

CONGRESSIONALLY DIRECTED
MEDICAL RESEARCH PROGRAMS:
PARTNERING FOR A CURE

I. Overview



Thirty-five years ago President Richard M. Nixon declared a “War on Cancer” and challenged the nation to find a cure. The 1971 National Cancer Act, which authorized substantial public investment into the U.S. cancer research enterprise, ushered in an era of scientific discovery and medical advances in cancer research. However, cancer and other diseases continue to exert a phenomenal toll on the American public. In fact, in 2006 it was estimated that **564,830** Americans would die from cancer, and approximately **1.399 million** Americans would be newly diagnosed with cancer.¹ Heightened public awareness and increased interest in health issues have continued to influence scientific research. Cancer research has drawn particular attention, due in part to the rising impact of cancer and the work of highly visible consumer advocacy organizations. In response to these concerns and the national commitment to end the war on cancer, the U.S. Congress directed the Department of Defense (DOD) to manage intramural and extramural research programs that focus on specific diseases. Beginning in fiscal year 1992 (FY92), the U.S. Army Medical Research and Materiel Command (USAMRMC)² received a \$25M (million) congressional appropriation for breast cancer research. The following year, Congress appropriated **\$210M** to the DOD for extramural peer-reviewed breast cancer research. The Congressionally Directed Medical Research Programs (CDMRP), a research directorate within the USAMRMC, has been responsible for managing the breast cancer appropriation as well as other targeted appropriations totaling almost **\$3.8B** (billion) through FY06 for research on breast, prostate, and ovarian cancers; neurofibromatosis; military health; chronic myelogenous leukemia; tuberous sclerosis complex; and other health concerns (see Figure I-1. CDMRP Funding History).

¹ American Cancer Society, *Cancer Facts and Figures*, 2006.

² Known as the U.S. Army Medical Research and Development Command prior to 1995.

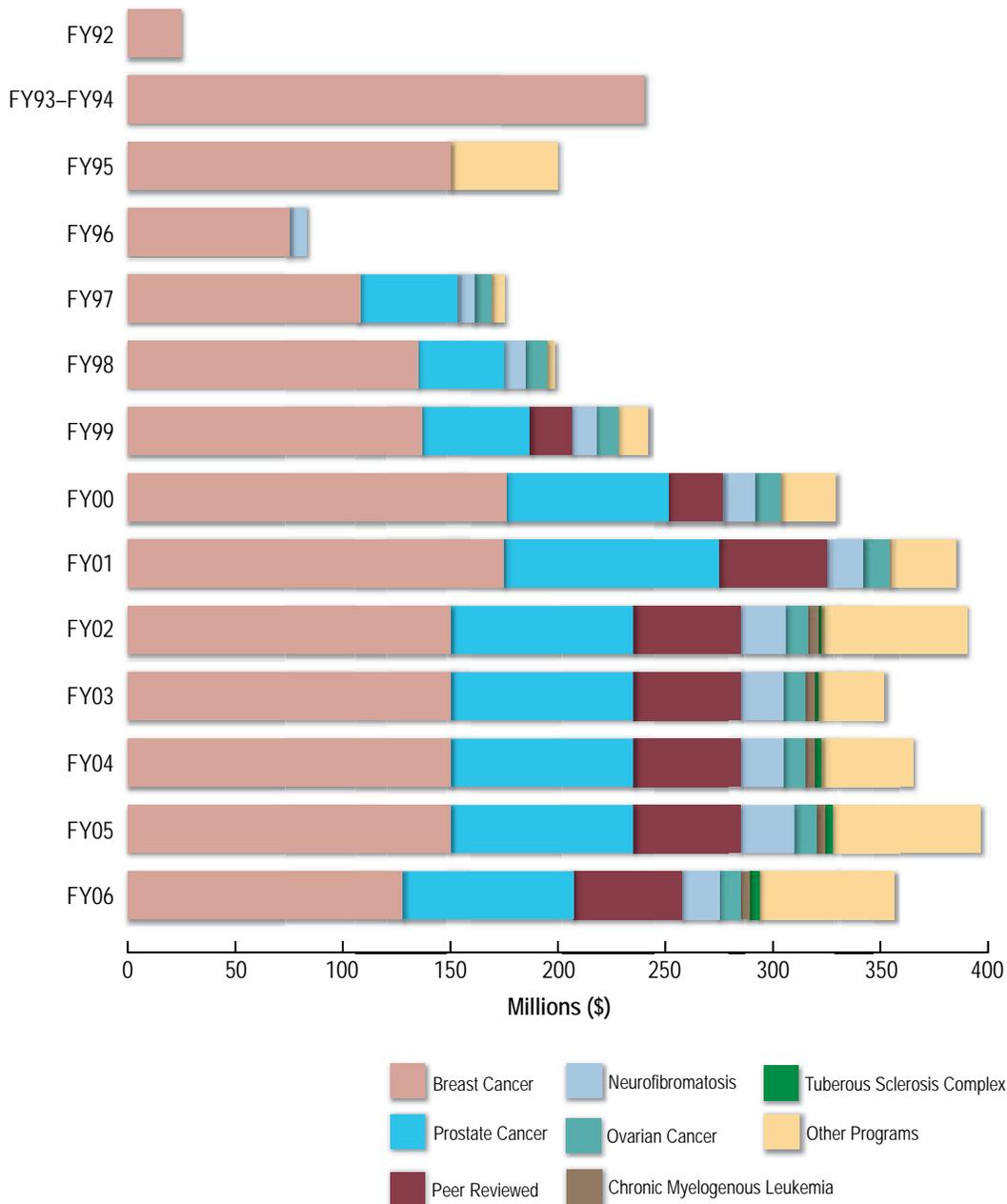


Figure I-1. CDMRP Funding History

The CDMRP's vision is to find and fund the best research to eradicate diseases and support the warfighter for the benefit of the American public. This is an ambitious and exciting goal, and advancements are being made. From FY92 through FY05, the CDMRP has managed **6,936** research grants, contracts, and cooperative agreements (Table I-1). The success of the programs, the work of consumer advocates, and the need for additional, focused biomedical research have led to continuing appropriations for programs managed by the CDMRP.

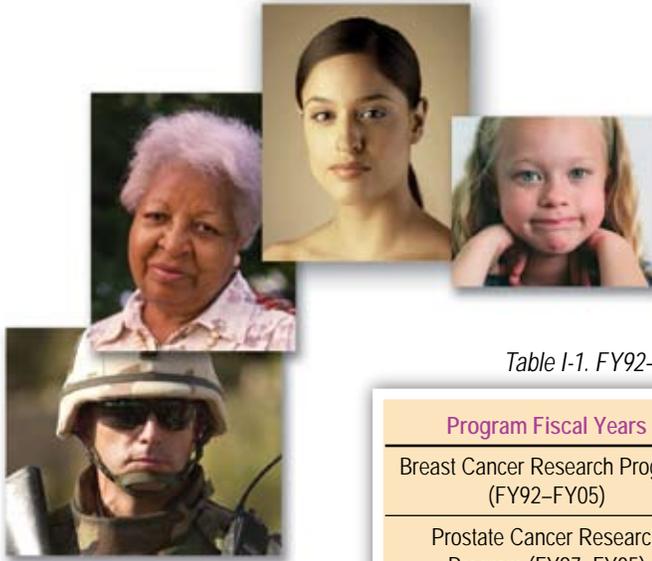


Table I-1. FY92–FY05 Awards Managed by the CDMRP

| Program Fiscal Years | Grants Managed | Dollars Invested |
|---|----------------|-------------------|
| Breast Cancer Research Program (FY92–FY05) | 4,674 | \$1,570.5M |
| Prostate Cancer Research Program (FY97–FY05) | 1,454 | \$569.2M |
| Neurofibromatosis Research Program (FY96–FY05) | 181 | \$134.8M |
| Ovarian Cancer Research Program (FY97–FY05) | 108 | \$79.1M |
| Peer Reviewed Medical Research Program (FY99–FY05) | 196 | \$251.1M |
| Chronic Myelogenous Leukemia Research Program (FY02–FY05) | 47 | \$15.5M |
| Tuberous Sclerosis Complex Research Program (FY02–FY05) | 35 | \$8.2M |
| Other Programs (FY95–FY05) | 241 | \$306.5M |
| TOTAL | 6,936 | \$2,934.9M |

Programs Managed by the CDMRP



In 2006, the CDMRP is celebrating its 15th anniversary. Since its inception, the CDMRP has managed 73 separate research programs that are aimed at improving the health of all Americans. Congressional appropriations directed toward these 73 research programs total almost \$3.8B. Seven of the programs managed by the CDMRP are considered primary programs because they either have

received or have the potential to receive multiple appropriations and are characterized by standing Integration Panels (IPs) composed of expert scientists, clinicians, and consumer advocates. The other programs managed by the CDMRP are characterized by a one-time appropriation and/or are institutionally based. Although the programs within the CDMRP share many common features, each program is unique and emphasizes the specific needs of its research and advocacy communities. Highlights of each of the seven primary programs follow with additional details found in the corresponding program sections. Section IX of this report contains information on the other programs managed by the CDMRP.

Breast Cancer Research Program

The DOD Breast Cancer Research Program's (BCRP's) vision is to eradicate breast cancer. The BCRP was the first program managed by the CDMRP and today is leaving a legacy for other programs within the CDMRP as well as for other funding agencies. As the second largest funder of extramural breast cancer research in the world, the BCRP has managed approximately \$1.96B from FY92 through FY06. In an effort to fight breast cancer, a research portfolio has been built that encompasses a wide spectrum of projects spanning the prevention, detection, diagnosis, and treatment of breast cancer (Figure I-2). Awards made through this program support innovative ideas, the training of future generations of scientists and clinicians, necessary research resources, and translational research. Through FY05, the BCRP has received 28,305 proposals and has made 4,674 awards. Additional details regarding the BCRP are included in Section II.

