National Cancer Institute

Organization

1. EB / NCI / CTEP
2. Money
3. Grants
4. Walk-Through of PA
5. Grants Management
6. R Grants
7. Other Information
8. What I Tell my PIs
9. Contact Information

Personal Observation:

Harder to do than anticipated! (too much information)

Goal: give you overview & where to look

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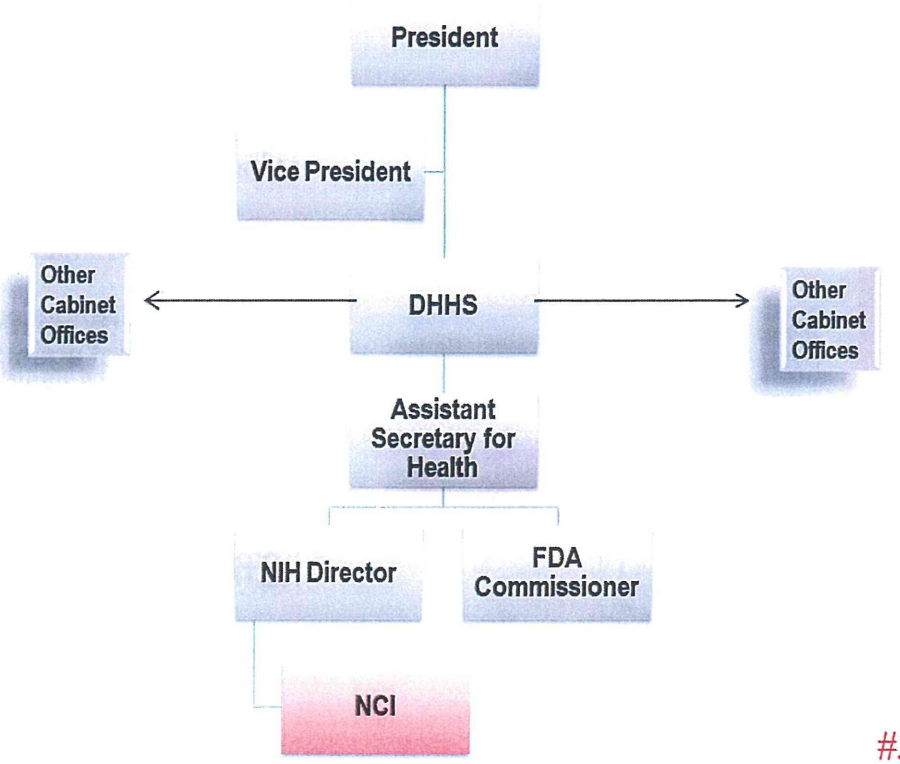
Executive Branch Organization



#54

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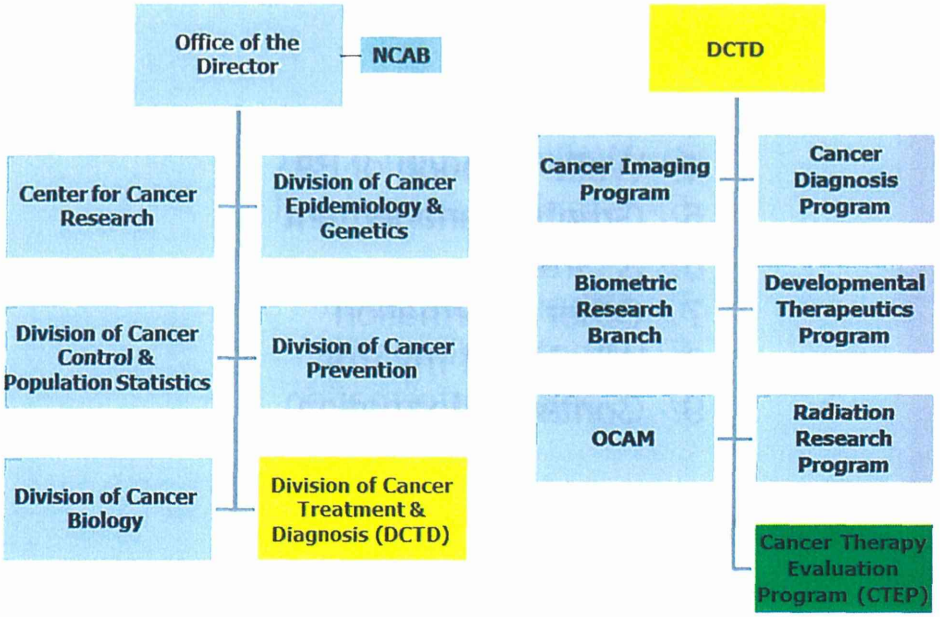
NCI Organization



