NCI PRE-APPLICATION WEBINAR

Specialized Programs of Research Excellence (SPOREs) in Cancer Health Disparities and Minority Health (CHD-MH)

RFA-CA-24-020 (U54 Clinical Trial Optional)

Translational Research Program (TRP)
Division of Cancer Treatment and Diagnosis (DCTD)
National Cancer Institute (NCI), National Institutes of Health (NIH)
trp.cancer.gov

NIH NATIONAL CANCER INSTITUTE

Webinar Recording: http://bit.ly/4bz8NkJ

May 7, 2024

U54 CHD-MH SPORE Pre-Application Webinar

- Overview of NCI SPORE Program
- Funding Policy
- Application Requirements
- Post-Submission Guidance & Peer Review
- NCI Pre-Application Consultations & Contact Info
- Q&A

NCI SPORE Program Overview

NCI SPORE Program

- **Since 1992, NCI has funded the P50 SPORE Program (PAR-23-284) for multi-project center grants focused on translational cancer research in:**
  - An organ-specific cancer
  - A group of highly related cancers (e.g., sarcoma, GI, neuroendocrine)
  - Cancers related by common biological pathway mutations/alterations or other cross-cutting themes, including cancer health disparities and minority health (CHD-MH)

- **The NCI SPORE Program is now also funding (for one receipt date) U54 SPORE (RFA-CA-24-020) multi-project center grants focused on CHD-MH translational research in populations who are underserved and/or underrepresented**

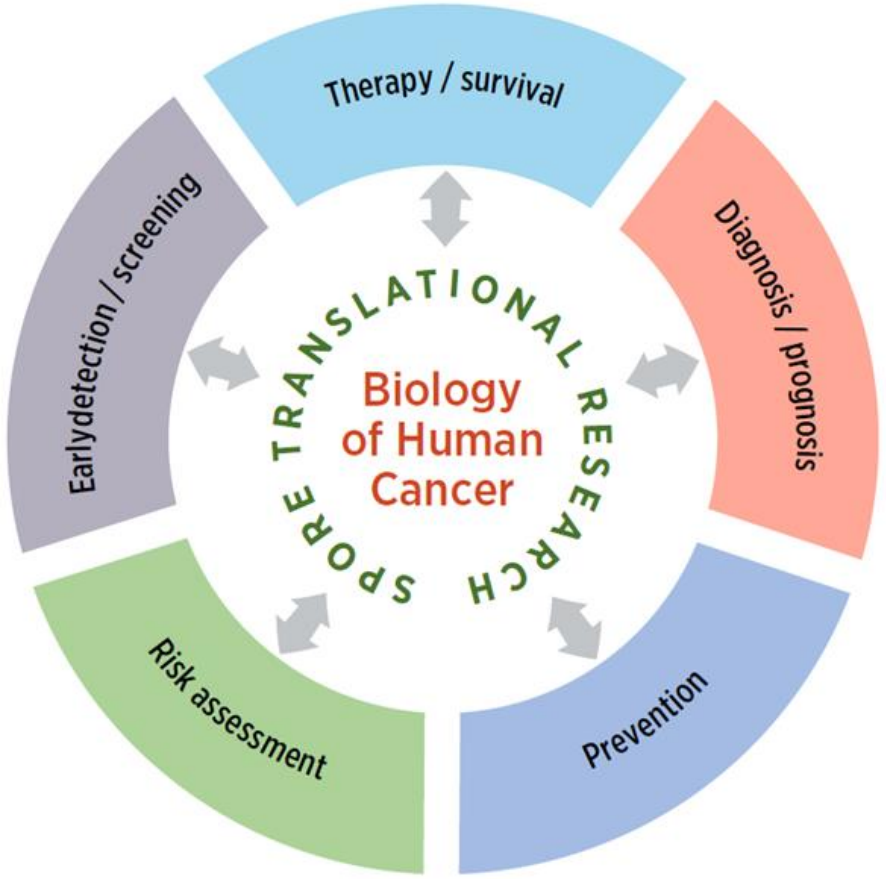
U54 CHD-MH SPORE Program: RFA-CA-24-020

- **U54 CHD-MH SPORE Scientific focus:**
  - Cross-cutting theme of translational CHD and/or MH research with the option to investigate more than one cancer type in populations who are underserved.

