

4000 DEFENSE PENTAGON WASHINGTON, D.C. 20301-4000

AUG 28 2019

The Honorable Adam Smith Chairman Committee on Armed Services U.S. House of Representatives Washington, DC 20515

Dear Mr. Chairman:

The enclosed report is in response to House Report 115–769, page 296, accompanying H.R. 6157, the Department of Defense (DoD) Appropriations Bill, 2019, concerning the status of the implementation of the recommendations contained in the April 2018 DoD report to Congress on the Metastatic Cancer Task Force.

This report provides an update on the implementation of these recommendations; summarizes the Congressionally Directed Research Programs (CDMRP) investments in Metastatic Cancer Research during Fiscal Year (FY) 2013 through FY 2017; describes metastatic research projects involving DoD or Department of Veterans Affairs (VA) investigators or resources; and illustrates success stories from DoD cancer research investments. During FY 2013 through FY 2017, CDMRP funded 807 awards for metastatic cancer research, totaling over \$595 million. Of these awards, 23 were granted to a DoD or VA organization, included a DoD or VA sub-award, and/or included use of samples from DoD or VA populations. CDMRP investments have also ultimately led to various therapeutics shown to improve patient outcomes.

Thank you for your interest in the health and well-being of our Service members, veterans, and their families. A similar letter is being sent to the other congressional defense committees.

Sincerely,

James N. Stewart

Assistant Secretary of Defense for Manpower and Reserve Affairs, Performing the Duties of the Under Secretary of Defense for

Personnel and Readiness

Enclosure: As stated

cc:

The Honorable William M. "Mac" Thornberry Ranking Member



**4000 DEFENSE PENTAGON** WASHINGTON, D.C. 20301-4000

AUG 28 2019

The Honorable James M. Inhofe Chairman Committee on Armed Services United States Senate Washington, DC 20510

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cc:

The Honorable Jack Reed Ranking Member



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AUG 28 2019

The Honorable Peter J. Visclosky Chairman Subcommittee on Defense Committee on Appropriations U.S. House of Representatives Washington, DC 20515

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Enclosure: As stated

cc:

The Honorable Ken Calvert Ranking Member



4000 DEFENSE PENTAGON WASHINGTON, D.C. 20301-4000

AUG 28 2019

The Honorable Richard C. Shelby Chairman Subcommittee on Defense Committee on Appropriations United States Senate Washington, DC 20510

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The Honorable Richard J. Durbin Vice Chairman

## REPORT TO THE CONGRESSIONAL DEFENSE COMMITTEES IN RESPONSE TO HOUSE REPORT

# 115-769, PAGE 296, ACCOMPANYING H.R. 6157, THE DEPARTMENT OF DEFENSE APPROPRIATIONS ACT, 2019

## "IMPLEMENTATION OF THE METASTATIC CANCER TASK FORCE RECOMMENDATIONS"



## SUBMITTED BY THE ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS

#### August 2019

The estimated cost of this report or study for the Department of Defense (DoD) is approximately \$5,700 in Fiscal Year 2019. This includes \$340 in expenses and \$5,360 in DoD labor.

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#### **EXECUTIVE SUMMARY**

This report is in response to House Report 115-769, page 296, to accompany H.R. 6157, the Department of Defense (DoD) Appropriations Bill, 2019. This report presents the implementation status of the 27 recommendations in the Metastatic Cancer Task Force report.

In 2018, the Assistant Secretary of Defense for Health Affairs submitted a report on the Metastatic Cancer Task Force, in response to the DoD Appropriations Bill, 2018, House Report 115-219, page 280. The report described the establishment and presented the findings of the task force, which focused on clinical and translational research aimed at extending the lives of advanced state and recurrent metastatic cancer patients.

#### **PURPOSE OF REPORT**

This report responds to the House Report 115-769, page 296, to accompany H.R. 6157, the DoD Appropriations Bill, 2019, Metastatic Cancer Research:

The Committee appreciates the report provided by the Department of Defense that contained recommendations on research for metastatic cancer. The Committee directs the Assistant Secretary of Defense (Health Affairs) to submit a report to the congressional defense committees not later than 60 days after the enactment of this Act on the status of the implementation of the recommendations contained in the report.