#55

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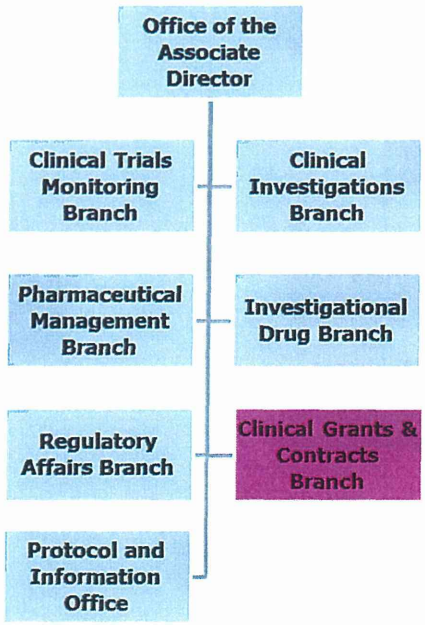
CTEP Organization



- sponsor clinical trials: review LOIs and protocols
- prepares / submits INDs
- coordinates distribution of investigational agents used in NCI-sponsored clinical trials
- program staff for grants portfolio (w/ clinical trial)
- program staff for ECTN and NCTN
- joint CTEP – FDA meeting

#56

Clinical Grants and Contracts Branch

- administrative and scientific management of two grant programs:
  - Clinical Oncology
  - Surgical Oncology
- pre-submission consults for R01s and P01s
- cooperative agreements: U01 for ABTC
- reviewers for outside organizations
- liaisons with outside organizations
- dissemination of grant-related information across CTEP

Dr. Roy S. Wu
Branch Chief

Program Directors

Dr. William Merritt
Dr. Min Song
Dr. William Timmer

Support Staff

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Investigational Drug Branch (IDB)

- Implements and oversees investigation drug program
- Collaborates with industry via P1 and PII studies
- Monitors clinical trials for S&E, AEs, *etc.*
- Annual report to FDA on oncology drugs
- ECTN

Section	Portfolios
Investigational Therapeutics I	Stem cell pathways; cell death; radiation sensitization; DNA-interactive agents; angiogenesis
Investigational Therapeutics II	PI3 kinase/AKT/mTOR; protein metabolism; cell cycle; microtubules; DNA repair; c-met
Investigational Therapeutics III	Ras/Raf/Mek/Erk; Her-targeted agents; cytokines; oncolytic viruses; epigenetic therapies; imids; cell therapies; monoclonal antibodies; vaccines; nuclear receptors

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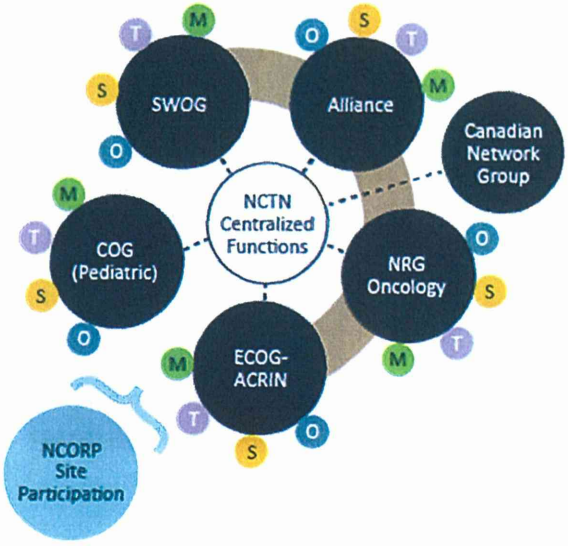
Clinical Investigations Branch (CIB)



