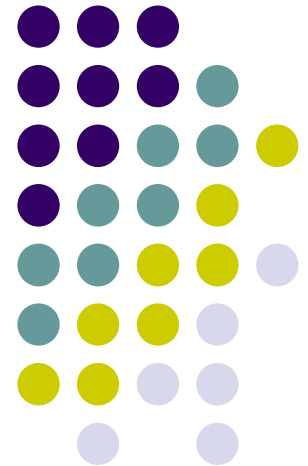


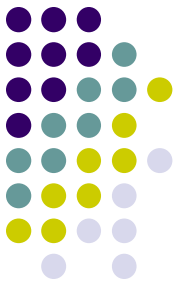
Writing a Research Grant: The Basics

Mary-Claire Roghmann, M.D., M.S.

Department of Epidemiology
and Public Health



All you ever wanted to know about grants...



- Why do you want a grant?
- Who will fund my research?
- How do I prepare a grant?
- How are grants reviewed?
- What do I do when I get a grant?



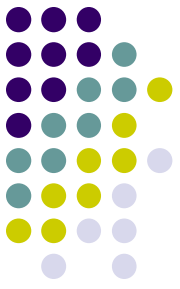
Why apply for a grant?

- Faculty
 - Coin of the realm
- Fellow
 - Entry into faculty position
- Resident/Student
 - Outstanding credential
- Research Staff
 - Autonomy
- Instant Respect
- \$\$ to do Your Study



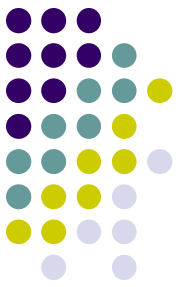
Before you start writing

- Define/refine your research question
- Identify your support base
 - institutional support
 - protected research time
 - mentors
 - collaborators
 - research team
- Collect preliminary data
- Learns the rules for the grant application



Funding Source Terms

- grant vs. cooperative agreement vs. contract
- investigator initiated
- RFA/RFP
 - request for applications or proposals
- PA
 - program announcements
- training grants
- LOI
 - letter of intent
- Peer-reviewed

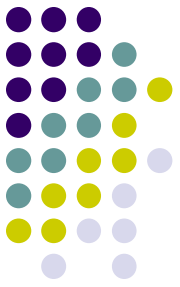


Funding Mechanisms at NIH

- RO1: investigator initiated research
- PO1: program project grants
- RO3: small grants program
- R21: exploratory/development grants

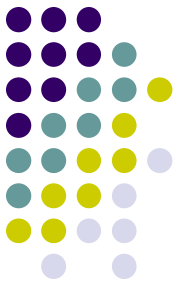
- T/F series: institutional and individual pre- and post-doctoral training grants
- K series: career development grants

Other Possible Peer-reviewed Funding Sources



- Department of Veterans Affairs
 - Merit review grants
 - Biomedical and Clinical Science Research
 - Health Services Research
 - Rehabilitation Research
 - Cooperative Studies Program
- Other federal agencies
 - CDC, FDA, EPA...
- Foundations

