hms | hsdm
office for postdoctoral fellows

Grantcraft for Postdocs

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February 22, 2021

1. Introduction to Grants
NIH Grant Mechanisms

2. Grant Anatomy and Physiology
Careers and Fellowships

Break

3. Title, Aims, Abstract
4. Research Strategy: Addressing Review Criteria

5. Peer Review
6. Program and IC Action, Resubmitting

1. NIH Overview
Who am I and Why am I Here?

- New investigators
- Students, Postdocs, clinical fellows
- Training, Transition, Established
  - PhD or clinician
- Which Institute or Center?
- For me, for my trainees
- US citizen/permanent resident or international
  - Diversity

What is a Research Grant?

An award from a "sponsor" or funding agency

Awarded to the *institution*, not the person

In "partial" support of a project or projects

Different from a research contract

What is NIH?

27 Institutes and Centers

Institutes (e.g NCI, NIAID) and Centers (e.g. NCATS, FIC) can award grants

Offices (e.g. ORWH) cannot make grants directly

NIH "IC" Structure

- Extramural Research Program
  - Support of research and training through grants and contracts at more than 1,700 research institutions throughout the U.S. and abroad
- Intramural Research Program
  - Research conducted in NIH laboratories and clinics in Bethesda+
  - Administrative & support costs

Extramural

- https://www.nih.gov/grants-funding
- https://researchtraining.nih.gov/
- With few exceptions, only US citizens or permanent residents are eligible for training and career awards.
  - **Notable**: K99/R00
- There are generally no citizenship requirements for research (R) grants

Training and Career Development Home

https://researchtraining.nih.gov/

Institute/Program Matrix

Training Advisory Committee

https://researchtraining.nih.gov/tac-roster

New and Early Stage Investigators

https://grants.nih.gov/policy/new_investigators/

New = no previous R01 - varies by IC

Early = <10 years - prioritized at review, funding

Grants Fundamentals

- Investigator-Initiated R01
  - Submission = spontaneous
  - Assigned by CSR for Peer Review and ?funding
  - Scientific Merit review by regular CSR study section
  - Funding or resubmission
- Funding Opportunities: RFA, PA *or non-R01*
  - Submission = invited (an identified Program)
  - Assignment automatic: Why IC priorities matter!
  - Scientific Merit Review by IC or Special committee
  - May not be able to resubmit
- The NIH Guide

https://grants.nih.gov/funding/searchguide/index.html#/

"Standard" NIH Receipt Dates

K: Feb, June, October 12

Most R: February, June, October 5, 16

Most F: April, August, December 8

Investigator-Initiated Applications

Two independent assignments
Made by Center for Scientific Review (CSR)
using: title, abstract, optional Assignment Request Form

Number format: 1R01HD056789-01, -01A1

Assignment	Review	Institute
Function	Peer Review	2nd level review
		Funding
Unit	Study Section	Program
Person	SRO	Program Officer

Non-R01 and solicited applications *different*

The NIH Guide to Grants and Contracts

Subscribe to Table of Contents

COVID-19 info for NIH applicants and funding recipients

https://grants.nih.gov/policy/natural-disasters/corona-virus.htm

https://grants.nih.gov/grants/guide/COVID-Related.cfm

Extramural Training
Institutional (T32)

- Large "umbrella" grant to an institution
- A starting point if you are a new mentor
- Program advertises and selects trainees
  – candidates apply to the program, not to NIH
- May be open to predocs and/or postdocs – varies by institution
- In some cases, clinicians may be appointed for their research year (or more)
- Recent language inclusive of preparation for research-related careers

Extramural Training
Individual Fellowship

- F30: MD-PhD students in combined program
- F31 Predoctoral: specific ICs, diversity
- F32 Postdoctoral
- Candidate applies with sponsor to NIH
- As a sponsor, you need a *training record*
- Maximums:
  – Five years of predoc funding (F30 = six)
  – Three years of postdoc funding
  – any combination of institutional and individual
- Training and fellowships provide stipend, health insurance, some related expenses

Career (K) Awards

- Mostly salary, some research costs
- Mentored or Independent
- Mentored K's usually require 75% effort on research and are limited to 5 years (any combination)

Individual Career Awards

- Clinicians
  – K08: Any research including basic
  – K23: Patient Oriented Research
  – K24: Midcareer POR and mentoring
- Nonclinicians
  – K01 et al. – use varies by IC
  – K02: when already funded
- Transition Awards – *use varies by IC*
  – K22: Clinician or postdoc to junior faculty

Pathways to Independence (PI)

A trans-NIH Career Transition Award K99/R00:
PA-20-188 (et al.)
Phase I= 1-2 years senior postdoc @<100K/yr
Phase II=Independent research grant @ <249K/yr
contingent on getting a job
Initial goal n=150-200 per FY
(267 in 2018, 257 in 2019, 298 in 2020)
Domestic institutions only but foreign citizens are eligible!
Standard Receipt dates

Institutional Careers (K12)

- Various ICs: Specialty areas
  - hematology, oncology, neurology, eye
- Clinical Research, GTPCI, CTSA (KL2)
  - Multidisciplinary or not disease specific
- NIH Interdisciplinary
  Women's Health, Clinical Research…
  - includes some PhD's
- Like a T32 – apply to the program, not NIH

Research (R) Grants

- Flexible budget and duration
- Small, medium and large
  - R03, R21, R15
  - R01: The gold standard
  - P01 (Program Project) and Centers
    - Subprojects are "R01 equivalents"
- No requirement for US citizenship or location