This report provides an update on the implementation of the Task Force's 27 recommendations. For the purposes of this report, metastatic cancer is defined as cancer that has spread beyond the primary organ of origin and regional lymph nodes and has spread into other major organ sites. Metastatic cancer is responsible for the majority of cancer-related deaths. When cancer returns after a period of remission, it is considered a recurrence. Distant recurrence refers to cancer that has metastasized.

# <u>Congressionally Directed Medical Research Programs (CDMRP) Efforts in Metastatic Cancer Research</u>

TABLE 1: CDMRP INVESTMENTS FROM FISCAL YEAR (FY) 2013 TO FY 2017

Program	Cancer Type/Topic	Number of Awards	Funding
Peer Reviewed Cancer	Bladder	9	\$5.2M*
Research Program	Blood	1	\$0.4M
(PRCRP)	Brain	3	\$1.8M
	Cancer in children,	1	\$0.6M
	adolescents, and young adults		
	Cancers related to radiation	1	\$0.4M
	exposure		
	Colorectal	16	\$8.3M

Program	Cancer Type/Topic	Number of Awards	Funding
	Immunotherapy	2	\$0.8M
	Kidney	7	\$3.9M
	Liver	11	\$5.0M
	Lymphoma	3	\$1.5M
	Melanoma and Other Skin	19	\$9.8M
	Mesothelioma	1	\$0.4M
	Neuroblastoma	4	\$2.4M
	Pancreatic	6	\$3.4M
	Pediatric Brain Tumors	3	\$1.7M
	Stomach	12	\$5.7M
	PRCRP Total:	99	\$51.3M
Breast Cancer	Breast	284	\$326.5M
Research Program			
(BCRP)			
Kidney Cancer	Kidney	2	\$0.7M
Research Program			
(KCRP)			
Lung Cancer Research	Lung	37	\$11.9M
Program (LCRP)			
Ovarian Cancer	Ovarian	53	\$33.4M
Research Program			
(OCRP)			
Prostate Cancer	Prostate	332	\$171.5M
Research Program			
(PCRP)			
TOTAL:		807	\$595.3M

<sup>\*</sup> Million

## <u>Metastatic Research Projects Involving DoD or Department of Veterans Affairs</u> (VA) Investigators or Resources

As shown in Table 1, CDMRP cancer programs funded 807 awards totaling over \$595 million focused on metastatic cancer in FY 2013-FY 2017. Twenty-three of these awards were made to a DoD or VA organization, included a DoD or VA subaward, and/or included the use of samples from DoD or VA populations.

TABLE 2: DoD or VA Projects on Metastatic Cancer, FY 2013-FY 2017

Program	Cancer Type/Topic	Number of DoD or VA- Affiliated Awards	Funding	DoD and/or VA Organizations	DoD and/or VA Samples
	Colorectal	1	\$0.8M	VA	Yes – VA
PRCRP	Liver	1	\$0.2M	VA	Yes – VA
	Pancreatic	1	\$0.6M	VA	Yes – VA
BCRP	Breast	1	\$0.7M	VA	No
LCRP	Lung	8	\$1.7M	DoD and VA	Yes – VA
OCRP	Ovarian	2	\$0.3M	DoD	Yes – DoD
PCRP	Prostate	9	\$5.8M	DoD and VA	Yes – DoD and VA
	TOTAL	23	\$10.1M		

While CDMRP is a congressionally directed funding organization within the DoD that funds metastatic and other types of cancer research, the DoD also conducts cancer research that is primarily focused on Active Duty Service members. A major DoD effort in conducting cancer research is led by the Uniformed Services University of the Health Sciences (USUHS) Murtha Cancer Center Research Program (MCCRP), with emphasis on breast, gynecologic, and prostate cancers. The following is a summary of current MCCRP projects relevant to metastatic cancer.

