

Mark Alexander

Division of Cancer Control and Population Sciences, NCI

Maximizing Your Odds of Receiving an NIH Grant

A presentation to
HINTS Data Users Conference



Employee Information



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Today's Talk

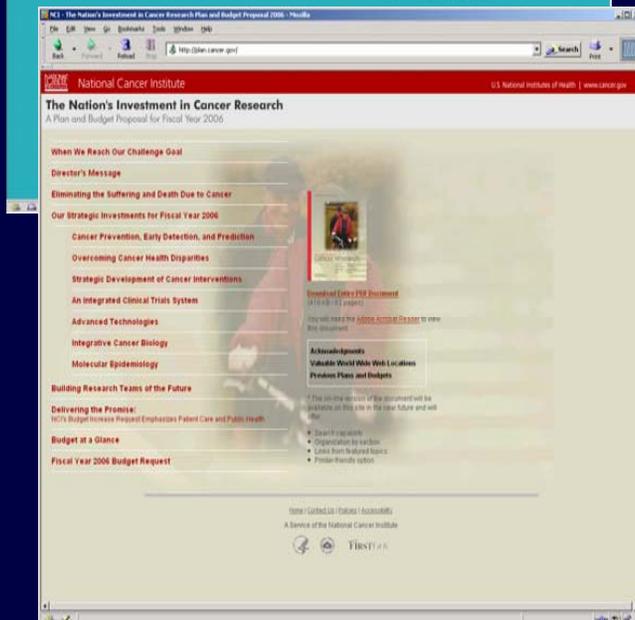
- ▶ **Familiarizing Yourself with NIH Planning and Priority-Setting Resources**
 - ▶ NCI Strategic Priorities (Example)
 - ▶ NCI Bypass Budget (Example)
 - Cancer Control Initiatives
- ▶ **Submitting a Successful Grant Application**
 - ▶ Contacts
 - ▶ Tips
 - ▶ Process

NCI Strategic Priorities (2005)

- ▶ **Bioinformatics**
- ▶ **Integrative Cancer Biology**
- ▶ **Strategic Development of Cancer Interventions**
- ▶ **Integrated Clinical Trials System**
- ▶ **Molecular Epidemiology: Understanding the Causes of Cancer**
- ▶ **Early Detection, Prevention, Prediction**
- ▶ **Overcoming Health Disparities**

NCI's FY05/FY06 Broad Research Priorities:

<http://plan.cancer.gov/plan.html>



- ▶ **Genes and the Environment**
- ▶ **Research on Tobacco and Tobacco-Related Cancers**
- ▶ **Optimizing Energy Balance to Reduce the Cancer Burden**
- ▶ **Improving Treatment Outcomes and Quality of Life for Cancer Survivors**

- ▶ **Cancer Prevention, Early Detection, and Prediction**
- ▶ **Advanced Technologies**
- ▶ **Overcoming Cancer Health Disparities**
- ▶ **Molecular Epidemiology**

PRIORITIES

DISCOVERY ----- DEVELOPMENT ----- DELIVERY

Congress, IOM,
National
Dialogue on
Cancer,
NCAB/BSA/BSC,
Advocates,
Professional
Associations

