Writing a Compelling Grant Application

Beda Jean-Francois, PhD
Program Director, Clinical Research in Complementary and Integrative Health Branch
National Center for Complementary and Integrative Health (NCCIH)

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Learning goal

- Learn how to develop a compelling ePCT application
- Tips from Collaboratory PIs

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Important things to know 👓

- Online resources are available for the development of pragmatic trial grant applications
- NIH continues to update 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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National Institutes of Health

NIH
National Institutes of Health

- NIH is made up of 27 institutes and centers, or ICs
- ICs award >80% of the NIH budget each year for research studies
- Each IC has a budget and a director, and typically their own review for large trials

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Find the right NIH program official

- IC mission and priorities
  - Focus on a specific disease area, organ system, or stage of life
  - Use Matchmaker tool in NIH RePORTER for suggestions
  - Talk to program officials
  - Consult your mentor and colleagues

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NIH RePORTER matchmaker tool

- Use draft of specific aims
- Email query to program official rather than call (we telework and attend meetings)

NIH RePORT RePORTER

Matchmaker

Enter abstracts or other scientific text to find potential Program Officials, ICs, and review panels for your research. ?

○ Similar Projects
○ Similar Program Officials

15,000 characters left

Reset   Search

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Matchmaker results (example)

- This can help to connect you with the most appropriate PO(s)
- Prepare agenda and questions, to productively interact!
- Program officer can recommend a study section or two

Find the right NOFO

- Request for Application (RFA)
  - For specific areas of science where more research is needed, and applications are encouraged for investigator-initiated research in this specific area of science
- Notice of Special Interest (NOSI) and Program Announcement (PA, PAS, PAR)
  - For an area of scientific interest for one or more ICs where investigator-initiated research is needed

NIH scientific contacts

NCCIH	Wendy Weber	**NIDA**	Sarah Duffy
NCI	Wynne Norton	**NIDCR**	Dena Fischer
NHLBI	Larry Fine	**NIDDK**	Susan Medley
NIA	Marcel Salive	**NIMH**	Matthew Rudorfer
NIAAA	Brett Hagman	**NINDS**	Rebecca Hommer
NIAID	Clayton Huntley	**NINR**	Karen Kehl
NIAMS	Chuck Washabaugh	**ODP**	Elizabeth Nielson
NIMHD	Larissa Aviles-Santa		

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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
- Choose sites with access to diverse populations

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Application don'ts

- 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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NIH online resources

https://researchmethodsresources.nih.gov/

- Research methods resources on designing pragmatic and group randomized trials
- NIH Grants Guide: finding NOFOs
- NIH Guidance on Biosketches
- NIH Peer Review
- NIH General Application Guide
- NIH Inclusion Policies for research involving human subjects

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Think through team diversity

- Rethinking Clinical Trials Website: Diversity Workshop Video Modules https://rethinkingclinicaltrials.org/training-resources/diversity-workshop-video-modules/

- NCCIH Hot Topic Webinar: Engaging Diverse Communities in Complementary and Integrative Health (recording online)

- ❖ NIH UNITE Initiative https://www.nih.gov/ending-structural-racism

- NIH continues to support increased participation of women and minority populations in

NCCIH Hot Topic Webinar: Engaging Diverse Communities in Complementary and Integrative Health Research

Date: April 27, 2021 - 12:00 p.m. ET to 2:00 p.m. ET
Location: Virtual

NIH Pragmatic Trials Collaboratory Fellowship

Dr. Stephanie Ibemere
Implementation Science Core
GRACE Demonstration
Project

Dr. Kaitlyn McLeod
Health Equity Core
Nudge Demonstration
Project

- Early career investigators from underrepresented minoritized (URM) groups
- 1 year fellowship (started July 2023)
- Embedded in Core Working Group and research with a Demonstration Project
- Curriculum focused on pragmatic clinical trials

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Important things to do

- Read relevant Funding Opportunity Announcement multiple times
- Identify program staff at your target NIH Institute/Center and review your Specific Aims and any questions about them
- Obtain adequate feedback on the Research Plan from the entire study team

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Resource: The Living Textbook

Visit the Living Textbook of Pragmatic Clinical Trials at

www.rethinkingclinicaltrials.org

Tips from the Demonstration Projects

- What is 1 key tip you would recommend for developing a strong UG3 or UH3 pragmatic grant proposal

Question & Answer

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