Extramural- priority populations

- Research Supplements to Promote Diversity in Health-Related Research
  PA-21-071
- Re-entry
- PI of existing research grant applies to NIH administratively to add a specific qualifying individual to the project – high school through junior faculty

Oddballs

New Innovator Award (DP2)
64 Awards in 2019, 59 in 2020
RFA RM-20-012
Receipt Date was August 21 - usually annual

NIH Director's Early Independence Award (DP5)
13 Awards in 2019, 14 in 2020
RFA RM-20-014
Receipt Date was September 4 - usually annual

Who is funded

And why do I need to know?
- RePORTER database

"Research Portfolio Online Reporting Tool - Expenditures & Results"

NEW: https://reporter.nih.gov/
Classic: http://projectreporter.nih.gov/reporter.cfm

Finding a collaborator
Finding a mentor for a trainee
Finding a sponsor for a supplement
Finding model titles and abstracts

Matchmaker

https://projectreporter.nih.gov/reporter_matchmaker.cfm

2. Anatomy and Physiology of an Application

Criteria for Scientific Merit

The Parts: Where they go, what they do

R, K and F applications:
Common and Peculiar Parts

What *is* "Merit?" Scored Criteria, Research Grants

Updated March 9, 2018

- Significance
- Investigator(s)
- Innovation
- Approach
- Environment

⇨ Individually scored 1-9

Significance

Does the project address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed project rigorous?* If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

*Changed as of 1/25/19 NOT-OD-18-228

Investigator(s)

"Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?"

Innovation

"Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical *concepts, approaches or methodologies, instrumentation, or interventions*? Are [they] novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application [of these] proposed?"

Approach

"Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project?* Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? …(more)

Approach

"… Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects? If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of individuals of all ages (including children and older adults)*, justified in terms of the scientific goals and research strategy proposed?"

*Changed 1/25/19: NOT-OD-18-228

Environment

"Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?"

Additional Review Criteria

- Human subjects protection
  Separate criteria for exempt, non-exempt
- Inclusion of women, minorities, individuals across the lifespan
- Vertebrate animals
- Biohazard protection
- Resubmission - responses
- Renewal – progress
- Revision - appropriateness

⇨ Count in overall impact/priority score

Additional Review Considerations

- Applications from Foreign Organizations
- Select Agent Research
- Resource Sharing Plans
- Authentication of Key Biological and/or Chemical Resources
- Budget and Period of Support
- Additional Comments to the Applicant

⇨ Do not count in score

Your Application
Electronic Submission

The SF424(R&R)
http://grants.nih.gov/grants/how-to-apply-application-guide.htm
Register ahead in Grants.gov and eRA Commons

Forms F: You have to scroll down!

Parts of an R Application

- Project Summary/Abstract and Narrative
- Specific Aims - 1 page
- Research Strategy - 6 or 12 pages
  - Significance
  - Innovation
  - Approach
    Preliminary Studies or Progress
- Special Issues (human subjects, vertebrate animals, etc)
- Letters

Remember - Connect Hypothesis-Aims-Experiments-Data

R and K Parts - Where do they go?

SF 424 "Research and Related"

Cover - Administrative Data
PHS Cover Letter - required for mentored Ks
Project/performance Site
R&R Other Project Information
R&R Senior/Key Persons Profile (Expanded)
PHS Research Plan
PHS Career Development Award Supplemental Form

(Letters of Reference)

R, K, F Applications
Other Project Information

Item 7. Proposal Summary/
Abstract: 30 lines
Item 8. Narrative:
2-3 sentences
Item 9. Bibliography and
References Cited
Item 10: Facilities & Other Resources
Item 11: Equipment
Item 12: Other Attachments

Item 10: Addresses Institutional Commitment and Environment…

How does the scientific environment contribute to the probability of success?
- institutional support
- physical resources
- intellectual rapport

How will the research benefit from
- unique features of the scientific environment
- subject populations
- collaborations

Item 10: …Addresses Institutional Commitment and Environment

For ESIs, "facilities" includes training, collegial, logistical and financial support:
- career enrichment programs
- guidance in supervision of trainees
- availability of organized peer groups
- protected time for research with salary

Senior/Key Persons Profile Addresses "Investigator"

New, Early Stage, newly independent:
Appropriate Experience and Training

Biosketch (5 pp) includes
Part A, Personal statement: "Briefly describe why your experience and qualifications make you particularly well-suited for your role"

Do not repeat your CV!

New: May explain reasons affecting productivity

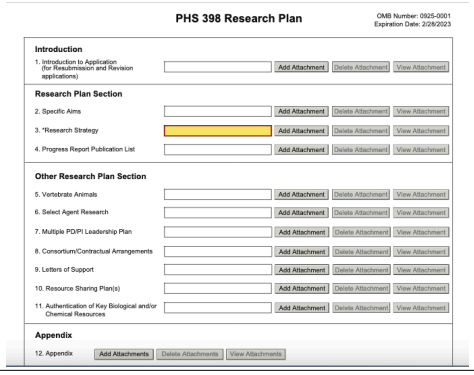
Part B - positions
Part C - contributions to Science - Read!
  Up to five, need not relate to this application
  Up to four citations each
  URL to full publications via My Bibliography

Part D - For fellowships, Scholastic record
  For all others, Research Support

Examples!

