Obtaining Funding in Clinical Research

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What are the ingredients of a successful grant?

1. You need a hypothesis.
2. You should have a plausible explanation for why testing this hypothesis is interesting and/or important.
3. You should provide preliminary data (your own or your mentor’s) that document the feasibility of your planned experimental approach, and
4. Your experimental approach must follow logically from all of the above.
5. Your training and research environment needs to be suitable for the planned studies.
To have a successful grant, you need to get it funded........
Types of research funding

- Institutional funds to support trainees’ research (often from Divisional sources)
- Funds from your own mentor’s research program
- Mentored research grants (K23, K01)
- Independent research grants (Rs)
Research Funding Sources

- NIH (both to institutions and to individual investigators or trainees)
- Institutional (Divisional) funds
- Research foundations
- Industry foundations and grants
- Individual donors
Sources of Biomedical Research Funding in the US

THE ALPHABET SOUP OF NIH GRANTS

Getting started:

• T-32: an Institutional Training Grant, typically awarded to clinical divisions or basic science departments

• F-32: aka NRSA, entry-level Individual Training Grant

• K (career) awards
  • Mentored=K01, K08, K07,K23,K99
Mentored K Awards

- KO1, KO7, K12, K23, K99-ROO
- Support mentored research experience for transition to independence
- Support clinicians and basic scientists (KO8, Mentored Clinical Scientist Development Award)
- K12: institutional
- Clinical research individual Ks
  - K23: clinician-scientist (must have a clinical degree); Mentored Patient-Oriented Research Career Development Award
  - K01: PhD scientist Mentored Research Scientist Development Award
Eligibility Criteria for K Awards

Candidate:
- Doctoral degree, clinical or research
- No more than 5 years postdoctoral training (check PA announcement)
- US citizen, non-citizen national or permanent resident (except K99/R00)
- Not eligible if previous PI on R or K grants

Duration: 3-5 years

Effort: minimum 75%; maybe different for surgical disciplines
Anatomy of a Mentored K Award

• Main sections:
  – The Candidate sections (3) 1-Candidate’s background, 2- Career goals and objectives, 3- Career development activities during award period
  – Research Plan

These sections combined cannot exceed **12 pages**

  • Training in the responsible conduct of research 1 page
  • Environment and Institutional Commitment to Candidate 1 page
  • Statements by Mentors, Co-Mentors, and Collaborators 6 pages
  • ~3 letters of references no page limit
For information on K awards see the NIH website – “K Kiosk”

http://grants.nih.gov/training/careerdevelopmentawards.htm

Contact the appropriate Program Officer!
Career Award Wizard

• Designed to help you identify an Individual NIH Career Award that might be right for you
• Asks a series of Questions
• Leads to a number of award options
• Gives further direction to get details about awards
Career Development Awards (K Awards) for Individuals with a Health-Professional Doctorate

- Medical School
- Residency
- Specialty/Sub-Specialty
- Independent Investigator

- Mentored Clinical Scientist Development Program (K12) (note: two types)
- Mentored Clinical Scientist Development Award (K08)
- Mentored Patient-Oriented Research CDA (K23)
- Career Enhance Award for Stem Cells Res. (K18)
- Midcareer Investigator in Patient-Oriented Research (K24)
What is clinical research?
(Definition per NIH)

• Patient-oriented research*
• Epidemiologic and behavioral studies
• Outcomes or health services research

* The NIH defines patient-oriented research as research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) that requires direct interactions with human subjects. Patient-oriented research includes study of the disease, therapeutic interventions, and clinical trials.
Clinical Research Enhancement Act of 2000

• “The Director of NIH shall undertake activities to support and expand the involvement of the NIH in clinical research.”

