**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**PUBLIC HEALTH SERVICE**
**NATIONAL INSTITUTES OF HEALTH**
**NATIONAL CANCER INSTITUTE**

# 3rd VIRTUAL JOINT MEETING of the BOARD OF SCIENTIFIC ADVISORS AND NATIONAL CANCER ADVISORY BOARD

**Summary of Meeting**
**December 1–2, 2020**

**Virtual Meeting**
**National Cancer Institute**
**National Institutes of Health**
**Bethesda, Maryland**

**BOARD OF SCIENTIFIC ADVISORS and**
**NATIONAL CANCER ADVISORY BOARD JOINT MEETING**
**BETHESDA, MARYLAND**
**Summary of Meeting**
**1–2 December 2020**

The Board of Scientific Advisors (BSA) of the National Cancer Institute (NCI) and the National Cancer Advisory Board (NCAB) convened for the 3rd Virtual Joint Meeting on 1–2 December 2020. The meeting was open to the public on Tuesday, 1 December 2020, from 1:00 p.m. to 4:44 p.m. and Wednesday, 2 December 2020, from 1:00 p.m. to 4:44 p.m., and closed to the public on Monday, 30 November 2020, from 12:00 p.m. to 1:00 p.m. The NCAB Acting Chair, Dr. Scott W. Hiebert, Hortense B. Ingram Chair in Cancer Research, Professor of Biochemistry, Department of Biochemistry, Vanderbilt University School of Medicine and BSA Chair, Dr. Dafna Bar-Sagi, Saul J. Farber Professor, Department of Biochemistry and Molecular Pharmacology and Medicine, Executive Vice President and Vice Dean for Science, and Chief Scientific Officer, New York University (NYU) Langone Health, NYU School of Medicine, presided during the open session. Dr. Hiebert presided during the closed session. In the open session, the BSA considered new requests for applications (RFAs), cooperative agreements (Coop. Agr.), and requests for proposals (RFPs) of new and re-issue concepts presented by NCI Program staff.

**BSA Members**

Dr. Dafna Bar-Sagi (Chair)
Dr. Kenneth C. Anderson
Dr. Michael John Becich
Dr. Mary C. Beckerle (absent)
Dr. Melissa L. Bondy
Dr. Otis W. Brawley
Dr. Graham A. Colditz
Dr. Christopher M. Counter
Dr. Carol E. Ferrans
Dr. Keith T. Flaherty
Dr. Karen E. Knudsen
Dr. James V. Lacey, Jr.
Dr. Michelle M. Le Beau
Dr. Sylvia Katina Plevritis
Dr. W. Kimryn Rathmell
Dr. Leslie L. Robison
Dr. Martine F. (Sheer) Roussel
Dr. Robert D. Schreiber
Dr. Victoria L. Seewaldt
Dr. Kevin M. Shannon
Dr. David Sidransky
Dr. Ian M. Thompson, Jr.
Dr. David A. Tuveson
Dr. Robert H. Vonderheide
Dr. Eileen P. White
Dr. Cheryl L. Willman

**NCAB Members**

Dr. Scott W. Hiebert (Acting Chair)
Dr. Peter C. Adamson
Dr. Francis Ali-Osman
Dr. Anna D. Barker
Dr. Deborah Watkins Bruner
Dr. Yuan Chang
Dr. Howard J. Fingert
Mr. Lawrence O. Gostin
Dr. Andrea A. Hayes-Jordan
Dr. Nikan Khatibi
Dr. Timothy J. Ley
Dr. Electra D. Paskett
Dr. Nancy J. Raab-Traub
Dr. Margaret R. Spitz
Dr. Susan Thomas Vadaparampil
Dr. Max S. Wicha

**Alternate *Ex Officio* NCAB Members**

Dr. Michael A. Babich, CPSC (absent)
Dr. Joseph R. Graber, DOE
Dr. Michael Kelley, VA
Dr. Aubrey Miller, NIEHS
Dr. Richard Pazdur, FDA (absent)
Dr. Craig D. Shriver, DoD (absent)
Dr. Kerry Souza, NIOSH (absent)
Dr. Lawrence A. Tabak, NIH (absent)
Dr. Aaron Tustin, OSHA

**Members, Scientific Program Leaders, National Cancer Institute, NIH**

Dr. Norman E. Sharpless, Director, National Cancer Institute
Dr. L. Michelle Bennett, Director, Center for Research Strategy
Dr. Oliver Bogler, Director, Center for Cancer Training
Dr. Philip E. Castle, Director, Division of Cancer Prevention
Dr. Stephen J. Chanock, Director, Division of Cancer Epidemiology and Genetics
Dr. Henry P. Ciolino, Director, Office of Cancer Centers
Dr. Robert Croyle, Director, Division of Cancer Control and Population Sciences
Dr. William Dahut, Scientific Director for Clinical Research, Center for Cancer Research
Dr. James H. Doroshow, Deputy Director for Clinical and Translational Research
Dr. Dan Gallahan, Director, Division of Cancer Biology
Mr. Peter Garrett, Director, Office of Communications and Public Liaison
Dr. Satish Gopal, Director, Center for Global Health
Dr. Paulette S. Gray, Director, Division of Extramural Activities
Dr. Ed Harlow, Special Advisor to the NCI Director
Dr. Toby T. Hecht, Deputy Director, Division of Cancer Treatment and Diagnosis
Dr. Sara Hook, Director, Office of Scientific Operations, NCI at Frederick
Dr. Tony Kerlavage, Director, Center for Biomedical Informatics and Information Technology
Dr. Douglas R. Lowy, Principal Deputy Director, National Cancer Institute
Dr. Glenn Merlino, Scientific Director for Basic Research, Center for Cancer Research
Dr. Tom Misteli, Director, Center for Cancer Research
Dr. Margaret Mooney, Associate Director, Cancer Therapy Evaluation Program
Dr. Henry Rodriguez, Acting Deputy Director, Center for Strategic Scientific Initiatives
Mr. Jeff Shilling, Chief Information Officer and Chief of Infrastructure and Information Technology Services Branch, Center for Bioinformatics and Information Technology
Ms. Donna Siegle, Executive Officer and Deputy Director for Management, Office of the Director
Dr. Dinah Singer, Deputy Director, Science Strategy and Development
Dr. Sanya Springfield, Director, Center to Reduce Cancer Health Disparities
Dr. Louis M. Staudt, Director, Center for Cancer Genomics
Mr. Michael Weingarten, Director, Small Business Innovation Research and Small Business Technology Transfer Programs
Dr. Robert Yarchoan, Director, Office of HIV and AIDS Malignancy
Dr. Maureen Johnson, Executive Secretary, Office of the Director

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### WEDNESDAY, 2 DECEMBER 2020

## MONDAY, 30 NOVEMBER 2020

## I. NATIONAL CANCER ADVISORY BOARD (NCAB) CLOSED SESSION—DR. SCOTT W. HIEBERT

*"This portion of the meeting was closed to the public in accordance with the provisions set forth in Sections 552b(c) (6), Title 5 U.S. code and 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2)."*

*There was a discussion of personnel and proprietary issues. Members absented themselves from the meeting during discussions for which there was a potential conflict of interest, real or apparent.*

## TUESDAY, 1 DECEMBER 2020

## II. CALL TO ORDER AND OPENING REMARKS—DRS. SCOTT W. HIEBERT AND DAFNA BAR-SAGI

Dr. Scott W. Hiebert called to order the 3rd Virtual Joint Board of Scientific Advisors (BSA) and National Cancer Advisory Board (NCAB) meeting. He welcomed members of the Boards, *ex officio* members, liaison representatives, staff, and guests. Members of the public were welcomed and invited to submit to Dr. Paulette S. Gray, Director, Division of Extramural Activities (DEA), National Cancer Institute (NCI), in writing and within 10 days, any comments regarding items discussed during the meeting. Dr. Hiebert reviewed the confidentiality and conflict-of-interest practices required of Board members in their deliberations.

**Motion.** A motion to accept the minutes of the 2 September 2020 NCAB Meeting was approved unanimously.

Dr. Hiebert called Board members' attention to the future meeting dates listed on the agenda.

## III. NCI DIRECTOR'S REPORT—DR. NORMAN E. SHARPLESS

Dr. Norman E. Sharpless, Director, NCI, welcomed members of both the BSA and NCAB to the 3rd Virtual Joint Meeting of these Boards and reviewed the agenda. He provided an update on the NCI budget, COVID-19-related activities, progress in cancer research, and other NCI activities.

**NCI Budget and Appropriations.** Dr. Sharpless reminded the BSA and NCAB members that NCI regular appropriations have steadily increased since fiscal year (FY) 2015. The FY 2020 budget continues the appropriations for the Cancer Moonshot℠ and Childhood Cancer Data Initiative (CCDI). The NCI also received a $306 million (M) supplemental appropriation to support COVID-19 serology, awarded in April 2020. The FY 2021 National Institutes of Health (NIH)/NCI budget appropriations process is uncertain for the NIH and the NCI, given the circumstances caused by the COVID-19 pandemic. The federal government is operating under a continuing resolution (CR) that funds the government through 11 December 2020. Every four years comes the possibility of the NCI leadership's changing with a new Administration. Dr. Sharpless assured the BSA and NCAB members that the NCI will continue to carry out its mission as it has during several previous transitions in government, regardless of the outcome. He noted that Ms. M. K. Holohan, Director, Office of Government and Congressional Relations (OGCR), NCI, will provide further details on the NCI FY 2021 budget later in the meeting.

The Cancer Moonshot[SM] appropriation approved under the 21st Century Cures Act has created scientific networks and teams, built new infrastructures, and coordinated first-time initiatives at a momentum and pace that would be counterproductive to science if discontinued. Advancing the Cancer Moonshot[SM] initiatives to a traditional NCI mechanism will require critical planning, without inhibiting the progress of existing NCI programs. Updates on the Cancer Moonshot[SM] progress will be provided at a future meeting.

The NCI released its *Annual Plan and Budget Proposal for Fiscal Year 2022* (also called the Bypass Budget or Professional Judgment Budget) in September 2020. This year, the NCI Professional Judgment Budget for FY 2022 proposes a "5 in '25" plan to increase funding for the Research Project Grant (RPG) pool, with the goal of reaching a 15th percentile payline for R01 grants for established investigators by FY 2025. This plan and rate of increase (i.e., $200 M) has enabled the NCI to reach the 10th percentile in FY 2020, but additional funding will be needed for multiple years to reach the 15th percentile payline. To achieve this aspirational and resource-intensive goal by FY 2025 without making cuts to major programs (e.g., NCI-Designated Cancer Centers) outside of the RPG pool, the NCI will need continued support from Congress.