http://grants.nih.gov/grants/forms/biosketch.htm

The Research Plan
Addresses Significance, Innovation, Approach


PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 2/28/2023

Introduction
1. Introduction to Application (for Resubmission and Revision applications)

Research Plan Section
2. Specific Aims
3. *Research Strategy
4. Progress Report Publication List

Other Research Plan Section
5. Vertebrate Animals
6. Select Agent Research
7. Multiple PD/PI Leadership Plan
8. Consortium/Contractual Arrangements
9. Letters of Support
10. Resource Sharing Plan(s)
11. Authentication of Key Biological and/or Chemical Resources

Appendix
12. Appendix

Add Attachment | Delete Attachment | View Attachment

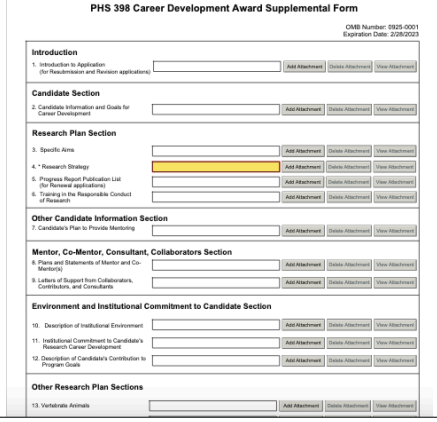
Scored Review Criteria – K's

F, K are different from R

- Candidate = YOU
- Career Development Plan/Career Goals & Objectives/ Plan to Provide mentoring
- Research Plan
- Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s)
- Environment and Institutional Commitment to the Candidate

⇨ Individually scored 1-9

K Supplemental Form


PHS 398 Career Development Award Supplemental Form

OMB Number: 0925-0001
Expiration Date: 2/28/2023

Introduction
1. Introduction to Application (for Resubmission and Revision applications)

Candidate Section
2. Candidate Information and Goals for Career Development

Research Plan Section
3. Specific Aims
4. * Research Strategy
5. Progress Report Publication List (for Renewal applications)
6. Training in the Responsible Conduct of Research

Other Candidate Information Section
7. Candidate's Plan to Provide Mentoring

Mentor, Co-Mentor, Consultant, Collaborators Section
8. Plans and Statements of Mentor and Co-Mentor(s)
9. Letters of Support from Collaborators, Contributors, and Consultants

Environment and Institutional Commitment to Candidate Section
10. Description of Institutional Environment
11. Institutional Commitment to Candidate's Research Career Development
12. Description of Candidate's Contribution to Program Goals

Other Research Plan Sections
13. Vertebrate Animals

Add Attachment | Delete Attachment | View Attachment

Parts of a K Application like an R

Proposal Description
Personnel
Budgets
Candidate and mentor(s) Biosketches – 5 pp
Other support for mentor(s), not candidate
Resources: "space, equipment, and other resources and facilities"

Special Parts of a K Application… Address Candidate and CD Plan…

Candidate and Research Strategy = 12 pp

- Candidate's Background – beyond the biosketch
- Career Goals and Objectives – keep project in mind
- Career Development/Training Activities During Award
  - New skills and knowledge
  - Other than research itself

Training in Responsible Conduct of Research - 1 p

Special Parts of a K Application… Addresses Mentor(s)…

Plans and Statements by Mentor(s), Co-Mentor(s) 6 pp
Letters from Collaborators, Contributors,Consultants 6 pp
How they will contribute to your career development
- Training and CD Plans
- Support available
- Supervision and Mentoring
- Your teaching, clinical, committee demands; time available for research
- Plan for transition to independence includes past record

Special Parts of a K Application… Address Institutional Environment and Commitment…

Institutional Environment 1 p
Commitment to training/career development
- Available facilities
- Available research support
- Training opportunities

Institutional Commitment 1 p
- Protected time, resources (you and mentor)
- Quality & relevance to scientific development
- Commitment to retention, development, and advancement of the candidate

Special Parts of a K Application… Addresses Research Plan

- Research Strategy like an "R"
  - -But must connect to your career goals
  - -When combined with the CD activities above, will allow you to achieve those goals
  - -Less detail expected, especially in future years but enough to convince reviewers
  - -Relationship between proposed research and mentor's ongoing research program

You write it
- -but preview and discuss with sponsor, others

…Special Parts of a K Application Addresses Candidate

Mentored Ks: Cover Letter required (SF 424 Item 21)
List References (3), not part of project
-Meaningful input on your experience, qualifications
-Separate instruction page

Scored Review Criteria - F's

⇗ F, K are different from R

- Fellowship Applicant – YOU
- Sponsors, Collaborators, and Consultants
- Research Training Plan
- Training Potential
- Institutional Environment & Commitment to Training

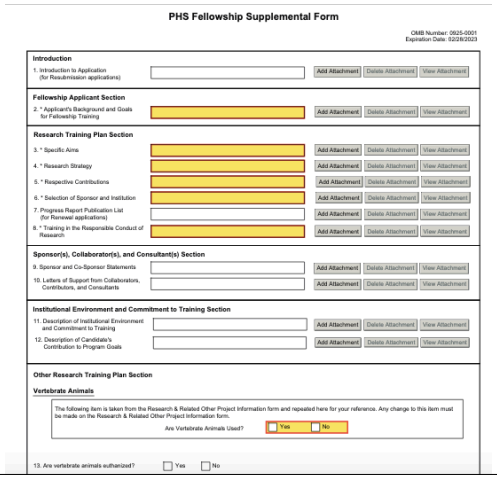
⇨ Individually scored 1-9

Fellowship-Specific Instructions

SF 424 “Research and Related”