• “The Director of NIH shall make grants (to be referred to as ‘Graduate Training in Clinical Investigation Awards’) to support individuals pursuing master’s or doctoral degrees in clinical investigation.” (K30)

• “The Director of the National Center for Research Resources shall award grants for the establishment of GCRCs to provide the infrastructure for clinical research.” (now CTSA)
“The Secretary, acting through the Director of the NIH, shall establish a program to enter into contracts with qualified health professionals under which such health professionals agree to conduct clinical research, in consideration of the Federal Government agreeing to repay, for each year of service conducting such research, not more than $35,000 of the principal and interest of the educational loans of such health professionals.”

(LRP)

- The Director of the NIH shall make grants (to be referred to as ‘Mentored Patient-Oriented Research Career Development Awards’) to support individual careers in clinical research.” (K-23 awards)

- “The Director of the NIH shall make grants (to be referred to as ‘Mid-Career Investigator Awards in Patient-Oriented Research’).”(K-24 awards)
NIH Support of Clinical Research

- Clinical Research Study Sections
- K-23, K-24 Programs
- Clinical and Translational Research Centers (CTSAs)
- K-30 Programs - Clinical Research Curriculum Award
- K-12 Programs
Clinical Research Study Sections at NIH

Reorganization of study sections
• Recommendation that clinical research grants be reviewed in clinical research study sections or in sections that are reviewing a lot of clinical research
• Some clinical research study sections:
  • AIDS Clinical Studies and Epidemiology
  • Clinical and Integrative Cardiovascular Sciences
  • Clinical and Integrative Diabetes and Obesity
  • Clinical, Integrative and Molecular Gastroenterology
  • Clinical Oncology
  • Clinical Research and Field Studies of Infectious Diseases

http://www.csr.nih.gov/Roster
K-23 Mentored Patient-Oriented Research Career Development Award

- Development of the independent research scientist in the clinical arena
- 3-5 yrs, 75% commitment
- Non renewable
Patient-Oriented Research

• Researcher interacts **directly** with study participants, preferably in ongoing clinical activities.

• Researchers who propose to only analyze extant databases or biological specimens, see study participants briefly (e.g., for a blood draw), or design a patient questionnaire that will be administered by other medical support staff, are **not** conducting POR.

• Epidemiologic, nutrition, behavioral and social science research are included in spectrum of POR as long as researcher interacts directly with study participants.
K23 Goal:

• Ensure future cadre of well-trained scientists working in POR areas who will become competitive for NIH research project (R01) grant support.

• Encourage research-oriented clinicians to develop independent research skills and gain experience in advanced methods/experimental approaches needed to become an independent investigator conducting POR.

• Increase pool of clinical researchers who can conduct POR studies, capitalizing on discoveries of biomedical research and translating to clinical settings.

• Support career development of investigators who have made a commitment to POR.
What’s the NIH looking for in K awards?

Overall Impact of the proposed work and the applicant’s research development, based on...

Scored Review Criteria:

– Candidate
– Career Development Plan
– Research Plan
– Mentor, and Consultant and/or Collaborator
– Environment and Institutional Commitment to the Candidate
– Additional Review Criteria
K23 Key Elements: Career Development Program

• 3-5 consecutive years
• At least 75% of recipient's full-time professional effort must be devoted to the program, although up to 100% effort may be requested
• Remainder of applicant's time should be devoted to other research-related and/or teaching pursuits consistent with objectives of award
• Candidate expected to develop knowledge, skills and expertise in POR relevant to career goals.
• Should include didactic, laboratory, interdisciplinary and field experiences in their career development plan as needed.
K23 Key Elements: Mentor(s)

• Primary sponsor/mentor required
• Mentor, together with applicant responsible for planning, direction, and execution of program.
• Mentor
  – should be recognized as accomplished investigator in proposed research area
  – have track record of success in training independent investigators in patient-oriented research
  – have sufficient independent research support to cover costs of proposed research project in excess of allowable costs of award
• Candidates may also nominate co-mentors as appropriate
• Where feasible, women, individuals from diverse race and ethnic groups, and individuals with disabilities should be involved as mentors to serve as role models.
K23 Key Elements: Environment

Applicant institution must:

• have well-established record of research career development activities
• have qualified research faculty to serve as mentors
• demonstrate a commitment to development of candidate as a productive, independent investigator
• allow protected time needed by applicant
Questions

