U.S. Department of Health & Human Services • National Institutes of Health

National Center for Complementary and Integrative Health

Research/Funding Opportunities at NCCIH

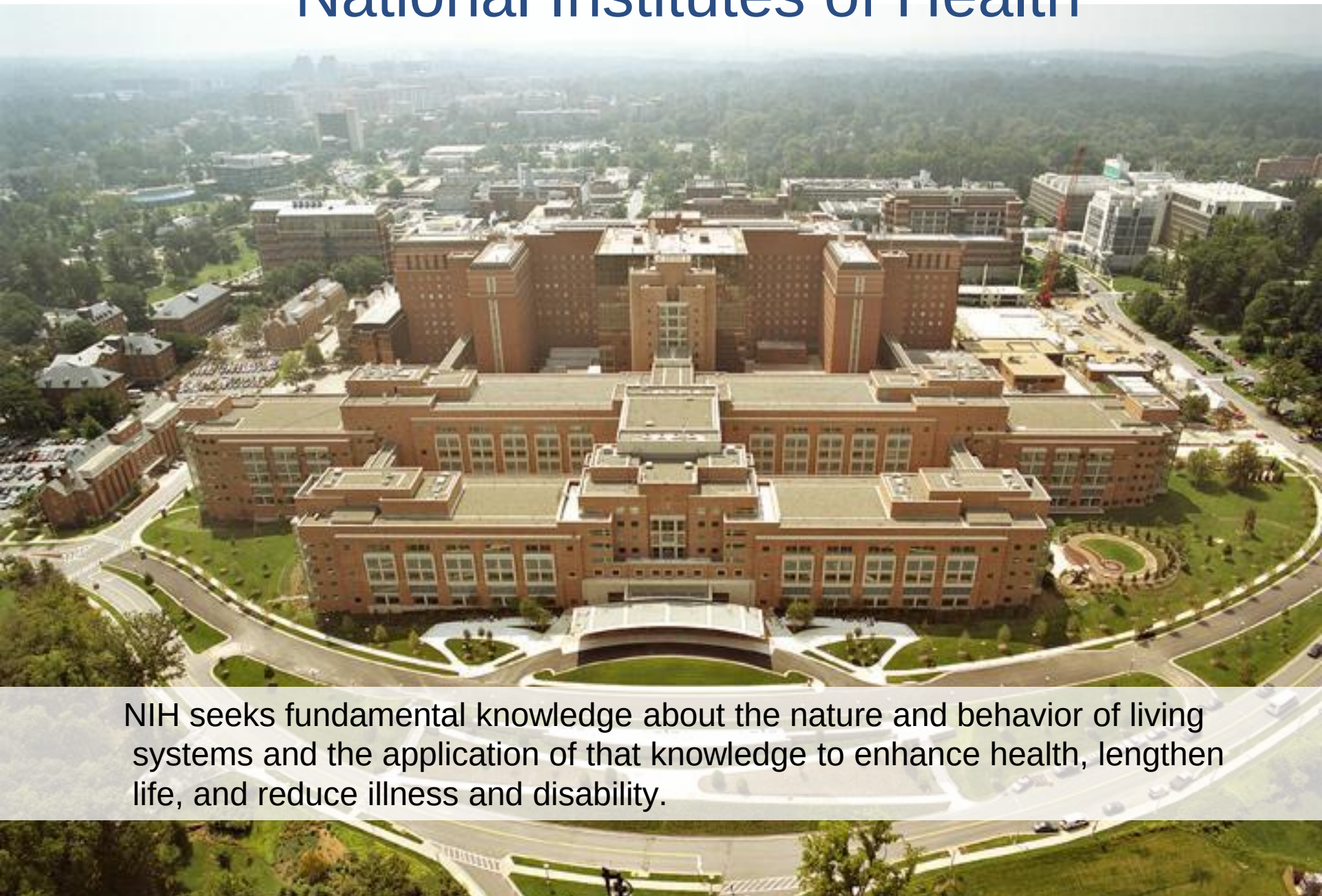
Mindful Families, Schools & Communities: Research-to-Practice
Promoting Child Well-Being meeting; April 29, 2017

Eve E. Reider, Ph.D.

Overview

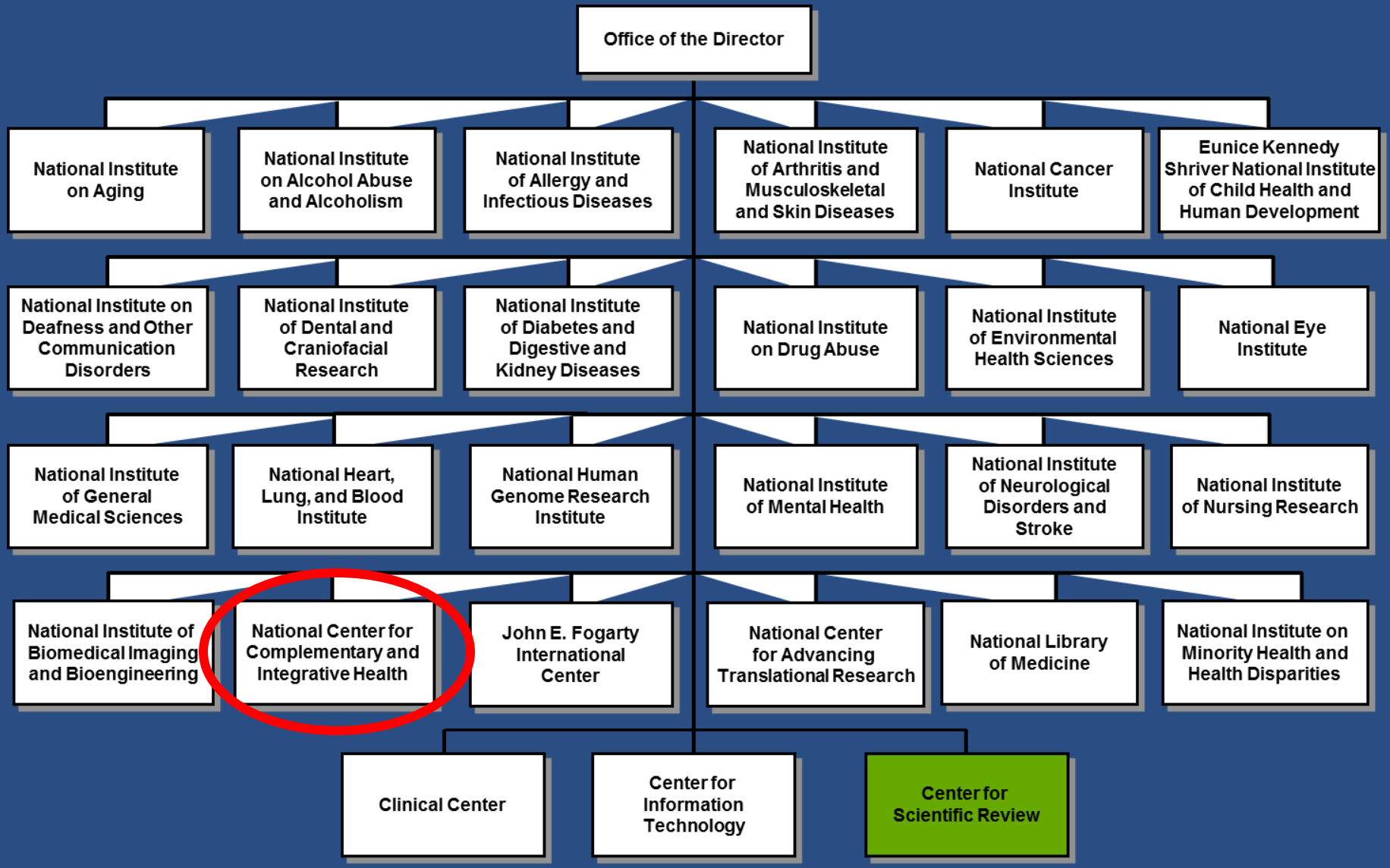
- **NIH and NCCIH Missions and Strategic Plans**
  - **Health Promotion/Disease Prevention**
- Funding
  - NIH
  - NCCIH
    - Training
    - Research
- Recent NCCIH Youth Focused Prevention Efforts