Cover - Administrative Data
Project/performance Site
R&R Other Project Information Component
R&R Senior/Key Person Profile (expanded)
PHS Cover Letter - required
PHS Fellowship Supplemental Form

Letters of Reference



PHS Fellowship Supplemental Form

OMB Number: 0925-0001
Expiration Date: 02/28/2023

Introduction
1. Introduction to Application (for Resubmission applications) — Add Attachment | Delete Attachment | View Attachment

Fellowship Applicant Section
2. * Applicant's Background and Goals for Fellowship Training — Add Attachment | Delete Attachment | View Attachment

Research Training Plan Section
3. * Specific Aims — Add Attachment | Delete Attachment | View Attachment
4. * Research Strategy — Add Attachment | Delete Attachment | View Attachment
5. * Respective Contributions — Add Attachment | Delete Attachment | View Attachment
6. * Selection of Sponsor and Institution — Add Attachment | Delete Attachment | View Attachment
7. Progress Report Publication List (for Renewal applications) — Add Attachment | Delete Attachment | View Attachment
8. * Training in the Responsible Conduct of Research — Add Attachment | Delete Attachment | View Attachment

Sponsor(s), Collaborator(s), and Consultant(s) Section
9. Sponsor and Co-Sponsor Statements — Add Attachment | Delete Attachment | View Attachment
10. Letters of Support from Collaborators, Contributors, and Consultants — Add Attachment | Delete Attachment | View Attachment

Institutional Environment and Commitment to Training Section
11. Description of Institutional Environment and Commitment to Training — Add Attachment | Delete Attachment | View Attachment
12. Description of Candidate's Contribution to Program Goals — Add Attachment | Delete Attachment | View Attachment

Other Research Training Plan Section

Vertebrate Animals

The following item is taken from the Research & Related Other Project Information form and repeated here for your reference. Any change to this item must be made on the Research & Related Other Project Information form.

Are Vertebrate Animals Used? ☐ Yes ☐ No

13. Are vertebrate animals euthanized? ☐ Yes ☐ No

Reference Letters Address “Applicant”

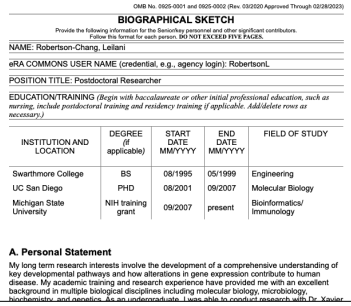
List them in Cover Letter: SF424 Cover, p. 2, Item 21

References (at least 3), not sponsor of this application
- Carefully selected
- Meaningful input on your research potential
- Graduate or medical preferred, not undergrad
- At least one from outside current department
- If omitting thesis advisor, explain!
- Must be able to respond timely

R&R Senior/Key Person Profile (expanded) Addresses “Applicant”

Same format, 5 pp
A: Personal Statement
B: Positions
C: Contributions

Different:
Section D



OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Robertson-Chang, Leilani

eRA COMMONS USER NAME (credential, e.g., agency login): RobertsonL

POSITION TITLE: Postdoctoral Researcher

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE (if applicable)	START DATE MM/YYYY	END DATE MM/YYYY	FIELD OF STUDY
Swarthmore College	BS	08/1995	05/1999	Engineering
UC San Diego	PHD	08/2001	09/2007	Molecular Biology
Michigan State University	NIH training grant	09/2007	present	Bioinformatics/ Immunology

A. Personal Statement

My long term research interests involve the development of a comprehensive understanding of key developmental pathways and how alterations in gene expression contribute to human disease. My academic training and research experience have provided me with an excellent background in multiple biological disciplines including molecular biology, microbiology, biochemistry, and genetics. As an undergraduate, I was able to conduct research with Dr. Xavier

Part B - positions - F’s include MM/YY start date
Part C - contributions to Science - Read!
- “Up to five," need not relate to this application
- Up to four citations each
- URL to full publications via My Bibliography

Part D - For F’s, Scholastic Performance
(science/professional grad courses)
For K’s, Research Support

Examples!

http://grants.nih.gov/grants/forms/biosketch.htm

F Supplemental Form…

Applicant Section
2. Background and Goals - 6 pp

Research Training Plan Section
3. Specific Aims - 1 p

4. Research Strategy - 6 pp *including figures*
You write, but consult extensively with mentor(s)

5. Respective Contributions - 1 p
6. Selection of sponsor and Institution - 1 p
8. Responsible Conduct of Research - 1 p

Addresses Applicant

Background and goals

A. Research experience is stage-specific
For postdocs, is any part of your PhD or earlier postdoc?
B. Training Goals and Objectives
How will this award enable you to meet your goals?
What will you learn?
How will the research → your transition to next stage?
C. Activities Planned
By year, what percent of each?
What skills will you learn?
Timeline!

Addresses Research Training Plan

- Quality of the research
  Integrated with training or career plan
  Feasible, distinct from sponsor's
- Publish, present, meet
- Experiences to develop professional skills

NOTE:
The project, sponsor, and environment are a *unit*

Addresses "Training Potential"

- Does the experience provide needed skills
- Take advantage of your strengths, address gaps
- Document that you need it and it's of value
- A sound foundation to launch your research career

Translation:
Does it provide something you do not already have (experimental or conceptual)?

