Pancreatic Cancer Action Network Webinar: NIH Grantsmanship for New Investigators

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Focus of this Session

NIH Grants: Changes in Review and Funding Opportunities

- Review Issues
- Program Director's role
- Current NCI Funding Policies
- Grantsmanship Issues

NIH Grants Session: Focus

R01 and R21 grant applications

- **Review**
- **Grantsmanship**

Review Issues

NIH Process for a Research Grant

National Institutes of Health

Research Grant Application

School or Other Research Center

Center for Scientific Review

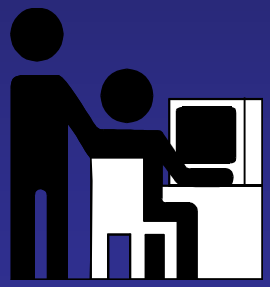
Study Section

Institute

Advisory Councils / Boards

Institute Director

Initiates Research Idea



Submits Application

Allocates Funds

Conducts Research

Functions of CSR

- Referral
  - Central Receipt Point
  - Institute Assignment
  - Referral to IRGs and Study Sections
- Scientific Review
  - Review of most research and research training applications for scientific merit

Applications are Assigned to:

- Institutes based on:
  - Overall mission
  - Specific programmatic mandates and interests
- Initial Integrated Review Groups (IRG) and Study Sections based on:
  - Specific review guidelines

- **MAJOR CHANGES FOR APPLICANTS!** Shorter page limits … restructured forms … new instructions
- For application submissions due on or after January 25, 2010, the time is now to **find out how**
- http://enhancing-peer-review.nih.gov/restructured_applications.html

Short Applications (Jan 25, 2010)
Reduction in pages

- Introduction to Revision Application : 1
- Specific Aims: 1
- Research Strategy R01: 12
- Research Strategy R21: 6
- Biographical Sketch: 4

Shorter Applications R01

- Research Strategy
  a) Significance
  b) Innovation
  c) Approach
- Investigator: under biographical sketch
- Environment: Resources format page

Specific Aims

- State concisely the goals
- Summarize expected outcome(s)
- Impact of the proposed research will exert on the research field(s) involved

Research Strategy: (a) Significance

- Explain: Importance of the problem or critical barriers to progress in the filed that the R01 addresses
- Explain: how the proposed research will increase scientific knowledge, technical capability, and/or clinical practice in one or more broad fields
- Describe: how the concepts, methods, technologies, treatments, services or preventive interventions that drive this field will be changed if the proposed aims are achieved.

Research Strategy: (b) Innovation

- Explain: how the R01 challenges and seeks to shift current research or clinical practice paradigms
- Describe: any novel theoretical concepts, approaches or methods , instrumentation or intervention(s) to be developed or used, and any advantage over existing methods/technologies.
- Explain: refinements, improvements or new applications of theoretical concepts, approaches or methods.

Research Strategy: c) Approach

- Describe: the overall strategy, methodology, and analyses to be used
- Discuss: potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- If project in the early stages of development, describe strategies to establish feasibility, and discuss: *management of high risk aspects of the proposed work*

Research Strategy: Preliminary studies for new applications/progress reports for competing renewals or A1 applications

- Pre**liminary studies – part of the Approach** section
- Reviewers asked to place less emphasis on Prelim data on ESIs

- Progress reports: part of the Approach section

Oncology 1: Basic Translational IRG (OBT)

- Cancer Molecular Pathology (CAMP)
- Cancer Etiology (CE)
- Cancer Genetics (CG)
- Molecular Oncogenesis (MONC)
- Tumor Cell Biology (TCB)
- Tumor Microenvironment (TME)
- Tumor Progression & Metastasis (TPM)

Oncology 2: Translational Clinical IRG (OTC)

- Basic Mechanism of Cancer Therapeutics
- Cancer Biomarkers
- Chemo/Dietary Prevention
- Cancer Immuno-pathology and Immunotherapy
- Clinical Oncology
- Drug Discovery and Molecular Pharmacology
- Developmental Therapeutics
- *Oncology 2 Translational Clinical SBIR/STTR

  3 study sections focusing on Radiation Biology and Therapeutics, Drug Development and Therapeutics, Diagnosis and Treatment

NIH Grants: Changes in Review

January 2009

Early stage Investigator Policy NOT-OD-09-013

May 2009 Review Meetings

9-point scoring system

Enhanced Review Criteria

Formatted Review Critiques

Scoring of Individual Review Criteria

Clustering of New PI-R01s during Review

January 2010

Shorter Applications for R01s & other Mechanisms

1-9 Scoring System

- The new scoring system will use a 9-point scale (1 = exceptional, 9 = poor)
- This scale will be used for overall impact/priority scores AND for individual criterion scores
- Preliminary impact/priority scores will help determine which applications are discussed –upper half discussed (R21, R01, *R01)

