National Cancer Institute

A Useful Reference?

The NIH R01 Tool Kit

Science Careers Editors
27 July 2007

Editor's note: In September 2001, Science's Next Wave published "Getting an NIH R01," which became the most frequently accessed Next Wave article for several years after. Since 2001, the National Institutes of Health has made many changes to its programs, including, notably, a transition to electronic applications. Meanwhile, we've continued to learn more about the process and how to make it work to your advantage. Science *Careers (Science's Next Wave's successor) reworked the article in July 2007 to reflect the changes at NIH and our new insights. As noted in the original text, we will continue to update the article periodically as conditions change.*

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Other Information

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NIAID R01s

Includes 4 outstanding R01s and their respective Summary Statements (by permission of PIs)

http://www.niaid.nih.gov/researchfunding/grant/pages/appsamples.aspx#rpindex

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Program Director/Principal Investigator (Last, First, Middle):

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title:

Total Planned Enrollment:

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Females**	**Males**	**Total**
Hispanic or Latino			
Not Hispanic or Latino			
Ethnic Category: Total of All Subjects *			
Racial Categories			
American Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			
White			
Racial Categories: Total of All Subjects *			

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

for a R01 with a clinical trial

PHS 398/2590 (Rev. 06/09) Page ___ Targeted/Planned Enrollment Table Format Page

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Other Places to Check

- Office of Human Research Protections (OHRP)

  http://www.hhs.gov/ohrp/news/distributionlist.html

- Office of Laboratory Animal Welfare (OLAW)

  http://grants2.nih.gov/grants/olaw/references/list.htm

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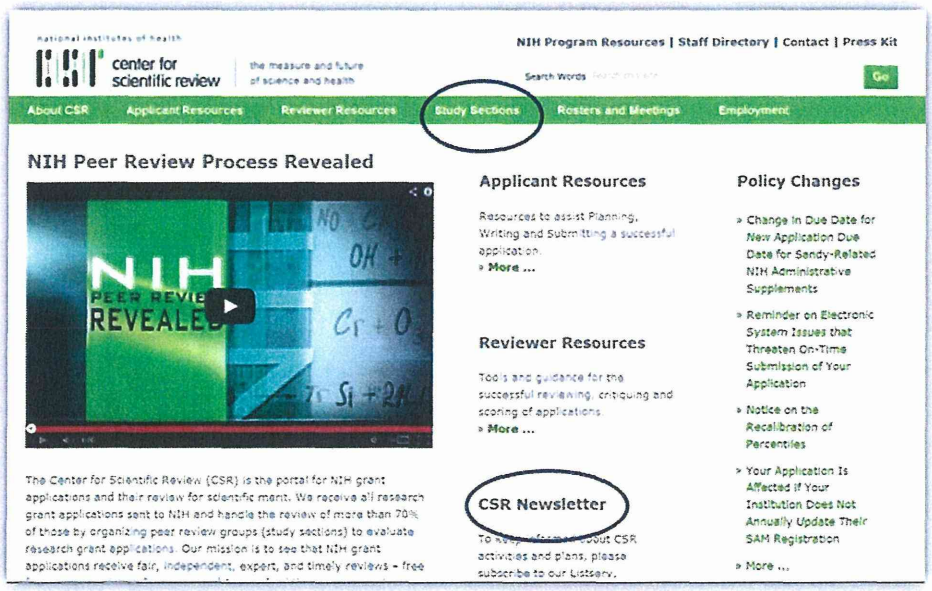
Center for Scientific Review



Grants are reviewed in SS in CSR: ***www.csr.nih.gov***
Always check roster; these people will be reviewing your grant.

