FOIA Number: 2008-1524-F

FOIA MARKER

This is not a textual record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

Collection/Record Group: Clinton Presidential Records

Subgroup/Office of Origin: Office of Science and Technology Policy

Series/Staff Member: Jerold Mande

Subseries:

OA/ID Number: 13033

FolderID:

Folder Title:
Department of Defense Prostate Cancer Research [2]

Stack:	Row:	Section:	Shelf:	Position:
S	66	4	3	1

The Assistant Secretary of Defense (Health Affairs)

Facsimile Cover Sheet

To: Jerry Mande
Organization:
Phone:
Fax: 202 456-6027

From: Gary A. Christopherson,
Acting Principal Deputy Assistant Secretary
Organization: OASD(HA), RM3E346 Pentagon
Phone: 703-697-2111
Fax: 703-614-3537

Date: 7/28/97
Pages with cover page: 2

Jerry,

Here is some background that I received from the Army R&D on the prostrate cancer research. As you indicated, this research will not be funded until a year from now. This is apparently about the standard time for them. Under the right conditions, this can be shortened to closer to a year.

Gary

Attachment

OFFICE OF THE DIRECTOR
ENVIRONMENTAL AND LIFE SCIENCES
ROOM 3D129, THE PENTAGON
WASHINGTON, DC 20301-3080

TO:
Jerry Mand, OSTP 202 456-6027

FROM: Christine Eisemann
FAX: 703-693-7042
VOICE: 703-697-8535
EMAIL: christine.eisemann@osd.mil

SUBJECT:

Mr. Mand -

George Singley asked me to provide you the enclosed information paper concerning the Department of Defense's Prostate Cancer Research Program. I trust it will meet your needs. If you require any further information, or wish to discuss the information paper, please feel free to call me at (703) 697-8535.

Regards,

Christine Eisemann

Med. Research & Materials Command

Col. Irene Rich 301-619-7071
Col. Lindsey (sp?)

Peer Review Mtgs - Jan - Hotels booked

Recommended Award List - mid-April

For next yr. FY98 16mos → 11mos.

Receipt of funds - is a critical hurdle

Reinvention of acquisition

Fast track - 8mos strategy

Breast $135M FY98
$10M ovarian
$9.8M neuro

FY 98 $40M
Ctr for Prostate Ca Disease - Walter Reed
Col David McCloud
$1.7-2M - $5M

INFORMATION PAPER

PROSTATE CANCER RESEARCH PROGRAM

The FY97 Defense Appropriations Conference Report provided $38M for peer-reviewed prostate cancer research within the Army medical research and development account. The Army subsequently established a Prostate Cancer Research Program, which is being executed by the U.S. Army Medical Research and Materiel Command (USAMRMC).

The USAMRMC received funds for the Prostate Cancer Research Program in January, 1997 and published a solicitation in July, 1997. Proposal selection is expected to be finalized by April, 1998, and contract awards will be completed by the end of September, 1998. The timing of these major events reflects the USAMRMC's development and execution of a careful, multi-staged approach for management of the Prostate Cancer Research Program.

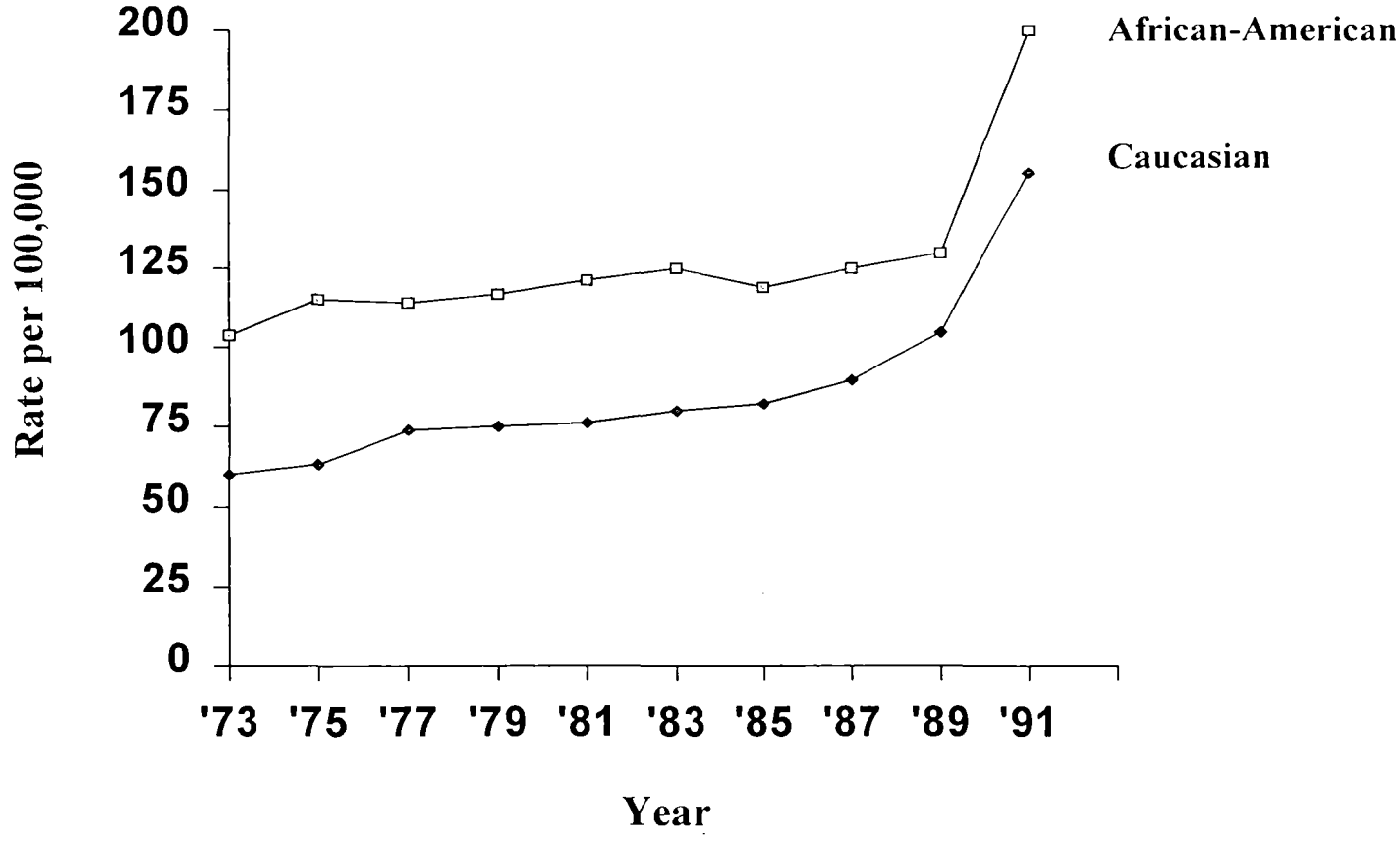
This management approach is derived from guidance originally provided by the Institute of Medicine for the Army's successful Breast Cancer Research Program. The approach includes development of an initial program strategy and implementation plan under the guidance of an Integration Panel of stakeholders, consumer advocates, medical scientists, and practitioners. A Broad Agency Announcement is published and widely advertised within the medical research community, and investigators are afforded three months for the development of scientifically sound, innovative approaches to prostate cancer research questions. A two-tiered review is then used to evaluate the technical merit and programmatic relevance of submitted proposals. These two tiers of review are fundamentally different. The scientific merit review is a criterion-based process in which individual proposals are evaluated for scientific and technical merit. Programmatic review is a comparison-based process in which proposals from multiple disciplines compete in a common pool. By utilizing both levels of the two-tiered system, the USAMRMC is able to achieve a balanced research portfolio for the prostate cancer research program.

The USAMRMC's management approach for the Prostate Cancer Research Program will require approximately 15 months from the receipt of funds to the first contract award. This schedule is approximately the same as that followed for the initial year of the Breast Cancer Research Program. The schedule allows the necessary time to perform, thoroughly and carefully, all essential steps of the program development process. The USAMRMC Prostate Cancer Research Program continues to evaluate the use of "fast track" reviews and other potential process improvements which may accelerate the time to contract award. The Prostate Cancer Research Program will continue to emphasize excellence in program definition, research project design, and critical evaluation to ensure that the program maintains the highest scientific and programmatic quality, and responsiveness to the needs of the prostate cancer community.

DEPARTMENT OF DEFENSE PROSTATE CANCER RESEARCH PROGRAM

COL Irene M. Rich, DNSc.
Program Director

The Prostate Cancer Problem: Incidence

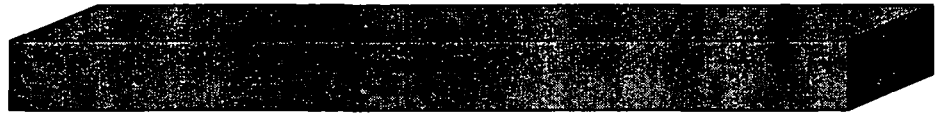


Source: SEER Program, NCI, based on an approximate 10 percent sample of the U.S. population

The Prostate Cancer Problem: Mortality

Age-adjusted Cancer Death Rates, 1987-1991

African-American Male



52.0

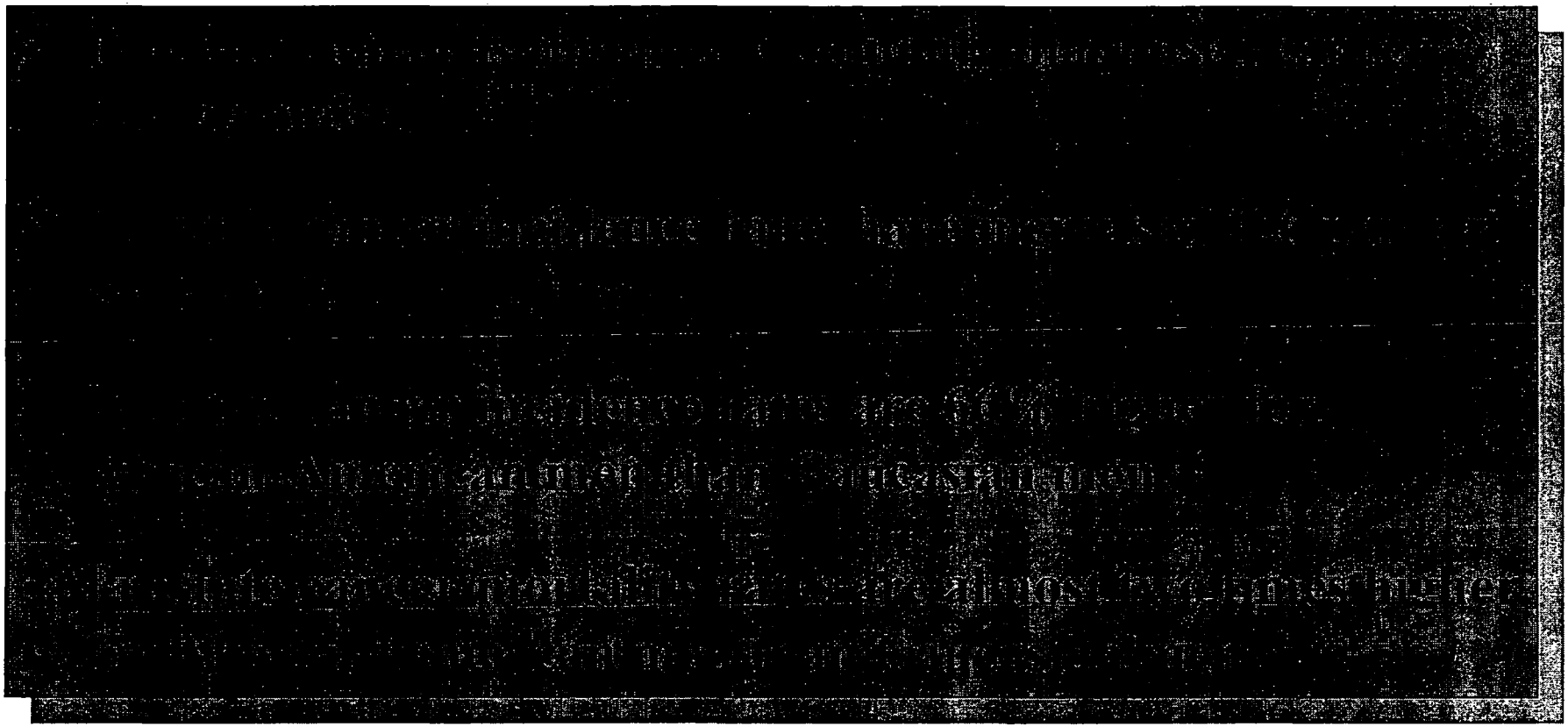
Caucasian Male

23.6

Mortality rates per 100,000 (age-adjusted to 1970 U.S. standard).

Source: NCHS public use tape

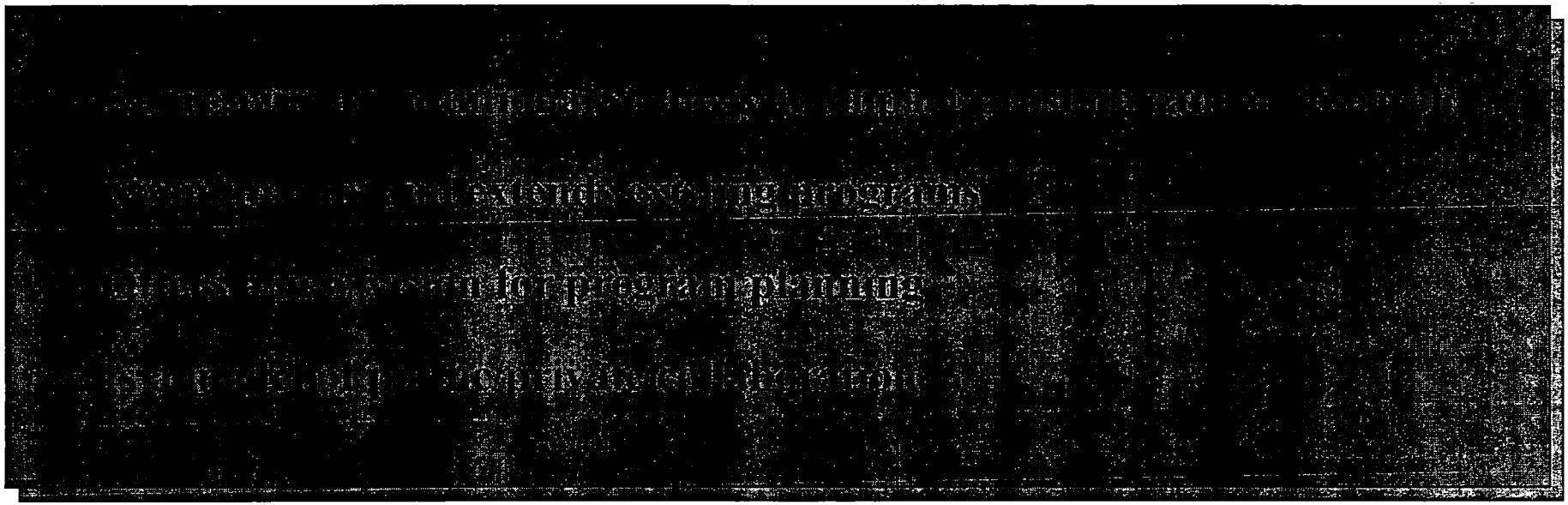
The Prostate Cancer Problem: Facts



Sources: SEER Cancer Statistic Review, 1973-1993
American Cancer Society, Cancer Facts & Figures-1997