HHS
Priorities:
Prevention,
HP 2010,
Health
Disparities

NIH
Roadmap

New
Strategic
Priorities

Bypass
Budget
Scientific
Priorities

Disease-
Specific
Progress
Review
Groups

Division
Programmatic
Initiatives

2015 Goal: To
eliminate the suffering
and death from
cancer.



2003

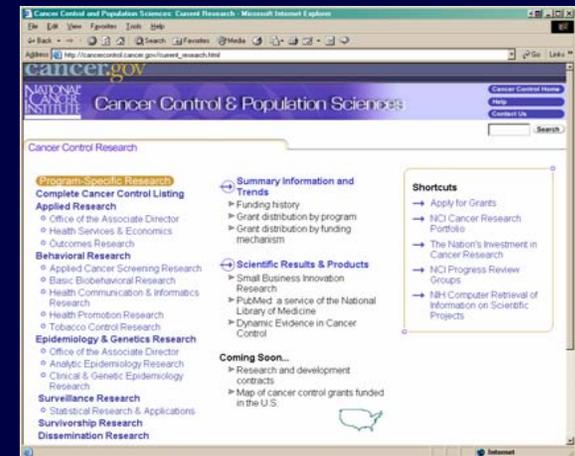
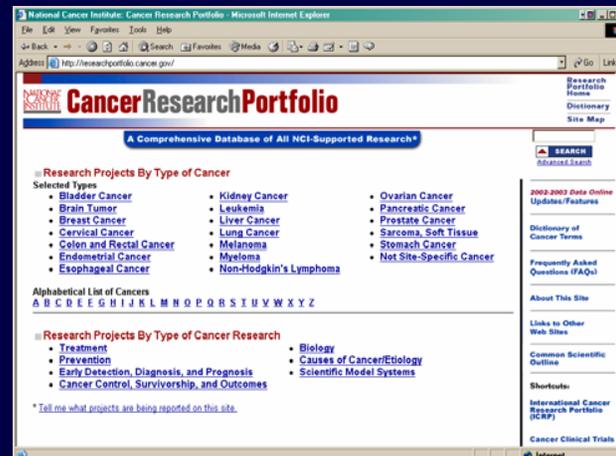
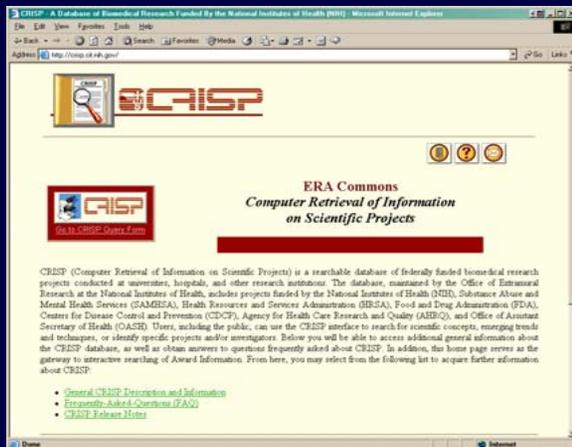
2015

Examples of Initiatives from Different Planning Levels

- ▶ **Congressional: Breast Cancer & the Environment Centers (w/NIEHS)**
- ▶ **DHHS: Quality of Cancer Care Comm.; Health Disparities PRG**
- ▶ **NIH: Centers for Population Health and Health Disparities**
- ▶ **PRG/IOM: New Tobacco Products**

Survey NCI's Active Research Portfolio

- ▶ **CRISP** (<http://crisp.cit.nih.gov/>)
- ▶ **Cancer Research Portfolio** (<http://researchportfolio.cancer.gov/>)
- ▶ **DCCPS Current Research** (<http://cancercontrol.cancer.gov/>)



Where are the NCI Dollars Allocated? The NCI Research FY04 Allocation

**NCI FY04
Appropriation
\$4.7B**



- Cancer Centers
- Training & Education
- Cancer Control Contracts
- Intramural
- Research Management & Support
- Other

Research
Project
Grant
Funds (RPG)
\$2B

SBIR/STTR Set-Aside
\$91M

Non Competing Commitments
\$1.5B

Available Competing Funds

\$492M

Submitting a Successful Grant Application: **NCI Contacts**

Program Directors

- Identify resources for locating funding opportunities
- Direct applicant to grant mechanisms that match the goal or intent of the project and experience of the investigator
- Identify gaps in scientific knowledge
- Knowledgeable about NCI grant portfolio
- Attend study section reviews