- NCTN: coordination and oversight
- Steering Committees

LEGEND

- Centralized Functions:
  - Centralized Institutional Review Board
  - Cancer Trials Support Unit
  - Imaging and Radiation Oncology Core (IROC) Group
  - Common Data Management System Central Hosting
- 30 Lead Academic Participating Sites (LAPS)
- O Operations
- S Statistics & Data Management
- T Tumor Banks
- M Member Sites

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Money $$

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QUICK GUIDE FOR GRANT APPLICATIONS

Revised September 2010

INTRODUCTION

The guide is organized according to the major sections of the SF 424 (or PHS398) Grant Application Instructions. Each section is described, and a checklist is provided detailing what that section should cover. In addition, suggestions are included to enhance an application's success. The checklists are not exhaustive, but rather are designed to jog the application writer's memory and ensure completeness. This document in no way obviates the need for an inexperienced applicant to seek further advice from experienced colleagues or from appropriate NCI program personnel.

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Fiscal Year 2013 NCI Budget in Review

This section provides a brief summary of the distribution of the NCI Fiscal Year 2013 budget. Additional information on the NCI budget is accessible from the NCI Home Page (http://www.cancer.gov).

Summary

FY 2013 funds available to the NCI totaled $4.789 billion, reflecting a decrease of 5.5 percent, or $278 million from the previous fiscal year.

Fiscal highlights:

- Of the total NCI budget, 41.8 percent of the funds were allocated for Research Project Grants (RPGs).
- The total number of RPGs funded was 4,816 (including SBIR).
- Almost one-fourth of the RPGs awarded were new (Type 1) or competing renewal (Type 2) awards.
- NCI funded1,095 competing RPGs.
- Almost one-third of the total NCI budget supported ongoing, non-competing (Type 5) RPGs.
- R01 grants were funded to the 9th percentile.
- 159 grants – totaling over $71 million – were funded as Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) awards.
- Intramural Research comprised 17 percent of the total NCI budget. Of this amount, about 79 percent was for Labs and Bench Research and the remaining was for infrastructure and support.

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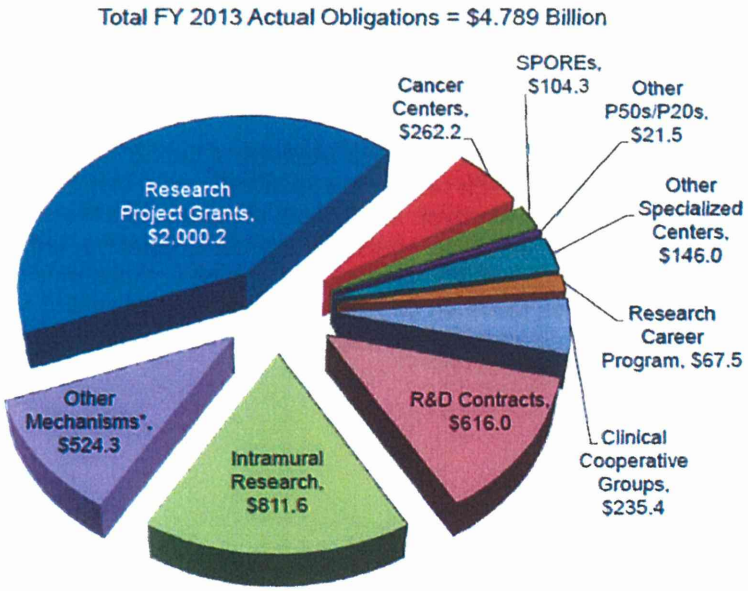
FY2013 Obligations by Mechanism