# • GYNECOLOGIC CANCER PREVENTION WITH PROGESTIN AND VITAMIN D – Gynecologic Cancer Center of Excellence

 Progesterone and calcitriol reduce invasive potential of endometrial cancer cells by targeting adenosine diphosphate (ADP)-ribosylation factor 6 (ARF6), neural precursor cell expressed developmentally down-regualted protein 9 (NEDD9), and membrane type 1 matrix metalloproteinase (MT1-MMP)

# • E39 VACCINES AND OTHER TREATMENTS IN GYNECOLOGIC CANCER PATIENTS – Gynecologic Cancer Center of Excellence

- o Folate Binding Protein vaccine (E39) in ovarian and endometrial cancer
- E39 vaccines and other treatments in gynecologic cancer patients
- Interim analysis of a phase I/IIa trial assessing E39+GM-CSF (granulocyte-macrophage colony-stimulating factor), a folate binding protein vaccine, to prevent recurrence in ovarian and endometrial cancer patients

# • PREDICTION OF RECURRENCE IN BREAST CANCER PATIENTS THROUGH PLASMA PROTEOMICS – Clinical Breast Care Project

 Development of a new blood plasma-based assay for detection and surveillance

### **Success Stories from DoD Cancer Research Investments**

CDMRP invested in preclinical, translational, and/or clinical research that ultimately led to Food and Drug Administration (FDA) approval and/or commercialization for the following clinical approaches for metastatic cancer. All of the therapeutics listed have been shown to improve patient outcomes, such as progression-free survival or overall survival.

TABLE 3: SUCCESS STORIES FROM DOD CANCER RESEARCH INVESTMENTS

Clinical Approaches	Overview	Cancer Type
Herceptin® (trastuzumab)	An FDA-approved monoclonal antibody that targets the human epidermal growth factor receptor 2 (HER2) and is part of standard-of-care treatment regimens for HER2+ early-stage and metastatic breast cancers.	Breast
Ibrance® (palbociclib)	An FDA-approved treatment in combination with an aromatase inhibitor or hormone therapy to treat hormone-positive metastatic breast cancer.	Breast
Kisqali® (ribociclib)	An FDA-approved treatment in combination with an aromatase inhibitor or hormone therapy to treat hormone-positive metastatic breast cancer in premenopausal and menopausal women.	Breast
Verzenio™ (abemaciclib)	An FDA-approved treatment in combination with an aromatase inhibitor or hormone therapy, as well as a monotherapy, to treat hormone-positive metastatic breast cancer.	Breast
Adjuvant Tamoxifen Longer Against Shorter (ATLAS)	The ATLAS clinical trial determined that risk of recurrence or death from breast cancer was reduced in women who took tamoxifen for 10 years versus those who took it for 5 years; these findings changed clinical practice.	Breast
MetaSite Breast™	A clinically validated test that measures Tumor Microenvironment of Metastasis (TMEM) sites to predict metastatic potential of the primary tumor. MetaSite Breast™ is licensed to MetaStat, Inc., and is analytically validated under Clinical Laboratory Improvement Amendments (CLIA) and publicly available.	Breast

Clinical Approaches	Overview	Cancer Type
MenaCalc™	MenaCalc <sup>™</sup> can be used as a prognostic marker for distant recurrence of breast cancer. MenaCalc <sup>™</sup> is licensed to Metastat, Inc., and has been clinically validated for use in treatment decision-making. It has also been used for other cancer types, including non-small cell lung carcinoma, as an independent prognostic factor and predictor of metastasis.	Breast; others
Breast Cancer Index	A commercially available (bioTheranostics) biomarker-based quantitative assessment test for risk of early and late recurrence of breast cancer.	Breast
Sentinel Lymph Node Biopsy	A standard of care method that enables clinicians to determine both tumor staging and whether more extensive surgery is necessary for breast cancers that have invaded the lymph nodes.	Breast
Velcade ® (bortezomib)	An FDA-approved chemotherapy for multiple myeloma that inhibits proteasomes, leading to cancer cell death.	Multiple myeloma
XGEVA® (denosumab)	An FDA-approved antibody that blocks the bone resorption protein receptor activator of nuclear factor kappa-B ligand (RANKL), and slows the progression of prostate cancer bone metastasis and prevents skeletal-related events (such as fractures) which often occur after androgen deprivation therapy.	Prostate
Xtandi® (enzalutamide)	An FDA-approved androgen receptor (AR) inhibitor to treat both non-metastatic and metastatic castration resistant prostate cancer (CRPC) patients.	Prostate
Zytiga® (abiraterone)	An FDA-approved cytochrome P450 17A1 (CYP17) inhibitor for treating metastatic CRPC.	Prostate
NuSAP1	A biomarker associated with metastatic prostate cancer that is part of two commercially available assays (Decipher; Prolaris) used to help guide prostate cancer treatment.	Prostate
ERLEADA™ (apalutamide)	An AR inhibitor and the first FDA-approved drug for patients with non-metastatic CRPC. It was the first drug to be FDA-approved based on a new intermediate clinical endpoint measuring improvements in metastasis-free survival (time before disease metastasizes).	Prostate
Oncotype IQ AR-V7 Nucleus Detection Test	A commercially available liquid biopsy assay measuring the AR variant, AR-V7, in circulating tumor cells to guide treatment (precision medicine) of metastatic CRPC.	Prostate