Science Management

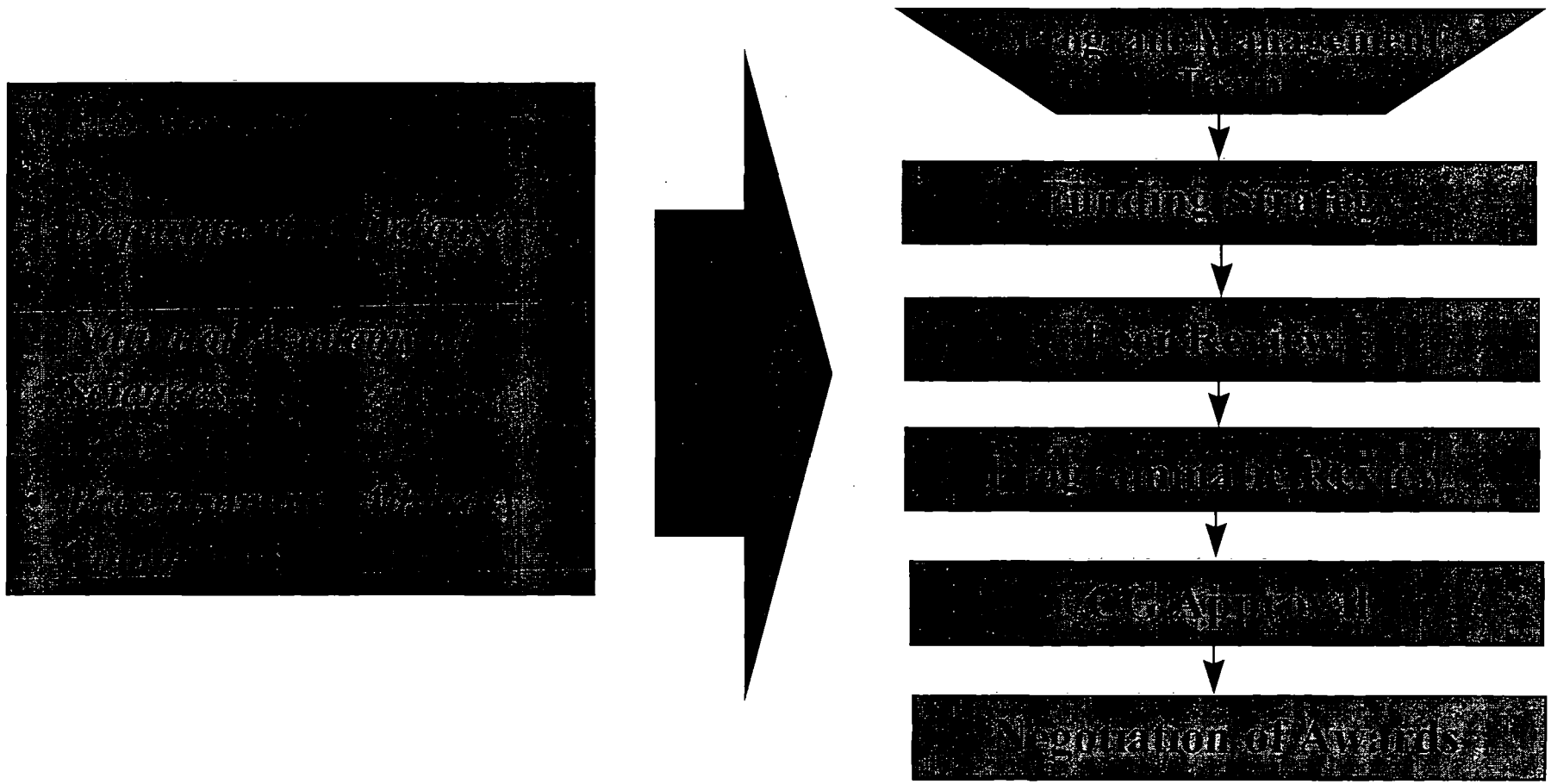
Program Overview



Unique Program Features

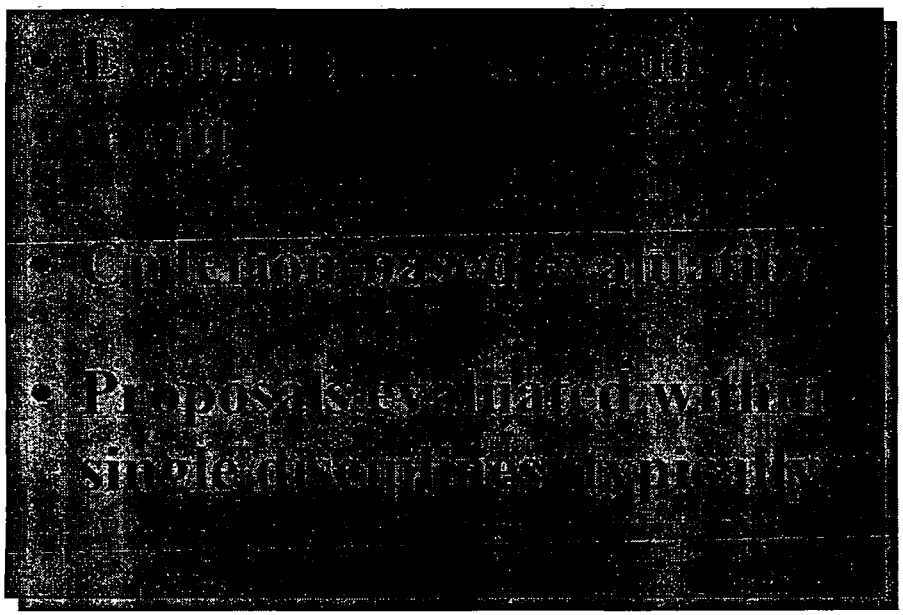
- **Congressionally Directed**
- **Targeted Research Priorities**
- **Flexible Science Management Model**
- **Two-Tiered Review**
- **Consumer Participation**

Science Management Model

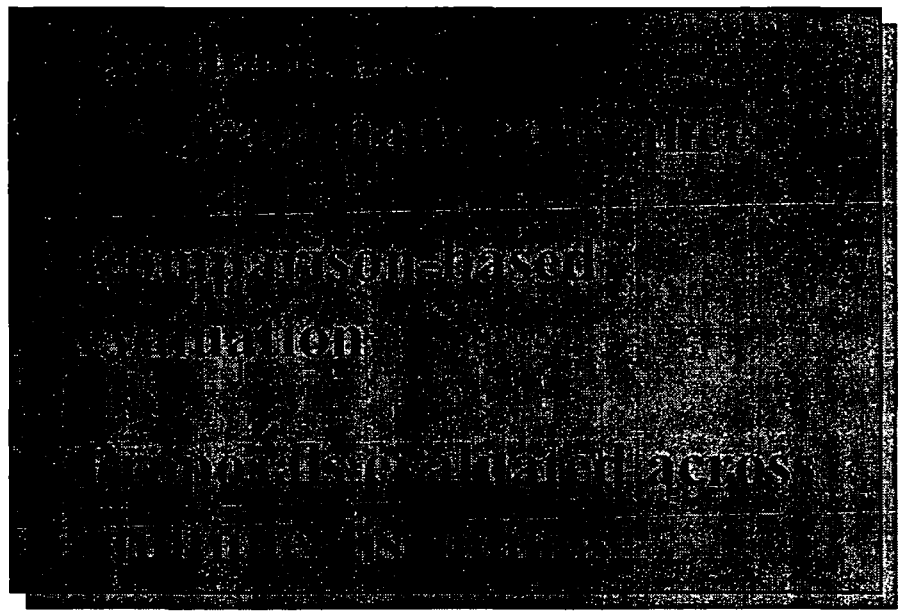


Peer vs. Programmatic Review

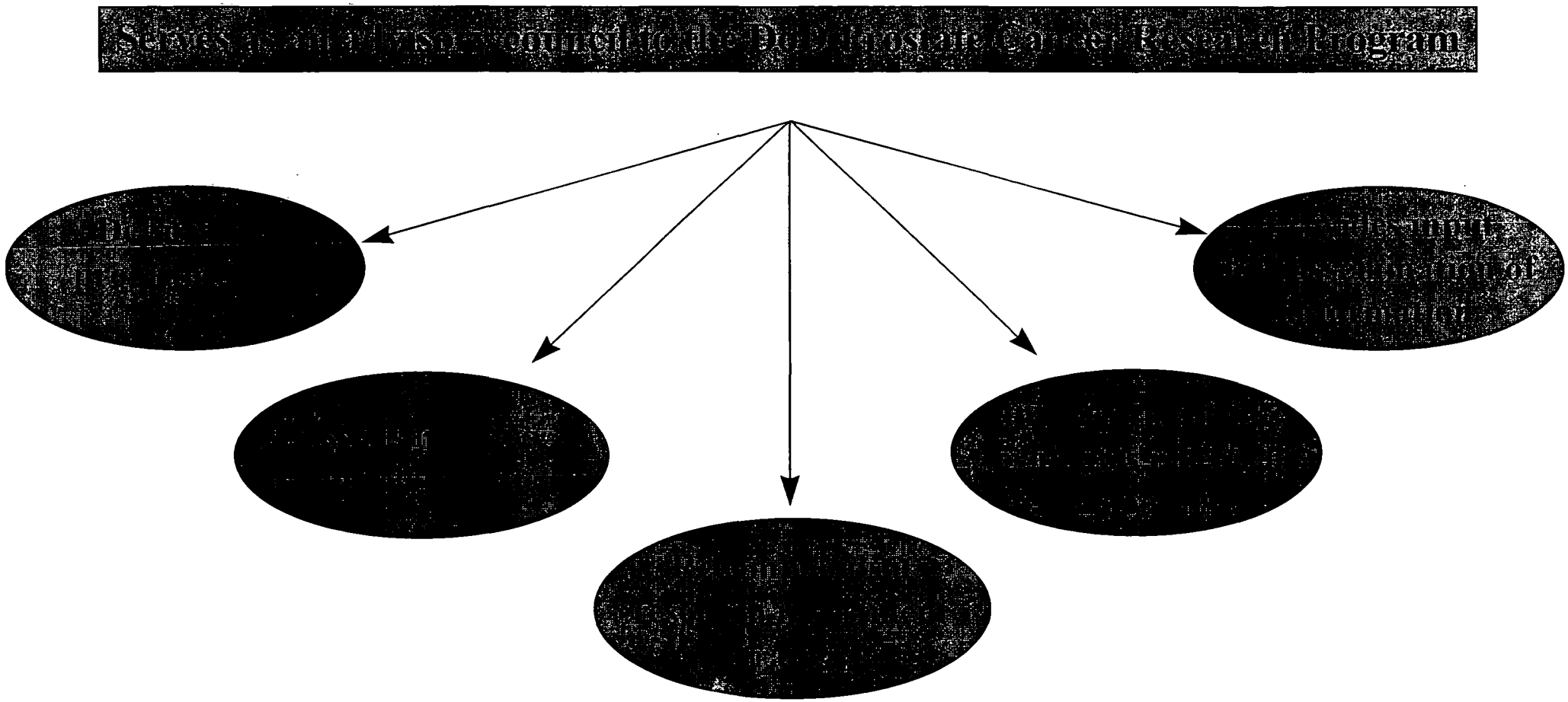
Peer Review



Programmatic Review



Integration Panel



FY 97 PCRP Science Management Timeline

1997 **1998** **1999-2002**

Execution Window **Science Management Window**

Milestones - Year 1:

1. Receipt of Funds
2. Recommendations from Advisory Bodies
3. Investment Strategy
4. Announcement (BAA)
5. Receipt of Proposals

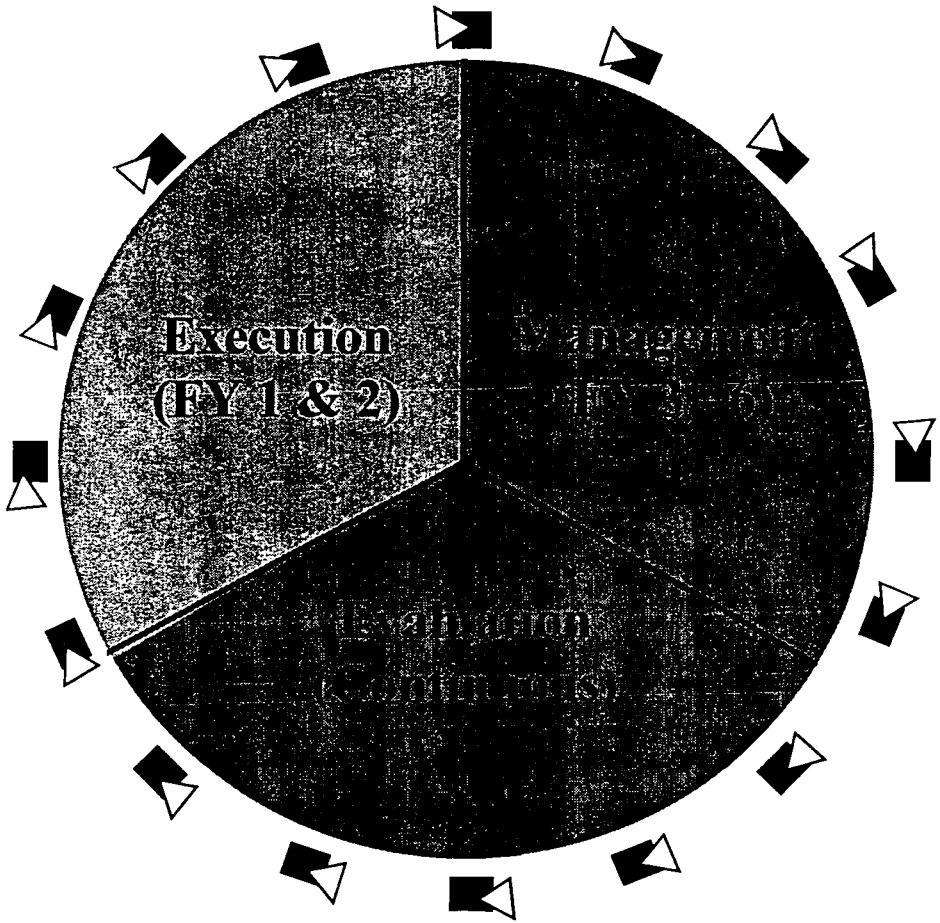
Milestones - Year 2:

6. Peer Review
7. Programmatic Review
8. Negotiations and Funding

Milestones - Years 3 - 6:

9. Manage Grants & Contracts
   - Progress Reports
   - Site Visits
10. Phase II Awards (subject to FY 200 appropriation)
11. Disseminate Research Findings

Program Evaluation Cycle



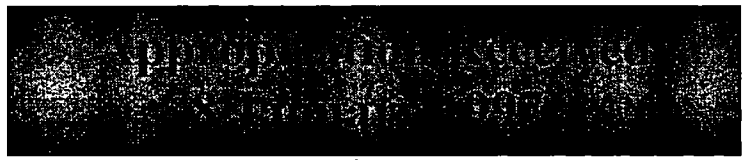
Program Evaluation

- Identify Gaps
- Vision Setting
- Track Research Products
- Feedback from Stakeholders
- Link to Cutting-Edge Technology

Process Improvement

PCRP Investment Strategy

Program Strategy Development



Stakeholders Input
1-2 April 1997

Integration Panel Input
2-3 June 1997

FY 97 Prostate Cancer Research Congressional Language

Reduce the incidence of prostate cancer and develop more effective, more specific, and less toxic forms of therapy for patients by funding research that is:

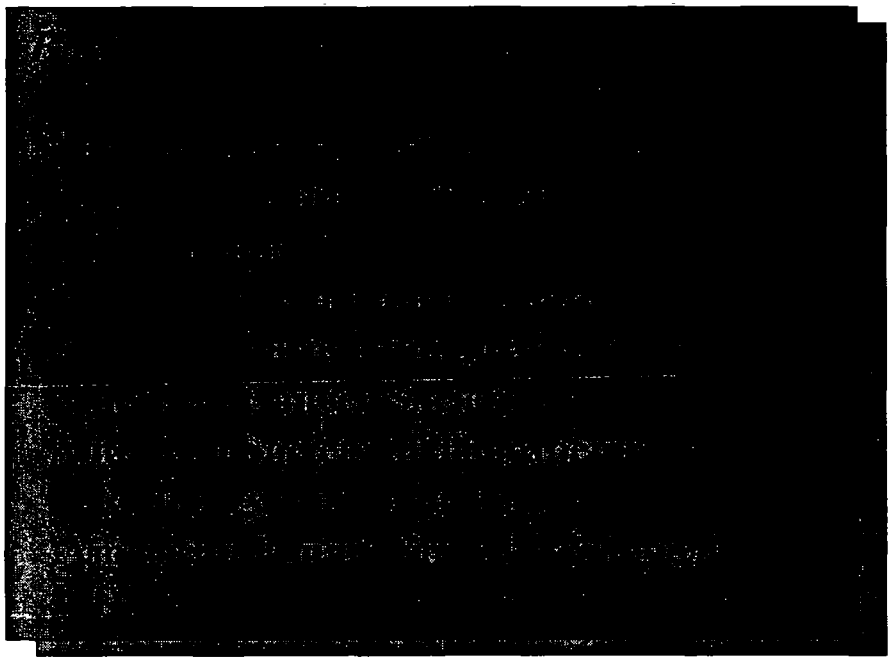
Program Strategy Development

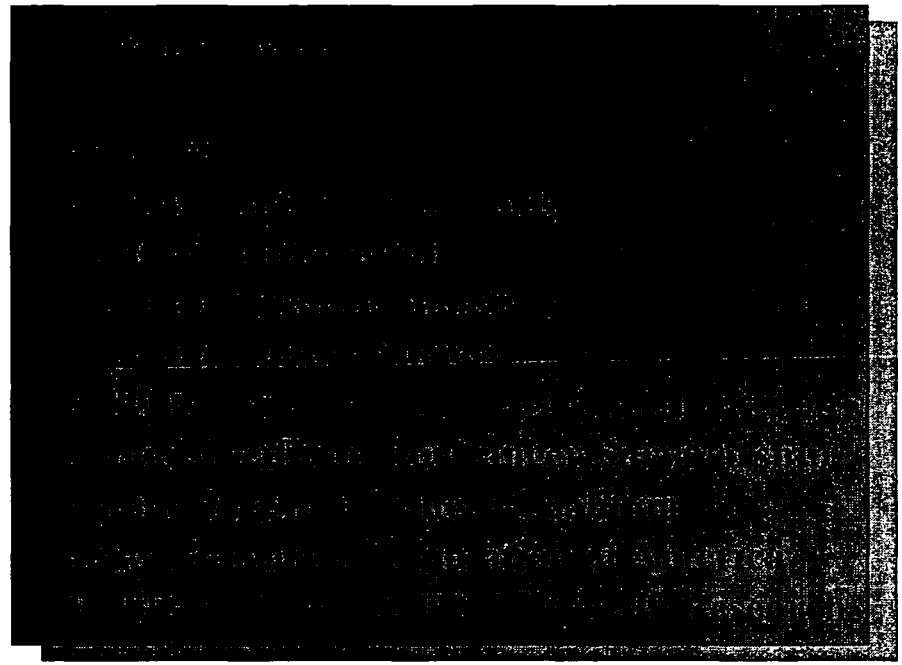
Appropriation Received
8 January 1997

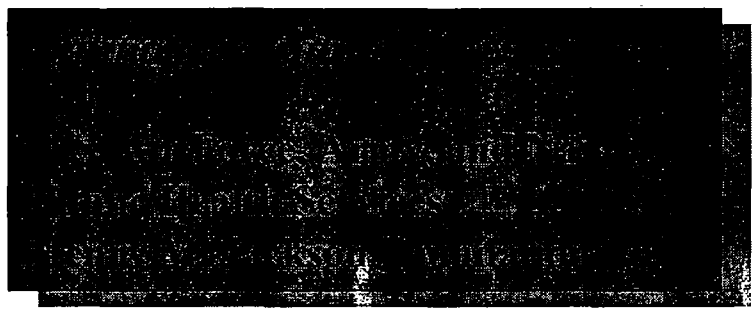
Integration Panel Input
2-3 June 1997

Prostate Cancer Stakeholders

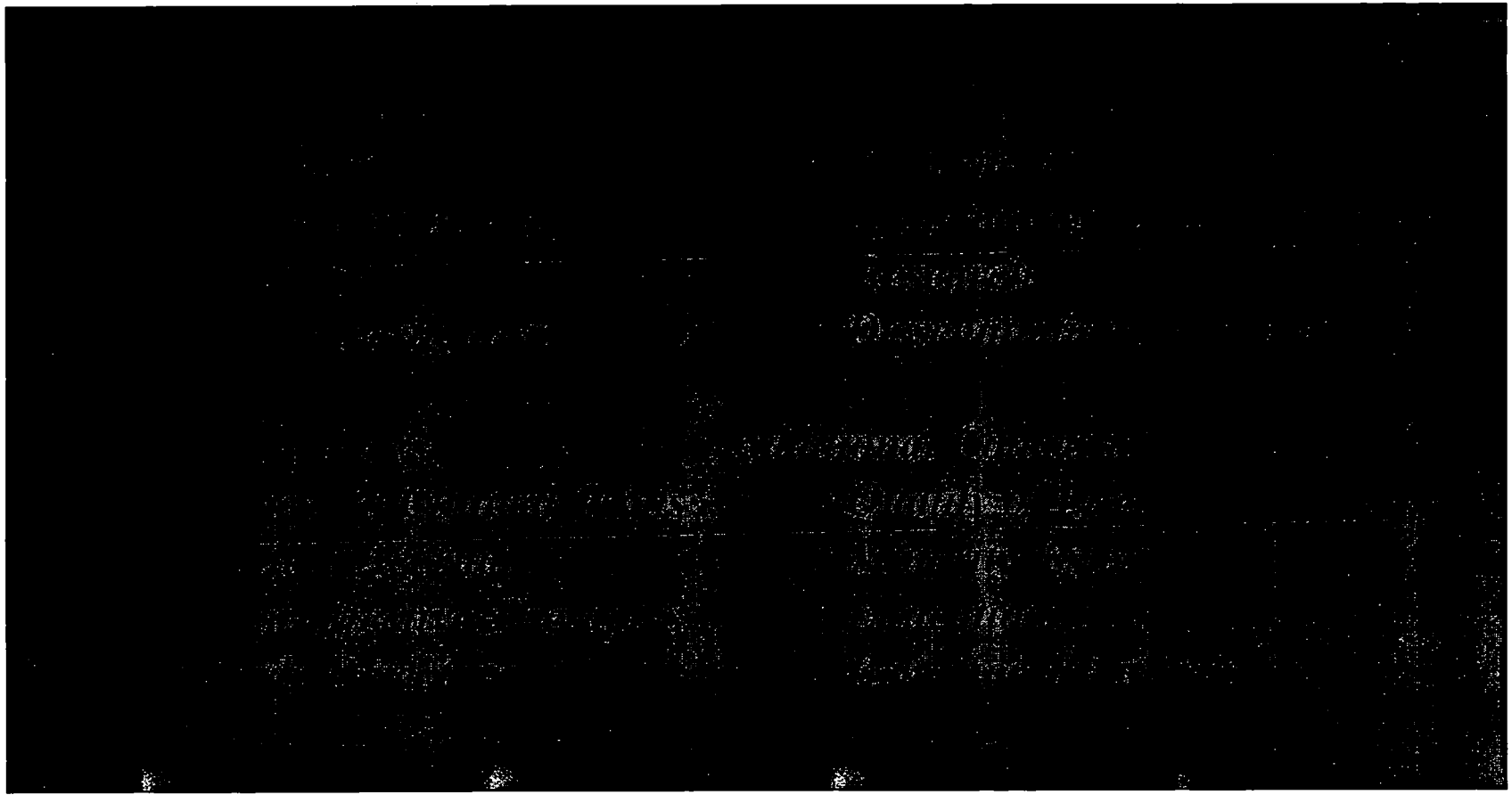
Panel composed of distinguished basic and clinical scientists, advocacy participants, and military personnel.







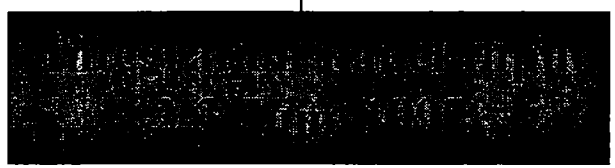
FY 97 PCRP Stakeholders Meeting Identifying Priorities, Concerns, and Gaps in Prostate Cancer Research



Program Strategy Development

Appropriation Received
8 January 1997

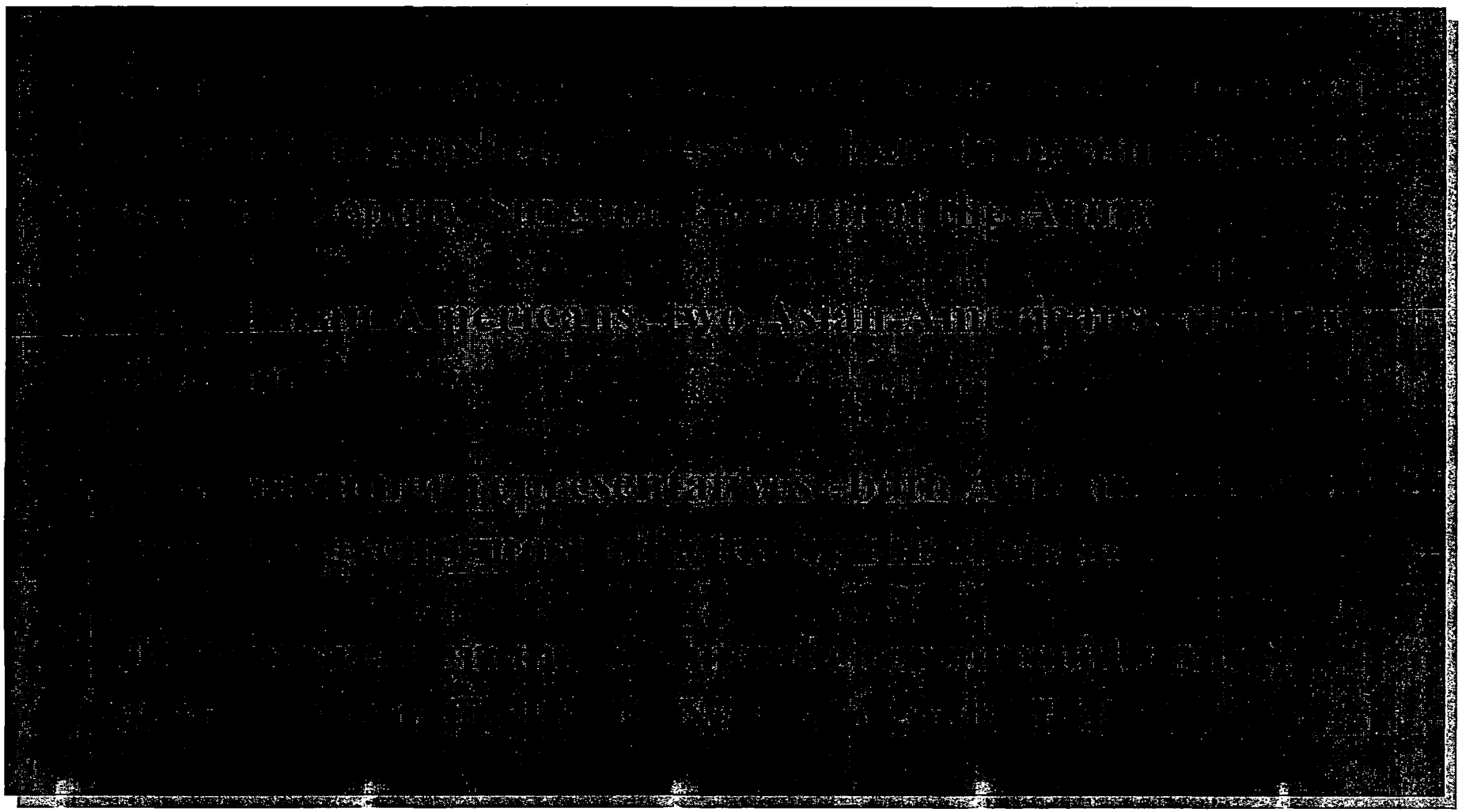
Stakeholders Input
1-2 April 1997



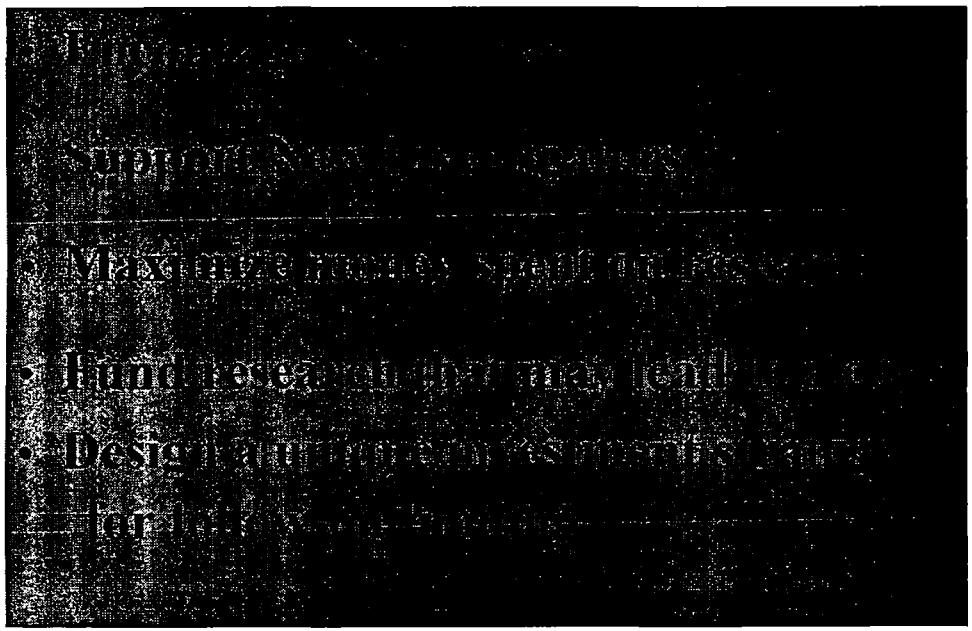
Prostate Cancer IP Members: Regional and Discipline Representation

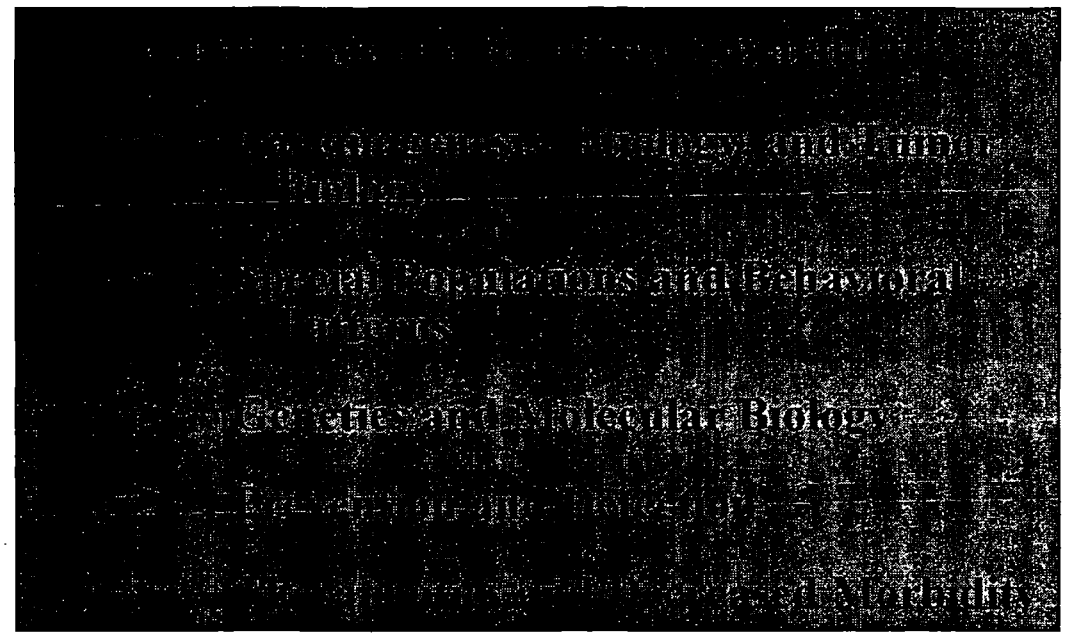
- Medical Oncology
- Biostatistics
- Nursing
- Pharmacology
- Advocates
- Molecular Biology
- Genetics
- Urology
- Cell Biology
- Radiation Oncology
- Pathology

