

## **NIH Fellowship Application Process**

#### Sheri Holmen, PhD

## Overview of Session

- What type of research is funded by NIH
- Who Is Eligible for an NIH Grant?
- NIH funding mechanisms
- Understanding the NIH format and Peer Review Process
- Review Criteria
- Writing tips for successful applications
- Scoring

## What type of research is funded by NIH?

- Projects that support the advancement of the NIH mission: enhancing human health, extending healthy life, and reducing the burdens of illness and disability.
- Projects of High Scientific Caliber
- NIH-Requested Research
  - Funding opportunity announcements (FOAs)
    - program announcements (PAs)
    - requests for applications (RFAs)
    - <u>https://grants.nih.gov/funding/searchguide/index.html#/</u>

## What type of research is funded by NIH?

#### Unsolicited Research

Parent announcements (PAs)

#### Unique Research Projects

- To ensure that your project, or a similar project, has not been funded, visit the NIH Reporter website and search by topic. <u>https://projectreporter.nih.gov/</u>
- NIH Reporter can also help you identify which Institute/Center and study section your grant would fit best

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5 R03 CA212798 02	PLUMBAGIN IN COMBINATION WITH VEMURAFENIB FOR BRAF-MUTANT MELANOMA	<u>AFAQ, FARRUKH</u>	UNIVERSITY OF ALABAMA AT BIRMINGHAM	2018	NCI	NCI	\$74,250	
5 K23 EY027466 03	PREDICTING OCULAR OUTCOMES, QUALITY OF LIFE AND SURVIVAL AFTER PROTON BEAM RADIOTHERAPY OF CHOROIDAL MELANOMA	AFSHAR, ARMIN REZA	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	2019	NEI	NEI	\$210,392	
5 R01 CA218024 04	EPIGENETIC AND MICROENVIRONMENTAL REGULATION OF DORMANT DISSEMINATED CANCER	AGUIRRE-GHISO, JULIO A. et al.	ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI	2020	NCI	NCI	\$428,136	
□ <u>1 SC3</u> <u>GM136639</u> 01	KLF4-MEDIATED MYELOID PLASTICITY IN BREAST CANCER RECURRENCE	AI, WALDEN	BENEDICT COLLEGE	2020	NIGMS	NIGMS	\$97,389	
5 R01 CA202027 05	POST-TRANSLATIONAL CONTROL OF CANCER CELL STRESS RESPONSE AND METASTASIS	AIFANTIS, IANNIS et al.	NEW YORK UNIVERSITY SCHOOL OF MEDICINE	2020	NCI	NCI	\$459,505	
5 R01 CA210561 03	ADVANCING THE TRANSLATABILITY OF MOUSE MODELS FOR CANCER IMMUNOTHERAPY	AKHURST, ROSEMARY	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	2020	NCI	NCI	\$720,801	
3 R43 CA228721 01S1	TITLE: PRE-CLINICAL EVALUATION OF A NOVEL IMMUNE MODULATOR, ALPHA-TEA IN COMBINATION WITH IMMUNE CHECKPOINT BLOCKADE	AKPORIAYE, EMMANUEL T.	VEANA THERAPEUTICS, LLC	2019	NCI	NCI	\$50,521	
1 R43 CA228721 01	TITLE: PRE-CLINICAL EVALUATION OF A NOVEL IMMUNE MODULATOR, ALPHA-TEA IN COMBINATION WITH IMMUNE CHECKPOINT BLOCKADE	AKPORIAYE, EMMANUEL T.	VEANA THERAPEUTICS, LLC	2018	NCI	NCI	\$299,607	
☐ <u>1 101 BX003916 01A1</u>	ADMINISTRATION OF INTRATUMORAL IMMUNOCYTOKINE TO ACTIVATE IMMUNE REJECTION OF SPONTANEOUS CANINE MELANOMA	ALBERTINI, MARK R	WM S. MIDDLETON MEMORIAL VETERANS HOSP	2019	VA			
5 R21 DE026964 02	GENOME AMPLIFICATION AND DYSBIOSIS IN TONGUE CANCER	ALBERTSON, DONNA G et al.	NEW YORK UNIVERSITY	2018	NIDCR	NIDCR	\$237,750	
5 P50 CA140388 09 8550	INTEGRATING IPILIMUMAB IMMUNOTHERAPY WITH APPROVED	ALLISON, JAMES P	UNIVERSITY OF TX MD ANDERSON CAN CTR	2019	NCI		\$286,283	

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#### Who Is Eligible for an NIH Grant?

