

## 111 NHRI TRG RFA

### Topic #2: Immunotherapy: Impact on Immune System and New Challenges of Infectious Complications

- Objective:
  - The aim of the call is to enable translational, collaborative research projects that will address important questions relating to immune system malfunctions as well as infectious complications in patients treated with immunotherapy to elucidate the diverse mechanisms leading to these events and to address actionable approaches for their management.
- Background:
  - Immunotherapy, including, but not limited to, anti-cancer immunotherapy, immune modulators for autoimmune disease, is changing the practice of medicine. However, as immunotherapy becomes more popular, immune-related adverse events (irAEs) as well as a variety of unusual and/or opportunistic infections are also observed, which can result in prolonged hospitalizations and detrimental health outcomes. Given the complexity of these situations, there is a critical need for coordinated multidisciplinary approaches and translational research programs for early detection and intervention.
- Research Priority:
  - Research on taking a longitudinal observational approach to obtain clinical data on characteristics of patients treated with immunotherapy and to investigate the incidence, etiology and pathophysiology of irAEs as well as associated infectious complications. This may include the development of innovative technologies, including, but not limited to, identification of predictive biomarkers of patients at risk for better patient stratification at the start of therapy and influence clinical monitoring.
  - At least 3 interrelated and integrated component projects to link a major pathway or target for the investigated outcomes. One of the component projects should commit to establishing a Platform of Immunotherapy Registry to collect multi-center clinical data and samples and to identify all reportable cases of irAEs and serve as a foundation of the proposed project.
  - Research proposals with multi-institutional and multi-disciplinary collaboration should be stated.