…F Supplemental Form…

Sponsor(s), Collaborator(s), Consultant(s) Section
9. Sponsor and co-sponsor(s) 6 pp

A. Research Support Available
B. Previous Fellows and Trainees
C. Training Plan, Environment, Research Facilities
didactic, technical, collaborations, opportunities
relation to your career goals; transition to next
D. Number of Trainees/Fellows to be Supervised
E. Applicant's Qualifications and Research Potential

10. Letters of Support from Collaborators, Contributors, and Consultants - 6 pp

Addresses "Sponsor(s)…"

- Sponsor's qualifications to train you
  - Competitive funding
  - Interests match your needs
- Training record
- Plans to monitor your progress

…F Supplemental Form

11. Description of Institutional Environment and Commitment to Training - 2 pp

Other Research Training Plan Section, items 12 - 28
- if applicable, do not count in page limits
Vertebrate Animals
Human Embryonic Stem Cells…
Current/Prior NRSA support
Applications for Concurrent Support - 1 p

Budget Section

3. Title, Specific Aims, Abstract

First you need a Question/Hypothesis

Why the Title is Important

Constructing Specific Aims

Abstract and Aims Page: Similarities and Differences

Hypothesis/Research Problem

- Review the current literature
- Choose a problem:
  - The result will be important (it's worth doing)
  - You can do the work (it's feasible)
  - You can demonstrate the skills or you have a collaborator
- The hypothesis can be stated clearly
- The hypothesis can be tested
- The results can be interpreted

Defining a Research Problem

- Clear
- Focused – beware the "A-" word
- Solvable (feasible)
- Important – adds to the field
- Ideally, testing the hypothesis is important, supported or not

Developing a Research Problem

- Start early – know the literature
  - Where are the gaps
- Talks and abstracts – pay attention
- Talk to advisors, colleagues
- Build on your strengths, experience
- But – don't stand still
- Big enough
- You (+ sponsor, + environment) can do it

Parts of an Application

- Project Summary/Abstract - *separate*
  Item 7 of Other Project Information
- Specific Aims
  Item 2 of Research [Training] Plan
- Research Strategy - 6 or 12 pages
  - Significance
  - Innovation
  - Approach
    Preliminary Studies or Progress
- Special Issues (human subjects, vertebrate animals, etc)
- Letters

Feedback among Hypothesis-Aims-Experiments-Data

Title

- 200 characters (including spaces, punctuation)
- Descriptive (content)
- Appropriate (type/status)
- First Impression
  - Used for assignment

Grant "Types"
1R01HD123456-01A1

1	New	Submitted for the first time
2	Renewal	Competing for additional years
3	Revison	Expand scope of work of current award
A1	Resubmission	Revised or amended to address review
5	Continuation	Yearly Progress Reports

Concise and Descriptive Titles

Modest supplemental oxygen worsens lung injury in a murine model of sepsis

Reducing Total Cardiovascular Risk in an Urban Community

Estrogen Receptor Beta Regulation of the GnRH Neuron

Identifying a Cancer Stem Cell Population in Non-Small Cell Lung Carcinoma

New Titles

Elucidating Novel Mechanisms Controlling Cell Envelope Biogenesis in Streptococcus Pneumoniae

Single Cell Molecular Network Mechanisms of Cardiotoxicity Induced by Tyrosine Kinase Inhibitors

What is a Specific Aim

- An experiment or group of experiments
  - Designed to test hypothesis or answer a question
  - Designed to generate new knowledge

NIH directions

- One page
- Goals of the Research/Outcomes/Impact
- Specific Objectives
  - Test of a stated hypothesis
  - Create a novel design
  - Solve a specific problem
  - Challenge an existing paradigm or clinical practice
  - Address a critical barrier to progress in the field
  - Develop new technology

Planning Specific Aims

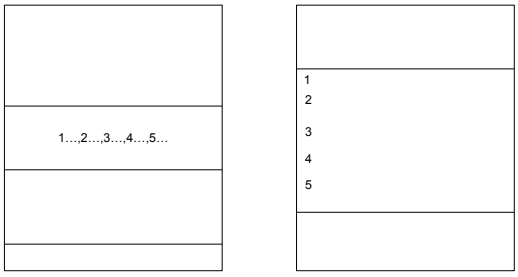
- How many? (3-5 works well)
- State concisely but clearly:
  - the objective
  - what information you will obtain
- Beware of "descriptive" Aims-sometimes necessary, but must be justified
- Logical order

Specific Aims: Content

- Begin with one-paragraph description
  - Long term objectives and research goal(s)
    - remember health-relatedness
  - Rationale - from known to unknown
  - Problem statement - key issues to be addressed
  - State your overall hypothesis or question
- Follow with numbered list of Aims
  - Specific Aim hypothesis, if any
  - Choose Aims with preliminary data - but show data later
  - Describe main approach or technique(s)
- Conclude with significance, implications

Specific Aims: Style

- Numbered list, easy to follow
- All aims should be related and in the right order
- Open with one sentence or bullet
- Use active verbs, e.g., “To determine . . .”
- OK to use underlining or bold for emphasis
- Brief paragraph stating protocol, methods and approach



Abstract Specific Aims Page

How Reviewers look at your Aims

- All reviewers will read
  - Title
  - Abstract
  - Specific Aims
- Reviewers want three things from your Aims:
  - What you want to do
  - How you are going to do it
  - So what?
- Reviewers will deduce from your Aims:
  - Fundability
  - Feasibility
  - Impact

How reviewers evaluate your Aims

- Are they precise and focused - “specific?”
- Do they test your hypothesis?
- Will you generate new knowledge?
- Do they relate logically to one another?
- If one Aim is not successful, will entire project fail?
- Do you orient the reader to the techniques used?

