Securing an NIH Grant

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National Cancer Institute

National Institutes of Health

HINTS Conference

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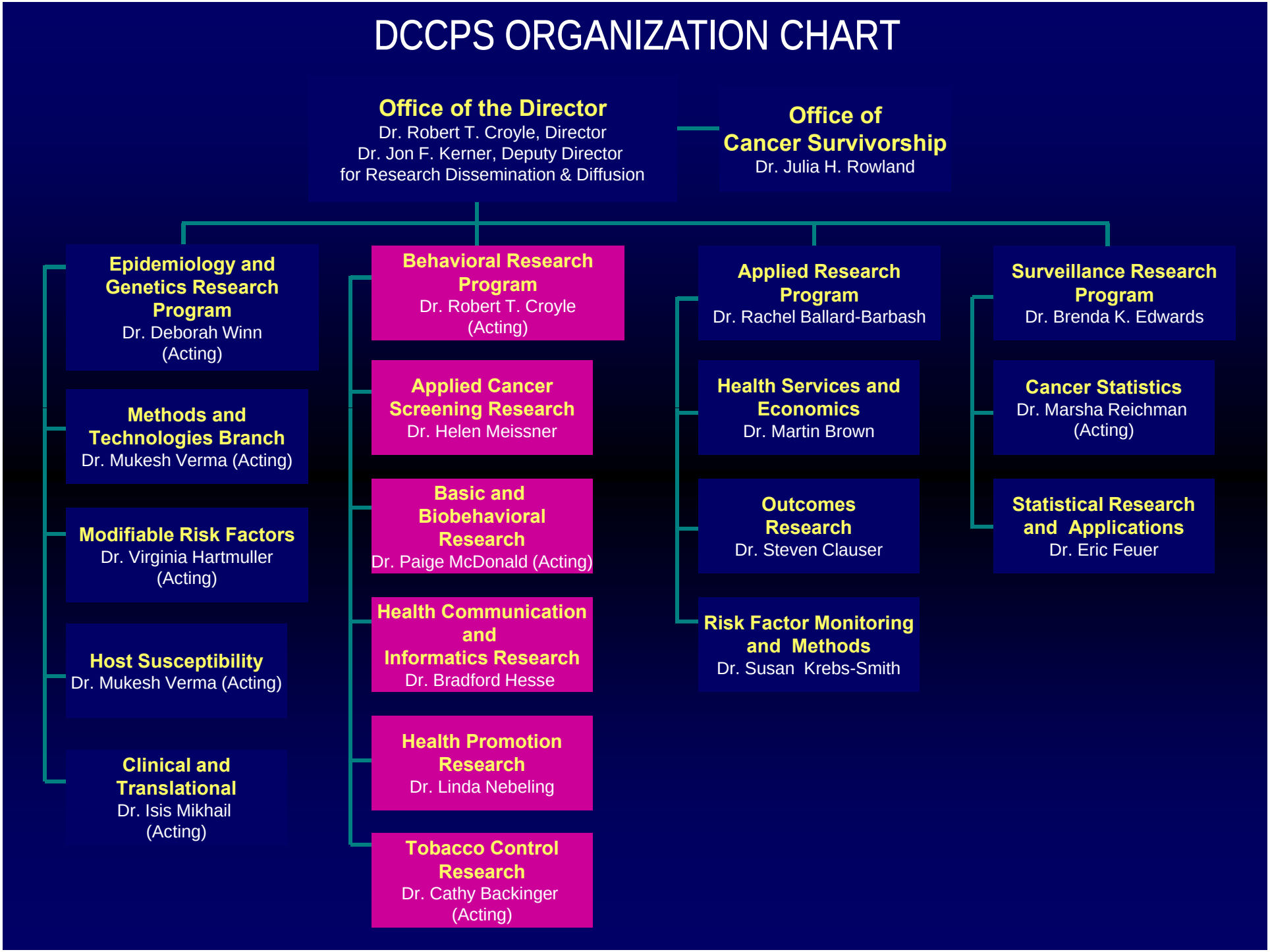
"But What About Funding?"

