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NIH Grants & NCI Initiatives in Image-Guided Interventions

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AAPM
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Outline

1. NIH Grant Application Process
1. NCI Initiatives in Imaging and Image-Guided Interventions

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National Institutes of Health

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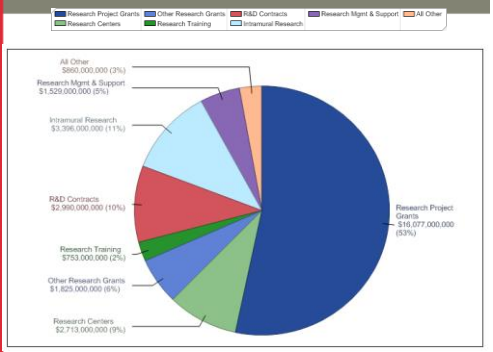
Total NIH Budget – FY2014



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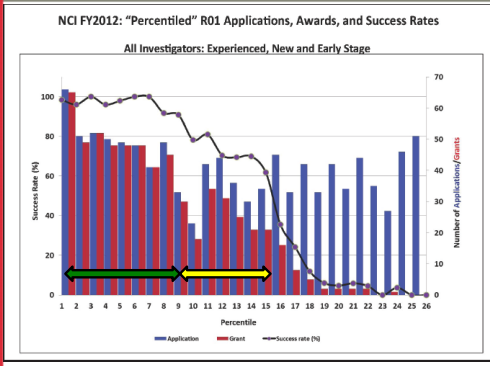
Proposals and Grants



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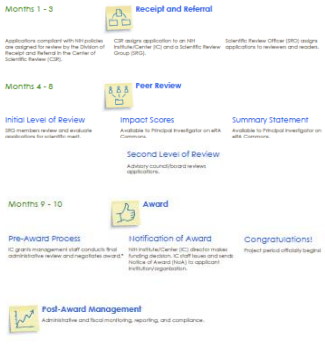
NIH Grant Process Overview



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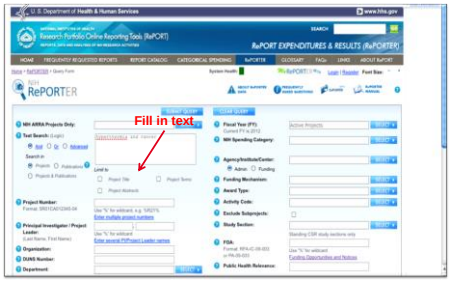
NIH RePORTER

Research Portfolio Online Reporting Tool



http://projectreporter.nih/gov/reporter.cfm

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19

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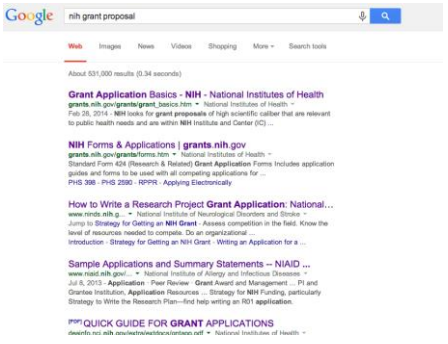
Many Resources Online



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New Investigators Guide to NIH Funding

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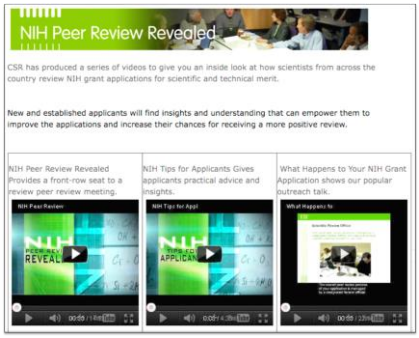
CSR – Video Resources Online



http://www.youtube.com/watch?v=fBDxI6l4dOA&feature=youtu.be

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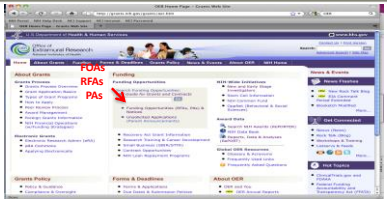
NIH's Office of Extramural Research Website
(http://grants.nih.gov/grants/oer.htm)