- Each type of NIH grant has its own eligibility requirements.
  - Eligibility information is in section III of each FOAs
  - NIH recognizes the <u>applicant institution</u> as the grantee

#### Individual Eligibility

 NIH supports scientists at various stages in their careers, from predoctoral students on research training grants to investigators with extensive experience who run large research centers.

#### Who Is Eligible for an NIH Grant?

#### Institutional Eligibility

• In general, domestic or foreign, public or private, non-profit or for-profit organizations are eligible to receive NIH grants.

#### Foreign Eligibility

 Foreign applicants are strongly encouraged to review the Eligibility section of the FOA to determine whether they are eligible to respond to that particular FOA.

## NIH Funding Mechanisms

NIH provides financial support in the form of grants, cooperative agreements, and contracts.

- F = Fellowships (pre- & post-doc)
- K = Career Development Awards
- T = Training Grants
- R = Research Projects
- P = Program Project/Center Grants
- U = Cooperative Agreements Grants

#### In Training and Career Development Awards

http://nexus.od.nih.gov/all/2011/10/07/trends-in-nih-training-and-career-development-awards/



#### Grant Cycles – Standard Dates

http://grants.nih.gov/grants/funding/submissionschedule.htm

Activity	Cycle I	Cycle II	Cycle III	
Due Dates: F Series	April 8	August 8	December 8	Share Results Plan
Scientific Merit Review	June – July	October – November	February - March	Manage Grant Award
Advisory Council Round	August or October	January	May	Make Award Months 9-10
Earliest Start Date	September or December	April	July	Review Application Refer Application
				Review         Receive and           Application         Refer Application           Months 4-8         Months 1-3

#### Division of Receipt and Referral (DRR)

Central receiving point for all competing applications, whether solicited or unsolicited. DRR:

- Checks for completeness
- Determines area of research
- Assigns application to specific NIH Institute or Center for possible funding
- Assigns an identification number
- Assigns application to a Review Group: Applications are assigned to a Scientific Review Group (SRG) or study section, that has the expertise to evaluate the scientific and technical merit
- Center for Scientific Review (CSR) reviews most R01s, fellowships, and small business applications
- Institute or Center (IC) review groups handle applications that have Institute specific features such as program projects, training grants, career development awards, and responses to RFAs.

#### Peer Review Process

- The first level of review is carried out by a Scientific Review Group (SRG) (aka study section)
  - composed primarily of non-federal scientists who have expertise in relevant scientific disciplines and research areas.
- The second level of review is performed by Institute and Center (IC) National Advisory Councils or Boards.
  - composed of both scientific and public representatives chosen for their expertise, interest, or activity related to health and disease.
- Final funding decisions are made by the IC Directors.

#### Scientific Review Officer (SRO)

- Each SRG is led by an SRO- an extramural staff scientist (PhD)
- Analyzes the content of each application, and check for completeness.
- Documents and manages conflicts of interest.
- Recruits qualified reviewers
- Assigns applications to reviewers
- Attends and oversees administrative and regulatory aspects of peer review meetings.
- Prepares summary statements for all applications reviewed.

## **SRG Members**

- Chair: Serves as moderator of the discussion of scientific and technical merit of the applications under review. Is also a peer reviewer for the meeting.
- **Reviewers:** Prepare a written critique for each application assigned,
- **Other NIH Staff:** Federal officials who have need-to-know or pertinent related responsibilities are permitted to attend closed review meetings.
- NIH IC or other federal staff members wishing to attend an SRG meeting must have advance approval from the responsible SRO.
  - These individuals may provide programmatic or grants management input at the SRO's discretion.

#### **Peer Review Meeting Procedures**

- Applications are reviewed based on established review criteria.
- Assigned reviewers summarize their prepared critiques for the group.
- An open discussion follows.
- Final scoring of overall impact scores is conducted by private ballot.

#### **Peer Review Criteria and Considerations**

#### • Overall Impact.

 Likelihood that the proposed training will enhance the candidate's potential for a productive, independent scientific research career in a health-related field.

#### Scored Review Criteria.

 Reviewers will consider each of the 5 review criteria in the determination of scientific and technical merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact.