Common Criticisms

- Too many Aims
  - Diffuse, unfocused, “ambitious”
- Will not lead to new knowledge
  - Unproductive, uninterpretable
- “Descriptive”
  - Fishing expedition, lack of focus
  - If you must include, justify!
- Vague (“to study, to explore…”)
- Technique-driven (missing context, significance)
- Cluttered (avoid references and quotations)

Abstract: Purpose

- The first impression
  - “You have only one chance to make a first impression.”
- Used to assign application (Study Section/Institute)
  - Make sure you also use Assignment Request Form
- All reviewers read all abstracts
- Reviewers re-read abstract before and during the Study Section meeting
- If grant is funded, abstract becomes public via RePORTer

NIH Instructions

- Part 1: Project Summary/Abstract (Item 7)
  - 30 lines
  - Broad objectives and Specific Aims
  - Health relatedness=mission relevance
- Part 2: Project Narrative (Item 8)
  - 2-3 sentences
  - Relevance to public health (lay language)
  - May be fundamental knowledge

Behind the directions

- Include a background statement to orient reader
- Clearly state overall hypothesis
- Note unique or novel features that distinguish your proposal
  - why should they fund you?
- You may mention a crucial resource you developed, but otherwise "*Avoid both descriptions of past accomplishments and the use of the first person"*
- Articulate the relevance to NIH's mission
- Give context, the significance of your work for the field.

Make it Readable

- Get all the reviewers on your side, not only those in your field
- Write for the generalist as well as the specialist
- Use clear language
  - No jargon
  - Minimal abbreviations
  - Avoid references and quotations, except those noted by NIH

Common Mistakes

- Aims or goals not stated
- Not consistent with Specific Aims
  - Use same order, same words
  - May be condensed
- Too technical
- Does not generate excitement
  - What is new about your work
  - What difference will it make?

4. Research Strategy

- A specific hypothesis
- Specific aims and objectives used to examine the hypothesis
- Methods to be used in each aim
- Possible problems and how they will be managed
- Alternatives if initial approaches do not work

Research Strategy - R vs K

Table 1

R01 Research - 12		K Career - 12	
Significance	2+	Background & Goals	1+
Innovation	1+	Career Dev Activities	2+
Approach Preliminary Design & Methods	9+	Research Strategy Significance Innovation Approach	9+

Significance

Why the study is needed

- An important problem or critical barrier to progress
- Strengths and weaknesses in rigor of prior research underlying proposal
- How knowledge/capability/practice will improve
- How the results will change the field

⇨ Concepts, methods, technology, treatment, services, prevention

Significance

1. General statement & introduction (1st paragraph)
   Describe your project, its relation to the field
2. Essential information only
   Limit to work directly relevant to your proposal
3. The present status
   Where is the field now?
   Gaps, Deficiencies, Barriers…
   Rigor of prior studies
4. Future directions
   Where is the field going? Where does it need to go?
   How does your work move it in that direction?
5. Final paragraph
   Assess the Impact as you and others progress

Innovation

- A paradigm shift?
- Advantage over *status quo*
- Is novelty narrow or broad?
- Refinement, improvement or new use?
- Not required for Fellowships! But…

Can be: concepts, approaches, methods, instrumentation, interventions

Innovation

- You ***must*** comment explicitly on Innovation
  - Reviewers will ask: How do you challenge existing paradigms, exploit new theoretical or practical tools or significantly refine current applications?
  - Reviewers will ask: Is novelty limited to one field or is it more broadly applicable?
- Not all grants need be highly innovative
  - Balance innovation with feasibility
  - Varies with mechanism (0 to mandatory)
  - Do not oversell - rare to be truly novel

Approach:
Preliminary Studies…

- Purpose: To show feasibility
- You have the gene - antibody - mouse model…
- You have the skill (show data or publications) or have enlisted a collaborator
- Your hypothesis is based on pilot data (yours or others')
- The pilot data are of good quality (figures are key!)
- Not always required but will help you… *if good*
- Less weight in R01s from Early Stage Investigators

…Preliminary Studies

- Your published studies
  - Summarize
  - Useful to document experience -> "Investigator"
  - Can document independence or collaborations
- Your unpublished work
  - Not as strong as publications (yours, others')
  - Provide in more detail
  - Useful for strengths, weaknesses of methodology
- Use visuals to show data, ease reader fatigue

Approach
Structure…

- Function: to describe what you'll do to achieve Aims
- Begin with an overview (brief or extended)
  - To discuss model or framework underlying your proposal
  - To address weaknesses in rigor of prior studies
  - To highlight elements of design or methods that are essential and used often (eg, *General Issues in Experimental Design*)

Approach
…Structure

Repeat each Specific Aim as a new section
- Same order, wording as Abstract, Aims page
- Use narrative to present relevant elements
  - experimental design
  - related procedures and methodology

- As much detail as possible in space allowed
- Concluding paragraph: include timeline

Approach
Contents…

- Rationale
  - Logic of your particular experimental approach
  - Cite preliminary data which give proof of principle
  - Why particularly suited to Specific Aims
  - Describe plans to address weaknesses in the rigor of the prior research
- Protocol(s)
  - Experimental design, choice of appropriate controls
  - Animal or human subjects*: pros and cons
  - Variables to be measured: justify choices
    - time points, doses, patient characteristics, etc.