NCI/NIH Funding Opportunity Announcements (a few)

PA-13-302: Research Project Grants (***Parent R01***)
PAR-13-146: NCI Exploratory/Developmental Research Grant (***NCI Omnibus R21***)
PAR-13-321: National Cancer Institute Program Project (***P01***) Applications
PAR-14-007: NCI Small Grants Program for Cancer Research (***NCI Omnibus R03***)
PAR-14-116: Quantitative Imaging for Responses to Cancer Therapies(***U01***)
PAR-13-185: Image-guided Drug Delivery in Cancer **(R01)**
PAR-13-169: Academic-Industrial Partnerships for Translation of in-vivo Imaging Systems for Cancer Investigations (**R01**)

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Hints about writing the proposal

- **Start with an original, compelling idea that will generate excitement.**
  - **should not be incremental in nature**
  - **but should also not be over-ambitious**
- **Stay focused on a cancer problem**
  - **appropriate model**
- **Early in the proposal (abstract and body) establish:**
  - **Significance and Innovation of your project**
  - **research objectives should be presented early**
- **Present a clear and direct hypothesis**
- **Present alternatives**
  - **carefully balance confidence in planned work with a rational well-conceived back-up plan**
- **Include appropriate expertise in your team**
- **Appropriate Timeline**
- **Request appropriate funding**
  - **too little or too much reflects poorly on the applicant**

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Pay attention to details

- **Follow application instructions carefully**
  -Fonts, margins, page limits, etc…
- **Make the application easy to read**
  - Figures appropriately sized
  - Poor grammar and text errors reduce scores
  - Avoid jargon and abbreviations
- **Biosketch(s) and supporting documents up-to-date**
- **Letters of support that address the proposal**
- **Proofread (and re-check uploads)**
  - Stuff happens when uploading
- **No application should be submitted without internal review**

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Specific Aims

- **Rationale:** how does this design relate to your hypotheses? reasoning (IN DETAIL)?
- **Methods:** list general approaches first, explaining why the methods you propose are the best available for your questions. **Don't forget to address statistical analysis.
- **Anticipated results:** spend a great deal of thought as to potential outcomes and their likelihood. Explain how you will interpret the different outcome scenarios and how these results relate back to your hypotheses. This is an opportunity to demonstrate creativity and enthusiasm for the data to be obtained, and competently addressed.
- **Problems and pitfalls:** All experiments have pitfalls, but extraordinarily large pitfalls are likely to be unreasonable; hence, this section should serve as a reality test. Explain the pitfalls, and how alternate approaches will be used to overcome them if they occur. Do not think that avoiding mentioning a pitfall is a good strategy - it usually doesn't work. The reviewer will very likely notice the pitfall and believe that you are not aware of it, decreasing confidence in your ability to manage the data.

http://www.ninds.nih.gov/funding/grantsmanship_checklist.htm

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New Investigators/Early Stage Investigators

- **It is especially important to stress level of independence, institutional support & mentoring available**
- **Project should be distinct from your mentor's work**
- **New Investigator (NI)**

  PD/PI who has not yet competed successfully for a substantial NIH research grant

  Multiple PD/PI applications - all PD/PIs must meet requirements for NI status.
- **Early Stage Investigator (ESI)**

  PI who qualifies as a New Investigator AND is within 10 years of completing the terminal research degree or is within 10 years of completing medical residency (or equivalent)
- **NI & ESI will be clustered together for review**
- **Any advantages apply only to R01 applications**

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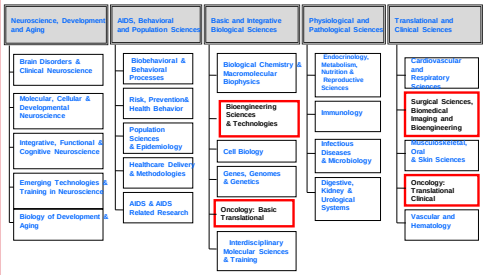
Center for Scientific Review

Divisions and Integrated Review Groups (IRGs)



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Review Criteria

- **Overall Impact**
  - Assessment of the likelihood for the project to *exert a sustained, powerful influence on the research field(s) involved*
- **Core Review Criteria**
  - **Significance:** Does the project *address an important problem or 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?
  - **Investigator(s)**
  - **Innovation**
  - **Approach**
  - **Environment**