## 5 Core Review Criteria (fellowships)

- **Applicant** Qualifications of the applicant
- Sponsor(s) Qualifications and mentoring track record of the sponsor(s), funding available (R01 or equivalent)
- Research Training Plan Feasibility/strength/match of strategy to project aims.
- Training Potential Must have a well developed training plan
- Institutional Environment & Commitment to Training– Institutional support/resources

#### What does it take to be competitive?

- Demonstration of commitment to research
  - Clearly articulate long-term career goals and how this fellowship will help you achieve those goals
- Evidence of strong mentor-mentee relationship
- Strong letters of reference
- Good project
- <u>Clear</u> training plan to show how you will develop research skills
- Likelihood of research independence

## Applicant

- Must have a baccalaureate degree
- Must be currently enrolled in a PhD or equivalent research degree program, a formally combined MD/PhD program, or other combined professional/clinical and research doctoral in the biomedical, behavioral, or clinical sciences at an accredited institution
- Must not be pursuing an MD, DDS, or other clinical, health-professional degree and/or training (with the exception of a combined degree program as mentioned above)
- May receive up to 5 years of aggregate Kirschstein-NRSA support at the predoctoral level, including any combination of support from an institutional training grant (e.g., T32 or T90) and an individual fellowship award (F31)

#### **Biosketch**

- A: personal statement
  - Make sure it is relevant to the current application
- B: positions and honors
  - List relevant positions (not education/training) and honors/awards
- C: Contributions to science (limit 5 with 4 publications each)
  - Make sure to include Complete List of Published Work in MyBibliography: <a href="http://www.ncbi.nlm.nih.gov/sites/myncbi/sheri.holmen.1/bibliography/41161076/public/?sort=date&direction=ascending">http://www.ncbi.nlm.nih.gov/sites/myncbi/sheri.holmen.1/bibliography/41161076/public/?sort=date&direction=ascending</a>
- D: Research Support and/or scholastic performance (courses taken and grade received)
  - Make sure to list the funding that is currently supporting you

#### **Biosketch**

Allows applicants to:

- describe the magnitude and significance of their scientific contributions (including publications)
- provide more detailed information about their research experience in the context of the proposed project
- Explain any gaps in work history, productivity, etc.

#### Keep in Mind...

- DO NOT Exceed maximum allowable contributions to science (5)
- DO NOT Provide more than 4 citations per contribution
- Biosketch is limited to 5 pages
- Only include a link to full list of publications no other links are allowed
- MyBibliography must be PUBLIC for others to access it
- Images and graphs are allowable but do not circumvent page limits!

#### **Complete list of Publications**

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## Sponsor(s)

- May have more than one:
  - Include biosketch for each
- Other support page required for each sponsor
  - Should reveal that there is additional funding for the trainee (R01 or equivalent)
- List of previous trainees/fellows (or select examples if there are many) to demonstrate track record of successful mentoring

- Detailed Training plan for the applicant
  - Mentor-trainee interaction
  - Grant writing
  - Presentations and papers
  - Professional skills development
  - Ethical conduct in science
  - Environment
  - Number of trainees to be supervised
  - Applicant's qualifications and potential for a research career

#### **Research Training plan**

- Must propose a dissertation research project and training program that fall in a research area within the scientific mission of the participating NIH Institutes
- Aims Page (1 page)
- Significance
- Innovation
   6 page limit
- Approach
  - Experimental design
  - Expected outcomes, potential problems, alternative approaches
  - Future directions
- Literature Cited

#### **Specific Aims**

What are you going to do?

In theory, easiest part to write: Only 1 page! Only 2-3 aims!

In reality, most difficult part to write:

Sink or swim on this page: first impression!

#### **Specific Aims**

- Should be: 1. Concise and clear
  - 2. Focused
  - 3. Independent yet interdependent
  - 4. Worthwhile, even exciting
  - 5. Innovative, impactful

6. Successful completion of the aims should <u>significantly</u> advance the field!

#### 1. Why Concise and Clear?

- Reviewers have little time to read and understand your grant proposal (concise)
- At study section: "Everyone is famous for 15 minutes," but only for 15 minutes! Reviewers have to sell your proposal to the panel. To do so, they need to understand it quickly (clear). Don't think you'll impress them by making your proposal so complex that <u>only</u> you are "smart" enough to understand it.
- Bottom Line: time is highly limited--wasting a reviewer's time or causing confusion will <u>not</u> endear you to him/her

