

Living Textbook Grand Rounds Series
Tips for Putting Together a
Successful PCT Grant Application

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Agenda

- Confirm PCT is the best design
- Find the right NIH program official
- Find the right funding opportunity announcement (FOA)
- Write a strong proposal that addresses review criteria



Does your study have the right design?

- Be clear about the hypothesis you want to test and then design the study to test that hypothesis
- PCTs are not the appropriate design to answer clinical trial questions

Key differences between explanatory and pragmatic trials

| | EXPLANATORY | PRAGMATIC |
|------------------------------|---|--|
| Research question | Efficacy: Can the intervention work under the best conditions? | Effectiveness: Does the intervention work in routine practice? |
| Setting | Well-resourced “ideal” setting | Routine care settings including primary care, community clinics, hospitals |
| Participants | Highly selected | More representative with less strict eligibility criteria |
| Intervention design | Tests against placebo, enforcing strict protocols & adherence | Tests 2 or more real-world treatments using flexible protocols, as would be used in routine practice |
| Outcomes | Often short-term surrogates or process measures; data collected outside of routine care | Clinically important endpoints; at least some data collected in routine care |
| Relevance to practice | Indirect: Not usually designed for making decisions in real-world settings | Direct: Purposefully designed for making decisions in real-world settings |

Adapted from Zwarenstein M, Treweek S, Gagnier JJ, et al. BMJ. 2008;337:a2390. doi: 10.1136/bmj.a2390. PMID: 19001484



Important things to know

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

National Institutes of Health



National Institutes
of Health

- NIH is made up of 27 institutes and centers, or ICs
- ICs award >80% of the NIH budget each year to extramural investigators
- Each IC has a budget and a Director, and often their own review for large trials



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 (specific aims)
- Consult your mentor and colleagues

NIH RePORTER matchmaker tool

U.S. Department of Health & Human Services Text Size A A A

NIH Research Portfolio Online Reporting Tools
(RePORT)

Search

HOME | ABOUT RePORT | FAQs | GLOSSARY | CONTACT US

QUICK LINKS | RESEARCH | ORGANIZATIONS | WORKFORCE | FUNDING | REPORTS | LINKS & DATA

Home > RePORTER > Matchmaker MyRePORTER Login | Register | RePORTER Manual | System Health: GREEN

NIH RePORTER
Version: 7.40.0

About RePORTER DATA | FAQ | ExPORTER | RSS of Newly Added Projects

QUERY | BROWSE NIH | **MATCHMAKER** | SEARCH PUBLICATIONS BETA

Use Matchmaker to find similar projects and program officials

Enter abstracts or other scientific text and Matchmaker will return lists of similar projects from RePORTER or program officials associated with those projects. These matches are based on the terms and concepts used in the submitted text. Up to 15,000 characters are permitted. Matchmaker summarizes the projects by the program official, institute or center, review panel, and activity code. [VIEW TUTORIAL](#)

Enter your Text:

Terms will be weighted by frequency of appearance in the text above. The process is automated and confidential. The Matchmaker system does not track and store submitted text. Characters left: 15000

[CLEAR](#) [SIMILAR PROJECTS](#) [SIMILAR PROGRAM OFFICIALS](#)

Download Readers:

Matchmaker results (example)



Matchmaker Results

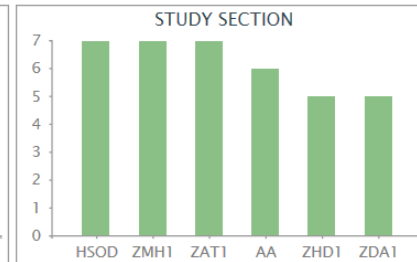
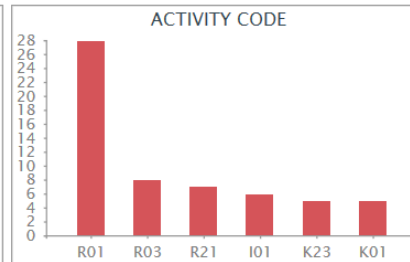
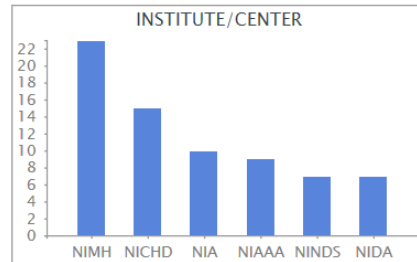
Matchmaker New Query

