Data Access Agreement

This Data Access Agreement governs access to Managed Access Data by the Research Community.

Background:

The researcher who contributed the Data for release by Managed Access ("Data Producer") together with their Collaborators, are the Custodians of that Data and hold such ownership rights as may exist in relation to such Data. UMIC is committed to providing access to the Research Community (by way of the UMIC Database) for Research purposes in accordance with the Data Release and Access Policy.

In signing this Data Access Agreement, the Recipient and the Recipient Institution agrees to be bound by the terms and conditions contained herein, and agree to ensure that all Data Users comply with the terms and conditions of this Agreement.

For the sake of clarity, the terms of access set out in this Data Access Agreement apply both to the Recipient and the Recipient Institution. However, it is not intended that the Recipient be liable as an individual under this Agreement; the Recipient Institution shall be liable on their behalf for any defaults.

This Agreement shall be effective as of the date on which the Data Access Committee confirms their approval of the Data Access Application [INSERT DATA DEPOSITION APPLICATION REFERENCE DA(E/M)_INI_DDMMYY: ___-____-_____]

Terms and Conditions:

In signing this Agreement:

1. The Recipient and the Recipient Institution agree to only use the Data for the Planned Analysis.

2. The Recipient and the Recipient Institution agree to preserve, at all times, the confidentiality of the Data. In particular, they undertake not to use, or attempt to use, the Data to compromise or otherwise infringe the confidentiality of information on the Donors.

3. The Recipient and the Recipient Institution agree to protect the confidentiality of Donors in any Publications that they prepare by taking all reasonable care to limit the possibility of Donor identification.

4. The Recipient and the Recipient Institution agree not to link or combine the Data provided under this Data Access Agreement to other information or other data available to them in a way that could identify the Donors, even if access to that data has been formally granted to the Recipient and the Recipient Institution, or is freely available without restriction.

5. The Recipient and the Recipient Institution agree not to transfer or disclose the Data, in whole or part or any copies thereof, in whole or part (in any medium), to anyone not listed as: a) a Data User in Schedule VI of this Data Access Agreement; b) a Co-Applicant on the Planned Analysis

who's institution has signed as Recipient Institution in a parallel Data Access Agreement for this Planned Analysis; or c) a Co-Applicant's Data User as listed in Schedule VI of the parallel Data Access Agreement for this Planned Analysis, except as necessary for data safety monitoring, national audits or as required by law.

6. The Applicant shall be responsible for submitting any appropriate applications for new Co-Applicants to the Data Access Committee on behalf of a Planned Analysis. In order for a new Co-Applicant to receive the Data, whether Third Party or Member, their institution must sign a Data Access Agreement, to be submitted in conjunction with the updated Data Access Application.

7. The UMIC's DAC hereby confirms that it has secured from the Data Producer in the associated deposition documentation warranties that the Data have been obtained in accordance with all relevant laws and guidelines and that the Data have been obtained from Donors that have given their consent for their tissue samples and Data to be used for research purposes.

8. Subject to Clause 7 above, the Recipient and the Recipient Institution agree that the UMIC's DAC, the Data Producer(s) or Collaborator(s) involved in the creation, funding or protection of the Data:

    a. Make no warranty or representation, express or implied as to the accuracy, quality or comprehensiveness of the Data;

    b. Exclude to the fullest extent permitted by law all liability for actions, claims, proceedings, demands, losses (including but not limited to loss of profit) and any associated costs made against the Recipient or the Recipient Institution that may arise (whether directly or indirectly) in any way whatsoever from the Recipient's use of the Data or from the unavailability of, or break in access to, the Data for whatever reason and;

    c. Bear no responsibility for the further analysis or interpretation of these Data.

9. The Recipient and the Recipient Institution agree to follow the *Fort Lauderdale Guidelines* included as Schedule I of this Agreement and the *Toronto Statement* included as Schedule II of this Agreement. This includes but is not limited to:

    a. recognising the contribution of the Data Producer, their Collaborator(s) and funders as stipulated by the Data Producer in the associated deposition documentation or otherwise disclosed by the Data Access Committee, and the Primary Publication describing and analysing the Data (as appropriate);

    b. the version of the Data;

    c. the role of the UMIC;

    d. and the role of any Collaborators or funders of the Data Management, as stipulated by the Data Producer in the associated deposition documentation or otherwise disclosed by the Data Access Committee

    in all Publications arising from the Planned Analysis, in whole or in part. An example of suitable wording is provided in the Publication Policy attached as Schedule III of this Agreement.

10. The Recipient and the Recipient Institution agree to follow the Publication Policy. This includes respecting the Publication Moratorium to enable Data Producers and their Collaborators to publish the first written manuscript describing and analysing the Data in a peer-reviewed journal or equivalent ("Primary Publication").

11. The Recipient and Recipient Institution understand and acknowledge that the Data are protected by copyright and other intellectual property rights, and that duplication, except as reasonably required to carry out the Planned Analysis, or sale of all or part of the Data on any media is prohibited.