## 2. Why Focused?

- Reviewers have a limited amount of time to present each grant
- The primary reviewer needs to convey to the panel specifically what will be done, how it will be done, why it is important to do, and <u>that it will be done in the time</u> <u>allotted</u>
- The proposed aims must be logical, doable, and direct (best way); hypothesis must be testable AND worthy of testing

#### If Possible, Be Hypothesis Driven

Why? Basically, because that's the scientific method:

- Observation
- <u>Hypothesis</u>
- Experiments/controls
- Revision of hypothesis
- Bottom line: "the best scientists" adhere to the scientific method. Hypothesis-driven research is very much in vogue, and is considered cutting edge and focused; one of the best things to hear on study section: this is hypothesis-driven research!
- Hypothesis-driven research is considered the gold standard

#### 3. Why Independent yet Interdependent?

- The fatal flaw: to be able to do one aim requires a specific result from another aim--the aims are not independent
- Another flaw: if the aims are not interdependent (i.e., related and synergistic), then the grant is viewed as nonfocused
- Bottom Line: When it comes to choosing specific aims, think, think, think! And rewrite, rewrite, rewrite! Then, rewrite, rewrite and rewrite again

#### 4. Why Worthwhile, Even Exciting?

- Grants scores are based on level of <u>enthusiasm</u> (should be exciting)
- Ask yourself: if all works as planned will anyone actually care about what is learned?
- Bottom line: the panel, acting as an advocate for the NIH, must decide how best to spend NIH's limited resources (note: resources are always limited)

#### Significance

- Does the project address an important problem or a critical barrier to progress in the field?
- 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?
- Is there a strong scientific premise for the project?

#### **Scientific Premise**

- **GOAL:** Ensure that the underlying **scientific foundation** of the project—concepts, previous work, and data (when relevant)—is sound.
- Pertains to the **underlying evidence/data** for the project
- Address under Significance
- "Is there a strong scientific premise?"
  - Specifically, has the applicant provided sufficient justification for the proposed work?
  - Cited appropriate work and/or preliminary data?
  - Appropriately identified strengths and weaknesses in prior work in the field?
  - Proposed to fill a significant gap in the field?
  - OR has the applicant explained why this is not possible?

#### 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 the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense?
- Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

## Approach

- Is the strategy well-reasoned and appropriate?
- Are expected outcomes, potential problems, and alternative strategies presented?
- Is it feasible and will particularly risky aspects be managed?
- Have the investigators addressed relevant biological variables, such as gender, for studies in vertebrate animals or human subjects?
- If the project involves human subjects, is it justified in terms of the scientific goals and research strategy proposed?

#### **Scientific Rigor**

**GOAL:** Ensure a strict application of scientific method that supports robust and unbiased design, analysis, interpretation, and reporting of results, and sufficient information for the study to be assessed and reproduced. Give careful consideration to the methods and issues that matter in your field.

- Pertains to the **proposed research**
- Address under **Approach**
- Addition to review criteria: Are there strategies to ensure a robust and unbiased approach?
  - Possible considerations, if appropriate for the scientific field and research question, include plans for determining group sizes
  - analyzing anticipated results
  - reducing bias
  - ensuring independent and blinded measurements
  - improving precision and reducing variability
  - including or excluding research subjects
  - managing missing data

#### **Training Potential**

- Proposed training should provide the applicant with:
  - experience conducting research using appropriate, state-of-the-art methods, as well as presenting and publishing the research findings as first author;
  - the opportunity to interact with members of the scientific community at appropriate scientific meetings and workshops (including NIH-sponsored meetings, where available); and
  - a strong foundation in research design, methods, and analytic techniques appropriate to the proposed dissertation research.
  - Should document the need for the proposed research training and the expected value of the proposed fellowship experience as it relates to the individual's goals for a career as an independent researcher

#### 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 components**

- Respective contributions
  - Did the applicant compose of the aims, write the proposal independently, etc.?
- Selection of Institution
- Selection of Sponsor(s)

#### Additional review criteria

- As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit and in providing an overall impact score, but will not give separate scores for these.
- Human Subjects
- Vertebrate Animals
- Training in Responsible Conduct of Research

## **Additional Review Considerations**

 As applicable, reviewers will consider each of the following items, but will not give scores for these items and should not consider them in providing an overall impact score.