- **Projects may address, but are not limited to, the following areas of investigation:**
  - Discovery, validation, and assessment of how various determinants of health intersect with the biology of cancer to affect cancer incidence, diagnosis, treatment, early detection, and prevention in populations who are underserved.
  - Characterization of the biological impact of social determinants of health and identifying specific biological pathways that might be targeted by clinical or public health interventions.
  - Hypothesis generating studies characterizing risk factor prevalence or biological differences in populations who are underserved.
  - Understanding the role of determinants of health and comorbidities on toxicity to therapeutic interventions in populations who are underserved.

U54 CHD-MH SPORE Program

- **Translational Research:** Using 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.



U54 CHD-MH SPORE Program: Key Definitions

- **Cancer Health Disparities:** Health differences that adversely affect specific populations, based on one or more of the following health outcomes:
  - Higher incidence, prevalence, or earlier onset of cancer
  - Higher prevalence of risk factors, unhealthy behaviors, or clinical measures in the causal pathway of a cancer outcome
  - Higher rates of condition-specific symptoms, reduced global daily functioning, or self-reported health-related quality of life using standardized measures
  - Premature and/or excessive mortality from cancer where population rates differ
  - Greater global burden of cancer using standardized metrics

- **Minority Health:** The investigation of distinctive health characteristics and attributes of underserved populations in biomedical research to understand health outcomes in these populations.
- **Populations Who Are Underserved (and/or underrepresented):** NIH-designated populations with health disparities, including Black/African American, Hispanic/Latino, Indigenous and Native American persons; Asian Americans, Native Hawaiians, and Pacific Islanders; less privileged socioeconomic status populations; persons who live in rural areas; persons with disabilities; and sexual and gender minority populations including, but not limited to, persons who identify as lesbian, gay, bisexual, asexual, transgender, Two-Spirit, queer, and/or intersex.

U54 CHD-MH SPORE Program: Mechanism

- **U54 CHD-MH SPOREs use the NIH Cooperative Agreement Mechanism:**
  - Promotes interactions between funded U54s to support community outreach and engagement and sharing of resources and best practices.
  - Establishes a U54 CHD-MH SPORE Program Coordinating Committee to organize U54 SPORE network activities, including monthly and annual U54 SPORE meetings and ad hoc working groups.
  - Allows SPOREs to include intramural investigators as key personnel
  - Allows NCI program to assist, as needed, in supporting the scientific direction of the SPORE

SPORE Component Comparison

	P50 SPORE	U54 CHD-MH SPORE
Minimum 3 Translational Research Projects	Yes	Yes
Administrative Core	Yes	Yes
Biospecimen/Pathology Core	Yes	Yes
Scientific Collaborations	Yes	Yes
Dev. Research Program & Career Enhancement Program	Yes	Yes
Community Outreach and Engagement (COE) Core	No	Yes
Community Advisory Board	No	Yes
Coop. Agreement Program Coordinating Committee	No	Yes
Human Endpoint (in each Project)	Yes	Yes (e.g., pilot/feasibility studies)
NIH-Defined Clinical Trial	Yes	Optional
Project Co-Leadership (Basic and Applied)	Yes	Yes (e.g., epidemiologists or social scientists)
Budget Cap	$1.4M DC	$1.6M DC

Key Dates for U54 CHD-MH SPORE Applications (RFA-CA-24-020)

Letter Of Intent	Application Receipt	Peer Review	Council Review	Anticipated Start Date
Aug 26, 2024	Sept 26, 2024	Feb 2025	May 2025	Summer 2025

Note: Sept 26, 2024 is the only receipt date for RFA-CA-24-020.

U54 SPORE Funding Policy

Funding Policy

- **Scientific assessment of SPORE applications is conducted through a peer-review process by Special Emphasis Panels.**
- **Overall Impact Score is assigned to each grant.**
- **All applications compete for the same pool of available funds.**
- **Program establishes and NCI leaders approve a funding plan. Four U54 CHD-MH SPORE awards are anticipated with the current NCI budget.**
- **Funding decisions are based on overall impact score and availability of funds. However, programmatic priorities may also play a role:**
  - **Any Project that does not score well may be removed (including its budget)**
  - **Any required SPORE Component that does not score well may jeopardize funding of the entire grant**
  - **Scientific, budgetary, and commitment overlap are not permitted**

U54 SPORE Requirements

SPORE Eligibility

- **Minimum Research Base: Four investigators with a significant role on the SPORE (as SPORE Director, Project Co-Leader, or Core Director) must have an independently funded peer-reviewed grant or serve as an overall/site chairperson on an active NCI-sponsored clinical trial in the SPORE organ site or the expertise required for the SPORE project/core.**