National Institutes of Health

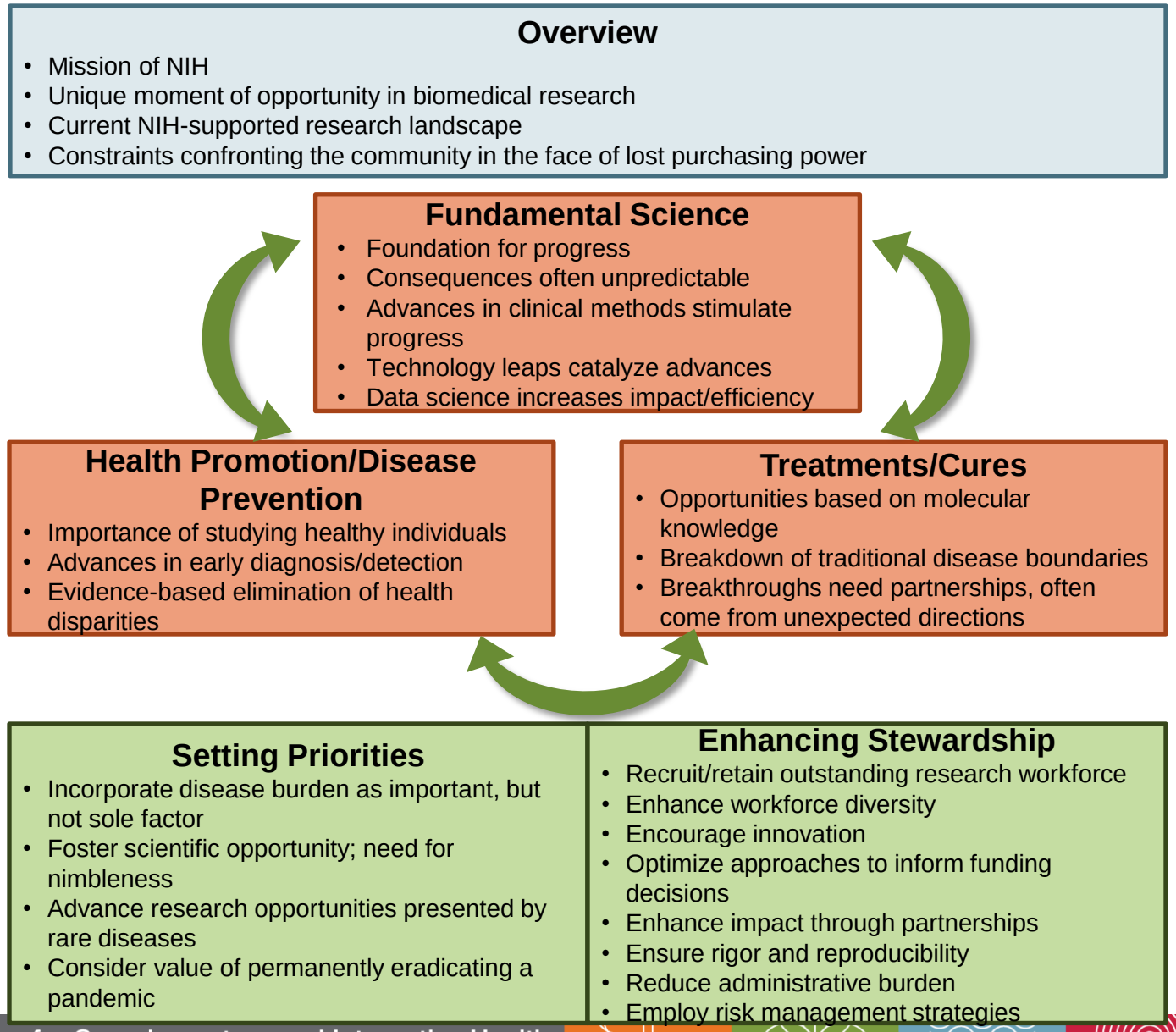


NIH seeks fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

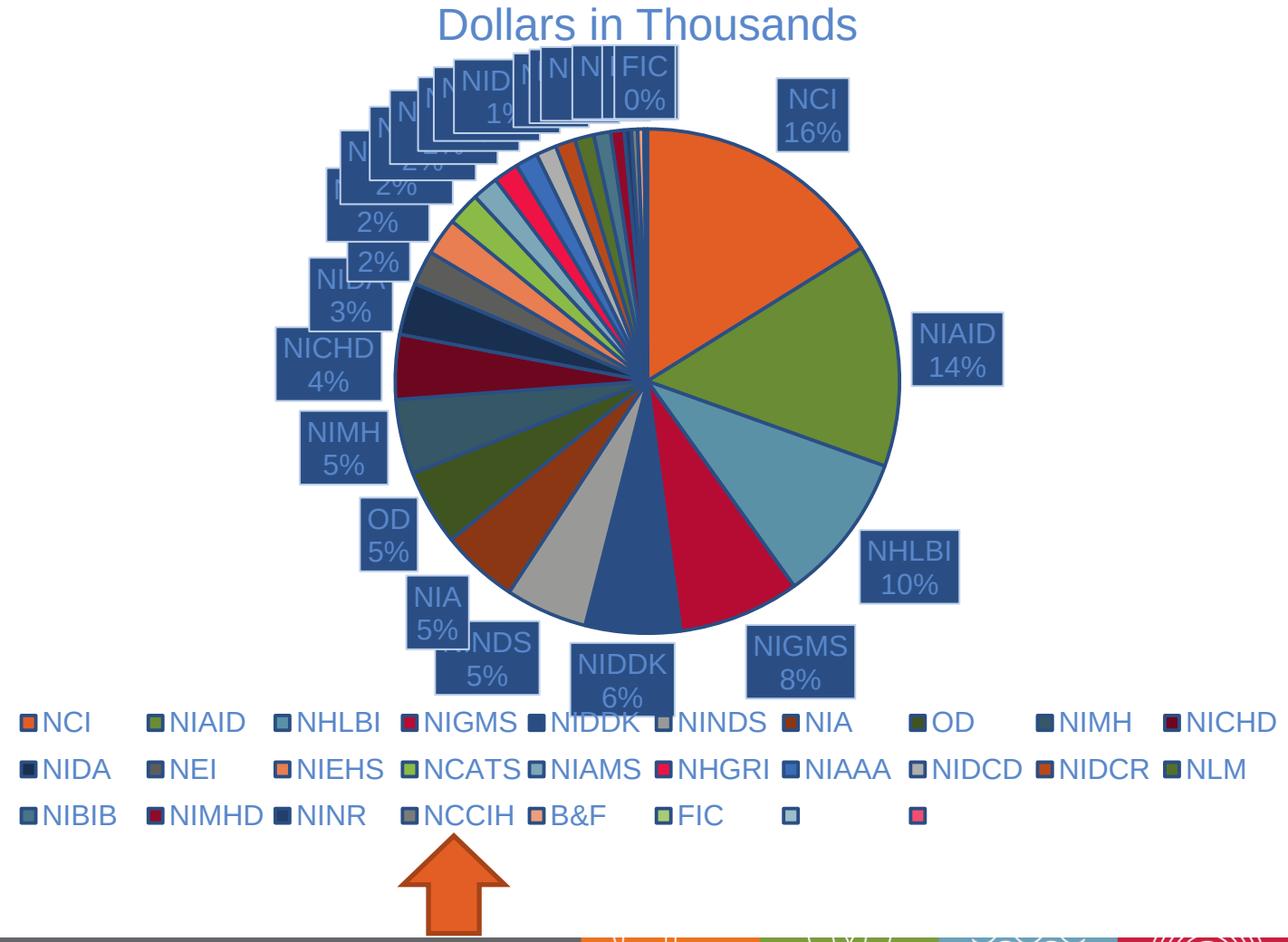
Applications Can Be Funded by One of 24 NIH Institutes or Centers



