

Contracts that restrict patent filing or impose patent-licensing obligations

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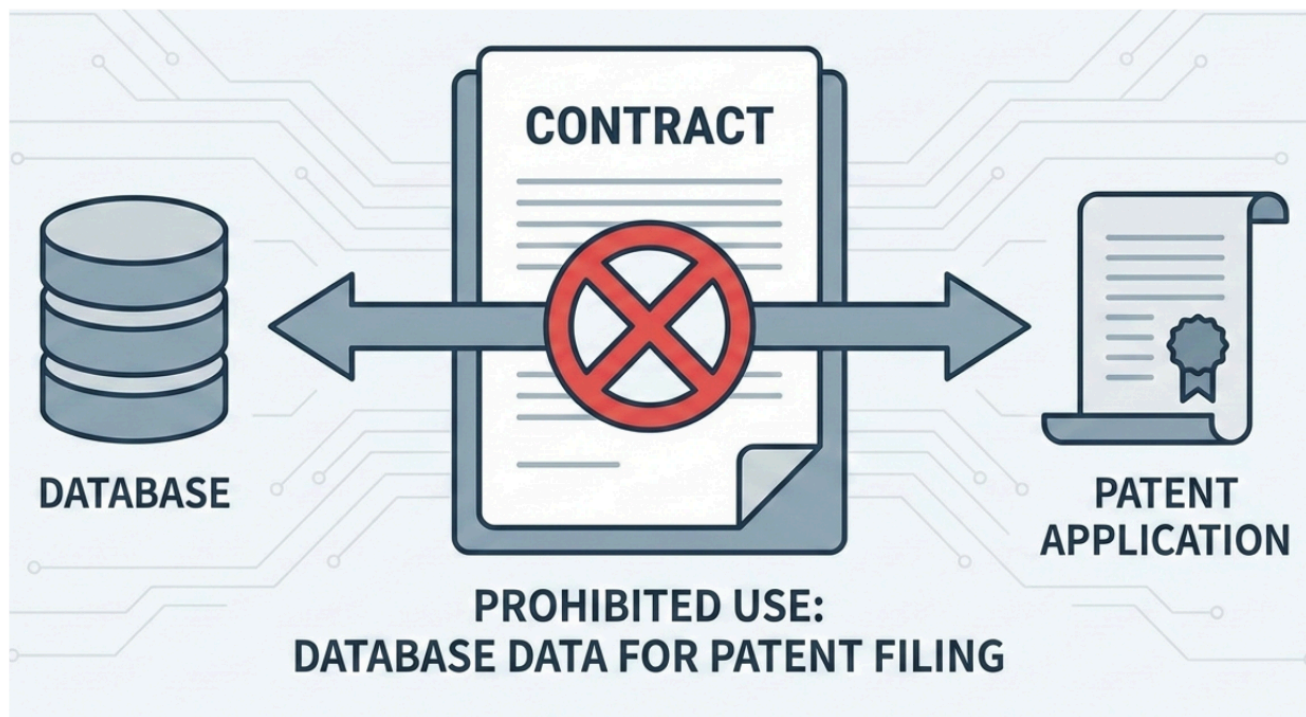


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Introduction

This briefing note compiles examples of contractual language from data-sharing agreements and material transfer agreements (MTAs) that include restrictions on patent filing or requirements for licensing. The examples are drawn from research consortia, databases, and MTAs and are presented together in this briefing note.

International HapMap Project

The International HapMap Project is a collaboration among industry, academic and non-profit biomedical research entities, located in Canada, China (including Hong Kong), Japan, Nigeria, the United Kingdom, and the United States, launched in October 27 to 29, 2002. From the abstract in the cited article in Nature:

The goal of the International HapMap Project is to determine the common patterns of DNA sequence variation in the human genome and to make this information freely available in the public domain. An international consortium is developing a map of these patterns across the genome by determining the genotypes of one million or more sequence variants, their frequencies and the degree of association between them, in DNA samples from populations with ancestry from parts of Africa, Asia and Europe. The HapMap will allow the discovery of sequence variants that affect common disease, will facilitate development of diagnostic tools, and will enhance our ability to choose targets for therapeutic intervention.¹

The project's own history on the site of the National Human Genome Research Institute (NHGRI) describes the original data release policy as including a "click-wrap" license that was originally imposed to prevent "parasitic patents."

