Biomarkers Consortium
Antitrust Policy and Guidelines

It is the unqualified policy of the Biomarkers Consortium (or "Consortium") to conduct its activities in strict compliance with the antitrust laws of the United States. As a collaboration of private businesses, notwithstanding the involvement of public entities, the Biomarkers Consortium must conduct its activities in compliance with the antitrust laws of the United States, particularly the Sherman Act, 15 U.S.C. § 1 *et seq*. Federal government entities participating in the Biomarkers Consortium do not intend by their participation to create any implied immunity for, or otherwise to affect the antitrust liability and obligations of, non-federal government entities participating in the Consortium. Nor shall review of any activity by legal counsel for the Foundation for the National Institutes of Health ("FNIH") confer any immunity.

This document establishes Antitrust Guidelines to help ensure that the activities of the Biomarkers Consortium are conducted well within the limits established by the antitrust laws and avoid even the appearance of conduct that could undermine public confidence in and support of the Consortium or give rise to a challenge under those laws. It is the responsibility of all Consortium participants to abide by these guidelines.

HOW AND WHY ANTITRUST LAW APPLIES TO THE BIOMARKERS CONSORTIUM

The purpose of the Consortium is avowedly procompetitive: to combine the complementary resources and expertise of public-sector entities, academia, and private entities in the pharmaceutical, biotechnology, and medical devices industries to expedite the "pre-competitive" identification, validation, qualification, and commercial development of biological disease markers and related healthcare products.

Nevertheless, because private participants may compete with each other—by selling, buying, licensing or creating technology or products— issues may occur that could give rise to significant antitrust concern. For example, a private industry participant conceivably might have an incentive to attempt to use the Consortium unfairly to promote a particular technology or product or to exclude another for commercial reasons. Or, the un-safeguarded sharing of confidential, competitively sensitive information of competing companies' pricing, production, or innovation plans could unreasonably facilitate (or be used as evidence of) collusion.

Any indication of improper commercial bias or the facilitation of collusion on activities outside the legitimate scope of the Consortium could expose the Consortium and its members to antitrust risk. It is therefore critical that every participant in Consortium projects familiarize themselves and abide by the policies and guidelines articulated herein.

I. Commercial Activities of Private-Sector Participants

The Consortium is not intended, in any way, to coordinate or restrict the commercial activities of its participants, particularly its private-sector participants, beyond the activities of the Consortium itself.

- Private-sector participants remain completely free to engage in any research, development, production, or marketing activity regarding biomarkers or otherwise that does not infringe on intellectual property owned by any member of the Consortium or violate commitments regarding intellectual property arising out of the activities of the Consortium, as specified in the Consortium's General Intellectual Property and Data Sharing Principles.

- No participant in the Consortium shall take or seek any action relating to the Consortium for the purpose of excluding products or technology of competitors from a market or impeding research and development relating to such products or technology.

- In general, legal counsel for the FNIH should review and have an opportunity to comment on public communications by the Consortium, excluding scientific peer-reviewed communications.

II. Restricted Topics

All meetings, communications, decisions, and other activities of the Consortium should be limited to what is reasonably necessary and appropriate to achieve the Consortium's legitimate purpose, i.e., to accelerate and expand the development of medically useful biomarker technologies and products.

The following restricted topics shall not be discussed or addressed in any Consortium activities, without prior review and approval by legal counsel to FNIH.

- Current or future prices, terms or conditions, pricing policies, costs, profits, or market shares of private-sector companies or goods or services offered by them.

- Intentions or plans about commercial activities, including product advertising and promotional, research and development outside the Consortium, production or pricing policies, and whether to deal with specific customers or classes of customers (including governmental programs).

- Speculation or predictions about how commercial activities of private-sector companies might change in response to business or legislative developments.

- Discussion of any topic of commercial significance to competing private-sector companies may involve risks of antitrust compliance.

When in doubt about any topic for discussion or action, Consortium participants should consult legal counsel to FNIH.

III. Meetings and Teleconferences

Meetings and teleconferences of committees, work groups, and other entities established by the Consortium shall be conducted as follows.

- In general, meetings and teleconferences of the EC and SCs shall be conducted by the Chair of the committee or other Consortium participant authorized to determine the agenda and to terminate the meeting or teleconference if appropriate. An agenda shall be prepared in

advance of the meeting or teleconference and discussions and decisions should adhere to the agenda.

- Minutes shall be kept of all meetings of the EC and SCs and should be reviewed by legal counsel to FNIH in draft form prior to being finalized or disseminated. Minutes should accurately summarize any actions taken. They should avoid attributing specific comments to particular person because of the potential for incompleteness or inaccuracy.

- Legal counsel to FNIH should be present at all meetings of the EC.

- Wherever feasible, agendas should be circulated in advance of meetings or teleconferences of project teams and working groups and a record of the matters discussed and/or action taken should be provided to the relevant SC chair. Where an agenda has not been prepared in advance, a record of the teleconference or meeting nonetheless should be prepared and provided to the relevant SC chair as soon as reasonably possible following the meeting or teleconference, briefly identifying the subject matter, participants, and any decisions or action taken. A clearly marked electronic mail from a designated participant in the meeting or teleconference to the SC chair is sufficient record for the purposes.

