Funding and Grantsmanship for Comparative Effectiveness and Patient-Centered Outcomes Research

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Topics to be Discussed

- Funding Agencies
  - Federal
    - National Institutes of Health, Agency for Healthcare Research and Quality
  - Voluntary Health Organizations, Professional Societies, Foundations, Industry

- Types of Awards
  - Grants, Contracts, Cooperative agreements,
    - e.g. Research grants, fellowships, career development awards

- Funding Announcements

- Identifying Sources of Support

- Grantsmanship Helpful Hints
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U.S. Dept. of Health and Human Services

Food and Drug Administration

Centers for Medicare & Medicaid Services

Centers for Disease Control and Prevention

Substance Abuse and Mental Health Services Administration

National Institutes of Health

Health Resources and Services Administration

Agency for Healthcare Research and Quality

Agency for Toxic Substances and Disease Registry

Adapted from: NIH (DRG) - Peer Review of NIH Research Grants Applications
Agency for Healthcare Research and Quality (AHRQ)

- Supports research designed to improve the quality, safety, efficiency, and effectiveness of health care.

  - Comparative Effectiveness
  - Prevention and Care Management
  - Value
  - Health Information Technology
  - Patient Safety
  - Innovations/Emerging Issues
AHRQ: Comparative Effectiveness

Comparing treatment options for different health conditions

Improve health care quality by providing patients and physicians with state-of-the-science information on which medical treatments work best for a given condition.

Provides comparisons of drugs, medical devices, tests, surgeries, or ways to deliver health care so that patients and their families understand what treatments work best and how their risks compare.
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- Identifying Sources of Support
- Grantsmanship Helpful Hints
## NIH Extramural Program

<table>
<thead>
<tr>
<th>Mechanism</th>
<th>NIH Role</th>
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</thead>
<tbody>
<tr>
<td>Grant</td>
<td>Patron (Assistance, encouragement)</td>
</tr>
<tr>
<td>Cooperative Agreement</td>
<td>Partner ( Assistance but substantial program involvement)</td>
</tr>
<tr>
<td>Contract</td>
<td>Purchaser (Procurement)</td>
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</tbody>
</table>
Types of Awards

- Research grants
- Career development awards
- Training grants
- Individual fellowships
- Career transition awards
- Cooperative agreements
- Administrative supplements
- Institutional Clinical & Translational Science Award (CTSA)
- Contracts
- Loan Repayment Program
Not All Funding Opportunities are the Same

- **Different mission statements**
  - Career development (K’s)
  - Research project (R’s)

- **Different funding**
  - Stipend/Salary
  - Comprehensive research costs

- **Different time frames**
  - Not renewable: 5 years (K’s), 3 years (F’s), 2 years (T’s)
  - Renewable: 4 years-5 years (R01) each competitive period
Types of Awards

Research Projects

(Traditional R01)

- To support a discrete, specified project related to the principal investigator's interests and competence. Most of the research that NIH supports is through this funding mechanism.
Research Project Grants: Applications, Awards, and Success Rates
Research Career Programs (K)

- Provides predominantly salary support
  - Specified salary levels (e.g. NIDDK: $90K, NCI: $100K)
- Minimum effort: e.g. 75%, (some exceptions to 50%) Research and Career Development activities
- Up to 5 years
- US citizen/permanent resident
- Reduce effort to 50% in last 2 years if PI of NIH research grant
Career Development (K) Support to Research Grant (R01)

- K08/K23 → R01
- K12 → K23 → R01
- K12 → K23 → R01
- K08/K23 → R01
- K12 → R01
Mentored Clinical Scientist Development Award (K08)

- Support to develop outstanding independent clinician research scientists
- Basic and translational science
Mentored Patient-Oriented Research
Career Development Award (K23)

- For investigators just after specialty training; not renewable;

Mid-Career Investigator In Patient-Oriented Research Career Development Award (K24)

- Support for clinicians to allow for time to devote to patient-oriented research and to mentor beginning clinical investigators;
Patient-oriented research:
- Research conducted with human subjects (or on material of human origin, i.e. tissues, specimens, and cognitive phenomena)
- Investigator directly interacts with human subjects

