Establishing Successful Research Programs: Seeking the Coveted NIH R01

Prepared for Des Moines University

Webinar Date April 19, 2017

Relevant to the content of this CME activity, Ms. Sutcivni has no conflicts with commercial interests to disclose.

Logistics

- Feel free to ask clarifying questions at any time. We will be monitoring the chat box.
- There will also be time for questions and discussion after the presentation.
- Slides (with embedded hyperlinks) will made available for attendees after the presentation.

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AGENDA

- NIH Grant Mechanisms Explained
- Interesting Facts – R15 & R21 vs R01
- New Investigator / Early Investigator
- Why R01 – Research Faculty Retention and Tenure
- R01- Competitive but Possible! (Sister School stats)
- Q & A

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NIH Research Priorities

NIH's mission is to **seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.** The agency's goals are

- to foster fundamental creative discoveries, innovative research strategies, and their applications as a basis for ultimately protecting and improving health;
- to develop, maintain, and renew scientific human and physical resources that will ensure the Nation's capability to prevent disease;
- to expand the knowledge base in medical and associated sciences in order to enhance the Nation's economic well-being and ensure a continued high return on the public investment in research; and
- to exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science.

NIH National Institutes of Health
Turning Discovery Into Health

$32.3 billion
Annual Budget

80% FOR EXTERNAL GRANTS

~50,000
Active Awards

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NIH GRANT MECHANISMS EXPLAINED

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Types of NIH Proposals – Activity Codes

- R series – research
- K series – career development
- T & F series – research training and fellowships
- P series – program project / center grants
- Various others – resource grants, trans-NIH programs, and others
- Full List of All Type Descriptions: http://grants.nih.gov/grants/funding/funding_program.htm

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Types of NIH Proposals

Small Research Grant Program (R03). The R03 small grant supports discrete, well-defined projects that realistically can be completed in two years and that require limited levels of funding. Because the research project usually is limited, an R03 grant application may not contain extensive detail or discussion. Accordingly, reviewers should evaluate the conceptual framework and general approach to the problem. Appropriate justification for the proposed work can be provided through literature citations, data from other sources, or from investigator-generated data. Preliminary data are not required, particularly in applications proposing pilot or feasibility studies.

Exploratory/Developmental Research Grant Program (R21): The R21 exploratory/developmental grant supports investigation of novel scientific ideas or new model systems, tools, or technologies that have the potential for significant impact on biomedical or biobehavioral research. An R21 grant application need not have extensive background material or preliminary information. Accordingly, reviewers will focus their evaluation on the conceptual framework, the level of innovation, and the potential to significantly advance our knowledge or understanding. Appropriate justification for the proposed work can be provided through literature citations, data from other sources, or, when available, from investigator-generated data. Preliminary data are not required for R21 applications; however, they may be included if available.

Types of NIH Proposals

NIH Clinical Trial Planning Grant Program (R34): The NIH Clinical Trial Planning Grant Program (R34) supports development of Phase III clinical trials. This program supports the establishment of the research team, development of tools for data management and research oversight, definition of recruitment strategies, finalization of the protocol, and preparation of an operations/procedures manual. The Clinical Trial Planning Grant is not designed for the collection of preliminary data or the conduct of pilot studies to support the rationale for a clinical trial. Accordingly, reviewers will focus their evaluation on the rationale for the proposed clinical trial and the design/protocol of the proposed trial in its current, early form.

Academic Research Enhancement Award (AREA/R15): DMU is Eligible for the R15

The Academic Research Enhancement Award (AREA) Program (R15) supports meritorious research, exposes students to research, and serves to strengthen the research environment of the institution. The AREA program supports small research projects in the biomedical and behavioral sciences conducted by undergraduate and/or graduate students and faculty in institutions that have not been major recipients of NIH research grant funds. Both the institution and the PI must be determined eligible to apply. Preliminary data is not required.

Types of NIH Proposals

NIH Pathway to Independence Award (K99/R00):

The NIH Pathway to Independence Award program is intended to increase and maintain a strong cohort of new and talented NIH-supported independent investigators. The program is designed to facilitate a timely transition from a mentored postdoctoral research position to a stable independent research position with independent NIH or other independent research support at an earlier stage than is currently the norm.

Which Takes Us To….

