



Health Care Systems Research Collaboratory

*Rethinking Clinical Trials®*

# Writing a Grant Application

Marcel Salive, MD, MPH  
National Institute on Aging

***Essentials of Embedded Pragmatic Clinical Trials Seminar***



## Learning goal

Learn how to develop a compelling ePCT application



## 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

# National Institutes of Health



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



# Understand NIH: find the right fit

## IC mission and priorities

- Focus on a specific disease area, organ system, or stage of life
- Use the Matchmaker tool in [NIH RePORTER](#) for suggestions
- Talk to program officials
- Consult your mentor and colleagues

# NIH RePORTER

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: 7.39.0

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**

[https://projectreporter.nih.gov/reporter\\_matchmaker.cfm](https://projectreporter.nih.gov/reporter_matchmaker.cfm)

# Matchmaker results



# Grant versus cooperative agreement

Under assistance relationships:

- Grants (R) are used when no substantial programmatic involvement is anticipated between the Federal agency and the recipient during performance of the assisted activity
- Cooperative agreements (U) are used when substantial programmatic involvement is anticipated between the Federal agency and the recipient during performance of the assisted activity
- Not necessarily important for developing the application



# NIH Research Collaboratory: RFA-RM-16-019

## Scientific contacts from participating NIH Institutes and Centers

<b>NCCIH</b>	Robin Boineau	<b>NIDA</b>	Sarah Duffy
<b>NCI</b>	Erica Breslau	<b>NIDCR</b>	Dena Fischer
<b>NHLBI</b>	Barbara Wells	<b>NIDDK</b>	Andy Narva
<b>NIA</b>	Marcel Salive	<b>NIMH</b>	Jane Pearson
<b>NIAAA</b>	Brett Hagman	<b>NINDS</b>	Robin Conwit
<b>NIAID</b>	Clayton Huntley	<b>NINR</b>	Jeri Miller
<b>NIAMS</b>	Chuck Washabaugh	<b>ODP</b>	Rachael Ballard
<b>NICHD</b>	Sue Marden		

Use Matchmaker tool in [NIH RePORTER](#) for suggestions

# Which study section?

- Mostly Institute-specific special emphasis panels
- Center for Scientific Review (CSR) Study sections
  - **Health Services Organization and Delivery Study Section**
  - Health services research studies that include multidisciplinary investigations of the organization, delivery, utilization, and outcomes of health services, including availability, access and acceptability; quality of care; costs and cost-effectiveness; *comparative effectiveness*; and financing of health care. Clinical study settings include inpatient, outpatient, sub-acute, acute, community-based, rehabilitative, and long-term care.
- An important question to discuss with NIH program staff, particularly with respect to pragmatic vs explanatory trial

Source:

<https://public.csr.nih.gov/StudySections/IntegratedReviewGroups/HDMIRG/HSOD/Pages/default.aspx>

# Finding a funding announcement: www.grants.nih.gov



## Grants & Funding

NIH's Central Resource for Grants and Funding Information

Entire Site



Search this Site



[eRA](#) | [NIH Staff](#) | [Glossary & Acronyms](#) | [FAQs](#) | [Help](#)

HOME

ABOUT GRANTS

FUNDING

POLICY &  
COMPLIANCE

NEWS & EVENTS

ABOUT OER

[Home](#) » [Funding](#) » [Funding Opportunities \(RFAs, PAs\) & Notices](#) » [Advanced Funding Opportunities & Notices Search Results](#)

## Advanced Funding Opportunities & Notices Search Results

### Related Links:

Active Funding Opportunities (RFAs & PAs) For Issuing Organization: NIA

Search within All Matching Records:

Search

- [Funding Opportunities & Notices](#)
- [Advanced Funding Ops Search](#)
- [Advanced OER Site Search](#)
- [Search Help](#)