Dr. Sharpless announced that the NCI has tentatively established interim paylines for FY 2021 competing grants (Type 2); 9th percentile for established and new investigators, 14th percentile for early-stage investigators (ESIs), and 9th percentile for exploratory grants (R21). Further details have been provided on the NCI blog, *NCI Bottom Line: A Blog About Grants and More*.

**NCI COVID-19 Activities.** Dr. Sharpless reported that the $306 M supplemental appropriation to the NCI to develop, validate, improve, and implement serological testing and associated technologies is being put into operation. This appropriation, awarded in conjunction with the fourth COVID-19 emergency bill, is separate from the NCI's regular appropriations and does not shift the NCI's priority from cancer. Dr. Sharpless highlighted some of the programs and initiatives being supported by the supplemental COVID-19 funding. The NCI collaborated with the National Institute of Allergy and Infectious Diseases (NIAID), U.S. Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), Biomedical Advanced Research and Development Authority (BARDA), and other research groups to establish the SARS-CoV-2 Serology Validation Program.

The Frederick National Laboratory for Cancer Research (FNLCR) has been assisting the FDA in evaluating commercially available serology devices (i.e., assays) for SARS-CoV-2 (the coronavirus causing COVID-19) detection. As of 15 October 2020, the FNLCR had generated and delivered performance data on 104 of the 282 assays received. The FDA granted an Emergency Use Authorization (EUA) to approximately 25 assays validated at the FNLCR that met the acceptance criteria or regulatory status for both sensitivity and specificity.

On 8 October 2020, the NCI, in collaboration with NIAID, launched the Serological Sciences Network for COVID-19 (SeroNet), with the goal to increase the national capacity for serological testing and advance understanding of all aspects of immune response to SARS-CoV-2. The NCI has issued 24 grants (U54s and U01s) and 4 contracts to support establishing the components of SeroNet, including Serological Sciences Centers of Excellence, Serological Sciences Research Projects, and Serological Sciences Capacity Building Centers, all within the extramural community. The FNLCR human papillomavirus (HPV)/SARS-CoV-2 Serology Laboratory has a key role in the operation and management of this network.

Dr. Sharpless announced that the online COVID-19 Seroprevalence Studies Hub (COVID-19 SeroHub) is now live. An online dashboard designed to assist researchers and policy makers in

monitoring SARS-CoV-2 seroprevalence and U.S.-based studies, COVID-19 SeroHub is a collaborative effort of the U.S. Department of Health and Human Services (HHS), CDC, NIAID, and FNLCR.

The NCI COVID-19 in Cancer Patients Study (NCCAPS) is in progress. As of 29 October 2020, 810 trial sites have been activated across the Experimental Therapeutics Clinical Trials Network (ETCTN), NCI National Clinical Trials Network (NCTN), and NCI Community Oncology Research Program (NCORP) in 49 states and Puerto Rico. A total of 283 patients have been screened and 224 enrolled in NCCAPS, and the trial is now open to pediatric cancer patients.

Dr. Sharpless explained that, overall, the weekly accrual for therapeutic trials across the NCTN is recovering following a sharp decrease during the COVID-19 pandemic. The NCI is concerned that the large screening and prevention trials that are already below target accrual rates have further decreased in enrollment, prolonging the times to complete these trials. In addition, the NCI remains concerned about cancer care in the United States, especially because hospitals are having to cancel elective procedures and delay care to preserve capacity for COVID-19 patients. Discussions have been ongoing with hospitals, health care leadership, and medical societies about prioritizing care for cancer patients. Many groups have begun to develop best practices to triage cancer patients during the pandemic.

**Progress in Cancer Research.** Dr. Sharpless highlighted recent NCI-led cancer research progress. Dr. Louis M. Staudt, Director, Center Cancer Genomics, Center for Cancer Research (CCR), and Dr. S. Percy Ivy, Associate Chief, Investigational Drug Branch, Division of Cancer Treatment and Diagnosis (DCTD), reported in the 19 November 2020 issue of *Cancer Cell* about a study evaluating exceptional responders to cancer therapies. The results identified molecular features that could potentially explain exceptional responses to treatment in 24 percent of cancer patients studied. In addition, Division of Cancer Control and Population Sciences (DCCPS) investigators reported in the 29 October 2020 issue of *Cancer Epidemiology, Biomarkers*, *and Prevention* that persistent high levels of county-level poverty are associated with increased mortality. A second report evaluating the impact of rural versus urban counties soon will be released.

Dr. Sharpless reminded the BSA and NCAB members that NCI-Molecular Analysis for Therapy Choice (NCI-MATCH) trial rapidly accrued 6,000 patients across 1,100 sites in the NCORP and other NCI networks. Patients were randomized to targeted therapies based on the results of genetic tumor sequencing. The NCI-MATCH demonstrated how such complex trials with multi-arm treatment design can be conducted in a real-world setting. Findings from treatment arms reaching their target accruals are being reported, data are supporting correlative studies, and eight treatment arms still are accruing. The Children's Oncology Group (COG)-led Pediatric MATCH trial also is accruing patients. In this next phase of the NCI-MATCH series, the NCI is sponsoring successor trials, Combination (Combo) MATCH and acute myeloid leukemia (AML)/Myelodysplastic Syndromes MATCH (MyeloMATCH); both are expected to open in 2021.

Dr. Sharpless reported that the Cancer Grand Challenges (CGC), a partnership with Cancer Research UK, launched in August 2020, with an added emphasis on both international multidisciplinary teams and patient involvement. The CGC will use the Provocative Questions Initiative funds every other year and also is supported by Cancer Research UK funds. Nine CGCs were published in October 2020 and can be accessed from the NCI website. The first stage of the competition involves expressions of interest from the teams, which will be accepted through April 2021. The CGC is one way to encourage and support high-risk, extremely innovative cancer research on a large scale, complement the NCI investigator-initiated and RPG research portfolios, and is expected to stimulate innovative ideas in overcoming barriers to research and make fundamental biological advances that will have direct impact on cancer patients.

**NCI Role in the Faculty Institutional Recruitment for Sustainable Transformation (FIRST) Initiative**. Dr. Sharpless described the NIH Common Fund initiative, FIRST, which the NCI administers. FIRST will establish a national network of large Coop. Agr. to academic institutions committed to the development of minority faculty. A related grant to establish a FIRST Coordinating Evaluation Center will be issued and will be managed by the National Institute on Minority Health Disparities (NIMHD). FIRST seeks to create cultures of inclusive excellence at NIH-funded institutions by implementing a set of well-integrated evidence-based strategies and evaluating their impact based on specified metrics on culture inclusion and diversity. The NCI anticipates issuing U54 funding opportunity announcements (FOAs) in the coming weeks. Dr. Sharpless expressed appreciation to Dr. Sanya Springfield, Director, Center to Reduce Cancer Health Disparities (CRCHD), and her staff for their efforts in assisting the development of FIRST.

**National Cancer Act 50th Anniversary.** Dr. Sharpless remarked that since its passage, the National Cancer Act of 1971 has accelerated a number of programs (e.g., NCI-Designated Cancer Centers and Surveillance, Epidemiology, and End Results [SEER]) establishing the mainstay of the Nation's investment in cancer research. The National Cancer Act assured high-level access of the NCI to Congress and the White House, appointed advisory committees (e.g., NCAB and President's Cancer Panel), and enabled the NCI Bypass Budget (also called the Professional Judgment Budget) process. In addition, the Act established the FNLCR, providing the NCI with a government laboratory for targeted, high-priority cancer research projects. Importantly, the Act united patients, scientists, and doctors, as well as industry and government, in one vision. In FY 2021, the NCI will commemorate the 50th anniversary of the Act, with the broad goal to ignite enthusiasm for scientific research and funding to continue the fight against cancer, as well as to inspire the next generation of diverse talent. The NCI tagline "Nothing Will Stop Us" conveys NCI's commitment to promote its mission, regardless of the situation or circumstance—a message reiterated in the COVID-19 era.

**Questions and Answers**

In response to a question about the updates on the Tomosynthesis Mammographic Imaging Screening Trial (TMIST), Dr. Sharpless explained that an NCI Clinical Trials and Translational Research Advisory Committee (CTAC) *ad hoc* Working Group on Cancer Screening Trials was approved by the NCAB at its 2 September 2020 meeting. The roster is complete, and the Working Group was charged to advise the NCI on the real-world impact of the COVID-19 pandemic on screening trials, including TMIST.

Dr. Andrea A. Hayes-Jordan, Byah Thompson Doxey Distinguished Professor of Surgery, Division Chief, Pediatric Surgery, Surgeon-in-Chief, The University of North Carolina Children's Hospital, asked whether FIRST would include efforts to increase the pipeline of faculty from underrepresented minorities, which remains a critical issue. Dr. Sharpless remarked on the NCI's long-standing commitment to developing the pipeline for underrepresented minorities within the Intramural Continuing Umbrella of Research Experiences (iCURE) program. He noted that the initial phase of the FIRST initiative will fund both small and large academic institutions committed to faculty development. Dr. Sharpless clarified that the NCI anticipates issuing the FIRST FOAs in the 2020 calendar year.

Because increases to paylines depend on funding and the number of applications the NCI receives, Dr. Sharpless elaborated on the challenge to predict whether reaching the 15th percentile would involve multiple FYs or solely appropriations increases from Congress.

## IV. LEGISLATIVE REPORT—MS. M.K. HOLOHAN

Ms. Holohan reported on the status of FY 2021 appropriations, prospects for COVID-19 supplemental funding, and provided a look ahead to the 117th Congress. She noted that the government is currently operating under a CR that expires on 11 December 2020 and noted that starting the fiscal year under a CR is not uncommon, and that over the past 15 years, there has been on average more than 3 CRs a year before a final appropriation was completed. Historically, election years have correlated with final appropriations coming late into the fiscal year, particularly when the leadership in one or both chambers changes. In the past eight election years, only one appropriation bill was completed before the start of the fiscal year.

Congressional leadership has indicated a desire to link the next COVID-19 supplemental funding bill to the FY 2021 appropriations omnibus, so those will likely proceed together. Appropriators recently agreed on allocations for the 12 spending bills and discussions will focus on resolving policy differences regarding the House and Senate approaches to FY21 appropriations. Policy disputes funding for a border wall and designation of emergency funding measures in relation to existing budget caps.