12. The Recipient and the Recipient Institution agree not to make intellectual property claims on the Data, nor use the Data to make a related intellectual property claim, and not to use or encumber the results of the Planned Analysis in a manner that would prevent or block access to, or use of, any element of the Data, or conclusions drawn directly from the Data.

13. The Recipient and the Recipient Institution recognise that nothing in this Data Access Agreement shall operate to transfer to the Recipient or Recipient Institution any intellectual property rights relating to the Data. Subject to Clauses 12 and 14, the Recipient and the Recipient Institution can elect to perform further research with the results of the Planned Analysis that would add intellectual and resource capital to the Data and decide to obtain intellectual property rights on these downstream discoveries. In this case, the Recipient and the Recipient Institution agree to implement licensing policies that will not obstruct further research with the Data and to follow the U.S. National Institutes of Health *Best Practices for the Licensing of Genomic Inventions (2005)* in conformity with the Organisation for Economic Co-operation and Development *Guidelines for the Licensing of the Genetic Inventions (2006)*. These two policies (NIH and OECD) are included as Schedule IV and V of this Agreement.

14. The Data were contributed by members of the Research Community with the objective of improving health. If results arising from the Recipient and the Recipient Institution use of the Data could provide health solutions for the benefit of people in the developing world, the Recipient and the Recipient Institution agree to offer non-exclusive licenses to use such results to low income and low-middle income countries (as defined by the World Bank) promptly on request. Such licenses shall be granted on a reasonable basis, which in the event of a request for research use only, shall be fully paid up, revenue-free and otherwise without cost to the requesting party.

15. Upon conclusion of the Planned Analysis, the Recipient and the Recipient Institution hereby agree to destroy/discard the Data held unless obligated to retain the Data for archival purposes in conformity with applicable law. Any Data which is not destroyed shall remain subject to the terms of this Agreement.

16. The Recipient and the Recipient Institution will ensure that the list of Data Users in Schedule VI is maintained and kept up-to-date and forward an updated copy of this Schedule to the Data Access Committee to reflect any changes or departures in researchers, collaborators and personnel within 30 days of the changes made. Pending confirmation of receipt of the updated list of Data Users from the Data Access Committee, any individual not listed as a Data User may not use the Data.

17. The Recipient and the Recipient Institution must notify the Data Access Committee prior to making any significant change(s) to the Planned Analysis. The Scientific Steering Committee will

notify the Data Producer of any request to change the Planned Analysis and shall liaise with the Data Producer in making a decision on the requested amendment.

18. The Recipient and the Recipient Institution will notify the Data Access Committee as soon as they become aware of a breach of the terms or conditions of this Data Access Agreement.

19. The UMIC's DAC reserves the right to terminate this Agreement immediately in the event of a breach by the Recipient, Co-Applicant(s), Data Users, or the Recipient Institution. Upon termination or otherwise upon conclusion of the Planned Analysis, the Recipient and the Recipient Institution will be required to destroy any Data held, including copies and backup copies thereof unless obligated to retain the Data for archival purposes in conformity with applicable law. Any Data which is not destroyed shall remain subject to the terms of this Agreement.

20. The Recipient and the Recipient Institution accept that it may be necessary for The UMIC's DAC to alter the terms of this Data Access Agreement as required by a change in the Current Consent or another regulatory change which impacts on the scope of Data usage. In this event, the DAC will contact the Applicant who will flow down this information to all Co-Applicants and the Recipient and Recipient Institution agree that their continued use of Data shall be dependent on the parties entering into a new version of this Data Access Agreement and use of the Data shall be suspended until execution.

21. It is understood by the Recipient and the Recipient Institution that Data: should only be accessible to named users (Data Users and the Recipient only); Data files should either have user Unix read/write access, not group or world access, or project-specific Unix groups should be used for group access that contain only those names authorised to access the Data; User IDs within groups should be reviewed at 6 monthly intervals by the Recipient; Data kept on laptops should be encrypted when not in active use, either in individual encrypted files or in encrypted directories/partitions; and Data should not be held on USB keys or other portable hard drives. The Recipient Institution hereby represents that they have equivalent security measures in place and will store the Data in accordance with this Clause. If requested, the Recipient and the Recipient Institution will allow data security and management documentation to be inspected to verify that they are complying with the terms of this Data Access Agreement.

22. The Recipient Institution hereby agrees to submit a report to the Data Access Committee containing all data, results, and conclusions, if requested or otherwise promptly on completion of the Planned Analysis. The Data Access Committee agrees to treat the report and all information, data, results, and conclusions contained therein as confidential information belonging to the Recipient Institution until the Recipient has Published on the project.

23. Further to the obligations set out in the recitals to this Data Access Agreement, the Recipient and the Recipient Institution agree to distribute a copy of this Data Access Agreement and explain its content to any person mentioned in Schedule VI. The Recipient Institution shall be liable for any breach of this Data Access Agreement by any Data User.