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What I Tell my PIs

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R01 Grants

General

no specific PA for R01 with clinical trial

R01s may be submitted for 3, 4, or 5 years

pre-clinical plus clinical trial in same grant

modular budge to $ 250 K / yr (max $ 500 K w/ approval)

Research Strategy: 12 pages

New Investigator on shorter R01s

3 yr proposal

Aim 1: clinical trial
Aim 2: correlatives

caveat: need appropriate supporting data

5 yr proposal

Aim 1: pre-clinical studies
Aim 2: clinical trial
Aim 3: correlatives

caveat: need some pre-clinical data; can't get all in grant (*i.e., all animals died, now what?*)

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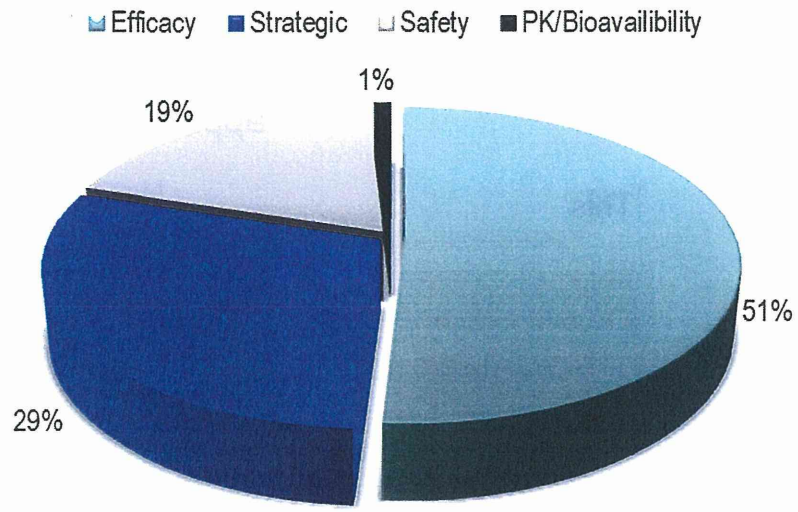
Causes of Phase II Trial Failures



2008-2010 Overall Phase II Success Rate: 18%

Nature Rev. Drug Disc. 10,1(2011)

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Specific Aims Page

- The most critical page in the application
  (i.e., what page do you turn to first?)
- It is a one page summary of the application
  - Why is this problem significant?
  - What is the exciting preliminary data?
  - What are the hypothesis supported by the data?
  - How will this project significantly impact the field?
  - Make sure to emphasize important points that you absolutely want the review to know
  - Make the reviewers want to keep reading
- A simple list of your Aims is good
  - Be general
  - Avoid long list of things you are going to do

This page is really the [initial] marketing of your grant.

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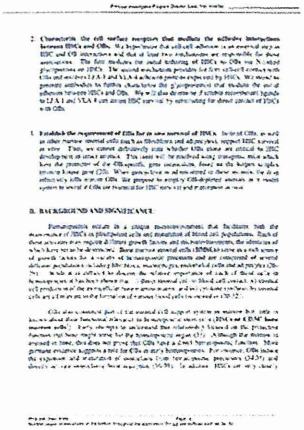
R01 Submission Tip

Consider the reviewers: submit a well-written application

This:



Not this:

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R01 Submission Tip

- include enough detail to show you can do the work
- acknowledge competing hypotheses
- know peer-review criteria:

40%
investigator
prelim data; CV
environment
space; collaborators

60%
approach
will it work?
significance
impact on field
innovation
rationale; perspective

impact v significance

impact: probability to exert a sustained powerful influence
significance: does it address an important problem in the field

can have high significance but low impact

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R01 Submission Tip

- Notify your administrators early; multiple layers of institutional approval
- Finish science 8 weeks before submitting
- Give grant to senior PI to review
- Once written, do not read your grant for two weeks; then review and critique it
- Make sure references are correct and hyperlinked
- Involve a biostatistician early in the process (to be repeated)
- Give statistical section(s) to senior biostatistician to review

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Submission Tip: Resubmissions

Don't give up! Initial failure is common.

