

Funding for PBRN research: Practical Insights

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Disclaimer

- We have no conflict of interests.
- Presenting highlights of our opinions of issues to consider for preparing compelling application.
- Granting agencies (e.g. DHHS, CIHR)generated material should be considered the definitive instructions for grant applications

Outline

- Application Process, Personnel
- Research Concept Preparation
 - Initial Concept
 - Funding Sources
 - Alignment
- Grant Submission and Assignment
- Review Process:
 - Garnering Insights
 - Expectations
- Post-Review
- Advice/Lessons Learned
- Discussion of PBR Methods Concept Paper examples from current fellows



Poll Question #1

Have you been involved in submitting a grant proposal?

- Yes
- No

Slide 4

- **RR([1** I think it would be better to ask about their type of involved in a grant proposal Roper, Rebecca (NIH/NHLBI) [E], 2/9/2017
- RR([2 No, PI for small grant, under 75K; PI for med grant 75-200K; PI for larger grant;, Roper, Rebecca (NIH/NHLBI) [E], 2/9/2017
- RR([3 key personnel for any other grant size Roper, Rebecca (NIH/NHLBI) [E], 2/9/2017

Prep: Application Process

- When/How:
 - Register ERA Commons/ResearchNet (Canada)
- What:
 - US: SF-424 forms; Canada (online)
 - Funding Opportunity Announcement specifications (be aware of updates)
- Where:
 - ► <u>AHRQ:</u>
 - o http://www.ahrq.gov/funding/process/grant-app-basics/index.html
 - NIH: https://grants.nih.gov/grants/grants_process.htm
 - ► <u>Grants.Gov</u>
 - o <u>http://www.grants.gov/web/grants/view-opportunity.html?oppId=280809</u>
 - CIHR
 - o <u>http://www.cihr-irsc.gc.ca/e/795.html</u>
- Who: Get-to-know the players
 - Roles of personnel at your institution and funding organization

Familiarize yourself with the Process



Get your feet wet

► 15-minute video provides <u>breadth of Grantmanship issues</u>. (Must See)

- Peer Review (Must See)
 - https://www.youtube.com/watch?v=fBDxl6l4dOA
- New Investigator to NIH (applicable to AHRQ), (Must See)
 - o <u>https://grants.nih.gov/policy/new_investigators/index.htm</u>
 - <u>https://grants.nih.gov/grants/new_investigators/investigator_policies_faqs.htm#Eligibility</u>
- ► <u>15-minute</u>, NIH overview for R01 application (as appropriate)
 - Includes NIH Early Career Development Award
- National Science Foundation: 90-minute video (as appropriate) learning from the review process, to write good proposal

What

 Forms and Instructions are specified in Funding Opportunity Announcement

Funding Announcements

- Program Announcements—Recurring generally for 3 years
- Request for Applications (RFA)---
- o Look for supplemental grants
 - E.g., Information specialists for NIH grants https://www.nlm.nih.gov/ep/InfoSplmnts.html
- Keep abreast of changes in requirements
 - Notice of Intent for new Funding Announcements
- Note differences across mechanisms and funding institutions

Agencies Wants You to Succeed



Review RFA in full Pay attention to review criteria

Who



- At your institution(s):
 - Authorized Organizational Representative
 - Mentor(s)
 - Prospective pre-submission informal grant reviewers
 - Institutional Review Board, Point of Contact/Process
 - Technical experts—(e.g., analytical)
 - Letters of Support (in-kind and otherwise)

Funding agency

- Project Officer within Institute (CIHR, NIH)
- Point of Contact
- Project Officer
- Receipt and Referral Officer
- Grants Management Officer
- Scientific Review Officer (not in Canada)

Funding Sources

- Federal Agencies: CIHR, NIH, AHRQ, CDC, PCORI, and other DHHS agencies
 - Register for receipt of new and updated notices
- Foundations: Robert Wood Johnson, Gates, Hecht, Michael Smith, Alberta Innovates
- Professional Societies: AAFP, AAP, AHA, Janus
- Local institutions: pilot funding
- Request for Proposals
- Special Emphasis Notices

Grants and Contracts

• Grants:

- Funding Opportunity Announcements
- One-time solicitations, (RFA)
 - o (Recurring) Program Announcements
 - o Standard Due Dates for Competing Applications
- Special Emphasis Notices

Contracts:

- Agency Indefinite Delivery, Indefinite Quantity (IDIQ)
 - e.g., AHRQ, <u>Accelerating Change and Transformation in</u> <u>Networks (ACTION) III</u>
- ► Fed BIZ Ops, <u>https://www.fbo.gov/</u>
 - Example DHHS pre-solicitation, <u>https://www.fbo.gov/index?s=opportunity&mode=form&id=df8d</u> <u>bb0725cef4137b05948dde26dafd&tab=core&_cview=1</u>
 - Example of CDC call for Rapid research projects, e.g., ZYKA research studies, <u>https://www.fbo.gov/index?s=opportunity&mode=form&id=e5a</u> <u>37487b90172f20b4e301a7c0a21a4&tab=core&_cview=0</u>

AHRQ Grant Mechanisms and Continuum of Research



 R18 – Large Demonstration/ Dissemination Grants

Dissertations

Poll Question #2

Do you currently have (or plan to apply) for a Career Development Award (CDA)/Clinician Scientist award?

- A. Have (or had) a CDA/Clinician scientist
- B. Plan to apply for a CDA/Clinician scientist
- C. No CDA/clinician scientist or no plans to apply for one

Career Training

- NIH: Loan repayment program
- NIH: <u>https://researchtraining.nih.gov/</u>
 - Contact NIH Program Officers: <u>https://researchtraining.nih.gov/tac-roster</u>
- CIHR clinician scientist
- AHRQ: <u>http://www.ahrq.gov/funding/training-grants/index.html</u>
 - Subscribe to AHRQ Training updates: <u>https://subscriptions.ahrq.gov/accounts/USAHRQ/subscribe</u>r/new?topic_id=USAHRQ_23
 - Contact AHRQ Program Officers:

QUESTION BREAK

Initial Concept

- Sketch out your research concept and desired impact
 - research plan,
 - key personnel,
 - data sources,
 - analytical methods,
 - protection of human subject's plan,
 - anticipated duration of the study

Alignment



- Search databases of funded research awards
 - Add examples of research databases (NIH reporter, AHRQ Gold, etc)
- Type of funding or grant award needed
 - Pilot/exploratory study, Career development, Regular proposal, Clinical Trial planning (<u>http://grants.nih.gov/grants/funding/funding_program.htm</u>)

Why, compose/fund this proposal?

- PI-initiated project well mapped to Agency
 Program
 Announcement
- Responsive application to one-time Request for Application (RFA) or Special Emphasis Notice
- Well-written grant applications deftly and repeatedly articulate the importance and distinctive value of their team and research project.
- Compelling proposals are pieces of literature

Funding Opportunity Announcement

- Each funding source has guidance documents for proposal submission, but usually contain:
 - Abstract/Public relevance statement
 - Research Plan
 - Protection of Human Subjects—(does not count toward page limit)
 - Data Sharing Plan
 - Dissemination Plan
 - Letters of Support
 - Biosketches
 - Budget and budget justification
 - Appendices—(language of FOA dictates whether reviewers must consider material in appendices in their technical merit assessment.)

Know Your Audience and Their Expectations



Be clear, compelling



Budget items

- Investigator & research staff effort
- Participant Reimbursement
- Procedures (labs, radiology, etc)
- Practice Reimbursement
- Meetings/Conference Calls
- Travel (local and scientific)
- Consultants, Data Safety Monitoring Board
- Subcontracts

Application

- Title
 - Avoid overstatement
- Specific Aims
 - Clarity
 - Demonstrate
 - o likelihood to achieve
 - o Appropriateness and necessity of sequence
- Timeline
 - Be practical
 - Acknowledge challenges
 - Identify mitigation strategies and leadership plans
- Protection of Human Subjects
- Letters of Support
- Supplemental material (post submission)—know what is allowed

Receipt and Referral

 <u>NIH</u> and AHRQ have some differences in Receipt and Referral Processes

Read the fine print, e.g., allowable number of PIs

 PI's ERA Commons account identifies stage of application

Withdrawal ?

• What to do if similar applications submitted to different institutions, and one is to be funded?

QUESTION BREAK

Review Process

- Review criteria (outlined in RFP)
- Request for review panel (suggest in cover letter; contact scientific review administrator)
- Reviewer meeting
- Final Score
 - Protection of Human Subjects
 - Budget
 - AHRQ Priority Populations
- Summary Statement

Peer Review Scores

Impact	Score	Descriptor	Additional Guidance on Strengths/Weaknesses
High	1 2 3	Exceptional Outstanding Excellent	Exceptionally strong with no weaknesses Outstanding Very strong with only some minor weaknesses
	4	Very Good	Strong but with numerous minor weaknesses
Medium	5	Good	Strong but with at least one moderate weakness
	6	Satisfactory	Some strengths but also some moderate weaknesses
	7	Fair	Some strengths but with at least one major weakness
Low	8	Marginal	A few strengths and a few major weaknesses
	9	Poor	Very few strengths and numerous major weaknesses

Non-numeric score options: DF = Deferred, AB = Abstention, CF = Conflict, NP = Not Present, ND = Not Discussed.

