



Biomarkers Consortium General Intellectual Property and Data Sharing Principles

I. Introduction

The goals of the Biomarkers Consortium are to:

1. promote the discovery, development, qualification, and regulatory acceptance of biomarkers;
2. make research results and data arising under a Project Team (“PT”) activity broadly available, subject to agreed upon data sharing plans; and
3. to help speed disease-specific research.

Biomarkers Consortium activities support the expeditious development of biomarkers to ensure that safe, innovative, and effective new medicines and diagnostics are developed to address healthcare needs, improve medical care, and promote and improve public health.

The intent of this document is to outline general principles relating to Intellectual Property and Data sharing aspects of the Biomarkers Consortium. The purpose of these principles is 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 relevant requirements of antitrust law.

All Participants agree to implement the Intellectual Property and Data Sharing Principles of the Biomarkers Consortium. In the context of individual projects, Participants agree to explore all mechanisms available, consistent with their individual missions and the interests of the public health, to do so most effectively.¹

The principles address the following issues:

- The advance planning and approval of specific projects;

¹ It is understood that existing Federal statutes, regulations and established policies will govern the conduct of any Federal Participant in the Biomarkers Consortium.

- The management of pre-existing Data and other Intellectual Property, including, for example, confidential research Data or patented inventions shared by members for specific Biomarkers Consortium projects; and
- The management of new Data and Intellectual Property arising from Biomarkers Consortium-sponsored projects.

The principles apply to all activities of the Biomarkers Consortium as carried out by both Biomarkers Consortium members and Project Team Participants, subject to any applicable Federal statutory or regulatory requirements or policies.

II. Definition of Key Terms

“Biomarkers Consortium” or “Consortium” refers to a public-private scientific partnership between the Foundation for the National Institutes of Health (“FNIH”), the National Institutes of Health (“NIH”), the Food and Drug Administration (“FDA”), the Centers for Medicare & Medicaid Services (“CMS”), members of the pharmaceutical, biotechnology, diagnostics, and medical device industries, members of non-profit organizations, and academicians.

“Biomarkers Consortium Antitrust Policy and Guidelines” are set forth in a separate document.

“Project Team” (“PT”) refers to a group of individuals or entities created by the Biomarkers Consortium to plan and execute a particular scientific project. Participants in each PT (“PT Participants”) shall be listed in a roster of PT Participants which shall define the membership of each PT, to be maintained and updated by FNIH. PT Participants may be drawn from any segment of the Federal agencies or public or private entities that form the Biomarkers Consortium, or may be otherwise appointed by the Executive Committee or Steering Committee from academia, advocacy, or other organizations, provided that they are making substantial contributions, financial or otherwise, in the project.

“Data” refers to information relating to characteristics and observations of a scientific or technical nature including information and results arising from scientific experiments, regardless of form or the media on which they may be recorded. The term includes raw data, derived data, proprietary data, technical data and compilations of data. For the purposes of this definition, the term does not include data incidental to the administration of Biomarkers Consortium projects, such as financial, administrative, cost and pricing, or management information.

“Participant” refers to any party paying annual dues to the Biomarkers Consortium (“Contributing Members”), companies that contribute to Biomarkers Consortium projects, and other individuals representing academia, advocacy, industry or other organizations that make substantial contributions, financial or otherwise, to Biomarkers Consortium activities and who appear on membership rosters.

“Federal Participant” refers to the National Institutes of Health (“NIH”), the Food and Drug Administration (“FDA”), the Centers for Medicare & Medicaid Services (“CMS”) or any other entity of the federal government, and to any employee or representative of such an entity, that is a Participant in the Biomarkers Consortium or otherwise involved in the Biomarkers Consortium’s activities.

“Non-Federal Participant” refers to any Participant that is not a Federal Participant of the Biomarkers Consortium.

“Third Party” refers to an individual or entity that is not a Participant or otherwise involved in the Biomarkers Consortium.

“Invention” refers to any subject matter and discovery patentable or otherwise protectable under Title 35 of the United States Code.

“Biomarkers Consortium Inventions” are Inventions conceived or first reduced to practice in the conduct of a Biomarkers Consortium project.

“Intellectual Property” refers to patents, patent applications, know-how, trade secrets, copyrights, and computer programs.

III. Project Plans and Approval

No Project Plan will be initiated or implemented prior to EC authorization. The EC and SC concept review and approval process is outlined in the document *Two-Phased Project Approval Process: Concept Clearance and Project Plan Review*.