Integration Panel Composition

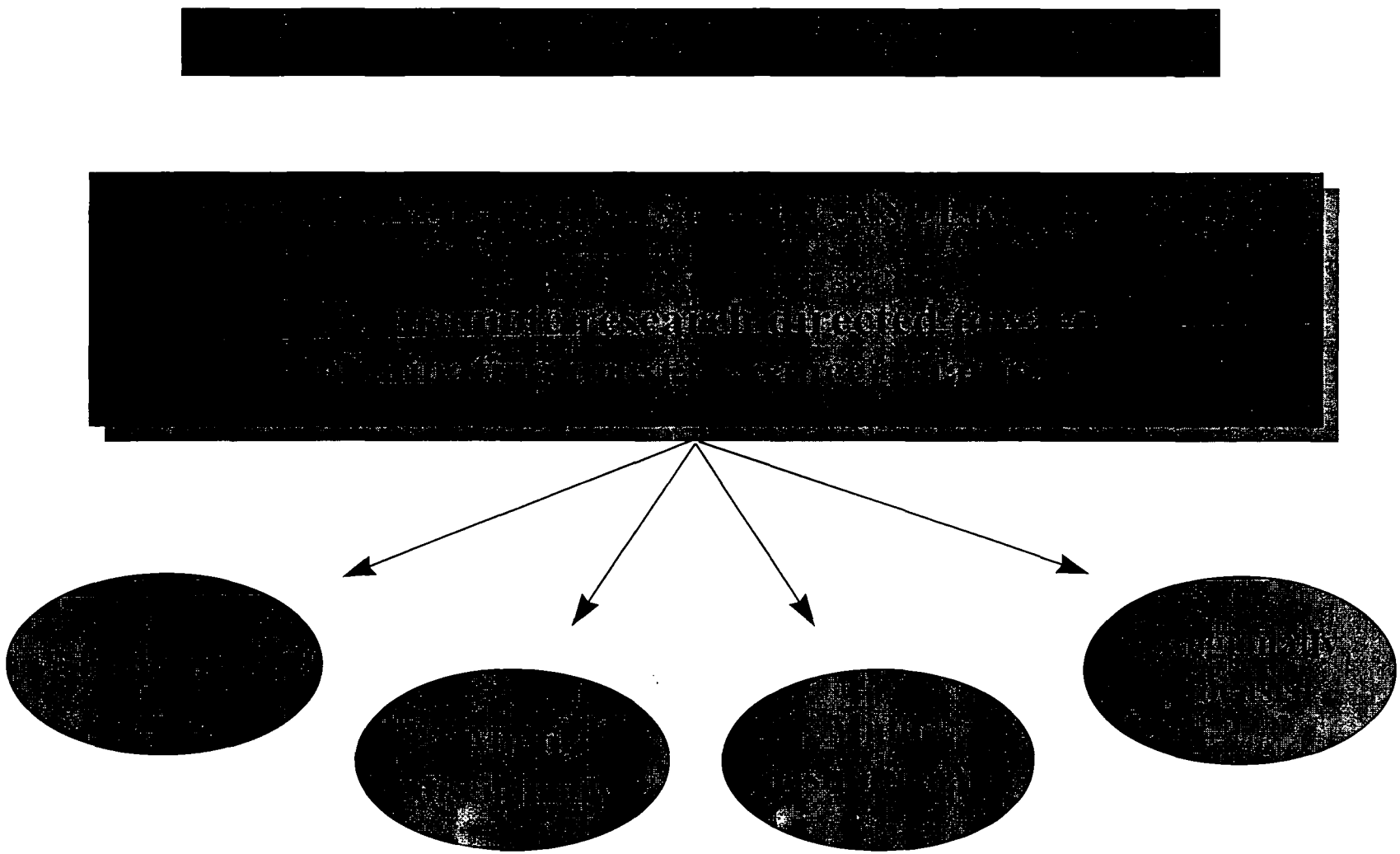


FY 97 PCRP Blue Ribbon Panel Meeting: Integration Panel Recommendations



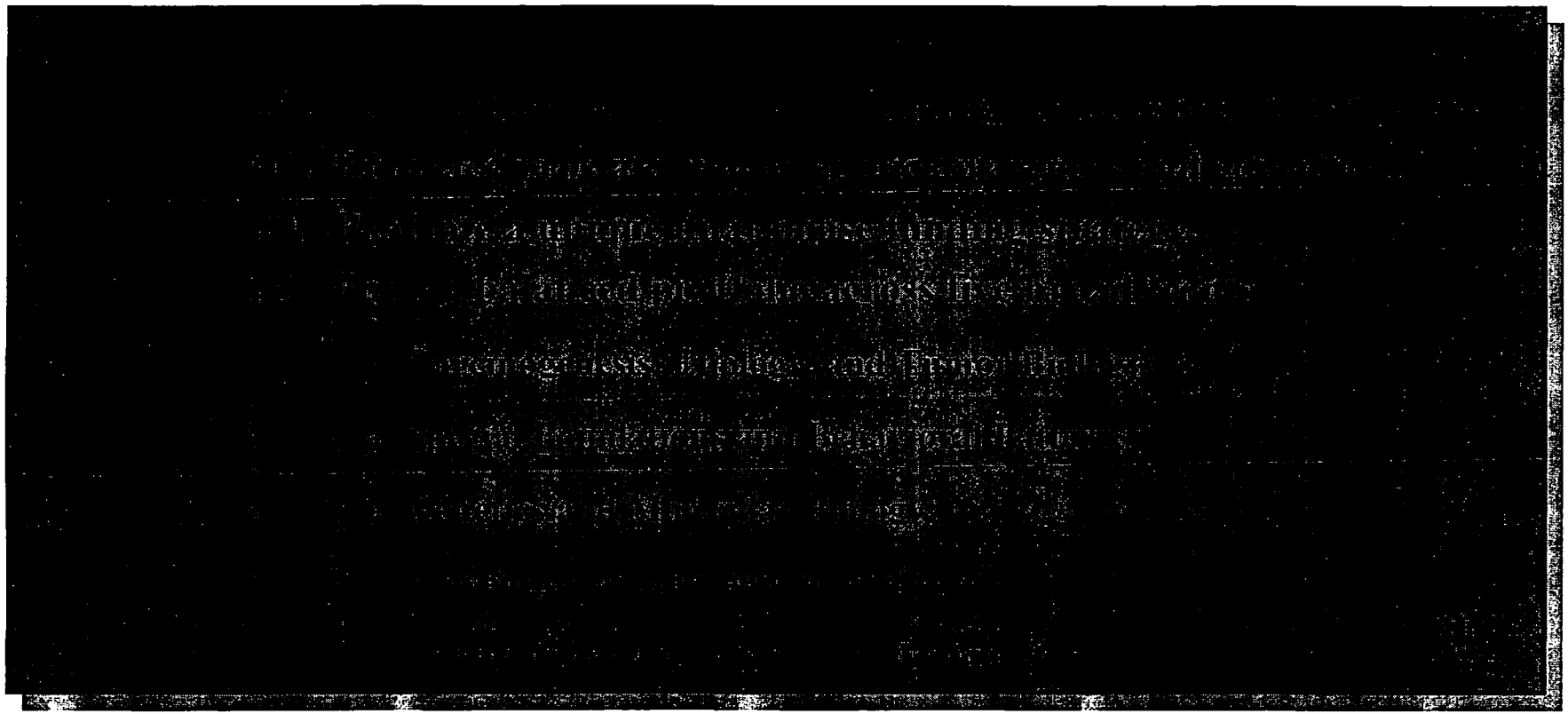


PCRP Program Philosophy

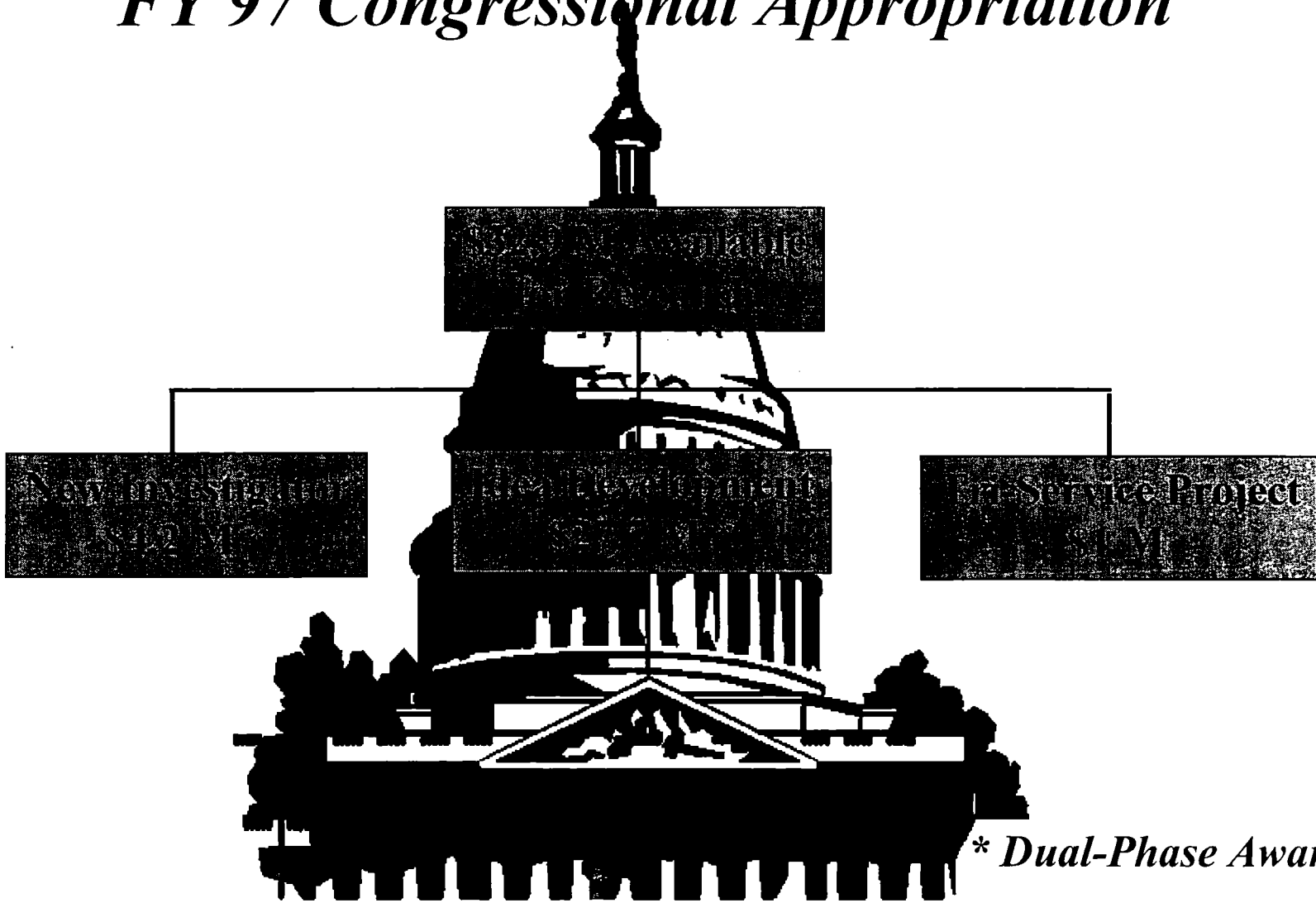


PCRP Program Philosophy (cont.)

[redacted]



FY 97 Congressional Appropriation



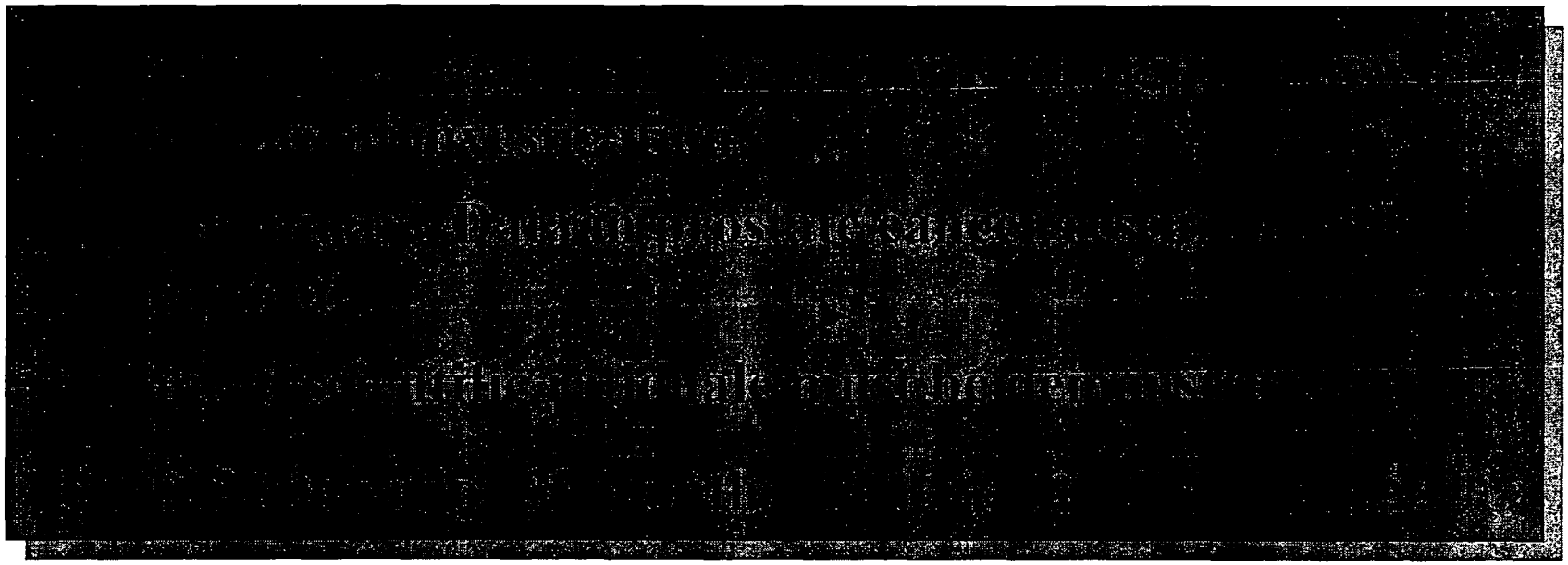
** Dual-Phase Awards*

New Investigator Awards

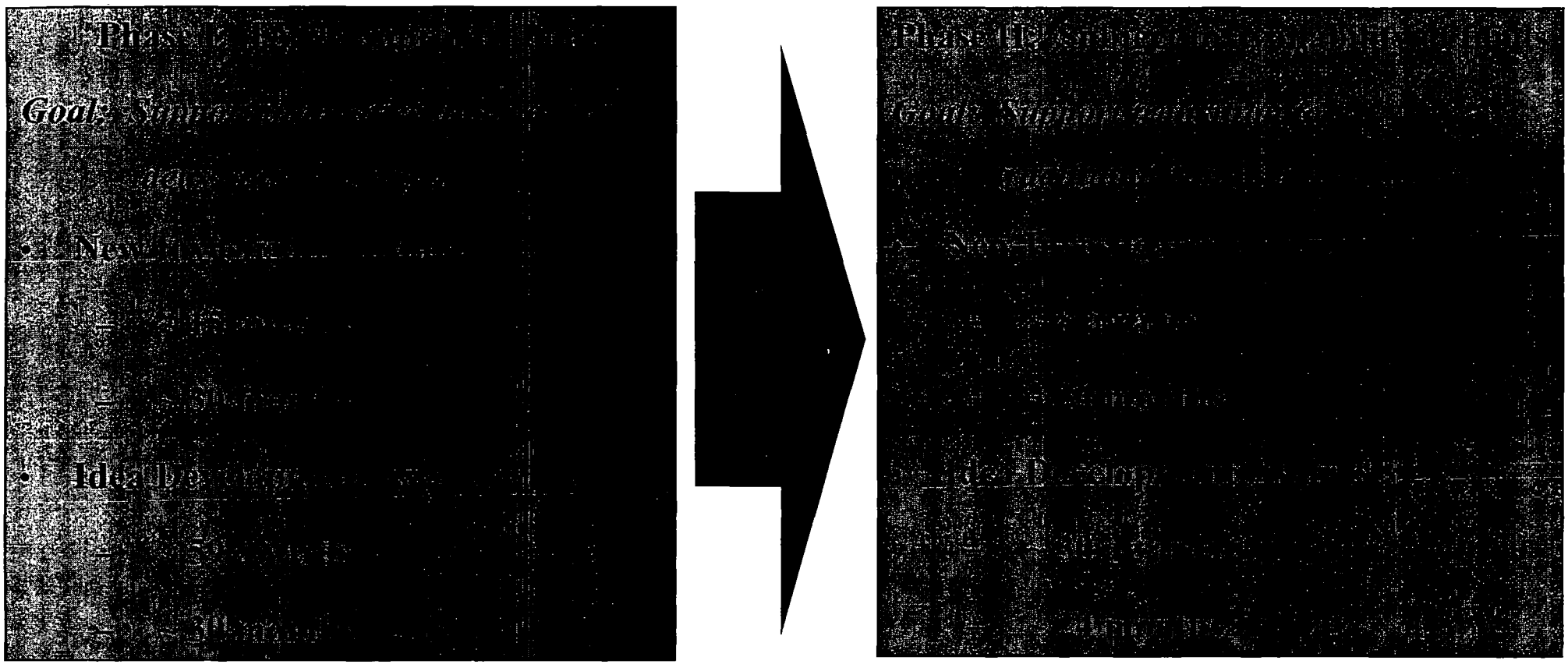
[redacted]