- **Domestic for profit and not for profit institutions**
- **Basic and clinical expertise**
- **Access to cancer patient population**
- **Statement of institutional commitment**
- **Only one U54 CHD-MH SPORE submission per institution is permitted**

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**
- **Is not currently a P50 SPORE Director**
- **Appropriate time commitment**
  - ≥ 2.4 person months per PD/PI for applications with less than 3 PD/PIs
  - ≥ 1.8 person months per PD/PI for applications with 3 or more PD/PIs

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

Multi-PD/PI Requirements

- **Designate a contact PD/PI from the submitting institution**

- **A Multi-PD/PI Leadership Plan must be attached to the Overall component and should describe:**
  - Rationale for multi-PD/PI
  - Administrative, technical, and scientific responsibilities for each of the PDs/PIs
  - Governance and organizational structure of the leadership team and the research projects
  - Process for making decisions on scientific direction and allocation of resources
  - Procedures for resolving conflicts
  - Data sharing and communication plans
  - Fiscal and management coordination
  - Publication and intellectual property policies

- **Each PD/PI (SPORE Director) must meet minimum effort requirement of ≥ 2.4 PM (or ≥ 1.8 PM for 3 or more PD/PIs)**

Note: Further details on Multi-PD/PI applications and preparing the Leadership Plan can be found on the NIH Multi-PD/PI site.

SPORE General Features

- Team concept
- Flexibility to realign resources
- Collaborations
- Involvement of patient advocates
- Encourage participation of individuals from diverse backgrounds, underserved groups, women, and individuals with a disability
- Budget:
  - $1.6M direct cost/year cap
  - Applications exceeding the budget cap may not be reviewed

Components of SPORE Application

- **Overall: Program Overview** (30-page limit)
  - Includes Scientific Collaboration section and Data Management and Sharing Plan attachment
- **Admin Core: Administrative Core** (12-page limit)
  - Includes required Community Advisory Board and External Advisory Board
- **Core: Shared Resources Cores** (12-page limit/core)
  - Biospecimen/Pathology Core required
  - Community Outreach & Engagement Core required
  - Other Cores (animal, stat, clinical, etc.) optional
- **Project: Translational Research Projects** (12-page limit/project)
- **Dev Res Prog: Developmental Research Program (DRP)** (12-page limit)
- **Career Enh Prog: Career Enhancement Program (CEP)** (12-page limit)

Note: Specific Aims: A one page "Specific Aims" is allowed in each component.

Overall (Program Overview)

- Overall goals and research strategies of the entire SPORE
- Uniqueness of the proposal; why a SPORE grant and why now?
- Impact on the field if all the aims of the SPORE are completed successfully
- Includes Scientific Collaboration section
- Data Management and Sharing Plan (attachment)
- Multi-PD/PI Leadership Plan (attachment) if applicable

Scientific Collaboration

- **This is the only scored section of the Overall component.**
- **Demonstrate a commitment to both horizontal and vertical collaboration.**
  - **Horizontal: Collaboration with others outside the SPORE to complete a proposed specific aim. (Collaboration between the SPORE Projects/Cores is not considered Horizontal Collaboration.)**
  - **Vertical: Collaboration with or hand-off to an entity outside the SPORE that extends SPORE translational research beyond the specific aims of projects along the translational continuum**
- **Description of collaborative efforts/agreements within the SPORE community and with outside research groups**
- **Leadership related to initiating and implementing successful collaborations**
- **Scientific collaboration is not required for every SPORE project.**

Data Management and Sharing (DMS) Plan Attachment (Overall)

- **Describe component-specific information in the DMS Plan (attach to the Overall component)**
- **Do not attach a DMS Plan in the components**
- **Describe Data Type; Tools, Software, and Code; Standards; Data Preservation, Access, and Timelines; Access, Distribution, and Reuse Considerations; and Oversight**
- **Integrate genomic data sharing requirements into the DMS plan**

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Individual Research Projects

- Test novel translational ideas
- Minimum of 3 projects required
- Project co-leaders:
  - Basic and clinical/applied scientists (minimum 2)
  - Each having minimum effort of 0.6 person months
- Interaction of projects with cores
- Human application/endpoint within the project period (clinical trial optional)

What is a Human Endpoint?