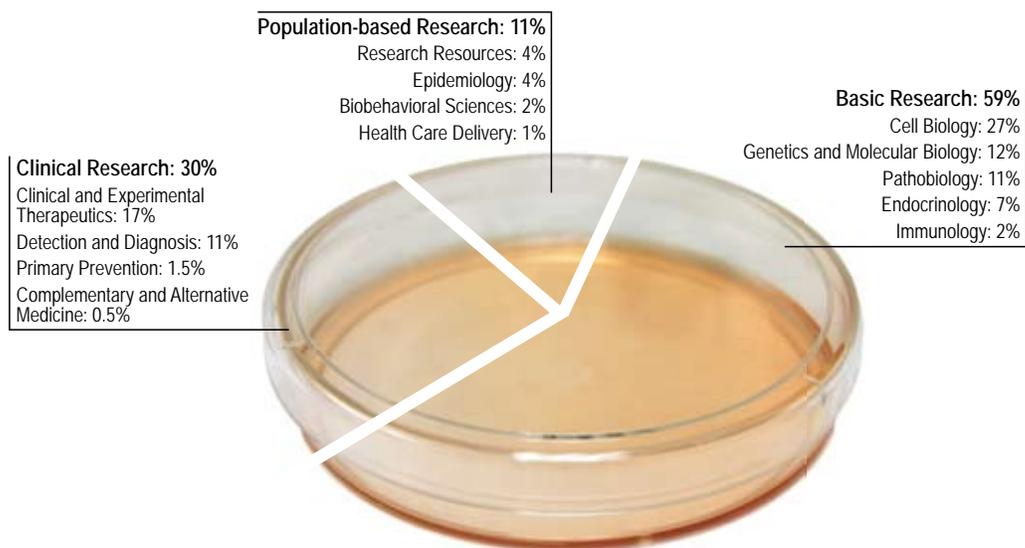


Figure I-2. FY92-FY05 BCRP Portfolio by Research Area

Prostate Cancer Research Program

The DOD Prostate Cancer Research Program's (PCRP's) vision is to conquer prostate cancer. The PCRP is the second largest funder of extramural prostate cancer research in the United States and has been responsible for the management of \$730M in congressional appropriations through FY06. Since its inception, the PCRP has been committed to strengthening translational research in prostate cancer and addressing the significant disparities in the incidence and mortality rates of prostate cancer that exist among different ethnic groups. The program has designed several award mechanisms to stimulate research in these areas. The program's portfolio includes basic, clinical, and population-based research (Figure I-3). Through FY05, this program has received 6,207 proposals, leading to 1,454 awards. The PCRP is described in greater detail in Section III.

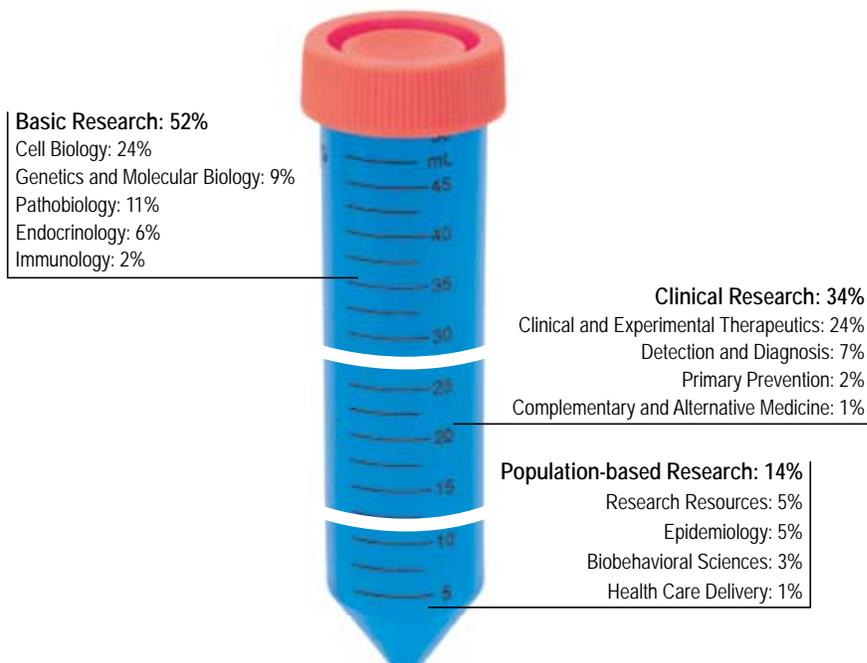


Figure I-3. FY97–FY05 PCRP Portfolio by Research Area

Neurofibromatosis Research Program

The DOD Neurofibromatosis Research Program's (NFRP's) vision is to decrease the impact of neurofibromatosis (NF) and schwannomatosis. As a leader in NF research funding worldwide, the NFRP has managed \$172.3M in congressional appropriations from FY96 through FY06. The NFRP has supported a multidisciplinary portfolio aimed at improving and enhancing the quality of life of persons with NF and schwannomatosis (Figure I-4). Over the years, the program has placed emphasis on building collaborative connections throughout the NF community including support for large natural history studies and consortium awards. From FY96 through FY05, the NFRP received 612 proposals that led to 181 awards. Further details on the NFRP appear in Section IV.

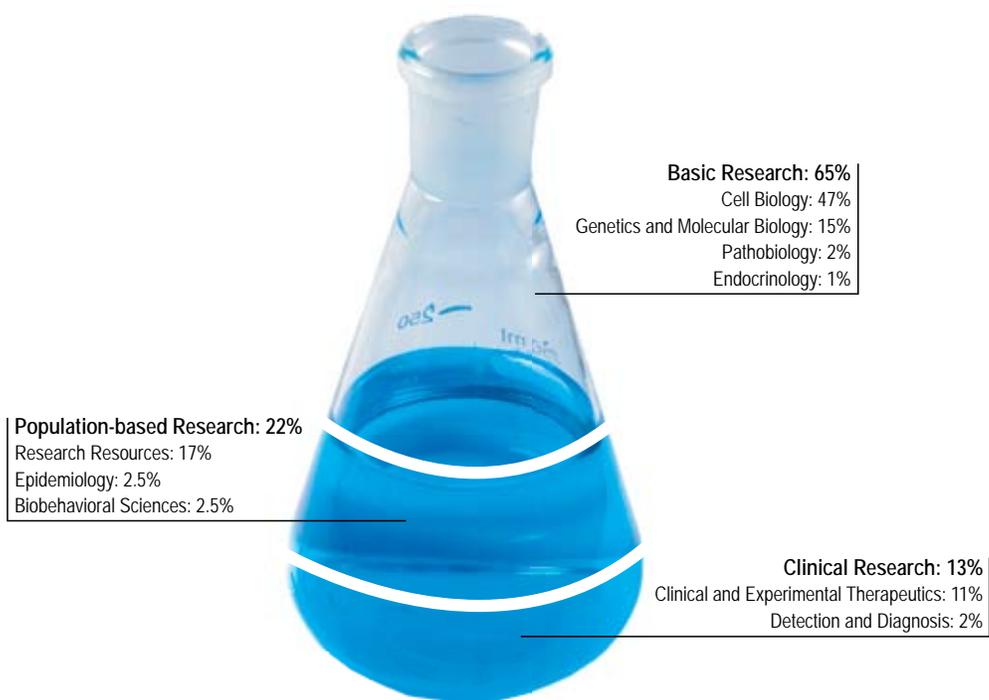


Figure I-4. FY96-FY05 NFRP Portfolio by Research Area

Ovarian Cancer Research Program

The DOD Ovarian Cancer Research Program’s (OCRP’s) vision is to eliminate ovarian cancer. The OCRP has built a multidisciplinary portfolio (Figure I-5) that spans basic, clinical, and population-based research. Over the years, the program has impacted progress in the field of ovarian cancer research through the support of collaborations across disciplines and institutions, funding for pioneering research, and the training of new investigators in the ovarian cancer research field. Appropriations for the FY97 through FY06 OCRP total \$101.7M. Since the program’s inception through FY05, 1,101 proposals have been received, and 108 awards have been made. The OCRP is described in greater detail in Section V.

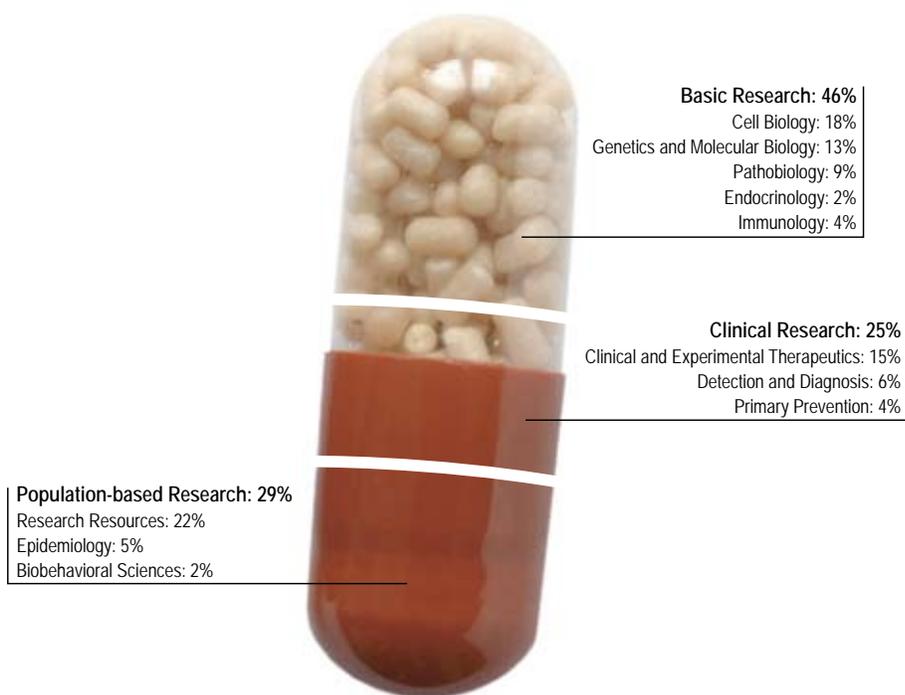


Figure I-5. FY97–FY05 OCRP Portfolio by Research Area

Peer Reviewed Medical Research Program

The DOD Peer Reviewed Medical Research Program's (PRMRP's) mission is to support research on issues with direct relevance to military health to include family members and veterans.