DCCPS ORGANIZATION CHART



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Program Directors are your "Friends"

- **Your PD's are there to answer questions:**
  - Identify resources to locate funding opportunities
  - Direct investigators to grant mechanisms that match the goal or intent of their projects and experience
  - Identify gaps in scientific knowledge
  - Have knowledge of NCI grant portfolio
  - Attend Study Section reviews (can follow-up after review of grant)

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NIH Grants Administrators

- NIH Scientific Review Administrator (SRA)
  - **Decides which Study Section will review grant application**
  - **Assigns reviewers**
  - **Organizes and conducts fair and impartial review**
  - **Generates summary statement**

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NCI Grants Administrators

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- NCI Office of Grants Administration (OGA)
  - **Sends "Just-In-Time" letters**
  - **Reviews and administers budget**
  - **Tracks Institutional Review Board (IRB) approval and institution "assurance"**
  - **Reviews percentages of effort and overlapping of support**
  - **Issues Notice of Grant Award**

NIH Center for Scientific Review Process

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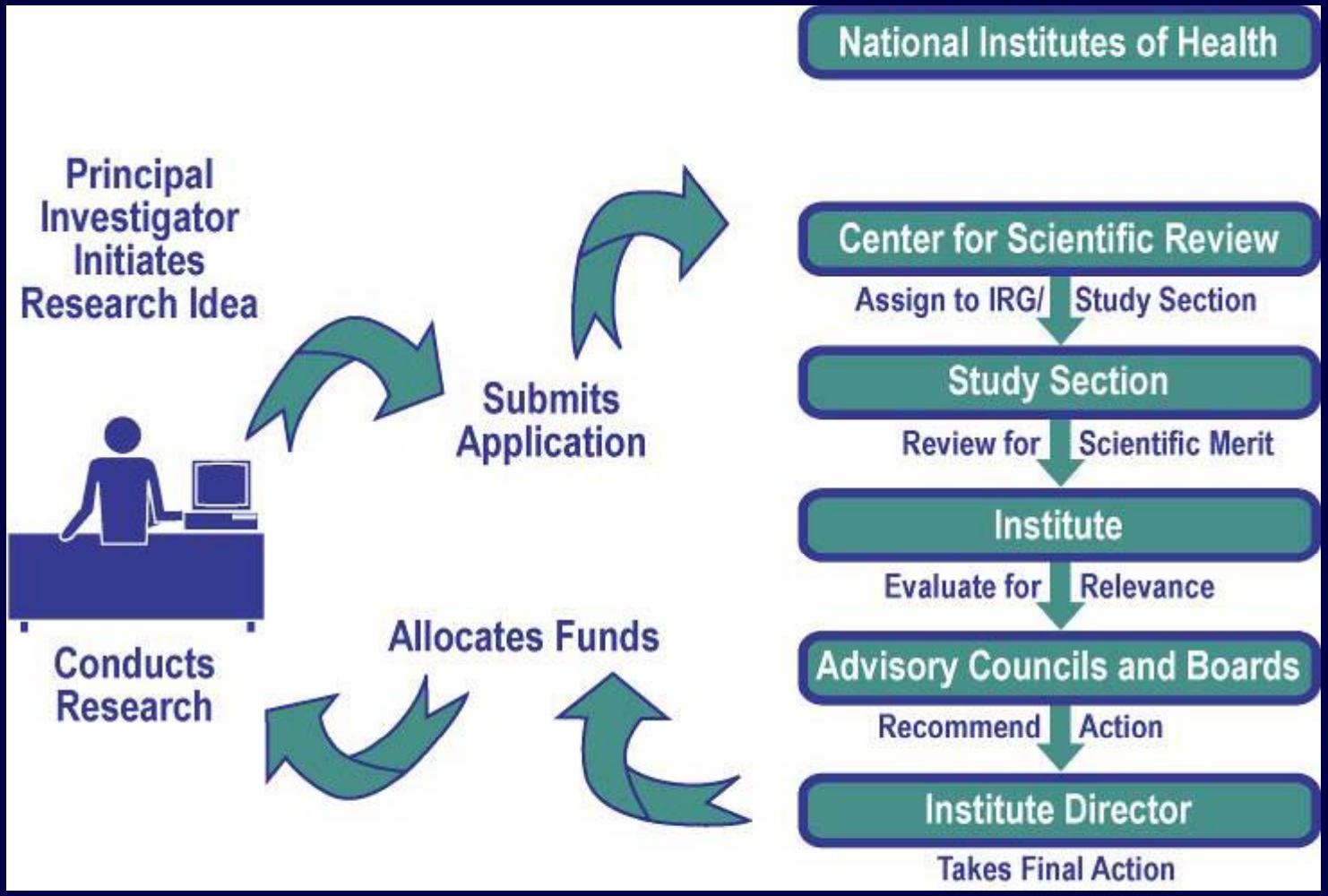