Idea Development Awards

[redacted]

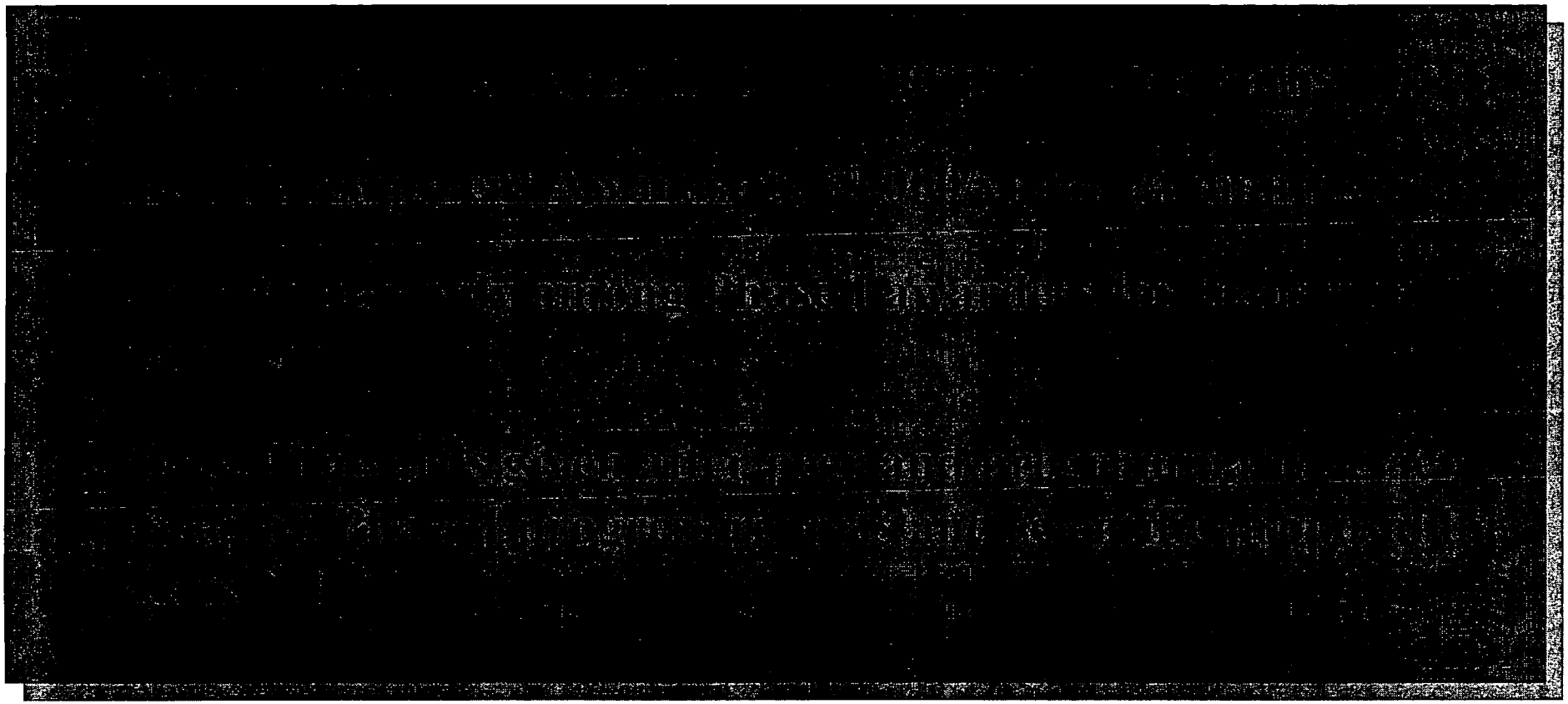


Dual-Phase Research Awards



Phase II Awards

(contingent on availability of funds in FY 00)

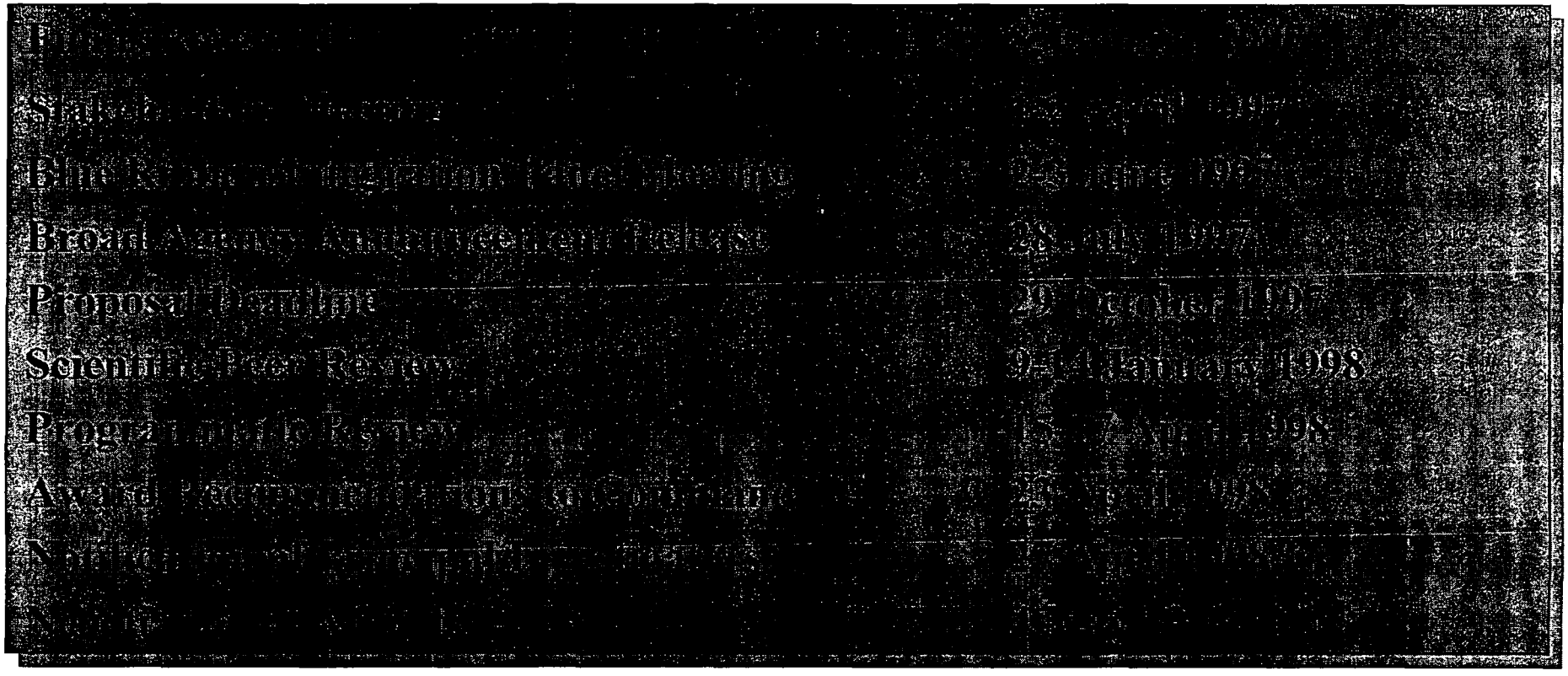


Tri-Service Project

[redacted]

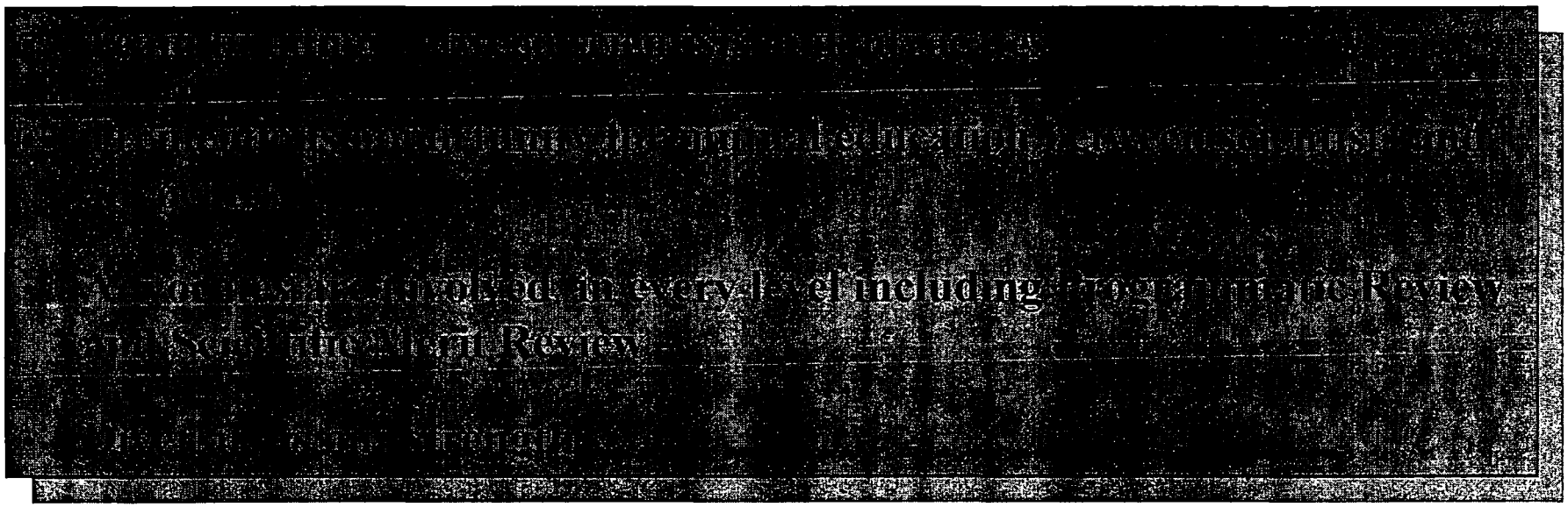
[redacted]

FY 97 PCRP Operation Plan and Timeline

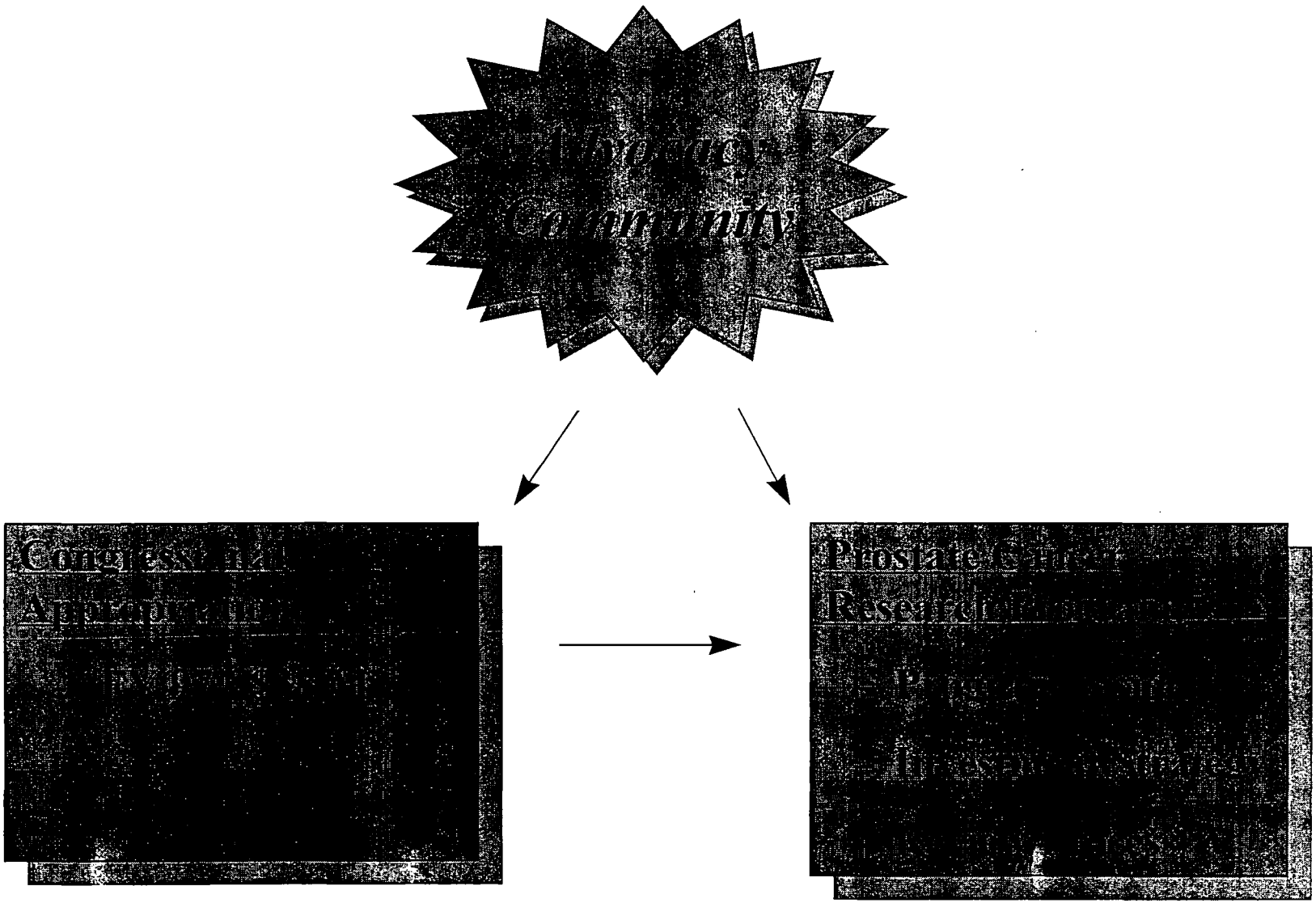


Advocate Participation in the PCRP

Department of Defense Congressionally Directed Medical Research Programs: A model of public/private partnership



Impact of Advocates in the PCRP



Advocacy Participation in the PCRP: Stakeholders and Integration Panel

American Foundation of Urological Disease (AFUD)

