

# How to Plan and Prepare a Successful Grant Application



## *Session 2* *Selling the Grant*

Presented December 13, 2007 by the UAMS Office of Grants and Scientific Publications

# Session Outline

- ◆ **Peer Review and Review Criteria—what are these?**
- ◆ **Specific Aims**
  - Purpose: making the big sell
  - Content and organization
- ◆ **Other Elements of the Research Plan**
  - Background & Significance
  - Preliminary Studies
  - Research Design & Methods
- ◆ **UAMS resources/requirements and electronic submission**

# Aiming to Please



# Sell Yourself, Your Work, Your Ideas

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- ◆ **Grant writing is marketing writing**
- ◆ **After it is accurate, make it compelling**
- ◆ **Engender enthusiasm**
- ◆ **Give your reviewer reasons to advocate your proposal**
- ◆ **Leave your competition in the dust**

Here is Why. . .

## ***The Grim Statistics***

**The average age at which an investigator first obtains R01 funding has increased by five to six years—to 42 for PhD degree holders and 44 for MD and MD/PhD degree holders.**

# Understand Peer Review

## ◆ *Inside the NIH Grant Review Process*

- **A video on peer review at NIH produced by the Center for Scientific Review**
- **Mock study section meeting provides an inside look at how NIH grant applications are reviewed for scientific and technical merit**
- **Shows how outside experts assess applications and how review meetings are conducted to ensure fairness**
- **Includes information on what applicants can do to improve the chances of a positive review**

# Review Criteria for an Individual Fellowship Application

- 1. Candidate**
- 2. Sponsor and Training Environment**
- 3. Research Proposal**
- 4. Training Potential**

# Candidate

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- ◆ **Candidate's previous academic and research performance.**
- ◆ **Potential to become important contributor to biomedical, behavioral, or clinical science.**

# Where to Add. . .

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- ◆ **Personnel (Budget Justification)**
- ◆ **Applicant/Fellow Biosketch**
- ◆ **Previous Research Experience Section**
- ◆ **Significance**
- ◆ **Preliminary Data**
- ◆ **Research Design and Methods**

# Sponsor and Training Environment

- ◆ **Quality of training environment.**
  - Institutional commitment
  - Facilities and related resources
  - Availability of research support
- ◆ **Qualifications of sponsor as mentor and as researcher.**
- ◆ **Quality/appropriateness of unique research training opportunities proposed at foreign site.**

# Where to Add. . .

- ◆ **Resources (Forms)**
- ◆ **Significance**
- ◆ **Preliminary Data**
- ◆ **Research Design and Methods**
- ◆ **Section I. Respective Contributions**
- ◆ **Section J. Selection of Sponsor/Institution**
- ◆ **Letters of Support**

# Research Proposal

- ◆ **Merit of scientific proposal**
  - **Significance**
  - **Approach**
  - **Innovation**
- ◆ **Potential of training plan to serve as sound foundation for productive research career**

# Where to Add. . .

## **Significance**

- ◆ **Research Proposal Description/Abstract**
- ◆ **Specific Aims**
- ◆ **Significance**

## **Approach**

- ◆ **Preliminary Data**
- ◆ **Rationale in RD&M**

## **Innovation**

- ◆ **Specific Aims**
- ◆ **Significance**
- ◆ **Research Design and Methods**

# Training Potential

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- ◆ **Value of proposed fellowship experience as it relates to candidate's needs in preparation for career as independent researcher.**

# Where to Add. . .

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- ◆ **Significance**
- ◆ **Section J. Selection of Sponsor/Institution**

# R01 Review Criteria

**Significance  
Approach  
Innovation  
Investigator  
Environment**

**A copyrighted, annotated R01 proposal\* is available online**

*\*The grant application, sar-Mediated Regulation in Staphylococcus aureus©, was prepared by Mark S. Smeltzer, PhD, and annotated by the National Institute of Allergy and Infectious Diseases (NIAID).*

# Main Sections of F32

## Form pages

### Research Training Plan

- A. Specific Aims (~1/2 p.)
- B. Background & Significance (1½–2 pp.)
- C. Preliminary Studies/Progress Report (2–3 pp.)
- D. Research Design & Methods (4–6 pp.)
- E. Human Subjects
- F. Vertebrate Animals
- G. Literature Cited
- H. Resource Sharing
- I. Respective Contributions
- J. Selection of Sponsor and Institution
- K. Responsible Conduct of Research



≤10 pages

### Appendix

# Writing the Specific Aims



# Selling Your Ideas

- ◆ ***Specific Aims* section is one of the most important parts of the application**
- ◆ **It serves as an executive summary of your proposed research**
- ◆ **It allows you to “market” your ideas to the funding agency**
- ◆ **Use this section when obtaining early critiques/feedback from internal and external reviewers**

# Angles on Aims

- ◆ **Specific Aims are like arrows**

*They aim for a target and together reach an overall goal*

- ◆ **Specific Aims are like fingers**

*They all function together but can also work separately—some are more important than others*

# Specific Aims

***“List the broad, long-term objectives and what the specific research proposed...is intended to accomplish. State the hypotheses to be tested.”***

**PHS 398 instructions**

# Present a Focused Plan

**General, compelling introduction of topic to capture reader (overarching problem). Broad description of what is known about problem and what questions remain unanswered that your overall goal may address.**

**What has been achieved toward that goal (your research and that of others) and specific gaps in knowledge you now plan to address. Hypothesis based on preliminary data. Specific aims to test hypothesis. Significance.**

# Organization

- ◆ State the **overarching problem** that this project will address.
- ◆ Describe, in very general terms, what is known about this problem and what question remains unanswered—e.g., your **overall goal**.

# Organization

- ◆ Briefly describe the **results of your preliminary data and the work of others** (what has been done toward achieving the overall goal).
- ◆ Describe the **specific gap in knowledge** you now plan to address.
- ◆ Provide the **overall hypothesis** that logically flows from your preliminary work.

# Organization

- ◆ State each **specific aim** of your research in terms of the goal and/or outcome of the research, if successful (“**what**” you are trying to accomplish).
- ◆ Briefly describe the **general experimental design** and/or methods to be used to carry out your aim(s) (“**how**” you will accomplish it).

# Organization

- ◆ Explain, in 1 or 2 sentences, the **significance** of your research; i.e., how your results will **advance the scientific field** and the **health relevance**. Link to goals of PA/RFA and/or institute when applicable (check web sites).

*And do all this in 1 page!*

# Overarching Problem

**The cure rate and 10-year event-free survival (EFS) for multiple myeloma remains low despite the introduction of high-dose chemotherapy supported by autologous peripheral blood stem cell transplantation (auto-PBSCT) and the application of novel drugs.**

# Overall Goal

The cure rate and 10-year event-free survival (EFS) for multiple myeloma remains low despite the introduction of high-dose chemotherapy supported by autologous peripheral blood stem cell transplantation (auto-PBSCT) and the application of novel drugs.

**New therapeutic modalities that are non-cross-resistant with chemotherapy, such as immunotherapy with natural killer (NK) cells, are clearly needed to improve outcome, particularly in patients with chemotherapy-resistant myeloma.**

# Results (Preliminary Data/Background) Toward Achieving Goal

The cure rate and 10-year event-free survival (EFS) for multiple myeloma remains low despite the introduction of high-dose chemotherapy supported by autologous peripheral blood stem cell transplantation (auto-PBSCT) and the application of novel drugs. New therapeutic modalities that are non-cross-resistant with chemotherapy, such as immunotherapy with natural killer (NK) cells, are clearly needed to improve outcome, particularly in patients with chemotherapy-resistant myeloma.