Access Points for Grant Information



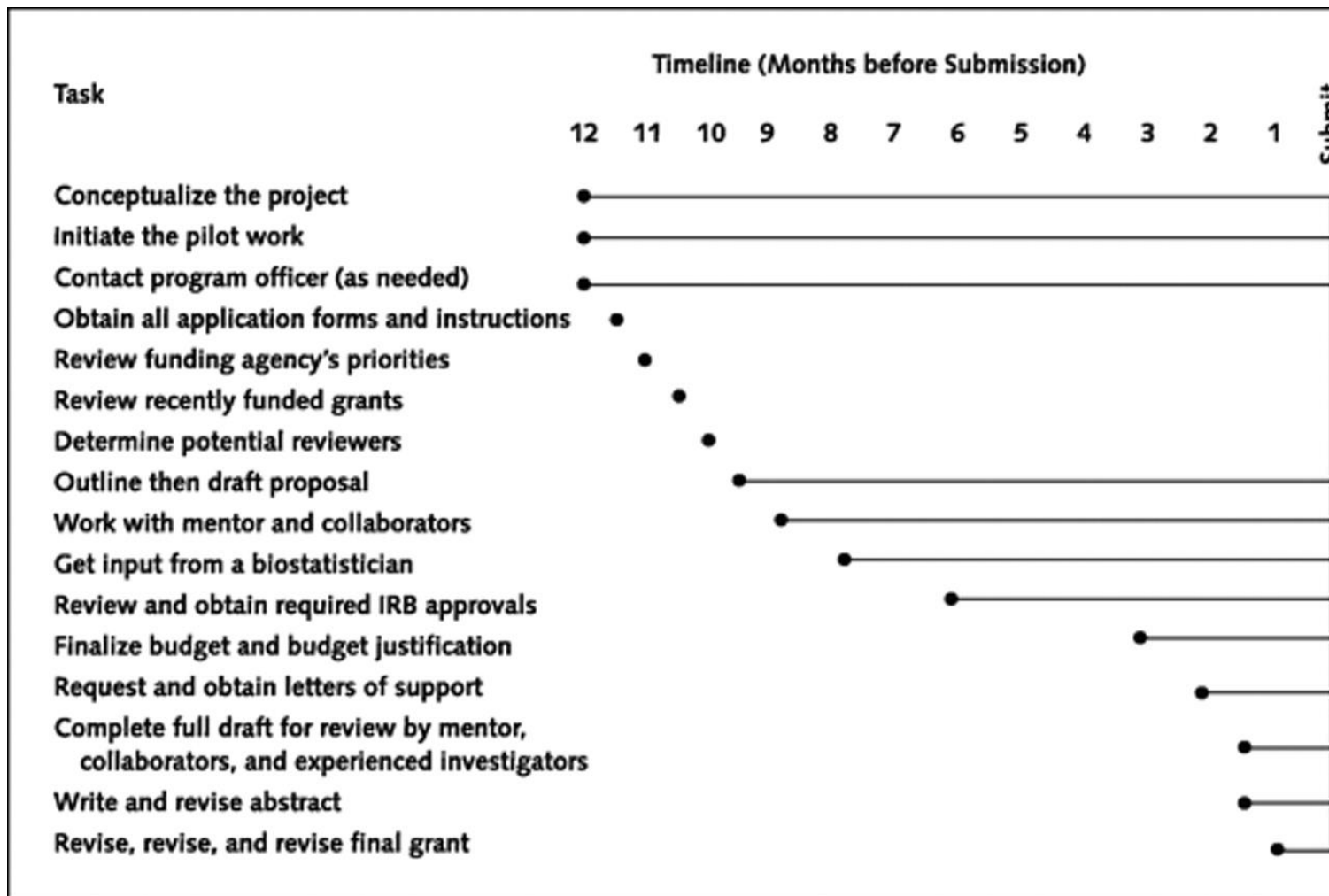
- Talk to your colleagues
- Sign up for e-mail alerts

Preparing the Grant



- Fundamental Principle
 - The more time you plan in advance of writing,
 - the less time you will waste on crafting language for the wastebasket and
 - the more clear and focused your final proposal will be;
 - However.....you will never get a grant, you don't submit.

Grant-writing Timeline



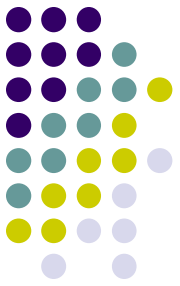
Inouye, S. K. et. al. Ann Intern Med 2005;142:274-282



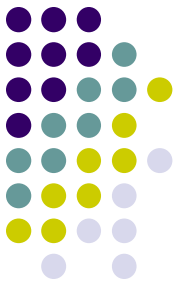
Don't forget to...

- Read the instructions!!!
 - RFA/PA:
 - Deadlines (this is not your deadline)
 - When it might be funded
 - Funding limits
 - Number of pages
 - Review criteria
- Route the grant!
 - Basic concept: grant/contract is awarded to University, not investigator

NIH RO1 Grant Structure



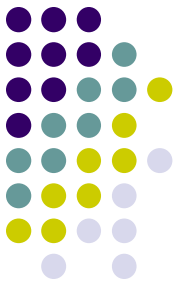
- Title page
 - Title of grant
- Project Summary
 - Narrative
 - Public Health Relevance
- Budget
- Biosketches
- Resources
- Research Plan
 - Introduction
 - Revisions only
 - Specific Aims
 - Research Strategy
 - Significance
 - Innovation
 - Approach
 - Preliminary Data
 - Human Subjects
 - Literature Cited



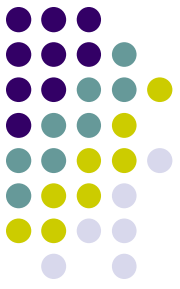
NIH RO1 Grant Budget

- Total costs = indirect costs + direct costs
- Don't forget:
 - adequate personnel salaries (~80%)
 - statistical assistance
 - supplies
 - other expenses
 - participant compensation
 - study cell phone
 - travel