Dollars in Millions



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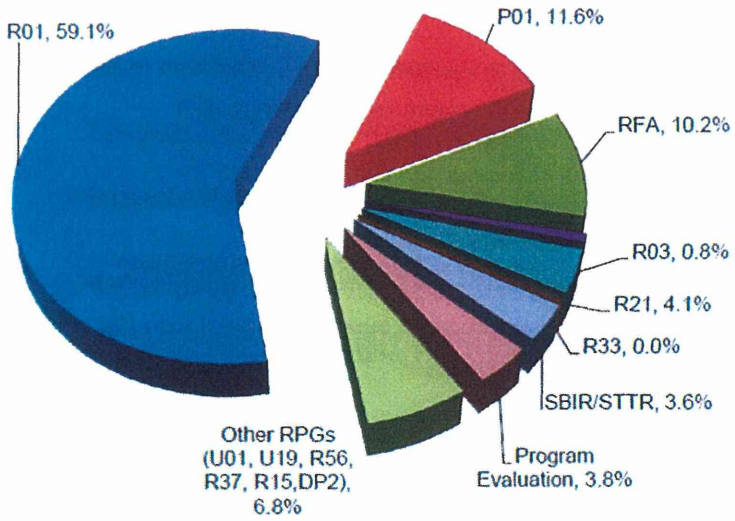
FY2013 Percent Share of Total RPG Funds



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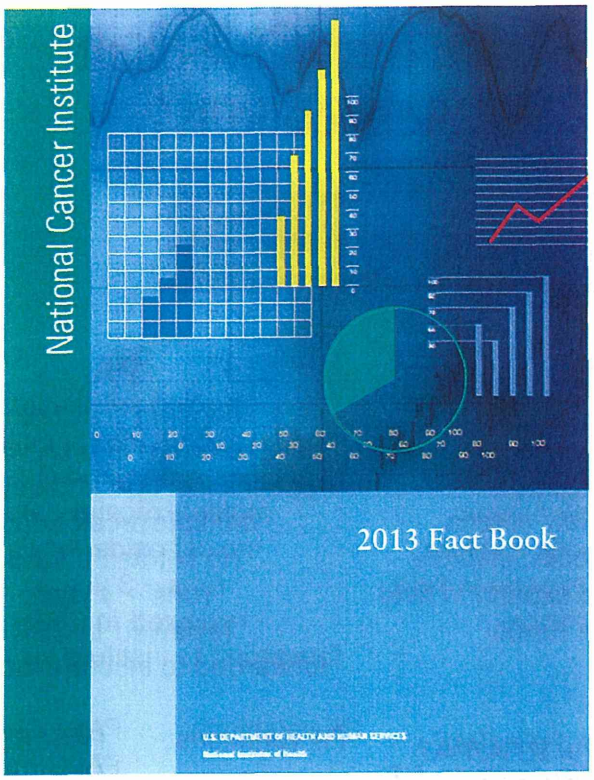
National Cancer Institute



NCI Factbook

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National Cancer Institute

Grants

#66

National Cancer Institute

How Does the NCI Solicit Grant Applications?

Request for Applications (RFA)
Program Announcement (PA)

RFA

one time request
defined research topic
one receipt date
includes review criteria
reviewed in specific institute
review committee experts in field
set-aside funds

PA

ongoing solicitation
build research in a specific area
specifies scope and objective
multiple receipt dates
no set-aside funds
runs ~ 3 years
reviewed in CSR
forwarded to institute for funding

WHO CAN WRITE A RFA/PA?
ANY ORGANIZATION; B/C DEFINES $$ AND OBJECTIVES OF PGM

PA variations: PAS: $$
PAR: institute review

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How does a Grant get Submitted?

via *Grants.gov*: the Federal government's online portal for any person, business, or State, Local and Tribal government to electronically:

1. find grant opportunities
2. apply for grants

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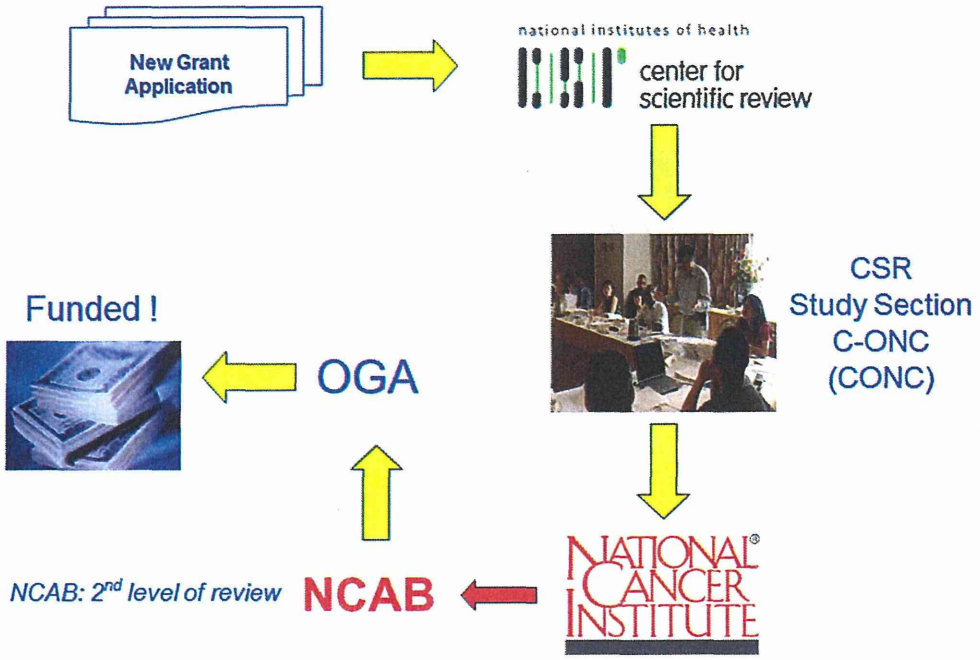
How Does a Grant get Funded?



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Paylines and Funding

0th to 9th Percentile

virtually all funded

10th to 15th Percentile Process

"zone of uncertainty"

Funding decisions: *"… grants that fill a gap in the portfolio or propose an novel or promising approach to an important problem."*

Internal CTEP review (may include BRB if stat issues in SS)

PD: one-page overview of grant.

Discussed, rank-ordered, and sent to SPL for final decision.

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What is the NIH Funding?

NIH Research Portfolio Online Reporting Tools (*RePORT*)

http://projectreporter.nih.gov/reporter.cfm

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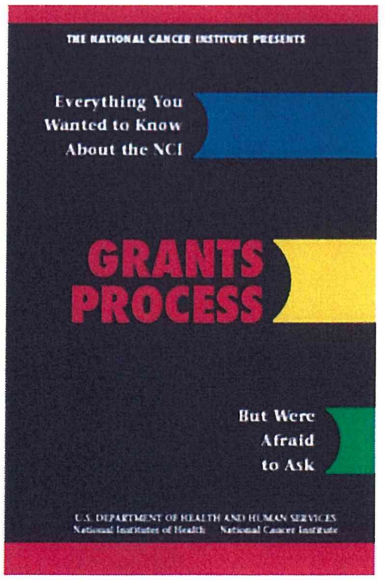
NCI Grants Process Book

www.cancer.gov/aboutnci/organization/oga/grants_process_book.pdf



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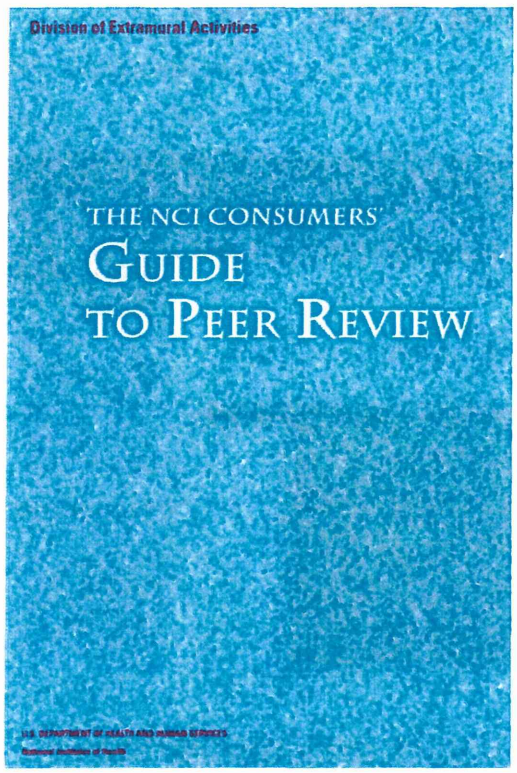