**We have shown that chemo-resistant myeloma cells can be killed by killer-cell immunoglobulin-like receptor (KIR)–ligand mismatched (KIR–L MM) NK cells from an allogeneic, haplo-identical donor. In addition, we have transfused haplo-identical KIR–L MM NK cells in the setting of an auto-PBSCT in a pilot trial of 8 patients with advanced myeloma. This immunotherapy proved to be safe and did not cause graft versus host disease (GvHD) or rejection of the autograft.**

# Specific Gap in Knowledge

The cure rate and 10-year event-free survival (EFS) for multiple myeloma remains low despite the introduction of high-dose chemotherapy supported by autologous peripheral blood stem cell transplantation (auto-PBSCT) and the application of novel drugs. New therapeutic modalities that are non-cross-resistant with chemotherapy, such as immunotherapy with natural killer (NK) cells, are clearly needed to improve outcome, particularly in patients with chemotherapy-resistant myeloma. We have shown that chemo-resistant myeloma cells can be killed by killer-cell immunoglobulin-like receptor (KIR)–ligand mismatched (KIR–L MM) NK cells from an allogeneic, haplo-identical donor. In addition, we have transfused haplo-identical KIR–L MM NK cells in the setting of an auto-PBSCT in a pilot trial of 8 patients with advanced myeloma. This immunotherapy proved to be safe and did not cause graft versus host disease (GvHD) or rejection of the autograft.

**However, although these initial clinical results are encouraging and suggest that complete responses can be induced, the NK cell doses transfused are likely not sufficient to destroy a large myeloma burden. We now propose building on these initial results with a 3-pronged approach for enhancing the clinical efficacy of NK cell therapy for myeloma.**

# Overall Hypothesis

The cure rate and 10-year event-free survival (EFS) for multiple myeloma remains low despite the introduction of high-dose chemotherapy supported by autologous peripheral blood stem cell transplantation (auto-PBSCT) and the application of novel drugs. New therapeutic modalities that are non-cross-resistant with chemotherapy, such as immunotherapy with natural killer (NK) cells, are clearly needed to improve outcome, particularly in patients with chemotherapy-resistant myeloma. We have shown that chemo-resistant myeloma cells can be killed by killer-cell immunoglobulin-like receptor (KIR)–ligand mismatched (KIR–L MM) NK cells from an allogeneic, haplo-identical donor. In addition, we have transfused haplo-identical KIR–L MM NK cells in the setting of an auto-PBSCT in a pilot trial of 8 patients with advanced myeloma. This immunotherapy proved to be safe and did not cause graft versus host disease (GvHD) or rejection of the autograft. However, although these initial clinical results are encouraging and suggest that complete responses can be induced, the NK cell doses transfused are likely not sufficient to destroy a large myeloma burden. We now propose building on these initial results with a 3-pronged approach for enhancing the clinical efficacy of NK cell therapy for myeloma.

**We hypothesize that we can further improve the killing of chemo-refractory myeloma with KIR–L MM NK cells by activating and expanding the NK cells and by modulating the interaction between NK effectors and myeloma targets.**

# Specific Aims

## General Experimental Design

To test this hypothesis, we will pursue the following specific aims.

- ◆ **Specific Aim 1: Determine if NK cell dose and potency can be reliably increased by expanding and activating NK cells prior to infusion.**

Expansion of NK cells is important if we are to overcome the myeloma burden. Without expansion, there will be too few NK cells and too many myeloma cells to eradicate all chemo-refractory myeloma. Prior to infusion, we will stimulate KIR–L MM haplo-identical NK cells with K562 cells transfected with membrane-bound IL15 and the co-stimulatory molecule 4-1BB ligand. We contend that NK cells can be expanded >100-fold and be highly activated to kill primary myeloma with this *in vitro* manipulation.

- ◆ **Specific Aim 2: Evaluate whether antibody-dependent cellular cytotoxicity (ADCC) of NK cells can be enhanced by flagging myeloma cells for NK cell detection and elimination.**

We will use a humanized antibody to CS-1, a CD2 receptor family molecule expressed by myeloma cells but not by normal tissues, to confer myeloma-specific NK cell cytotoxicity. This antibody will effectively ‘flag’ myeloma cells for ADCC-mediated killing by NK cells. It has been well established that antibodies, such as rituximab (anti-CD20), have potent anti-lymphoma effects through ADCC. We hypothesize that anti-CS1 will have a similar effect in myeloma.

- ◆ **Specific Aim 3: Determine if myeloma vulnerability to NK cell killing can be increased by downregulation of inhibitory ligands on myeloma cells.**

Over 50% of NK cells from KIR–L MM donors are non-alloreactive to myeloma cells due to the presence of human leukocyte antigen (HLA)–class I ligands on myeloma cells, which interact with inhibitory receptors on NK cells, preventing myeloma cell kill. However, NK cells avidly kill targets that either do not express or only weakly express HLA-class I. A prime example is the NK-sensitive cell line K562, which lacks expression of HLA-class I. We propose that by treating patients with proteasome inhibitors, we should be able to downregulate HLA-class I on myeloma cells, which will then allow killing of myeloma by all NK cells, including non-alloreactive NK cells. This will greatly increase the number of NK cells available to destroy the myeloma burden.

# Health Relevance

**Successful implementation of our 3-pronged strategy for enhancing the efficacy of NK cell therapy for myeloma should make myeloma cells as susceptible to killing as the highly NK-sensitive cell line K562. Results of these studies can then be used to improve our current protocol employing KIR–L MM NK cell therapy for patients with refractory myeloma. In future, this treatment approach could be applied in the autologous setting as additional frontline therapy for newly diagnosed myeloma patients. In addition, this research could lead to more efficacious treatment for other NK cell–sensitive malignancies.**

[Final Aims Page](#)

# Problems and Solutions: Specific Aims

- ◆ **Work is too expansive, therefore not feasible**

*Change some aims to future studies*

- ◆ **Aims presented are methods**

*Move “how to” information to RD&M section*

- ◆ **Poor structure/organization**

*Refer to “reverse triangle” organization*

- ◆ **Failure to link significance of proposed work to health or clinical outcomes**

*Don't forget to “sell” your proposal*

# The Rest of the Research Plan



- ◆ **Background & Significance**
  - ◆ **Preliminary Studies**
- ◆ **Research Design & Methods**
  - ◆ **Literature Cited**

# Background & Significance

“Briefly sketch the background leading to the present application, critically evaluate existing knowledge. . .

- ◆ **An *informed* literature review. . .**

specifically identify the gaps that [your] project is intended to fill.

- ◆ **highlighting where your work fits in the big scheme of things. . .**

State concisely the importance and health relevance of the research described in this application by relating the specific aims to the broad, long-term objectives.”

- ◆ **and why it is significant!**

# Once upon a time. . .

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- ◆ **Two main sections**
  - **Background**
  - **Significance**
- ◆ **These need to tell a story**

# Organization of Background

- ◆ **Use descriptive subheads to guide the reviewer.**
- ◆ **Avoid large spans of text (instead, use multiple small paragraphs).**
- ◆ **Conclude each subsection with how your work will address the current gaps.**
- ◆ **Be diplomatic and nondogmatic in treating opposing points of view.**
- ◆ **Focus on relevant studies.**
- ◆ **Use diagrams, schemes, flow charts (a picture is worth 1000 words!).**

# Organization of Significance

- ◆ **Use “Significance” as the main heading of this section.**
- ◆ **Address the review criteria.**
- ◆ **Effectively use bold face type.**
- ◆ **If project is basic research, do not overstate the clinical significance.**

# Some Examples

- ◆ **Illustrating with schemes and flow charts**
- ◆ **Filling the gaps**
- ◆ **Selling language**
- ◆ **Addressing the review criteria**
- ◆ **Examples**

# Problems and Solutions: Background

- ◆ Failure to discuss basis for proposed work
- ◆ Failure to discuss your own pilot work

***List all relevant prior work and your own preliminary data***

- ◆ Uncritical acceptance of published literature
- ◆ Out of date citations
- ◆ Prior studies are misquoted

***Provide critical, balanced, accurate review of most recent research in the literature***

- ◆ Conceptual bias is evident
- ◆ Logic leading up to proposed work is faulty

***Use care in constructing rationale for proposed studies***

- ◆ No references to work of potential reviewers

***Look up membership of potential review groups to identify possible reviewers and cite their relevant work***

*Adapted from Maureen Hannley, PhD. Winning Grant Applications: A Primer. American Academy of Otolaryngology–Head and Neck Surgery Foundation.*

# Problems and Solutions: Significance

- ◆ Failure to discuss the significance of proposed problem

- ◆ Reviewer has to ask: “So What?”