Appropriations for the FY99 through FY06 PRMRP total \$344.5M. Through FY05, the PRMRP has developed a portfolio of research that covers 196 medical research projects in 60 topic areas that have direct relevance to military health. Figure I-6 reflects the FY99 through FY05 PRMRP portfolio by research area. PRMRP-supported research has begun to yield products and technologies aimed at improving military health and readiness. Additional features of the PRMRP are detailed in Section VI.

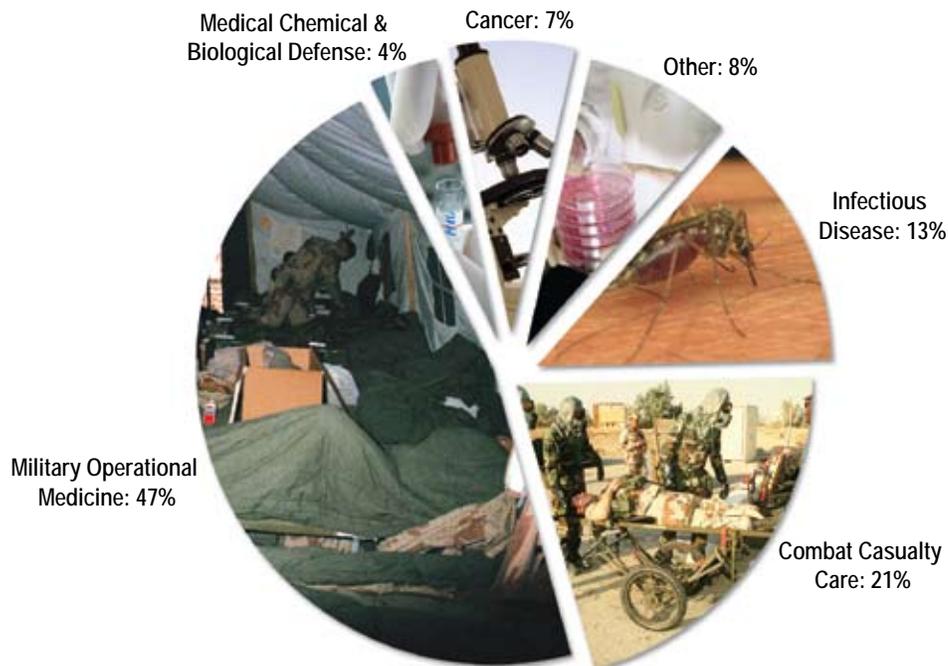


Figure I-6. FY99-FY05 PRMRP Portfolio by Research Area

Chronic Myelogenous Leukemia Research Program

The DOD Chronic Myelogenous Leukemia Research Program's (CMLRP's) vision is to perfect the existing treatments and develop new diagnostic and therapeutic approaches for chronic myelogenous leukemia (CML). The CMLRP was established in FY02, and to date the program has managed \$22.05M in congressional appropriations for research in CML. A total of 47 awards have been made through FY05. The program has built a portfolio of research that is advancing the discovery of new frontiers in CML including basic, clinical, and population-based research (Figure I-7). More detailed information regarding the CMLRP can be found in Section VII.

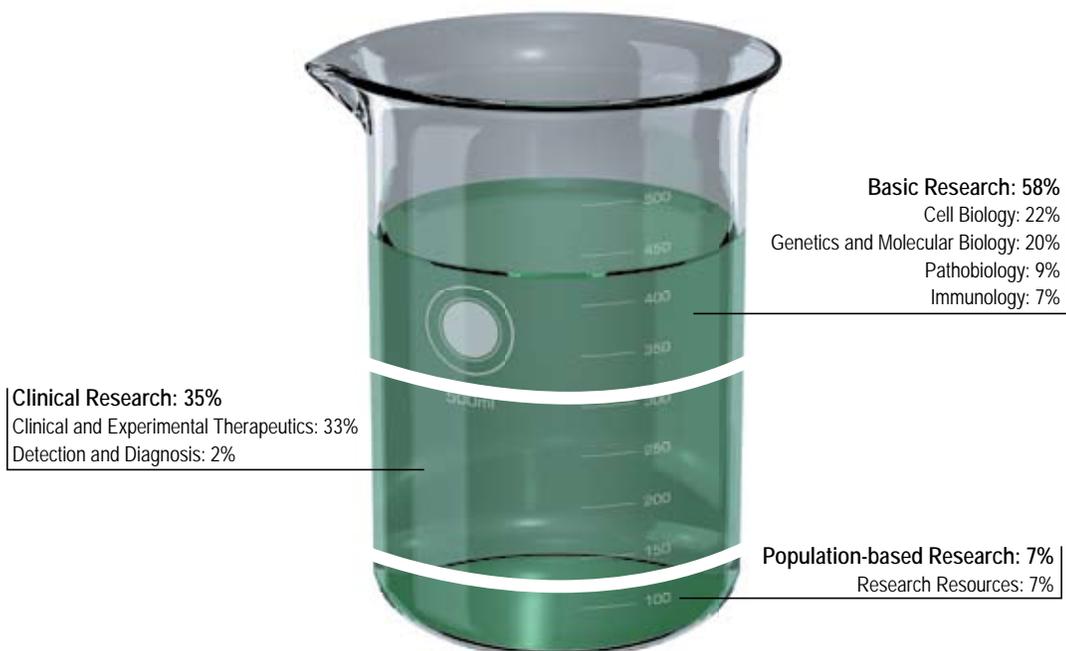


Figure I-7. FY02–FY05 CMLRP Portfolio by Research Area

Tuberous Sclerosis Complex Research Program

The DOD Tuberous Sclerosis Complex Research Program's (TSCRPs) vision is to lessen the impact of tuberous sclerosis complex (TSC). The TSCRPs was established by a \$1M appropriation in FY02 for TSC research, and to date the program has managed \$13.5M in congressional appropriations. The TSCRPs has funded 35 awards through FY05 in basic, clinical, and population-based research (Figure I-8). Projects funded by this program are advancing progress in TSC research and span the spectrum of groundbreaking concepts and ideas, natural history studies, and the development of clinical resources. The TSCRPs is described in more detail in Section VIII.



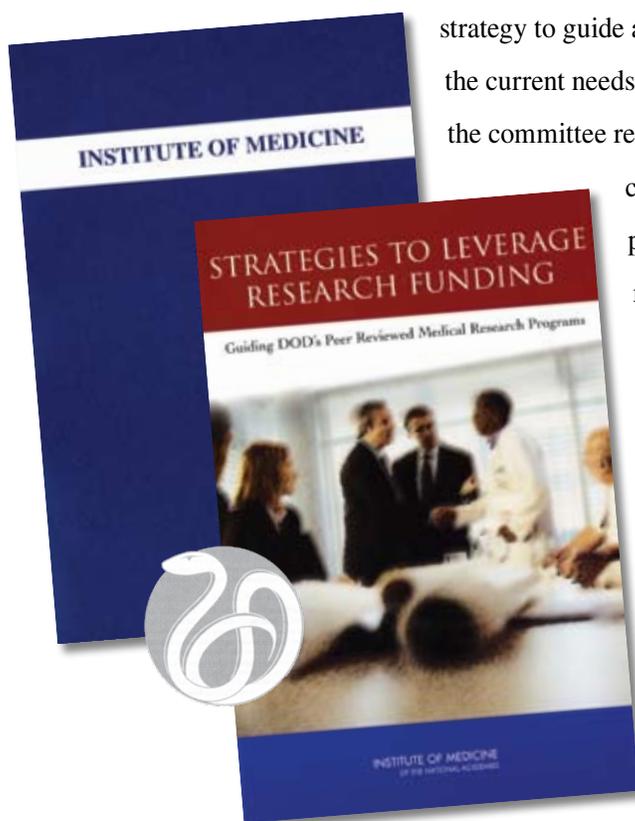
Figure I-8. FY02–FY05 TSCRPs Portfolio by Research Area

Program Development through Science Management

In FY92 the USAMRMC received a \$25M congressional appropriation for breast cancer research. The following year, the USAMRMC received a \$210M congressional appropriation for breast cancer research. Recognizing that breast cancer was outside its core expertise, the Army sought the advice of the National Academy of Sciences (NAS) to effectively manage the FY93 breast cancer appropriation. In response, the NAS Institute of Medicine (IOM) issued a report entitled *Strategies for Managing the Breast Cancer Research Program: A Report to the U.S. Army Medical Research and Development Command*. The IOM committee made two pivotal recommendations in this report. First, the committee recommended an annual investment

strategy to guide allocations of funds that best address the current needs in breast cancer research. Second, the committee recommended a two-tier review strategy

consisting of scientific peer review and programmatic review. This two-tier review system was designed to ensure that the research portfolio reflects not only the most meritorious but also the most programmatically relevant science. Both of these recommendations have become cornerstones in the administration of the majority of programs managed by the CDMRP.



The CDMRP utilizes a flexible and responsive 7-year management cycle that spans all phases of program execution, from the development of a vision through the completion of research grants (Figure I-9). All programs within the CDMRP depend upon yearly, individual congressional appropriations. These funds are not in the President’s budget; Congress adds them annually to the DOD appropriation to fund new programs or to continue existing DOD programs. The effectiveness of the programs, the work of consumer advocates, and the need for additional, focused biomedical research have led to continuing appropriations for programs managed by the CDMRP.

