

**Report of the
Specialized Programs of Research
Excellence (SPORE)
Program Evaluation Working Group of
the National Cancer Institute (NCI)
Clinical Trials and Translational
Research Advisory Committee (CTAC)**

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WORKING GROUP ROSTER

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Contents

Introduction and Working Group Charge	1
Value of SPORE Program	1
Contributions of SPORE Program	3
Recommendations for NCI Actions to Enhance Effectiveness of SPORE Program.....	3
SPORE Program Requirements—Conclusions and Recommendations.....	4
SPORE Program Features—Conclusions and Recommendations	6
Recommendation on the Future of the SPORE Program.....	6

Introduction and Working Group Charge

In response to a request from the Clinical Trials and Translational Research Advisory Committee (CTAC), the National Cancer Institute (NCI) convened an 11-member Specialized Programs of Research Excellence (SPORE) Program Evaluation Working Group (the “Working Group”), chaired by Dr. Nancy Davidson. Following a series of orientation calls and the distribution of reference materials concerning the SPORE program, including a copy of the SPORE evaluation report prepared by the IDA Science and Technology Policy Institute (STPI), the Working Group met on January 27, 2014 for a one-day, in-person session.

The Working Group had a dual charge. First, they were asked to provide expert input on the value of the SPORE program to the NCI and the overall cancer research enterprise. Second, they were asked to make one of the following three recommendations regarding the future of the SPORE program.

1. The SPORE Program Announcement should be re-issued with the program continuing in its current configuration (perhaps with minor modifications); or
2. The NCI should consider some substantive changes to the SPORE Program; or
3. More information is needed for the Working Group to determine if the SPORE Program should continue in its current configuration or should be substantively changed.

This report documents the outcomes of the January 27 Working Group meeting. The first section presents the Working Group’s conclusions with regard to the overall value of the SPORE program. The second section describes their conclusions concerning specific contributions made by the SPORE program to various aspects of oncology research and practice. The third section presents three Working Group recommendations for ways in which the NCI might enhance the effectiveness of the SPORE Program. The fourth and fifth sections describe conclusions and recommendations on various requirements and features, respectively, of the program. The final section presents the Working Group’s recommendation with regard to the future of the SPORE program.

Value of SPORE Program

The Working Group reached two important overarching conclusions concerning the SPORE program.

- 1. It remains important for the NCI to have a funding program focused exclusively on translational research.***
- 2. The SPORE program represents a longstanding effort that has been successful in filling this niche and in which the NCI should take pride.***

In reaching these conclusions, the Working Group noted the following. First, the SPORE program has promoted the value of translational research, bringing to the fore its issues, challenges, and rewards. It has transformed and revolutionized patient-focused multidisciplinary

translational research by creating a focus on diseases and promoting the integration of basic science with clinical research. It has also been highly successful in building the infrastructure, training the individuals, and producing the multidisciplinary teams needed to produce research results in the service of clinical benefits for patients. Going forward, the Working Group reached consensus that although these capacity building activities remain important, especially for new SPORE awards, the program should place increasing emphasis on the impact of SPORE research on patient care and clinical practice.

The Working Group identified the following specific benefits of the SPORE program.

- ***Catalyzes translational research at individual institutions and nationwide.*** The SPORE program has fostered a culture of team science at participating institutions and launched the careers of a cadre of translational investigators. It has served as a template for how institutions can achieve a critical mass of investigators who work collaboratively to make translational breakthroughs. The SPORE program also pioneered engagement of the patient advocate community in oncology research, serving as a model for including advocates more broadly in both the NCI and other organizations' translational and clinical research efforts.
- ***Enhances quality of translational research even at non-SPORE institutions.*** The program has strengthened translational research not only at participating institutions, but also at institutions that do not have a SPORE award. These latter institutions endeavor to build translational research capabilities in order to compete successfully for a future SPORE award. Moreover, individuals who participate in a SPORE award, and then move on to other institutions, remain involved in translational research activities.
- ***Facilitates the leveraging of funds from other sources, especially industry.*** In the translational research community, SPORE awards are considered validation that the research is meritorious and highly deserving of support. As a result, a SPORE award facilitates obtaining additional funds from other government programs, foundations and especially industry to expand the team's translational research endeavors and more importantly to fund early and late stage clinical testing of interventions and biomarkers developed by SPORE projects.
- ***Promotes creative "bottom-up" investigator-initiated translational research.*** Although the SPORE program has certain structural requirements designed to facilitate translational research, it does not in any way dictate the science. Investigators and teams are free to choose their own translational goals and approaches for linking scientific discovery to patient and public benefit. This scientific and intellectual flexibility is essential to the program's success.
- ***Builds and sustains a strong translational research infrastructure.*** The SPORE program has facilitated the development of a research infrastructure at participating institutions that has been critical for translational research efforts. In particular, the requirement that SPOREs have a biospecimen core has not only created high quality

individual repositories but also led to the development of supporting infrastructure for tissue banking.