***Clearly state how proposed work will benefit your field***

- *What new knowledge will be gained?*

- *Why should this work be conducted?*

- *What is the clinical significance (impact on human health)?*

- ◆ Failure to address review criteria

***Address all the review criteria:***

- *Significance*

- *Approach*

- *Innovation*

- *Investigator*

- *Environment*

*Adapted from Maureen Hannley, PhD. Winning Grant Applications: A Primer. American Academy of Otolaryngology–Head and Neck Surgery Foundation.*

# Preliminary Studies

**“An account of the preliminary studies pertinent to the application. . .**

**◆ The work that has been completed. . .**

**Information that will also help to establish the experience and competence of the investigator.”**

**◆ that will establish your ability to perform the proposed studies and interpret the results.**

***“Preliminary data often aid the reviewers in assessing the likelihood of the success of the proposed project.”***

# Organization

- ◆ **Use descriptive subheads to highlight each study.**
- ◆ **Cite any publication resulting from a preliminary study.**
- ◆ **Tie your studies back to your hypothesis.**
- ◆ **Interpret results critically.**
- ◆ **Use figures and tables that *add* information (not merely repeat what is in the text).**
- ◆ **Indicate how the proposed research is the next step in your long-term goals.**

# Some Examples

- ◆ **Using bullet lists**
- ◆ **Illustrating with schemes and flow charts**
- ◆ **Using descriptive sub-heads**
- ◆ **Establishing expertise**
- ◆ **Making your language work to sell!**
- ◆ [Examples](#)

# Problems and Solutions: Preliminary Studies

- ◆ No preliminary data
- ◆ Preliminary data are not relevant to proposed work

*May need to postpone application in order to acquire data or develop appropriate collaborations*

- ◆ Data do not demonstrate ability of investigator to conduct studies

*Data need to be presented clearly, with supporting figures and graphs*

- ◆ Data do not demonstrate feasibility of project

*Assemble team of Co-Is with appropriate preliminary data*

- ◆ Data have been misinterpreted

*Consult with a statistician*

*Adapted from Maureen Hannley, PhD. Winning Grant Applications: A Primer. American Academy of Otolaryngology–Head and Neck Surgery Foundation.*

# RD&M should. . .

- ◆ **Describe how you will carry out the work of accomplishing each specific aim**
- ◆ **Describe**
  - **Conceptual or clinical framework of the research design**
  - **Procedures and analyses to be used**
- ◆ **Include sufficient experimental detail**
- ◆ **Detail how data will be collected, analyzed, and interpreted, as well as the data-sharing plan if applicable**

# RD&M should. . .

- ◆ **Describe any new methodology and its advantage over existing methodology**
- ◆ **Describe any novel concepts, approaches, tools, or technologies for the proposed studies**
- ◆ **Discuss expected results, potential difficulties/limitations of proposed procedures, alternative approaches**
- ◆ **Provide a timetable for accomplishing aims**
- ◆ **Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised**

# Organizing the RD&M

## D. RESEARCH DESIGN & METHODS (limited to 13–16 PAGES)

RATIONALE/HYPOTHESIS

OVERALL STUDY DESIGN

SPECIFIC RESEARCH DESIGN & METHODS

*Specific Aim 1.* [statement of aim]

***Rationale/Hypothesis.***

***Approach.***

***Methods.***

***Data Analysis/Statistical Methods.***

***Expected Results, Potential Problems, and Solutions.***

GENERAL METHODS

# Sample Project Timeline

## TIME LINE

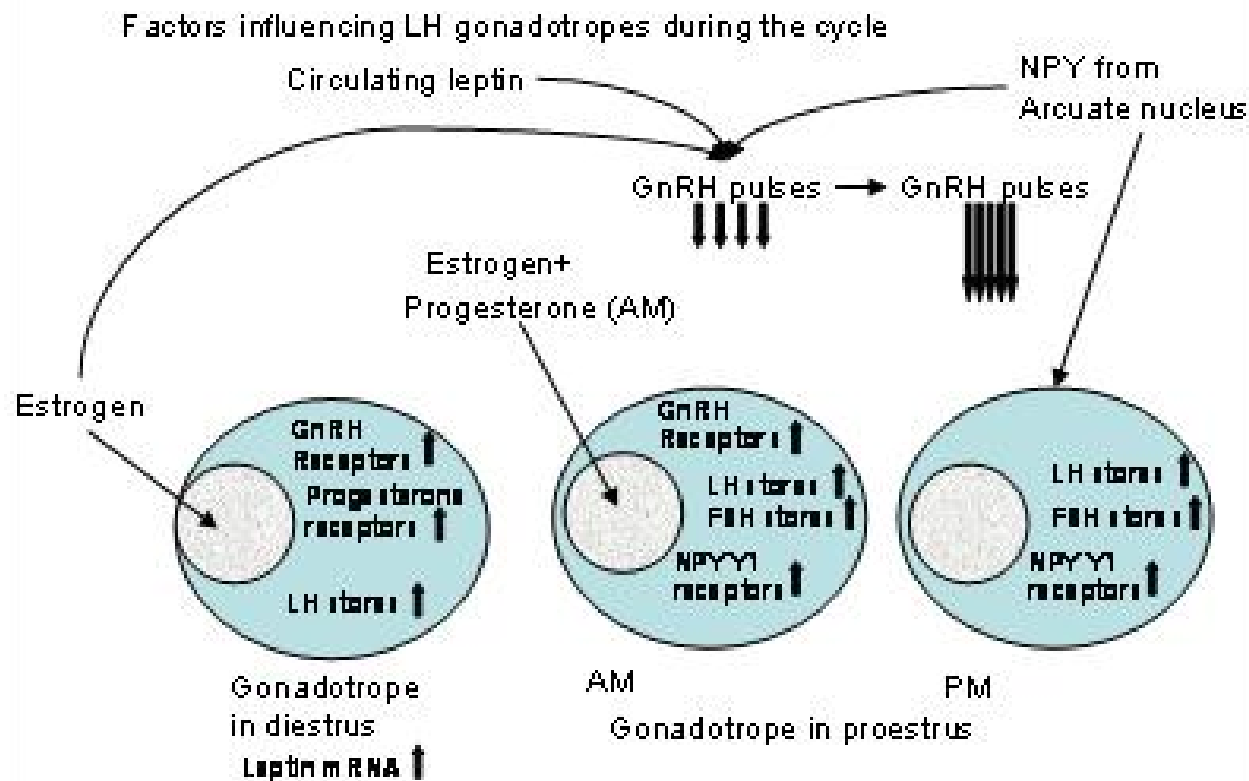
	Year 1	Year 2	Year 3	Year 4	Year 5
<b>Specific Aim 1</b>					
Sub-Aim 1	→				
Sub-Aim 2	→				
<b>Specific Aim 2</b>					
Sub-Aim 1	→				
Sub-Aim 2			→		
Sub-Aim 3				→	
<b>Specific Aim 3</b>					
Sub-Aim 1		→			
Sub-Aim 2			→		
Sub-Aim 3				→	