Each Project Plan submitted to the Biomarkers Consortium EC shall, at minimum, address the following issues:

- Setting project objectives.
- Identifying the information, materials, methods, Intellectual Property rights and regulatory or governmental approvals necessary to achieve the project objectives; identifying any impediments to achieve the project objectives, including but not limited to licenses, confidentiality agreements, contract obligations, limitations related to consent (Data, materials, or sample use), or other legal or contractual barriers to achieving project goals; and evaluating the likelihood of achieving the project objectives. This should include identifying relevant pre-existing Data, which should be limited and sufficient to achieve the goals of the project.
- Establishing clear rules for the triggers, timing, and scope for PT Participants to disclose to the SC or other appropriate Biomarkers Consortium Committee any patents or patent applications that the PT Participants control that relate to the project objectives, whether pre-existing, arising during the course of the project, or arising out of the activities of the Biomarkers Consortium.

- In general, each PT Participant shall disclose to the SC or appropriate Biomarkers Consortium Committee the existence of any patents or patent applications owned by the Participant, controlled by the Participant, or licensed by the Participant with authority to disclose, that: (i) refer to or rely upon any Data to be shared in the project; or (ii) whose use or practice is reasonably likely to be required to accomplish the objectives of the project or use the results of the project,. The disclosures will include the identity of such patents or patent applications relevant to the project as soon as they become material to the discussion, but in no case later than the submission of the project plan to the EC.
- Any new Participant prior to joining a PT shall agree to conform to the aforementioned principles.
- All disclosures should identify and summarize the relevant substance of the patent or patent application and how it relates to the specific project objective(s). Confidential information will be kept confidential consistent with the Biomarkers Consortium Addendum to the Foundation for NIH's Confidentiality Policy.
- Establishing clear rules for the ownership and/or licensing of any Data and Intellectual Property arising from the Biomarkers Consortium project or disclosed by Biomarkers Consortium members as relating to the project objectives. Such rules should be embodied in a binding agreement among PT Participants and must be reviewed by FNIH counsel for antitrust compliance prior to final acceptance by the parties. Project Plans shall address any restrictions that apply to the use of pre-existing Data.
- For projects where pre-existing data from multiple sources will be used, PT Participants, in consultation with FNIH antitrust counsel, will aggregate pre-existing data to the extent necessary to comply with antitrust guidelines. Such data will then be analyzed in the aggregated form and should be anonymized for company/institution source.
 - Demonstrating how Participants in the PT will comply with all applicable human subjects research and other privacy laws and regulations.
- Defining a plan for use and analysis of pre-existing Data and Data generated in the course of the project.

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.

- Establishing a comprehensive plan to manage and distribute materials and samples generated in the course of the project.
- Identifying a roster of the PT Participants, to be updated as necessary.
- Defining project scope and term, including beginning and ending milestones.

IV. Pre-Existing Data and Intellectual Property

- The PT's activities will require the use of pre-existing Data and Intellectual Property, including, for example, confidential research data or inventions shared by PT Participants for specific projects. The following guidelines will govern the sharing of pre-existing Data and Intellectual Property with PT Participants.
- As a condition of continued participation in a project, all PT Participants will adhere to the rules established under the project plan and approved by the EC for disclosure of patents, patent applications, or other Intellectual Property.
- Non-Federal Participants in a PT will grant all other Participants of that PT a limited, non-exclusive, royalty-free and remuneration-free license to use each Participant's relevant pre-existing Data and Intellectual Property for research purposes only in connection with the project. Any other licenses necessary for the project must be agreed upon by the Participants in the PT before the project commences.
- Each Federal Participant in a PT will grant all other Participants of the PT access on a non-exclusive, royalty-free, and remuneration-free basis, to its pre-existing Data, materials, and know how for research purposes in connection with the project. In addition, Federal Participants in a PT will seriously consider requests from all other Participants in the PT for licenses to inventions under 37 C.F.R. Part 404, including remuneration free research use licenses limited to the scope of Biomarkers Consortium project.
- The PT will seek to obtain limited, non-exclusive licenses from Third Parties to use pre-existing Data and Intellectual Property if determined necessary, preferably on royalty and remuneration-free terms, for research purposes only in connection with the project.

- The Biomarkers Consortium, its members, and the pertinent PT Participants will not gain any ownership rights to pre-existing Data and Intellectual Property of any other party as a result of participating in Biomarkers Consortium activities.
- PT Participants will have the right to analyze pre-existing Data within the scope of the project and data analysis plan using their own methodologies with the express condition that they will disclose methods and results arising out of their analysis to the PT within a reasonable time to be agreed by the PT. The status of any inventions from such activity should be covered or considered in the project-specific Intellectual Property plan.