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THE COVETED R01

Research Project Grant Program (R01)

- The Research Project Grant (R01) is the original and historically oldest grant mechanism used by NIH. The R01 provides support for health-related research and development based on the mission of the NIH. R01s can be investigator-initiated or can be solicited via a Request for Applications. Investigator-initiated applications have no specific program requirements, however the R01 research plan proposed by the applicant must be related to the stated program interests of one or more of the NIH Institutes and Centers based on their missions.

- The Research Portfolio Online Reporting Tools (RePORT) website provides information about research grants including the number of funded new and competing R01s, average award dollars and characteristics of successful research project grants.

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COMPARISON OF POPULAR "R" SERIES GRANT TYPES

R01	R03	R21	R15
Research Project Grant	Small Grant Program (R03)	NIH Exploratory / Development Grant Award (R21)	Academic Research Enhancement Award (AREA) (R15)
Supports discrete, specified, circumscribed projects	Supports pilot studies, secondary analysis and other contained projects.	Supports exploratory and developmental projects	Supports small scale health-related projects and Stimulates research in institutions that have not been major recipients of NIH support
Up to 5 years	Up to 2 years	Up to 2 years	Up to 3 years
No award limit, but typically $500K/year (direct costs)	Up to $50,000 per year (direct costs)	Up to $275K total	Up to $300,000 total
Preliminary data expected and required	Preliminary data variable (data correlates with success)	No preliminary data required (however data correlates with success)	No preliminary data required (however data correlates with success)

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TRUE OR FALSE?

Question: The NIH R21 is "easier" to get than an R01

Question: The NIH R21 is a good "Starter Grant"

Question: The R15 is a "mini – R01"

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ANSWERS

ALL are FALSE!!

R15 is a "Mini-R01" Urban Myth – Eligibility Rules Apply

There are two levels of eligibility for AREA grants: the eligibility of the institution and the eligibility of the principal investigator (PI).

Institutional Eligibility

- Only domestic accredited public or non-profit private institutions of higher education are eligible.
- The institution must grant baccalaureate or advanced degrees in the biomedical or behavioral sciences.
- **The institution may not receive more than $6 million per year in NIH support in each of 4 of the last 7 years. Please view the AREA Program Institutional Eligibility website for more information.**

Principal Investigator Eligibility

- **The PI must have a primary appointment at an AREA-eligible institution.**
- **The PI may not be the PI of an active NIH research grant at the time of an AREA award.**
- **The PI may not be awarded more than one AREA grant at a time.**

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R15 VS R01

The R15 Academic Research Enhancement Award (AREA) Program lists research topics of particular interest to each NIH Institute/Center(IC): **AREA Grant Research Objectives**.

Independent Program Officers for the AREA R15 program are also listed for each IC.

The R01 provides funding to support investigator-initiated research, also known as unsolicited research, as a result of an investigator submitting a research grant application to NIH in the investigator's area of interest and competency.

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R15 VS R01

AREA R15 Rating Criteria

NIH Review Criteria at a Glance

R15 Guide for Reviewers

NIH R15 Program Website

NIH R15 Program Resources (Top submission errors, FAQs, Sample Biosketch, AREA Blog, AREA Podcast, etc.)

R01 Rating Criteria

R01 Guide for Reviewers

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R15 is a "Mini-R01" Urban Myth

Overall Impact R15
Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project: to make an important scientific contribution to the research field(s) involved, to provide research opportunities to students, and to strengthen the research environment of the institution, in consideration of the review criteria and additional review criteria (as applicable for the project proposed).

Overall Impact R01
Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project: to exert a sustained, powerful influence on the research field(s) involved, in consideration of the review criteria and additional review criteria (as applicable for the project proposed).

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NIH Rating Criteria: Significance

R15

- Does the project address an important problem or a barrier to progress in the field? Is there a strong scientific premise for the project?
- 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?
- **If funded, will the AREA award have a substantial effect on the school/academic component in terms of strengthening the research environment and exposing students to research? Is there a strong scientific premise for the project?**

R01

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

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NIH Rating Criteria: Investigator(s)

R15

- Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project?
- If Early Stage Investigators or New Investigators, or 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(s)/PI(s), do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?
- Do the PD(s)/PI(s) have suitable experience in supervising students in research?

R01

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- If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)?
- If the project is collaborative or multi-PD(s)/PI(s), do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?
- **Do the PD(s)/PI(s) have suitable experience in supervising students in research?**

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NIH Rating Criteria: INNOVATION (No differences)

R15

- 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?