Review criteria each scored from 1-9

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9-Point Scoring Scale

Impact	Score	Descriptor
High Impact	1	Exceptional
	2	Outstanding
	3	Excellent
Moderate Impact	4	Very Good
	5	Good
	6	Satisfactory
Low Impact	7	Fair
	8	Marginal
	9	Poor

The **impact score is NOT a numerical average of the criterion scores**, as each reviewer determines the relative importance of the criterion scores for each grant under consideration. The scoring system utilizes a 9-point rating scale (1 = exceptional; 9 = poor). The final overall impact 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; the final overall impact score is reported on the summary statement. Thus, the final overall impact scores range from 10 (high impact) through 90 (low impact).

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Summary Statement

The following results are provided to the applicant and the assigned NIH Institute(s) or Center(s) that may fund it.

- Essentially unedited critiques
- Scores for each review criterion
- Administrative notes if any

If an application is discussed, additional feedback is given

- Summary of review discussion
- An overall impact/priority score and percentile ranking
- Budget recommendations

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Common Mistakes in NIH Applications

- Problems with significance:
  - Not significant nor exciting nor new research
  - Lack of compelling rationale
  - Incremental and low impact research
- Problems with specific aims:
  - Too ambitious, too much work proposed
  - Unfocused aims, unclear goals
  - Limited aims and uncertain future directions
- Problems with experimental approach:
  - Inappropriate level of experimental detail
  - Feasibility of each aim not shown
  - Little or no expertise with approach
  - Lack of appropriate controls
  - Not directly testing hypothesis
  - Correlative or descriptive data
  - Experiments not directed towards mechanisms
  - No discussion of alternative models or hypotheses
  - No discussion of potential pitfalls
  - No discussion of interpretation of data
- Problems with investigator:
  - No demonstration of expertise or publications in approaches
  - Low productivity, few recent papers
  - No collaborators recruited or no letters from collaborators
- Problems with environment:
  - Inadequate institutional support

http://www.ninds.nih.gov/funding/grantwriting_mistakes.htm

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when you get the summary statement

Communicate with your Program Director

***If fundable*, prepare just-in-time information for submission**
-IACUC, IRB approvals
-updated other support
-information must be current (< 6 mos)

***If you must resubmit*:**
-Don't rush it
-Talk over review with Program Director
-Carefully and succinctly address critiques
-If you rebut a review point, do so respectfully, with supporting evidence. Don't rebut the reviewer!
-Get external review of revised application prior to resubmission

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New Policy for Application Submission

Notice Number: NOT-OD-14-074

The NIH will accept a new (A0) application following an unsuccessful resubmission (A1) application. The subsequent new application need not demonstrate substantial changes in scientific direction compared to previously reviewed submissions, and must not contain an introduction to respond to the critiques from the previous review.

Background: In this extended period of tight funding, [single resubmission policy] resulted in many meritorious research applications being deemed ineligible for additional submissions, and many investigators having to propose substantial changes to productive research programs. New Investigators may have been significantly affected because new research directions may be quite difficult during this phase in their careers.

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Outline

1. NIH Grant Application Process
1. **NCI Initiatives in Imaging and Image-Guided Interventions**

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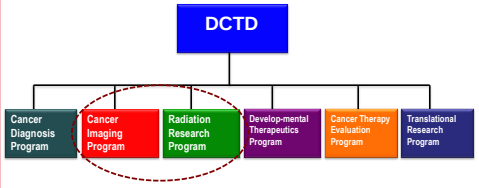
Division of Cancer Treatment and Diagnosis (DCTD)

Funding Programs in DCTD



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CIP/NCI Initiatives in Imaging and IGI

1. Early Phase Clinical Trials (R01)
2. Academic Industry Partnerships (R01)
3. Quantitative Imaging Network (U01)
4. Image-Guided Drug Delivery (R01)
5. Imaging & Biomarkers for Early Detection (R01)

25

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Academic-Industrial Partnerships (R01) – [PAR-13-169]

- Purpose: Development and Validation of Imaging Systems and Methods
- Requires Partnership between academic and industry PI/co-PI
- Includes investigations of IGI-systems
- Standard R01 Application Receipt Dates
- SEP Review (CSR)