Contact NIH

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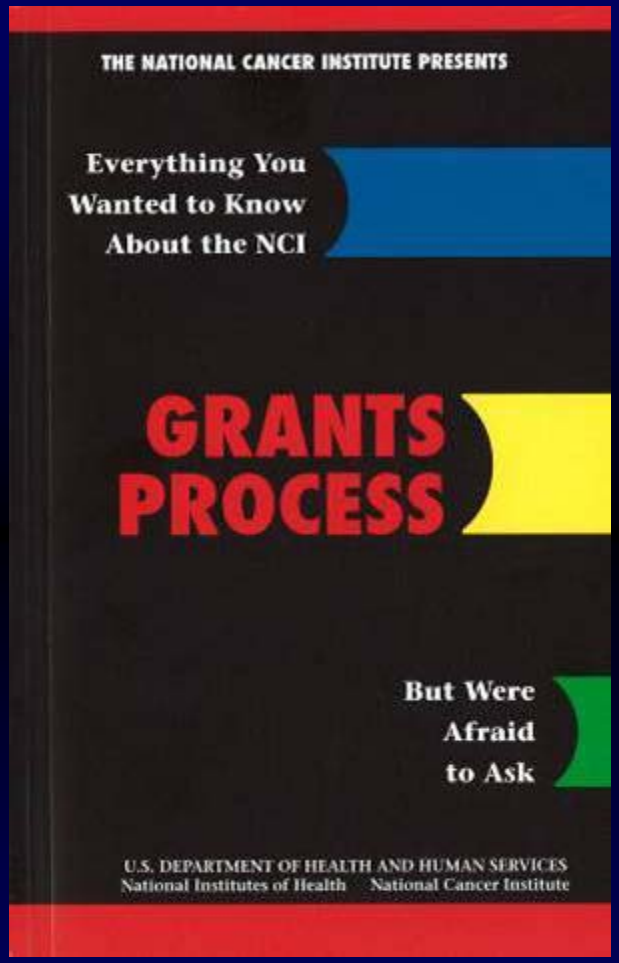
- NIH – http://www.nih.gov
- Computer Retrieval of Information on Scientific Projects (CRISP)

  http://crisp.cit.nih.gov
- NIH Guide to Grants and Contracts
- Check current policies
- Identify funding mechanism

NCI Grants Process Book

Access the booklet:
www3.cancer.gov/admin/gab

Caution! The booklet does not address NIH's transition to mandatory use of the new SF424 Research and Related (R&R) application and electronic transmission of submissions via *Grants.gov.* Learn more: era.nih.gov/ElectronicReceipt/



Types of Funding Opportunity Announcements (FOA)

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- **Program Announcement (PA):** Statement of ongoing research interest by Institute/Center
  - **No set-aside monies (usually)**
  - **Investigator-initiated awards are now in response to a parent PA**
    - **PA-07-070--Parent R01:**

    http://grants.nih.gov/grants/guide/pa-files/PA-07-070.html

- **Request for Applications (RFA):** Special research initiative
  - **Set-aside monies and specially assembled review group**