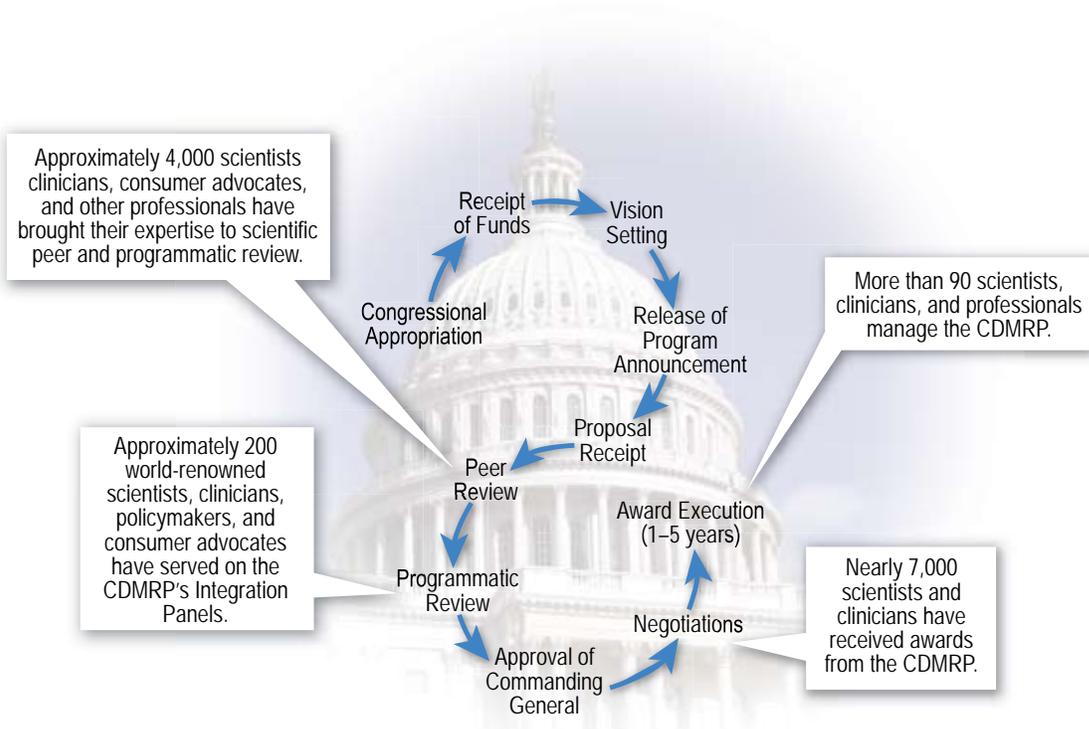


Figure I-9. CDMRP Flexible Execution and Management Cycle

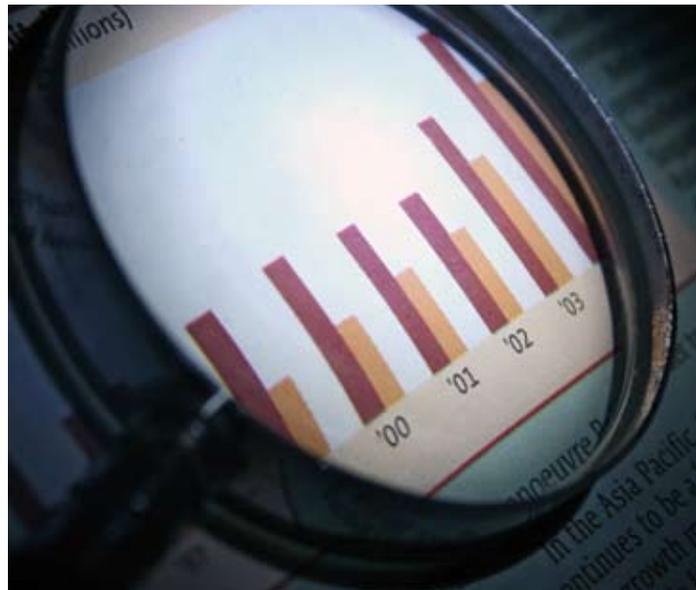
Standards of Ethics

The CDMRP maintains the highest standards of ethics in all of its practices—from program development through science management. The CDMRP was created in response to the concerns of individuals affected by cancer and disease. As a steward of these appropriated funds, the CDMRP develops, implements, and maintains programs that employ fair selection processes, are of high scientific quality and programmatic relevance, and are responsive to the needs of the American public. All scientific peer reviewers and programmatic reviewers must uphold the highest standards of conduct to preserve the integrity of the review process, including disclosure of conflicts of interest and maintenance of confidentiality. Over the years, the CDMRP has implemented process improvements that are rigorous, efficient, cost-effective, and transparent. These business practices have enabled the CDMRP to administer an increasing number of biomedical research programs and an increasing number of awards within each program. As a result of these approaches, an average annual administrative cost of less than 9 percent across CDMRP programs was achieved in FY05, thus maximizing the amount of appropriated funds available for research. Public awareness of the CDMRP is also a critical component of guarding the public trust, and efforts used to promote communication are highlighted in the following section, Research Information Dissemination.



Setting the Vision

Early in each fiscal year, each program's Integration Panel—an expert panel of scientists, clinicians, and consumer advocates—meets to deliberate issues and concerns unique to the individual program and establishes a vision and an investment strategy for the coming year. The development of an annual investment strategy stems from the 1993 IOM recommendations³ and provides a high degree of flexibility. It allows each program to identify underfunded and underrepresented areas of research and to encourage research in those areas that are considered the most critical to patients, consumers, clinicians, and laboratory researchers. The investment strategy provides the framework and direction necessary to most effectively obligate each congressional appropriation while avoiding unnecessary duplication with other funding agencies. (See Appendices A and B for summaries of congressional appropriations by program and year.)



³ Institute of Medicine, *Strategies for Managing the Breast Cancer Research Program: A Report to the U.S. Army Medical Research and Development Command*, The National Academies Press, 1993.

Investment Strategy

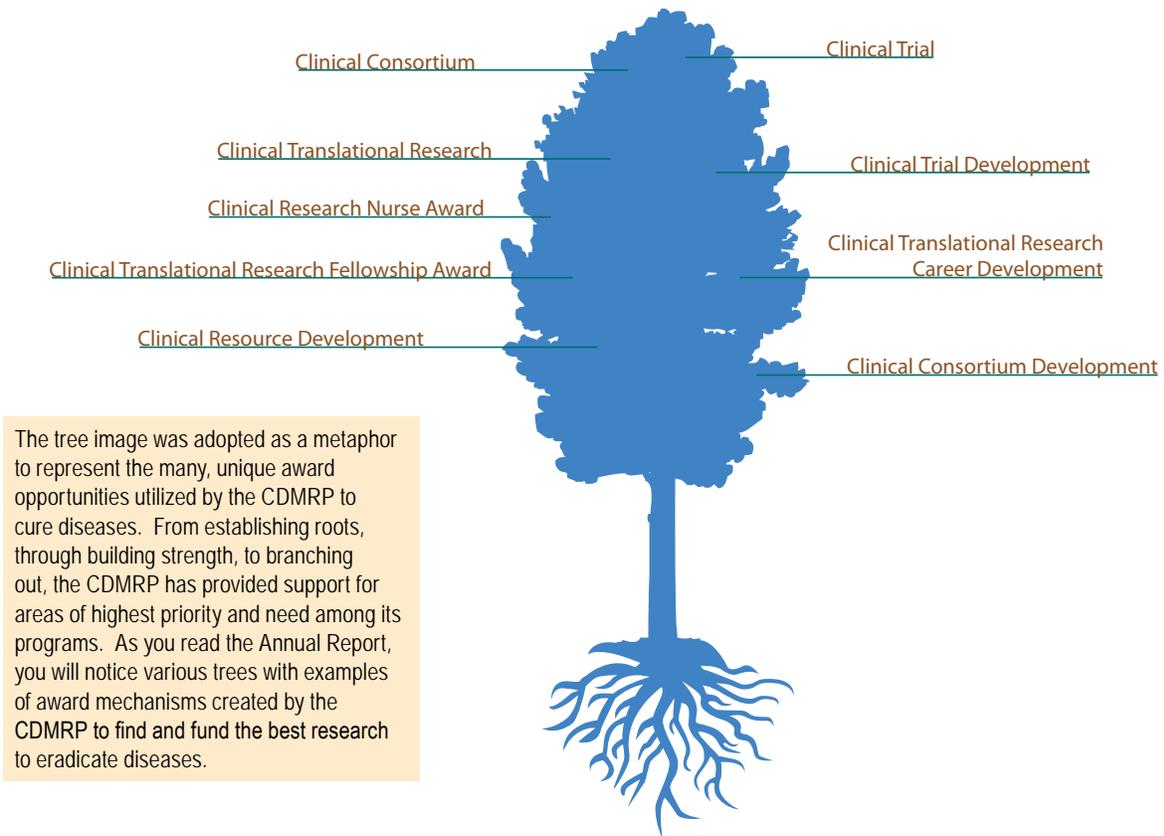
A critical component of the investment strategy is developing specific award mechanisms that capture the current needs of both the research and advocacy communities. Once an investment strategy is developed, a separate program announcement outlining the award mechanisms offered for each of the research programs managed by the CDMRP is developed in conjunction with each Integration Panel and released each fiscal year. The CDMRP has utilized more than 35 different types of award mechanisms that fall predominantly into four categories: clinical research, innovative research, training and recruitment, and research resources as shown in Figure I-10.



Figure I-10. CDMRP Funding Philosophy

Clinical Research

The CDMRP has supported the necessary research that will accelerate discoveries in basic science to the clinical setting. Basic science research typically begins in the laboratory where researchers may be studying cellular and molecular structures and events underlying biological processes. Typically, after extensive studies in animal and humans cells, research then progresses to animal models. If this stage of research is successful, clinical testing can be conducted in humans after approval by the U.S. Food and Drug Administration. The CDMRP has supported several award mechanisms that promote the application of new knowledge and techniques to patient care. Through FY05, the CDMRP has funded 94 awards that specifically focus on clinical research.