American Prostate Society

Cancer Research Foundation of America

CaP CURE

Maryland Prostate Center

Matthews Foundation for Prostate Research

National Coalition for Cancer Survivorship

National Prostate Cancer Coalition

Prostatitis Foundation

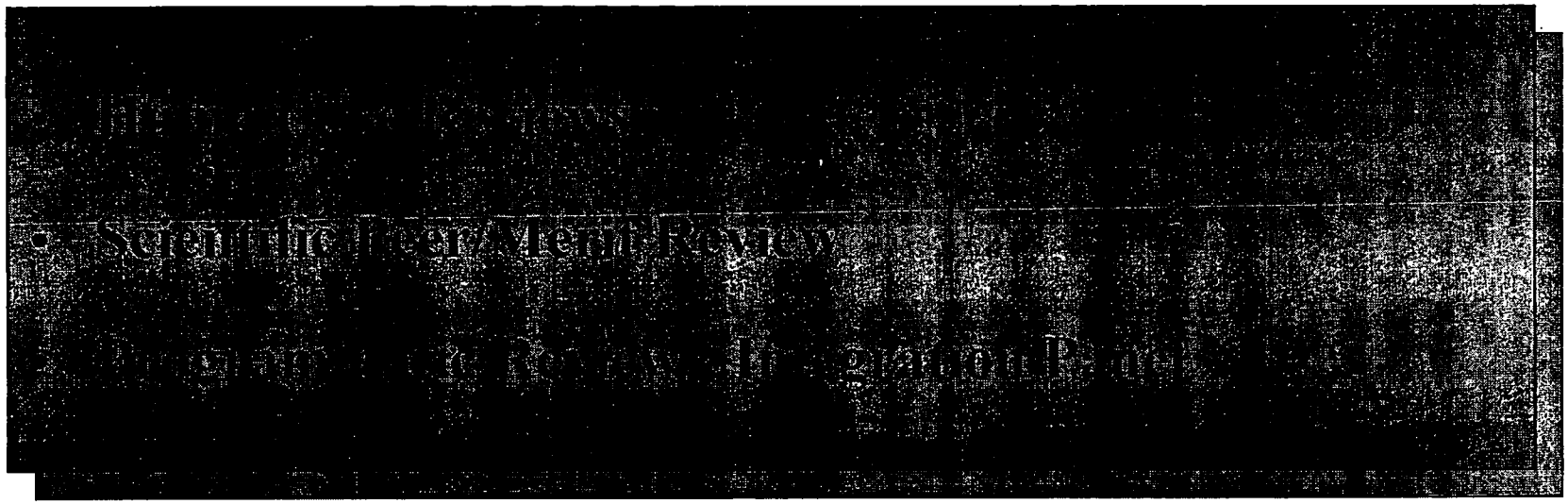
Real Men and Women Cook

US TOO International, Inc.

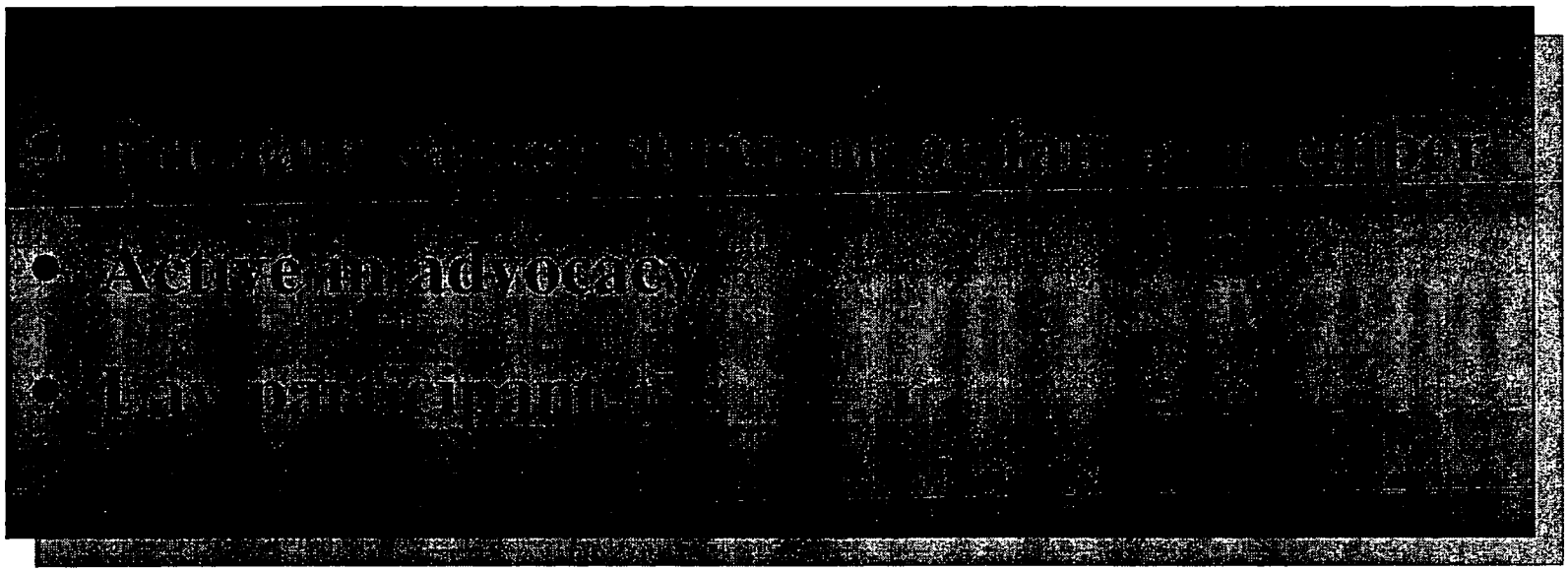
Value-Added of Advocates' Involvement in Congressionally Directed Medical Research Programs

- **Contributes unique professional and personal experiences**
- **Adds perspective, passion, and a sense of urgency**
- **Ensures that the human dimensions of prostate cancer are incorporated into scientific considerations, program policy, investment strategy, and research focus**

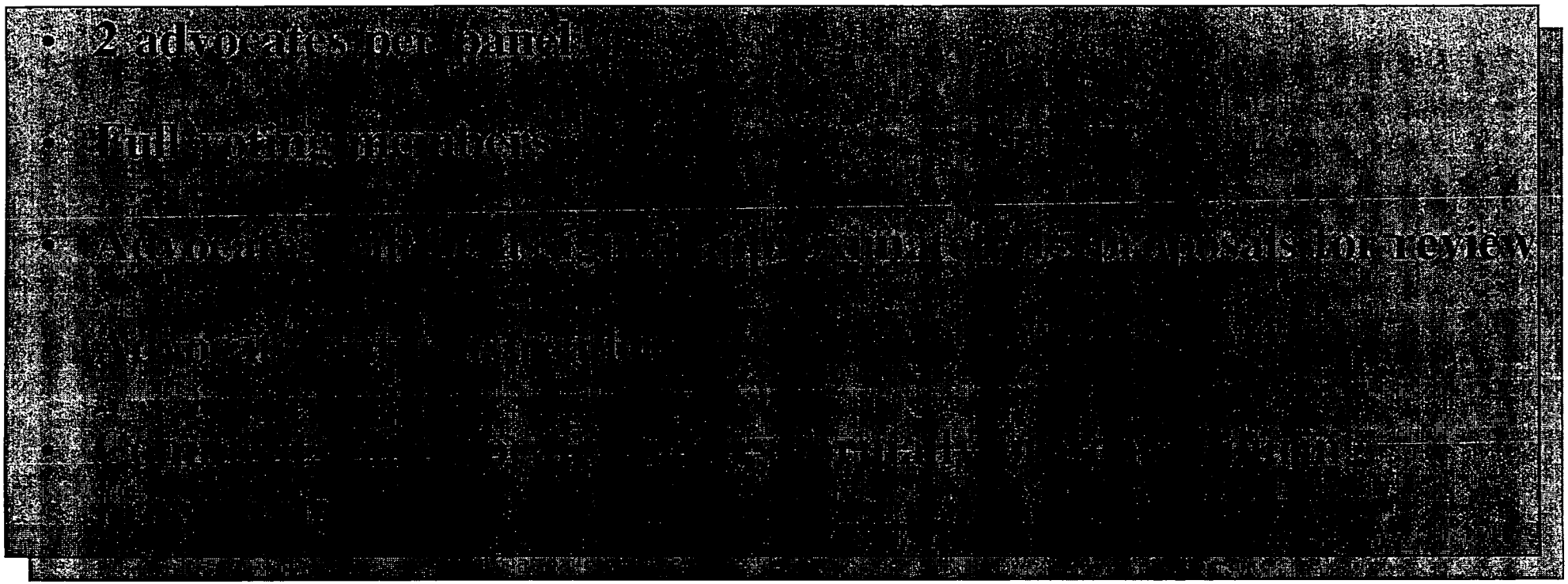
Opportunities for Advocate Involvement in the PCRP



Definition of Consumer Advocate in Scientific Peer/Merit Review



Advocates in Scientific Merit Review: Past Inclusion Strategy



Advocates in Scientific Merit Review: FY 95 Breast Cancer Research Program Preliminary Findings

Advocate Responses:

Positive Trends

- Scientists were willing to listen to advocate's perspective
- Advocates added an important perspective
- Advocates had an increased appreciation for the efforts of the scientists
- The human element has been incorporated into funding decisions

Negative Trends

- Advocates felt intimidated and withheld input
- More time and resources are needed for preparation

Advocates in Scientific Merit Review: FY 95 Breast Cancer Research Program Preliminary Findings

Scientist Responses:

Positive Trends

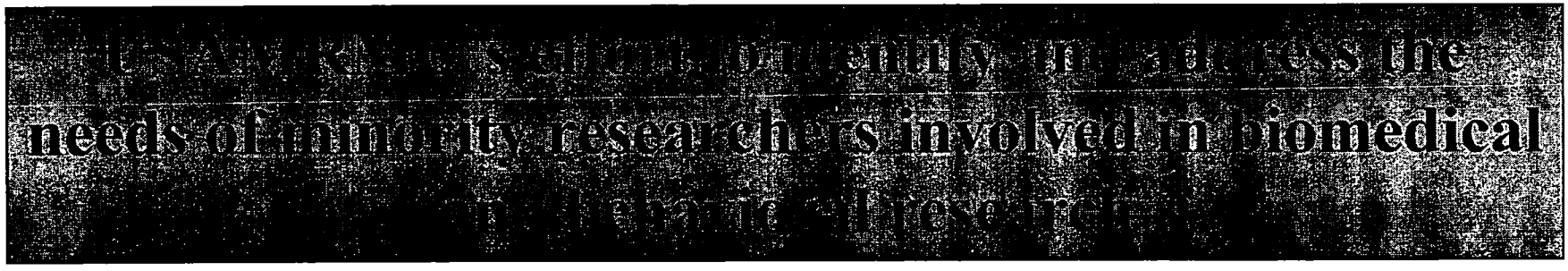
- An excellent compnent and implicitly beneficial
- Advocate comments were acknowledged and sought
- Advocates remind scientists of human dimensions and relevance
- Advocate presence promoted communication
- Opportunity for mutual education
- Education of advocates could result in increased science funding

Negative Trends

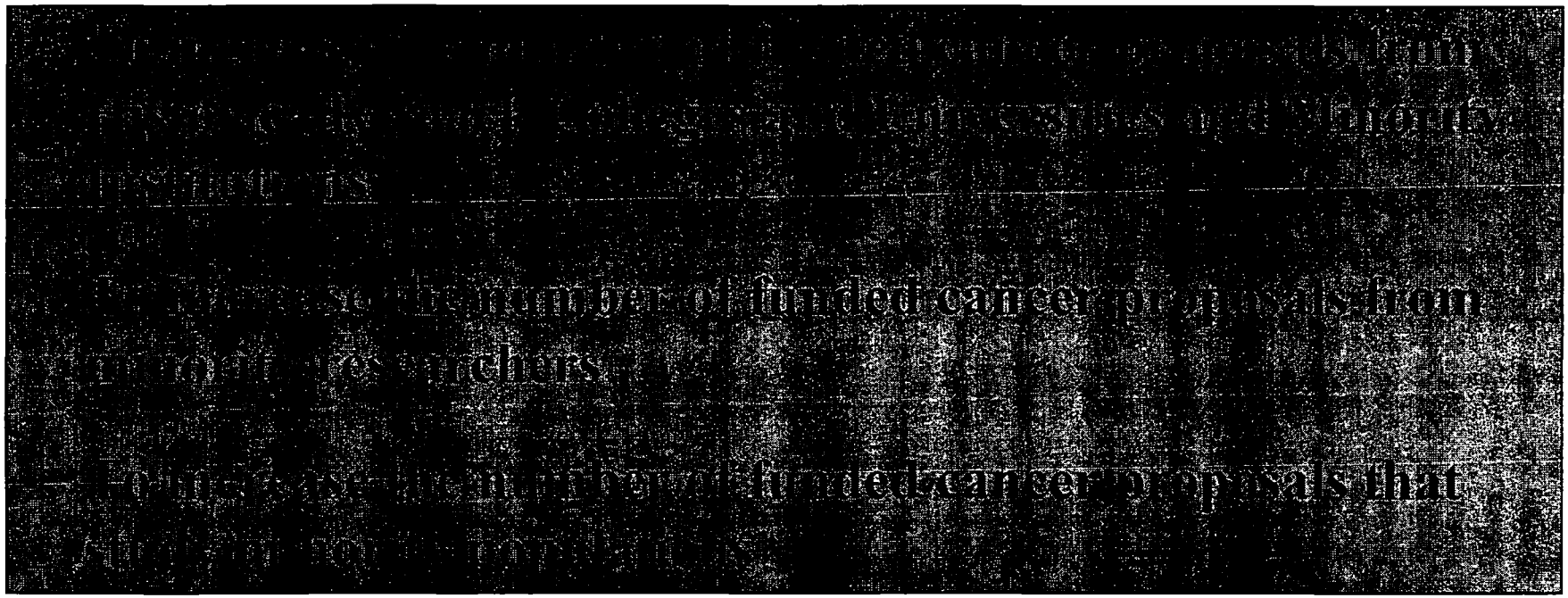
- Participation is unneccessary
- Advocates were bewildered in the face of specialized knowledge
- Advocates occassionally made uneducated comments