* Do not duplicate material in HS and Clinical Trials Info Form

Approach
Contents…

- Data analysis*
- Obtain statistical consultation if needed
  e.g. to do power calculations for sample size
- Indicate anticipated results
- Interpret those results in terms of hypothesis, Aims
- Describe implications for the field
- Potential problems, alternatives, benchmarks

*Unless addressed in Resource Sharing Plan

Approach
…Contents

- How design deals with relevant biological variables such as sex
- Hazardous materials/procedures and precautions
- If hESC, justify if on a line not from NIH registry
- If "gaining experience" in a clinical trial, what is your role

"New" Rigor and Reproducibility Policy: Bad News, Good News

1) Rigor of the prior research forming the basis of the proposed research
2) Rigorous experimental design for valid, robust, and unbiased results
3) Consideration of relevant biological variables
4) Authentication of key biological and/or chemical resources.

5. Peer Review and Resubmission

27 Institutes and Centers

Most have Intramural and Extramural Divisions
Extramural: Program, Review, Policy

Center for Scientific Review (CSR) - not a Research entity
Conducts Peer Review for other IC's
Almost all investigator initiated R01 applications, some others

Institute Review Committees
Conduct Peer Review of FOAs, most non-R01

Who Conducts Review?

Dual Review:

Applications reviewed at two levels
- Study Section
  - Reviews applications for scientific and technical merit
- Institute Advisory Council
  - Reviews recommendations of the Study Section
  - Judges significance of proposed research to the goals of the Institute
- ~9 months from receipt of grant to funding

Grant Assignment

Center for Scientific Review (CSR)
An independent unit within NIH
- Receives and numbers applications
- Assigns application Study Section for review and Institute for funding consideration
  - Assignment request form!
- Sends you SRO and PO contact info
- Administers and staffs Study Sections
- Collates scores and distributes reviews to Institutes

Study Section - R's

- Administered by CSR
- Independent of any specific institute
- Review grants based on subject matter not institute
  - A single endocrine-related study section may review grants assigned to NIDDK, NICHD, NIA, NCI, NIEHS, etc

Critical CSR Information

http://public.csr.nih.gov/

- Description of study sections
- Meeting dates
- Membership rosters
- SRO contacts
- Reviewer Guidelines
- Examples of review templates

more…

Critical CSR Information

Applicant Resources
Reviewer resources
Study Sections

IC Peer Review

Ks, RFAs, and non-R01s are different

- Assigned an Institute, but not a CSR study section
- Sent directly to the appropriate Institute, reviewed by dedicated 'in house' study sections
- Specific Institute web sites have study section specifics including rosters, dates, etc.

Study Section Staff

Scientific Review Officers (SRO)
- All aspects of study section *except* scientific review
- Assignment of grants to reviewers
- Final preparation of the written reviews
- Interaction with applicants while in review

Grants Technical Assistants
- Clerical and logistical

Study Section Members

Regular Members (15-20)
- Selected by SRO; appointed by NIH Director
- Serve 3-4 years
- Review and vote
- One member serves as chair

– Ad Hoc Members
- Serve at a single meeting to provide expertise in a specific area
- 2-20 per meeting

Scoring System

NOT-OD-09-024

Nine point scale
for Overall Impact and for each Scored Criterion

1= Exceptional to 9=Poor

Aggregate score 10-90

Before the Meeting

- 2-3 reviewers per application (primary, secondary & reader)
- Primary and secondary reviewers upload written critiques prior to the meeting
- Each enters a score for five core criteria
- Each enters a preliminary impact score
  – Overall impact, NOT weighted average

'Triaging'

- Applications Not Discussed
  – Discussed in decreasing order until ~half done
  – Applications not discussed still get criterion scores but no overall score
  – In past, unscored applications received written critiques but no numbers
- If lacks merit or has serious ethical problems: Not Recommended for Further Consideration

Study Section Meeting

- 2-3 days, three times per year: February, June, October
- In Before Times, usually held in a hotel in the Washington DC/Bethesda area
- 60-100 grants reviewed per meeting
- Attempts to make more flexible, less onerous

Sequence of Review

- 5-15 minutes/application
  - Primary and secondary reviewers present strengths and weaknessesi
  - Comments from the reader
  - Open discussion
  - All study section members give a final impact score
- Afterwards, CSR calculates mean and multiplies by 10 for overall impact score

Scores and Percentiles

- Research applications ranked by impact or priority score and a percentile is calculated
- To 'normalize' scoring behavior across study sections
- Calculated by comparison with applications reviewed within CSR over the previous three meetings
- Calculated only to nearest integer

➢It is generally the percentile that determines the 'fundability' of a grant

Funding – R's

The Payline

- All applications reviewed in one funding cycle are ranked by the Institute by percentile
- The payline is the percentile ranking below which all applications will be funded
- The payline varies from institute to institute

What do the scores mean?