- Resource Sharing Plans
- Budget and Period of Support
- Biohazards

## Scoring

- 9-point rating scale (1 = exceptional; 9 = poor) for all applications
- Before the SRG meeting, each reviewer assigned to an application gives a separate score for each of the 5 criteria.
  - The preliminary scores determine which applications will be discussed at the meeting (top 50%).
- For each application that is discussed at the meeting, a final impact score is given by each eligible committee member (without conflicts of interest) including the assigned reviewers.

#### What do the 1-9 scores mean?

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

#### FELLOWSHIPS & CAREER AWARDS

#### **Overall Impact:**

The likelihood that the proposed training (F) or career development (K) will enhance the candidate's potential for a productive, independent scientific research career in a health-related field.

S	Overall Impact	High	Medium	Low	v		
	Score	123	456	78	9		
			7	L			
pos er d val can h po hing tive, nder ve s	es training evelopment ue/benefit didate who otential for into a nt scientist. some or no s in the	e.g. Proposes career develo or moderate for the candi high or mode for further de but weaknes criteria reduc impact to me	igh ca fit m is va ial ca fa fa fa ta	career development of moderate or low value/benefit for the candidate who has moderate or low poter for further developmen Weaknesses in the crit reduce the overall imp to low.			
		e.g. Proposes career develo	s training or opment of	e.	.g. Pr	oposes tra	ining or

Evaluating Overall Impact e.g. Pro Consider the 5 criteria or caree (weighting based on reviewer's of high judgment): for the o has high Fs Ks develop Applicant Candidate product Sponsor(s) Career indepen Research Development May ha Training Plan Plan/Goals\* weakne. Research Plan Training Potential Mentor(s)\*\* criteria. Environment & Institutional career development of low Environment & Institutional moderate value/benefit for Commitment Commitment value/benefit for the the candidate who shows candidate who shows low moderate potential. May and other score influences, e.g. potential. May have some have some weaknesses in weaknesses in the criteria. the criteria. \*K05 and K24: Plan to Provide

human subjects, animal welfare, inclusion plans, and biohazards

Mentoring \*\*K02: Consultants/Collaborators

5 is a good, medium-impact application. The entire scale (1-9) should always be considered.

## Scoring

- Final score for each discussed application is determined by calculating the mean score from all the eligible members' impact scores, and multiplying the average by 10 (range 10-90)
- Impact scores are not reported for applications that are not discussed
  - reported as ++ on the face page of the summary statement
  - The applicant will see the scores and comments from the assigned reviewers for each of the criteria on their summary statement.
- Scores typically post to NIH Commons within 2-3 days after the meeting.
- Summary statement will post to NIH Commons within 2-4 weeks.





#### Understanding the Percentile

- A percentile is the approximate % of applications that received a better overall impact/priority score from the SRG during the past year.
- For applications reviewed in ad hoc study sections, a different base may be used to calculate percentiles.
- All percentiles are reported as whole numbers.
- Only a subset of all applications receive percentiles. The types of applications that are percentiled vary across different NIH Institutes and Centers.
- The summary statement will identify the base that was used to determine the percentile.

# The NIH utilizes 2 stages of review when making funding decisions

1.Evaluating applications for Scientific Merit (conducted in *SRG*) 2.Funding decisions made by the Institutes

The institutes consider **percentiles**, not overall impact scores, in making funding decisions.

Percentiles are a function of <u>rank</u> -- where a particular overall impact score falls in relation to other overall impact scores in 3 rounds of the study section. Note that the score itself does not factor into the percentile calculation.

Percentile = 100 (Rank – 0.5)/Total # of R01s in 3 rounds

#### Second Level of Review

- The Advisory Council of each IC performs the 2nd level of review.
   Recommendation Process
- NIH program staff members examine applications, their overall impact scores, percentile rankings (if applicable) and their summary statements and consider these against the IC's needs.
- Program staff provide a grant-funding plan to the Advisory Board/Council.
- The Advisory Board/Council also considers the IC's goals and needs and advises the IC director.
- It is not funded until you receive the notice of award (NOA).

## Writing Tips: Take home message

- Start early, plan ahead
- Read successful grants
- No typos, figures easy to read, legends clear. . .
- Have peers/mentors (not friends) read the application and provide constructive critiques

#### Know this website!

