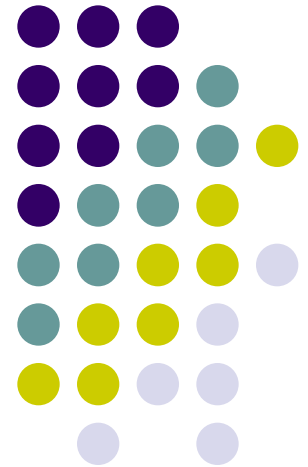


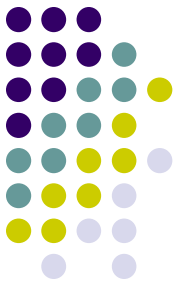
Writing a Research Grant: The Basics

Mary-Claire Roghmann, MD, MS

Department of Epidemiology
and Public Health



All you ever wanted to know about grants...



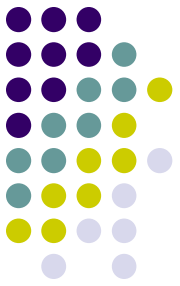
- Why do you want a grant?
- Who will fund your research?
- How do you prepare a grant?
- How are grants reviewed?
- What do you do when you get a grant?

This talk is a broad overview. I recommend taking advantage of grant writing resources.



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

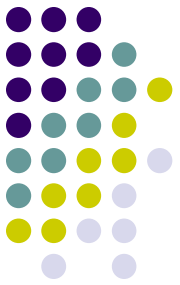
- Define/refine your research question
- Collect preliminary or pilot data
- Identify your support base
 - institutional support
 - protected research time
 - mentors
 - collaborators
 - research team
- Learn the rules for the grant application



Funding Source Terms

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

Federal Funding Mechanisms



Research

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

Training

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

Other Common Funding Sources

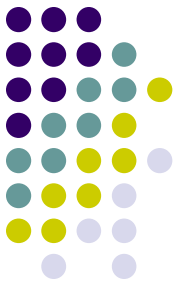


- Department of Veterans Affairs
 - Merit review grants
 - Biomedical and Clinical Science Research
 - Health Services Research
 - Rehabilitation Research
 - Cooperative Studies Program
- Other federal agencies
 - CDC, AHRQ, FDA, DoD...
- Foundations