Initiative for Biomedical and Behavioral Minority Research

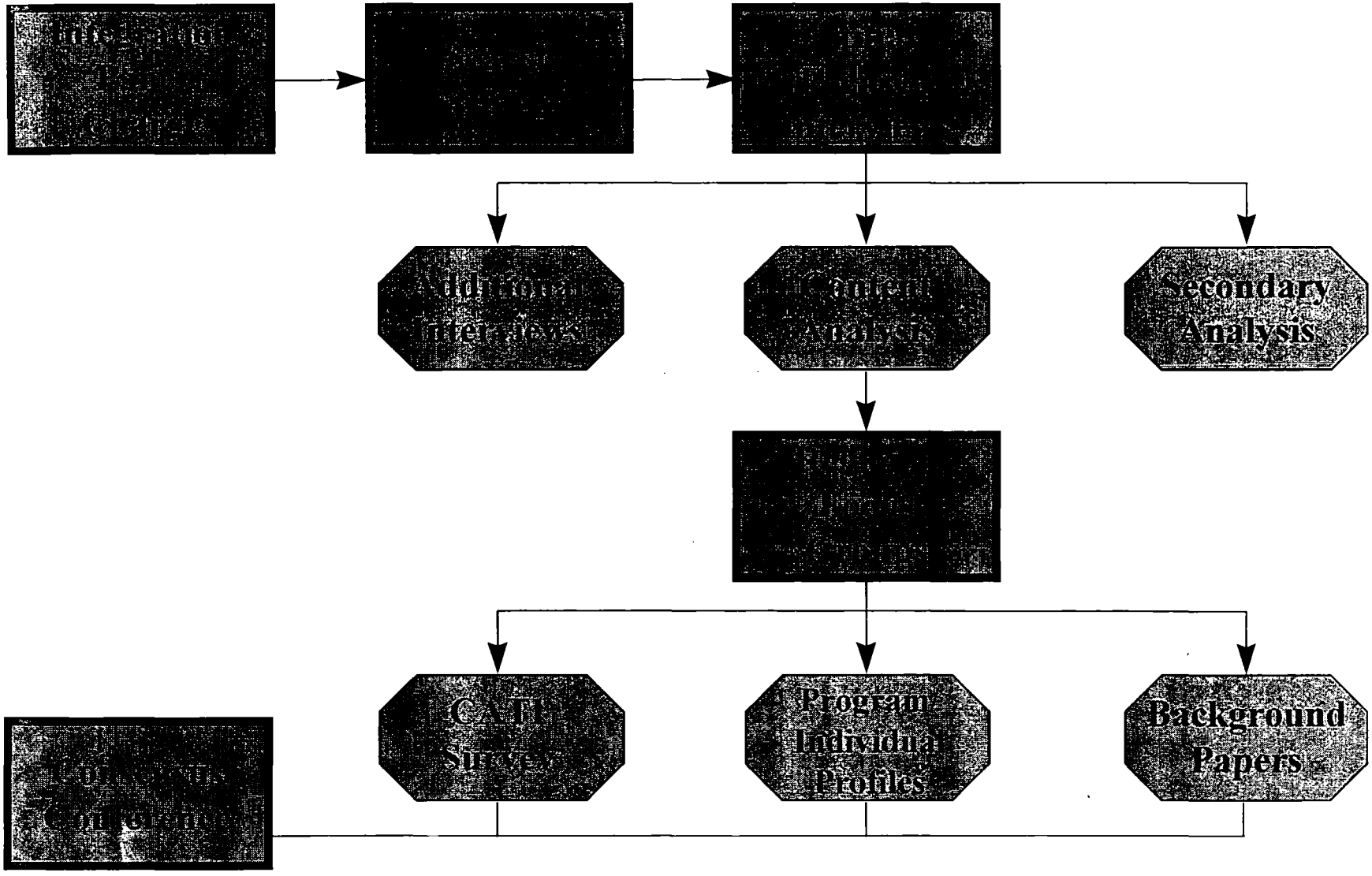
Initiative for Biomedical and Behavioral Minority Research



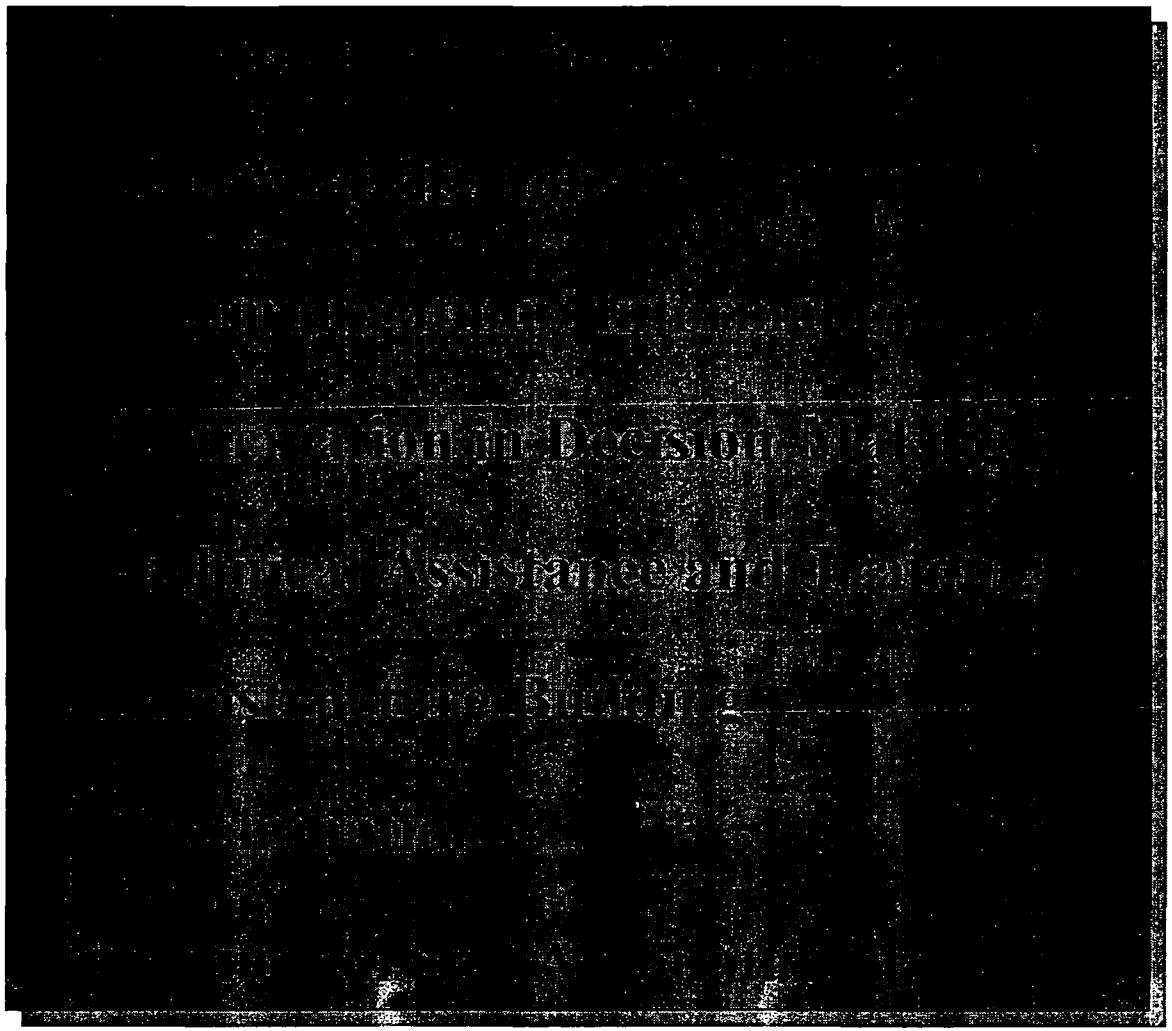
Goals of the Initiative for Biomedical and Behavioral Minority Research



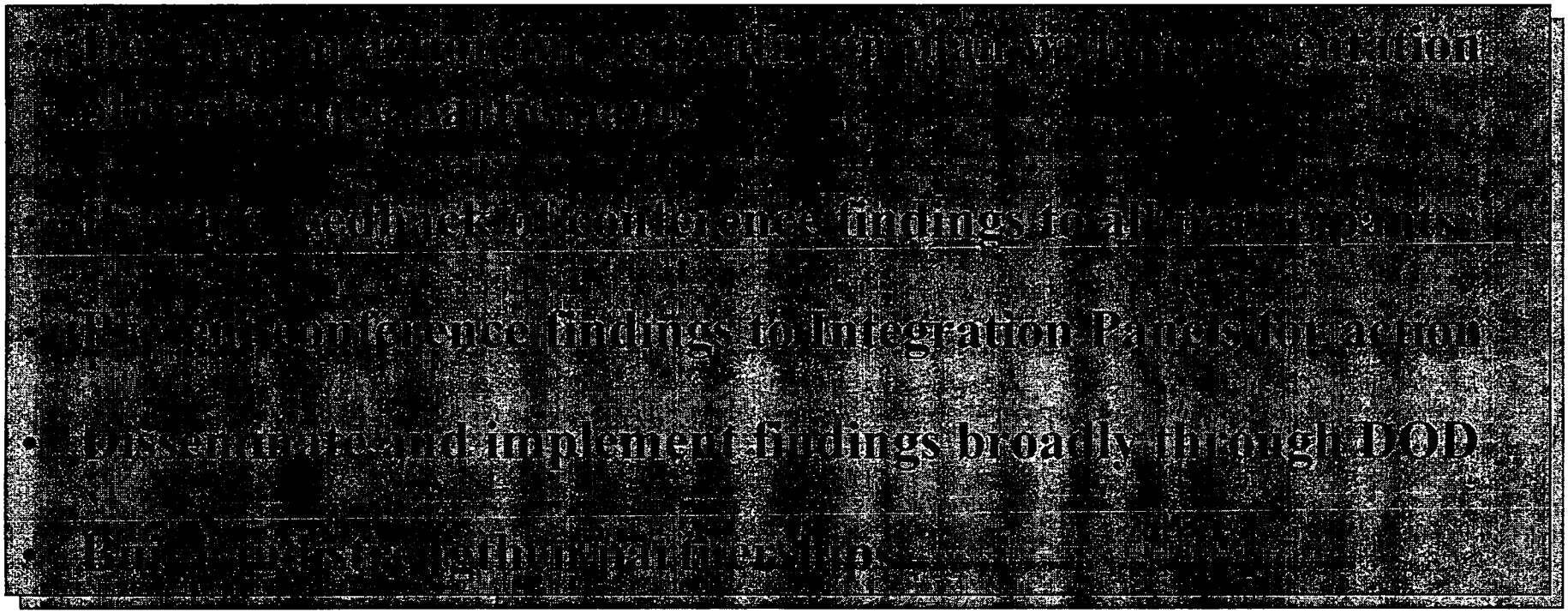
Partnership Strategy



Preliminary Findings

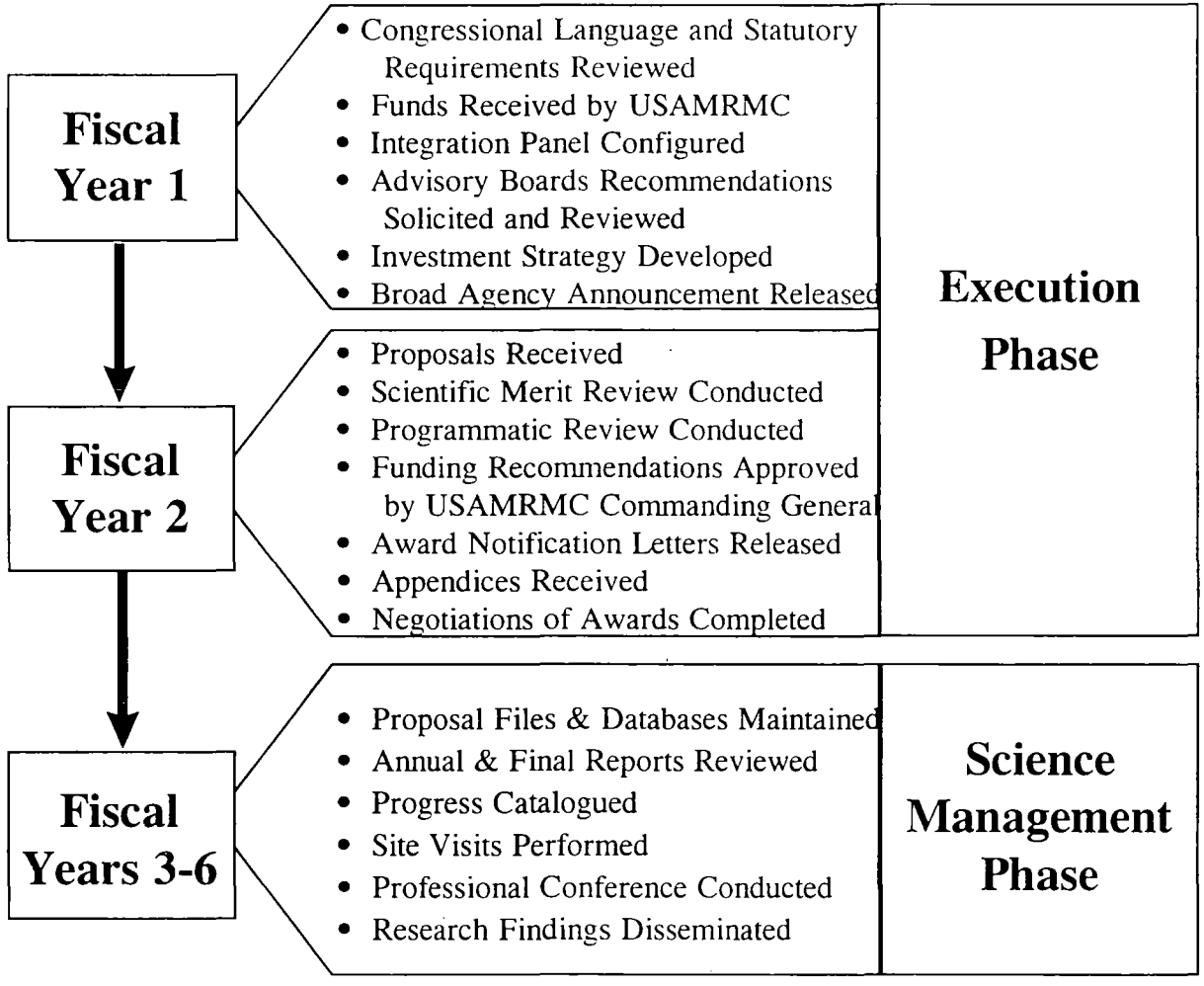


Next Steps


Research Conference findings to Integration Panels for action
Disseminate and implement findings broadly through DOD

Closing Comments

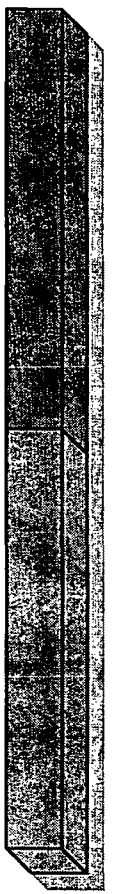
Program Milestones



PCRP Operation Plan and Timeline

FY 97 Appropriation

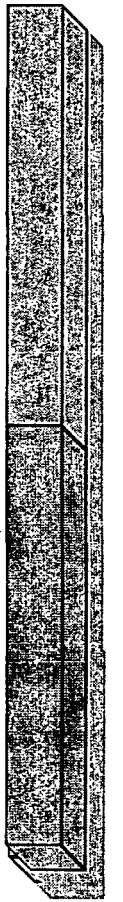
Funds Received	8 Jan 97
Stakeholders Meeting	1-2 Apr 97
IP Planning Meeting	2-3 Jun 97
BAA Release	28 Jul 97
Proposal Deadline	29 Oct 97
Peer Review	9-14 Jan 98
Programmatic Review	15-17 Apr 98
Negotiations Begin	4 May 98



Time from Funds Received to First Award 15 months

FY 98 Appropriation: Fast Track

Funds Received	8 Jan 97
IP Planning Meeting	18 Apr 98
BAA Release	20 May 98
Proposal Deadline	8 Jul 98
Peer Review	8-13 Sep 98
Programmatic Review	16-20 Nov 98
Negotiations Begin	4 Dec 98



Time from Funds Received to First Award 11 months

Unique Vision Derived from Diverse Perspectives

- **Evolution of investment strategy**
- **Complementary niche that broadens the national effort**
- **Innovations in science evaluation**
- **Opportunities for new investigators and new ideas**