- Study criticisms in SS:
  - decide if problems are repairable
  - carefully address each criticism
  - keep a positive tone and attitude
  - thank the SS: *"We thank the reviewers for their critical comments and …"*
  - emphasize interim progress
  - request new or same reviewers? *(normally, SS assigns same reviewers)*

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Submission Tip: Clinical Trial R01

- advantage of a CT: binary output: Y / N
- bad trial design is "*coup de grâce*" for CT R-01

  (SS has biostat reviewer)
- same for correlatives
- put *Clinical Protocol* in *Human Subjects* section (no pg limit)
- always state what you will do next with your results
- no Phase III trials in grants

Problem Areas:

- have a testable hypothesis with a suitable timeline; include milestones
- have sufficient preliminary data
- aim 2 follows aim 1 *etc*
- alternative plan(s)?
- appropriate selection and documentation of study population

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R01 Submission Tip

- Always have:

  "The hypothesis of this study is …"

- If you are proposing a 3 year R01, consider saying:

  "This is a preliminary (or limited, or pilot) study [involving a clinical trial]"

  -- right up front --

- Use *LikeThis* tool in eRA Commons to see what your colleagues are studying
- Use your mentor; discuss potential ideas / projects
- If you are a *New Investigator*: consider putting senior PI on grant as mentor; favorably viewed by SS.

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Submission Tip: Resubmissions

- New "A0 Policy": resubmit A1 as new grant

  (but of course fix it up)

***My rule**: You owe it to yourself to re-submit*

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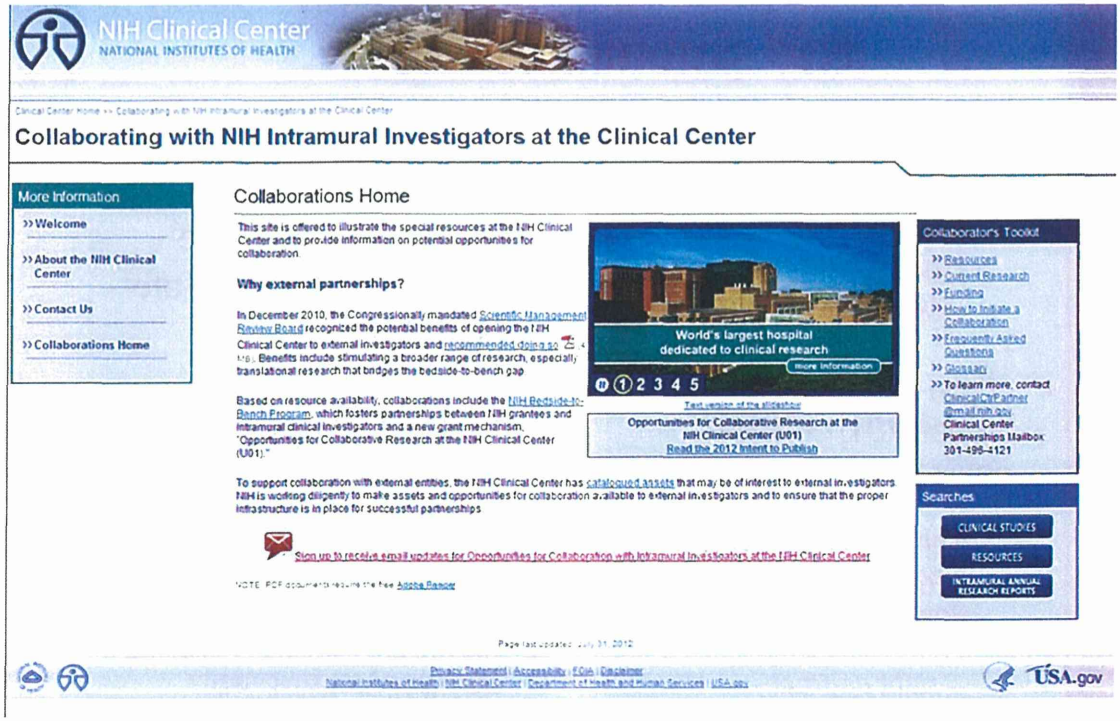

