

Current Process
For
Proposing and Evaluating RFAs

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Initiatives are intended to:

- Facilitate the development of emerging areas of cancer research**
- Respond to resource/infrastructure needs identified by the research community**
- Respond to critical public health needs**

The Evolution of an Initiative:

- **Discern a scientific opportunity from the ongoing survey of cancer biology research**
- **Determine the state of the science and whether an initiative is needed**
- **Develop a concept narrative**
- **Select appropriate funding and announcement mechanisms**
- **Submit for concept review**

Discern a Scientific Opportunity from the Ongoing Survey of Cancer Research

- Scientific publications
- Scientific meetings, seminars, journal clubs, etc
- Reports (e.g. IOM, CTWG, TRWG)
- State of the Science meetings
- Grant applications and annual reports
- Study section discussions
- Interactions with extramural investigators

Determine the State of the Science

If there is an emerging area or one in which recent advances have renewed interest:

Sponsor a workshop or think tank to determine:

- **Current state of the science**
- **What approaches/questions are being pursued**
- **Any areas of opportunity or gaps in which NCI support could make a difference**
- **Get recommendations from investigators about their needs**

Determine whether there is adequate evidence to warrant developing an NCI initiative.

If so:

- **Sponsor a follow-up workshop or working group**
- **Develop a concept proposal**

(Occasionally, an initiative will be proposed in response to a specific Congressional directive)

Concept Proposal

Concept proposal format parallels any request for funding:

- **Background:**

- A scientific review of the field, including major findings and questions
- A portfolio analysis of NIH-supported research in the area

- **Rationale:**

- Description of scientific gaps and/or opportunity
- Description of scientific scope of proposed initiative
- Why is it a high priority?

- **Specific Aims:**

- Statement of specific goals that the initiative is intended to achieve

- **Approaches:**

- Justification of the proposed funding mechanism (R21, RO1, U01, etc) and budget are appropriate to the goals of the initiative

Select the Appropriate Funding Opportunity Announcement (FOA)

The choice of funding announcement is driven by the goals of the initiative:

- Program Announcement (PA)**
- Program Announcement with Review (PAR)**
- Request for Application (RFA)**

Select the Appropriate Funding Opportunity Announcement (FOA)

<u>Goal</u>	<u>Mechanism</u>	<u>FOA</u>	<u>Set-aside</u>	<u>Review</u>	<u>Funding</u>
<ul style="list-style-type: none"> • General area of interest • Exploratory 	R21, R01, PO1	PA	No	CSR (Standing Study Section)	Payline
<ul style="list-style-type: none"> • Targeted • Multidisciplinary • Specialized 	R21 U01(R01) U54(PO1)	PAR	No	NCI/CSR (SEP)	Case-by- case
<ul style="list-style-type: none"> • Growing area with great promise • Transdisciplinary • Would benefit from NCI participation • Training 	U01 (R01) U54 U56 (PO1) P50	RFA	Yes	NCI	Funding plan

Concept Review

Levels of review:

- Branch
- Division
- Scientific Program Leadership
- BSA

Frequency:

As necessary
3X/year
3X/year
3X/year

Review Criteria:

- Scientific opportunity – is this an important area that will benefit from, or depends on, NCI support
- Does it require NCI review panels?
- For RFAs:
 - Budget – is a set-aside necessary? Is it appropriate to the goals of the initiative?
 - Are multiple Divisions interested in co-sponsoring the initiative
 - Priority relative to other proposed RFAs

Examples of Recent NCI Initiatives

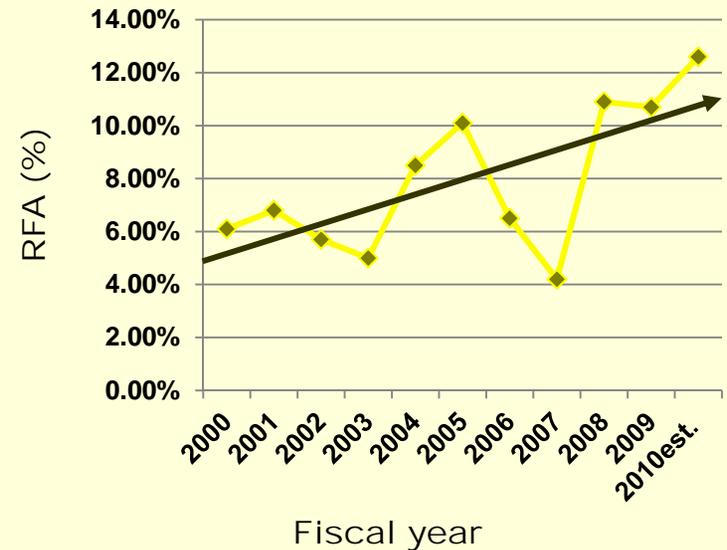
<u>Initiative</u>	<u>Purpose</u>	<u>Challenge</u>	<u>Mechanism</u>
MMHCC (DCB)	Develop and validate a novel experimental resource and approach	<ul style="list-style-type: none"> • Provide resource to research community • Develop common criteria for resource use 	U01 (cooperative agreement)
ICBP (DCB)	Support an emerging transdisciplinary field	<ul style="list-style-type: none"> • Integrating different disciplines • Training and outreach 	U54/U56 (cooperative agreement)
TREC (DCCPS- lead)	Multidisciplinary research in an area of public health	<ul style="list-style-type: none"> • Recruit different disciplines to address a public health problem 	U54 (cooperative agreement)
EDRN (DCP)	Accelerate discovery and translation	<ul style="list-style-type: none"> • Establish collaborations for biomarker discovery • Establish specialized labs and centers 	U01, U24 (cooperative agreement)
CITN (DCTD)	Stimulate Phase I and II clinical trials	<ul style="list-style-type: none"> • Assemble multi-investigator teams to test “high priority” agents identified by community 	U01 (cooperative agreement)