Scoring of Individual Review Criteria

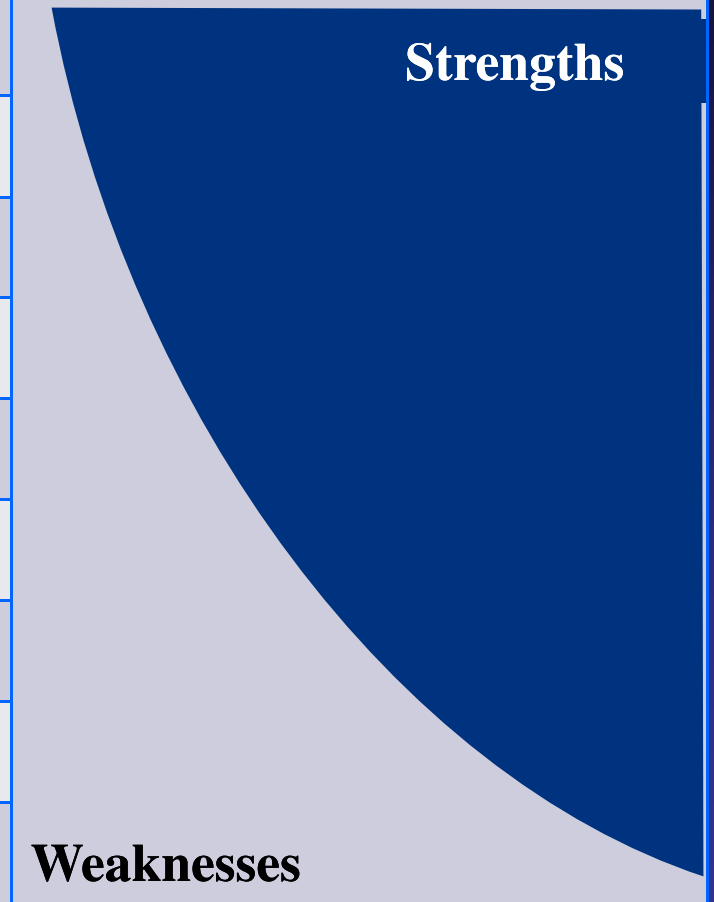
Significance
Investigator(s)
Innovation
Approach
Environment

Each core criteria will receive a score

1- 9 Scoring Scale
1 = exceptional
9 = poor

***Overall impact/priority score**
1 = exceptional, 9 = poor
***For discussed applications only**

Scoring Descriptions

Impact	Score	Descriptor	Strengths/Weaknesses
High Impact	1	Exceptional	
	2	Outstanding	
	3	Excellent	
Moderate Impact	4	Very Good	
	5	Good	
	6	Satisfactory	
Low Impact	7	Fair	
	8	Marginal	
	9	Poor	

Non-numeric score options: NR = Not Recommended for Further Consideration, DF = Deferred, AB = Abstention, CF = Conflict, NP = Not Present, ND=Not Discussed

Score	Descriptor	Additional Guidance on Strengths/Weaknesses
1	Exceptional	Exceptionally strong with essentially no weaknesses
2	Outstanding	Extremely strong with negligible weaknesses
3	Excellent	Very strong with only some minor weaknesses
4	Very Good	Strong but with numerous minor weaknesses
5	Good	Strong but with at least one moderate weakness
6	Satisfactory	Some strengths but also some moderate weaknesses
7	Fair	Some strengths but with at least one major weakness
8	Marginal	A few strengths and a few major weaknesses
9	Poor	Very few strengths and numerous major weaknesses

Minor Weakness: An easily addressable weakness that does not substantially lessen impact
Moderate Weakness: A weakness that lessens impact
Major Weakness: A weakness that severely limits impact

Summary Statements

Summary statements for ALL applications will include the criterion scores and critiques posted by assigned reviewers

Overall impact/priority scores of discussed applications will be the mean of scores voted by all eligible reviewers, multiplied by 10

Impact/Priority Score: Average of all reviewers' Impact/Priority score votes

No arithmetic relationship to individual criterion scores.

Final scores will range from 10 - 90 in whole numbers

Summary Statements – continued

Format similarity:

Critiques presented in the order of reviewer assignment

If an application is discussed, there will be a Resume and Summary of Discussion section

Format changes:

Critiques will consist of bulleted comments under each review criterion and separated into strengths and weaknesses

Focus on major strengths and weaknesses

NIH expectation is for shorter, more focused critiques

Scores listed in a group at the beginning of each reviewer's critique will not be reported as average

Sample of Critique

CRITIQUE 1

Significance:	2
Investigator(s):	2
Innovation:	3
Approach:	2
Environment:	1

1. Significance

Strengths

- A major strength of this application is that text text text text text text text text text text text text text text text text text
- A moderate strength of this application is text text text text text text text text text text text text text text text text text text text text text text text text text text text text text text text text
- A minor strength is text text text text text text text text text text text text text text text text text text text text text text text text text text text text text text text text text text