Q. What is the difference between a KO8 and K23 award?
A. The only difference between these two awards is the type of research supported. The K23 is exclusively for patient-oriented research (or a combination of patient-oriented and laboratory research), while the KO8 is for research that is not patient-oriented. Budgetary caps are different. Eligibility requirements and review criteria are identical for the two awards.
Questions

• **Q. Who can apply for a KO8/K23 award?**
  
  **A.** These awards are intended to develop independent clinician-scientists, therefore, applicants must have a clinical degree and be actively involved in clinical duties. Eligible candidates may have an M.D., D.V.M., Pharm.D., or other equivalent clinical degree.
Questions

Q. Who would be seen as too senior to apply for a KO8 or K23?
A. If an individual has substantial research experience in his or her current area of research, a substantial publication record, and preliminary data, s/he may be too senior for this mentored award, even if s/he is still a junior faculty member. Such individuals should consider applying for an independent-type grant mechanism such as the RO1, RO3, or R21.
K99/ROO: Pathway to Independence Award

*Purpose:* to increase and maintain a new cohort of independently funded investigators by facilitating receipt of an R01 award earlier in an investigator’s career

- Clinical or research doctorate
- Provides for both mentored (up to 2 yrs) and for independent research (up to 3 yrs)
- No more than 5 years postdoctoral training; check “Pathway to Independence” website
- Non-citizens are eligible
Information about NIH career development awards:

http://grants.nih.gov/training/careerdevelopmentawards.htm

The “K KIOSK”
There are three deadlines per year for submission of K Awards

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<tr>
<th>Receipt</th>
<th>Review</th>
<th>Council</th>
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<td>Oct. 12</td>
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<td>May-June</td>
<td>July</td>
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- Resubmission (i.e., amended) applications are submitted one month later than the dates noted above
- Applications must be received electronically on or before the receipt date
- Applications are submitted by institutional officials
- Your Grants Officer may have a much earlier submission deadline
SELECT RESEARCH CAREER DEVELOPMENT AWARDS APPLICATIONS, AWARDS, AND SUCCESS RATES

- K01
- K02
- K08
- K23
- K24

Success Rate

Fiscal Year


K08 42%
KO1/K23 34%
K99 22%
Clinical Research Curriculum Award (K30)

• Provide trainees with skills needed to translate basic discoveries into clinical treatments

• Stimulate inclusion of multidisciplinary, didactic training as part of career development of clinical investigators

• Support development of formal course work in design of clinical research projects, hypothesis development, biostatistics, epidemiology, disease mechanisms, medical technology, human genetics, and legal, ethical, and regulatory issues related to clinical research

• Goal: produce clinical researchers who can successfully compete for research support and are knowledgeable about the complex issues associated with conducting sound clinical research
Harvard K30

### Year 1

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<td>- Introduction to human investigation with introductory genetics, IRB workshops, bioinformatics</td>
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<td><strong>Selection of mentor-based clinical research projects</strong></td>
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- Genetics in clinical investigation
- Advanced biostatistics
- Principles of pharmacology for the clinical investigator (9-day intensive course in January)
- Fundamental methods of clinical trials

### Mentor-based Clinical Research Projects

**Longitudinal Clinical Research Seminar Series**
Bioethics in clinical research, mock IRB/study section, career development, progress reports

### Year 2

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| **Commercializing science and high technology**
Harvard Business School |

**Student thesis presentations**

**Longitudinal Clinical Research Seminar Series**
Case studies, student-led seminars
Clinical Translation Science Awards (CTSAs)

• Launched 2006
• National consortium of medical research institutions
• Goals
  – Reduce time for laboratory discoveries to become treatments for patients
  – Engage communities in clinical research efforts
  – Train clinical and translational researchers
Grant Opportunities

