Funding and Grantsmanship for Extramural Support

Department of Obstetrics & Gynecology
Research “Boot Camp”

October 2, 2017

Jaime S. Rubin, Ph.D.
Vice Chair for Investigator Development
Dept. of Medicine
jsr9@columbia.edu

Course: “Funding and Grantsmanship for Research and Career Development Activities”

http://grantscourse.columbia.edu/
Topics to be Discussed

- Funding Agencies
  - Government
    - Federal: NIH
  - Non-Government: Voluntary Health Organizations, Professional Societies, Foundations, Industry

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

- Identifying Funding

- Approaches for Competitive Applications
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Federal Agencies

- Dept. of Agriculture
- Dept. of Defense
  - Congressionally Directed Medical Research Programs (CDMRP)
- Dept. of Education
- Dept. of Energy
- Dept. of Health & Human Services
  - National Institutes of Health
- Dept. of Homeland Security
- Dept. of Justice
- Environmental Protection Agency
- National Aeronautics & Space Administration
- National Science Foundation
National Institutes of Health

Adapted from: NIH (DRG) - Peer Review of NIH Research Grants Applications

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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

Jaime S. Rubin, Ph.D.: http://grantscourse.columbia.edu
Agency for Healthcare Research and Quality (AHRQ)

“Mission is to produce evidence to make health care safer, higher quality, more accessible, equitable and affordable…”

- “invests in research on the Nation's health delivery system that goes beyond the "what" of health care to understand "how" to make health care safer and improve quality…

- creates materials to teach and train health care systems and professionals to put the results of research into practice…

- generates measures and data used by providers and policymakers.”

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Centers for Disease Control and Prevention (CDC)

Supports programs to “protect America from health, safety and security threats”

Funds grants and cooperative agreements to support public health programs (national and international)

- **National Institute for Occupational Safety and Health**
  - Mentored Research Scientist Development Award (K01)
  - Exploratory/Developmental Grant Program (R21)
  - Small Research Program (R03)

- **Center for Global Health**
  - President's Emergency Plan for AIDS Relief (PEPFAR)

Food and Drug Administration (FDA)

“ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation... regulating the manufacturing, marketing, and distribution of tobacco products…”

Orphan Products Clinical Trials Grants Program: Supports “the clinical development of products for use in rare diseases or conditions where no current therapy exists or where the proposed product will be superior to the existing therapy.”

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Health Resources and Services Administration (HRSA)

**Mission:**

“To improve health and achieve health equity through access to quality services, a skilled health workforce and innovative programs.”

**Goals**

- **Goal 1:** Improve Access to Quality Health Care and Services
- **Goal 2:** Strengthen the Health Workforce
- **Goal 3:** Build Healthy Communities
- **Goal 4:** Improve Health Equity

Health Resources & Services Administration

- Bureau of Health Workforce
- Bureau of Primary Health Care
- Healthcare Systems Bureau
- HIV/AIDS Bureau
  - Ryan White HIV/AIDS Program
- Maternal and Child Health Bureau

  - **Topics:** Maternal/Women's Health, Perinatal & Infant Health, Child Health, Adolescent & Young Adult Health, Children with Special Health Care Needs
Non-government, Non-Profit Agencies Funding Agencies

- Voluntary Health Organizations
- Professional Societies
- Private Foundations
Research

ACOG offers a research award in the area of women’s health policy and also posts information on available awards outside our organization.

Warren H. Pearse Women’s Health Policy Award

**Purpose:** To explore an aspect of health care policy.

**Description/Criteria:** This research award will provide $10,000 to support research which explores an aspect of health care policy that assists, defines, or restricts the ability of a physician to deliver health care to women in the general population, or in a specific area. Application deadline: **December 15.**
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### NIH Extramural Program

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

Adapted from: NIH (DRG) - Peer Review of NIH Research Grants Applications

Types of Awards

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

- **Different mission statements**
  - Fellowships (F’s)/Training grants (T’s)
  - Career development (K’s)/Scholar awards
  - Research project (R’s)

- **Different funding**
  - Stipend vs. Salary/Fringe benefits
  - Pilot awards vs. Comprehensive research costs

- **Different time frames**
  - Not renewable: e.g. 5 years (K’s), 3 years (F’s), 2 years (T’s)
  - Renewable: 4 years–5 years (R01) each competitive period
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Research Grant (NIH R01)

- Supports a discrete, specified project
- “Comprehensive” funding
- Modular budgets up to $250,000/year
- Multi-year
- Flexibility
- Most of the research that NIH supports is through this funding mechanism
Research Grant (NIH R01)

- Funds research project
  - Salaries of PI and other research personnel
  - Supplies, reagents, etc
  - Animal costs
  - Patient care costs
  - Core facilities
  - Travel to national meetings
- Multi-Year (4yrs – 5yrs)
- Renewable
  - e.g. original grant + 2 renewals = 15yrs
Exploratory/ Developmental Grants (R21)

- Encourages new, exploratory and developmental research projects by providing support for the early stages of project development. Sometimes used for pilot and feasibility studies.