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Early Phase Clinical Trials in Imaging & IGI (R01) - [PAR-14-166]

- 3-year clinical trials of novel imaging and IGI
- Intended to accelerate the development of imaging and IGI modalities, methodologies, and agents through the early stages of clinical development -such as trials evaluating safety and preliminary efficacy
- Phase I & II studies to establish treatment parameters and early therapeutic efficacy
- SEP Review (CSR)

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Quantitative Imaging for Evaluation of Response to Cancer Therapies (U01) – [PAR-14-116]

- Quantitative imaging of response to therapies, including IGI, to facilitate clinical decision making
- Development and implementation of QI methods and tools and their applications to current or pending Phase I/II clinical trials
- Funded teams join the Quantitative Imaging Network (QIN)

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Image-Guided Drug Delivery in Cancer (R01) – [PA-13-185]

- Development of integrated platforms for multifunctional and multiplexed oncologic IGDD systems
- Development of quantitative in-vivo imaging methods in IGDD in cancer
  - interrogate tumor/drug interaction
  - imaging studies of biodistribution, PK/PD, Tx response
  - perform imaging studies in non-human primates or large animal models for toxicity screening
- Special Emphasis Panel (SEP) Review

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Imaging and Biomarkers for Early Cancer Detection (R01) – [PAR-13-189]

Collaborative imaging and tissue/blood biomarkers (BM) research to improve early cancer detection and screening

- Validated BM + investigational imaging
- Established imaging + investigational BM
- SEP Review

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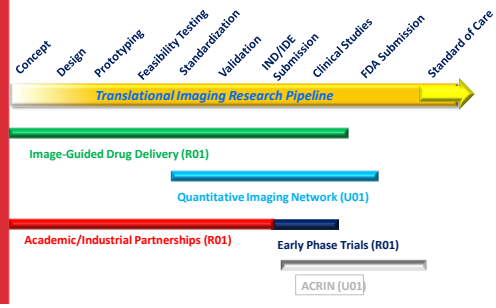
Translational Research Support



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Small Grants

- **Omnibus R03**
  - **Pilot studies, secondary analysis, etc.**
  - **2 years**
  - **$100,000 direct costs**
- **Omnibus R21**
  - **Exploratory / Developmental Research**
  - **2 years**
  - **$275,000 direct costs**
- **Omnibus R15**
  - **Academic Research Enhancement Award (AREA)**
  - **Eligibility criteria**
  - **3 years**
  - **$300,000**

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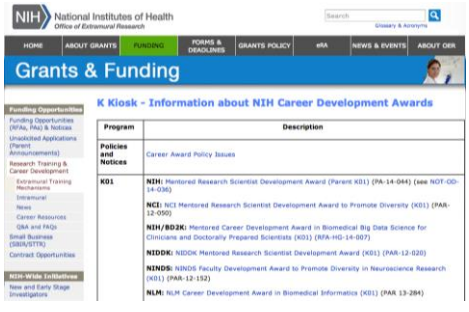
Training K Awards



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Final Points

- Contact an NCI Program Director to discuss a potential
  ~ 6 months ahead of receipt date
- Include Cover Letter with suggestion of Study Section and
  2-3 key areas of expertise (Review) and Program Directo
  (Program) assignment
- The budget situation is fluid and is limiting funding for science across the board.
- Program prioritization of near payline scores for potential
  funding increases scrutiny of overlap and impact.
  - Program Directors advocate for strong grants internally through this process.
- Many clear and compelling proposals in all fields continue to be funded.
- DO NOT GIVE UP!

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Important Websites

NIH Office of Extramural Research:
http://grants.nih.gov/grants/oer.htm

NIH RePORTER:
http://projectreporter.nih.gov/reporter.cfm

NCI Division of Extramural Affairs:
http://deainfo.nci.nih.gov/

Cancer Imaging Program:
http://imaging.cancer.gov

Radiation Research Program:
http://rrp.cancer.gov

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31

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NCI Contacts

Program Directors

- **Radiation Research Program**
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- **Cancer Imaging Program**
  Keyvan Farahani, PhD farahani@nih.gov