

A New Approach to P30 Cancer Center Support
Grant Funding

Report of the National Cancer Advisory Board *Ad Hoc*
Cancer Centers Working Group

February 2014

February 25, 2014

National Cancer Advisory Board
National Cancer Institute
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Board Members

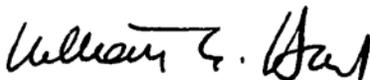
On behalf of the National Cancer Advisory Board's (NCAB) Ad Hoc Cancer Centers Working Group (WG), I'm pleased to submit this report. In keeping with our charge, the report assesses whether current funding guidelines for the NCI Cancer Centers are appropriate and sufficient, and if not, what aspects might be changed.

After a year of fact-finding and deliberation, the WG members reached consensus on several issues: The extraordinary value of the NCI-designated centers to the national cancer program; the importance of the designation as an imprimatur that allows other resources to be leveraged and; the crucial support provided by the Cancer Center Support Grant for research infrastructure. They also agreed that the current funding approach perpetuates historical disparities between centers and that a new approach should be considered. Understanding there are challenges inherent in change of this nature, recommendations within this report are intended to encourage and facilitate that change.

The WG members would like to express their thanks to the NCAB and National Cancer Institute staff for their support of this effort.

We hope the report will prove to be of value to you, the NCAB members, and to the leadership of the National Cancer Institute.

Sincerely,

A handwritten signature in black ink, appearing to read "William N. Hait".

William N. Hait, M.D., Ph.D.
Chair

National Institutes of Health
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National Cancer Advisory Board Cancer Centers Working Group

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Executive Summary

In fall of 2012, the National Cancer Advisory Board (NCAB) of the National Cancer Institute (NCI) established an *Ad Hoc* Working Group (WG) to consider the funding policies for NCI-designated Cancer Centers, and if appropriate, to recommend changes. NCI leadership and the Board recognized a need to examine the complex historical funding patterns that have influenced current P30 Cancer Center Support Grant (CCSG) award levels, assess potential disparities, and consider whether alternative approaches should be explored.

The WG included ten members from a diverse array of cancer centers and from the private sector. The members met in person or via teleconference six times over a 1 year time frame, heard presentations from NCI leadership, and reviewed current funding policies and approaches, with the following conclusions:

- There are significant disparities in the size of the CCSG awards, often with no apparent rational basis.
- The interim funding approach in the current 2012 CCSG Guidelines better manages expectations of centers in regard to award levels and retains a flat budget, but perpetuates these disparities.
- NCI-designated cancer centers differ in type, organizational structure, and other environmental factors. These affect the importance of specific CCSG components.
- NCI designated cancer centers should be evaluated on what they do, and how well they do it. The impact of the science emerging from the center and how that was enabled by the CCSG should be paramount.
- There are components of the CCSG process that could be further optimized to decrease administrative burden, increase flexible use of funds, and stress the most significant science.
- Underperforming centers should be carefully reviewed; cessation of funding should be considered.

The Working Group then discussed a variety of approaches to address the disparities in funding. After review of several example models, a consensus emerged on the following recommendations:

Recommendation 1: CCSG funding should be comprised of three components: a base award; multipliers of the base, predicated on merit and size; and a possible supplement.

- **The base award should vary by center type (basic, clinical, comprehensive), based on applicable CCSG guidelines. At the time of each renewal, the base award should be the starting point.**

- **Merit funding should be calculated on a linear scale as a percent multiplier of the base award, using impact score.**
- **Size should be calculated as a percent multiplier of the base award, using the figure for total peer-reviewed funding reported by the center.**
- **Supplements should be based on review of proposed novel programs, cores, or new initiatives, and alignment with NCI priorities.**

Recommendation 2: Cancer Center Administrators should be involved in the planning for implementation of the new approach.

Recommendation 3: Proposed changes should be framed in the context of the NCI and Centers mission. The timeline and mode of communicating changes will determine their acceptability.

