

Grantsmanship for NCI R01 and R21 applications

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Spectrum of medical physics

Development



INTERNAL FUNDING

Clinical
implementation

Technology
improvements

INDUSTRY FUNDING

Translational
research

NIH FUNDING

Cutting edge
research

Number of
physicists

Now

1

2

5

10

20

Time (yrs)



- NIH is made up of **27 Institutes and Centers**, each with a specific research agenda, often focusing on particular diseases or body systems
- For Medical Physics funding the most important institutes are:
 - **National Cancer Institute (NCI)**
 - **Division of Cancer Treatment and Diagnosis**
 - The Cancer Diagnosis Program
 - The Cancer Imaging Program
 - The Cancer Therapy Evaluation Program
 - The Developmental Therapeutics Program
 - The Radiation Research Program
 - The Translational Research Program
 - The Biometrics Research Branch
 - The Office of Cancer Complementary and Alternative Medicine
 - **National Institute of Biomedical Imaging and Bioengineering (NIBIB)**
 - **Discovery Science and Technology Division**
 - **Applied Science and Technology Division**
 - **Inter-Disciplinary Training Division**



Most popular NIH funding mechanisms

- **R01** – Research Projects
- **R21** – Exploratory/Developmental Awards
- **R41/R44** – Small Business Awards
- **K/F** – Training Awards
- **P01** – Research Program Project Awards
- **R&D Contracts** - NIH's direct involvement



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- **R01 Research Project Grant**
 - Support a discrete, specified, circumscribed project (3-5 years)
 - Institutional sponsorship assures the NIH that the institution will provide facilities necessary to conduct the research and will be accountable for the grant funds
- **R21 Exploratory/Developmental Grants**
 - Encourage the development of new research activities (2 years)
 - No pilot data required



Application types

- **Unsolicited/Investigator initiated** applications http://grants.nih.gov/grants/guide/parent_announcements.htm
- **Initiated** applications: <http://grants.nih.gov/grants/guide/weeklyindex.cfm>
 - **Program Announcements (PAs)**
 - Statement of new or ongoing NIH interest in a certain research area
 - **Requests for Applications (RFAs)**
 - Statement soliciting applications in a well-defined scientific area to accomplish specific program objectives
 - Set-aside of money
 - Might need Letter of Intent (LOI)
 - Might have special review panel



Before even writing a grant...

- **Discuss ideas with colleagues**
 - Be very self-critical
 - Going through the process of explanation and discussion will help to clarify and focus your ideas
- **Write up your recent work and submit it to a peer-reviewed journal(s)**
 - Track record, as judged by publications, is an important criterion
- **Carry out appropriate preliminary (pilot) studies, so that their results can be included in the application**
 - For some type of grants (R01) preliminary data is mandatory, for some other (R21) very welcome
- **Get necessary expertise on board**
 - Good collaborators are invaluable
- **Get familiar with the write-up and submission process**
 - Writing a good grant takes a lot of time



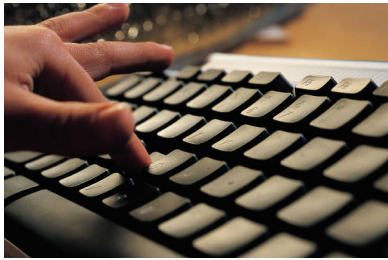
Before even writing a grant...

- Register as a user of NIH eRA Commons: commons.era.nih.gov/commons/
- Check for RFAs and Pas: www.grants.gov
- Check for deadlines: grants.nih.gov/grants/funding/submissionschedule.htm
 - New R01 applications: Feb 5, Jun 5, Oct 5
 - R01 renewals: Mar 5, Jul 5, Nov 5
 - Deadlines for applications in response to RFAs and PAs may differ
- Consult your local (University/Hospital) grant office for specific instructions how to go through the submission process



- How to write a successful grant

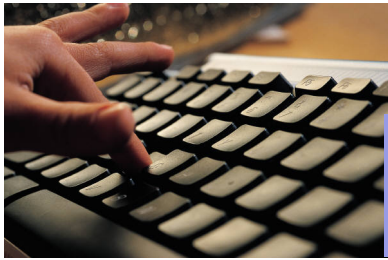




Outline (science)