Matching Records: 109

Sorted by: Release Date (Desc) then Announcement Number

# Read FOA carefully

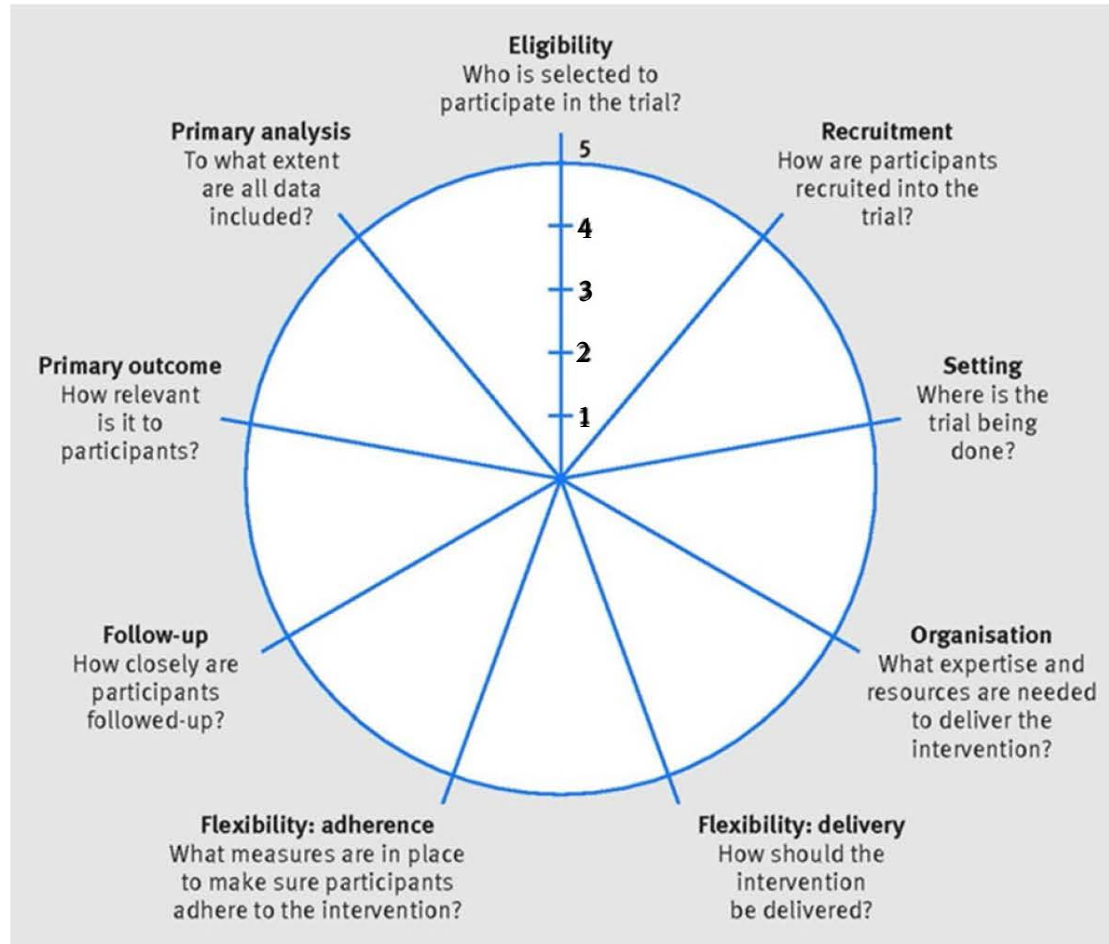
- Funding Opportunity Description and Research Opportunities section is crucial, of course
- Application and Submission Information for page limits and specifics for the Aims and Research Strategy sections
- Look at Application Review Information for Review criteria, since they may NOT be STANDARD; they are often specific for the FOA
- READ CAREFULLY and several times

# NIH review criteria—clinical trials

- Application may include study design, methods, and intervention that are not by themselves innovative but address important questions or unmet needs
- Has new questions under each of the standard criteria, in particular the Approach section should address Study Design, Data Management and Statistical Analysis.
- One Additional Review Criteria for **Study Timeline**

Is the study timeline described in detail, taking into account start-up activities, the anticipated rate of enrollment, and planned follow-up assessment? Is the projected timeline feasible and well justified? Does the project incorporate efficiencies and utilize existing resources (eg, CTSA's, practice-based research networks, electronic medical records, administrative database, or patient registries) to increase the efficiency of participant enrollment and data collection, as appropriate? Are potential challenges and corresponding solutions discussed (eg, strategies that can be implemented in the event of enrollment shortfalls)?

# PRECIS-2 domains



PRECIS-2 source: Kirsty Loudon et al. BMJ 2015;350:bmj.h2147. Copyright 2015 by British Medical Journal Publishing Group. Used by permission.

# Common application pitfalls

- Overly ambitious—beyond the life/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

# Avoid receiving these summary statement comments

Data provided did not establish the feasibility of recruitment

The premise of the study is based on weak evidence

No adequate description of how activities in the planning phase would inform activities in the implementation phase

Concerned whether outcomes of this study would drive a change in clinical practice

Amount budgeted for a biostatistician is much too low



# 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


# Application dos

- Justify the research
- Include pilot data
- Reduce complexity
- Ensure aims are capable of advancing the field
- Choose appropriate expert personnel
- Link data collection and analysis to aims
- Justify 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

# NIH research methods resources

 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

<https://researchmethodsresources.nih.gov>



## 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 with them
- Obtain adequate feedback on the Research Plan from the entire team

# NIA resources: Blog

[www.nia.nih.gov/research/blog](http://www.nia.nih.gov/research/blog)

## Pragmatic clinical trials: Testing treatments in the real world

June 07, 2017



Marcel SALIVE,  
*Health Scientist Administrator,  
Division of Geriatrics and Clinical Gerontology (DGCG).*

Clinical Research

Funding Opportunities

Research

Do you know the difference between an explanatory and a pragmatic clinical trial? Many researchers are familiar with explanatory clinical trials, which look at the effectiveness of a particular intervention to improve health in a controlled setting. But what makes a clinical trial pragmatic?

### Blog Topics

Select Topic ▼

ABOUT THIS BLOG

COMMENT POLICY

NIA FUNDING INFORMATION



**NIH** National Institute  
on Aging