# Illustrations...

- ◆ **Help reviewers understand visually your rationale and approach**
- ◆ **Delineate**
  - **Larger picture into which your proposed work fits**
  - **Your planned approach to the overall work and to each specific aim**
  - **Interrelations of specific aims**
  - **Alternative pathways with decision trees**

# Illustrating the Larger Picture

## ◆ Events preparing the gonadotrope for the luteinizing hormone surge.

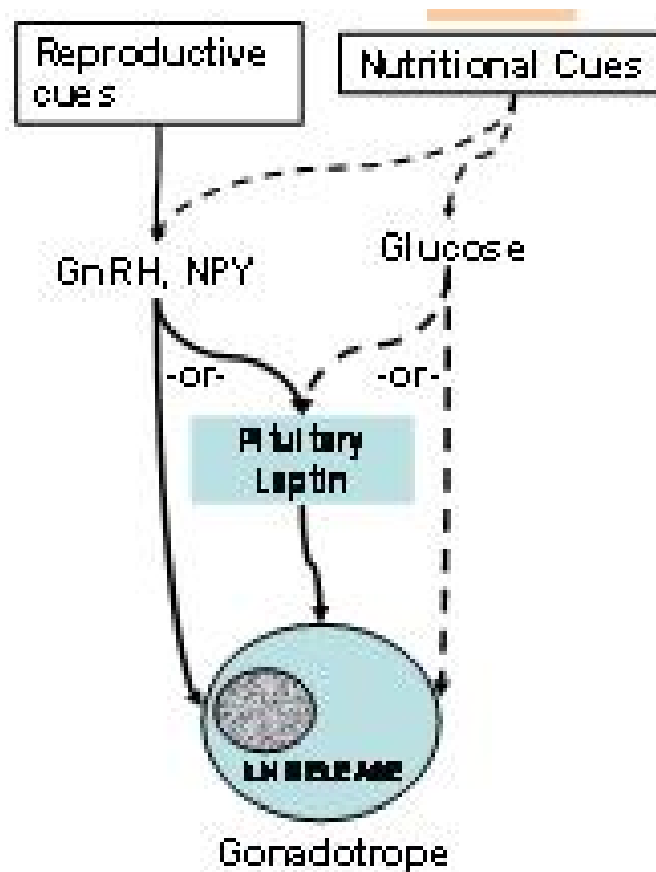


Important notes:

1. Leptin promotes LH secretion best in proestrus
2. Peak pituitary leptin protein expression is in proestrous PM

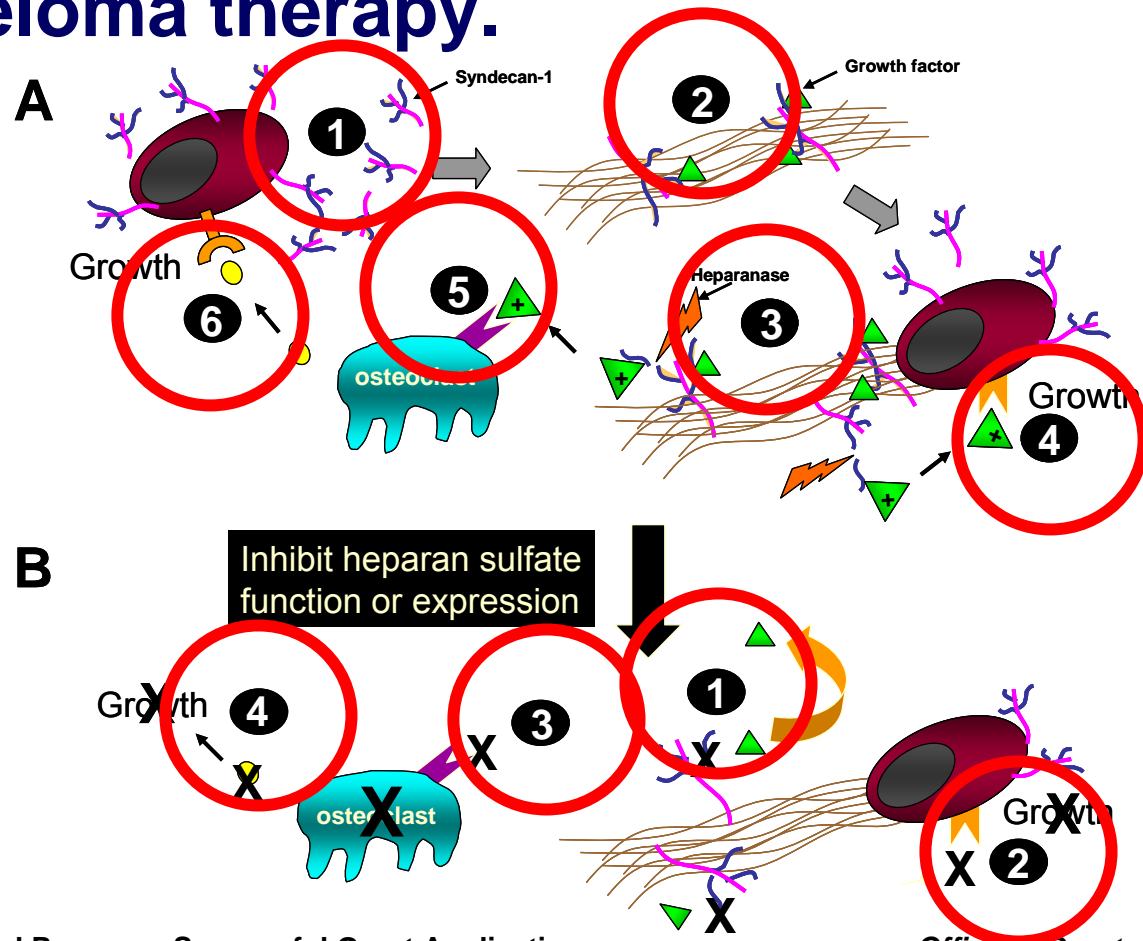
# Illustrating Your Planned Overall Approach

- ◆ Proposed factors that may be needed to regulate luteinizing hormone in men or women