- 2 years of funding

- Budget: $275,000 (D.C.) over two years

- Investigator-initiated R21 studies not funded by all Institutes
Small Research Grants (R03)

- Supports, e.g.:
  - Pilot or feasibility studies;
  - Collection of preliminary data
  - Secondary analysis of existing data
  - Small, self-contained research projects
  - Development of new research technology

- 2 years of funding
- Budget: Direct costs up to $50,000/yr
- Not renewable
- Some Institutes only accepts applications in response to their specific funding opportunity announcements

Types of Awards

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- **Career development awards**
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Research Career Programs (K)

- Provides predominantly salary support
- Minimum requirements for the amount of effort that must be devoted to research and career development (e.g. 75%, some exceptions to 50%)
- Up to 5 years
- Specified salary levels
- US citizen/permanent resident.
- Can reduce effort to 50% in last 2 years if PI of NIH research grant
Mentored Patient-Oriented Research Career Development Award (K23)

- **Patient-oriented research:** Research conducted with human subjects (or on material of human origin) for which an investigator directly interacts with human subjects

- **Research areas:** (1) Mechanisms of human disease, (2) Therapeutic interventions, (3) Clinical trials, and (4) Development of new technologies
Mentored Clinical Scientist Development Award (K08)

- Support to develop outstanding independent clinician research scientists
- Basic and translational science

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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

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Research Career Development Awards

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
- **AHRQ K08**: Mentored Clinical Scientist Research Career Development Award for individuals with a clinical doctoral degree or Ph.D./other doctoral degree in a clinical discipline

- **AHRQ K01**: Mentored Research Scientist Research Career Development Award - for individuals with a research doctoral degree

- Health Services Research -
- Quality,
- Safety,
- Efficiency, and
- Effectiveness of health care

CDC K01:

National Institute for Occupational Safety and Health

Mentored Research Scientist Development Award

“career development experience in occupational health and safety research leading to research independence”
Research Career Development/Scholar Programs

- Doris Duke Charitable Foundation
  - Clinical Scientist Development Award
- Robert Wood Johnson Foundation
  - Harold Amos Medical Faculty Development Program
Mentored Clinical Scientist Development Program Award (K12/KL2)

- Support to an institution for the career development experiences of clinicians leading to research independence.
- Institutions recruit and select candidates into their programs
- Candidates must meet the same criteria as for the individual mentored clinical scientist development award.

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
CTSA Awards: A Home for Clinical and Translational Science

Source: Zerhouni (NIH) [9/06]

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Mentored Clinical Scientist Development Program Award (KL2)

- CTSA - Clinical and Translational Scientist Award
- CUMC TRANSFORM Scholars Mentored Career Development program
  [Training and Nurturing Scientists for Research that is Multidisciplinary]

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
NIH Career Development Support to Independent Research Funding

K01/K08/K23 → R01

K12 | K23 → R01

K12 | K23 → R01

K01/K08/K23 → R01

K12 → R01
CTSA Awards: A Home for Clinical and Translational Science

Source: Zerhouni (NIH) [9/06]

Research-Oriented Masters Degree Programs

- Comprehensive courses in clinical research/
  “Patient-Oriented Research”
  - Biostatistics, epidemiology, study design,
    bioethics, legal and regulatory issues
- For the career development of clinical investigators

CU Irving Institute/CTSA Funding Programs

- **TRANSFORM TL1 Postdoctoral Training Program:** Two-year program combining integrated didactic training, mentoring, and research related to precision medicine.

- **KL2 Program:** TRANSFORM KL2 Scholars Mentored Career Development program

- **Irving Scholars:** Florence and Herbert Irving Clinical Research Career Awards - $60,000/year for 3 years

CU Irving Institute/CTSA Funding Programs

- **Irving Institute/CTO Pilot Awards**: $50,000 awards for P&S junior faculty to conduct pilot studies leading to future independent funding

- **Imaging Core Pilot Awards**: Funding for junior investigators: magnetic resonance imaging (MRI), optical imaging, PET tomography, single photon emission computed tomography/computed tomography (SPECT/CT), and ultrasound
Collaborative and Multidisciplinary Pilot Research Awards (CaMPR): Two-phase program that provides planning and start-up funding to newly-configured investigative teams to support the planning of novel, cross-disciplinary projects.

