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

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Working Group Chair
March 12, 2014
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
• 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.