Submitting a Successful Grant Application: **NCI Contacts**

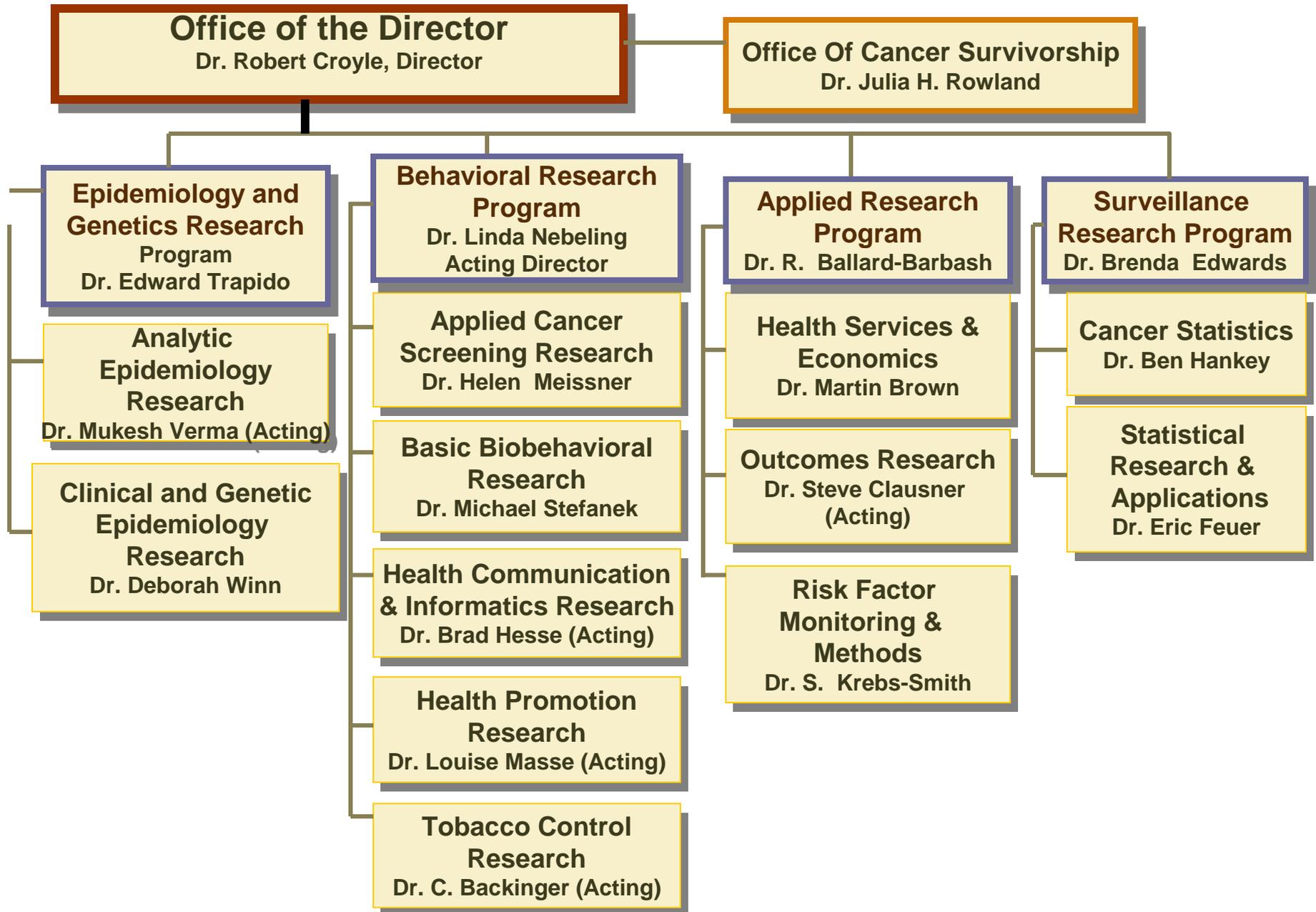
- Use organizational chart to match Branch/Office to research content
- Email brief query about research interest and questions about funding to Program Director (PD) in identified Branch/Office

Include:

“If this area of research is not suitable for the [Branch, Office, or Program], please forward to the appropriate Program Director.”

