PROGRAM DESCRIPTION
The Cancer Research Institute (CRI) is launching a clinical trials program to support innovative clinical studies from clinicians and academic researchers with the goal of advancing immunotherapies that will provide the greatest impact on patient outcomes. CRI will prioritize selection of trials that address areas of high unmet need in cancer and seek mechanistic insights using deep correlative studies. To maximize the impact of each clinical trial, CRI will advise on selected studies to coordinate and optimize clinical trial design and translational studies.

PROJECT CRITERIA
This program provides funding for clinician-scientists aiming to launch innovative phase I/II or phase II clinical studies using novel immunotherapies. In addition to the merits of the clinical and scientific rationale, studies will be selected based on their novelty, feasibility, and clinical impact. Competitive applications will have a strong focus on yielding mechanistic insights into clinical response and potentials for biomarker discovery and/or validation. CRI will make an effort to coordinate selected trials by standardizing sample collection, correlative assays and analyze as well as data sharing, including, if applicable, deposition of immunogenomic data into the CRI iATLAS platform.

APPLICANT ELIGIBILITY
Candidates for a clinical trial grant must be the Principal Investigator (PI) of the proposed study. CRI has no citizenship restrictions, and research supported by the award may be conducted at medical schools or research centers in the United States or abroad. Please note that CRI does not support research at for-profit institutions.

FINANCIAL INFORMATION
This clinical trials program will provide up to USD $1 million for novel immunotherapy clinical trials. The funds may be used for salaries, supplies, patient costs, correlative assays, and data analyses. Payment will be structured into milestones to ensure that studies will advance and be brought to completion.

DEADLINES
The deadline to submit an Initial Protocol Concept is December 1, 2022. Candidates will be notified in February if they are invited to submit a full proposal, including protocol. Invited applications are due May 1. If these deadlines fall on the weekend, proposals will be accepted until the close of business that following Monday.

INITIAL PROTOCOL CONCEPT
The Initial Protocol Concept must be submitted electronically using the CRI online submission portal. If this is the first time you are submitting a grant application to CRI you will be asked to create a new user account to catalogue all applications you submit to CRI.

The Initial Protocol Concept must include:
1. PDF/Cover Sheet (1 page)

2. A brief protocol concept (maximum 2 pages, excluding study schema and references) including:
   a. Study rationale
   b. Primary objectives
   c. Secondary objectives
   d. Number of patients to be treated
   e. Patient eligibility criteria
   f. Sample collection plan
   g. Biostatistics plan

3. A separate one-page study schema should be uploaded outlining the clinical design.

4. A brief translational plan (maximum 1 page, excluding references)
   a. Translational aims and rationale
   b. Assays intended to use and samples to be tested

5. Biographical sketches for PI(s) and co-PI(s) (limit bibliography to past 5 years or publications relevant to proposed study)

To Apply:

Submit an Initial Protocol Concept through our submission portal:

https://www.grantrequest.com/SID_205?SA=SNA&FID=35118
[Note: To be finalized at a later date]

FULL PROPOSAL INSTRUCTIONS (incorporating feedback from review committee)

1. Expanded Protocol Concept
   a. Detailed study rationale
   b. Preclinical and/or clinical data with references

2. Expanded Translational Plan
   a. Detailed study rationale including data and references
   b. List of all translational activities with samples to be tested for each
   c. Vendors and/or academic lab partners for each proposed translational work
   d. Data analysis and deposition plan

3. Budget
   a. Breakdown of clinical and translational budgets
   b. Updates on additional funding sources (applied vs. secured)

4. Other updates
   a. Drug supply updates
      i. Letter of support from pharma/biotech indicating drug supply
   b. Regulatory updates (IRB process, IND filing)

5. Brief Summary of Changes Made to Incorporate Feedback