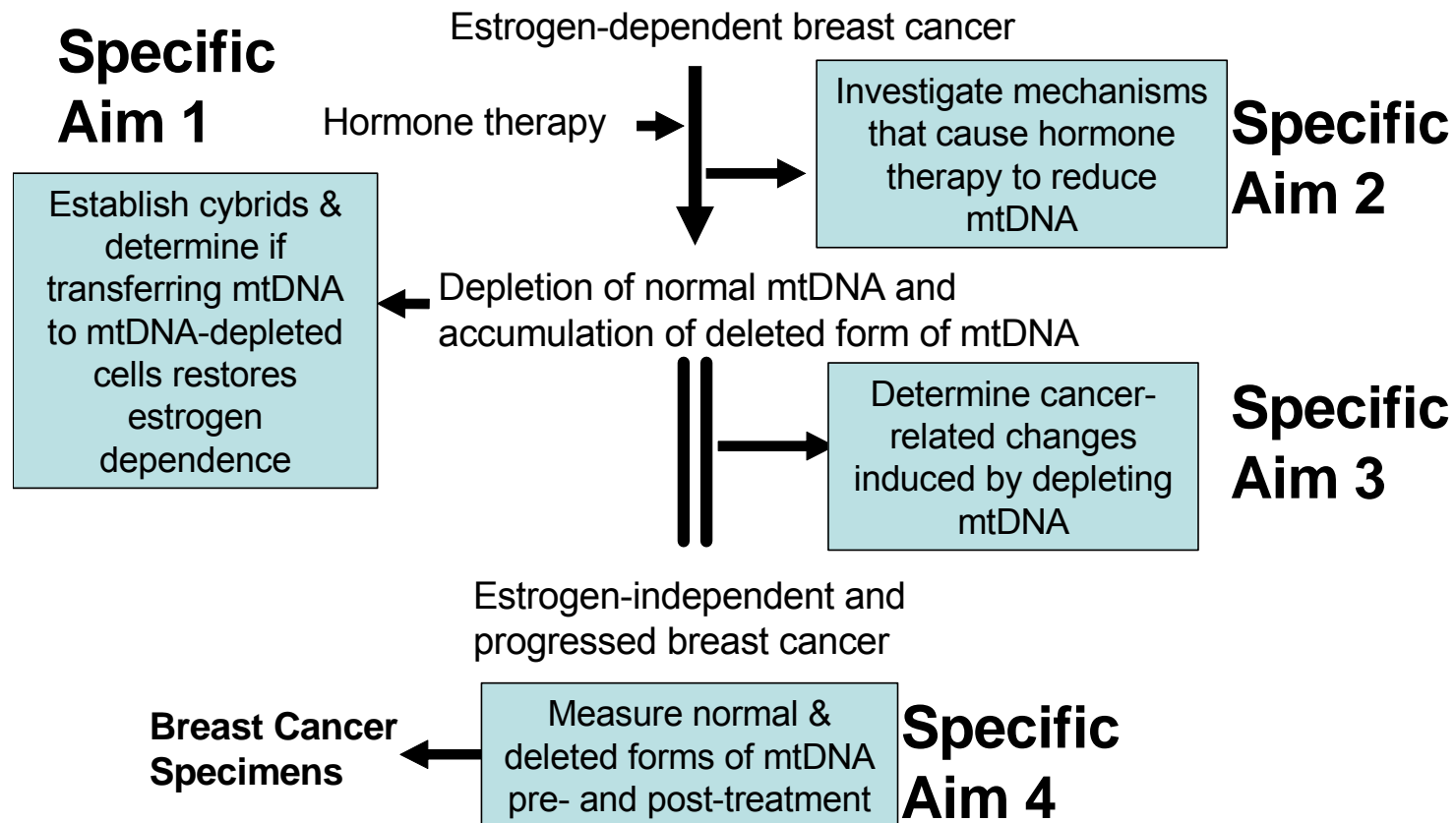
# Illustrating Your Rationale/Approach

## ◆ Rationale for targeting heparan sulfate for myeloma therapy.

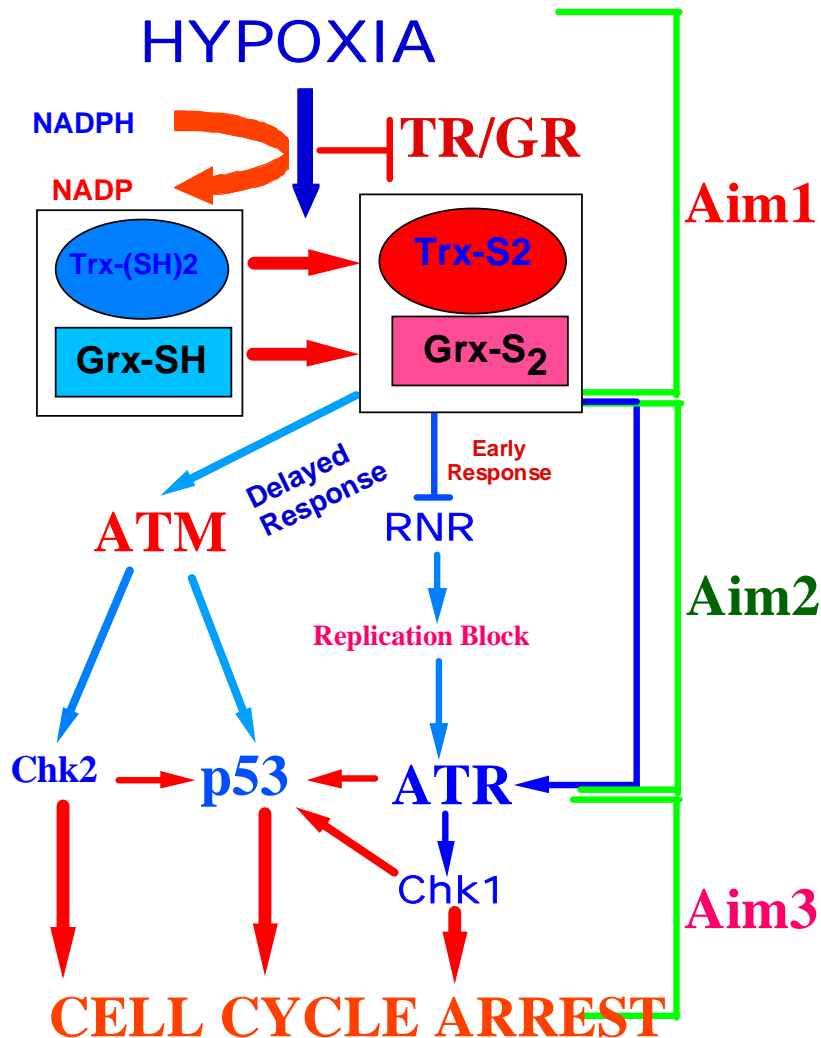


# Illustrating the Interrelations of Your Aims

- ◆ **Is mtDNA depletion correlated with estrogen independence and breast cancer progression?**



# Illustrating the Interrelations of Your Aims



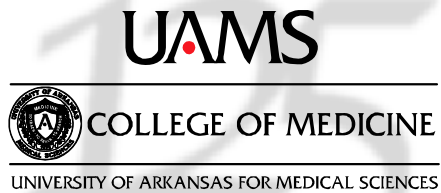
- ◆ **Role of thioredoxin/ glutaredoxin redox state in activation of cell cycle checkpoints in hypoxia.**

# Found Web Resources: Tutorials: Annotated R01 & Summary Statement

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- ◆ Research Design and Methods **section**  
(click here for pdf)

# Some Tips and Tricks



# Tip No. 1

**Never** assume that the reviewers will know what you mean.

**Always** be explicit about what you want the reviewers to know and what they need to know.

# Tips and Tricks — General

- ◆ **Whenever you write, you are writing to an audience: Know your audience; help them understand**
- ◆ **A grant proposal is at least as much a persuasive document as it is a scientific one**
  - Persuade reviewers of the importance of your ideas and work
  - Persuade reviewers that the proposal is reasonable and feasible
  - Persuade reviewers of your ability to do the work
- ◆ **Be focused and clear**
- ◆ **Never assume that reviewers will know what you mean**
- ◆ **Start each paragraph with a good topic sentence**
- ◆ **Avoid using excessive or unusual jargon, abbreviations, or acronyms**
- ◆ **Be sure you have addressed each of the review criteria**

# Tips and Tricks — Specifics

- ◆ **Do not repeat identical procedures that apply to more than one Specific Aim**
- ◆ **Do not describe well-known or standard procedures**
- ◆ **Do describe new procedures or procedures unlikely to be known by reviewers**
- ◆ **Explain why new methods are better than existing methods**
- ◆ **Anticipate potential criticisms by reviewers, and discuss possible weaknesses and ambiguities**

# Literature Cited

- ◆ **For each reference, include full bibliographic data:**
  - Names of all authors (names of editors)
  - Title of journal article, book chapter, book
  - Name of journal, title of book
  - For journals: year of publication, volume number, inclusive page numbers
  - For books: city, state: publisher, year of publication, page numbers of chapter.
- ◆ **Be concise: Limit references to current literature pertinent to the proposed research**