- International HapMap Project,
<https://www.genome.gov/10001688/international-hapmap-project>

The HapMap project has also been described as follows:

"The HapMap project began in 2002, seeking to encourage collaboration among researchers contributing to a common database of what was intended to be "pre-competitive" research resources. The managers were faced with the prospect that some might use the database to file patents, effectively creating new barriers for researchers. To address this risk, access to the database was initially restricted to registered users, who were asked to agree to limits on the uses of the data, as regards filing of patents. The "International HapMap Project Public Access License" prohibited users from filing any patent applications that contain claims to any composition or use of any single nucleotide polymorphism ("SNP"), genotype or haplotype data obtained from the Genotype Database. The HapMap license was restrictive, creating problems in the

¹ The International HapMap Consortium. The International HapMap Project. Nature 426, 789–796 (2003).
<https://doi.org/10.1038/nature02168>

dissemination of the data, but designed to protect the database so it would later enter the public domain. After a period of time, the registration requirement was eliminated, and its initial purpose was considered to have achieved its objectives by many participants.”

The original 2003 version of the license included restrictions on filing patents.

International HapMap Project Public Access License 1.1. PubRL 4 (1 August 2003)

International HapMap Project Public Access License 1.1 [2003] PubRL 4 (1 August 2003) <https://www.worldlii.org/int/other/PubRL/2003/4.html>

...

You may access and conduct queries of the Genotype Database and copy, extract, distribute or otherwise use copies of the whole or any part of the Genotype Database's data as you receive it, in any medium and for all (including for commercial) purposes, **provided always that:**

by your actions (whether now or in the future), you shall not restrict the access to, or the use which may be made by others of, the Genotype Database or the data that it contains;

in particular, but without limitation,

you shall not file any **patent applications** that contain claims to any composition of matter of any single nucleotide polymorphism ("SNP"), genotype or haplotype data obtained from the Genotype Database or any SNP, haplotype or haplotype block based on data obtained from the Genotype Database; and

you shall not file any **patent applications** that contain claims to particular uses of any SNP, genotype or haplotype data obtained from the Genotype Database or any SNP, haplotype or haplotype block based on data obtained from, the Genotype Database, unless such claims do not restrict, or are licensed on such terms that that they do not restrict, the ability of others to use at no cost the Genotype Database or the data that it contains for other purposes; and

you disclose data obtained as a result of your access to and use of the Genotype Database only to other parties who have first confirmed to you in writing that they too are licensees under the terms of the International HapMap Project Public Access License and so are bound by equivalent terms and conditions to those that you have accepted under this License. If you were to include the details of the

individual genotypes in a publication, you could not conform to this clause; therefore, you may not include in publications the data on genotypes of individual HapMap samples that you obtained from the Genotype Database. However, you may publish conclusions based on such data, you may cite the Project database as your source of the data so that others may obtain access to them on the same terms as you obtained them, and you may provide the individual genotypes supporting those conclusions to any individual who has confirmed to you in writing that s/he is a licensee under the terms of the International HapMap Project Public Access License. . . .

Structural Genomics Consortium

The Structural Genomics Consortium is a global public-private partnership that supports the discovery of medicine through open-access research. It was set up to fast-track new medical discoveries by fostering collaboration among networks of scientists and making all its research output freely available.²

Funding for the consortium includes: Structural Genomics Consortium receives funds from Bayer AG, Boehringer Ingelheim, Bristol Myers Squibb, Genentech, Genome Canada through Ontario Genomics Institute, Canada Foundation for Innovation, Ontario Research Fund, MITACS, EU/EFPIA/OICR/McGill/KTH/Diamond Innovative Medicines Initiative 2 Joint Undertaking [EUOPEN grant 875510], Janssen, Merck KGaA (aka EMD in Canada and US), Pfizer, and Takeda.