This new approach to funding does not solve all of the issues raised and discussed during the course of WG meetings. While it has the potential to correct historical disparities via a standardized formula that can be used across fiscal years, it does not address the unpredictability of the NCI budget or the potential fiscal and administrative hardships for centers with large decreases in awards. Implementation options (e.g., one time adjustment, slow phase-in, or some combination thereof) will require further modeling by the NCI and the individual centers to assess hypothetical outcomes.

If implemented, these recommendations will produce a major change in how centers are funded. Clearly, the way in which they are communicated will help determine their acceptability. The importance of transparency, fairness, input from Centers, and “fine-tuning” in this process should be recognized. And finally, it must be framed within the mission of the NCI and national cancer program.

Report of the NCAB Cancer Centers *Ad Hoc* Working Group

Charge to the Cancer Centers *Ad Hoc* Working Group

At its September 2012 meeting, the National Cancer Advisory Board (NCAB) of the National Cancer Institute (NCI) voted to create an *ad hoc* Cancer Centers Working Group (WG) -

To assess whether current funding guidelines for the NCI Cancer Centers are appropriate and sufficient, and if not, what aspects might be changed. The working group is charged to provide appropriate guidance on policies and metrics relevant to the allocation of funds to NCI-designated centers in a time of fiscal stringency.

History and Significance of the Cancer Centers Program

The National Cancer Act officially established the Cancer Centers Program in 1971. The legislation was based on the report of a congressional committee, which concluded that a formalized cancer centers program would provide a unity of purpose, a centralized platform for sharing concepts and resources, and a management structure necessary to achieve progress toward the goal of preventing and curing cancer. The Act grandfathered in twelve existing centers and authorized the establishment of additional centers. It also implemented a standard funding mechanism (the P30 Cancer Center Support Grant or CCSG) and guidelines, and created an administrative and organizational home for the program at the NCI.

Based on this early legislation, qualified applicant institutions receive the CCSG award and accompanying NCI designation for successfully meeting a spectrum of rigorous competitive standards associated with scientific and organizational merit. While CCSG requirements have evolved over the years, the grant continues to support research infrastructure that enhances collaborative, transdisciplinary research productivity. CCSG grants provide funding for formalized cancer research Programs, shared research resources, scientific and administrative management, planning and evaluation activities, development of new scientific opportunities, and centralized clinical trial oversight and functions.

Although the CCSG does not directly fund the wider range of activities at cancer centers, an NCI-designated Cancer Center links state-of-the-art research and care, thus perpetuating the translational continuum. To decrease cancer incidence and mortality among populations within its catchment area, including minority and underserved populations, it also establishes partnerships with other health delivery systems and state and community agencies for dissemination of evidence-based findings.

Today, there are sixty-eight NCI designated Cancer Centers in thirty-three states and the District of Columbia. Seven of these are centers performing basic laboratory research only; forty-one are comprehensive cancer centers, conducting transdisciplinary research across the full spectrum of cancer science (basic laboratory, clinical, and prevention control and population science); and twenty are centers conducting a combination of research in some, but not necessarily all, of these areas. Most of the centers are matrixed within larger academic medical centers, but several are freestanding, and others are comprised of a consortium of institutions.

Since its inception, the Cancer Centers Program of the NCI has become the envy of the world. In few if any other countries is there the same commitment to excellence in multi-disciplinary cancer research and the promotion of translational science that reduces the burden of cancer. This effort, now funded for over forty years, has brought enormous benefits to the health of the American people. The NCI-designated Cancer Centers serve as a major platform for advancing national priorities in cancer research, with investigators in centers holding the majority of all extramural funding the NCI provides. Due to rigorous review standards, the designation is prestigious, serving as an imprimatur that leverages other sources of support and funding. The CCSG award itself provides essential support for infrastructure spanning the spectrum of cancer research.

Origins of This Report

The National Cancer Advisory Board is a presidentially-appointed panel established by the National Cancer Act. It is granted statutory responsibility to advise the Secretary of Health and Human Services (HHS) and the NCI Director with respect to activities carried out by the Institute. NCAB members are leading cancer scientists who meet regularly to approve grants and advise the NCI leadership regarding initiatives and changes in policies in programs.