NIH RO1 Other Sections



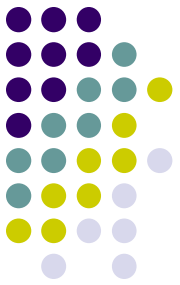
- Biosketches
 - 5 pages
 - Specific format
 - Tailored to grant topic
 - Personal statement
 - Contributions to Science
 - Up-to-date
- Resources/Equipment
 - Facilities
 - Tailored to grant topic
 - Up-to-date



NIH Review Criteria

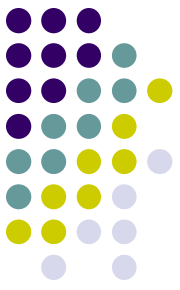
- Significance: importance of problem, new knowledge to be gained, impact on field
- **Approach**: conceptual framework, design, methods, analytic plan, alternative
- Innovation: novel concepts, approaches, methods
- Investigator: training, experience, productivity
- Environment: supportive scientific environment, institutional support

- Low scores are good; unscored is bad



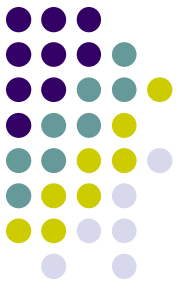
Research Plan

- Specific Aims (1 page)
- Research Strategy (12 pages)
 - Significance
 - 1-1.5 pages
 - Innovation
 - 0.5-1 pages
 - Approach
 - Preliminary data



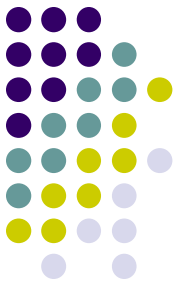
Specific Aims Section

- State the problem and the gap in knowledge which answering your question will fill
- Explain the background from which your hypotheses emerged (conceptual model)
 - Previous/preliminary work
- Lists proposed studies (aims) with hypothesis
 - Identify study design and population
 - Predicted outcomes
- Relate specific aims to long term goals of your research program and why it's important



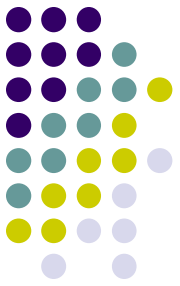
BREAK FOR HOMEWORK ASSIGNMENT

Writing the Significance Section



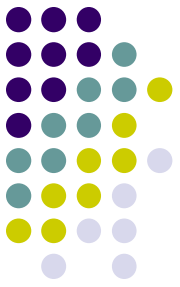
- Begin: Identify research problem you propose to address
 - Critical analysis of salient, most important, relevant primary literature
 - Identify “gaps” in knowledge/need for more research
 - How will your research address this need?
- Explain importance of resolving problem – clear sentence, *italicize*
 - Link to mission of NIH institute, include public health aspects
- If you carry out your research, what will be impact on field (on other research, theories/constructs driving field, etc)

Significance is in the Eye of the Beholder



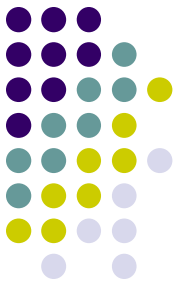
- Reviewer specific
 - Target a [specific study section](#)
 - Find the roster
 - M.D. vs. Ph.D.
 - Clinical vs. Laboratory Research
 - Quantitative vs. Qualitative Research
 - What has the Study Section funded before?
 - Matchmaker in NIH Reporter
- Institute specific
 - [What's its mission?](#)
 - Talk to the Program Officer

Innovation starts with a novel question



- Provide new findings!
- Confirm or refute previous findings
 - Refute a commonly held belief
 - Confirm a **controversial** finding
- Extend previous findings
 - New populations
 - Insight into the mechanism

Innovation is NOT simply “science that hasn’t been done yet”



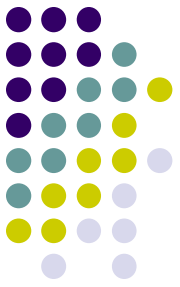
DOCTOR FUN presents HEADS UP



"Say ... we just happen to have this human head we've been keeping alive ... and we just happen to have this decapitated gorilla..."