www.cc.nih.gov/translational-research-resources/index.html

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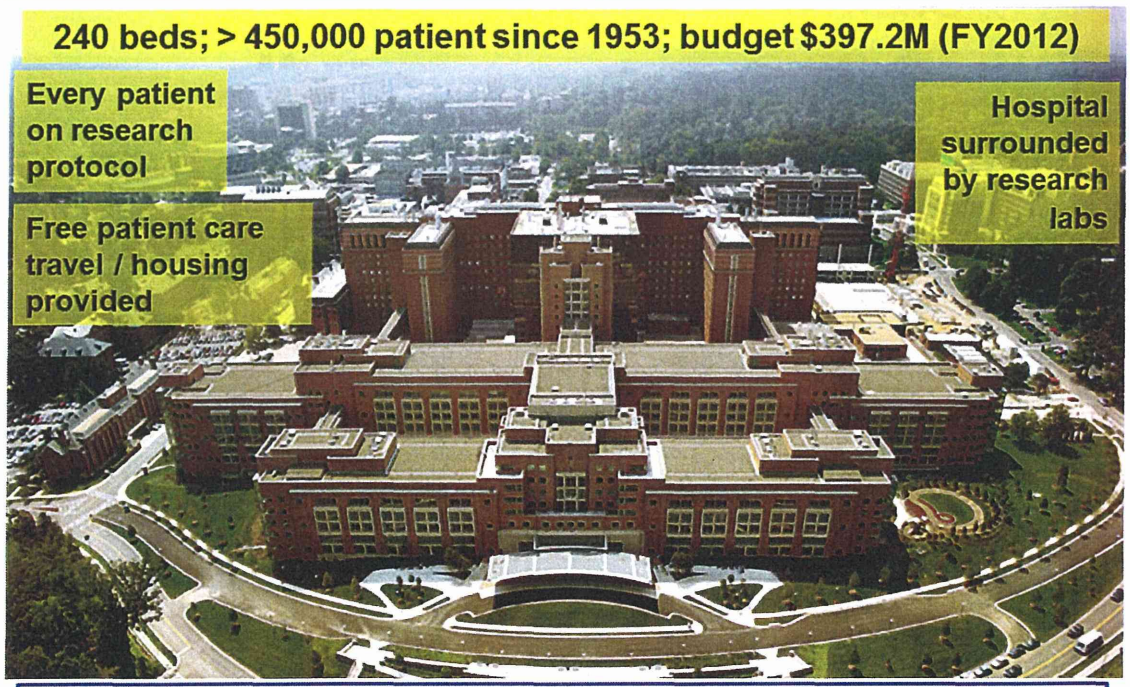
NIH Building 10 Clinical Center (NCI CCR)



2,250 CC employees; 17 Institutes / Centers that use hospital
1,255 credentialed physicians > 1,400 active protocols

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Questions?

"We'd now like to open the floor to shorter speeches disguised as questions."

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Contact Information

"We just made a big cancer breakthrough; have a cigar."

William C. Timmer, Ph.D.