# Managing References

- ◆ **Invest in a reference citation database manager**
  - Reference Manager
  - EndNote
- ◆ **Consider how accurately and neatly your references, as well as the entire grant proposal, are prepared to be a reflection of how rigorously you conduct your scientific experiments**

# Problems and Solutions: RD&M

- ◆ **Research objectives unclear**
  - *Before you begin, list aims and all experiments to support each aim*
- ◆ **Rationale for experiments not provided (why important, how relevant)**
- ◆ **Methods do not correspond to aims**
  - *Write a Rationale/Approach/Methods for each Specific Aim*
- ◆ **Proposed experiments simply descriptive, not testing a specific hypothesis**
  - *Make sure each aim is hypothesis-driven and that experimental approach is logical*
- ◆ **Diffuse, superficial, or unfocused research plan**
  - *Provide sufficient methodological detail*
  - *Use graphics to plan and illustrate your experiments*

# Problems and Solutions: RD&M

- ◆ **No justification of experimental model**
  - *Provide evidence that model or methods have been pilot tested*
- ◆ **Failure to determine sample size**
  - *Make sure you have a power analysis*
- ◆ **No statistical section; data analysis section is inadequate or incorrect**
  - *Get input from statistician on design and analysis*
- ◆ **No “Plan B”**
  - *Chart out experiments with decision trees showing alternative pathways should you get negative results.*
  - *Assume nothing—discuss all the “What if’s”*

# UAMS Resources and Requirements and Electronic Submission



- ◆ **Who to contact in IRB and IACUC**
- ◆ **ARIA website**
  - ◆ **Electronic submissions**
- ◆ **Examples and Checklists**

# Human Subjects

*Purpose is to describe the involvement of human subjects and ensure the protection of the rights and welfare of study participants*

- ◆ **Includes descriptions of**
  - Risks to subjects
  - Adequacy of protection against risks
  - Potential benefits of research
  - Importance of knowledge to be gained
- ◆ **Include Data & Safety Monitoring Plan**
- ◆ **Address inclusion of women, minorities, and children**
- ◆ **Be consistent with Research Plan**

# Human Subjects

***All research involving human subjects requires an Institutional Review Board (IRB) approval.***

***At UAMS, the IRB number is  
686-5667***

# Vertebrate Animals

*Purpose is to describe use of vertebrate animals and ensure their humane treatment*

- ◆ **Includes descriptions of**
  - Use of animals
  - Justification (species, sample size)
  - Veterinary care
  - Procedures
  - Euthanasia
- ◆ **Be consistent with Research Plan**

# Vertebrate Animals

***All research involving vertebrate animals requires a review by the Institutional Animal Care and Use Committee (IACUC).***

***At UAMS, the IACUC contact is  
Linda Laney, 686-5347***

# ARIA

*What is it?*

*Who uses it?*

*How do you get registered on it?*

*How do you access it?*

# Electronic Submission at NIH

*Most NIH grant applications are submitted electronically* ([click here for pdf](#))

## ◆ Transition from PHS 398 to SF 424

(<http://grants2.nih.gov/grants/funding/424/index.htm>)

## ◆ Register on eRA Commons

– PIs work through [Office of Research & Sponsored Programs](#)

(Suzanne Alstadt, 686-8846)

– PIs do not need to register for Grants.Gov

# Electronic Receipt: How It Works

1. **Search for and identify a grant opportunity.**
2. **Download the grant application package.**
3. **Complete the application.**
4. **Send proposal to ORSP.**
5. **Grants.Gov performs basic validation and virus check on submitted application. Track the status of the submitted application package at Grants.Gov.**
6. **eRA software performs NIH business rule validation on application.**
7. **Check eRA Commons for validation results.**
9. **Authorized Organizational Representative (AOR) has authority to “reject” image.**
10. **NIH begins processing the application.**

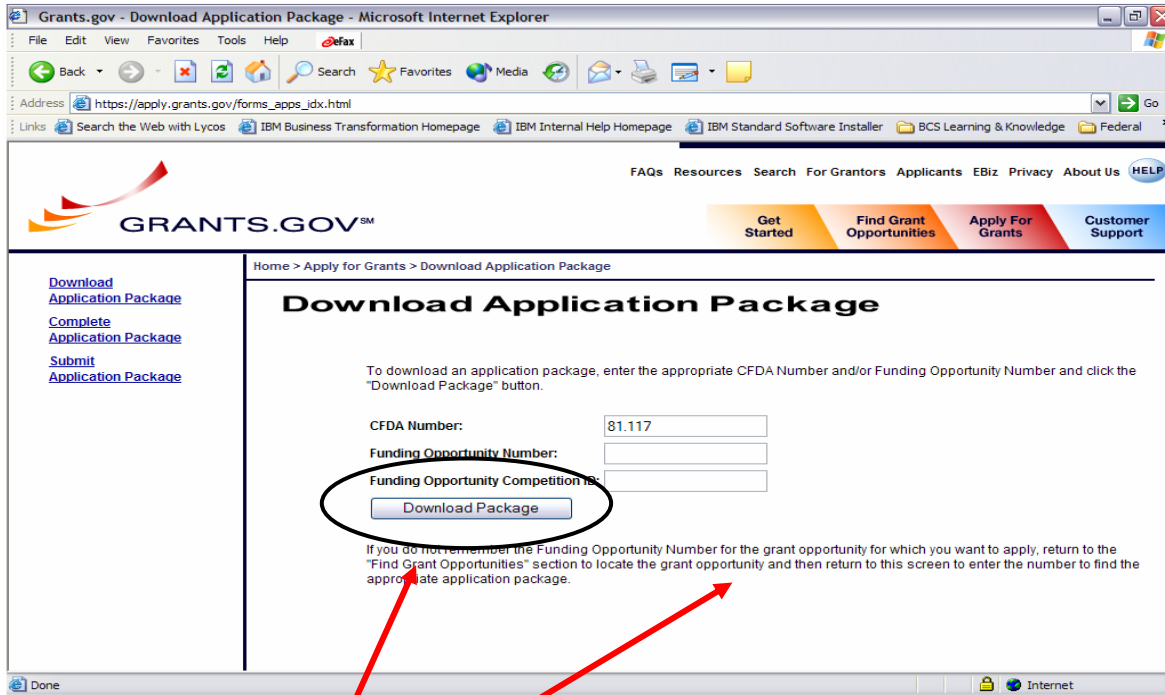
# Step 1. Identify grant opportunity

- ◆ NIH Guide
- ◆ Grants.Gov
- ◆ **Other foundations and funding opportunities on the Web**

## Step 2. Download the application

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- ◆ **Be sure that you have downloaded the PureEdge Viewer!**



Easy to follow pages and instructions to find and download application packages to any desktop

## Step 3. Complete the application

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- ◆ **Be sure to save a copy of the application locally on your computer.**

Select "Save" to save the application package to your hard drive

Address: http://apply.grants.gov/opportunities/packages/oppPAR-06-089.xfd

**Grant Application Package**

**Opportunity Title:** Innovations in Biomedical Computational Science and Te  
**Offering Agency:** National Institutes of Health  
**CFDA Number:**  
**CFDA Description:**  
**Opportunity Number:** PAR-06-089  
**Competition ID:**  
**Opportunity Open Date:** 12/26/2005  
**Opportunity Close Date:** 03/01/2006  
**Agency Contact:** GrantsInfo  
Telephone: (301) 435-0714  
Email: GrantsInfo@nih.gov

This electronic grants application is intended to be used to apply for the specific Federal funding opportunity referenced here.  
If the Federal funding opportunity listed is not the opportunity for which you want to apply, close this application package by clicking on the "Cancel" button at the top of this screen. You will then need to locate the correct Federal funding opportunity, download its application and then apply.

