Frequently Asked Questions: PAR 25-325

Eligibility Questions

- **What specimen types can be studied under this PAR?**
  Under this PAR, many types of biospecimens may be studied, including but not limited to: core biopsies, fine needle aspirates, tissue exudates, blood/plasma, urine, saliva, breast milk, feces, sweat, cerebrospinal fluid, pleural aspirates, esophageal aspirates.

- **Can foreign institutions apply?**
  Yes, foreign institutions can apply. It is encouraged to find a US partner.

- **Can I partner with industry and/or can industry apply? What about startup companies? What about biobanks?**
  Yes; academic, nonprofits, for-profit, government and other organizations are all eligible to apply, provided their application is responsive to the Notice of Funding Opportunity (NOFO). See the full eligibility information in the NOFO here.
  The program has received applications from small biotech companies in response to this NOFO. Most applications use a collaborative approach wherein an academic investigator has an industry partner who supports a clinical trial or provides access to clinical trial samples. If you are particularly interested in translational academic-industrial partnerships, check out the Academic-Industrial Partnerships for Translation of Technologies for Diagnosis and Treatment (R01 – Clinical Trial Optional): PAR-25-337.

- **Are early-stage PIs eligible?**
  Yes, multiple PIs can be included, and this is encouraged.

- **Are projects that generate reference materials for assay development appropriate?**
  No, the NOFO does not support generation of quality standards for an assay.

- **What kind of collaborators should be included on the project team?**
  Successful applications often have multidisciplinary project teams with expertise in the areas appropriate for the proposed studies, including pathologists, radiologists, oncologists, molecular biologists, and/or statisticians. Applicants must demonstrate experience in assay development and are encouraged to collaborate with investigators involved in clinical trials.

- **What is considered responsive to the NOFO? Non-responsive?**
  Responsive:
  - Clinically relevant emerging/established biomarkers
  - Teams with appropriate expertise
  - Studies relevant to biomarker assays utilized in clinical treatment trials or development of biomarker assays
  - Existing and emerging clinical analysis platforms
  - Focused research using small tissue and liquid biopsies

  Non-responsive:
  - Biomarker discovery approaches
  - Development of novel biospecimen fixatives/technologies
  - Projects related to early detection biomarker assays
  - Projects focused on global cancer genomic/proteomic studies

Application Questions

- **What are potential preanalytical issues that my project could address?**
  In solid tumors, issues may include but are not limited to:
  - Biopsy methodology in a medical setting
  - Tumor heterogeneity
  - Preservation method (formalin, RNAlater, frozen, etc.)
  - Sample processing, handling and/or storage (timing and temperature considerations)
  - Tradeoffs (morphology vs. molecular preservation)

  In liquid biopsies, issues may include but are not limited to:
  - Collection device in a medical setting
  - Collection methodology in a medical setting
  - Sample processing, handling and/or storage (timing and temperature considerations)

- **How should the specific aims be structured?**
  In general, the aims should address pre-analytical issues associated with the biomarker assay of interest. One specific aim should target validating pre-analytics in a set of clinical samples. For more guidance, contact the Program Directors listed below.

- **Is preliminary data required?**
  While not required, it is highly encouraged to have preliminary data to demonstrate the potential success of your project.

- **How can the application cover 'Innovation' when this type of research, by nature, may not be seen as innovative?**
  Applications should describe where there are bottlenecks based on literature review and how the proposed research could fill critical gaps. Based on your team's expertise, consider whether the proposed work is novel or innovative because it has never been done before or because there is a need/gap in the field. The Biospecimen Research Database (BRD) is a helpful resource for literature search.
- **Should an application focus on one or more cancers?**
  An application should be focused within the parameters defined in the NOFO, which may limit a proposal to one cancer with potential applicability to several cancers. Preliminary data should support the focus on the cancer type(s).
- **Do I need to partner with a clinical trial group to have a successful application? Can you help me connect with a clinical trial group?**
  Collaboration with a clinical trial group is encouraged but not required. Access to clinical trial samples is beneficial if there is not a clinical trial collaborator. Program staff are happy to meet with applicants to discuss clinical trial collaboration and facilitate introductions with NCI's Clinical Therapy Evaluation Program (CTEP).

