

Writing / Getting Great Research Grants

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**Writing a Competitive
Grant Proposal is a
Readily Learnable Skill**

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It Can Even Be Fun!

Why the NIH?

- Sutton's Law
 - “that's where the money is”
- Many different awards
 - R, K, P, U ...
- Long-term funding
 - most awards for 3-5 years
 - often renewable
- Highly valued
 - peer-review recognized “stamp of approval”
 - useful or required for promotion
- Topic related to human health

Ready, Set Plan!

Build Your Research Program First

- Plan ahead
- Find a mentor
- Develop institutional collaborators
- Target funding sources appropriate for both individual and program maturity
- Develop & maintain departmental & institutional funding

Important Groundwork

Before You Start Writing

- Think up a good idea
- Review the literature
- Give a lecture on the topic
 - pay attention to feedback from the audience
- Reality test with a mentor
 - refine the ideas together

Guidelines for Writing a Successful Grant Proposal

Read the Directions

Follow the Directions

Grantwriting Pointers

General Guidelines

- Think like a reviewer at all times
- Take pity on the reviewers
 - your proposal should be interesting and reasonably easy to read
- Use formatting for clarity
 - text, figures, legends must be legible to presbyopic 50+ year-old
 - \geq margin & font guidelines
 - subheadings & boldings

Grantwriting Pointers

General Guidelines (con'd)

- Remember your job
 - think journalist, not novelist
 - this is not the time to wax eloquent
 - your goal: get the \$\$ in order to do the science
- Don't be shy
 - bare your soul locally first
 - ask for help early and often
 - write (or draft) all letters of support

NIH Review Criteria

- Overall Impact (new criterion)
 - “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 *five core review criteria*, and additional review criteria (as applicable for the project proposed)”

Overall Impact:

The likelihood that a project will have a sustained and powerful influence on science (and/or clinical practice and/or technological developments?)

Overall Impact	High	Medium	Low
Score	1 2 3	4 5 6	7 8 9

e.g. Applications are addressing a problem of high importance in the field. May have some or no technical weaknesses.

e.g. Applications may be addressing a problem of high importance in the field, but weaknesses in the criteria bring down the overall impact to medium.

e.g. Applications may be addressing a problem of moderate importance in the field, with some or no technical weaknesses

e.g. Applications may be addressing a problem of moderate/high importance in the field, but weaknesses in the criteria bring down the overall impact to low.

e.g. Applications may be addressing a problem of low or no importance in the field, with some or no technical weaknesses.

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

Evaluating Overall Impact:

Consider the 5 criteria: significance, investigator, innovation, approach, environment (weighted based on reviewer's judgment)

NIH Review Criteria

■ Significance

- does the research address an important problem?
- if successful, how will knowledge be advanced?
- what will be effect on concepts that drive the field?

■ Approach

- are the conceptual framework, design, methods and analyses adequately developed, well integrated and appropriate to the aims?
- does the applicant acknowledge potential problem areas and consider alternative approaches?

NIH Review Criteria (con'd)

■ Innovation

- are the aims original and innovative?
- are novel concepts, approaches or methods proposed?
- does the project challenge existing paradigms or develop new methodologies or technologies?

■ Investigator

- is the investigator appropriately trained and well suited to carry out the proposed research?
- is the proposed research appropriate to the experience level of the principal investigator and co-investigators?

NIH Review Criteria (con'd)

- Environment

- does the scientific environment in which the work will be done contribute to the overall probability of success?
- do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements?

Grant Components

The “Other Stuff”

- Abstract
- Budgets and Budget Justification
- Biosketches
- Environment/Resources
- Letters of Support

Grant Components

The “Research Plan”

- Specific Aims
- Research Strategy
 - Significance
 - innovation
 - approach
 - preliminary studies for new applications
 - progress report for renewal/revision applications
- Human Subjects
- Animal Subjects

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A. SPECIFIC AIMS

The proposed research seeks to apply decision analytic techniques in order to evaluate recently developed, minimally invasive approaches to percutaneous, in-situ tumor ablation, in patients with hepatic metastases from colorectal carcinoma (CRC). In so doing, we also propose to extend our ongoing analysis of operative metastasectomy, and to evaluate several diagnostic strategies which might be used in potential candidates for either surgical or minimally invasive therapies directed at liver metastases. To date, none of these (surgical or percutaneous) techniques has been formally evaluated in order to determine their relative cost effectiveness. Furthermore, the importance of diagnostic imaging in selecting candidates for therapy — specifically the potential impact of diagnostic accuracy on treatment outcomes — has received relatively little attention. ¶