24. The Recipient and the Recipient Institution shall not use the name or logo of UMIC or any personnel in any marketing, without first obtaining the written consent of the UMIC's DAC.

25. Nothing in this Agreement shall create, imply or evidence any partnership or joint venture between the parties or the relationship between them of principal and agent. No party has the authority to make any representation or commitment, or to incur any liability on behalf of the other and each party shall be severally liable for any breach of this agreement.

26. This Agreement (and any dispute, controversy, proceedings or claim of whatever nature arising out of this agreement or its formation) shall be construed, interpreted and governed by the laws of England and Wales and shall be subject to the exclusive jurisdiction of the English courts.

THE TERMS OF THIS DOCUMENT ARE NON-NEGOTIABLE

ACCEPTED AND AGREED BY an authorised institutional representative of Recipient Institution: (For External Investigators, he/she should be the same person mentioned under the relevant Section B on the Data Access Application for External Investigators as the institutional representative of the Recipient Institution)

Name ____ANTONIO DE LA PLAZA LARREA_____ (block letters)

Title and position ___SENIOR CONTRACTS MANAGER RESEARCH CONTRACTS UCL_____

Institution ___UNIVERSITY COLLEGE

LONDON_____ (name of legal entity)

Signature DocuSigned by: Antonio De la Plaza Larrea 90D6AADFB0FC44E...

Date 27 September 2024

I have read and understood the terms of this Agreement and agree to use the Data in accordance with them.

Recipient:

Name ____MARYAM SHOAI_____ (block letters)

Title and position ____RESEARCH FELLOW_____

Institution ___UNIVERISTY COLLEGE LONDON_____

Signature Signed by: 3DA5171D2B6342D...

Date 27 September 2024

SCHEDULES

SCHEDULE I	*SHARING DATA FROM LARGE-SCALE BIOLOGICAL RESEARCH PROJECTS: A SYSTEM OF TRIPARTITE RESPONSIBILTY "THE FORT LAUDERDALE GUIDELINES" (2003)*
SCHEDULE II	*"THE TORONTO STATEMENT" (2009)*
SCHEDULE III	PUBLICATION POLICY
SCHEDULE IV	NIH*, BEST PRACTICES FOR THE LICENSING OF GENOMIC INVENTIONS (2005)*
SCHEDULE V	OECD, *GUIDELINES FOR THE LICENSING OF GENETIC INVENTIONS (2006)*
SCHEDULE VI	List of Data users

SCHEDULE I

SHARING DATA FROM LARGE-SCALE BIOLOGICAL RESEARCH PROJECTS: A SYSTEM OF TRIPARTITE RESPONSIBILTY "THE FORT LAUDERDALE GUIDELINES" (2003)

Sharing Data from Large-scale Biological Research Projects: A System of Tripartite Responsibility
Report of a meeting organised by the Wellcome Trust and held on 14–15 January 2003 at Fort Lauderdale, USA.

Introduction
The Wellcome Trust sponsored a meeting on 14–15 January 2003 to discuss how, at this point in the development of the field of genomics, pre-publication data release can promote the best interests of science and help to maximise the public benefit to be gained from research. About 40 people attended the meeting, among them large-scale sequence producers, sequence users including computational biologists, representatives of the major nucleotide sequence databases, journal editors, and scientists interested in other large-scale datasets. The discussion took as a given that published data are available in their entirety for any use by any investigator, and focused on issues involved in making data broadly available *prior* to publication.

The meeting concluded that pre-publication release of sequence data by the International Human Genome Sequencing Consortium, and other sequence producers, has been of tremendous benefit to the scientific research community in general. While not all were in a position to make commitments for their funding agencies, the meeting attendees were in broad agreement that, to encourage the continuation of such benefits, the sequence producers, sequence users and the funding agencies recognise and implement a system based on 'tripartite responsibility'.

Specifically,

- The meeting attendees enthusiastically reaffirmed the 1996 Bermuda Principles, which expressly called for rapid release to the public international DNA sequence databases (GenBank, EMBL, and DDBJ) of sequence assemblies of 2kb or greater by large-scale sequencing efforts and recommended that that agreement be extended to apply to all sequence data, including both the raw traces submitted to the Trace Repositories at NCBI and Ensembl and whole genome shotgun assemblies.
- The attendees recommended that the principle of rapid pre-publication release should apply to other types of data from other large-scale production centres specifically established as 'community resource projects'.
- The attendees recognised that pre-publication data release might conflict with a fundamental scientific incentive – publishing the first analysis of one's own data. The attendees noted that it would not be possible to absolutely guarantee this incentive without applying restrictions that would undermine the rationale for rapid, unrestricted release of data from community resources. Nonetheless, it is essential that excellent scientists continue to be attracted to these projects. To encourage this, the scientific community should understand that pre-publication data release needs active communitywide support if it is to continue to receive widespread support from the producers. The contributions and interests of the large-scale data producers should be recognised and respected by the users of the data, and the ability of the production centres to analyse and publish their own data should be supported by their funding agencies.