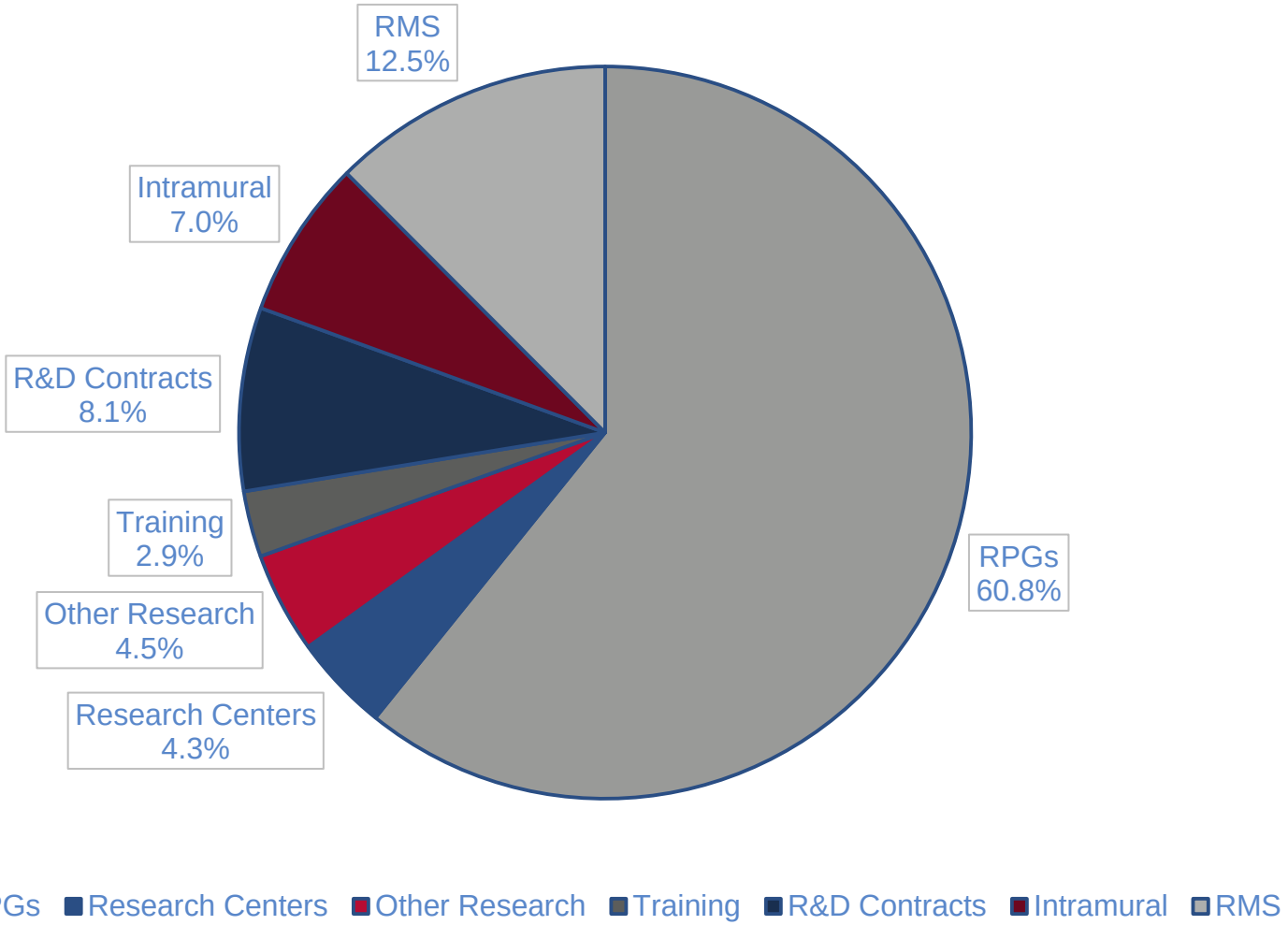
NIH-Wide Strategic Framework



2016 NIH Appropriations



NCCIH 2016 Funding: $130.8 million

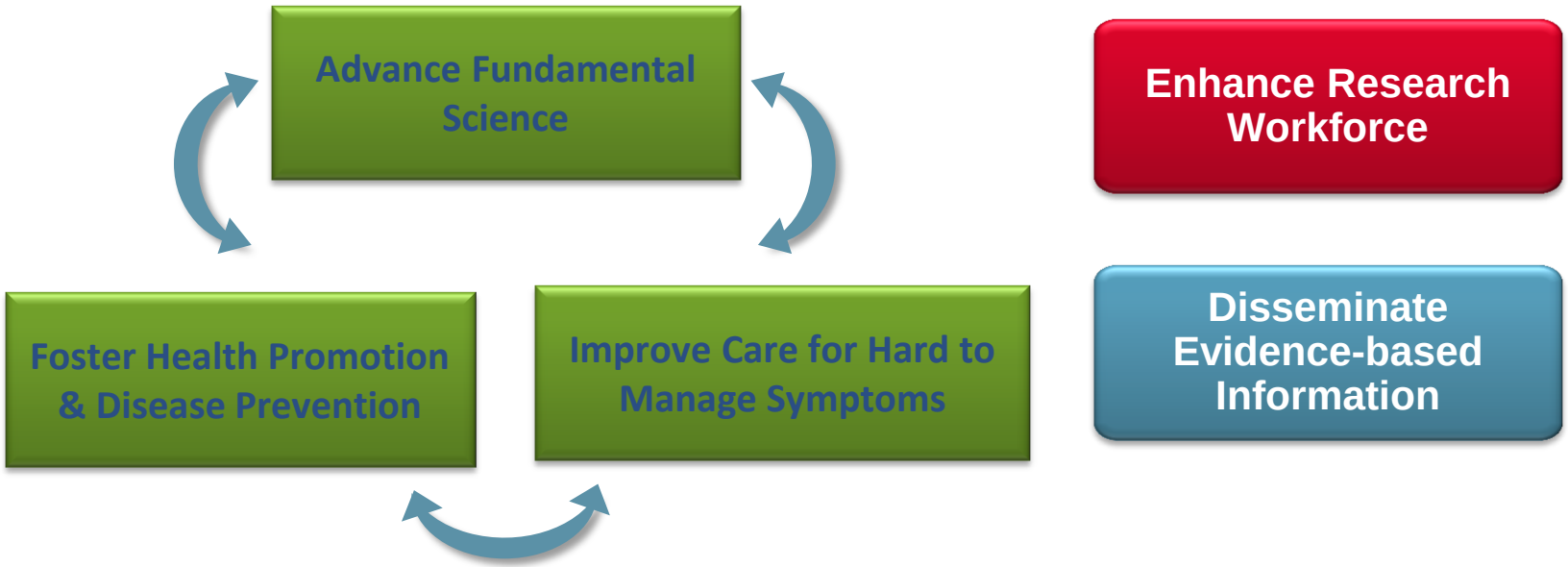


The NCCIH Mission

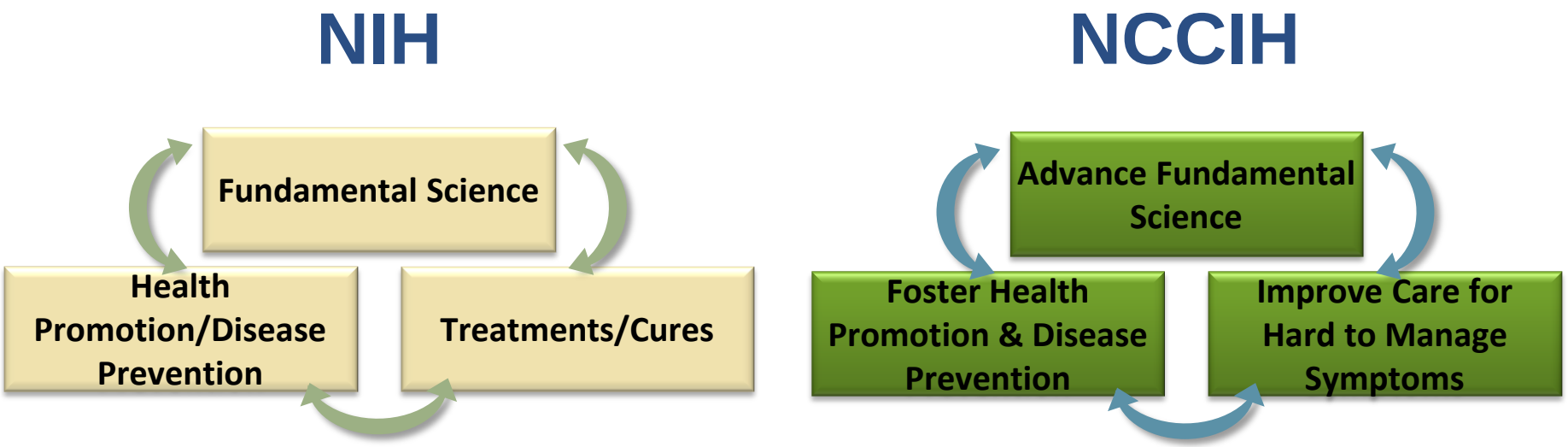
Define, through rigorous scientific investigation, the usefulness and safety of complementary and integrative interventions and their roles in improving health and health care.

2016-2021 NCCIH Strategic Plan

Overview
NCCIH Mission and Vision
Priority Setting



Alignment of NCCIH Research Objectives with NIH-Wide Strategic Plan



Objective 1. Advance Fundamental Science and Methods Development.

Advance Fundamental Science

Improve Care for Hard to Manage Symptoms

Foster Health Promotion & Disease Prevention

- Advance understanding of basic biological mechanisms of action of natural products, including probiotics.
- Advance understanding of the neurobiological mechanisms through which mind and body approaches affect health, resiliency, and wellbeing.
- Develop new and improved research methods and tools for conducting rigorous studies of complementary health approaches and their integration into healthcare.

Objective 2. Improve Care for Hard-to-Manage Symptoms

- Develop and improve complementary health approaches and integrative treatment strategies for managing symptoms such as pain, anxiety, and depression.
- Conduct studies in “real world” clinical settings to test the safety and efficacy of complementary health approaches, including their integration into healthcare.

Objective 3. Foster Health Promotion & Disease Prevention

Advance Fundamental Science

Improve Care for Hard to Manage Symptoms

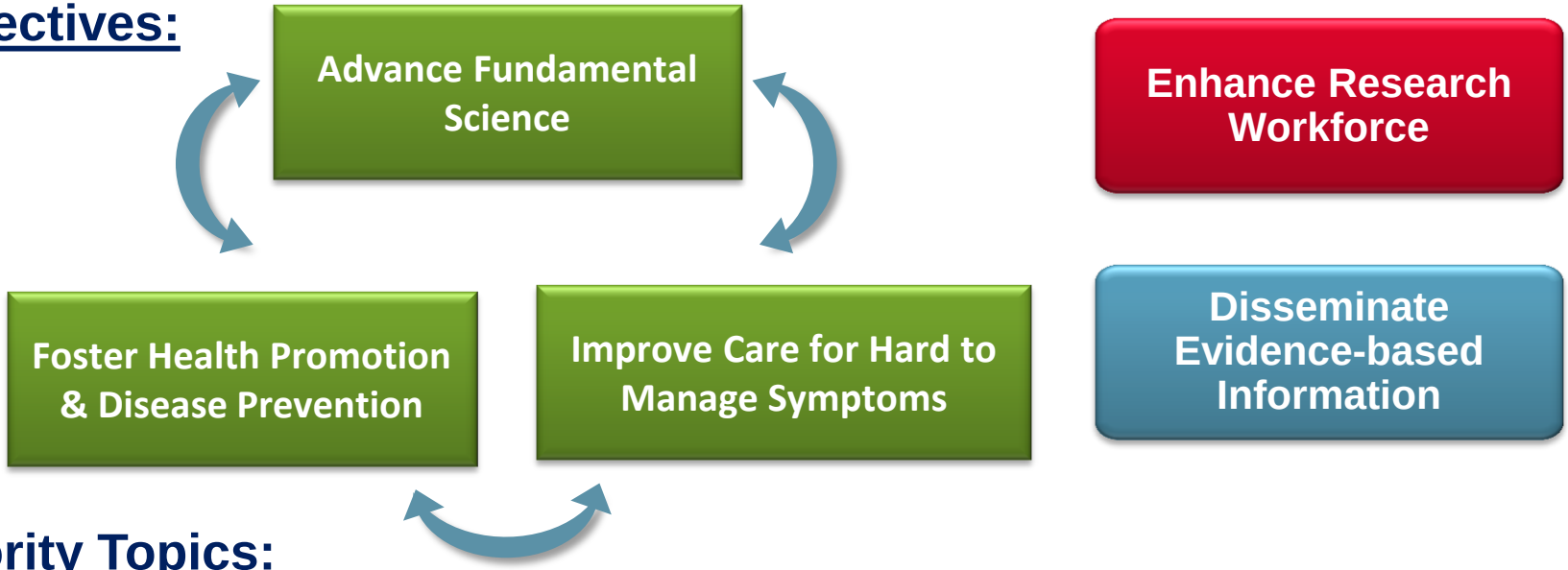
Foster Health Promotion & Disease Prevention

- Investigate mechanisms of health resilience and practices that improve health and prevent disease.
- Study complementary health approaches to promote health and wellness across the lifespan in diverse populations.
- Explore research opportunities to study and assess the safety and efficacy of complementary health approaches in non-clinical settings such as community- and employer-based wellness programs.

