Writing a Compelling ePCT Grant Application

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Learning goals

- Provide tips on NIH matchmaking
- Identify elements of a compelling ePCT application

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Definitions:

- **Embedded pragmatic clinical trials** are conducted within the health care delivery setting and are "primarily designed to determine the effects of an intervention under the usual conditions in which it will be applied", which is in contrast with explanatory trials that "are primarily designed to determine the effects of an intervention under ideal circumstances" (http://www.bmj.com/content/350/bmj.h2147). "

- There are "three key attributes of pragmatic clinical trials (PCTs):

  - (1) an intent to inform decision-makers (patients, clinicians, administrators, and policy-makers), as opposed to elucidating a biological or social mechanism;

  - (2) an intent to enroll a population relevant to the decision in practice and representative of the patients or populations and clinical settings for whom the decision is relevant; and

  - (3) either an intent to (a) streamline procedures and data collection so that the trial can focus on adequate power for informing the clinical and policy decisions targeted by the trial or (b) measure a broad range of outcomes

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Pragmatic or Implementation Trials RFA-AT-22-001

- Milestone-driven phased cooperative agreements for efficient, large-scale pragmatic or implementation trials
- Single application
  - One year planning phase - UG3, direct cost cap $500K
  - 2-4 year study conduct phase - UH3, direct cost cap $1M/yr
- At least 3 partnering HCS must be identified in the project, unless a strong justification for fewer HCS is provided in the application
- Include a diverse patient population that approximates the US population of patients with the condition being studied

https://grants.nih.gov/grants/guide/rfa-files/RFA-AT-22-001.html

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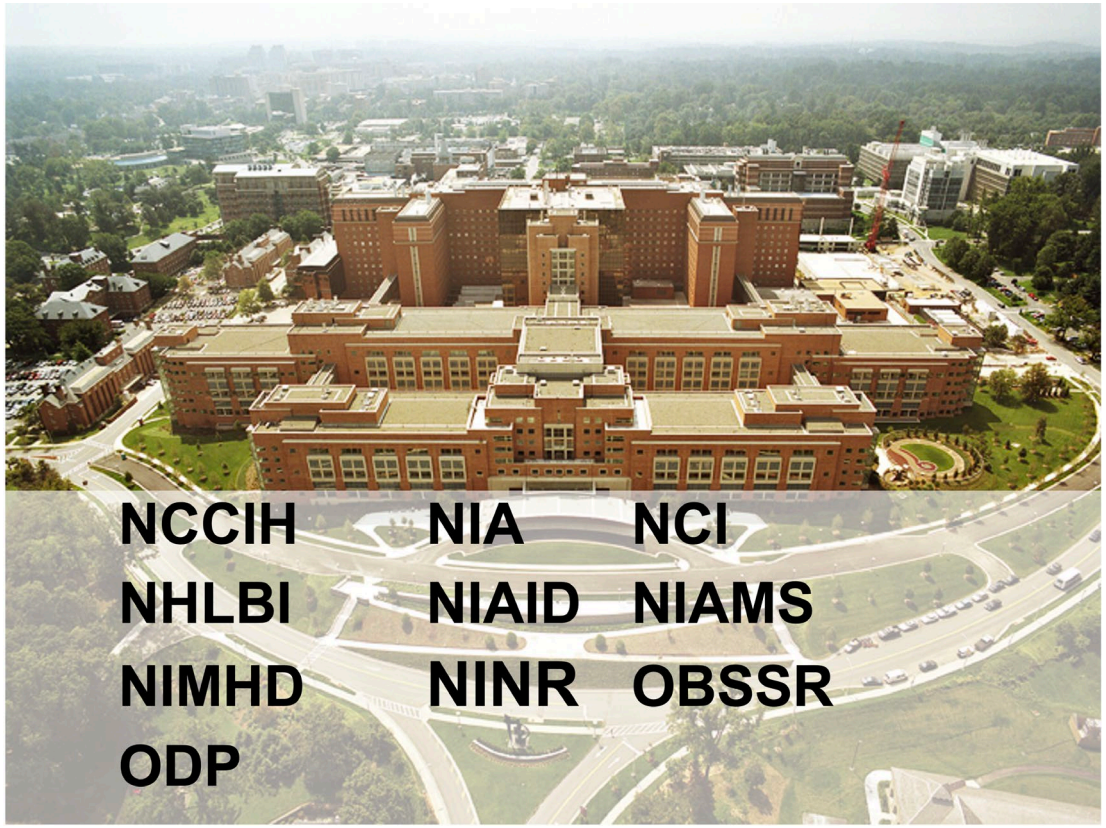
Pragmatic or Implementation Trials RFA-AT-22-001