Clinical Approaches	Overview	Cancer Type
Quantitative	An FDA 510(k)-cleared software tool that	Breast,
Total Bone	automatically identifies and contours tracer uptake in	Prostate
Imaging Software	bone for full or partial body imaging scans. QTxl 1.0	
(QTxI 1.0)	fuses a series of scans from a patient over time,	
	allowing for evaluation of changes to each tumor	
	hotspot and determination of treatment response by	
	individual tumor metastases.	
Rubraca®	A poly ADP ribose polymerase inhibitor approved by	Ovarian
(rucaparib)	the FDA as a maintenance therapy for women with	
	recurrent epithelial ovarian, fallopian tube, or primary	
	peritoneal cancer to prevent progression to advanced	
	(metastatic) disease.	
OVA1®	An FDA-cleared blood test to help evaluate an ovarian	Ovarian
	mass prior to a planned surgery. OVA1® is an aid to	
	further assess the likelihood that malignancy is	
	present when the physician's independent clinical and	
	radiological evaluation does not indicate malignancy.	

### Status of the Metastatic Cancer Task Force Report Recommendations

The Metastatic Cancer Task Force's 27 recommendations were primarily intended for the national cancer efforts by federal funding organizations that support cancer research, such as the National Cancer Institute and CDMRP, but the recommendations also rely and call upon the cancer research community (e.g., scientists, clinicians, survivors) for concerted research efforts. The MCCRP of USUHS is mainly focused on Active Duty Service members with cancer in the Military Health System (MHS). While there are over a thousand new cancer diagnoses in Active Duty Service members annually, there are only a few with metastatic cancer on Active Duty since they are medically retired prior to or at that stage.

Implementing the Task Force's recommendations requires the efforts of a number of federal agencies. CDMRP includes many of these agencies in their vision setting and proposal review process to ensure awareness of the strategic plans and investments being made.

## TABLE 4: STATUS OF THE METASTATIC CANCER TASK FORCE REPORT 27 RECOMMENDATIONS

Actions Taken (applicable to all 27 recommendations): CDMRP cancer programs incorporated text in FY 2019 Program Announcements that encourages applicants to review the Metastatic Cancer Task Force report recommendations and submit research ideas to address these recommendations, provided they are within the limitations of the funding opportunity (e.g., Clinical Trial Award) and fit within the program's priorities. CDMRP cancer programs also included information about the task force recommendations in the materials for its FY 2019 vision setting meetings where

program strategy and funding opportunities were discussed and determined. Further actions taken for each specific recommendation are indicated below.