This opportunity is only open to organizations, applicants who are submitting grant applications on behalf of a company, state, local or tribal government, academia, or other type of organization.

\* Application Filing Name:

**Mandatory Documents**

- SF424 (R&R)
- PHS 398 Research Plan
- PHS 398 Cover Page Supplement
- PHS 398 Checklist
- SBIR/STTR Information
- Research & Related Subaward Budget
- Research & Related Other Project Information

**Mandatory Completed Documents for Submission**

All mandatory fields are highlighted and denoted with an asterisk

All Mandatory Documents must be completed in order to submit the application

**Submission**

Submit Save Print Cancel Check Package for Errors

This opportunity is only open to organizations, applicants who are submitting grant applications on behalf of a company, state, local or tribal government, academia, or other type of organization.

Application Filing Name: [Redacted]

**Mandatory Documents**

- SF424 (R&R)
- PHS 398 Research Plan
- PHS 398 Cover Page Supplement
- PHS 398 Checklist
- SBIR/STTR\_Information
- Research & Related Subaward Budget
- Research & Related Other Budget Information

Open Form

Optional Documents

- PHS 398 Cover Letter File

Open Form

Move Form to Submission List

Move Form to Documents List

**Mandatory Completed Documents for Submission**

Open Form

Move Form to Submission List

Move Form to Documents List

**Optional Completed Documents for Submission**

Open Form

**Instructions**

- 1** Enter a name for the application in the Application Filing Name field.
  - This application can be completed in its entirety offline; however, you will need to login to the Grants.gov website during the submission process.
  - You can save your application at any time by clicking the "Save" button at the top of your screen.
  - The "Submit" button will not be functional until the application is complete and saved.
- 2** Open and complete all of the documents listed in the "Mandatory Documents" box. Complete the SF-424 form first.
  - It is recommended that the SF-424 form be the first form completed for the application package. Data entered on the SF-424 will populate data fields in other mandatory and optional forms and the user cannot enter data in these fields.
  - The forms listed in the "Mandatory Documents" box and "Optional Documents" may be predefined forms, such as SF-424, forms where a document needs to be attached, such as the Project Narrative or a combination of both. "Mandatory Documents" are required for this

Optional documents may or may not need to be filled out – refer to the agency specific instructions

To open a form, highlight the form and then click

“Open Form”

The screenshot shows a web application window titled "Submission" with a PureEdge POWERED logo. At the top, there are navigation buttons: Submit, Save, Print, Cancel, and Check Package for Errors. Below this is a notice: "This opportunity is only open to organizations, applicants who are submitting grant applications on behalf of a company, state, local or tribal government, academia, or other type of organization." A yellow highlight is placed over the "Application Filing Name" field. The main content area is divided into four sections: "Mandatory Documents", "Mandatory Completed Documents for Submission", "Optional Documents", and "Optional Completed Documents for Submission". Each section contains a list of documents and an "Open Form" button. The "Mandatory Documents" list includes SF424 (R&R), PHS 398 Research Plan, PHS 398 Cover Page Supplement, PHS 398 Checklist, SBIR/STTR\_Information, Research & Related Subaward Budget, and Research & Related Subaward Budget. The "Optional Documents" list includes PHS 398 Cover Letter File. The "Mandatory Completed Documents for Submission" and "Optional Completed Documents for Submission" sections are currently empty. Below the document lists is an "Instructions" section with two numbered steps: 1. Enter a name for the application in the Application Filing Name field. 2. Open and complete all of the documents listed in the "Mandatory Documents" box. Complete the SF-424 form first.

**\* Application Filing Name:** [Yellow Highlighted Field]

**Mandatory Documents**

- SF424 (R&R)
- PHS 398 Research Plan
- PHS 398 Cover Page Supplement
- PHS 398 Checklist
- SBIR/STTR\_Information
- Research & Related Subaward Budget
- Research & Related Subaward Budget

**Optional Documents**

- PHS 398 Cover Letter File

**Instructions**

- 1** Enter a name for the application in the Application Filing Name field.
  - This application can be completed in its entirety offline; however, you will need to login to the Grants.gov website during the submission process.
  - You can save your application at any time by clicking the "Save" button at the top of your screen.
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Select this icon to receive field-sensitive help

RR\_SF424 Page 1

Close Form      Next      Print Page      About

**APPLICATION FOR FEDERAL ASSISTANCE**  
**SF 424 (R&R)**

<b>1. * TYPE OF SUBMISSION</b> <input type="radio"/> Pre-application <input type="radio"/> Application <input type="radio"/> Changed/Corrected Application	<b>2. DATE SUBMITTED</b> //	<b>Applicant Identifier</b> 
	<b>3. DATE RECEIVED BY STATE</b> //	<b>State Application Identifier</b> 
	<b>4. Federal Identifier</b> 	

**5. APPLICANT INFORMATION**

\* Organizational DUNS: [Redacted]

\* Legal Name: [Redacted]  
Department: [Redacted]      Division: [Redacted]  
\* Street1: [Redacted]      Street2: [Redacted]  
\* City: [Redacted]      County: [Redacted]      \* State: [Redacted]      \* ZIP Code: [Redacted]  
\* Country: USA

Person to be contacted on matters involving this application

Prefix: [Redacted]      \* First Name: [Redacted]      Middle Name: [Redacted]      \* Last Name: [Redacted]      Suffix: [Redacted]  
\* Phone Number: [Redacted]      Fax Number: [Redacted]      Email: [Redacted]

<b>6. * EMPLOYER IDENTIFICATION (EIN) or (TIN):</b> [Redacted]	<b>7. * TYPE OF APPLICANT:</b> Please select one of the following Other (Specify): <input type="checkbox"/> Women Owned <input type="checkbox"/> Socially and Economically Disadvantaged
<b>8. * TYPE OF APPLICATION:</b> <input type="radio"/> New <input type="radio"/> Resubmission <input type="radio"/> Renewal <input type="radio"/> Continuation <input type="radio"/> Revision If Revision, mark appropriate box(es).	<b>9. * NAME OF FEDERAL AGENCY:</b>

Submit button will not become activated until the following has been completed:

- All **Mandatory Fields** have been completed
- All **Mandatory Documents** have been completed and move to the Completed box
- All **applicable Optional Documents** have been completed and moved to the Completed box

Submission

Submit Save Print Cancel Check Package for Errors

GRANTS.GOV™

Grant Application Package

Opportunity Title: Innovations in Biomedical Computational Science and Te  
Offering Agency: National Institutes of Health  
CFDA Number:  
CFDA Description:  
Opportunity Number: PAR-06-089  
Competition ID:  
Opportunity Open Date: 12/16/2005  
Opportunity Close Date: 03/01/2006  
Agency Contact: GrantsInfo  
Telephone: (301) 435-0714  
Email: GrantsInfo@nih.gov

This electronic grants application is intended to be used to apply for the specific Federal funding opportunity referenced here.

If the Federal funding opportunity listed is not the opportunity for which you want to apply, close this application package by clicking on the "Cancel" button at the top of this screen. You will then need to locate the correct Federal funding opportunity, download its application and then apply.

This opportunity is only open to organizations, applicants who are submitting grant applications on behalf of a company, state, local or tribal government, academia, or other type of organization.

