NIH Collaboratory

Health Care Systems Research Collaboratory

Rethinking Clinical Trials®

Writing a Grant Application

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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

National Institutes of Health

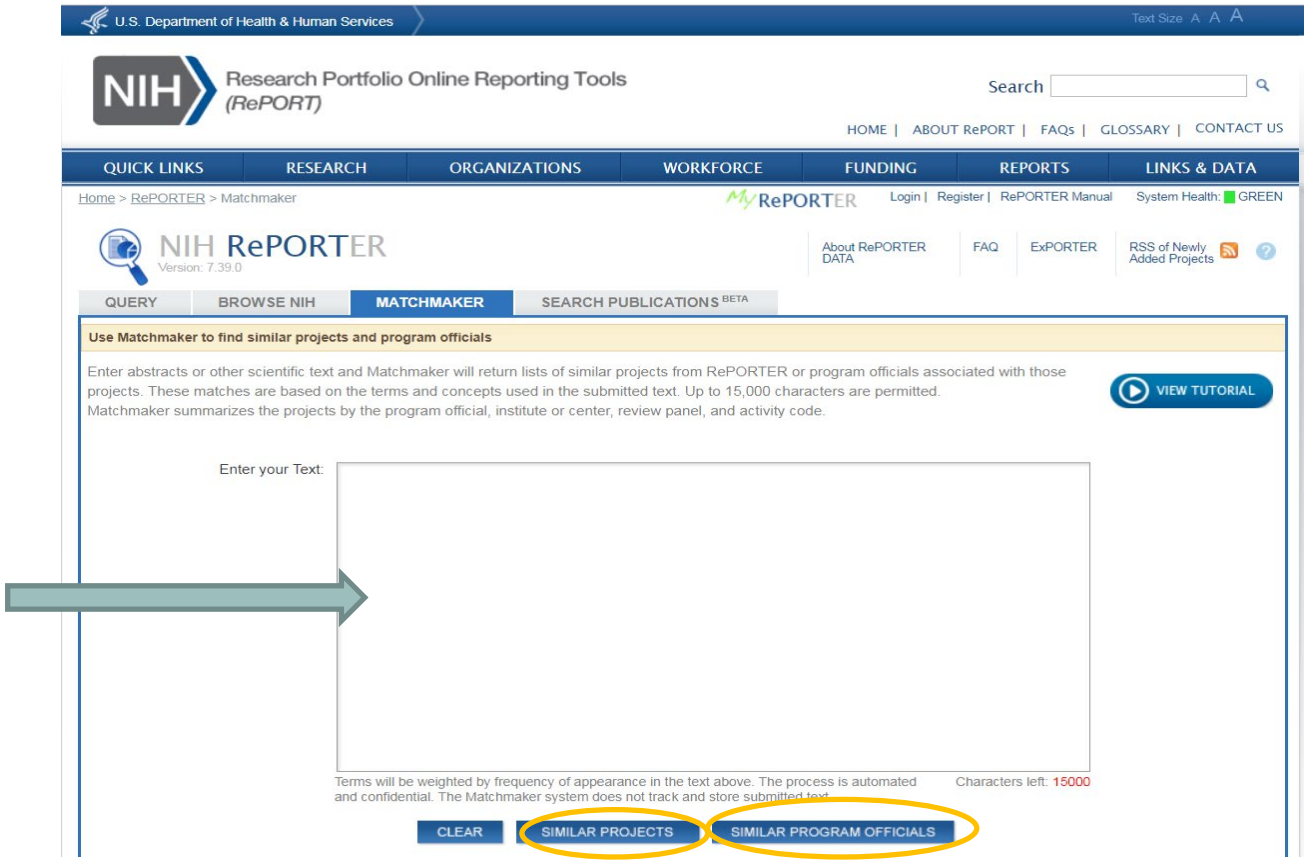
- NIH is made up of 27 institutes and centers (IC)
- ICs award >80% of the NIH budget each year
- Each IC has a budget and a director, and typically their own review for large trials