Research areas:
(1) Mechanisms of human disease
(2) Therapeutic interventions
(3) Clinical trials
(4) Development of new technologies
Mentored Research Scientist Development Award (K01)

Not all NIH Institutes participate in program

Participating Institutes may use for different purposes

- Train in a new field
- Specific research areas
- Hiatus in research career
- Increase research workforce diversity
Mentored Research Scientist Development Awards (K01)

- National Institute of Allergy and Infectious Diseases (NIAID):
  - Outcomes Research

- National Heart, Lung, and Blood Institute (NHLBI):
  - Comparative Effectiveness Research
- AHRQ K08: Mentored Clinical Scientist Research Career Development Award
  - Quality,
  - Safety,
  - Efficiency, and
  - Effectiveness of Health Care

- AHRQ K18: Mentored Career Enhancement Award in Patient Centered Outcomes Research for Mid-Career and Senior Investigators
  - To prepare candidates to be independent investigators in Patient-Centered Outcomes Research (PCOR), by providing them the methodological skills required for comparative effectiveness research (CER)
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  - Federal
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  - Grants, Contracts, Cooperative agreements,
    - e.g. Research grants, fellowships, career development awards

- **Funding Announcements**

- **Identifying Sources of Support**

- **Grantsmanship Helpful Hints**
Patient-Centered Outcomes Research Institute (PCORI)

- Non-government agency, Created in 2010
- [http://www.pcori.org/](http://www.pcori.org/)
- National Priorities for Research and Research Agenda
  - High-impact patient-centered outcomes research
  - PFA: PCORI Funding Announcements
- Accelerated Process to Targeted PFAs
  - “…questions solicited directly from patients and other stakeholders through our website, workshops, and roundtables…”
PCORI: National Priorities for Research and Research Agenda

1. **Assessment of Prevention, Diagnosis, and Treatment Options** - Projects that address critical decisions that patients, their caregivers and clinicians face with too little information

2. **Improving Healthcare Systems** - Projects that address critical decisions that face health care systems, the patients and caregivers who rely on them, and the clinicians who work within them
3. Communication and Dissemination Research - Projects that address critical elements in the communication and dissemination process among patients, their caregivers and clinicians

4. Addressing Disparities - Projects that will inform the choice of strategies to eliminate disparities

5. Accelerating Patient-Centered Outcomes Research and Methodological Research - Projects to improve the nation’s underlying capacity to conduct patient-centered outcomes research rapidly, efficiently and consistently over time
<table>
<thead>
<tr>
<th>Action</th>
<th>Cycle I</th>
<th>Cycle II</th>
<th>Cycle III</th>
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<td>PFA Release Date</td>
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<td>Online System Opening Date</td>
<td>May 15</td>
<td>September 17</td>
<td>January 15</td>
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<td>Letter of Intent (LOI) Due Date</td>
<td>June 15</td>
<td>October 15</td>
<td>February 15</td>
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<td>Informational Training Programs</td>
<td>July – August</td>
<td>October – November</td>
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<td>Application Deadline</td>
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<td>December 17</td>
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<td>Merit Review Dates</td>
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<td>January – March</td>
<td>May – July</td>
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<td>August/September</td>
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<td>Earliest Start Date</td>
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<td>May</td>
<td>September</td>
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<td>Online System Opening Date</td>
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<td>May 15, 2013</td>
<td>September 17, 2013</td>
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<td>Informational Webinars (Specific dates to be posted on pcori.org.)</td>
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<td>January 2014</td>
<td>May 2014</td>
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<td>1. Assessment of Prevention, Diagnosis, and Treatment Options</td>
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<td>Maximum Project Period</td>
<td>3 Years</td>
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<tr>
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<td>Maximum Project Period</td>
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<tr>
<td>Maximum Project Period</td>
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<td>TBD</td>
<td>3 Years</td>
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</table>
PCORI: Accelerated Process to Targeted PFAs