Recomm	nendation	Implementation Status
to include translation researche scientists in fields o medicine	to research, e clinicians, and basic ers, data, and experts ther than (e.g., chemists,	FY 2019 CDMRP award mechanisms supporting translational and clinical research require or encourage interdisciplinary teams, including partnerships between basic, translational, and clinical scientists (e.g., PRCRP Translational Team Science Award; LCRP and KCRP Translational Research Partnership Awards; OCRP Clinical Development Award; PCRP Translational Science Award; Melanoma Research Program (MRP) Translational Research Award).
	r evaluating sponses to	<ul> <li>CDMRP is supporting cancer immunotherapy studies relevant to developing standardized criteria for evaluating patient response to immune therapies.</li> <li>The national efforts include the Cancer Moonshot's Partnership for Accelerating Cancer Therapies (PACT) led by the National Institutes of Health (NIH) in partnership with the Foundation for the NIH (FNIH) and several pharmaceutical companies. Development and standardization of biomarkers to understand how immunotherapies work in some patients, and to predict their response to treatment, are urgently needed for these therapies to provide benefit to the maximum number of people. PACT's efforts will identify, develop, and validate biomarkers to advance the understanding of response and resistance to immunotherapies. A targeted funding opportunity was released in December 2018.</li> </ul>
utilized to compariso	criteria nose presently allow better on of clinical atients with	Implementing this recommendation requires the efforts of outside agencies and is not within the scope of CDMRP efforts.
cancer where the cancer where the cancer where the cancer where cancer	strata for vith metastatic no are vineligible for	<ul> <li>The FY 2019 PRCRP offered two funding opportunities for clinical trials in rare cancers.</li> <li>MCCRP of USUHS is enrolling metastatic cancer patients in several protocols (i.e., Biobanking and Outcomes; Oncology Research Information Exchange Network [ORIEN]; Applied Proteogenomics Organizational Learning and</li> </ul>

	1 41		
	nmendation		Implementation Status
laborate location rare tur comorb	abnormal ory values, n of metastases, mor types, pidities, and onditions)	• N p () r	Outcomes [APOLLO] proteogenomics, and Breast Cancer Research Foundation [BCRF] liquid biopsy). MCCRP will enroll available metastatic cancer patients on active duty being treated at Murtha Cancer Center (MCC) network sites across the military medical treatment facilities (MTFs) and medical centers in the MHS.
ease the burden trials properties to centralicate a reporting additionate con applicate IRBs)	ition of ions across	6 () () () () () ()	The funding opportunities offered by CDMRP already encourage the use of centralized IRBs. Moreover, CDMRP regularly holds a kick-off meeting among the clinical trial investigator(s) and their team(s), the CDMRP Science Officer, and the Human Protections Research Scientist in the DoD Office of Research Protections. When required, the Office of Regulated Activities is consulted on clinical trials involving FDA-regulated products.
diagnos tracers that are and spe detection	in novel stic imaging and techniques e more sensitive ecific for the on of early atic disease		CDMRP cancer programs have and will continue to nvest in this type of research.
develor diagnos monito	e biomarker pment for the sis and	C	CDMRP cancer programs have and will continue to offer award mechanisms that support biomarker development for diagnosis and monitoring of metastatic disease.
approp biopsie duratio disease decisio laborate	tion, when riate, and liquid es throughout the n of metastatic e for clinical n-making, ory research, blecularly-driven	F G G	Metastatic cancer studies funded by CDMRP cancer programs already support tissue acquisition and/or iquid biopsy. Biorepositories that include metastatic samples were established by the following programs/funding opportunities: PCRP Prostate Cancer Biorepository Network; OCRP Program Project Award; OCRP Outcomes Consortium Award; DCRP Resource Development Award; and LCRP Lung Cancer Biospecimen Resource Network.

Recommendation	Implementation Status
	<ul> <li>MCCRP tissue research protocols have been implemented at 10 DoD facilities.</li> <li>MCCRP has a liquid biopsy clinical trial for metastatic breast cancer patients that is actively enrolling.</li> </ul>
9. Increase research investigating the etiology, progression, and treatment of metastatic disease	<ul> <li>CDMRP cancer programs have and will continue to invest in this type of research. Program priorities or strategic goals include investigating the etiology, progression, and treatment of metastatic disease.</li> <li>MCCRP is in the process of implementing its APOLLO protocol at all 10 DoD facilities, which will facilitate investigations into the metastatic process, with a focus on enrolling Active Duty Service members with cancer.</li> </ul>
10. Encourage and support studies to develop more accurate and representative models of metastatic disease	<ul> <li>One of the OCRP's priorities is to develop more accurate and representative models of metastatic disease. Other CDMRP cancer programs also support research in developing and using representative models of metastatic disease if it is within the limits of the funding opportunity and fits within the program's priorities.</li> <li>An NIH funding opportunity (PAR-17-245) resulting from Cancer Moonshot Blue Ribbon Panel recommendations supports the enhanced applicability of mammalian models for translational research.</li> <li>An NIH funding opportunity (PA-19-174) resulting from Cancer Moonshot Blue Ribbon Panel recommendations supports collaborations with the Patient-Derived Xenograft Development and Trial Centers Research Network, which is focused on using patient-derived models.</li> </ul>
11. Explore novel funding mechanisms to support longer term basic and translational studies of metastatic disease	<ul> <li>CDMRP cancer programs have and will continue to offer award mechanisms along the full spectrum of basic, translational, and clinical research, including clinical trials for up to a four-year period of performance.</li> <li>Openly competed funding opportunities allow investigators who led successful studies to submit a new proposal for CDMRP funding to support the next phase of research.</li> <li>Some CDMRP programs offer an Expansion Award mechanism, which allows previously funded investigators to continue to expand upon their</li> </ul>