Published by NCI DEA

responsible for reviewing
NCI grants
(RFAs and P01s)

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Walk Through:

PA 13-302: Research Project Grant (Parent R01)

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A Good Place to Start (OER)

http://grants.nih.gov/grants/grantbasics.htm

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Review and Award Cycles

Office of Extramural Research: ***grants.nih.gov/grants/oer.htm***

	Cycle I	Cycle II	Cycle III
New R01 R01 resubmission	Feb 5th March 5th	June 5th July 5th	October 5th November 5th
Scientific Merit Review	June - July	October - November	February - March
NCAB	September - October	January - February	May - June
Earliest Start Date	October	April	July

Basically: submit grant: wait 4-5 mo for review,
wait 4-5 mo for NCAB,
wait 2-3 mo for NGA letter.

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Grants Management

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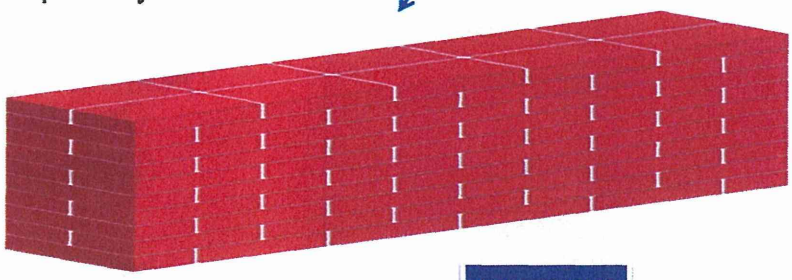
Program versus Review

SRO / SRA

sets up Study Sections

"wall of impartiality"



PD / PO

PI's contact for all grant questions and for discussion of Summary Statement

Best grant pre-submission tip: contact your PD

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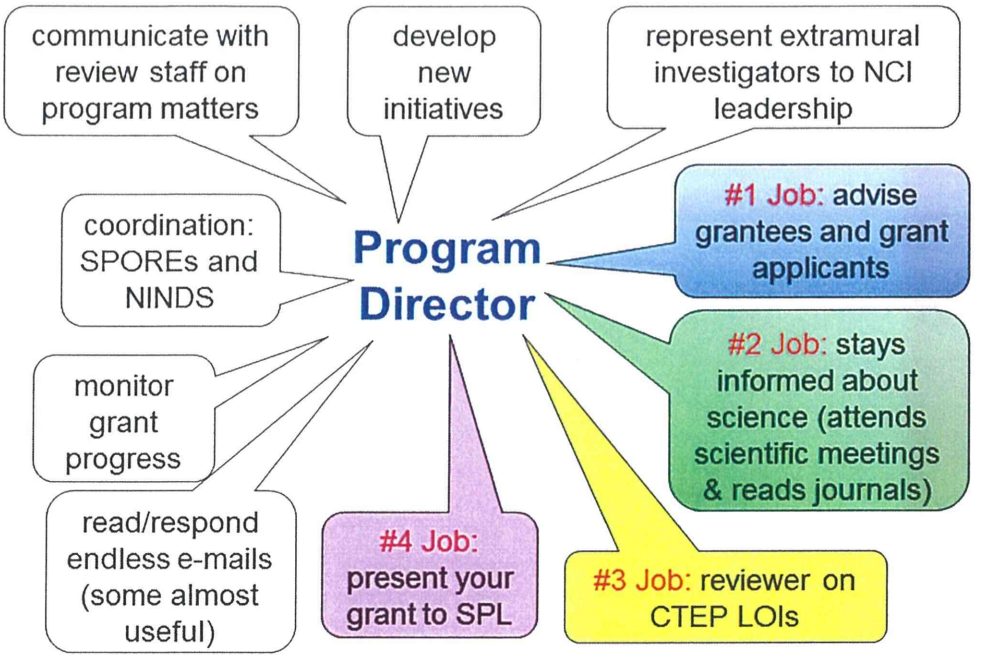
Role of the Program Director