- **At least one of the following six human endpoints should be proposed in each SPORE research project:**

1) **Early phase clinical trials*, including pilot/feasibility studies, of new investigational drugs (INDs) and biologics, experimental procedures, medical devices, or combinations thereof**

2) **Early phase clinical trials*, including pilot/feasibility studies, of new combinations or new uses of the FDA-approved agents and devices**

3) **Discovery and development of biomarkers, only when measurements are made in human biospecimens, or directly in human subjects**

*To qualify as a human endpoint, the clinical trial protocol must be developed by the project leader/SPORE investigators.

What is a Human Endpoint? (continued)

- **SPORE human endpoints cont'd:**

  4) **Laboratory studies using clinical materials that lead to new clinical hypotheses (reverse translation)**

  5) **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.**

  6) **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 are considered programmatically appropriate as a human endpoint for SPORE translational projects.
†A pre-IND meeting is not required prior to submission but plans for the meeting should be discussed in the application.

Administrative Core

- **Administration of translational research**
  - **Communication**
  - **Succession plan for the SPORE Director**
  - **Fiscal management:**
    - **Budget for advisory boards and SPORE-relevant meetings/workshops**
    - **Discretionary funds of up to $50,000 per year may be requested. Often matched by institutions.**
- **Leadership**
- **Integration of SPORE within the Institution**
- **Cancer patient population**
- **Planning and evaluation activities**
  - **External Advisory Board and Community Advisory Board (required); Internal Advisory Board (optional)**
  - **Involvement of patient advocate(s) (encouraged)**
- **Letters of support from the institution (and cancer center)**

Administrative Core- Continued

- **Data Systems Attachment in the Administrative Core:**
  - **Provide a plan describing the SPORE bioinformatics capabilities and SPORE data management capabilities, systems, platforms, and tools needed to support human and non-human research within the Projects and Cores, as they relate to the cancer center, institution, or other NIH/NCI initiatives.**
  - **For projects with clinical trials, describe the procedures for data management, quality control and quality assurance of data at clinical site(s) or at center laboratories, as applicable. Describe the methods for standardization of procedures for data management to assess the effect of the intervention and quality control.**

Shared Resources Cores

- **Core Director must have minimum effort of 0.6 person months**
- **Cross-talk between cores and projects**
- **Integration or augmentation with institutional or cancer center cores**
- **Biospecimen/Pathology core (*required*)**
- **Community Outreach & Engagement core (*required*)**
- **Other specialized cores (*optional*)**
  - **Animal**
  - **Clinical**
  - **Biostatistical**
  - **Bioinformatics**
  - **Others**

Biospecimen/Pathology Core

- Support scientific projects of the SPORE through integration with cancer center biospecimen core and clinical laboratory
- Pathological, clinical, family history information and linkage to databases,

  etc.
- Pre-analytical (parameters of collection and preservation) and analytical considerations
- Priority plan to share biospecimens with others in the scientific community
- Specimen collection, correlative studies, and registry/existing datasets require a Human Subjects Section
- Technology development that supports research projects may be included

Community Outreach & Engagement (COE) Core

- **SPOREs are expected to engage with and perform research relevant to the populations within their catchment area to achieve SPORE research objectives and decrease cancer burden in populations who are underserved:**
  - **Thoroughly analyze the demographics and cancer burden of the catchment area.**
  - **Establish partnerships with individuals and groups in the SPORE catchment area, which may include community members, patients, advocates, healthcare delivery systems, state and community agencies, and coalitions.**

Community Outreach & Engagement (COE) Core (continued)

- **COE Core should describe plans for the following intra- and inter-SPORE activities:**
  - **Outreach to and engagement with underserved populations within the SPORE catchment area to inform cancer research efforts.**
  - **Communicating the needs of underserved populations and community partners within the SPORE catchment area to SPORE members in order to catalyze research.**
  - **Facilitation of patient accrual, if applicable, including description of efforts to achieve planned enrollment, stated objectives, and clinical endpoints.**
  - **Dissemination and implementation of evidence-based interventions, public education, health policy recommendations, influence on health policy, etc.**
  - **Development of novel methodologies, including machine learning, and standardization of metrics for assessment of disparities and health outcomes in underserved populations.**
  - **Integration of SPORE COE activities with the Cancer Center COE Component, if applicable.**

Biostatistical Core (Optional) Recommendations

- **Description of statistical analysis plans for each experiment:**
  - **Justification of power calculations and sample sizes**
  - **Appropriate statistical tests**
  - **Assessment of data quality and reproducibility**
- **Innovative statistical methodology**
- **Appropriate effort level, expertise, education, and duties/responsibilities for key personnel and staff**
- **Cross-talk between core and projects/programs**