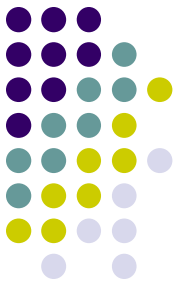
From Wendy Sander's Talk on the Research Problem

Be Innovative in Multiple Ways



- Does your research approach the question from fresh perspective?
- Does your research approach bring together novel expertise?
- Does your research approach use a novel combination of technologies?

Writing the Innovation Section

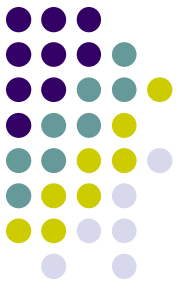


- Brief recap of what is known and not known
- Highlight the ways that your project is innovative
 - Novel concept
 - Novel approach
 - Novel methodology
 - Tools, expertise
- Translate innovation into impact

Significance vs. Innovation



- impact on the field
- important, public-health problem
- a fundamentally new way of conceptualizing or carrying out the research

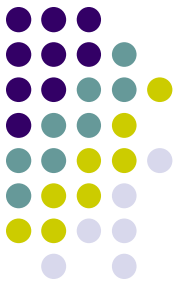


Research Plan

- Specific Aims
- Research Strategy
 - Significance
 - 1-1.5 pages
 - Innovation
 - 0.5-1 pages
 - **Approach**
 - **Preliminary data**

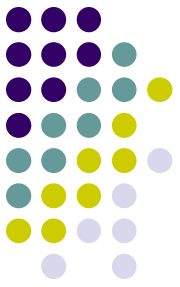
13 pages

Approach Review Criteria



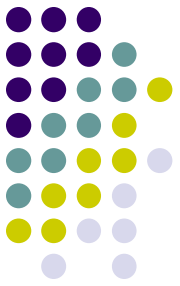
- Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project?
- Does the applicant acknowledge potential problem areas and consider alternative tactics?

Outline of Design and then Methods



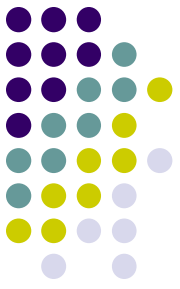
- Protocol/experiments
 - Conceptual framework
 - Rationale
 - Advantages of methodology chosen
 - Novel concepts, approaches, tools, or technologies
 - Data collection, analysis, interpretation
 - Anticipated Outcomes
 - Potential Problems, Alternative Approaches
- Details of all procedures/methods
 - Describe and reference all new procedures
 - Describe and reference all procedures reviewers may not know
 - Reference standard procedure
- Consider combining Design and Methods so that it reads in the order in which the study will be done.**

Potential Problems, Alternative Approaches



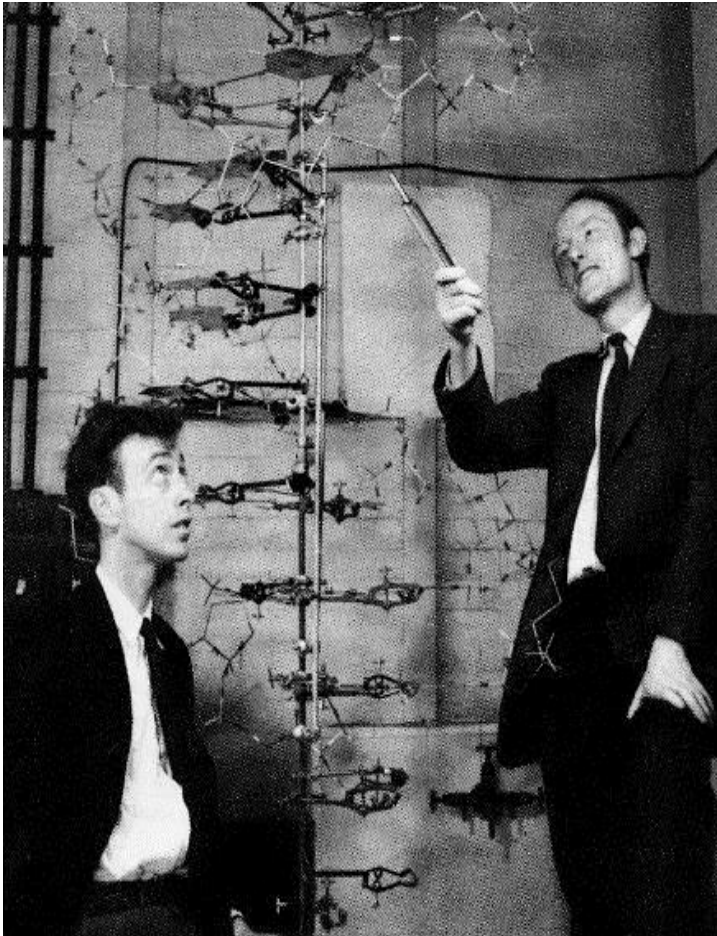
- What could go wrong?
 - Enrollment
 - Study measurements
 - Confounding
 - Generalizability
- Have a plan to deal with it
 - Do not raise unsolvable problems
- Do not cut from this section!