V. New Data and Biomarkers Consortium Inventions

The Biomarkers Consortium's activities are also expected to lead to new Data and Biomarkers Consortium Inventions. The following guidelines will govern any new Data or Biomarkers Consortium Inventions.

- As a condition of continued participation in a project, all PT Participants will adhere to the rules established in the project plan and approved by the EC for licensing Biomarkers Consortium Inventions and utilizing any Data arising from the Biomarkers Consortium project or disclosed by PT Participants as relating to the project objectives.
- 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.
- Inventorship will be governed by U.S. law. In the case of sole Inventorship, ownership of Biomarkers Consortium Inventions will be governed by the policies of the employer of the inventor. In the case of joint Inventorship, ownership of Inventions will be governed by the policies of the employer of each inventor.
- For Biomarkers Consortium Inventions made under a Federal governmental grant or contract subject to the *Bayh-Dole Act*, FNIH will require, as a condition of PT participation, Federal grantees or contractors to voluntarily grant: (a) a non-exclusive, remuneration-free license to each of the other PT Participants and (b) a non-exclusive, remuneration-free research license to others.
- Agencies within the Federal government will give serious consideration to requests for licenses, on a non-exclusive basis, for Consortium Inventions owned by the Federal government in accordance with 37 C.F.R. Part 404.
- Participants in the PT will notify the EC before abandoning any of their patents or patent applications directed toward Biomarkers Consortium Inventions related to a biomarker or use of a biomarker or a product containing a biomarker. For non-

Federally owned or funded Inventions, Participants in the PT will permit the EC, at its option, to find a Participant of the Biomarkers Consortium or Third Party to take title (the “Prosecuting” Party) and pursue the patent(s) or patent application(s) at their own expense. In the event the EC finds such Prosecuting Party to take title, the PT Participant abandoning the patent or patent application shall assign the patent or patent application to the Prosecuting Party without further limitation to the right to direct and control prosecution of the application, to grant sublicenses and to enforce, provided the Prosecuting Party grants (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.

- The licensing of Biomarkers Consortium Inventions shall not be restricted to PT Participants or Biomarkers Consortium members.
- Biomarkers Consortium Participants, grantees, and funding recipients will not be forbidden by virtue of their participation in the Biomarkers Consortium to challenge the validity or enforceability of patents or other intellectual property of other Biomarkers Consortium Participants, grantees, and contractors, including patents or Intellectual Property arising from Biomarkers Consortium-sponsored activities.
- Notwithstanding any of the above guidelines, neither the Biomarkers Consortium nor FNIH will have any ownership rights in Biomarkers Consortium Inventions.
- PT Participants will have the right to analyze Data generated in the course of the project plan within the scope of the project and data analysis plan using their own methodologies with the express condition that they will disclose methods and results arising out of their analysis to the PT within a reasonable time to be agreed upon by the PT. The status of any Inventions from such activity should be covered or considered in the project plan.

VI. Participation of Funding Recipients

The Biomarkers Consortium may seek to accomplish the collection, storage, analysis or other activities associated with specific Biomarkers Consortium-sponsored projects through funding agreements.

- Non-Federal funding agreements, in furtherance of Biomarkers Consortium projects, shall: (1) ensure that each individual involved in the project as a funding recipient will treat the project and all Data and Intellectual Property relating to the project as strictly confidential; (2) ensure that the funding recipient will have no rights or interests in Data arising from their participation in a Biomarkers Consortium project²; (3) ensure that all PT Participants receive a non-exclusive,

² In special cases where contracting parties develop tools based on their own proprietary platforms to manage or otherwise manipulate data involved in the project, such parties

remuneration-free license to any Inventions made under the funding agreement related to the project, and that others will receive a non-exclusive license for research use of such Inventions; and (4) outline the expectation that Inventions arising from Biomarkers Consortium research will either be commercialized or otherwise made available for licensing for commercial development of a product.

- Funding agreements entered into by Federal PT Participants will be governed by applicable Federal law, including the *Bayh-Dole Act*. Determinations of Exceptional Circumstance under 35 U.S.C. § 202 (“DEC”) will be considered on a case-by-case basis. In the absence of a DEC, Federal Participants will request data access and intellectual property plans from applicants that address the principles of this document.

may retain commercial rights to such tools provided they will grant non-exclusive research use licenses to PT Participants.