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Bethesda, MD 20892

240-276-6130

william.timmer@nih.gov

#113

The Role of a Program Director

NCI Division of Cancer Biology New Grantee Workshop
October 18-19, 2010

Jerry Li, MD, PhD
Division of Cancer Biology
NCI/NIH

#114-124 のスライドは帰国後の質問に応えて、4/3/2015 に Dr. Timmer より御提供いただいた。

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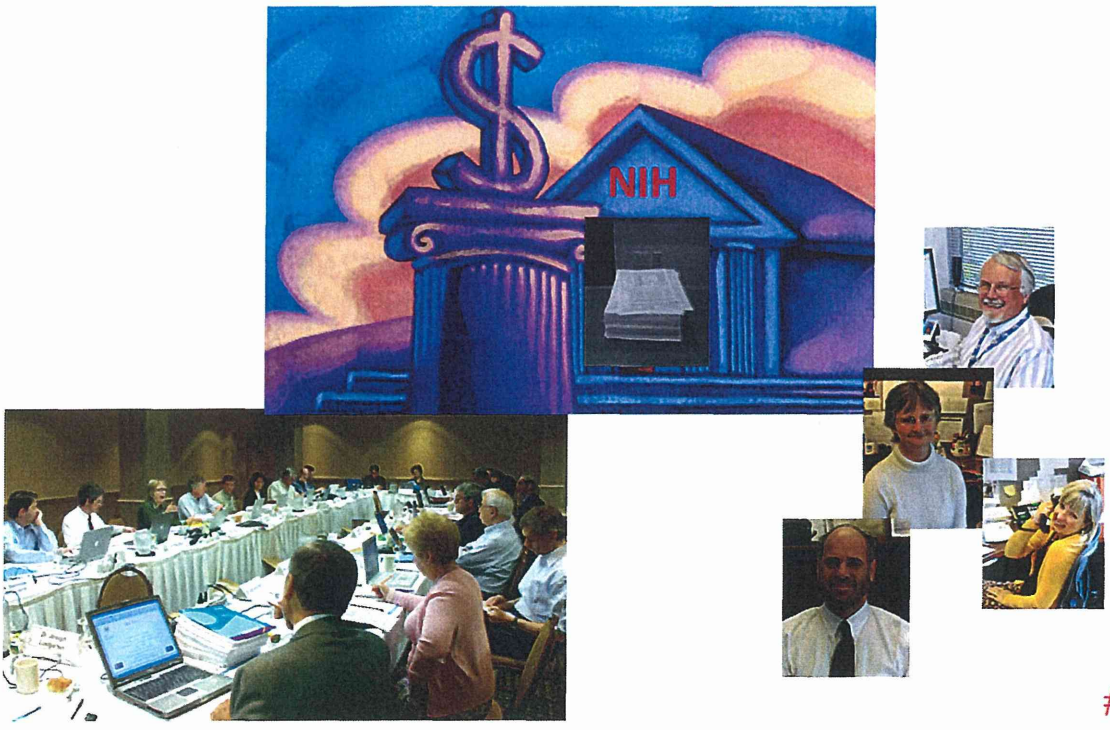
Who makes the funding decision?



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What is a Program Director?

"The NIH official responsible for the programmatic, scientific, and/or technical aspects of a grant"

-from the NIH Program Administrators' Handbook

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What are the key responsibilities?

- **Serve as a liaison between the scientific community and the NIH Institute**
- **Serve as a steward of federal funds**

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What do program directors do?

I. Grants Administration (pre-award)

- Advise scientists on grant applications
- Attend study section reviews
- Advise applicants on summary statements and resubmissions
- Manage appeals
- Make funding recommendations to Council and Institute upper management if needed
- Give presentations at Council meetings and senior staff meetings if needed
- Resolve issues on scientific overlap, budget, human/animal subjects and other IRG concerns, foreign applications/foreign components
- Work with grants management specialists on making awards

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What do program directors do?

I. Grants Administration (post-award)

- Monitor progress of research grants
- Enforce compliance of regulations, policies, special terms of the award
- Report major advances to NIH
- Review annual progress report and authorize non-competitive renewal
- Contact point for requests of administrative supplement funding
- Advise on renewal applications (10% budget increase cap for NCI)
- Serve on steering committees of cooperative agreement awards if needed
- Coordinate interactions of research grants/contracts/cooperative agreements

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What do program directors do?

II. Programmatic Development (New Initiatives)

- Maintain broad knowledge of science and technology in the areas of grant portfolio
- Attend scientific meetings/conferences
- Organize workshops on specific topics
- Identify gaps/needs/opportunities in the research field
- Determine appropriate grant mechanism(s) to achieve goals
- Draft RFA, RFP, PA

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How can program directors help you?

- **Pre-application**
  - Suggest the right institute/program/grant mechanism
  - Suggest study sections with the right expertise
  - Answer general questions about NIH policies, procedures
  - Coordinate prior approval for large budget requests (> $500k DC/year) and conference grants
- **Application submitted – peer review**
  - Contact Scientific Review Officers

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How can program directors help you?

- Post-review
  - Help interpret written critiques
  - Advise on resubmission
  - Provide feedback from the program's perspective
  - Negotiate reduction of scope (Specific Aims)

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How can program directors help you?

