

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)



**NIH PRAGMATIC TRIALS
COLLABORATORY**

Rethinking Clinical Trials®

Learning goal

- Learn how to develop a compelling ePCT application
- Tips from Collaboratory PIs
- Q & A with attendees

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

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



National Institutes
of Health

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

NIH RePORTER matchmaker tool

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



Matchmaker

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

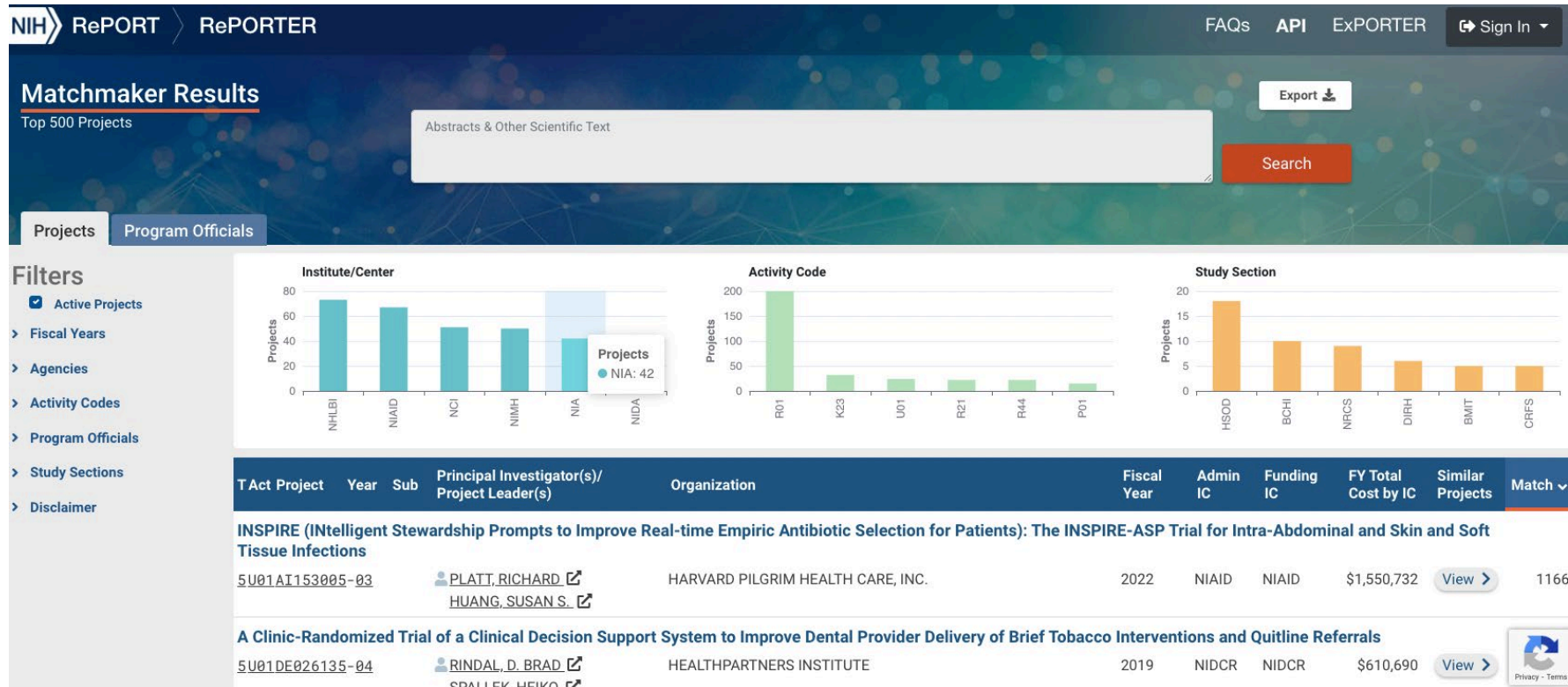
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- Similar Projects
- Similar Program Officials

Reset

Search

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 FOA

- 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
NCI Wynne Norton
NHLBI Larry Fine
NIA Marcel Salive
NIAAA Brett Hagman
NIAID Clayton Huntley
NIAMS Chuck Washabaugh
NICHD Sue Marden
NIMHD Larissa Aviles-Santa

NIDA Sarah Duffy
NIDCR Dena Fischer
NIDDK Susan Medley
NIMH Matthew Rudorfer
NINDS Rebecca Hommer
NINR Karen Kehl
ODP Elizabeth Nielson

Tailor the application

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

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

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

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

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



NIH online resources

<https://researchmethodsresources.nih.gov/>

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

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

COVID-19 Public health information from CDC Research information from NIH | Español NIH staff guidance on coronavirus (NIH Only)

ENDING STRUCTURAL RACISM

UNITE



file:///H:/trennial report data/The NIH UNITE Initiative _ National Institutes of Health (NIH).html

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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

Tips from the Demonstration Projects

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