The 2024 SGC Open Science Policy³

The Structural Genomics Consortium (“SGC”) is a partnership of public and private funders (“Members”) formed to support and engage in pre-competitive research to better understand human disease biology and to facilitate the discovery of new medicines. The SGC’s scientific program is carried out at host academic institutions (“Institutions”) and the scientists who are formally associated with the SGC at these Institutions (“SGC Scientists”) engage in research to generate enabling reagents and knowledge related to proteins of potential therapeutic relevance. The SGC believes that these outputs will have maximal benefit if released into the public domain without restriction on use, and thus has adopted this Policy . . .

The SGC, SGC Scientists, and their research collaborators must commit to making their open access research outputs (materials and knowledge) publicly available without restriction on use. This means the SGC and SGC Scientists will seek to place open access results arising from SGC Scientists’ research projects (internal or collaborative) in the public

² <https://www.thesgc.org/>

³ <https://www.thesgc.org/sites/default/files/2025-02/SGC%20Open%20Science%20Policy.pdf>

domain and may not file for patents or other registered intellectual property protections in respect of the outputs of these research projects . . . [emphasis added]

FNIH Consortia / Accelerating Medicines Partnership

The Accelerating Medicine Partnership (AMP) is a portfolio of Foundation for the National Institutes of Health (FNIH)-managed public-private consortia created by NIH and major pharmaceutical companies to share early-stage scientific data and jointly validate disease targets, biomarkers, and tools, typically with stringent open-science and IP-restriction rules.

In their 2023 Summary of the AMP Policies, it states:

*“Pre-existing IP must be free to be used by the partnership. **All research discoveries are intended to be released into the public domain, with no pre-emptive patenting.** In rare instances when this is not possible, FNIH will determine fair strategies for distributing IP to encourage broad commercialization and balanced public health benefit and review them with the Steering Committee and Executive Committee.”⁴ [emphasis added]*

More broadly, the AMP has noted that the initiative is intended to have data that is deposited in a rapid and timely way in a repository that is accessible for use by the broad biomedical community. As such, they note that “the research supported under the AML initiative is intended to be pre-competitive and will neither make use of proprietary pre-existing intellectual property nor is expected itself to produce patentable findings.”⁵

Accelerating Medicines Partnership: Parkinson’s Disease (AMP PD)⁶

The AMP PD program is a public-private partnership managed by the Foundation for the National Institutes of Health and funded by the National Institute of Neurological Disorders and Stroke (NINDS) in partnership with the Aligning Science Across Parkinson's (ASAP) initiative; Celgene Corporation, a subsidiary of Bristol-Myers Squibb Company; GlaxoSmithKline plc (GSK); The Michael J. Fox Foundation for Parkinson's Research; AbbVie Inc.; Pfizer Inc.; Sanofi US Services Inc.; and Verily Life Sciences.

Data Use Agreement

Last Updated 10.04.2024

16. I acknowledge that the AMP PD program and GP2 have separate intellectual property (IP) policies and agree as follows:

⁴ https://fnih.org/wp-content/uploads/2023/05/AMP-SBI-Concept_to-AMP-EC.pdf

⁵ <https://grants.nih.gov/grants/guide/rfa-files/RFA-DK-14-003.html>; and <https://grants.nih.gov/grants/guide/rfa-files/rfa-dk-19-505.html>

⁶ https://oncinfo.org/_media/wiki%3Aidsp_amp-pd_zare_knowledge-platform_alf_04apr2025_fe_dua.pdf

a. Data from the AMP PD program were generated under and are subject to an existing arrangement that has the following AMP PD Intellectual Property Policy that states: “**AMP PD users agree not to file patent applications on research discoveries made using the AMP PD Data, except in the rare instance when a consensus of the Foundation for the National Institutes of Health (FNIH), the AMP PD Steering Committee and the AMP Executive Committee agree that it is in the best interests of the partnership and public health to do so.** Intellectual property developed under National Institutes of Health (NIH) awards are subject to applicable Federal law, regulation, and NIH policy.” Accordingly, it is in the rare instance that the AMP PD Steering Committee, through an approval protocol, will deem that it is in the best interest of the AMP PD program and the public health to grant an exception. If an exception is granted, I agree to grant the funding partners of the AMP PD program a nonexclusive, worldwide, royalty-free, sublicensable license to use and/or disclose the intellectual property rights in and to the research discoveries made using the AMP PD Data for noncommercial research purposes. [emphasis added]