Weaknesses

- A major weakness is text text text text text text text text text text text text text text text text text
- A moderate weakness is text text text text text text text text text text text text text text text text text
- A minor weakness is text text text text text text text text text text text text text text text text text text text text text text text text text text text text text text text text text text

(expand the list as needed, but not to exceed one-quarter page)

Slide 25

MSOffice1 , 4/16/2009

MSOffice2 , 4/16/2009

Early Stage Investigator (ESI) Policy

- **NIH will support New Investigators at success rates comparable to those for established investigators (submitting new applications)**

  ~1650 ESIs will be funded in FY 2009

- **ESIs will comprise a majority of the NIs supported (FY 2009 funding and beyond) appropriate consideration for ESI eligibility.**

- **All NIs will need to update their eRA Commons profiles, and will now see their eligibility displayed in eRA Commons.**

Goals of Identifying Early Stage Investigators (ESIs)

- Encourage transition to independence for investigators
- Counter trend of increasing time spent in training phase of career
- Strongly encourage New Investigators (NIs), particularly ESIs, to apply for R01 grants when seeking first-time NIH funding

Enhancing NIH Peer Review

- **Facilitate changing nature of science**
- **Identify and encourage new and early stage investigators**
- **Ease burden on research enterprise**
- **Streamline time to award**
- **Fund the best science, by the best scientists, with the least amount of administrative burden**
- **ESIs will constitute the majority of NIs supported under this policy**

Enhancing Peer Review at NIH Web Site

http://enhancing-peer-review.nih.gov

NCI Perspective

What happens to the application after submission?

Grant Application Referral & Scientific Review

Study Section

Scientific Review Officer

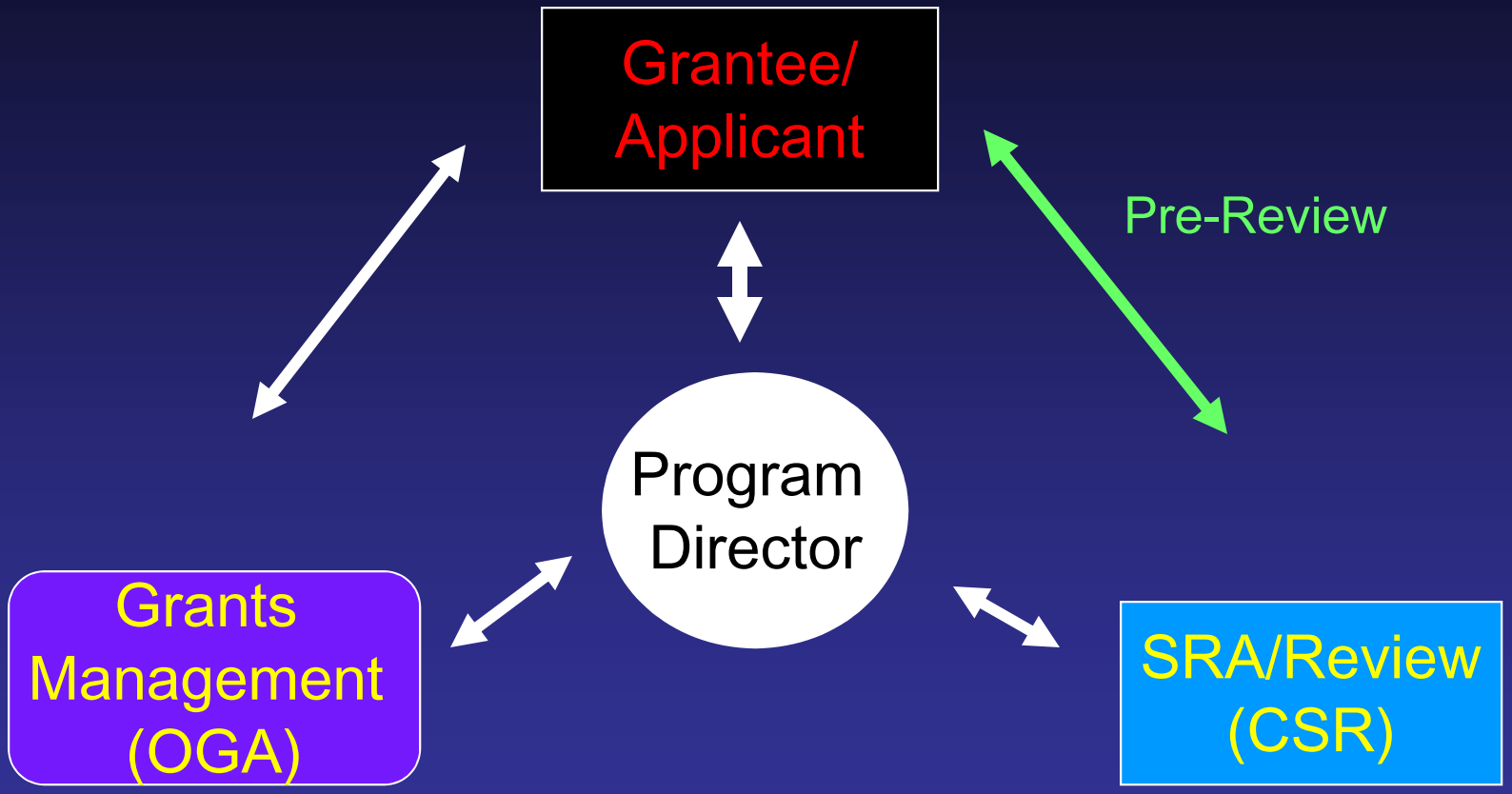
Summary Statement

NCI

Program Director

Applicant

The Program Director



After review, the Program Director serves as the point of contact and Scientific Manager of your Grant