- Treatment Options for Uterine Fibroids
- Treatment Options for Severe Asthma in African-Americans and Hispanics/Latinos
- Preventing Injuries from Falls in the Elderly
- Treatment Options for Back Pain
- Obesity Treatment Options in Diverse Populations
American Heart Association

Mentored Clinical and Population Research Award

- Early career investigators
- Proposals are encouraged on “…behavioral outcomes, risk factor outcomes, disease outcomes, cost benefit analyses, efforts to evaluate outcomes of patient care delivery…”
- Founders Affiliate: $75,000/year for two years
- National: $77,000/year for two years
PhRMA Foundation

“…owes its success to the pharmaceutical companies that have provided their generous support…”

“…to support young scientists in disciplines important to the pharmaceutical industry by awarding them competitive research fellowships and grants…”

http://www.phrmafoundation.org/

Adherence, Health Outcomes, Informatics, Pharmacology/ Toxicology, Pharmaceutics,
PhRMA Foundation - Health Outcomes

Burden of Disease
Comparative Effectiveness Analysis
Compliance/Adherence
Cost Consequences Analysis
Cost-Benefit Analysis
Cost-Effectiveness Analysis
Cost Utility Analysis
Health Outcomes Research
Health Related Quality of Life

Health Services Research
Patient Satisfaction
Patient Preferences
Pharmacoeconomics
Patient Reported Outcomes
Psychometric Evaluation of Questionnaires Research Methods
Symptom Measures
Tolerability
PhRMA Foundation - Health Outcomes

- **Pre-Doctoral Fellowships**
  - Advanced Ph.D. candidates, stipend of $25,000 per year for a maximum of two years

- **Post-Doctoral Fellowships**
  - $55,000 annual stipend (for up to 2 years) to graduates of PharmD., M.D., and Ph.D. programs
PhRMA Foundation - Health Outcomes

- **Research Starter Grants**
  - Instructor or assistant professor (or equivalent)
  - Funding for salary, technical assistance, equipment, and travel

- **Sabbatical Fellowships**
  - $40,000 stipend (6 mo-1 yr) for mid-career scientists to learn new skills and develop new collaborations in health outcomes research and training
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NIH/AHRQ
Funding Announcements

Diagram:
- RFA: Targeted research
- Institute-Specific PA: Research in a stated area of scientific interest
- Parent PA: Investigator-initiated research in any area

Arrows indicate the progression from broad to narrow research areas.
Funding Opportunity Announcement (FOA)

- FOA Mechanism
  - Published in the NIH Guide for Grants and Contracts (RFAs, PAs) and Grants.gov
  - Grants.gov notice includes application information and forms
Parent Announcement

Funding Opportunity Announcement for unsolicited investigator-initiated grant applications (e.g. R01)

- Allows electronic submission of grant applications that are not in response to specific Program Announcement or RFA.
- Published in the NIH Guide for Grants and Contracts and Grants.gov
- Grants.gov notice includes application information and forms
Program Announcement (PA)

- No set-aside of funds
- Describes existence of an NIH extramural research program
- May describe new or expanded interest in a particular extramural program
- May be a reminder of a continuing interest in an extramural program
- Applications reviewed at Center for Scientific Review (CSR) not the Institute
- Published in the *NIH Guide for Grants and Contracts* and Grants.gov
Program Announcement (PAR)

- PAR Mechanism
  - Grant applications are reviewed at the Institute and not the Center for Scientific Review (CSR)
  - Usually some applications are funded
Program Announcement (PAS)

- PAS Mechanism
  - Program Announcement with dedicated funding
    - “Set aside funds”
  - Funds applications that may receive a score below the payline
  - Research area coincides with programmatic interests of Institute
  - Funds allocated throughout duration of the PAS
Request For Applications (RFA)

- Formal announcement describing an institute initiative in a *well-defined scientific area*
- Invitation to the field to submit *research grant or cooperative agreement* applications for a one-time competition
- *Set-aside of funds* for a certain number of awards
- Published in the *NIH Guide for Grants and Contracts* and *Grants.gov*
Request For Proposals (RFP)