Current participating Institutes, Centers and Offices



New Areas of Focus

- Implementation Science trials study strategies for implementing evidence-based interventions into healthcare delivery.
- Trials to address health disparities in health care delivery
- Engaging health care systems with less historical involvement in research studies

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NCCIH Areas of Interest

Applications should include a complementary or integrative interventions with **strong evidence of efficacy to warrant their inclusion in health care delivery:**

- Management of chronic pain conditions
- Promotion of whole person health, health restoration, emotional well-being, or resilience
- Prevention or treatment of symptoms including sleep disorders or disturbances, depression, anxiety, post-traumatic stress (disorder), and obesity
- Enhancement of adherence to medications or prescribed behavioral approaches
- Reduction of inappropriate use of medications or substances
- Improving minority health and eliminating disparities in the above conditions

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NCCIH expects to support 1-2 projects

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NIA Areas of Interest

NIH National Institute on Aging

Include but are not limited to:

- Compare effectiveness of treatment strategies for comorbid conditions that occur frequently in combination with Alzheimer's disease and Alzheimer's disease-related dementias (AD/ADRD).
- Evaluation of beneficial and adverse outcomes from differing management strategies for multiple chronic conditions, testing an intervention, or coordinating several interventions.
- Evaluation of benefits and harms of screening for cognitive impairment in community-dwelling older adults in primary care–relevant settings, and effect on decision-making, patient, family or caregiver, and/or societal outcomes.
- Evaluation of benefits and harms of interventions for mild cognitive impairment or mild to moderate dementia in older adults in terms of decision-making, patient, family or caregiver, and/or societal outcomes.

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NIA expects to support 1-2 projects

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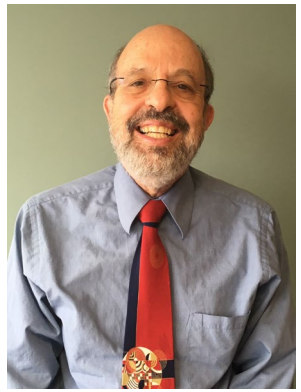
NHLBI's Perspective (Key criteria)

- If at least two of the three or more participating health care systems are Federal Qualified Health Center (FQHC) networks or similar safety net health care systems.
- Applications that propose embedded pragmatic clinical or implementation trials which focus on improving heart, lung, blood, or sleep (HLBS) disorders in an underserved US patient populations who have suffered a disproportionate disease burden, and which focus on interventions to reduce health disparities are high priority.
- Many examples are listed but they are only illustrative



Lawrence Fine email:
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An email with the RFA number and your tentative specific aims are helpful.

If you know a NHLBI program official who is likely to be interested in your topic, reaching out to them directly or cc them is a good idea.

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NINR Areas of interest

- NINR supports research that builds the scientific foundation for nursing practice and policy across diverse clinical and community settings to advance the prevention, detection, and management of disease and disability across the lifespan.

- NINR encourages research that integrates factors at multiple levels to identify their role in health, health improvement and health inequities with the goal of improving the health of individuals, families, and populations by translating science in order to maximize the impact of findings on practice and policy.