Role of Program Staff

- Advise Applicants
  - Application Process
  - New/Revised Grant Applications
- Attend Study Section Meetings
- Resolve Problems that Impede Research Progress
- Advocate for your Application

Major Research Grant Mechanisms

R01 - Basic NIH research grant mechanism

- Requires preliminary data; Modular $250K DC/yr, 5 years; renewable

NOTE - NCI gives new investigators 4-5% better payline on R01s

R21 - Exploratory/Developmental Grant; High-risk research

- No preliminary data; proof-of-principle ;$275k total DC, 2 years, not renewable

R03 - Small Research Grant

- Little or no preliminary data; proof-of-principle; $50k / year, 2 years;

  not renewable

IMPORTANT - NCI does NOT accept R21s or R03s unless in response to a PA or RFA

Major Research Grant Mechanisms

R15 - Academic Research Enhancement Awards (AREA)

- To stimulate research in educational institutions that provide baccalaureate or advanced degrees, but that have not been major recipients of NIH support (AREA Grants)
- Up to $150k, 1-3yrs

P01 – Program Projects

- To support of an integrated, multi-project research program involving /=3 independent investigators who share knowledge and common resources.
- has a well-defined central research focus involving several disciplines or several aspects of one discipline
- Requires letter of intent and discussion with Program Officials

Types of NIH Grant Announcements

PA = Program Announcement
- PAR = with Special Review
- PAS = with Set Aside Funds

RFA = Request for Applications
- Special Review
- Funds Set Aside

REMEMBER: Apply using the electronic application package for the FOA associated with your specific RFA, PA, or Parent Mechanism.

NCI Organizations Funding/Supporting Extramural Research

Division of Cancer Biology (DCB)

Division of Cancer Control and Population Sciences (DCCPS)

Division of Cancer Prevention (DCP)

Division of Cancer Treatment and Diagnosis (DCTD)

Center to Reduce Cancer Health Disparities (CRCHD)

Office of Cancer Complementary and Alternative Medicine (OCCAM)

Office of Technology and Industrial Relations (OTIR)

Division of Extramural Activities (DEA)

Center for Bioinformatics (CB)

Division of Cancer Biology, NCI

Mission:

- To ensure continuity and stability in basic cancer research
- To encourage and facilitate the emergence of new ideas, concepts, and technologies
- To promote a balance between the continued support of existing research areas and selective support of emerging research areas
- To provide guidance, advice, funding information and financial support to grantees and applicants
- To encourage the expansion of new research areas through sponsorship of initiatives and funding mechanisms

Cancer Initiation→ Progression → Metastasis

DCB Branches

Cancer Cell Biology (CCBB)
Cancer Etiology (CEB)
Cancer Immunology and Hematology/Oncology (CIHB)
DNA and Chromosome Aberrations (DCAB)
Tumor Biology and Metastasis Branch (TBMB)
Structural Biology and Molecular Applications (SBMAB)

DCB Programs and Consortia

Integrative Cancer Biology Program (ICBP)
Mouse Models of Human Cancers Consortium (MMHCC)
Tumor Microenvironment Network (TMEN)

The Tumor Microenvironment initiative focuses on expanding our understanding of the role of the tumor microenvironment in cancer initiation, progression and metastases. Through this initiative, NCI intends to generate a more comprehensive understanding of the composition of the stroma in normal tissues, with the goal of delineating the mechanisms of tumor-stromal interactions in human cancer.

Welcome To the Integrative Cancer Biology Program Website

The Integrative Cancer Biology Program (ICBP) focuses on the analysis of cancer as a complex biological system. A cornerstone of the program is the development and implementation of computational models of processes relevant to cancer prevention, diagnostics and therapeutics.