NCCIH 2016-2021 Strategic Plan

Overview
NCCIH Mission and Vision
Priority Setting

Objectives:



Priority Topics:

- Pain Management
- Probiotics & the Gut-Brain Axis
- Neurobiological Effects & Mechanisms
- Biological Signatures of Natural Products
- Health Promotion & Disease Prevention
- Innovative Clinical Trial Designs
- Science Literacy & Clinical Research

Disease Prevention and Health Promotion Across the Lifespan: What Does Success Look Like?

Over the course of the next 5 to 10 years, the research NCCIH supports in this area will lead to an increased number of efficacious and effective life-course specific complementary health-promoting and disease-prevention approaches (e.g., mind and body interventions) that can be delivered at different levels (e.g., universal, selective, indicated), in different contexts (e.g., family, school, community, medical centers, child welfare and juvenile justice systems, and homeless shelters) that also include populations at risk (e.g., families living in poverty, children who have experienced abuse, and military families).

Disease Prevention and Health Promotion Across the Lifespan

Objectives:

- Develop and test theory-based interventions that are developmentally appropriate and target vulnerable populations across levels of intervention in different settings
- Investigate mechanisms of action, including underlying behavioral processes and the underlying biological and neurobiological mechanisms that are modified by an intervention.
- Develop and refine sensors and other innovative technologies (e.g., smartphone apps and wearable activity monitors) that can be used to deliver and measure prevention intervention effects and outcomes

Disease Prevention and Health Promotion Across the Lifespan

Prenatal Through Young Adulthood:

- Develop and test complementary and integrative prevention approaches that include the adults most influential in children's lives with the goal of improving the development and well-being of children
- Utilize outcome measures that employ multiple methods (e.g., neurobiological, behavioral) for those involved in, or the focus of the intervention (e.g., students, teachers, parents).
- Develop and test theory-based mind and body prevention interventions for adolescents and young adults, including universal interventions for the general population and selective, indicated interventions for those who are particularly vulnerable.

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- **Funding**
  - **NIH**
  - **NCCIH**
    - **Training**
    - **Research**
- Recent NCCIH Youth Focused Prevention Efforts

NIH Funding

https://grants.nih.gov/grants/oer.htm

- Grants and Funding

https://grants.nih.gov/grants/about_grants.htm

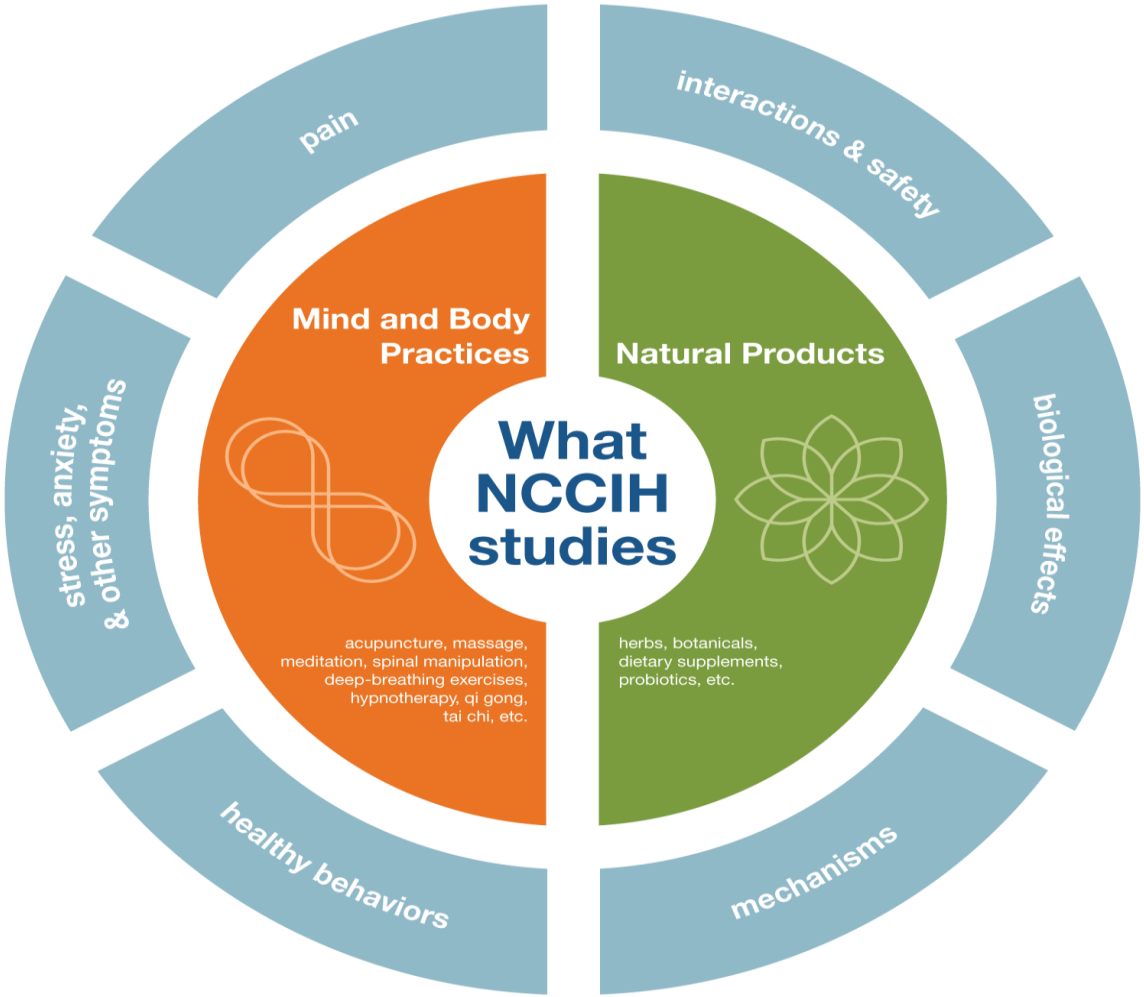
https://grants.nih.gov/grants/how-to-apply-application-guide.html

https://grants.nih.gov/funding/index.htm

NIH Guide to Grants and Contracts

- Program Announcements (PAs)
- Request for Applications (RFAs)
- Notices

What Does NCCIH Fund?



NCCIH Grants and Funding Information

- https://nccih.nih.gov/grants

- NCCIH Funding Opportunities
- Types of Grants and Contracts
- NCCIH Clinical Research Toolbox
- Grant Application Resources
- Awarded Grants and Contracts

NCCIH Division of Extramural Research

Clinical Research Branch:

Funds clinical trials of natural products and mind-body interventions

Basic and Mechanistic Research Branch:

Funds basic and mechanistic studies of complementary health approaches

NCCIH Training

- https://nccih.nih.gov/training

- About Research Training and Career Development
- Awards and Opportunities
- Institutional Training Sites
- Grant Application, Review, and Award Processes
- More Training Resources

- Lanay Mudd, Ph.D., Program Director

Description of Current Funding Opportunities

Individual Training

- F30: dual-degree pre-doctoral (*new)
- F31: pre-doctoral
- F32: post-doctoral

Institutional Training

- T32: training for pre- and post-doctoral
- T35: short-term training

Career Development

- K01: research scientist
- K08: clinician scientist
- K23: patient-oriented clinician scientist
- K99/R00: post-doctoral to independence
- K24: mid-career health-professional doctoral degree

Administrative Supplements

- Diversity: undergraduate through faculty
- Re-Entry: post-doctoral or faculty at time of interruption
- CAM Practitioner: ND, DC, L. Ac., MT, or similar

VIEWPOINT

Toward a New Era of Trust and Transparency in Clinical Trials

JAMA October 4, 2016 Volume 316, Number 13 1353

Kathy L. Hudson, PhD
National Institutes of Health, Bethesda, Maryland.

Michael S. Lauer, MD
National Institutes of Health, Bethesda, Maryland.

Francis S. Collins, MD, PhD
National Institutes of Health, Bethesda, Maryland.

"NIH must ensure that supported trials investigate a mission-relevant question that is of high priority, do not needlessly duplicate previously conducted trials (in contrast to providing needed replication), and have the highest likelihood to advance knowledge and improve health. To achieve this goal, a number of challenges in the design, efficiency, and reporting of clinical trials need to be addressed."

"NIH has launched a multifaceted effort to improve the quality and efficiency of clinical trials"

VIEWPOINT

Toward a New Era of Trust and Transparency in Clinical Trials

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"Specifically, these changes are aimed at enhancing the application and award processes, increasing NIH's ability to assess the merits and feasibility of clinical trial applications; improving over-sight and transparency; and increasing the sharing of clinical trial results."

