

Integrating Health Disparities into Immuno-Oncology (IO) Research

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Integrating Health Disparities into Immuno-Oncology Research

■ **Outstanding Scientific Gaps:**

- Multi-layered impediments in access to care are significant drivers in health disparities
- Interdisciplinary research and implementation science gaps include racism, socioeconomic status, and geographic origin
- Health disparities persist and need to be directly addressed in the IO research ecosystem
- Critical need for complementary basic research focused on the intersection between health disparities and immuno-oncology research

■ **Basic Science Challenges in Cancer Health Disparities Research:**

- Complex and overlapping biological and immunological factors impacting the disparities
- Difficult to access sufficiently powered and/or well-curated specimens; lower numbers of under-represented groups recruited into clinical trials

- **Basic Science Objectives:** To integrate health disparities research throughout the NCI immuno-oncology research continuum

Research Gaps in Health Disparities in Immuno-Oncology

- **Overarching Research Gaps:**

- Understanding inflammatory, metabolic and immune profiles of immunotherapy treatment response across under-represented populations
- Investigating genetic, immune signatures, immune infiltrates, and/or distinct tumor immune microenvironments that may underly the cancer health disparities

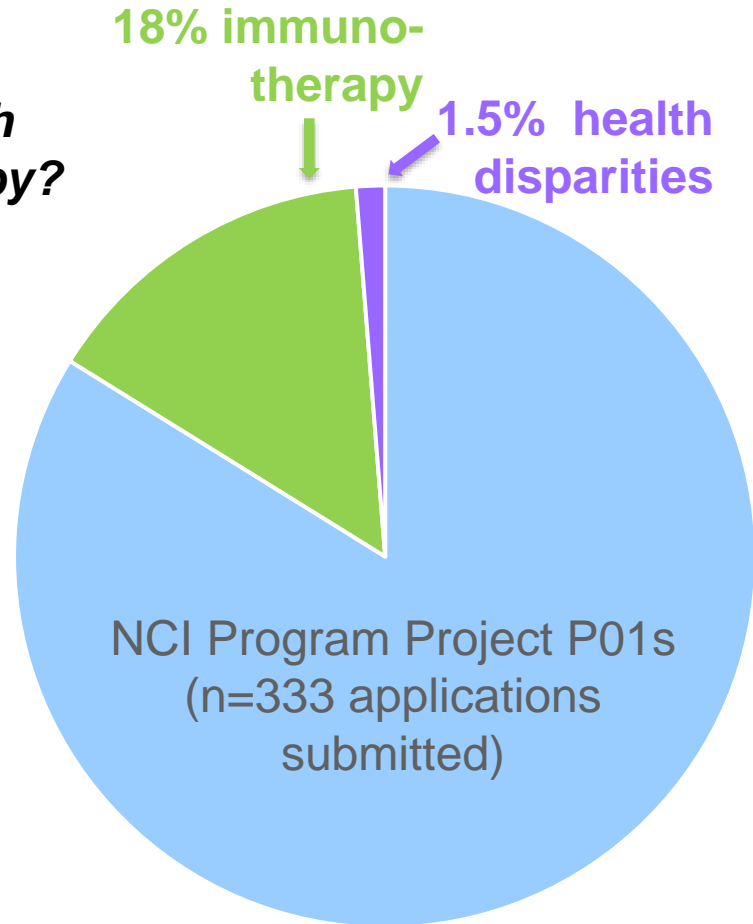
- **Specific Research Examples:**

- Characterizing unique gene expression and immune infiltration profiles in breast cancer subtypes across African American and Caucasian patients
- Understanding how distinct genetic and immune signatures in the tumor microenvironment are associated with colon cancer disparities
- Developing animal models that recapitulate the breadth of immune responses across under-represented populations
- Characterizing disparities in immunotherapy response, resistance and immune-related adverse events

P01 Portfolio Analysis

Are P01 applications being submitted with both health disparities and immunotherapy?

- Between FY2017-21, 333 investigator-initiated P01 applications submitted to NCI
- 18% of applications submitted (n=59) with immunotherapy, 12 awarded, **none with health disparities**
- 1.5% applications submitted (n=5) with health disparities, 1 awarded, **none with immunology**
- Thus, there is a potential pool of applicants that can be refocused to fully integrate health disparities into IO research



Integrating Health Disparities into Immuno-Oncology Research

- **Problem:** The portfolio analysis indicates there is a potential applicant pool for studying health disparities in immuno-oncology. However, multi-disciplinary projects that incorporate health disparities research remain an unmet need.
- **Solution:** Tackling these complexities will require a multi-pronged programmatic approach to integrate health disparities into IO research:
 1. Ongoing basic and translational research programs supported through NCI
 2. Support feasibility and planning projects to strengthen studies for P01s

Building Foundational Health Disparities and IO Research

- The **aspirational goal** is to build a cohort of immuno-oncology (IO) P01s* with integrated health disparities research. This is a high bar given requirements for P01 integration and track record of collaborations/publications.