Evaluation of RFA Outcomes

- Evaluation is independent of sponsoring Division
 - Program establishes criteria for evaluation, based on the goals established in the original RFA
 - Independent evaluation by subject matter experts, staffed by independent contractor
- Evaluation criteria include, but are not limited to:
 - Publications attributable to grants funded through the RFA
 - Impact on field of science, as assessed by non-grantees in field
 - Management of the initiative by NCI Program Staff, as assessed by grantees
 - For initiatives that develop infrastructure support:
 - Development of resources for the community
 - Training and outreach to the broader community
- If reissuance of the RFA is being requested, the evaluation must accompany the concept proposal presented to the SPL and BSA

Annual RFA Set-Asides Since 2000

Fiscal Year	RFA Set-Aside	Total Competing	Percent RFA to Total Competing
2000	23,775	387,083	6.1%
2001	28,576	417,233	6.8%
2002	24,987	436,120	5.7%
2003	24,740	491,722	5.0%
2004	41,848	494,527	8.5%
2005	44,568	439,871	10.1%
2006	26,873	415,067	6.5%
2007	18,463	434,713	4.2%
2008	49,591	457,036	10.9%
2009	49,011	457,834	10.7%
2010est.	65,168	516,598	12.6%



Issues to Consider:

- **What are appropriate criteria for issuing an RFA?**
- **Are these the right processes for proposing and evaluating RFAs?**
- **What fraction of the discretionary RPG budget is reasonable to set-aside for RFAs?**
- **How should RFA concepts be prioritized?**
- **What should RFA's attempt to achieve?**

Supplementary Background Material

FY 09 RFA's

RFA	DOC	Set Aside for Year 1	RFA Title
RFA-CA-09-011	DCB	\$22.5 M	The Integrative Cancer Biology Program (ICBP): Centers for Cancer Systems Biology (CCSB) (U54)
RFA-CA-09-026	DCB	\$2 M	The Biology of Estrogen Receptor-Negative Breast Cancer in Various Racial and Ethnic Groups (U01)
RFA-CA-09-001	DCCPS	\$10 M	NIH-Supported Centers for Population Health and Health Disparities (CPHHD) (P50)
RFA-CA-09-002	DCCPS	\$24 M	Transdisciplinary Cancer Genomics Research: Post-Genome Wide Association (Post-GWA) Initiative (U19)
RFA-CA-09-003	DCCPS	\$2 M	Replication and Fine-Mapping Studies for the Genes Environment and Health Initiative (GEI)(R01)
RFA-CA-09-025	DCCPS	\$5.4 M	Cancer Intervention and Surveillance Modeling Network (CISNET) (U01)
RFA-CA-09-503	DCCPS	\$3.67 M	Cancer Care Outcomes Research and Surveillance (CanCORS) Consortium (Limited Competition) [U01]
RFA-CA-09-017	DCP	\$10- \$11 M	The Early Detection Research Network: Biomarker Developmental Laboratories (U01)
RFA-CA-09-018	DCP	\$9 - \$10 M	Early Detection Research Network: Clinical Validation Centers (U01)
RFA-CA-09-019	DCP	\$3 M	The Early Detection Research Network: Biomarker Reference Laboratories (U24)
RFA-CA-09-020	DCP	\$2 M	Early Detection Research Network: Data Management and Coordinating Center and Statistics and Biomarker Resource Center (U24)
RFA-CA-09-022	DCP	\$21.2 M	Community Clinical Oncology Program (U10)
RFA-CA-09-023	DCP	\$4.3 M	Minority-Based Community Clinical Oncology Program (U10)
RFA-CA-09-502	DCTD	\$2.55 M	Cancer Disparities Research Partnership (CDRP) Program: Limited Competition (U54)
RFA-CA-09-504	DCTD	\$8.75 M	Limited Competition: Support for Human Specimen Banking in NCI-Supported Clinical Trials - Cooperative Group Banks (CGB) (U24)

FY 09 RFA's (Cont.)

