, World Intell. Prop. Org. (1995) https://www.wipo.int/tk/en/databases/con tracts/texts/ubmta.html.
- ²³ Thinh Kguyen, Science Commons: Material Transfer Agreement Project, 3(2) Innovations Tech., Governance, Globalization 137, 137–43 (2007).
- ²⁴ Linda Kahl et al., Opening Options for Material Transfer, 36(10) Nature Biotech. 923, 923–27 (2018).
- ²⁵ Kguyen, supra note 23, at 140.
- ²⁶ More than 300 institutions have become signatories of the UBMTA. See UMBTA Signatories, Ass'n of Univ. Tech. Managers, https://autm.net/surveys-and-tools/agreements/material-transferagreements/mta-toolkit/uniform-biological-material-transfer-agreement/ubmta-signatories (last accessed May 8, 2023). Addgene, one of the biggest repositories of plasmids in the world, is an example of successful implementation of the UBMTA. Addgene, acting as an intermediary, continues to use the UBMTA for sharing plasmids deposited in its repository. See MTA: UBMTA, Addgene, https://www.addgene.org/agreement/h (last accessed May 8, 2023).

To remedy this situation, the Science Commons MTA permitted, under certain circumstances, the commercial use of materials, but continued to prohibit their further distribution. To overcome this limitation, the Open MTA was designed. The Open MTA not only allows its use to for-profit and nonprofit entities alike but also permits the use for commercial purposes and the further distribution of materials and derivatives (including tissue samples). Its design was based on the principles of nondiscrimination, access, attribution, redistribution, and reuse.²⁷ Despite their differences, these standardized MTAs constitute essential tools to guarantee and facilitate redistribution of biological materials.

Moreover, because standard MTAs can be easily adopted, they also enable biobanks to integrate in wider biobank networks,²⁸ participating in that way as nods in an open and growing network of human body commons.²⁹

Although the use of MTAs to facilitate the construction of human body commons is not completely new, their use has highlighted some of the advantages of using private law to facilitate the commons. But there are also disadvantages to consider. First, if MTAs do not include clauses on how research results would return to the commons (the problem of reseeding the commons described above), MTAs may in fact contribute to the privatization of research instead of advancing its opening. Second, the limits of MTAs stem from their contractual nature: as contracts are, as a general rule, not enforceable against third parties,^{3°} it would be difficult for the original provider of the materials to start an action against a third party who received the materials from the recipient side of the MTA. In other words, MTAs are not very useful in enabling the circulation of materials and data under the same set of rules and limitations.

Perhaps because of this very reason, private law has also relied – beyond contract – on property law for the circulation of research materials and the promotion of open science. The case of the Structural Genomics Consortium (SGC) Open Science Trust Agreement (OSTA) provides an important example.

SGC is a charity registered in the United Kingdom, the mission of which is to accelerate research in new areas of human biology and drug discovery.³¹

- ²⁷ The Open MTA was developed as a collaborative effort led by the Biobricks Foundation and the OpenPlant Synthetic Biology Research Centre. See Frequently Asked Questions, BioBricks Found., https://biobricks.org/openmta-faq/ (last accessed May 8, 2023); The Open Material Transfer Agreement, BioBricks Found., https://biobricks.org/open-material-transfer-agreement/ (last accessed May 8, 2023).
- ²⁸ Darren Shickle et al., Inter- and Intra-biobank Networks: Classification of Biobanks, 77(4) Pathobiology 181, 181–90 (2010).
- ²⁹ See Andrea Boggio, Population Biobanks' Governance: A Case Study of Knowledge Commons, in Governing Medical Knowledge Commons 102–20 (2017) (a parallel between population biobanks and knowledge commons).
- ³⁰ Niva Elkin-Koren, What Contracts Cannot Do: The Limits of Private Ordering in Facilitating a Creative Commons, 74 Fordham L. Rev. 375 (2005).
- ³¹ For information on the Structural Genomics Consortium and the Open Science Trust Agreement, see Frequently Asked Questions – SGC Open Science Trust Agreement,

Unlike MTAs, in which a bilateral agreement is concluded between provider and recipient, the SGC OSTA is an agreement in which the recipient of the materials agrees to become a trustee of the research material.