As part of an ongoing evaluation of operative metastasectomy, we have recently developed and validated a Markov decision model with which to compare the outcomes (treatment effectiveness and cost) associated with a variety of strategies for managing patients with CRC liver metastases. This model (see *Preliminary Data*) tracks up to 15 individual metastatic lesions per patient, and simulates the growth, detection, and treatment of each of these lesions. Patient outcomes are modeled on the basis of the number and size of the lesions present, in combination with the success of each test/treat strategy in detecting and removing them. Utilizing this model, we have compared patient outcomes associated across a wide range of assumptions concerning lesion number and size, rate of growth, diagnostic test performance, treatment efficacy, and cost. This research, by modeling the combined effects of testing and treatment strategies is unique in that it attempts to optimize both diagnostic liver imaging and treatment based on patient outcomes, and also because it included an explicit evaluation of the important interaction between diagnostic imaging and treatment strategies. These evaluations would have been virtually impossible to carry out in actual clinical trials, due to the very large number of combinations of diagnostic tests and operative approaches which were studied. An additional advantage of the modeling approach is that it can help to identify specific comparisons, and facilitate the design of clinical trials, that can provide data necessary to resolve questions which cannot be answered on the basis of current knowledge. ¶

We now propose to further develop and refine this model in order to include in-situ tumor ablation, and to perform cost effectiveness analysis of strategies for diagnostic imaging and in-situ ablation in patients with CRC liver metastases. The research will proceed in a stepwise fashion, from model development and validation, through careful assessment of a variety of test/treat strategies. The research will include a careful analysis of the important determinates of cost effectiveness, the level of uncertainty of these determinates, and how these determinates might be affected by alternate health care delivery settings or policies. Initially, we will refine our existing cost effectiveness model in order to include strategies for in-situ tumor ablation, and to take into account any additional data which have become available since the model was originally developed. Subsequently, we will compare in-situ tumor ablation to operative metastasectomy, taking into account several variables which might affect the effectiveness and/or cost (e.g., maximum number of lesions which will be treated, number of repeat resections or re-treatments allowed, etc.) of these therapies. Next, we will explore the potential impact of pre-treatment diagnostic imaging on the cost and effectiveness of treatment. For example, more accurate diagnostic imaging should improve treatment outcomes by correctly identifying all lesions which are present, and thereby permitting each of these lesions to be targeted for treatment. Each of these analyses will be performed from the societal perspective as well as from other potentially interesting and/or relevant perspectives (e.g., third-party payer, health system, patient), in order to investigate the potential for different health care delivery settings or decision making perspectives to influence health outcomes at a population level. Finally, we will examine the

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relevance of cost effectiveness analysis in this setting by investigating the potential for cost and/or cost effectiveness information to influence the decision making process, and thereby alter health outcomes, in patients undergoing treatment for CRC liver metastases. ¶

Specific long term goals are: 1) to determine the most cost-effective strategy(ies) for managing patients with potentially curable liver metastases from colorectal carcinoma, 2) to explore the possibility that minimally invasive therapies — given their generally lower cost and associated morbidity and mortality — could provide relatively cost-effective life extension in patients with incurable metastatic disease, and 3) to identify those areas where uncertainty regarding important determinants of cost effectiveness might benefit from further analysis and/or data collection. ¶

Specifically, and as described in detail below, the proposed project seeks to carry out the following **Specific Aims**: ¶

AIM 1: Investigate the cost effectiveness of percutaneous, in-situ ablation, relative to hepatic metastasectomy, in patients with liver metastases from colorectal cancer (CRC). ¶

- a) → Evaluate the relative cost-effectiveness of operative and in-situ ablative treatment strategies in patients with potentially curable CRC liver metastases. ¶
- b) → Estimate the impact of in-situ tumor ablation on survival and costs in patients where complete elimination of metastases is unlikely, in order to evaluate its potential role as a palliative therapy. ¶