- *Good Clinical Practice (GCP) training for investigators and NIH staff responsible for conducting or overseeing clinical trials (NOT-OD-16-148)*
- *All applications for clinical trials to be submitted in response to clinical trial specific Funding Opportunity Announcements (NOT-OD-16-147 & NOT-OD-17-043)*
- *Single IRB of record for NIH multisite studies (NOT-OD-16-094)*
- *Clinical trial registration and summary results information reporting (NOT-OD-16-149)*

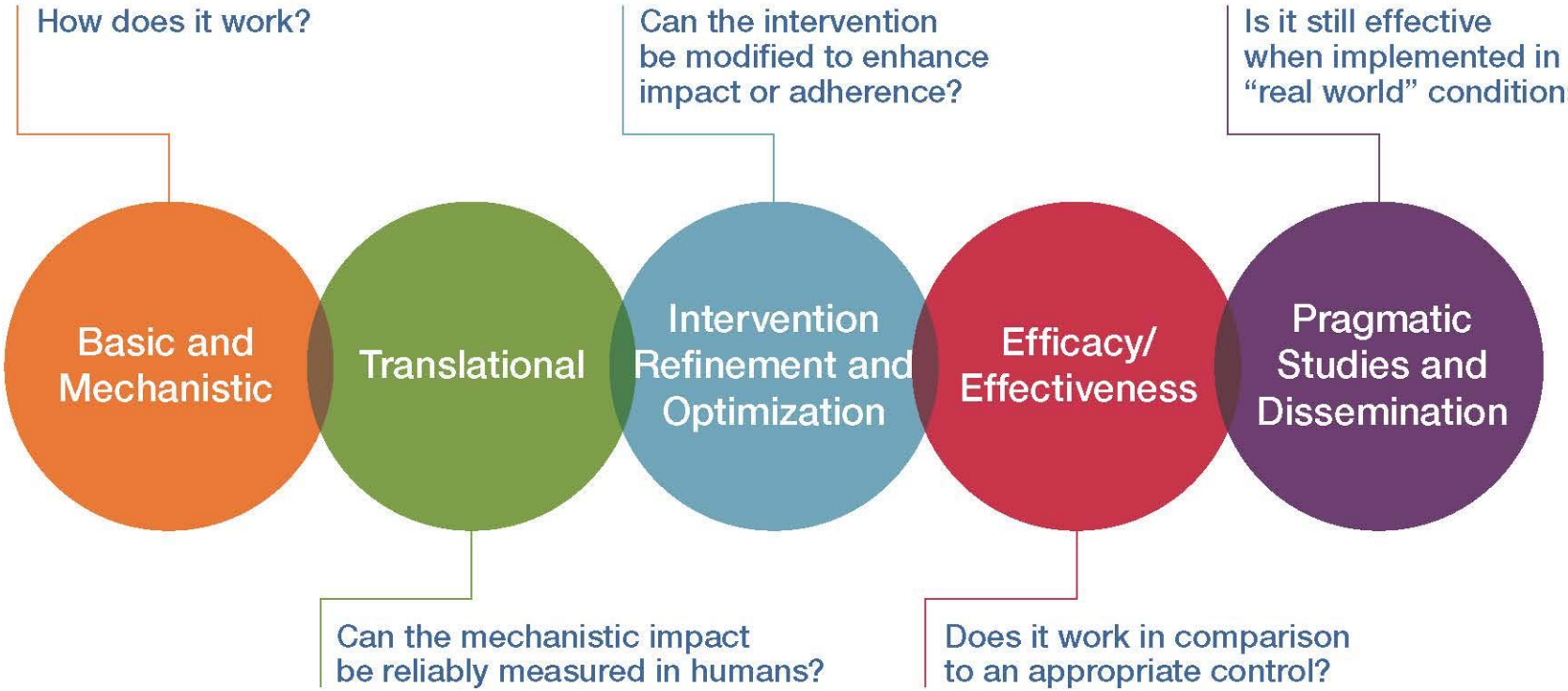
Common Limitations of Trials

- Single site studies reduce generalizability and it is unclear if the intervention can be delivered in other places with fidelity

- When the study fails to demonstrate the hypothesized benefit…
  - Was the intervention delivered correctly?
  - Did the participants get enough of the treatment?
  - Was it the right duration or frequency of the intervention?
  - Was the right population selected or were they too progressed in condition or symptoms?

Often lack key **building blocks** for designing the efficacy trial

NCCIH Framework for Human Subjects Research



Investigator-Initiated Mind and Body Clinical Trial FOAs

Title	FOA Number	Purpose
Phased Innovation Award for Mechanistic Studies to Optimize Mind and Body Interventions in NCCIH High Priority Research Topics (R61/R33)	PAR-17-149	Establish the impact of the intervention on a biological mechanism/psychological process. In the next phase, optimize the impact on the mechanism/process by modifying delivery of the intervention, combining it with other known interventions, or selecting for a more mechanism-relevant population, and assess the association w relevant clinical outcomes.
Innovation Award for Mechanistic Studies to Optimize Mind and Body Interventions in NCCIH High Priority Research Topics (R33)	PAR-17-162	Optimize the impact on the mechanism or process by modifying delivery of the intervention, combining it with other known interventions, or selecting for a more mechanism-relevant population, and assess the association with relevant clinical outcomes.
Exploratory Clinical Trials of Mind and Body Interventions for NCCAM High Priority Research Topics (R34)	PAR-14-182	Early phase intervention refinement; assessment of fidelity and adherence; selection of appropriate patient population and outcome measures
NCCIH Mind and Body Clinical Trial Cooperative Agreement (U01)	PAR-17-215	Mid stage intervention testing to refine recruitment and retention methods, improve fidelity of intervention delivery, and improve data collection quality across multiple sites. Alternatively, evaluate which components of an intervention are necessary, or identify the best algorithm for delivery of care.
Clinical Coordinating Center for NCCIH Multi-Site Investigator-Initiated Clinical Trials of Mind and Body Interventions (Collaborative UG3/UH3)	PAR-17-175	Clinical Coordination of a multi-site efficacy, effectiveness, or pragmatic trial. Trial should be fully powered to measure clinical outcomes and use multiple sites to enhance generalizability of study outcomes.
Mind and Body Intervention Multi-Site Clinical Trial Data Coordinating Center (U24)	PAR-17-173	Companion Data Coordinating Center for multi-site clinical trials to ensure independence and objectivity of data collection and analysis.

Changes in How to Submit Clinical Trial Applications to NCCIH

- NCCIH is no longer accepting most **clinical trial applications** through the Parent R01 FOA (NOT-AT-17-006)
  - Applications after May 8, 2017 use new FOAs
  - We have developed more specific funding opportunities that will allow researchers to incorporate a higher degree of relevant information in their grant applications.
  - Use the new FOAs for all stages of clinical outcome trials

- What human subjects applications will NCCIH accept via the Parent R01 FOA?
  - Observational human studies – cohort, case control, survey
  - Secondary data analysis – datasets or biorepositories
  - Mechanistic focused human studies (no aims to examine clinical outcomes)

Phased Innovation Award for Mechanistic Studies to Optimize Mind and Body Interventions in NCCIH High Priority Research Topics R61/R33 and R33 (PAR-14-179 and PAR-17-162)

- R61 Phase
  - Establish whether the intervention can modulate a biological mechanism or psychological process in humans
  - Demonstrate intervention(s) and control condition can be delivered consistently
- R33 Phase of R61/R33 or direct R33
  - Optimize the impact on the mechanism or process by:
    - Modifying the delivery of the intervention
    - Combining the intervention with other effective interventions
    - Selecting for a more mechanism-relevant population

- See Blog by Dr. Chen and link to Webinar for these FOAs "New Funding Initiatives on Phased Innovation Award for Mechanistic Studies…" October 16, 2015

Wen Chen, Ph.D.

Phased Innovation Award for Mechanistic Studies to Optimize Mind and Body Interventions in NCCIH High Priority Research Topics R61/R33 and R33 (PAR-14-179 and PAR-17-162)

- See NCCIH Blog by Dr. Wen Chen and link to Webinar for these FOAs "New Funding Initiatives on Phased Innovation Award for Mechanistic Studies to Optimize Mind and Body Interventions" October 16, 2015
  - https://nccih.nih.gov/research/blog/phased-innovation-initiatives

- Blinding issues can be challenging for mind and body interventions.
  - See NCCIH Blog by Dr. Catherine Meyers "Planning for Effective Blinding" October 13, 2015
    - https://nccih.nih.gov/research/blog/effective-blinding-plan

- Contact Dr. Wen Chen to determine which FOA is the best for human mechanistic research on mind and body interventions

Wen Chen, Ph.D.

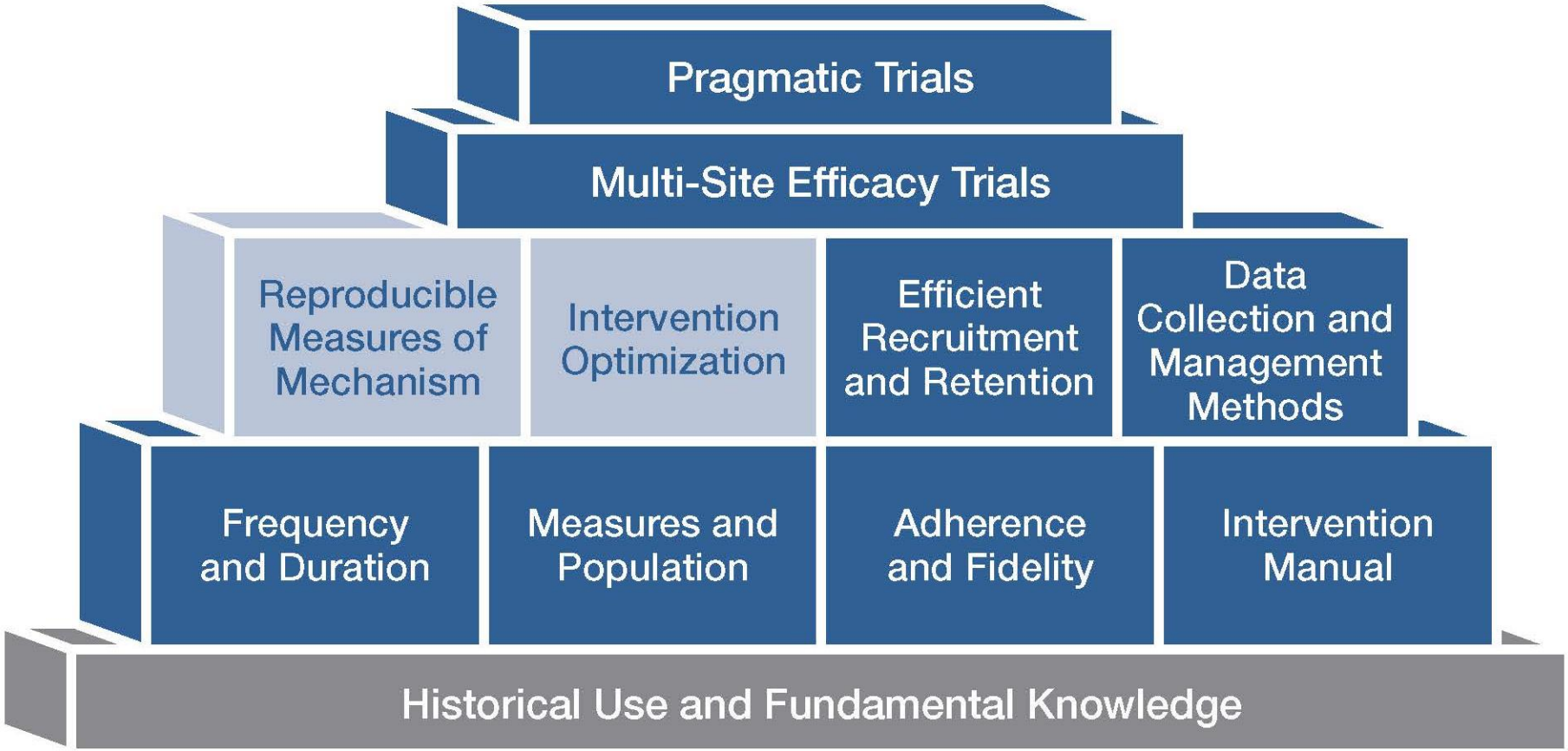
What is a Phased Award?