- In the context of this FOA, priority will be given to studies that propose projects that:

    - Study social needs care, integrating services that address health-related social risk factors and social needs within the context of clinical practice and health care delivery

    - Projects that are targeted at the medically underserved, uninsured, and underinsured populations

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NINR expects to support one project

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NIAMS Areas of Interest

Study topics for pragmatic trials of interest to NIAMS include:

- Approaches to improve the management of chronic rheumatic, muscle, bone, joint, and/or skin diseases in adults and children, particularly through testing the use of different regimens to optimize outcomes and reduce known risks.

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NIAMS expects to support 1 project

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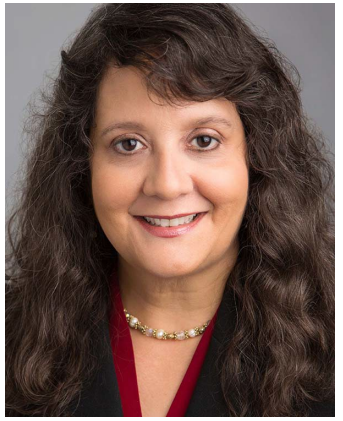
NIMHD Areas of Interest

- NIMHD is interested in multilevel pragmatic intervention studies within the context of health care systems that serve primarily or a significant number of patients from populations with health disparities:
  - Multi-level interventions focused on reducing unnecessary or preventable emergency care utilization.
  - Multi-level interventions focused on reducing delayed health care system response to needed emergency care especially in remote or low-income settings and for patients for whom English is not their primary language.
  - Interventions testing the incorporation of technology to enhance communication between the patient and the health care system, and promote patient agency and decision making and/or medical adherence.
  - Interventions focused on older adult wellness aimed at reducing polypharmacy and serious or incapacitating medication side effects, and accounting for sociocultural determinants of health.
  - Studies focused on enhancing timely access to services conspicuously delayed for many patients from populations with health disparities.
  - Multi-level interventions on facilitating access and referral to timely palliative and/or end of life care for patients from populations with health disparities.



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NIMHD expects to support 1 project

NIMHD Research Framework

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Important things to know 

- Online resources are available for the development of pragmatic trial grant applications
- NIH has new policies and forms related to clinical trial grant applications
- Some things, such as milestones and safety monitoring, may be negotiable around the time of an award

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Tailor the application

Tailor your application to address all the FOA-specific instructions and review criteria

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Common application pitfalls

- Overly ambitious–beyond the life or length of the application
- Missing or inappropriate control groups
- Lack of sufficient expertise or skilled collaborators needed to complete the studies
- Not sufficient publications in the area of proposed studies
- Insufficient statistical power
- Cannot recruit the needed population

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Application dos

- Justify the research
- Include pilot data
- Address potential overlaps
- Reduce complexity
- Ensure aims are capable of advancing the field
- Choose appropriately expert personnel for a multidisciplinary team
- Link data collection and analysis to aims
- Justify the use of multiple sites and sample size

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Application dont's

- Skip any steps (eg, literature review)
- Use dense or confusing writing style
- Use appendix inappropriately
- Include untestable aims
- Include non-relevant aims or fishing expeditions
- Assume that prior collaboration is irrelevant

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Strategies for success

- Pose a clear research question
- Convince the reviewer your study is worth doing
- Sell your research plan–highlight the strengths
- Identify weaknesses and explain how you will deal with them
- Tailor your application to the funding agency
- Obtain feedback from your collaborators, consultants, and others

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Watch the Technical Assistance Webinar

https://videocast.nih.gov/watch=45075

Technical Assistance Videocast for NIH Health Care Systems Research Collaboratory – Pragmatic and Implementation Trials of Embedded Interventions (UG3/UH3) – RFA-AT-22-001

Questions after the Conference?