- Post-award
  - Nominate exceptional grantees for various awards
    - Presidential Early Career Awards for Scientists and Engineers (PECASE)
    - Method to Extend Research in Time (MERIT) Awards
      (Contact PD for exciting new discoveries/progress/publications)
  - Approve key personnel changes, large budget carryovers
    (Submit annual progress report on time, 6-8 weeks before anniversary)
  - Approve change of institution (contact PD asap)
  - Approve second no-cost extension
  - Discuss opportunities of administrative supplement funding
    - DCB APRC https://dcb.nci.nih.gov/News/Pages/DCBAPRCFY10.aspx
    - Diversity supplement http://grants.nih.gov/grants/guide/pa-files/PA-08-190.Html
  - Approve final report

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DCB Division of Cancer Biology

Search GO

Home | Branches | Programs | Funded Research | Funding Opportunities | Grant and Policy Information | Research Resources | News and Reports | About Us

Funding Opportunities

- DCB Program Announcements (PAs, PARs, PAS)
- DCB Requests for Applications (RFAs)
- DCB NIH Guide Notices
- DCB - Applications to Promote Research Collaboration Program
- NCI - Funding Opportunities
- The NIH Common Fund / Roadmap
- NIH Guide for Grants and Contracts
- General Information About Funding Opportunities

NCI News Releases

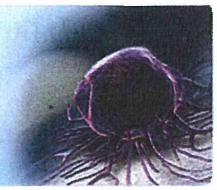
- News Note: A new dual vaccine for protection against both smallpox and anthrax
- Addition of immunotherapy boosts pediatric cancer survival:Children with neuroblastoma see improved outcome when immunotherapy is added to standard therapy
- The impact of HPV vaccines and screening tests on cervical cancer prevention: A National Cancer Institute Science Writers' Seminar
- Studies on combat related substance use and abuse to be funded by NIH and VA
- New breast cancer committee to establish federal research agenda

Division of Cancer Biology

Office of the Director

Integrates the activities of the component Branches and programs by establishing priorities, allocating resources, and evaluating program effectiveness with the advice of the NCI Board of Scientific Advisors, the National Cancer Advisory Board, and other advisory committees.

Prev | || | Next



The Division of Cancer Biology (DCB) supports and coordinates research projects in basic cancer biology at universities, hospitals, research foundations, and businesses across the United States and abroad. As part of the National Cancer Institute, the Federal Government's principal agency for cancer research and training, DCB provides funding for research that investigates the basic biology behind all occurrences of cancer. While not often discussed at a Doctor's office or in a patient setting, this research reveals the minute details of what happens biologically when cancer forms or does not form, when cancer cells are drug resistant or they respond positively to a new therapy, and when cancer spreads or a patient goes into remission. Basic cancer biology provides the building blocks to new treatments, clinical trials and improved understanding of the disease. Without the study of cancer biology, much of the progress made over the years in the search for a cure for cancer may never have occurred.

In pursuit of the advancement of this crucial field, the mission of the DCB is to ensure continuity and stability in basic cancer research while encouraging and facilitating the emergence of new ideas, concepts, and technologies. The grants that are funded each year investigate biological aspects of every form of cancer, from targeted, long-running studies that are revealing the microscopic details of cell processes, to high-risk yet scientifically sound, innovative research approaches that hold great promise for providing key insights into tumor development. The Division also supports think-tanks and other meetings aimed at identifying crucial research areas that need additional funding, and works to expand new research areas by sponsoring a range of funding mechanisms and initiatives designed to enable research in the most promising areas.

The six branches and 3 major NCI programs managed by the Division seek to advance basic cancer research through investigator-initiated research projects and programs. The scientific discoveries from this research base are critical to the NCI and the future of cancer research since they form the scientific foundation on which strategies for

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VII. 事前に準備していた質問事項

2/28/2015 版（3/3/2015 に NCI 側に送付）

Major Question Points

1. How does NCI operate PDCA (Plan-Do-Check-Act) cycle in the NCI-funded research?
2. What is the role of PD (Program Director), PO (if any) and SRA (Scientific Review Administrator)?