R01

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- 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?

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NIH Rating Criteria: APPROACH

R15

- Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the 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?

R01

- Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the 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?

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NIH Rating Criteria: APPROACH (Con't)

R15

- 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 children, justified in terms of the scientific goals and research strategy proposed?
- **Does the application provide sufficient evidence that the project can stimulate the interests of students so that they consider a career in the biomedical or behavioral sciences?**

R01

- 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 children, justified in terms of the scientific goals and research strategy proposed?

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NIH Rating Criteria: ENVIRONMENT

R15

- Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed?
- **Does the application demonstrate the likely availability of well-qualified students to participate in the research project?**
- **Does the application provide sufficient evidence that students have in the past or are likely to pursue careers in the biomedical or behavioral sciences?**

R01

- **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?**

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R21 URBAN MYTH

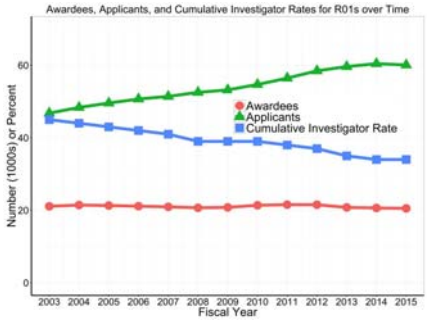
One urban myth has been that R21s have a higher success rate than R01, which is actually contrary to what the data show.

R01 VS R21 DATA (2012-2014)

	FY2012	FY2013	FY2014
Number of R01-equivalent grant applications:	29,627	28,044	27,502
Number of R01-equivalent awards:	5,437	4,902	5,163
Success rates for R01-equivalent applications:	18%	17%	19%
Total amount of funding that went to competing R01-equivalent awards:	$2,335,391,619	$2,072,911,352	$2,290,939,281
Total amount of NIH funding that went to R01-equivalents (competing and non-competing):	$11,021,860,936	$10,174,867,296	$10,359,458,392
Number of R21 grant applications:	13,743	13,229	14,331
Number of R21 awards:	1,932	1,771	2,013
Success rates for R21 applications:	14%	13%	14%
Total amount of funding that went to competing R21 awards:	$422,632,904	$382,713,272	$433,814,063
Total amount of NIH funding that went to R21s (competing and non-competing):	$774,963,587	$763,384,905	$807,267,070

INTERESTING FACTS
R03 VS R21 VS R15 VS R01

R01 – Applicants vs Awardees



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The DATA Shows Steep Competition for the R01

In the preceding slide, the red line shows the number of unique researchers holding at least one competing or non-competing R01, while the green line shows the number of unique researchers seeking to obtain funding over a 5-year window.

The number of unique R01 awardees has actually *declined* over time, specifically by about 5% between 2011 and 2015. Meanwhile, the number of unique R01 applicants has substantially increased. The cumulative R01 investigator rate has declined from 45% to 34% between 2003 and 2015.

Red = Awardees

Green = Applicants over 5-year window

Source: NIH Blog

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The Competition is Even More Steep for the R21!

The next slide shows analogous data for R21 grants, which compared to R01 grants offer less money over less time ($275K max over 1-2 years vs $500k/year for 5 years). The number of unique awardees has increased over time, but so have the number of unique applicants, **yielding cumulative investigator rates that are actually lower than those seen with R01s.**

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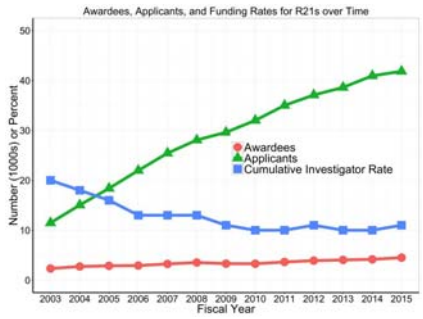
R21 Data Reveals Lower Investigator Rates than the R01!



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R15 Data Reveals Lowest Success Rate of Them All!