Email: nccihwebinarq@nih.gov

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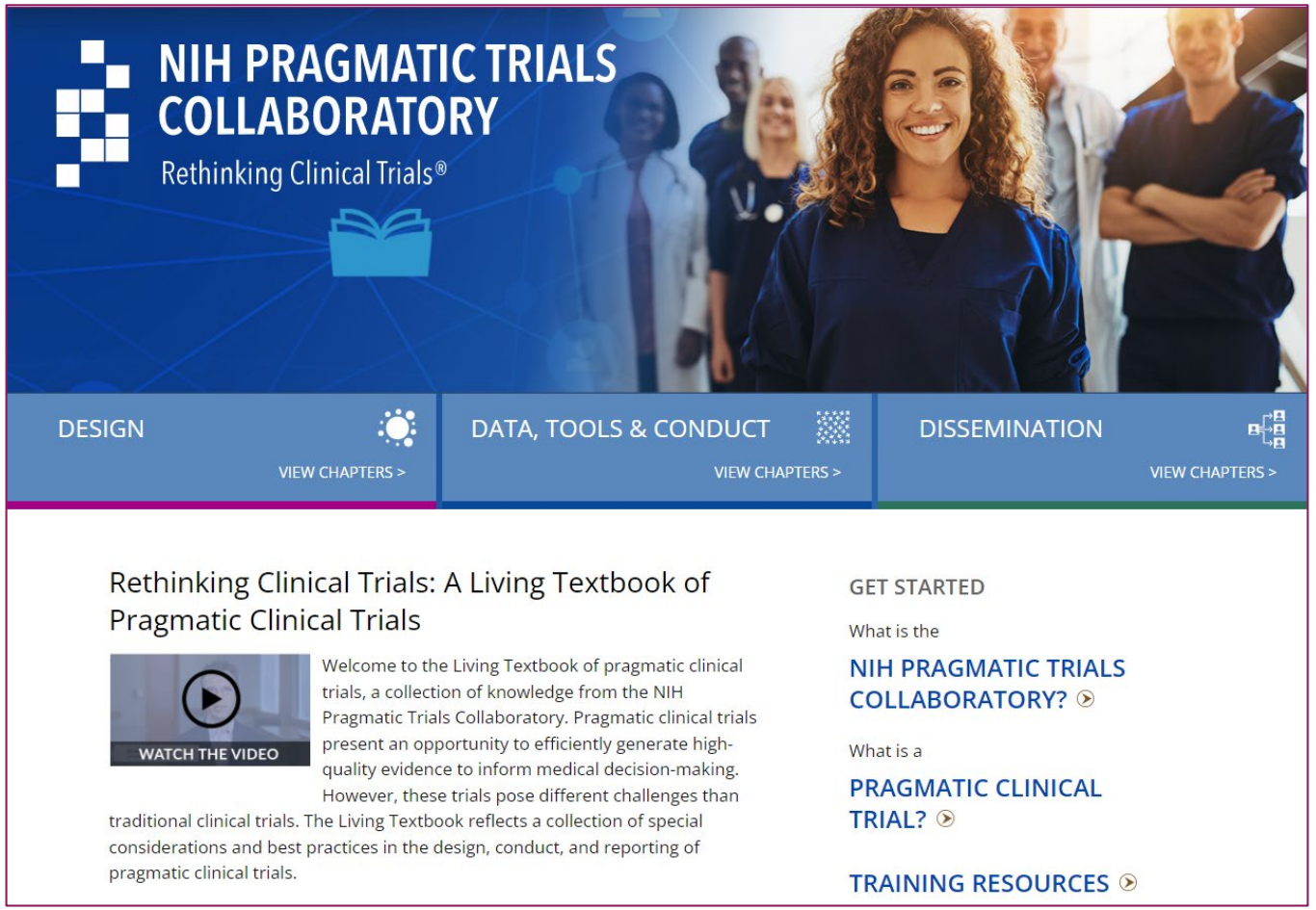
Resource: The Living Textbook

Visit the Living Textbook of Pragmatic Clinical Trials at

www.rethinkingclinicaltrials.org



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