- The EC and SCs shall retain all agendas, minutes and other records of meetings and teleconferences throughout the duration of the related project and should consult with the FNIH regarding the handling of such documents upon the termination of the project.

IV. Selection of Research Projects

The Consortium has adopted a process for the identification and approval of Consortium activities.[1] This process shall be adhered to, along with the following principles.

- As a general matter, the consideration and selection of Consortium activities should be fair, unbiased, and as transparent as possible with reasonable opportunity for input by all materially affected stakeholders.

- In particular, the consideration of proposals should not be limited to those proposed by Consortium participants. Any public solicitation of proposed project concepts which might be made should be broadly publicized to as many private industry and other entities active in the relevant field as reasonably possible.

- Project concept proposals and proposed project plans should be recorded in writing. Decisions to accept or reject a concept proposal or project plan also should be recorded in writing, along with a brief explanation of the bases for the decision. Minutes of meetings of the Executive Committee or a Steering Committee may constitute such written record but should include all material reasons for rejecting any proposal.

- A concept proposal or project plan should not be rejected solely on the basis of objection by a private-sector participant that competes, or is developing technology that could compete, with a private-sector proponent of the concept proposal or project plan. (A commercial interest for this purpose is defined as an interest in an existing technology or product or one under development.)

[1] See *Biomarkers Consortium Two-Phased Project Approval Process: Concept Clearance and Project Approval Plan.*

- Any member of the Executive Committee or of a Steering Committee having a commercial interest in a specific project should disclose the existence and nature of the interest or recuse himself or herself from voting. Any recusal of a member of the Executive Committee or Steering Committee shall not prevent there from being a quorum by virtue of the recusal.

- An agenda should be distributed to all Consortium participants in advance of any meeting of the Executive Committee at which the Committee will deliberate on a concept proposal or project plan. Consortium participants may request a copy of the relevant concept proposal and/or project plans from FNIH.

- No project plan shall be initiated prior to review and approval by FNIH counsel to ensure compliance with these Guidelines and the antitrust laws.

- Any question or complaint about conflicts of interest or potentially anticompetitive conduct should immediately be brought to the attention of the EC.

V. Award and Negotiation of Research Grants and Contracts

It is expected that research projects adopted by the Consortium will be implemented through the award of research grants and/or contracts pursuant to the Biomarkers Consortium Grantee/Contractor Selection Principles and Policies.

VI. Sharing of Data

The pooling of information from private-sector and public-sector participants is a central element of the Consortium's effort to expedite biomarker research and development efforts. Otherwise confidential scientific research data and results may be shared among participants, subject to the Consortium's General Intellectual Property and Data Sharing Principles. In general, however, participants should not share with each other any confidential information about commercial activities of private-sector participants, particularly any restricted topics outlined above.

As provided in the General Intellectual Property and Data Sharing Principles, each Consortium project plan, which must be reviewed and approved by legal counsel to FNIH in advance of project implementation, will include policies governing data sharing. Although no hard and fast rules can be relied upon, project plans that involve collecting and disseminating confidential private-sector information should incorporate the following practical precautions.

- Legal counsel to FNIH should be consulted on the appropriateness of collecting and aggregating data in-house or by an independent third party.

- Legal Counsel should review and approve all confidential and competitively sensitive information prior to its dissemination to ensure that such information is sufficiently aggregated that confidential and competitively sensitive information about the commercial activities of individual companies cannot be deduced from it.

- Subject to the foregoing precautions, if unagreggated, confidential and competitively sensitive data about individual private-sector companies are collected by any authorized person or persons, such data should never be shared outside the Project Team, except to the extent required by law, and should be returned to its sources, given to an independent third party bound to maintain its confidentiality, or destroyed as soon as it has been aggregated, except where subject to federal regulation regarding document retention.

- Any form collecting confidential, competitively sensitive information from private-sector companies should include a statement that the information will be handled in conformity with these guidelines and the raw information not disseminated or shared, except to the extent required by law, with other private-sector participants.

VII. Intellectual Property Guidelines

To facilitate the use of data and technologies in expanded biomarker research and development efforts while ensuring adequate incentives to commercialize biomarker technologies, the Consortium will follow its General Intellectual Property and Data Sharing Principles, which in part govern (1) the sharing of Intellectual Property with Consortium participants and (2) the use of intellectual property arising from Consortium-sponsored projects.

The Principles incorporate the following guidelines, in order to prevent misuses of the Consortium's processes to the detriment of competition:

- Except as authorized or required by law, no entity or person shall be required by virtue of their participation in the Consortium to grant exclusive licenses to anyone.

- Consortium participants, grantees, and contractors will not be forbidden to challenge the patents or other intellectual property of other Consortium participants, grantees, and contractors, including patents or intellectual property arising from Consortium-sponsored activities.

- Clear rules will govern whether and, if so, when and under what circumstances Consortium participants, grantees, and contractors will be required to disclose the existence of patents or patent applications regarding inventions relevant to the activities of the Consortium.

- Any research data and results, research technologies, and other intellectual property collected by or shared with the Consortium will be covered by a written contract with the contributor in conformity with these principles.