The next slide shows analogous data for R15 grants, which compared to R01 grants offer less money over less time The number of unique awardees has decreased over time, but the number of unique applicants has risen, **yielding cumulative investigator rates that are actually lower than those seen with R01s.**

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R15 Success Rates

Year	Number of R15 New Applications	Number of R15 Awards	Success Rates R15	Success Rates R01
2014	2333	283	12.1%	19.0%
2013	2190	249	11.3%	17.0%
2012	1951	236	12.09%	18.0%

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NIH Data Resources

NIH Research Portfolio Online Reporting Tool (RePorter)

NIH Success Rates

Grant omics
Grant omics Blog

NIH Databook

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NEW INVESTIGATOR STATUS

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New Investigator Defined

Definition of New Investigator: In general, a Program Director/Principal Investigator (PD/PI) is considered a New Investigator if he/she has not previously competed successfully as PD/PI for a substantial NIH independent research award. Specifically, a PD/PI is identified as a New Investigator if he/she has **not** previously competed successfully for an NIH-supported research project **other than** the following early stage or small research grants or for the indicated training, infrastructure, and career awards:

- Pathway to Independence Award-Research Phase (R00)
- Small Grant (R03)
- Academic Research Enhancement Award (R15)
- Exploratory/Developmental Grant (R21)
- Research Education Grants (R25, R90, RL9, RL5)
- Clinical Trial Planning Grant (R34)
- Dissertation Award (R36)
- Small Business Technology Transfer Grant-Phase I (R41, UT1)
- Small Business Innovation Research Grant-Phase I (R43, U43)
- Shannon Award (R55)
- NIH High Priority, Short-Term Project Award (R56)
- Competitive Research Pilot Projects (SC2, SC3)
- Resource Access Award (X01)

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Early Stage Investigator (ESI)

Definition of Early Stage Investigator: A Program Director/Principal Investigator who qualifies as a New Investigator is considered an Early Stage Investigator (ESI) if he/she is within 10 years of completing his/her terminal research degree or is within 10 years of completing medical residency (or the equivalent).

The ESI designation helps to differentiate between established and early-career investigators, and helps NIH meet the goal of accelerating the transition to an independent scientific career.

It is expected that ESIs will constitute the majority of funded NIs.

New Investigator Perks

https://www.niaid.nih.gov/grants-contracts/new-investigators

When applying for your first independent NIH research grant, new and early-stage investigators get some breaks:

- Higher paylines
  - NIH sets target numbers for funding new and early-stage R01 investigators.
  - Most (but not all) NIH Institutes set special paylines for early-stage investigators
  - Example: NIAID uses a higher R01 payline, making it easier for new investigators to get an award. Go to NIAID Paylines for current information.

New Investigator Perks

NIH New Investigator policies **are designed to counter advantages enjoyed by well-established investigators and to encourage early transition to independence.**

- Applications from New Investigators are segregated to the extent possible so that they can be reviewed in relationship to applications from other New Investigators.
- After review, **NIH Institutes and Centers are required by policy to maintain comparable award rates for new (type 1) applications from both Experienced and New Investigators**.
- Further, approximately half of the awarded New Investigators should be Early Stage Investigators.
- Of special note is the ability to request an extension of the Early Stage Investigator (ESI) period to account for time away from research

More New Investigator Perks

Initial Peer Review

Peer reviewers look more at potential than achievement—they weigh your academic and research background heavily.

- Reviewers may expect new R01 investigators to have fewer preliminary data and publications than more established researchers do.
- When feasible, new and early-stage investigator applications are not interspersed with those of established investigators at the review meeting.
- You get at least one month to revise and resubmit your R01 application for the next review cycle. You receive your summary statement no later than March 10, July 10, or November 10, and instead of following the standard resubmission deadlines, you can resubmit by April 10, August 10, or December 10, respectively.

Still Not Convinced? Not Quite Ready for the R01? Need More Preliminary Data?

Consider Pathway to Independence Award (K99-R00) or the NIH Director's New Innovator Award (DP2).

The Pathway to Independence Award provides support as a postdoctoral scholar transitions from a training position to a faculty position.

The NIH Director's New Innovator Award (DP2) is designed to stimulate applications for grants to support highly innovative research approaches. Applicants for DP2s must be Early Stage Investigators!

The New and Early Stage Investigator Website includes links to New Investigator pages at each of the NIH Institutes and Centers (ICs). IC websites frequently include a description of IC specific policies and initiatives for scientists at the beginning of their independent careers.

New and Early Stage Investigator Perks Limited to R01!