AIM 2: Investigate the impact of pre-treatment diagnostic imaging on the cost effectiveness of operative and in-situ ablative therapy in patients with CRC liver metastases. ¶

- a) → Determine the extent to which pre-treatment diagnostic imaging influences the cost and outcome of treatments directed at CRC liver metastases. ¶
- b) → Compare several diagnostic strategies which might be used to select patients for liver resection or in-situ tumor ablation. ¶

AIM 3: Investigate the impact of cost and/or cost effectiveness considerations on decision making in patients with CRC liver metastases. ¶

- a) → Compare the ranking of several imaging and treatment strategies based on effectiveness alone to that obtained using cost and/or cost effectiveness. ¶
- b) → Estimate population-wide differences in cost and/or effectiveness attributable to decisions made using cost and/or cost effectiveness considerations. ¶

AIM 4: Investigate the impact of analytic perspective on the relative cost effectiveness of imaging and treatment strategies in patients with CRC liver metastases. ¶

- a) → Compare the ranking of several imaging and treatment strategies based on analyses from different perspectives (societal, hospital, patient, etc). ¶
- b) → Estimate population-wide differences in cost and/or effectiveness attributable to decisions made from different perspectives. ¶

Page Break

|| •A. •SPECIFIC AIMS¶

The proposed research will apply decision analytic techniques to the evaluation of recently developed, minimally invasive approaches to percutaneous, in-situ tumor ablation, in patients with hepatic metastases from colorectal carcinoma (CRC). As part of an ongoing evaluation of operative metastasectomy, we have developed and verified a Markov decision model and compared the outcomes associated with a variety of strategies for surgical management of patients with CRC liver metastases. Utilizing this model, we specifically assessed the relative cost-effectiveness of management strategies across a range of assumptions concerning lesion number and size, rate of growth, diagnostic test performance, treatment efficacy, and cost. The model was verified by “predicting” the results (e.g., tumor recurrence rates, 5-year survival) of clinical trials reported in the literature. The research is unique in that it evaluates both imaging and treatment based on patient outcomes, and also because it explicitly evaluates the interaction between diagnostic imaging and treatment strategies. These evaluations would have been virtually impossible to carry out in clinical trials, due to the many combinations of tests and operative approaches studied.¶

We now propose to further develop, verify, and utilize this model in order to perform cost-effectiveness analysis of strategies for imaging and in-situ ablation in patients with CRC liver metastases. The research will proceed from model development and validation through a careful assessment of several test/treat strategies, and will include careful analysis of the important determinates of cost-effectiveness, their uncertainty, and the effects of alternate health care delivery settings or policies. Each analysis will be performed from a societal perspective, and from other perspectives which may be relevant, such as that of the third-party payer, health care delivery system, or patient. ¶

The research will investigate the following hypotheses: 1) that in-situ ablation – given its lower cost, morbidity, and mortality – is more cost-effective than operative metastasectomy as a treatment for liver metastases; 2) that the cost-effectiveness of surgical and percutaneous therapies for liver metastases can be significantly improved by improvements in diagnostic test performance; and 3) that in-situ ablation can provide palliative life extension at an acceptable cost, in patients who are not likely to be cured. ¶

The research described in this proposal will carry out the following **Specific Aims:**¶

AIM-1: → Determine the cost-effectiveness of percutaneous, in-situ ablation, relative to hepatic metastasectomy, in patients with liver metastases from colorectal cancer (CRC).¶

- 1.1 → Develop and verify a Markov decision model based on previously developed and verified models used to evaluate the cost-effectiveness of hepatic metastasectomy. ¶
- 1.2 → Determine the relative cost-effectiveness of operative and in-situ ablative treatment strategies in patients with potentially curable CRC liver metastases. ¶
- 1.3 → Estimate the impact of in-situ ablation on survival and costs in patients where cure is unlikely, in order to evaluate its potential role as a palliative therapy. ¶

AIM-2: → Determine the impact of pre-treatment diagnostic imaging on the cost-effectiveness of operative and in-situ ablative therapy.¶

- 2.1 → Determine the extent to which pre-treatment diagnostic imaging influences the cost and outcome of treatments directed at CRC liver metastases. ¶
- 2.2 → Compare diagnostic strategies which might be used to select patients for operative metastasectomy or in-situ tumor ablation. ¶

AIM-3: → Investigate the impact of the analytic perspective on the relative cost-effectiveness of imaging and treatment strategies in patients with CRC liver metastases.¶

- 3.1 → Compare the ranking of several imaging and treatment strategies based on analyses from different perspectives (societal, hospital, patient, etc). ¶
- 3.2 → Estimate population-wide differences in cost and/or effectiveness attributable to decisions made from different perspectives. ¶

What Changed?