In September of 2012, the NCAB approved establishment of the *Ad Hoc* Cancer Centers Working Group to evaluate current funding guidelines for the NCI-designated Cancer Centers and to provide guidance on whether and how funding policies should be changed. The WG included 10 scientific leaders and directors from NCI-designated cancer centers and industry, among them 1 NCAB member (Cullen) and 2 members of the NCI Board of Scientific Advisors (Dang, Gerson). The NCI centers represented were of varying types (basic, clinical, and comprehensive), sizes, and organizational structures; and had a broad geographic distribution. The WG was chaired by Dr. William Hait, Senior Vice-President of Research and Development at Johnson and Johnson, former member of the NCI Board of Scientific Advisors, and former director of an NCI-designated cancer center.

The WG met for a full day in Bethesda on February 6th, 2013 and via teleconference on six occasions (March 14, April 12, May 20, and November 25 2013; and January 3, 2014) to hear

presentations from the NCI Director, Dr. Harold Varmus, and the Director of the Office of Cancer Centers, Dr. Linda Weiss, and to discuss policies and data relevant to their charge.

Background of the Funding Issue

The size of CCSG awards is based primarily on the merit of the application, with quality of science and value-added the major drivers. Although the focus on merit has remained fairly consistent over the 40 year history of the award, a variety of factors have skewed the distribution of CCSG funds, with resulting inequities. Awards may be inappropriately lower for newer centers, centers that have had a poor review in the past (even if now markedly improved), and centers that compete in years when the NCI budget is low or when all centers perform well and there are few funds to reallocate. Today, fifty percent of the CCSG budget is held by the twenty-five percent of centers with highest awards, while only ten per cent is held by the twenty five percent of centers with the lowest.

Several factors add to the complexity of revising the award structure: 1) NCI funding has decreased, and is likely to remain flat or decrease further in the coming years; 2) There is a continuing interest from universities in attaining the designation for their cancer center; 3) NCI must be responsive to imperatives to support geographically distributed centers and accessibility for underserved populations; and 4) CCSG awards are rarely terminated. As a result, the number of centers continues to grow and the budget continues to be stretched.

Cancer centers have raised concerns about the equity of the budgeting process for some time, with no resolution. Issues have included how funds might be more fairly allocated in a time of budget constraint and change, and the metrics on which the size of awards should be based.

In 2012, the NCI modified its guidelines to limit the size of budget requests and awards. This was presented as an interim funding measure only, pending the outcome of WG deliberations.

Activities and Deliberations of the Working Group

Prior to discussing whether a new approach was warranted, the WG reviewed specific questions posed by Dr. Varmus in delivering the charge:

- Are the new guidelines appropriate and sufficient to counter concerns about current distribution, *e.g.*, should we change the ‘cap’; launch new centers with larger or smaller budgets; change the allowable rate of increase?
- Are there better methods for making funding decisions and if so, what metrics should be used and how much consideration should be given to the ways in which core funds are used?

- Are there other ways to make budgeting more flexible, without increasing the base budget, *e.g.*, through supplements or cooperative agreements, and what would be the appropriate use of such alternative resources?

Members discussed their perspectives on the major challenges in CCSG award funding, the value and significance of the CCSG in their own institutions, their thoughts on the major NCI priorities for cancer center program investment (*e.g.* quality of science, interactions, translations, regional balance, diversity) and what policy changes they might consider for the centers program, taking a programmatic perspective and assuming no increases in the overall centers budget. During the meetings, they also reviewed slides and other documents related to:

- The impact of center diversity on needs and funding considerations
- Historical and current budget request and funding policies
- Trends in CCSG funding over time
- Distribution of CCSG funds by application component and center type
- Data on current awards and research funding awarded to centers

The WG then focused its efforts on: 1) understanding the disparities created by historical funding approaches; 2) establishing the underlying principles necessary to develop a viable alternative; 3) reviewing example funding models for consistency with those principles; 4) recommending a new approach that would instill greater objectivity and fairness into the funding process; and 5) identifying potential benefits and drawbacks of that new approach. It did not attempt to evaluate scientific productivity or merit of specific CCSG grants, which are reviewed by NCI Internal Review Group (IRG) Subcommittee A.