Community resource projects
A 'community resource project' is a research project specifically devised and implemented to create a set of data, reagents or other material whose primary utility will be as a resource for the broad scientific community. Recent examples of community resource projects include the International

Human Genome Sequencing Consortium, the Mouse Genome Sequencing Consortium, the Mammalian Gene Collection, the SNPs Consortium, and the International HapMap Project. The products of community resource projects have, over the past several years, become increasingly important as drivers of progress in biomedical research. The scientific community will best be served if the results of community resource projects are made immediately available for free and unrestricted use by the scientific community to engage in the full range of opportunities for creative science. At the same time, it is crucial that the scientific community recognises and respects the important contribution made by the scientists who carry out community resource projects.

Tripartite sharing of responsibility

An optimised system for generating community resources involves three constituencies within the scientific research community – resource producers, resource users, and funding agencies. Each of the three has a unique and critical role to play in ensuring the growth and development of the community resource system.

A. **Funding agencies**. Funding agencies are the major sources of support of research projects leading to community resources and projects that depend on the availability of such resources. Funding agencies have a critical role in determining the quality and breadth of community resources through the peer review evaluation system and as the sources of scientific research policies. For these reasons funding agencies should:

1. designate appropriate efforts as community resource projects, and encourage resource producers to prepare and submit Project Descriptions (see below) for publication;
2. require, as a condition of funding, free and unrestricted data release from community resource projects to appropriate central and searchable public databases, and vigorously ensure that this occurs;
3. encourage more investigators to serve the community through involvement in such projects. In particular, the agencies should ensure that investigators engaged in generation of such datasets have sufficient support for curation, maintenance and distribution of the data to the community, as well as resources to perform initial analyses using the resources that they have generated;
4. ensure that a centralised view of existing community resource projects is available as an information source for the community;
5. support central databases that will house and distribute the data in a way that prevents fragmentation of the data.

B. **Resource producers**. Community resources are often expensive efforts. For this and other reasons, they are frequently established and supported as unique facilities. The scientists who organise and operate community resources are, accordingly, in a uniquely responsible position. The community is dependent on the success of their efforts and they often face relatively little direct competition. Resource producers should:

1. when feasible, publish a Project Description. The purpose of the Project Description, which will be a new type of scientific publication, is to inform the scientific community about the resource project and to provide a citation to reference the source of the data. The Project Description should be written at the beginning of the project and describes the plans for and scope of the production and analyses that the data producer intends to undertake. It will often include a timeline for production goals and data release.
2. produce consistently high quality data;
3. make the data generated by the resource immediately and freely available without restriction;

4. recognise that even if the resource is occasionally used in ways that violate normal standards of scientific etiquette, this is a necessary risk set against the considerable benefits of immediate data release.

C. **Resource Users.** Community resource datasets benefit the users enormously, giving them the opportunity to analyse the data without the need to generate it first. The datasets are, in general, much larger, richer and of higher quality than individual laboratories could normally generate. In contributing to what ideally is a symbiotic and synergistic situation, resource users should:

1. appropriately cite the source of the data analysed and acknowledge the resource producers. The early publication of a Project Description, as suggested above, would provide users with an appropriate reference to cite before the data are formally published;
2. recognise that the resource producers have a legitimate interest in publishing prominent peer-reviewed reports describing and analysing the resource that they have produced (and that neither the Project Descriptions nor data deposits in databases are the equivalent of such publications);
3. respect the producer's legitimate interests as set out, e.g. in a Project Description, while being free to use the data in any creative way. There should be no restrictions on the use of the data, but the best interests of the community are served when all act responsibly to promote the highest standards of respect for the scientific contribution of others. In some cases, this might best be done by discussion or coordination with the resource producers;
4. assist journals and funding agencies to play their proper roles in ensuring, through the peer review system, that the system works fairly for all constituents.

Large-scale genome sequencing

Large-scale genome sequencing projects are clearly community resource projects, and serve as a well-developed example to illustrate the general principles described above. The Bermuda Principles (http://www.gene.ucl.ac.uk/hugo/bermuda.htm) were developed in 1996 by the scientists engaged in the International Human Genome Sequencing Consortium and their funding agencies, and have been the basis of a successful system for achieving rapid and open data release. Now, in 2003, the meeting attendees, recognising the role of users as well as producers and funders in effecting a successful system, enthusiastically recommend the reaffirmation of the Bermuda Principles for continued large-scale sequencing projects, and recommend that:

1. They should be extended beyond their initial application to sequence assemblies of a minimum size from BAC-based sequence projects so that they apply to rapid (i.e. as soon as possible) release of both raw and assembled sequence data, subject only to the data meeting appropriate quality assessment standards.
2. Funding agencies, users and sequencing centres should all honour their obligations, as described above.

Other community resource projects

In the near future, many other large datasets will be produced as community resources.