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Types of Grant Mechanisms

- R03 – Small Research Grants
- R21 – Exploratory/Developmental Grants
- R01 – Research Projects
- R13 – Conference Grants
- P01 – Research Program Projects
- K-Awards NCI – Training Awards

http://deainfo.nci.nih.gov/flash/awards.htm

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R03: Small Research Grants

- Provide short-term awards for testing new techniques, secondary analyses of existing data, and development of innovative projects that could provide a basis for more extended research
- Characteristics:
  - **< $50K per year, 2-year maximum (nonrenewable)**
  - **3 submissions—initial and 2 amended**
  - **Special NCI review committee**

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R21: Exploratory/Developmental Grants

- Support development of pilot projects, feasibility studies, and intervention studies that are creative, novel, high-risk/high-payoff, and produce innovative advances
- Characteristics:
  - **Up to $275K/year for 2 years (nonrenewable)**
  - **3 submissions—initial and 2 amended**
  - **Only in response to Program Announcement**

R01: Research Project Grants

- Traditional investigator-initiated grant providing support for discrete, specified research
  - **If > $500K/year, need to request NIH Center for Scientific Review (CSR)/Institute Program Director approval to submit—at least 6 to 8 weeks before submission deadline for NCI DCCPS**
  - **Up to 5 years (usually 3–5 years)**
  - **3 submissions—initial and 2 amended**

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R13: Conference Grants

- Provide support for national and international meetings valued for promoting Institute/Center goals
  - **Prior approval required before submission of application; contact Program Director**
  - **Any U.S. organization eligible**
  - **Typically $10–25K/year for up to 5 years**
    - **Amount dependent on score, timeliness, budget, NIH interest**
  - **3 submissions—initial and 2 amended**

P01: Research Program Projects

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- Support an integrated, multiproject research approach involving a number of independent investigators who share knowledge and common resources and have a shared, well-defined research program goal
- There is a defined central research focus involving several disciplines or several aspects of one discipline
- DCCPS-supported examples:
  - **Collaborative Genetic Study of Nicotine Dependence**
  - **Statistical Methods for Medical Studies**
  - **Etiologic Studies of Gastric Cancer**

Career Development Awards

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Career Development Programs (K series)

- **K01 Mentored Research Scientist Development Award**
- **K08 Mentored Clinical Scientist Development Award**
- **K22 NCI Transition Career Development Award**
- **K23 Mentored Patient-Oriented Research Career Development Award**

http://grants1.nih.gov/training/careerdevelopmentawards.htm

New K Award

- NIH Pathway to Independence Award (K99/R00): ≤ 5 yrs, with 2 phases
  - Phase 1: mentored support, 1-2 years
  - Phase 2: independent support, 3 yrs; contingent on securing independent research position

grants.nih.gov/grants/new_investigators

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"My question is: Are we making an impact?"

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Develop Your Idea

- Generate preliminary data
- Enlist collaborators, include letters of commitment
- Review successful proposals of other colleagues

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Preparing the Application

- Clear, concise writing style
- Be focused
- Don’t rush
- Critique, critique, and critique again
- Follow up with NIH program directors after review

Preparing the Application (cont'd)

- Read instructions!
- Never assume that reviewers "know what you mean"

- Provide appropriate reasoning for and description of research design including:
  - Participant selection
  - Data collection
  - Data analysis
  - Data interpretation
- Anticipate human subject issues

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Review of Research Grants

- Study Section review criteria:
  - **Significance**
  - **Approach**
  - **Innovation**
  - **Investigator**
  - **Environment**

- Learn more about the review process and view NIH video of mock Study Section meeting: *cms.csr.nih.gov*

Design Issues

- Sampling Methods
- Power Calculations
- Theoretical-based Intervention
- Compliances
- Data Acquisition and Management
- Participant Training and Monitoring
- Data Analysis

Potential Issues

- Research Design
  - Does it work? Preliminary data
  - Valid Instruments
  - Reality check – subject burden
  - Will compliance rate(s) be adequate

Potential Issues

- Human Subjects
  - Inclusion
    - Minorities, women, children, gender
  - Protection
  - Exemptions applicable
  - Potential benefits or risks*

*Risks include the possibility of physical, psychological, or social injury resulting from research.