At the initial meeting of the WG in February 2013, several general areas of consensus emerged about the Centers and the value added by the CCSG award and the NCI designation:

- Cancer Centers bring enormous value to their universities, communities, region and nation, by aggregating top scientists around collaborative cancer research efforts that have made massive progress toward the ultimate goal of eliminating the nation's burden of cancer.
- The NCI designation is the cancer research imprimatur that allows other resources to be leveraged, including institutional funds, space, tenure lines, dedicated philanthropy staff, and authorities; and the support of cancer advocacy groups, state governments, and other entities.
- The CCSG mechanism provides the essential framework for structuring the centers, and for the rigorous peer review process that results in the highly prestigious and coveted NCI designation.

- Support provided by the CCSG for clinical research infrastructure and shared resources is irreplaceable.

The WG members spent some time reviewing funding policies and current funding patterns. Ultimately, they agreed that:

- The significant disparities in the size of the CCSG awards appear to have no rational basis and are often predicated on factors other than merit, including the duration of the grant, the availability of funds in the years in which the grant was re-competed, etc.
- The interim funding approach in the current 2012 CCSG Guidelines better manages expectations of centers in regard to award levels and retains a flat budget, but has the unintended consequence of promulgating these disparities by allowing no room for growth.
- There are three types of cancer centers (basic, clinical, comprehensive) with several different organizational structures (freestanding, matrixed within an academic medical center, or part of consortium). Each center has unique environmental factors that affect the importance of specific CCSG components.
- There may be too much pressure on CCSG applicants to cover too many important areas of cancer research; centers cannot do everything. They should be evaluated on what they do, and how well they do, not on what they do not cover. The impact of the science emerging from the center and how that was enabled by the CCSG should be paramount.
- There are components of the CCSG process that could be further optimized to decrease administrative burden, increase flexible use of funds, and stress the most significant science. As currently structured, there is little leeway for launching new infrastructure or opportunity for growth.
- There are underperforming centers that should be carefully reviewed; cessation of funding should be considered.

The Working Group then discussed a variety of approaches to address the disparities in funding. After review of multiple example models, a consensus emerged on the recommendations below.

Recommendations of the Working Group

- Recommendation 1: The award should be comprised of three components: a base award; multipliers of the base, predicated on merit and size; and a possible supplement.**
- **The base should to some extent be predicated on the standard components required of a center; it would thus vary by center type (basic, clinical, comprehensive). At the time of renewal, a predetermined base award applicable to all centers of the same type should be the starting point.**

- **Multipliers of the base:**
 - **Merit funding should be calculated on a linear scale as a percent multiplier of the base award, using impact/priority score. Performance history of the center, prior to the 5 year time frame being evaluated, should not factor into the award. The base award should be reduced if a center scores poorly in review; i.e., the merit scale reduces the award above a certain score.**
 - **Funding for size should be determined as a percent multiplier of the base, using the figure for total peer-reviewed funding reported by the center. This formula should be kept simple and not duplicate what is already in other aspects of the review.**
- **Supplements should be based on review of proposed innovative programs, cores, or other new initiatives, and consistency with NCI priorities such as precision medicine and global health.**

Recommendation 2: Cancer Center Administrators should be involved in the planning for implementation of the new approach.

Recommendation 3: Proposed changes should be framed in the context of the NCI and Centers mission, not a reaction to fiscal constraints. The timeline and mode of communicating changes will determine their acceptability.

The WG members ultimately recommended a model in which fifty percent of the Centers Program direct cost budget was invested in base awards, thirty percent in merit funding, fifteen percent in funding for size, and five percent for supplements and new initiatives.

Conclusions

This new approach to funding does not solve all of the issues raised and has both potential benefits and problems. For example, it addresses the problem of accretion since each renewal will recomplete for a predetermined base award applicable to all centers of the same type. It also negates the need for the proscription of caps, since the playing field will be leveled by formula-based budgeting.

This form of budgeting does not fully address the unpredictability of the size of the NCI budget in a given year of grant renewal, but it should help minimize the impact over time. In addition, decreased funding, particularly for the large matrix-type centers, may create administrative and fiscal hardships for the centers and, when applicable, the parent institutions.