While only a few of the meeting attendees were familiar with data types other than large-scale sequences, the attendees recommended that appropriate implementation of the principles discussed should be devised for other community resource projects, such as large-scale protein structure determination or gene expression analysis. In many of these cases, the solutions, in terms of such considerations as data quality standards, data storage and dissemination modes, and producer and user interests, are only beginning to emerge. Development of effective systems for achieving the objectives of the community resource concept should be an integral component of the planning and development of such new community resources.

Research materials and tools

Some of the issues involved in ensuring rapid and open access to finite resources, such as reagents, clones, cell lines and other material resources, are different from those pertaining to electronic datasets. The meeting attendees strongly encouraged the relevant funding agencies, resource producers and users to develop practical approaches to maximising the benefit of this type of resource to the scientific community and to research.

Pre-publication release of other data

Beyond community resource projects, many valuable datasets could come from other sources.
Still different issues arise in the case of resources that emerge from research efforts whose primary goal is not resource generation. In such cases, contribution of the data to the public domain as a resource is more a voluntary matter. To obtain the clear benefit that would ensue from converting such datasets into community resources as rapidly as possible, incentives should be developed by the scientific community to support the voluntary release of such data prior to publication, by appropriately recognising and protecting the interests of scientists who wish to share such pre-publication data with the community.

SCHEDULE II
"THE TORONTO STATEMENT" (2009)

The full article, *Pre-publication data sharing*, Nature, **461**: 168-70 (2009), is available at: http://www.nature.com/nature/journal/v461/n7261/full/461168a.html

Rapid pre-publication data release should be encouraged for projects with the following attributes:

- Large scale (requiring significant resources over time)
- Broad utility
- Creating reference datasets
- Associated with community buy-in

Funding agencies should facilitate the specification of data-release policies for relevant projects by:

- Explicitly informing applicants of data-release requirements, especially mandatory prepublication data release
- Ensuring that evaluation of data release plans is part of the peer review process
- Proactively establishing analysis plans and timelines for projects releasing data pre-publication
- Fostering investigator-initiated pre-publication data release
- Helping to develop appropriate consent, security, access and governance mechanisms that protect research participants while encouraging pre-publication data release
- Providing long-term support of databases

Data producers should state their intentions and enable analyses of their data by:

- Informing data users about the data being generated, data standards and quality, planned analyses, timelines, and relevant contact information, ideally through publication of a citeable marker paper near the start of the project or by provision of a citable URL at the project or funding agency website
- Providing relevant metadata (e.g., questionnaires, phenotypes, environmental conditions, and laboratory methods) that will assist other researchers in reproducing and/or independently analysing the data, while protecting interests of individuals enrolled in studies focusing on humans
- Ensuring that research participants are informed that their data will be shared with other scientists in the research community
- Publishing their initial global analyses, as stated in the marker paper or citable URL, in a timely fashion
- Creating databases designed to archive all data (including underlying raw data) in an easily retrievable form and facilitate usage of both pre-processed and processed data

Data analysts/users should freely analyse released prepublication data and act responsibly in publishing analyses of those data by:

- Respecting the scientific etiquette that allows data producers to publish the first global analyses of their dataset
- Reading the citeable document associated with the project
- Accurately and completely citing the source of prepublication data, including the version of the dataset (if appropriate)
- Being aware that released pre-publication data may be associated with quality issues that will be later rectified by the data producers
- Contacting the data producers to discuss publication plans in the case of overlap between planned analyses

● Ensuring that use of data does not harm research participants and is in conformity with ethical approvals

Scientific journal editors should engage the research community about issues related to pre-publication data release and provide guidance to authors and reviewers on the third-party use of pre-publication data in manuscripts

SCHEDULE III
UMIC PUBLICATION POLICY

Please refer to MRC/UVRI and LSHTM policy on sharing of data.

UMIC is committed to the principles of rapid data release. However, it is understood that the type of analyses and planned Publications need to be monitored in order to prevent overlapping use of resources and interests.

1. Please acknowledge the use of Data as follows in any Publications based upon it in addition to authorship requirements:

    a. *"This study makes use of [the resources of]/ [data generated or collated by] the Uganda General Population Cohort (GPC) - a population-based open cohort study established in 1989 by the MRC/UVRI and LSHTM"*

    AND

    b. Cite the relevant Primary Publication (if applicable).

    - Fatumo, S., Mugisha, J., Soremekun, O. S., Kalungi, A., Mayanja, R., Kintu, C., ... & Kaleebu, P. (2022). Uganda Genome Resource: A rich research database for genomic studies of communicable and non-communicable diseases in Africa. *Cell Genomics*, *2*(11), 100209.

    - Gurdasani, D., Carstensen, T., Fatumo, S., Chen, G., Franklin, C. S., Prado-Martinez, J., ... & Sandhu, M. S. (2019). Uganda genome resource enables insights into population history and genomic discovery in Africa. *Cell*, *179*(4), 984-1002.