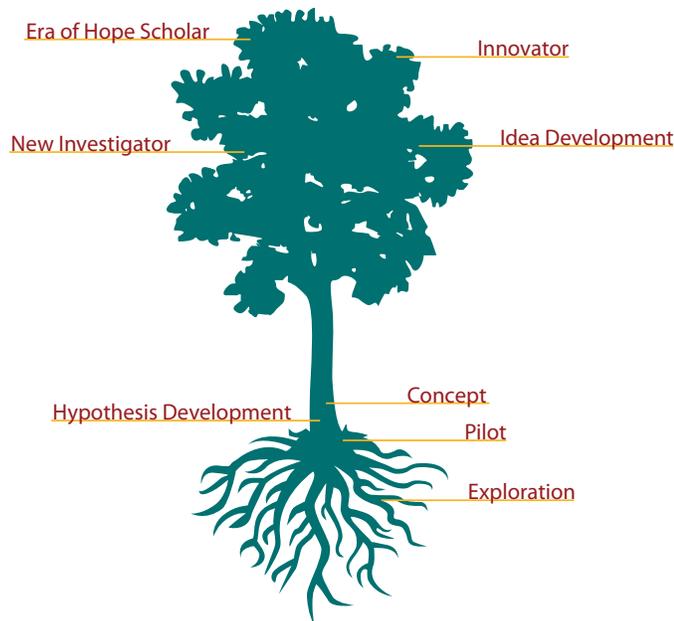


The tree image was adopted as a metaphor to represent the many, unique award opportunities utilized by the CDMRP to cure diseases. From establishing roots, through building strength, to branching out, the CDMRP has provided support for areas of highest priority and need among its programs. As you read the Annual Report, you will notice various trees with examples of award mechanisms created by the CDMRP to find and fund the best research to eradicate diseases.

Figure I-11. Examples of CDMRP Award Mechanisms That Emphasize Clinical Research

Innovative Research

In 1993, a recommendation was made to the USAMRMC by the IOM to “create an environment in which creative ideas and first-rate research can flourish and in which investigators are not afraid to gamble on risky but alluring ideas.”⁴ Today, the CDMRP’s central philosophy is innovation. The CDMRP fills research gaps by funding high-risk, high-gain research that other agencies will not venture funding. Many of the award mechanisms offered by the CDMRP emphasize support for the exploration of revolutionary ideas and concepts that could ultimately lead to a critical discovery or major development in the battle to cure disease. While each mechanism has different award requirements, all share the common goal of advancing innovative ideas, creative solutions, and breakthrough technologies. Through FY05, the CDMRP has funded 3,713 awards that specifically encourage innovative scientific ideas and approaches to disease eradication.



⁴ Institute of Medicine, *Strategies for Managing the Breast Cancer Research Program: A Report to the U.S. Army Medical Research and Development Command*, The National Academies Press, 1993.

Figure I-12. Examples of CDMRP Award Mechanisms That Emphasize Innovative Research

Training and Recruitment

The CDMRP has played a major role in training scientists at all points in their careers. In the 1993 IOM report, it was stated that the “best investment the program can make is to stimulate talented new investigators....”⁵ The CDMRP’s commitment to training the best and the brightest to eradicate human diseases is demonstrated by its portfolio of funded projects, nearly one-third of which focus on training and recruitment. The CDMRP has supported both new researchers in the field and established scientists interested in extending their expertise to the study of other diseases. A total of 1,982 awards have been made through FY05 in the training arena.

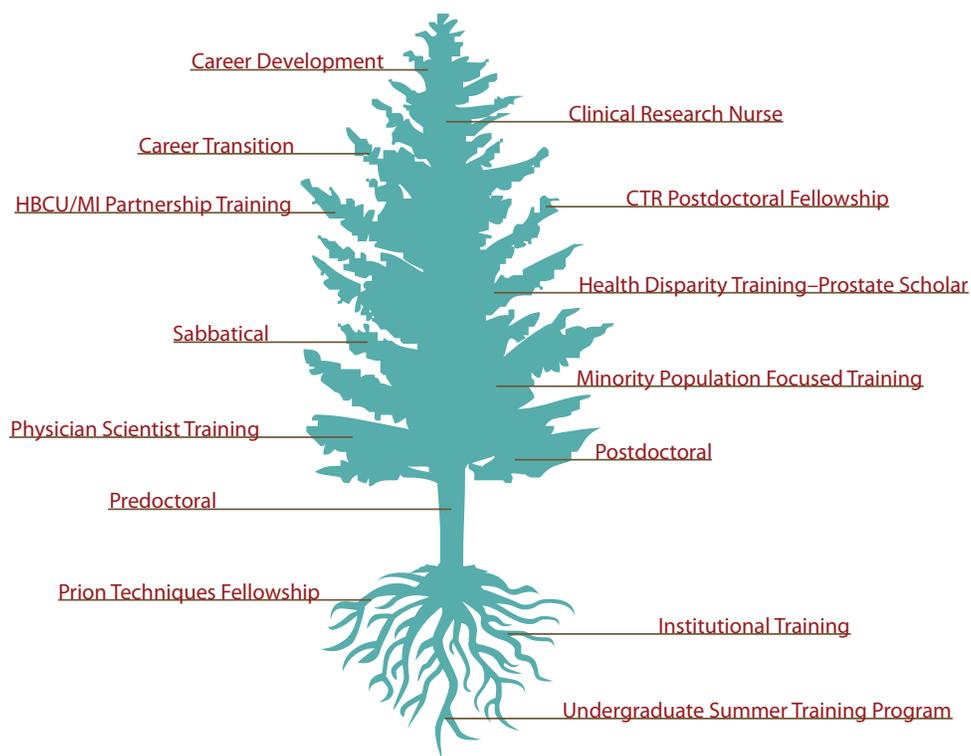


Figure I-13. Examples of CDMRP Award Mechanisms That Emphasize Training and Recruitment

⁵ Institute of Medicine, *Strategies for Managing the Breast Cancer Research Program: A Report to the U.S. Army Medical Research and Development Command*, The National Academies Press, 1993.

Research Resources

In the 1993 IOM report, it was noted that “research in breast cancer is impeded by inadequate access to resources that are appropriate for sharing—including tumor samples, cell lines, animal models, DNA probes, follow-up data on women diagnosed with breast cancer, information about ongoing clinical trials, and economic data to evaluate the cost of care.”⁶ Based on this clear need in 1993 and the need for similar support identified by IPs in subsequent years, the CDMRP has funded 118 research resources awards through FY05. These awards are designed to provide researchers with support to (1) create or obtain materials and data from multiple sources that would otherwise be difficult to acquire or (2) establish and support centers or consortia that can provide a foundation for future research.

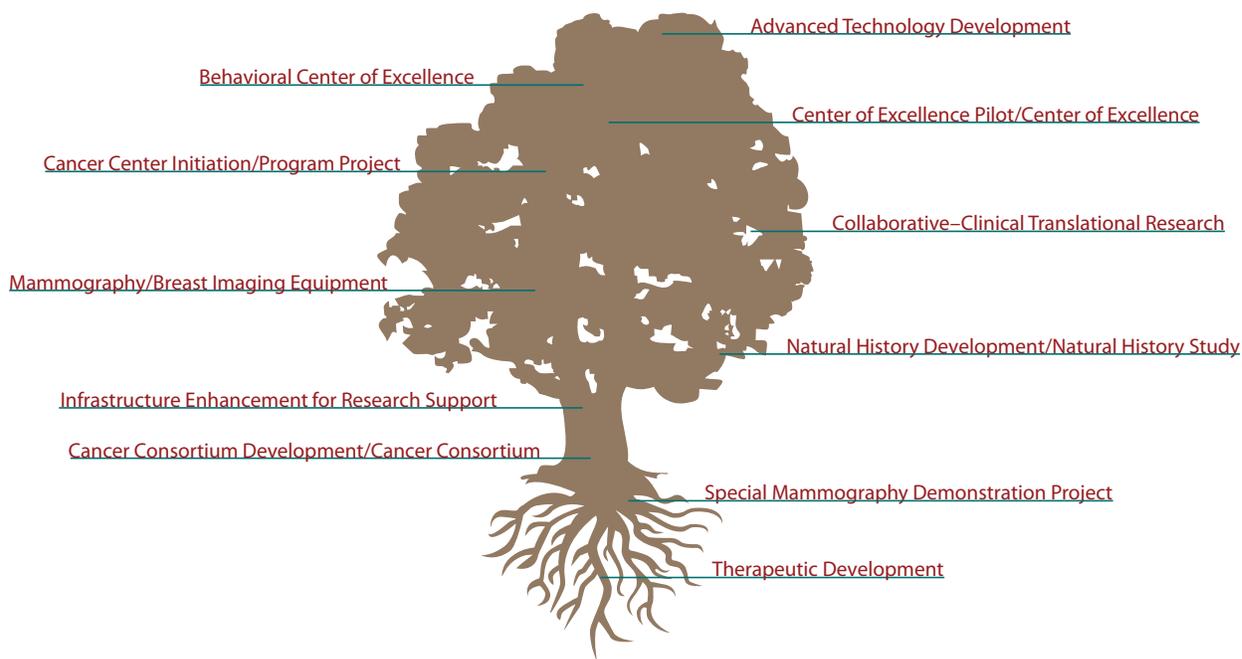


Figure I-14. Examples of CDMRP Award Mechanisms That Emphasize Research Resources

⁶ Institute of Medicine, *Strategies for Managing the Breast Cancer Research Program: A Report to the U.S. Army Medical Research and Development Command*, The National Academies Press, 1993.

Program Management

Electronic Proposal Submission and Review

An innovative online proposal submission website (i.e., eReceipt) was developed in 2000 by the CDMRP for applicants to electronically submit new proposals using a simple and integrated approach



to proposal submission. This eReceipt website is also used by applicants and the CDMRP to manage in-progress and past proposals. To date, more than 20,700 proposals have been received electronically.