- From two pages to one page
 - body was long and overly verbose
 - remember, it's the "Specific Aims Page"

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What Changed?

- Clearly stated hypotheses
 - related to aim & methods
 - shows that research is “hypothesis-driven”

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What Changed?

- Only Three Aims
 - all relate to hypotheses
 - strong verbs (develop, determine, compare)
 - do not require hierarchical success

• A. → SPECIFIC AIMS ¶

The delivery of healthcare relies heavily on information; inaccessible or inaccurate information can lead to inappropriate care, a reduction of the quality of care and medical errors. Research conducted over the past several decades has clearly demonstrated that Information Technology (IT) can improve the quality and safety of healthcare, yet it is widely acknowledged that the IT infrastructure in healthcare lags behind other industries. Managing information is particularly challenging in Radiology because of dramatic increases in the number, size and complexity of imaging studies. Medical Imaging Informatics (MII) systems, generally comprised of digital imaging systems, radiology information systems, picture archiving and communication systems (PACS), and voice recognition technology can help address this challenge. MII systems have the potential to improve the quality and safety of care by enhancing effectiveness, timeliness and efficiency, yet fewer than 15% of hospital Radiology departments have fully implemented them. The low percentage of Radiology departments with fully implemented MII systems represents an opportunity to improve the quality and safety of patient care. However, the decision to deploy a comprehensive MII system is often based on financial considerations, rather than the potential to improve quality and safety. A better understanding of the financial and operational value of MII systems will facilitate decision making regarding MII deployment and result in substantial improvements in healthcare quality and safety. **In this study, we will assess the impact of Medical Imaging Informatics (MII) on healthcare costs and quality. Our over all goal is to develop a "business case for quality" related to MII utilization.** The findings of our study will be widely disseminated. This information will help translate existing research into practice and further the AHRQ's goals in the area of quality and safety. ¶

Deployment of a comprehensive MII system at Massachusetts General Hospital (MGH) began in 1995. The potential for cost savings was a deciding factor in the decision to proceed. Preliminary analysis suggests there has been a substantial return on investment for these technologies. Wide scale MII deployment at New York University (NYU) Medical Center is now underway. We propose to evaluate MII deployment at MGH and NYU. The opportunity to study MII deployment at two large academic medical centers that went through the process almost a decade apart presents a unique opportunity to better understand the value of MII and to isolate the effects of MII from other secular trends in healthcare. Our analysis will identify the financial implications of deploying MII systems, including the costs and savings attributable to their use. We will also determine the effect of MII on healthcare quality and safety, by examining outcomes such as process times, provider and capital utilization efficiency, and management errors. Finally, using data from several smaller and/or rural hospitals, we will develop models that can be used to predict the value of MII in different settings. ¶

The research will increase our knowledge and understanding of the value of MII and provide data that will facilitate rational decision making concerning the implementation of MII in a variety of health care settings. The multidisciplinary research team is experienced in all aspects of Medical Imaging Informatics, financial analysis and technology assessment, and is well qualified to conduct the proposed research. The research will carry out the following **Specific Aims:** ¶

- **AIM-1: → Determine the financial impact of the deployment of a comprehensive MII system in two large academic Radiology departments. ¶**
 - 1.1 → Determine the financial costs associated with MII deployment at MGH and NYU. ¶
 - 1.2 → Calculate cost savings and increased revenue attributable to MII deployment at MGH/NYU. ¶
 - 1.3 → Determine the rate of return earned and payback period for MII deployment at MGH/NYU. ¶

HYPOTHESIS: MII systems can provide meaningful financial returns within 3 years of deployment. ¶
- **AIM-2: → Determine the impact of MII on healthcare quality, focusing on the dimensions of quality as defined by the Institute of Medicine. ¶**
 - 2.1 → Analyze trends in process times, dictated studies, duplicate studies, and the efficiency of provider and capital utilization before and after MII deployment at MGH and NYU. ¶
 - 2.2 → Conduct a pilot study to demonstrate the value of an informatics-based approach to reducing patient management errors following imaging studies. ¶