The DCB Home Page

http://dcb.nci.nih.gov/

The NCI Research and Funding Page

www.cancer.gov/funding

Trans-NIH Initiatives

- **Multiple initiatives on biomedical computational science and technology**
  - PAR-09-219 Exploratory Innovations in Biomedical Computational Science and Technology (R21) ;

    PAR-09-218 (R01); PAR-09-220 (SBIR [R43/R44])

    PAR-09-221 (STTR [R41/R42])
- RFA-GM-10-009 Title: Exceptional, Unconventional Research Enabling Knowledge Acceleration (EUREKA) (R01)
- PA-08-190 Research Supplements to Promote Diversity in Health-Related Research

Websites for researchers

Probes made by the Molecular Libraries program
http://mli.nih.gov/mli/

PubChem, a dataset of chemical structures and assay results
http://pubchem.ncbi.nlm.nih.gov/

A database of in vivo imaging agents (MICAD)
http://www.ncbi.nlm.nih.gov/bookshelf/corehtml/pmc/homepages/bookshelf/micad.html

PMAP, a database for analyzing proteolytic events and pathways
http://www.proteolysis.org/proteases

A database of systematic histone mutations & their associated phenotypes
http://www.histonehits.org

A human protein reference database
http://www.hprd.org

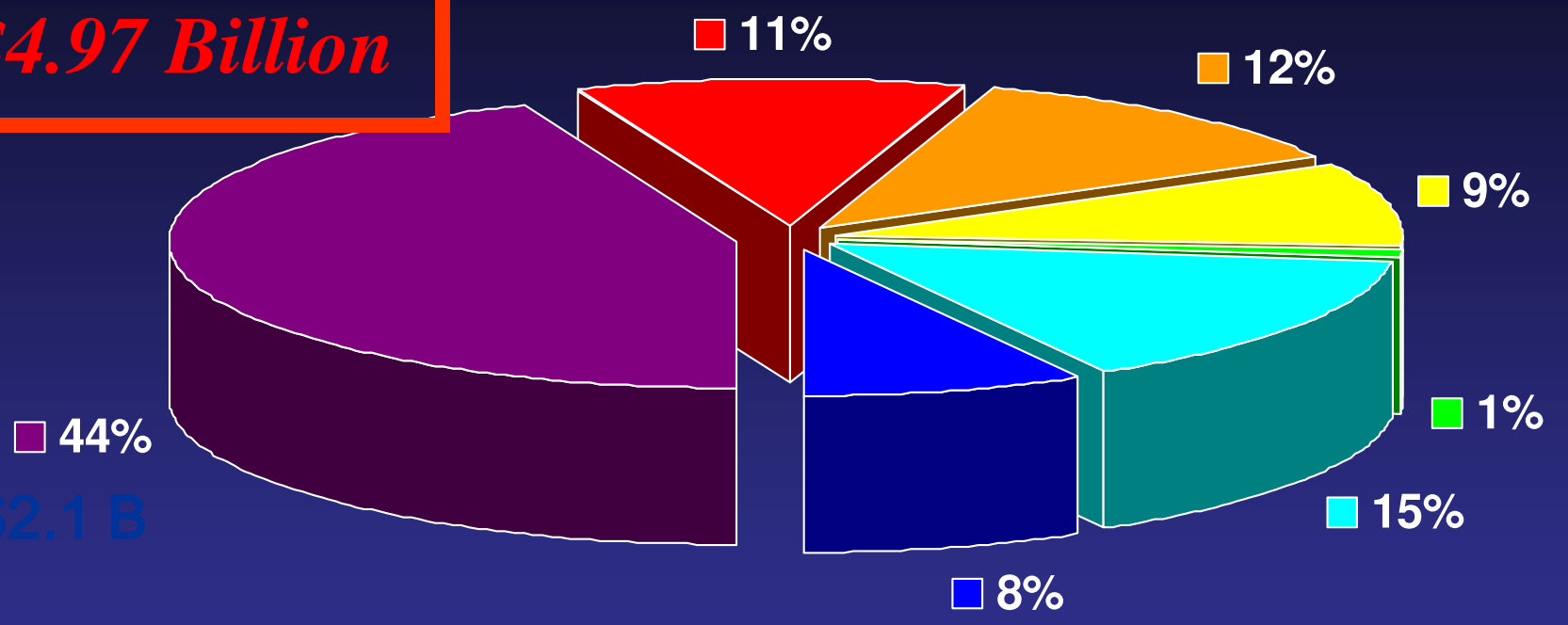
A community portal for sharing & integration of human protein data
http://www.humanproteinpedia.org

NCI Appropriation (in millions)

2005	$4,805
2006	$4,796
2007	$4,795
2008	$4,828
2009	$4,969

FY 2009 Appropriation for NCI:

$4.97 Billion



- Research Project Grants (44%)
- Research Centers (11%)
- R&D Contracts (12%)
- Other Research (9%)
- Training (1%)
- Intramural Research (15%)
- Research Mgmt & Support (8%)