Bench to Bedsde Awards (formally CaMPR-BASIC): To form a new collaborative team consisting of two principal investigators at the Assistant Professor level: one from a Basic Science department and one from a Clinical department.
CU Irving Institute/CTSA Funding Programs

- **Health Practice Research Pilot Awards:** For junior investigators to pursue an informatics-based project in an operational clinical setting (w/ the Dept of Biomedical Informatics)

- **Personalized Medicine Pilot Awards:** For research focused on approaches to tailor medical care (prevention, diagnosis, and/or treatment) to the individual patient.

CU Irving Institute/CTSA Funding Programs

- **Integrating Special Populations (ISP) Pilot Awards:** For research focused on four special populations to support the formation of newly-configured investigative teams aimed at studying diseases across the lifespan and using rare diseases as tools to study more common ones.

- **Translational Therapeutics (TRx) Awards:** Two-phase accelerator program designed to leverage Columbia’s proficiency in drug discovery and provide access to Entrepreneurs and Industry to advance novel therapeutics from the lab towards commercialization and clinical implementation.

Community-Based Participatory Research Training And Pilot Awards Program: The Program consists of a free course Introduction to CBPR and competitive pilot funding. At the conclusion of the course, participants will be eligible to apply for a one-year pilot grant.
Reach for the First R01 Course: Participants receive five free hours of biostatistical consulting, access to CTSA resources, two expert pre-reviews on an early draft of their R01 application, and bi-monthly, closely-monitored meetings to ensure structure and timeliness in completing the tasks required to successfully submit a first R01 application.
CUMC Research Training/Didactic Programs

- **Columbia Summer Research Institute (CSRI):** 5-week (10 credit) training program in research design and statistical analysis for patient oriented research.

- **Epidemiology and Population Health Summer Institute (EPIC):** Dept. of Epidemiology's series of week-long, non-credit courses provides opportunities to gain foundational knowledge and applied skills for advancing population health research.

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- Identifying Funding

- Approaches for Competitive Applications
Identify Funding

- Identify appropriate funding agencies
  - Government
  - Non-government

- Identify appropriate funding mechanisms
  - Research
  - Training

- Create a calendar of application deadlines for identified funding programs

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
- Acknowledgement section of publications, oral/poster presentations, press releases, etc.

General Resources

- **Grants.gov**
  - Database and application system for Federal grants

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

- **Foundation Center**
  - [http://foundationcenter.org/](http://foundationcenter.org/)
Other Sources of Information

- Sponsor publications/website/social media which describe research/programmatic interests (e.g. newsletters, strategic plans, annual reports)

- Sponsor e-mail alert modules
  - NIH
      - Able to save queries and have “ongoing” results e-mailed as funding alerts
The Foundation Center

New York
32 Old Slip, 24th Floor
New York, NY 10005-3500
tel: 212-620-4230
http://foundationcenter.org/
http://foundationcenter.org/newyork/

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• **Library:** Books, periodicals, and other print and electronic resources; Lending program, “Foundation Directory Online Professional”

• **Courses:**
  - Proposal Writing
  - Proposal Budgeting
  - Finding Grants

• **Chat Live:** Chat online with a reference librarian
The Foundation Directory Online

- 100,000 Grantmakers
- 3.4 million grants
- Tax statements (990’s) showing previous awards
- Access via Columbia University
  - [http://www.columbia.edu/cgi-bin/cul/resolve?clio3328966](http://www.columbia.edu/cgi-bin/cul/resolve?clio3328966)
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<tr>
<th>Grantmaker Name</th>
<th>City, State / Country</th>
<th>Total Assets</th>
<th>Total Giving</th>
</tr>
</thead>
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<tr>
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<td>Seattle, WA</td>
<td>$40,412,918,228</td>
<td>$3,860,217,004</td>
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<td>GE Foundation</td>
<td>Fairfield, CT</td>
<td>$18,326,782</td>
<td>$106,397,515</td>
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<td>Dell Foundation, Michael and Susan, The</td>
<td>Austin, TX</td>
<td>$761,627,288</td>
<td>$73,083,411</td>
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<td>Johnson &amp; Johnson Family of Companies Contribution Fund</td>
<td>New Brunswick, NJ</td>
<td>$62,142,489</td>
<td>$68,165,203</td>
</tr>
<tr>
<td>California Wellness Foundation, The</td>
<td>Woodland Hills, CA</td>
<td>$870,208,767</td>
<td>$39,828,164</td>
</tr>
</tbody>
</table>
National Institutes of Health

Tips for Writing Grant Applications
- http://grantscourse.columbia.edu/writing.htm
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- Approaches for Competitive Applications
Approaches for Competitive Applications

- Identify Funding
- Prepare to Write the Grant Application
- Complete the Grant Application

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Approaches for Competitive Applications

- Identify Funding
- Prepare to Write the Grant Application
- Complete the Grant Application
It’s not the will to win, but the will to prepare to win that makes the difference.