The House Appropriations Committee passed ten of the twelve FY21 spending bills in July, including the House Appropriations Subcommittee on Health and Human Services, Education, and Related Agencies (Labor–HHS) bill that included a $5.5 billion increase to the NIH, $5 B of which was designated as emergency funding. The House bill would provide an NCI appropriation of $6.9 B, including $414 M in emergency funding and $190 million for the Cancer Moonshot℠. In November, the Senate Appropriations Subcommittee released its FY21 Labor–HHS bill which included a $2 B increase for the NIH and a $282.5 M increase for the NCI, including $87.5 M designated to prioritize competing grants and sustain commitments to continuing grants. The Senate FY 2021 bill did not include emergency funding designations.

In May 2020, the House passed a $3 trillion Health and Economic Recovery Omnibus Economic Solution (HEROES) Act. This bill included a $4 B appropriation to the NIH to prevent, prepare for, and respond to coronavirus, $3 B of which was allocated for costs related to the reduction in laboratory productivity. The Senate rejection of the $3 trillion price tag of the HEROES Act, resulted in negotiations being stalled for months. In September the Senate introduced a $300 billion COVID-19 aid package, followed by a $500 B package in October 2020; both failed to garner enough votes to proceed. With an increasing number of COVID-19 positive cases, unemployment claims, and housing and food insecurity issues, bipartisan pressure for a compromise is growing. A bipartisan group of senators is actively working with House members to elevate and publicize the urgent need for a compromise, which is likely to be attached to the FY 2021 appropriations omnibus bill.

Ms. Holohan explained that a lame-duck session of Congress occurs when one Congress meets after its successor is elected but before the end of its own constitutional term. The 117th Congress will begin on January 3th. The new Congress will conduct leadership elections, including chair of the House and Senate Appropriations Committees. Rep. Nita Lowey (D-NY), current chair of the House Appropriations Committee, will retire at the end of the 116th Congress, and several candidates are running to replace her as Chair of the Appropriations Committee. Ms. Holohan reviewed some of the potential outcomes of the race for the 117th Congress in both the House and Senate, some of which are still being decided. After the internal elections for leadership across the committees, ongoing issues with a COVID-19 supplemental bill and the differences in the House and Senate approaches to the FY 2021 appropriations will need to be addressed.

**Questions and Answers**

Dr. Anna D. Barker, Chief Strategy Officer, Ellison Institute for Transformative Medicine, University of Southern California, asked Ms. Holohan to comment on the slate of candidates being considered for chair of the House Appropriations Committee. Ms. Holohan noted that she could not speak to the outcome of the internal elections, however, members were informed that the race potentially could be decided between two candidates, both of whom are strong supporters of cancer research. She conveyed the NCI's appreciation for the ongoing bipartisan support from Congress.

## V. PRESIDENT'S CANCER PANEL REPORT—DR. JOHN P. WILLIAMS

Dr. John P. Williams, Breast Cancer Surgeon, Medical Director, Breast Cancer School for Patients, Clinical Professor, Institute for Biohealth Innovation, George Mason University, presented the report of the President's Cancer Panel (Panel or PCP), which he chairs. In addition to Dr. Williams, the Panel members include Dr. Edith P. Mitchell, Clinical Professor of Medicine and Medical Oncology, Department of Medical Oncology, Director, Center to Eliminate Cancer Disparities, Associate Director, Diversity Affairs, Sidney Kimmel Cancer Center, Thomas Jefferson University, and Mr. Robert A. Ingram, General Partner, Hatteras Venture Partners. Dr. Williams expressed appreciation to the NCI for its continued support of the PCP operations.

Dr. Williams noted that two themes, innovation and implementation, are framing the 2020 topics and also embody the functioning of the Panel as a whole. By way of a re-introduction of the Panel since its last report to the Boards, Dr. Williams emphasized that the Panelhas been and continues to be tasked with identifying timely cancer topics. The Panel is responsible for implementation of those topics in the broader National Cancer Program. This current Panel met for its inaugural meeting in January 2019 and began its activities by attending the NCI BSA and NCAB meetings and engaging the NCI leadership, division directors, and implementation science team in discussions on priorities, opportunities, and disparities in cancer. Resources were identified, and a PCP team consisting of NCI staff was established. Priorities shifted early to consider COVID-19 and cancer screening as a next topic. Dr. Williams acknowledged the NCI PCP team and expressed appreciation to the members for their support.

Regarding its history and mission, the PCP was established with the signing of the National Cancer Act in 1971 and is required to monitor the development and execution of the activities of the National Cancer Program and report directly to the President of the United States regarding any barriers to the progress in reducing the burden of cancer. The purpose of the Panel remains unchanged, but activities are evolving to merge innovation with the topics being considered. The National Cancer Program engages stakeholders at all levels to address the burden of cancer in the United States, including government (federal and local), private organizations, health care providers, and individuals. An introductory video emphasizing the PCP's extended purpose has been generated and can be accessed from the Panel's website (https://prescancerpanel.cancer.gov/), along with past and future reports and soon, video versions of the recommendations.

Dr. Williams elaborated on the rationale for addressing cancer screening. The NCI observed a dramatic decrease in screening in NCI clinical trials as the COVID-19 pandemic evolved. In fact, COVID-19 caused a disruption in care on all levels (e.g., screening, diagnosis, treatment, and research) and has exacerbated health disparities. In these times of uncertainty, the field is open to change and innovation, and the widespread use of telehealth is one such innovation. The PCP sees an opportunity to advance efforts to reduce a barrier or highlight an opportunity on this topic. In the June 2020 issue of *Science*, Dr. Sharpless presented data modeling the potential impact of COVID-19 on cancer screening, calling attention to the additional cancer deaths for two common cancers—breast and colon—during the next 10 years compared with a scenario without a disruption in care.

The Panel selected the 2020 topic, "Improving Resilience and Equity in Cancer Screening: Lessons from COVID-19 and Beyond." Four working groups consisting of two co-chairs and four members have been established to evaluate screening pre-, during, and post-COVID-19 in four tumor types—breast, cervical, colorectal, and lung—and identify opportunities, barriers, and solutions. The working groups began weekly meetings in August 2020 and are anticipated to complete their activities by February 2021. The PCP convened virtual stakeholder meetings to capture input from the broader cancer community, and a final report, including actionable recommendations, is anticipated to be completed in summer 2021.

## VI. WHY AND HOW NCI USES THE U01 MECHANISM—DR. MICHELLE BERNY-LANG

Dr. Michelle Berny-Lang, Program Director, Center for Strategic Scientific Initiatives (CSSI), Office of the Director (OD), presented on the NCI's use of the Coop. Agr., specifically the U01 (research project) funding mechanism, in response to a request by the Boards for information on this topic. She first provided a general overview of the Coop. Agr. The *NIH Policy Manual* stipulates that Coop. Agr. are used when substantial programmatic involvement is anticipated between the federal agency (e.g., the NCI) and the awardee. In addition to the U01, other common U-type activity codes used by the NCI encompass a broad range of activities, research, and resources. The NIH's purpose (of substantial involvement) as a partner is to support and/or stimulate the awardee's activity, but the primary responsibility resides with the awardee. The roles and responsibilities are defined clearly in the terms and conditions of the award, and an Institute or Center official must concur with the use of the Coop. Agr. mechanism.

The U01 Coop. Agr. and the R01 grant are investigator-led research projects funded by the NCI RPG pool, but the U01 is distinct in terms of NCI's substantial involvement. The NCI has an additional engagement in U01 management but does not direct the science of the project. The U01 programs and structures vary from the smaller, more simpler models of U01s addressing a similar research topic to complex structures that can be networked with U54s (specialized centers) and U24s (resource-related projects) focusing on two or more topics with a common goal.

Dr. Berny-Lang pointed out that the CSSI, in collaboration with NCI staff external to the CSSI, conducted a qualitative and quantitative analysis of the NCI U01 programs and their awards, purpose, and outcomes. This analysis also included interviewing numerous NCI program staff well acquainted with developing U01-related scientific concepts for BSA approvals to provide insight on the NCI reasons for using this mechanism. The overall theme was that the U01s are used to facilitate progress more effectively toward a shared research goal, build a community of practice, collaboratively address a well-defined research need, or leverage unique or limited resources. The investigator-led projects within the U01 programs are enhanced by Coop. Agr. activities and enable U01 programs outputs (e.g., enhanced coordination or flexibility in responding to public health emergencies) beyond what is possible with an R mechanism.

Dr. Berny-Lang described three examples of NCI U01 programs. The Cancer Intervention and Surveillance Modeling Network (CISNET), a consortium of U01s, uses simulation modeling to extend clinical trial evidence and epidemiologic and surveillance data to guide public health research and priorities. The Cancer Systems Biology Consortium (CSBC) is composed of individual U01 projects within a larger consortium and addresses multiscale and dynamic cancer processes using experimental and computational approaches. The Pancreatic Cancer Detection Consortium (PCDC), a consortium of U01s, is developing and testing new molecular and imaging biomarkers to detect early-stage pancreatic ductal adenocarcinoma and its precursor lesions. In addition to these examples, the NCI uses the U01 mechanism to support intramural-extramural collaborations, enabling extramural researchers to access to intramural technologies and expertise and investigation of shared scientific interest.

From FY 2010 to FY 2019, the NCI awarded 619 competing U01 awards, the majority of which were in response to NCI-initiated FOAs, including the Cancer Moonshot[SM] U01s. In the same time period, the NCI issued a 10-fold greater number of R01 grants, which comprise the majority of the RPG pool funds. The total U01 costs average at $600,000 per year per award, whereas the R01 costs steadily increased from $325,000 to $450,000 per year per award. This cost difference between the U01s and R01s can be attributed to such factors as fewer modular awards, type of research, program infrastructure, and collaborative funds. Regarding publication outputs, the U01s have a slightly higher average citation impact and show slight increase in publication productivity when corrected for funding compared with R01s.

Dr. Berny-Lang concluded that Coop. Agr. play an important role in NCI's research portfolio and noted that the selection of a funding mechanism should be guided by the scientific needs of an initiative. She reiterated that U01s, a small fraction of the NCI RPG pool, are primarily awarded through NCI-initiated FOAs and present an effective approach to achieve common goals and enable research outputs that may be more difficult to achieve through R mechanisms.