According to the SGC's website:

A trust such as the OSTA is a legal mechanism under which an appointed trustee takes legal possession of property but assumes a duty to use or manage that property to benefit certain beneficiaries, which can be third parties and/or the public. With the OSTA, unlike under an MTA, by becoming a trustee of SGC-provided research material, a recipient is undertaking a specific duty to benefit the public through open science.³²

Some of the obligations of the trustee include (1) not seeking or enforcing intellectual property rights covering the material, which could deter or prevent others in the research community from using the material to further the public good, and (2) placing the research findings and data resulting from their work with the material into the public domain, which helps to accelerate discovery.

Furthermore, the trustee is permitted to disseminate "the material to other researchers who likewise agree to become trustees, thus expanding the community of researchers committed to open science for the public good."³³

According to the SGC, the rationale behind such an agreement, instead of an MTA, for example, is that treating the materials, not as a proprietary good, but as a public one to be shared broadly, accelerates discoveries stemming from the use of the material. Although initially mandated (i.e., the investigator requesting the materials must become a trustee), further transfers to new trustees must happen on a voluntary basis.

While the OSTA was not specifically designed to share HBM,³⁴ one can envision ways to modify it and include the possibility of sharing materials of human origin.³⁵ More specifically, it would be possible at the point of collection of the materials, for example, via broad consent mechanisms, to enable circulation of materials that otherwise could not circulate freely. An alternative to consent mechanisms for the circulation of materials of human origin would be to devise a specific set of

Structural Genomics Consortium, https://www.thesgc.org/sgc-open-science-trust-agreements (last accessed May 8, 2023).

³⁴ Aled Edwards et al., A Trust Approach for Sharing Research Reagents, 9(392) Sci. Translational Med. 1, 1–3 (2017). The idea of putting highly commercially valuable reagents and data in the public domain is not new. See, e.g., Declan Butler, GlaxoSmithKline Goes Public with Malaria Data, Nature (Jan. 20, 2010), https://www.nature.com/articles/news.2010.20 (Glaxo's released 13,500 structures of possible drugs against Malaria into the public domain).

³⁵ Here, the question on the existence of property rights on HBM is of paramount importance. However, it is beyond the scope of this chapter to dwell in this litigious issue.

³² Id.

³³ Id.

principles for which research on HBM without consent would be legally and ethically permissible.

In addition to contracts and property law, other private law instruments allow for the creation of institutions of collective action for the construction of the human body commons. Cooperative-based initiatives for the governance of health data are particularly interesting.

Health data cooperatives are associations of individuals under a cooperative structure for the collective governance of their individual health data for mutual benefit.³⁶

According to some cooperative models for the use of health data, when data are controlled by citizens themselves, potential value of data can be maximized, while at the same time guaranteeing the protection of the data subjects' rights. Thus, one could think of models in which the storage and secure handling of data is overseen by a trusted entity: the cooperative (co-op). Users could purchase a membership certificate for an amount of money and use the co-op as a trusted repository.

Although the cooperative model was initially intended for genomic data, nothing prevents people from depositing all kinds of personal or health data, regardless of their origin (e.g., applications, wellness devices, and medical devices). In this way, the members of the cooperative would have the right to vote on decisions related to the benefits derived from the exploitation of their data by third parties.

Under this model, a pharmaceutical or medical technology company, for example, would pay a sum of money for the right to exploit the data that the members of the cooperative have decided to share, and could also, depending on the agreements adopted, deliver the results of the research to the accounts of the associates or to the cooperative. The economic benefits of the information that the cooperative obtains from the exploitation of the data could be reinvested in research programs or other types of projects of public interest.

Data cooperatives are a perfect example of a CPR that integrates different sorts of data and data sources for biomedical research.

MIDATA *Genossenschaft* (MIDATA), a Swiss health data cooperative, serves as a case in point. According to its articles of association,³⁷ MIDATA operates a secure IT platform for the processing and sharing of personal data, and in particular, health data. The cooperative makes the platform available to natural persons so they can use it to store and share their data as self-determining agents with the aim of supporting research purposes.

³⁶ See generally E. Hafen et al., Health Data Cooperatives – Citizen Empowerment, 53(2) Methods Info. Med. 82 (2014); Alessandro Blasimme et al., Democratizing Health Research through Data Cooperatives, 31(3) Phil. Tech. 473, 473–79 (2018); Van Ilse Roessel et al., Potentials and Challenges of the Health Data Cooperative Model, 20(6) Pub. Health Genomics 321 (2018).