Recommendation	Implementation Status
Necommendation	successful CDMRP-funded research in a limited
	competition.
12. Study the metastatic process to identify therapeutics that will treat existing metastases, prevent the development of metastases, and/or target dormant cancer cells	CDMRP cancer programs have and will continue to invest in this type of research. CDMRP cancer programs' priorities or strategic goals already include identifying or developing therapeutics to treat or prevent metastases or target dormant cancer cells.
13. Optimize use of existing therapies (e.g., chemotherapy, hormonal, targeted, and immunotherapy)	<ul> <li>CDMRP cancer programs already offer award mechanisms supporting this type of research and have invested in studies on existing therapies.</li> <li>MCCRP opened a clinical trial looking at utility of aspirin therapy. MCCRP is also a member of two national cooperative cancer study groups studying various existing therapies.</li> </ul>
14. Evaluate medications that are currently FDA-approved for other indications as well as underdeveloped investigational agents for the treatment or prevention of metastasis	CDMRP cancer programs already offer award mechanisms supporting this type of research and have invested in studies on medications that are currently FDA-approved for other indications.
15. Identify the determinants of efficacy for immunotherapy	<ul> <li>Cancer immunotherapy studies are supported by CDMRP cancer programs. In addition, immunotherapy is a congressionally directed topic funded under the FY 2019 PRCRP, and immunotherapy is a research priority for the OCRP.</li> <li>The National efforts include the Cancer Moonshot's PACT led by the NIH in partnership with the FNIH and several pharmaceutical companies. PACT's efforts will identify, develop, and validate biomarkers to advance the understanding of response and resistance to immunotherapies. A targeted funding opportunity was released in December 2018.</li> </ul>
16. Increase research on less widely studied cancers	CDMRP only supports research on cancers or cancer topics specified by Congress. The FY 2019 PRCRP includes rare cancers as a congressionally directed topic.
17. Promote interdisciplinary	<ul> <li>CDMRP cancer programs already offer specific funding mechanisms to support and incentivize</li> </ul>

Recommendation	Implementation Status
collaborations by developing specific funding mechanisms, incentives, and resources for data sharing	interdisciplinary collaborations. "Partnering awards" support multiple investigators from diverse disciplines who prepare and submit a joint application, with an incentive of higher funding available for such collaborations.
18. Incentivize investigator career development in metastatic cancer research through recognition of group and collaborative science by academic promotion and tenure committees	<ul> <li>CDMRP cancer programs offer award mechanisms intended to initiate and sustain career development for future leaders in cancer research. Moreover, some of those award mechanisms allow applications from early-career investigators to be considered for funding separately from those of senior established investigators. The OCRP Academy Award is not a traditional career development award but is a unique, interactive, virtual career development and research training platform providing intensive mentoring, national networking, collaborations, and a peer group for junior faculty. The FY 2019 KCRP also offers an Academy Award to develop a cadre of kidney cancer scientists and clinicians.</li> <li>Fully implementing this recommendation requires the efforts of academic research institutions in addition to DoD investments.</li> </ul>
19. Streamline the proposal requirements and timelines for federal funding agencies	The U.S. Army Medical Research and Materiel Command, U.S. Army Medical Research Acquisition Activity, and CDMRP coordinate to streamline the proposal requirements and funding timelines to the maximum extent practicable.
20. Recruit and incentivize senior scientists to serve on review panels to ensure that the most qualified reviewers are providing scientific evaluations of research proposals	CDMRP uses a two-tier review processes that was most recently reviewed by the National Academy of Medicine, which includes a robust peer review recruitment strategy that ensures that the most qualified reviewers are providing scientific evaluations of research proposals.
21. Implement warm/rapid autopsy programs and establish metastatic tissue repositories of annotated clinical samples (with primary and metastatic tumor specimens) to be	The PCRP funded the development of a multi- institutional biorepository for annotated primary and metastatic tumor specimens, which includes a warm/rapid autopsy program. The OCRP funded development of the Australian Ovarian Cancer Study, which established an extensive biorepository of primary tumor tissue and ascites fluid. The samples from both of these biorepositories were