**Questions and Answers**

NCAB Acting Chair, Dr. Hiebert, asked about the comparison of the U01 with the P01 mechanism. Dr. Melissa Antman, Senior Scientific Program Analyst, Center for Research Strategy (CRS), explained that the original statistical model included other activity codes, including the P01. These data were not presented in today's overview but can be shared with the Boards.

Dr. Michael John Becich, Chairman and Distinguished University Professor, Department of Biomedical Informatics, Professor of Pathology, Computing/Information, Clinical/Translational Sciences, and Bioengineering, Associate Vice Chancellor for Informatics in the Health Sciences, Co-Director, Center for Commercial Application (CCA) of Healthcare Data, Associate Director, Hillman Cancer Institute (HCI), Associate Director, Clinical and Translational Science Institute (CTSI), University of Pittsburgh School of Medicine, inquired on whether the U01s always have been included in the RPG pool statistics in terms of funding. Dr. Sharpless clarified that some, but not all, U01s are supported by RPG funding.

Dr. David A. Tuveson, Roy J. Zuckerburg Professor, Director of the Cancer Center, Cold Spring Harbor Laboratory, asked how often an investigator funded by an U01 had converted to an R01 to continue a project. Dr. Berny-Lang responded that the answer varied by program and called attention to the nanotechnology program, in which a project begins in an U54 center and can transition to a U01 and subsequently to an R01. The goal is that the U01s would foster this type of movement in the field.

Dr. Max S. Wicha, Madeline and Sidney Forbes Professor of Oncology, Director, Forbes Institute for Cancer Discovery, Founding Director Emeritus, University of Michigan Rogel Cancer Center, Professor of Internal Medicine, Division of Hematology and Oncology, University of Michigan, asked to what extent the NCI can ensure that the best ideas emerging from R01s are fueling the new ideas for establishing a U01 consortium. He elaborated that it is critical that opportunities not be missed because of the process to select a particular project for funding. Dr. Berny-Lang remarked that this question extends beyond selecting an activity code and noted that it would be challenging to predict the next program to advance without ongoing portfolio reviews and input from the external community via NCI-hosted workshops.

Dr. W. Kimryn Rathmell, Cornelius A. Craig Professor, Department of Medicine, Director, Division of Hematology and Oncology, Vanderbilt University Medical Center, asked whether the NCI

had considered renewable U01s. Dr. Sharpless pointed out that the NCI has on occasion renewed U01 grants. The goal is that RFA-driven research topics do not continue without end, but eventually compete in the RPG pool, with exception of U01s that support clinical trial networks.

In response to a question from Dr. Barker on assessing the success of the U01 mechanism to build resources and affect data-sharing, Dr. Berny-Lang replied that without the U01 structure, the more-than-2,000 longitudinal biospecimens collected across the PCDC would be significantly less. She further stated that use of the U01 mechanism for the SeroNet will be critical for data-sharing. Dr. Sharpless added that the anticipation is that the U01s would facilitate data-sharing, and a future discussion can focus on funding data-sharing efforts, especially those connected with large NCI-supported networks. Dr. Dinah Singer, Deputy Director, Science Strategy and Development, NCI, commented that the U01 mechanism adheres to the NIH-wide data-sharing policy. She explained that the use of the U01 for Cancer Moonshot$^{SM}$ projects, and recently the SeroNet, has allowed the NCI to incorporate requirements for immediate open access to publications and immediate data-sharing, which would not have been otherwise easy to accomplish.

Dr. Sylvia Plevritis, Chair, Department of Biomedical Data Science, Professor, Departments of Biomedical Data Science and Radiology, Stanford University School of Medicine, commented on how the U01 structure is promoting team science and asked whether the NCI leadership has considered changes to the review process and study sections to reflect this new interdisciplinary science. Dr. Sharpless explained that U01s are solicited via FOAs, which generally are reviewed by dedicated study sections within the NIH Center for Scientific Review (CSR). Discussions are ongoing with the CSR on ways to improve the peer-review process for NCI grants; a key variable is the expertise of the scientific reviewers. Although the CSR review process is the preference, Dr. Sharpless noted that the NCI's use of Special Emphasis Panels to consider those topics that are less likely to have a fair chance in the CSR structure.

Dr. Douglas R. Lowy, Principal Deputy Director, NCI, remarked that the NCI continually works to reduce "top-down" research, which includes the U01 proposals, and to prioritize "true" investigator-initiated research. The challenge is to balance support for vital networks versus the individual principal investigator. He called attention to the increase in multi–principal investigator R01s that could begin to address any team science concerns.

## VII. RFA/COOP. AGR./RFP CONCEPTS—NEW AND RE-ISSUE—NCI PROGRAM STAFF

### Division of Cancer Control and Population Sciences

### Metabolic Dysregulation and Cancer Risk: A Transdisciplinary Approach to Obesity-Associated Cancer Research (New RFA/Coop. Agr.)—Dr. Tram Kim Lam

Dr. Tram Kim Lam, Program Director, DCCPS, presented a new RFA concept on metabolic dysregulation and cancer risk, a transdisciplinary approach to obesity-associated cancer research. The aim of this RFA is to support transdisciplinary research that will enhance the field's knowledge of the dynamics and underlying mechanisms that link obesity, metabolic dysregulation, and cancer risk. The goals are to understand the mechanisms of how obesity-related metabolic dysregulation (e.g., insulin resistance) affects cancer risk, characterize cross-talks between metabolic dysregulation and key biologic processes in obesity-related cancer risk, and develop common measures and readouts of obesity-related metabolic dysregulation for different cancer types.

Dr. Lam explained that the concept emphasizes research in humans and will accommodate strategies using preclinical models, interventions, and observations. The proposed projects must address

one of the following objectives: investigate the mechanistic role of metabolic dysregulation as it relates to the obesity and cancer link, characterize an altered metabolic profile (e.g., metabolic-related markers) to identify high-risk individuals, or test interventions designed to modify obesity-altered metabolic pathways to decrease cancer risk. This RFA will support U01 research projects and a U24 coordinating center; a steering committee will oversee the activities.

**Subcommittee Review.** Dr. Ellen P. White, Chief Scientific Officer, Deputy Director, Associate Director for Basic Research, Rutgers Cancer Institute of New Jersey, Distinguished Professor, Molecular Biology and Biochemistry, Rutgers, The State University of New Jersey, expressed the Subcommittee's strong support for the concept. The Subcommittee appreciated the NCI staff responses to its suggestion to clarify the research question and refine the scope. The Subcommittee recommended including statements in the RFA on engaging underserved populations and providing guidance on what research is not supported.

The first-year cost for the one-time issuance is estimated at $8 M for six U01 awards, with a total cost of $40 M for 5 years.

**Questions and Answers**

Dr. Lam confirmed that the RFA considered diversity between individuals of different race and ethnicity regarding insulin resistance thresholds, as well as investigations on the microbiome.

**Motion.** A motion to approve the DCCPS' new RFA/Coop. Agr. entitled "Metabolic Dysregulation and Cancer Risk: A Transdisciplinary Approach to Obesity-Associated Cancer Research" was approved unanimously.

**Exercise and Nutrition Intervention to Improve Cancer Treatment-Related Outcomes in Cancer Survivors (New RFA/Coop. Agr.)—Dr. Frank Perna**

Dr. Frank Perna, Program Director, DCCPS, presented a new RFA concept on exercise and nutrition intervention to improve cancer treatment-related outcomes in cancer survivors, which was developed in collaboration with the Obesity and Cancer Working Group. Adverse physical consequences among cancer survivors can increase risk of treatment interruptions. It is well known that exercise and nutrition intervention improve fitness, body composition, and nutritional status. These interventions generally are well tolerated, can be tailored, and can be delivered in conjunction with cancer therapies. Few studies have focused on the time period shortly before or during cancer treatment and treatment-related outcomes. In addition, the American College of Sports Medicine recently updated its *Exercise Guidelines for Cancer Survivors* and considers exercise safe, with strong supporting evidence.

The two-fold purpose of this RFA is to (1) understand how exercise and nutrition interventions (alone or combined) affect treatment-related outcomes for curative/life-extending therapies and (2) address research gaps regarding specific exercise and nutrition interventions across cancer sites and treatment protocols. The goal is to help patients successfully complete planned treatment with effective overall outcomes. This RFA will support five U01 project grants investigating nutrition interventions prior to and during treatment and will establish a U24 research coordinating center.

**Subcommittee Review.** Dr. Leslie L. Robison, Chairman, Department of Epidemiology and Cancer Control, St. Jude Children's Research Hospital, Associate Director, St. Jude Comprehensive Cancer Center, expressed the Subcommittee's strong support for the concept, which is an ideal approach to addressing this topic and research gap. The Subcommittee appreciates the NCI's expanding the scope to include cancer survivors younger than 18 years of age and anticipates that this RFA will stimulate additional innovative approaches on early interventions. It was emphasized that access to the nutritional interventions in minority and underserved populations would be critical.

The first-year cost for the one-time issuance is estimated at $6.37 M for five U01 awards, with a total cost of $31.8 M for 5 years.

**Questions and Answers**

Dr. Hayes-Jordon suggested including interventions for amputees, who comprise a subset of young adult sarcoma patients, in the study population.

Dr. Peter C. Adamson, Global Head, Oncology Development and Pediatric Innovation, Sanofi, recommended including in RFAs/proposals the general rationale for why pediatric patients are being excluded from a study.

**Motion.** A motion to approve the DCCPS' new RFA/Coop. Agr. entitled "Exercise and Nutrition Interventions to Improve Cancer Treatment-Related Outcomes in Cancer Survivors" was approved unanimously.

## Division of Cancer Treatment and Diagnosis

### Drug Development Support for the Cancer Therapy Evaluation Program (New RFP)— Dr. Julie Rhie

Dr. Julie Rhie, Senior Regulatory Affairs Scientist, Regulatory Affairs Branch, Cancer Therapy Evaluation Program **(**CTEP), DCTD, presented a new RFP concept for development support for CTEP. Dr. Rhie noted that this RFP is being reviewed by the BSA in light of a change in the NCI policy and a reclassification of the contract task as research and development (R&D) support. This contract will support four general task areas: regulatory reporting, safety reporting, DCTD Investigational Drug Branch, and agreement-related tasks.

Specifically, the RFP will support CTEP in fulfilling FDA regulations for investigational new drug (IND) applications, as well as FDA Center for Devices and Radiological Health submissions. Support will be provided to triage expedited safety reports, draft FDA safety submissions, and maintain an adverse-event help desk to assist participating clinical sites and pharmaceutical collaborators. This RFP also will provide support to the DCTD Investigational Drug Branch (IDB) with study solicitation and the letter-of-intent review process and collaborator interactions, such as protocol review requests, publication routing, and IND documentation forwarding.

