FNIH
Foundation for the National Institutes of Health

Novel Biomarkers RFA Submission Form

Title of Project		
Principal Investigator(s) (submitter) Name: Title: Submitting Organization: Address: e-mail: Tel: ***Co-investigator(s) (add more as needed)*** Name: Title: Submitting Organization: Address: e-mail: Tel:		
Submission Date:		
Time Period of Project:		
Project Total Budget:		
Internal Use Only		
WG Decision, Date:		
Joint Steering Committee Decision, Date:		
Executive Committee Decision, Date: *(if needed)*		

Section 1: Project Overview *(500 words maximum)*

Describe the biomarker assay to be developed, the clinical/scientific need for the biomarker/assay, and the disease target or capability gap being addressed.

1.1 Specific Aims and Objectives

1.2 Project Deliverables/Outputs

1.3 Applicability *- Describe why this project is appropriate for the PACT Novel Biomarkers RFA, the pre-competitive nature of the project, and how the project is novel.*

- Include a brief description of other efforts known to the applicant to ensure non-duplication.
- Classify the project based on its current stage of development towards regulatory qualification:
    - Stage 1: *Biomarker Identification and/or Definition* – Includes early discovery research with screening assays and collection of correlative data to select a biomarker for a given condition.
    - Stage 2: *Analytical Validation and Consistency* – Includes studies to analytically validate a given assay or biomarker and show its detection consistency.
    - Stage 3: *Assay Standardization and/or Clinical Utility* – Includes studies that are endeavoring to standardize an assay across multiple research or clinical laboratories, and/or are conducting a statistically appropriate study to validate the clinical utility of a given assay or biomarker.
    - Stage 4: *Regulatory Qualification and/or Clinical Use* – Includes studies that are collecting necessary data on analytically and clinically validated biomarkers to build the case for regulatory qualification or widespread clinical deployment of a biomarker.

Section 2: Scientific Design *(2000 words maximum)*

2.1 Background and Supporting Data

- Including Precision, Reproducibility, Target Tissue

2.2 Experimental Plan

- Describe in detail the scientific strategy, design and logistics. Include how the study design will address the project goals and objectives.
- Describe in detail the experiments to be conducted
- Describe the type of data to be analyzed (retrospective and/or prospective)

2.3 Analytical Methods

- Describe in detail analytical methods that will be used.
- Provide a statistical analysis plan.
- If any studies are designed to replicate preliminary data or findings from prior studies, please describe those clearly.

2.4 Technologies and Assays

- Describe the current technologies or assays to be used in the project.
- If project is in Stage 3 or Stage 4, please provide analytical validation data for the assay(s) to be used.

2.5 Human/Animal Subjects

- Will human / animal subjects be involved in this Project? If so, how?

Section 3: Data and Intellectual Property Sharing Management Plan *(1000 words maximum)*

Please note: Use of pre-existing IP and sharing of newly generate IP must comply with PACT IP and Data Sharing Guidelines, which can be made available upon request.

3.1 Describe pre-existing intellectual property (IP) that could have a bearing on the project.

3.2 List any relevant existing patents and patent applications held by key participants in the project (include patent number, title, submission date).

3.3 Describe any new IP that may be generated.

3.4 Describe plans for risk management concerning:

- Data Use
- Data security
- Legal compliance

3.5 Describe plans for depositing data in the Cancer Immunologic Data Commons or a similarly approved NCI/public database upon initial publication.

Section 4: Timeline, Milestones, Deliverables and Budget *(1000 words maximum)*

4.1 Provide a timeline for deliverables, and an end date for the project.

4.2 Describe the milestones and how will progress on achieving them will be assessed.

- Describe any opportunities for interim feasibility assessment(s) based on Project progress.

4.3 Project Budget

- Please complete the high-level budget table below *in addition to* attaching a detailed budget justification explaining the need for the costs requested with detailed breakdown of costs. Application will not be reviewed if both of these items are not included.

Category	% FTE	Year 1	Year 2	Total
Personnel				
List each FTE individually with their percentage *(add lines as appropriate)*				
Supplies				
(add lines as appropriate)				
Equipment				
Subcontracts				
List each individually *(add lines as appropriate)*				
Total Direct Cost				
Overhead (15% of direct costs in lines above)				
Total Project Costs				

4.4 Detail any existing funding relationships.

Section 5: Program Support *(500 words maximum)*

5.1 List key personnel, including names, titles and role in the Project.

- List collaborators, advisors, and/or hired consultants outside the consortium.

Section 6: Legal Agreements

6.1 Legal Agreements

- List any contracts, memoranda of understanding, grants, data or material transfer agreements that are likely to be necessary to execute the project plan.

Section 7: Provide a brief bio for each investigator in the project *(less than one page each)*

Attachments

Please attach detailed budget and justification.