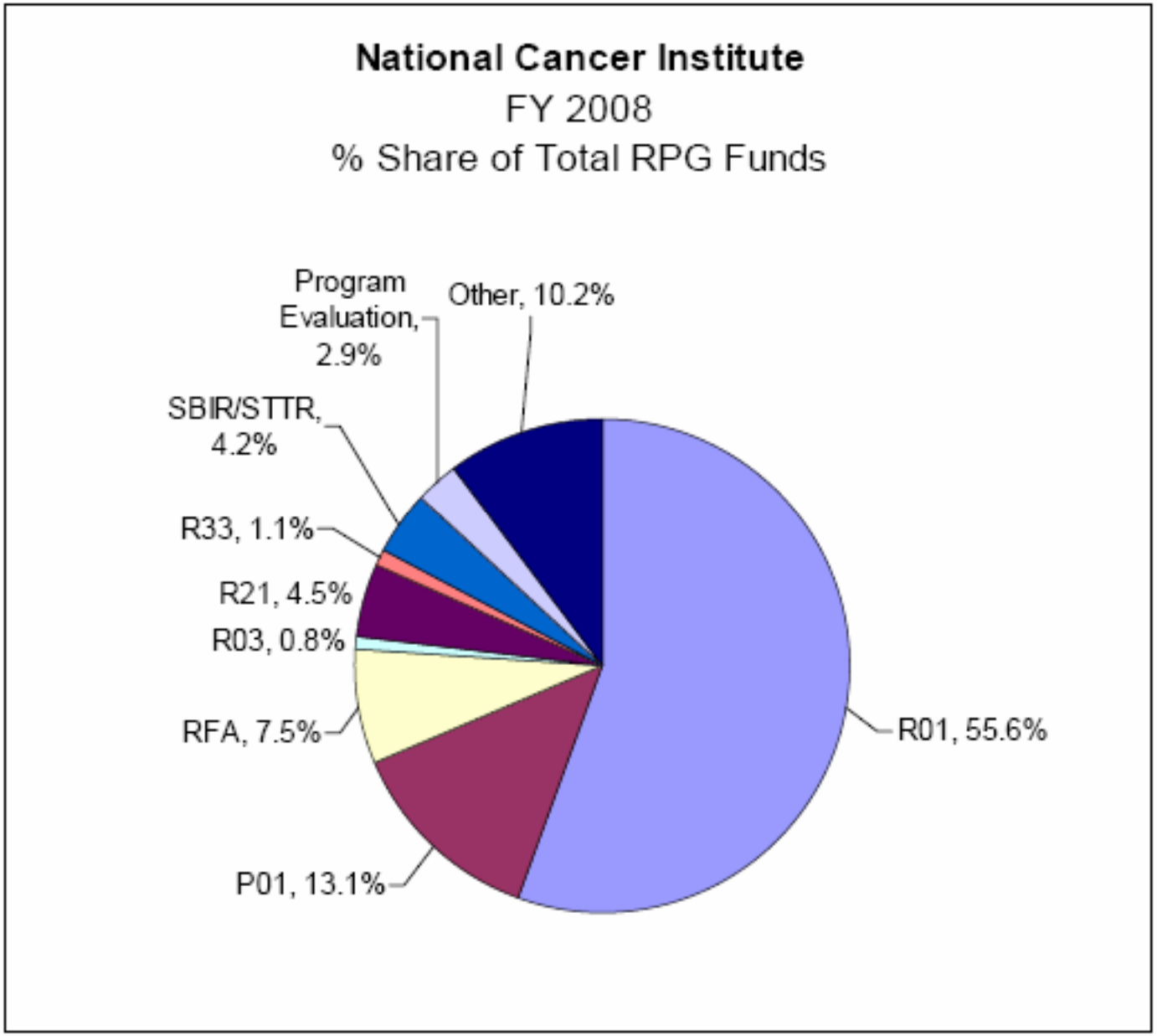
NCI Paylines

R01 & R21

NCI Paylines 2009-2010

Mechanism	Percentile/ priority score		
	ARRA(2009)	2009	2010
R01	16.1-25.0	16%	15%
*R01	22.1-25.0	22	20%
R21	16.2-25.0	16%	15%
R03	211-225ps	210	30
R15	176-200ps	175	25

* New Investigators and ESIs


National Cancer Institute
FY 2008
% Share of Total RPG Funds
Program Evaluation, 2.9%
Other, 10.2%
SBIR/STTR, 4.2%
R33, 1.1%
R21, 4.5%
R03, 0.8%
RFA, 7.5%
P01, 13.1%
R01, 55.6%