Bespoke AAV Gene Therapies to Treat Rare Diseases for AMP Bespoke Gene Therapy Consortium⁷

The Bespoke Gene Therapy Consortium (BGTC) is an AMP initiative focused on rare diseases. In particular, BGTC is dedicated to making gene therapy a reality for people with rare genetic diseases affecting populations too small to be viable from the current commercial perspective. The goal of the BGTC is to evaluate methodologies to streamline the process of AAV gene therapy clinical trials initiation for pediatric and adult monogenic disease.

Partners of the BGTC include Thermo Fisher Scientific, Genethon, Biogen Inc, Novartis, National Organization for Rare Disorders, and Danaher Corporation.

All applicants to BGTC will be expected to comply with the AMP BGTC IP Principle:

*Given its precompetitive research focus and commitment to making results of that research available as broadly and promptly as possible, it is not expected that BGTC will generate novel IP. BGTC award recipients may use pre-existing IP for work done under the partnership. BGTC research awardees **agree not to file patent applications on research discoveries made under the partnership**, except in the rare instance when a consensus of FNIH and the BGTC agree that it is in the best interests of the partnership and public health to do so. IP developed by the NIH or under NIH awards are subject to applicable Federal law, regulation, and policies.*

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<https://fnih.org/sites/default/files/2022-07/BGTC%20RFP%20Bespoke%20Gene%20Therapy%20Clinical%20Trials%20FINAL%2020220712.pdf>

AMP Systems Biology of Inflammation

The AMP Systems Biology of Inflammation concept proposes to leverage existing and new-miomics datasets to develop a new paradigm in approaching diseases and treatments based on shared molecular pathways. Design phase partners include AbbVie, AstraZeneca, Biogen, Eisai, Gilead, GSK, Janssen, Merck, Novartis, Pfizer, Regeneron, Roche, Sanofi and Takeda.

*“Rights to existing IP used to generate AMP data or interrogate AMP data remain with the inventor. AMP SBI will not ‘reach through’ to any background IP. However, **no new IP may be generated using AMP or AMP SBI data**. AMP SBI is committed to open science and creating a resource for the research community at large.”⁸*

AMP Rheumatoid Arthritis, Systemic Lupus Erythematosus & Related Autoimmune Disorders

The AMP RA/SLE program works to improve our understanding of autoimmune diseases through a focus on rheumatoid arthritis (RA) and systemic lupus erythematosus (SLE). The overall goal of the program is to ascertain and define shared and disease-specific biological pathways through a molecular and cellular-level ‘disease deconstruction’ approach to identify relevant drug targets for the treatment of autoimmune diseases.

Private sector partners that provided financial support to the project include AbbVie, Arthritis Foundation, Bristol-Myers Squibb, GSK, Janssen, Lupus Research Alliance, Lupus Foundation of America, Merck, Rheumatology Research Foundation, Pfizer, Sanofi and Takeda.

*“This project will operate under the general policies of the Accelerating Medicines Partnership. [...] **Any novel findings that might be generated from biomarker identification and validation would be published and thus made available in the public domain so as to facilitate the broadest possible application to enabling the development of treatments for AMP AIM, including development of downstream IP, without any pre-emptive patent restrictions.** There is a potential for intellectual property to be developed around the methods and technologies needed to generate any validated data, but these too would be downstream inventions (e.g., xxx) that could be broadly enabled by but would not be part of the proposed AMP activities.”⁹*

Parkinson’s Progression Markers Initiative¹⁰

Parkinson’s Progression Markers Initiative (PPMI) is a study collaboration with partners to create an open-access data set and biosample library to speed scientific breakthroughs and new

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<https://fnih.org/our-programs/accelerating-medicines-partnership-amp/amp-systems-of-biology-inflammation/>

⁹ https://fnih.org/sites/default/files/2021-12/AMP%20AIM_Concept%20for%20Web_Dec2021.pdf