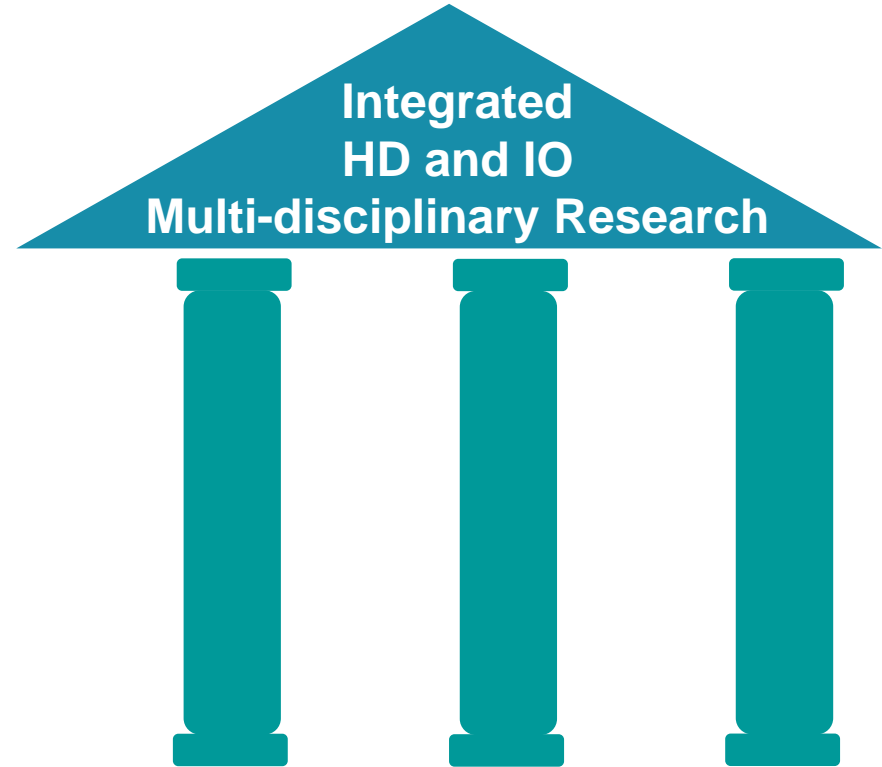


Integrated
HD and IO
Multi-disciplinary Research

*Or other multi-disciplinary research projects

Building Foundational Health Disparities and IO Research

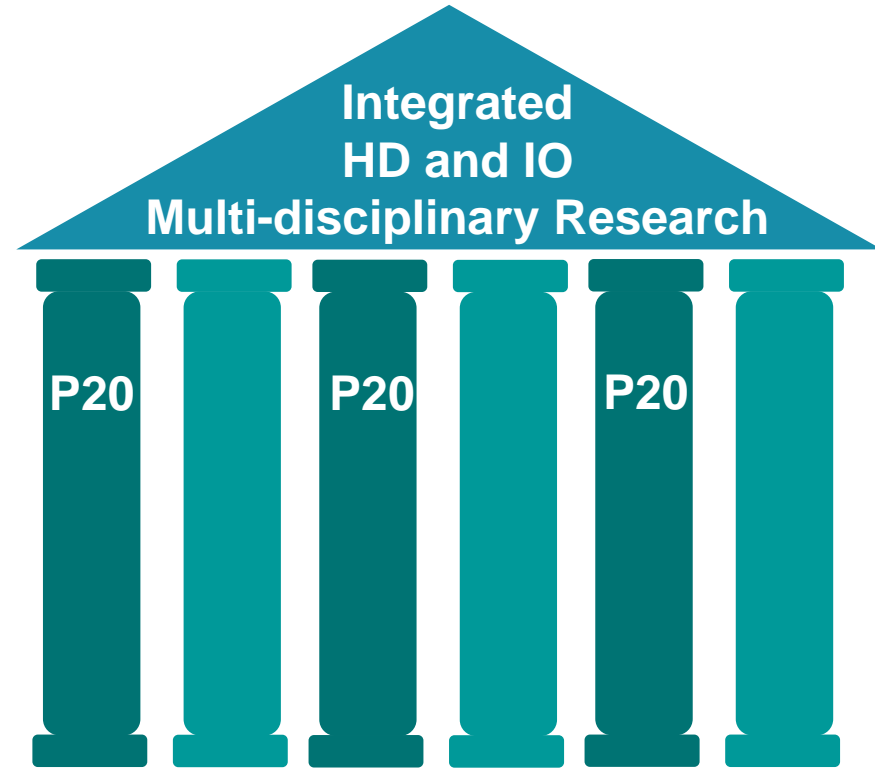
- The aspirational goal is to build a cohort of immuno-oncology (IO) P01s* with integrated health disparities research. This is a high bar given requirements for P01 integration and track record of collaborations/publications.
- Successful **multi-disciplinary research** will require **foundational feasibility** projects:
 1. Support ongoing NCI programs through NOSIs (Notice of Special Interest)