Reasons to consider the R01 (vs other "R" Type):

- ESI status will be considered only on applications for traditional research grants (R01s) and the NIH Directors New Innovator Awards (DP2s).
- Only ESIs may apply for DP2s, meaning early stage investigators compete only against other ESIs.
- R21 mechanism is actually more competitive than the R01!

RETENTION

Retention of Awardees in Research Project Grant (RPG) Funding Pool

Three cohorts of first-time R01-equivalent awardees — those who received their first R01-equivalent award in 1989, 1997, or 2003.

	1989	1997	2003
Overall R01-equivalent success rate that year	27.9%	30.1%	30.2%
Number of first-time NIH R01-equivalent awardees	1,693	1,597	1,778
Average age of awardees	39.2	40.4	42.6
Average length of award	3.9	4.1	4.1
Average amount of first year award	$137,670	$179,880	$318,285
Average amount of 1st year award in 1986 constant dollars	$118,317	$114,354	$165,507

Why These Cohorts? – Relation to NIH Budget

We looked at these three time periods because of their relation to the NIH budget when their initial award was coming to end, i.e., what was the budget like when they would need to re-compete.

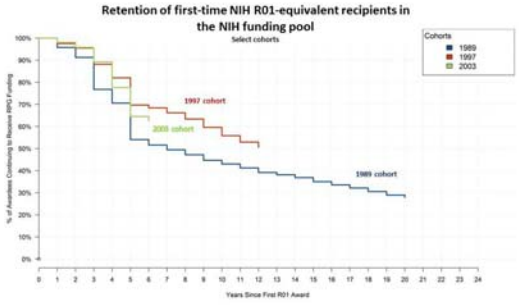
- For the cohort with an initial award in 1989, four years later (1993), the NIH budget took a dip with little to no growth for a few years.
- For the cohort with an initial award in 1997, four years later (2001) the NIH budget was in the midst of doubling.
- Finally, for the cohort with an initial award in 2003, four years later (2007) the NIH budget was not growing and was actually losing purchasing power

Retention Curve

Using Kaplan-Meier, a type of statistical analysis used to determine the likelihood that a specific event will occur (in this case, dropping out of the RPG funding pool) over the course of time, to analyze the number of years between the first year of R01-equivalent funding, and the last time an individual receives any additional research project grant (RPG) funding – whether it be from the non-competing continuation of their 1st R01 or another RPG award,

…we discover that for all three cohorts (1989, 1997, 2003) many PIs stop receiving NIH RPG funding about three to five years after they receive their first year of R01 funding.

R01 Equivalent PI Retention Curve for 1989, 1997, and 2003 Cohorts



Key Takeaways

- A significant number of first time PIs appear to drop out of RPG funding status following their initial award regardless of the economic times;
- **All three cohorts had dropped between 30 to nearly 50% within 5 years of the initial award**.

Analysis: These data seem to support the concept that if there is an intervention needed in retaining scientists in research, it would need to come at the renewal stage of the first award, or as some call it the "second" award.

Another Reason to Support R01 Applications: We know that the R21 typically results in funding gaps due to short grant term and relatively small ceiling amount of funding ($250K total over 1-2 years), increasing the likelihood that a funded investigator will drop, and will not continue with his/her research enterprise.

The R01 is Highly Competitive and also Possible!

Rosalind Franklin – Chicago

- 25 Active R01 or equivalent projects in 2016 and 2017 alone, representing more than 10 NIH Institutes and Centers
- Approximately $8.6 Million in active R01 research funding
- More than 50 Active R21 projects.

Creighton University – Omaha

- 11 Active R01 or equivalent projects in 2016 and 2017, representing five NIH Institutes and Centers
- Approximately $4.6 Million in active R01 research funding
- 26 Active R21 projects

Des Moines University – Des Moines

- 0 Active R01 or equivalent projects in 2016 and 2017

Jacklyn Sutcivni

Grants Consultant

Jackie's career as a grant writer spans a broad range of disciplines. Since 2000, she has helped institutions of higher education, healthcare agencies, not-for-profit organizations, and governmental entities obtain more than $87 million dollars in grant funding. A former research assistant, healthcare professional, public administrator, staff grantwriter for higher education, and small business owner, Jackie brings a range of skills and experience to every engagement. Specializing in federal grant submissions, her expertise in federal grant program design, implementation, and management are immediately evident. She is especially skilled in advancing initiatives through the development of multi-partner and consortium grant proposals and balancing faculty and administrative perspectives.