\* Application Filing Name: Completed Application

Mandatory Documents

Move Form to Submission List =>

Move Form to Documents List <=

Mandatory Completed Documents for Submission

SF424 (R&R)  
PHS 398 Research Plan  
PHS 398 Cover Page Supplement  
PHS 398 Checklist  
SBIR/STTR\_Information  
Research & Related Subaward Budget  
Research & Related Other Budget Information

Optional Documents

Move Form to Submission List =>

Optional Completed Documents for Submission

PHS 398 Cover Letter File

Helpful Hint: To get the "Submit" button activated, use the "Check Package for Errors" Button to find uncompleted Mandatory Fields

# Step 4. Send final proposal to ORSP for submission

- ◆ **Office of Research & Sponsored Programs is your Authorized Organizational Representative (AOR)**
- ◆ **They will submit the proposal to Grants.Gov**

# Electronic Routing at UAMS

- ◆ **Use ARIA for routing internal review form**
- ◆ **Attach draft PureEdge for internal review**
- ◆ **“Signed-off” by PI, Division Head, Department Chair, Dean’s Office CoM, ORSP**
- ◆ **Needed for all grant applications**
- ◆ **Deadline is 48 hours before due date**

# Step 5. Validation and virus check by Grants.Gov

## ◆ Successful Submission

- Submitter will receive successful Grants.Gov verification email
- Application downloaded by the agency
- Agency-specific tracking number assigned\*  
*\*This is an optional email notification – if an agency does not assign agency-specific tracking numbers, you will not receive this email.*

## ◆ Unsuccessful Submission

- Submitter will receive an email that the application failed the Grants.Gov verification process
- Email will list what the applicant needs to correct

# Submitted Application Confirmation

Scroll to the bottom of the confirmation screen to receive:

Grants.Gov Tracking Number

Date/Time Stamp

Submission Confirmation - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Refresh Home Search Favorites Media History Print Size

Address <http://trapply.grants.gov/GGProcessServlet> Links

If your application is successfully validated and subsequently retrieved by the grantor agency from the Grants.gov system, you will receive an additional email. This email may be delivered several days or weeks from the date of submission, depending on when the grantor agency retrieves it.

You may also monitor the processing status of your submission within the Grants.gov system by using the following steps:

1. Go to <http://www.grants.gov>
2. Click on the "Applicants" link at the top of the Grants.gov home page
3. Login to the system using your AOR user id and password
4. Click on the "Application Status" link at the left of your screen.

Note that once the grantor agency has retrieved your application from Grants.gov, you will need to contact them directly for any subsequent status updates. Grants.gov does not participate in making any award decisions.

**IMPORTANT NOTICE:** If you do not receive a receipt confirmation and either a validation confirmation or a rejection email message within 48 hours, please contact us. The Grants.gov Contact Center can be reached by email at [support@grants.gov](mailto:support@grants.gov), or by telephone at 1-800-518-4726. Always include your Grants.gov tracking number in all correspondence. The tracking numbers issued by Grants.gov look like GRANTXXXXXXXXXX. Contact Center hours of operation are Monday-Friday from 7:00 A.M. to 9:00 P.M. Eastern Standard Time.

The following application tracking information was generated by the system:

<b>Grants.gov Tracking Number :</b>	GRANT00007332
<b>CFDA Number :</b>	86.436
<b>CFDA Description :</b>	Surveys, Studies, Investigations, Demonstrations and Training Grants and Cooperative Agreements_Section 1442 of the Clean Water Act
<b>Funding Opportunity Number :</b>	ABC123
<b>Funding Opportunity Description :</b>	Biological Criteria Program
<b>Agency Name :</b>	Training 1110
<b>Application Name of this Submission :</b>	Test Package
<b>Date/Time of Receipt :</b>	2006.01.16 2:08 PM, EST

It is suggested you Save and/or Print this response for your records.

CLOSE

# If submission is unsuccessful

- ◆ **Corrected submission must be submitted through Grants.Gov**
- ◆ **Cover letter must accompany application explaining the corrections**
- ◆ **Grants.Gov is currently allowing one week for submission of corrected applications.**

*Expect this time frame to shorten in the future.*

# Step 6. Track status of submission

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- ◆ **Can track status at Grants.Gov**
- ◆ **You will eventually receive email that NIH has received your application.**

# Step 7. eRA software performs NIH business rule validation


- ◆ **For a list of Common validation errors, visit**

[http://www.washington.edu/research/osp/gg\\_tips.html#err](http://www.washington.edu/research/osp/gg_tips.html#err)

# Step 8. Check eRA Commons for validation results

- 1. Application processed successfully**
- 2. Application processed with warnings (no errors)**
- 3. Application processed with errors (and possibly warnings)**
  - Corrected application must be submitted through Grants.Gov
- 4. eRA Commons User ID not valid**
  - Corrected application must be submitted through Grants.Gov

# Viewing Application Errors/Warnings

Address  <https://commons.era.nih.gov/commons/status/piSearchResult.jsp> Links >>

Version 2.7.2.6






[Home](#) [Admin](#) [Institution Profile](#) [Personal Profile](#) **Status** [eSNAP](#) [Internet Assisted Review](#) [Links](#) [Help](#)

**Status Result**

## Status Result - PI Status

**Important:** The NIH provides the JIT (Just in Time) link in the Commons for applications receiving a percentile of less than 30 or for applications receiving a priority score of between 100 and 300 if no percentile is provided. Please await instructions from the NIH on whether to complete this information. Furthermore, there is a system problem with the Commons, which shows the JIT link for NRSA applications (Fellowships and Training applications). Please do not submit the JIT information for these types of applications through the Commons. Please submit JIT information for training grants and fellowships through email or fax. Finally, JIT requires a Signing Official (SO) at your Institution to send the request to the NIH. As a Principal Investigator, you are able to save this information. However, you must notify an individual with SO rights to forward the information to the NIH. Thank you for your cooperation.

1 - 37 of 37 1

Application ID	Proposal Title	Institution	Application Status	Status Date	Action
			Withdrawn	05/01/2000	
<a href="#">TN:16292</a>			eSubmission Error		










2

3

Internet

## Status Information

### eSubmission Errors/Warning

-  The Total Direct Costs for the Entire Proposed Project Period must be equal to the sum of the Total Direct Costs for each budget period.- Error
-  The sum Total of DC less Consortium F&A for the entire project period must be equal to the sum of DC less Consortium F&A for each budget period.- Error
-  The Street Line 3 in the PI contact information does not match the information recorded in the PI's NIH eRA Commons account. Please check the PI's preferred employment address in the Commons, and resubmit.- Error
-  The position title for PD/PI: [REDACTED] does not match the position title listed in his/her NIH eRA Commons account. Please check the eRA Commons, and resubmit.- Error
-  The total indirect costs must be equal to the sum of indirect costs for each budget period.- Error
-  You must enter a valid EIN- Error
-  The total cost requested for Budget Period 2 must be equal to the direct costs plus the indirect costs requested for that budget period.- Error
-  The Street Line 4 in the PI contact information does not match the information recorded in the PI's NIH eRA Commons account. Please check the PI's preferred employment address in the Commons, and resubmit.- Error
-  The name prefix for Key Person: [REDACTED] does not match the name prefix listed for his/her NIH eRA Commons account. - Warning

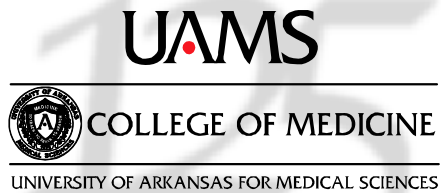
## Step 9. AOR can reject the application.

- ◆ **If no rejection within 2 business days of image availability, application automatically proceeds to next step in NIH processing**
- ◆ **If failed, all errors must be corrected and entire corrected package submitted to Grants.Gov**

# Step 10. NIH begins processing the application.

- ◆ **eRA Commons saves the data and grant image**
- ◆ **Applicants can track progress in eRA Commons**

# The Take-Home Message



# To be successful. . .

***Don't forget to "market" yourself and your ideas.***



# Submit a Grant!

- ◆ We hope we've provided some guidance.
- ◆ We wish you the best of luck in your grant-writing efforts.