Review Outcome
New vs. Experienced PI

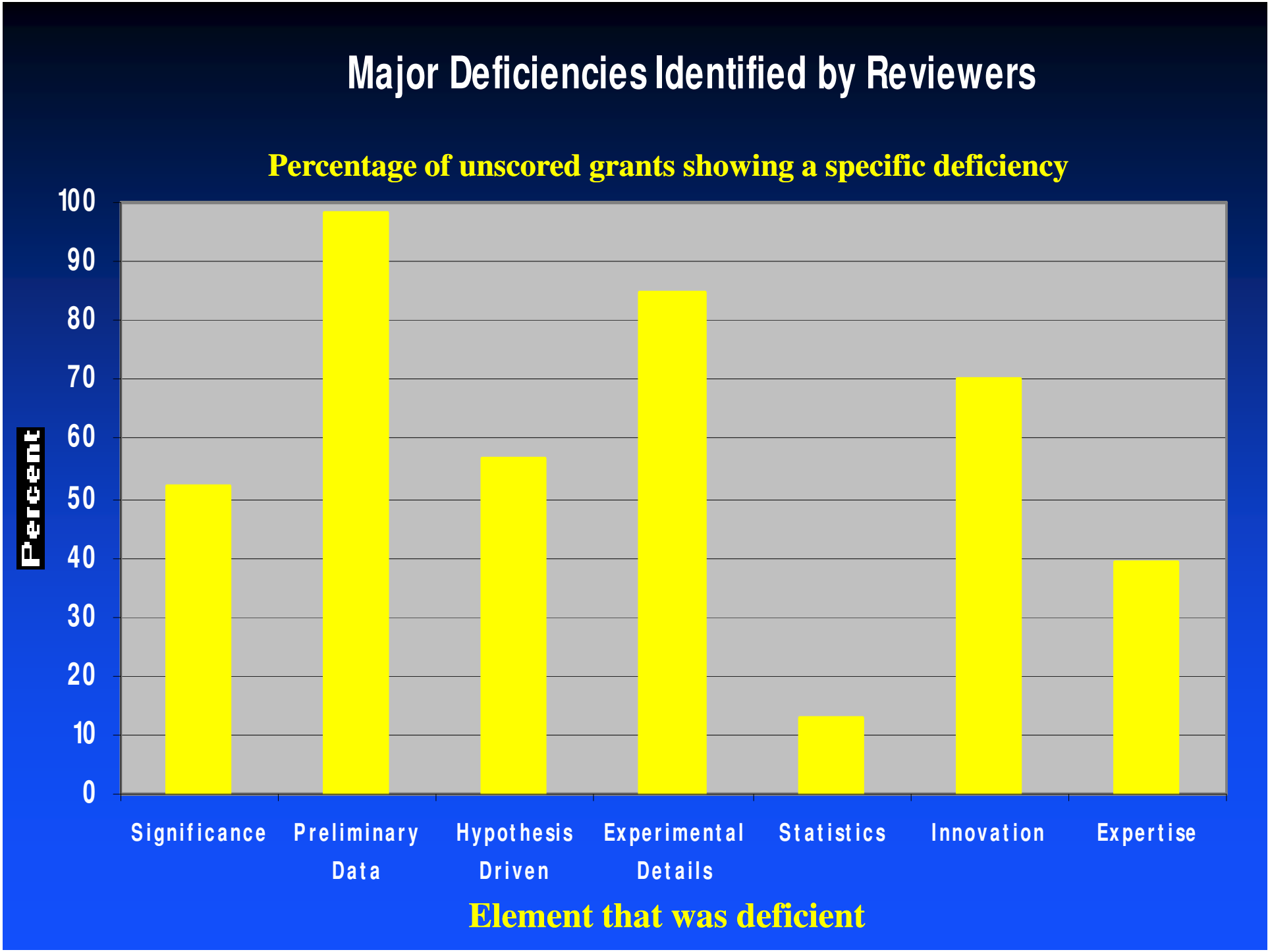
- New Application
  - No Difference
- Competing Renewal
  - Significant Difference

Summary Statement

Frequent Concerns

Based on 100 triaged summary statements

Major Deficiencies Identified by Reviewers



Significance

- Relevance to human cancers
- Will it advance the field?

Approach

- Is it hypothesis-driven?
- Do you have supportive preliminary data?
- How do you plan to verify your hypothesis?
- Do you have alternative strategies if the proposed plan does not work?

Approach: Keep it focused

- Be realistic about what you will be able to accomplish in the proposed time frame
- Present a timeline

