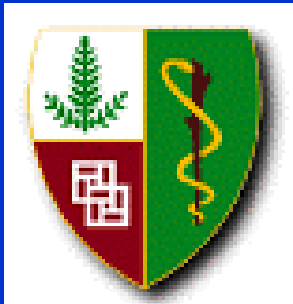


GRANT PREPARATION: AN EXPERT'S PERSPECTIVE

**YOUNG SURGICAL INVESTIGATORS
CONFERENCE
MARCH 4, 2006**

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**“DREAMS DON’T COME
TRUE – PLANS DO”**

**“I AM A GREAT BELIEVER
IN LUCK,
AND I FIND THE HARDER I
WORK,
THE MORE I HAVE OF IT.”**

- Stephen Leacock

GRANT PREPARATION

- **Start Early!**
- **> 3 months for your first grant**
- **Manage your schedule**
- **Last three weeks are critical –**
 - **do not be distracted**
 - **IACUC protocols**

GRANT PREPARATION

- **Understand the process**
- **Submission Deadlines:**
February 1st, June 1st, October 1st
- **Revisions:**
March 1st, July 1st, November 1st
- **RFA's**
- **“Study Section” review approximately 3 months later**

PREPARING AN R01

The Mechanics

Research Plan (25 pages)

A = Specific Aims (1-2 pages)

B = Background and Significance (3-4 pages)

C = Preliminary Studies (10-12 pages)

D = Research Design and Methods (10-12 pages)

PREPARING AN R01

Specific Aims

- **The most important page(s)!**
- **No more than Four Aims**
- **Keep them simple in concept and short**
- **Avoid fishing expeditions**
- **Avoid descriptive approaches**
- **Avoid “domino aims”**
- **Discuss with others and often**
- **Can be “organic” as you prepare the application**
- **State your central hypothesis clearly !!!!**

GRANT PREPARATION

Specific Aims

- **Introductory paragraph to “set the table”**
- **Finish with “central hypothesis”**
 - Specific and testable
- **Aims are designed to test hypothesis**
- **Avoid descriptive terms**
 - I use “To determine...”
- **Avoid “domino Aims” where if one Aim does not work, the next is at risk**

GRANT PREPARATION

Specific Aims

- **Avoid “too much” ambition**
- **Stay focused**
- **Balance between too conservative or predictable results and “overly ambitious”**
- **You must have preliminary data to support each Aim.**

PREPARING AN R01

Background and Significance

- Like a manuscript introduction
- You can only screw this up
- Review the areas explored by each Aim
- Point out the “hole” in the literature that your Aim explains or investigates
- Reviewer should understand why you have proposed your Aims
- Reviewer should predict your Aims

PREPARING AN R01

Preliminary Studies

- **Very important**
- **I personally break them out by Specific Aim**
- **Keep figures clean and easy to read**
- **Transition between studies – tell a story**
- **State what you've done and what remains to be explored in Specific Aim X**
- **State why these data are important for the related Aim**

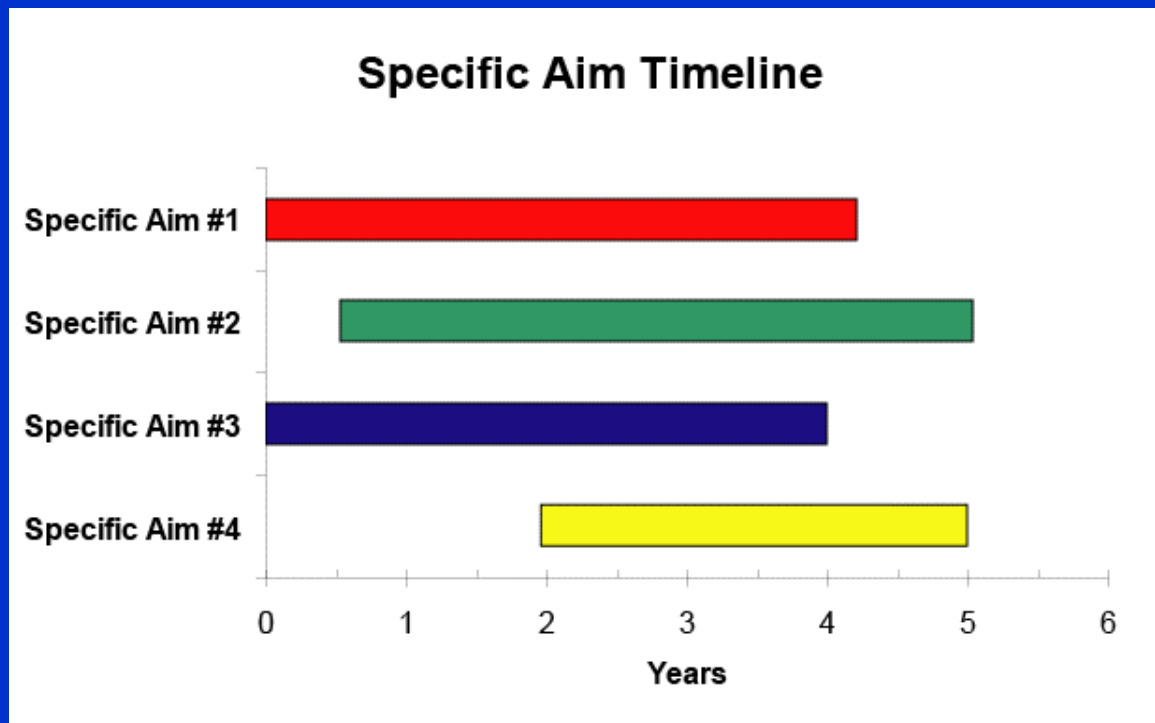
PREPARING AN R01

Research Design and Methods

- **Materials and Methods for each Aim**
- **Restate Aim**
- **State your hypothesis for that Aim**
- **Provide a rationale**
- **Methods – refer to appendix manuscript(s) for details (or Preliminary Studies) when possible**
- **Potential Problems / Alternative Solutions – Important!**
 - **Think through carefully; especially if you do not show supporting preliminary data or have a history of publishing in this area.**