Preliminary Data as the “Hook”



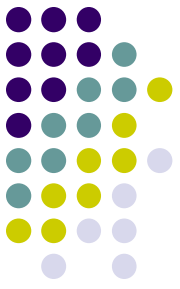
- One piece of preliminary data that sets the direction of the grant
 - Compelling
 - Believable
- Part of your long term research goals
 - Ideally this grant should be the next logical step from your last grant
 - Preliminary data should be from your K grant

Research Problem Should Lead to Future Studies

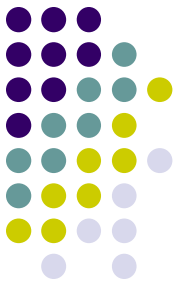


- Will project be complete at end of study or lead to related studies? (Continuity – especially important for early stage investigator)
- Will research findings be important one year after study is complete? Ten years after?

Other Purposes of Preliminary Data



- The proposed studies are feasible in the hands of the PI
 - Should always be supportive
- Expertise in all the procedures in which there is direct responsibility
 - Write after the methods is done
- Proposed collaborations actually function to produce usable data
 - Not just a letter of support

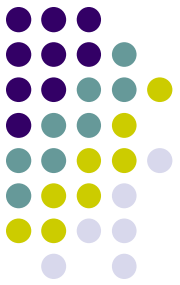


Human Subjects

- Protection of Human Subjects
 - If exempt, explain why exempt
 - If non-exempt, go to next slide
- Inclusion of Women and Minorities
 - Targeted Enrollment Form
- Inclusion of Children

- *Contributes to score; can administratively hold up application*

Grantsmanship

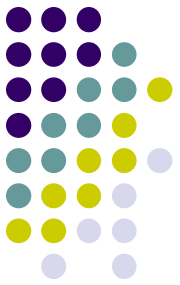


- Get internal reviews from your peers/mentors
 - if possible, get comments from someone with study section experience
- FOCUS on your question
- Don't push the due date
 - as with fine wine, grants improve with age
 - but... you will never get a grant you don't submit
- Make the grant easy to read



Organize your work

- Use subheadings
 - general to specific
 - serve as a guide to the reviewer
- Use tables to support your text
- Figures
 - present conceptual models of your research question
 - preliminary data
 - time line