- Follow up with PD
 - Email abstract or specific aims
 - Email or telephone to discuss grant mechanism and career objectives

Division of Cancer Control & Population Sciences



Applications Submitted to NIH

- ▶ ~ 46,000 grant applications submitted each year
- ▶ ~ 25-30% are funded
- ▶ ~ 3,200 review meetings
- ▶ ~ 80 National Advisory Committees
- ▶ > 200 million pieces of paper
- ▶ Electronic submission updates



NIH Review Process

National Institutes of Health
Center for Scientific Review

Assign to IC IRG (Study Section)

Study Section

Review for Scientific Merit

Institute

Evaluate for Relevance

Advisory Councils and Boards

Recommend Action

Institute Director

Takes final action

Initiate
Research Idea



Submit
Application

Revise/Resubmit

Allocate Funds



NCI Contacts, cont.

Scientific Review Administrator (SRA)

- Decides on where grant application will be reviewed
- Assigns reviewers
- Organizes and conducts fair and impartial review
- Generates summary statement

Grants Administrator Officer or Technical Assistant (GAB)

- Issues Notice of Grant Award
- Reviews and administers budget
- Tracks IRB approval and institution “assurance”
- Reviews percentages of effort and overlap of funding support (Other Support)

Extramural Research

NIH has 3 major funding instruments to support extramural research:

- **Grant:** Investigator decides the research to be designed or developed and the approach.
- **Contract:** Government decides the research to fill their perceived need and establishes detailed requirements.
- **Cooperative Agreement:** Similar to grants, but awarding Institute/Center (IC) and recipient have substantial involvement in carrying out the project's activities.

Types of Funded Research

Program announcements (PA): statement of
Ongoing research interest by Institute/Center

- No set aside monies
- Given higher priority if scored in the fundable range
- Better positioned to get “funding by exception”
- Announced in the NIH Guide
(<http://grants.nih.gov/grants/guide/index.html>)

Request for applications (RFA): special research initiative-funds set
aside & special review

- Set aside monies, and specially assembled review group
- One-time application – no revisions/resubmissions

Request for proposals (RFP): call for contract proposals

Investigator initiated mechanisms



NIH Grant Mechanisms

R03 Small Grants



- <\$50K per year
- 2 yrs total duration
- 2 aims
- * *One amendment only!*
- * *No thesis or dissertation support!*

R01 Traditional investigator-initiated grants

- <\$500K/yr
- if \geq \$500K need to request CSR/Institute approval at least 6 weeks prior to submission
- 3-5 yrs
- 3-4 aims with sub-aims
- 3 submissions – initial and 2 amended

NIH Grant Mechanisms, cont.

R21 (NCI) Exploratory/Developmental Grant

- \$275 across
- 2 yrs
- 3 submissions – initial and 2 amended

R13 Conference Grants

- Paid with Division “discretionary funds” (NCI)
- Typically, \$10-25K/yr (1-5yrs)
- Reviewed by internal NCI panel (NCI)
- Request that other Institutes are “co-funders”

NIH Grant Mechanisms Fellowships, Career Development, and Training

Fellowships (F series)

- F32 Individual Postdoctoral Fellows
- F33 Senior Fellows
- F31 NIH Predoctoral Fellowship Awards for Minority Students

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

Fellowships, Career Development, and Training, cont.

Training (T series)

- T32 Institutional Research Training Grants
- Predoctoral Research Training Partnership Award (TU2)

Cancer Prevention Fellowship Program

NCI Division of Cancer Prevention

- MPH – 1 year, tuition and salary paid
- NCI – 2 years

Opportunities for Minority Scientists

- ▶ NCI Comprehensive Minority Biomedical Branch
 - Minority Supplements
 - NCI Training Programs

- ▶ Program Announcement: Initiative for Minority Students: Bridges to the Doctorate (see NIH Guide)

- ▶ National Institute of General Medicine:
The Minority Access to Research Careers Program