Access Points for Grant Information



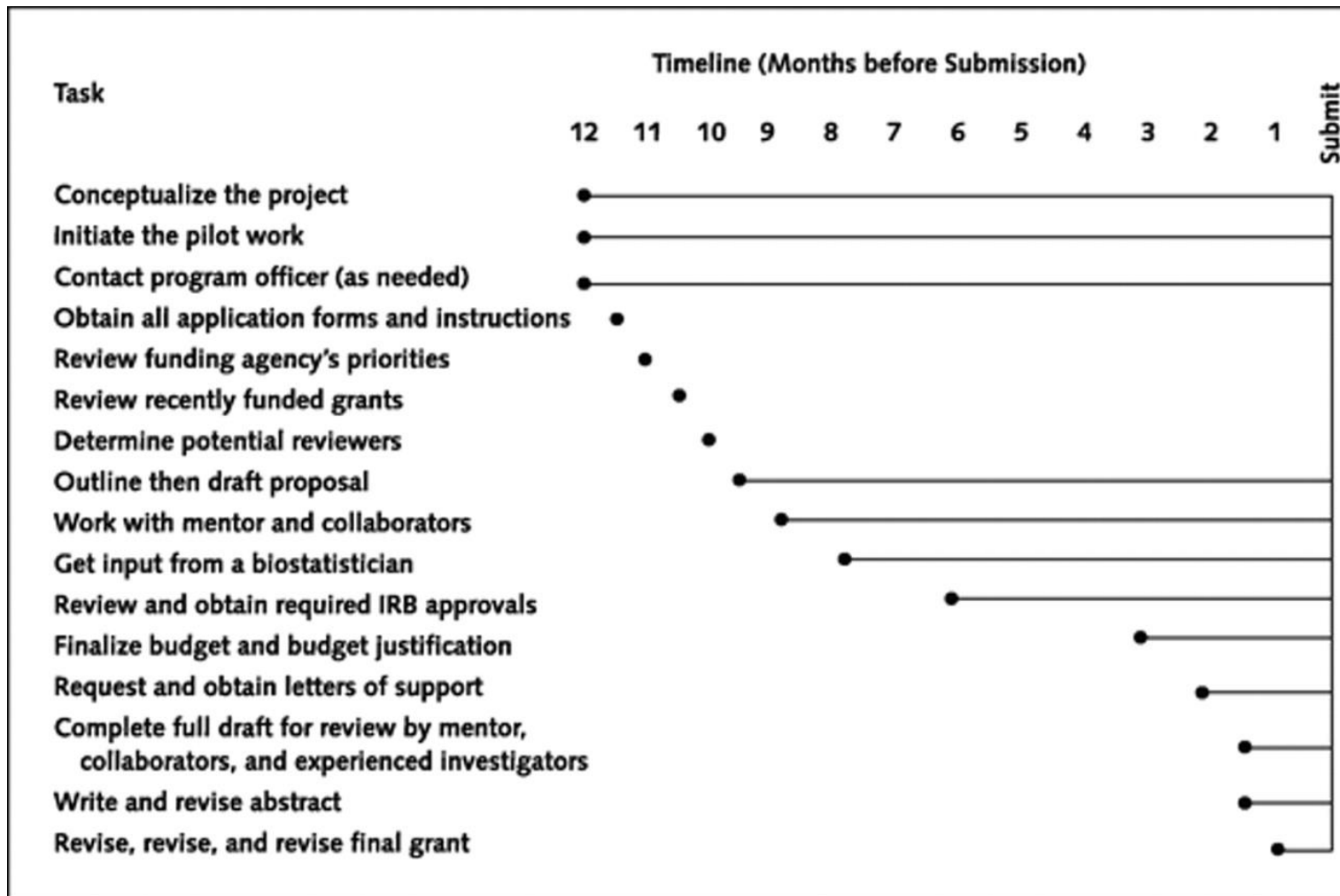
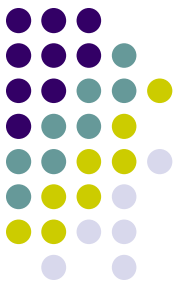
- Talk to your colleagues
 - How are they funded
- Become a part of research networks
 - CDC EpiCenter example
- Sign up for e-mail alerts



Preparing the Grant

- Fundamental Principle
 - The more time you think 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 an institution, not investigator

(NIH) RO1 Grant Structure

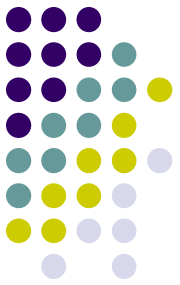


- Title page
 - Title of grant
- Project Summary
 - Narrative
 - Public Health Relevance
- Budget
- Biosketches
- Resources
- Research Plan
 - Introduction
 - Revisions only
 - Specific Aims
 - Research Strategy
 - Significance
 - Innovation
 - Approach
 - Preliminary Data
 - Human Subjects
 - Literature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



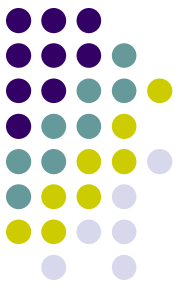
NIH RO1 Grant Budget

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



NIH RO1 Other Sections

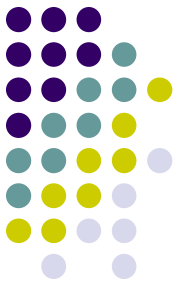
- Biosketches
 - 5 pages
 - Specific format
 - Tailored to grant topic
 - Personal statement
 - Contributions to Science
 - Up-to-date
- Resources/Equipment
 - Facilities
 - Tailored to grant topic
 - Up-to-date