It also does not address whether this type of redistribution of funds will result in the overall good for cancer research and ultimately for cancer patients.

The WG discussed how these changes might be made, a slow phase in, a one-time tap or graduated tax, or an annual adjustment to awards. It is essential that additional budget modeling be conducted by the NCI and by individual centers based on some hypothetical outcomes to a CCSG application using this type of award mechanism. It was recommended that Cancer Center Administrators be involved in this planning.

Clearly, the way in which these proposed changes are communicated will help determine their acceptability. The importance of transparency, fairness, input, and “fine-tuning”, should be recognized. And finally, it must be framed within the mission of the NCI and national cancer program, not a reaction to difficult budget times or redistribution for political purposes. Rather, we must continuously stress the remarkable success of the Cancer Centers program, its overall importance and impact, and that these changes are designed to enhance, not harm this national treasure.

Meeting Agendas

Agenda for Centers Working Group Meeting
February 6, 2013
31/11A01

- 8:30 a.m. Welcome and Introductions/Required Announcements/Meeting Logistics
Dr. William Hait
Dr. Linda Weiss
- 8:45 a.m. Perspectives on Cancer Center Support Grant (CCSG) Funding
Committee Members
- 9:45 Break
- 10:00 a.m. Charge to the Working Group
Dr. Harold Varmus (by teleconference, time approximate)
- 11:30 Lunch
- 12:15 p.m. Background and Overview of CCSG Funding Policies and Issues
Dr. Linda Weiss
- 1: 30 p.m. Approach to the Working Group Charge
Dr. William Hait
Committee Members
- 2:30 p.m. Recap and Next Steps
Dr. William Hait
Committee Members
- 3:00 p.m. Adjourn

Agenda
Cancer Centers Working Group
March 14, 2013
9:00 – 10:00 a.m.

1. Discussion of feedback at Directors' Retreat/other input from directors to the WG members
2. Recommendations on definition of the base and the multiplier
 - a. What is more important – a higher base or higher multiplier?
 - b. How many 'base' tiers should there be and what factors should determine them?
 - c. What factors should be included in the multiplier, e.g. priority score, impact, size future plans, underserved populations?
 - d. What should be the relative weights of these factors?
 - e. Should the multiplier be both above and below 1, e.g., to reflect concerns (below) and reward impact/progress (above)?

Cancer Centers Working Group
Teleconference Agenda
April 12, 2013
12 p.m. – 1 p.m. EDST

1. Review of Meeting Summary from 3-14
2. Discussion of analyses
 - a. Baseline costs
 - b. Example models
 - c. Overarching issues
3. Next steps

Cancer Centers Working Group
Teleconference Agenda
May 20, 2013
4:30 – 5:30 p.m. EDT

1. Review of Meeting Summary from 4-12
2. Discussion of analyses
 - a. Median costs of baseline and clinical components
 - b. Correlations under current and projected models
 - c. Projected redistribution of funds
3. Discussion/definition of a clinical trials metric
4. Next steps

5.

Cancer Centers Working Group
Teleconference Agenda
November 25, 2013
2:30 – 4:00 pm EST

1. Update:

- a. NCI activities since the June NCAB WG presentation
- b. Input/comments from WG members

2. Review of modifications to the example model:

- a. Post sequestration budget and base award figures
- b. Continuous priority score scale for merit calculation
- c. Correlation between funding and continuous scale

3. Discussion of the size/complexity metric, focusing on the following questions:

- a. What attributes do you think are important to consider in recognizing the size/complexity of a center?
- b. What are the potential advantages and disadvantages of including these attributes in the model?
- c. Who gains/loses as a consequence of their potential inclusion?
- d. How standard/verifiable do the attributes need to be?
- e. What proportion of the DC budget should be invested in size/complexity?

4. Next steps

Cancer Centers Working Group
Teleconference Agenda
January 3, 2014
4:00 – 5:00 pm EST

1. Review/discussion of example models
2. Potential language changes to the CCSG FOA
3. Next steps?
 - a. Final recommendations
 - b. Presentation at NCAB
 - c. Presentation at Center Directors' Retreat
4. FY 2014 Centers budget