- Introduction to Application
(if resubmission)
- **Specific Aims**
- **Research Strategy**
 - Significance**
 - Innovation**
 - Approach**
 - Preliminary Studies/Progress Report (if renewal)
- **References**

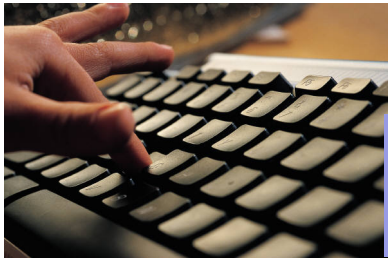




Specific Aims

- Recommended length: 1 page
- Use numbered list of the Aims (maybe 2-4 aims)
- Describe concisely and realistically what the proposed research is intended to accomplish
- Provide objectives
- Hypothesis or hypotheses to be tested (helpful!)
- Assigned reviewers read the entire application. Other members of the study section (who have full scoring rights) may only read the aims



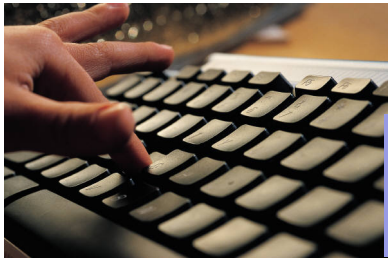


Research Strategy

Significance

- State the rationale for the proposed project
- State the problem to be investigated and the potential contribution of this research
- State the gaps that the project is intended to fill
- Summarize the existing knowledge, including literature citations and highlights of relevant data



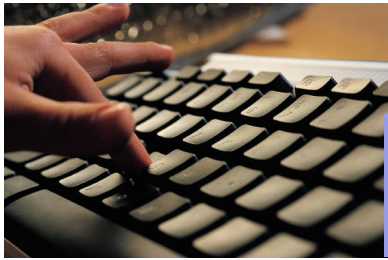


Research Strategy

Innovation

- Describe any new methodology used and why it represents an improvement over the existing ones
- Be realistic ... not overly ambitious. The idea must be novel but of course feasible



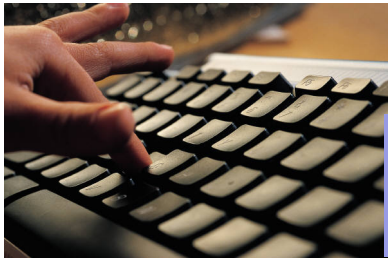


Research Strategy

Approach

- Sections corresponding to the number of specific aims
- Describe specific methods to be employed
- Convince reviewers that this methodology will work
- Discuss the way in which the results will be analyzed and interpreted
- Discuss potential difficulties and limitations and how these will be overcome or mitigated
- State expected results





Budget Justification

Personnel

X. Pert, PhD, Project Leader (1.8 cal months) Dr. Pert is an Associate Professor of Radiation Physics in the Department of Radiation Oncology. He is an expert in electron dosimetry and will oversee the experimental work. ... Dr. Pert has conducted major electron dosimetry projects.

TBN, PhD Research Fellow (12 cal months) A Research Fellow will work on implementing specific IMRT related components into the Monte Carlo framework. Further, this person will ...

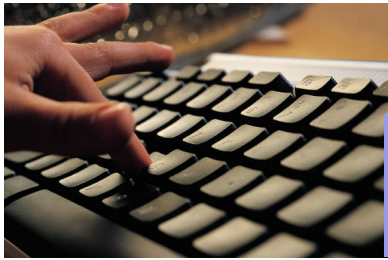
Equipment

...

Travel

Funds are requested for two trips per year for the PI....





Others

- **Cover letter**
- **Biosketches**
- **Resources**
- **Environment**
- **Protection of Human Subjects**
- **Inclusion of Women and Minorities**
- **Targeted/Planned Enrollment Table**
- **Inclusion of Children**
- **Vertebrate Animals**
- **Multiple PD/PI Leadership Plan**
- **Consortium/Contractual Arrangements**
- **Letters of Support**
- **Resource Sharing Plans**



- NIH peer review process





Your contact: Scientific Review Officer (SRO)

- Identifies and assigns reviewers to the SRG
- Point of contact for applicants



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Scientific Review Groups (SRGs)

Make recommendations:

- **Scientific and technical merit**
- **Budget and project duration**
- **Human subjects, vertebrate animals, biohazards**

Study Sections do *not* make funding decisions!