Dr. Rhie highlighted some of the FY 2020 funding accomplishments. The drug development contract supported more than 190 INDs and 391 protocols and staff filed 27 new IND applications to the FDA, prepared and submitted more than 1,700 electronic IND submissions, and provided protocol support for the Adult and Pediatric MATCH trials. The safety team addressed 14,204 adverse-event help desk queries and processed 5,791 adverse-event reports and more than 300 initial written reports. This RFP will include provisions continuing the four task areas, including enabling the Regulatory Affairs Branch and IDB staff to manage the large CTEP portfolio.

**Subcommittee Review.** Dr. Keith T. Flaherty, Director, Clinical Research, Massachusetts General Hospital Cancer Center, expressed the Subcommittee's enthusiasm and strong support for the concept, which involves essential work for the CTEP. The drug development contract has been successful and efficient in leveraging the expertise of the CTEP internal staff to support CTEP's large portfolio of clinical trails.

The first-year cost for the one-time issuance is estimated at $8.68 M for a 1-year contract, with a total cost of $86.8 M for 9 option years.

**Motion.** A motion to approve the DCTD's new RFP entitled "Drug Development Support for the Cancer Therapy Evaluation Program" was approved unanimously.

**Clinical Proteomic Tumor Analysis Consortium (CPTAC) (Re-Issue RFA/Coop. Agr.)—Dr. Henry Rodriguez**

Dr. Henry Rodriguez, Director, Office of Cancer Clinical Proteomics Research, DCTD, presented the re-issue RFA concept for the CPTAC, which launched in 2011. CPTAC achieves its goals through two connected activities. The Tumor Characterization Program, funded in FY 2016, supports Proteome Characterization Centers (PCCs) and Proteogenomic Data Analysis Centers (PGDACs) to generate, integrate, and analyze proteogenomic data from treatment cases. The Translational Research Program, funded in FY 2017, supports Proteogenomic Translational Research Centers (PTRCs) and Proteogenomic Data Analysis Centers (PDACs) to analyze preclinical and clinical trial data.

Dr. Rodriguez provided an update on the CPTAC accomplishments. The Tumor Characterization Program comprehensively characterized 13 tumor types over 4 years: nine directly from the CPTAC, and four from international collaborations. Investigators are on schedule to characterize an additional three tumor types by the end of 2021. The Translational Research Program supported studies on AML, breast, and ovarian cancers, which have generated key research findings and are informing future research. The AML and breast cancer studies have been approved for access to specimens from clinical trials, and the ovarian study investigators soon will submit their application for similar access. The CPTAC manages the largest public repositories of proteogenomic data sets, assays, and reagents. This public data warehouse contains portals for antibodies, assays, and data. Recommendations from the CPTAC scientific evaluation panel and input from the cancer research community have informed modifications to the program.

This RFA re-issuance will continue the efforts and goals of the CPTAC program to perform comprehensive tumor characterization and apply proteomics to clinical trial research. Future directions for the Tumor Characterization Program include expanding post-translational modifications measurements, incorporating metabolomics and microenvironment profiling, and incorporating preclinical models and metastatic and rare tumors. For the Translational Research Program, efforts will focus to extend the specialized analytical expertise in clinical trials beyond the network and develop pilot studies that address NCI clinical trial needs.

**Subcommittee Review.** Dr. Kenneth C. Anderson, Kraft Family Professor of Medicine, Harvard Medical School, Director, Jerome Lipper Multiple Myeloma Center, Dana–Farber Cancer Institute, expressed the Subcommittee's enthusiasm and strong support for the re-issuance concept. Dr. Anderson commended the NCI on the success of this flagship program, which clearly has met its goals, noting that the data warehouse is a strength of the program. The Subcommittee anticipates that the CPTAC program will increase understanding in cancer pathogenesis and improve diagnosis, prognosis, and treatment for cancer patients. Regarding another relevant area for use of protein-based methods, the Subcommittee suggested including predictive biomarkers.

The first-year cost for the one-time re-issuance is estimated at $11.3 M for 11 awards, with a total cost of $56.5 M for 5 years.

**Motion.** A motion to concur on the DCTD's re-issue RFA/Coop. Agr. entitled "Clinical Proteomic Tumor Analysis Consortium (CPTAC)" was approved unanimously.

## Office of the Director

### NCI Youth Enjoy Science (YES) Research Education Program (New RFA)—Dr. Alison Lin

Dr. Alison Lin, Program Director, CRCHD, presented a new RFA concept on the NCI YES research education program. She explained that the YES is the newest member of the CRCHD Continuing Umbrella of Research Experiences (CURE) program. During the past 24 years, CURE has supported more than 4,000 students and scientists spanning from middle school to ESIs from across the Nation. The CURE program was developed in response to the urgent need to grow and sustain a cancer research workforce that reflects the diverse demographics of the Nation and has worked to prioritize support for individuals from underrepresented populations in the biomedical sciences.

To meet the goals of CURE to increase the size of the talent pool, emphasize the scientific areas of greatest need, and expand and extend the training period, the NCI established the P30 CURE Supplements (P30S) to be awarded to the NCI-Designated Cancer Centers. In 2016, the P30S CURE program ended, and efforts continued with establishment of the R25 YES program, with similar goals. Former P30S awardees have applied, and 12 of 28 received the YES award. The R25 YES applications require applicants to engage in three activities: acquire research experience, develop curriculum/methods, and perform outreach. This requirement remains the same for the RFA.

Dr. Lin noted some of the outcomes of the YES programs. From FY 2018 to FY 2019, eight YES programs supported 431 students; the majority of resided in hard-to-reach areas in terms of conducting outreach. The programs collectively generated three manuscripts, one book, and six podcasts. This new RFA will continue the efforts of the YES program, including promoting collaboration.

**Subcommittee Review.** Dr. Victoria L. Seewaldt, Ruth Ziegler Professor, Chair, Department of Population Sciences, Beckman Research Institute, City of Hope, expressed the Subcommittee's enthusiasm and strong support for the concept. The Subcommittee strongly recommended increasing the scope and expanding the reach of the YES program to have an impact on other sites, which will require an increase in the RFA budget to fund additional programs.

The first-year cost for the one-time issuance is estimated at $1.73 M for four R25 awards, with a total cost of $5.19 M for 3 years.

**Questions and Answers**

Dr. Michelle M. Le Beau, Arthur and Marian Edelstein Professor of Medicine, Director, University of Chicago Comprehensive Cancer Center, The University of Chicago, inquired on whether the YES grant would support virtual training programs to increase access and outreach to additional students. Dr. Lin pointed out that a number of the YES programs provided virtual training during the summer of 2020, and principal investigators are discussing ways to incorporate these types of platforms for the future.

Dr. Cheryl L. Willman, The Maurice and Marguerite Liberman Distinguished Endowed Chair in Cancer Research, University of New Mexico (UNM) Distinguished Professor of Pathology, UNM School

of Medicine, Director and CEO, UNM Comprehensive Cancer Center, UNM, reflected on her experience with YES programs and recommended that the NCI consider increasing the RFA budget to fund additional YES programs across the United States. Other BSA and NCAB members echoed Dr. Willman's comments.

**Motion.** A motion to approve the OD's new RFA entitled "NCI Youth Enjoy Science (YES) Research Education Program" was approved unanimously.

## Division of Cancer Prevention

### Low-Dose CT Lung Cancer Screening Image and Data Resource (New RFP)—Dr. Paul Pinsky

Dr. Paul Pinsky, Chief, Early Detection Research Branch, Division of Cancer Prevention (DCP), presented a new RFP concept on a low-dose CT (LDCT) lung cancer screening and data resource. Although LDCT screening for lung cancer has been shown to reduce lung cancer mortality in the National Lung Screening Trial (NLST) and confirmed in the European NEderlands-Leuvens Longkanker Screening ONderzoek (commonly called NELSON) trial, the false-positive rate (FPR) of the screening test is high. A high FPR increases short-term anxiety in patients, contributes to health care costs, and is a barrier to wide adoption LDCT. Dr. Pinsky noted that one approach to reducing the FPR is developing artificial intelligence (AI) and machine learning tools to assist radiologists in interpreting LDCT screening and diagnostic images. AI tool development requires a large library of CT images and corresponding clinical data. The existing NLST CT image library is widely used in the field, but it now is outdated by 15 years.

This RFP will support developing a new LDCT lung cancer screening image library using current LDCT technology in a standard clinical setting, with diagnostic CT images and demographics. All data will be made available to the research community through a controlled process. Retrospective de-identified images and data will be collected, and no patients will be enrolled. The DCP is proposing a cost-effective approach of leveraging the Division of Cancer Epidemiology and Genetics (DCEG) Connect for Cancer Prevention Study (Connect) to incorporate a biospecimen component. The aim is to collect images and biospecimens from lung cancer cases over 5 to 7 years in a sub-cohort of high-risk smokers for biomarker discovery and subsequently correlations with CT features.

**Subcommittee Review.** Dr. Plevritis expressed the Subcommittee's support for the concept. The Subcommittee appreciated the NCI staff responses to their concerns on the composition of the image library, unclear coordination with the FDA, and linkage to biospecimens and recommended including radiology reports in the collection. The Subcommittee encouraged expanding the RFP to include digital pathology for future proofing.

The estimated budget for the one-time issuance and 1 award is a total cost of $7 M.

**Questions and Answers**

Dr. Robert Vonderheide, John H. Glick MD Abramson Cancer Center's Professor, Professor of Medicine, Perelman School of Medicine, Director, Abramson Cancer Center, University of Pennsylvania, asked whether use of biobank samples for retrospective biomarker discovery would be allowed. Dr. Phillip E. Castle, Director, DCP, expressed concerns about data quality, sample collection, and consent, but is not against this approach.

**Motion.** A motion to approve the DCP's new RFP entitled "Low-Dose CT Lung Cancer Screening Image and Data Resource" was approved unanimously.

## WEDNESDAY, 2 DECEMBER 2020

## VIII. CALL TO ORDER AND OPENING REMARKS—DRS. SCOTT W. HIEBERT AND DAFNA BAR-SAGI

Dr. Hiebert called to order Day 2 of the 3rd Virtual Joint Board Meeting of the BSA and NCAB and welcomed members of the Board, *ex officio* members, liaison representatives, staff, and guests.