Export All Projects

100 projects similar to concepts from the entered text. (100 maximum)

Show/Hide Search Criteria

Click on chart labels to filter search results by the Institute/Center or Activity Code or Study Section



Click on the column header to sort the results

Records per page 25

[Click here to view detailed Charts](#)

1 2 3 4

1 of 4 [Next](#) [Last](#)

T: Application Type; Act: Activity Code; Project: Admin IC, Serial No.; Year: Support Year/Supplement/Amendment

| Match Score | T | Act | Project | Year | Sub # | Project Title | Contact PI / Project Leader | Organization | FY | Admin IC | Funding IC | FY Total Cost by IC | Similar Projects |
|--------------------------|------|-----|---------|----------|-------|--|-----------------------------|--------------------------|------|----------|------------|---------------------|------------------|
| <input type="checkbox"/> | 3046 | 5 | UH3 | MH106338 | 04 | A POLICY RELEVANT US TRAUMA CARE SYSTEM PRAGMATIC TRIAL FOR PTSD AND COMORBIDITY | ZATZICK, DOUGLAS E | UNIVERSITY OF WASHINGTON | 2017 | NIMH | NIMH | \$219,246 | |



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
 - Usually single receipt date and special emphasis review panel
 - Specifies amount of funds available and number of awards that may be made



Find the right FOA

- Parent Program Announcements (PA)
 - Allow investigator-initiated applications in many areas of science
 - Confirm Institute or Center participation
- Other Program Announcement (PA, PAS, PAR)
 - For an area of scientific interest for one or more ICs where investigator-initiated research is needed
 - Often multiple receipt dates
- Usually reviewed by standing study section



NIH scientific contacts

- Check the FOA for the Scientific Contact of the relevant IC
- If applying to parent FOA consider contacting IC contact:

NCCIH Robin Boineau
NCI Erica Breslau
NHLBI Catherine Stoney
NIA Marcel Salive
NIAAA Brett Hagman
NIAID Clayton Huntley
NIAMS Chuck Washabaugh
NICHD Sue Marden

NIDA Sarah Duffy
NIDCR Dena Fischer
NIDDK Susan Mendley
NIMH Jane Pearson
NIMHD Benyam Hailu
NINDS Robin Conwit
NINR Karen Huss
ODP Jacqueline Lloyd




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



Don't assume that the study panel is going to understand what pragmatic means. They may have their own completely different definition than you, and it's important that you get on the same page early on in your application.

Application dos



- Justify the research
- Include pilot data
- Address potential overlaps
- Reduce complexity
- Ensure aims will advance 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

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 research methods resources

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

 U.S. Department of Health & Human Services



Research Methods Resources

Home

GRT

IRGT

GRT Sample Size Calculator

Glossary

References

FAQs

Feedback

The NIH is launching a series of initiatives in 2017–2018 to enhance the accountability and transparency of clinical research. These initiatives target key points along the entire clinical trial lifecycle, from concept to results reporting.

- Expanded [ClinicalTrials.gov registration and reporting policy](#) covers all NIH-funded clinical trials, effective January 18, 2017.
- New [clinical trial requirements](#) for NIH grants and contracts with due dates on or after January 25, 2018.
- New [application forms \(FORMS-E\) and application guide](#) for all NIH research applications with due dates on or after January 25, 2018.
- New [review criteria](#) for clinical trial applications with due dates on or after January 25, 2018.
- New [single IRB policy](#) for research applications for multi-site studies with due dates on or after January 25, 2018.