Recommendation	Implementation Status
widely accessible to the research community	<ul> <li>collected with the intent for distribution to the research community.</li> <li>MCCRP of USUHS has an ongoing tissue banking protocol that is operational now at 10 MTFs and medical centers across the MHS, which seeks to obtain tissue specimens from Active Duty Service members with cancer including stage 4 (metastatic) deposits.</li> </ul>
22. Improve access to care and clinical trial participation for patients with metastatic cancer, particularly for underrepresented groups	<ul> <li>MCCRP has rolled out its "core" clinical trial biobank protocol and opened its metastatic breast cancer liquid biopsy protocol BCRF at two sites; it also employs clinical trial personnel at 10 DoD facilities in its novel DoD Cancer Clinical Trials Network and works with national consortia of cancer centers to identify and open further studies focusing on metastatic cancer patients.</li> <li>CDMRP Program Announcements supporting clinical trials and clinical research involving human subjects include language highlighting special attention given to inclusion of women and/or minorities, as consistent with the Belmont Report.</li> <li>PCRP's Prostate Cancer Clinical Trial Consortium requires that an average minimum percentage of 5 percent of the subjects recruited to the clinical trials must represent minority communities, although the average actually accrued is approximately 20 percent, which far exceeds the minimum required.</li> <li>OCRP Clinical Development Award encourages a statement addressing how the clinical research could, whether in the short term or long term, lead to significant reduction or elimination of the disproportionate effects of ovarian cancer on diverse populations.</li> <li>Fully implementing this recommendation requires the efforts of outside agencies in addition to DoD investments.</li> </ul>
23. Ensure enrollment on clinical trials reflects the demographics of the U.S. population	<ul> <li>MCCRP has always sought to have diverse representation of enrolled patients in all trials that reflect the DoD demographic.</li> <li>Fully implementing this recommendation requires the efforts of outside agencies in addition to DoD investments.</li> </ul>
24. Increase cancer patient awareness of healthcare resources,	<ul> <li>Several of MCCRP's patient outreach programs (such as the June 2018 Cancer Awareness Day and May 2018 Melanoma Awareness Day) already focus</li> </ul>

Recommendation	Implementation Status
encourage adherence to treatment, and inform patients about risk factors for metastasis (e.g., compliance, obesity, smoking, and alcohol use)	on these activities. Furthermore, MCCRP supports Nurse Navigators, who enroll patients in research studies, help them navigate through those programs, and help them adhere to research and clinical treatments throughout the process.  Fully implementing this recommendation requires the efforts of outside agencies in addition to DoD investments.
25. Evaluate the role of social networks as they relate to outcomes for patients with metastatic cancer	CDMRP funding opportunities are already available to support this type of research. The Peer Reviewed Cancer, Prostate, Ovarian, and Kidney Cancer Research Programs' priorities already include survivorship, quality of life, and patient-reported outcomes.
26. Study whether inclusion of palliative care for patients with metastatic cancer extends life and determine which patients and families would most benefit from these resources	CDMRP cancer programs already offer funding mechanisms that allow for proposals in this research area, and the programs have invested in research on palliative care/quality of life.
27. Create standardized survivorship care plans for patients with metastatic cancer and validate whether their use improves outcomes for these patients	<ul> <li>MCCRP has already developed, implemented, and rolled out survivorship care plans in all of the 16 cancer clinics of MCCRP at Bethesda. The present national benchmark is under 50 percent; MCCRP is at 85 percent.</li> <li>Implementing this recommendation requires the efforts of outside agencies and is not within the scope of CDMRP efforts.</li> </ul>