Innovation

- Novel Reagents
- Novel Technology
- Conceptually Novel
- Change in paradigm

Environment

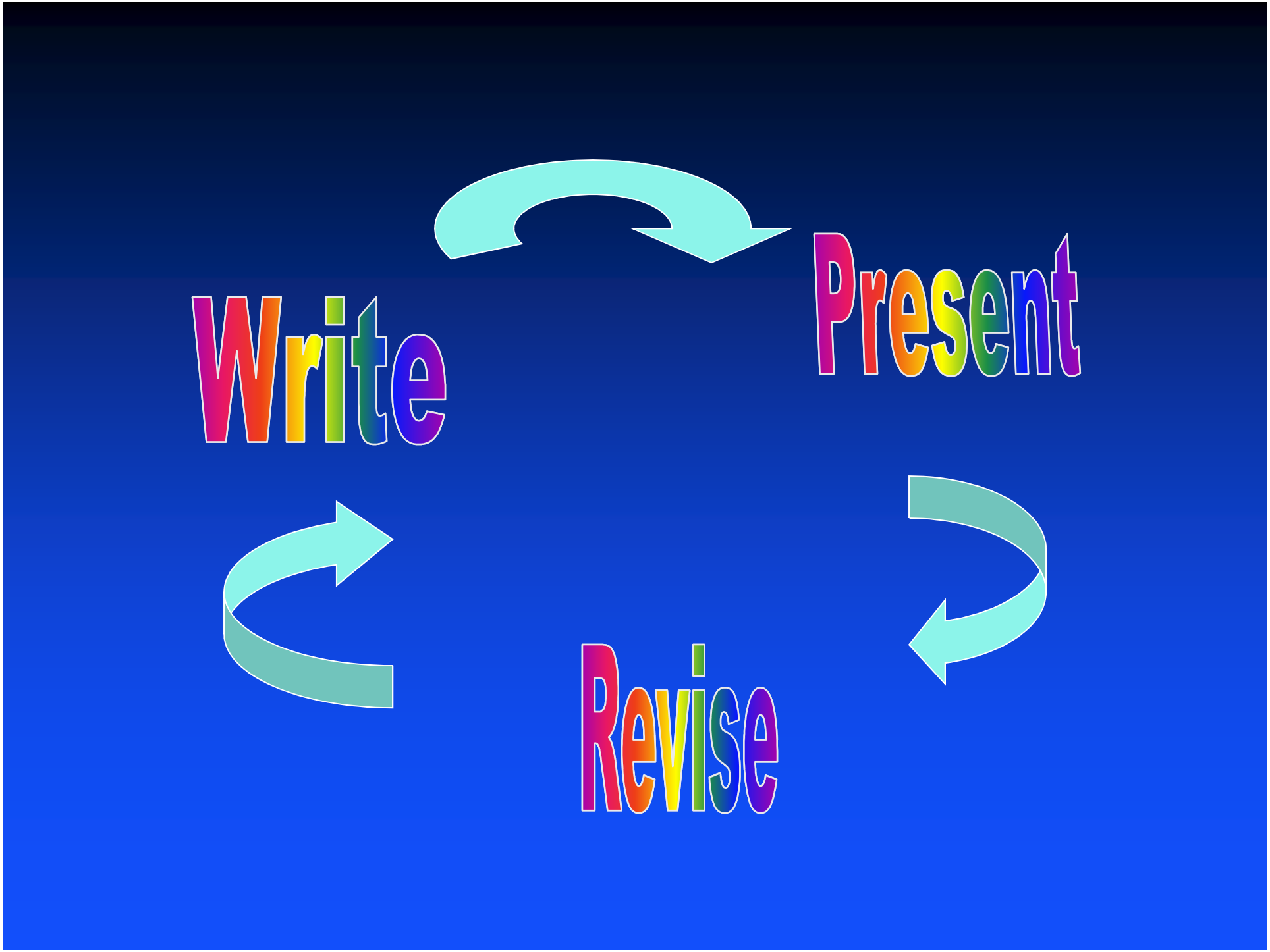
- Institution Support
- Leadership
- Collaborators
- Consultants
- Letters of support

Preliminary Data

- Feasibility Data
  - Technology available
  - Reagents/constructs available & characterized
  - Assays working in your lab
  - Models available

Good Grantsmanship
Reviewer Friendly Application

- Discuss Ideas Before Writing
- Get Feedback As You Write
- Use Easily Understood Illustrations
- Provide a Clear Message


Write
Present
Revise

Aim to succeed the first time!

Do not send in a grant prematurely – you will end up wasting time!!

- **Caution:** only one revision allowed

NCI-Funded Grants

- Cancer.gov
  - -Research Programs
    - ◆Research portfolio

FUNDING OPPORTUNITIES

Cancer.gov

Funding Opportunities

Program Announcements

NCI Initiatives

- **Etiology, Prevention, and Treatment of Hepatocellular Carcinoma**
  PA-08-243 (R01); PA-08-244 (R21); PAR-08-245 (P01)

- **Stem Cells and Cancer**
  PA-08-165 (R21)

- **Pilot studies in Pancreatic Cancer**
  PA-08-209 (R03); PA-08-208 (R21)

- **Collaborative Research in Integrative Cancer Biology and the Tumor Microenvironment**
  PAR-09-026 (U01)

- **Studies of Energy Balance and Cancer in Humans**
  PA-09-148 (R01) ; PA-09-149 (R21)

- **PAR-09-160 Exploratory/Developmental Grants Program for Basic Cancer Research in Cancer Health Disparities PAR-09-160 (R21)**

- **Diet, Epigenetic Events, and Cancer Prevention**
  PA-09-234 (R01); PA-09-235 (R21)

- **Many other R21s, SBIR (R43/R44) http://grants.nih.gov/grants/guide/index.html**

Role of Program Staff

- Planning and Writing Phase
- Submission – Self Referral
- (caveat – CSR and SRA determine the SS)
- Review - Quick Feedback
- Post Review – Options

NCI Staff Contacts

- Cancer.gov
  - Research Funding
    - Staff contact

NIH Resource Room
at the AACR meetings

Meet

- NCI Program and Review Staff
- CSR Review Staff

Discuss

- NCI Funding Opportunities
- Your Application/Summary Statement
- Potential Study sections