- Used when the supported research has two distinct phases (e.g. R61/R33) with separate aims
- Transition to the second phase is dependent on whether the first phase achieves the negotiated milestones
  - Examples include: recruiting and retaining participants on time; demonstrating a priori defined metrics for impact on a biological mechanism or psychological process

- If milestones are met, transition to the second phase of funding occurs after administrative review

- One application and peer review process to evaluate both phases
  - Clear go/no-go criteria help reviewers understand when you would vs would not proceed to second phase

Examples of Building Blocks of Mind and Body Clinical Trials



Exploratory Clinical Trials of Mind and Body Interventions for NCCAM High Priority Research Topics R34 (PAR-14-162)

- What this mechanism will support
  - *Early phase* clinical trials of mind and body approaches
  - Provide data critical for planning and design of a subsequent controlled cohort, efficacy or effectiveness, or pragmatic trial
    - Intervention refinement
    - Feasibility
    - Acceptability

- What this mechanism will NOT support
  - Tests of efficacy or effectiveness, including tests of “preliminary efficacy”
  - Studies to validate biomarkers of mind and body approaches

Lanay Mudd, Ph.D.

Exploratory Clinical Trials of Mind and Body Interventions for NCCAM High Priority Research Topics R34 (PAR-14-162)

- Building Blocks desired as preliminary data prior to R34 trial
  - None required
  - Application should provide rationale for why the intervention has promise of clinical benefit

Lanay Mudd, Ph.D.

NCCIH Mind and Body Clinical Trial Cooperative Agreement U01 (PAR-17-215)

- What this mechanism will support
  - Develop and test adaptive interventions
  - Optimize interventions by identifying critical elements
  - Assess multi-site fidelity and feasibility
  - “Dosing studies” to determine duration or frequency of the intervention with best adherence or impact on biological mechanism/psychological process
  - Final building blocks to prepare for multisite efficacy trial

- What this mechanism will NOT support
  - Multi-site efficacy or effectiveness trials
  - Single site efficacy or effectiveness trials
  - Interventions for the treatment or prevention of cancer

Lanay Mudd, Ph.D.

NCCIH Mind and Body Clinical Trial Cooperative Agreement U01 (PAR-17-215)

- Building Blocks desired as preliminary data prior U01 trial
  - No significant safety concerns in previous studies
  - Demonstration that proposed U01 clinical trial is feasible from R34 or other pilot studies:
    - Recruitment, randomization, adherence, retention, complete follow-up data collection
  - Completion of final data collection from any pilot studies

  - Not required, but highly desired
    - Intervention can reliably produce a meaningful impact on biological mechanism or psychological process

Lanay Mudd, Ph.D.

What is a U Mechanism?

- U mechanisms – U01, UG3/UH3, and U24
  - Cooperative agreement awards
  - Used for Investigator-Initiated applications
  - Used by the federal government when the funding agency anticipates federal staff will have involvement in the activities of the award
  - At the time of funding, NCCIH will assign two staff members to work with investigators:
    1. Program Director who is responsible for the administration of the award, review of progress reports, etc.
    2. Project Scientist who works directly with the investigators as part of the team and participates in trial planning and oversight during the trial

NCCIH New Multi-Site Randomized Controlled Trial FOAs UG3/UH3 & U24

- *Companion FOAs*
  - Clinical Coordinating Center UG3/UH3
  - Independent Data Coordinating Center U24
  - ALL multi-site trials must submit BOTH applications at same time

- Will support multi-site clinical trials
  - Efficacy Trials
  - Effectiveness Trials
  - Pragmatic Trials
  - Dissemination and Implementation Trials

- Most will exceed budgets of $500,000 direct costs/yr
  - Per NIH policy, need NCCIH Permission to Apply
- Current instructions on NCCIH website for > $500K grants:
  - https://nccih.nih.gov/grants/policies/over500k

Robin Boineau, M.D., M.A.

NCCIH New Multi-Site Randomized Controlled Trial FOAs UG3/UH3 & U24

- Building Blocks desired as preliminary data prior to multi-site trial
  - Clinical Trial is Feasible
    - Specific intervention can be adhered to by patient population
    - Ability to recruit, retain, and randomize participants
    - Ability to follow protocol and complete data collection
    - Intervention can be delivered with fidelity at multiple sites
  - Data to justify intervention delivery (duration, frequency, timeline)
  - No significant safety concerns in previous studies

  - Not required, but highly desired
    - Intervention can reliably produce a meaningful impact on biological mechanism or psychological process
    - Intervention has been optimized to enhance this impact

Robin Boineau, M.D., M.A.

Why Multi-Site Efficacy Trials?

- To meet evidence guidelines for rigor and reduce bias, efficacy trials are most informative if they:

1. Are conducted as multi-site trials
   - Increases likelihood of generalizability of the results
   - Increases diversity of the population to meet NIH policy and guidelines on the inclusion of women and minorities as subjects in clinical research
   - Demonstrates intervention can be delivered with fidelity at more than one location

2. Have independent data coordination (companion U24)
   - Provides methods for consistent data collection from sites
   - Assures independent data quality confirmation and analysis

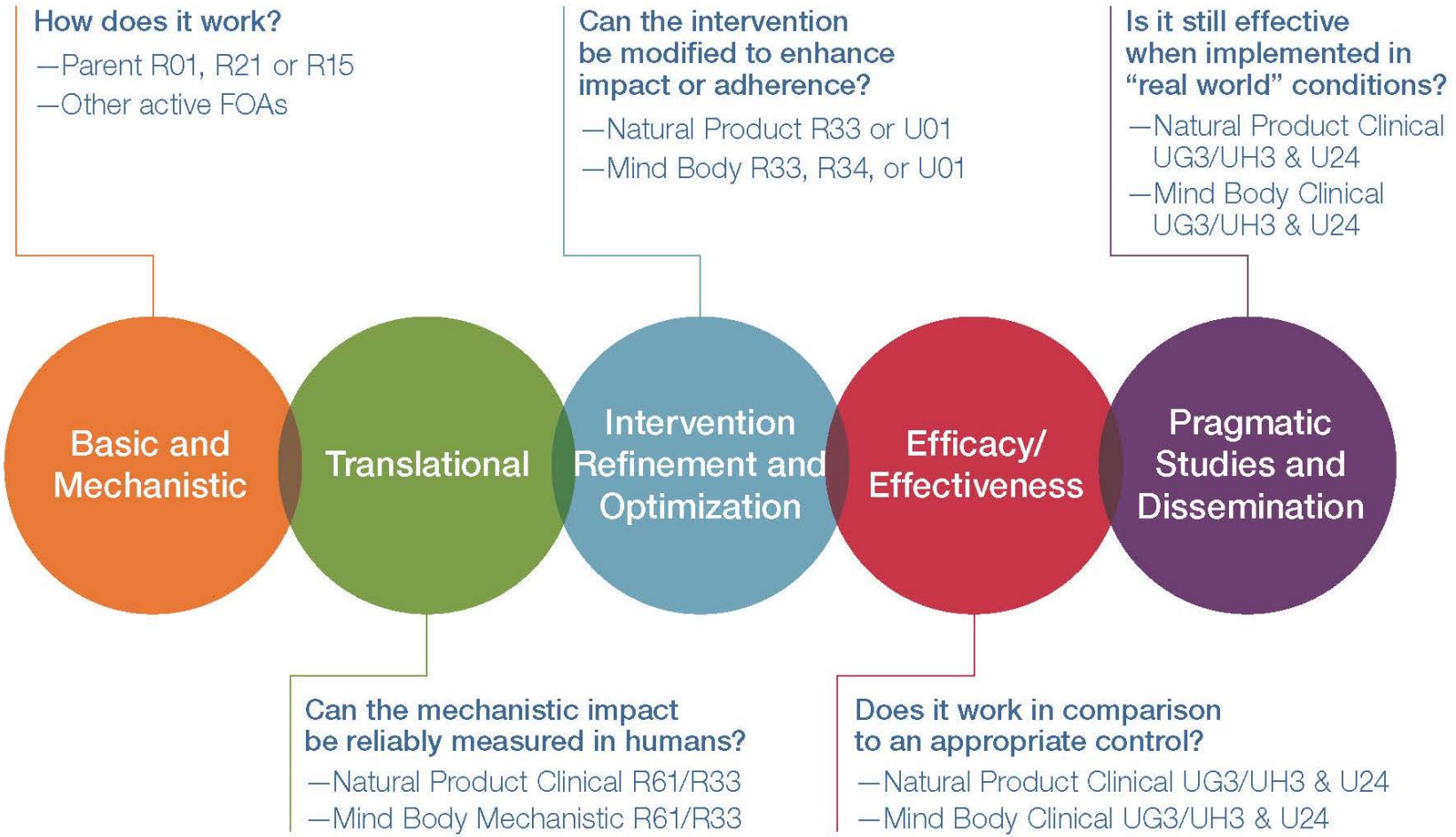
Why a Phased Award (UG3/UH3) for multisite clinical trials?