Developmental Research Program (DRP)

- **Explore innovative ideas**
  - **Pilot projects**
  - **High-risk/high-payoff projects**
  - **Collaborations**
- **Human endpoint not required**
- **Provide a plan for solicitation, review, and award**
- **Minimum of $50,000 direct cost per year from the NCI for awardees, often matched by institutions**
- **Funds should not be used for purchase of large equipment**
- **DRP Director should have minimum effort of 0.3 person months**
- **Potential for promotion to full SPORE project**

Career Enhancement Program (CEP)

- **Encourage investigators to develop careers in translational cancer research**
  - **Not a training program: pre- or post-doctoral, pre-clinical or clinical fellows are not eligible.**
  - **Investigators with faculty appointments within one year are eligible.**
- **Provide a plan for solicitation, review, and award with special emphasis on recruitment of women, individuals from underrepresented racial and ethnic groups, as well as individuals with disabilities**
- **Provide a short description of the types of potential candidates, the names and research activities of translational science mentors/advisors, and the process for monitoring progress of the candidates**
- **Minimum of $50,000 direct cost per year from the NCI for awardees, often matched by institutions**
- **CEP Director should have minimum effort of 0.3 person months**
- **Potential for promotion to full SPORE project**

Important NIH Policy Notices

- **Limited Allowable Appendix Materials (NOT-OD-17-098)**
  - IRB-approved and draft clinical trial protocols allowed for SPORE FOA

- **Scientific Data Sharing Policies (NOT-OD-21-013)**
  - Data Management and Sharing (Planning and Budgeting)
  - Genomic Data Sharing
  - Other Sharing
  - Accessing Data

- **Human Subjects & Clinical Trials Information Form**
  - Basic Information
  - Study Population Characteristics
  - Protection & Monitoring Plans (e.g., Data Safety & Monitoring Plan & Single IRB Plan)
  - Protocol Synopsis (not applicable for correlative studies)
  - Other Clinical Trial Information

- **Additional Human Subjects & Clinical Trial Information:**
  - NIH Clinical Trial Requirements and Inclusion Policy
  - NIH Definition for Human Subjects and Clinical Trials

SPORE Requirement Summary

- **Minimum of three translational research projects with a human endpoint (clinical trial optional)**
- **Scientific Collaboration**
  - **Included in Overall (Program Overview)**
- **Shared Resources Cores:**
  - **Biospecimen/pathology: required**
  - **Community Outreach & Engagement Core: required**
  - **Stats, clinical, animal, etc.: optional**
- **Administrative Core**
- **Developmental Research Program (DRP)**
- **Career Enhancement Program (CEP)**
- **External Advisory Board Members**
- **Community Advisory Board Members**
- **Commitment to participate in U54 SPORE Program Coordinating Committee meetings/workshops**
- **Minimum Time Commitment:**
  - **SPORE Director(s): ≥ 2.4 person months (or ≥ 1.8 person months for 3 or more PD/PIs)**
  - **Project Co-Leader(s): ≥ 0.6 person months**
  - **Core Director(s): ≥ 0.6 person months**
  - **DRP/CEP Director(s): ≥ 0.3 person months**

Pre- and Post-Submission Guidance & Peer Review

Pre- and Post-Submission Guidance

- **During application submission, there is an optional PHS Assignment Request Form to:**
  - **List individuals who should not review your application, with rationale**
  - **Identify scientific areas of expertise needed to review your application**

- **Post-submission, the NIH point of contact is the Scientific Review Officer (SRO). SRO contact information is available in eRA Commons.**

- **Allowable post-submission materials (see NOT-OD-19-083).**

NCI Review Process

Pre-Meeting

- Administrative review (compliance with NIH policies)
- Meeting details (date and location)
- Areas of expertise
- Reviewer recruitment
- Post-submission material
- Reviewer roster: verify necessary expertise, manage conflicts

Review Meeting

- Reviewed per NIH-policy & guidelines
- Potential translational impact is assessed, considering scientific & technical merits

Post-Meeting

- Overall Impact Score available within 3 business days post-review
- Summary statements available 6-8 weeks post-review

Scoring Criteria for Individual Components

Impact	Descriptor	Score
High	Exceptional	1
	Outstanding	2
	Excellent	3
Moderate	Very Good	4
	Good	5
	Satisfactory	6
Low	Fair	7
	Marginal	8
	Poor	9