(NIH) Review Criteria

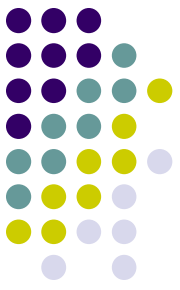
- Significance: importance of problem, new knowledge to be gained, impact on field
 - Scientific premise
- Approach: conceptual framework, design, methods, analytic plan, alternatives
 - Rigor&reproducibility
- Innovation: novel concepts, approaches, methods
- Investigator: training, experience, productivity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

Low scores are good; unscored is bad



Research Plan

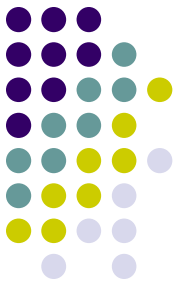
- Specific Aims (1 page)
- Research Strategy (12 pages)
 - Significance
 - 1-1.5 pages
 - Innovation
 - 0.5-1 pages
 - Approach
 - Preliminary data



Specific Aims Section

- State the problem and the gap in knowledge which answering your question will fill
- Explain the background from which your scientific hypotheses emerged
 - Scientific premise
- Lists proposed studies (aims) with statistical hypotheses
 - Identify study design and population
 - Predicted outcomes
- Relate specific aims to long term goals of your research program and how it will advance your research area

Writing the Significance Section



- Begin: Identify research problem you propose to address
 - Critical analysis of salient, most important, relevant primary literature (Scientific premise)
 - 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



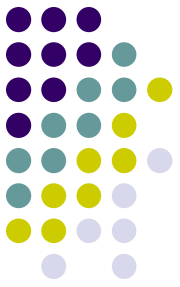
- Reviewer specific
 - Target a [specific study section](#)
 - Find the roster
 - M.D. vs. Ph.D.
 - Clinical vs. Laboratory Research
 - Quantitative vs. Qualitative Research
 - What has the Study Section funded before?
 - Matchmaker in NIH Reporter, Assisted Referral Tool
- Institute specific
 - [What's 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

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



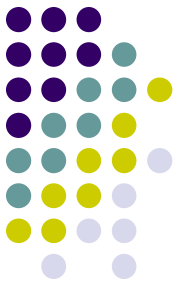
- Brief recap of what is known and not known
- Highlight the ways that your project is innovative
 - Novel concept
 - Novel approach
 - Novel methodology
 - Tools, expertise
- Translate innovation into impact

Significance vs. Innovation



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

Significance is more important than Innovation

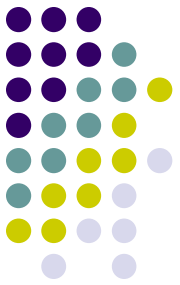


Research Plan

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

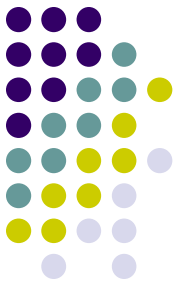
13 pages

Approach Review Criteria



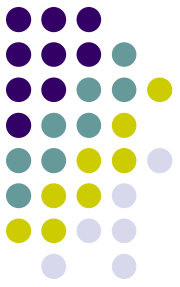
- Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project?
- Does the applicant acknowledge potential problem areas and consider alternative tactics?