*Or other multi-disciplinary research projects

Building Foundational Health Disparities and IO Research

- The aspirational goal is to build a cohort of immuno-oncology (IO) P01s* with integrated health disparities research. This is a high bar given requirements for P01 integration and track record of collaborations/publications.
- Successful multi-disciplinary research will require foundational feasibility projects:
 1. Support ongoing NCI programs through NOSIs (Notice of Special Interest)
 2. **P20**: Feasibility and planning studies to build collaborations, appropriate sample sets, and generate preliminary data for subsequent application submissions



*Or other multi-disciplinary research projects

P20: Planning and Feasibility Studies to Integrate and Develop Health Disparities in Immuno-Oncology Research

- **Goal:** P20 grants will support planning and feasibility studies to integrate health disparities into multi-disciplinary immuno-oncology research studies. It is expected preliminary studies from the P20 will enable the development of investigator-initiated multi-disciplinary projects (e.g., P01s, multi-disciplinary R01s, et al.).
- **Research Scope:**
 - Initial studies to establish sufficiently powered and/or well-curated specimens from groups under-represented in clinical trials
 - Feasibility/pilot studies to test exploratory or novel hypotheses on immune mechanisms, immune response, and/or treatment response/resistance underlying cancer health disparities
 - Planning studies to build collaborations/teams, generate resources (e.g., tools, reagents), or other collaborative research infrastructure

P20: Planning and Feasibility Studies to Integrate and Develop Health Disparities in Immuno-Oncology Research

- **Requirements:**
 - Integration of underserved populations
 - Multi-disciplinary teams with complementary expertise in both cancer health disparities and immuno-oncology research
- **Budget:** 2-3 awards each for 2 years capped at \$250,000 DC per year (\$1.0M TC for Year 1)
- **Justification for an RFA:**
 - No current NIH P20 parent announcement
 - Enable specific RFA requirements for responsiveness and specific review criteria
- **Building on the SPORES P20 as a model:**
 - RFA-CA-17-033 and RFA-CA-19-034 aim to establish foundational research for SPORE application submissions.

P20: Planning and Feasibility Studies to Integrate and Develop Health Disparities in Immuno-Oncology Research

- **Scientific Outreach and Program Coordination:**
 - Pre-application outreach to both HD and IO research communities
 - Programmatic coordination with both CRCHD and DCB staff
- **Evaluation Criteria and Metrics of Success:**
 - Establishment of complementary, multi-disciplinary research teams with strengths in both cancer health disparities and immuno-oncology research
 - Pre-application or submission of well-integrated multi-disciplinary research projects (e.g., P01s or R01s)
 - If the P20 team is developing an investigator-initiated program project (P01), has the P20 team formed an advisory board to review an initial P01 application submission plan?
 - Publications and metrics of collaboration

Incorporating BSA Reviewer Comments:

- ***Health disparities are rooted in access to care factors, not underlying biology:***
 - We fully agree disparities in access to care and quality of treatment are paramount problems to be addressed by the research community.
 - The scope of this P20 program extends beyond access factors alone and is designed to complementarily investigate how biology/immunology may interact with the many complex, interrelated contributors to IO-related disparities.

- ***Access to care, racism, socioeconomic and geographic origin must be addressed:***
 - The P20 program will solicit complementary, multi-disciplinary research teams to address these multi-layered problems.
 - Feasibility or pilot studies will enable exploration of novel or high-risk hypotheses.

Discussion