Proposals received in response to published announcements are subjected to a two-tier review derived from 1993 IOM recommendations.⁷ The two tiers are fundamentally different as depicted below. Scientifically sound proposals that most effectively address the unique focus and goals of the program are then recommended to the Commanding General, USAMRMC, for funding.

Peer Review

- ❖ Evaluation of scientific merit
- ❖ Criteria-based evaluation
- ❖ Proposals evaluated by scientific discipline, specialty area, or award mechanism

Programmatic Review

- ❖ Evaluation of programmatic relevance
- ❖ Comparison-based evaluation
- ❖ Proposals evaluated across multiple disciplines

⁷ Institute of Medicine, *Strategies for Managing the Breast Cancer Research Program: A Report to the U.S. Army Medical Research and Development Command*, The National Academies Press, 1993

Grants Management

Awards are made in the form of grants, contracts, or cooperative agreements, and the research is executed over 1 to 5 years, depending on the type of award mechanism. With 6,937 awards made through FY05 and with approximately 500 to 600 new grants being processed each year, the management of these grants, contracts, and/or cooperative agreements is a major focus of the CDMRP. As such, the CDMRP makes certain that the research supported by the American public is monitored thoroughly for technical progress and compliance with animal and human use regulations.

Each CDMRP award is assigned to a Grants Manager for the life of that grant, ensuring a broad knowledge of each grant, continuity among all parties involved in the award, and the most comprehensive assistance possible to the

Principal Investigator. To assist with the grants management process, the CDMRP developed a state-of-the-art database called the Electronic Grants System (EGS) in FY02 to enable real-time electronic management of CDMRP proposals from proposal receipt to award closeout. EGS is a customized and integrated business system that securely allows multiple users within the USAMRMC to input data, download reports, and manage daily administrative tasks associated with

grants. The implementation of EGS has allowed the CDMRP to virtually eliminate the paper processing of grants, which not only saves time and money but also increases the accuracy of the grant management processes.



Program Evaluation

The CDMRP's program evaluation division was established to ensure that the CDMRP is finding and funding the best research to eradicate diseases. Based on a recommendation from the IOM to "develop and implement a plan with benchmarks and appropriate tools to measure achievements and progress toward goals of the BCRP both annually and over time"⁸ and because the CDMRP is accountable for the expenditure of congressional appropriations, the CDMRP established a program evaluation division to specifically assess research relevance, productivity, and accomplishments. Combined with the activities of the grants management division (detailed earlier), these efforts have collectively enabled the CDMRP to evaluate program operations and outcomes. An example of a program evaluation analysis is highlighted under Evaluation of the Inquiry Review Panel (IRP).



⁸ Institute of Medicine, *A Review of the Department of Defense's Program for Breast Cancer Research*, The National Academies Press, 1997.

Evaluation of the Inquiry Review Panel

The IRP was established by the CDMRP to enable grant applicants to address queries and complaints regarding the acceptance, scientific peer review, or programmatic review of their proposals. IRP appeals must be based on the occurrence of factual or procedural errors that occur at receipt, peer review, or programmatic review. At the end of 2005, CDMRP scientists began to quantitate the results of the IRP process to provide data that would inform IRP participants and the process. Inquiries from FY99 through FY05 were analyzed. During this time, 17,471 proposals were received across programs. The results suggested that, across all programs from FY99 to FY05, only 1% of all funding decisions were appealed. Of the total number of appeals during this time frame (n=219), 36% (n=79) went to a re-review, and 10% (n=21) of all appeals resulted in a positive funding decision. These results could be interpreted as a validation of the CDMRP review processes and suggest that the occurrence of a perceived factual or procedural error is a rare event.



Research Information Dissemination

The CDMRP continues to recognize the importance of communication and dissemination of program information to its multiple stakeholders, including Congress, consumer advocates, DOD, scientists and clinicians, and the public at large. The CDMRP has supported several efforts to foster program awareness, as follows.

<http://cdmrp.army.mil>

The CDMRP website disseminates up-to-date program information to the public and the research community. Annually, approximately 8,700 visits are made to the homepage along with more than 14,500 total visits to the overall website. Features of the website include:

- ❖ Research Programs—individual programs managed by the CDMRP
- ❖ Funding Opportunities—calls to the scientific and clinical communities to submit proposals under individual award mechanisms offered by research programs
- ❖ Consumer Participation—information on consumer involvement in scientific peer review
- ❖ Search Awards—search engines for posted awards that search by various criteria (including research program, fiscal year, Principal Investigator, institution, research topic, award mechanism, and clinical trial); the award amount, an abstract, and resulting publications are provided for each award
- ❖ Annual Report—archives of CDMRP Annual Reports
- ❖ What's New—the most recent CDMRP happenings, including CDMRP-supported meetings, scientific accomplishments achieved by CDMRP-funded investigators, and press releases
- ❖ Publications—documents about recent CDMRP happenings including press releases, fact sheets, and program award books
- ❖ About Us—summary information about the CDMRP
- ❖ Related Links—links to other sites

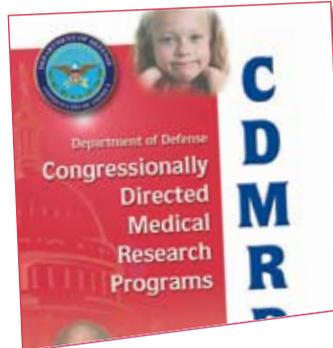


Funding Opportunities and Award Information

Programs within the CDMRP prepare and issue program announcements that provide details on individual award mechanisms, the application process, and requirements for submitting proposals.

The following publicity efforts are directed toward alerting the scientific research community when new program announcements are released and propagating the word on funded awards:

- ✿ Posting program announcements on the CDMRP website.
- ✿ Posting award information on the CDMRP website.
- ✿ Notifying websites that specialize in biomedical grant notification.
- ✿ Alerting more than **800** research administrators of upcoming award opportunities with pre-announcements and release date announcements.
- ✿ Notifying more than **50** professional associations, **10** military research laboratories, **6** federal agencies, and more than **200** consumer advocacy organizations of upcoming funding opportunities.
- ✿ Advertising both in broadly focused professional journals and on federal business websites.
- ✿ Utilizing targeted e-mails and advertising for specific award mechanisms and outreach.
- ✿ Sending **27,000** e-mails to prior applicants, scientific peer reviewers, and individuals who have requested that their names be placed on the CDMRP notification list.
- ✿ Sending press releases to cancer research news outlets.
- ✿ Distributing CDMRP electronic news items to more than **200** consumer advocacy groups.
- ✿ Exhibiting the CDMRP display at national scientific meetings.



INNOVATOR AWARD
 A lifetime opportunity to change the course of science and medical discovery and make an extraordinary impact on breast cancer.

The Breast Cancer Research Program (BCRP) Innovator Award seeks to identify and fund uniquely gifted individuals who have a history of visionary scholarship, leadership, and creativity. This prestigious award will provide the recipient with unprecedented freedom to pursue a novel course of action that could ultimately lead to a critical discovery or major advancement in the battle to eradicate breast cancer. Acknowledging that critical insights often come from those with an outside perspective, the BCRP is looking for creative thought-leaders from all fields, not just the sciences traditionally involved in breast cancer research.

Funding for Innovator Awards can be requested for a maximum of \$5 million in direct costs for up to a 5-year performance period.

Applicants must be nominated to be considered for this award; however, self-nominations will be accepted. Nominations will be screened to determine which nominees meet the intent of the award, and selected nominees will be invited to submit a complete proposal.

-Clinical Consortium Award-



A pioneering, multi-institutional approach to expediting prostate cancer clinical research

The Prostate Cancer Research Program (PCRP) believes that rapid advances in marketing novel and effective therapeutic interventions in prostate cancer treatment will be made by assembling leading clinical investigators into a multi-institutional team that seeks, identifies, and facilitates the best prostate cancer clinical research available. The fiscal year 2005 (FY05) PCRP Clinical Consortium Award was established to encourage the formation of a multidisciplinary, multi-institutional consortium whose function will be to facilitate the rapid execution of collaborative Phase II or Phase II-linked Phase I (Phase I/II) clinical trials of promising new therapeutic approaches for the management or treatment of prostate cancer. This is to combine the efforts of the most highly accomplished scientists, researchers, and clinicians whose contributions to prostate cancer research will be assembled to form a consortium that will promote high-impact clinical trials that are anticipated to be funded up to a maximum of \$5 million in direct and indirect costs.

Please see Prostate Cancer Research Program Opportunities at <http://pcrp.army.mil>

This document is a synopsis of the award. Detailed descriptions of eligibility, submission requirements, and other information are available at <http://pcrp.army.mil>

Department of Defense Breast Cancer Research Program
 Research Funding Available as a Result of a \$127.5 Million Congressional Appropriation

Proposals are due in May 2006 for the following awards:

- Predoctoral Traineeship
- Multidisciplinary Postdoctoral
- Idea
- Synergistic Idea*

The overall goal of the Breast Cancer Research Program (BCRP) is to promote innovative research directed toward the eradication of breast cancer. The BCRP also places great importance on fostering and maintaining multi-disciplinary and/or multi-institutional collaborations and alliances. Although the BCRP encourages high-risk, high-gain research, such projects must demonstrate solid scientific judgment and rationale.

***New This Year:**

The Synergistic Idea Award supports innovative, high-risk/high-reward breast cancer research collaborations between two independent, faculty-level (or equivalent) investigators who address a central problem or question in breast cancer research from synergistic and complementary perspectives. The proposal may be structured as either two separate but complementary and highly synergistic objectives or as a balanced and synergistic collaboration integrated into a single project.

See our website at <http://cdmrp.army.mil> or call 301-619-7079 for more information.



