

Specialized Programs of Research Excellence (SPORE)

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SPORE Program

❖ What is a SPORE?

- **Multi-project, specialized center grant (P50)**
 - **Minimum of 3 projects required (clinical trial required; EPPS encouraged)**
 - **Project co-leaders (basic and clinical/applied scientists; ≥ 2)**
 - **Interaction of projects with cores (i.e. Biospecimen Core)**
- **Supports investigator-initiated translational research**
- **Contributes to improved prevention, early detection, diagnosis, and treatment of cancer**

❖ SPORE Translational Research Goals

- **All proposed SPORE projects must be translational and focused on the biology of human cancer with the goal of reaching a translational human endpoint.**

Translational Research in SPORE

Translational research uses knowledge of human biology to develop and test the feasibility of cancer-relevant interventions* in humans *AND/OR* determines the biological basis for observations made in individuals with cancer or in populations at risk for cancer

** The term “interventions” is used in its broadest sense to include molecular assays, imaging techniques, drugs, biological agents, and/or other methodologies applicable to the prevention, early detection, diagnosis, prognosis, and/or treatment of cancer.*

What is a Human Endpoint?

- ❖ **At least one of the following types of human endpoints should be proposed in each SPORE research project:**
 - **Early phase clinical trials of new investigational drugs (INDs) and biologics, experimental procedures, medical devices, or combinations thereof**
 - **Early phase clinical trials of new combinations or new uses of the FDA-approved agents and devices**
 - **Discovery and development of biomarkers, only when measurements are made in human biospecimens, or directly in human subjects**
 - **Laboratory studies using clinical materials that lead to new clinical hypotheses (reverse translation)**
 - **IND-directed toxicological studies* conducted following a pre-IND meeting with the FDA in which the plan proposed by the investigators is acceptable to the FDA**
 - **Population, behavioral, or psychosocial studies, when these studies address mechanistic aspects of the biology of the disease**
- ❖ **Cell lines, organoids, xenografts, or patient-derived xenografts (PDX) using primary human tumors **are not sufficient** as human endpoints**

*Although IND-directed toxicology studies do not involve human beings, these studies are the last steps before clinical trials begin, and are therefore considered programmatically appropriate as a human endpoint for SPORE translational projects.

SPORE Scientific Focus

Each SPORE grant should focus on:

❖ **An organ-specific cancer**

or

❖ **A group of highly related cancers, such as sarcoma, gastrointestinal, neuroendocrine, etc.**

or

❖ **Cancers related by common biological pathway mutations/alterations or other cross-cutting themes, such as pediatric cancers, virally-related cancers or cancer health disparities.**

Submitting a CHD-Focused SPORE

- ❖ **Clear vision for selection of the SPORE mechanism (versus a P01 or 3 separate R01s)**
 - **Justify why a SPORE and why now**
- ❖ **Cross-Cutting Health Disparities Theme**
 - **Projects can span multiple organ-sites**
 - **Not necessary for projects to be connected by a common biological mechanism**
 - **Demonstrate access to patient cohorts and archival samples for rigorous scientific studies**

SPORE Requirement Summary

- ❖ **Minimum of three translational research projects with a human endpoint** (up to \$1.4M DC/YR)
 - ❖ Renewals may submit two large-scale continuation projects
 - ❖ A clinical trial in at least one project
- ❖ **May include one or more EPPS projects** (up to \$120K = up to \$1.52M DC/YR)
- ❖ **Scientific Collaboration**
 - Included in Overall (Program Overview)
- ❖ **Shared Resource Cores:**
 - Biospecimen/pathology: required
 - Stats, clinical, animal, etc.: optional
- ❖ **Administrative Core**
- ❖ **Developmental Research Program (DRP)**
- ❖ **Career Enhancement Program (CEP)**
- ❖ **External Advisory Board Members**
- ❖ **Commitment to attend and participate in SPORE-relevant meetings/workshops**
- ❖ **Minimum Time Commitment:**
 - SPORE director(s): ≥ 2.4 person months
 - Project co-leader(s): ≥ 0.6 person months
 - Core director(s): ≥ 0.6 person months
 - DRP/CEP director(s): ≥ 0.3 person months
- ❖ ***Intellectual Property Management Plan (required at the time you submit JIT)***