Not Recommended for Further Consideration=NRFC

Overall Impact Score Characteristics

PROGRAM CHARACTERISTICS	OVERALL IMPACT	SCORE RANGE
Projects uniformly superb - essentially no weaknesses; strong supporting cores; and outstanding progress for competing renewals • Sustained powerful impact of all projects on the human disease • High likelihood that all translational research objectives will be achieved during the project period • Exceptional research approaches and high innovation • Highly qualified investigators; strong collaboration between basic and applied co-leaders **Programmatic components superb** • Uniformly strong developmental programs • Superb overall program organization and capabilities, administration, and horizontal and vertical scientific collaborations	**High**	**1**
Projects uniformly strong - only a few weaknesses; strong supporting cores; and excellent progress for competing renewals • High impact of all projects on the human disease • Likely that most translational research objectives will be achieved during the project period • Strong research approaches; innovation may vary • Highly qualified investigators; strong collaboration between basic and applied co-leaders **Programmatic components uniformly strong** • Uniformly strong developmental programs • Strong overall program organization and capabilities, administration, and horizontal and vertical scientific collaborations		**2 OR 3**
Generally strong projects - moderate to significant weaknesses, but strengths prevail; generally strong supporting cores; and good progress overall for competing renewals • High likelihood that most projects will impact the human disease • Likely that some of proposed translational research objectives will be achieved during project period • Generally well designed research approaches, but some deficiencies; innovation may vary • Highly qualified investigators; evidence of collaboration between basic and applied co-leaders **Programmatic components generally strong** • Generally strong developmental programs • Generally strong overall program organization and capabilities, administration, and horizontal and vertical scientific collaborations	**Moderate**	**4 OR 5**
Uneven quality of projects - significant weaknesses in several projects; quality of cores may be uneven; and uneven progress for competing renewals • Some projects not likely to have impact on the human disease • Unlikely to achieve some of proposed translational research objectives during the project period • Uneven quality of research approaches, but some substantial concerns; innovation may vary • Qualified investigators; evidence of collaboration between basic and applied co-leaders **Programmatic components uneven** • Quality of developmental programs may be high or low • Quality of overall program organization and capabilities, administration, and horizontal and vertical scientific collaborations uneven	**Moderate to Low**	**6 OR 7**
Serious weaknesses in most projects– weaknesses prevail; quality of cores may be uneven; and limited progress for competing renewals • Most projects unlikely to have impact on the human disease • Unlikely to achieve most of proposed translational research objectives during the project period • Many problems in research approaches, even if ideas are excellent; innovation may vary • Qualified investigators; limited evidence of collaboration between basic and applied co-leaders **Programmatic components uneven** • Quality of developmental programs may be high or low • Quality of overall program organization and capabilities and administration may be high or low, and serious weaknesses in horizontal and/or vertical scientific collaborations	**Low**	**8 OR 9**

NCI Pre-Application Consultations & Contact Information

U54 CHD-MH SPORE Pre-Application Consultations

- **Scientific Pre-Application Consultation**
  - 2-hour virtual meeting with NCI program to discuss applicant's proposed SPORE Program, Project Aims, Cores, CEP, and DRP
  - EAB review of SPORE projects strongly encouraged prior to NCI consult
  - Contact Dr. Leah Hubbard (leah.hubbard@nih.gov) to schedule

- **Administrative Pre-Application Consultation**
  - 90-minute virtual meeting with NCI program to discuss NIH policies and guidelines related to preparing and submitting a SPORE application
  - Contact Ms. Tamara Walton (tamara.walton@nih.gov) to schedule

NCI Contacts For U54 SPORE Inquiries

Scientific Inquiries:	Administrative and Data Management & Sharing Inquiries:
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Access to Webinar Slides, Recording, and FAQs

- **The webinar recording, slides, and written FAQs should be available on the TRP website within one week of the webinar: https://trp.cancer.gov/**

Webinar Q&A Session

Write Your Questions in the Chat Now

Important Websites

- **TRP/SPORE Program:** http://trp.cancer.gov
- **SPORE Program Advances:** https://trp.cancer.gov/spore_advances/spore_advances.htm
- **Division of Cancer Treatment & Diagnosis (DCTD):** http://dctd.cancer.gov/
- **U54 CHD-MH SPORE RFA:**

  https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-24-020.html
- **Data Management and Sharing Plan:** https://sharing.nih.gov/

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Thank You!

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