Minor Weakness: An easily addressable weakness that does not substantially lessen impact.

Moderate Weakness: A weakness that lessens impact.

Major Weakness: A weakness that severely limits impact.

CIHR Peer Review-familiarize yourself

Learning Modules

- CIHR offers a number of learning modules to help you gain in-depth knowledge about our programs (foundation and project grants, training grants), processes and tools. These modules are intended to support stakeholders submitting an application for funding, or participating in the review of a funding application. New lessons will be added regularly to this page. Please visit frequently.
- http://www.cihr-irsc.gc.ca/e/47021.html

Aiming for Perfection



Peer Review Process

- NIH <u>http://grants.nih.gov/grants/peer/guidelines_gen</u> eral/scoring_system_and_procedure.pdf
- AHRQ http://w/

http://www.ahrq.gov/funding/process/review/peer proc.html

• CIHR

http://www.cihr-irsc.gc.ca/e/795.html

Post Summary Statement

- Agency/Division initial review
 - PO may contact PI for clarification information regarding technical merit, key personnel
 - Division discussion
 - PO writes internal funding memo, articulating recommendation for funding
- Scientific Council meeting
 - PO presents recommendation
 - Fields questions from Senior Leadership (AHRQ)
 - Senior Leadership (AHRQ)/ National Advisory Council (NIH) votes recommendation
- Agency Director

Pre-award

- Authorized Organizational Representative (AOR): The AOR, also known as <u>Signing Official</u> (SO) in the eRA Commons
- Questions/Clarifications regarding proposal
 - Grants Management Officer to AOR

Award

- Notice of Award
- Issued by Grants Office, provides terms of grant and reporting
- Requirements Grant Reporting
 - Timeliness
- Close-out requirements
- Notifying PO of forthcoming publications
 - JournalPublishing@ahrq.hhs.gov

Good grantsmanship skills are demonstrated throughout the award and close-out period.

Funding Eligibility

 US only: Scored DHHS applications responding to a PA are eligible for funding for up to one year after review.

Resubmit or New

- Most grants are not funded in the first round—
- Reviewer comments are helpful for deciding
 - on revisions to research plan, investigative team, etc.
 - Or, configuring new proposal
- Note that <u>renewal/resubmission/revision</u> applications may have different due dates than <u>new applications</u>.
- Timing for resubmission will likely be <u>2nd or 3rd</u>
 <u>cycle due date</u> after your first submission

Advice/Lessons learned

- Stay updated on funding announcements/opportunities
- Read a successfully funded proposal
- Assess previous funding for related projects
- Discuss potential funding sources with mentors
- Contact Project Officers for interest and advice
- Prepare application in advance to allow mentor/collaborator review, internal institutional review (mock review board)
- Prepare budget as an initial step to see what you can afford within budget limits
- Collaborate with senior investigator as co-I on one of their grant submissions
- Observe/participate Operations manager with experience in grant submissions

Poll Question #3

In your preliminary search for funding opportunities for your concept paper, which funding agency seemed the most appropriate for your submission?

- A. CIHR
- B. AHRQ/NIH/CDC/HRSA (US federal agencies)
- C. PCORI
- D. Institutional pilot funding
- E. Foundation or Industry

Discussion of PBR Methods Concept Papers

- Short description of project idea
- Initial thoughts on potential funding sources
- Current and future tasks for pursuing funding

Poll Question #4

When do you plan to submit your proposal for funding?

- A. Summer 2017
- B. Fall 2017
- **C**. Winter 2018
- D. Spring 2018

QUESTIONS?

Resources

- <u>http://www.grants.gov</u>
- CIHR, <u>http://www.cihr-irsc.gc.ca/e/46880.html</u>
- NIH, <u>http://grants.nih.gov/grants/about_grants.htm</u>
- AHRQ, <u>http://www.ahrq.gov/funding/process/index.html</u>
- CDC, <u>http://www.cdc.gov/funding/index.html</u>
- HRSA, <u>http://www.hrsa.gov/grants/index.html</u>
- PCORI, <u>http://www.pcori.org/funding-opportunities</u>
- Medical Societies, search Wikipedia for "Medical associations based in the United States"
- Your local institution's grants office resource page
- PhRMA Foundation, <u>http://www.phrmafoundation.org</u>
- Robert Wood Johnson Foundation, <u>https://www.rwjf.org</u>