HYPOTHESIS: MII systems can result in measurable improvements in healthcare quality. ¶
- **AIM-3: → Develop and validate a model to predict the impact of a comprehensive MII system on financial and quality outcomes in different hospital settings. ¶**

HYPOTHESIS: The effects of MII deployment on financial and quality outcomes can be estimated based on hospital and practice characteristics such as total volume, staffing, and case mix. ¶

Summary

“Formula” for Specific Aims Page

- 1 PAGE – now a specific requirement
- Statement of overall goal(s)
- Body
 - brief background, importance & indictment of existing knowledge or literature
 - preliminary data/team accomplishments
 - general methodologic approach
 - deliverables
 - +/- hypotheses if not specific to aims

Summary

“Formula” for Specific Aims Page

■ 3 Aims

- strong action words
- avoid hierarchical success
- +/- hypotheses if associated with each aim

Research Strategy

- Significance
- Innovation
- Approach
 - preliminary studies (new applications)
 - progress report (renewal/resubmissions)

Significance

- Why spend the money?
 - current state of knowledge, unresolved issues
 - demonstrate potential impact on healthcare
 - project does NOT need to be too large in scope;
FOCUS IS GENERALLY VERY IMPORTANT
- Relationship to other work in the field
 - should be scholarly, objective, well-referenced,
BUT this is not a review article or book chapter
 - provide compelling justification for research
 - know the study section & reference their work

Innovation

- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields
- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved

Approach/Preliminary Studies

- Demonstrate your expertise
 - as a researcher
 - with specific techniques to be used
 - clinical expertise & access to patients
 - highlight expertise of collaborators and demonstrate how theirs will complement yours
- Results must support aims of study
 - ideally, preliminary studies suggest need for the research you are proposing to conduct
 - indicate to reviewers that specific aims are reasonable, based on current knowledge & work
 - note: NIH uses 5% acceptable failure rate

Approach/Research Methods (1)

■ Overview

- summarize work to be done and importance
- often similar to body/text of Aims page
- overall approach should seem logical
- think of this as “the big picture”

■ Research team/environment

- describe roles of key personnel
- convince reviewers that you have the best possible team
- highlight institutional strengths that make it likely the proposed research will be successful

Approach/Research Methods (2)

- Timeline/timetable
 - generally includes text & graphics
 - justify funding period or expect to be cut
 - detail helps to convince reviewers that you understand the project & methods
- Detailed methods
 - parallel the aims and test hypotheses – put them in VERBATIM (and check to confirm!)
 - include recruitment strategies, sample size calculations & statistical approaches
 - absolutely no “hand waving” – if you know you are glossing over something, then fix it

Approach/Research Methods (3)

- Anticipated results & limitations
 - important section that is frequently omitted
 - anticipate potential problems & propose solutions
 - provides reviewer insight into how you might handle the problems that will almost invariably arise

Why Grants Fail

- Poor science
 - the quality of the research is the most important aspect of any grant proposal – sending in an application with poor science is the SUREST WAY TO FAIL
- Poor organization
 - if the proposal is hard to follow, the reviewer will get frustrated and/or angry and simply give up

Why Grants Fail (con'd)

- Poor integration
 - the different parts of the proposal must clearly relate to each other – you must convince the reviewer that the work is worth doing (background), can be done (preliminary studies) and has been carefully thought through (methods)
- Contradiction, superficiality
 - proposal should be internally consistent & detailed enough that the reviewer doesn't have to wonder what you will really do with all the time & money that you are asking for

Why Grants Fail (con'd)

- Lack of qualifications
 - the PI (you) should be capable of doing the work
 - collaborators & support personnel should be sufficiently qualified & adequately funded
 - work should be feasibly conducted in the institution and scientific environment

Summary

- Generate an OUTSTANDING PROPOSAL
- Capture the reviewers' interest
- Focus ... less is often more

Finally ...

There's no such thing as grantwriting
... just **re-writing** and **re-writing** ...
that's why they call it **RE-SEARCH!**

GOOD LUCK!