- Planning phase (UG3) and implementation phase (UH3)
- Transition to the second phase is dependent on whether the negotiated milestones are met for both the CCC and DCC
  - Examples include: finalize and get NCCIH and DSMB approval for protocol and study documents; IRB approvals at all sites; negotiate contracts for sites; develop study database and data management plan; create site training materials, etc
  - https://nccih.nih.gov/grants/toolbox#milestone

- One application and peer review process to evaluate both phases

- Planning phase demonstrates team's ability to meet deadlines and prepare for the launch of the trial

Framework for Human Subjects Research



Review Process

- Applications submitted to our new clinical trial FOAs will be reviewed by special review panels familiar with NCCIH's research priorities and the goals of the new FOAs.
- Applications must include special attachments (described in the FOA) that will allow applicants to provide study details in a standardized way.
    - Examples – protocol synopsis, clinical trial experience table, regulatory communication plan, etc

- Review panels will be able to use this additional information for their assessment of important aspects such as rigor, feasibility, and potential impact of the trial.

- CAREFULLY READ THE FOA!!
- Be sure your application is complete: https://nccih.nih.gov/grants/funding/clinicaltrials/mind-body#par17175

Slava Soldatenkov, Ph.D.

RFA on Pragmatic Trials

- NCCIH Participation in NIH Health Care Systems (HCS) Research Collaboratory - Pragmatic Clinical Trials UG3/UH3 (RFA-16-019)
  - Webinar: April 25, 2017

- NCCIH Blog by Dr. Robin Boineau about this RFA
  - https://nccih.nih.gov/research/blog/health-systems-researchers

- Letters of Intent Due May 2, 2017 and Applications due June 2, 2017

NIH HCS Research Collaboratory

Demonstration Projects for Pragmatic Clinical Trials

RFA-RM-16-019

- Milestone-driven phased cooperative agreements for efficient, large-scale pragmatic clinical trials
- One year planning phase (UG3, direct cost cap $500K) and 2-4 year implementation phase (UH3, direct cost cap $1M/yr) – in a single application
- At least 3 partnering HCS must be identified in the project, unless a strong justification for fewer HCS is provided in the application
- Pragmatic trials are “primarily designed to determine the effects of an intervention under the usual conditions in which it will be applied” in contrast with explanatory trials which “are primarily designed to determine the effects of an intervention under ideal circumstances” (http://www.cmaj.ca/content/180/10/E47.full)
- Several criteria for pragmatic trials & partnering HCS listed in the FOA
- Projects must be responsive to Research Areas for the 11 participating Institutes & Centers listed in the FOA

NIH HCS Research Collaboratory RFA-RM-16-019

11 Participating Institutes & Centers

- NCCIH Robin Boineau
- NIA Marcel Salive
- NHLBI Barbara Wells
- NIDDK Andy Narva
- NIDA Sarah Duffy
- NINDS Salina Waddy
- NICHD Sue Marden
- NINR Jeri Miller
- NIAMS Chuck Washabaugh
- NIDCR Jane Atkinson
- ODP Rachael Ballard

Issues to Keep in Mind before Submitting a Pragmatic Trial Application to NCCIH

- Trials proposing to study regulated products (dietary supplements, devices or biologics) must have US Food and Drug Administration approval or clearance for the indication being studied in the trial
- Strong preliminary data for the intervention must be available for the specific clinical condition (positive efficacy study(s))

- NCCIH priorities for pragmatic trials:
  - Address questions that are of major public health importance
  - Intervention must be well-characterized and available so that it can be delivered within existing systems
  - Leverage passive data collection of study outcomes via existing systems such as electronic health records
  - Trial design must incorporate rigorous controls preferably via randomization

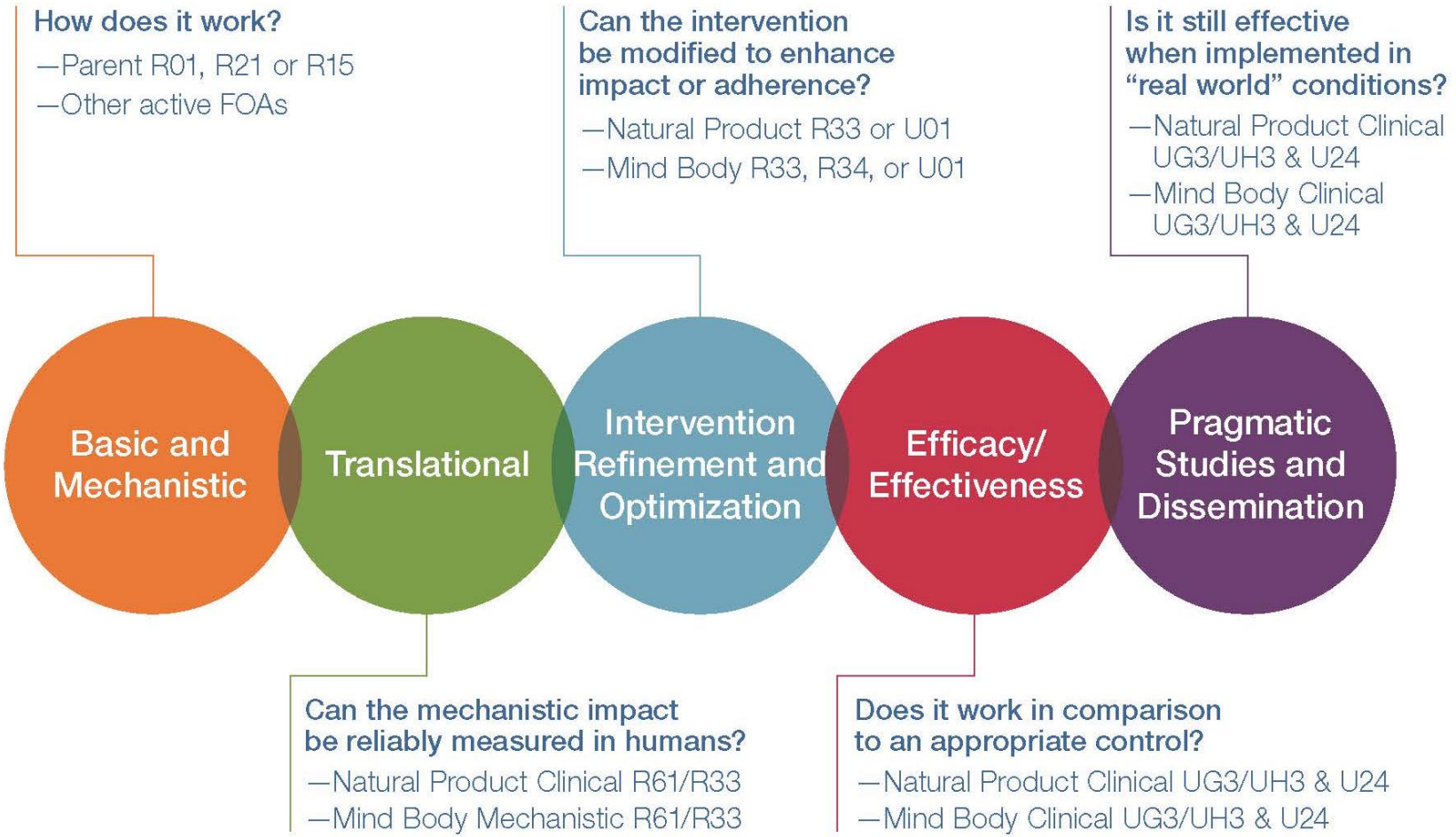
Resources

- NCCIH new website for key information about clinical trial FOAs:
  - https://nccih.nih.gov/grants/funding/clinicaltrials
  - FOA description, links to FOA, required application elements, and Program Director contact information