Budget Questions

- **What is the budget?**
  Project budgets are limited to $250,000 in direct costs per year for a maximum of five years.
- **Are indirect costs included in the cap?**
  No, indirect costs are not included in the cap.

Review Process Questions

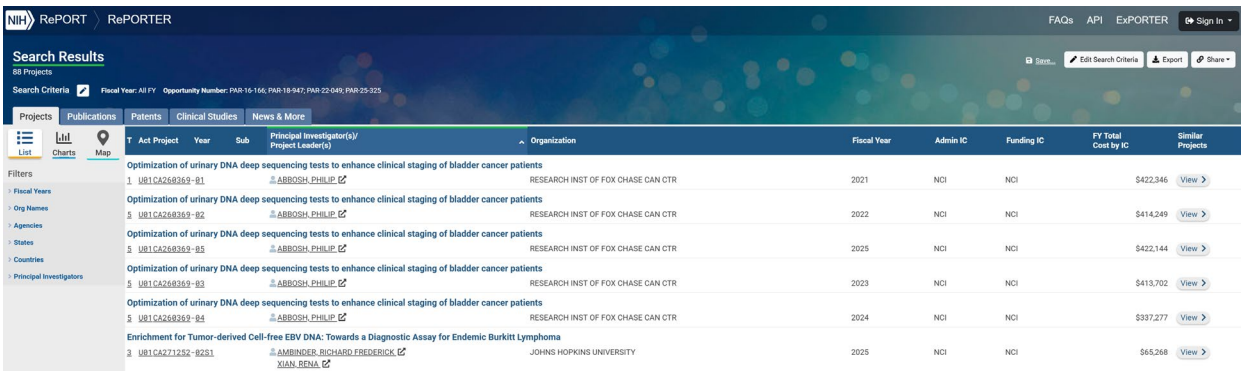
- **Are there common reasons why an application is deemed non-responsive?**
  An application's responsiveness depends on peer review and whether guidance in the NOFO was followed. It is application-dependent, and common application issues include, but are not limited to: showing a lack of focus; listing overly ambitious project goals; not presenting enough proposed research to justify proposed cost; not including enough preliminary data, or data is unconvincing.
- **What percentage of applications get funded?**
  This is a non-percentiled, score-based merit process. The number of projects

funded varies due to many factors including the fiscal year, competition, budget considerations, and more.

Miscellaneous

- **What does the cooperative agreement with NCI oversight entail?**
  The U01 cooperative agreement mechanism involves scientific involvement by the Program staff to guide, coordinate, and/or participate in project-related activities.

- **Are there examples of funded projects?**
  Yes. Please review the NIH RePORTER list (example screenshot below) for more details.



  Examples of cancer types studied in funded projects include, but are not limited to: Breast, Glioblastoma, T-Cell Lymphoma, Lung, Prostate, Bladder, Hepatocellular carcinoma, Pancreatic, Acute Myeloid Leukemia, Cholangiocarcinoma.
  Examples of biospecimen types studied in funded projects include, but are not limited to: Blood/plasma/bone marrow, bronchoalveolar lavage, core biopsies/fine needle aspirates, urine, cyst fluid, pleural effusion, saliva, cerebrospinal fluid

- **What resources are available?**
  Below are helpful links and resources in biospecimen science:
  - Biospecimen Evidence-Based Best Practices (BEBPs)
  - Biospecimen Standard Operating Procedures (SOPs)
  - Biospecimen Research Database (BRD)

Other resources:

- Contact the Program Directors with any additional questions:
  Dr. Lokesh Agrawal lokesh.agrawal@nih.gov
  Dr. Ping Guan ping.guan@nih.gov
  Dr. Abhi Rao abhi.rao@nih.gov
- Information about the PAR 25-325 U01 NOFO
- Information about the PAR 25-074/05 UH2/UH3 NOFO
- NCI's Innovative Molecular Analysis Technologies (IMAT) program
- NCI's Specimen Resource Locator
- NCI's National Clinical Trials Network (NCTN) Navigator
- NCI's Cooperative Human Tissue Network (CHTN)