Department of Defense Congressionally Directed Medical Research Programs

CDMRP

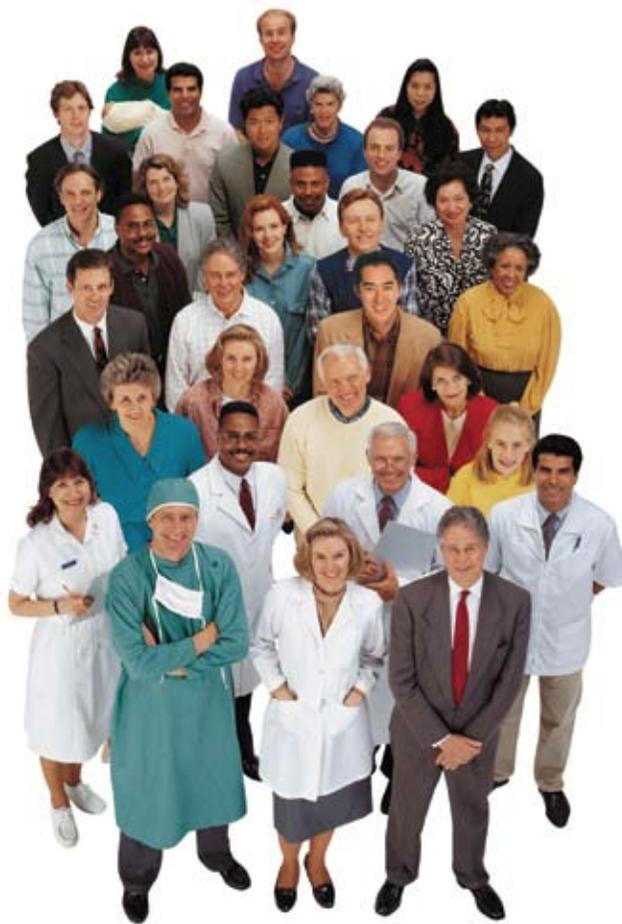
Vision: Find and fund the best research to eradicate diseases and support the warfighter for the benefit of the American public.

Mission: We provide hope by promoting innovative research, recognizing untapped opportunities, creating partnerships, and guarding the public trust.

U.S. Army Medical Research and Materiel Command

Partnering with Communities to Cure Disease

The success of the CDMRP can be attributed to the collective wisdom and dedication of the people involved—scientists, research managers, consumers, and those who are ultimately most affected by policy and research. Public, private, government, and military partnerships occur in all aspects of the programs and are central to the success of the CDMRP. These effective partnerships are leading closer to cures for many diseases and are facilitating the CDMRP's ability to effectively address critical health issues. These efforts are summarized on the following pages.



Consumers Advocates and the CDMRP

The unique voices and experiences of survivors and their families have played a pivotal role in the establishment and growth of the CDMRP. The relentless work of thousands of advocates has resulted in almost **\$3.8B** in appropriations for targeted diseases through FY06. Today, the CDMRP is a recognized leader in integrating consumers in virtually all aspects of program execution. Consumers for most of the primary programs are survivors of the respective diseases and representatives of consumer advocacy organizations. The value of consumer involvement is derived from each individual's firsthand experience with the disease. This adds a perspective, passion, and a sense of urgency that ensure that the human dimension is incorporated in the program policy, investment strategy, and research focus. For instance, approximately **35** consumers have served on IPs from 1993 to the present while others have been active participants in executing some research projects. More than **860** consumers have served on scientific peer review panels since 1995. Finally, consumers have had opportunities to learn about the scientific advances by attending multidisciplinary meetings held by the CDMRP, such as the BCRP's Era of Hope meetings. For more information on consumer involvement and serving as a consumer reviewer in the first tier of review (peer review), see the consumer involvement pages on the CDMRP website (<http://cdmrp.army.mil>).



The Scientific Community and the CDMRP

The scientific community is essential in assisting the CDMRP in shaping the future of health care. The fulfillment of program goals requires cooperation and communication across multiple scientific and clinical disciplines. To date, more than 4,000 scientists and clinicians have provided the necessary subject matter expertise on peer review panels. Approximately 200 world-renowned basic scientists, clinicians, and policymakers have participated in vision setting and programmatic review as IP members, and more than 200 scientists have served as ad hoc programmatic reviewers. More than 90 scientists, clinicians, and professionals currently are involved in all phases of program execution and science management of the CDMRP. Collectively, these scientists have assisted the CDMRP in funding more than 6,100 researchers in an effort to tackle the complex causes of disease and translate this knowledge to improved disease prevention, patient survival, and quality of life.

Working with Minority and Underserved Populations

In 1998, the CDMRP established the Minority and Underserved Populations Program to enhance the ability of the CDMRP to address significant disparities that exist in the incidence, morbidity, and mortality among different ethnic groups for many of the diseases for which the

CDMRP provides support. The purpose of the Minority and Underserved

Populations Program is to address disparities in underserved, understudied, and underrepresented communities. Its mission is to enhance the CDMRP's efforts in this area by creating new award mechanisms, reaching out to communities

through improved communication, and partnering with other agencies.

In total, the CDMRP has made **83** health disparity and

Historically Black Colleges and Universities/Minority Institutions

(HBCU/MI) partnership awards totaling **\$31.5M**.



International Cancer Research Partners



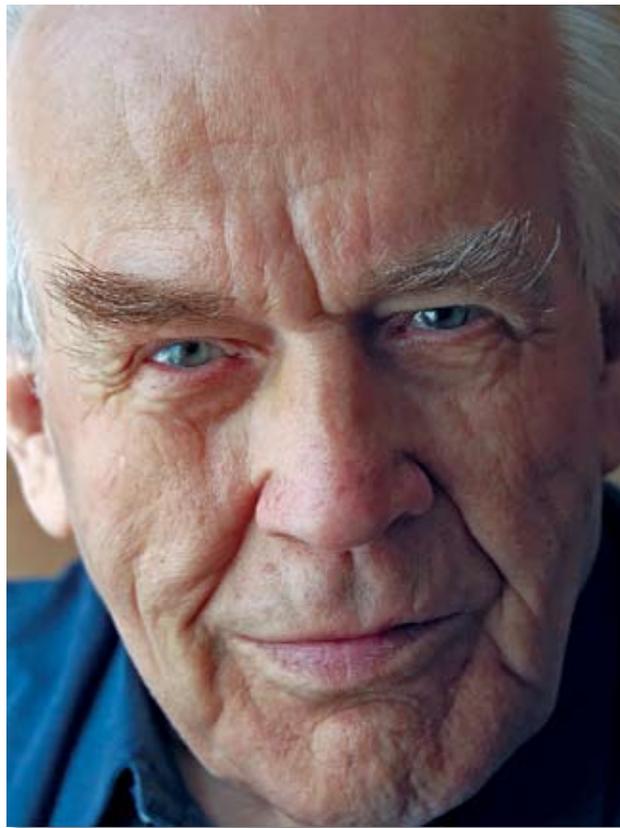
Under the direction of the National Cancer Institute (NCI) and the CDMRP, a group called the International Cancer Research (ICR) Partners was formed in 2000 to impact cancer research through global, international collaboration and coordination. Today, the ICR Partners represent 8 U.S.- and 18

U.K.-based cancer funding organizations that have come together to classify their respective research portfolios using a common coding scheme (called the Common Scientific Outline) as well as to facilitate communication and collaboration among cancer researchers, cancer funding organizations, health care policymakers, health care professionals, cancer survivors, and anyone with an interest in the most current cancer research. The ICR Partners developed a relational database of cancer research supported by its members called the International Cancer Research Portfolio (ICRP). The ICRP is available to the public and enables users to browse, search, and/or sort research portfolios by many data fields including type of cancer, funding organization, and research area—<http://www.cancerportfolio.org/>.

The ICR Partners are as follows: NCI, CDMRP, American Cancer Society, California Breast Cancer Research Program, Oncology Nursing Society, Prostate Cancer Foundation, California Cancer Research Program, Susan G. Komen Breast Cancer Foundation, and U.K. National Cancer Research Institute (includes 18 funding organizations).

Prostate Cancer Funders' Group

The Prostate Cancer Funders' Group is composed of 14 prostate cancer funding organizations that collectively strive to eliminate prostate cancer. Some of the goals of this group are to pool resources and knowledge, establish collaborations, open the lines of communication, identify roadblocks to progress, and implement international initiatives to move prostate cancer research forward, specifically in the areas of tissue bank protocols, biomarker validation, bone metastasis, and clinical trials.



Gynecological Cancer Foundation Allied Support Group

The CDMRP is a member of the Gynecological Cancer Foundation Allied Support Group, a group composed of 8 major ovarian cancer funders and 14 advocacy organizations to facilitate synergy among organizations that share goals of prevention and early detection of gynecological cancers. This group collaborates on educational, advocacy, and research projects. Additional information about the support group can be accessed at

<http://www.thegcf.org/about/allied.htm>



Multidisciplinary Meetings

Era of Hope

The BCRP has sponsored four major international scientific meetings, called the Era of Hope, to provide a forum for thousands of scientists, clinicians, health care providers, and consumers to communicate ideas and promising new directions in breast cancer research. These meetings have provided unprecedented opportunities for developing future collaborations and disseminating program information.

Military Health Research Forum

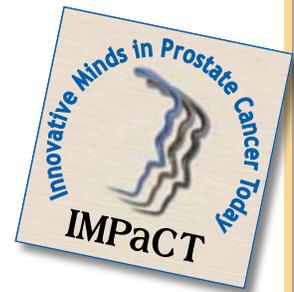
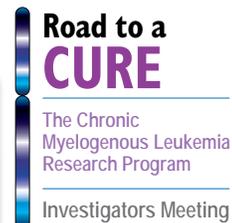
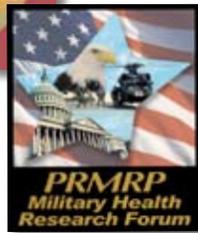
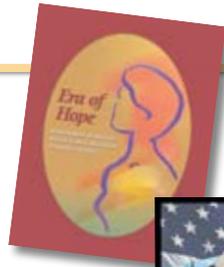
The PRMRP has sponsored two Military Health Research Forums to provide a means for investigators funded by the program to present their research findings, products, and technologies and to develop future collaborations related to military health research. In addition, the forum emphasizes ways to expedite the transition from research to field-usable products and/or methods.