Contributions of SPORE Program

The Working Group came to consensus that the output of the SPORE program has been excellent, speeding translational research and leading to interventions and biomarker tests that have become incorporated into clinical practice. The Working Group considered the 67 SPORE “major advances” identified in the STPI Evaluation Report to represent substantive and material contributions. It was noted, however, that there was some variation in the importance of the advances across disease sites and that therapeutic and clinical contributions have been slightly more substantial than those in prevention and population science. Other important contributions noted by the Working Group included success in establishing industry collaborations especially for the support of clinical trials and serving as a nucleus around which consortia, largely supported by foundations, have coalesced, particularly for the support of early phase trials.

The Working Group also discussed the value of developing benchmarks against which the impact of SPORE funded translational research could be measured. The goal would be to compare the SPORE return on investment with that of industry, foundations, other NCI funding programs, etc. However, it was agreed that data is unlikely to be available with which to establish valid benchmarks across different funding sources and that subjecting the SPORE program to such benchmarks without applying them to other NCI-funded research programs would be unfair.

Recommendations for NCI Actions to Enhance Effectiveness of SPORE Program

In the course of its deliberations, the Working Group developed three recommendations for actions that the NCI could take to improve the effectiveness of the SPORE program.

- ***Facilitate even greater coordination with NCI programs through which SPORE results can be moved into clinical trials.*** The Working Group recommended that the NCI explore approaches whereby results developed by SPORE projects can be even more efficiently moved into clinical trials through the NCI Experimental Therapeutics program (NExT), Cancer Centers, the N01/U01 early-phase clinical trials programs, the National Clinical Trials Network Groups and other intramural and extramural clinical trials programs and resources.
- ***Facilitate even greater interaction with targeted NCI basic research mechanisms.*** The Working Group recommended that the NCI explore approaches to develop or expand linkages with The Cancer Genome Atlas, the Physical Science Oncology Centers and other targeted intramural and extramural initiatives designed to generate discoveries that SPOREs might take forward into translation.
- ***Further encourage co-funding of SPORE projects by third parties.*** The Working Group recommended that the NCI explore approaches for further promoting industry or

foundation joint funding for SPORE projects and awards. Although opportunities and approaches exist to establish such joint funding, the Working Group concluded that additional effort by the NCI to promote such joint funding could be very beneficial.

SPORE Program Requirements—Conclusions and Recommendations

The Working Group, as part of their deliberations, considered certain current requirements of the SPORE program as well as the potential value of some new requirements. Based on these discussions, conclusions and recommendations were reached with regard to seven current or potential program requirements.

- ***Organizing themes for SPORE awards.*** The Working Group agreed that the SPORE program should continue to focus on translational research in organ-specific cancers and groups of highly related cancers. However, the Working Group recommended that the language in the Program Announcement related to “groups of highly related cancers” be modernized, expanded and made more explicit. The Program Announcement should make clear that “groups of highly related cancers” encompasses SPOREs organized around common biological pathways or other themes that cross multiple organ sites. The announcement should also provide multiple examples of such pathways and themes in order to stimulate creative thinking and innovative proposals by prospective SPORE investigators. The Working Group concluded that SPOREs focused on pathway-driven or other novel cross-cutting themes have great potential for innovation and high scientific impact, as well as for synergy across projects and leveraging of funds from other sources.
- ***Solicitation of SPORE applications focused on NCI-wide research priorities.*** The Working Group acknowledged that from time to time, the NCI might consider encouraging the development of SPORE applications focused on certain NCI-wide research priorities (e.g., the current recalcitrant cancers initiative). The Working Group supported publicizing such priorities through the SPORE Program Announcement and other venues and incorporating alignment with NCI-wide research priorities in the SPORE review criteria. However, they were opposed to creating set-aside funds for SPOREs directed at specific cancers or biological pathways.
- ***Reaching a “human endpoint” in 5 years.*** The Working Group concluded that each SPORE project should be required to reach a human endpoint and that the current definition was well crafted and understood. It was also concluded that the 5 year requirement should be continued as a longer time frame would reduce the focus of investigators on reaching patient/public benefit. It was also noted that reviewers would be a good judge of when a project was advancing sufficiently even if technically the human endpoint had not been reached in 5 years.
- ***Requirement for early detection, prevention, or population science project.*** Although there was not complete consensus, the majority of Working Group members recommended that all SPORE applications should be required to include an early detection, prevention, or population science project. A small minority recommended that the requirement should be eliminated for all organ sites while another small minority

recommended that the current practice of requiring such a project only for breast, prostate, lung and GI SPOREs be continued. During this discussion the Working Group noted that the definition of “population science” in the Program Announcement should be revised to encompass the full spectrum of activities along the patient care continuum.