## IX. STATUS REPORT: CHILDHOOD CANCER DATA INITIATIVE (CCDI) —DRS. JAMES H. DOROSHOW AND WARREN KIBBE

Dr. James H. Doroshow, Deputy Director, Clinical and Translational Research, and Director, DCTD, explained that the BSA CCDI Working Group, charged to advise the NCI on the implementation of the CCDI, presented its final report outlining 24 specific recommendations across seven broad thematic areas in pediatric and adolescent and young adult (AYA) research. The NCI is actively addressing the Working Group recommendations. The detailed CCDI Working Group Report can be accessed from the NCI website.

**Year 1 FY 2020 Portfolio.** In FY 2020 (Year 1), Congress appropriated $50 M to the NCI to initiate the CCDI. Dr. Doroshow discussed some of the in-progress activities by broad categories and the distribution of funds. For the recommendations to develop a catalog of all available data and develop a federated pediatric cancer data ecosystem for research, the NCI is starting to build a pediatric data catalog prototype ($2 M) of all available childhood cancer data registries and data repositories and has established the National Childhood Cancer Registry (NCCR) ($7 M) to link clinical patient data. A Preclinical Pediatric Data Commons is being established to build an infrastructure for preclinical data models.

For data aggregation and data transfer, the NCI issued NCI-Designated Cancer Center supplements to collect data from registries and repositories and is working with the Childhood Cancer Survivor Study (CCSS) to transfer clinical data ($9 M). In response to the recommendations to generate new cancer models and sequence data, efforts are focused on leveraging the diagnostic tumors and germline samples from the Pediatric MATCH trial, secondary cancers from the CCSS, and other cell lines ($9 M). For developing and adapting analytic and computational tools, automated data curation, pathology interpretations of images, and data harmonization have been initiated ($7 M). A Rare Pediatric Tumor Cell Atlas also is being developed ($4 M). The NCI has supplemented intramural and extramural grants and contracts to support new childhood cancer research projects ($10 M).

**Vision for Years 2–10.** Dr. Warren Kibbe, Chief, Translational Biomedical Informatics, Department of Biostatistics and Bioinformatics, Chief Data Officer, Duke Cancer Institute, Duke University School of Medicine, reported on the goals, program structure, and governance for future years. The foundational goals for future years of the CCDI are to gather data from every child and AYA diagnosed with cancer, develop core data from consented patients using patient-level data in a secure manner, and create a system that brings data of different types and sources together in a way that incentivizes researchers to query the available data for new research.

Regarding program structure, the CCDI will consist of three focus areas. The National Childhood Cancer Cohort aims to gather data from every child diagnosed with cancer in the United States and the NCCR is a critical component. The Childhood Molecular Characterization Protocol has the goals to expand access to comprehensive molecular sequencing, develop NCI-recommended guidelines, create a

comprehensive database, and aligns with the Rare Pediatric Tumor Atlas. The Childhood Cancer Data Platform is designed to federate data from multiple children's cancer institutions and community-based and NCI-supported sources. A CCDI coordination center will organize the activities across the program.

Four working groups, co-chaired by NCI and extramural experts, and composed of members of the NCI staff, external experts, and advocates, will manage the building of the CCDI components and oversee implementation. The CCDI governance structure will consist of a Steering Committee to address high-level strategic and crosscutting issues and a CCDI Engagement Committee to involve the wider childhood cancer community in the CCDI.

**Questions and Answers**

In response to a question from Dr. Adamson on leveraging the COG Project: Every Child cohort of 28,000 children to build the national cohort, Dr. Kibbe explained that Project: Every Child provided the framework for the National Childhood Cancer Cohort and will be foundational to this effort, which may not have been made clear during his presentation.

Dr. Willman suggested including epidemiologic and behavioral data collection as a component of the CCDI and exploring direct patient engagement approaches.

Dr Hayes-Jordan asked whether the extramural grants focused on a specific childhood cancer and whether other grants will be available in the future. Dr. Doroshow clarified that CCDI extramural grants for Year 1 were supplements to existing grants to facilitate on-going activities, such as developing analytical tools for interrogating aggregated data. The NCI is in the planning phase for FY 2021 appropriations.

Dr. Melissa L. Bondy, Chair and Professor, Department of Epidemiology and Population Health, Co-Director, Center for Population Health Sciences, Associate Director for Population Sciences, Stanford Cancer Institute, asked how the multiple data sources (e.g., CCSS) would be incorporated. Dr. Doroshow pointed out that CCSS has been a resource for the DCTD. One of the major challenges for the CCDI will be data aggregation: incentives likely will be necessary federate these data.

Dr. Robison commented that AYA in the context of the CCDI does not encompass the full spectrum to age 39 as is defined by the NCI, which may need to be clarified to the extramural community. He suggested a presentation at a future meeting on how various databases will be integrated into the NCCR as well as the National Childhood Cancer Cohort. Dr. Sharpless agreed that a discussion on the NCCR would be a topic to consider for a future meeting.

Dr. Kevin M. Shannon, American Cancer Society Research Professor, Auerback Distinguished Professor of Molecular Oncology, Professor, Department of Pediatrics, School of Medicine, University of California, San Francisco, suggested establishing a CCDI office within the NCI with a director to assist in coordinating data-sharing efforts across the pediatric cancer research community.

## X. BSA PREVENTION *AD HOC* WORKING GROUP REPORT—DRS. GRAHAM A. COLDITZ AND JUDY E. GARBER

Dr. Judy E. Garber, Susan F. Smith Chair, Chief, Division of Cancer Genetics and Prevention, Dana–Farber Cancer Institute, Professor of Medicine, Harvard Medical School, and Dr. Graham A. Colditz, Niess-Gain Professor of Surgery, Professor of Medicine and Associate Director Prevention and Control, Alvin J. Siteman Cancer Center, Deputy Director, Institute for Public Health, Chief, Division of Public Health Sciences, Department of Surgery, Washington University School of Medicine in St. Louis,

presented the BSA *ad hoc* Working Group on Prevention report on strategies to accelerate progress in cancer prevention research.

Dr. Garber explained that the Prevention Working Group was charged to consider how best to utilize the significant resources and personnel of the NCI in developing and sustaining a cancer prevention and early detection research program. She acknowledged the Working Group members and remarked on some of the special challenges inherent in cancer prevention and screening research that can impede progress, such as the long timeline for trials and assessment of an intervention's efficacy as well as the need for successful conduct of prevention research in all communities. To address these challenges, the research community must be incentivized to expand to prevention and screening research. Addressing disparities and social determinants of health must be at the forefront of all prevention research planning and implementation.

Dr. Colditz summarized the Working Group recommendations across six broad crosscutting themes:

***Increasing lifestyle and environment research.*** Target multiple behaviors simultaneously. Use mobile application and wearable technologies (e.g., mHealth). Use AI and machine learning in preventive technologies, jointly with mHealth approaches. Implement early interventions in children/AYA before behavioral habits are engrained. Study the impact of behavior change on recurrence and mortality (i.e., tertiary prevention).

***Enabling research that addresses prevention in disparate populations.*** Identify new strategies to bring evidence-based cancer prevention interventions to reduce the burden of cancer for all populations. Increase basic and translational science to focus on populations experiencing cancer disparities. Develop a deeper understanding of how racism drives cancer risk. Increase eligibility for research studies and clinical treatment trials of populations with multiple comorbidities as experienced by populations with cancer disparities and promote the development of patient engagement approaches tailored to minority and underserved populations.

***Optimizing opportunities using biomarkers in cancer prevention research.*** Continue to invest in biomarker development. Convene a working group to provide critical and thoughtful assessment of the most important opportunities in the field.

***Expanding data science opportunities in risk stratification and point of care precision prevention.*** Accelerate adaptation of technologies for real time, point of care diagnostics, monitoring, and decision making. Build rubrics and standards for machine learning and AI models as a priority. Develop strategies for visualizing data. Use updated data sources to detect the change point and timing of interventions. Maximize populations engaged in prevention research technologies innovation. Refine analytic approaches and point of care communication opportunities

***Promoting novel and innovative research designs.*** Invest in deeper understanding of mechanisms underlying obesity and cancer. Generate and evaluate vaccines that anticipate the most likely neoantigens in the highest risk populations. Invest in AI directed toward improvement in prediction of aggressive versus indolent behavior of early-stage solid tumors. Study approaches that integrate diverse data from novel data sources. Invest in biostatistics and bioinformatics across all areas. Address unique challenges of chemoprevention research.

***Consideration of infrastructure resources the NCI could facilitate to enhance prevention research.*** Enhance initiatives similar to the Pre-Cancer Atlas that bridge technology development

to work on established tumors to premalignancy. Develop inexpensive, point of care technologies to enhance early detection in healthy people. Leverage NCI resources (e.g., SEER) and expertise in spatial sciences/geographic information system mapping to assess and monitor progress in reducing cancer incidence and disparities. Link translational and population scientists with existing tissue/clinical archives to study mechanisms of cancer evolution with time and treatment.

**Questions and Answers**

Dr. Margaret R. Spitz, Professor, Department of Medicine, Dan L. Duncan Cancer Center, Baylor College of Medicine, called attention to one additional barrier/challenge to prevention research: The limited efforts to build a pipeline of scientists focused on cancer prevention, especially with the discontinuation of the Cancer Prevention, Control, Behavioral Sciences, and Population Sciences Career Development (K07) Award.

Dr. Deborah Watkins Bruner, Senior Vice President for Research, Robert W. Woodruff Professor in Nursing, Emory University, suggested incorporating behavior science into the research.

Dr. Susan Thomas Vadaparampil, Associate Center Director, Community Outreach, Engagement, and Equity, Moffitt Cancer Center, remarked on the importance of patient engagement as a component of prevention in addition to the science.

**Motion.** A motion to accept the report of the BSA *ad hoc* Working Group on Prevention was approved unanimously.

## XI. RFA/COOP. AGR./RFP CONCEPTS—NEW AND RE-ISSUE—NCI PROGRAM STAFF

### Division of Cancer Biology

### Program on the Origins of Gastroesophageal Cancer (New RFA/Coop. Agr.)—Dr. Rihab Yassin

Dr. Rihab Yassin, Chief, Cancer Cell Biology Branch, Division of Cancer Biology (DCB), presented a new RFA concept to establish a program on the origins of gastroesophageal cancer. Dr. Yassin explained that gastroesophageal cancers are aggressive cancers with poor survival rates. Although the incidence of distal stomach cancers has significantly decreased in the United States and Western Europe, the incidence of proximal stomach, gastroesophageal junction, and lower esophagus cancers have significantly increased. This increased incidence could be attributed to etiologic factors such as diet, gastroesophageal reflux disease, or obesity. Although advances in genomics and molecular characteristics have provided insight into these cancers, many questions on their origin remain.