2. Authorship in any Publication shall be determined in accordance with standard academic practice.

3. All parties and any Collaborators and/or Data Users should note that the UMIC bears no responsibility for the analysis or interpretation of these Data.

SCHEDULE IV
NIH, BEST PRACTICES FOR THE LICENSING OF GENOMIC INVENTIONS (2005)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
Best Practices for the Licensing of Genomic Inventions: Final Notice
Federal Register / Vol. 70, No. 68 / Monday, April 11, 2005 / Notices (p18413)
(for supplementary information, please see the original publication)

Introduction

The Public Health Service's (PHS) primary mission is to acquire new knowledge through the conduct and support of biomedical research to improve the health of the American people. This mission is advanced by the intramural research efforts of government-owned and –operated laboratories and by the extramural research efforts funded through grants and contracts. PHS seeks to maximise the public benefit whenever PHS owned or funded technologies are transferred to the commercial sector. Motivated by this goal, we offer the following best practices for the licensing of government-funded genomic inventions.

Genomic inventions include a wide array of technologies and materials such as cDNAs; expressed sequence tags (ESTs); haplotypes; antisense molecules; small interfering RNAs (siRNAs); fulllength genes and their expression products; as well as methods and instrumentation for the sequencing of genomes, quantification of nucleic acid molecules, detection of single nucleotide polymorphisms (SNPs), and genetic modifications. Much of the value associated with the commercial use of these technologies involves nucleic acid-based diagnostics, potential gene therapy applications, and the development of new DNA and RNAbased therapeutics.

Background

Among the benefits derived from PHS conducted and supported biomedical research are effective and accessible new healthcare treatments and services. Practical realisation of these benefits depends on the ability and willingness of private sector partners to develop and commercialise new technologies arising from PHS conducted and funded research. For potential preventive, diagnostic, and therapeutic products, the interest of the private sector in commercialising new technologies often depends on the existence of patent protection on the technology in the United States and foreign countries.

The Bayh-Dole Act of 1980 allows PHS grantees and contractors to seek patent protection on subject inventions made using Government funds and to license those inventions with the goal of promoting their utilisation, commercialisation, and public availability. Recipients of PHS grants and contracts have a role in implementing the requirements of the Bayh-Dole Act (*https://sedison.info.nih.gov/iEdison*). In 1986,
Federal laboratories, including PHS research laboratories at the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and the Centres for Disease Control and Prevention (CDC), were given a statutory mandate under the Federal Technology Transfer Act (P.L. 99–502) and Executive Order 12591 to ensure that new technologies developed in those laboratories were transferred to the private sector and commercialised.

PHS recognises that patenting and licensing genomic inventions presents formidable challenges for academic and government technology transfer programmes because of the complexities in bringing

these technologies to the marketplace in a way that balances the expansion of knowledge and direct public health benefit with the commercial needs of private interests.

The following represents best practices recommendations to the intramural PHS technology transfer community as well as to universities, hospitals and other non-profit PHS funding recipients. These recommendations are not intended to constitute additional regulations, guidelines or conditions of award for any contract or grant, although they are consistent with existing policies set out in Sharing Biomedical Research Resources (*http://ott.od.nih.gov/NewPages/RTguide□final.html*) and Developing Sponsored Research Agreements (*http://ott.od.nih.gov/spons□research.html*).

Patent Protection
Like other emerging technology areas, patents directed to genomic inventions tend to issue with claims that are broad in scope. Public health-oriented technology transfer must balance the rewards of broad intellectual property protection afforded to founders of enabling genomic inventions with the benefits of fostering opportunities for those striving to improve upon those innovations.

Therefore, in considering whether to seek patent protection on genomic inventions, institutional officials should consider whether significant further research and development by the private sector is required to bring the invention to practical and commercial application. Intellectual property protection should be sought when it is clear that private sector investment will be necessary to develop and make the invention widely available. By contrast, when significant further research and development investment is not required, such as with many research material and research tool technologies, best practices dictate that patent protection rarely should be sought.

Best Licensing Practices
The optimal strategy to transfer and commercialise many genomic inventions is not always apparent at early stages of technology development. As an initial step in these instances, it may be prudent to protect the intellectual property rights to the invention. As definitive commercial pathways unfold, those embodiments of an invention requiring exclusive licensing as an incentive for commercial development of products or services can be distinguished from those that would best be disseminated non-exclusively in the marketplace.

Whenever possible, non-exclusive licensing should be pursued as a best practice. A non-exclusive licensing approach favors and facilitates making broad enabling technologies and research uses of inventions widely available and accessible to the scientific community. When a genomic invention represents a component part or background to a commercial development, non-exclusive freedom-to-operate licensing may provide an appropriate and sufficient complement to existing exclusive intellectual property rights.