Cell Biology

Biostatistics

Pharmacology

olecular Genetics

olecular Biology

Pathology

Advocate

Nursing

Hematology

Radiation Oncology

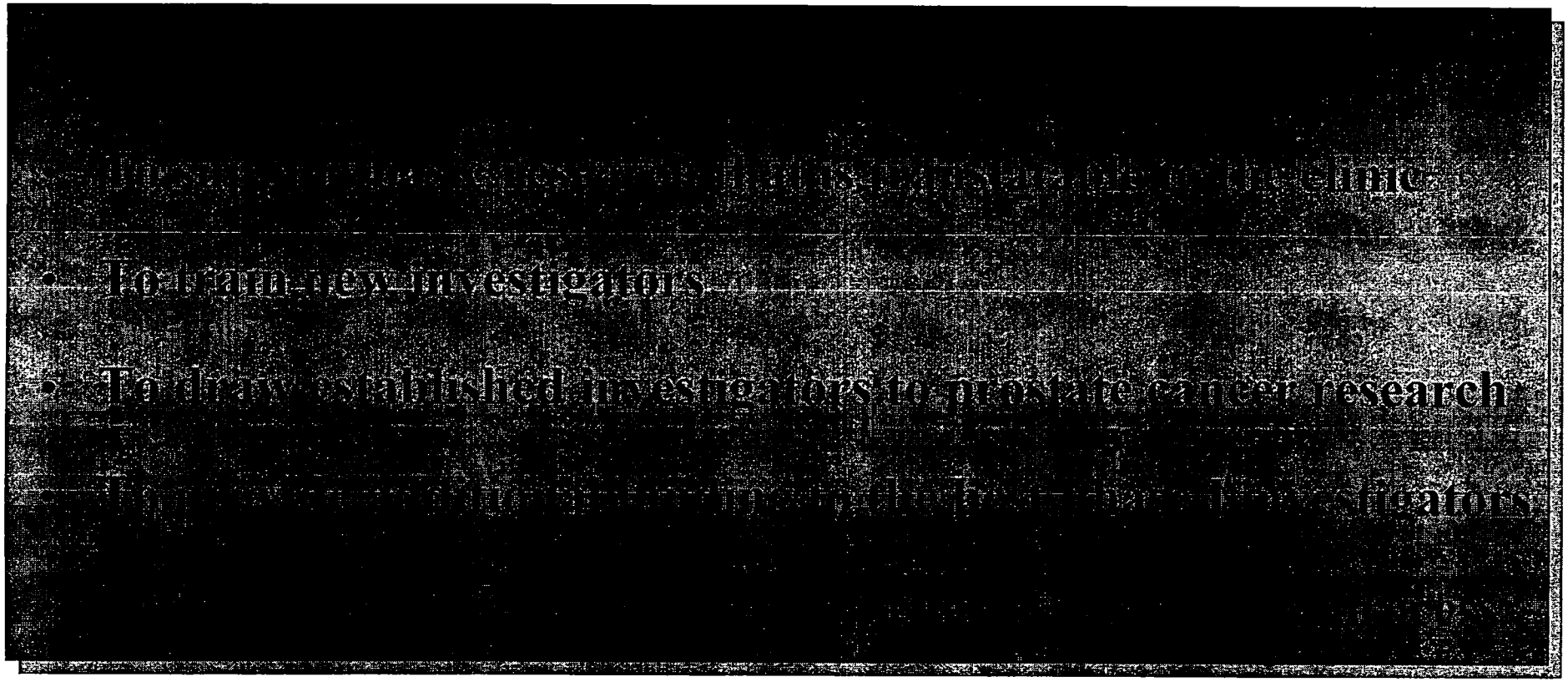
Medical Oncology

Radiology

Experimental Therapeutic

Urology

New Opportunities to Impact Prostate Cancer Research



15 December 1997

INFORMATION POINTS

Prostate Cancer Research Program

MAIN POINTS:

- Congress directed the U.S. Army's involvement in the current Prostate Cancer Research Program.
- $38M was appropriated in FY 97 for peer reviewed research in prostate cancer that is multi-institutional, multidisciplinary, and regionally focused.
- Co-ordination of funding and research efforts with other sources (public and private, including specifically, the National Institutes of Health—National Cancer Institute, the American Cancer Society, CaPCURE, and the American Foundation for Urological Disease) have been made to prevent duplication and allow the U.S. Army's research approach to complement current efforts.
- A stakeholders meeting was held in April 1997 to solicit opinions from the prostate cancer scientific and advocacy/support communities about direction for the program.
- An guiding Integration Panel (IP) was recruited and a meeting was held in June 1997. The IP is composed of civilian scientists, clinicians, and patient advocates, as well as military scientists/clinicians from related fields of basic and clinical research in urology and oncology.
- Coordination of funding and research efforts with other sources (public and private) have been made to allow the U.S. Army's research approach to complement current efforts.
- Coordination with current Prostate Cancer Research with the U.S. Army Center for Prostate Disease Research at Walter Reed Army Medical Center is also on-going.
- A Broad Agency Announcement (BAA) soliciting proposals across all areas of basic, clinical, behavioral, and epidemiological research was released 29 July 1997.
- The objective of the FY 97 PCRP is to promote innovative ideas that will lead to better understanding and control of prostate cancer.
- The FY 97 PCRP encourages innovative, multi-institutional, multidisciplinary, and regionally focused research that is directed toward eliminating prostate cancer.
- Award negotiation of FY 97 funds will begin in May 1998. All funds will be obligated by 30 September 1998.
- Funds have been appropriated by Congress in FY 98 to continue the prostate cancer research program, and the planned time-line for implementing the FY98 program will decrease the time between funding receipt and allocation by at least 2-3 months.

19 November 1997

INFORMATION PAPER

Prostate Cancer Research Program

OVERVIEW:
The U.S. Army began managing Congressionally Directed Medical Research Programs in FY 92 with a breast cancer research program focused on short-term, high-technology research aimed at early detection and novel interventions. In FY 97 the Joint Appropriations Bill 104-863 provided $38M for both basic and clinical research in prostate cancer. The U.S. Army was designated as the Department of Defense (DOD) executive agent. As such, the U.S. Army Medical Research and Materiel Command (USAMRMC) is conducting a peer- and programmatically-reviewed prostate cancer research program (PCRP). The PCRP is following an execution strategy recommended by the Institute of Medicine, Congressional language, and a panel composed of patient advocates and scientists/clinicians who are experts in prostate cancer research (Integration Panel; IP). The funding will be available to Military, Government, and non-Government researchers.

U.S. ARMY POSITION:
The U.S. Army is executing a prostate cancer research program in accordance with the intent of the FY 97 Appropriations Act, using the same highly focused, goal-directed strategy that is applied to all of its medical research efforts.

MAIN POINTS:
- Congress directed the U.S. Army's involvement in the current PCRP.
- $38M was appropriated in FY 97 for peer reviewed research in prostate cancer that is multi-institutional, multidisciplinary, and regionally focused.
- A stakeholders meeting was held in April 1997 to solicit opinions from the prostate cancer scientific and advocacy/support communities about direction for the program.
- An IP was recruited and a meeting was held in June 1997. The IP is composed of civilian scientists, clinicians, and patient advocates, as well as military scientists/clinicians from related fields of basic and clinical research in urology and oncology.
- A Broad Agency Announcement (BAA) soliciting proposals across all areas of basic, clinical, behavioral, and epidemiological research was released 29 July 1997.
- The objective of the FY 97 PCRP is to promote innovative ideas that will lead to better understanding and control of prostate cancer.
- The FY 97 PCRP encourages innovative, multi-institutional, multidisciplinary, and regionally focused research that is directed toward eliminating prostate cancer.
- Award negotiation of FY 97 funds will begin in May 1998. All funds will be obligated by 30 September 1998.
- Funds have been appropriated by Congress in FY 98 to continue the prostate cancer research program.

FACTS:
a. Origin of the Program
The PCRP was established in FY 97 by public law (P.L. 104-863, *The National Defense Authorization Act for Fiscal Year 1997*) to address "the need for both basic and clinical research in prostate cancer in order to reduce the incidence of this life-threatening disease and to develop more specific and less toxic forms of therapy for patients in all stages of the disease." One hundred million dollars was authorized and $38M appropriated in the U.S. Army Medical Advanced Technology program element for the establishment of a prostate cancer research study. Congress urged that the DOD give highest priority to funding research that is multi-institutional, multidisciplinary, and regionally focused.

b. Disease Background

Cancer of the prostate is the most commonly diagnosed cancer (accounting for 36% of all cancers) in men. An estimated 334,500 men will be diagnosed with prostate cancer in 1997 and approximately 41,800 will die from the disease. Prostate cancer is second only to lung cancer as a leading cause of cancer deaths in men. The incidence rates are 66% higher for African-American men than Caucasian men. Mortality rates are more than two times higher for African-American men than Caucasian men. Currently, there is no cure for locally advanced or metastatic prostate cancer.

c. FY 97 Operation Plan and Timeline

Congressionally directed medical research programs, such as the PCRP, have a lifetime of approximately six years, spanning from Congressional appropriation of funds to completion of research projects (see Figure 1). The timeline for the FY 97 PCRP is outlined in Table 1. The USAMRMC received funds for prostate cancer research on 8 January 1997. During this first program year, Congressional language was analyzed, a stakeholders meeting was held (1-2 April 1997), and an IP representing a wide range of scientific perspectives and ethnic diversity was recruited and convened (2-3 June 1997). The IP is composed of prestigious scientists and clinicians, some of whom are associated with the DOD, as well as representatives of the patient advocacy/support community. With the assistance of the IP, an investment strategy was developed and a solicitation for research proposals (BAA) was crafted and released on 28 July 1997. On 29 October 1997, 605 prostate cancer research proposals were received, which will be peer-reviewed in January 1998 and programmatically reviewed in March 1998. Awards will be made beginning in May 1998, and all funds will be obligated no later than 30 September 1998. Years 3-6 of the program are for the management of funded research projects. Projects will be monitored for technical progress and compliance.

As described above, all proposals submitted to the PCRP will undergo two independent reviews. In the first tier of review, scientific merit will be assessed. In addition to the scientific review, proposals will be evaluated by the IP for the second-tier review. Programmatic review is a comparison-based process for the prioritization of scientific excellence (as determined by the scientific merit review) to select the best research that fulfills the ultimate program goals. These goals are defined by criteria developed by the IP and outlined in the BAA. The aim of the process is to fund the most programmatically relevant and scientifically excellent research portfolio.

d. FY 97 Program Objectives and Goals

The intent of the program is to promote innovative ideas and technology through both clinical and basic science to conquer prostate cancer. The program mission is to promote innovative, multi-institutional, multidisciplinary and regionally focused research directed toward eliminating prostate cancer. The program was designed only after consultation with other national prostate cancer research funding agencies (specifically, the National Institutes of Health—National Cancer Institute, the American Cancer Society, CaPCURE, and the American Foundation for Urological Disease) to avoid overlap of programs and to target under-represented avenues of research and novel applications of existing technologies. Coordination with the U.S. Army Center for Prostate Disease Research at Walter Reed Army Medical Center is also on-going.

The five primary goals of the program are (1) to pursue new directions and breakthrough ideas and approaches in prostate cancer, (2) to prepare new scientists and encourage established investigators to join in the battle against prostate cancer, (3) to embrace prostate cancer public awareness and education, (4) to promote a unique dual-phase funding strategy, and (5) to fund a balanced attack across broad disciplines of prostate cancer. The programmatic strategy is being implemented by a solicitation for proposals in two subcategories: New Investigator Awards and Idea Development Awards. The intent of the New Investigator Award category is to promote and reward innovative projects that lack pilot data and encourage new investigators to enter the prostate cancer research field. The Idea Development Awards are intended to support established investigators with highly innovative projects.

The programmatic strategy embodies the continuing evolution and flexibility of the USAMRMC in managing the DOD Congressionally Directed Medical Research Programs. A unique dual-phase funding strategy is being implemented. Phase I awards will be made across five broad disciplines of prostate cancer research to both young and established investigators. After two years of research, the USAMRMC will challenge all funded investigators to compete for two additional years of support, pending appropriations in FY 00. This unique dual phase strategy was

designed to encourage the rapid development of ideas in Phase I and to provide transition support to position investigators for competition in traditional funding mechanisms in Phase II.

e. Minority Capacity Building

A ground-breaking conference on strengthening the national biomedical/behavioral research in the scientific minority community was held on 23-26 October 1997 in Vienna, VA. The purpose of the conference was to create a strategic plan that will help guide the U.S. Army's efforts to build minority medical research capacity and to serve as a model for military, civilian, business, and educational initiatives. The conference sought to improve both the quality and scope of research into health initiatives and the ability of minority researchers to serve as leaders and participants in programs geared to health needs of underserved populations. The DOD and the U.S. Army have historically played a leadership role in providing true equal opportunity to U.S. citizens. The conference was consistent with President Clinton's "National Conversation about Race" and the role of the U.S. Army in leadership development that bridges minority concerns. Recommendations from the conference are being analyzed and will be implemented in the FY 98 PCRP.

f. FY 98 PCRP Timeline

Funds have been appropriated in FY 98 to continue the PCRP. A tentative timeline for the program is shown in Table 1. The 1998 PCRP BAA will be released in May 1998 with a submission deadline in July 1998. Proposals will be peer-reviewed in September 1998 and programmatically reviewed in November 1998. Award negotiations will begin in December 1998 and will be completed by 30 September 1999.

SUMMARY

Congress appropriated $38M for prostate cancer research for FY 97. The BAA for the FY 97 program was released on 29 July 1997. Over 600 proposals were received on 29 October 1997. Awards to investigators will commence in May 1998 and will be completed by 30 September 1998. Additional funding for the PCRP in FY 98 has been appropriated. Awards to investigators should commence on or about December 1998. Additional information regarding Congressionally Directed Medical Research Programs managed by USAMRMC can be obtained by accessing our world wide web site at http//mrmc-rad6.army.mil.

Figure 1. Milestones for Congressionally Directed Medical Research Programs

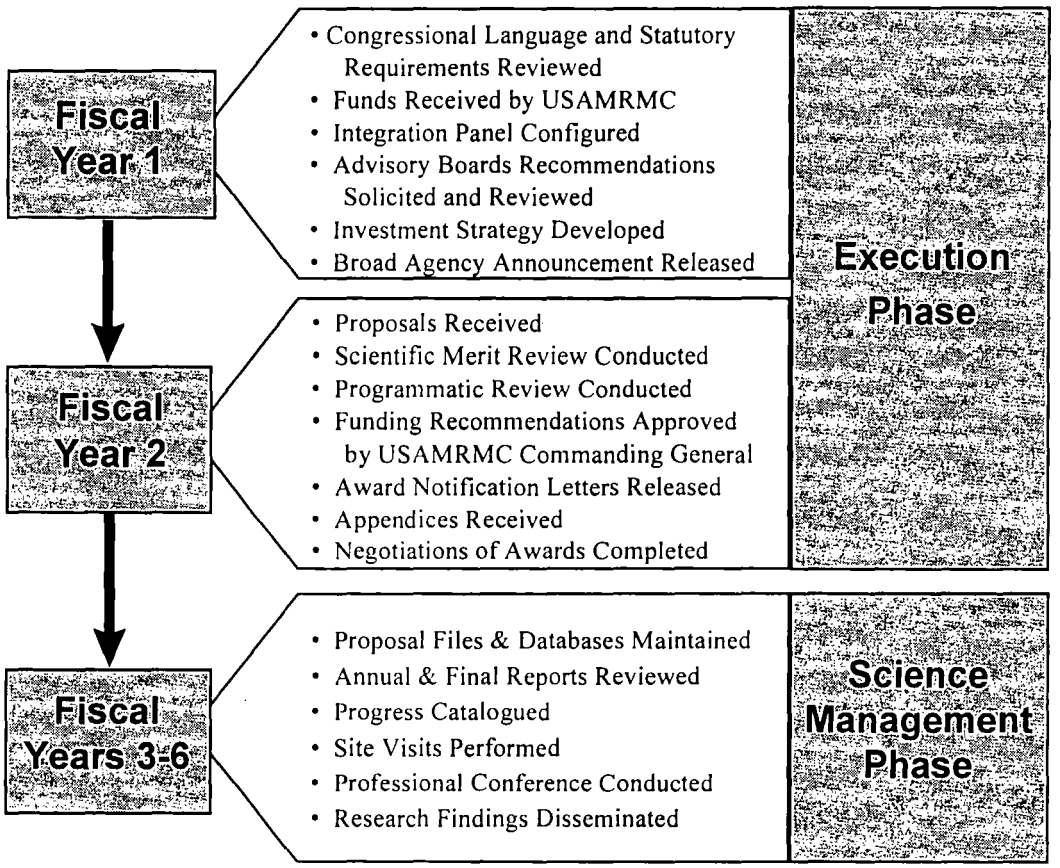


Table 1. PCRP Timeline

Funds Received	8 Jan 97
Stakeholders Meeting	1-2 Apr 97
Investment Strategy Meeting	2-3 Jun 97
BAA Release	28 Jul 97
Proposal Deadline	29 Oct 97
Peer Review	9-14 Jan 98
Programmatic Review	15-17 Apr 98
Award Negotiations Begin	4 May 98