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My (CTEP) Grants Portfolio

Primary Solid Tumors

Head & Neck, Lung, Liver, CRC, Sarcoma, Pancreatic

Lower Incidence Cancers

thyroid, gastric, NB, Rb, skeletal, ACC

Brain Portfolio

RPG Grants

Adult Brain Tumor Consortium (UM1 Grant)

Only grants with a clinical trial

Q: How do I keep up w/ science: meetings and readings

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Other CTEP PDs Grant Portfolio

Hematologic Malignancies	Gynecologic Cancers
Leukemia / Lymphoma	Breast
MM / MDS	Kidney
Stem cell transplantation	Melanoma
Myeloproliferative diseases	Pharmacogenomics
BMT Consortium	GU / Skin
CITN Consortium	
William Merritt, Ph.D.	Min Song, Ph.D.

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R-01 Post Award Tips

- PD and PI Interaction Continues
  - PD is available for consultation on administrative and scientific grant issues.
  - PD reviews yearly grant progress via RPPR (CT enrollment; listing in *clinicaltrials.gov* progress on aims; PubMed compliance)
- NCE: 1st year: automatic
  2nd year: justification required.

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R Grants

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Grant Nomenclature

- Grant type:
  - type 1: competing: new grant – first year
  - type 5: continuing: out years (year 2, 3, 4 etc)
  - type 2: renewal: competing (type 1) up for renewal
- Numbering: 1 CA 123456 – 01 A1
  type: institute: serial number: original / resubmission
- Budget:

  up to $500,000 / year direct cost
  modular: $25,000 / module; 10 modules max / year

  direct versus indirect costs

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"R" Grants

- R01: Investigator – Initiated
- R21: Small Grants

  PAR12-145: NCI Omnibus R21 $275,000 DC total

  PAR12-144: NCI Omnibus R03 $100,000 DC total

  reviewed in NCI and not CSR

  PA10-071: Conference Grants R13 $5000

- P01: Program Project Grants – Senior PIs

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Organization of the R01

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Revised September 2010

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#86

PROJECT SUMMARY/ABSTRACT Project Summary: The purpose of the Project Summary/Abstract is to describe succinctly every major aspect of the proposed project. It should contain a statement of objectives and methods to be employed. Members of the Study Section who are not primary reviewers may rely heavily on the abstract to understand your application. Consider the significance and innovation of the research proposed when preparing the Project Summary.

The Project Summary must be no longer than 30 lines of text, and follow the required font and margin specifications.

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RESEARCH PLAN (Overview)

Purpose: NIH has restructured the applications by aligning the structure and content with review criteria. This alignment will help ensure that both reviewer and applicant expectations coincide for a more efficient and transparent application process.

The Research Strategy/Plan is now organized into three sections: Significance, Innovation, and Approach. The assessment of this research plan will largely determine whether or not the application is favorably recommended for funding.

R01 format is a maximum of 12 pages

#88

RESEARCH PLAN PART 1: Specific Aims Purpose: The purpose of the specific aims is to describe concisely and realistically the goals of the proposed research and summarize the expected outcome(s), including the impact of the proposed research will exert on the research fields involved. **Recommended Length**: one page. **Content**: The specific aims should cover:

- broad, long-term goals;
- the specific objectives and hypotheses to be tested;
- summarize expected outcomes; and
- describe impact on the research field.

#89

RESEARCH PLAN PART 2: Significance Purpose: The Significance section should explain the importance of the problem or describe the critical barrier to progress in the field that is being addressed. Explain how the proposed research project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields. Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved. **Recommended Length**: Approximately 1-2 pages

#90

RESEARCH PLAN PART 3: Innovation Purpose: Explain how the application challenges and seeks to shift current research or clinical practice paradigms. Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions. Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

Recommended Length: The recommended length of the innovation section is 1/2-1 page.

#91

RESEARCH PLAN PART 4: Approach Purpose: The purpose of the approach section is to describe how the research will be carried out. This section is crucial to how favorably an application is reviewed. **Recommended Length**: The maximum recommended length of the approach section is 9-10 pages.

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