Examples - Subheadings

6. Research Strategy

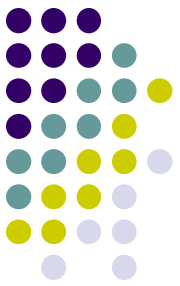
b. Significance

*Types of Costs and Different Perspectives in
Costs of Healthcare*

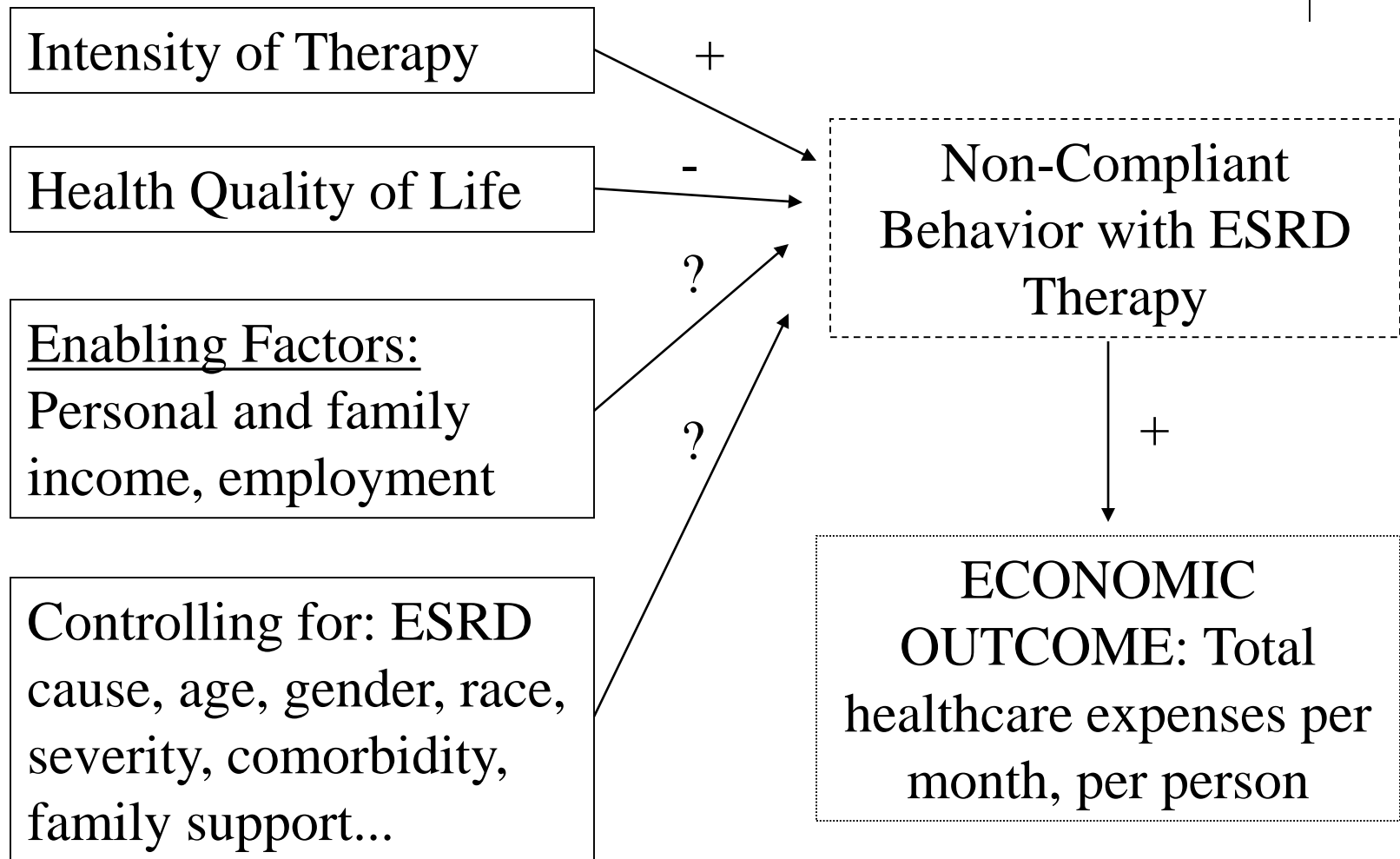
*Methods for Estimating Costs of Nosocomial
Infections [McGowan, 1981 #23]*

*Prior Cost Estimates of Surgical Site infections
(Summary Table in Appendix)*

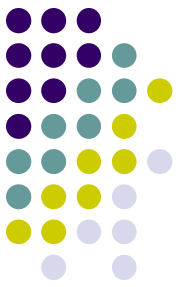
*A New Method for Estimating Costs of Healthcare-
Activity Based Costing*



Example – Figure- “shows the theory”

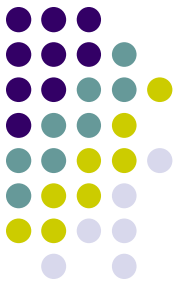


From D. Bradham



NIH Grant Evaluation

- Submission (new grants): ~October 1, February 1, June 1
- Sent to NIH Center for Scientific Review
 - assigned to an Institute and Initial Review Group (IRG)
 - Track your grant in eCommons
- Reviewed by IRG
 - primary and secondary reviewer, and discussant



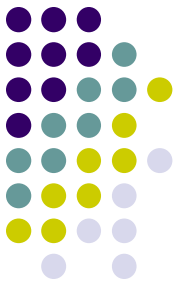
NIH Grant Outcome

- Institute Council
- **FUNDED!**

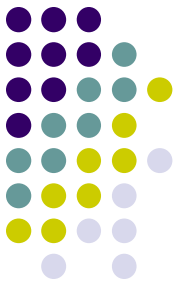
or

- not funded
 - “pink sheets”
 - resubmit

Post-Award Grant Management



- IRB approvals obtained
 - IRB and Grant Titles must match
- Account number assigned
- GET THE WORK DONE!
- Annual non-competitive renewals
- Get ready for resubmission!



*There is no
substitute for a
great
question.*