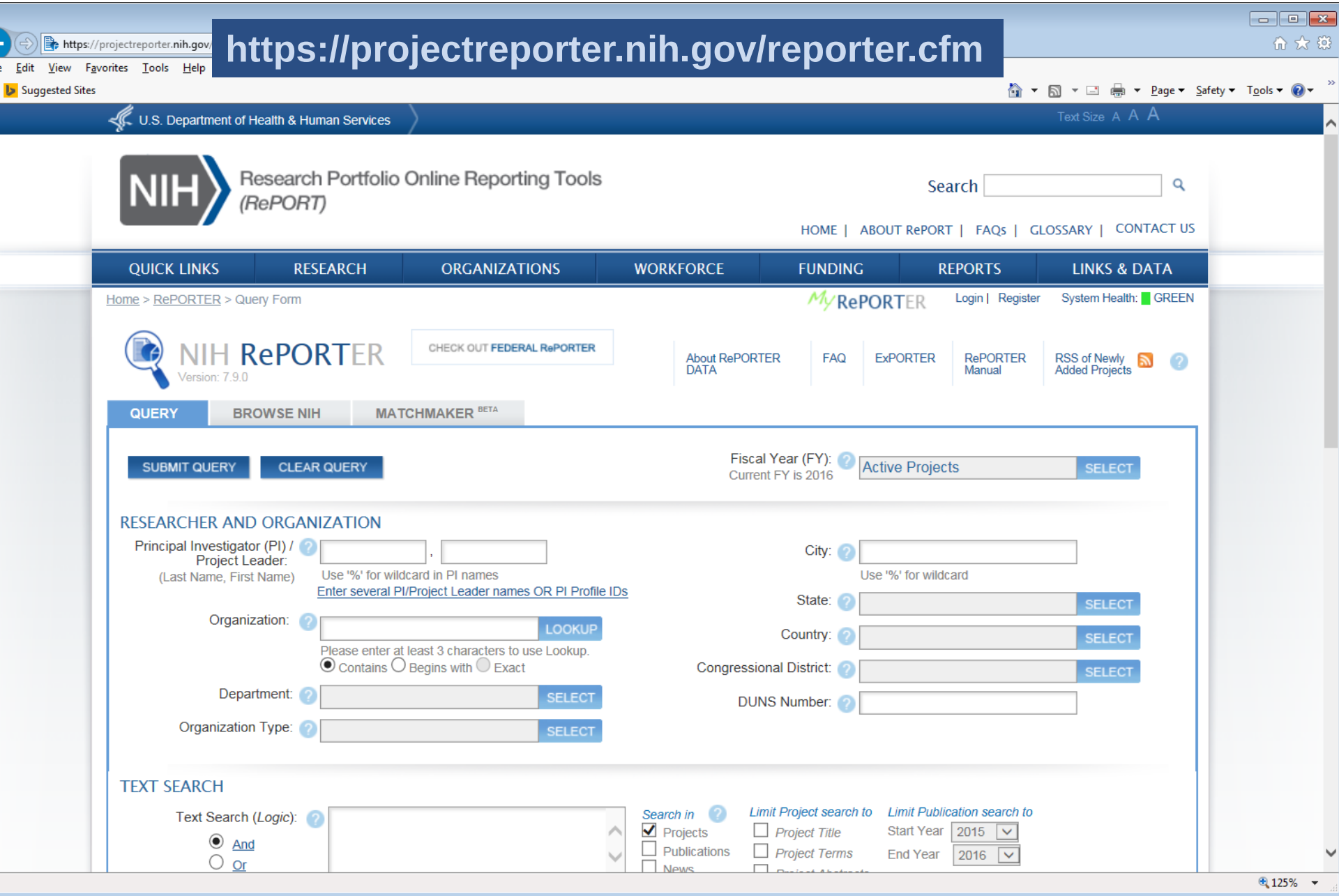
- NCCIH Clinical Trial FOA Frequently Asked Questions
  - https://nccih.nih.gov/grants/funding/clinicaltrials/faq

- General questions about which FOA to use:
  - nccihderinquiries@mail.nih.gov

Range of Research Questions



https://projectreporter.nih.gov/reporter.cfm



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- **Recent NCCIH Youth Focused Prevention Efforts**

Recent NCCIH Youth Focused Prevention Efforts

- 2016 NIH ODP P2P Workshop: Advancing Research to Prevent Youth Suicide (ODP, NIMH, NIDA, NCCIH)
  - 2017 SPR Roundtable
  - Reider & Sims, 2016, Family-Based Prevention Interventions: Can the Onset of Suicide Ideation and Behavior be Prevented? *SLTB, 46 (Suppl*. 1), 4-7. DOI: 10.1111/sltb.12252
- 2016 NCCIH Workshop: Research on Mind-Body Approaches to Improve Children's Health
- 2016 SPR roundtable: The Potential of Mindfulness Approaches to Improve Children's Health (Greenberg, Robertson, Coatsworth, Miller, Duncan)
- 2016 ICIMH roundtable: Do Mindfulness Approaches Have the Potential to Prevent Substance Use and Abuse in Youth? (Miller, Mendelson, Coatsworth, Davidson)
- 2016 NCCIH Strategic Plan: Foster Health Promotion/Disease Prevention

Research on Mind-Body Approaches to Improve Children's Health

August 8-9, 2016

Bethesda, Maryland

Background

- A body of research exists that is examining the efficacy of mind-body approaches with adult populations
- Strong interest in and use of mind-body approaches to improve the health of children and youth across the life-course
- The evidence base for mind-body approaches for youth is quite small (e.g., review by Greenberg and Harris, 2012)
- A recent meta-analysis found mindfulness appears to be a promising intervention modality for youth, for clinical and non-clinical populations, compared to active alternative treatments, for a range of outcomes (Zoogman et al., 2014, Mindfulness)

Goals of Proposed Workshop

1) Understand current use of mind-body approaches for children in the general population;
2) Review the evidence base for mind-body approaches in improving children's health, including use by relevant people in children's lives (e.g., parents, teachers);
3) Discuss important methodological issues (e.g., proximal and long-term measures, control groups, use of pragmatic designs);
4) Discuss concepts of health promotion, prevention of disorders, and resilience, and within the research agenda;
5) Determine the way forward in establishing a research agenda that is efficient and impactful (gaps, opportunities, priorities)

Frameworks

- Developmental Stage
- Level of Intervention
- Contexts
- Vulnerable Populations
- Areas of Health

Questions Addressed in Presentations

- What is the question and does it derive from a theoretical model?
- What is the intervention?
- Is the intervention adapted for developmental stage? What is the rationale?
- Methodology
  - What can you tell us about the methodology?
  - What is the comparator or control group, how was it chosen, and why?
- Outcome measures
  - What are the primary domains and what else are you trying to capture?
- How have you thought about fidelity?

It was a Collaborative Event

- Participating NIH institutes, offices and centers
  - NICHD, NIDA, NIMH, NIAAA, NIMHD
  - ODP and OBSSR contributed co-funding
- Other Agencies
  - Dept of Education, ACF
- Foundations
  - RWJF, Holistic Life Foundation

Insights for A Research Agenda: Big Picture

Greenberg

Status of field: early stage of development, study designs and measures less than optimal, and long-term follow-up data lacking

Research designs needed:

- Comparative effectiveness trials
- Experimental and micro
- Pooled data analyses

Broad issues to consider

- Focus on developmental transitions
- Which interventions to investigate?
- The roles of suffering and motivation
- The importance of mixed methods
- Understanding individual differences
- Whole-school models

Davidson

Status of field: small sample sizes, inadequate experimental designs, with great heterogeneity in sample sizes

Critical research issues:

- Nature of comparison group is crucial
- Need for an independent measure of mindfulness
- Long-term longitudinal studies will play an important role
- The importance of context, including the ethical framework in which mindfulness is framed
- Frequency and duration
- How to measure formal and informal practice
- Understanding how regular habits are established
- Individual differences

Suggestions for the Research Agenda

Methodological Designs

- Micro trials
- Comparative effectiveness
- Design experiments and rapid cycles of innovation and testing
- Controls designed to assess nonspecific effects
- Training of facilitators and teachers

Measures

- Need PROMIS (Patient-Reported Outcomes Measurement Information System) instruments for measuring stress, resilience, mindfulness
- Observation
- Need *in situ* measures (e.g., mindful classrooms)
- Better understanding of psychophysiology
- Measures that could be utilized for tracking schools as safe, supportive, caring environments (e.g., Classroom Assessment Scoring System)
- Standardized measures of implementation

Suggestions for the Research Agenda

Mechanisms of Action

- Executive functioning
- Rumination
- Self-compassion
- Coping repertoire
- Motivation
- Integration of mechanisms/measurement across disciplines
- Effects of cellular physiology, epigenetics, etc.
- Caring, responsive community
- Safe, supportive (adult caregiver) relationship

Implementation Approaches

- Combining teacher and child observations; also combining child and parent
- In person vs. online/app
- Workplace context
- Technology (virtual reality/sensors)
- Around (before/after) normative life transitions
- Whole-school design

Suggestions for the Research Agenda

Special Populations

- Juvenile justice
- Child welfare
- Health conditions
- Human service professionals
- Underserved
- Trauma exposed youth
- Law enforcement
- Race and ethnicity issues

Prioritized Research Questions

- Which interventions work best, for whom, under what conditions, and at what ages?
- Does enhancing an age appropriate evidence-based prevention intervention with mind-body approaches increase the efficacy of the intervention?
- What are the proximal measures of key mediating processes?
- What are the long-term effects of implementing mind-body interventions that are focused on children and the important people in their lives? What are the outcomes for parents, teachers, and children?
  - What role does practice contribute to long-term effects?
- Are the effects of mind-body interventions similar to or superior to active control groups?

Measures

- What is an independent measure of mindfulness (e.g., breath counting)?
- What is an independent measure of compassion that is not based on self-report?
- What performance or biological measures contribute to a better understanding of the effect of mind-body interventions?
- How is mindfulness and compassion related to well-being and health?
- What are the multiple methods of outcomes that should be measured to understand the potential impact of mind-body practices?

Implementation Approach

- Is the impact of an intervention enhanced when it is implemented across contexts and focuses both on the children and the important people in their lives (e.g., home, school, parents, teachers, and children)?
- What is the optimal frequency and duration of mindfulness practice for individuals of different ages?
- What is the effect of in person versus online/applications versus a combined approach in outcomes?
- What role does the organization (e.g., schools) contribute to effects of an intervention?
- What role should adaptation play for different populations?
- What role does training and fidelity of implementation play in outcomes? What training models are best to use?
- What role does preference (e.g., SMART designs) play in outcomes for different populations (e.g., gender)?

Microtrials and Pooling/Integrating Data Sets

Microtrial Research Questions

- What are the proximal mechanisms of outcomes?
- What are the effects of different dosages of practice?

Pooling/Harmonizing Data Sets

- What are the effects of the interventions when data sets are combined?
  - What are the effects on subgroups (e.g., minority populations)?
  - What are the effects on low base rate behaviors (e.g., suicidal ideation and behavior)?

Discussion

Eve E. Reider, Ph.D.
ereider@mail.nih.gov