IMPACT

The PCRCP will host a conference in September 2007 during National Prostate Cancer Awareness Month called “IMPACT: Innovative Minds in Prostate Cancer Today.” The intent of the meeting is to promote the exchange of ideas and explore innovative avenues of research that will advance the prostate cancer field in a forum highlighting PCRCP-supported studies. The IMPACT meeting will recognize the program’s successes in funding innovative and high-impact research, addressing health disparities, and training the next generation of prostate cancer researchers.

Road to a Cure—The CML Investigators Meeting

The CMLRP will sponsor its first research conference in December 2006 called the “Road to a Cure” to facilitate dissemination of research accomplishments, communication, and the development of future collaborations. The meeting will provide a means for funded investigators and consumer advocates to share ideas and promising directions in CML research.



Collaborative Research Mechanisms

The CDMRP has supported several different award mechanisms that foster strong partnerships and collaborations in the scientific community. Since 1997, **\$209M** has been invested across the programs to establish **116** Consortia, Centers, and Program Projects. In addition, **83** awards totaling **\$31.5M** were awarded to HBCU/MI under different mechanisms that support collaboration. Combined, these award opportunities are enabling research communities to pool and leverage their resources and knowledge to move one step closer to disease eradication.

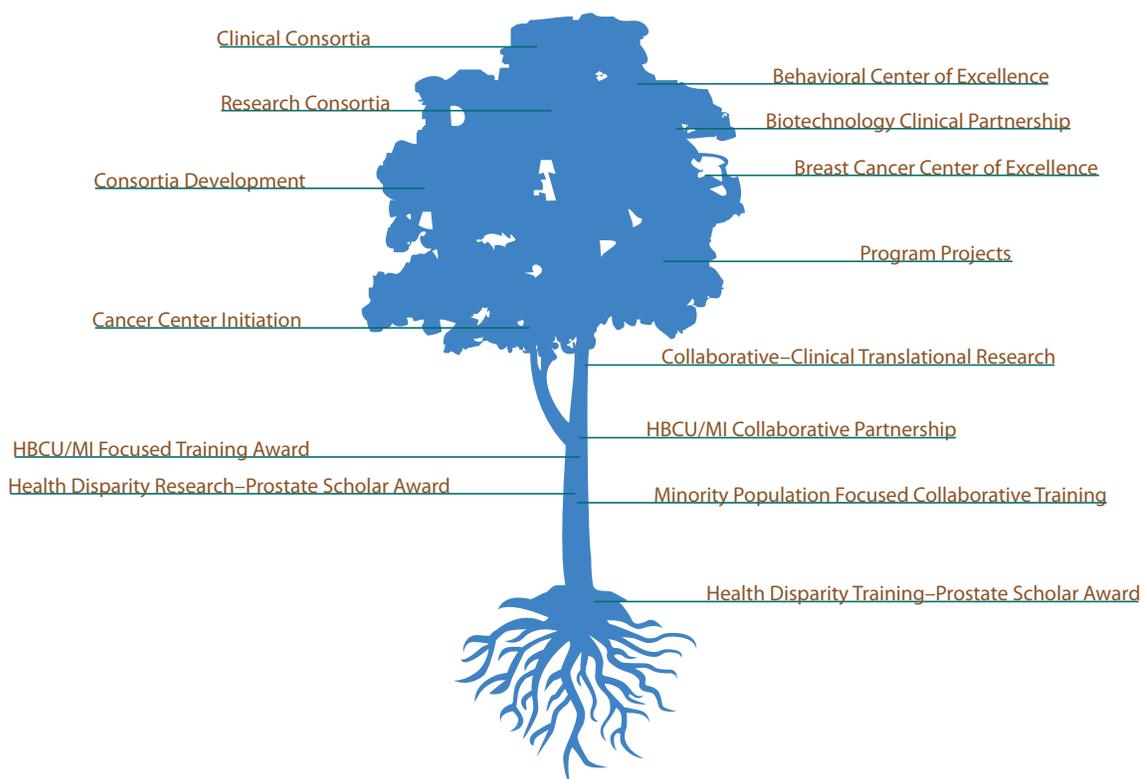


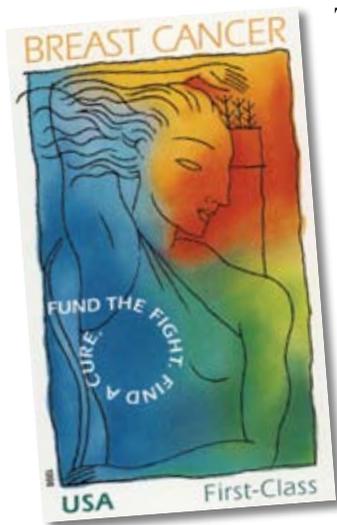
Figure I-15. Examples of CDMRP Award Mechanisms That Support Collaborative Research

Small Business Innovation Research/ Small Business Technology Transfer

The CDMRP has been working together with the Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) programs to leverage research and product development not supported elsewhere by the CDMRP. The SBIR/STTR programs are designed to harness the innovative talents of U.S. small businesses for our country's military and economic strength. The SBIR/STTR programs fund early-stage research and development efforts to support projects that fulfill a DOD need and have the potential for commercialization in the military and private sector markets. These programs are product driven with the intent that a technology, product, or service will be developed that the government can potentially use and that the small business or research institution can commercialize outside the SBIR/STTR programs. Through September 2006, the CDMRP has supported **\$14M** in SBIR/STTR programs including product development across breast, prostate, ovarian, and lung cancers, as well as work in military health-related disciplines such as angiogenesis and wound healing, prion-related diseases such as "mad cow disease," and detection of biological and chemical agents.



Breast Cancer Research Stamp



The Breast Cancer Research Stamp, a 45-cent semi-postal stamp, is the first semi-postal stamp in our nation's history. The Breast Cancer Research Stamp was introduced by Public Law 105-41, which resulted from the work of breast cancer advocates who raised the national public interest in breast cancer research. Net revenues from the Breast Cancer Research Stamp are used to support breast cancer research at both the DOD BCRP and the National Institutes of Health, with the BCRP receiving 30 percent of the

funds raised from the sale of this stamp. Since the introduction of the Breast Cancer Research Stamp in 1998, the BCRP has received 16 installments totaling **\$15.1M**. These monies have been used to fully fund 30 BCRP Idea Award proposals and partially fund another Idea Award proposal submitted to the BCRP. Awards supported under this legislation have impacted the discovery of the basic biology of cancer cell development, tumor formation, the role of the immune system, and advances in early detection techniques. These discoveries have resulted in numerous published papers and several patent applications. The BCRP is honored to be a part of our nation's first fundraising stamp effort and will continue to carefully invest the dollars generated by the Breast Cancer Research Stamp to find and fund the best science from the nation's most innovative, qualified scientists and clinicians. Additional information about the DOD's involvement in the Breast Cancer Research Stamp can be found in Appendix C.

Shaping Tomorrow

Solving today's health crises remains an ambitious challenge, but the CDMRP believes that through effective collaborations and partnerships, diseases will be cured. In 2007, the CDMRP will continue to change the landscape of science in targeted diseases.



15 Years of Partnering for a CURE

1992

\$25M appropriated for research on breast cancer screening and diagnosis for military women and their family members.

1993

Grassroots efforts influenced public policy leading to a congressional appropriation of \$210M for peer-reviewed breast cancer research.

1995

Consumers were integrated into the scientific peer review process.

1996

The NFRP was established by an \$8M appropriation.

1997

The PCRCP was established by a \$45M appropriation.

The OCRP was established by a \$7.5M appropriation.

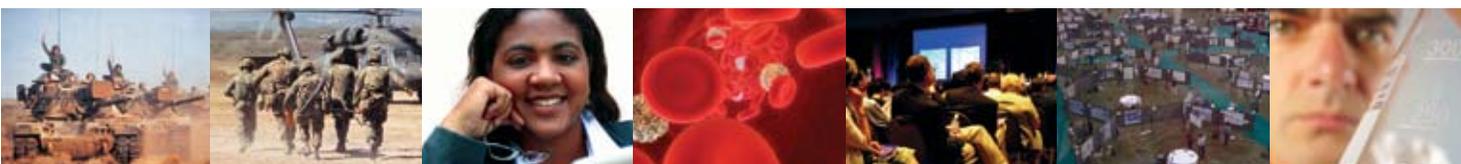
The BCRP sponsored its first Era of Hope meeting.

1998

The BCRP was the recipient of 30 percent of the funds raised by the issuance of our nation's first semi-postal stamp, the Breast Cancer Research Stamp.

The CDMRP website was launched.

The CDMRP established the Minority and Underserved Populations Program.



1999

The PRMRP was established by a \$19.5M appropriation.

2000

The first electronic proposal submission was offered resulting in the receipt of 41 electronic proposals.

The BCRP sponsored its second Era of Hope meeting.

2002

The CMLRP was established by a \$5M appropriation.

The TSCRП was established by a \$1M appropriation.

\$42.5M was appropriated for research on prion diseases.

Electronic submissions were offered for all award mechanisms resulting in the receipt of more than 2,900 electronic proposals.

The BCRP sponsored its third Era of Hope meeting.

The Electronic Grant System was launched enabling real-time electronic management of CDMRP grants.

2004

The PRMRP sponsored its first Military Health Research Forum.

2005

The BCRP sponsored its fourth Era of Hope meeting.

The National Prion Research Program sponsored its first Investigators Meeting.

A product management database was developed to identify and track CDMRP-supported products and technologies.

2006

The Gulf War Veterans' Illnesses Research Program was established by a \$5M appropriation.

More than 39,200 CDMRP proposals were received to date of which 20,749 have been through electronic proposal submission.

More than 6,100 scientists and clinicians have received awards from the CDMRP.

73 separate research programs have been managed by the CDMRP.

More than 860 consumers have served on scientific peer review panels since 1995.