- Formal announcement describing an institute initiative in a well-defined scientific area

- Invitation to the field to submit contract applications for a one-time competition

- Set-aside of funds for a certain number of awards

- Published in FedBizOpps
Request For Applications (RFA)

- **Research on Comparative Effectiveness and Implementation of HIV/AIDS and Alcohol Interventions (NIAAA)** (deadline: May 29, 2013)
  - **R01**: RFA-AA-13-003, 4 awards, $2.5 million in total costs for fiscal year 2013
  - **R21**: RFA-AA-13-004, 2-3 awards, $0.5 million in total costs for fiscal year 2013
Request For Applications (RFA)

- **International Traumatic Brain Injury Research Initiative: NIH Cooperative Program for Comparative Effectiveness of Clinical Tools and Therapies** (U01)
  - RFA-NS-13-008
  - Deadline: April 1, 2013

- **Neurological Disorders and Stroke** (NINDS)
  - $3.3 million to support co-funding of 1 award (FY2013)

- **Biomedical Imaging and Bioengineering** (NIBIB)
  - $250,000 to support co-funding of 1 award (FY2013)

- **Deafness and Other Communication Disorders** (NIDCD)
  - $200,000 to support co-funding of 1 award (FY2013)
Program Announcement (PA)

- Disorders of Human Communication: Effectiveness, Outcomes and Health Services Research
  - National Institute on Deafness and Other Communication Disorders (NIDCD)
  - R01: PA-13-102
  - R21: PA-13-103

- Application Due Date(s): Standard dates
- The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications
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How to Find Funding Opportunities

- Networking
- Speak to colleagues who are in a similar field
- Speak to colleagues who have been on governmental or private agency review panels
- Speak to colleagues who are on (advisory) boards of private agencies
Web Resources

- **SPIN funding database**
  - [https://www.infoed.columbia.edu/](https://www.infoed.columbia.edu/)
  - SMARTS e-mail alert module

- **GrantsNet**
  - Funding database for junior investigators
  - Funding news e-mail alerts
  - [http://sciencecareers.sciencemag.org/funding](http://sciencecareers.sciencemag.org/funding)

- **National Institutes of Health**
- **Grants.gov**
  - Database and application system for Federal grants

- **FedBizOpps (Federal Business Opportunities)**
  - Single point-of-entry for Federal contracts

- **Tips for Writing Grant Applications**
  - [http://grantscourse.columbia.edu/writing.htm](http://grantscourse.columbia.edu/writing.htm)
Other Sources of Information

- Sponsor publications which describe research interests (e.g. newsletters, annual reports)
- Sponsor e-mail alert modules
  - NIH
    - “List of Lists”: [https://list.nih.gov/](https://list.nih.gov/)
    - “NIAID-EMAIL ALERTS” Profile: [http://visitor.constantcontact.com/optin.jsp?edit=r&m=1100850163367&r=1101202977468&ea=jsr9%40columbia.edu&lang=en](http://visitor.constantcontact.com/optin.jsp?edit=r&m=1100850163367&r=1101202977468&ea=jsr9%40columbia.edu&lang=en)
The Foundation Center

The Foundation Directory Online

Searchable database (fee) of approx 80,000 foundations and their tax statements (990’s)
Access via Columbia University (“free”)

http://www.columbia.edu/cgi-bin/cul/resolve?clio3328966

79 Fifth Avenue (at 16th St.)
New York, NY 10003-3076
Tel: (212) 620-4230
Fax: (212) 691-1828

http://foundationcenter.org/
http://foundationcenter.org/newyork/
SPIN
Sponsored Programs Information Network

- Database of funding opportunities
- National and international government and private funding agencies
- Research grants, fellowships, career development, etc.
- Searchable fields
  - Keywords
  - Applicant type (e.g. Postdoctoral, Young Investigator)
  - Award Types (e.g. Equipment, Fellowship)
  - Sponsor Type (e.g. Foundations, Voluntary Health Organization)
SMARTS
SPIN Matching and Research Transmittal Service