RFA	DOC	Set Aside for Year 1	RFA Title
RFA-CA-09-010	OD/ OCG	\$18 M	Genome Characterization Centers and Genome Data Analysis Centers for The Cancer Genome Atlas Research Network (TCGA)[U24]
RFA-CA-09-016	OHAM	\$4 M	Developing Research Capacity in Africa for Studies on HIV-Associated Malignancies (D43)
RFA-CA-09-004	OTIR	\$1 M	Innovative and Applied Emerging Technologies in Biospecimen Science (R21)
RFA-CA-09-005	OTIR	\$1 M	Innovative and Applied Emerging Technologies in Biospecimen Science (R33)
RFA-CA-09-006	OTIR	\$1 M	Application and Use of Transformative Emerging Technologies in Cancer Research (R21)
RFA-CA-09-007	OTIR	\$1.5 M	Application and Use of Transformative Emerging Technologies in Cancer Research (R33)
RFA-CA-09-008	OTIR	\$3 M	Innovative Technology Development for Cancer Research (R21)
RFA-CA-09-032	CRCHD	\$23.57 M	Community Networks Program (CNP) Centers for Reducing Cancer Disparities through Outreach, Research and Training (U54)
RFA-CA-09-501	CRCHD	\$5 M	Comprehensive Minority Institution/Cancer Center Partnership (Limited Competition U54)
RFA-CA-09-009	CSSI	\$15 - \$21 M	Physical Science-Oncology Centers (U54)
RFA-CA-09-012	CSSI	\$20 - \$27 M	Centers of Cancer Nanotechnology Excellence (CCNEs)(U54)
RFA-CA-09-013	CSSI	\$5 -\$7 M	Cancer Nanotechnology Platform Partnerships (U01)
RFA-CA-09-014	CSSI / CTB	\$2.5 M	Cancer Nanotechnology Training Centers (CNTCs)(R25)
RFA-CA-09-015	CSSI / CTB	\$2 M	Pathway to Independence Award in Cancer Nanotechnology Research (K99/R00)

FY 10 RFA's

RFA	DOC	Set Aside for Year 1	RFA Title
RFA-CA-10-021	DCB	\$9.05 M	Tumor Microenvironment Network (TMEN) (U54)
RFA-CA-10-006	DCCPS	\$15 M	Transdisciplinary Research in Energetics and Cancer (U54)
RFA-CA-10-008	DCCPS	\$12 M	State and Community Tobacco Control Policy and Media Research (U01)
RFA-CA-10-501	DCCPS	\$2 M	Coordination Center for Transdisciplinary Research in Energetics and Cancer (Limited Competition U01)
RFA-CA-10-010	DCP	\$1.8 M	Community Clinical Oncology Program Groups (U10)
RFA-CA-10-011	DCP	\$1.5 M	Community Clinical Oncology Program Research Bases (U10)
RFA-CA-10-012	DCP	\$2 M	Minority-Based Community Clinical Oncology Program Groups (U10)
RFA-CA-10-014	DCP DCB	\$6 M	Barretts Esophagus Translational Research Network (U54)
RFA-CA-10-015	DCP DCB	\$0.5 M	Coordinating Center for the Barretts Esophagus Translational Research Network (U01)
RFA-CA-10-007	DCTD	\$1.6 M	Cancer Immunotherapy Trials Network (U01)
RFA-CA-10-001	DCCPS, DCB, DCTD, DCP, OD	\$1.5 M	Innovative and Early-Stage Development of Emerging Technologies in Biospecimen Science (R21)
RFA-CA-10-002	DCCPS, DCB, DCTD, DCP, OD	\$2.25 M	Validation and Advanced Development of Emerging Technologies in Biospecimen Science (R33)
RFA-CA-10-003	DCCPS, DCB, DCTD, DCP, OD	\$2.25 M	Application and Early Stage Development of Emerging Technologies in Cancer Research (R21)
RFA-CA-10-004	DCCPS, DCB, DCTD, DCP, OD	\$2.25 M	Validation and Advanced Development of Emerging Technologies for Cancer Research (R33)
RFA-CA-10-005	DCCPS, DCB, DCTD, DCP, OD	\$5 M	Innovative Technology Development for Cancer Research (R21)

FY 10 RFA's (Cont.)

RFA	DOC	Set Aside for Year 1	RFA Title
RFA-CA-10-502	OHAM	\$4.68 M	AIDS Malignancy Clinical Trials Consortium (Limited Competition U01)
RFA-CA-10-009	SBIRDC	\$10 M	SBIR Phase II Bridge Awards to Accelerate the Development of Cancer Therapeutics, Imaging Technologies, Interventional Devices, Diagnostics, and Prognostics toward Commercialization (R44)
RFA-CA-10-013	SBIRDC	\$2 M	Innovative Emerging Molecular Analysis Technologies (SBIR R43/R44)
RFA-CA-10-503	CRCHD	\$5.25 M	Comprehensive Partnerships to Reduce Cancer Health Disparities (Limited Competition U54)
RFA-CA-10-016	CSSI	\$15 - \$24 M	Clinical Proteomic Technologies for Cancer Initiative (CPTC): Proteome Characterization Centers (U24)



Basic research



Translational/clinical research



Non-Division based



Population research



Technology Development