Human Subject Issues

- Recruitment and informed consent
  - Vulnerable populations
  - Incentives
  - Informed Consent
    - Participation
    - Use of information
    - Future analysis

http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm

Other Important Issues

- **Data Safety and Monitoring Plan**

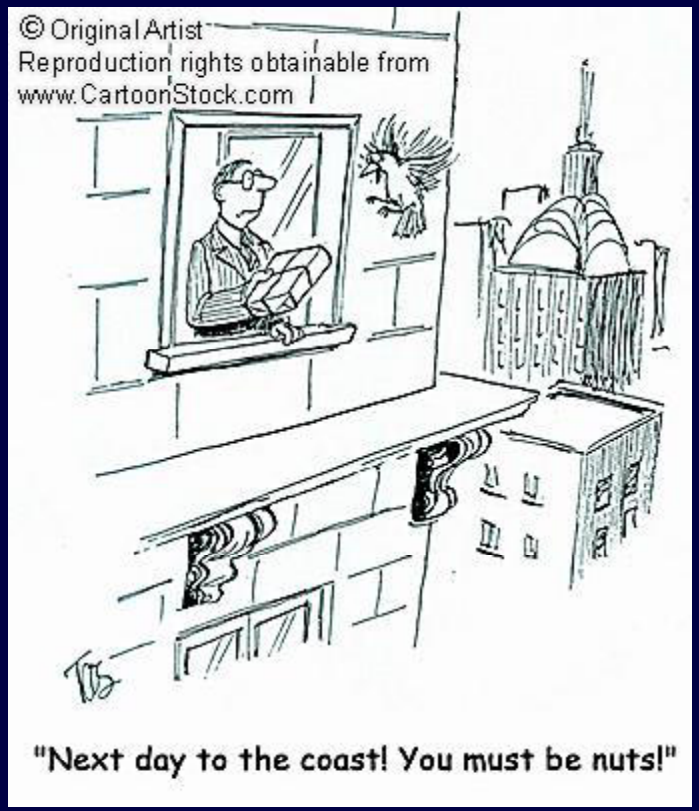
  http://grants.nih.gov/grants/guide/notice-files/not98-084.html

- **Policy on Data Sharing**

  http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

Key Deadlines

- New R01's: Feb 5, June 5, and Oct 5
- New R03's and R21's: Feb 16, June 16th, and Oct 16
- Resubmission/
  Competing continuation: one month after above dates
- SBIR/STTR: April 5, Aug 5, and Dec 5



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The "Top Ten" List

1. Read and re-read the program announcement
2. Assemble a strong research team
3. Use the strongest study design possible
4. If you have not been on a study section, confer with someone who has
5. Be sure to document the innovations(s)
6. Document strong access to the study population
7. Make sure the writing, organization, & grammar are as tight as possible (write, re-write…read, re-read)
8. Seek reviews before submission
9. Make careful use of the summary statement
10. Persevere and don't take rejection personally

(Source: Ross Brownson 1/13/2004)

Most Common Problems

- Lack of new or original ideas
- Diffuse, superficial or unfocused research plan
- Lack of knowledge of published relevant work
- Lack of experience in the essential methods
- Uncertainty concerning the future directions
- Questionable reasoning in methodological approach
- Absence of an acceptable scientific rationale
- Unrealistically large amount of work
- Lack of sufficient methodological detail
- Uncritical approach

If you don't remember anything else…

1. Read Instructions!
2. Re-write, re-write, re-write….
3. Call your program director!

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GOOD LUCK!

"This is Doctor Bagshaw, discoverer of the infinitely expanding research grant."

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