¹⁰ <https://www.ppmi-info.org/sites/default/files/docs/ppmi-data-use-agreement.pdf>

treatments. The PPMI a public-private partnership – is funded by the Michael J. Fox Foundation for Parkinson's Research and funding partners, including 4D Pharma, Abbvie, AcureX, Allergan, Amathus Therapeutics, Aligning Science Across Parkinson's, AskBio, Avid Radiopharmaceuticals, BIAL, BioArctic, Biogen, Biohaven, BioLegend, BlueRock Therapeutics, Bristol-Myers Squibb, Calico Labs, Capsida Biotherapeutics, Celgene, Cerevel Therapeutics, Coave Therapeutics, DaCapo Brainscience, Denali, Edmond J. Safra Foundation, Eli Lilly, Gain Therapeutics, GE HealthCare, Genentech, GSK, Golub Capital, Handl Therapeutics, Insitro, Jazz Pharmaceuticals, Johnson & Johnson Innovative Medicine, Lundbeck, Merck, Meso Scale Discovery, Mission Therapeutics, Neurocrine Biosciences, Neuron23, Neuropore, Pfizer, Piramal, Prevail Therapeutics, Roche, Sanofi, Servier, Sun Pharma Advanced Research Company, Takeda, Teva, UCB, Vanqua Bio, Verily, Voyager Therapeutics, the Weston Family Foundation and Yumanity Therapeutics.¹¹

The PPMI data use agreement states the following:

I will comply with the PPMI Intellectual Property (IP) Policy that states:

- A. *Rights to any non-PPMI IP (“Background IP”) that a researcher uses in analyzing or manipulating PPMI data, information, biospecimens, materials, or results (“Study Materials”) may not be claimed by any other researcher or institution;*
- B. *No researcher or institution may claim any IP rights to any Study Materials or inventions arising out of the Study Materials; and,*
- C. *Researchers who publish or present analyses of Study Materials will make these freely available without charge to the research community through the PPMI website, when not prohibited by journal copyright terms and conditions.*

Material Transfer Agreements (Plants and Biological Materials)

Model Material Transfer Agreement suggested by the Biotechnology Industry Organization (BIO)¹²

The Biotechnology Innovation Organization (BIO) is a biotechnology advocacy organization representing biotech companies, industry leaders, and state biotech associations in the United States and more than 35 countries around the globe.

BIO's Model Material Transfer Agreement states the following:

Article 4. Use of Materials

4.3. The [Transferee] shall not seek patents or plant variety protection rights in the Materials as such as they are listed in Article 2 (i.e., materials in the form they are transferred to the [Transferee]). The [Transferee] may apply for the grant of patents claiming inventions developed

¹¹ <https://www.ppmi-info.org/sites/default/files/docs/PPMI%20Funding%20Partners.pdf>

¹² <https://www.wipo.int/tk/en/databases/contracts/texts/bio.html>

using samples of the transferred Materials, including inventions embodied in modified forms of the materials, or for the grant of plant variety protection claiming varieties developed using samples of the transferred Materials.

Confidentiality and Material Transfer Agreement - Plant Breeding Anti-Contamination¹³

Memorandum of Agreement between the National Research and Innovation Agency and J Government, regarding Research, Assessment, Implementation, Invention and Innovation of New Superior Varieties of Cotton, Kasna Flower, Child Peanut and Seraya Corn in Bali, 2022.

The Partner acknowledges and agrees that:

(a) the Material is made available for investigational use only;

(b) it will not obtain or attempt to obtain any patent protection in relation to: i.) any part of the Material (or any modification or use of any part of the Material); or ii.) any materials that could not have been made but for having access to the Material, without the prior written consent of the Company;

Germplasm License Agreement for "Line Ten" between Her Majesty the Queen in Right of Canada (Licensor) and Company Canada Inc. (Licensee)¹⁴

Line Ten is going to be used as a parent in a Company breeding program to develop new hybrid lines, and new open-pollinated lines, which may become varieties sold to farmers. No other permitted use or applications. The Company is a grain company in Canada; its actual identity is confidential.

