

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

Nancy Davidson, M.D.

Working Group Chair

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CTAC Meeting

Working Group Background

- SPORE Program Announcement – approval spring 2014 for January 2015 submissions
- Formal evaluation conducted by the IDA Science and Technology Policy Institute (STPI) as part of standard procedure for renewing Program Announcements for large programs
- NCI Clinical Trials and Translational Research Advisory Committee (CTAC) voted to form a small Working Group to provide advice on the value of the SPORE program and make a recommendation as to its future

Working Group Members

- Nancy Davidson (Chair)
- James Abbruzzese
- Gerold Bepler
- Deborah Collyar
- James Griffin
- Scott Lippman
- David Mankoff
- Chris Takimoto
- Louis Weiner
- George Wilding
- Cheryl Willman
- Jim Doroshow – NCI Liaison
- Jennifer Hayes – Exec. Sec.

Working Group Charge and Deliverable

- **Charge: Provide expert input on the value of the SPORE program and make one of three recommendations**
 - The SPORE Program Announcement should be re-issued with the program continuing in its current configuration (perhaps with minor modifications); or
 - The NCI should consider some substantive changes to the SPORE Program; or
 - 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
- **Deliverable: Report to CTAC responsive to the charge**

Reference Materials Provided

- **STPI 2013 SPORE Evaluation Report**
 - STPI synthesis of distinctive contributions of the SPORE Program based on Report information
 - Consolidated information on SPORE Major Advances from Report
 - Consolidated data on success in achieving a “human endpoint” from Report
- **Updated SPORE Funding Opportunity Announcement**
- **P01 Funding Opportunity Announcement**

Conclusions on Value of SPORE Program

- **Overarching conclusions**
 - It remains critical for the NCI to have a funding program focused exclusively on translational research
 - The SPORE program represents a longstanding effort that has been successful in filling this niche and in which the NCI should take pride
- **Transformed and revolutionized translational research**
 - Creates focus on diseases
 - Promotes integration of basic science with clinical research
- **Builds foundation for research in the service of patients**
 - Infrastructure
 - Training individual scientists
 - Producing multidisciplinary teams
- **Working Group recommends increasing program's emphasis on impact of SPORE research on patient care/clinical practice**
 - Emphasis on capacity-building remains important, especially for new SPORE awards

Key Benefits of SPORE Program

- **Catalyzes translational research at individual institutions and nationwide**
 - Fosters culture of team science
 - Launches translational research careers
 - Serves as template for achieving a critical mass of translational scientists
 - Pioneered engagement of advocates in translational and clinical research
- **Enhances quality of translational research at non-SPORE institutions**
 - Institutions build translational capacity in order to be competitive for a SPORE award
 - SPORE participants continue in translational research after moving to a new institution
- **Facilitates leveraging of funds from other sources, especially industry**
 - Validation represented by a SPORE award facilitates obtaining funds from other sources
 - Especially important for funding early and late stage human testing
- **Promotes creative “bottom-up” investigator-initiated translational research**
 - Awardees free to choose translational goals and approaches
 - Scientific and intellectual flexibility essential to success of program
- **Builds and sustains a strong translational research infrastructure**
 - Biospecimen/pathology core essential to translational success
 - Builds strong individual repositories and enabling tissue banking infrastructure

Contributions of SPORE Program

- **Overall output of SPORE program deemed exceptional**
 - Speeds translational research
 - Leads to interventions and biomarkers introduced into clinical practice
- **SPORE Major Advances from STPI Evaluation Report**
 - Substantial, material contributions to oncology research and practice
 - Some variability in importance across disease sites
 - Therapeutic and clinical contributions sometimes more substantial than those in prevention and population science
- **Other contributions**
 - Leveraging substantial industry support for clinical trials of SPORE-derived interventions and biomarkers
 - Serving as nucleus for coalescing foundation-funded consortia, particularly for support of early phase trials

Potential NCI Actions to Enhance SPORE Program Effectiveness

- **Facilitate even greater coordination with NCI clinical trials programs**
 - NCI Experimental Therapeutics program (NExT)
 - Cancer Centers
 - N01/U01 early-phase trial programs
 - National Clinical Trials Network Groups
- **Facilitate even greater interactions with targeted basic research initiatives**
 - The Cancer Genome Atlas
 - Physical Science Oncology Centers
- **Further encourage joint funding by third parties**
 - Opportunities exist (e.g., NIH Foundation)
 - Promote joint funding by industry and foundations

SPORE Program Requirements Conclusions and Recommendations (1)

- **Organizing themes for SPORE awards**
 - Support for current focus on organ-specific cancers and “groups of highly related cancers”
 - Modernize, expand and make more explicit language describing “groups of highly related cancers” and provide examples (e.g., GI cancers, pediatric cancers, oncogenic signaling pathway activation, virally-induced malignancies)
- **Solicitation of SPOREs in response to NCI research priorities**
 - Support for promoting and including alignment in review criteria
 - Opposed to “set-aside” funding for such SPOREs
- **Reaching a “human endpoint” in 5 years**
 - Strong support for requirement
- **Early detection, prevention, or population science project**
 - Majority recommended extending requirement to all SPOREs
 - Minority votes for no requirement at all or requirement only for selected organ sites

SPORE Program Requirements Conclusions and Recommendations (2)

- **Requirement to build collaborations**
 - Strongly supported
 - Praised SPORE success in collaborations
 - PA language on collaborations should be made more explicit
- **Limitations on SPOREs per organ site**
 - No support for setting arbitrary limits on the number of SPOREs in each organ site
 - Distribution of SPORE awards across organ sites should be driven by the quality of the science
- **Term limits for SPORE awards**
 - No support for a limit to the number of consecutive 5-year renewals
 - Reasonable number of new SPORE awards in recent years
 - 50% of projects in SPORE renewal awards are new

SPORE Program Features Conclusions and Recommendations

- **Flexibility Option**
 - Strongly endorsed
 - Praised as unique and valuable feature of SPORE program
- **Biospecimen/Pathology Core**
 - Unanimously endorsed
 - Critical for SPORE success and a great benefit to host institutions
 - Encouraged greater integration with and leveraging of institutional resources
- **Developmental Research and Career Development Programs**
 - Valuable features that should be maintained
 - Funds should be combined to a single fund
 - Flexibility to fund best candidate projects independent of DRP/CDP character

Future of the SPORE Program

Unanimous Recommendation

SPORE Program Announcement should be re-issued and the program should continue in its current configuration with minor modifications