In those cases where exclusive licensing is necessary to encourage research and development by private partners, best practices dictate that exclusive licenses should be appropriately tailored to ensure expeditious development of as many aspects of the technology as possible. Specific indications, fields of use, and territories should be limited to be commensurate with the abilities and commitment of licensees to bring the technology to market expeditiously.

For example, patent claims to gene sequences could be licensed exclusively in a limited field of use drawn to development of antisense molecules in therapeutic protocols. Independent of such exclusive consideration, the same intellectual property rights could be licensed non-exclusively for diagnostic testing or as a research probe to study gene expression under varying physiological conditions.

License agreements should be written with developmental milestones and benchmarks to ensure that the technology is fully developed by the licensee. The timely completion of milestones and benchmarks should be monitored and enforced. Best practices provide for modification or termination of licenses when progress toward commercialisation is inadequate. Negotiated sublicensing terms and provisions optimally permit fair and appropriate participation of additional parties in the technology development process.

Funding recipients and the intramural technology transfer community may find these recommendations helpful in achieving the universal goal of ensuring that public health consequences are considered when negotiating licenses for genomic technologies.

PHS encourages licensing policies and strategies that maximise access, as well as commercial and research utilisation of the technology to benefit the public health. For this reason, PHS believes that it is important for funding recipients and the intramural technology transfer community to reserve in their license agreements the right to use the licensed technologies for their own research and educational uses, and to allow other institutions to do the same, consistent with the Research Tools Guidelines.

Conclusion

PHS recognises that these recommendations generally reflect practices that may already be followed by most funding recipients and the intramural technology transfer community with regard to licensing of genomic and other technologies. PHS also acknowledges the need for flexibility in the licensing negotiation process as the requirements of individual license negotiations may vary and may not always be adaptable to these best practices.

Dated: April 5, 2005.

Mark L. Rohrbaugh,

Director, Office of Technology Transfer, National Institutes of Health.

SCHEDULE V
OECD, GUIDELINES FOR THE LICENSING OF GENETIC INVENTIONS (2006)

The full report, including Background, Preface and PART II: Annotations, is available at: http://www.oecd.org/dataoecd/39/38/36198812.pdf

PART I: PRINCIPLES AND BEST PRACTICES FOR THE
LICENSING OF GENETIC INVENTIONS

A. Scope

These Guidelines apply to the licensing of intellectual property rights[1] that relate to genetic inventions used for the purpose of human healthcare. Within these Guidelines, the term "Genetic Invention" includes nucleic acids, nucleotide sequences and their expression products; transformed cell lines; vectors; as well as methods, technologies and materials for making, using or analysing such nucleic acids, nucleotide sequences, cell lines or vectors. This definition is intended to be forward looking to encompass highly related future developments.

B. Principles and Best Practices

1. Licensing Generally

Principles

1. A Licensing practices should foster innovation in the development of new genetic inventions related to human healthcare and should ensure that therapeutics, diagnostics and other products and services employing genetic inventions are made readily available on a reasonable basis.

1. B Licensing practices should encourage the rapid dissemination of information concerning genetic inventions.

1. C Licensing practices should provide an opportunity for licensors and licensees to obtain returns from their investment with respect to genetic inventions.

1. D Licensees and licensors should have reasonable certainty over their rights and the limitations to those rights in relation to genetic inventions.

Best Practices

1.1 License agreements should permit licensees to develop and further improve the licensed genetic inventions.

[1] For the purpose of these Guidelines, intellectual property rights include patents, undisclosed information (also known as trade secrets or proprietary information), trademarks, and copyright.

1.2 Licence agreements should clearly set out which parties obtain, retain, receive and maintain ownership of, grant rights to and enforce intellectual property rights, including with respect to the improvements and new genetic inventions developed from the licensed technology**.**

1.3 Licence agreements should clearly set out which of the parties, if any, has the right to engage in collaborative research with third parties and set out the ownership of any intellectual property rights flowing from such collaborative research.

1.4 Confidentiality provisions should be carefully drafted so as to permit the dissemination of information pertaining to genetic inventions while taking into account the need to file patent applications, to protect undisclosed information and to capitalise on the inventions in the marketplace**.**

1.5 License agreements should not provide the licensor with exclusive control over human genetic information, including collections of such information, derived from individuals through the use of the licensed genetic invention.

1.6 Rights holders should be encouraged to agree to licensing terms and conditions that maximise the utilisation of their genetic inventions.

1.7 License agreements should clearly stipulate the duties, obligations and responsibilities of the parties and address the rights of the parties to use the improvements to the licensed genetic invention following any, including early, termination.

1.8 License agreements should define the roles and responsibilities of the parties in the commercialisation, if any, of the products and services arising from the use of the licensed genetic invention.

2. Healthcare and Genetic Inventions

Principles

2. A Licensing practices should seek to strike a balance between the delivery of new products and services, healthcare needs, and economic returns.

2. B Licensing practices should ensure that patients benefit from the highest applicable standards with respect to privacy, safety and good laboratory methods available pursuant to the laws of their jurisdiction or those of the jurisdiction of the service provider using the genetic invention.