SPORE Application Eligibility, Timeline, Success Rates, Funding, & Opportunities in CHD

SPORE Eligibility

- ❖ **Minimum Research Base: Four investigators with a significant role in a SPORE (as project co-leader, core director, or SPORE Director) must have an independently funded peer-reviewed grant or serve as an overall/site chairperson on an active NCI-sponsored clinical trial.**
- ❖ **Domestic for profit and not for profit institutions**
- ❖ **Basic and clinical expertise**
- ❖ **Access to cancer patient population**
- ❖ **Statement of institutional commitment**

SPORE Director(s) Qualifications

- ❖ **Recognized scientific leader in the field**
 - Basic or clinical/applied investigator
 - May act as a project co-leader, co-investigator, or core director
- ❖ **Prominent role within institution or cancer center**
- ❖ **Identifies new translational research opportunities**
- ❖ **Appropriate time commitment (≥ 2.4 person months)**
 - Applies to each PD/PI in the case of multi-PDs/PIs applications

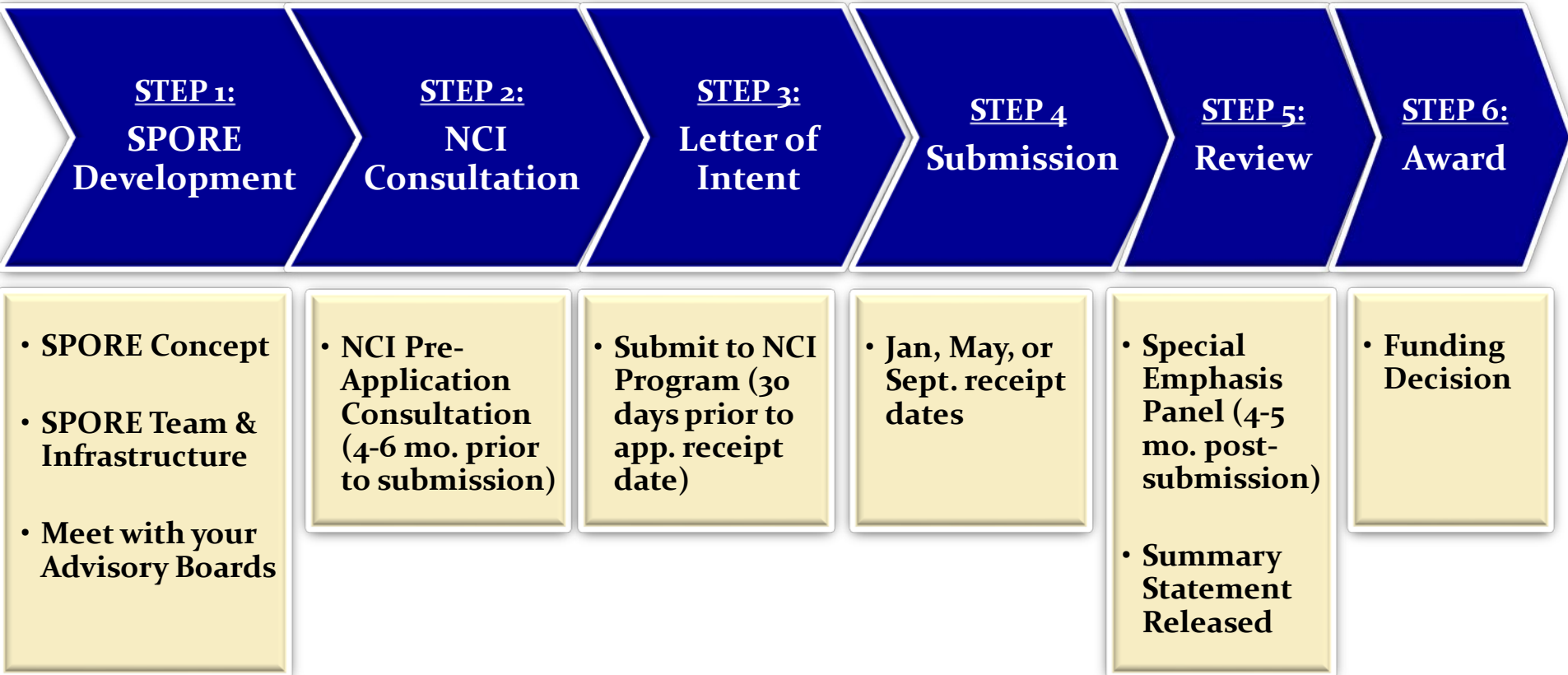
Note: Project Director (PD) or Principal Investigator (PI) is known as the SPORE Director