...according to the following categories:

A) Pre-award (e.g. fund allocation strategy among various research fields and cancer sites, research theme settings, review and selection) vs. post-award (project management, report and evaluation)

B) Intra- vs. extra-mural research

C) Basic/ exploratory vs. clinical research

*It may be difficult to run the PDCA cycle for the exploratory, creative studies, which are often found in the basic research. Does the NCI/Division change the way they run PDCA depending on the characteristics of research fields such as basic research, translational research and clinical trial?

D) Bottom-up vs. top-down (project or contract-type) research

Factual data

1 Portfolio of research projects and studies funded by NCI
http://fundedresearch.cancer.gov/nciportfolio/about.jsp
http://www.cancer.gov/cancertopics/factsheet/NCI/research-funding

2 About Program director (PD)/ Program officer (PO, if any)/ Scientific Review Administrator (SRA)

2.1 Number

2.2 Background

2.3 Selection and evaluation processes

3 About PD/PO/SRA supporting staffs

3.1 Number

3.2 Background

4 About National Cancer Advisory Board

4.1 Relationships with PD and SRA
http://deainfo.nci.nih.gov/advisory/ncab/ncab.htm

2/15/2015 版

I) Overall points (intra- and extra-mural research)

1 Pre-award

1.1 How does NCI decide the funding proportion of bottom-up (investigator-proposed) and top-down (project-type) research?

1.2 How does NCI decide the relative proportion of funding among different research fields, such as the 7 categories of CSO (https://www.icrpartnership.org/cso.cfm)?

1.3 How does NCI apply PDCA cycle for the above decisions 1.1 and 1.2?

2 Post-award

2.1 How does NCI apply PDCA cycle for each individual study?

II) Specific points

1 Is it correct to understand that RFA (Request for Application) corresponds to the top-down (project-type) grant?

1.1 How much proportion of the NCI grant is allocated to RFA? What is the future prospect of RFA? Do you think that role of RFA increases, decreases or stays essentially as it is?

1.2 Who can propose RFA? PD or PD plus recommendation by National Cancer Advisory Board?
http://deainfo.nci.nih.gov/advisory/ncab/ncab.htm

1.3 On the other hand, is it correct to understand that a "select-pay" is a part of the bottom-up research proposals but hand-selected by PD not purely based on the percentile (approx. 25%) of CSR score? Is "select-pay" about 15% of the NCI grant? (Sone T, 2004)

2 It may be difficult to run the PDCA cycle for the exploratory, creative studies, which are often found in the basic research. Does the NCI/Division change the way they run PDCA depending on the characteristics of research fields such as basic research, translational research and clinical trial?

3 The progress management may demand alterations (including a premature termination) of the study plan. How does the Division (PD/PO) enforce such alterations?

III) Extra-mural research

5 Portfolio of research projects and studies funded by NCI
http://fundedresearch.cancer.gov/nciportfolio/about.jsp
http://www.cancer.gov/cancertopics/factsheet/NCI/research-funding

6 About Program director (PD)/ Program officer (PO, if any)/ Scientific Review Administrator (SRA)

6.1 Number

6.2 Background

6.3 Selection and evaluation processes

6.4 Specific roles and duties

7 About PD/PO/SRA supporting staffs

7.1 Number

7.2 Background

7.3 Roles and duties

8 About National Cancer Advisory Board

8.1 Relationships with PD and SRA
http://deainfo.nci.nih.gov/advisory/ncab/ncab.htm

IV) Intra-mural research

1 How does NCI apply PDCA cycle in the intra-mural research?

1.1 Does NCI request a progress report?

1.2 If yes, what level in the organization is requested for the progress report? (e.g. Division, group, program, branch, individual researcher)

1.3 Frequency, points and format of the report?

1.4 When NCI or Division finds some problems on the research progress, what measures does NCI/Division take (for example, hearing or site visit)?

1.5 Who are members of hearing/ site visit teams?

V) Research support mechanisms

1 Human research protections

2 Public relationships

3 Intellectual property

4 Regulatory sciences

5 Biobank

6 Research core facility

7 Biostatistics and bioinformatics

- Intra-mural
- Extra-mural