This RFA is proposing to establish a program dedicated to understanding the origins of upper gastric and junctional esophageal adenocarcinomas. Efforts will focus on comparing and contrasting the contributions of inflammation, molecular events, and the cell of origin in driving early transformation. The NCI anticipates that establishing such a program would attract investigators from other disciplines to interject innovative ideas, models, and technological advances. The overall aim is to build a cadre of investigators who would be central to catalyzing this research moving forward and overcoming challenges and complexities.

**Subcommittee Review.** Dr. Tuveson expressed the Subcommittee's support for the concept, which is addressing a knowledge gap on the pathogenesis of gastroesophageal cancers and has the potential to build the research base. Dr. Tuveson elaborated on what is known about gastroesophageal

cancers, touching on the genetic component and suggested further research in this area. The Subcommittee appreciated the NCI staff responses to its concerns on the selection of funding mechanisms and suggested exploring the R21 mechanism as one way to interject new ideas for the program.

The first-year cost for the one-time issuance is estimated at $6.6 M for five to six R01 awards and one R24 award, with a total cost of $33 M for 5 years.

**Questions and Answers**

Dr. Shannon suggested supplementing grants of the NCI K08 awardees already studying this topic to participate in the new gastroesophageal cancer program.

Dr. James V. Lacey, Jr., Director and Professor, Division of Health Analytics, Department of Computational and Quantitative Medicine, Beckman Research Institute, City of Hope, commented that only one of the program evaluation principles specifically addresses gastric cancers and asked about the evolution of the concept and cancer-related benchmarks. Dr. Yassin noted that specific benchmarks for the research, particularly for animal models, have been included in the RFA, as has investigator training on the essentials to sustaining an R01.

**Motion.** A motion to approve the DCB's new RFA/Coop. Agr. entitled "Program on the Origins of Gastroesophageal Cancers" was approved unanimously.

**Translational and Basic Science Research in Early Lesions (TBEL) Initiative (New RFA/Coop. Agr.)—Dr. Elizabeth Woodhouse**

Dr. Elizabeth Woodhouse, Program Director, DCB, presented the Translational and Basic Science Research in Early Lesions (TBEL) initiative, a new RFA concept, which was developed in collaboration with the DCP. The overall objectives are to support multidisciplinary studies that bridge the basic biology-translation gaps; gain biological insights on early lesion-specific blockers and drivers of disease progression; build on established predictive markers, retrospective data/samples, and computationally derived and biologically backed leads; and improve the understanding of early lesion fate for better risk stratification. Dr. Woodhouse emphasized that this RFA also will help to identify tumor and stromal targets that may improve existing screening methodologies, inform the development of new screening approaches to unscreened tumors, and establish biology-backed data to guide "precision prevention."

The TBEL mechanism and structure will consist of U54 specialized centers, a U24 coordinating center, and complimentary multi–principal investigator basic science and translational projects. The broad focus will be on lung, kidney, thyroid, bladder, pancreas, breast, prostate, and hematopoietic cancers, all based on the results of the NCI portfolio analysis of early lesion and microenvironment basic biology and translational research. TBEL will leverage existing NCI initiatives and programs, such as the Cancer Systems Biology Consortium (CSBC) and the NCI-Cancer Research UK CGCs.

**Subcommittee Review.** Dr. Le Beau expressed the Subcommittee's strong support for the concept, which is using a clinical integrative approach to understand what defines early lesions. The Subcommittee thinks that this concept is timely and provides significant opportunity to better understand the heterogenous tumor microenvironment. The Subcommittee appreciated the NCI staff responses to their suggestions and subsequent updating of the RFA.

The first-year cost for the one-time issuance is estimated at $9 M for five U54 awards and one U24 award, with a total cost of $45 M for 5 years.

**Questions and Answers**

Dr. Becich commended the early lesion and translational portfolio analyses and suggested including this type of information in future scientific concept reviews to help inform the BSA deliberations.

**Motion.** A motion to approve the DCB's new RFA/Coop. Agr. entitled "Translational and Basic Science Research in Early Lesions (TBEL) Initiative" was approved unanimously.

**Division of Cancer Control and Population Sciences**

**Centers on Telehealth Research and Cancer-Related Care (New RFA)—Dr. Roxanne Jensen**

Dr. Roxanne Jensen, Program Director, DCCPS, presented the Centers on Telehealth Research and Cancer-Related Care new RFA concept. Because of the COVID-19 pandemic in-person care delivery rapidly transitioned to telehealth and provides an opportunity to improve cancer care by researching telehealth approaches. To better understand the scientific gaps and research opportunities for cancer care delivery, the NCI released a request for information (RFI) in July 2020 and received nearly 50 submissions. The common theme of the RFI responses emphasized the need for rapid development of a telehealth-focused evidence base across the cancer care continuum.

This RFA proposes establishing Centers on Telehealth Research and Cancer-Related Care (Research Centers), leveraging the P50 mechanism. Each Research Center will propose an overarching research theme that must address a high-priority cancer care delivery research need. This RFA will support Research Centers consisting of an administrative core, research and methods program, and practice laboratory. The Research Centers will conduct signature projects focusing on high-impact, pragmatic research and pilot projects of iterative, rapid-cycle research. The outcome will be a national collaboration on the leading edge of cancer-related telehealth.

**Subcommittee Review.** Dr. Karen E. Knudsen, Executive Vice President, Oncology Services, Jefferson Health, Enterprise Director, NCI-Designated Sidney Kimmel Cancer Center at Jefferson, Chair, and Hilary Koprowski Endowed Professor, Department of Cancer Biology, Thomas Jefferson University, expressed the Subcommittee's strong support for the concept. The Subcommittee agreed that this telehealth initiative in cancer care delivery will continue beyond the COVID-19 pandemic, and the U54 mechanism is the best approach to assess the impact of cancer-related telehealth. Because of the anticipated robust response to the RFA, the Subcommittee suggested that the NCI increase the RFA budget to fund additional Research Centers and explore innovative ways to reach rural populations with limited access to Wi-Fi, as well as include clinical trials as a component of cancer care delivery research.

The first-year cost for the one-time issuance is estimated at $4.2 M for three awards, with a total cost of $21 M for 5 years.

**Questions and Answers**

Dr. Vonderheide called attention to major barriers to telehealth not addressed in the RFA: third-party payer support and the inability to practice across state lines. Dr. Sharpless emphasized that the Centers for Medicare & Medicaid Services issues federal policies and that the NCI's role is to research the effects of those policies and then fund the research that addresses policies best for patients. Whether or not telehealth will, for example, reduce or increase health disparities is a research question that remains.

**Motion.** A motion to approve the DCCPS' new RFA entitled "Centers on Telehealth Research and Cancer-Related Care" was approved unanimously.

## Office of the Director

### Cancer Prevention, Detection, Diagnosis, and Treatment Technologies for Global Health—The Affordable Cancer Technologies (ACTs) Program (Re-Issue RFA/Coop. Agr.)—Subcommittee

**Subcommittee Review.** Dr. Carol E. Ferrans, Harriet Werley Endowed Chair for Research Professor, Department of Biobehavioral Health Sciences, College of Nursing, University of Illinois at Chicago, expressed the Subcommittee's enthusiasm and strong support for the re-issuance concept. Dr. Ferrans made several key points about the program, which focuses on bringing affordable cancer technologies to address global health issues and underserved areas. The program has had major accomplishments during the current funding cycle, including publications and innovative technologies. The ACTs program is the only government-funded program of its kind and has the potential for improving global health related to cancer and implications for underserved, under-resourced areas in the United States. The Subcommittee was pleased with the positive feedback in the report from the external reviewers about the ACTs program. In this next phase, the program will transition to a UH2/UH3 mechanism. The Subcommittee commends the current education and training efforts and suggested they be further expanded and that design ideas be included in the RFA.

The first-year cost for the one-time re-issuance and 3 annual issuances is estimated at $4M for 6 awards, with a total cost of $ 60M for 7 years.

**Questions and Answers**

Dr. Hayes-Jordan sought clarity on whether the RFA renewal would focus on developing technologies for specific low- and middle-income countries (LMICs), particularly those countries previously having access to a particular technology. Dr. Francis Ali-Osman, Margaret Harris and David Silverman Distinguished Professor of Neuro-Oncology, Professor Emeritus of Neurosurgery, Duke University Medical Center, added that the RFA is not directed at a particular country and noted that once a technology is developed and validated, it is open for application evenly across the United States and globally.

Dr. Paul Pearlman, Program Director, Center for Global Health (CGH), commented that the CGH is agnostic about where the work takes place. The focus is on addressing cancer in a local setting (e.g., LMICs) appropriate for the technology. The CGH also is undecided on whether to require multisite validations for the technologies, which also would depend on the individual applications. He noted that the CGH has funded 21 ACTs projects operating in more than 30 countries.

**Motion.** A motion to concur on the OD's re-issue RFA/Coop. Agr. entitled "Cancer Prevention, Detection, Diagnosis, and Treatment Technologies for Global Health—The Affordable Cancer Technologies (ACTs) Program" was approved unanimously.

### Re-Competition of the NCI at Frederick Operations and Technical Support Contract of the FNLCR (New RFP)—Dr. Sara S. Hook

BSA Chair, Dr. Bar-Sagi, explained that the concept had not previously been considered by the BSA in an open session and is being introduced at this meeting.

Dr. Sara S. Hook, Associate Director, NCI-Frederick, presented the FNLCR contract re-competition RFP concept. The FNLCR is 1 of 42 Federally Funded Research and Development Centers (FFRDCs) sponsored by a government agency to support all aspects of basic and applied research and R&D. The FNLCR is the only FFRDC solely dedicated to biomedical research and performs work on behalf of the NCI Divisions, Offices, and Centers; 17 other NIH Institutes and Centers (ICs); and 6 other federal agencies. Approximately 70 percent of the FNLCR work on the contract is devoted to the NCI and cancer research and roughly 30 percent for other ICs and agencies biomedical research. The NIH approves the NCI's sponsorship of the FNLCR every 5 years.