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<th>Grant Type</th>
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<td>Independent or Established</td>
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<td>Program/Center</td>
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Harvard CTSA=Harvard Catalyst

http://catalyst.harvard.edu/
K Mentored Awards- Given to Institutions

- K12-MENTORED CLINICAL SCIENTISTS DEVELOPMENT PROGRAM AWARD BIRCWH - Building Interdisciplinary Research Careers in Women's Health
- KL2-Medical Research Investigator Training (MeRIT) Program Catalyst
- MDs, PhDs, MD/PhDs
- Usually 2 years of salary support
LRPs

• In exchange for a two-year commitment to your research career, NIH will repay up to $35,000 per year of your qualified educational debt, pay an additional 39% of the repayments to cover your Federal taxes, and may reimburse any state taxes that result from these benefits.

• May be renewed
  – “Is there a limit to the number of renewals allowed?
  – No. As long as you continue to meet the eligibility criteria and have eligible debt, you may apply for an LRP renewal.”

http://www.lrp.nih.gov
NIH Loan Repayment Programs

- Clinical Research (trans-NIH)
- Pediatric Research (trans-NIH)
- Clinical Research by Individuals from Disadvantaged Backgrounds (NCMHD)
- Minority Health Disparities Research
- Contraception and Infertility Research (NICHD)
Clinical Research LRPs

New Applications

Renewals

36% 69%

www.lrp.nih.gov
Welcome to the Partners Research Management Internet

PREPARING OR SUBMITTING A PROPOSAL?
Materials and information needed to prepare, submit and review a proposal can be found in the Proposal section. Read More »

MANAGING AN AWARD?
Materials and information needed to set up, manage and update a grant, initiate charges and monitor funds can be found in the Award Management section. Read More »

COLLABORATING THROUGH SUBCONTRACTS OR CONTRACTS?
Materials and information related to negotiating and executing agreements, foundation awards, incoming contracts and outgoing subcontracts can be found in the Contracts section. Read More »

ACCOUNTING FOR A GRANT OR CONTRACT?
Materials and information related to billing, payments, accounting, financial reporting and the close out of an award or agreement can be found in the Research Finance section. Read More »

http://resadmin.partners.org/rm_home/
Friday Funding Opportunities

To receive weekly emails regarding funding, sign up for the Friday Funding Opportunities, maintained through Research Administration

http://bwhbri.partners.org/ResearchAdmin/Grants/RICSFundingOpps.asp
Awards offered Fall 2011

For the following awards, applications must be submitted online no later than Tuesday, October 18, 2011 by 5:00PM

- AXA Research Fund Postdoctoral Fellowship
- Damon Runyon Cancer Research Foundation Clinical Investigator Award
- Dana Foundation Program in Brain and Immuno-imaging
- Dana Foundation Program in Neuroimmunology of Brain Infections and Cancers
- Ellison Foundation New Scholars Program in Aging
- Macy Foundation Faculty Scholars Program
- Mary Kay Innovative/Translational Cancer Research Award
- Packard Fellowships in Science and Engineering
- Rita Allen Faculty Scholars Program

The following awards are offered solely to Harvard appointed applicants and therefore no preliminary internal application is required. Because these awards are administered by the sponsor rather than the HMS Foundation Funds, instructions, deadlines, and application requirements will vary. Please visit the links below for individual award instructions.

- Bullock-Wellman Postdoctoral Fellowship
- William F. Milton Fund

http://www.hms.harvard.edu/FoundationFunds/
The Center for Faculty Development & Diversity (CFDD) provides comprehensive strategies and support for career advancement and professional development of all faculty and fellows at Brigham and Women’s Hospital.

With a focus on advancing and supporting an inclusive and diverse faculty, within the Center are three specialized offices. The Office for Multicultural Faculty Careers (OMC) provides support for professional development, career planning and mentoring of underrepresented minority faculty. The Office for Research Careers (ORC) addresses the specific needs of postdoctoral scholars and career scientists in the research community. And the Office for Women’s Careers (OWC) serves the professional development and advancement of women faculty.

http://www.brighamandwomens.org/medical_professionals/career/cfdd/default.aspx