

The Biomarkers Consortium Principles and Policies on Selection and Award of Grants or Contracts Funded by FNIH Under The Biomarkers Consortium

Grantee/Contractor Selection and Award Principles:

The selection and award of grants and/or contracts funded under The Biomarkers Consortium (BC) will be conducted to ensure fairness, impartiality and inclusiveness, as well as conformity with all BC policies. These Principles and Policies apply to the selection of grants or contracts funded by FNIH in the context of The Biomarkers Consortium. Federal grants and contracts awarded for the conduct of projects carried out under The Biomarkers Consortium Project Teams (PTs) will be governed by Federal law and NIH policies and procedures.

Policies for FNIH Contract and Grant Awards Under The Biomarkers Consortium:

- Steering Committee (SC) and/or PT participants will recommend solicitations for entities to conduct work relevant and important to the progress of the PT to the Executive Committee (EC).
- Following EC approval, FNIH will compose a team to draft a solicitation for each new grant or contract opportunity.
- Scientific and technical assistance will be sought from the relevant SC and/or PT, and the SC and/or PT members should all review the draft solicitation (subject to any limitations based on conflicts of interest).
- The FNIH will take reasonable steps to make each solicitation widely known to the public (including academic institutions, private-sector companies, and other organizations) through means appropriate to ensure broad dissemination.
- All solicitations will include information regarding the scope of the solicitation; the requirements for a responsive proposal; criteria for review; timelines; and conditions and terms of award and post-award management.
- The FNIH will administer and oversee the process for the selection and award of grants and/or contracts resulting from such solicitations published as above.

- o Administrative review will be undertaken by FNIH staff to assess the responsiveness and completeness of proposals received. Those deemed complete and responsive will be forwarded to an appropriate review panel for substantive assessment.
- FNIH will compose review panels in consultation with the relevant SC and/or PT. The review panels will assess the proposals submitted pursuant to a solicitation, as set forth in the subsequent sections of this document. The FNIH will broadly seek experts as needed to serve on each evaluation panel.
 - o The FNIH Conflict of Interest and Confidentiality Policies for FNIH-Managed Initiatives, including any Biomarkers Consortium-specific Addenda to these policies shall apply to all review panels for BC activities.
 - o Review panels may include BC members, but should include only those competent to assess the proposals.
 - o Potential review panel members will be screened by FNIH for real and apparent conflicts of interest prior to finalizing review panel membership. FNIH may waive the conflict of interest restrictions and otherwise manage the potential or real conflict when there is no other practical means of securing appropriate expertise to review a particular application or proposal.
 - o FNIH will make reasonable efforts to include on the review panels representatives from all relevant stakeholder groups participating in The Biomarkers Consortium.
- These policies do not preclude FNIH from entering into non-competitive awards/supplements where warranted, subject to the review of FNIH antitrust counsel and approval by the EC.
- An expedited review process may be used where warranted by the nature of the solicitation, subject to the review of FNIH antitrust counsel and EC approval.

Peer Review Panel Assessment of Proposals: An objective peer-review process will be used to assess responses to solicitations and to provide recommendations to the EC for funding consideration by FNIH.

- Proposals will be forwarded for review to ascertain that the proposals meet the specifications set forth in the solicitation; that the proposed plan is feasible, of high quality, and is appropriately budgeted and staffed; and that the proposed plan meets the standards for the work sought. Additional evaluation criteria will be articulated in the solicitation.
 - o The Evaluation Criteria should mirror the requirements in the solicitation.
 - o If weights are assigned to individual Evaluation Criteria, that information should be included in the solicitation.
 - o All of the factors for determining the award should be identified (technical, cost/price, past performance, etc.) in the solicitation.
 - o The review process should examine proposals from both a technical and business perspective.

To assure objectivity and fairness in the evaluation process, an objective individual(s) designated by the FNIH will manage all aspects of the technical and business review processes. The individual(s) will be charged on behalf of the FNIH with the initial screening for conflicts of interest.

For All Responses to BC Solicitations: The review panel will assess applications and proposals independently on merit, responsiveness, feasibility, quality and additional specified criteria. Reviewers will be instructed that assessments should be made objectively, not based on commercial or proprietary interests.

- Once the review panel has completed its assessment, the SC or PT sponsoring the solicitation will prioritize and rank the assessed proposals with the aim of achieving the most efficient and effective use of funds to achieve the project goals. Committee members will be instructed that assessments should be made objectively and not based on commercial or proprietary interests. The SC shall approve all those proposals that best meet these criteria.
- A proposal will not be rejected solely on the basis of objections by a private-sector participant that competes with a private-sector proponent of the proposal.
- Written documentation of the review process, including responses, evaluations, and decisions, will be recorded for each proposal and maintained for a period of three years following each award, unless 1) a longer period is required by law or 2) confidentiality considerations dictate that some content of unsuccessful applications (e.g., personally identifiable medical or genetic data) be destroyed or returned to the applicant.
- Legal counsel to the FNIH shall review each award recommendation to ensure compliance with The Biomarkers Consortium Antitrust Guidelines and the antitrust laws.
- The panel's evaluation along with the SC award recommendations will be provided to the FNIH and The Biomarkers Consortium EC for recommendation to the FNIH's Board of Directors for a final funding decision.
- Information regarding any submitted proposal, including detailed costs and other commercially significant information included in specific proposals shall be considered FNIH records and will be provided to reviewers and relevant decision-makers subject to a confidentiality agreement that, among other things, states that any information provided will be used only for the purposes of the review and selection process.
- All participants involved in the development, review, and selection process for Consortium grants and contracts will sign a Statement in which they agree to abide by the FNIH Conflict of Interest and Confidentiality Policies for FNIH-Managed Initiatives.

Award and Post-Award Management: The details of the award and post-award management will be described in the terms and conditions of each award.