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Scientific Review Groups (SRGs)

- Each study section has 12-24 members who are primarily from academia (roster is public)
- Study sections (typically) convene face-to-face meetings
- As many as 100 applications are reviewed by each study section in one or two days





Reviewer Assignments

- ≥ 3 qualified reviewers based on scientific content
- based on expertise of reviewer
- conflicts of interest
- reviewer workload: ~ 8-12
- reviewers receive grants about 1 month in advance



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SRG Meeting Procedures

- ~ 50% streamlined
- if 100 applications/SRG meeting, 50 applications to discuss and score

~ 14 minutes/application
~ 3 minutes/reviewer

***Clarity and brevity
are essential!***

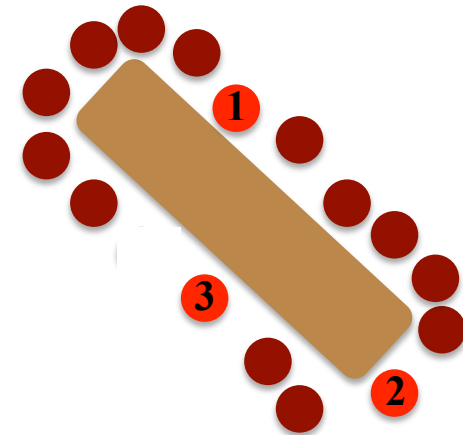


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SRG Meeting Procedures

Discussion format

- Members with conflicts excused
- Initial overall score of each assigned reviewer
- Primary reviewer explains project, strengths/weaknesses
- Other assigned reviewers follow
- Open discussion (full panel)
- Final overall scores of assigned reviewers
- Final scores of all SRG members





New investigator

A PI who has not yet competed successfully for a substantial, competing NIH research grant, e.g. R01

- The NIH will support applications from NIs at success rates comparable to those for new applications submitted by established investigators
- NI applications are streamlined and discussed separately



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eRA Commons Post Review

- **Priority Score**
 - ✓ Three days after conclusion of SRG meeting
- **Summary statement**
 - ✓ 4 – 8 weeks after conclusion of SRG meeting

After the Review

- **Consult Program Officer**
- **Consider resubmission (once!)**
 - ✓ Consider critiques in summary statement
 - ✓ Address critiques in introduction and text



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Funding Decision

Institute Director makes the funding decision

- **Factors Considered:**
 - **Scientific Merit**
 - **Contribution to Institute Mission**
 - **Advisory Council Recommendation**
 - **Program Balance**
 - **Availability of Funds**





Advisory Council/Board

**Panel of scientific experts provide advice to
Institute Director on**

- Research priority areas
- Funding
- Policy and program development
- Appeals of review recommendations; cannot change priority score from SRG but can defer to re-review



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- Review criteria, scoring



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Scoring system

Score	Descriptor	Additional Guidance on Strengths/ Weaknesses
1	Exceptional	Exceptionally strong with essentially no weaknesses
2	Outstanding	Extremely strong with negligible weaknesses
3	Excellent	Very strong with only some minor weaknesses
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
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

Minor Weakness: An easily addressable weakness that does not substantially lessen impact

Moderate Weakness: A weakness that lessens impact

Major Weakness: A weakness that severely limits impact





Review Criteria (individually scored)

- **Significance:** Does the study address an important problem? How will scientific knowledge be advanced?
- **Innovation:** Are there novel concepts or approaches? Are the aims original and innovative?
- **Approach:** Are design and methods well-developed and appropriate? Are problem areas addressed?
- **Investigator:** Is the investigator appropriately trained?
- **Environment:** Does the scientific environment contribute to the probability of success? Are there unique features of the scientific environment?

There is also an overall score (“overall impact”)





Review Criteria (not scored)

- **Protections for Human Subjects**
- **Inclusion of Women, Minorities, Children**
- **Vertebrate Animals**
- **Biohazards**
- **Revision/Resubmission issues**



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Summary statement

Example

CRITIQUE 1:

Significance: 3

Investigator(s): 1

Innovation: 4

Approach: 4

Environment: 1

CRITIQUE 2:

Significance: 9

Investigator(s): 3

Innovation: 8

Approach: 8

Environment: 3



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