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



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

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		

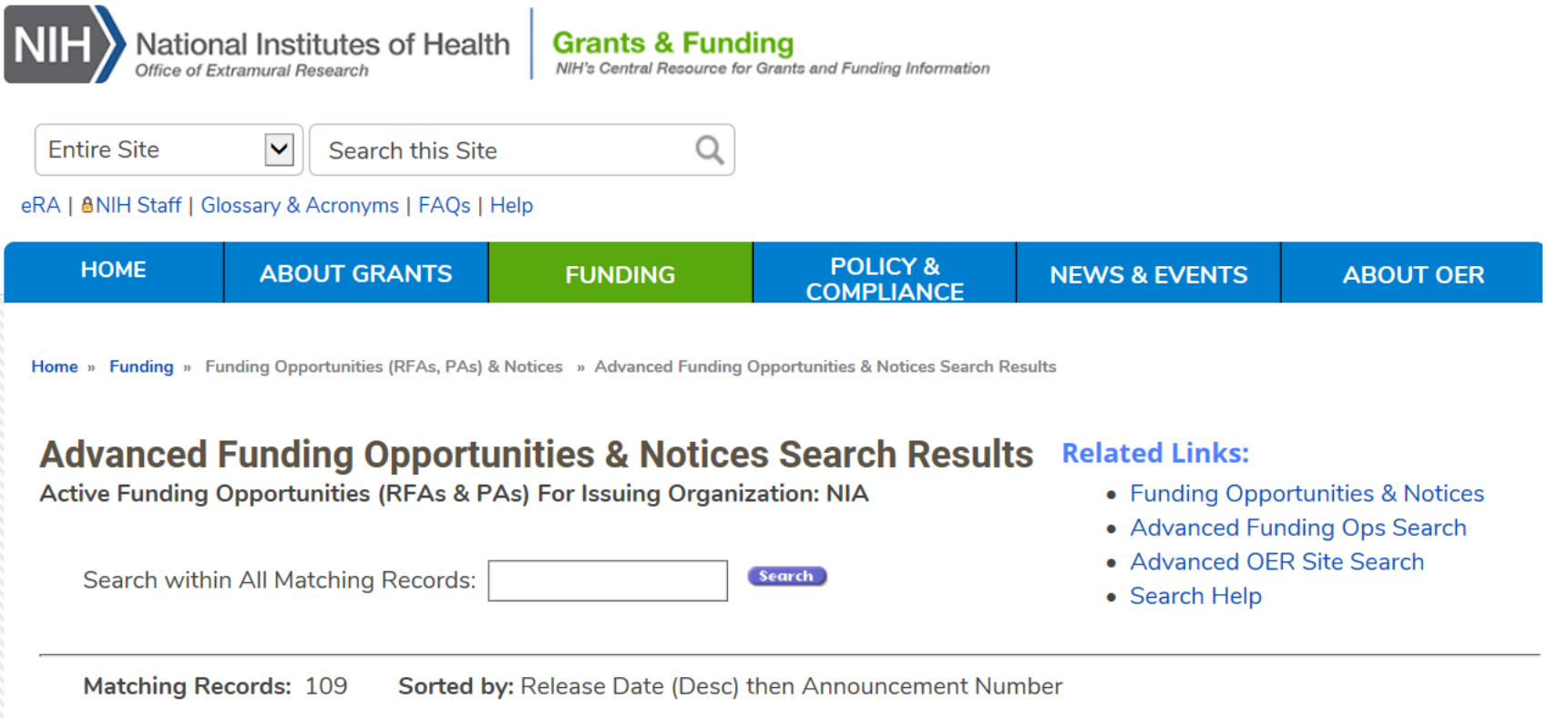
Use Matchmaker tool in NIH RePORTER for suggestions

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



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

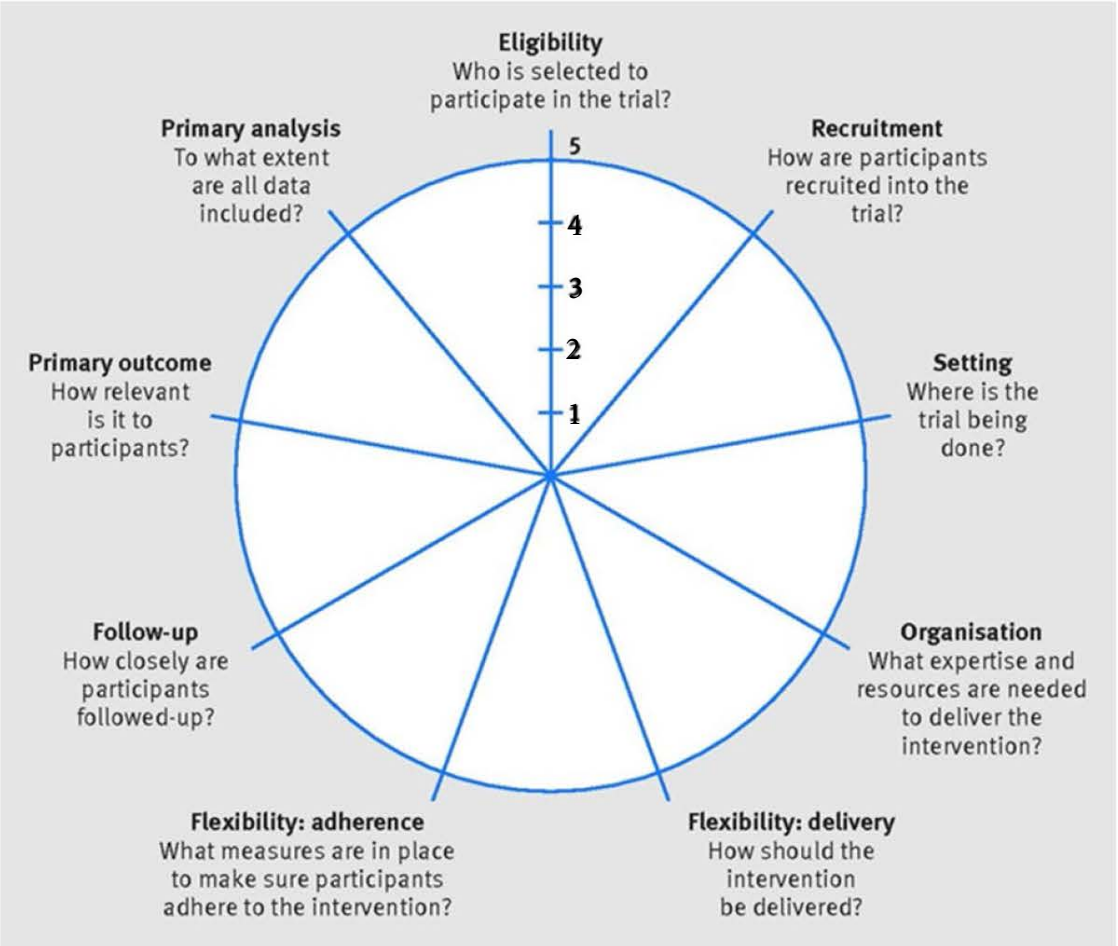
NIH review criteria—clinical trials

- 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, CTSAs, 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)?

Source: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-118.html

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

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

Pragmatic clinical trials: Testing treatments in the real world

June 07, 2017

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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

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NIA FUNDING INFORMATION

NIH National Institute on Aging