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



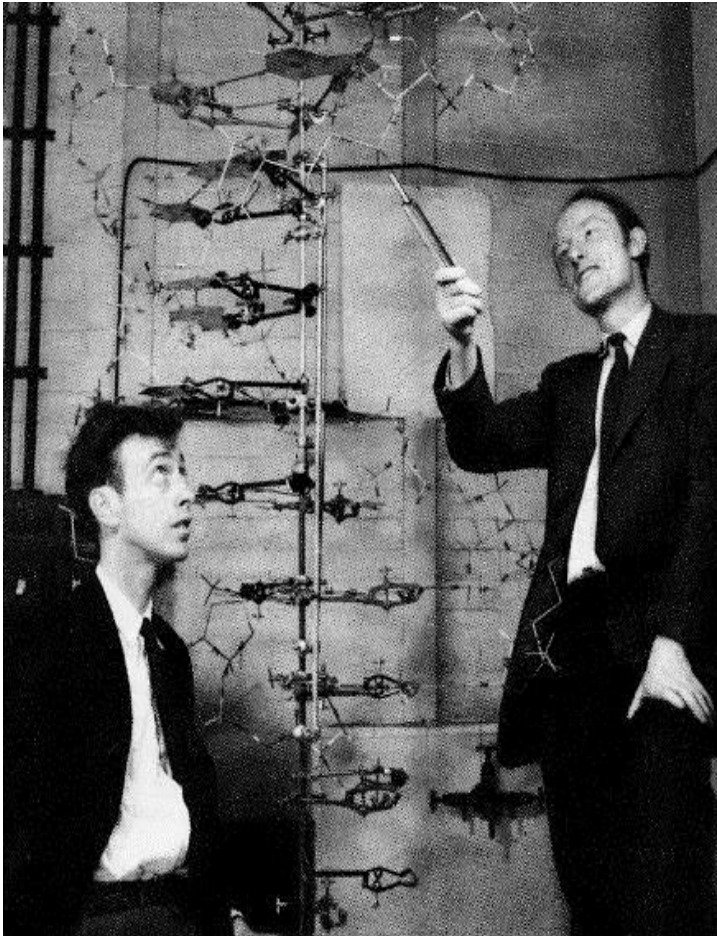
- What could go wrong?
 - Enrollment
 - Study measurements
 - Confounding
 - Generalizability
- Have a plan to deal with it
 - Do not raise unsolvable problems
- Do not cut from this section!

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

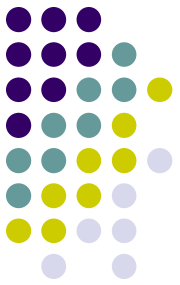


- Will project be complete at end of study or lead to related studies? (Continuity – especially important for early stage investigator)
- Will research findings be important one year after study is complete? Ten years after?

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

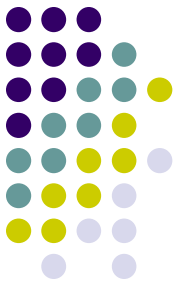
- Protection of Human Subjects
 - If exempt, explain why exempt
 - If non-exempt, go to next slide
- Inclusion of Women and Minorities
 - Targeted Enrollment Form
- Inclusion of Children

- *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
 - timing
- 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 follow