*4.3 It is agreed that CANADA is the sole owner of Line Ten and has the right pursuant to the Plant Breeders' Right Act to issue a license. The LICENSEE shall have no rights in and to the foregoing except as may be expressly granted hereunder and the **LICENSEE shall not apply for any patent or other right and shall not divulge or disclose, without the prior written consent of CANADA**, any information, material or documents concerning same or make available in any way or use Line Ten except as expressly provided in this LICENCE AGREEMENT, mainly to use the Line Ten in a breeding program of the LICENSEE to produce a VARIETY OR VARIETIES for the use of the LICENSEE.*

¹³ <https://www.wipo.int/tk/en/databases/contracts/texts/2023-11-0001.html>

¹⁴ <https://www.wipo.int/tk/en/databases/contracts/texts/lineten.html>

Model Material Transfer Agreement: Consultative Group on International Agricultural Research (CGIAR)¹⁵

The material is held in trust under the terms of an agreement between [Centre] and FAO, and the recipient has no rights to obtain Intellectual Property Rights (IPR) on the germplasm or related information.

Material Transfer Agreement for Plant Genetic Resources held in trust by the Center¹⁶

The Center is making the material described available as part of its policy of maximizing the utilization of genetic material for research. One of the conditions is as follows:

The material is held in trust under the terms of this agreement, and the recipient has no rights to obtain Intellectual Property Rights (IPRs) on the material or related information.

Material Transfer Agreement between Party A and Party B (confidential)¹⁷

Confidential agreement on the exchange of rice genetic resources for breeding. On the rights and obligations of the recipient, the Material Transfer Agreement states that:

The Recipient shall not claim any intellectual property or other rights that limit the facilitated access to the Material provided under this Agreement, or its genetic parts or components, in the form received from the Multilateral System.

Material Transfer Agreement between ICABIOGRAD and NAFRI, ARC (Laos)¹⁸

The Indonesian Center for Agricultural Biotechnology and Genetic Resources Research and Development and the Agriculture Research Center (ARC), and the National Agriculture and Forestry Research Center (NAFRI) of Laos enter into a Material Transfer Agreement to exchange rice genetic resources for breeding. The agreement states the following:

¹⁵ <https://www.wipo.int/tk/en/databases/contracts/texts/cgiar.html>

¹⁶ <https://www.wipo.int/tk/en/databases/contracts/texts/centers.html>

¹⁷ https://www.wipo.int/tk/en/databases/contracts/texts/2019_09_mta_irri_icabiograd_iaard.html

¹⁸ https://www.wipo.int/tk/en/databases/contracts/texts/2019_10_mta_nafri_icabiograd_iaard.html

The Recipient shall not claim any intellectual property or other rights that limit the facilitated access to the Material provided under this Agreement, or its genetic parts or components, in the form received from the Multilateral System.

Standard Material Transfer Agreement: International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGRFA)¹⁹

Article 12.4 of the International Treaty on Plant Genetic Resources for Food and Agriculture provides that facilitated access under the Multilateral System shall be provided pursuant to a Standard Material Transfer Agreement, and the Governing Body of the Treaty, in its Resolution 1/2006 of 16 June 2006, adopted the Standard Material Transfer Agreement. The Agreement states the following:

The Recipient shall not claim any intellectual property or other rights that limit the facilitated access to the Material provided under this Agreement, or its genetic parts or components, in the form received from the Multilateral System.

Principles, Policies, and Guidelines

Human Genome Project Bermuda Principles 1996²⁰

In a 1996 summit in Bermuda, leaders of the international Human Genome Project agreed on a set of principles at the International Strategy Meeting on Human Genome Sequencing, Bermuda, 25th-28th February 1996, sponsored by the Wellcome Trust. The agreed principles included the following:

Primary Genomic Sequence Should be in the Public Domain

It was agreed that all human genomic sequence information, generated by centres funded for large-scale human sequencing, should be freely available and in the public domain in order to encourage research and development and to maximise its benefit to society.