PREPARING AN R01

Provide a Timeline for Completing the Specific Aims



PREPARING AN R01

- **Human Subjects**
 - Exempt or not (Expedited)
 - Women and minorities / children
 - Enrollment table
- **Animal Justification**
 - Answer the five questions
 - Put in table for animal #
 - Refer to this table in your Research Design & Methods

PREPARING AN R01

Forms

- **Budget**
 - **Modular < \$250,000**
 - **Non-Modular > \$250,000**
- **Justification**
 - **Ask collaborators about % effort**
- **Personnel – rule of thumb (assumption of \$250,000/yr)**
 - **3 People + PI on an R01**
- **Break out supplies vs. animals on budget**
- **Congruence between budget, justification, and section F**

PREPARING AN R01

Letters of Support

- **Start early**
 - Detailed discussion ahead of time
 - % effort or “effort as needed”
- **Send a draft**
- **Great way to add expertise where you need it**
- **Be specific about what they will help you with**

PREPARING AN R01

Biosketches

- **Four Pages**
- **Honors & Publications: two page max!**
- **Review format with RMG personnel**
- **Research Support: ongoing and completed**

GRANT PREPARATION

Rate Limiting Steps

- Request letters of support early
- Request updated Biosketches early
- Budget: modular or detailed
- Justification of personnel, supplies, animals (per diem and purchase)
- Breed wild-type animals to save \$
- Resources - incorporate the “strengths” of your institution

GRANT PREPARATION

Key Points

- **Clearly state a *central hypothesis***
- **No more than 4 Specific Aims**
- **11 or 12 point font– make it easy to read**
- **Make figures & legends clear to READ**
- **Demonstrate that you can perform or are capable of doing the experiments proposed**
- **Cover letter with grant**

GRANT PREPARATION

Appendix

- **Can add an appendix**
 - up to 10 manuscripts (Accepted or In Press)
- **Can save space by referring to Methods in Appendix #X**
- **Five copies**

GRANT PREPARATION

Supplemental Data

- **Approximately 3 months after grant is submitted**
- **E-mail SRA of Study Section to ask when the last day you can submit**
- **3-7 pages PDF format**
- **Break out data along Specific Aims**
- **PDF of manuscripts accepted for publication during interim**
- **Demonstrate that you are actively working on the grant**

NIH GRANTS

Peer Review

- Understand the process
- Study Section members receive package of grants to review
- Post review and preliminary score (approximately 50% triaged)
- Primary, secondary, tertiary reviews given orally at study section
- Discussion of application
- Grants scored by all members (1.0 – 5.0 scale)
- Score posted 1-2 days later on NIH Commons

NIH GRANTS

R01 Summary Statement

- **Significance**
 - Usually what you tell them
- **Approach**
 - Research design & methods
- **Innovation**
- **Investigator**
- **Environment**
- **Overall evaluation**

NIH GRANTS

K08 Summary Section

- **Candidate**
- **Career development plan**
- **Research plan**
- **Mentor**
- **Environment and institutional commitment**
- **Responsible conduct of research**

NIH GRANTS

Summary Statement (“Pink Sheet”)

- 6-8 weeks following study section
- “Summary and discussion” section at the beginning reflects discussion
- Critiques from each reviewer
- Speak with program officer whose name is listed on pink sheet
 - They often sit in on Study Section and can provide valuable information not in critiques
 - Ask what the most recent Institute pay line was

NIH GRANTS

Revision

- **3 page introduction to revised application**
 - Follows resources and prior to Specific Aims
- **Think manuscript revision**
- **Global concerns**
- **Address critiques point-by-point**
- **Make changes obvious**
- **Do NOT argue with reviewers**

NIH GRANTS

Revision

- A_0, A_1, A_2 Applications
- Very few A_0 applications funded
- ? When to re-submit ?
- My opinion: When you can address the concerns of the reviewers
- Balancing Act: Waiting to acquire new data versus roster changing
- Achilles heel of NIH peer review
 - New Reviewers with New Concerns
 - Increasing frequency with \uparrow number of revised grants submitted

NIH Grants

Big Picture

- “Steroid Effect” is over
- Pick a mentor in your area of interest
- Ask them to review your grant– **EARLY!**
- Think about center or Roadmap interdisciplinary grants and get involved!
- See your School of Medicine CTSA PI and ask how you can participate (Roadmap collaborative initiatives)

FUNDING WARS

- **ACS and societies - 1:3 leverage on K08**
- **Persistence pays off: especially now!**
- **All funding is “green”**
- **DOD, DARPA, NSF**
- **Translational- A strategic advantage for surgeons!**

STAYING FUNDED

- **You have a grant..... Now comes the hard part--- competing renewals!**
- **First renewal is really hard (now... they all are)**
- **Must be productive— not only in Surgical Journals**
- **Work proposed is a logical extension of data**
- **Science is not linear**

FINAL THOUGHTS

- **Identify a mentor / collaborator**
- **Stay with it!**
- **Think about CTSA and collaborative groups**
- **Culture change at School of Medicine →
? value of collaborative grants**
- **Leverage our translational advantage**