- Automated daily e-mail alert system
- Reports of relevant funding opportunities from SPIN database based on investigator-selected keywords

http://spa.columbia.edu/funding/search-funding-spin
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<tr>
<th>Project Code</th>
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<th>Title</th>
<th>Investigator</th>
<th>Institution</th>
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<tr>
<td>1 R01</td>
<td>HS019853</td>
<td>WASHINGTON HEIGHTS INITIATIVE COMMUNITY-BASED COMPARATIVE EFFECTIVENESS RESEARCH</td>
<td>BAKKEN, SUZANNE</td>
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<td>1 R01</td>
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<td>1 R03</td>
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<td>DETERMINING A LEARNING CURVE FOR COMPLEX LAPAROSCOPIC GASTROINTESTINAL SURGERY</td>
<td>FOWLER, DENNIS LEE</td>
<td>COLUMBIA UNIVERSITY HEALTH SCIENCES</td>
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<td>1 R01</td>
<td>HS021470</td>
<td>KEEP IT CLEAN FOR KIDS: THE KICK PROJECT</td>
<td>LARSON, ELAINE LUCILLE</td>
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<td>BUILDING TOWARD ICD-11: IMPROVING THE CODING OF QUALITY AND PATIENT SAFETY DATA</td>
<td>PINCUS, HAROLD A</td>
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<td>VALIDATION OF NURSE PRACTITIONER PRIMARY CARE ORGANIZATIONAL CLIMATE QUESTIONNAIR</td>
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<td>1 R36</td>
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<td>HOSPITAL AND COUNTY-LEVEL PREDICTORS OF IMMEDIATE BREAST RECONSTRUCTION POST-MAST</td>
<td>RICHARDS, CATHERINE ANN</td>
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<td>5 R18</td>
<td>HS018158</td>
<td>FLU ALERT: INFLUENZA VACCINE ALERTS FOR PROVIDERS IN THE ELECTRONIC HEALTH RECORD</td>
<td>STOCKWELL, MELISSA S</td>
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<td>1 R36</td>
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<td>USER INTERFACES FOR COMMUNICATING INPATIENT MEDICATION THERAPIES</td>
<td>WILCOX, LAUREN GABRIELLE</td>
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## NIH: Funding for Various Research, Condition, and Disease Categories (RCDC)

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<td>Comparative Effectiveness Research</td>
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Total Number of Research/Disease Areas: 233

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<td>5R25MH084785-04</td>
<td>Treating Children with Trauma: An Evidence Based Curriculum</td>
<td>SHEAR, KATHERINE</td>
<td>COLUMBIA UNIV</td>
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<td>NIMH</td>
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<td>Using Multimedia Technologies to Disseminate an HIV Prevention Intervention</td>
<td>WITTE, SUSAN</td>
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<td>NIDA</td>
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Topics to be Discussed

- **Funding Agencies**
  - **Federal**
    - National Institutes of Health, Agency for Healthcare Research and Quality
  - Voluntary Health Organizations, Professional Societies, Foundations, Industry

- **Types of Awards**
  - Grants, Contracts, Cooperative agreements,
    - e.g. Research grants, fellowships, career development awards

- **Funding Announcements**

- **Identifying Sources of Support**

- **Grantsmanship Helpful Hints**
When Preparing an Application:

- Read instructions
- Never assume that reviewers “will know what you mean”
- Refer to literature thoroughly and thoughtfully
- Explicitly state the rationale of the proposed investigation
- Include well-designed tables and figures
- Present an organized, lucid write-up
Elements of a Good Proposal

- Feasible
- Relevant
- Unique
- Innovative
- Clear
- Brief
- Consistent
Common Problems with Grant Applications from New Investigators

- Overly ambitious
- Not independent of previous mentor’s research
- Fishing expedition
- Not hypothesis driven
- Descriptive, not mechanistic project
- Unfocussed
- No or insufficient preliminary data
- Unrealistic budget
- Methodologies beyond the expertise of investigator or research team
Good Luck!