Organize your work

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



Examples - Subheadings

6. Research Strategy

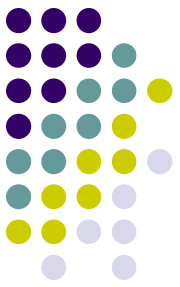
b. Significance

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

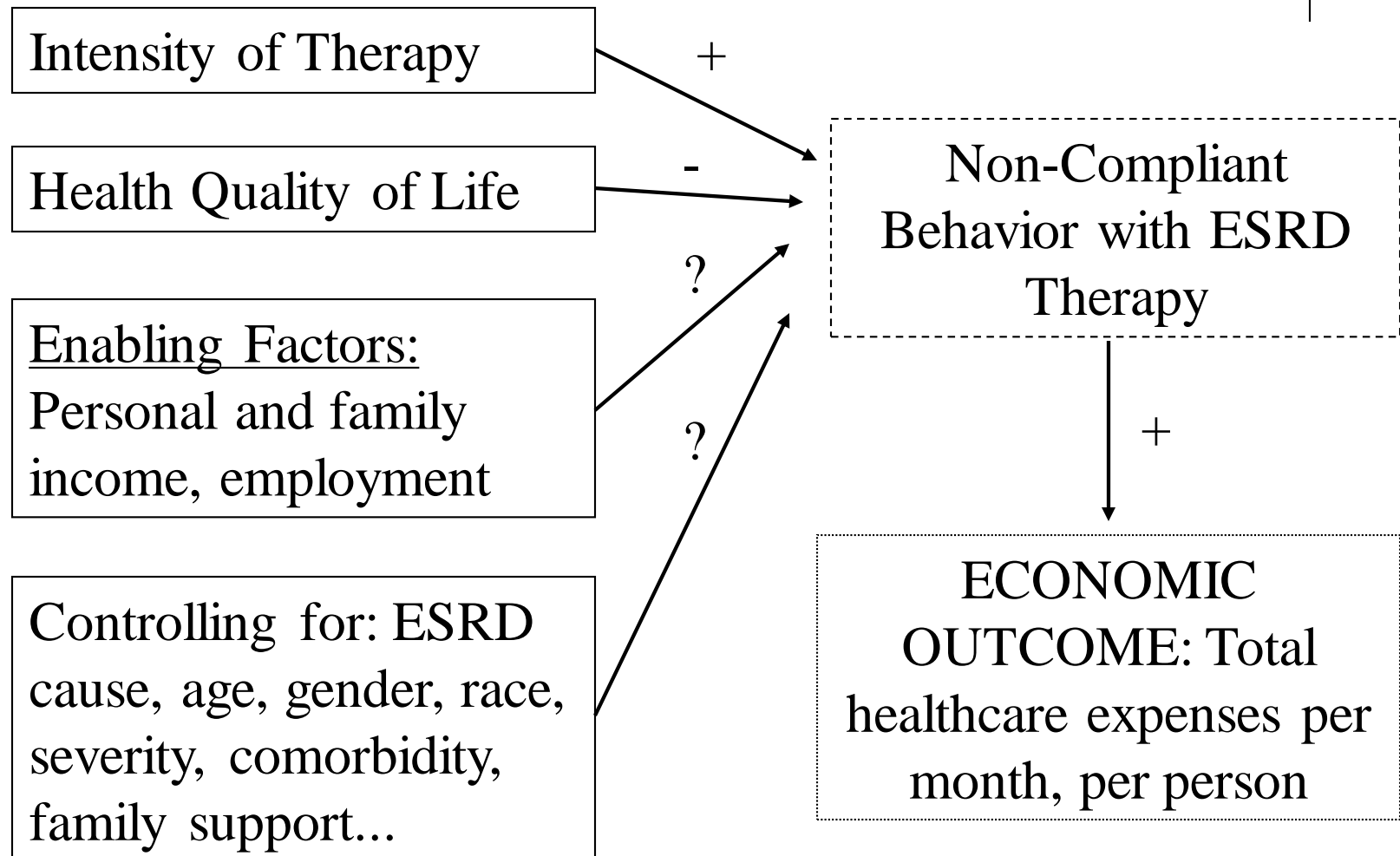
*Methods for Estimating Costs of Nosocomial
Infections [McGowan, 1981 #23]*

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

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

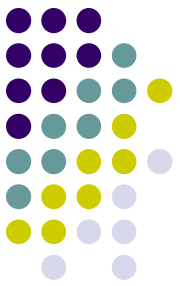


Example – Figure- “shows the theory”

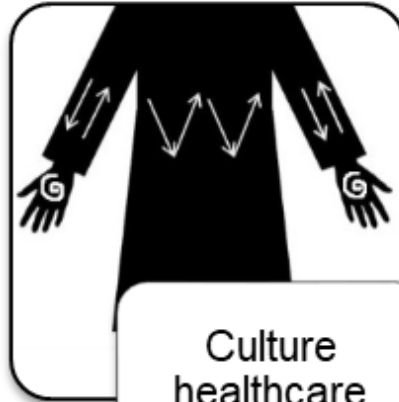


From D. Bradham

Aim 1 Approach



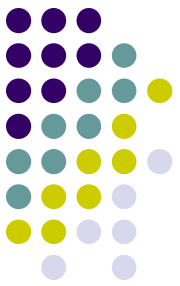
Identify colonized patients using surveillance cultures



Culture healthcare worker gown and gloves on room exit

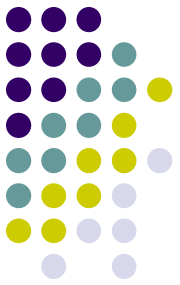


Obtain patient level variables



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

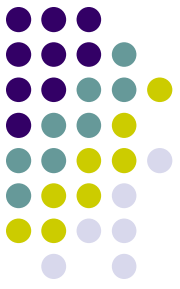
Post-Award Grant Management



- 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.*