



Topic 10: Developing a Compelling Application

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Collaboratory ePCT Training Workshop

Outline

- Which Institute?
- Which FOA?
- Strategies for success
- Resources
- Q&A

Understand NIH: find the right fit

Where's the money?

- NIH is made up of 27 institutes and centers 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



IC mission and priorities

- Focus on a specific disease area, organ system, or stage of life
- Check their website
- Use Matchmaker tool in NIH RePORTER for suggestions
- Speak with program officials
- Consult your mentor & colleagues

NIH RePORTER

NIH Research Portfolio Online Reporting Tools (RePORT)

Search

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

Home > RePORTER > Matchmaker

My RePORTER Login | Register | RePORTER Manual System Health: GREEN

NIH RePORTER Version: 7.24.0 CHECK OUT FEDERAL RePORTER

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

Use Matchmaker to find similar projects

Enter abstracts or other scientific text and Matchmaker will return a list of 100 similar projects from RePORTER. These matches are based on the terms and concepts used in the submitted text. Up to 15,000 characters are permitted. [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

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Source: https://projectreporter.nih.gov/reporter_matchmaker.cfm

Matchmaker results



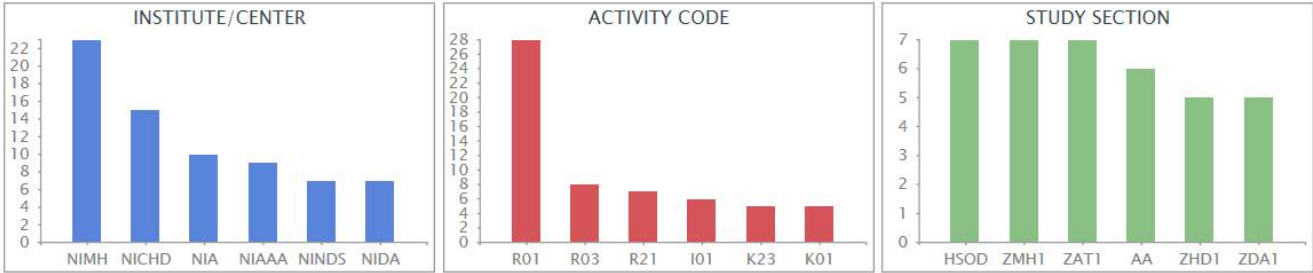
Matchmaker Results

Matchmaker New Query

Export All Projects GO

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 1 2 3 4 Click here to view detailed Charts 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 F	UNIVERSITY OF WASHINGTON	2017	NIMH	NIMH	\$219,246	

Grant vs 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

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

Which study section?

- Mostly Institute-specific special emphasis panels
- 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

2017 NIH RFAs: RM-16-019 AG-17-059

- Demonstration Projects that include an efficient, large-scale pragmatic clinical trial; Alzheimer focus
- Multiple NIH Institutes, topics vs NIA
- Collaborate with 2+ HCS, n/a
- Part of NIH Collaboratory vs standalone
- Mechanism UG2/UH3 vs R21/R33

Review Criteria RFA-RM-16-019

Scored Criteria

- Significance
- Investigators
- Innovation
- Approach
- Environment

Additional Review Criteria

- **Milestones**
- Resources and Data Sharing Plan
- **Software Sharing Plan**
- Protection of HS
- Inclusion of Women, Minorities & Children
- Biohazards

All these aspects are considered by reviewers and they do influence the “Overall Impact” score of an application

Several review criteria, as well as the language under the criteria in this FOA, are NOT STANDARD; they are specific for this FOA – READ CAREFULLY

Pragmatic trials of managing multimorbidity in Alzheimer's disease

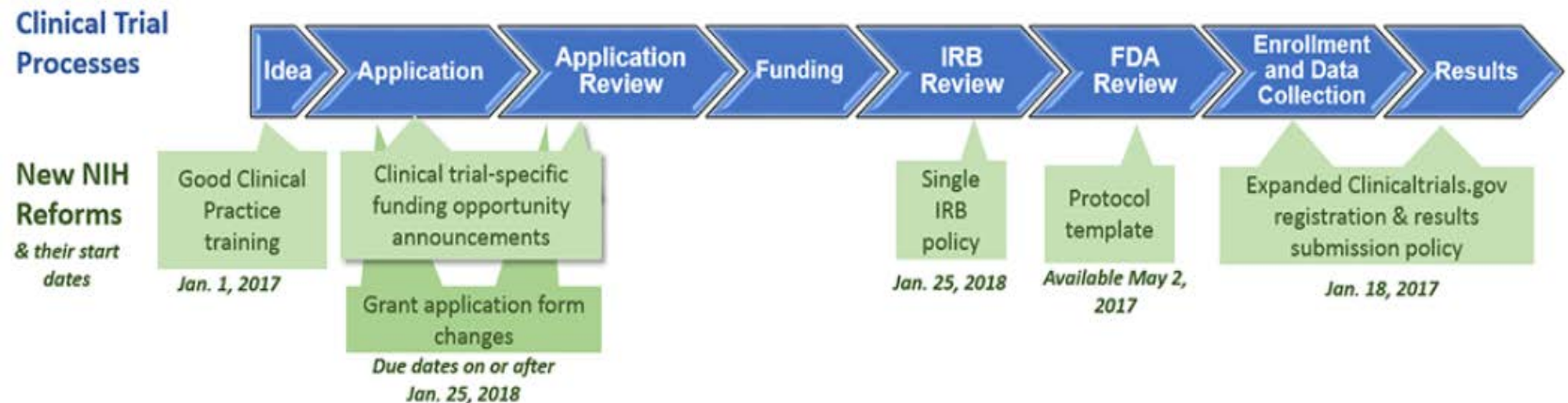
- RFA-AG-18-028
- R01 Clinical Trial Required
- Reissue of RFA-AG-17-059
- Due date: March 26, 2018
- Conduct research involving pragmatic clinical trials into improving the effectiveness of treatment strategies for comorbid conditions that occur frequently in combination with Alzheimer's disease and related dementia (ADRD)
- Phasing is optional
- Uses new clinical trial review criteria