NIH Genomic Data Sharing Policy²¹

The NIH Genomic Data Sharing policy applies when investigators or institutions are funded by the NIH and generate large-scale human or non-human genomic data, and if they generate small-scale genomic data that NIH or the funding institutes or centers determines should be shared

¹⁹ <https://www.wipo.int/tk/en/databases/contracts/texts/smta.html>

²⁰ <https://web.archive.org/web/20020221205116/http://www.gene.ucl.ac.uk/hugo/bermuda.htm>

²¹ <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html>

because of the state of the science, programmatic priorities, utility, and/or value of the data for the research community. The NIH's Genomic Data Sharing policy states the following on intellectual property:

VI. Intellectual Property

NIH encourages patenting of technology suitable for subsequent private investment that may lead to the development of products that address public needs without impeding research. However, it is important to note that naturally occurring DNA sequences are not patentable in the United States.³⁴ Therefore, basic sequence data and certain related information (e.g., genotypes, haplotypes, p-values, allele frequencies) are pre-competitive. Such data made available through NIH-designated data repositories, and all conclusions derived directly from them, should remain freely available, without any licensing requirements.

*NIH encourages broad use of NIH-funded genomic data that is consistent with a responsible approach to management of intellectual property derived from downstream discoveries, as outlined in the NIH Best Practices for the Licensing of Genomic Inventions⁷⁰ and Section 8.2.3, Sharing Research Resources, of the NIH Grants Policy Statement.⁷¹ **NIH discourages the use of patents to prevent the use of or to block access to genomic or genotype-phenotype data developed with NIH support.** [emphasis added]*

Biomarkers Consortium General Intellectual Property and Data Sharing Principles from 2023²²

The Biomarkers Consortium is a pre-competitive public-private biomedical research partnership managed by the Foundation for the National Institutes of Health (FNIH) that endeavors to discover, develop, and seek regulatory acceptance of drug development tools/solutions (e.g., disease biomarkers and surrogate endpoints) to support new drug development, preventive medicine, and medical diagnostics.

Core activities of the Biomarkers Consortium are funded by membership dues from the private sector. Some of these for-profit partners include Amgen, AstraZeneca, Biogen, Boehringer Ingelheim, GSK, Johnson&Johnson, Lilly, Merck, Novartis, Novo Nordisk, Pfizer, Roche and Sanofi.

The 2023 Intellectual Property and Data Sharing principles are aimed to facilitate the use of data and technologies in expanded biomarker research and development efforts conducted by the Biomarkers Consortium while ensuring adequate incentives to commercialize biomarker technologies and while ensuring compliance with antitrust law. The principles apply to all activities of the Biomarkers Consortium as carried out by both Biomarkers Consortium members and Project

²² <https://fnih.org/wp-content/uploads/2023/05/bmc-intellectual-property.pdf>

Team Participants, subject to any applicable Federal statutory or regulatory requirements or policies.

Relevant provisions on open access and intellectual property are as follows:

“Overall, the goals of the Biomarkers Consortium are to: [...]

2. Make research results and data arising under a Project Team (PT) activity broadly available, subject to agreed upon data sharing plans.

[...]

Establishing rules and conditions for addressing confidentiality, Data access, Intellectual Property, and rights in Data for any funding recipients utilized in the conduct of the PT project.

- *Establishing a comprehensive Data access plan defining which data arising from the project will be made publicly available, when, and how; a publication plan if appropriate; and scope, mechanisms and methods of Data access. The Data access plan shall include, but need not be limited to, provisions regarding the following factors: (1) timing of any public Data release; (2) protection of Data that raises privacy concerns; (3) protection of confidential or proprietary Data that have been pooled in order to complete the required analysis or have been generated in the analysis; (4) appropriate handling of Data that may become part of a regulatory submission; and (5) address use of data by individual Participants, for example whether Participants’ analysis of Data falls within the scope of project plan.*

[...]

*Non-federal Participants in the PT having an ownership interest in Biomarkers Consortium Inventions will have the right to protect the Inventions, **provided the Participants grant: (a) a non-exclusive, remuneration-free license for the Inventions to each of the other PT Participants and (b) a non-exclusive research license for the Inventions to others.*** [emphasis added]

Open Access Initiatives with Flexible IP Policies

GISAID EpiFlu™ Database Access Agreement²³

GISAID maintains a global database for influenza gene sequences along with associated data, including virological, clinical, epidemiological and demographic information (if available) for all influenza viruses, including but not limited to H5N1 sequences (the "GISAID EpiFlu™ Database") for the purpose of facilitating the sharing, research and investigation of such sequences and associated data.