2. C Licensing practices should not be used to restrict the choice of other products or services by patients and their healthcare providers.

2. D Licensing practices should encourage appropriate access to and use of genetic inventions to address unmet and urgent health needs in OECD member countries and non-member economies.

Best Practices

2.1 Rights holders should broadly license genetic inventions for research and investigation purposes.

2.2 Rights holders should license genetic inventions for health applications, including diagnostic testing, on terms and conditions that seek to ensure the widest public access to, and variety of, products and services based on the inventions.

2.3 Licensing practices should permit national or local providers to use genetic inventions in order to provide healthcare services, even if the rights holder is based in another jurisdiction.

2.4 Licensing agreements relating to products and services incorporating personal health information should facilitate compliance by the licensor and the licensee with the highest applicable privacy and other relevant laws.

2.5 License agreements should not restrict access by the licensee's researchers to databases generated from licensed genetic inventions in their efforts to develop new therapies, products or services**.**

2.6 License agreements should permit licensees, for example healthcare providers, to offer patients flexibility and choice with respect to the selection of the type and nature of healthcare products and services.

3. Research Freedom

Principles

3. A Licensing practices should increase rather than decrease access to genetic inventions for research purposes.

3. B Commercial considerations in public research activities should not unduly hinder the academic freedom of researchers.

3. C Commercial considerations in public research activities and, in particular, the need to preserve the opportunity to seek patent protection on inventions arising from these activities, should not unduly limit the ability to publish in a timely manner the results of research.

3. D Commercial considerations in public research activities should not unduly limit the educational training of students.

Best Practices

3.1 License agreements should clearly delineate research areas, information and time frames in which researchers and students cannot publish or present papers or theses without violating confidentiality obligations. Licensors and licensees should inform all relevant individuals, including students, of the scope of confidentiality obligations in a timely fashion.

3.2 Licensors and licensees should educate their researchers with respect to intellectual property law, especially the effects of public disclosure on the patentability of inventions, confidentiality obligations and restrictions commonly contained in agreements.

3.3 Confidentiality provisions should provide that academic research arising pursuant to the license agreement can be freely published or disclosed, with as minimum a delay as possible, subject to the need to protect proprietary information disclosed to the licensee or arising from such research.

3.4 Delays in publications of academic research necessary, for example, for the filing of patent applications, should be limited and reasonable in the circumstances.

3.5 Confidentiality provisions in licensing agreements should be drafted as narrowly as suitable and should not prevent the possibility of reasonable disclosure in exceptional public health situations, in light of the objectives of the parties and the applicable law.

4. Commercial Development

Principles

4. A Foundational genetic inventions should be licensed so as to be broadly accessible.

4. B Licensing practices should be used as an effective means to create value for licensors and licensees through the development of new products and services from genetic inventions.

4. C Licensing practices should strive to overcome co-ordination problems resulting from the need to access multiple genetic inventions.

Best Practices

4.1 Should several licenses be required, license agreements should include a mechanism to set a reasonable overall royalty burden for genetic invention products and services, including research tools.

4.2 Licence agreements should include terms that maintain low barriers for access to genetic inventions. This may mean that such agreements do not include, for example, excessive up-front fees.

4.3 Licence agreements should avoid reach-through rights so as to foster broad and unencumbered utilisation of the genetic invention and so as to not discourage or stifle subsequent innovations.

4.4 Private and public sector participants should develop mechanisms to decrease transaction costs in acquiring rights to use technology.

4.5 Organisations that may enter into license agreements should educate their decision-makers about the opportunities to use the least restrictive licensing practices, as appropriate, as a means to maximise the benefits from genetic inventions for society, shareholders and other stakeholders.

5. Competition

Principles

5. A Licensing practices pertaining to genetic inventions should foster economic growth through innovation and substantive competition, while complying with the applicable competition laws.

5. B Licensing practices should not be used to expand the breadth of exclusive rights beyond the scope of the relevant intellectual property rights.

Best Practices

5.1 Licence agreements should avoid unduly restrictive tied-selling.

5.2 Licence agreements should avoid non-compete clauses in areas beyond the scope of licensed genetic invention.

5.3 Licence agreements relating to foundational genetic inventions should generally be non-exclusive to encourage broad access for researchers and patients and broad use of the genetic invention.

SCHEDULE VI
LIST OF DATA USERS

Research Project: [INSERT TITLE OF APPROVED RESEARCH PROJECT]

This Schedule VI, as updated and amended by the Parties, is subject to the terms of the Data Access Agreement executed [INSERT DATE] and by signing this Schedule, both Parties hereby agree to be bound by the terms of the Data Access Agreement when conducting the Planned Analysis detailed herein.

Date:

Recipient: _____ Recipient Institution: _____

Recipient's registered email address: _____

I have read the terms and conditions of this Agreement and agree to be bound by them.

Name of Data User(s):	**Signature of Data User(s):**	**Data User's email address:**