Bear Bryant, University of Alabama
Prepare to Complete the Grant Application

- Speak with Agency Program Officer
- Speak with colleagues who are/were awardees
- Review funded applications if possible
- Review agency’s review criteria
- Identify what will make the application more competitive
  - Research and/or career development arrangements
  - Access to core facilities/research resources
- Strengthen “Preliminary Work/Pilot Data”
- Who will write confidential letters of reference?
Research and Career Development Arrangements

- Multiple Principle Investigators (research awards)
- Multiple Mentors (mentored awards)
- Advisors (mentored awards)
- Co-investigators/Collaborations
- Subcontracts to other institutions
- Multidisciplinary/Interdisciplinary

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Prepare to Complete the Grant Application

- Identify and meet with Co-investigators, Collaborators, Consultants, Advisors
  - Identify roles and responsibilities
  - Administrative requirements
    (e.g. if other countries/institutions are involved)
- Identify necessary core facilities and other research resources
- Meet with research administrators
- Human subjects, lab animals and any other regulatory issues?

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Identify Funding

Prepare to Write the Grant Application

Complete the Grant Application
Complete the Grant Application

- Review the application instructions
- Identify the different components
- Create a checklist
- Create an outline
  - Content, Length of section *(vis a vis page limits)*
- Identify and delegate responsibilities for the different components
  - Technical/Scientific
  - Administrative – e.g. budget
  - Regulatory
  - Draft letters of collaboration/support

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Complete the Grant Application

- Confirm page limits for each component
- Create a schedule for any required meetings
- Determine:
  - Shared computer drive/folders
  - Naming of files (dates?)
  - Track changes?
  - Font, margin, format of literature citation
- Set a **firm** time-line for each responsibility
  - Writing milestones
  - Absolute deadline date for final compilation

Complete the Grant 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 (“the hypothesis of my study is...”)
- Discuss **limitations** and potential “challenges” and how these will be addressed (e.g., “alternate approaches”)
- Include well-designed **tables and figures**
- Present an **organized**, lucid write-up (use an **outline**)
- Ask colleagues to **review** and comment
Complete the Grant Application

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- Ask colleagues to review and comment
Include Well-Designed Tables and Figures

- Include explanatory caption with the figure (not buried in text)
- Not overly complicated
- Informative, even if printed in black and white
- Easy for the reviewers to read

Tips:

- Bold label in text (e.g., Fig. 4) so it’s easier for reviewers to locate relevant text for individual Figure
- Try to have Figure and relevant text on the same page
# Timeline for Specific Aims and Benchmarks/Milestones of Research Progress

<table>
<thead>
<tr>
<th>Benchmarks/ Milestones</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
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<tbody>
<tr>
<td>Summary of Specific Aim 1a</td>
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<tr>
<td>Summary of Specific Aim 1b</td>
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<tr>
<td>Summary of Specific Aim 2a</td>
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<td></td>
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<tr>
<td>Summary of Specific Aim 2b</td>
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<tr>
<td>Summary of Specific Aim 3</td>
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</tbody>
</table>
Anticipate Questions and Answer them before they are asked

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Not everything that can be counted counts.
Not everything that counts can be counted.

Research Plan Section
3. Specific Aims
4. * Research Strategy

Candidate Section
2. Candidate Information and Goals for Career Development

Quote Investigator suggests crediting sociologist William Bruce Cameron
http://quoteinvestigator.com/2010/05/26/everything-counts-einstein/

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Investigator

- Competent
- Enthusiastic
- Thorough
- Professional
Personal Statement/
Candidate’s Background

When describing a previous research experience:

- What was the hypothesis/scientific question?
- Why was the study important?
- What were the findings and conclusions?
- What were your role and responsibilities?
- What did you learn and accomplish?
  - “Intellectual aspects”
  - Do not focus on technical aspects
- Cite any resulting publications
- Describe any honors/awards and conference/workshop presentations

Possible Problems Specific for Mentored Awards

Mentor

- Too many other responsibilities (e.g. administrative, clinical)
- Too many other mentees (e.g. students, post-docs)
- Not appropriate scientifically
- Too junior
- Limited experience as a mentor
- Limited funds to support proposed research
Elements of a Good Proposal

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

- Does not address/follow funding agency’s mission, specific instructions, budget limits, etc.
- 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
NIH: one round of applications
Bell Curve of Reviewer’s Grant Applications

Definitely do not fund

Fine

Definitely fund

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Poor Statistics
Research Resources
not Adequately Described

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Career Development/
Research Training Plan
not Comprehensive
Figure Caption Font too Small
All Components of the Application are as Strong as Possible
Good Luck!