²³ <https://gisaid.org/terms-of-use/>

GISAID has a number of funders. In 2024, these included a combination of commitments, donations and grants from countries (Argentina, Australia, Brazil, China, Congo, Ethiopia, France, Malaysia, New Zealand, Russia, Senegal, Indonesia, Singapore and South Africa), the Rockefeller Foundation, and corporate donations (Sanofi, Pfizer and GSK).

Access to GISAID is covered by the Database Access Agreement that states that:

“Intellectual Property. You acknowledge and agree that:

- I. It is your sole responsibility to obtain any additional authorization or license as may be necessary for your use of the Data.*
- II. **You agree not to offer or impose any terms on the Data that alter or restrict either the terms of this Agreement or the rights of Authorized Users granted hereunder.** Subject only to any pre-existing third party rights on the Data, You acknowledge and agree that all Data will be freely shared among and used by all other Authorized Users.*
- III. You understand that Authorized Users intend to use the Data provided by You for research purposes and/or for the development, testing and dissemination of interventions such as vaccines, diagnostics and therapeutics. [emphasis added]*

The Cancer Genome Atlas Data Use Certification Agreement 2025²⁴

The NIH established the central data repository for The Cancer Genome Atlas (TCGA), which stores clinical, biospecimen, molecular characterization, and imaging data for samples from 11,000 patients spanning 33 cancer types. Access to human genomic data is provided to research investigators who, along with their institutions, have certified their agreement with the terms of access. The intellectual property related provision is as follows:

By requesting access to dataset(s), the Requester and Approved Users acknowledge the intent of the NIH that anyone authorized for research access through the DAR follow the intellectual property (IP) principles as summarized below:

- Achieving maximum public benefit is the ultimate goal of data distribution through the NIH controlled-access data repositories. The NIH encourages broad use of NIH controlled-access data that is consistent with a responsible approach to management of intellectual property derived from downstream discoveries and expects that the Requestor and Approved User(s) adhere to licensing practices consistent with the NIH Research Tools Policy.*

*The NIH considers these data as pre-competitive and **urges Approved Users to avoid making IP claims derived directly from the dataset(s). It is expected that these NIH-provided data, and conclusions derived therefrom, will remain freely available, without requirement for licensing.** However, the NIH also recognizes the importance of intellectual property in promoting the development of new therapies and products; as such, there is no restriction on development of commercial products resulting from the knowledge gained from the research project. Ownership of*

²⁴ https://dbgap.ncbi.nlm.nih.gov/aa/wga.cgi?view_pdf&stacc=phs000178.v11.p8

all intellectual property generated by activities under the research project will be governed by applicable patent law. [emphasis added]

Alzheimer's Disease Neuroimaging Initiative (ADNI)²⁵

The ADNI study actively supports the investigation and development of treatments that slow or stop the progression of Alzheimer's disease (AD). The ADNI study tracks the progression of the disease using biological markers (biomarkers; for example, chemicals found in blood, or changes to the brain observed in MRI and PET scans), together with clinical measures (cognitive and neuropsychological tests), to assess the brain's structure and function over the course of three disease states (cognitively normal/unimpaired, mild cognitive impairment, dementia). ADNI provides study data and biospecimens (samples) to qualified researchers worldwide.

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Whole Genome Sequencing (WGS) Agreement from 2021 stipulates the conditions under which provision of ADNI Whole Genome Sequence data may occur. Regarding intellectual property, the Agreement states:

“You will not acquire any rights, including, but not limited to, patent rights and trade secrets in the genetic data, and nothing in this document shall be construed as granting you a license to any patent rights or other intellectual property rights.” [emphasis added]

²⁵ https://adni.loni.usc.edu/wp-content/uploads/2021/02/ADNI_WGS_Agreement_February_2021.pdf