³⁷ Articles of Association, MIDATA Genossenschaft (2019), https://www.midata.coop/wp-content/ uploads/2019/08/MIDATA_Statuten_20190626_EN.pdf.

MIDATA promotes the collective interests of account holders by enabling the shared use of their personal data. Individual account holders can consent to data analysis and secondary use by third parties in return for economic compensation.³⁸

At this point, it becomes evident how data cooperatives, as a form of CPR, can successfully manage genomic and other types of health data, while at the same time reseeding the commons with the profits and research results arising from the use of pooled data.

MIDATA is also relevant from the point of view of managing privacy in the human body commons.³⁹ Although in this case, explicit informed consent is necessary for the processing and sharing of health data, it is possible to find other legal pathways to govern health data sharing and access for secondary uses. Moreover, although data cooperatives have not yet proliferated, it is very likely that an increase in their number will follow their legal recognition by the EU Data Governance Act.

9.4 CONCLUSION

From the analysis of theories on the human body commons and private law examples from biomedical practices, several conclusions can be derived: (1) It is necessary to integrate different types and sources of data, facilitating interoperability and data sharing; (2) due to the circular nature of knowledge and data commons, to build a human body commons, it is necessary to strike an equilibrium between the positive societal data sharing spillovers and data protection and other individual human rights; (3) HBM, and not only knowledge and data, must be integrated in the analysis; and (4) it is paramount to establish clear rules for the reseeding of the human body commons in such a way that the intellectual products of the past become the input for future knowledge.

Furthermore, because human body commons integrate different types of resources (i.e., HBM, health data, and scientific knowledge), a combination of different types of commons is necessary for its further construction and development: top-down Open Commons and carved-out Common Pool Resources commons. By way of explanation, public ordering solutions open the scope of the public domain for the creation of open human body commons, while private ordering solution create common property regimes.

New theories on data, which facilitate the repurposing and reuse of health data, would change the status of personal health data from highly excludable to non-

³⁸ Id. at 2 (Article 2(h)).

³⁹ For a detailed analysis of privacy and MIDATA, see Felix Gille and Effy Vayena, How Private Individuals Maintain Privacy and Govern Their Own Health Data Cooperative: MIDATA in Switzerland, in Governing Privacy in Knowledge Commons 53–69 (Madelyn R. Sanfilippo et al. eds., 2021). On privacy in the commons, see generally Madelyn R. Sanfilippo et al., Governing Privacy in Knowledge Commons (2021).

excludable. In this sense, a jump from a CPR to an OC can be envisioned with the help of regulatory instruments, which allow to bypass consent for the use of data for the "common good."

For HBM, the embodied resource of the human body commons, it seems difficult to imagine a fully open commons. However, private law has proven useful for the circulation and sharing of materials and associated data. Here, commons on HBM can be organized as multiple nodes (e.g., biobanks) of CPR connected to a wider mixed network of health data OC and CPR.

For scientific knowledge, it is necessary to guarantee that the developments and innovation derived from the use of OC and CPR in HBM and health data, return and reseed the commons in the forms of knowledge, benefit sharing, and money. This could be enabled by top-down regulation or by forms of collective action and negotiation (e.g., health data cooperatives) with data users and industry.

This chapter demonstrated how contracts, property, and other private law mechanisms may be used as vehicles for the governance of health research resources and health policy.

Such policy must develop a framework to avoid freeriding from actors using the commons, as well as a normative framework well-grounded in the promotion and protections of human dignity and human rights,⁴⁰ with specific reference to the right to health and the right to enjoy the benefits of science may be a good starting point.

⁴⁰ Roberto Andorno, Human Dignity and Human Rights as a Common Ground for a Global Bioethics, 34(3) J. Med. Phil. 223 (2009); Roberto Andorno, Principles of International Biolaw: Seeking Common Ground at the Intersection of Bioethics and Human Rights (2013); Eric M. Meslin & Ibrahim Garba, Biobanking and Public Health: Is a Human Rights Approach the Tie that Binds?, 130(3) Hum. Genetics 451 (2011); Bartha M. Knoppers et al., A Human Rights Approach to an International Code of Conduct for Genomic and Clinical Data Sharing, 133(7) Hum. Genetics, 895 (2014).