The Research Methods Resources website provides investigators with important research methods resources to help them satisfy these new requirements. While the website currently only addresses methodological issues inherent in trials that randomize groups or deliver interventions to groups, new methods-related topics and resources will be added in the future. For a guided tour of this website, please refer to a recent [Mind the Gap webinar](#), which presents additional information about its relevance to the new NIH requirements for clinical trials applications, a summary of the methodological issues inherent in nested study designs, and a demonstration of how to use the Group-Randomized Trials (GRT) Sample Size Calculator.

Trials that Randomize Groups or Deliver Interventions to Groups



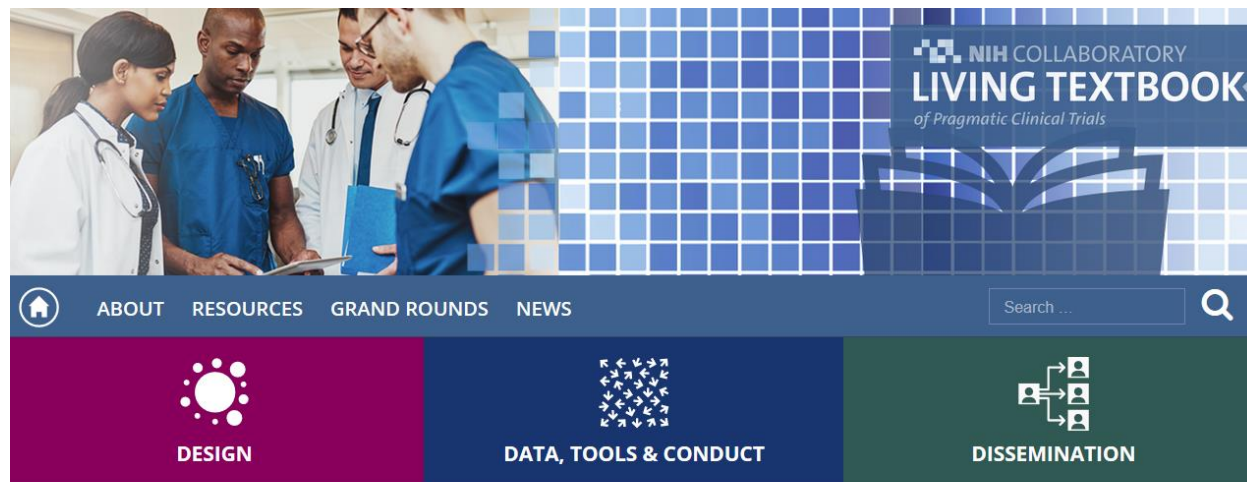
Important things to do

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

ePCT Resource: The Living Textbook

Visit the Living Textbook of Pragmatic Clinical Trials at

www.rethinkingclinicaltrials.org



Rethinking Clinical Trials: A Living Textbook of Pragmatic Clinical Trials



Welcome to the Living Textbook of pragmatic clinical trials, a collection of knowledge from the NIH Health Care Systems Research Collaboratory. Pragmatic clinical trials are performed in real-world clinical settings with highly generalizable populations to generate actionable clinical evidence at a fraction of the typical cost and time needed to conduct a traditional clinical trial. They present an opportunity to efficiently address critical knowledge gaps and generate high-

GET STARTED

What is the

[NIH COLLABORATORY?](#) >

What is a

[PRAGMATIC CLINICAL TRIAL?](#) >

[BUILDING PARTNERSHIPS](#) >

Design chapter: Developing a Compelling Grant Application



DESIGN



DATA, TOOLS & CONDUCT



DISSEMINATION

DEVELOPING A COMPELLING GRANT APPLICATION

SECTION 1

Introduction

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