RFA's, K's, T's, (F's) are different

- Receive impact/priority scores
- Percentiles may or may not be calculated
- Funded from best scores to worst until funding pool is exhausted
- ICs differ!
- Based on the score, difficult to determine if application is in fundable range

The Critique

After the reviews are complete

- Written reviews collated by SRO
- Inappropriate comments edited
- Identifies your Program Officer
- Program Officer also receives the Critique

The Critique

– SRO's 'Resume and Summary' of discussion included in the review

– Pay close attention to the summary!

– PO able to provide feedback for improving application if not in funding range.

Institute Anatomy

IC Divisions of Extramural Research

NICHD has 12 Branches, each divided into Programs

Scientific Review Branch - 8 subcommittees

IC People: Program Officers

Your application/grant is assigned to a PO, a scientist with a specific interest in your area of research

POs administer the grants in their portfolios

- Attend study sections, may hear *your* application reviewed
- Portfolio includes applications reviewed in many study sections
- Offer "administrative guidance" on applications
- Perform administrative (staff) reviews

Know Your Program Officer

– Cultivate the interest of your Program Officer; can greatly help your research program

– Call, email or meet them at scientific and medical meetings

– Unlike study section, Program Officers have input into funding

– Program Officers have an interest in your success

The Second Review Level

Institute Advisory Council or Board

- Most applications must be approved by Council
  - exception: Fellowships, small awards
- Only then is an application legally eligible for funding
- Respected scientists and lay members
- Provides Institute with programmatic and policy advice
- Reviews the outcome of study section, judges significance of proposed research to goals of the Institute

Institute makes decisions based on scientific merit, program relevance and funds available

Not Funded?

Don't be Discouraged

- Know NIH or Agency policy
- Fully Scored or Not Discussed
- Critique
- Other Sources of Help

NIH Policy

Only one chance to resubmit
37 month time limit
Keep same title, grant number
-A1 added to year counter
After that, must recast as a "New" application
New title
New grant number
May submit unfunded application again as "New"

Fully Scored or Not Discussed?

- If fully scored, how close to payline?
  - More information
  - Administrative relief?
- If not, how close?
  - Less information
  - Was PO in the room?

Critique

- Go through it meticulously!
- +/- SRO's summary of discussion
- Did the reviewers seem to agree on criterion scores and "level of enthusiasm?"
- Did the reviewers clearly note strengths and weaknesses?
- If so, did they see similar or different ones?

Critique

Identify criticisms point by point
For each criticism, ask:
- It is reasonable/correct?
- How would you respond?
  Accept (≠Agree) or not?

Then discuss with mentor(s) and PO

Other Sources of Help

- Your own mentor(s)
- Local faculty who have been on study section
- Colleagues who have resubmitted successfully
- Program Officer

Writing the Introduction: Content

One page
Be very clear - organize by Reviewer
Number each point within a section
Use bold or underline to highlight key points
Indicate how you will show changes
Give signposts to new or changed information
For each point:
Accept - revise (content or writing)
If stand firm - JUSTIFY!
- Support with data, yours or others'

Writing the Introduction: Style

Diplomatic - polite but not obsequious
Show respect for the reviewers' intelligence
Buzzwords and phrases
"I did not make … sufficiently clear…"
NOT "You idiot!"

"Reviewer #1 correctly states…however…"
NOT "Rev. #1 failed to realize…"

Writing the Introduction: Major New Material?

The Introduction cannot fully accommodate
New Specific Aims
Major new experiments,
model systems, techniques, etc.

Identify these additions and give signposts

Consider carefully has the application become "New"

Not Funded? How Your Application Can Get a Second Look

- High Program Relevance
  - How do you find out?
- New Investigator
- Dual Assignment
- Women's Health Research etc.

Closing Thoughts

- Choose the right mechanism
- Consult Program Officer: especially if not R01
- Obtain and follow any special instructions or additional information
- Don't be in a rush
- Get feedback from trusted mentors
- Ask questions-and listen to the answers!

Administrative/Technical Issues

- Human subjects: Consult with staff regarding inclusion of women, minorities, and people across the lifespan
- Sponsor's sections
  - training or career development plans
- Institutional commitment
- Collaborations: Letters should be specific, documenting availability of a technique, reagent, equipment, or subjects

Appearance

- Presentation counts!
- Write clearly and logically. Get the reviewers on your side
- Writing and neatness are not science issues, but sloppiness may suggest to the reviewers that the other aspects of your work are careless as well
- Proofread with care--Start, but don't stop, with your spell checker
- Have someone outside your own group read the application

What Don't They Tell You?

- "…strongly encouraged" or "…will be considered a strength" mean "We would require this but we're not allowed to say so."
- "…must be strongly justified" means "Don't do this if you can possibly avoid it."
- If the language seems confusing or ambiguous, ASK!

Most Important:

WORK WITH A HUMAN!

NIH staff not only are able to help you, they want to help you

How to find a human

Search the Institute that funds your area:
There may be a directory by program.

Is there a recent FOA in your field?
Who is the scientific contact?

You belong to a professional society.
Is there an NIH staffer among the members?

You know someone with a grant.
Who is the Program Director?

Use Matchmaker

How to find a human

Search the Institute that funds your area:
There may be a directory by program.

Is there a recent PA or RFA in your field?
Who is the scientific contact?

You belong to a professional society.
Is there an NIH staffer among the members?

You know someone with a grant.
Who is the Program Director?

Funding

– Institute sends a Notice of Award to successful applicants

– Notice includes the approved budget and the budget for later years

R's: budget may be reduced by an 'administrative' cut in addition to budget cuts recommended by study section

What it means to you!