Key Dates for SPORE Applications (PAR-18-313)

| Letter Of Intent | Application Receipt | Peer Review | Council Review | Anticipated Start Date |
|------------------|---------------------|----------------|----------------|------------------------|
| Dec 25, 2017 | Jan 25, 2018 | June/July 2018 | Oct 2018 | Summer 2019 |
| April 25, 2018 | May 25, 2018 | Oct/Nov 2018 | Jan 2019 | |
| Aug 25, 2018 | Sep 25, 2018 | Feb/Mar 2019 | May 2019 | |
| Dec 25, 2018 | Jan 25, 2019 | June/July 2019 | Oct 2019 | Summer 2020 |
| April 25, 2019 | May 25, 2019 | Oct/Nov 2019 | Jan 2020 | |
| Aug 25, 2019 | Sep 25, 2019 | Feb/Mar 2020 | May 2020 | |
| Dec 25, 2019 | Jan 25, 2020 | June/July 2020 | Oct 2020 | Summer 2021 |
| April 25, 2020 | May 25, 2020 | Oct/Nov 2020 | Jan 2021 | |
| Aug 25, 2020 | Sep 25, 2020 | Feb/Mar 2021 | May 2021 | |

Note: NIH standard due dates for **P series** apply. SPORE PAR 18-313 expires January 8, 2021.

SPORE Application Timeline



SPORE Funding

| Status | FY'12 | FY'13 | FY'14 | FY'15 | FY'16 | FY'17 |
|---------------------------|-------|-------|-------|-------|-------|-------|
| Requested | 38 | 51 | 40 | 36 | 34 | 48 |
| Awarded | 9 | 14 | 10 | 8 | 8 | 7 |
| Success Rate (T1 & T2) | 23.6% | 27.5% | 25.0% | 22.2% | 23.5% | 14.6% |

Cancer Health Disparities (CHD) Opportunities

- ❖ CHD research is a priority for the NCI
- ❖ Administrative Supplements
 - ❖ Tool and Resource Development to Address Racial and Ethnic Disparities in Multiple Myeloma ([NOT-CA-18-077](#)) – applications recently due
 - ❖ Support Cancer Disparity Collaborative Research (Clinical Trial Optional; [PA-18-842](#))
- ❖ Feasibility and Planning Studies for the Development of SPOREs to Investigate CHD (P20) – recently reviewed ([RFA-CA-17-033](#))
- ❖ SPORE ([PAR-18-313](#)) – cross-cutting themes are encouraged

P01 vs SPORE Requirements

| Criteria | P01 | SPORE |
|---|-----|------------------|
| Projects Required to Interact | Yes | No |
| Core(s) must support more than one project | Yes | No |
| Minimum Number of Projects | 3 | 3 |
| Minimum Research Base | No | Yes |
| Project Co-Leadership (Basic & Clinical/Applied) | No | Yes |
| Required Cores | No | Admin; Tissue |
| Collaborations with outside investigators | No | Yes |
| Developmental Research Program & Career Enhancement Program | No | Yes |
| Minimum Effort Requirements | No | Yes |
| Human Endpoint Requirement | No | Yes |
| Flexibility Option (i.e., Replace Project) | No | Yes |

Important Websites

- ❖ **TRP/SPORE Program:**
<http://trp.cancer.gov>
- ❖ **Division of Cancer Treatment & Diagnosis (DCTD):**
<http://dctd.cancer.gov/>
- ❖ **SPORE Program Announcement:**
<http://grants.nih.gov/grants/guide/pa-files/PAR-18-313.html>
- ❖ **NCI's National Clinical Trials Network:**
<http://www.cancer.gov/research/areas/clinical-trials/nctn>
- ❖ **NCI Disease-Specific Steering Committees:**
<http://www.cancer.gov/aboutnci/organization/ccct/steering-committees>
- ❖ **Office of Extramural Research (OER):**
<http://grants.nih.gov/grants/oer.htm>

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