- ▶ Office of Research on Minority Health

Submitting a Successful Grant Application: **Process**

▶ Preparing the PHS 398 Application

- ▶ HIPAA Privacy Rules
- ▶ Certificates of Confidentiality
- ▶ Data Safety and Monitoring
 - IMPORTANT:** Look under Special Circumstances tab for behavioral research guidelines
- ▶ Human Subjects Protection
- ▶ Assurances and IRB Registration
 - IRB approval is not needed before submission, but application must address human subject protection
- ▶ Inclusion/Exclusion of Women, Children and Minorities

Typical Sequence for Proposal Development

- ▶ Problem or need
- ▶ Significance/Background
- ▶ Specific aims
- ▶ [Theoretical model]
- ▶ Research plan, including HIPAA, human subjects, data safety monitoring
- ▶ Progress report/preliminary studies
- ▶ Budget
- ▶ Biographical sketches
- ▶ Abstract

Outline of Research Proposal

- ▶ **Literature search and preliminary draft of relevant materials**
 - ▶ Look up publications of reviewers
 - ▶ Use only those articles which are relevant to support aims

- ▶ **Theoretical model(s)**
 - ▶ Essential in intervention level studies
 - ▶ Non-essential or inappropriate for exploratory level
 - ▶ If no model, explain why
 - ▶ When possible, use diagram

Outline, cont.

Hypotheses & Specific Aims

- Rarely more than 3 overall hypothesis with 2-3 aims
- Operationalize definitions
- State null and alternative (directional)
- Implications if hypotheses are/are not supported

Research Design

- Describe design (e.g., 3-group, cross-sectional, nested, cross-over)

Outline, cont.

Methods

- Setting
- Subject selection
 - Power analysis for each aim - OVERSAMPLE
 - Numerators/Denominators - DESCRIBE POPULATION
 - Describe who, when, where, why of recruitment
 - Attrition – procedures to minimize drop outs
 - Procedures for recruiting hard-to-reach populations
- Measures
 - Reliability & validity, population norms
 - Rationale for use

Outline, cont.

- Procedures
 - Detailed
- Data Analysis
 - Use “highest order” analysis
 - In quantitative designs, use multivariate approach
 - In qualitative designs, provide details of analysis, software, etc. & assume that reviewers have no experience with qualitative methods
 - Be consistent in analytic approach for aims
 - Include a biostatistician in writing & research team
 - Provide mock tables or figures for major analyses

Outline, cont.

Potential results

- ▶ Implications for public health, community, individuals, and their families
- ▶ Describe how proposed research, if successful, will lead to future funding applications

Limitations of study

- ▶ Describe how limitations will be addressed

Data Sharing Plan [Dissemination] – how and to whom will results be made public?

- Oral presentations at professional conferences
- Peer-reviewed journals
- Offer participants opportunity to get results in lay language

Budget and Justification

- ▶ Justify effort and expertise for all personnel
 - New PI should be at $\geq 20\%$ effort
 - Do not use “To Be Announced” for key personnel
 - Justify equipment and supply requests
 - Consultants from other institutions are less expensive than “co-investigators”
- ▶ Anticipate salary/operating increases for future years
- ▶ Include two trips for conference presentations
- ▶ NCI usually cuts budget – programmatic cuts

Submission Timeline

- ▶ Submission dates for investigator initiated applications: **October 1, February 1, June 1**
R03: December 20, April 20, August 20
- ▶ Study section review about 4 months after submission: Feb-March, June-July, Oct-Nov
- ▶ Advisory Council about 2 months after review: May-June, Sept-Oct, January-February
- ▶ Earliest possible award ~ 10 months from submission date

Submission, cont.

- ▶ Electronic submission
 - ▶ <http://grants.nih.gov/grants/edocs.htm>
(electronic application)

- ▶ Cover letter
 - Request IC Assignment and Review Group if you have a preference
 - Suggest additional review expertise if needed (CSR website)
 - Check for conflict of interest with reviewers

It all starts here:

<http://cancer.gov/>

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