Pragmatic trials for dementia care in long-term services and support settings

- PAR-18-585
- R61/R33 - Clinical Trial Required
- Reissue of RFA-AG-17-065
- Due dates: March 27, 2018; February 20, 2019; and February 20, 2020
- Pragmatic trials for dementia care in LTSS settings designed to address practical comparative questions faced by Alzheimer's disease (AD) and AD-related dementia (ADRD) patients, clinicians and caregivers (both paid and unpaid) and intended to improve quality of care, quality of life, improve cost-effectiveness and reduce disparities
- Pilot research to test the feasibility of implementing and integrating LTSS interventions (R61 phase) that, if successful, can transition to an R33 phase for implementation of large pragmatic trials, using administrative review as basis to advance
- Uses new clinical trial review criteria

NIH clinical trial requirements

- Series of initiatives in 2017-2018 to enhance the accountability and transparency of clinical research
- Clinical Trial-specific Funding Opportunities
- Clinical Trial-specific Review Criteria
- Single IRB requirement

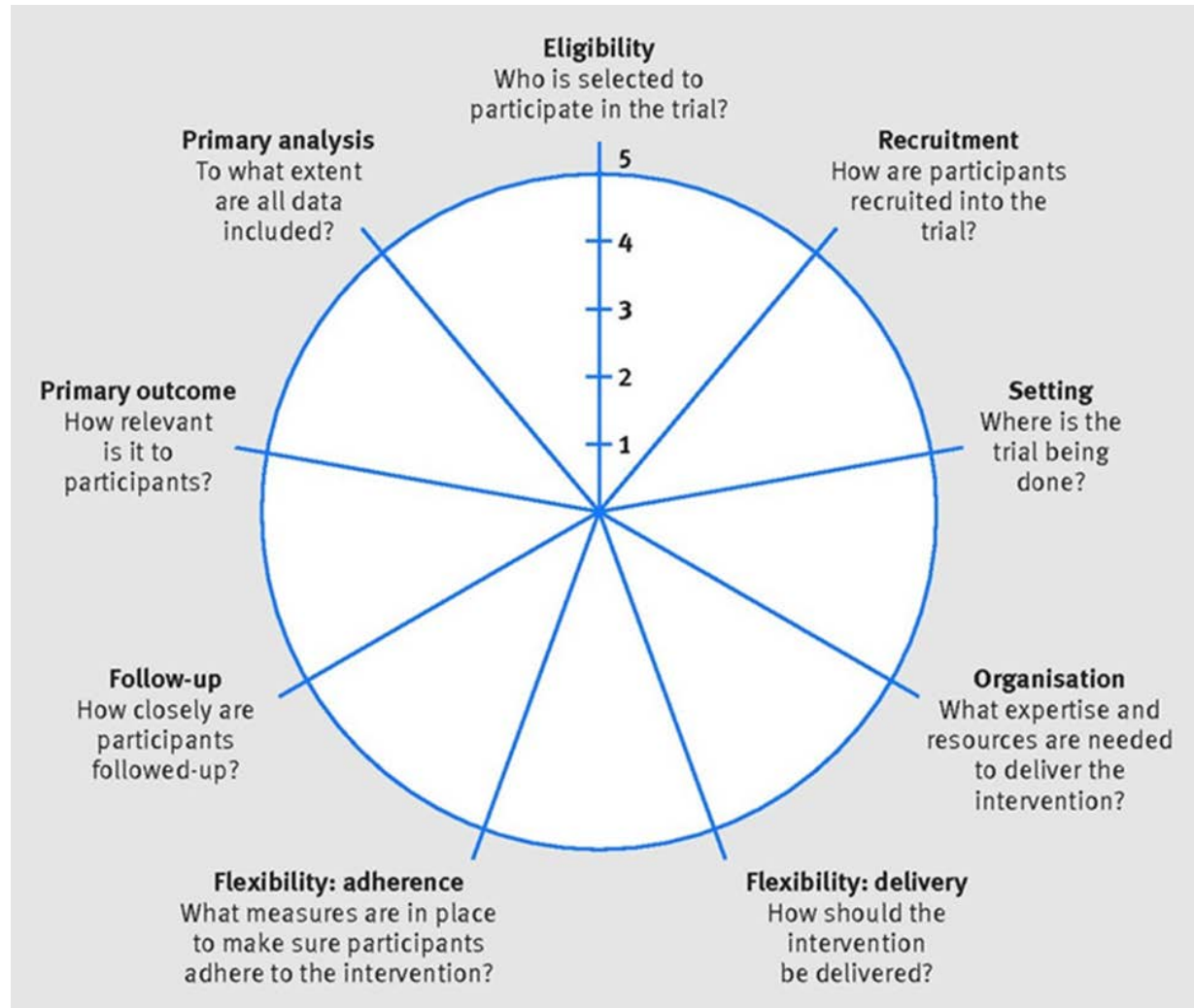


New review criteria—clinical trials

- 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





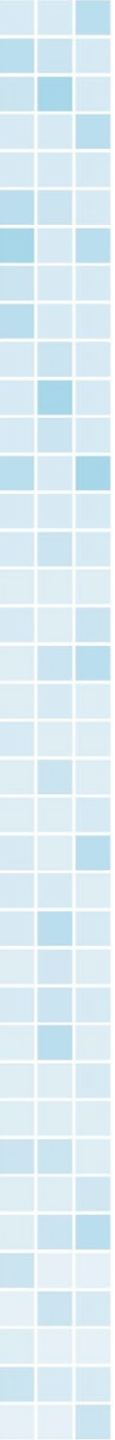
**Some real (troubling) summary
statement comments ...**

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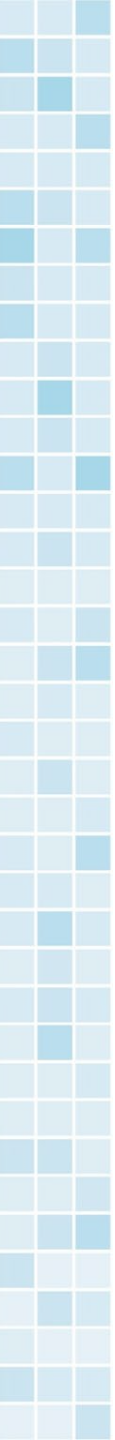
“The premise of the study ... is based on weak evidence”

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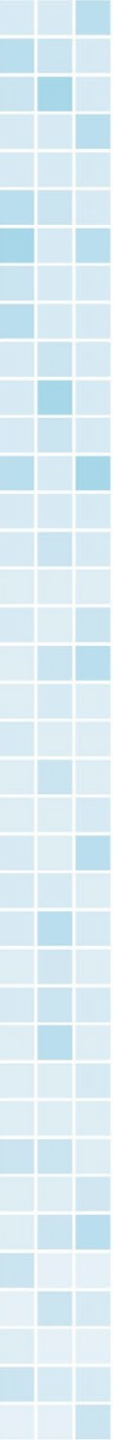
“Data provided did not establish
the feasibility of recruitment”

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“The differences in anticipated [outcome] rates upon which the study is powered are quite large—larger differences than are seen in other similar trials”

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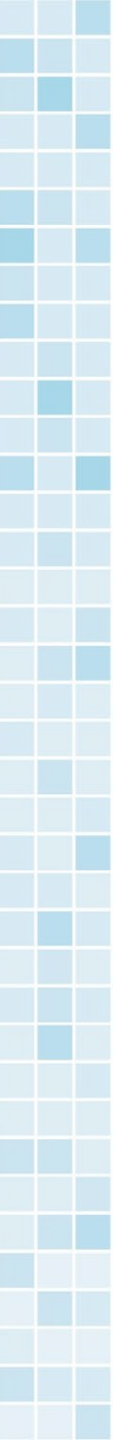
“No adequate description of how activities in the planning phase would inform activities in the implementation phase of the study”



“Concerns include the inclusion/exclusion criteria for the study, inadequate power for the study, and whether outcomes of this study would drive a change in [clinical] practices”



“There are no measures of
intervention fidelity”

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“Investigative team ... had limited experience with multi-systems clinical trials”

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“Amount budgeted for a
biostatistician is much too low”

Common 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

Strategies for success

- The research question posed must be clear
- The most elegant methods, techniques, and procedure are worthless if you do not convince the reviewer that the study is worth doing
- High tech is no substitute for solid logical planning
- Sell your research plan—highlight the strengths
- Identify weaknesses & explain how you will deal with them
- Tailor your application to the funding agency
- Obtain feedback of your collaborators, consultants & others

Dos and don'ts

DO

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

Dos and don'ts

DON'T

- Skip any steps (eg, literature review)
- Use dense/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

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

Discussion questions

- Non-disease vs disease-specific institute?
 - Consult program officers for both
- Single vs multiple PI? Suitability for assist mechanism (U)?
- What materials would be good for training reviewers?
- Other individual questions that might be of more general interest



Important things to know

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



Important things to do

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



For further information, contact

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Next steps for your project