The FNLCR is housed at the NCI-Frederick campus in Frederick, Maryland, occupies space in 100 buildings, and employs 2,200 full-time staff (contractors) and 750 federal employees. The FNLCR conducts strategic research through rapid, flexible, and collaborative approaches, and the scientific projects supported are developed based on opportunities and need. Major projects are approved by the NCI Boards, particularly the Frederick National Laboratory Advisory Committee (FNLAC) or other IC advisory committees, and progress reviews are conducted by the FNLAC working groups as appropriate.

Dr. Hook noted some of the FNLCR's achievements. The FNLCR supports more than 400 NIH-sponsored clinical trials annually; has produced more than 130 biopharmaceutical products, of which 60 are in clinical trials; and has characterized more than 400 candidate nanoformations, two of which recently received market approvals. In the past 5 years, the FNLCR produced 70 lots of clinical products through two good manufacturing practices (GMP) programs. The FNLCR has supported several projects, including the CPTAC, Cancer Moonshot$^{SM}$, and The Cancer Genome Atlas, and the contract primarily focuses on cancer, AIDS, and emerging infectious diseases.

The FNLCR is coordinating three national mission programs. The RAS (oncogene) Initiative, a hub and spoke model of research and collaboration, is investigating RAS biology using four novel approaches with various collaborators. The RAS Initiative Structural Biology Group has solved more than 60 RAS crystal structures and the program has distributed more than 10,000 plasmids and 800 cell lines to 558 academic institutions worldwide. The National Cryo-Electron Microscopy (Cryo-EM) Facility (NCEF) launched in 2017 and is exclusively available to the extramural community at no cost to the user. To date, the NCEF has supported 370 cancer-related projects from 39 institutions and assisted research enabling 25 publications in high-impact journals. The FNLCR has a key role in the NCI COVID-19 response and is supporting several activities, including NIAID COVID-19 clinical trials, SeroNet Coordinating Center, and the NCI-FDA SARS-CoV-2 Serology Validation Program. Dr. Hook noted that the NCI and other IC/agency annual appropriations and obligated funds ($592 M in FY 2019) to the FNLCR to support its activities varies depending on the scientific need and available resources.

Regarding future directions, the NCI envisions that the FNLCR will provide to NCI-supported investigators access to services, tools, and resources not readily available to individual laboratories; serve as a hub for technology development, and function as a nucleus for large scale projects. Dr. Hook informed the BSA and NCAB members that the NCI issued an RFI soliciting new ideas on the next national mission program for the FNLCR. The NCI proposes the following operational principles critical for the future success of the FNLCR: Pursue high-risk/high-reward projects; maintain a full intellectual scientific partnership with the NIH; build relational bridges for shared success; nurture a spirit of organizational excellence; operate in a transparent, accountable, and effective manner; and demonstrate boldness and creativity in ideas and execution.

The FNLCR contract re-competition is a three year process which begins at this meeting with the BSA concept review and involves the solicitation for proposals, evaluations, and negotiations. The NCI anticipates awarding the contract in August 2023. Dr. Hook explained that the competition is open and any applicant meeting the objectives of the statement of work is free to apply. She expressed appreciation

to Dr. Kristin Komschilies McConville, Deputy Director, Office of Scientific Operations (OSO), FNLCR, and FFRDC Contracting Officer, Ms. Lisa Coleman, Head Contracting Officer, NCI, other OSO staff, and NCI and NIAID staff for their support with the concept.

**Subcommittee Review.** Dr. Vonderheide expressed the Subcommittee's enthusiasm and strong support for the concept. He explained that the BSA is considering a request to endorse the NCI's desire to continue the FNLCR as a contract operated FFRDC but is not asked to conduct a scientific or budgetary review or review the performance of the current contractor. The Subcommittee emphasized several key points. The FNLCR dates back to the National Cancer Act of 1971, became a national laboratory in 2012, and is a unique resource to the NCI supporting research activities not performed elsewhere. The FNLCR provides, nimble, rapid, and focused responses to urgent, critical scientific questions spanning from basic science to clinical trials.

**Questions and Answers**

Dr. Howard J. Fingert, Consultant, asked whether an educational program at the FNLCR to engage students in science had been developed. Dr. Hook noted that the FNLCR has sponsored a summer research program for school students for the past 30 years, has trained more than 1,200 students, and recently received a Presidential mentoring award. Approximately 80 percent of students completing the program pursue scientific careers.

In response to a query from Dr. Bar-Sagi on initiatives or projects that may not have produced the anticipated results, Dr. Hook explained that initiatives that are not meeting expectations are phased out expeditiously with discretion. The NCI regularly reviews and evaluates its projects and overall investments.

Dr. Barker suggested developing messaging to increase awareness of the collaborative opportunities and unique national resources of the FNLCR.

**Motion.** A motion to concur on the OD's new RFP entitled "Re-competition of the NCI at Frederick Operations and Technical Support Contract of the FNLCR" was approved unanimously.

**ONGOING AND NEW BUSINESS—DRS. SCOTT W. HIEBERT AND DAFNA BAR-SAGI**

Dr. Hiebert invited the Subcommittee Chairs to present their respective reports.

**NCAB *ad hoc* Subcommittee on Population Science, Epidemiology, and Disparities.** Dr. Electra D. Paskett, Marion N. Rowley Professor of Cancer Research, Director, Division of Cancer Prevention and Control, Department of Internal Medicine, College of Medicine, The Ohio State University, and Chair of the NCAB *ad hoc* Population Science, Epidemiology, and Disparities Subcommittee, presented the report of the 30 November 2020 meeting. The NCI Director, Dr. Sharpless, attended the meeting. Dr. Paskett noted that Dr. Deborah M. Winn, Senior Advisor to the Director, DCP, and Executive Secretary, announced that she would be retiring in January 2021 and that Dr. Castle will be the new Executive Secretary of the Subcommittee.

Dr. Paskett reported that the Subcommittee reviewed the plan outlined in the September 2020 meeting, which included the CRS performing an analysis of the extramural cancer grants related to research conducted in Black/African American populations across the cancer continuum. Dr. Melissa Antman, Senior Scientific Program Analyst, CRS, presented the pilot data from this analysis. The pilot analysis demonstrated clearly that the information could be assembled using automated systems with manual curation. The next step will be to review and synthesize these data. The Subcommittee proposed

the formation of an *ad hoc* Working Group on Strategic Approaches and Opportunities for Research on Cancer Among Racial and Ethnic Minorities and Underserved Populations. The Subcommittee next reviewed and edited the functional statement for the Working Group and proposed a term of 2 years for the group to complete its work. Dr. Paskett noted that the Subcommittee selected four populations under the minority, underserved groups that would be the focus the Working Group: (1) Black/African American populations, (2) Hispanic/Latino populations, (3) rural populations, and (4) older adults. Data on gender across the four groups also will be examined.

**Motion.** A motion to concur with establishing an NCAB *ad hoc* Working Group on Strategic Approaches and Opportunities for Research on Cancer Among Racial and Ethnic Minorities and Underserved Populations was approved unanimously.

**Motion.** A motion to accept the report of the 30 November 2020 NCAB *ad hoc* Population Science, Epidemiology, and Disparities Subcommittee meeting was approved unanimously.

**NCAB Planning and Budget Subcommittee.** Dr. Barker, Chair of the NCAB Planning and Budget Subcommittee, presented the report of the 30 November 2020 meeting. The NCI Director, Dr. Sharpless, and Principal Deputy Director, Dr. Lowy, attended the meeting. The Subcommittee was provided an overview of the FY 2021 budget, including current trends and unknown factors—by Mr. Patrick McGarey, Associate Director for Finance and Legislation, and Executive Secretary. Dr. Barker summarized Mr. McGarey's overview. It is uncertain when the FY 2021 budget will be approved. The House appropriations bill designates an increase of $54 M (0.8% increase) for the NCI, plus an additional $414 M for the NCI to restore reduced laboratory productivity resulting from the COVID-19 pandemic. The Senate appropriations bill designates an increase of $282.5 M (4.4% increase) for the NCI but does not include additional funds to restore laboratory productivity.

The Subcommittee discussed the loss of productivity in the cancer enterprise across all laboratories, including the NCI-Designated Cancer Centers that suspended research because of the COVID-19 pandemic. Dr. Sharpless in his remarks to the Subcommittee, explained the challenge to quantify this type of productivity loss. Dr. Barker pointed out the importance of conveying to Congress the amount of sacrifice being made, which is likely to have an impact on cancer care in the future. Discussions also focused on the challenging decisions the NCI was confronted with to preserve talent, salaries, the infrastructure, and valuable resources (e.g., NCTN). The Subcommittee suggested publicly acknowledging and expressing appreciation to the NCI leadership for their insight and early decisions, which has significantly reduced the severity of the loss of productivity.

**Questions and Answers**

Dr. Timothy J. Ley, Professor of Medicine and Genetics, Division of Oncology, Department of Medicine, Washington University School of Medicine in St. Louis, recommended including a statement in the Subcommittee report commending the NCI for its leadership during the COVID-19, which he read:

"The NCAB commends the NCI for their leadership during the early phases of the COVID-19 pandemic, and strongly endorses not only their work in understanding the impact of COVID-19 for patients with cancer, but importantly, for their foresight in taking action to maintain the Nation's cancer research workforce, infrastructure, programs and networks that are essential in driving current and future advances in the care of all patients with cancer."

**Motion.** A motion to accept the report of the 30 November 2020 NCAB Planning and Budget Subcommittee meeting was approved unanimously.

**Motion.** A motion to approve an amendment to the report of the 30 November 2020 NCAB Planning and Budget Subcommittee meeting, to include a statement expressing the Board's appreciation of the NCI's leadership and responsiveness to maintaining cancer care and research during the COVID-19 pandemic was approved unanimously.

**Motion.** A motion to concur with the NCAB Subcommittee on Planning and Budget's statement in support of the NCI was unanimously approved.

**Future Agenda Items.** The BSA and NCAB members were asked to forward any suggestions for potential future agenda items to the respective Board chairs and Dr. Gray

## XII. ADJOURNMENT—DR. SCOTT W. HIEBERT

Dr. Hiebert thanked all the Board members, as well as the visitors and observers, for attending. There being no further business, the 3rd Virtual Joint Meeting of the BSA and NCAB was adjourned at 4:44 p.m. on Wednesday, 2 December 2020.

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| Date | Dafna Bar-Sagi, Ph.D., Chair, BSA |
| Date | Scott W. Hebert, Ph.D., Acting Chair, NCAB |
| Date | Paulette S. Gray, Ph.D., Executive Secretary |