- ***Requirement to build collaborations.*** The Working Group concluded that the SPORE program had been quite successful in building translational research collaborations and that the requirement to collaborate should be maintained. In particular, they noted success in leveraging funding and expertise through collaboration, with industry collaborations and SPOREs serving as a nucleus for large-scale collaborations, such as clinical trials consortia, as prime examples. The Working Group also made two recommendations concerning how the Program Announcement might be clarified with regard to the collaboration requirement. The first was to revise the language around collaboration to inform review by explicitly stating that: (a) investigators be credited for creative use of collaborations to complete project aims and facilitate handoff for downstream development; (b) not every project within a SPORE must involve collaboration; and (c) not every SPORE must have all the various types of collaborations outlined in the Program Announcement. The second language modification was to clarify that a population scientist could fill one or both of the basic/applied (clinical) roles in the required multidisciplinary research teams.
- ***Limitations on SPOREs per organ site.*** The Working Group strongly recommended that the current practice be continued whereby the distribution of SPORE awards across organ sites is driven by the quality of the science as judged by peer review. There was no Working Group support for setting arbitrary limits on the number of SPOREs in each organ site.
- ***Sun-setting SPORE awards.*** The Working Group supported the current policy which does not limit the number of consecutive 5-year terms for which a SPORE award can be renewed. In reaching this conclusion, they took note of the fact that there has been a reasonable percentage of new SPORE awards in recent years and that about 50% of the projects proposed in SPORE competitive renewal awards are new. They also noted that building translational research capacity and bringing research that produces patient benefit to fruition takes time. The Working Group agreed that intense and rigorous peer review is the best way to ensure the quality of renewing awards and noted that allowing multiple PIs on SPORE awards may be useful in facilitating mentorship and bringing new PIs into ongoing SPOREs.

SPORE Program Features—Conclusions and Recommendations

In addition to considering certain program requirements, the Working Group also discussed various features of the SPORE program, reaching conclusions and recommendations on three programmatic features.

- ***Flexibility option.*** The Working Group strongly endorsed the flexibility option as being highly positive and valuable and considered it a unique feature of the program that should be continued.
- ***Biospecimen/Pathology Core.*** The Working Group unanimously endorsed the requirement for a biospecimen/pathology core, which they viewed as critical for the SPOREs' success and a great benefit to their host institutions. However, the concern was raised that some SPORE biospecimen/pathology cores have become siloed from institutional resources and could be better harmonized. To address this concern, the Working Group recommended that SPORE applications be required to describe how the SPORE biospecimen/pathology core is integrated with and leverages the biospecimen/pathology resources supported by the host institution, most typically an NCI-designated Cancer Center. They further recommended that the letter of commitment from the host institution should also describe the integration and synergies between their institutional biospecimen/pathology resources and those of the SPORE.
- ***Developmental Research and Career Development Programs.*** The Working Group considered both of these to be valuable features of the SPORE program that should be continued. They noted that the Developmental Research Program (DRP) brings both younger and later-stage investigators into translational research in specific disease areas, especially smaller diseases, which generates new ideas and approaches and enriches SPORE science. The DRP awards also seed new SPORE research projects and are attractive candidates for co-funding by the host institution. The Career Development Program (CDP) awards were also viewed as bringing investigators into translational research in specific disease areas, and being attractive for host institution co-funding. In addition, CDP awards were praised for launching translational research careers and producing some highly impressive scientific results. In order to provide SPORE PIs with maximum flexibility to use these funds wisely, the Working Group recommended that DRP and CDP funds be consolidated into a single pool from which PIs, in consultation with their SPORE External Advisory Boards, have the flexibility to direct funds to each program based on the best candidate projects rather than having separate DRP and CDP funding lines.

Recommendation on the Future of the SPORE Program

The Working Group members were unanimous in recommending that the SPORE Program Announcement should be re-issued with the program continuing in its current configuration with the minor modifications described above.